A Novel Design for the Housing of Bileaflet Mechanical Heart Valves
(St. Jude Medical Model); A Computational Approach

by

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The undersigned certify that they have read, and recommend to the College of Graduate Studies for acceptance, a thesis entitled:

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Abstract

The St. Jude Medical (SJM) bileaflet mechanical heart valve (MHV) was approved by the Food and Drug Administration in the late 70’s. The basic idea for the design of the valve is simply two semicircular flat plates pivoting on recessed hinges. The SJM valve provides improved hemodynamics compared to preceding MHV models. The overall performance of SJM valves, such as the symmetry of centralized blood flow, the complete opening of leaflets, and minimal pressure drop across the valve is satisfactory; however, non-physiological hemodynamics which may lead to red blood cell (RBC) lysis and thrombogenicity (often related to incomplete wash in the hinges area) still remains a major issue. In this thesis, a design improvement was proposed to the housing of the SJM valve. It is suggested that applying 10% ovality to the housing while its perimeter remains constant may improve the hemodynamics of the SJM valve significantly.

In the first step, a quick computational platform was developed to assess the hemodynamic performance of the proposed design during the closing phase. Results indicated a clear hemodynamic improvement of the proposed design over the conventional design. In the next step, a novel computational platform was developed using computational fluid dynamics (CFD) method in order to evaluate the hemodynamic performance of the new design in details in the opening phase. Using this platform, the hemodynamic behavior of the proposed design was quantitatively compared to those of the conventional design. In particular, high shear stress zones, recirculation areas, velocity vectors in different sections and time phases, and the overall valve pressure drop for both conventional design and the proposed design were successfully investigated. Also, in order to evaluate the performance of MHVs at elevated heart rates (HRs), the proposed computational platform was successfully applied.

Results indicated that hemodynamics was improved in the proposed design. This improvement is characterized by a lower pressure drop across the valve and lower shear stress zones in multiple locations compared to the conventional SJM valve. The proposed design shows promise and merits further development.
Preface

A version of Chapter 3 has been published. Mohammadi H, Jahandardoost M, Fradet G. (2015) Elliptic St. Jude bileaflet mechanical heart valve. *Cardiovascular Syst.*, 3(1):1. I was the coauthor of this paper. I contributed into this paper by collecting and assembling data, data analysis and interpretation, writing the article. Dr. Mohammadi contributed into this publication by developing the numerical method used for this paper, writing and edition of this manuscript.

A version of Chapter 4 has been published. Jahandardoost M, Fradet G, Mohammadi H. (2015) A novel computational model for the hemodynamics of bileaflet mechanical valves in the opening phase. *Journal of Engineering in Medicine*. 229(3):232-244. I wrote the manuscript which was further revised by Dr. Mohammadi.

A version of Chapter 5 has been published. Jahandardoost M, Fradet G, Mohammadi H. (2016) Effect of Pulsatility Rate on the Hemodynamics of Bileaflet Mechanical Prosthetic Heart Valves (St. Jude Medical valve) for the Aortic Position in the Opening Phase; A Computational Study. *Journal of Engineering in Medicine*. 1-16. I wrote the manuscript which was further revised by Dr. Mohammadi.

A version of Chapter 6 has been published. Jahandardoost M, Fradet G, Mohammadi H. (2016) Hemodynamic study of the elliptic St. Jude medical valve; A computational study. *Journal of Engineering in Medicine*. 230(2):85-96. I wrote the manuscript which was further revised by Dr. Mohammadi.

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For all of the mentioned journal publications, Dr. Fradet contributed to the manuscripts by providing technical comments.

**List of Publication:**

The following lists of articles have been either published or accepted by the peer-reviewed journals and comprise the main content of this thesis dissertation.


