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# A new type of inferior vena cava filter and its animal experiment

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**Abstract:** This article explains the definition of pulmonary embolism as well as its causes and elaborates on a new type of inferior vena cava filter(VCF)we have developed. Shaped like a waistdrum, the VCF is mainly made of TiNi shape memory alloy-wire. It has a subulate wire frame which can intercept the thrombus on each side. Its medial body is made up of straight shape memory alloy-wire . Every pillar is bound by several shape memory alloy springs. This type of inferior vena cava filter has a good resistance to fatigue and is hard to be broken. Through animal experiments its framework has been proved to be lasting. Neither deformation nor fragmentation happened when the VCF had been kept in the body for a long time. The thrombus interception efficiency of our VCF is higher than imported VCFs. The filter is unfavorable for thrombosis. After implantation, the IVC was completely unimpeded and no displacement occurred. Moreover the VCF did little damage to the Wall of vein. Neither IVC perforation nor haematoma occurred after the operation.

**Key words:** shape memory alloy; inferior vena cava filter; pulmonary embolism

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## 1 Introduction

Pulmonary embolism(PE), also called lung embolism, is the clinical pathological physiological syndrome of the dyshemia in the lung caused by thrombus or other kinds of embolus clogging the pulmonary artery and its branches. In 75%－90% of the cases, pulmonary artery embolus has its source in the veins in lower limbs and the cavitas pelvis. The thrombus amotioes from the vein and is sent to the cor dextrum by bloodstream. At last it reaches the pulmonary artery and thus pulmonary embolism comes on. There are about 630,000 people suffering from the pulmonary embolism every year in America and 200,000 of them die of it. Anticoagulant therapy, which can reduce the death rate of the pulmonary thromboembolism from 30% to 10%, has always been the conventional therapy to the pulmonary thromboembolism. However, in some cases, we must implant a mechanical device in the inferior vena cava (IVC) to prevent the embolus from going up, so as to guard ourselves against the pulmonary thromboembolism. Since 1950s, many patients have adopted methods such as vena caval ligation, plication and Adams de Weese clips to avoid pulmonary thrombembolism, but they often resulted in shock and other serious complications , the postoperative death rate being 4%－50%. The birth of VCF heralded great achievements in treating the deep vein phlebothrombosis and preventing and treating the pulmonary thromboembolism. Meanwhile, it can also make

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the blood in the vena cava flow smoothly. It is easy and safe to place the inferior vena cava filter in the inferior vena cava by percutaneous puncture and this method has been adopted extensively in recent years.

The permanency inferior vena cava filter is to remain in the body for a long period after implantation, so the material of the filter must be biocompatible and safe. It is also important to avert complications. At present, the permanancy inferior vena cava filters with worldwide application are mainly: Greenfield Filter (GF), Trap Ease Filter(TEF), Bird's Nest Filter(BNF), Simon Nitinol Filter(SNF) and so on, all of whom share the advantages of having strong capability to catch the thrombus and good machinery and biological stability, leaving less impact on the blood flow, being able to remain unobstructed for longer periods, causing few complications and being easy to operate. They have been applied to clinic abroad extensively. But the high price of foreign filters and the absence of domestic filters fit for clinical use have hindered the generalization and the application of this technology at home.

An American scholar, Ferrs E placed 324 filters in 320 patients. Having followed them up for eight years, he drew conclusions that the rate for long-term success of the operation was 88%, the recurrence rate of the pulmonary embolism was 5.36%(15/280), the thrombosis rate in the inferior vena cava was 13.57%(38/280), the incidence rate of the phlebostenosis was 4.69%(9/192), the incidence rate that the inferior vena cava filter shifted to the right heart or the lung artery was 1.07%(3/280) and the incidence rate that the filter pierced through the wall of inferior vena cava was 6.25%(20/320). Among the common clinical complications, "VCF shift" occurs because the IVC is too big in diameter and the frictional force between the filter and the vein wall is relatively small. "VCF sloping" relates to both the structure of the filter's fixture and the method of placing the VCF. "IVC perforation" usually occurs when the VCF have claws and hooks. It is reported that the incidence rate of IVC perforation is 0 when the filter has straight pillars as its fixture.

