

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

M. Nicolas <sup>a,d</sup>, M. Malvè <sup>c,a,d</sup>, E. Peña <sup>a,d</sup>, M.A. Martínez <sup>a,d</sup>,  
R. Leask <sup>b</sup>

<sup>a</sup>*Aragón Institute of Engineering Research (I3A), University of Zaragoza, Spain.*

<sup>b</sup>*Department of Chemical Engineering, McGill University, Montreal, Quebec*

<sup>c</sup>*Public University of Navarra, Department of Mechanical Engineering, Energetics  
and Materials, Pamplona, Spain.*

<sup>d</sup>*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

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## 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 filter, 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

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

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

## 39 2 Materials and methods

### 40 2.1 *In vitro* set-up

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

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

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

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

## 65 *2.2 Preparation of the clots*

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

73 The clots used for the experiment are divided in two different categories: small clots and large clots,  
74 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  
75 clots), and large clots range from  $65.45mm^3$  to  $220.9mm^3$ . 1200 clots of each of the two categories  
76 have been analyzed and used to study its size distribution. Image J (National Institutes of Health,  
77 Bethesda, Md) has been used to process the images and measure the particles sizes.

### 78 2.3 Testing procedures

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

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

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

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

### 97 2.4 Numerical validation

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

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

## 105 **3 Results**

### 106 *3.1 Particle size distribution*

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

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

### 123 *3.2 Filtering efficiency. Clot-Trapping Capacity*

124 The modified Günther Tulip filter had the lowest clot capture efficiency, as it may be expected (Table  
125 2 and Figure 5a and b). The results show that this filter cannot be used to prevent PE because there

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

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

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

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

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



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

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

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

164

### 165 *3.3 Pressures*

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

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

179 in the flow rate increases considerably the pressure drop between the two points. A lot of studies  
180 on inferior vena cava filters use a flowrate of  $2L/min$  (Katsamouris et al., 1988; Neuerburg et al.,  
181 1993; Korbin et al., 1994; Qian et al., 1994) but the reason why a flow rate of  $3L/min$  has also been  
182 used is to compare the pressure drops obtained for two different flow rates, and to double check the  
183 pressure drop measurements. Besides, there is an increase in the flow rate of the IVC after Valsava  
184 maneuver (Gindea et al., 1990; Eichenberger et al., 1995),so by using a  $3L/min$  flowrate the behaviour  
185 of the filter in more adverse conditions is represented. All pressure readings in Table 3 are expressed  
186 in mmHg. The same procedures were repeated for both the Günther Tulip and the Celect filters and  
187 similar results were observed, which means that both filter have the same effect in pressure.

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

#### 194 4 Discussion

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

198 If the results from our experiment are compared to previous work (Ferdani et al., 1995; Katsamouris  
199 et al., 1988; Hammer et al., 1994), the Günther Tulip and Celect filters performed fairly well. In Kat-  
200 samouris et al. (1988) investigations, 3 filters (Movin-Udin, Amplatz and Günther basket) presented  
201 an increase in pressure above  $20cmH_2O$  ( $\simeq 15mmHg$ ) when 3 clots were trapped meanwhile the other  
202 3 filter models (Simon Nitinol, Kimray-Greemfield and bird's nest) presented a pressure increase of  
203 almost  $5cmH_2O$  ( $\simeq 3.7mmHg$ ) when 6 clots were trapped (which is very close to our results). The  
204 main reason of the differences in the pressure drops between filter models is that some of them are

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

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

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

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

233 to be taken into account.

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

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

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

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

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## 272 **6 Conflict of interest**

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

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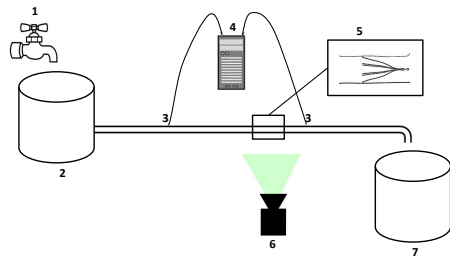
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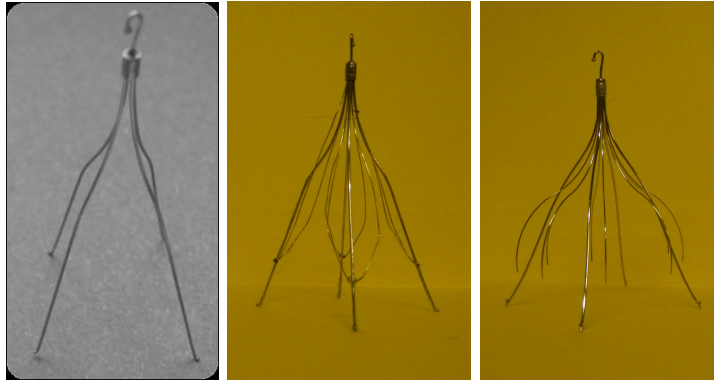


