In vitro comparison of Günther Tulip and Celect filters. Testing filtering efficiency and pressure drop

M. Nicolas [a,d], M. Malvè [c,a,d], E. Peña [a,d], M.A. Martínez [a,d], R. Leask [b]

[a] *Aragón Institute of Engineering Research (I3A), University of Zaragoza, Spain.*

[b] *Department of Chemical Engineering, McGill University, Montreal, Quebec*

[c] *Public University of Navarra, Department of Mechanical Engineering, Energetics and Materials, Pamplona, Spain.*

[d] *Centro de Investigación Biomédica en Red en Bioingeniería, Biomateriales y Nanomedicina (CIBER-BBN), Spain.*

Corresponding author E. Peña. E-mail: fany@unizar.es Phone: (+34) 876.55.52.33

Abstract

In this study, the trapping ability of the Günther Tulip and Celect inferior vena cava filters was evaluated. Thrombus capture rates of the filters were tested *in vitro* in horizontal position with thrombus diameters of 3 and 6 mm and tube diameter of 19 mm. The filters were tested in centered and tilted positions. Sets of 30 clots were injected into the model and the same process was repeated 20 times for each

different condition simulated. Pressure drop experienced along the system was also measured and the percentage of clots captured was recorded. The Günther Tulip filter showed superiority in all cases, trapping almost 100% of 6 mm clots both in an eccentric and tilted position and trapping 81.7% of the 3 mm clots in a centered position and 69.3% in a maximum tilted position. The efficiency of all filters tested decreased as the size of the embolus decreased and as the filter was tilted. The injection of 6 clots raised the pressure drop to 4.1 mmHg, which is a reasonable value that does not cause the obstruction of blood flow through the system.

Key words: Pulmonary embolism, inferior vena cava, Günther Tulip filter, Celect fitler, clot capture rate, filter efficiency.

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1 Introduction

Pulmonary embolism (PE) is a serious, potentially life-threatening condition. It is due to the blockage in a lung artery. The cause is usually a blood clot that dislodges from the deep veins in the lower extremities and travels to the lungs (Ren et al., 2012). Consequently, inferior vena cava (IVC) filters have been used to prevent recurrent PE in patients who are at very high risk, who are unresponsive to anticoagulation therapy, or in whom anticoagulation is contraindicated (Leask et al., 2004). IVC filters are used to intercept and trap large clots while allowing clot-free blood to pass freely towards the heart. As a result of the effort made to find the best filter device, there is a considerable number of filter devices in the market that are used in patients and tested by researchers.

There are many numerical investigations and *in vitro* experiments that study the filter flow dynamics. Couch et al. (1997); Leask et al. (2001) have previously studied flow fields surrounding a vena cava filter using a noninvasive technique called photochromic. Furthermore, Singer et al. (2009) evaluated the flow hemodynamics of the TrapEase vena cava filter including simulated thrombi of multiple shapes, sizes, and trapping positions. Numerical studies on vena cava filters usually neglect the interaction between blood flow, the filter and the thrombi, but in order to evaluate the effectiveness of a filter and design new models, it is important to study other factors such as the clot capture efficiency.

Clot capture efficiency has been quantified in *in vitro* studies, in which model clots are released into a mock circulation system, with the relative capture efficiency of various IVC filters analyzed statistically (Stewart et al., 2008). Hosaka et al. (1993) studied the DIL and the Greenfield vena cava filters' clot-trapping ability in relation to the absolute diameter of the simulated vena cava before filter insertion and the clot size. Ferdani et al. (1995) tested six umbrella-type percutaneous inferior vena cava filters using a mock circulation device, for different flow rates and different filter positions. Lorch et al. (2002) evaluated 10 permanent and retrievable vena cava filters and compared them with the TrapEase filter. Katsamouris et al. (1988) tested six different filters and measured the pressure gradient across the filters. Other literature reports of *in vitro* studies analyzes the influence of the orientation of the IVC on clot capture efficiency, being an upright patient represented by a vertical configuration of the IVC whereas a supine patient is represented by a horizontal configuration. Lorch et al. (2002) observed that thrombus capture rates were significantly higher in the vertical position. Xian et al. (1995) went

a little further in their research and studied the influence of number of emboli on the trapping ability of the Greenfield, Vena Tech-LGM and Günther Tulip. It was observed that the proportion of trapped clots dropped with ascending clot rank and it was stated that the filter function deteriorates as the number of clots delivered increases.

Most of the authors have done their research using filters such as Greenfield, DIL, Mobin-Uddin, Simon Ninitol, bird's nest, Vena Tech-LGM filter or TrapEase filters, but there are few investigations (Lorch et al., 2002; Xian et al., 1995)in newer models like the Günther Tulip and Celect filters. For that reason, the aim of this *in vitro* study is to evaluate the clot capture efficiency of the Günther tulip and Celect filters, under different conditions and to prove, if possible, the superiority of one of the filters over the others.

2 Materials and methods

2.1 In vitro set-up

Flexible and transparent polyvinyl chloride tubing of 19mm of inner diameter was used to simulate the vena cava. The model was fixed in the horizontal position and connected to two different reservoirs: A and B. From reservoir A the fluid circulated into the system in a stationary flow. Reservoir B was used to store the fluid from the system. As stated by Couch et al. (1997), the *in vivo* flow conditions of blood are approximately 2L/min so the flow rate was maintained at about 2L/min by adjusting the height of the outflow reservoir B. Reservoir A was continuously topped up in order to maintain a constant pressure and flow rate in the system (see Figure 1). Although some authors use a pulsatile flow for the experiments (Hosaka et al., 1993; Xian et al., 1995), a steady-state flow was used for these experiments since the blood flowing through veins barely carry any pulse because it is returning to the heart. The fluid used to simulate blood was comprised of 35% by volume of glycerol in water. The fluid was maintained at room temperature and had a density of $1.091 g/cm^3$ and a dynamic viscosity of 0.0036 Pa.s, which is very approximate to blood dynamic viscosity (0.0035 Pa.s). The fluid used was Newtonian with a Reynolds number of 674. Blood is known to behave in a non-Newtonian fashion but

in a vessel of this diameter these effects will not be significant (Couch et al., 1997). Some authors such as Leask et al. (2004, 2001); Singer et al. (2009); Harlal et al. (2007); Neuerburg et al. (1993); Korbin et al. (1994) have also used a flow rate of 2L/min for IVC studies and utilized a Reynolds number of about 600. The reason why our Reynolds number is a bit higher is mainly because the fluid properties are slightly different and the diameter of the tubing used is also different.

To ensure that the flow entering the filter was laminar and fully developed, the flow phantom tube was constructed with an entrance length of 137 cm. This corresponded to 7 tube diameters and ensured a parabolic velocity profile under the flow conditions used in these experiments.

Three different filters were used to study their efficiency. Firt, a simple,modified Günter Tulip, not commercial filter was used. This filter is only used for mechanical testing in the lab. The Celect IVC filter and the Günter Tulip filter were also used. See Figure 2 for details on the filters used.

2.2 Preparation of the clots

The simulated clots were prepared from 200 mL of water and 10 gr of Agar. The blood clots were modelled as spheres for these experiments. Although the shape of the clots varies widely and have been approximated by different shapes in various works (Couch et al., 1997; Stewart et al., 2008; Robinson et al., 2013), no single shape can be rigorously assigned to a clot due to the inherently complex and random nature of its formation. Hence, a sphere not only alleviates the problem of various orientations of clots upon entry into the IVC, but also can be thought of as an averaged shape/orientation (Swaminathan et al., 2006).

The clots used for the experiment are divided in two different categories: small clots and large clots, as it is seen in Figure 3. Small clots range from $8.2mm^3$ to $33.51mm^3$ (2.5 mm to 4 mm diameter clots), and large clots range from $65.45mm^3$ to $220.9mm^3$. 1200 clots of each of the two categories have been analyzed and used to study its size distribution. Image J (National Institutes of Health, Bethesda, Md) has been used to process the images and measure the particles sizes.

2.3 Testing procedures

The filters were placed in the middle of the simulated IVC in a horizontal position. The filters were assessed in two different positions: central and eccentric. The eccentric position wanted to represent placement errors or migration of the filter, since sometimes the filter moves from its central position after it is released inside the vena. The eccentric position was set with the main axis of the filter placed at the maximum angle possible relative to the IVC.

Clot trapping capacity was assessed by placing clots of various sizes into the flow system and counting the number of clots trapped passing through the filter. For each filter, 30 clots of each size were introduced at once. The trapped clots were removed between observations and the number of clots that passed through were recorded. This process was repeated 20 times for each filter and each size of clots, with the filter positioned centered. Furthermore, the Günther Tulip filter and the Celect filter were also positioned in a tilted position, and the same process was repeated 20 times for each clot size and each filter. The experiment was repeated a total of 200 times, and a total of 6000 clots were used.

Pressure drop of the system was also measured using a traceable manometer in order to observe the effects of the clots in the pressure equilibrium of the system. The pressure was measured at two different points of the system in order to obtain the pressure drop. The first point was positioned 90 cm upstream from the filter, and the second point was 10 cm downstream from the filter.

Student's *t-test* for independent samples was used to evaluate differences between filtration capacities of each filter.

2.4 Numerical validation

Two numerical simulations were carried out to validate the pressure drop measurements taken *in vitro*. Two different geometries were modelled. First, an idealized IVC with a filter inside of the vena and then, a IVC with the filter and 8 thrombi attached to it. Since the pressure drop experienced using different models of filters did not vary, only the (Günther Tulip) was used for both simulations. Computational meshes were created using Ansys Icem (Ansys Inc. Software, Canonsburg, PA, USA) and the numerical

CFD simulations were carried out using Ansys CFX (Ansys Inc. Software, Canonsburg, PA, USA). See Figure 4 for details on the numerical simulation.

