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NUMERICAL AND ANALYTICAL ANALYSES OF THE PLATELET LYSIS INDEX AND HEMOLYSIS FOR EFFICIENCY EVALUATION OF CENTRAL VENOUS CATHETERS

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Abstract. Hemodialysis is a procedure applied mainly to patients with kidney diseases and consists of filtering the blood with external equipment. One of the most widely used forms of access is the Central Venous Catheter (CVC), which has different geometries from each manufacturer. The objective of this study is to evaluate the efficiency of a catheter through the platelet lysis index (PLI) and the particle's percentage under high shear stress which can increase the blood cell lysis. In this study, numerical simulations were performed on catheters with different side holes geometries for comparison with a no side holes model considering blood as a non-Newtonian fluid. The analyses were performed with ANSYS Fluent and post-processed with MATLAB to obtain the velocity and shear stress contour, as well the effects of these parameters on the particles inside the domain to simulate the blood cells and to evaluate the PLI and blood cell lysis. The best results were obtained for the no side holes, straight side holes, and conical side holes 1 catheters, with low PLI. The lowest efficiency was observed for the oblique side holes 1 and conical side holes 2 catheters.

Keywords: Central Venous Catheter, platelet lysis index, blood flow, shear stress, residence time.

1. INTRODUCTION

Hemodialysis is a type of replacement procedure to renal function that can last through all patient's life or until a kidney transplant (Guedes and Guedes, 2012). This treatment consists of a blood filtration process carried out by an external pump and a dialyzer, which replaces the renal functions (Machado, 2013).

The hemodialysis procedure is performed by filtering the blood through external equipment. The patient's blood is directed to the filtration process using an artificial circulation system. In the equipment, dialysis is performed using a semi-permeable membrane that allows the removal of impurities and toxic substances. After the process, the blood returns to the bloodstream.

One of the most common vascular access for treatment is the implantation of a Central Venous Catheter (CVC), (tube introduced into body cavities to drains or inject fluids) in a large vein (Guimarães et al., 2016).

Recently, Neves (2020), presents a data survey of patients undergoing hemodialysis treatment in Brazil, between 2009 and 2018. This study concluded that was an increase in the number of patients submitted to chronic dialysis treatment by 72%, totaling 133,464 patients, of which 23.6% use a CVC as vascular access. One of the biggest complications during hemodialysis treatment is related to inlet lumen clogging. This life spam reduction is due to platelet activation that occurs in regions of high shear stress, such as the entry holes in the catheter lumen. This effect can cause blood cells to collapse (hemolysis).

Several catheter geometries are available on the market and, therefore, evaluating the efficiency of a catheter has become a necessary task to understand the impact of this type of equipment on the blood cells, as they significantly affect the blood flow's pressure field. One way to evaluate the efficiency of a catheter is through the Platelet Lysis Index (PLI), developed by Giersipen (1990), which quantifies the platelet activation using the cell's residence time in regions of high shear stress. Application of the PLI as a form of numerical validations for catheters of different geometries can be found in studies by Timothy (2015), Haniel (2019), and Owen (2020).

The study presented in this article proposes an evaluation of the efficiency of, double lumen and symmetric, Central Venous Catheters applied in hemodialysis procedures using PLI from particles injected in numerical simulations (Computational Fluid Dynamics – CFD) of blood flow. Therefore, this study aims to evaluate the rate of blood cell lysis on different geometries of symmetrical catheters through the identification of the shear stresses developed by the blood flow in the inlet and outlet's lumens, as well as the residence time of blood cells in the regions of higher shear stress. Most of the time, blood can be described as a non-Newtonian fluid, since the components of this suspension are mostly platelets, red blood cells, and proteins on a liquid phase, the plasma. The literature suggests Carreau's model as a

satisfactory rheological model to characterize the blood's behavior. To evaluate the residence time of the blood cells, particles were injected in the same direction as the flow in all the simulations.