(a)



(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

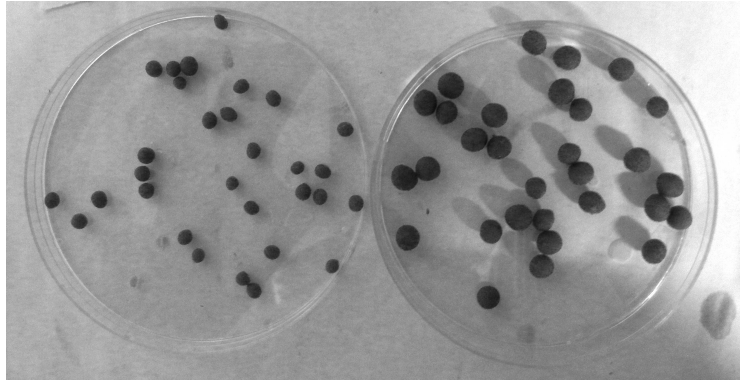


(a)

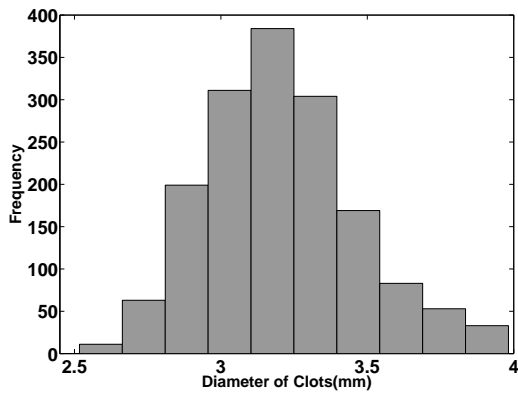
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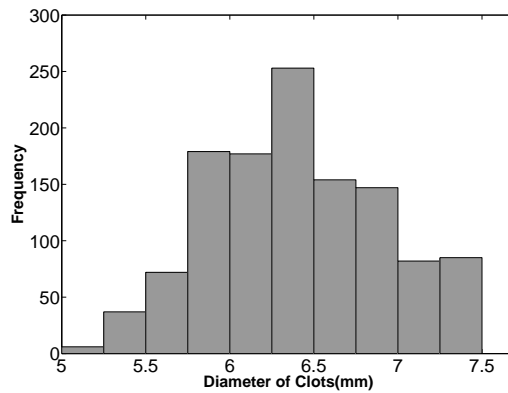
Fig. 2. IVC filters used for the experiment: (a) Modified Günther Tulip filter, (b) Günther Tulip filter, (c) Celect filter. They are low profile, asymmetric, retrievable, made of a cobalt-chromium alloy filters Cook (2014) that are manufactured by Cook Medical (Bloomington, IN). The design of the Celect 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 apex 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

