Comparative Analyses of Blood Flow Through Mechanical Trileaflet and Bileaflet Aortic Valves

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Abstract

The paper describes one of many issues concerning the human circulatory system. The simulation of blood flow through an artificial aortic heart valve using the finite element method (FEM) is the main subject of the paper. The studies aim to verify the performance of mechanical aortic valves of two types, i.e. bileaflet (BIL) and trileaflet (TRI) valves. The blood was modelled as Newtonian and non-Newtonian. Although the design of our TRI valve is preliminary and needs to be optimised, our results highlight some advances of such a valve geometry. This is manifested mainly by a central blood jet, contributing to more physiological blood flow and decreasing the risk of haemolysis. The central flow minimises the risk of leaflet dislocation. In addition, lower stresses extend the durability of the valve. However, the TRI valve geometry has also disadvantages, for instance, the occurrence of small peripheral streams or relatively low effective orifice area. The valves' performance was assessed by means of the reduced stress in the valves, the shear stress in the aortic wall, flow velocity field, and the effective orifice area. The maximum von Mises stress for the BIL valve leaflets is 0.3 MPa, and for the TRI valve: 0.06 MPa. The maximum flow velocity for the BIL valve is 4.52 m/s for 40° and for the TRI valve is 5.74 m/s. Higher shear stress is present in the BIL (151.5 Pa) than for the TRI valve (49.64 Pa).

Introduction

Artificial heart valves, often referred to as mechanical valves, have been implanted since the 1950s. Every year, around 300 000 artificial heart valves are clinically applied [1]. By the highest systemic loads, the most frequently replaced valve is the aortic valve.

The function of the aortic valve is to regulate the blood flow constantly. Any malfunction of the valve can lead to the creation of coagulated masses of blood, which flows through the cardiovascular system can cause undesirable obstruction of vessels of small cross-sections. The bileaflet (BIL) mechanical aortic valve has been studied for years. Many aspects related to its functioning were investigated in vitro or in silico, such as structural strength [2], damage of platelets [3], flow patterns and shear stress distribution [4], the valve overall hydrodynamic performance, the valve closing sounds or the cavitation phenomenon. Despite many studies, there is still a problem with thrombus formation, leading consequently to anticoagulation therapy, in patients with an implanted mechanical heart valve. It has been reported that an unphysiological fluid flow pattern determines thrombosis formation. Therefore, we started to work on designing a mechanical trileaflet heart valve that would correspond to the construction of the natural aortic valve and allow for central blood flow. Unlike other researchers, we included the ventricle in the simulation and adopted the non-Newtonian nature of blood flow to represent the physiological flow of the blood stream.

Recent numerical simulations of blood flow through mechanical valves have shown various approaches in modelling the haemodynamic effects. The haemodynamic consequences of blood flow across a mechanical valve were studied in silico with different flow patterns (laminar or turbulent), blood was defined as a Newtonian or non-Newtonian fluid, and various boundary conditions were assumed. Abbas
et al. [5] investigated how the tilting angle of BIL implantation influences blood flow rate and shear stress distribution in the leaflets. They modelled blood as a non-Newtonian fluid and assumed the flow to be laminar. A physiological blood velocity profile was set at the inlet of the numerical model to simulate the flow. On the other hand, Kuan et al. [6] investigated hinge microflow fields of bileaflet mechanical heart valves, modelled blood as a Newtonian fluid. They prescribed the velocity and pressure boundary conditions at the inlet and outlet by using the given wavefront. A similar approach related to boundary conditions was presented in [7], where the authors presented the effects of pannus formation on blood flow through a bileaflet heart valve and the dynamical performance of BIL during the whole systolic phase, respectively. Also, in [8], the velocity profile was set at the inlet. However, the authors implemented the three-element Windkessel model to predict pressure at outlets. The numerical model presented in [9] assumed pressure boundary conditions at the inlet and outlet of the blood vessel under consideration. The authors developed an integrated fluid-structure interaction (FSI) model using smoothed particle hydrodynamics for the fluid domain coupled to a nonlinear finite element formulation. The FSI model was also applied in [10], where the effect of nonlinear leaflet material properties on aortic valve dynamics was investigated. When the flow is fully developed at the outflow, the boundary conditions can be of the Neumann type, i.e. a zero-gradient pressure or a zero-gradient velocity. Such an approach is presented in [11], where the authors showed the results of blood flow simulations and described trends of flow fields and shear stress distribution in the aorta wall. Table 1 summarises briefly the review of blood flow modelling through the bileaflet mechanical aortic valve.
| Paper | Aim of study | Blood flow | Boundary conditions (BCs) |
|-------|--------------|------------|--------------------------|
| [2]   | Structural strength comparison of two BMHV s | No blood flow | Fluid pressure applied on leaflet surface |
| [3]   | Simulation of platelets around hinges during the mid-diastole phase | Laminar, Newtonian fluid | Flat level velocity BC and stress-free BC |
| [4]   | Investigation of flow downstream of a dysfunctional BMHV | Turbulent, k-ω model, Newtonian fluid | Velocity flow BC (inlet), ambient pressure (outlet) |
| [5]   | Numerical quantification of the implantation tilt angle of BIL on platelet activation | Laminar, Carreau-Yasuda model, Non-Newtonian fluid | The physiological blood velocity profile |
| [6]   | Comparison hinge microflow fields of BIL | Turbulent, Spalart-Almaras model, Newtonian fluid | Velocity and pressure BCs were prescribed using the given waveforms |
| [7]   | Pannus formation on blood flow through a bileaflet heart valve | Turbulent, Newtonian fluid | Physiological inflow rate |
| [8]   | To elucidate the effect of coronary arteries in the leakage flow through hinges in BILs | Non-Newtonian fluid | Velocity boundary conditions, Windkessel model at outlets |
| [9]   | To develop a fully-coupled fluid-structure interaction framework that combines smoothed particle hydrodynamics and nonlinear finite element method to be applied in the investigation of the aortic and mitral valve’s response | Smoothed particle hydrodynamics | Pressure profile |
| [10]  | Investigation of nonlinear leaflet material properties influence on aortic valve dynamics | Turbulent, Newtonian fluid | Pressure profile |
To determine the fluid and structural dynamics of aortic valves