The catheters used in this study have geometrical variations on the side holes for the inlet and outlet lumens (no side holes, straight side holes, conical side holes, and oblique side holes). According to Owen (2020), the inclusion of side holes in a symmetrical catheter has shown an increase in its performance, with a higher flow rate inside the catheter and decreasing the shear stress. It is expected that the results point to higher efficiency for oblique and conical catheters comparing to the others, according to the literature, due to the direction of the geometry. Finally, it is also intended to culminate in the evaluation of the catheters based on the PLI, an indicator accepted by the medical community.

2. METHODOLOGY

The governing numerical equations applied in this study using the ANSYS Fluent 2020 Academic Version were: mass conservation, Eq. (1):

$$\frac{\partial \rho}{\partial t} + \vec{\nabla} \cdot (\rho \vec{u}) = 0, \quad (1)$$

where ρ is the fluid density, t represents the time, \vec{u} is the velocity field, and $\vec{\nabla}$ is the nabla operator; and the momentum conservation:

$$\frac{\partial(\rho \vec{u})}{\partial t} + \vec{\nabla} \cdot (\rho \vec{u} \vec{u}) = -\vec{\nabla} p + \vec{\nabla} \cdot (\vec{\tau}), \quad (2)$$

where p is the pressure, and $\vec{\tau}$ is the viscous part of the stress tensor. The velocity magnitude $U = |\vec{u}|$ should be further employed to characterize the velocity field.

2.1 Catheter's geometries

A double lumen symmetrical catheter of size 12 Fr (French) was developed with the use of Space Claim, from ANSYS 2020 R2. The side holes were added using the same catheter to evaluate the influence of variations in PLI only through different side holes in the inlet and outlet lumens.

As a way to decrease the computational time, bilateral symmetry simplification was applied. The catheter with no side holes is presented in Fig. 1 below.



Figure 1. No side holes symmetrical double-lumen Central Venous Catheter.

The dimension of the vein in which the catheter is inserted was defined based on Owen (2020), with a diameter of 20 mm. The dimensions of the catheter and the vein are shown in Tab. 1.

Table 1. Catheter and vein dimensions.

Catheter external diameter	4 mm (12 FR)
Catheter intern diameter (Double – D design)	3 mm
Wall thickness between inlet and outlet lumens	0.2032 mm
External wall thickness	0.3302 mm
External wall thickness in the tip of the catheter	0.1651 mm
Vein internal diameter	20 mm

The catheter dimension was based on articles, manufacturers' catalogs, and patents available such as Medtronic's catalog (2020) and the patent US1019533 (2019). The side holes are based on the study of Owen (2020), which evaluated the platelet activation in different types of catheters. One of the suggested ideas for future works is the proposal of an

alternative geometry that reduces the effects of platelet activation. The side holes submitted to the simulation are located at a distance of 25 mm from the rip of the catheter and are presented in Fig. 2 below.

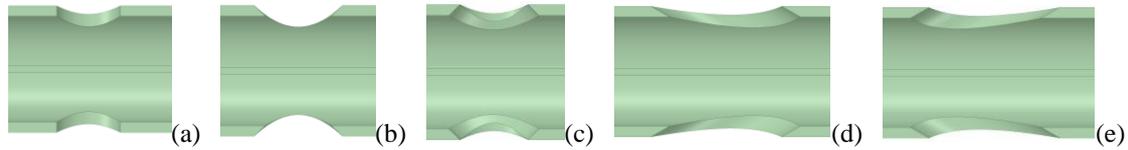


Figure 2. (a) Straight side holes; (b) Conical side holes 1; (c) Conical side holes 2; (d) Oblique side holes 1; (e) Oblique side holes 2.

The side holes have a 2 mm diameter and the holes with an angled cut have a 30° with the external wall of the catheter.

2.2 Mesh

The mesh was built of finite volumes inside the vein and the lumens of the catheter. Due to geometry variations inside the domain, an unstructured tetrahedral mesh was applied with increased refinement at the internal and external regions of the catheter and the surface of the vein. The size of the volumes was set using the inflation and face sizing properties and the volume has a size in the order of 0.0013 m, outside the catheter, to 0.00016 m inside the entry lumen. This variation represents 38.85% of the catheter diameter at the external region and 4.78% for the internal region. The mesh setting used in all simulations is presented in Tab. 2 below.