Nickel-titanium shape memory alloy (SMA) with the hot memory characteristic is produced from the raw materials of titanium and nickel with vacuum inductive melting technique. It is corrosion-resistant, abrasion-resistant, biocompatible and unfavorable for thromboses. Moreover it has no magnetism. Nitinol wires have a good resistance to fatigue and are easier to prepare than Nitinol tubes. They can help us avert IVC perforation and the VCF brisement if we use Nitinol wires to make the VCF with a reasonable structure. Having tested and improved many times, we have developed a kind of filter made of silk Nitinol wires. The aims of the research are to evaluate the effect of this new type of VCF on fatal pulmonary embolism and to provide experimental basis for developing safe and effective domestic filters.

## 2 Material and method

### 2.1 Material

The nitinol wire with an analyzed nickel content of 55.6%−56%(mass fraction)(Table 1) used to make the VCF is 0.3−0.5 mm in diameter.

**Table 1 Chemical compositions of the shape memory alloy tested**

| Compositions | Ti | Ni | C | O | H | N |
|---|---|---|---|---|---|---|
| Content/%(mass fraction) | 44.2 | 55.72 | 0.08 | 0.056 | 0.0013 | 0.0017 |

The mechanical properties of the nitinol wires (after heat treatment) selected to make the VCF are as follows:

tensile strength: $\sigma_b = 1336$ MPa, yield strength: $\sigma_{0.2} = 589$ MPa; spreading rate: $\delta = 11\%$ fatigue strength: $\sigma_{-1} = 558$ MPa (cycle index>107)

**2.2 Structural design**

The inferior vena cava filter (VCF) consists of the support parts in the middle and filtration parts on both sides (Fig. 1). The support parts are six groups of straight pillars made up of 12 straight wires. A large number of clinical cases have verified that a straight-pillar structure can effectively prevent the filter from sloping. Each filtration parts is a cone-shaped interception network. The straight pillars together with 12 small nitinol springs wound around them are the fixture of the VCF. The frictional force between the springs and the vein wall keeps the filter from shifting. The springs can hardly pierce through the vein wall. We fix the ends of the nitinol wires on both sides in two pure titanium casings. To prevent the VCF from falling apart, we adopt both welding and machinery pressure joining to connect the nitinol wires to the casings. A sophisticated process is adopted to polish the VCF to reduce the thrombosis rate caused by the filter itself.

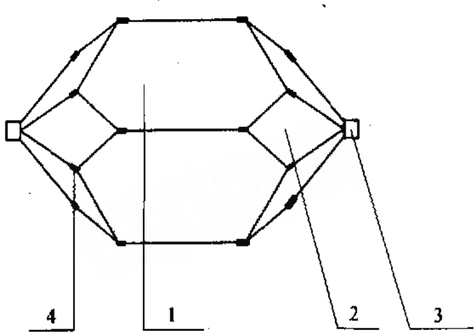

**Fig. 1** Schematic diagram of the VCF
1—support part; 2—filtration part; 3—titanium casing; 4—nitinol memory alloy springs

**2.3 Manufacturing process flow**

2.3.1 Producing nitinol wires

A nearly equiatomic nitinol alloy with an analyzed composition of 55.8%Ni is prepared from the raw materials of titanium (purity 99.9%, mass fraction) and nickel (purity 99.97%, mass fraction) with vacuum inductive melting technique. The ingot is then forged and drawn to wires 0.3—0.5 mm in diameter.

2.3.2 Stock Mould

The material of the stock mould should have a low heat capacity and a resistance to oxidation. Two sets of moulds are prepared: one was used to form the IVC for the first time (No. 1 mould) and the other for the second time (No. 2 mould).

