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Retrievable IVC Square Stent Filter: Experimental Study

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Abstract

Purpose: In vitro and in vivo evaluation of a new retrievable, home-made, inferior vena cava (IVC) Square stent filter (SSF) with two trapping levels.

Methods: In vitro, the SSF was compared in a flow model with the stainless steel Greenfield filter (SGF) for emboli-trapping efficiency by serially passing 300 emboli of 3 and 6 mm in diameter and 15–30 mm in length in each type of filter. Nine swine were used for the in vivo testing of the SSF for deployment and retrievability, emboli-trapping efficiency, stability, and self-centering ability and two were used (total of 11 swine) for testing repositioning and retrievability of the SSF at 2 weeks and for gross and histologic IVC changes at 2 months.

Results: In vitro, the SSF and SGF had similar efficiency in trapping large emboli but the SSF had significantly better efficiency than the SGF for trapping all sizes of emboli (91.7% vs 81%), medium size emboli (93% vs 80%), and small emboli (86% vs 69%). Efficiency decreased in both filters from the first to the fifth embolus in each series but was still significantly better for the SSF. With the SSF, 89% of emboli were caught at the primary and 11% at the secondary filtration level. In the nine animals used for acute studies, the SSF was easily placed in all 27 attempts, assumed a central position 26 times, and was easily retrieved in 21 of 22 attempts. One tilted filter needed additional manipulation for retrieval. During emboli injection in five swine, the SSF had 97.2% emboli-trapping efficiency and demonstrated good stability. In the two animals used for longer-term evaluation, the filters were easily retrieved 2 weeks after implantation. Histologic evaluation at 2 months showed neointimal proliferation around the SSF wires in contact with the IVC wall, which was otherwise normal.

Conclusion: The SSF is a promising filter. It is easy to place and retrieve, is stable after placement, and has high efficiency for trapping emboli. Promising results justify further experimental and eventual clinical studies with a commercially manufactured SSF.

Key words: Embolism, pulmonary—Inferior vena cava—Filters—Interventional procedures, experimental—In vitro studies—In vivo studies

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Several temporary filtering devices have been developed for insertion into the inferior vena cava (IVC) by transcatheter technique; they are either temporary or retrievable filters. Temporary filters are modified catheters or intraluminal devices attached to a tethering catheter or a wire for retrieval 1–6 weeks after implantation [1–10]. The retrievable filters are usually self-expanding and self-attaching devices which can be removed or, if indicated, left in place permanently. Percutaneous retrieval of these devices requires new jugular and/or femoral vein catheterization. There is an approximately 2-week period for removal or repositioning of the filter before it becomes fixed to the caval wall by endothelialization [11–17].

We developed a new retrievable square stent filter (SSF) with two trapping levels. We tested it in vitro and in vivo for deployment, repositioning, retrievability, efficiency of trapping emboli, and longer-term local changes on the IVC.

Materials and Methods

This protocol was approved by the Oregon Health Sciences University Animal Care and Use Committee. All animal facilities are accredited by the American Association for the Accreditation of Laboratory Animal Care and meet all federal (Public Health Service and National Society for Medical Research) guidelines for animal care.