Table 2. Mesh parameters applied to the symmetrical catheters.

Parameter	Domain section	Setting
Body Sizing	All the domain	$1.3 \cdot 10^{-3}$ m / Soft
Inflation	Internal vein surface	10 layers/Growth rate: 1.2
	Internal entry lumen surface	10 layers/ Growth rate: 1.2
	Internal exit lumen surface	5 layers/ Growth rate: 1.2
Face Sizing	External catheter surface	Element size: $2.25 \cdot 10^{-4}$ m
	Internal entry lumen surface	Element size: $1.6 \cdot 10^{-4}$ m
	External entry lumen surface	Element size: $3 \cdot 10^{-4}$ m
	Internal side holes surface	Element size: $1.6 \cdot 10^{-4}$ m

The mesh convergence study was based on the method proposed by Celik (2008) to obtain the Grid Convergence Index (GCI). With the use of 3 meshes of a different number of volumes, each one having 50% fewer volumes than the immediately most refined, the GCI and the average velocity were obtained for each mesh and compared with Richardson's approximation for velocity. The mesh study outcomes are presented in the results.

2.3 Blood rheological model

Blood can be modeled as a non-Newtonian fluid, meaning that its viscosity is not constant, and change depending on the shear stress. Therefore, the shear stress is not directly proportional to the strain rate.

Based on this principle, the literature has various rheological models that can characterize non-Newtonian fluids. The study of Karimi (2014) compares 9 different non-Newtonian rheological models for the simulation of blood flow, and their results showed that the Carreau model (Carreau, 1968) satisfactorily describes the blood flow behavior. Owen (2020) and Comin (2019) used this rheological model to simulate blood through catheters. In this way, Carreau's model is defined by Eq. (3).

$$\mu = \mu_{\infty} + (\mu_{\infty} + \mu_0)[1 + (\lambda\dot{\gamma})^2]^{\frac{n-1}{2}} \quad (3)$$

where μ is the fluid viscosity that varies with the strain rate $\dot{\gamma}$. μ_{∞} and μ_0 are the viscosity for high and low strain rate, respectively, λ , time constant for the transition period between constant and variable viscosity, and n is the power-law index. The blood's density is defined as $\rho = 1050$ Kg/m³. The values applied for the blood modeling at Eq. (3) are presented in Tab. 3 below.

Table 3. Parameters applied for Carreau's model.

$\mu_{\infty} = 0,00345 \text{ Pa} \cdot \text{s}$
$\mu_0 = 0,025 \text{ Pa} \cdot \text{s}$
$\lambda = 25 \text{ s}$
$n = 0,25$

2.4 Boundary conditions

The inlet velocity of the vein is considered constant, with a magnitude of 0.3 m/s, according to Mareels (2007). And the outlet region of the vein is defined as a constant pressure of 0 Pa. The inlet and outlet regions inside the catheter are defined the same as Owen (2020) and Timothy (2015), a mass flow of 0.0035 kg/s and a negative pressure of -905 Pa , respectively. The negative pressure generates the suction effect of the peristaltic pump inside the dialysis machine.

The vein is considered as a wall with no-slip conditions, as well as the catheter. The symmetrical plane that splits the geometry is defined as symmetry at Fluent. This setting assures that the geometry will be mirrored after the simulation and that any variation of the velocity field occurs with the fluid passing through the symmetrical plane.

Figure 3 below shows the inlet, outlet, wall, and symmetry regions of the domain.

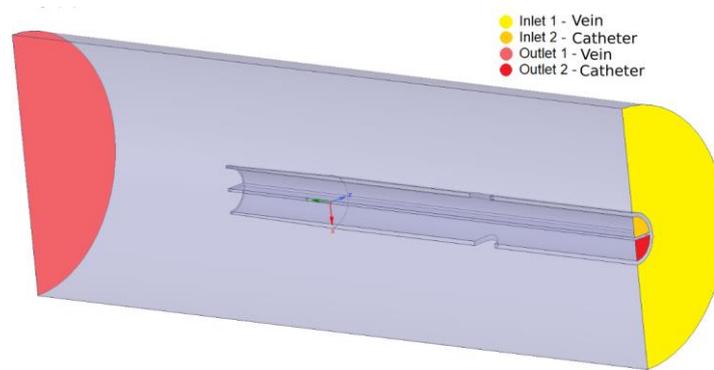


Figure 3. Computational domain showing the inlet and outlet regions of the fluid flow.

