

## Removal of Retrievable Inferior Vena Cava Filters 90 Days After Implantation in an Ovine Model: Is There a Time Limit for Removal?

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**OBJECTIVE:** To study the feasibility and safety of removing retrievable Günther-Tulip vena cava filters (GTFs) 90 days after their implantation in an ovine model.

**MATERIAL AND METHODS:** Thirty GTFs were implanted in 30 ewes and retrieval was attempted at 90 days. Conventional cavography was performed in all cases before and after retrieval in order to evaluate inferior vena cava patency and record dimensions. The presence of complications related to placement and retrieval of the filter from the inferior vena cava was also recorded. The force required to remove the filters was measured using a modified commercial dynamometer adapted to the GTF retrieval set. Histologic study focused on the inferior vena cava wall.

**RESULTS:** Implantation was performed successfully in all cases (100%). One ewe developed a small focus of thrombosis around 1 of the legs of the filter and another presented a small thrombus within the filter. Retrieval of the filter was attempted in all 30 sheep at 90 days and the result was satisfactory in all but 1 case (96.6%). None of the GTFs required a force greater than 12 N to disengage the hooks of the filter from the wall. No complications were detected on venacavography or at autopsy. Variable degrees of fibrosis were observed in the histologic study.

**CONCLUSIONS:** Retrieval of GTFs 90 days after implantation in an ovine model was feasible, safe, and easy, and required little force (median, 4.2 N).

**Key words:** *Filters. Inferior vena cava. Pulmonary embolism.*

¿Cuál es el tiempo límite para retirar un filtro de vena cava? Filtros opcionales de vena cava inferior: recuperación 90 días después de su implantación. Modelo ovino

**OBJETIVO:** Estudiar la posibilidad y la seguridad de recuperar filtros opcionales de vena cava Günther-Tulip (FGT) a los 90 días de su implantación inicial en un modelo animal ovino.

**MATERIAL Y MÉTODOS:** Se implantaron 30 FGT en otras tantas ovejas hembras y se intentó recuperarlos 90 días después de su implantación. Se realizó cavografía convencional en todos los casos antes y después de la recuperación, para evaluar la permeabilidad de la vena cava. Se obtuvieron medidas de la vena cava y se documentó la presencia de complicaciones relativas a la implantación y recuperación del filtro de vena cava inferior (VCI). Se midió la fuerza requerida para recuperar los filtros de vena cava con un dinamómetro comercial modificado y adaptado al equipo de recuperación de FGT. El estudio histológico se centró en la pared de la VCI.

**RESULTADOS:** La implantación se efectuó con éxito en todos los casos (100%). Una oveja desarrolló un pequeño foco de trombosis en una de las patas del filtro y otra presentó un trombo pequeño en el interior del filtro. Se intentó la recuperación del filtro en las 30 ovejas y, excepto en un caso, el resultado fue satisfactorio (96,6%). En la recuperación de los 30 FGT, la fuerza necesaria para desenganchar las patas del filtro de la VCI fue menor de 12 newtons (N). No se observó ninguna complicación en los cavogramas ni en la autopsia. Se observaron diferentes grados de fibrosis en el estudio histológico.

**CONCLUSIONES:** En un modelo animal ovino, la recuperación de FGT a los 90 días de su implantación es posible, segura y fácil, y requiere poca fuerza (mediana: 4,2 N).

**Palabras clave:** *Filtros. Vena cava inferior. Embolia pulmonar.*

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### Introduction

Inferior vena cava filters have been found to be safe and effective for the prevention and treatment of pulmonary embolism when anticoagulation is not possible or has failed.<sup>1,2</sup> Permanent filters are being superseded by

temporary filters, particularly retrievable ones, as these have the advantage of avoiding the long-term complications of permanent filters, while still preventing pulmonary embolism in the short term.<sup>3-7</sup> The permanent presence of a foreign body in the vena cava leads to thrombosis in 8% to 32% of cases, making lifelong anticoagulation necessary.<sup>1-3</sup> In consequence, the removal of inferior vena cava filters has clear clinical advantages that outweigh the risks that this action may carry.<sup>8</sup>

The ideal time to leave a filter in place is unknown; Millward<sup>8</sup> considered that there should be no limit, but we do not know of any commercially available filter for which no recommended maximum dwell time is given. Animal models should be used to evaluate prolonged dwell times in order to guarantee their safety for use in humans.

