A Comparative
In Vitro Analysis of the Hobin-Uddin,
Kimray Greenfield and Nitinol Blood Clot Filters
by
Martin Raymond Prince

Submitted in Partial Fulfillment
of the Requirements for the
Degree of
Master of Science
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A Comparative In Vitro Analysis of the Kimray Greenfield, Mobin-Uddin and Nitinol Blood Clot Filters

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Martin Raymond Prince

Submitted to the Department of Mechanical Engineering on May 20, 1982 in partial fulfillment of the requirements for the Degree of Master of Science in Mechanical Engineering

Abstract

The Mobin-Uddin, Kimray Greenfield and Nitinol Inferior Vena Cava (IVC) interruption devices were analyzed in an in vitro simulation of the human inferior vena cava to evaluate the correctness of filter positioning, the clot capturing effectiveness, interference with blood flow and security of filter anchoring. This simulation reproduced the temperature, pressure, flow rate and vena cava sizes normally encountered in the human. It also included a movie camera and specially oriented mirrors to document three simultaneous projections of the filter delivery and the arrival of an embolus at the filter for later slow motion analysis. The Kimray Greenfield filter tended to assume a less effective tilted orientation; in large cavae it allowed 7mm diameter emboli to pass through. The Mobin-Uddin Umbrella captured emboli well but presented a significant obstruction to flow and demonstrated a tendency to dislodge in large vena cava and migrate with the fluid stream. The most effective device was the Nitinol filter which was well-oriented, captured clots effectively and showed negligible flow interference. The in vitro performance of the Kimray Greenfield and Mobin-Uddin filters reflects observations reported in the clinical literature. The Nitinol filter is still experimental and has not yet been used in humans but its superior in vitro performance is encouraging.

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Introduction

Each year an estimated 630,000 Americans suffer significant health problems when large clots that form in the veins of the lower limbs or pelvis break loose and migrate to the lungs (Figure 1). For 200,000 Americans these clots, called pulmonary emboli, will be fatal (1). These emboli plug pulmonary arteries blocking the flow of blood into the lungs. This result is so dangerous that clinicians are willing to take substantial risks to vigorously treat patients for whom there is a high probability of emboli migrating to the lungs (Table 1).

The standard treatment for pulmonary embolism, anticoagulation therapy, effectively reduces the mortality but carries a significant risk of bleeding complications (2). Occasionally these clots can be removed with surgery (3) or with thrombolytic (clot dissolving) drugs (4), in time to save a patient's life. An alternative form of treatment in patients precluded from receiving anticoagulation is to modify the shape of the lumen of the largest vein leading from the legs to the lungs (the inferior vena cava (IVC)) so that clots, which migrate from the lower part of the body, are arrested in the IVC and cannot reach the lungs. This is presently accomplished by three techniques:

a) direct abdominal surgery on the IVC to subdivide its lumen by suture material or external clips (5) (Figure 2A);
b) neck or groin surgery to expose a major vein for insertion
of a transvenous filter (Figure 2B) via an incision in the vein wall (6-8) (Figure 3); or
c) percutaneous catheterization of the femoral or other peripheral vein (without surgery) and insertion of a memory wire (Nitinol) filter into the IVC via this catheter (9) (Figures 2B & 4).

Each of the present clinical procedures involves significant problems. IVC interruption by the direct abdominal surgical approach is effective in preventing pulmonary embolism but there is a 14% mortality rate associated with using general anesthesia on these acutely ill patients (10). Surgery for the indirect insertion of transvenous devices (see Figure 3) is much less dangerous primarily because it involves only local anesthesia. Despite this advantage, complications such as filter migration, vein wall perforation, filter misplacements, infection, filter breakage, and the like have all been described in the clinical literature (9,11-19). Furthermore, clinicians still await a well controlled analysis of the ability of these filters to capture emboli in the human.

The transcatheter, memory wire, Nitinol filter is still experimental and has not yet been approved for clinical use. However, the catheterization procedure is clearly much simpler than neck, groin, or abdominal surgery. If, in addition, the transcatheter device proves to be effective in capturing emboli, it would constitute a considerable advance in the treatment of pulmonary embolism. To provide more information on this issue
this research compares the clot capturing capability of an experimental transcatheter device, the Nitinol filter, with two transcaval devices currently used clinically, the Greenfield Filter and the Mobin-Uddin Umbrella.

In Vivo Studies Versus In Vitro Simulation

The first methodological consideration was the relative value, at this stage of research/development, of in vivo versus in vitro analysis. In vivo studies using experimental animals to evaluate these devices have not been carried out easily (20-23). Appropriate research animals are expensive and animal experiments require substantial preparation time; thus, only a limited amount of data can be collected in this way. Another problem is that the x-ray studies used to evaluate implanted devices provide only a limited view of what's happening in the IVC. Further, each data point must be derived from a different animal with different IVC anatomy, cava caliber, flow rate, and other factors. For these reasons, it is not possible to adequately control experimental conditions nor to provide appropriate data for statistical analysis. The most important limitation on experiments with dogs, the classic cardiovascular research animal, is that they do not, in the case of the IVC, provide a completely realistic simulation of human anatomy and physiology. For example, when these devices are squeezed into a 13mm diameter dog IVC they may have very different shapes than
when they expand to fill a 28mm diameter human IVC (Figure 5 & 6).