2.5 Convergence criteria and simulation setting

The convergence criteria applied in the simulation to all the geometries were: continuity residual lower than 10^{-2} ; and mass flow of -0.0035 kg/s at the outlet plane inside the inlet lumen of the catheter. The convergence was met after 25,000 iterations.

The solutions of the governing equations were obtained applying the SIMPLE scheme with the gradient solved through Least Squares Cell Bases, pressure by Second Order and momentum, Second-Order Upwind. The relaxation coefficients applied in the simulations are shown in Tab. 4 below.

Table 4. Relaxation coefficients.

Pressure = 0.3
Density = 1
Body forces = 1
Momentum = 0.7

Since is not possible to obtain the shear stress of the fluid over the catheter by default with ANSYS, a User Defined Function (UDF) in C language was compiled and hooked to the simulation to calculate the shear stress after the convergence. The UDF obtains the shear stress through the velocity gradients of the fluid and its viscosity provided by the Carreau model.

The CGI was applied with the use of an Excel spreadsheet. The results of the velocity, shear stress, and residence time fields were processed with the CFD-Post from ANSYS 2020 R2 and MATLAB 2012b.

2.6 Residence time and cell lysis

The residence time is obtained from the particle's injection inside the blood flow to represent the platelet and the red cells. The particles were set massless and injected at the same two inlet planes of the domain (vein and outlet lumen of the catheter). Based on the results of the simulation, it is possible to correlate the residence time with the shear stress of the flow and get data on the residence time of particles under a region of high shear stress.

The most accepted way to evaluate the efficiency of a catheter is through the Platelet Lysis Index (PLI), proposed by Giersipen (1990), and applied on catheters in the studies of Timothy (2015), Haniel (2019), and Owen (2020). The PLI is defined by Eq. (4).

$$PLI = At_p^{0,77} \tau_p^{3,075} \quad (4)$$

where $A = 3,31 \cdot 10^{-6}$ is an experimental constant, t_p , the residence time of a particle and τ_p is the shear stress over the particle's path.

The PLI obtained in this study has considered the residence time of the particle inside the domain when exposed to stress fields of 10 Pa and 30 Pa. 10 Pa is considered a minimum value of pressure to cause platelet lysis without the need to look at the resistance time of the particle. And the minimum value to occur hemolysis is 30 Pa. However, both the platelet lysis and the hemolysis can happen for a longer residence time combined with regions with lower shear stress.

2.7 Post-processing

The results of velocity through time and shear stress through the total time of the particles injected into the domain were exported from Fluent to MATLAB 2012b and processed to generate mean values and graphs to compare quantitatively. For each particle, the values of shear stress and velocity magnitude by the time were obtained. From these data, the arithmetic mean and standard deviation were calculated for each particle by Eq. (5) and Eq. (6) below.

$$\bar{x} = \frac{1}{m} \sum_{i=1}^m x_i \quad (5)$$

$$s_x = \sqrt{\frac{1}{m-1} \sum_{i=1}^m (x_i - \bar{x})^2} \quad (6)$$

where m is the number of points through the time of the analyzed parameter and x_i is the value of the parameter. The PLI was obtained applying Eq. (4) on the mean values of shear stress and the residence time of the particles inside the domain. The mean PLI is defined by the mean PLI for each particle injected.

The variables used to compare each catheter were the PLI, residence time, and the mean shear stress of each geometry.

3. RESULTS

3.1 Mesh study

The mesh study applied as proposed by Celik (2008) and the results for the 3 meshes are presented in Fig. 4 below.