The initial recommendation from the manufacturers of the retrievable Günther-Tulip vena cava filters (GTFs) was for their removal after a maximum of 14 days; this recommendation was supported by experimental studies in both dogs<sup>9</sup> and pigs.<sup>10</sup> Five years after those initial studies, which demonstrated in both animal models that removal of the filter was difficult after a period longer than 14 days, it was shown that this difficulty could be related to the small diameter of the vena cava in the animals used.<sup>9</sup>

In addition, there have been isolated case reports of removal times of over 100 days with GTFs and other makes of filters,<sup>5,11-15</sup> and series in which removal was performed at 30 days.<sup>16</sup> Further studies in ewes with other filter prototypes have found little difficulty removing the filter at 3 to 5 months.<sup>17,18</sup> However, those studies were performed with small groups of animals and the process of retrieval was not studied in depth.

In view of this situation, we performed an experimental study using an animal model with an inferior vena cava diameter similar to that of human beings, systematically retrieving the GTFs at 90 days after implantation. In each animal, the force necessary to retrieve the filter was measured and the histopathologic changes occurring at the site of insertion of the filter into the inferior vena cava wall were studied.

## Material and Methods

### Study Design

This was a prospective, descriptive, nonrandomized study performed on 30 ewes. A GTF was implanted in each animal. The study adhered to the norms established by the animal care committee of Universidad de Zaragoza and was approved by them under the number PI07/05.

### Animal Model

The animals used for all phases of the experiment came from the animal experimentation department of Universidad de Zaragoza. The experimental animals were of the ovine species (Rasa Aragonesa) and female; weight ranged from 55 to 65 kg and the mean age was 11 months (range, 10-14 months). This animal model was chosen as it had already been used in experiments on vena cava filters and had also been used previously by this team in other similar experiments. The ewe is a manageable animal, of adequate size, that recovers well after surgery, with few complications.

### Care and Anesthesia of the Experimental Animal

The animals had the vaccinations and deparasitation required for their species and had not been used in any other experimental study.

Six hours before the operation, they were transferred to the stables of the Minimally Invasive Techniques Unit (Hospital Clínico Veterinario), where they were put into individual boxes and their general state of health was confirmed to be satisfactory. All the sheep received general anesthesia throughout all the procedures, using the following anesthetic protocol: *a*) an intramuscular injection of xylazine (0.1 mg/kg) as preanesthetic medication; *b*) an intravenous injection of ketamine (4 mg/kg) into the cephalic or tarsal vein; *c*) after intubation, maintenance of anesthesia with 2% to 2.5% isoflurane in oxygen; and *d*) insertion of a nasogastric tube to avoid aspiration and possible lesions due to material that might be regurgitated. Monitoring of the heart and respiratory rates, oxygen saturation, and electrocardiogram was performed in all animals.

All the sheep were anticoagulated with bemparin (Hibor-Rovi Laboratory, Madrid, Spain), a low molecular weight heparin, at a dose of 50 U/kg/d. The surgical approach was via the right jugular vein in all cases.

### Filter Insertion

The GTF of William Cook Europe (Bjaeverskov, Denmark) was used in all the animals. The devices were introduced percutaneously into the inferior vena cava via the internal jugular vein under ultrasound guidance (Titan, Sonosite, Spain). All the operations were performed in the minimally invasive techniques unit. Cavography (C-arm, Philips V-29) using 30 mL of iopamidol 370 (Bracco Diagnostics Inc, Milan, Italy) was performed before insertion of the filter. All the filters were inserted using an 8.5F introducer, carefully following the manufacturer's instructions, which have been described by other authors.<sup>1,19</sup>

### Cavography and Measurements of the Inferior Vena Cava

Immediately after inserting the filter as a temporary device, cavography was performed in the 30 sheep to obtain images of the implantation site. The aim of cavography was to determine the presence and degree of tilt of the filter, perforation of the wall of the vena cava by the legs of the filter, and any damage to extravascular structures. In addition, the cavogram enabled us to measure changes in the diameter of the lumen during the respiratory phases and Valsalva maneuver (Figure 1). Measurement of the diameters of the vena cava was performed using a calibrated catheter and a measurement tool incorporated in the computer equipment of the x-ray arc; this tool uses the calibrated catheter as a reference and provides the values corresponding to 2 points chosen on the image.