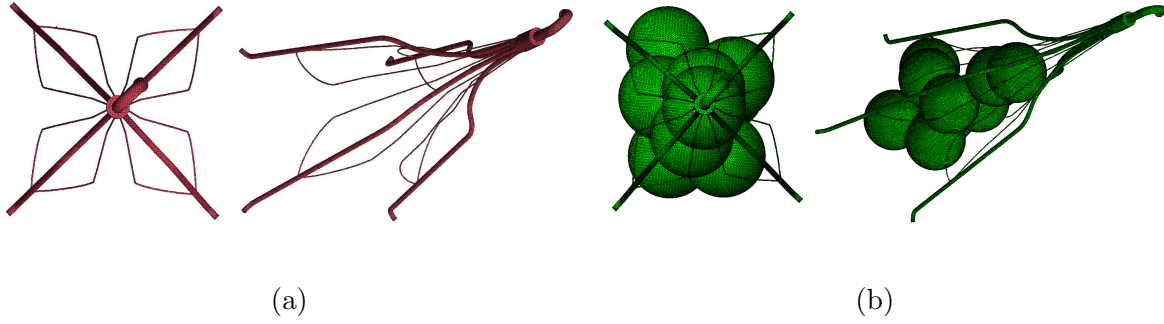
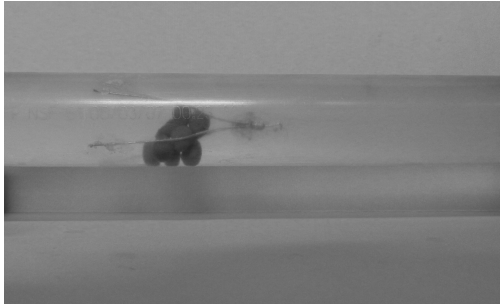
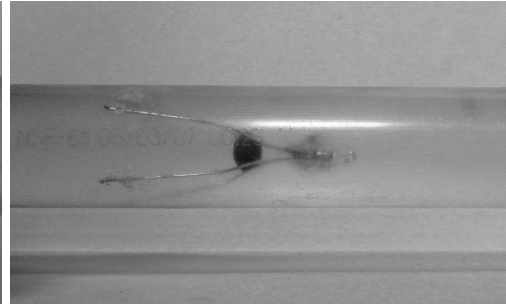


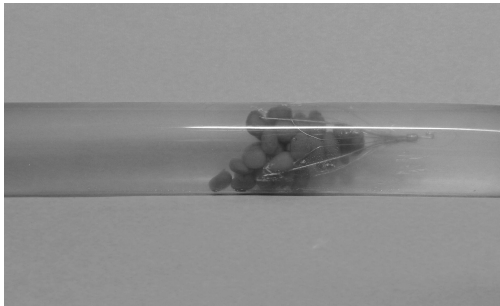
Fig. 4. Finite element mesh of the Günther Tulip filter (a) without thrombi and (b) with some thrombi. The two different geometrical models were built using the commercial software SolidWorks (Dessault, SolidWorks Corp., France). Then, Ansys Icem (Ansys Inc. Software, Canonsburg, PA, USA) was used to 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) where 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.



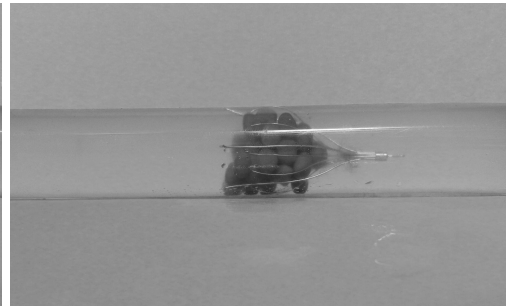
(a) Modified Günther Tulip with large clots trapped



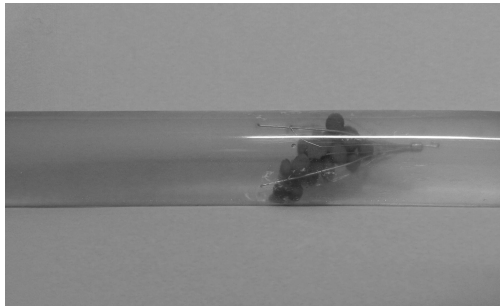
(b) Modified Günther Tulip with small clots trapped