In addition to above mentioned journal publications, I succeeded to present my research work in the internationally recognized conferences and symposiums as follows:


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<th>Parameter</th>
<th>Description</th>
<th>Unit</th>
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<tr>
<td>$\rho$</td>
<td>Fluid density</td>
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<td>$\mu$</td>
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**List of Abbreviations**

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</tr>
<tr>
<td>LVV</td>
<td>Left ventricle volume</td>
<td>mL</td>
</tr>
<tr>
<td>PI</td>
<td>Performance index</td>
<td>-</td>
</tr>
<tr>
<td>PIV</td>
<td>Particle image velocimetry technique</td>
<td>-</td>
</tr>
<tr>
<td>R</td>
<td>Radius of the valve</td>
<td>m</td>
</tr>
<tr>
<td>RANS</td>
<td>Reynolds averaging Navier-Stokes equation</td>
<td>-</td>
</tr>
<tr>
<td>RBC</td>
<td>Red blood cell</td>
<td>-</td>
</tr>
<tr>
<td>RSS</td>
<td>Reynolds shear stress</td>
<td>Pa</td>
</tr>
<tr>
<td>S</td>
<td>Shear strain rate</td>
<td>1/s</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
<td>Unit</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>SJM</td>
<td>St. Jude Medical valve</td>
<td></td>
</tr>
<tr>
<td>SS</td>
<td>Shear stress</td>
<td>Pa</td>
</tr>
<tr>
<td>SST</td>
<td>Shear stress transport model</td>
<td></td>
</tr>
<tr>
<td>SV</td>
<td>Stroke volume</td>
<td>mL</td>
</tr>
<tr>
<td>TSS</td>
<td>Turbulent shear stress</td>
<td>Pa</td>
</tr>
<tr>
<td>VSS</td>
<td>Viscos shear stress</td>
<td>Pa</td>
</tr>
<tr>
<td>WSS</td>
<td>Wall shear stress</td>
<td>Pa</td>
</tr>
</tbody>
</table>
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Dedication

To my father who dedicated his whole life to offer his endless support for his family. Your sacrifices and kindness will not ever be forgotten. You have an especial place in my heart.

To my mother who sacrificed her entire life to provide us unconditional love and support. Your love inspired me throughout my life.

To my lovely wife whose continuous support helped me get through my difficulties during my PhD study.
Chapter 1: Introduction

1.1 Overview

According to the recent report released by the American Heart Association in 2015, cardiovascular diseases are undisputedly the leading cause of human death. Worldwide, they are responsible for the deaths of more than 17 million patients annually \[1\]. Amongst all cardiovascular diseases, heart diseases are the most serious as they affect someone every 43 seconds in the United States alone \[1\]. Moreover, valvular diseases are one of the main causes of the heart diseases, as they are associated with substantial morbidity, mortality, and treatment \[2\]. There are two main possible and available options for treatment of a diseased valve. The first is to have it reconstructed, which involves tissue engineering or regenerative medicine. The second is to have it replaced by a prosthetic heart valve (PHV), which involves medical device design and development, and is the focus of this thesis.

1.1.1 Anatomy of the Heart

The human heart consists of two synchronized parallel reciprocating pumps that are responsible for the circulation of blood throughout the whole body. There are 2 primary circulation systems in the human body: (1) pulmonary circulation and (2) systemic circulation. The pulmonary circulation transports the deoxygenated blood from the right side of the heart (right ventricle) to the lungs. Then, the oxygenated blood returns back from the lungs to the left side of the heart (left atrium). The systemic circulation transports the oxygenated blood from the left side of the heart (left ventricle) to the whole body, with the exception of the heart and lungs. The blood flow through the heart is regulated by 4 cardiac valves: the aortic valve, the mitral valve, the pulmonary valve, and the tricuspid valve. The required mechanical energy for circulation is provided by the heart’s muscles. In simple terms, the aortic and pulmonary valves direct blood flow out of the ventricles, whereas the mitral and tricuspid valves direct blood flow from the atria to the ventricles (Figure 1.1). The aortic and pulmonary valves function passively and they open and close due to a pressure gradient across them. The mitral and tricuspid valves act semi-passively with the help of papillary muscles and chordae tendineae in addition to the valve pressure gradient \[3\]. The left
ventricle has higher pressure (80-120 mmHg) during systole (forward flow), because the resistance against blood flow and consequently energy loss in the systemic circulation is high \[4,5\]. However, the right ventricle has lower pressure, with a range of 15-30 mmHg during systole \[2\]. Therefore, the mitral and aortic valves are more prone to failure because of consistently higher operational pressure \[6\]. The focus of this thesis is on aortic valve prostheses.