Three types of respiratory movement (forced inspiration, expiration, and the Valsalva maneuver) were simulated with the animal intubated under general anesthesia, and the following parameters were recorded: heart rate, electrocardiogram, blood pressure, oxygen saturation, PaO<sub>2</sub>, and PaCO<sub>2</sub> using capnography.

Forced inspiration was achieved using intermittent positive pressure ventilation, with 1 deep insufflation from the reservoir bag to reach a pressure of 35 mm H<sub>2</sub>O in the airway. It was impossible to simulate forced expiration in the animal, as this is a voluntary act, and we therefore used the data recorded at the end of the plateau of the physiologic respiratory curve determined by capnography. The Valsalva maneuver was simulated by occluding the orotracheal tube and compressing the greatest possible surface area of the abdomen of the sheep using a wide strip of cloth.

The luminal area of the inferior vena cava was calculated using the formula for the area of an ellipse:

$$a = \frac{\pi \times d_1 \times d_2}{4}$$

where  $a$  is the luminal area,  $d_1$  the largest diameter of the inferior vena cava, and  $d_2$  the smallest diameter. The measurements were taken 3 mm below the renal vein. The cavogram images taken immediately after insertion of the filter were obtained during inspiration, expiration, and the Valsalva maneuver.

#### Filter Removal

All filters were removed via the external jugular vein. Cavography was performed before and after retrieval. The filters were removed using the GTF removal set (William Cook Europe, Bjaeverskov, Denmark). A modified, commercially available dynamometer (Gilca, SA, Zaragoza, Spain) (Figure 2) was used to provide an objective measurement of the force necessary to dislodge the device from the wall of the vena cava and to introduce the legs of the filter into the removal sheath; thus, the dynamometer provided a quantitative measure of the degree of difficulty of removal. This dynamometer has a scale between 0 and 9.8 N, with an accuracy of  $\pm 1\%$ .

The degree of difficulty in recovery of the filter was classified in the following way: *a*) no difficulty, with a force range between 0 and 4.41 N; *b*) moderate difficulty, with a force range between 4.41 and 5.88 N; *c*) great difficulty, with a force range between 5.88 and 9.8 N; and *d*) impossible to remove, if the force exceeded 9.8 N.

The retrieval techniques have been previously described.<sup>11,18</sup> Cavography was performed on completion of the retrieval procedure in order to evaluate possible bleeding from the inferior vena cava and any other complication.

#### Pathology

Excision of the abdominal cava was performed by open surgery under general anesthesia. The sheep was placed in the supine position and a xiphoid to pubis midline laparotomy was made. The abdominal organs were displaced manually in order to locate the inferior vena cava, which was then carefully dissected, ligating the renal and lumbar veins. Finally, the vena cava was ligated proximally in the liver and distally at the iliac bifurcation.

The vena cava was removed and euthanasia of the animal was performed immediately thereafter with an intravenous injection of 20 mEq of potassium with 1 g of sodium pentothal. For its subsequent study, the surgical specimen was introduced into a labeled, sterile container with a 10% solution of formol.

#### Study Characteristics

Any technical problem that occurred during the implantation of the filter was recorded<sup>7</sup>: tilt of the filter greater than 20° with respect to the axis of the vena cava or contact of the introducer hook with the wall of the vena cava (when either of these 2 situations occurred, the filter was removed immediately and was reimplanted correctly), perforation of the wall of the vena cava by any of the filter structures, or incomplete opening of the device.