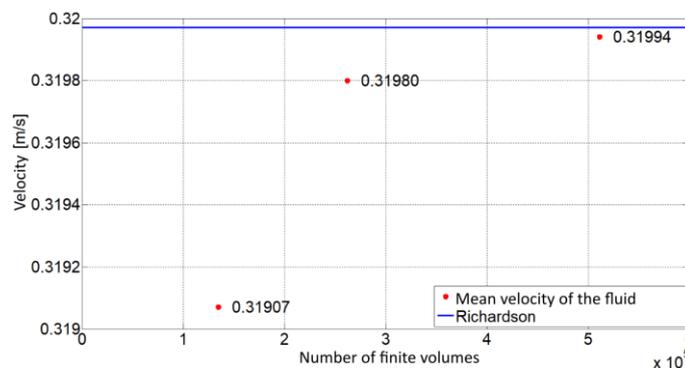


Figure 4. Average velocity per number of finite volumes for each mesh.

In Fig. 4 we verify a satisfactory approximation for the mesh of 511,610 finite volumes with an error near to 0.0094% to the velocity obtained with Richardson's approximation. With this error, the mesh independence is guaranteed for the

mesh of 511,610 finite volumes. Therefore, the simulation results are not impacted significantly by the mesh of the domain.

The GCI values of Celik's method for mesh convergence are shown in Tab. 5 below.

Table 5. Grid Convergence Index.

Convergence Index	
GCI_{32}	0.000674
GCI_{21}	0.000129
Proximity GCI_{32}/GCI_{21}	0.000671

At Tab. 5, the proximity for the ratio between the meshes analyzed gave a value similar to the GCI_{32} . This similarity confirms that the solutions obtained for the most refined mesh are inside the asymptotic convergence region and provide more data for the mesh independence achieved as shown in Fig. 4.

3.2 Velocity Magnitude Field

The velocity fields obtained with the simulations enable the identification of the effects caused by the side holes geometries over the blood flow. The symmetry plane was chosen to present the velocity fields because it corresponds to the central region of the catheter.

Figure 5 below presents the velocity magnitude fields plotted by CFD-Post. It is possible to observe the fluid flow differences for each side hole, as well the effects over the tip of the inlet and outlet lumens. The fluid through the domain presented a maximum velocity between $2.69 \text{ e } 3.08 \text{ m/s}$. These maximum values can be found inside the lumens.

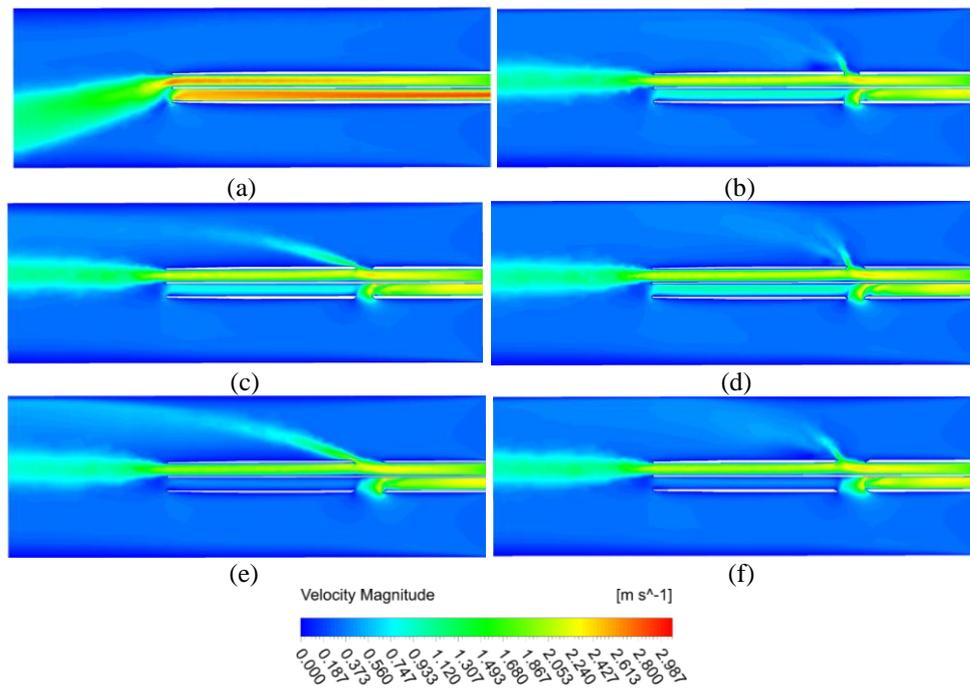


Figure 5. Velocities fields: (a) No side holes; (b) Straight side holes; (c) Conical side holes 1; (d) Conical side holes 2; (e) Oblique side holes 1; (f) Oblique side holes 2.