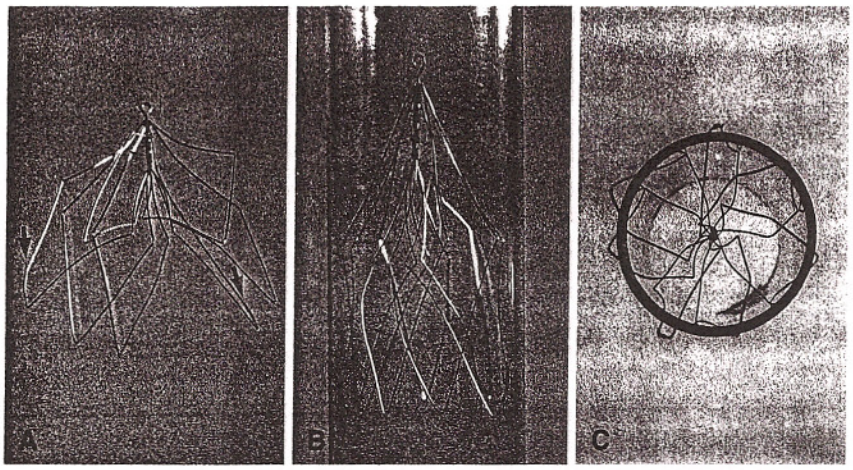

Fig. 1. The retrievable Square stent IVC filter (SSF). **A** Unrestrained SSF with a hook for percutaneous retrieval and three barbs for self-attachment to the IVC wall (arrows). **B, C** SSF in a plastic tube 25 mm in inner diameter. **B** Frontal view, **C** View from above.

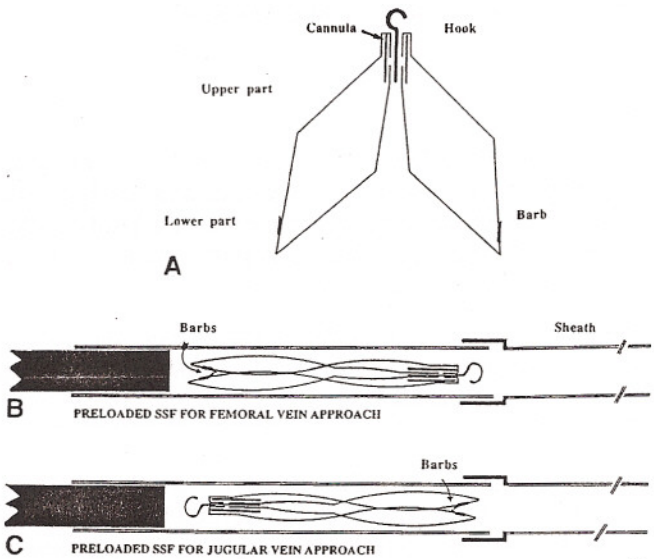

Fig. 2. Scheme of the retrievable Square stent IVC filter (SSF). **A** The stainless steel wire of the squares and the hook are connected to a cannula and crimped and soldered together. **B** The SSF preloaded into a 7 Fr cartridge for the femoral vein approach. When loaded into a cartridge, the barbs normally are oriented medially (arrow) toward the center and do not contact the cartridge or the delivery sheath wall. **C** The SSF preloaded into a 7 Fr cartridge for the jugular vein approach. With jugular introduction the pusher (black) rests against the filter's hook.

Device Description

The SSF is made of 0.0075″ stainless steel wire formed into seven, 24-mm-long squares. The squares are connected to a 20-gauge, thin-wall cannula and crimped and soldered together (Fig. 1). A reinforced stainless steel hook, allowing percutaneous retrieval, is attached to the connecting cannula. Tubular barbs are positioned on three lateral legs of the SSF allowing its self-attachment to the IVC wall (Figs. 1, 2). The seven lateral parts of the square come in direct contact with the IVC wall during SSF introduction and keep the filter in a central position.

The SSF is compressed and preloaded into a 7 Fr cartridge. When compressed, the barbs are oriented toward the center of the cartridge. The SSF is introduced through a 7 Fr [inner diameter (ID)] sheath (Cook, Bloomington, IN, USA) by pushing with a 6.5 F polyvinyl chloride pusher catheter (Cook) (Fig. 2). Once expanded, the SSF has two levels of filtration: one formed by the lower parts and the other by the upper parts of the squares. An Amplatz goose-neck snare (MicroVena, White Bear Lake, MN, USA) is used to retrieve the SSF.