2.3.3 Weaving the filter and forming it for the first time

Weave the filter with the nitinol wires prepared and tie it up on the No. 1 mould. Then form it by heating them at the temperature of 450—550℃ for about 20 minutes.

2.3.4 Assembling the filter

Mount the pure titanium casings onto the filter by machinery pressure joining, and weld them on the tip with a laser welder.

2.3.5 Putting the filter in order and forming it for the second time

Arrange the nitinol wires which have been formed for the first time. Make sure that the wires do not twine or overlap one another. Twine the nitinol memory alloy springs round the sections where the wires converge and tie it up to the No. 2 mould. Then form it for the second time by heat treatment at 450—550℃ until the shape of the filter becomes the same as that of the mould. After the two periods of heat treatment, the phase-transition temperature of the filter should meet the following condition: 20℃<Af<33℃, so that the filter is soft and flexible at room temperature and harden with the characteristic of hyperelasticity and resumes its former shape at body temperature.

2.3.6 Polishing

Polish the filter mechanically to give a better gloss to the surface in order to discourage thrombosis and improve the appearance of the product. First polish the filter crudely with abrasive material whose diameter is about 1mm. Then polish it again with fine sand. During the first process, the grain size of the abrasive material, the polishing speed, the duration of the polishing must be strictly controlled.

## 3 Performance test on the filter

### 3.1 Determination of supporting strength

On the AG-25T computer controlled accurate omnipotent testing machine, when the filter is heated to the body temperature and pressed till its diameter shortens to one half of its former one, its pressure value is shown in Table 2.

**Table 2 Radial supporting strength of the filter**

| Specification/mm | Size pressed/mm | Radial supporting strength/N | Remarks |
|---|---|---|---|
| Φ20 | 10 | 6.08 | Heating to 38℃; Holding for 5 minutes |
| Φ20 | 10 | 6.22 | |

### 3.2 Determination of phase-transition temperature

The DSC curve drawn by testing samples made of wires cut from each sector of the filter with the German DSC-200PC thermal analyser is shown in Fig.2.

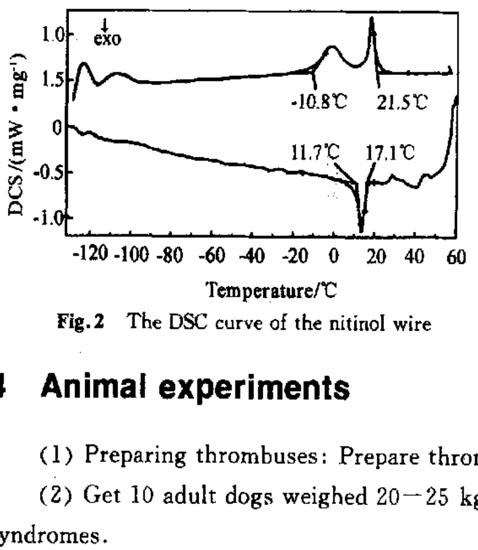


**Fig.2** The DSC curve of the nitinol wire

It is clear to see from Fig.2 that after the two periods of heat treatment, the phase-transition temperatures of the filter are 17.1℃(Ms) and 21.5℃(Af). Thus, between 0℃ and 10℃ the filter is soft and flexible, easy to be packed into the 8F pipe and at the body temperature the filter, that resumes its former shape and becomes hard and resilient, gives out continuous and tenacious supporting strength, which makes the filter cling closely to the the vessel wall and displacement impossible.

## 4 Animal experiments

(1) Preparing thrombuses: Prepare thrombuses with the size of 3 mm×10 mm and 5 mm×25 mm .

(2) Get 10 adult dogs weighed 20—25 kg. Implant self-made filters into their bodies and observe the syndromes.

(3) Inject the two kinds of thrombus separately into the dogs and calculate the interception rates of the filters towards these two kinds of thrombuses.