| Paper | Aim of study | Blood flow | Boundary conditions (BCs) |
|-------|--------------|------------|--------------------------|
| [11]  | Turbulent, Newtonian fluid | Zero-gradient pressure |

There are relatively few reported studies of blood flow simulation through a trileaflet (TRI) mechanical aorta valve. Claiborne et al. [12] conducted an optimisation process of a trileaflet valve simulating blood as a Newtonian fluid in a turbulent flow. They imposed velocity boundary conditions at the inlet and zero pressure at the outlet. They aimed to optimise the leaflet profile to obtain the lowest pressure gradient in forwarding flow, lowest max velocity in forwarding flow, and the highest effective orifice area. The findings they achieved allowed them to advance valves closer to clinical viability. A polymeric valve was also a subject of interest of other studies [13]. The authors analysed the haemodynamic and thrombogenic performance of the trileaflet valve using simulation of blood flow as a Newtonian fluid. They defined the boundary conditions in terms of energy sources using the Mie-Grüneisen equation of state relating pressure and internal energy per unit volume. However, they do not provide the Grüneisen parameters for blood, they used parameters adequate for water. Recently, several studies related to how a TRI valve affects blood flow have been developed. Bruecker and Li [14] introduced an in-vitro pulse-duplicator generating early helical flow in the valve plane and experimentally investigated the influence of that flow on fluid behaviour after bi- and trileaflet valves in the ascending aorta. They hypothesised that physiological right-handed helix in the ascending aorta might partly be maintained by early swirl in the ventricle outflow tract entering the aortic arch. They concluded that the TRI valve better conserved the helical flow than the BIL valve. Schaller et al. [15] implanted four novel mechanical prostheses of the aortic valve in sheep. The mechanical valves consisted of three leaflets made of poly-ether-ether-ketone. The housing was manufactured from medical-grade titanium-aluminium-vanadium alloy (TiAl6V4). Their research aimed to ameliorate the mechanical valve's haemodynamic performance and reduce anticoagulation treatment. The in-vivo preliminary results were auspicious because the valves induced excellent haemodynamic and are characterised by a shallow risk of thrombotic events.

The primary aim of the present study is to compare the BIL and TRI aortic valves' performance during uniform blood flow model and boundary conditions. To complete the task, we performed numerical simulations of the flow through the TRI valve. The review of the literature shows that the blood flow simulations are conducted under various assumptions. The available comparative studies pertaining BILs and TRIs show superiority of TRI valves over BILs [16, 17]. In the cited research, however, the authors simulated blood as a Newtonian fluid and investigated a polymeric TRI valve [16] or a metallic one with thin leaflets [17]. The authors of the latter paper stated that their findings might help to improve the development of the TRIs further. Our research follows that conclusion and introduces a design of a TRI valve and compares its haemodynamic performance with a BIL valve. The results of the simulations may contribute to the determination of new design parameters for trileaflet aortic valves, which will improve their cardiologic performance and ensure proper haemodynamic parameters. The TRI design presented in the paper is the first conceptual approach that we wanted to verify.
The secondary aim of our study is to determine the effect of Newtonian/non-Newtonian fluid flow assumption on blood flow directly behind the trileaflet valve, as that concerning the bileaflet valve is very well known [18].