In Vitro Testing

For in vitro testing, the diameter of the SSF was 35 mm with a length of 40 mm. When the SSF was constrained to a 25-mm diameter the length increased to 43 mm. Efficiency in trapping emboli was tested using a flow model simulating the IVC. The test system was constructed from a transparent plastic tube with an internal diameter of 25 mm through which water at 35–37°C was circulated at a rate of 2.5 L/min. Emboli were prepared from porcine blood by filling two different-sized plastic tubes which were kept at room temperature for 24 hr and then stored in a refrigerator until testing. Three sizes of emboli were used: small (3 mm in diameter by 20 mm in length), medium (6 mm in diameter by 15 mm in length), and large (6 mm in diameter by 30 mm in length).

Testing was done with the flow model in a horizontal position. After the filter was delivered through a sheath, emboli were injected through a 10-mm-wide side-arm tube. They were injected individually in 1-min intervals using five emboli of the same size for one testing series. Each embolus was closely followed and retention of embolus was recorded as success. After the injection of five emboli was completed, the filter was removed, cleaned, and replaced in the model for a new series of five-emboli injections. Altogether, a 60-injection series was done with each filter, 20 with each embolus size. The stainless steel Greenfield IVC filter (SGF) (Meditech, Boston Scientific, Natick, MA, USA) was used for in vitro comparison with the SSF. There were 300 emboli injections for the SSF and 300 for the SGF.

Animal Studies

For in vivo testing, due to the smaller diameter of the swine IVC, the seven squares used to construct the SSF were 18 mm long. The

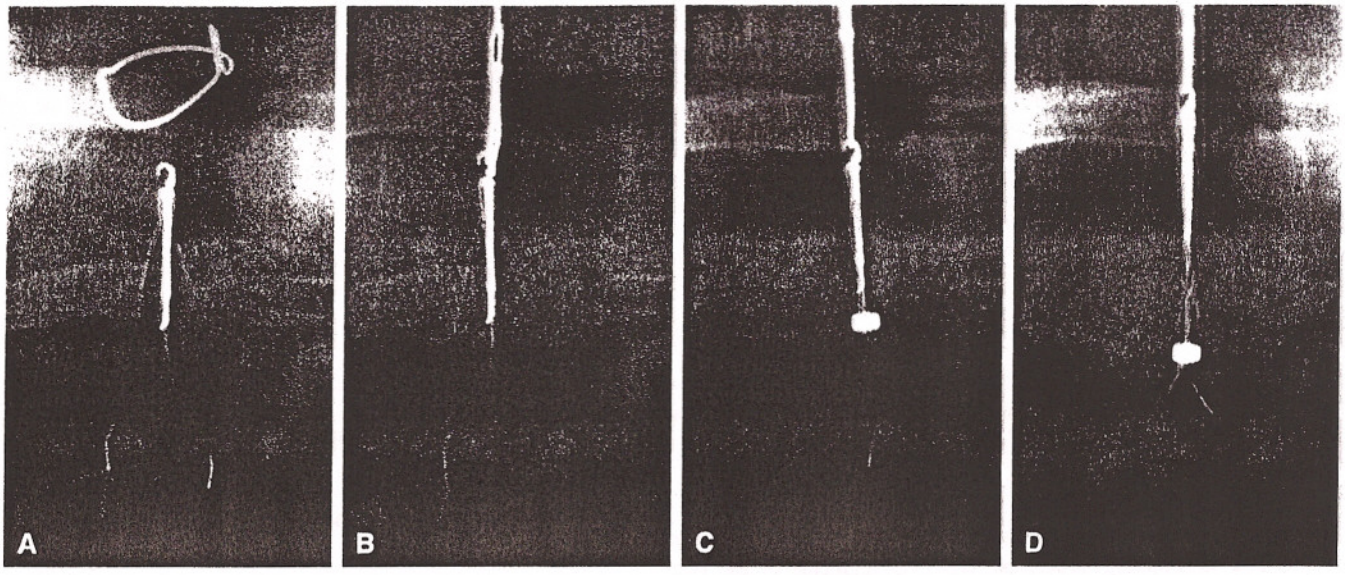

Fig. 3. Transjugular Square stent filter retrieval. **A** A goose-neck snare, introduced through an 8 Fr retrieval catheter and 10 Fr sheath, is above the filter hook. **B** The filter hook is captured and engaged. **C** The snare is held while the 8 Fr retrieval catheter is advanced over the filter until it is partially collapsed. **D** The collapsed filter is pulled into the 8 Fr catheter after its detachment from the IVC wall.

