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Evaluation of migration forces of a retrievable filter: Experimental setup and finite element study

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ABSTRACT

The aim of this paper is to provide a computational study of migration forces of a retrievable filter (Günther Tulip inferior vena cava filter). Using an experimental setup and finite element simulation, the migration forces and stress at the end of the anchored hooks in the struts were estimated. After that, the estimation value of migration stress (τ_{rup}) was used to analyze the effect of different mechanical factors (strut thickness, vena cava diameter) in the migration of the IVC filter.

Our results show that the migration stress is $\tau_{rup} = 4.37\,\mathrm{N/mm^2}$. Using this value we obtain that the filter with higher strut diameter ($\phi_{strut} = 0.45$ mm) shows the maximal migration forces in every cava diameter. On the other hand, the value of the migration force decreases when the cava diameter increases. In addition, the finite element simulations also show that there are contact between the struts of the filter and the vein in regions close to the anchors.

1. Introduction

Deep vein thrombosis and its sequelae pulmonary embolism and post-thrombotic syndrome are some of the most common disorders with a yearly incidence of approximately one case per 1000 person-years. Venous thromboembolism (VTE) is the third most common cardiovascular disease after myocardial infarction and stroke [1–3]. A thrombus either arises spontaneously or is caused by clinical conditions including surgery, trauma, or prolonged bed rest [4]. Several factors have been proposed to explain the persistence of the high incidence of VTE with its associated morbidity and mortality. Venous thromboembolism is often asymptomatic, mis-diagnosed, and unrecognized at death, and there is a lack of routine postmortem examinations. These factors are thought to result in marked underestimates of VTE incidence [5,6].

For patients with objectively confirmed or with a high clinical suspicion of VTE, the American College of Chest Physicians (ACCP) recommends treatment with anticoagulants (low molecular weight heparin or unfractioned heparin) and in special circumstances thrombolytic drugs [7]. When contraindication or complication of anticoagulation in an individual at high risk for recurrent PE exists, is recommended the interruption of the blood flow in the inferior vena cava, so inferior vena cava filters are indicated.

Vena cava filters were introduced in the 1960s as a mechanical means to prevent pulmonary embolism PE [8]. Vena cava filters may be permanent, temporary, or retrievable. Permanent filters are deployed and remain in place in the vena cava for the rest of the patient's life. Temporary filters, connected to the outside by a catheter or guide wire, remain in the vena cava for a certain period of time, but must always be removed at some point. Retrievable or optional filters, which resemble permanent filters, may either be removed or left in place indefinitely [9,10]. Indications for filter retrieval are based on the clinical situation, and the success rate decreases as the time post placement increases [11].

Three are the main considerations about filters: (i) fixation at the vein wall (in order to avoid migration), (ii) retrievability (extract the filter without clinical complications), and (iii) capability of the filter to avoid embolism (retain 100% of big-size thrombi avoiding obstruction). Both (i) and (ii) depend on the filter fixation system and the reactivity of the vena cava wall, but they are opposite characteristics, so a stable equilibrium must exist between them.

Retrievable filters maintain their position, avoiding migration, by hooks, radial pressure or barbs. Due to the anchoring barb positioned on each strut, they can present complications. The endothelium tries to cover the barbs so that the filter extraction could be difficult or even not possible [12]. Moreover, anchoring barbs can damage endothelial tissue of the vein wall with associated clinical complications. Anyway both mentioned problems

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normally prevent migration and make difficult the filter extraction [13,14].

Filter migration can happen immediately after deploying or some day after its insertion [14,15]. It is normally asymptomatic but it can lead to very severe complications, for example, migration to the cardiac cavities (cardiac arrest, need for open cardiac surgery).

In order to avoid or minimize the mentioned risks, new filter designs are of urgent necessity because the ideal device has yet to be developed. The devices research field was historically developed in the industry, being the companies the main research community. However, there are numerous research studies in the specialized literature. Stenting technique, for example, is continuously improving thanks to studies and related published papers [16–19]. Compared with stents, filters are less documented in literature [20,12,21–23]. Moreover, most of this works are correlated only with clinical results, few of them were focused in the improvement in filter design [24–27].

In addition, every substantial model modification and each new prototype should be tested *in vivo*, reproducing in animal models similar human conditions. Unfortunately, investigation in animals is anatomically restricted. It is in fact not possible to reproduce with sufficient precision human pathologies in animal models [28]. Devices are conceptually designed for human so that their implantation in animals is subjected to adaptation which sometimes changes completely the investigated object.