In the paper, 3D flow patterns and velocity profiles of blood flow in the aorta behind the two types of mechanical valves are presented. Achieving more real behaviour of blood stream during cardiac cycling is possible by including the ventricle in the numerical model. By direct comparison of the numerical results, we could assess the performance of the valves from the haemodynamic point of view.

**Methods**

**Geometrical modelling**

The geometrical model of the whole system consisted of the left ventricle and a fragment of the aorta. The model was based on the data available on the GrabCAD platform (https://grabcad.com/), which enables users to download geometric models, including models of anatomical parts of the human body. We used SolidWorks 2019 CAD software to create the 3D models of the anatomical components of our system and those of the valves (Figure 1).

In our study, we considered two types of mechanical valves, i.e. bileaflet valve and trileaflet valve. It has to be noted that although the models are based on the known designs of bi-and trileaflet valves, our models of the valves differ from them mainly in the construction of the annular ring. The internal diameter of the outlet of both prostheses is 21 mm, the external diameter of the ring is 27 mm, the profile height is 16,5 mm. Additional, for the TRI valve, we proposed a new leaflet curvature (Figure 2). The shape of the leaflets influences the pattern of velocity fields, which determine the haemodynamic quality of the valve. The design of the valve prostheses enables unidirectional blood flow. The valve outlet surface is tapered. It is modelled in a way to reduce flow turbulence. In the presented model of a BIL valve, the ring has additional covers to protect the leaflets in the closed position. The leaflets of both valves are embedded in blind holes, allowing them to rotate freely between 0° (fully open) and 60° (fully closed). In the open position, the plane of the leaflets of a BIL valve forms an angle of 90° to the surface of the outlet. The presented models are simplified. In fact, the ring's rim is lined with material, attached through titanium fastening rings, which enables the valve to be implanted in the outlet of the aorta.

The internal diameter of the ascending aorta was assumed to be 27 mm and its length 40 mm. The valve ring inside the aortic outlet was projected, which allowed us to define the constraints determining the valve position in the system.

**Boundary conditions**

Two different numerical methods are widely used in the study of flow through heart valves. One approach neglects the leaflet motion, focusing on fixed leaflets with constant or pulsatile flow [19, 20]. The other method is to simulate the movement of the leaflets. In our research, we decided to analyse the blood flow...
at three positions of the valves’ leaflets defined using angle with respect to the vertical plane (passing through the symmetry axis of the valve) 40°, 20° and 0° (fully opened valve). A scheme of the complete opening of the valve is shown in Figure 3.

A representation of pulsatile flow was obtained by measuring blood flow velocity [21-23]. The correlation of the flow velocity and the time opening of the leaflets was determined utilising the Doppler ultrasound examination in an adult human being [21]. A 6th-degree polynomial interpolation (Equation (1)) was used to describe the flow mathematically. In the time span from 0.36 s to 0.38 s a linear function was adopted (Equation (2)). The flow velocity at the time that followed until the end of the cycle was described using Equation (3). The length of one cycle was assumed to be 0.8 s. Heart rate was 75 beats per minute.

\[
\begin{align*}
\text{for } t \in <0;0.36 \text{ s}) & \\
\quad v &= 10259.13 \cdot t^6 - 13602.92 \cdot t^5 + 6827.23 \cdot t^4 - 1500.76 \cdot t^3 + 90.61 \cdot t^2 + 9.54 \cdot t \\
\text{for } t \in <0.36;0.38 \text{ s}) & \\
\quad v &= 2.5 \cdot t - 0.95 \\
\text{for } t \in <0.38;0.8 \text{ s}) & \\
\quad v &= 0
\end{align*}
\]

Equation (1)

It was assumed that the valve opens at 0.04 s of the flow cycle, and the process of the valve opening lasts 0.04 s [24]. The valves are, thus, fully opened after 0.08 s of the flow cycle. Regarding this, the values of the flow velocity at the considered leaflet positions were estimated utilising Equation (1).

The flow velocity values were determined at the inlet, which was defined at the entrance to the left ventricle. A constant pressure of 14 kPa was described at the aortic outlet, corresponding to the average pressure of the systolic and diastolic phases in a healthy human [25]. Boundary conditions are summarised in Figure 4.

The pulsatile nature of the blood and the geometry of the natural system means that vortices can form behind the aortic valve. To reflect physiological flow as accurately as possible, we have assumed turbulent blood flow and utilized the k-ε model to define its turbulent characteristics.

There is a general opinion that blood can be modelled as Newtonian in the case of large arteries. In our work, we investigate the shear effect, for which the fluid model adopted can be of great importance. We, therefore, considered two blood models (Newtonian and non-Newtonian) during blood flow through the TRI valve. Based on the results, we determined how the adopted blood model affects the results. Blood flow through the BIL valve was modelled as non-Newtonian.