SSF's unrestricted diameter was 24 mm and its length 31 mm. In a 15-mm-diameter tube, its length was 33 mm. In vivo testing was carried out in 11 swine. Nine young swine weighing 25–40 kg were used for acute studies; two adult microswine weighing 66 and 75 kg were used for chronic studies. Each swine was sedated with Tiletamine HCl and Zolazenam HCl 3–6 mg/kg i.m. (Fort Dodge Laboratories, Fort Dodge, IA, USA) and atropine sulfate 1 ml i.m. (American Regent Laboratories, Shirley, NY, USA). The animals were ventilated by mask with Isoflurane (Burns Veterinary Supply, Rockville Centre, NY, USA) and were subsequently intubated and maintained at 2% Isoflurane with 2 L/min of O_2. After induction of general anesthesia, a cutdown was performed to access the left or right femoral vein and a 7 Fr Teflon sheath (Cook) was inserted for SSF delivery. A percutaneous right or left transjugular puncture was used to introduce a 10 Fr sheath (Cook) for filter retrieval. For transjugular SSF placement, a 7 Fr Teflon sheath was advanced through the 10 Fr sheath into the IVC.

Cavograms were performed before and after SSF deployment and were retrieved by injecting 30 ml of sodium meglumine diatrizoate (Squibb Diagnostics, Princeton, NJ, USA) through a 5 Fr pigtail catheter (Cook) introduced through the delivery sheath and positioned into the distal IVC. After cavography, the tip of the delivery sheath was positioned in the mid IVC. Location of the renal veins was identified by injection of a small amount of contrast medium. The filters were advanced through the delivery sheath with a 6.5 Fr pusher catheter. When the filter reached the tip of the sheath, the pusher catheter was held stable while the sheath was withdrawn until the SSF was released and fully expanded. Three infra- or supra-renal implantations and two to three retrievals were performed in each animal with a total of 27 implantations and 22 retrievals done in nine animals. A new filter was used for each animal. The position of the SSF in the IVC, whether centered or tilted, was recorded after each implantation.

For retrievals, a goose-neck snare with an 8 Fr guiding catheter (Cordis, Miami, FL, USA) was advanced through the 10 Fr sheath from the transjugular approach into the IVC above the filter hook. After the snare was deployed, the filter hook was captured and engaged. While holding the snare, the 8 Fr guiding catheter was advanced over the filter until it partially collapsed. The guiding catheter with the collapsed filter was then advanced caudally to detach it completely from the IVC wall. When free of the IVC wall, the filter was pulled into the guiding catheter completely or partially, if some barbs were oriented outside, and removed through a 10 Fr sheath (Fig. 3). Four animals were sacrificed after the last SSF retrieval with an overdose of pentobarbital sodium (Euthasol; King Pharmaceuticals, Bristol, TN, USA) administered intravenously, and a necropsy was performed.

The other five acute swine were used for assessing the in vivo emboli-trapping efficiency and stability of the SSF. Barium-impregnated blood emboli of two different sizes were injected into a femoral vein after the last filter placement. Emboli were made from fresh swine blood impregnated by a few milliliters of barium sulfate (250% W/V, E-Z-HD, E-Z-E Co., Westbury, NY, USA) in 6-mm plastic tubes and refrigerated for 24 hr. The clots were then cut into two different sizes, 6 mm in diameter by 15 mm in length and 6 mm by 30 mm. In these five animals the 7 Fr femoral sheath was replaced with a 14 Fr Teflon introducer sheath (Cook). Four emboli of each size were then injected individually at 1-min intervals through the sheath into a femoral vein for a total of eight emboli per animal. Capture of the emboli and stability of the filter was observed under fluoroscopy. After chest films in the lateral and antero-posterior position were taken, the animals were sacrificed and necropsy was performed.