3 Results

3.1 Particle size distribution

Descriptive Statistics have been used to present a quantitative description of the main features of the data set (see Table 1). When analyzing the size distribution of small clots (Figure 3 b), the mean, median and mode are equal to 3.2 mm. The three values are the same and coincide with the peak of the histogram of Figure 3 b, which means that the data follow a normal distribution. The standard deviation is 0.26, which indicates that the data are concentrated around the mean and that the diameter is less variable. The histogram for small clots is bell-shaped, following a normal distribution, in agreement with the observations made from the central tendency values recorded. The histogram is symmetrical, the same amount of data falls on both sides of the mean and has skewness (the measure of the asymmetry of a histogram) of 0. The histogram has a tall and narrow shape as a consequence of the low standard deviation.

The results of the analysis for large clots are a little bit different. The mean and median are equal to 6.4, but the mode has a greater value of 6.9. The histogram is not as symmetric as for small clots but it still follows a tendency similar to a normal distribution, as it is observed in Figure 3 c. The standard deviation for large clots is 0.5 which is larger to the one obtained for small clots. The data is more spread out around the mean and the histogram has a wider shape, as a consequence of the higher standard deviation.

3.2 Filtering efficiency. Clot-Trapping Capacity

The modified Günther Tulip filter had the lowest clot capture efficiency, as it may be expected (Table 2 and Figure 5a and b). The results show that this filter cannot be used to prevent PE because there

is a huge percentage of thrombi (almost 80% of big clots and 94.5% of small clots) that pass through the filter, meaning that pulmonary embolism is more likely to occur if this filter is used.

The most effective filter was the Günther Tulip filter in all cases, as shown in Table 2. For large clots, its effectiveness is almost 100% and it is barely reduced when the filter is set in a tilted position. For smaller clots, its effectiveness is reduced by about 11% when the filter is tilted. Filter 3 also shows good results when trapping large clots but its effectiveness trapping small clots is not as good and is reduced by 20% when the filter is tilted.

Statistical evaluation was performed using Student's *t-test* (see Table 2) to evaluate differences between filtration capacities ($\alpha \leq 0.05$). The results showed that the filtering efficiency of both Günther Tulip and Celect filters over the modified Günther Tulip were higher ($p < 0.001$). No significant statistical differences were observed between the Günther Tulip and Celect filters when small and large clots were inserted in the system in an eccentric position. On the other hand, when small clots were used in a tilted position, it was demonstrated that the Günther Tulip filter is significantly more efficient than the Celect filter ($p = 0.01$).

All filters showed higher capture rates for large thrombi compared with small thrombi. Differences were more significant when the filters were tilted since the effectiveness of the device for large clots remained constant while it was reduced for smaller clots. Overall, looking at the results, the most efficient filter in terms of clot trapping ability seems to be the Günther Tulip and less efficient filter seems to be the modified Günther Tulip.

It is observed in Figures 5 that the effect of gravity, as it will be discussed later in this paper, affects the results. The modified Günther Tulip is only able to trap clots that pass exactly through the center of the IVC while the clots flowing closer to the wall of the IVC passed more easily since the filter does not have secondary struts. When smaller clots are injected in the model, the effectiveness of the filter decreases considerably, being able to trap a smaller number of clots. Figure 5 shows the results obtained for the three filter models when large and small clots are injected in the model, being the filter set in a centered position. It is observed that the efficiency of both filters is excellent thanks to the secondary legs. The secondary struts help the filter trap the clots that do not travel directly through the center of the model. When small clots are thrown in the model, Figure 5 and Table 2

show that the efficiency of all the filters decreases. Most of the clots travelling through the center of the model are still trapped but some of them pass more easily through the struts.

Figure 6 shows the results obtained for the Günther Tulip and the Celect filters when the filter is tilted. If Figure 5 and 6 are compared it can be observed that the volume of large clots captured by the filters does not vary. On the other hand, Figure 6c and d and Table 2 show that the efficiency of the filters decreases, when small clots are used. 6 mm clots are big enough to not affect the filter efficiency when it is tilted meanwhile 3 mm clots that travel directly away from the dependent wall of the IVC pass more easily.

In conclusion, the efficiency of all filters tested decreased as the size of the embolus decreased and as the filter is tilted, as it could be expected. The Günther Tulip filter resulted as the most efficient filter.

3.3 Pressures

The pressure drop barely changed when the filter was inserted with respect to the measurements taken with no filter in the system. For both tests there was always a slight increase in pressure upstream. Higher pressures were recorded when some clots (6-8) were present in the filter. Subsequently, the effect of trapped clots on pressure drop was measured by injecting sequentially 8 clots and recording the pressure drop. 6 clots were needed to be trapped before a comparable increase of the pressure occurred. All the measurements were repeated 6 times to make sure that the recordings were consistent with each other, and the averaged values were reported in Table 3. Prior to injection of clots, the pressure drop was almost the same for the model with and without the filter inside. This shows that the presence of the filter in the model does not essentially vary the pressure gradient. Besides, as stated by Rahbar et al. (2011) and as shown by Leask et al. (2004, 2001); Harlal et al. (2007), the disturbances caused by the filters at a Reynolds number of 600 are negligible. The injection of 8 clots raised the pressure drop to 4.1 mmHg.

The pressure drop was also measured using a flow rate of 3 L/min. Table 3 shows that the increase

in the flow rate increases considerably the pressure drop between the two points. A lot of studies on inferior vena cava filters use a flowrate of $2L/min$ (Katsamouris et al., 1988; Neuerburg et al., 1993; Korbin et al., 1994; Qian et al., 1994) but the reason why a flow rate of 3L/min has also been used is to compare the pressure drops obtained for two different flow rates, and to double check the pressure drop measurements. Besides, there is an increase in the flow rate of the IVC after Valsava manuever (Gindea et al., 1990; Eichenberger et al., 1995),so by using a 3L/min flowrate the behaviour of the filter in more adverse conditions is represented. All pressure readings in Table 3 are expressed in mmHg. The same procedures were repeated for both the Günther Tulip and the Celect filters and similar results were observed, which means that both filter have the same effect in pressure.

The results obtained in the numerical simulations are in accordance with the in-vitro measurements. For the model with the Günther Tulip filter the pressure drop recorded was $0.5mmHg$, which is similar to the in-vitro results of $0.6mmHg$. For the second model, where 8 thrombi are attached to the filter, the pressure drop obtained was $4mmHg$, meanwhile the pressure drop measured in vitro was $4mmHg$. Figure 7 shows the pressure experienced along the model in a plane. It is observed how little the filter affects the pressure in the system meanwhile the thrombi cause a sudden decrease in the pressure.

4 Discussion

Clot capture rates in our experiment went from 5.5% to 99.5%. It was observed, in general, that the efficiency of the filter was reduced when the size of clots was reduced and when the position of the filter was tilted. The best-ranked filter is the Günther Tulip filter,.

If the results from our experiment are compared to previous work (Ferdani et al., 1995; Katsamouris et al., 1988; Hammer et al., 1994), the Günther Tulip and Celect filters performed fairly well. In Katsamouris et al. (1988) investigations, 3 filters (Movin-Udin, Amplatz and Günther basket) presented an increase in pressure above $20cmH_2O$ ($\simeq 15mmHg$) when 3 clots were trapped meanwhile the other 3 filter models (Simon Nitinol, Kimray-Greemfield and bird's nest) presented a pressure increase of almost $5cmH_2O(\simeq 3.7mmHg)$ when 6 clots were trapped (which is very close to our results). The main reason of the differences in the pressure drops between filter models is that some of them are

designed for high clot-trapping capacity, and for that reason they impede flow the most and result in adverse flow conditions (Katsamouris et al., 1988). Ferdani et al. (1995) studied the difference in pressure by 6 vena cava filters and obtained similar results to our investigations, which show that the filters used by them have similar performance in terms of flow impedance. If the IVC is collapsed or close to being collapsed, due to a big amount of clots trapped around the filter, there is a huge increase in pressure inside the vena. Hirsch and Hoak (1996) state that the risk of thrombosis is elevated when the obstruction of the vena cava occurs. For that reason, if the filter causes obstruction of the vena cava, thrombosis is more likely to occur. Furthermore, Leask et al. (2004) also stated that successful treatment of thrombosis requires the filter to provide high filter efficiency without impeding the blood flow, in order to prevent from thrombosis. To conclude, the filters that result in a great increase of pressure after clot entrapment, will have the highest potential for IVC thrombosis.

In vitro models have limitations that may raise questions about the clinical relevance of experimental studies. The tubing used in our model to represent the IVC was rigid. The deformations of the IVC were not taken into account, but respiratory variation and Valsalva result in profound changes in the diameter of the IVC (Murphy et al., 2008). Different results may be obtained if these deformations are considered.

A second model limitation was the effect of gravity on flowing blood clots, and the influence of this effect on clot-trapping capacity of each filter. As blood flow velocity is highest in the center of the IVC, emboli are believed to be carried along the center of the blood stream (Qian et al., 1994). As shown by Lorch et al. (2002); Katsamouris et al. (1988); Robinson et al. (2013), clot capture rates were significantly higher with the device in the vertical position. In this report, tests were only performed in a stable horizontal position similar to that in supine patients. As a result of gravity, clots failed to remain in the center of the fluid column in the phantom and sometimes had a tendency to flow along the dependent wall of the IVC and passed more easily through the filter struts. So the effect of gravity decreases the clot capture rates when the experiment is performed in the horizontal position.

When testing the filter in a tilted position, the devices were pushed into as much tilt as the model would allow so the effect of the tilt in the effectiveness of the filter was studied in a worst scenario case. When looking at the results obtained with the filters in a tilted position, this considerations has

to be taken into account.