![Heart valve anatomy](image)

**Figure 1.1.** Heart valve anatomy \[7\]

### 1.1.2 **Dynamics of the Heart Valves**

The human heart functions by the contraction and relaxation of heart muscles during systole and diastole, respectively. In simple terms, diastolic pressure is the applied pressure on the arterial walls when the heart is relaxed in between heart cycles. Systolic pressure is the amount of pressure that blood exerts on arteries while the heart is contracted. During systole, the aortic and pulmonic valves are open to let the blood flow through, while the mitral and tricuspid valves are closed to prevent regurgitation flow from ventricles to the atria. However, during diastole the aortic and pulmonary valves are closed as the ventricles are filled with blood during contraction while the mitral and tricuspid valves are fully open.
There is a short period of time when all heart valves are closed which is called isovolumetric contraction and relaxation \[8\].

Figure 1.2 illustrates the aortic and mitral valve pressure and flow rates during one cardiac cycle for a native valve. The aortic valve starts to open when the pressure of the left ventricle exceeds the aortic pressure, and remains fully open until the aortic valve pressure gradient becomes negative. The maximum ventricle pressure during systole can reach up to 80-120 mmHg in a healthy adult, depending on the physical condition and age. During systole, there is a low aortic pressure gradient in order of only few mmHg, while this pressure gradient gets up to 80 mmHg during diastole, Figure 1.2 \[2\].

![Wiggers diagram showing the dynamics of the Mitral and Aortic valves with aortic, atrial and ventricular pressure and ventricular volume during the cardiac cycle \[9\].](image)

The function of the aortic valve leaflets can be divided into four stages: the opening phase, the fully open phase, the closing phase and the fully closed phase. The opening and closing phases are considerably shorter than the fully open phase (Figure 1.2). The opening phase of aortic valve takes only 20-30 ms, while the fully open phase accounts for one third of a cycle which is around 860 ms for the normal heart rate of 70 beats per minute (bpm) \[2\].
1.1.3 Heart Valve Disease

There are two major types of valve disease, (1) valvular stenosis and (2) valvular insufficiency, which might affect all 4 cardiac valves. Valvular stenosis is when the orifice area (OA) of the valve in the opening phase is smaller than normal, which is due to calcified or fused cusps. The narrowed OA makes the heart work much harder in order to maintain the same efficiency. Valvular insufficiency or incompetence is when a valve does not close tightly or does not seal well. The diseased valve works with less efficiency simply because some blood will leak backwards across the valve. In this case, the heart has to work harder to compensate for the defective valve. Valvular heart disease, i.e., stenosis and insufficiency, may lead to heart failure and other symptoms.

The valvular heart diseases can be categorized into mild, moderate and severe levels of insufficiency/stenosis as outlined in Table 1.1. The diseased native valve might require implantation in case of moderate to severe insufficiency/stenosis [10–12].

**Table 1.1. Classification of the diseased Aortic valve [10–12].**

<table>
<thead>
<tr>
<th>Level of Stenosis/Incompetence</th>
<th>Mean Systolic Pressure Drop mmHg (Stenosis)</th>
<th>Percentage of the Incompetence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>20-30</td>
<td>20-30</td>
</tr>
<tr>
<td>Moderate</td>
<td>30-50</td>
<td>30-60</td>
</tr>
<tr>
<td>Severe</td>
<td>&gt;50</td>
<td>&gt;60</td>
</tr>
</tbody>
</table>

1.1.4 Types of Prosthetic Heart Valves

The performance of a PHV can be evaluated by hemodynamics, durability, thrombogenicity and pressure drop. An ideal PHV is known to provide a hemodynamic performance similar to that of the native valve, including a lower pressure drop, less hemodynamic complications with lower level of thrombogenicity, and high durability [13]. Despite of variety of designs proposed for PHVs over the past 50 years, the ideal valve is yet to be found.