For the longer-term study, the SSF was placed in two adult microswine under sterile conditions from the transjugular approach. Percutaneous transjugular retrieval of the filters was done 2 weeks after placement. New filters were then implanted by the transjugular approach in close proximity to the implantation sites of the removed filters. After a 2-month follow-up, both swine were sacrificed and necropsy with histologic examination was performed.

Table 1. In vitro emboli-trapping efficiency of retrievable Square Stent Filter (SSF) and Greenfield Filter (SGF)

Emboli	Number and percentage of captured emboli for each series				
	1st (n = 20)	2nd (n = 20)	3rd (n = 20)	4th (n = 20)	5th (n = 20)
SSF					
Small	19 (95)	18 (90)	17 (85)	17 (85)	15 (75)
Medium	19 (95)	19 (95)	18 (90)	19 (95)	18 (90)
Large	20 (100)	20 (100)	19 (95)	19 (95)	18 (90)
Mean	(96.7)	(95.0)	(90)	(91.7)	(85)
SGF					
Small	18 (90)	16 (80)	15 (75)	11 (55)	9 (45)
Medium	19 (95)	17 (85)	17 (85)	15 (75)	12 (60)
Large	20 (100)	19 (95)	19 (95)	18 (90)	18 (90)
Mean	(95)	(86.7)	(85)	(73.3)	(65)

Emboli were injected individually at 1-min intervals to a total of five of each size in one series: small (3 × 20 mm), medium (6 × 15 mm), and large (6 × 30 mm). Five series (20 emboli) of each size were injected for a total of 300 emboli for the SSF and 300 emboli for the SGF

Gross examination of the animals concentrated mainly on the IVC and surrounding structures. The IVC segments of the two longer-term animals were fixed in buffered 10% formalin, cross-sectioned, processed through alcohol and xylene, and embedded in paraffin. Four-micron paraffin sections were stained with hematoxylin and eosin, or with elastin. Digital photomicrographs were made on a Zeiss Axiophot microscope equipped with a Polaroid Digital Microscope camera [Carl Zeiss, Jena, Germany].

Statistical Analysis

Results are reported as the mean, number, and percentage of emboli trapped by filters. Differences in in vitro emboli-trapping efficiency between the two filters were examined for statistical significance by the Student's paired t-test. A p value of less than 0.05 was considered to represent a significant difference.

Results

In Vitro Study

Numerical results of the emboli-trapping efficiency of both filters tested are summarized in Table 1 and their comparison is demonstrated graphically in Figure 4. The SSF had a mean trapping efficiency of 91.7% for emboli of all sizes, 96% for large emboli, 93% for medium size, and 86% for small emboli. The efficiency for the SSF was similar to that of the SGF (94%) for trapping large emboli, but was significantly better than the SGF efficiency (80%, $p < 0.05$) for medium sized, and (69%, $p < 0.05$) for small emboli. Eighty-nine percent of the emboli trapped by the SSF were captured at the caudal filtration level and 11% at the proximal.

Both filters had a high mean efficiency for trapping the first embolus, 96.7% for the SSF and 95% for the SGF. The mean efficiency gradually decreased with the number of injected emboli and was 85% for the SSF and 65% ($p < 0.05$) for the SGF for the fifth embolus. The decrease in trapping efficiency from the first to the fifth embolus was minimal only for large emboli and the same for both filters—from 100% to 90%. There was, however a significant decrease in efficiency for small and medium-size emboli particularly for the SGF. The SSF trapping decreased from 95% to 75% ($p < 0.05$) for small and from 95% to 90% for medium-size emboli. For the SGF it decreased from 90% to 45% ($p < 0.01$) for small and 95% to 60% ($p < 0.01$) for medium-size emboli.