The clot size which leads to clinically significant pulmonary embolism remains unclear and dependent on factors such as former pulmonary embolization and pre-existing lung disease (Lorch et al., 2002). The sizes used for this experiment are similar to the diameters used by Lorch et al. (2002); Katsamouris et al. (1988); Xian et al. (1995). In our opinion, in cases where only capture of large emboli is necessary, such as in young patients with a healthy lung, the Celect filter can be recommended. On the other hand, if PE has to be prevented in patients with impaired pulmonary function or in a poor general condition who may not be able to tolerate even small emboli, the insertion of a more efficient filter such as the Günther Tulip could be recommended.

An IVC filter cannot be chosen only on the basis of this experiment. Other factors such as ease of placement and documented clinical results must be taken into account. In vitro models are an important tool to evaluate the characteristics and performance of different filter models but they are limited and cannot reflect filter performances under the in vivo conditions in all aspects. However, in vitro testing help us to eliminate the most deficient models and understand how filters work inside the body. We realize that the method used to evaluate the efficiency of the filter simulates the worst case scenario leading to vena cava occlusion when using large clots. There are many different possibilities that can be studied when studying filtering efficiency, but we considered that studying the worst case scenario could be a good option to evaluate the efficiency of filters.

To obtain clinically relevant results a more complex model should be done. Our model is a simplified *in vitro* IVC model, but we can observe the efficiency of the filter models used, being the Günther Tulip the most efficient of them. We can also conclude that the pressure through the system only increases significantly for the Celect and Günther Tulip when most of the space inside the vena is collapsed by clots. Neuerburg et al. (1993) studied the performance of the Günther Tulip *in vivo*. It was observed that the filter showed a good hemodynamic behavior in the flow circuit. Besides, the *in vivo* fatigue testing of the filter revealed a high mechanical testing and the filter demonstrated a good biocompatibility with complete endothelization of the wires being in contact with the caval wall. This *in vivo* finding along with our *in vitro* results demonstrate that the Günther Tulip is very good option to be used in patients.

Clinical observation studies as the ones performed by Neuerburg et al. (1993); Ferris et al. (1993); Athanasoulis et al. (2000) together with valid *in vitro* investigations are important steps on the way to design an ideal vena cava filter. Clinical observations reveal important aspects about the filters such as penetration of the wall, migration of the filter, and ease of placement but in vitro models allow to do very complete studies on filter efficiency.

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6 Conflict of interest

None of the authors of this work has conflict of interest with other people and organizations.

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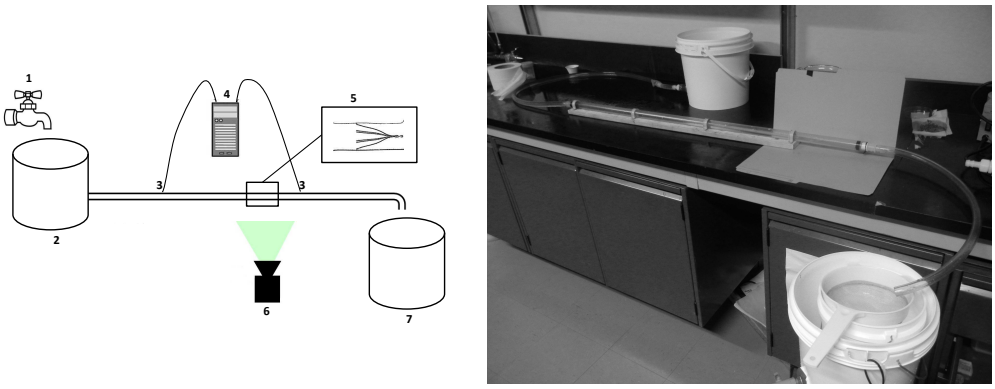
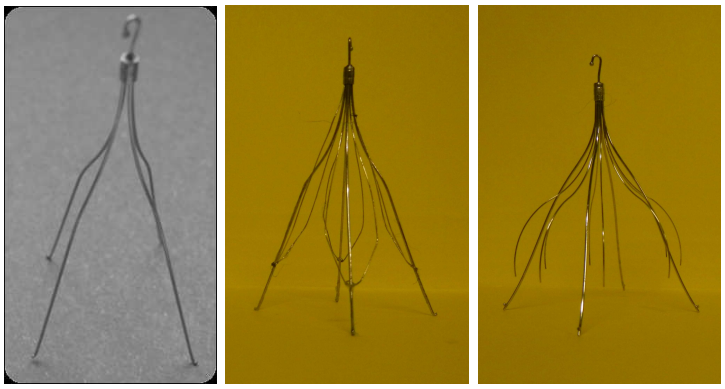


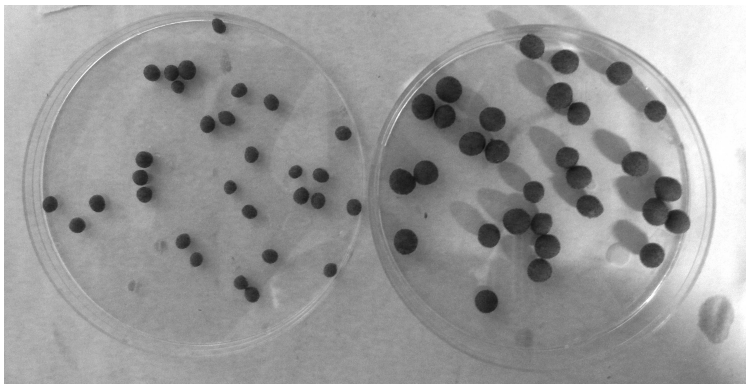
(a) (b)

Fig. 1. Experimental set up: 1. Top-up, 2. Reservoir A, 3. Pressure tabs , 4. Traceable manometer, 5.IVC system, 8. Video recorder, 7. Reservoir B

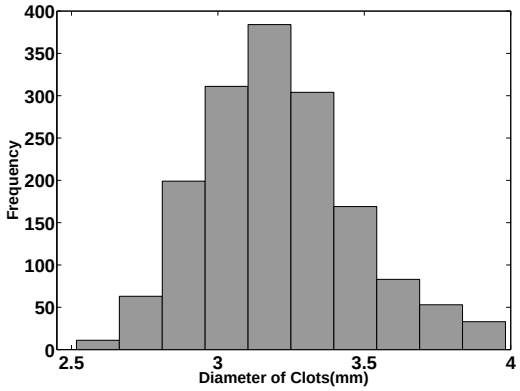


(a) (b) (c)

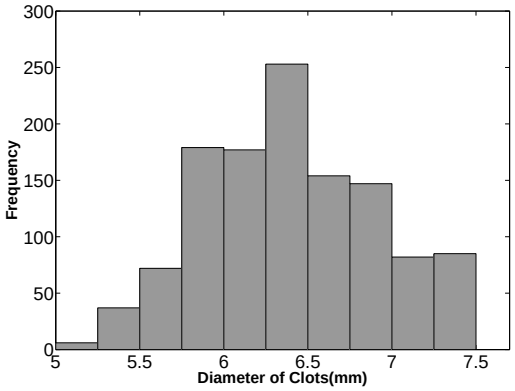
Fig. 2. IVC filters used for the experiment: (a) Modified Günther Tulip filter, (b) Günther Tulip filter, (c) Celect filter. They are low profile, asymmetric, retrievable, made of a cobalt-chromium alloy filters Cook (2014) that are manufactured by Cook Medical (Bloomington, IN). The design of the Celect follows that of the Günther Tulip filter. Both of them have a half-basket shape with a length of 45 mm and a maximum diameter of 30 mm Cook (2014) and have a retrieval hook at the appex to allow percutaneous retrieval or repositioning De Gregorio et al. (2003).



(a) Clots prepared

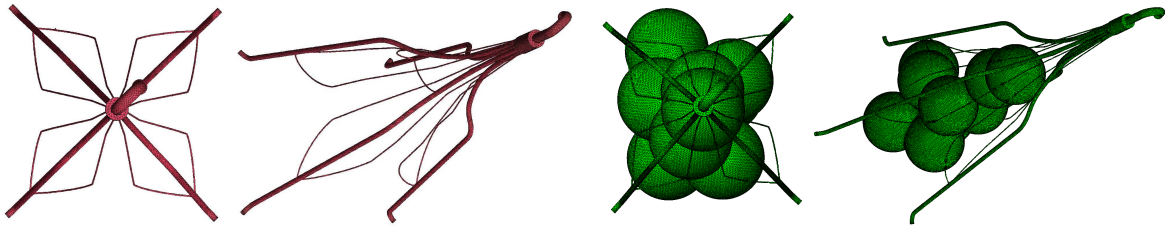


(b) Small clots histogram



(c) Large clots histogram

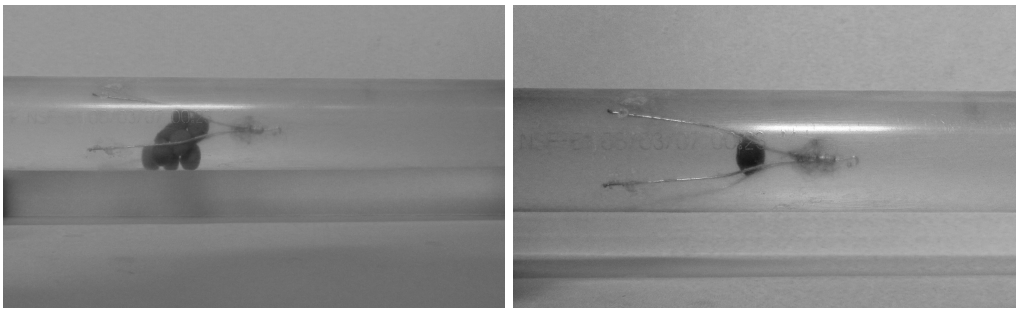
Fig. 3. (a) Clots prepared for the experiment. **left: small clots range from** $65.45mm^3$ **to** $220.9mm^3$ **(2.5 mm to 4 mm diameter clots), right: large clots range from** $8.2mm^3$ **to** $33.51mm^3$ **(5 mm to 7.5 mm diameter clots)**. (b) frequency histograms of the sample clots, used to estimate the probability distribution of the feret's diameter variable