When it was impossible to remove the filter despite several attempts, failure to retrieve was recorded. Particular attention was paid to the onset of the following complications: extravasation of contrast and hematomas within or beside the wall of the vena cava.

The histopathologic study was performed to detect fibrotic reactions in the endothelium of the vena cava at the site where

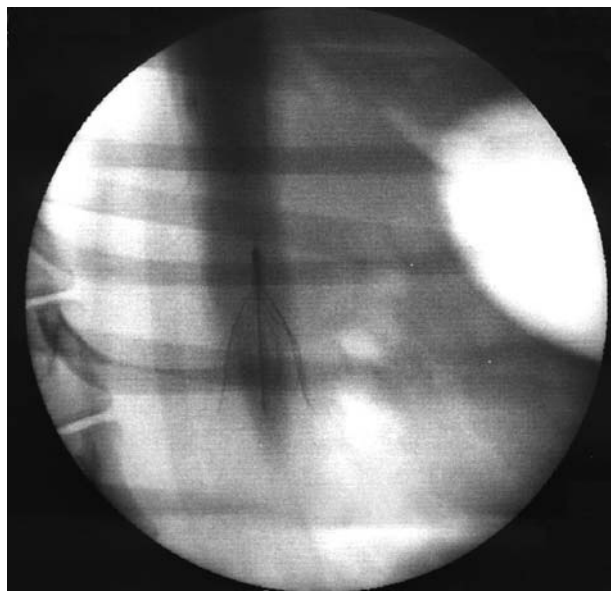


Figure 1. Phlebography of a sheep vena cava with filter during inspiration.



Figure 2. Modified dynamometer adapted to the Günther-Tulip filter removal equipment.

the hooks were lodged and any other alterations of the wall of the vein and adjacent retroperitoneal tissues.

## Results

### Filter Insertion

All the GTFs were inserted satisfactorily. Tilt of the filter greater than 15° was observed in 3 sheep. The filter was not repositioned in these cases.

### Cavography

The diameters of the vena caval lumen obtained on cavography in the different phases of respiration are shown in Table 1.

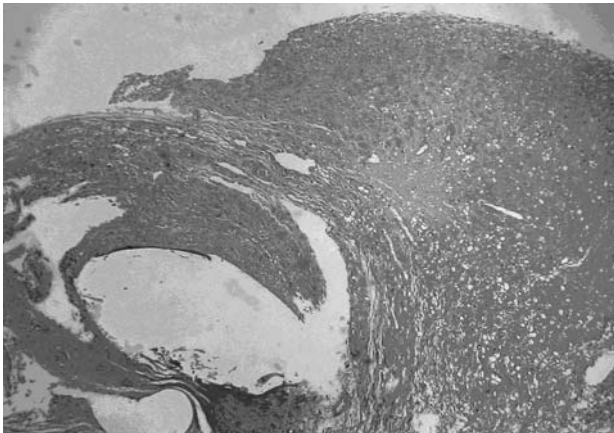


Figure 3. Histological preparation of the wall of the vena cava. A fibrous band may be seen around the site of implantation of the filter.

### Filter Retrieval

Filter retrieval was attempted in all 30 sheep and was completed successfully in 29 (96.6%); retrieval was impossible in 1 case despite applying a force, as indicated on the dynamometer, greater than 10 N. The median force required to remove the filters was 4.2 N (Table 2).

The two filters that required a moderate force (4.9 N for both filters) for retrieval had a tilt less than 15° with respect to the axis of the vena cava, whereas the filter that could not be removed had a tilt greater than 15° and the superior hook had become incorporated into the wall of the vena cava.