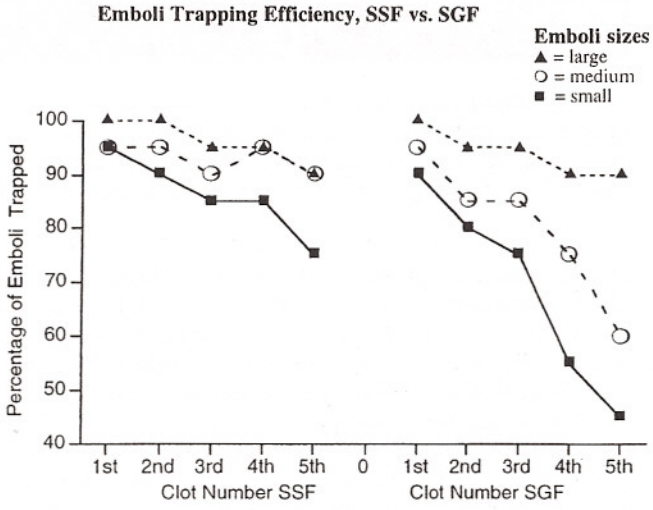

Fig. 4. Efficiency graphs of the retrievable Square stent filter (SSF) and stainless steel Greenfield filter (SGF) for trapping all sizes of emboli in a flow model. Numbers represent a mean. Differences between trapping efficiency of small and medium-size emboli were statistically significant ($p < 0.05$).

In Vivo Study

In the acute swine study, the SSF was easily introduced via the right (n = 10) or left femoral vein (n = 8) or the jugular vein (n = 9). The SSF self-centered properly in the IVC during 26 insertions; in one case it was slightly tilted. The introduced filters remained in position and no migration was observed. Twenty-one filters were retrieved without any difficulties. For retrieval of the slightly tilted filter, manipulation with a 5 Fr Cobra catheter was necessary before