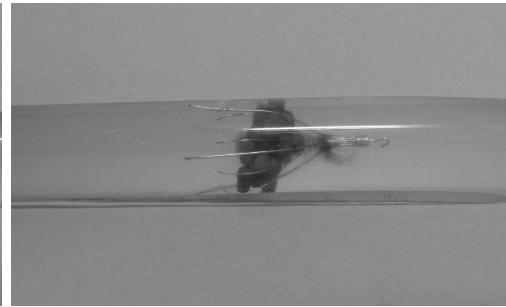
(c) Günther Tulip with large clots



(d) Celect with large clots

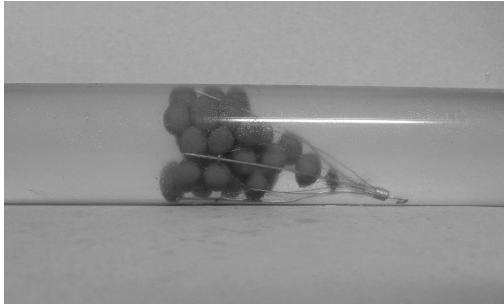


(e) Günther Tulip with small clots

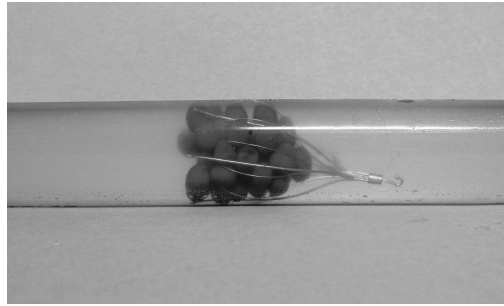


(f) Celect with small clots

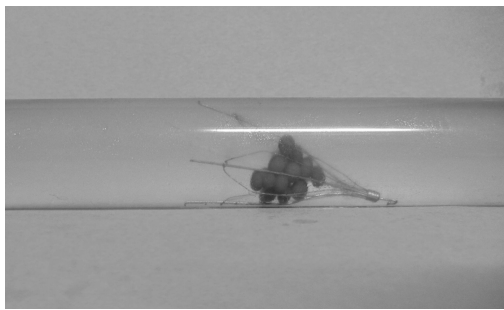
Fig. 5. Small and large clots trapped by the modified Günther Tulip, Günther Tulip and Celect filters



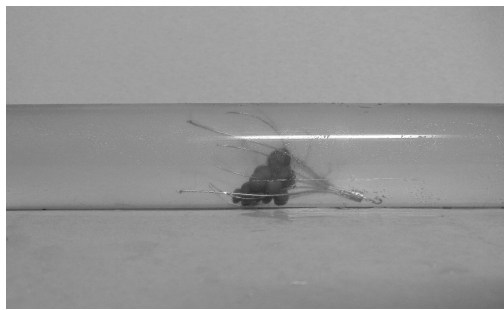
(a) Günther Tulip with large clots



(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 position

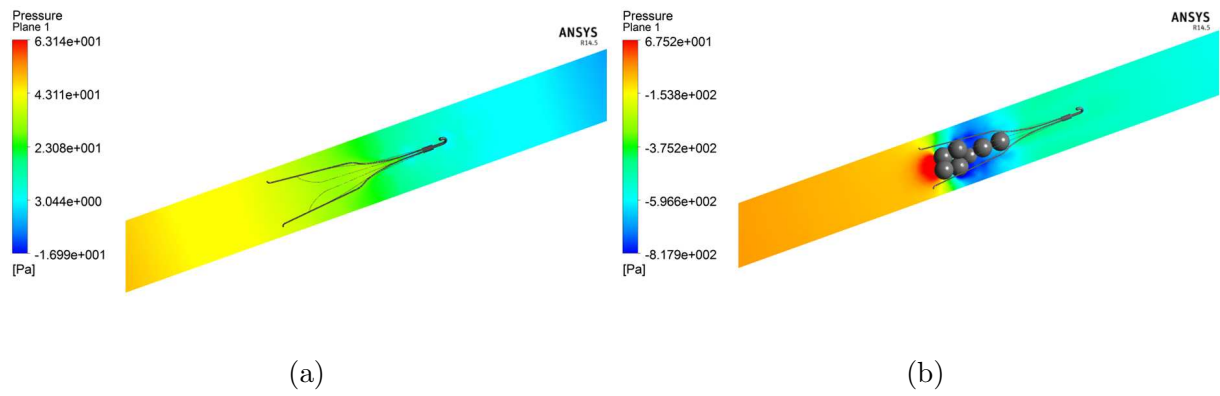


Fig. 7. Pressure along the numerical model

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

<b>Filter</b>	<b>without filter</b>	<b>with filter (2L/min)</b>	<b>with 6 clots (3L/min)</b>	<b>with 6 clots</b>
<b>Günther Tulip</b>	0.6	0.6	6.4	4.1
<b>Celect</b>	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 <sup>a,d</sup>, M. Malvè <sup>c,a,d</sup>, E. Peña <sup>a,d</sup>, M.A. Martínez <sup>a,d</sup>,  
R. Leask <sup>b</sup>

<sup>a</sup>*Aragón Institute of Engineering Research (I3A), University of Zaragoza, Spain.*