(a) (b)

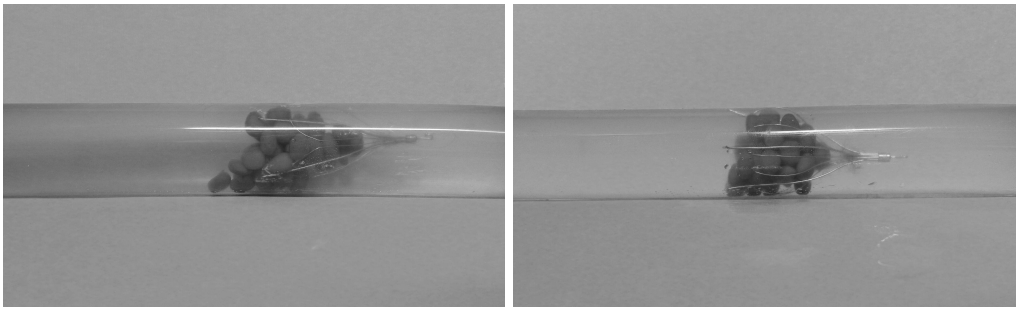
Fig. 4. Finite element mesh of the Günther Tulip filter (a) without thrombi and (b) with some thrombi.

The two different geometrical models were built using the commercial software SolidWorks (Dessault, SolidWorks Corp., France). Then, Ansys Icem (Ansys Inc. Software, Canonsburg, PA, USA) was used to obtain the numerical grids. In order to guarantee that the numerical results were grid independent, a mesh independence study was carried out prior to the presented simulations. Velocity profiles at different locations of the IVC model were compared for different grid sizes, concluding that meshes finer than $4 * 10^6$ for the model with the clots and $1 * 10^6$ for the model with the filter increased the computational time without adding precision to the solution. The fluid grids were imported in the commercial package Ansys CFX (Ansys Inc. Software, Canonsburg, PA, USA) were the fluid dynamics computations were carried out. The numerical approach used by this software is extensively explained in literature and given in details in CFX (2012). The fluid was assumed Newtonian, incompressible under steady conditions, laminar and had the same density and viscosity that was used in the experimental study. As boundary conditions, a steady parabolic flow profile with a total volume flow rate of 2L/min was imposed at both inlet and outlet of the IVC to match the experimental set-up and no-slip boundary conditions were applied at the wall, filter and clots. The convergence tolerance for both models was set to 10^{-8}, and the number of iterations was set to 500.



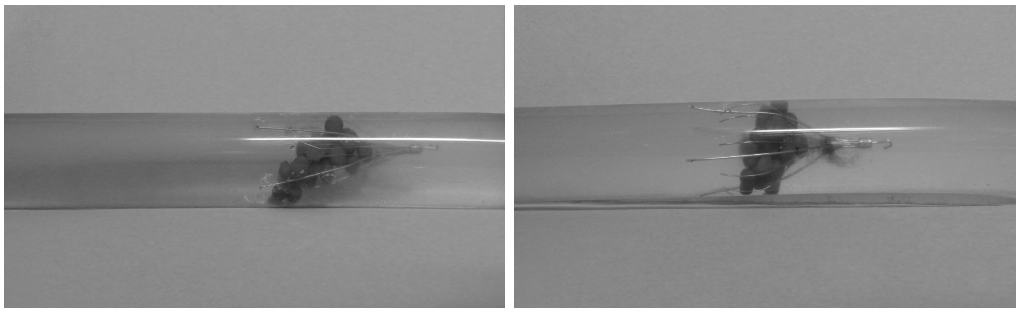
(a) Modified Günther Tulip with large clots trapped

(b) Modified Günther Tulip with small clots trapped



(c) Günther Tulip with large clots

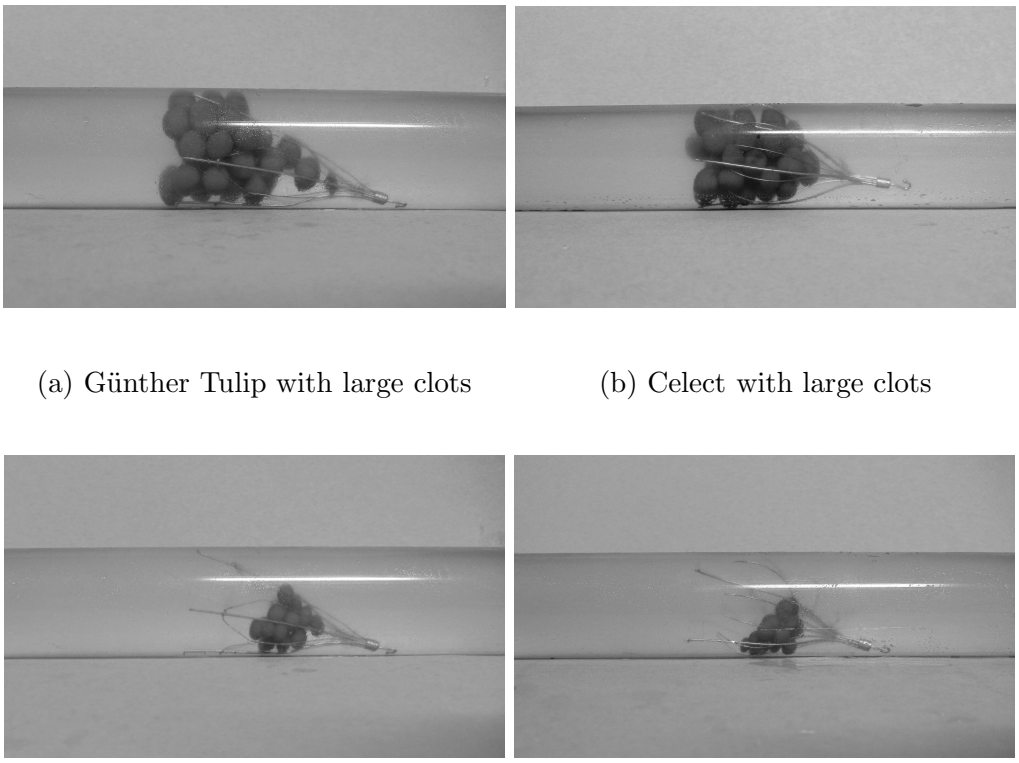
(d) Celect with large clots



(e) Günther Tulip with small clots

(f) Celect with small clots

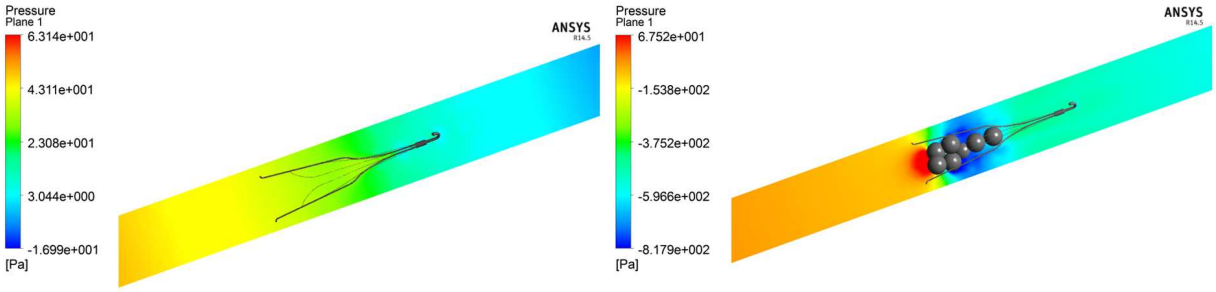
Fig. 5. Small and large clots trapped by the modified Günther Tulip, Günther Tulip and Celect filters



(a) Günther Tulip with large clots (b) Celect with large clots

(c) Günther Tulip with small clots (d) Celect with small clots

Fig. 6. Small and large clots trapped by the Günther Tulip and Celect filters in a tilted postion



(a) (b)

Fig. 7. Pressure along the numerical model

	small clots	large clots
Mean	3.2	6.4
Mode	3.2	6.9
Median	3.2	6.4
STD	0.26	0.5
Clots used	1200	1200
Min.size (mm)	2.5	5
Max.size (mm)	4	7.5

Table 1

Descriptive analysis for clot samples. Measures of central tendency (mean, median, mode) and measures of variability of dispersion (standard deviation, maximum, minimum)

Filter	**Centered position**		**Tilted position**	
	small clots	**large clots**	**small clots**	**large clots**
Modified Günther Tulip	5.5	21.2	-	-
Günther Tulip	81.7∗	99.5∗	69.3†	99
Celect	78.5∗	98.8∗	57.8	99.3

Table 2

Percentage of clots (%) captured by each filter in a centered and tilted position. (∗ $P<0.001$ using t-test, when compared with Filter 1 and † $P<0.01$ using t-test, when compared with Celect filter)

Filter	without filter	with filter (2L/min)	with 6 clots (3L/min)	with 6 clots
Günther Tulip	0.6	0.6	6.4	4.1
Celect	0.6	0.6	6.4	4.2

Table 3

Measured pressure drop experienced by 2 vena cava filters (mm Hg)

In vitro comparison of Günther Tulip and Celect filters. Testing filtering efficiency and pressure drop