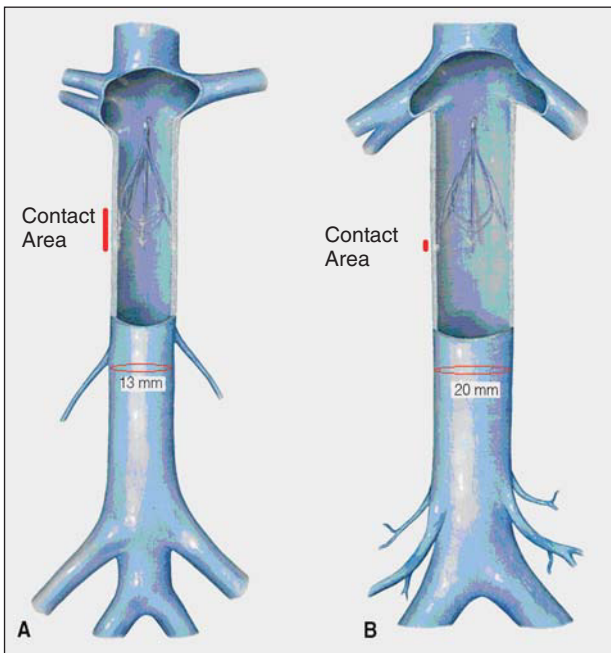


Figure 4. Günther-Tulip filters implanted in the inferior vena cava, showing the contact between the filter and the wall of the vena cava and its relationship to the diameter of the vein. In the pig model of the vena cava (A), with a diameter of 13 mm, the area of contact between the filter and the wall is greater than in the ovine model (B), in which the diameter is 20 mm.

TABLE 1  
Ovine Inferior Vena Cava Measurements Obtained on the Cavogram

Respiratory Movement	Median	Range	SD
Inspiration			
Largest diameter	18	17-20	1.06
Smallest diameter	18	17-20	1.07
Area, mm <sup>2</sup>	523	454-628	54.82
Expiration			
Largest diameter	16	14-19	1.89
Smallest diameter	16	13-18	1.73
Area, mm <sup>2</sup>	402	286-537	91.16
Valsalva			
Largest diameter	15	14-17	1.05
Smallest diameter	14	13-16	0.92
Area, mm <sup>2</sup>	319	286-427	43.67

TABLE 2  
Degree of Difficulty in Recovering the Filters From 30 Ewes

Degree of Difficulty	N	%
None, 0-4.41 N	27	90
Moderate, 4.41-5.88 N	2	6.6
Impossible, > 10 N	1	3.3

### Pathology

The pathologist reported different phases of subendothelial reaction in the wall of the inferior vena cava that had been in contact with the GTF for 90 days. Areas of resting smooth muscle cells predominated; in adjacent areas, these muscle cells had been replaced by collagen fibers that were beginning to form a fibrous band surrounding the union of the filter's thick and thin filaments (Figure 3).

More fibrosis was observed in those cases in which withdrawal was moderately difficult, and mainly surrounded the hooks of the legs, forming a hard, fibrous ring tight around the wire. In the filter that could not be removed, there was significant fibrosis that surrounded both the superior extraction hook and the legs, making it impossible to snare the filter. In this case, the surgical autopsy revealed a tear in the wall of the vena cava with a small hematoma in the wall that was not observed on the previous cavography.

### Discussion

The ideal vena cava filter should be retrievable in accordance with the criteria established by June<sup>20</sup> and Millward<sup>8</sup>; however, the optimal dwell time after implantation has not been established. Millward<sup>8</sup> indicated that this time should be unlimited, and should be decided according to clinical requirements. Decousus and coworkers<sup>21</sup> demonstrated that after day 12 following insertion, the filter did not provide any protection against pulmonary embolism, from which it may be deduced that, except for certain exceptions, according to these authors the filters can be removed after 12 days. De Gregorio and coworkers,<sup>16,22-24</sup> on the other hand,

considered that it was necessary to prolong the time the filter is left in place in some clinical situations, such as persistent hemorrhage, scheduled surgery, pregnancy, prolonged immobility, etc. However, there is insufficient evidence to decide conclusively which path should be followed.