Figure 5a shows an alteration in the blood flow trajectory due to the suction produced by the negative pressure of the entry lumen. Moreover, it is the catheter that presents the best-developed flow inside the lumen due to the absence of side holes. The fluid flows through the exit lumen of the remaining catheters are similar in trajectory. It is possible to evidence, in catheters with side holes, a decrease of blood velocity in the inflow lumen, in the regions between the tip of the catheter and the side hole. This can be explained by the addition of the side holes that decrease the blood flow on the tip since the hole is closer to the negative pressure generated by the equipment.

In some cases, as in catheters with oblique side holes, Fig. 5e and 5f, the fluid velocity in this region is close to zero, not impacting the flow in the rest of the lumen. It can be stated, then, that the oblique geometry causes the fluid to flow more smoothly within the entrance lumen.

3.3 Shear stress fields

The shear stress fields calculated by Fluent, using a UDF, are presented in Fig. 6 below. It is possible to see the effect of the variation of geometry on the shear stresses caused by the non-Newtonian fluid.

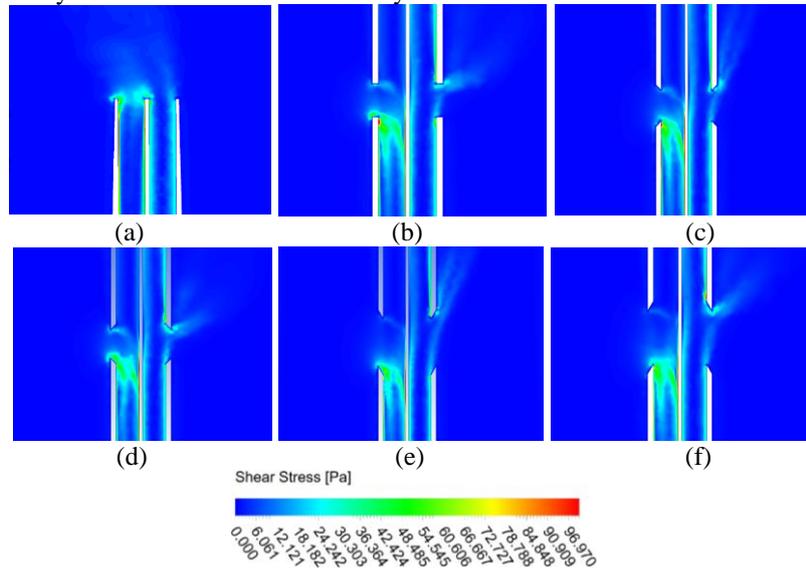


Figure 6. Shear stress fields: (a) No side holes (b) Straight side holes; (c) Conical side holes 1; (d) Conical side holes 2; (e) Oblique side holes 1; (f) Oblique side holes 2.

In Fig. 6b, a large region of high shear stress was observed both at the entrance and exit of the catheter lumen. This behavior is related to the abrupt change in the profile of the right-angled lateral hole. When compared to smoother profiles, such as the conical and oblique side holes catheter, Fig. 6c and 6f, the region of high shear stress is smaller.

For the conical catheters, even with a smaller area of high shear stress compared to those with straight side holes, it is possible to see in Fig. 6c and 6d some critical regions of shear on the wall of the entrance lumens and the edge of the hole in the exit lumen.

The simulations performed on the catheters with oblique side holes resulted in the shear stress fields in Fig. 6e and 6f. It can be seen that the catheter with oblique side holes 1 presents critical regions of shear, both at the entrance and at the exit of the catheter, which extends until the division of the lumens. For the catheter with oblique side holes 2, which has an inverse hole geometry to oblique side holes 1, a significantly smaller stress field is seen, but with critical regions on the inner wall of the catheter and in the exit lumen side hole.

