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Computational Fluid Dynamics (CFD) for blood flow in cardiovascular medical devices and blood damage prediction

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Abstract

Background: The hemodynamic performance of cardiovascular medical devices and their potential to cause blood damage are critical factors in ensuring patient safety and device efficacy. Computational Fluid Dynamics (CFD) has emerged as a valuable tool for simulating blood flow within these devices and predicting the risk of blood damage.

Objectives: This study aims to utilize CFD simulations to evaluate the local hemodynamic performance of a particular implantable device and to provide precise predictions about likely adverse clinical effects, cutting-edge techniques like laser doppler anemometry (LDA) or particle image velocimetry (PIV) must be accessible.

Methods: A patient-specific CFD model of the cardiovascular system and medical devices was developed based on medical imaging data. Hemodynamic parameters such as shear stress and flow recirculation were computed to identify regions of potential blood damage. The simulations were validated against data.

Results: The CFD simulations revealed intricate flow patterns and areas of concern within the medical devices. Elevated shear stresses and prolonged residence times were identified in certain regions, indicating a risk of blood damage. By quantifying these parameters, the study provided a comprehensive assessment of potential blood damage locations and severity levels.

Conclusion: CFD proved to be a robust approach for evaluating blood flow within cardiovascular devices and predicting potential blood damage. The study highlighted specific design modifications that could mitigate the risk of blood damage, thus contributing to the improvement of device safety. The integration of CFD with patient-specific data offers clinicians and engineers a powerful tool for optimizing cardiovascular device design and minimizing patient risk.

Keywords: Shear Stress, Hemolysis prediction, Devices Optimization, Cardiovascular implants, Fluid Dynamics, Damage Prediction.

Introduction

As of 1998, more than 3 million prosthetic heart valves have been implanted since the first one was done, which was about 50 years ago.[1] Each year, almost 300,000 people all over the world have heart valve implants, which include mechanical and biological tissue valves.[2] Valve replacement is a successful therapeutic procedure, however it is not risk-free. The clinical occurrence of thrombogenicity or blood trauma has been amply demonstrated by controlled experiments,[3] but the underlying causes are extremely complex and involve both bioengineering and clinical problems connected to the Virchow's triad .[4]

Particularly, it is hypothesised that thromboembolic events are initially brought on by both the surface materials of the device and the fluid dynamics that the prosthesis imparts on the blood flow.[5,6] Therefore, the research of cardiovascular implanted devices demands contemporary methodologies for medical device design creation and evaluation in order to guarantee the highest quality and consistency of function after implantation. It is important to underline that a heart valve closes and opens roughly 40 million times every year.[7]

The specific prosthetic flow field structures connected to

heart valves, such as flow stagnation, flow separation, and turbulence, particularly at peak systolic (diastolic) flow for the aortic (mitral) valve or during the leakage phase, for both mitral and aortic implants are one of the main concerns with regard to clinical use of heart valves. As contrast to the native valve, mechanical heart valves specifically introduce immobile structures (occluders) to the main flow through the valve itself. As a result, significant velocity gradients and, subsequently, the formation of turbulence are to be anticipated.[8] Actually, blood stream turbulence has frequently been linked to blood trauma, which is likely to cause thrombogenesis and hemolysis.[9,10]

The shear stress levels in the flow field frequently trigger the extrinsic chain of coagulation, and platelet activation[11] and erythrocyte membrane mechanical loading are the identified processes.[12] Laser doppler anemometry (LDA) and particle image velocimetry (PIV) are the industry standard tools for assessing the trauma potential of valve disturbed flows, even if CFD may be useful at the design level. In one of the early investigations using LDA, the highest risk of thrombosis during the clinical testing of a revolutionary mechanical valve was noted in.[14] Extremely high Reynolds shear stress values that were above the Reynolds shear stress damage threshold were found in close proximity to the hinge recess.[15,16]

It has previously been suggested to use the size of the turbulent eddies, the viscous shear strains, and the length of time that red blood cells spend passing through high turbulence zones to define the trauma that turbulence causes to blood cells.[14,17] The instantaneous viscous shear stress at which hemolysis occurs is equivalent to the shear stress thresholds identified through studies of laminar flow, demonstrating that viscous shearing plays a significant role in the turbulence-induced destruction of erythrocytes.[17] In the latter investigation, it was shown that the Kolmogorov length scales for the majority of turbulent hemolysis trials were comparable to the size of a red blood cell.

