In Vitro Hemodynamic Evaluation of a Simon Nitinol Vena Cava Filter: Possible Explanation of IVC Occlusion

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PURPOSE: To evaluate the local hemodynamics in the region of the Simon nitinol filter (SNF), used to prevent pulmonary emboli by capturing clot and promoting lysis.

MATERIALS AND METHODS: The hemodynamics of the Simon nitinol inferior vena cava (IVC) filter were evaluated under steady flow (Re = 600) in a 20-mm-diameter IVC model. The photochromic dye tracer technique was used to estimate the velocity and wall shear stress. These flow features were determined for the unoccluded and partially occluded (clot volume = 1,500 mm³) states of the SNF along its center plane.

RESULTS: A region of low velocities developed around the central axis of the filter extending from the leading edge of the central strut to the filter tip. This phenomenon was created by the strong redirection of flow toward the periphery of the filter. With the presence of the clot, these effects were enhanced, causing flow separation and recirculation. In addition, the shear stress on the hip of the clot was about 30 times that of the upstream value, and turbulence developed in the near-downstream region.

CONCLUSIONS: The extended region of almost-stagnant flow near the midsection of the umbrella region could lead to organization of thrombus and fibrin mesh network development. The presence of a simulated clot led to a significant increase in the size of the stagnant, thrombus-prone region as well as turbulence, which, overall, may contribute to caval occlusion.

Index terms: Embolism, pulmonary • Venae cavae, filters

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Abbreviations: IVC = inferior vena cava, SNF = Simon nitinol filter

VENA cava filters have been used for more than 20 years to treat recurrent pulmonary emboli with patients contraindicated for or unresponsive to anticoagulation therapy. Successful treatment requires the filter to be nonthrombogenic while providing high filter efficiency without impeding blood flow (1).

The Simon nitinol filter (SNF; NMT Medical, Woburn, MA) has become popular because it can be inserted through a small (9 F) applicator and its compact nature allows it to be used in cases in which the distance between the iliac bifurcation and renal veins is relatively small. Clinically, the rates for recurrent symptomatic pulmonary emboli with the SNF are lower than 5% (2–4). However, its caval occlusion rate (7%–50%) appears to be higher than those of its competitors (4–6), although this performance may be biased by differences in patient population and evaluation techniques (5,6).

The flow dynamics of a filter determine its ability to collect emboli and remain patent by fluid shear lysing of clots (7). The SNF has been shown to adequately capture simulated clots of various sizes (8,9). Flow analysis of the SNF has been limited to dye visualization technique that provided only qualitative information on the overall flow pattern (9). This did not provide the detailed velocity and shear stress maps needed to make effective comparison among filters, as we have shown in earlier studies of Vena Tech (LGM, France) and 12-F Greenfield (Boston Scientific/Medi-tech, Quincy, MA) filters (10,11).

In this study, we used a quantitative flow visualization technique to evaluate the velocity and shear stress patterns produced by the SNF in its unoccluded and partially occluded states.

METHODS

A rigid vena cava model and steady flow condition were used to determine the flow field created by the filter in its two states. The same flow conditions...
as our previous work with the 12-F Greenfield filter and Vena Tech LGM filter (10, 11) were used to allow for comparison of the hemodynamics of these filters. These basic studies may provide some insights into the clinical performance of vena cava filters.

**Test Model**

A 2.0-cm-diameter test section was machined from a block of ultraviolet-transparent acrylic. An 80-cm straight inlet was attached to the model to ensure that the inlet flow was fully developed; i.e., Poiseuille flow. **Figure 1** shows the main components of the experimental set-up. A section with a slightly larger diameter was machined into the main vessel to allow for the insertion of a plastic mounting ring that anchored the feet of the filter. This simulates the anchoring of the filter feet in vivo within the wall of the vena cava.

**Flow Visualization**

The photochromic dye tracer technique (12-14) was used to capture the flow displacement profiles in and around the filters. The test fluid comprised of deodorized kerosene (Shell-Sol 715; Shell Canada, Toronto, ON) and trace amounts (50 ppm) of photochromic dye (1',3',3'-trimethylindoline-6-nitro-benzospiropyran). This flow visualization technique uses an ultraviolet laser (VSL 337ND-10Hz; Laser Science, Newton, MA) to excite the photochromic dye, thereby transforming the transparent solution to a dye trace along the laser beam path. A charged couple device camera (MegaPlus 1.4; Eastman Kodak, San Diego, CA) and image board (model XPG 1000; Dipix, Ottawa, ON, Canada) were used to record the dye traces. For each position of the test section, the following steps were taken. An initial image of the model with no traces present ("background image") was acquired with the camera and stored on the imaging board. One image of the dye trace was acquired 0 milliseconds after firing the laser; that is, almost at the instant of trace formation, and is therefore seen as a straight line. The background image was subtracted from this image to isolate this time-zero trace or line. Another trace was then generated and imaged after it was displaced by the flow for 15 milliseconds. Five such traces were acquired and the average of these represent the average axial displacement profile. Subtraction of the time-zero trace from the averaged displaced profile yielded the net displacement of the trace. Therefore, for any given radial site along the trace, the net displacement divided by 15 milliseconds represents the velocity.