Scientific evaluation of an IVC interruption device in human subjects is not practical. The number, size, shape and clinical presentation of emboli found in humans are typically unpredictable. Furthermore the clinical background of each patient is unique. For obvious ethical reasons, the controlled injection of emboli into human subjects is not acceptable. The angiographic procedures which would be necessary to evaluate these devices might generate other medical problems such as allergic reactions to the X-ray contrast materials, infection, internal bleeding, thrombus formation, and even loss of limbs. These risks would be compounded by the poor general health of most patients for whom IVC interruption would be appropriate.

This study overcame many of the problems just described by evaluating the performance of IVC interruption devices in an in vitro simulation of the human IVC described previously (24). The simulated IVC was made completely of transparent materials to allow clear visualization of the filters during experimentation. The caval tissue was simulated with cellulose dialyzer tubing in three sizes within the range of observed human IVC sizes. Supporting apparatus controlled temperature, pressure and flow rate of the experimental fluid (saline in these experiments). A system of mirrors and a 16mm movie camera were set up to document three simultaneous views of filter performance for slow motion analysis. Filters and blood clot
were delivered to the simulated IVC via an access port. Figures 7 and 8 are diagramatic illustrations of the simulation. This apparatus was used to conduct a comprehensive in vitro analysis of the three previously mentioned filtering devices: the Kimray Greenfield, Mobin-Uddin and Nitinol Filters.
Experimental Design

Overview: This experiment examined four parameters of filter performance relevant to clinical application: 1) filter orientation in the IVC, 2) clot capturing ability, 3) filter interference with blood flow and 4) security of filter anchoring. Filter orientation was recorded immediately after delivery; clot capturing ability was determined by introducing canine blood clots of standardized sizes into the test system; filter interference with flow was measured as the pressure gradient across the filter; filter anchoring strength was measured by positioning the simulated vena cava vertically and attaching weights to the filter within.

Before these parameters could be evaluated, appropriate cava sizes and experimental flow rates were established. The former were determined by examining human venocavograms. Experimental flow rate was determined by adjusting the flow rate until the experimental emboli traveled at the same rate as emboli studied in vivo. Details of these two procedures and the experimental methods will be described in the following sections.

Determination of Cava Size: Since IVC interruption devices tend to have a more compact shape in smaller cavae, cava size would be expected to influence the test parameters. To determine the mean and standard deviation of human caval cross-sectional areas, at the level of filter engagement
follow-up x-ray films of patients at Beth Israel Hospital and Massachusetts General Hospital with KG filters were examined for a) cava diameter at site of hooks and b) filter length. The magnification factor for the filter was calculated from the measured filter length with equation (1):

\[
\text{magnification factor} = \frac{\text{measured filter length}}{\text{actual filter length}} \quad (1)
\]

Vena Cava diameter was calculated with equation (2)

\[
\text{actual vena cava} = \frac{\text{measured vena cava diameter}}{\text{diameter magnification factor}} \quad (2)
\]

Thus since the actual length of filter limbs for the Greenfield filter is known to be 4.6 cm these equations can be combined to form equation (3):

\[
\text{actual vena cava} = \frac{\text{measured vena cava diameter}}{\text{measured filter length}} \times 4.6 \text{ cm} \quad (3)
\]

Caval cross-sections were assumed to be nearly circular due to the uniform pressure of filter hooks on the inner wall of the vena cava. Additional support for this assumption came from computerized tomographic scans of human patients with vena cava filters taken at the Massachusetts General Hospital which all showed the vena cava to be circular in cross-section at the level of the filter hooks (25). Results are shown in Figure 9. Selection of experimental vena cava diameters was limited to the sizes of cellulose dialyzer tubing available. The three sizes acquired, 15 mm, 20 mm and 28 mm are reasonably representative of
Determination of Flow Rate: It is difficult to estimate the average blood flow rate through the infrarenal vena cava in the population of patients threatened by pulmonary emboli. In a normal, healthy adult total cardiac output at rest is 5 liters per minute (although it may increase to 15 liters per minute with exercise). It is estimated that during the resting state twenty percent of the cardiac output flows to the lower body (below the kidney level) (26). Patients diagnosed as being at high risk for pulmonary emboli are usually hospitalized and at rest. Therefore, their infrarenal IVC flow rate is one liter per minute.

Unfortunately this flow rate in a 20 mm diameter cava was insufficient to propel the experimental emboli to the filter at a perceptible rate. More realistic motion of emboli was obtained by increasing the flow to two liters/minute or 100 cm/sec. This clot motion was compared to cine films of opacified blood clots delivered to dogs and seemed comparable. The fluid velocity was standardized and appropriate volume flow rates were calculated for the other sizes of cavae as shown in Table 2.
Table 2

<table>
<thead>
<tr>
<th>Tubing Flat Width (mm)</th>
<th>Cava Diameter (mm)</th>
<th>Area (mm²)</th>
<th>Velocity (mm/sec)</th>
<th>Flow Rate (i/min)</th>
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<tr>
<td>24</td>
<td>15</td>
<td>183</td>
<td>100</td>
<td>1.1</td>
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<tr>
<td>32</td>
<td>20</td>
<td>314</td>
<td>100</td>
<td>2.0</td>
</tr>
<tr>
<td>44</td>
<td>28</td>
<td>616</td>
<td>100</td>
<td>3.6</td>
</tr>
</tbody>
</table>

**Evaluation of Filter Orientation and Anchoring Security:**

For optimal clinical functioning the filters are designed to be positioned along the central axis of the vena cava without tilt. The filters must also be securely anchored to prevent migration because a) movement toward the heart and lungs could be life threatening and b) backward migration, away from the heart and lungs, could perforate the vena cava, and possibly damage adjacent critical structures such as the aorta.