<sup>b</sup>*Department of Chemical Engineering, McGill University, Montreal, Quebec*

<sup>c</sup>*Public University of Navarra, Department of Mechanical Engineering, Energetics  
and Materials, Pamplona, Spain.*

<sup>d</sup>*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

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## 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 filter, 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

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

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

## 39 **2 Materials and methods**

### 40 *2.1 In vitro set-up*

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

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

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

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

## 66 *2.2 Preparation of the clots*

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

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

79 2.3 *Testing procedures*

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

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

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

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

98 2.4 *Numerical validation*

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



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

## 106 **3 Results**

### 107 *3.1 Particle size distribution*

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

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

### 124 *3.2 Filtering efficiency. Clot-Trapping Capacity*

125 The modified Günther Tulip filter had the lowest clot capture efficiency, as it may be expected (Table  
126 2 and Figure 5a and b). The results show that this filter cannot be used to prevent PE **because there**

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

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

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

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

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

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

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

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

167

### 168 *3.3 Pressures*

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

181 The pressure drop was also measured using a flow rate of 3 L/min. Table 3 shows that the increase in  
182 the flow rate increases considerably the pressure drop between the two points. **A lot of studies on**  
183 **inferior vena cava filters use a flowrate of 2L/min Katsamouris et al. (1988); Neuerburg**  
184 **et al. (1993); Korbin et al. (1994); Qian et al. (1994) but the reason why a flow rate of**  
185 **3L/min has also been used is to compare the pressure drops obtained for two different flow**  
186 **rates, and to double check the pressure drop measurements. Besides, there is an increase**  
187 **in the flow rate of the IVC after Valsava manuever Gindea et al. (1990); Eichenberger**  
188 **et al. (1995),so by using a 3L/min flowrate the behaviour of the filter in more adverse**  
189 **conditions is represented.** All pressure readings in Table 3 are expressed in mmHg. The same  
190 procedures were repeated for both the Günther Tulip and the Celect filters and similar results were  
191 observed, which means that both filter have the same effect in pressure.

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

## 198 4 Discussion

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

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

207 increase of almost  $5\text{cmH}_2\text{O}(\simeq 3.7\text{mmHg})$  when 6 clots were trapped (which is very close to our  
208 results). **The main reason of the differences in the pressure drops between filter models is**  
209 **that some of them are designed for high clot-trapping capacity, and for that reason they**  
210 **impede flow the most and result in adverse flow conditions Katsamouris et al. (1988).**  
211 Ferdani et al. (1995) studied the difference in pressure by 6 vena cava filters and obtained similar  
212 results to our investigations, which show that the filters used by them have similar performance in  
213 terms of flow impedance. **If the IVC is collapsed or close to being collapsed, due to a big**  
214 **amount of clots trapped around the filter, there is a huge increase in pressure inside**  
215 **the vena. Hirsch and Hoak (1996) state that the risk of thrombosis is elevated when**  
216 **the obstruction of the vena cava occurs. For that reason, if the filter causes obstruction**  
217 **of the vena cava, thrombosis is more likely to occur. Furthermore, Leask et al. (2004)**  
218 **also stated that successful treatment of thrombosis requires the filter to provide high**  
219 **filter efficiency without impeding the blood flow, in order to prevent from thrombosis.**  
220 **To conclude, the filters that result in a great increase of pressure after clot entrapment,**  
221 **will have the highest potential for IVC thrombosis.**

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

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

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

240 The clot size which leads to clinically significant pulmonary embolism remains unclear and dependent  
241 on **factors such as former pulmonary embolization and pre-existing lung disease** Lorch  
242 et al. (2002). The sizes used for this experiment are similar to the diameters used by Lorch et al.  
243 (2002); Katsamouris et al. (1988); Xian et al. (1995). In our opinion, in cases where only capture  
244 of large emboli is necessary, such as in young patients with a healthy lung, the Celect filter can be  
245 recommended. On the other hand, if PE has to be prevented in patients with impaired pulmonary  
246 function or in a poor general condition who may not be able to tolerate even small emboli, the insertion  
247 of a more efficient filter such as the Günther Tulip could be recommended.