M. Nicolas [a,d], M. Malvè [c,a,d], E. Peña [a,d],M.A. Martínez [a,d],

R. Leask [b]

[a] *Aragón Institute of Engineering Research (I3A), University of Zaragoza, Spain.*

[b] *Department of Chemical Engineering, McGill University, Montreal, Quebec*

[c] *Public University of Navarra, Department of Mechanical Engineering, Energetics and Materials, Pamplona, Spain.*

[d] *Centro de Investigación Biomédica en Red en Bioingeniería, Biomateriales y Nanomedicina (CIBER-BBN), Spain.*

Corresponding author E. Peña. E-mail: fany@unizar.es Phone: (+34) 876.55.52.33

Abstract

In this study, the trapping ability of the Günther Tulip and Celect inferior vena cava filters was evaluated. Thrombus capture rates of the filters were tested *in vitro* in horizontal position with thrombus diameters of 3 and 6 mm and tube diameter of 19 mm. The filters were tested in centered and tilted positions. Sets of 30 clots were injected into the model and the same process was repeated 20 times for each

different condition simulated. Pressure drop experienced along the system was also measured and the percentage of clots captured was recorded. The Günther Tulip filter showed superiority in all cases, trapping almost 100% of 6 mm clots both in an eccentric and tilted position **and trapping 81.7% of the 3 mm clots in a centered position and 69.3% in a maximum tilted position**. The efficiency of all filters tested decreased as the size of the embolus decreased and as the filter was tilted. The injection of 6 clots raised the pressure drop to 4.1 mmHg, which is a reasonable value that does not cause the obstruction of blood flow through the system.

Key words: Pulmonary embolism, inferior vena cava, Günther Tulip filter, Celect fitler, clot capture rate, filter efficiency.

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1 Introduction

Pulmonary embolism (PE) is a serious, potentially life-threatening condition. It is due to the blockage in a lung artery. The cause is usually a blood clot that dislodges from the deep veins in the lower extremities and travels to the lungs Ren et al. (2012). Consequently, inferior vena cava (IVC) filters have been used to prevent recurrent PE in patients who are at very high risk, who are unresponsive to anticoagulation therapy, or in whom anticoagulation is contraindicated Leask et al. (2004). IVC filters are used to intercept and trap large clots while allowing clot-free blood to pass freely towards the heart. As a result of the effort made to find the best filter device, there is a considerable number of filter devices in the market that are used in patients and tested by researchers.

There are many numerical investigations and *in vitro* experiments that study the filter flow dynamics. Couch et al. (1997) and Leask et al. (2001) have previously studied flow fields surrounding a vena cava filter using a noninvasive technique called photochromic. Furthermore, Singer et al. (2009) evaluated the flow hemodynamics of the TrapEase vena cava filter including simulated thrombi of multiple shapes, sizes, and trapping positions. Numerical studies on vena cava filters usually neglect the interaction between blood flow, the filter and the thrombi, but in order to evaluate the effectiveness of a filter and design new models, it is important to study other factors such as the clot capture efficiency.

Clot capture efficiency has been quantified in *in vitro* studies, in which model clots are released into a mock circulation system, with the relative capture efficiency of various IVC filters analyzed statistically Stewart et al. (2008). Hosaka et al. (1993) studied the DIL and the Greenfield vena cava filters' clot-trapping ability in relation to the absolute diameter of the simulated vena cava before filter insertion and the clot size. Ferdani et al. (1995) tested six umbrella-type percutaneous inferior vena cava filters using a mock circulation device, for different flow rates and different filter positions. Lorch et al. (2002) evaluated 10 permanent and retrievable vena cava filters and compared them with the TrapEase filter. Katsamouris et al. (1988) tested six different filters and measured the pressure gradient across the filters. **Other literature reports of *in vitro* studies analyzes the influence of the orientation of the IVC on clot capture efficiency, being an upright patient represented by a vertical configuration of the IVC whereas a supine patient is represented by a horizontal configuration.** Lorch et al. (2002) observed that thrombus capture rates were significantly higher in

the vertical position. Xian et al. (1995) went a little further in their research and studied the influence of number of emboli on the trapping ability of **the Greenfield, Vena Tech-LGM and Günther Tulip**. It was observed that the proportion of trapped clots dropped with ascending clot rank and it was stated that the filter function deteriorates as the number of clots delivered increases.

Most of the authors have done their research using filters such as Greenfield, DIL, Mobin-Uddin, Simon Ninitol, bird's nest, Vena Tech-LGM filter or TrapEase filters, but there are few investigations **Lorch et al. (2002); Xian et al. (1995)**in newer models like the Günther Tulip and Celect filters. For that reason, the aim of this *in vitro* study is to evaluate the clot capture efficiency of the Günther tulip and Celect filters, under different conditions and to prove, if possible, the superiority of one of the filters over the others.

2 Materials and methods

2.1 In vitro set-up

Flexible and transparent polyvinyl chloride tubing of 19mm of inner diameter was used to simulate the vena cava. The model was fixed in the horizontal position and connected to two different reservoirs: A and B. From reservoir A the fluid circulated into the system in a stationary flow. Reservoir B was used to store the fluid from the system. As stated by Couch et al. (1997), the *in vivo* flow conditions of blood are approximately 2L/min so the flow rate was maintained at about 2L/min by adjusting the height of the outflow reservoir B. Reservoir A was continuously topped up in order to maintain a constant pressure and flow rate in the system (see Figure 1). Although some authors use a pulsatile flow for the experiments Hosaka et al. (1993); Xian et al. (1995), **a steady-state flow** was used for these experiments since the blood flowing through veins barely carry any pulse because it is returning to the heart. The fluid used to simulate blood was comprised of 35% by volume of glycerol in water. The fluid was maintained at room temperature and had a density of $1.091 g/cm^3$ and a dynamic viscosity of 0.0036 Pa.s, which is very approximate to blood dynamic viscosity (0.0035 Pa.s). The fluid used was Newtonian with a Reynolds number of 674. Blood is known to behave in a non-Newtonian fashion but

in a vessel of this diameter these effects will not be significant Couch et al. (1997). **Some authors such as Leask et al. (2004, 2001); Singer et al. (2009); Harlal et al. (2007); Neuerburg et al. (1993); Korbin et al. (1994) have also used a flow rate of 2L/min for IVC studies and utilized a Reynolds number of about 600. The reason why our Reynolds number is a bit higher is mainly because the fluid properties are slightly different and the diameter of the tubing used is also different.**

To ensure that the flow entering the filter was laminar and fully developed, the flow phantom tube was constructed with an entrance length of 137 cm. This corresponded to 7 tube diameters and ensured a parabolic velocity profile under the flow conditions used in these experiments.

Three different filters were used to study their efficiency. Firt, a simple,modified Günter Tulip, not commercial filter was used. This filter is only used for mechanical testing in the lab. The Celect IVC filter and the Günter Tulip filter were also used. See Figure 2 for details on the filters used.

2.2 Preparation of the clots

The simulated clots were prepared from 200 mL of water and 10 gr of Agar. The blood clots were modelled as spheres for these experiments. Although the shape of the clots varies widely and have been approximated by different shapes in various works Couch et al. (1997); Stewart et al. (2008); Robinson et al. (2013), no single shape can be rigorously assigned to a clot due to the inherently complex and random nature of its formation. Hence, a sphere not only alleviates the problem of various orientations of clots upon entry into the IVC, but also can be thought of as an averaged shape/orientation Swaminathan et al. (2006).

The clots used for the experiment are divided in two different categories: small clots and large clots, as it is seen in Figure 3. **Small clots range from** $8.2mm^3$ **to** $33.51mm^3$ **(2.5 mm to 4 mm diameter clots), and large clots range from** $65.45mm^3$ **to** $220.9mm^3$**.** 1200 clots of each of the two categories have been analyzed and used to study its size distribution. Image J **(National Institutes of Health, Bethesda, Md)** has been used to process the images and measure the particles sizes.

2.3 Testing procedures

The filters were placed in the middle of the simulated **IVC** in a horizontal position. The filters were assessed in two different positions: central and eccentric. **The eccentric position wanted to represent placement errors or migration of the filter, since sometimes the filter moves from its central position after it is released inside the vena.** The eccentric position was set with the main axis of the filter placed at the maximum angle possible relative to the IVC.

Clot trapping capacity was assessed by placing clots of various sizes into the flow system and counting the number of clots trapped passing through the filter. For each filter, 30 clots of each size were introduced at once. The trapped clots were removed between observations and the number of clots that passed through were recorded. This process was repeated 20 times for each filter and each size of clots, with the filter positioned centered. Furthermore, the Günther Tulip filter and the Celect filter were also positioned in a tilted position, and the same process was repeated 20 times for each clot size and each filter. The experiment was repeated a total of 200 times, and a total of 6000 clots were used.

Pressure drop of the system was also measured using a traceable manometer in order to observe the effects of the clots in the pressure equilibrium of the system. The pressure was measured at two different points of the system in order to obtain the pressure drop. The first point was positioned 90 cm upstream from the filter, and the second point was 10 cm downstream from the filter.

Student's *t-test* for independent samples was used to evaluate differences between filtration capacities of each filter.

2.4 Numerical validation

Two numerical simulations were carried out to validate the pressure drop measurements taken *in vitro*. Two different geometries were modelled. First, an idealized **IVC** with a filter inside of the vena and then, a **IVC** with the filter and 8 thrombi attached to it. Since the pressure drop experienced using different models of filters did not vary, only the (Günther Tulip) was used for both simulations. Computational meshes were created using Ansys Icem (Ansys Inc. Software, Canonsburg, PA, USA) and

the numerical CFD simulations were carried out using Ansys CFX (Ansys Inc. Software, Canonsburg, PA, USA). See Figure 4 for details on the numerical simulation.