The greatest eddies are responsible for introducing turbulent energy into the flow, and the smallest eddies are responsible for dissipating it at the microscopic level.[18] The contact of the tiniest eddies with the cell membrane causes blood trauma in turbulent flows, such as those produced by artificial devices implanted in the circulatory system; in this scenario, hemolysis is not dependent on the exposure period. Instead, the turbulent viscosity should be greater than the inner viscosity of red blood cells if the smallest eddies are larger than one erythrocyte. This means that the shear stress acting on the erythrocyte must be In this situation, hemolysis is dependent on exposure time, and the PIV tracking technique allows us to link velocimetric field characteristics to blood problems. Blood damage prediction and fluid dynamics investigations of cardiovascular medical devices are high enough and applied for long enough to cause cell lysis.

In order to take into consideration, the interaction between turbulent flow and blood particles, the Reynolds shear stress is typically assessed.[19] Experimental evidence has amply supported the relationship between Reynolds shear stress and hemolysis or platelet lysis.[9,20]

This has allowed for the calculation of a hemolysis threshold that is dependent on Reynolds shear stress using the second-order central moments of the velocity.[9]

Later, the threshold value was altered to consider the flow field's three-dimensional loading on the red blood cells.[10]

Therefore, a precise estimation of turbulence levels, and more especially of the Reynolds stresses, is needed to quantify blood damage associated to a medical device in contact with blood. The hemolysis issue is often described in terms of the threshold level for lethal blood damage, but an unbiased comparison of in vitro and in vivo data is still absent. As was noted in,[23] it is still unclear how much lower mechanical loads may injure cells and how much this will shorten their predicted lifetime.

Objectives

This study aims to utilize CFD simulations to evaluate the local hemodynamic performance of a particular implantable device and to provide precise predictions about likely adverse clinical effects, cutting-edge techniques like LDA or PIV must be accessible.

Methods

Velocity measurements need to be exceedingly accurate

and precise in order to allow a reliable evaluation of the blood damage brought on by the usage of implantable devices. The two most important techniques for anemometric evaluations of prosthetic devices have appeared as LDA and PIV. The two main benefits of LDA are its small measurement volume and high temporal resolution, however because it uses a single point, it requires a lot of setup work and data collection time. Instead, PIV analyses images of flow that have been seeded with particles to enable velocity measurements over large flow zones.

The measurement is impacted by spatial averaging over the window in which a cluster of particles is examined since the computed velocity is an average of the velocities of the particles present in the so-called correlation window. As a result, accuracy might be affected, particularly in areas with significant velocity gradients, like those downstream of mechanical heart valves. It is crucial to remember that PIV usually encounters hardware limitations (for example, measurements are typically not permitted at very high frequencies). This is true despite the fact that PIV definitely offers benefits due to its ability to rebuild whole instantaneous flow fields across vast regions utilising just a pair of photos.

PIV system performance may also be constrained by camera speed and data storage characteristics. The ISS has long used LDA and PIV 3D setups to assess the fluid dynamics of medical equipment. To determine the propensity for thrombogenesis and hemolysis, two different kinds of investigations were carried out: A stereo PIV analysis of the flow through a valve with the most popular size (27 mm), at the highest flow regime, as suggested by the FDA to study the worst case with regard to turbulent flow,[19] and particle residence time in the case of low flow condition with smallest valve size (implying large vortices and flow separation).