The model was then moved to the next position (0.5 mm ± 0.01) and the entire process was repeated. Because of the limitation of beam penetration, the dye trace extended through only half the model diameter and therefore the model was examined from both sides to resolve each plane. Two orthogonal planes were evaluated for both states of the SNF.

**Flow Conditions**

The test fluid (μ = 1.43 cP) was circulated at a constant flow of 17.81 mL/sec, which resulted in a Reynolds number of 600 (Re = VDp/μ, where V is the average velocity, D is the diameter, and p and μ are the fluid density and viscosity, respectively). This corresponds to an equivalent blood flow rate of 2 L/min in a 2 cm diameter vena cava. Upstream data were acquired 3–6.5 cm from the filter, whereas around the filter, measurements were made over a distance of 5–6 cm distal to the opaque plastic insert.

**Clot Simulation**

A 1,500-mm³ ultraviolet transparent plug was used to simulate trapped emboli, similar to the clot volume in our previous study of the Titanium Greenfield filter (11). The clot was machined to fit within the contour of the filter legs. **Figure 2** shows the dimensions of the clot that consisted of a hemispherical upstream section and a conical downstream section.

**RESULTS**

Contour plots of the axial velocity were normalized by the theoretical average velocity for Poiseuille flow. In a
few locations in which the filter legs lie within the imaging plane (ie, the filter legs obstruct the laser beam), no measurements were made and the contour represents an average of the surrounding data. The wall shear stress, which is the product of the fluid viscosity and the wall velocity gradient, was similarly normalized by the theoretical wall shear stress for Poiseuille flow. In all cases, the flow field upstream of the filter agreed well with the theoretical Poiseuille values for the test fluid ($V_{avg} = 56.7 \text{ mm/sec, } \tau_p = 0.32 \text{ dynes/cm}^2$), corresponding to in vivo values of 107.7 mm/sec and 1.5 dynes/cm$^2$ (scaling discussed in Couch et al [11]).

Unoccluded Filter

The velocity profiles and the contour plot for the SNF are shown in **Figures 3a and b**. Overall, the filter redirects the high-velocity core flow toward the vessel wall mainly as a result of the resistance to flow produced by the central strut. Therefore, as the upstream high momentum core enters the first stage of the filter, it bifurcates around this cylindrical strut. A low velocity region develops around the central strut in the second stage that extends downstream of the filter tip. This region of almost stagnant fluid is presented in **Figure 3b** as the blue zone. The shift of the high-velocity fluid toward the vessel wall led to an almost doubling of the wall shear stress, as shown in **Figure 3c**. Similar features were seen in the orthogonal plane.

Partially Occluded Filter

Velocity and shear stress plots from the two planes of the partially occluded filter are presented in **Figures 4 and 5**. The filter asymmetry is reflected in the contour plots shown in **Figures 4b and 5b**, especially from the region of stagnant or reverse velocities (the blue/black zone) just distal to the clot. The 74% area reduction created by the "hip" (the widest point) of the clot caused flow to be diverted toward the wall and subsequently deflected by the wall toward the center of the vessel, near the downstream tip of the clot. Consequently, the wall shear stress was a maximum in the vicinity of the hip of the clot and its magnitude rapidly decreased because of strong deflection of the high-velocity fluid by the vessel wall. The upstream wall shear stress ($\tau_{wall}$) agreed well with the theoretical Poiseuille ($\tau_p$) value (top: $\tau_p/\tau_{wall} = 1.096 \pm 0.097$; bottom: $\tau_p/\tau_{wall} = 1.018 \pm 0.081$).

**Figure 4** shows a symmetric distribution of the velocity and shear. The high-momentum fluid is split evenly around the clot and is eventually deflected toward the center of the vessel by the wall. This creates a symmetric recirculation zone downstream from the clot. In the orthogonal plane as shown in **Figure 5**, the clot was offset slightly toward the lower wall and thereby biased the flow toward the top half of the clot. This asymmetric flow created instability, as seen in the jagged upper profiles downstream from the filter. A large recirculation zone developed toward the bottom half of the filter immediately downstream from the clot. The vessel wall shear stress increased by a factor of approximately 10 compared to the upstream or inlet value and returned to the upstream value quite.
rapidly near the midsection of the filter. This is an indication of the reflection of the high-velocity fluid from the vessel wall versus the slower return of the shear stress to the upstream value seen in the unoccluded state (Fig 3). Again, the asymmetry in the filter is reflected by the vessel wall shear stress (pink profiles) with Figure 4c being more symmetric as expected. On the clot itself, the shear stress peaked at approximately 30 times the upstream value in the vicinity of its hip, and then dropped sharply to negative values because of the onset of flow separation or recirculation (blue/black zone).