To evaluate filter orientation, MU and KG filters were purchased from Beth Israel Hospital's clinical service and loaded into appropriate delivery systems (Figure 3). The delivery capsule was then inserted into the simulated IVC. The filters were released by withdrawing the capsule from around the filter as recommended in the clinical literature (27). Nitinol filters were also delivered to the simulated IVC but via a French 8 angiographic catheter (see Figure 4). After each delivery the orientation (tilted or central) was noted. To evaluate filter anchoring security the simulated IVC was positioned vertically and a cup was hung from the leading tip of
the filter and filled slowly with water until the filter began sliding in the simulated vena cava tubing. The weight of the cup and water was measured and recorded as the filter holding force (Table 3). This procedure, including filter delivery and holding force measurement, was repeated ten times for each type of filter in each of the three sizes of simulated venae cavae.

Evaluation of Clot Capture and Flow Obstruction: The flow velocity was set to 100mm/sec as shown in Table 2. Temperature was adjusted to body temperature and the manometer measuring fluid pressure just upstream from the filter was set to zero. The filter was delivered into the simulated vena cava. A standardized blood clot, made previously from canine blood drawn into glass tubing and left at room temperature for more than one hour to ensure completion of the clotting process, was then introduced into the fluid flow 20 cm upstream from the filter. Arrival of this clot at the filter was carefully observed and recorded as follows:

+ captured completely
+- clot is captured but more than 1 cm protrudes through the filter
- clot passed completely through the filter

The +- category was adopted because protruding fragments of captured clots sometimes broke loose becoming, at least in part, an uncaptured embolus.

Occasionally the arrival of an embolus dislodged the filter
causing it to migrate downstream or obstruct flow through the filter so that no additional clots could reach the filter. These events were recorded as:

M migration of filter
I insufficient flow to bring clot to filter

Finally, pressure upstream from the filter was recorded. Since the manometer was initially set to zero, this pressure was the pressure gradient across the filter and thus reflected the severity of flow obstruction due to the filter and contained clot.

Two types of experiments were conducted. One involved delivery of a single 10 cm long clot to the filter. The other involved delivery of a set of five, two cm long clots in succession. Capture status and pressure changes were recorded for each individual clot.

**Determination of Test Clot Diameter:** The normal, healthy human body has a tremendous excess of pulmonary capacity utilising only a fraction of the vascular bed at rest (28). Thus, for a clot to be lethal, it must block most of the pulmonary arterial blood supply. For this reason, many clinicians feel that a clot is generally greater than 7mm in diameter when fatal (29). However, several smaller clots, embolizing in rapid succession, can have the equivalent effect of a single large clot. Also, a patient who already has seriously compromised pulmonary function may have a reduced
pulmonary reserve capacity. In such a case a single smaller embolus could be fatal. Indeed, the patients most commonly treated to prevent pulmonary embolism have prior heart or lung disease and may have sustained a previous pulmonary embolus that has further compromised their pulmonary function. For these reasons, capturing clots smaller than 7mm in diameter is desirable. This does not mean that very small clots, those less than 4mm in diameter, have to be captured. These are readily cleared from the pulmonary arteries by normal biological mechanisms in the lungs and do little or no harm (4). To summarize, then, an effective IVC filter should capture all clots 7mm or larger, most 4-7mm clots, but may let smaller clots through to avoid becoming unnecessarily occluded. In line with this reasoning this study is based upon testing the various filters with 4mm and 7mm diameter clots.
Results: Orientation and Anchoring Security

The three filters are designed to be oriented on the central axis of the vena cava and to lock into the caval wall. Each of the filters was analyzed with regard to these two parameters and is described by first defining its optimal filtering orientation, second, examining the probability of delivery into that orientation and third, by evaluating, the filter anchoring security.

**Greenfield Filter:** The optimal filtering orientation for this device is with the apex located on the central axis of the vena cava and the six limbs evenly spaced around the caval circumference (Figure 17). Any deviation from this optimum produces an asymmetry which increases the size of some spaces and decreases others. This allows more and larger clots to pass through the filter. Delivery of the KG filter into the optimal orientation occurred in only 8 of 30 deliveries while 22 were tilted. (Table 3)

Three causes of filter tilt were observed:

1) **Capule Weight:** During delivery the capsule containing the filter (see Figure 3) was heavy and tended to lie on the posterior surface of the caval lumen of the supine patient (Figure 10A). As the
filter was pushed out of the capsule, the apex emerged last and thus tended to hug the bottom of the cava in a tilted orientation (Figure 10).

2) Filter spring energy: As the filter emerged from the capsule it reached a critical point, at which the elastic energy stored in the filter was suddenly released and the filter sprung out into the vena cava (Figure 10C). Even the most careful operator would have difficulty controlling this.