A 19-mm bileaflet heart valve was measured using 2D PIV in the initial investigation. The valve was installed in the aortic position on the pulse duplicator used at Sheffield University. The mean aortic pressure (MAP) and heart rate (HR) were set at 100 mmHg and 72 bpm, respectively. Since particle residence times were recorded under low flow conditions, a worst-case analysis was conducted on this quantity. An in-plane particle tracking investigation produced particle trajectories using particle photographs created using a Lagrangian description of the flow. After that, the test section was divided into smaller domains, and residence times were computed.

The number of recorded trajectories passing through the aortic root during the relevant phase was then determined, accounting for all temporal samples in which each particle remained inside a given sub-domain. The process is finished by dividing the total determined period of residence by the number of particle pathways in order to obtain residence times in seconds.

In the second investigation, a 27-mm bileaflet heart valve was employed as the most usual measured diameter for comparison while stereo-PIV measurements were taken.

All three parts of velocity can be measured in two dimensions, or in the plane of light, using the stereo-PIV method.

In a nutshell, optical distortions are related to the accuracy of the in-plane velocity determination, whereas the accuracy of the out-of-plane velocity determination is mostly related to the angle between the two cameras: an accurate determination may be obtained with bigger angles. A nonlinear estimating approach was used to conduct stereo calibration on the cameras. For the three components of velocity to be correctly determined, stereo calibration is essential. On the Sheffield University pulse duplicator, stereo-PIV measurements were performed with the valve positioned in the aortic position.

It was required to have a cardiac output of 5l/min and a systole/cycle ratio of 0.35. For the second trial, we employed the same parameters: MAP=100 mmHg and HR = 72 bpm. The volumetric flow was measured with an electromagnetic flowmeter made by Gould-Statham. A sodium iodide-glycerol-water solution was used as the working fluid, and it had a kinematic viscosity of 1420 (6 3.7 10 v = m^2 /s), which is comparable to blood at high shear rates. The answer also made it possible to properly match the refractive index of the glass-blown aorta that was attached at the valve's outlet. Then, for this highly representative setup, both 1:1 kinematic and geometric similarity requirements were met. At the height of systole, measurements were taken. Re = 4Q / vD = 7360, where Q

is the maximum instantaneous flow rate and D is the nominal size of the valve, yielded the Reynolds number.

This suggests that turbulence was present when the data were taken. To calculate ensemble averaged quantities, N=300 instantaneous velocity measurements were employed. A precise measurement of the cross-plane velocity (W) was ensured by setting the angle between the axes of the two cameras at 60 degrees. The Scheimpflug arrangement made it possible to keep the focus constant over the whole image plane. Z=0 (crossing the valve axis) established the boundaries of the laser sheet plane.

The glassblown aorta was positioned coaxially on the valve outflow, as seen in Figure 1. The three Valsalva sinuses are smoothly connected to the segment of the aorta illustrated in Figure 1 by the valve orifice, and further downstream, the section resumes its circular shape. A dotted line representing the lighting plane is also displayed. The 2D investigation was conducted using a similar setup.

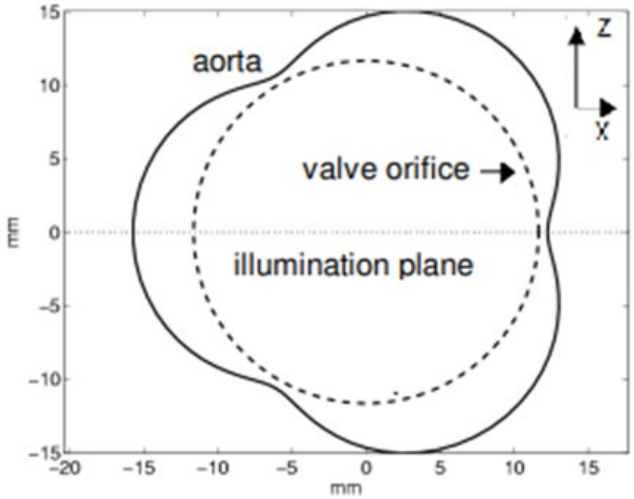

Figure 1. shows a sketch of the aorta and the valve orifice from the inflow side, with the latter's section depicted at its maximum span from the axis.