By defining blood as incompressible Newtonian fluid we assumed the density \( \rho = 1060 \text{ kg/m}^3 \) and viscosity \( \mu = 0.0035 \text{ kg/(m·s)} \) [26]. For the non-Newtonian blood flow, we defined the Carreau model. We
have assumed the following parametric values: relaxation time constant $\lambda = 3.313$ s, zero shear rate limit $\mu_0 = 0.056$ Pa•s, infinite shear rate limit $\mu_\infty = 0.0035$ Pa•s and power low index $n = 0.3568$ [27].

The ventricle and aorta materials were assumed to be isotropic and elastic medium with the Young modulus $E_a = 1$ MPa and Poisson's ratio $\nu = 0.49$. The leaflets were also modelled as an isotropic elastic solid material with the Young modulus $E_l = 2884$ MPa, $\nu_l = 0.39$, and the ring material was modelled as titanium alloy Ti-6Al-4V, whose characteristic mechanical parameters are: $E_r = 1.07 \times 10^5$ MPa, $\nu_r = 0.3$.

**Numerical modelling of blood flow**

Blood flow through a valve is a complex phenomenon. It includes both the movement of the fluid and the movement of the valve leaflets. The dynamics of blood circulation were determined using ANSYS 2020 R2 software. Three modules for blood flow analysis were used. The Mechanical module allowed us to determine the stress in the valve as well as in soft tissues. The Fluent module was used to define the flow parameters. The System Coupling module provided data exchange. Such a solution made it possible to perform FSI analyses, which made it possible to determine flow characteristics and the influence of structural response on cyclic fluid movement.

Referring to the previously presented boundary conditions and turbulent blood flow, the k-ε flow model was adopted. Taking into account the possible deformation of the mesh during the calculation, the option "Smoothing" was selected, allowing for smoothing of the mesh and the "Remeshing" option, allowing for regeneration of the too much distorted mesh. For the spatial discretisation of the momentum and turbulence equations within the liquid zone, a "Second Order Upwind" was used. To determine the stress distribution across the entire system, the leaflet rotation constraints and the contact between the leaflet guiding elements and blind holes were defined. The friction coefficient was assumed to be equal 0.1. In order to determine stress distribution, the FSI bonds were determined. This allowed us to take into account the contribution of the fluid on the stress distribution in the valves and aorta.

A pressure-based solver was used for the calculations. The model mesh was made of 150 000 finite elements. The mesh densification was performed for the valve leaflets, valve ring and ascending aorta (these areas participated in the FSI analysis). The mesh density mentioned above is optimal. We have verified that the number of the finite elements, which define our model, higher than the mentioned value 150 000 influence the results, i.e. values of stress, by approx. 1%. The solid imitating blood was created with 3 million finite elements. The number of blood finite elements was also verified in terms of the accuracy of the results. The settings of the simulations were defined such that the data exchange between the Fluent module and Transient Structural was allowed. Each step was recalculated five times (maximum iteration = 5), preventing sudden stress value jumps and solver errors. The selection of a good quality mesh and an appropriate time step allowed for stable computations.

**Results**
Determination of stress distribution in the leaflets and streamlines of the blood flow velocity field in the aorta was our main interest. Figure 5 shows the stress distributions in the BIL and TRI valve leaflets in the positions considered. The mounting of the leaflets in the valve ring was also analysed. These stresses are a consequence of the interaction of flowing blood with the leaflets. The results of the study are summarised in Table 2. The results obtained give some insight into the strength of the leaflet attachment structure in annular rings. Figure 6 depicts the flow of blood in the aorta for the same leaflets’ positions.

| Table 2 | Maximum values of von Mises stress in the valves for the BIL and TRI (non-Newtonian and Newtonian fluid) valves |
|---------|------------------------------------------------------------------------------------------------------------|
| **BIL valve non-Newtonian fluid** |                                                                                                           |
| Leaflet position [°] | stress in the pivots [MPa] | stresses in the ring [MPa] | stresses in the centre of the disc [MPa] |
| 0       | 5,09 | 5,64 | 0,30 |
| 20      | 2,94 | 3,46 | 0,20 |
| 40      | 3,02 | 3,20 | 0,17 |
| **TRI valve non-Newtonian fluid** |                                                                                                           |
| Leaflet position [°] | stress in the pivots [MPa] | stresses in the ring [MPa] | stresses in the centre of the disc [MPa] |
| 0       | 1,51 | 2,18 | 0,06 |
| 20      | 0,63 | 1,21 | 0,02 |
| 40      | 2,31 | 5,66 | 0,05 |
| **BIL valve Newtonian fluid** |                                                                                                           |
| Leaflet position [°] | stress in the pivots [MPa] | stresses in the ring [MPa] | stresses in the centre of the disc [MPa] |
| 0       | 2,99 | 3,36 | 0,08 |
| 20      | 0,82 | 1,51 | 0,02 |
| 40      | 1,62 | 3,83 | 0,07 |

In addition, the flow velocity field was shown in Figure 7 to verify the symmetry of the flow. Secondary rotations in the ascending aorta were also analysed. In Figure 8, tangential components of the blood velocity for fully opened valves are presented.