3) Filter Weight: Even if the Greenfield filter was delivered into the optimal central orientation, it was not likely to remain so for more than a few moments because the tilted orientation was thermodynamically more stable (Figure 10D). This was due to the weight of the filter itself, the lack of a centering support and the larger circle formed by the legs when tilted. It was also observed that the arrival of a clot would knock the filter into a tilted orientation. Thus, the filter's lowest energy state was in a tilted position. During clot capture trials of the Greenfield filter in a central orientation a support was necessary to hold the filter in that orientation.

Once delivered, the Greenfield had substantial anchoring
security in the 15mm and 20mm diameter cavae but this force dropped off dramatically in the 28mm cava. It was also observed that all of the hooks engaged the cava in the smaller sizes as compared with only a few hooks in the largest vena cava. Failure to engage the wall seemed to be caused by an inappropriate hook angle as shown in Figure 11. An appropriate hook angle is calculated in Figure 12 and was found to have about twice the holding force as the existing hook in 28mm diameter cavae.

Mobin-Uddin Umbrella: Since this device incorporates a silastic membrane between its tines, its performance was unaffected by slight tilting. Excessive tilting was undesirable because the filter would fail to span the caval lumen and would allow clots to slip through gaps between the filter and the vena caval wall. The sudden filter release from the capsule, the capsule resting against the posterior caval wall, and thermodynamic instability factors tended to result in a tilted orientation after delivery similar to that observed in the case of the KG filter. However, excessive tilting was prevented by the centering effects of the attached guidewire.

After delivery of the filter, two significant problems were noted. First, the filter was not large enough to engage the walls in the 28mm vena cava. It was therefore difficult to unscrew its delivery guidewire because the filter was not secured; the filter rotated with the guidewire as it was turned and did not easily separate. Once the filter did release it
usually fell on its side and rolled downstream. For clot capture studies the hooks had to be engaged by hand. Second, in the smaller cava, the silastic plastic sheet between the spokes formed deep folds as the spokes came closer together to accommodate the smaller cava size. These folds constituted channels larger than the holes in the membrane and permitted experimental clots to pass. The filtering qualities of the device were thus determined by the channel size, rather than by the size of holes in the mesh.

Holding forces for the MU filter were even larger than for the KG filter in the 15mm and 20mm diameter cavae but there was practically no anchoring security for the filter in the 28mm cava. Thus, delivering the Mobin-Uddin Umbrella filter into a 28mm or larger vena cava would carry a high risk of embolizing the filter itself.

**Nitinol Filter:** As with the KG filter, this filter is designed to function optimally with the apex centered and the limbs evenly spaced. However, the Nitinol filter has an additional orienting element at its apex, the mesh of overlapping loops, which centers the device automatically even if the limbs were tilted slightly. The Nitinol filter was easily delivered into this optimal orientation through the lumen of a French 8 angiographic catheter as shown in Figure 4. Of the 30 deliveries, all resulted in appropriate orientations although some were tilted slightly particularly in the 20mm
diameter cava (see Table 3).

Nitinol filter holding forces in the 15mm and 20mm diameter cavae were comparable to those of the Mobin-Uddin and Greenfield filters but security was substantially higher in the 28mm cava. More significantly, yield force resulted in the filter slipping along the cava as opposed to the caval tearing observed when excessive force was applied to the other devices. The experimental Nitinol filter hooks were not needle sharp and pressed into, but not through, the vena cava wall. In the smaller vena cava sizes the mesh provided additional anchoring security.

**Results: Clot Capturing Ability**

**Greenfield Filter:** This filter captured clots the least effectively, allowing 7mm diameter clots through in all three cava sizes (Figures 15-21). In its most common orientation, tilted, it let ~50% of the clots at least part way through. Clots passing part way through were considered potentially as dangerous as clots passing all the way through because the downstream, unprotected, protruding portion could break off and embolize to the lungs. It could also serve as a nidus for further clot formation on the downstream side of the filter, a possible source of lethal emboli.
This filter, when empty, captured small clots well since the limbs guided them to the apex where the mesh was finer. However, as soon as the apex filled with clot the flow was diverted to the wider peripheral spaces and all additional clots passed through. The observation that the later clots tended to pass through the filter is evident in Figures 17-21.

Sometimes, after its initial capture, a clot would be jarred free by the impact of another clot arriving at the filter. Similarly with a single long clot the leading end sometimes filled the apex and forced the trailing end to somersault through a larger peripheral space. The momentum could pull the rest of the clot through along with it.

This analysis suggests that if large peripheral holes exist, clots may first plug all of the small central holes diverting the flow and further clots through the remaining large openings at the periphery.

**Mobin-Uddin Umbrella:** The Mobin-Uddin membrane was fairly impervious to all test clots since its holes were only 3mm in diameter. Some 4mm diameter clots, however, passed through the channels between the tines created by the infolding of the silastic in accommodating smaller cavae. Other clots forced the Mobin-Uddin to tilt excessively creating a space between the membrane and the caval wall. Occasionally large pressure gradients across the filter forced 4mm clots through the 3mm diameter holes. Despite these problems, this device was
effective in capturing clots in the two smaller sized venae cavae (Figures 22 & 23).

In the 28mm vena cava, however, the filter did not engage the caval wall securely (Figure 24). Its orientation frequently changed with clot impact.