## 5 Experimental results

After over 10 animal experiments, it has been proved that:

(1) The filter has a steady shape and a stable structure, which ensures that neither deformation nor fragmentation occurs after the filter has remained in the body for a long time.

(2) The diameter of the convery sheathing canal is 8F. It is easy to release the filter. There was nei-

ther the possibility that the filter might open insufficiently nor obvious displacements of the filter while released.

(3) Instead of directional, the filter has a symmetrical structure, so that it could be implanted through either the internal jugular vein or the thigh con-vein.

(4) The filter intercepted the 3 mm×10 mm small thrombus at a rate of 94.5% and the 5 mm×25 mm large thrombus at a rate of 100%. Compared with the TrapEase Filter, there was no statistical distinction and compared with other imported filters, its interception efficiency ranks among the higher ones.

(5) The rate of thrombosis in the IVC where the filter was placed is 6.25. The filter itself is unfavorable for thrombosis. After implantation of the self-made filter, the patency rate of the IVC is 100%.

(6) With 6 groups of parallelly and evenly lined straight pillars and 2 twining nitinol springs on each group of pillars as the fixture of the filter, no displacement occurred after implantation.

(7) The filter has no claws or hooks, so that it did little damage to the wall of the vein. IVC perforation and retroperitoneal hematoma never occurred.

(8) After implantation, the filter had good effects in resisting thrombus, with no necessity to inject other thrombolytic drug.

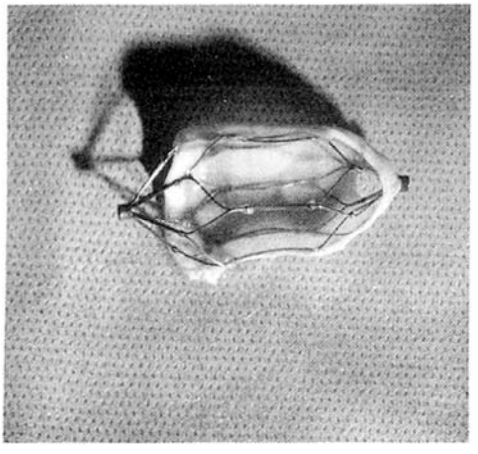

**Fig. 3** The inferior vena cava implanted self-made VCF

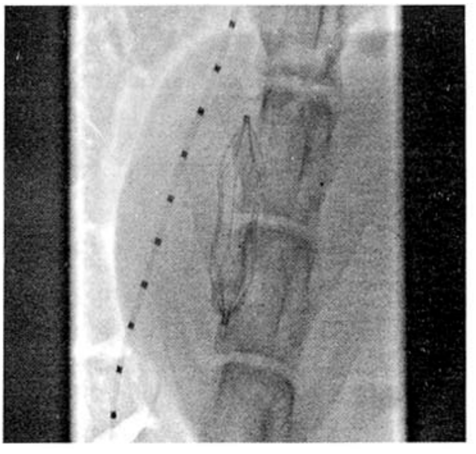

**Fig. 4** Embolus interception experiment

# 6 Conclusions

Made of nitinol memory alloy wires, the new IVC is corrosion-resistant, abrasion-resistant, biocompatible and unfavorable for thromboses. Moreover it has no magnetism. The nitinol memory alloy wire is proof against fatigue and is better in keeping the filter from breaking. The straight pillars ensure that the filter does not tilt. The memory alloy springs are not only effective in preventing displacement but also able to minimize the damage to the wall of vein, make IVC perforation impossible. There are many controllable factors influencing the normal pressure of the filter, such as the diameter of the wires, the size and structure of the filter, the composition of the alloy, the technique of heat treatment and so on, which enables us to adjust the normal pressure of the filter through choosing elements of the alloy and adapting the technique of heat treatment while guaranteeing the effects of filtration through altering the size and structure of the filter.

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