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

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

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

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

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## 280 6 Conflict of interest

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

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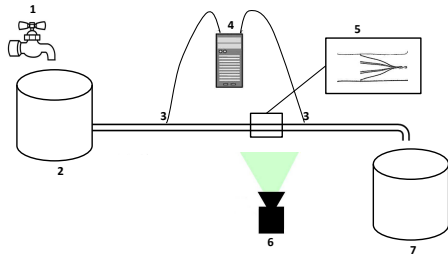
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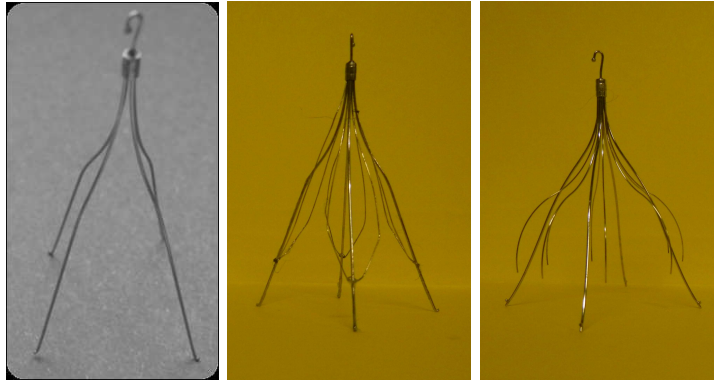


(a)



(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

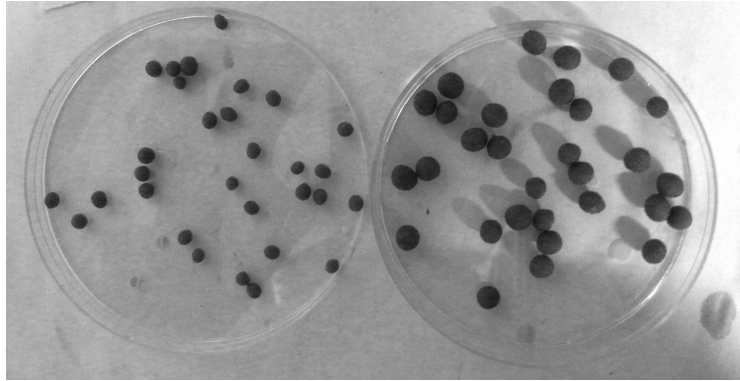


(a)

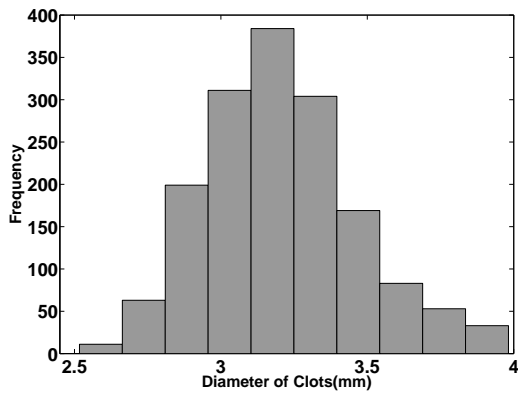
(b)

(c)

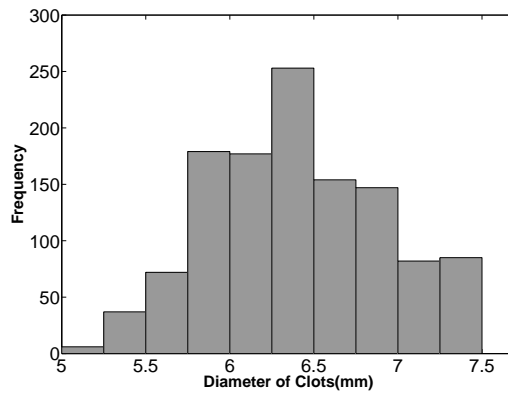
Fig. 2. IVC filters used for the experiment: (a) Modified Günther Tulip filter, (b) Günther Tulip filter, (c) Celect filter. They are low profile, asymmetric, retrievable, made of a cobalt-chromium alloy filters Cook (2014) that are manufactured by Cook Medical (Bloomington, IN). The design of the Celect 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 apex 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