3 Results

3.1 Particle size distribution

Descriptive Statistics have been used to present a quantitative description of the main features of the data set (see Table 1). When analyzing the size distribution of small clots (Figure 3 b), the mean, median and mode are equal to 3.2 mm. The three values are the same and coincide with the peak of the histogram of Figure 3 b, which means that the data follow a normal distribution. The standard deviation is 0.26, which indicates that the data are concentrated around the mean and that the diameter is less variable. The histogram for small clots is bell-shaped, following a normal distribution, in agreement with the observations made from the central tendency values recorded. The histogram is symmetrical, the same amount of data falls on both sides of the mean and has skewness (the measure of the asymmetry of a histogram) of 0. The histogram has a tall and narrow shape as a consequence of the low standard deviation.

The results of the analysis for large clots are a little bit different. The mean and median are equal to 6.4, but the mode has a greater value of 6.9. The histogram is not as symmetric as for small clots but it still follows a tendency similar to a normal distribution, as it is observed in Figure 3 c. The standard deviation for large clots is 0.5 **which is larger to the one obtained for small clots**. The data is more spread out around the mean and the histogram has a wider shape, as a consequence of the higher standard deviation.

3.2 Filtering efficiency. Clot-Trapping Capacity

The modified Günther Tulip filter had the lowest clot capture efficiency, as it may be expected (Table 2 and Figure 5a and b). The results show that this filter cannot be used to prevent PE **because there**

is a huge percentage of thrombi (almost 80% of big clots and 94.5% of small clots) that pass through the filter, meaning that pulmonary embolism is more likely to occur if this filter is used.

The most effective filter was the Günther Tulip filter in all cases, as shown in Table 2. For large clots, its effectiveness is almost 100% and it is barely reduced when the filter is set in a tilted position. For smaller clots, its effectiveness is reduced by about 11% when the filter is tilted. Filter 3 also shows good results when trapping large clots but its effectiveness trapping small clots is not as good and is reduced by 20% when the filter is tilted.

Statistical evaluation was performed using Student's *t-test* **(see Table 2)** to evaluate differences between filtration capacities ($\alpha \leq 0.05$). The results showed that the filtering efficiency of both Günther Tulip and Celect filters over the **modified Günther Tulip** were higher ($p < 0.001$). No significant statistical differences were observed between the Günther Tulip and Celect filters when small and large clots were inserted in the system in an eccentric position. On the other hand, when small clots were used in a tilted position, it was demonstrated that the Günther Tulip filter is significantly more efficient than the Celect filter ($p = 0.01$).

All filters showed higher capture rates for large thrombi compared with small thrombi. Differences were more significant when the filters were tilted since the effectiveness of the device for large clots remained constant while it was reduced for smaller clots. Overall, **looking at the results, the most efficient filter in terms of clot trapping ability** seems to be the Günther Tulip and less efficient filter seems to be the modified Günther Tulip.

It is observed in Figures 5 that the effect of gravity, as it will be discussed later in this paper, affects the results. The modified Günther Tulip is only able to trap clots that pass exactly through the center of the IVC while the clots flowing closer to the wall of the IVC passed more easily since the filter does not have secondary struts. When smaller clots are injected in the model, the effectiveness of the filter decreases considerably, being able to trap a smaller number of clots. Figure 5 shows the results obtained for the three filter models when large and small clots are injected in the model, being the filter set in a centered position. It is observed that the efficiency of both filters is excellent thanks to the secondary legs. The secondary struts help the filter trap the clots that do not travel directly

through the center of the model. When small clots are thrown in the model, Figure 5 and Table 2 show that the efficiency of all the filters decreases. Most of the clots travelling through the center of the model are still trapped but some of them pass more easily through the struts.

Figure 6 shows the results obtained for the Günther Tulip and the Celect filters when the filter is tilted. If Figure 5 and 6 are compared it can be observed that the volume of large clots captured by the filters does not vary. On the other hand, Figure 6c and d and Table 2 show that the efficiency of the filters decreases, when small clots are used. 6 mm clots are big enough to not affect the filter efficiency when it is tilted meanwhile 3 mm clots that travel directly away from the dependent wall of the IVC pass more easily.

In conclusion, the efficiency of all filters tested decreased as the size of the embolus decreased and as the filter is tilted, as it could be expected. The Günther Tulip filter resulted as the most efficient filter.

3.3 Pressures

The pressure drop barely changed when the filter was inserted with respect to the measurements taken with no filter in the system. For both tests there was always a slight increase in pressure upstream. Higher pressures were recorded when some clots (6-8) were present in the filter. Subsequently, the effect of trapped clots on pressure drop was measured by injecting sequentially 8 clots and recording the pressure drop. 6 clots were needed to be trapped before a comparable increase of the pressure occurred. All the measurements were repeated 6 times to make sure that the recordings were consistent with each other, and the averaged values were reported in Table 3. Prior to injection of clots, the pressure drop was almost the same for the model with and without the filter inside. **This shows that the presence of the filter in the model does not essentially vary the pressure gradient**. Besides, as stated by Rahbar et al. (2011) and as shown by Leask et al. (2004, 2001); Harlal et al. (2007), the disturbances caused by the filters at a Reynolds number of 600 are negligible. The injection of 8 clots raised the pressure drop to 4.1 mmHg.

The pressure drop was also measured using a flow rate of 3 L/min. Table 3 shows that the increase in the flow rate increases considerably the pressure drop between the two points. **A lot of studies on inferior vena cava filters use a flowrate of** $2L/min$ **Katsamouris et al. (1988); Neuerburg et al. (1993); Korbin et al. (1994); Qian et al. (1994) but the reason why a flow rate of 3L/min has also been used is to compare the pressure drops obtained for two different flow rates, and to double check the pressure drop measurements. Besides, there is an increase in the flow rate of the IVC after Valsava manuever Gindea et al. (1990); Eichenberger et al. (1995),so by using a 3L/min flowrate the behaviour of the filter in more adverse conditions is represented.** All pressure readings in Table 3 are expressed in mmHg. The same procedures were repeated for both the Günther Tulip and the Celect filters and similar results were observed, which means that both filter have the same effect in pressure.

The results obtained in the numerical simulations are **in accordance** with the in-vitro measurements. For the model with the Günther Tulip filter the pressure drop recorded was $0.5mmHg$, which is similar to the in-vitro results of $0.6mmHg$. For the second model, where 8 thrombi are attached to the filter, the pressure drop obtained was $4mmHg$, meanwhile the pressure drop measured in vitro was $4mmHg$. Figure 7 shows the pressure experienced along the model in a plane. It is observed how little the filter affects the pressure in the system meanwhile the thrombi cause a sudden decrease in the pressure.

4 Discussion

Clot capture rates in our experiment went from 5.5% to 99.5%. It was observed, in general, that the efficiency of the filter was reduced when the size of clots was reduced and when the position of the filter was tilted. The best-ranked filter is the Günther Tulip filter,.

If the results from our experiment are compared to previous work Ferdani et al. (1995); Katsamouris et al. (1988); Hammer et al. (1994), the Günther Tulip and Celect filters performed fairly well. In Katsamouris et al. (1988) investigations, 3 filters **(Movin-Udin, Amplatz and Günther basket)** presented an increase in pressure above $20cmH_2O$ ($\simeq 15mmHg$) when 3 clots were trapped meanwhile the other 3 filter models (Simon Nitinol, Kimray-Greemfield and bird's nest) presented a pressure

increase of almost $5cmH_2O(\simeq 3.7mmHg)$ when 6 clots were trapped (which is very close to our results). **The main reason of the differences in the pressure drops between filter models is that some of them are designed for high clot-trapping capacity, and for that reason they impede flow the most and result in adverse flow conditions Katsamouris et al. (1988).** Ferdani et al. (1995) studied the difference in pressure by 6 vena cava filters and obtained similar results to our investigations, which show that the filters used by them have similar performance in terms of flow impedance. **If the IVC is collapsed or close to being collapsed, due to a big amount of clots trapped around the filter, there is a huge increase in pressure inside the vena. Hirsch and Hoak (1996) state that the risk of thrombosis is elevated when the obstruction of the vena cava occurs. For that reason, if the filter causes obstruction of the vena cava, thrombosis is more likely to occur. Furthermore, Leask et al. (2004) also stated that successful treatment of thrombosis requires the filter to provide high filter efficiency without impeding the blood flow, in order to prevent from thrombosis. To conclude, the filters that result in a great increase of pressure after clot entrapment, will have the highest potential for IVC thrombosis.**

In vitro models have limitations that may raise questions about the clinical relevance of experimental studies. **The tubing used in our model to represent the IVC was rigid. The deformations of the IVC were not taken into account, but respiratory variation and Valsalva result in profound changes in the diameter of the IVC Murphy et al. (2008). Different results may be obtained if these deformations are considered.**

A second model limitation was the effect of gravity on flowing blood clots, and the influence of this effect on clot-trapping capacity of each filter. As blood flow velocity is highest in the center of the IVC, emboli are believed to be carried along the center of the blood stream Qian et al. (1994). As shown by Lorch et al. (2002); Katsamouris et al. (1988); Robinson et al. (2013), clot capture rates were significantly higher with the device in the vertical position. In this report, tests were only performed in a stable horizontal position similar to that in supine patients. As a result of gravity, clots failed to remain in the center of the fluid column in the phantom and sometimes had a tendency to flow along the dependent wall of the IVC and passed more easily through the filter struts. So the effect of gravity decreases the clot capture rates when the experiment is performed in the horizontal position.

When testing the filter in a tilted position, the devices were pushed into as much tilt as the model would allow so the effect of the tilt in the effectiveness of the filter was studied in a worst scenario case. When looking at the results obtained with the filters in a tilted position, this considerations has to be taken into account.