There are two types of prosthetic heart valves, bioprosthetic heart valves (BHV) and mechanical heart valves (MHV) as shown in Figure 1.3 [14]. BHVs have the human or
animal origins while MHVs are fabricated with the artificial materials such as pyrolytic carbon, titanium, cobalt, Delrin, Teflon and Dacron [6]. BHVs (Figure 1.3a,b), are known to have a hemodynamic performance similar to native valves; however, they are prone to calcification and the effective life time of these valves are limited to 10-15 years [6,13]. These types of valves can be classified into autografts, homografts and heterografts. Autografts are human valves taken from the same patient, while homografts are valves from another person taken post mortem. Heterografts, however, have animal origins and are derived from porcine or bovine aortic valves, as shown in Figure 1.3a,b. While the life span of BHVs is limited due to lack of living tissues, MHVs are distinguished for their superior structural durability (Figure 1.3c,d,e). However, the lack of biological materials and induced flow complications, such as turbulence and the existence of high shear stress zones around these valves, are thought to be the major sources of red blood cell (RBC) lysis and platelet activation [4,15]. The hemodynamic complications associated with MHVs necessitate lifetime anticoagulation therapy for the patient with the implanted artificial heart valve.

MHVs are dominantly used in heart valve replacements because of their durability. They have gone through numerous design modifications since the advent of ball and cage valves in 1952, which were the first generation of MHVs (Figure 1.1c) [6]. Despite its durability and reliable performance, caged-ball valves imposed high pressure gradient and hemodynamic complications [2,6]. The next generation of MHVs was the tilting disc valve (Figure 1.3d), which had better response time and lower pressure drop compared to ball and cage valves. However, because of their high leakage flow and hemodynamic complications, they could not remain on the market for long period of time [5,6]. The latest generation of MHVs were bileaflet valves with significant hemodynamic improvements compared to other types of MHVs. Bileaflet MHVs soon became the most implanted PHVs around the world [2,4,5]. Bileaflet MHVs, such as On-X and St. Jude Medical (SJM) valves, (Figure 1.3e) are comprised of two semicircular leaflets that can open to a maximum angle of 80-90 degrees. The hemodynamic performance, pressure drop, leakage flow and hinge design of these valves have significantly improved compared to previous generations of MHVs [2,6].
Among several types of MHVs, the SJM valve (Figure 1.1e), has the highest number of implantations (more than two million) so far around the world \cite{16}. The SJM valve was introduced to the market in 1978 and has undergone several design modifications ever since. It consists of two semicircular leaflets with the minimum and maximum angles of 25° and 85° with respect to the housing, respectively, (Figure 1.4a). The hinges are located inside the housing with cavity pivots, which provide enough shear stress to deliver proper washout during the closing phase and prevent blood cell cohesion at the low velocity flow of this region \cite{17}.

![Figure 1.3. Types of prosthetic heart valves, bovine valve (a) porcine valve (b), caged-ball valve (c), tilting-disk valve (d), St Jude Medical bileaflet valve (e) \cite{14}](image)

![Figure 1.4. Schematic view of the St. Jude Medical valve, (a) three dimensional model with leaflets and housing, (b) view of the maximum and minimum leaflet angles and three orifices \cite{18}](image)

The SJM valve design was meant to provide uniform flow with a lower level of flow abnormalities in order to reduce hemodynamic complications. The main flow of the SJM valve is characterized by three orifices around the leaflets (Figure 1.4b): the main orifice,
which is located at the center between two leaflets, and the side orifices, which originated from the flow between the leaflet and the valve housing \(^{[2,6,18]}\).

Choosing the most suitable PHV for a patient depends on many factors such as age, any particular medical considerations, and the patient’s preference \(^{[13]}\).

### 1.2 Problem Statement

Bileaflet MHVs are extensively used in heart valve implantations worldwide. However, hemodynamic complications due to non-physiological blood flow conditions around the valve still remain a major issue. These conditions are characterized by high shear stress zones, large recirculation areas, formation of vortex shedding after leaflets, high pressure drop across the valve, high regurgitation flow, etc. \(^{[4,6,19]}\). Although the performance of MHVs is satisfactory, there is still room for improvement as their hemodynamics can be improved substantially. This can be achieved by the optimization of key factors in the design and development of MHVs. These key factors are, but not limited to, low valve pressure drop, small regurgitation flow, low level of turbulence flow, low level of shear stress zones, small stagnation and recirculation zones, etc. \(^{[2,4,6]}\). In the following, each of the key factors are introduced in more detail.

**Valve Pressure Drop:** In general, one of the factors by which the efficiency of a prosthetic heart valve is characterized is the pressure drop across the valve. The lower the valve pressure drop, the lower workload imposed on the heart muscles. As a rule of thumb, the heart circulates blood through body 70-72 times in a minute; therefore, any small pressure drop caused by the implanted medical device can lead to an immense load stress on the heart muscles in longer term.