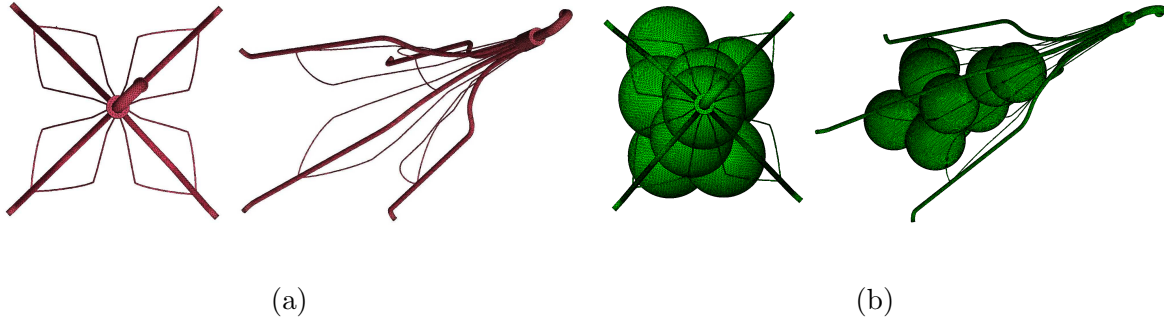
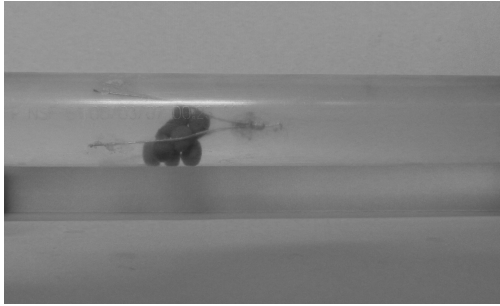
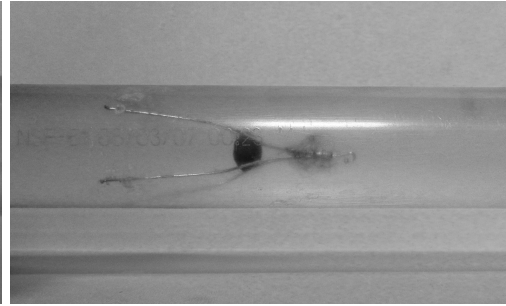


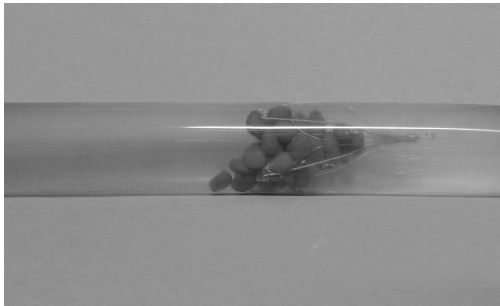
Fig. 4. Finite element mesh of the Günther Tulip filter (a) without thrombi and (b) with some thrombi. The two different geometrical models were built using the commercial software SolidWorks (Dessault, SolidWorks Corp., France). Then, Ansys Icem (Ansys Inc. Software, Canonsburg, PA, USA) was used to 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) where 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.



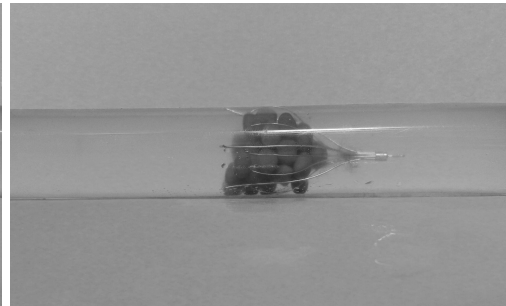
(a) Modified Günther Tulip with large clots trapped



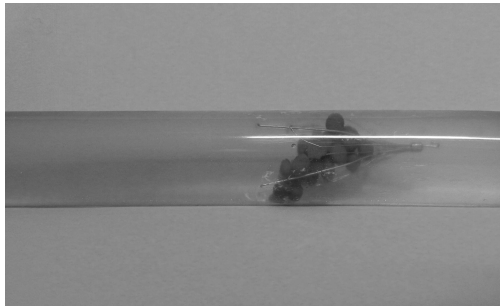
(b) Modified Günther Tulip with small clots trapped