Figure 9 shows shear stress in the ascending aorta wall induced by the flow in the considered positions of the leaflets, i.e. 0°, 20° and 40°.

To evaluate the performance of the two types of mechanical valves, we also calculated the effective orifice area $E_{OA}$, representing the cross-sectional area of the jet issuing from the valve at the point of its
most significant contraction. We used the corrected Gorlin formula in the form [28]:

$$E_{OA} = \frac{Q}{51.6 \sqrt{\Delta p}}$$  (4)

where: $Q$ is the root mean square of forwarding flow in mL/s, $\Delta p$ is the mean pressure difference across the valve in mmHg, and $\rho$ is the density of blood in g/cm$^3$. The number 51.6 is the gravitational acceleration constant. We assumed the blood density to be 1.06 g/cm$^3$. The mean pressure difference $\Delta p$, as well as the blood flow, were calculated in the numerical simulations of blood flow.

The maximum effective orifice area is 1.53 cm$^2$ for a BIL valve for an opening angle 0° and for a TRI valve 0.49 cm$^2$ (opening angle - 20°).

**Discussion**

The present work compares the performance of two types of mechanical aortic valves under the same flow conditions, i.e. flow type (turbulent), boundary conditions, and fluid model (Newtonian/non-Newtonian). Our aim was also to determine the effect of Newtonian/non-Newtonian fluid flow assumption on blood flow downstream of the trileaflet valve. In the paper, we proposed our design of the mechanical TRI valve, which differs from those already presented in the literature by the shape of the leaflets (Figure 2). Usually, authors offer a design with thin leaflets which, in the closed position, form a dome-like construction (see, e.g. [29]). The inner curvature of the leaflets is an additional factor contributing to vortex formation in the blood flow. In addition, due to the light construction of the leaflets, they violently decelerate at the valve closure, which causes haemolysis by squeezing the blood cells.

Studies on mechanical heart valves, including aortic valves, aim to decrease the risk of thrombosis, which requires anticoagulation treatment with various medicaments [30]. Such research is commonly conducted by means of in silico modelling. An alternative, although more expensive, might be ex vivo modelling [31]. Such a methodology was applied in the study of a novel trileaflet valve [15, 32]. The authors mounted the valve in a pulse duplicator that simulated the physiological system and studied, among others, clot formation. They found that the trileaflet valve causes only small and isolated deposits in the vicinity of the hinges. Platelet aggregation in the region of prosthesis hinges was also observed by Sari et al. [33] or Yun et al. [3]. Chinese researchers designed a new bileaflet valve [34], which provides haemodynamic results similar to those obtained for the commonly used St. Jude valve. However, the valve design and function still do not prevent the use of anticoagulation therapy. The available in silico, ex vivo, and in vivo modelling approaches provide an understanding of the diseases involved and help clinicians to predict the patients reaction to the implanted valve. The in silico method we used allows one avoid medical interference (e.g., transoesophageal echocardiography [33]), which is troublesome to the patients’ and may result in medical complications.
Our numerical results seem to indicate that the proposed leaflets curvature in the TRI valve causes less turbulent blood flow. This is manifested by the occurrence of smaller vortices behind the valve (Figure 6). This is highly desirable as turbulent flow is one of the factors leading to haemolysis reaction. The vortices in the BIL valve during flow can be seen in Figure 6a, b.

Modelling blood flow through blood vessels, which form a branching structure, requires that the model of this structure must be truncated. Thus, a problem of proper boundary conditions at the distal ends of the vessels arises. To make the simulations more realistic, the smaller vessels beyond the truncation point must be substituted by boundary conditions. In our studies, we defined a combination of flow rate and pressure at the inlet and outlet, respectively. This approach in modelling the blood flow boundary conditions is commonly used [4, 6]. The choice of the defined boundary conditions is confirmed by obtaining blood flow velocity field values through the partially and fully open BIL valve (Figure 6b, c) corresponding to values for the natural trileaflet aortic valve [35]. The instantaneous maximum velocity for the BIL valve corresponds to the moment of valve opening (Figure 6a). Compared to the BIL valve, there are significantly higher velocities in the TRI valve (maximum velocity value for BIL: 4,52 m/s, for TRI 5,74 m/s – non-Newtonian fluid and for TRI 5,89 m/s – Newtonian fluid). This is due to the curved shape of the TRI valve leaflets, which significantly affects the reduced flow field. Higher values of the flow velocity field for the case of a TRI valve compared to a BIL valve was also observed by Piatti et al. [13]. The geometric orifice area is 318 mm$^2$ for the BIL valve and 170 mm$^2$ for the TRI valve. The velocity values for the Newtonian and non-Newtonian models are similar. However, the character of flow seems to be different for non-Newtonian and Newtonian fluid (Figure 6d-f and g-i). A closer analysis of Figure 6 shows that the definition of the blood flow as a non-Newtonian fluid seems to give more realistic results. We have used streamline techniques to visualize the flow and, in particular, its direction to make the analysis results more clear. The streamlines in Figure 6d-f show more clearly the peripheral flow than those in Figure 6g-i. TRI valve flow shows deceleration of the peripheral flow for non-Newtonian fluid during leaflet opening (Figure 6d). This reduction in flow velocity can have a negative effect on blood haemodynamics as it can lead to flow stagnation or cause haemolysis.