Results

Figure 2 displays the systolic residence time distribution for the initial investigation. There are three distinct zones by an amount more than what is found throughout the rest of the section. The final portion of the systolic phase, when the flow direction changes as a result of valve regurgitation, has an impact on the residence time relative to the lower left portion of the aortic root. This zone may be crucial for potential thrombus formation because of platelet adherence to the aorta wall given that it is close to the wall and the related shear intensity is low. The other two high residence time zones are on the section's right side. The effects of sinus recirculation and how it interacts with the main flow can be used to explain them.

The average velocity field at peak systole is shown in Fig. 3 for the stereo PIV investigation; U and V are the cross-streams. W is the cross-stream vertical velocity, which in the Z direction is perpendicular to the laser sheet plane. The horizontal and longitudinal velocities, or X and Y directions, are represented by the letters H and L, respectively.

Each figure has a valve at the bottom, and the upward flow is controlled by the valve. The glassblown aorta and valve structure are both taken into consideration by the median plane of the flow, or the plane of illumination (as depicted in Figure 1). However, the stereo-PIV measurements imply that even in this plane, there are notable three-dimensional effects. Two structures that are symmetrically positioned with respect to the valve axis (x=0) near the bottom of the W velocity field are the telltale signs of ring vortices produced by the tips of the valve leaflets. The highest Reynolds shear stresses were discovered to be less than 50 Pa, which is far less than the established hemolysis threshold .[9,10]

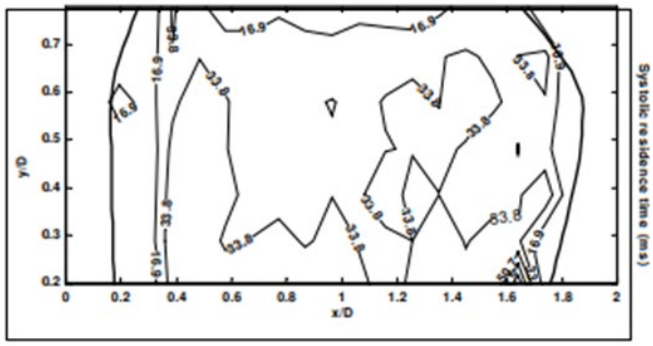

Figure 2. A 2D examination of the systolic residence time distribution. The open heart valve is at the top of the picture, and the forward flow is at the bottom.

Discussion

This study investigates the complex relationship between fluid dynamics, blood flow, and blood damage in the context of cardiovascular medical devices, specifically

focusing on prosthetic heart valves. It highlights the challenges and concerns associated with the design and use of these devices, considering factors like thrombogenicity, blood trauma, and hemolysis.

The author emphasizes that while valve replacement procedures are successful, they are not without risks, particularly due to factors related to blood-material interaction and fluid dynamics induced by the implanted devices. Thromboembolic events, often leading to thrombosis, are hypothesized to be influenced by both the device's surface materials and the flow dynamics it generates within the blood. These issues stem from the complexity of the underlying bioengineering and clinical factors, including aspects like the Virchow's triad.

The implications of different flow field structures associated with heart valves, such as flow stagnation, separation, and turbulence, which are of concern in clinical use were discussed. Mechanical heart valves introduce immobile structures to the blood flow, leading to velocity gradients and turbulence.[24] Blood turbulence has been linked to blood trauma, which can cause problems like thrombogenesis and hemolysis.[24,25] Shear stress levels in the flow can trigger coagulation and platelet activation, further contributing to blood damage.[26,27] Various techniques are used to assess the trauma potential of valve-induced disturbed flows. LDA and PIV are commonly used to evaluate the impact of blood flow on these devices. Ge et *al.* explored parameters such as Reynolds shear stress, turbulent eddies' sizes, viscous shear strains, and the time blood cells spend in high turbulence zones and concluded that the overall levels of the viscous stresses, which make up the actual flow environment experienced by cells, are apparently too low to cause damage to red blood cells, but could potentially damage platelets. Reynolds shear stresses neither directly contribute to the mechanical load on blood cells nor are a proper measurement of the mechanical load experienced by blood cells.[28]

The paper presents experimental investigations performed to analyze blood damage and flow dynamics using PIV and LDA techniques. These experiments were conducted on different sizes of prosthetic heart valves under various flow conditions. The authors discussed how measurements of velocity and residence time are crucial for evaluating blood damage caused by these implantable devices.