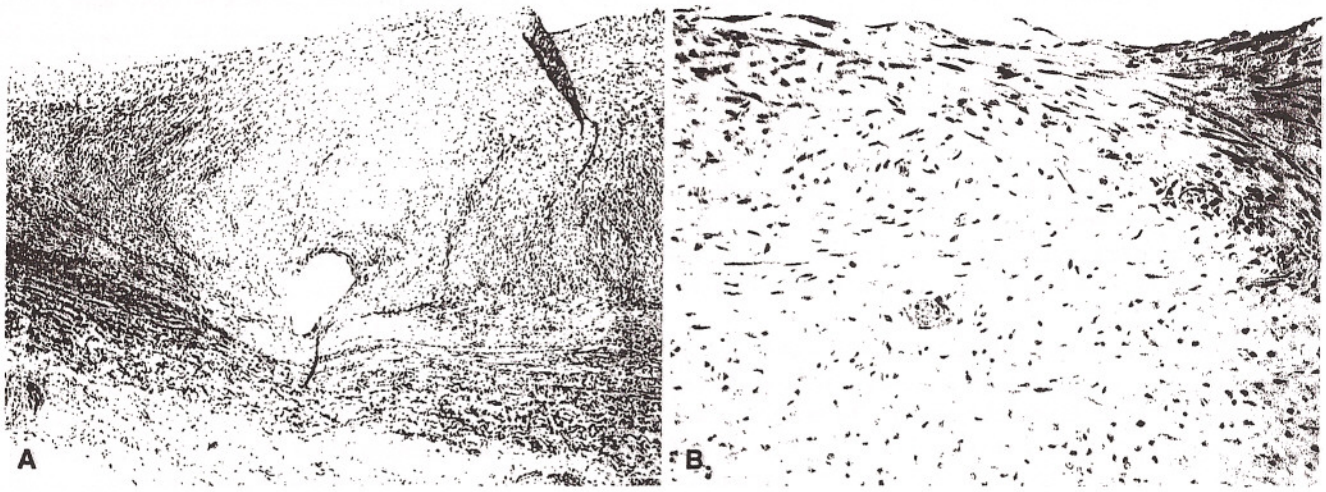

Fig. 5. Photomicrograph of a cross-section of the IVC obtained 8 weeks after the Square filter placement. **A** A thick layer of neointima, lined by endothelium, occupies the upper half of the image. Compressed muscle fibers of the vena cava wall underlie the neointima, and elastin fibers are evident within the adventitia. The hole in the center of the image represents the site of one of the filter wires (Elastin stain; original magnification 50 × 0). **B** A close-up view of the neointima reveals a mixture of spindled myofibroblastic cells and inflammatory cells, with an intact layer of endothelial cells along the luminal aspect (hematoxylin & eosin; original magnification 200×)

engaging the hook with the retrieval snare. All 22 filters were retrieved without damaging the wires. Follow-up cavograms after retrieval did not show any abnormalities of the IVC wall.

The SSF was evaluated for in vivo emboli-trapping ability, and stability was attained by injecting radiopaque emboli ($n = 40$) into the femoral vein. Filters remained stable after trapping 35 emboli at the caudal filtration level. Four emboli were trapped by the upper filtration level and only one embolus passed the filter, a pulmonary embolism rate of 2.5%. Follow-up cavograms showed good flow through the filters with emboli trapped mainly in the central portions of the SSF.

One of two filters retrieved 2 weeks after implantation had minimal endothelial tissue surrounding two legs. Posretrieval cavograms were normal without evidence of IVC injury. Cavograms 8 weeks after new filter placement in two miniswine showed a widely patent filter without clot formation. There was no filter migration or luminal narrowing of the IVC.

In our in vitro experiments we placed the same SSF 60 times and it always centered itself. In our in vivo experiments with 31 SSF placements, 27 in acute and 4 in chronic animals, we observed SSF tilting only once (3.2%). Barbs on the three legs of the filter assure a stable position without migration.

In nine acute animals each filter was placed in the IVC three times. It was retrieved three times in four animals and twice in five animals who were studied for in vivo emboli-trapping efficiency. No filter disruption was observed after repeated placement and retrievals in these acute animals. We experienced similar results with two filters that were retrieved and replaced 2 weeks after initial placement.

Pathologic Examination

Gross examination of nine acute animals showed traces of barbs penetrating into the IVC intima. There was no perforation of the IVC wall or evidence of hemorrhage in surrounding tissues. Necropsies of the two longer-term animals revealed incorporation of the filter struts that were in contact with the vein wall. Only small fibrin deposits without neointimal proliferation were observed on the free wire surface. There was no sign of stainless steel corrosion. Histology of the IVC wall in these swine showed complete endothelialization of the filter wires covered by neointima, fibrosis, and chronic inflammatory cells with no foreign body reaction (Fig. 5).

Discussion

An ideal IVC filter should be made of biocompatible, noncorrosive, nonthrombogenic, and nonferromagnetic material. Its design should be simple but mechanically durable. It should have the ability to be easily and safely introduced from the femoral, jugular, or brachial approaches with a small-caliber delivery catheter. It should self-center and not tilt at the implantation site. In addition, the ideal filter should be stable without migration and should be amenable to repositioning. It should trap all clinically significant emboli while maintaining IVC patency [18–20]. A retrievable IVC filter should also be easily and safely retrievable by jugular or femoral vein approaches up to 10–14 days after deployment, and possibly longer, without injury to the IVC wall [10]. Presently, no filter fulfills all these criteria; each has its weaknesses. Most retrievable filters showed promising results in in vitro and in vivo experimental studies [11–17].

However, these results were not completely realized in clinical studies; some filters allowed recurrent embolism or IVC occlusion [21–24] and some were difficult to retrieve [22].