There is a common belief that in large vessels, blood can be modelled as a Newtonian fluid. However, such an assumption might be a too far-fetched simplification in certain situations, e.g. during a flow through a mechanical aortic valve. The blood flow through both BIL and TRI valves is highly inhomogeneous in space and time. This was also noticed and documented by De Vita et al., [36], who simulated blood flow through a bileaflet valve modelling blood as Newtonian and non-Newtonian fluid. They stated that the non-Newtonian fluid model should be assumed, mainly when blood cells damage is investigated. Although the quantitative results of haemolysis simulations can differ with a non-Newtonian model applied, such an approach seems to give a more realistic wall shear stress distribution than a Newtonian fluid model [8, 37].

One of the very significant parameters influencing the behaviour of blood cells during flow is shear stress. According to Ge et al. [38] shear stress must be above 150 Pa to cause haemolysis and above 10 Pa to cause platelet activation. A high value of shear stress in the ascending aorta for the BIL valve (i.e. 151.5
Pa, 126.88 Pa and 114.45 Pa for cusp position 40°, 20° and 0°, respectively) may indicate the possibility of haemolysis. The risk is high, but the duration of exposition would still need to be considered. Exceptionally high shear stress (151.5 Pa) occurs at the valve opening (40° - Figure 9a). This stress is because the flow runs close to the aortic wall (Figure 6a, Figure 7a). Furthermore, vortices occur during valve opening (Figure 6a, b), which further increase the impact of blood on the aortic wall. In the case of the BIL valve, a decrease of wall shear stress with the deceleration of flow can be noticed (compare Figure 6a-c and Figure 9a-c). This is due to the fact that the shear rate increases because the main streamlines of the flow are concentrated in the peripheral regions of the aorta, i.e. near the aorta wall, which changes the geometry of the flow drastically. As the blood is a shear-thinning fluid, which means that its viscosity decreases with a shear rate increase, a higher shear rate makes the blood less viscous, which causes lower wall shear stress. The wall shear stress for the TRI valve is much lower, i.e. 30.56 Pa, 49.64 Pa and 30.99 Pa for leaflet position 40°, 20° and 0°, respectively (non-Newtonian fluid) and 69.21 Pa, 47.90 Pa and 38.84 Pa for leaflet position 40°, 20° and 0°, respectively (Newtonian fluid) - see Figure 9. This is related to the central flow of blood (Figures 6, 7). Due to the more established flow and decreasing flow velocity field, haemolysis should also not occur further down the aorta. The highest shear stresses in the TRI valve occur at an opening angle of 20° (Figure 9e). Blood, in this case, flows through the gaps between the leaflets and the valve ring that form when the leaflet opens. Analysis of Figure 9g-i shows that for Newtonian fluid, the maximal wall shear stress occurs at the angle 40°, i.e. at the beginning of the valve opening. This is in accordance with Figure 7g, which present velocity distribution at the same leaflet position. The viscosity of a Newtonian fluid is constant, and the shear effects take place right after the beginning of the flow. In the case of non-Newtonian fluid, the viscosity changes with time. Therefore, we can observe the maximal wall shear stress at the mid-position of the leaflets (Figure 9e) when the flow rate is low.