In the case of the GTF filter, the manufacturer recommended a maximum dwell time of 14 days, based on studies performed in animals<sup>9,10</sup> in which, after day 16, fibrosis developed that made retrieval impossible. We believe that this fibrosis could be related to incompatibility between the diameter of the animal's vena cava and the diameter of the filter. The diameters of the vena cava in the experimental animals used in those studies measured between 10 and 13 mm, approximately, whereas the diameter of the commercial filters used was conceived for human vena cava of up to 30 mm. The greatest degree of fibrosis was observed at the junction between the petal and the main foot of the filter, and it was probably this accumulation that was preventing removal of the filter.<sup>9</sup> The large area of contact of this part of the filter with the venous endothelium provoked a marked fibrotic reaction that surrounded the filter at this point and made its retrieval impossible after day 16 (Figure 4). In contrast, in larger diameter vena cava, such as those of sheep and humans which have a mean (SD) diameter of 17-20 (1.06) mm, only the hooks on the legs of the GTF enter into contact with the wall and anchor the filter. These hooks can be easily dislodged and withdrawn into the sheath, and the filter is recovered with no apparent injury.

These findings were confirmed in the sheep model, both at the time of retrieval of the filter and in the pathologic studies, which demonstrated that the endothelium was only changed in the area of the anchor hooks, with no alterations observed in the areas adjacent to the petals or legs of the filter. No significant damage to the wall of the vena cava and no alterations in the adjacent organs or in the pericaval retroperitoneal space were observed during the laparotomy or autopsy study.

However, there is reasonable concern about the force necessary to extract the hooks from the wall of the vena cava. Excessive force could seriously damage the vessel. At present there is no parameter that defines the ceiling of force above which damage to the vena cava could occur. For this reason, we considered it would be interesting to quantify the degree of difficulty in filter retrieval, as this would enable us to establish the ceiling of force for withdrawing any type of filter safely. All except one of the GTFs in our study were retrieved successfully using a mean force of less than 4.9 N. In the animal in which it was not possible to remove the filter despite using a force greater than 10 N, the autopsy did not reveal a hematoma of the wall. In our opinion, experimental studies should be continued in sheep, with longer dwell times, until rupture of the wall of the vena cava occurs, in order to determine the limit of force allowable to remove these filters without causing damage; the type of lesions occurring in the vena cava and its adjacent tissues and the degree and type of fibrosis in the endothelium can then be studied at autopsy. Our group is therefore evaluating filter retrieval in experimental animals after more than 30 days, under

fluoroscopic and laparoscopic guidance, using various degrees of force.<sup>25</sup>

As found by other authors,<sup>1,8</sup> the main reason that the filter could not be removed in our case was not the inclusion of the hooks of the filter legs into the wall of the inferior vena cava due to fibrosis, but rather the degree of tilt caused the superior retrieval hook to become incorporated into the wall, preventing the filter from being snared. It may therefore be deduced that the satisfactory implantation of a filter requires the correct angle and prevention of contact of the retrieval hook with the wall of the vein. In our opinion, this means that great care must be taken during implantation, with measures to prevent tilt; the filter may even need to be repositioned at the time of implantation<sup>19</sup> in order to guarantee its removal and the safety of the procedure.<sup>8</sup> In addition, when it is impossible to remove the filter, lifelong anticoagulation may be necessary to avoid the risks of thrombosis of the vena cava.

The possibility for removing a filter after an indefinite period means that this procedure can be an important prophylactic and therapeutic tool in the clinical management of patients with venous thromboembolic disease when anticoagulation is not recommended, is contraindicated, or has been withdrawn due to hemorrhagic complications. Multiple trauma patients with a high risk of thrombosis, neurosurgical patients, and those who are immobilized for long periods of time could benefit from these devices.<sup>26</sup> In addition, retrievable filters are also useful devices in patients diagnosed with venous thromboembolic disease in whom anticoagulation must be withdrawn temporarily for whatever reason. The use of a temporary filter that is simple and safe to implant and can be retrieved after an indefinite period could be beneficial in all those cases and, should it be necessary, may be used as a conventional permanent filter.

In conclusion, as reported by other authors, we consider there is no indication for the exclusive use of permanent filters, as although retrievable filters may be removed, they can also remain implanted indefinitely.<sup>1,8,27,28</sup> However, further studies in experimental animals are required to determine the maximum time the filters can remain in place and to establish the rupture force of the vena cava at the time of retrieval.

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