The clot size which leads to clinically significant pulmonary embolism remains unclear and dependent on **factors such as former pulmonary embolization and pre-existing lung disease** Lorch et al. (2002). The sizes used for this experiment are similar to the diameters used by Lorch et al. (2002); Katsamouris et al. (1988); Xian et al. (1995). In our opinion, in cases where only capture of large emboli is necessary, such as in young patients with a healthy lung, the Celect filter can be recommended. On the other hand, if PE has to be prevented in patients with impaired pulmonary function or in a poor general condition who may not be able to tolerate even small emboli, the insertion of a more efficient filter such as the Günther Tulip could be recommended.

An IVC filter cannot be chosen only on the basis of this experiment. Other factors such as ease of placement and documented clinical results must be taken into account. In vitro models are an important tool to evaluate the characteristics and performance of different filter models but they are limited and cannot reflect filter performances under the in vivo conditions in all aspects. However, in vitro testing help us to eliminate the most deficient models and understand how filters work inside the body. We realize that the method used to evaluate the efficiency of the filter simulates the worst case scenario leading to vena cava occlusion when using large clots. There are many different possibilities that can be studied when studying filtering efficiency, but we considered that studying the worst case scenario could be a good option to evaluate the efficiency of filters.

To obtain clinically relevant results a more complex model should be done. Our model is a simplified *in vitro* IVC model, but we can observe the efficiency of the filter models used, being the Günther Tulip the most efficient of them. We can also conclude that the pressure through the system only increases significantly for the Celect and Günther Tulip when most of the space inside the vena is collapsed by clots. Neuerburg et al. (1993) studied the performance of the Günther Tulip *in vivo*. It was observed that the filter showed a good hemodynamic behavior in the flow circuit. Besides, the *in vivo* fatigue

testing of the filter revealed a high mechanical testing and the filter demonstrated a good biocompatibility with complete endothelization of the wires being in contact with the caval wall. This *in vivo* finding along with our *in vitro* results demonstrate that the Günther Tulip is very good option to be used in patients.

Clinical observation studies as the ones performed by Neuerburg et al. (1993); Ferris et al. (1993); Athanasoulis et al. (2000) together with valid *in vitro* investigations are important steps on the way to design an ideal vena cava filter. Clinical observations reveal important aspects about the filters such as penetration of the wall, migration of the filter, and ease of placement but in vitro models allow to do very complete studies on filter efficiency.

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6 Conflict of interest

None of the authors of this work has conflict of interest with other people and organizations.

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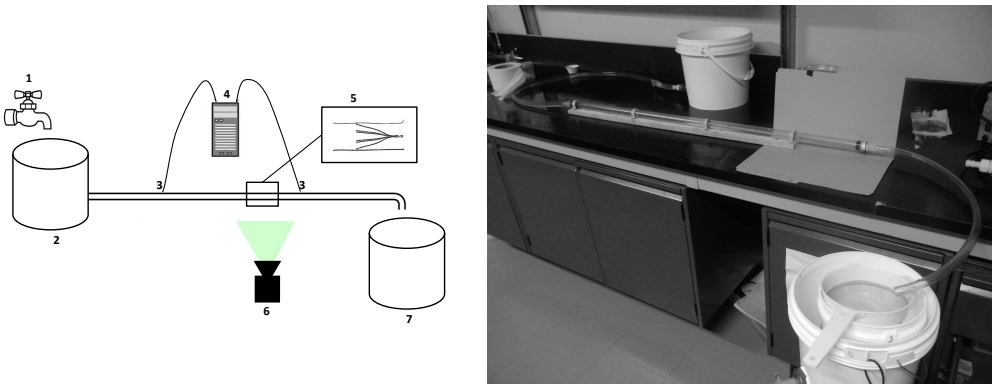
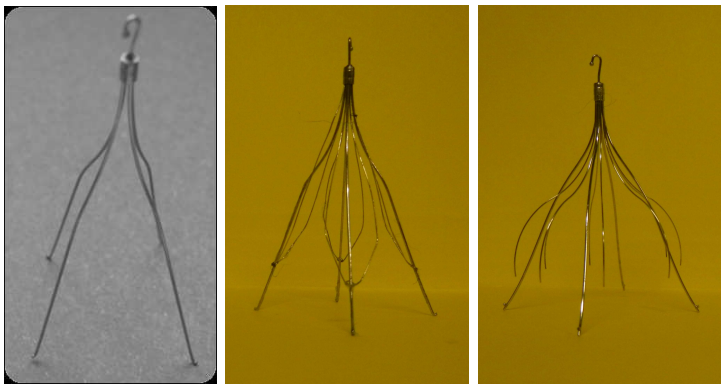


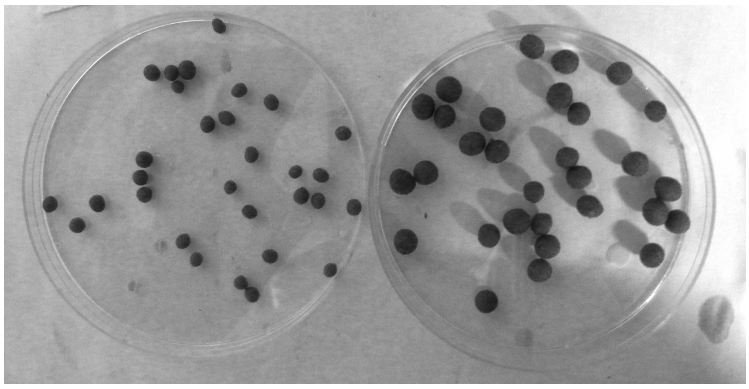
(a) (b)

Fig. 1. Experimental set up: 1. Top-up, 2. Reservoir A, 3. Pressure tabs , 4. Traceable manometer, 5.IVC system, 8. Video recorder, 7. Reservoir B

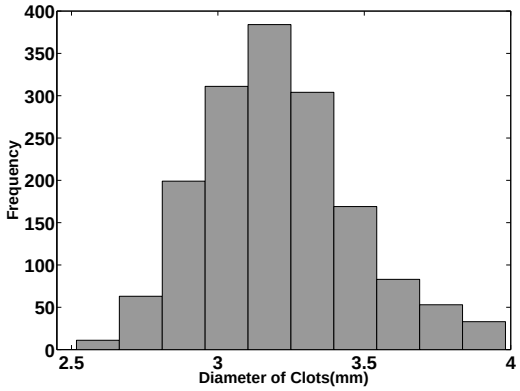


(a) (b) (c)

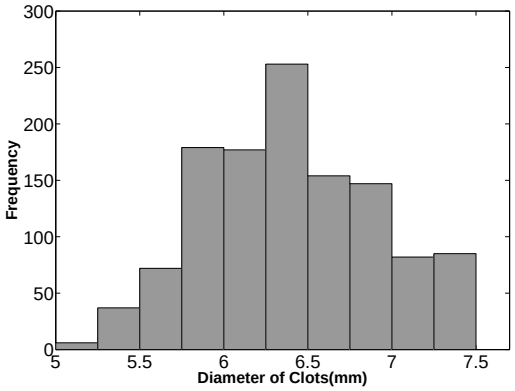
Fig. 2. IVC filters used for the experiment: (a) Modified Günther Tulip filter, (b) Günther Tulip filter, (c) Celect filter. They are low profile, asymmetric, retrievable, made of a cobalt-chromium alloy filters Cook (2014) that are manufactured by Cook Medical (Bloomington, IN). The design of the Celect follows that of the Günther Tulip filter. Both of them have a half-basket shape with a length of 45 mm and a maximum diameter of 30 mm Cook (2014) and have a retrieval hook at the appex to allow percutaneous retrieval or repositioning De Gregorio et al. (2003).



(a) Clots prepared

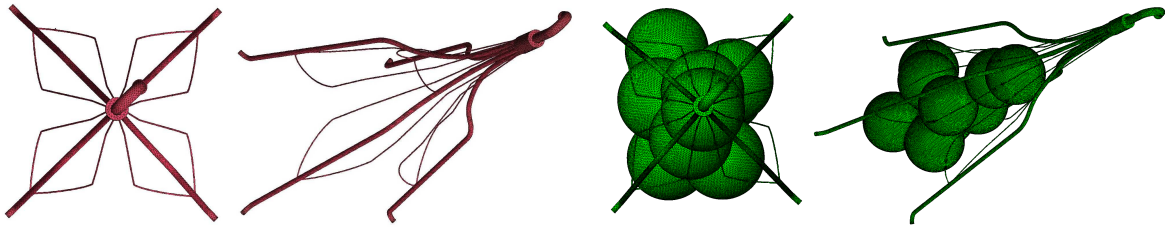


(b) Small clots histogram



(c) Large clots histogram

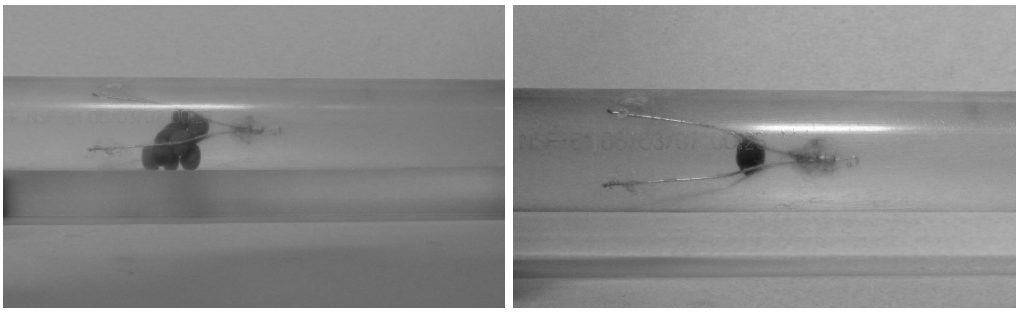
Fig. 3. (a) Clots prepared for the experiment. **left: small clots range from** $65.45mm^3$ **to** $220.9mm^3$ **(2.5 mm to 4 mm diameter clots), right: large clots range from** $8.2mm^3$ **to** $33.51mm^3$ **(5 mm to 7.5 mm diameter clots)**. (b) frequency histograms of the sample clots, used to estimate the probability distribution of the feret's diameter variable