The allowable stress value for the valve design is 32 MPa [39]. The von Mises stress analysis indicates that the highest stresses occur at the hinges and the place of leaflet attachment (Table 2, Figure 5). The maximum stresses are comparable for both valves (Figure 5c, d). The moment of occurrence of the highest stresses, 0° for the BIL valve (5.64 MPa) and 40° for the TRI (5.66 MPa), is due to the highest velocity values near the hinges (Figure 7c, d). The low stress values in the centre of the TRI valve leaflets (0.02-0.08 MPa) are influenced by the adopted thickness of the leaflets. According to Figure 2, the TRI leaflets thickness value varies from 0.6 to 2.6 mm. For the BIL valve (leaflet thickness 0.4 mm), these values are in the range of 0.17-0.30 MPa. Figure 7 directly shows the central flow at the TRI valve. The results of our simulations indicate that the maximum stress values are much smaller than the allowable values. We, therefore, conclude that the construction of the valves will not fail. However, it should be noted that we considered 75 beats per minute. With an increase in heart rate, Nasif et al. [39] observed a significant increase in stress. Our stress values may be underestimated due to the lack of consideration of recirculating flow. Exceeding the allowable stresses can lead to malfunction and failure of the valve over a long period, so valve motion analysis, which will be performed in future research, is necessary. To avoid possible high stress values, a different way of fixing the leaflet has to be considered. This will also
prevent the formation of gaps between the leaflet and the valve ring during valve opening. BIL valve flow is symmetrical (Figure 7a, b, c). It can therefore be concluded that the discs should not dislocate.

In our model, we did not consider the Valsalva sinuses. De Tulio et al. conducted numerical simulations of blood flow after a mechanical aortic valve and studied the influence of the aortic root geometry on blood behaviour in the region of sinuses [40]. They considered three models, i.e. three sinuses, one sinus in the form of an axisymmetric bulb, and a simple aorta without sinuses. Their results indicate that the geometry of the aortic root affects only marginally the kinematic features of blood flow downstream of a mechanical valve. Only minor changes in velocities were observed. However, differences in dynamics of blood flow are resulting from the aortic root geometry are noticeable. The authors of [18] observed the formation of vortices in the region of the sinuses. Their numerical results show a presence of negative velocities that they interpreted as blood recirculation in the sinuses. However, researchers do not consider coronary arteries, which have their origins in the sinuses and may significantly affect fluid dynamics in the aortic root. In consequence, the wall boundary condition is imposed on the inner surfaces of the sinuses. This is a factor that benefits vortex formation in the region. In [40], the authors modelled the aortic root geometry with coronary arteries truncated at a close distance from the aorta and defined boundary conditions which “are limiting in that, in general, they do not accurately replicate vascular impedance of the downstream vasculature”. This means that they did not consider the inertia of the fluid of all the neglected parts of the vascular network, nor did they consider the compliance of the arteries. The primary characteristics of coronary flow were analysed by Querzoli et al. [41]. They concluded that 75% of the flow in coronary arteries occurs during diastole. During systole, no distinct effects were observed, except for a secondary vortex region located at the inlet of the coronary vessel. The inclusion of coronary arteries in the model affects the delay and faster closure of the valve. Thus, it will be essential to model the coronary arteries when studying valve motion. In the present study, we decided to simulate fluid flow in a simplified aorta due to considerations for studying haemodynamic during valve opening in fixed positions.

Experimental studies on blood flow in the aorta showed its highly specific nature. Hansen et al., 2019 quantified the flow in ascending aorta by means of the vector flow imaging method [42]. Earlier, the method was used in vivo on the heart during surgery to describe qualitatively and quantitatively the cardiac flow [43]. The method makes it possible to measure the flow speed in two directions and proves a helical pattern of blood flow. Similar cardiac flow character was also visualised by means of magnetic resonance imaging [44]. Secondary rotations in cardiac flow are due to the natural way the heart beats and the curvature of the aortic arch. The tangential components of the flow velocity shown in Figure 8 represent the flow in a specific cross-section. In particular, they represent the direction of the blood flow, which allows one to observe whether a spiral flow occurs during the flow. Our simulation results do not indicate spiral flow in the aorta. Figure 8 only shows the presence of small circulations in the ascending aorta. The lack of spiral flow may be due to the use of a simplified aortic root. According to [45], spiral flow correlates with an extension of the sinuses of Valsalva.
To better assess valve performance, clinicians have developed a parameter to determine the degree of stenosis: the effective orifice area ($E_{OA}$), which is a measure of the effective valve opening during the forward flow phase. The highest $E_{OA}$ for the TRI valve corresponds to a valve opening angle of 20°. This is because the flow area at this position is the largest ($170 \text{ mm}^2$). The effective orifice area for the trileaflet valve indicates that the valve leaflets are too thick. The correct area should be approximately 1.5 mm$^2$. Changing the curvature of the leaflet will increase the flow area and reduce the flow velocity field value. This will have a positive effect on decreasing the pressure gradient upstream and downstream of the valve.

In our simulations, we modelled turbulent blood flow [46]. A similar assumption has been used by other researchers [4, 6, 7, 10, 11]. Our results indicate that the main turbulence occurs at the beginning of the leaflets opening and stabilises at the fully open position. In our opinion, this is due to the imposed boundary conditions. The analysis of blood flow through the valves at the 40° leaflets position does not take into account the fact that the blood is in constant move. The vortices visible in Figure 6a, b occur due to the fact that at the beginning, of the simulation the fluid after the valve was stationary.