Nitinol Filter: This filter has both a set of anchoring limbs and an umbrella-like mesh, both of which function as clot capturing elements. This combination would be expected to capture clots as effectively than the other devices and, in fact, the Nitinol filter captured nearly all clots in all three vena cava sizes (Figures 25-27). Paradoxically it captured clots better in the 20mm cava than in the 15mm cava. This resulted because the overlapping loops formed more uniform hole sizes at the 20mm diameter whereas some larger holes appeared in the slightly less uniform mesh in the 15mm diameter vena cava.

Results: Interference with Flow

Interference with flow reflected the tendency of the filter to occlude the IVC and was measured as the pressure gradient across the filter device. The KG and Nitinol filters both showed no measurable pressure gradient without clots and only minimal gradients occurred after delivery of experimental clots
(Figures 17-21 & 25-27). The MU filter, however, even without clots, created a measurable pressure gradient and after delivery of clots the pressure gradient increased markedly and sometimes exceeded the pressure limitations of the in vitro system (Figures 22-24). The vena cava upstream of the filter usually distended due to this pressure gradient while the downstream vena cava collapsed. If the filter was poorly secured, this often dislodged the filter and caused it to embolise. Many times flow through the Mobin-Uddin became so reduced that it was insufficient to carry additional clots to the filter. At other times pressure gradients across the Mobin-Uddin became so large that the vena cava tubing simply ripped apart.
Limitations of In Vitro Simulation

Obviously no model can perfectly simulate the human body. Failure to simulate tissue response, immune mechanism, the reticulo-endothelial system, adjacent structures, and other uniquely biological phenomena restrict use of this system to evaluating mechanical effects only. Analysis of these mechanical effects is limited by some of the simplifications in the system design. They can be enumerated as follows:

First, saline has different properties from blood, i.e. their densities and viscosities are different. These differences may have been compensated for by adjusting the flow velocity but one cannot be absolutely sure.

Flow in the vena cava is known to be pulsatile (29) but the simulation is strictly limited to uniform flow. Pulsatile flow might be expected to shake clots loose from the filter increasing the probability they would pass through any of the larger openings in the filtering devices.

The experimental emboli made by allowing dog blood to sit stagnant in a glass tube for one hour are probably not exact replicae of human emboli which have bizarre shapes and are formed over days or weeks developing substantial organization.

The simulating device was fixed in a horizontal position but patients might assume a variety of postures that could influence filter performance.
Caval tissue is much tougher and more elastic than the cellulose dialyzer tubing used in the simulation. This lack of perfect simulation probably had a marked effect on filter holding force determination (Table 3). Failure of the filter to stay secure in the vena cava was usually due to tearing of the cellulose dialyzer tubing. Human caval tissue would tear only when subjected to much higher forces.

Finally, humans also display much greater anatomical variation than can be modeled with three sizes of cylindrical tubing. In fact, body scans show the IVC before filter insertion to be oval in cross-section as opposed to a circular shape assumed by this model. A further complication is that human subjects have curving vessels with numerous branches and surrounding structures.

Many of these deviations from the real life situation were purposely designed into the simulation to optimize visualization and to generate a well controlled experiment. Some aspects could be improved. Lethal human blood clots could be acquired from autopsies and cut into standardized sizes. A pulsatile pump could generate pulsatile flow. Gelatin could be added to the saline to create a viscosity and density closer to that of blood without sacrificing visualization. Perhaps most importantly, the circulation modelling parameters could be studied during human surgical procedures or on experimental animals to determine optimal values for in vitro system capacitance, resistance, inertia, and pump characteristics.
Validation

Despite the problems enumerated above, this simulation goes a long way toward evaluating the relative utility of three types of intracaval devices. The validity of this comparison is verified by noting clinical observations that correlate with observations made in the in vitro simulation.

The MU was observed to occlude readily and generate large pressure gradients in vitro while the KG showed minimal pressure gradients and never occluded. Clinically the MU has a 73% incidence of occlusion and venous stasis (a condition caused by interference of venous flow out of a limb) while it is only 5% for the KG (13).

In 28mm diameter cavae in vitro the MU was observed to dislodge and migrate. Twenty-eight incidences of MU migration have been reported clinically in 2215 deliveries (28).

Tilting of the KG filter seen in vitro has been reported clinically (14,15), was seen in 50% of Beth Israel hospital KG filter patients and occurred in 63% of in vitro KG filter deliveries.

The MU and KG hooks are effective in preventing downstream migration but offer little resistance to migration distally, away from the heart. Distal migration of the MU and KG filter has been documented clinically (15,28).

These correlations with clinical observations suggest that
this simulation is a good model for predicting the clinical properties of new IVC blood clot filters.

Clinical Implications

Filter clot capturing ability and anchoring security diminished with increasing vena cava diameter. In the 28mm diameter cava the KG filter allowed most 7mm diameter clots to pass and the MU migrated. A decision to place a KG filter in a patient with a cava 28 mm or more in diameter should therefore be taken with caution and the MU is contraindicated. Future research might explore ways of retaining filter function in a wider range of cava diameters or develop multiple sizes of filters so appropriate filters will be available for every patient threatened by pulmonary embolism.