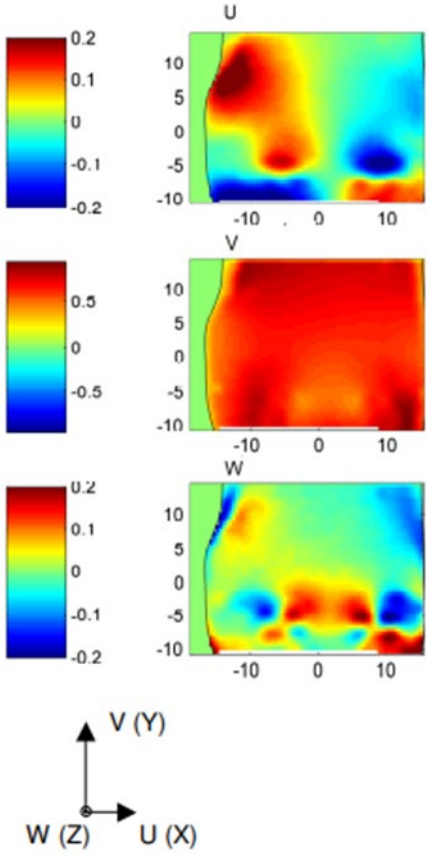

Figure 3. 3D study: extremely powerful components and a system that works well. Velocities are expressed in m/s.

The work presents several limitations and challenges associated with using CFD in this context:

Model Complexity and Simplifications: CFD simulations require the creation of detailed models of the geometry, fluid properties, and boundary conditions. However, overly complex models can lead to excessive computational requirements. To make simulations feasible, simplifications and assumptions are often necessary, which can affect the accuracy of the results.

Boundary Conditions: Accurate boundary conditions are necessary to replicate real-world conditions. In blood flow simulations, determining realistic inlet and outlet conditions can be difficult, especially when dealing with patient-specific cases.

Validation and Experimental Data: CFD simulations should be validated against experimental data to ensure accuracy. However, it was not possible to obtain accurate

experimental data for complex cardiovascular flows and this limited the ability to validate and refine simulations.

Patient-Specific Variability: Patient anatomies and physiological conditions can vary widely. Developing accurate patient-specific models requires access to detailed medical imaging data and the ability to create customized simulations, which can be logistically and technically challenging.

The PIV technique has advanced to the point that it can now estimate velocity fields with appropriate temporal and spatial resolution, making it a potent tool for researching the effectiveness and safety of implantable medical devices.

Conclusions

Medical devices like support life systems and heart valve prostheses have been studied for flow field characteristics, revealing complex case studies and transient flows. This paper aims were to integrate 2D and 3D CAD models into consumer electronics products, focusing on pediatric lifespan and third-party information's viability in slow-moving conditions.

The three components of the octagonal city were used in the 3D PIV study to calculate the Reynolds shear stress (RSS max) and offer a complete description of the flow field in the heavy flow zone without using any approximations to the flow field.

The study concluded that the maximum RSS values were associated with the slowest available device and were subsequently accepted for use in haemophilia treatment. Advanced geographic information systems could improve blood-contingency management strategies for humans and animals. Advancements in cardiovascular system performance could accurately assess implantable devices' hemodynamics and link success to blood damage modes.

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

Computational Fluid Dynamics: CFD;

Laser Doppler Anemometry: LDA;

Particle Image Velocimetry: PIV;

Mean Aortic Pressure: MAP;

Heart Rate: HR.

Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Role of the funding source

None.

Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional Review Board approval (code: xxx) was obtained (xx). The present study did not interfere with the process of diagnosis and treatment of patients and all participants signed an informed consent form.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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