The analyses confirm the validity of using three leaflets in the construction of the TRI valve. It is acknowledged that a TRI valve geometry causes more physiological closing compared to a bileaflet valve [47]. The rate of the cups closing influences the stimulation of platelet activation. Moreover, slower closing velocity decreases cavitation intensity [48] – another phenomenon contributing to blood cells deterioration. According to [47], the minimization of cavitation is also affected by thicker leaflets and a small rotation radius. This highlights the desirability of using thicker leaflets in the construction.

Our subsequent study will consider the motion of the leaflets for a thorough comparative analysis and determine the adopted method’s effect on haemodynamic results. The analysis will be performed on several cardiac cycles. This includes research on the influence of the inertia of the leaflets on the closing rate during the left ventricle diastole. Metal leaflets are expected to have a relatively high moment of inertia, resulting in far non-physiological blood flow. This factor can be reduced by applying different materials for the leaflets, such as polymers [13], polyurethanes, polytetrafluoroethylene, biodegradable elastomers, hydrogels [49] or biomaterials consisted of living tissues capable of active remodelling and self-repair [50].

Future research will focus on considering more real-world parameters of the blood. The Windkessel model will be used as a boundary condition. The influence of body fluids and other tissues on flow will also be taken into account. The aortic root will consider the sinuses of Valsalva and the coronary arteries. It will also be essential to show models characterising pathological states (restriction of leaflet motion in aortic stenosis).

Conclusions
Although the design of our TRI valve is preliminary and needs to be optimised, our results highlight some advances of such a valve geometry. This is manifested mainly by a central blood jet, contributing to more physiological blood flow and decreasing the risk of haemolysis (maximum shear stress for the BIL valve is 151.5 Pa, for the TRI valve 49.64 Pa) and, therefore, avoiding anticoagulation therapy in transplant patients. This will increase the possibility of implanting mechanical aortic valves in more patients. The central flow minimises the risk of leaflet dislocation. In addition, lower stresses extend the durability of the valve (maximum von Mises stress for BIL valve leaflets is 0.3 MPa and for the TRI valve 0.06 MPa). Another feature of the TRI valve is that it ensures similar blood flow regardless of the implantation angle. This is not the case for the BIL valve, which causes different flow patterns under various implantation angular orientations. Our numerical results indicate that the proposed leaflet curvature in the TRI valve results in less turbulent blood flow. This is a positive aspect of the TRI valve leaflet design, as vortices increase the risk of haemolysis.

The analyses also point to construction elements that should be improved. For instance, the parameter $E_{OA}$ should be increased. Reducing the curvature of the leaflet will increase the flow area and reduce the flow velocity field value. This will have a positive effect on decreasing the pressure gradient upstream and downstream of the valve.

The analyses confirm the validity of using three leaflets in constructing the TRI valve and indicate the advisability of further optimisation of the construction.

**Declarations**

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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**Figures**
Figure 1

Solid model of the: a) left ventricle and fragment of the aorta, b) BIL valve, c) TRI valve
Figure 2

Shape of the TRI valve leaflet

a)  b)  c)  d)  

Figure 3
Analysed leaflet positions for the BIL valve: a) 60°, b) 40°, c) 20°, d) 0° and for the TRI valve: e) 60°, f) 40°, g) 20°, h) 0°

Figure 4

Boundary conditions

| Position of leaflets [°] | Inlet [m/s] |
|-------------------------|-------------|
| 40                      | 0.55        |
| 20                      | 0.73        |
| 0                       | 0.97        |
Figure 5

Stress distributions in the valve for the BIL valve leaflets’ positions: a) 40°, b) 20°, c) 0° and for the TRI valve leaflets’ positions: non-Newtonian fluid d) 40°, e) 20°, f) 0°, Newtonian fluid g) 40°, h) 20°, i) 0°
Figure 6

Velocity fields of the flow through the BIL valve leaflets’ positions: a) 40°, b) 20°, c) 0° and for the TRI valve leaflets’ positions: non-Newtonian fluid d) 40°, e) 20°, f) 0°, Newtonian fluid g) 40°, h) 20°, i) 0°
Figure 7

Cross-sectional velocity fields for the opening angle of the BIL valve: a) 40°, b) 20°, c) 0°, for TRI valve: non-Newtonian fluid d) 40°, e) 20°, f) 0°, Newtonian fluid g) 40°, h) 20°, i) 0°

Figure 8
Tangential components of the flow velocity in ascending aorta for: a) BIL valve, b) TRI valve

Figure 9

Shear stress distributions in the ascending aorta wall for the BIL valve: a) 40°, b) 20°, c) 0°, for TRI valve: non-Newtonian fluid d) 40°, e) 20°, f) 0°, Newtonian fluid g) 40°, h) 20°, i) 0°