3.4 Injected particles

The particle injections into the flows presented in the previous section allowed the register of the shear stresses within the particles' trajectory, mimicking the blood cells. For each catheter, around 834 to 993 particles were injected into the vein and catheter entry regions. The mean values of residence time, shear stress, and velocity magnitude, the last two accompanied by their standard deviations, are presented in Tab. 6 below.

Table 6. Data obtained by tracking the injected particles throughout the domain.

Catheter	\bar{t}_p [s]	$\bar{\tau}_p$ [Pa]	s_{τ_p} [Pa]	\bar{U} [m/s]	s_U [m/s]
No side holes	0.2024	4.5466	3.5366	0.6900	0.2820
Straight side holes	0.2176	4.7108	4.4271	0.6392	0.2576
Conical side holes 1	0.1854	5.0605	5.3009	0.6523	0.2645
Conical side holes 2	0.1830	4.9397	4.5700	0.6397	0.2592
Oblique side holes 1	0.5819	4.8635	4.1664	0.6516	0.2586
Oblique side holes 2	0.4108	4.0434	3.8686	0.6306	0.2548

According to Tab. 6, the average residence time of each catheter, composed of the total average of the time of the particles inside the domain for each catheter, presented higher values for catheters with oblique side holes, in comparison to the catheter without side holes.

This behavior was not expected, because it was believed that the absence of side holes would increase the mean value of time, since, for the blood to enter or leave the catheter, the trajectory inside the lumens is longer. This can be justified by the region commented in the previous section, in Fig. 5e and 5f, with low velocity due to the presence of the side hole, which reduces the velocity of the particles, providing a consequent increase in the residence time between the entry lumen and the side hole.

The average particle velocities in each catheter returned values significantly lower than the maximum reached by the fluid, as noted in the previous section. From Tab. 6, the mean velocity values and the standard deviation of the particles remained similar between the catheters, without showing significant influence regarding the geometry of the side holes.

For the shear stresses, in Tab. 6, the average values obtained were between 4.04 Pa and 5.06 Pa, with the lowest stress being in the oblique side hole 2 catheter and the highest, in the conical side holes 1 catheter. The standard deviation returned high values when compared to the mean values, and this is justified by the particles that went through the high shear regions presented previously, as well as the large region of low shear stress between the external side of the catheter and the vein.

3.5 PLI, platelet activation, and hemolysis

The average PLI was estimated from the results of residence time and shear stress on each particle. By calculating the average PLI in each particle, the average PLI in each catheter was obtained. The Platelet Activation Index values are shown in Tab. 7 below.

Table 7. Mean values of Platelet Lysis Index (PLI) for each catheter.

Catheter	Mean value of PLI
No side holes	0.0080
Straight side holes	0.0024
Conical side holes 1	0.0012
Conical side holes 2	0.0249
Oblique side holes 1	0.0208
Oblique side holes 2	0.0037

From Tab. 7, the conical side holes 2 and oblique side holes 1 catheters were the ones that returned the highest PLI values compared to the others. This can be explained by the fact that the shear stress fields for these geometries presented critical regions in the side holes, as discussed in the previous section. The catheter without side holes also showed a critical stress field at its tip, but in a smaller region, thus being the third-highest PLI. The catheter with straight side holes, even with a region of high shear stress, did not significantly influence an increase in PLI by the particles. We can see that just variations in the geometry of the side holes of the same base symmetric catheter can significantly impact blood cell integrity.

As exposed in the previous chapter, the critical shear stress values for the occurrence of platelet activation and hemolysis are 10 Pa and 30 Pa, respectively. In Fig. 7 below, the percentage of particles, in each catheter, that are above the critical values are presented.