Many clinicians report that a 7mm diameter embolus is likely to be lethal or, at the very least, clinically significant (resulting in physiologic changes which can be detected by routine clinical exam). But the KG let 70% of 7mm diameter clots through despite its low reported recurrence rate for pulmonary embolism clinically (3). This observation can be explained in three ways. First, the present in vitro simulation may be unrealistic and 7mm diameter clots may not in fact pass through the KG filter. Second, the clinical findings reported may not reflect the true incidence of recurrent pulmonary embolisms with the KG filter. Finally, clinical trials of the KG filter may have yielded inaccurate results for the following
reasons: (1) the patients selected for study did not have migrating emboli, (2) more than one type of therapy was employed, e.g. filter plus anticoagulation, (3) there was inadequate patient follow-up, (4) there was insufficient follow-up time for the clinical studies to be conclusive. While the present analysis of the KG filter was as precise as possible, the results of this study do not permit complete resolution of these issues. But a filter that captures clots better than the KG in vitro is likely to capture clots effectively clinically.

Optimal filter design in terms of maximizing clot capturing ability while minimizing filter pressure gradients was achieved by the Nitinol filter which had the most uniform mesh. Redesigning the MU and KG filters to have more uniform meshes would probably improve their performance significantly. The MU could have a fish net like structure in place of the silastic membrane with occasional holes, thus reducing its obstructive effects. The KG could have the six tines branch to form 12 at the periphery where most clots currently get through.

The most significant implication of this research is that the favorable performance of the Nitinol filter warrants its further evaluation. This study showed it to anchor securely and to capture emboli effectively without obstructing the IVC; all this better than the two filters currently used clinically. In addition, the Nitinol filter is inserted without surgery. If it is shown also to be biocompatible (30 ), it should be
evaluated clinically.
Summary and Conclusions

An in vitro comparison was made of three filters designed to prevent clinically significant and especially potentially lethal emboli from reaching the lungs. Two of the filters, the Kimray Greenfield and Mobin-Uddin, are currently used clinically; the third, the Nitinol (a memory wire device), is experimental. The filters were delivered into an artificial vena cava where measurements of clot capturing ability, flow interference effects, anchoring security and orientation were obtained. The Mobin-Uddin captured clots well in small and average size cavae but was very occlusive. In large cavae the problem of Mobin-Uddin filter migration was severe. The Kimray Greenfield was not very occlusive but tended to fall into a tilted orientation and allowed large clots to pass, particularly after occlusion of the small spaces in the apex. The Nitinol filter captured clots well in all caval sizes, displayed the smallest occlusive effect and was remarkably stable. Since the Nitinol filter can be inserted into the vena cava through the lumen of a catheter, while the Greenfield and Mobin-Uddin require surgery, it is clearly the easiest and safest of the three devices to deliver.

While the present simulation of blood flow in the vena cava did not completely parallel that of the human, it was sufficiently close to permit a reasonable evaluation of the three filters. The excellent performance characteristics of the
Nitinol filter warrants further research on its biologic aspects through studies on both animals and selected human subjects.
REFERENCES


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Management of Pulmonary Embolism.


27. Correct technique for introducing filters


Table 1. Treatment of Pulmonary Embolism

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mechanism</th>
<th>Complications</th>
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</thead>
<tbody>
<tr>
<td>No treatment</td>
<td>---</td>
<td>18% have fatal recurrence of emboli</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>prevents new clot formation</td>
<td>hemorrhage and allergic reactions</td>
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<td>IVC Interruption</td>
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<td>sutures or clips</td>
<td>prevents migrating clots from reaching lungs</td>
<td>14% operative mortality, venous stasis and thrombophlebitis</td>
</tr>
<tr>
<td>intracaval devices</td>
<td>same</td>
<td>migration, infection, misplacement, perforation, breakage, air embolism, venous stasis and thrombophlebitis</td>
</tr>
<tr>
<td>Thrombolytic Drugs</td>
<td>digests clot biochemically</td>
<td>hemorrhage and allergic reactions</td>
</tr>
<tr>
<td>Embolectomy</td>
<td>surgical removal of embolus</td>
<td>17% operative mortality</td>
</tr>
</tbody>
</table>
Table 3  Filter Deliveries

<table>
<thead>
<tr>
<th>IVC diam (cm)</th>
<th>Mobin-Uddin</th>
<th>Greenfield</th>
<th>Nitinol</th>
</tr>
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<tbody>
<tr>
<td>15</td>
<td>20</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>15</td>
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<td>28</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>20</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Orientation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% tilted</td>
<td>60</td>
<td>90 *</td>
<td>60</td>
</tr>
<tr>
<td>% central</td>
<td>40</td>
<td>10 *</td>
<td>40</td>
</tr>
<tr>
<td>Holding Force</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>mean (gm)</td>
<td>83</td>
<td>117 0</td>
<td>77 55 34</td>
</tr>
<tr>
<td>standard</td>
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<td>33 0</td>
<td>12 6 22</td>
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<td>deviation</td>
<td></td>
<td></td>
<td>25 21 37</td>
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<tr>
<td># hooks engaged</td>
<td>6 5 0</td>
<td>6 4 2</td>
<td>0 0 0</td>
</tr>
<tr>
<td>Failure mode</td>
<td>tear</td>
<td>tear</td>
<td>slip</td>
</tr>
</tbody>
</table>

* the Mobin-Uddin Umbrella was not large enough to engage the cava walls in the 28mm diameter cava. For every delivery the filter simply rolled on downstream.
PULMONARY EMBOLISM