(a) (b)

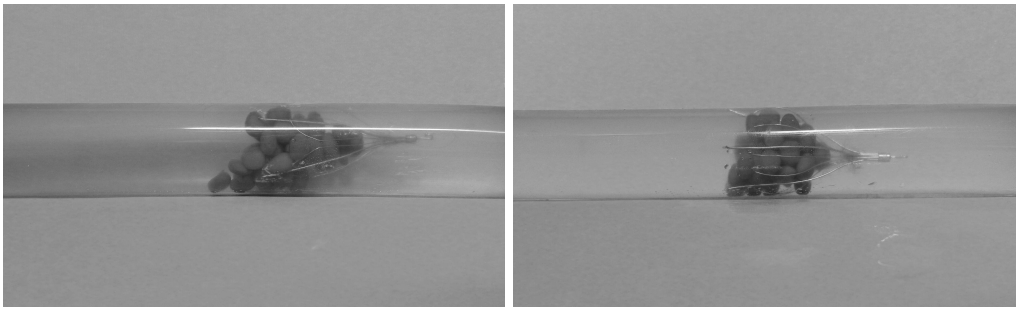
Fig. 4. Finite element mesh of the Günther Tulip filter (a) without thrombi and (b) with some thrombi.

The two different geometrical models were built using the commercial software SolidWorks (Dessault, SolidWorks Corp., France). Then, Ansys Icem (Ansys Inc. Software, Canonsburg, PA, USA) was used to obtain the numerical grids. In order to guarantee that the numerical results were grid independent, a mesh independence study was carried out prior to the presented simulations. Velocity profiles at different locations of the IVC model were compared for different grid sizes, concluding that meshes finer than $4 * 10^6$ for the model with the clots and $1 * 10^6$ for the model with the filter increased the computational time without adding precision to the solution. The fluid grids were imported in the commercial package Ansys CFX (Ansys Inc. Software, Canonsburg, PA, USA) were the fluid dynamics computations were carried out. The numerical approach used by this software is extensively explained in literature and given in details in CFX (2012). The fluid was assumed Newtonian, incompressible under steady conditions, laminar and had the same density and viscosity that was used in the experimental study. As boundary conditions, a steady parabolic flow profile with a total volume flow rate of 2L/min was imposed at both inlet and outlet of the IVC to match the experimental set-up and no-slip boundary conditions were applied at the wall, filter and clots. The convergence tolerance for both models was set to 10^{-8}, and the number of iterations was set to 500.



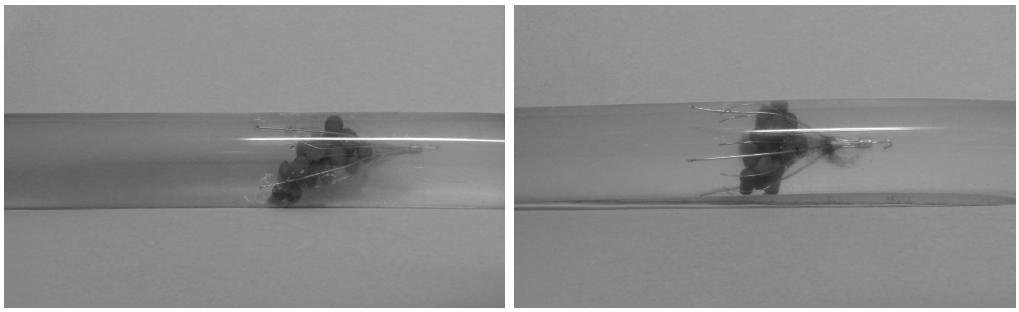
(a) Modified Günther Tulip with large clots trapped

(b) Modified Günther Tulip with small clots trapped



(c) Günther Tulip with large clots

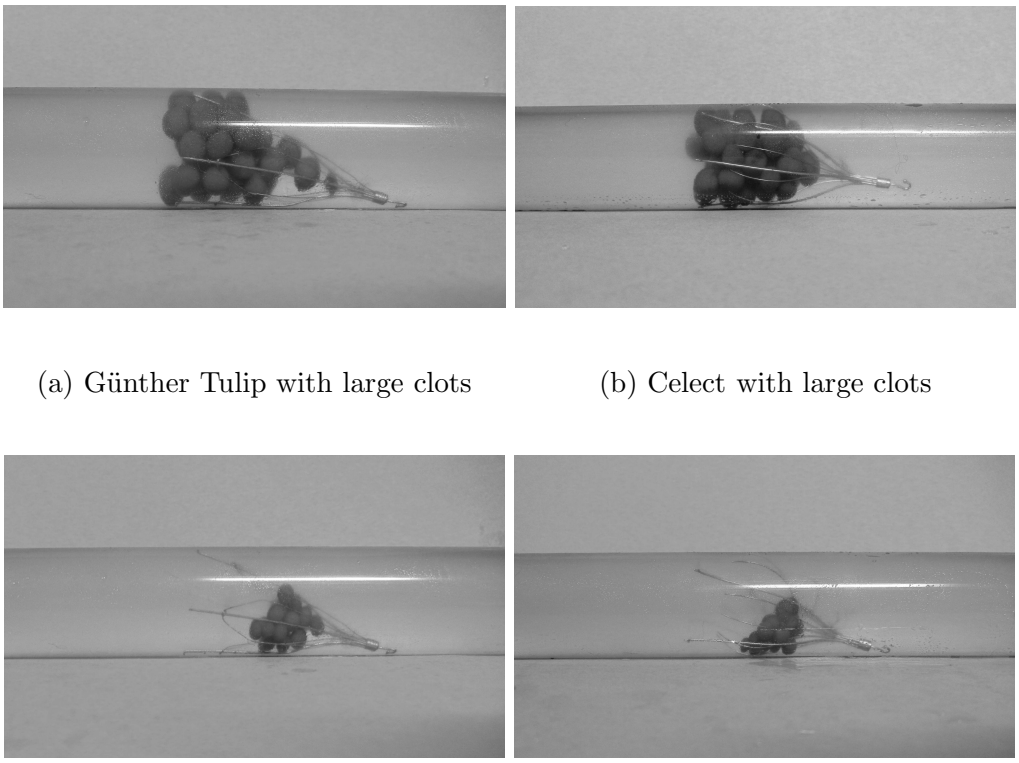
(d) Celect with large clots



(e) Günther Tulip with small clots

(f) Celect with small clots

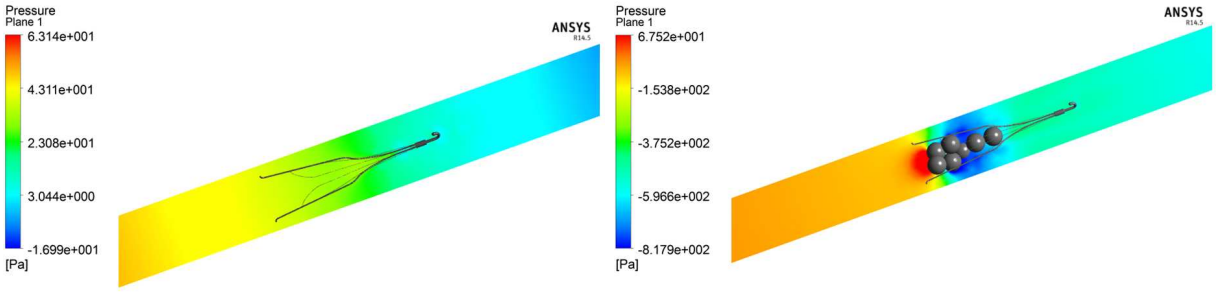
Fig. 5. Small and large clots trapped by the modified Günther Tulip, Günther Tulip and Celect filters



(a) Günther Tulip with large clots (b) Celect with large clots

(c) Günther Tulip with small clots (d) Celect with small clots

Fig. 6. Small and large clots trapped by the Günther Tulip and Celect filters in a tilted postion



(a) (b)

Fig. 7. Pressure along the numerical model

	small clots	large clots
Mean	3.2	6.4
Mode	3.2	6.9
Median	3.2	6.4
STD	0.26	0.5
Clots used	1200	1200
Min.size (mm)	2.5	5
Max.size (mm)	4	7.5

Table 1

Descriptive analysis for clot samples. Measures of central tendency (mean, median, mode) and measures of variability of dispersion (standard deviation, maximum, minimum)

Filter	**Centered position**		**Tilted position**	
	small clots	**large clots**	**small clots**	**large clots**
Modified Günther Tulip	5.5	21.2	-	-
Günther Tulip	81.7∗	99.5∗	69.3†	99
Celect	78.5∗	98.8∗	57.8	99.3

Table 2

Percentage of clots (%) captured by each filter in a centered and tilted position. (∗ $P<0.001$ using t-test, when compared with Filter 1 and † $P<0.01$ using t-test, when compared with Celect filter)

Filter	without filter	with filter (2L/min)	with 6 clots (3L/min)	with 6 clots
Günther Tulip	0.6	0.6	6.4	4.1
Celect	0.6	0.6	6.4	4.2

Table 3

Measured pressure drop experienced by 2 vena cava filters (mm Hg)

***Conflict of Interest Statement**

Conflict of interest statement the paper "**In vitro comparison of Günther Tulip and Celect filters. Testing filtering efficiency and pressure drop**", M. Nicolás, M. Malvè, E. Peña, R. Leask and myself.

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