The SSF showed encouraging results in our in vitro and in vivo experiments. Its simple strong design allows for easy and safe placement, stable position in the IVC, high trapping efficiency, and simple and safe retrievability. In our opinion, the SSF has the potential to be a clinically successful, permanent or retrievable filter. However, further experimental and mainly clinical studies will be necessary to confirm this potential.

The SSF is designed with seven squares connected by passing the medial legs through a canula which is soldered and crimped, making it a durable device. The same filter was used for all in vitro studies and one filter was used in each of the tested animals. The SSF was easily introduced through a 7 Fr (ID) sheath with a 6.5 Fr pusher catheter. When the SSF is compressed, the barbs are oriented medially towards the center and do not contact the sheath wall. For introduction from the femoral approach the pusher catheter contacts the compressed legs of the filter. With jugular introduction the pusher is against the filter's hook. Because of the strong fixation of the hook to the cannula and minimal friction during advancement of the filter there were no problems in placing three SSFs repeatedly in three animals (altogether nine times from the jugular approach). The SSF is relatively flexible, with some rigidity at its cannula connection and its hook, thus, it can be introduced through a curved catheter and therefore could be introduced from the brachial approach.

The SSF was highly efficient in trapping emboli. Comparing it with the SGF, the filters were similar only in trapping large emboli and the first embolus. For medium and small emboli and overall emboli trapping, the SSF was significantly more efficient. Because the SSF has two filtration levels, its filtration is tighter and its efficiency in trapping emboli is greater than the SGF. Most of the captured emboli (89% in the in vitro study) were trapped at the lower filtration level, which is formed by the lower parts of the squares. The remaining emboli (11%) were caught at the upper filtration level formed by the upper parts of the squares.

The retrieval technique for the SSF was similar to that of other filters with an apical hook [12–14]. Retrieval of the SSF was easy and simple in 23 of 24 attempts. In only one case, where the filter was tilted, was additional manipulation required to engage the filter hook with the snare. Retrieval is done from the jugular approach. Engaging the snare on the hook was without complications in our study. The hook has a small additional soldered curve at its end and is quite radiopaque. After engaging the hook it is important to apply only slight tension to the snare until the retrieving catheter is partially advanced over the filter, which at this point is partially collapsed. Further caudal movement of the retrieving catheter disengages the filter barbs completely from the IVC wall and allows for a rapid and atraumatic filter retrieval. In all 23 simple cases it took no more than 2–3 min to retrieve the filter and the retrievals were atraumatic. During collapse of the filter, the barbs on its legs orient mostly medially into the catheter lumen. But even when some barbs were oriented laterally and the filter did not retract completely into the 8 Fr catheter, the 10 Fr sheath assured atraumatic retrieval. We did not observe any significant injury to the IVC wall or other vascular structures even after retrieval of the three filters. There was only minimal injury to the IVC wall by the barbs, consisting of small puncture points at the site of the barbs that did not penetrate the IVC wall.

A period of 2 weeks is generally accepted as safe for retrieval of an IVC filter [10–14]. In our two animals we did not observe any changes on the IVCgram following retrieval at 2 weeks even when some endothelium was attached around two legs of one filter. After 2 weeks, the filter wires, which are in contact with the intima, became incorporated into the IVC wall making retrieval of the SSF and most other filters impossible without disruption of the vein wall. Animal studies showed that retrieval of the SGF is possible even after 3 weeks but is not recommended [25]. The Irie filter is the only device that enables retrieval after 1 month because of its two-part design and simultaneous removal of each part by the jugular and femoral approaches [15, 16]. If a 1-month placement of an SSF is desired, it could be easily achieved by repositioning the filter to a new caudal or cranial location after 14 days, with subsequent removal at 1 month.

Our study showed that the SSF has a durable design, can easily be placed and retrieved, is self-centering and stable, and has high efficiency for trapping emboli. More experimental, and especially clinical studies, are necessary to document its long-term potential for future clinical use.

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