We also observed the development of unsteadiness that is sometimes associated with flow reversal or separation. To estimate the degree of unsteadiness, the experiment for the occluded state was repeated to capture five individual traces at each position along the model. The difference between these instantaneous values and the mean was expressed as the root mean square value. This measure of unsteadiness is often referred to as the turbulence intensity of the flow field. In the symmetric plane, insignificant levels of unsteadiness were detected, in contrast to the asymmetric plane, where significant local unsteadiness developed. It is common for asymmetric flow fields to undergo transition to turbulence more easily than symmetric flow fields. The turbulence developed just distal to the site where separation was more pronounced, as shown in Figure 6.

DISCUSSION

Clinical evidence of the success of IVC filters is difficult to interpret because of variation in follow-up lengths, patient treatment, and methods of reporting (16). The SNF appears to possess a high filtering efficiency as reflected by its low rate of recurring symptomatic pulmonary emboli (2,3, 17,18). However, its caval occlusion rate is reportedly higher than other available filters (16). In patients with malignancy, MR imaging has suggested this rate may be as high as 50% \( (n = 10) \) (6). Others have reported occlusion rates of 7%–9% \( (n = 44) \) (2) and 17% \( (n = 18) \) (5) in unselected sequential patients, whereas McCowan et al (19) found a 25% caval occlusion rate in their follow-up study \( (n = 16) \).

The hemodynamics in and around a caval filter determines its ability to remain patent. Our results show that the compact design of the SNF leads to a low-velocity region along the central strut of the filter. Previous work investigating the Titanium Greenfield and Vena Tech filters in the unoccluded state showed a relatively smaller region of low velocity around and downstream of the filter tips (10). Reduced velocity also appeared in the shadow of the relatively thick legs of the Vena Tech filter.

With the presence of a centered 1,500-mm\(^3\) clot, this region grew significantly triggering flow separation (re-
verse flow) and some degree of turbulence for the SNF. A previous study on the 12-F Greenfield filter did not show any low velocity or flow separation for both states of the filter (11). The same clot volume was used with the 12-F Greenfield filter; however, because of its longer length, the area reduction at the hip region was 36%. With the more compact SNF, the area reduction was 74%. Katsamouris et al (9) found that the SNF and Greenfield filter produced similar pressure drops for multiple trapped emboli. However, for a single centered streamlined clot, our results show that the SNF filter produces a greater pressure drop (as indicated by the degree of flow separation), and hence greater resistance to caval flow, than the Greenfield design.

Low shear regions and recirculation zones have been shown in vitro to be thrombogenic (20,21). The extended region of almost stagnant flow near the midline of the umbrella section in the unoccluded state could lead to fibrin mesh network development and organized thrombus. The short profile of the SNF limits the volume of clot that can be captured in the center of the filter without triggering flow separation and instabilities in the flow field. In addition, high shear stress levels generated by turbulence were shown to promote thrombus formation (22). With regards to clot lysis, high shear force may be a factor (7), but it will be limited to a narrow region around the hip, unlike that seen with the Greenfield filter, with which more than 50% of the clot surface was exposed to high shear forces.

**LIMITATIONS**

This study was limited to steady flow in a rigid circular caval model. The vena cava is compliant and elliptical, with pulsatile fluctuations altered by respiration (15). However, steady-flow analysis is widely viewed as a means of providing the time-averaged behavior for pulsatile flow conditions. The clot shape was similar to that used in our earlier work so the hemodynamics could be compared. Also, asymmetric positioning of SNFs are common clinically, occurring in approximately 68% of cases (3). Therefore, the time-averaged in vivo flow effects could be more unfavorable than those we found because further asymmetry would produce greater flow separation and increased instability and turbulence.

**CONCLUSIONS**

No filter has proved its unequivocal superiority in all clinical situations. The SNF has gained popularity because of its small applicator size and short profile. However, the two-stage design seems to promote stagnation that quickly triggers flow separation and unsteadiness with the presence of a simulated clot. These hemodynamic features are considered to be thrombogenic and may therefore contribute to caval occlusion.
Figure 6. Turbulent intensity in the orthogonal plane. The turbulent intensity is a dimensionless parameter that represents the level of velocity fluctuation with respect to the mean velocity at any given point. Fluctuations of as much as 5% are seen on the upper half of the figure.

References