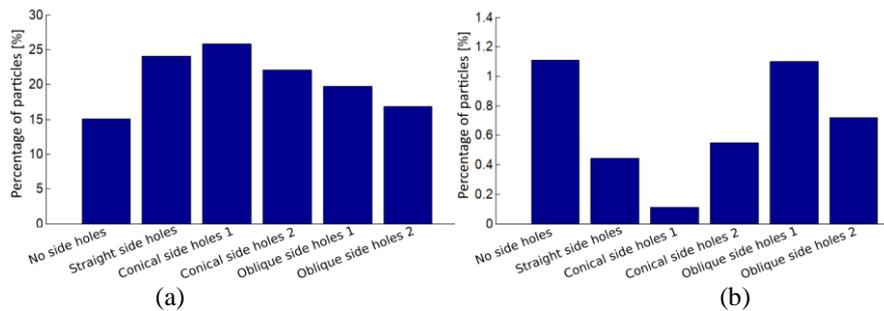


Figure 7. (a) Percentage of particles under platelet activation in each catheter ($\tau_p > 10$ Pa); (b) Percentage of particles under hemolysis in each catheter ($\tau_p > 30$ Pa).

Figure 7a shows that the catheter with conical side holes 1 has the highest percentage with 25.83% of the particles under platelet activation. The catheter with no side holes, on the other hand, presents 15.02% of platelet activation.

According to Fig. 7b, some of the percentage values of particles under hemolysis are the opposite of those under platelet activation. The conical side hole 1 catheter, for example, which has the highest percentage of platelet activation,

has the lowest percentage of hemolysis, 0.11%. This observation is also valid for the no side holes catheter with the highest percentage of particles under hemolysis and for the straight side holes catheter, which presents an inverse behavior.

However, the oblique hole catheter 1 has both a high percentage of particles under platelet activation and hemolysis, 19.78%, and 1.1%, respectively, concentrating a significant number of particles in regions of high shear stresses. As presented in the stress fields, this geometry returned the most critical shear stress profile among all, which may justify the results obtained for the particles.

4. CONCLUSION

The numerical study performed in different geometries of catheter side holes, to apply PLI as a way to quantify the efficiency of a catheter, made it possible to understand the effect of the quantities involved in the flow. It can be concluded that changes in the hole geometry significantly impact the flow, reflecting on the residence time, shear stress, and particle velocity.

Another point brought up in the study is that catheters with lateral holes may be less harmful to blood cells when comparing the mean values of PLI obtained and the distribution of shear stresses. This justifies its current use in dialysis therapy, besides the fact that a catheter with more side holes is more compatible with the varied forms of vascular access for each patient.

For the catheters analyzed in the simulations, it is possible to conclude that the catheters with the worst performances are the catheters with oblique side holes 1 and conical side holes 2. The geometries presented a critical shear stress region, high mean values of PLI, and also of particle rate under platelet activation and hemolysis, the last one only for the catheter with oblique side holes 1. The catheters that presented the best performance, based on the parameters used, were the ones with no side holes, straight side holes, and conical side holes 1. The particles injected on these geometries presented low mean values of PLI and the lowest mean particle rates under platelet activation, although it does not consider the time of the particles under these stresses. For the hemolysis rate, the catheter with no side holes presented one of the highest percentages, however, this only represents 1.11% of the particles under these shear stresses.

It is important to emphasize that the increase side holes may either increase the useful life of the catheter, allowing more access routes to the blood or accelerate platelet activation, generating clots inside the lumens and obstructing blood access. Thus, the decision of the type of catheter geometry to be used in the patient is up to the specialized health professional who must evaluate the difficulties of vascular access for the use of catheters with side holes or not, since, according to the study presented, there are catheters with side holes that have low PLI, combined with a low rate of platelet activation and hemolysis.

Some topics for future works based on the results of this study are: estimate the residence time of particles in regions of high shear stress, this can return more accurate values of standard deviation; apply this same study on catheters with different shape of side holes, in the market can be found catheters with rectangular and spiral side holes, for example; simulate with a different configuration of particles refinement, some mean values of PLI obtained were significantly higher than other just by the variation in the refinement; determine the rate of blood recirculating at the tip of the catheter, as seen in the no side holes one.

5. ACKNOWLEDGEMENTS

This optional section must be placed before the list of references.

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