Computational approach can be clearly used for filter designing which includes the complete cardiovascular mechanics. Traditionally, numerical simulation of cardiovascular problems could be applied to mechanical design of prosthesis, cardiac valves and bypass. The flexibility and the possibility to perform parametrical studies on cardiovascular problems make numerical methods an useful tool to minimize manufacturing costs and improving design. Recently, several fluid analysis were performed to analyze filter implants. For example, Stewart et al. [23] assumed the IVC and model thrombus are rigid to study the effect of IVC filters on blood flow, velocity patterns, and wall shear stress. Swaminathan et al. [22] use an arbitrary Lagrangian–Eulerian (ALE) analysis to study parameters like shear stress and stagnation zones and to evaluate the embolus capture characteristic of a Greenfield filter. Singer et al. [25] and Wand and Singer [24] developed three-dimensional models of the *TrapEase* and *Günther Celect* IVC filters with spherical thrombi to evaluate the hemodynamic effects of thrombi, renal vein inflow and filter position. Later, Singer et al. [26] used an optimization framework for designing vena cava filters to minimize the hemodynamic disruptions caused by different locations, sizes, and shapes of a model thrombus. However, all these previous models consider only hemodynamic simulations where the wall and the filter are rigid solids, so the interaction between the vein and the filter is not considered.

Considering the aforementioned, the aim of this paper is to provide a computational framework to study migration forces of a retrievable filter (Günther Tulip inferior vena cava filter). Using a finite element simulation of the filter and the vena cava and based on data of a *ex vivo* experimental study in sheep, the migration forces and stress at the end of the anchored hooks in the struts were estimated. After that, the estimation value of migration stress (τ_{rup}) was used to analyze the effect of different mechanical factors (strut thickness, vena cava diameter) in the migration of the IVC filter.

2. Materials and methods

The first part of the study is an experimental study on sheep. During the study, three different finite element models (FEM) were

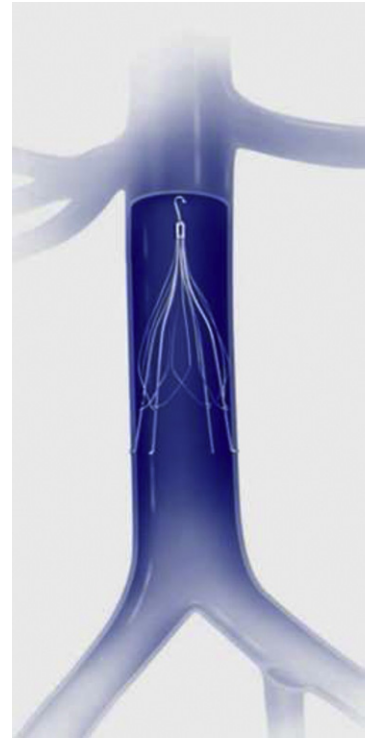

Fig. 1. The Günther Tulip vena cava filter of William Cook Europe deployed into the inferior vena cava.

developed. First, a FEM of the filter was used to estimated the elastic modulus of the filter material using experimental data and inverse analysis procedure. Second, a FEM of the animal experiment previously described was developed in order to estimate the rupture or migration tangential stress (τ_{rup}). And finally, another model of vena cava and filter were performed to analyze how the different geometrical parameters affect to the migration force of the filter.

2.1. Animal study. Ex vivo experiment

To evaluate *ex vivo* the force required for migration of the filter, we needed to recreate its fixation to the vena cava wall, deploying the filter for one month in a laboratory animal. This part of the study was performed on sheep, as it is the most used biomodel for vena cava filters, due to its adequate size and its similarities in venous anatomy with human beings. It had also been used previously by this team in other similar experiments [29].

Twelve Rasa Aragonesa ewes were used in the experimental study, deploying a retrievable Günther Tulip vena cava filter (GTF) in each of them. All animals were female; weight ranged from 55 to 65 kg and the mean age was 11 months (range, 10–14 months). The study was approved by the animal care committee of the University de Zaragoza.

All the sheep received general anesthesia (xylazine (0.1 mg/kg) and ketamine (4 mg/kg)), and were intubated and monitorized throughout all the procedures. The GTF of William Cook Europe (Bjaeverskov, Denmark) was used in all the animals. It is a conical filter with four long anchored primary legs and a secondary wire in the shape of Tulip petals. At the vertex, there is a hook intended for recovery. The devices were deployed percutaneously into the inferior vena cava *via* the external jugular vein under fluoroscopy guidance (BV Endura C-arm, Philips, The Netherlands), Fig. 1. All the operations were performed in the Minimally Invasive Techniques Unit of the University of Zaragoza. After 30 days, position and patency of the filters were confirmed by cavography and the