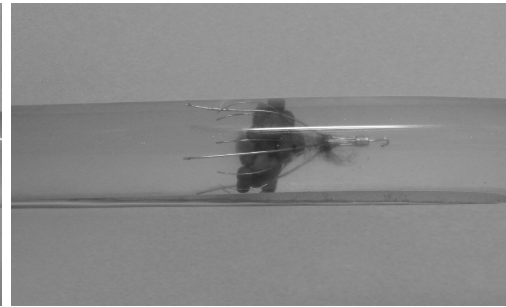
(c) Günther Tulip with large clots



(d) Celect with large clots

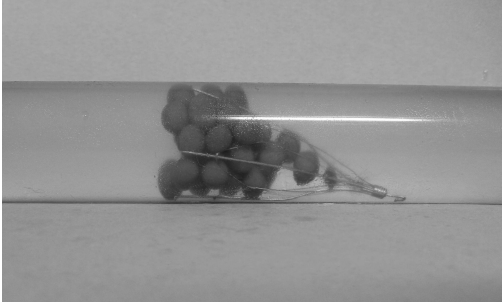


(e) Günther Tulip with small clots

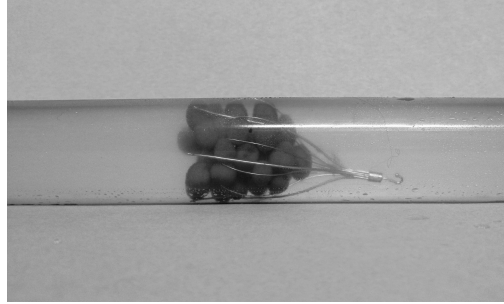


(f) Celect with small clots

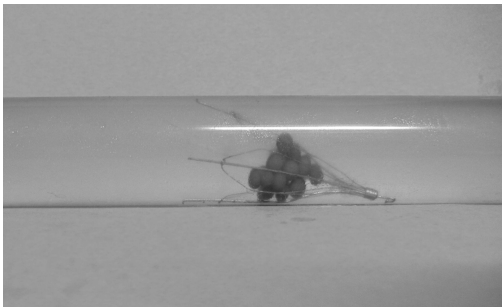
Fig. 5. Small and large clots trapped by the modified Günther Tulip, Günther Tulip and Celect filters



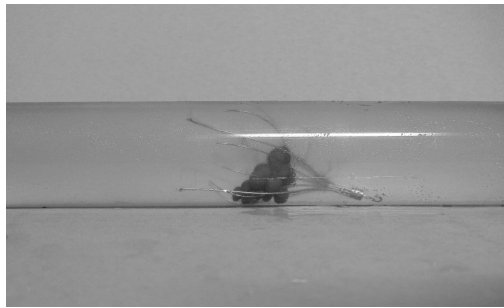
(a) Günther Tulip with large clots



(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 position



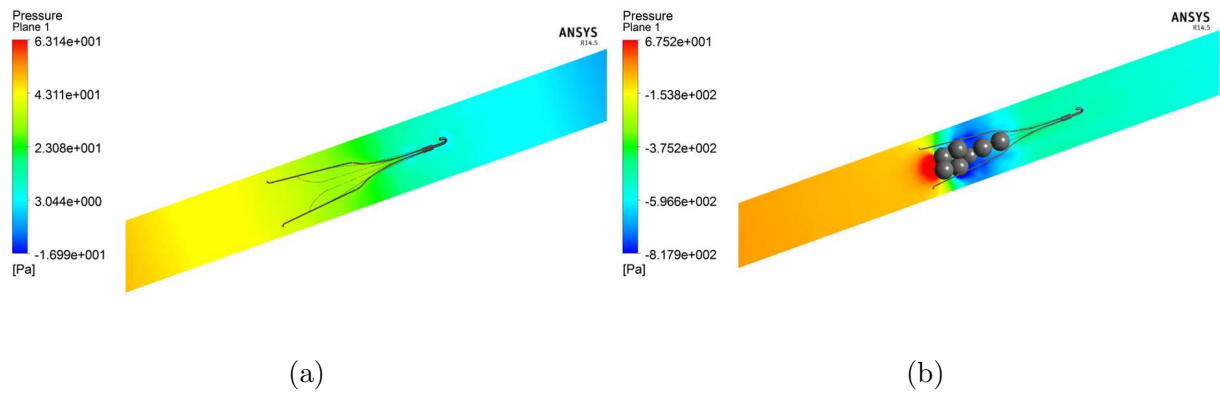


Fig. 7. Pressure along the numerical model

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

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