Physiology

1) Clot forms in lower body

2) Clot breaks loose and migrates toward lungs

3) Clot plugs pulmonary artery

Treatment

Anticoagulant therapy prevents new clot formation

IVC interruption prevents large clots from reaching the lungs

Surgery removes clot

Thrombolytic drugs lyse clots

Figure 1  Pulmonary Embolism: Physiology and Treatment.
Figure 2A  Direct surgical techniques for interrupting the IVC

intracaval devices
Mobin-Uddin

MU delivery capsule

KG delivery capsule

Kimray Greenfield

Nitinol

Figure 2B  Interruption devices that fit inside the IVC
TECHNIQUE FOR INSERTING THE KIMRAY GREENFIELD FILTER

A) Load filter into capsule.

B) Expose internal jugular vein under local anesthesia and insert capsule.

C. Advance capsule through heart and into inferior vena cava.
   Release filter from capsule.
   Withdraw capsule.

Figure 3  Indirect surgical approach for KG (technique is similar for MU).
INSERTION OF THE NITINOL FILTER

A) Insert needle through skin and into femoral vein.

B) Insert guidewire through needle and into femoral vein.

C) Remove needle leaving guidewire in vein.

Insert catheter into femoral vein by sliding over guidewire.

Figure 4a. Transcatheter approach to IVC interruption.
D) Attach filter storage and feeder device. Advance Nitinol filter into catheter (in its straight wire, low temperature form).

E) Push filter through catheter and into the IVC. (It recovers its high temperature filter configuration instantly upon contact with blood at body temperature).

F) Remove catheter and apply compression at site of needle puncture for 10 minutes to prevent bleeding.

Figure 4b. Transcatheter approach to IVC interruption.
Figure 5  Variations in filter mesh with changing vena cava diameter
- isolate two adjacent limbs
- look at the largest circle contained within the triangle defined by those limbs

\[
\sin(\theta) = \frac{a}{2b} = \frac{r}{c} \quad \Rightarrow \quad c = \frac{2rb}{a}
\]

\[
\cos(\theta) = \frac{c+r}{b} = \frac{2rb}{a} + \frac{r}{b} = r \left[ \frac{2b+a}{ab} \right]
\]

\[
2r = \left[ \frac{2ab}{2b+a} \right] \cos(\theta)
\]

\[
2r = \left[ \frac{2ab}{2b+a} \right] \cos\left( \sin^{-1}\left[ \frac{a}{2b} \right] \right)
\]

<table>
<thead>
<tr>
<th>Cava Diameter (mm)</th>
<th>Spacing between Hooks (mm)</th>
<th>Diameter of Largest Hole (mm)</th>
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</thead>
<tbody>
<tr>
<td>Dog size 10</td>
<td>5.2</td>
<td>3.6</td>
</tr>
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<td>12</td>
<td>6.3</td>
<td>4.3</td>
</tr>
<tr>
<td>14</td>
<td>7.3</td>
<td>5.0</td>
</tr>
<tr>
<td>Range of typical human 16</td>
<td>8.4</td>
<td>5.6</td>
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<tr>
<td>18</td>
<td>9.4</td>
<td>6.3</td>
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<td>20</td>
<td>10.5</td>
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<td>8.9</td>
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<td>28</td>
<td>14.7</td>
<td>9.5</td>
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<tr>
<td>Very large dog 30</td>
<td>15.7</td>
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<td>32</td>
<td>16.8</td>
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<tr>
<td>Large dog 34</td>
<td>17.8</td>
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<td>Human 36</td>
<td>18.8</td>
<td>11.9</td>
</tr>
<tr>
<td>38</td>
<td>19.9</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Figure 6. KG filter hole size as a function of cava diameter.
Figure 7. In vitro system hydraulics.
Figure 8. In vitro system optics.
Vena Cava Diameters in patients with Kimray Greenfield Filters

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Mean Cava Diameter</th>
<th>Standard Deviation</th>
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</thead>
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<tr>
<td>Kimray Greenfield with venogram</td>
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<td>20</td>
<td>3.8</td>
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<tr>
<td>Kimray Greenfield without venogram</td>
<td>45</td>
<td>19</td>
<td>3.2</td>
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<tr>
<td>Total</td>
<td>65</td>
<td>20</td>
<td>3.4</td>
</tr>
</tbody>
</table>

Figure 9. Infrarenal inferior vena cava diameters in KG filter patients.
Figure 10. KG filter delivery.

A) Filter in capsule.

B) Capsule withdrawn exposing filter.

C) At critical point filter jumps out.

D) Capsule removed.
EXISTING HOOK DESIGN

hook not engaged

SUGGESTED HOOK DESIGN

both hooks engaged

note larger hook angle increases the probability of hook engaging

Figure 11. Analysis of Greenfield filter hooks
Calculation of Optimal Greenfield Hook Angle

hook angle = \alpha

limb length = b

D = largest possible cava diameter

\theta = angle between limb and cava wall

\theta = \sin^{-1} \left( \frac{D}{b} \right)

if \ \alpha \leq \theta \ \text{then hook will not point into and engage cava}

if \ \alpha > 90 \ \text{hook will slip out of cava wall}

thus 90 > \text{optimal } \alpha \geq \theta

let D = 40mm and \ b = 46mm

90 > \alpha \geq 60

Figure 12. Determination of optimal KG filter hook angle.
Figure 13. Filter holding force versus cava diameter.
Average Filter Pressure Gradient versus Cava Diameter

Figure 14.- Average filter pressure gradients versus cava diameter.
Figure 15. Comparative clot capture performance.
Figure 16. Comparative clot capture performance (7mm clots only).