In order to evaluate the effect of valve pressure drop on the hemodynamic performance of PHVs, the effective orifice area (EOA) and performance index (PI) are usually used, as described by Gabby et al. \(^{[21]}\):

\[
EOA(cm^2) = \frac{Q_{rms}}{51.6\sqrt{\Delta p}} \tag{1-1}
\]
Chapter 1: Introduction

Elliptic St. Jude Bileaflet Mechanical Heart Valve

\[ PI = \frac{EOA}{A_{SR}} \]  

(1-2)

where \( \Delta p \) is the mean systolic/diastolic valve pressure drop in mmHg, \( Q_{rms} \) is the root mean square of systolic/diastolic flow rate (cm\(^3\)/s), 51.6 is the gravitational acceleration constant and \( A_{SR} \) is the valve swing ring area. The EOA is an implication of the valve efficiency. Lower EOA causes higher resistance to the forward flow and accordingly higher pressure drop and energy loss across the valve (Figure 1.5). The performance index (PI) is a dimensionless index which is used to evaluate the valve resistance to the flow independent from its size \([2]\).

**Figure 1.5.** Schematic view of the flow pattern through an implanted MHV. \( A_{SR} \), Swing ring area; \( A_{AN} \), Annulus area; EOA, effective orifice area

As reported in previous studies, SJM valves have average systolic pressure drop of 2-15 mmHg depending on the valve size (i.e. 21, 25, 27 mm) with a mean systolic flow of 100-400 ml/s. It should be mentioned that the pressure drop for a diseased native aortic valve with mild stenosis was reported to be 20-30 mmHg \([10-12]\).

**Regurgitation Flow:** During the closing phase (end of systole and onset of diastole), a fraction of blood flow moves back from the ascending aorta to the left ventricle due to dynamics of leaflets, which is called regurgitation flow, Figure 1.6. High regurgitation flow is a disadvantage for PHVs since it reduces the stroke volume and accordingly the overall
cardiac output. The regurgitation volume was reported to be in range of 20 to 30 ml/beat for the diseased valve with mild incompetence \[^{11}\], while this value is around 13 ml/beat for 27 mm SJM valve \[^{2,22}\].

![Flow Rate Profile](image)

**Figure 1.6.** Profile of aortic valve flow rate with respect to time during one cardiac cycle \[^{2}\].

**Shear Stress:** Hemodynamic issues associated with bileaflet MHVs are characterized by RBC lysis and thrombogenicity. These complications are caused by the exposure of blood cells to high shear stress zones. Recirculation zones and areas after the leaflets where vortex shedding is formed are considered high shear stress zones. Also, a possible small gap between the leaflets and housing due to manufacturing may cause jet flow, leading to the formation of high shear stress zones. In addition to high shear stress zones, exposure time to these zones plays a key role in blood complications. As reported, the critical SS value for the threshold of platelet activation is 10 Pa with the exposure time of 2.5 to 3.5 ms, while for RBC lysis these values are 400 to 800 Pa with the exposure time of 1 to 620 ms \[^{23–26}\].

The main purpose of this thesis is to introduce a new design for the SJM bileaflet MHV, which offers an improved overall hemodynamics compared to conventional designs.

### 1.3 Objective

The main objective of this thesis is to propose a new design in order to improve the dynamics of bileaflet MHVs in both closing and opening phases and to reduce the thrombogenic complications associated with current designs. The first ever bileaflet MHV with an elliptic housing was proposed. This design improvement was made on the SJM valve model such that our new design shall be called an elliptic SJM valve or “ESJM” valve. It is hypothesized
that the new design provides improved hemodynamics by reducing high shear stress zones and decreasing the pressure drop across the valve in the opening phase. In order to computationally assess the hemodynamics of the valves, two complementary computational platforms were developed; (1) A quick computational platform for a pilot study, and (2) A sophisticated computational platform based on the computational fluid dynamics (CFD) method for a thorough study. In the first step, the quick computational platform was applied in order to justify the proposed design and to evaluate whether or not it should be further considered. Upon the successful application of the pilot study, a sophisticated computational platform was designed, developed, and validated to effectively assess the hemodynamics of MHVs in the opening phase. The conventional SJM and the proposed ESJM valves were used for a hemodynamic study in the opening phase. Results were quantitatively compared and the advantages of the proposed design were extensively discussed.