## GREENFIELD

### 15mm

![Diagram of Greenfield device]

<table>
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<tr>
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<th>10cm 4mm</th>
<th>2cm 7mm</th>
<th>2cm 4mm</th>
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<td></td>
<td>1 2 3 4 5</td>
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<tr>
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</table>

- **P** pressure in cm of H₂O
- + %clots captured completely
- + %clots captured partially
- - %clots passing completely through filter
- I %cases of insufficient flow
- M %cases of filter migration

* pressure never exceeded 5cm of H₂O

**Figure 17.**
<table>
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<tr>
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</table>

P pressure in cm of H₂O
+ %clots captured completely
+- %clots captured partially
- %clots passing completely through filter
I %cases of insufficient flow
M %cases of filter migration

* pressure never exceeded 5cm of H₂O

Figure 18.
### Greenfield Tilted 2.0mm

<table>
<thead>
<tr>
<th>Length (cm)</th>
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<th>4mm</th>
<th>Diameter (mm)</th>
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<th>4mm</th>
<th>Order</th>
<th>Pressure (cm of H₂O)</th>
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<td>4</td>
<td>5</td>
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</table>

**P pressure in cm of H₂O**

+ %clots captured completely

+-%clots captured partially

- %clots passing completely through filter

I %cases of insufficient flow

M %cases of filter migration

* pressure never exceeded 5cm of H₂O

Figure 19.
**GREENFIELD**

**28mm**

<table>
<thead>
<tr>
<th>Length</th>
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</table>

P pressure in cm of H₂O

+ %clots captured completely

+- %clots captured partially

- %clots passing completely through filter

I %cases of insufficient flow

M %cases of filter migration

* pressure never exceeded 5cm of H₂O

Figure 20.
## GREENFIELD TILTED-28mm

<table>
<thead>
<tr>
<th>Length</th>
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<th>2cm</th>
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</table>

P pressure in cm of H₂O

+ %clots captured completely
+− %clots captured partially
− %clots passing completely through filter
I %cases of insufficient flow
M %cases of filter migration

* pressure never exceeded 5cm of H₂O

Figure 21.
## MOBIN-UDDIN

### 15mm

<table>
<thead>
<tr>
<th>Length</th>
<th>10cm</th>
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</thead>
<tbody>
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</tr>
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</table>

- **P** pressure in cm of H₂O
- + %clots captured completely
- + - %clots captured partially
- - %clots passing completely through filter
- I %cases of insufficient flow
- M %cases of filter migration

*pressure never exceeded 5cm of H₂O*

**Figure 22.**
### MOBIN-UDDIN

**20mm**

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- **P** pressure in cm of H₂O
- **+** %clots captured completely
- **+-** %clots captured partially
- **-** %clots passing completely through filter
- **I** %cases of insufficient flow
- **M** %cases of filter migration

*pressure never exceeded 5cm of H₂O

Figure 23.
### MOBIN-UDDIN

**28mm**

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</tr>
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</table>

P pressure in cm of H$_2$O

+ %clots captured completely

+- %clots captured partially

- %clots passing completely through filter

I %cases of insufficient flow

M %cases of filter migration

Figure 24.
### Nitinol

**15mm**

<table>
<thead>
<tr>
<th>Length</th>
<th>Diameter</th>
<th>10cm</th>
<th>2cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7mm</td>
<td>4mm</td>
<td>7mm</td>
</tr>
<tr>
<td>Order</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>100</td>
<td>100</td>
<td>100</td>
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<td>0</td>
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</tr>
<tr>
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<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>%cases of insufficient flow</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>%cases of filter migration</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Pressure in cm of H₂O</th>
</tr>
</thead>
</table>

- %clots captured completely
- %clots captured partially
- %clots passing completely through filter

*pressure never exceeded 5cm of H₂O

*Figure 25.*
### NITINOL

2.0mm

<table>
<thead>
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<th>Diameter</th>
<th>Order</th>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</tbody>
</table>

|        |          |       |      |      | 1   | 2   | 3   | 4   | 5   | Σ    |

- **P** pressure in cm of H₂O
- + %clots captured completely
- +- %clots captured partially
- - %clots passing completely through filter
- I %cases of insufficient flow
- M %cases of filter migration

* pressure never exceeded 5cm of H₂O

**Figure 26.**
**NITINOL**

28mm

<table>
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<tr>
<th>Length</th>
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<th>Diameter 7mm</th>
<th>4mm</th>
<th>2cm 7mm</th>
<th>1 2 3 4 5 Σ</th>
<th>4mm 1 2 3 4 5 Σ</th>
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</thead>
<tbody>
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<tr>
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</tr>
</tbody>
</table>

P pressure in cm of H₂O

+ %clots captured completely

+- %clots captured partially

- %clots passing completely through filter

I %cases of insufficient flow

M %cases of filter migration

* pressure never exceeded 5cm of H₂O

Figure 27.