The objective of this thesis is summarized as follows:

1.3.1 Quick Hemodynamic Assessment of Bileaflet MHVs in the Closing Phase; A Pilot Study

In a pilot study, the hemodynamic performance of the proposed design is analyzed in the closing phase and compared to that of conventional SJM models. Results show that while the elliptic SJM model offers a shorter closing phase (9.7% shorter), the regurgitation flow remains almost unchanged. In other words, even though the dynamic response of the valve is improved, the regurgitation flow did not decrease. Thus, a more efficient effective orifice area (EOA) is shown to be provided by the proposed model. The preliminary calculations presented in this study indicate improved hemodynamics of elliptic SJM valves compared to conventional models. As such, the proposed design shows promise and merits further development

1.3.2 A Novel Computational Platform for the Assessment of Hemodynamics of MHVs in the Opening Phase

To date, in almost all of the modeling studies on the hemodynamics of bileaflet mechanical heart valves, a velocity (mass flow)-based boundary condition and an axisymmetric geometry
for the aortic root have been assigned, which, to some extent, are erroneous. Also, there have been contradictory reports of the profile of velocity downstream of the leaflets. In some studies, it is suggested that the maximum blood velocity occurs in the lateral orifice, and in others it is postulated that the maximum velocities in the main and lateral orifices are identical. The reported values for the peak velocities range from 1 to 3 m/s, which highly depend on the model assumptions. The objective of this study is to demonstrate the importance of the exact anatomical model of the aortic root as well as realistic boundary conditions in the hemodynamics of the bileaflet mechanical heart valves. The model considered in this study is based on the St Jude Medical valve in a novel modeling platform. Through a more realistic geometrical model for the aortic root and the St Jude Medical valve, we have developed a new set of boundary conditions for the assessment of hemodynamics of aortic bileaflet mechanical heart valves. The results of this study are not only significant for the design improvement of conventional bileaflet mechanical heart valves, but also for the design of the next generation of prosthetic valves.

1.3.3 Effect of the Heart Rate on the Hemodynamics of Bileaflet MHVs (SJM Valve)

To date, the majority of studies performed regarding the hemodynamics of the bileaflet MHVs, a heart rate (HR) of 70-72 beats per minute (bpm) has been considered. However, the HR of ~72 bpm does not represent the entire physiological conditions under which heart valves function. In addition, HRs of 120 bpm or 50 bpm may lead to hemodynamic complications, such as plaque formation and/or thromboembolism in patients. In this study, the hemodynamic performance of bileaflet MHVs over a wide range of physiological HRs, i.e., 60-150 bpm, was studied in the forward flow phase. The model considered in this study was a St. Jude Medical (SJM) bileaflet mechanical heart valve with an inner diameter of 27 mm in the aortic position. Also, a similar model was developed for benchmarking of our results where the SJM valve was replaced by a simulated native aortic valve. The hemodynamic performance of the SJM valve in areas such as regions of high shear stress, recirculation zones, vortex shedding and velocity profiles were studied. Results suggest that the peak values of the velocity profile downstream of the valve increase as the HR increases, and the location of the maximum velocity changes with HR. Results also indicate that the
maximum values of shear stress and the wall shear stresses (WSS) downstream of the valve are proportional to the HR values. Also, in the SJM valve model, when the range of the HR is 90 bpm and higher the threshold of the platelet activation is met in multiple locations within the aortic root. This in turn may lead to thrombogenic complications. The findings of the current study may be of importance in the hemodynamic performance of bileaflet MHVs and may play an important role in potential design improvement of conventional prosthetic heart valves.

### 1.3.4 The Hemodynamic Study on the Proposed ESJM in the Opening Phase

In this study, the hemodynamics around the leaflets has been evaluated in the opening phase using a more sophisticated computational platform, computational fluid dynamics (CFD). Results suggested both lower shear stress (SS), lower wall shear stress (WSS), and an overall improved hemodynamic performance in the proposed design. This improvement is characterized by lower values of SS and WSS in the regions downstream of the leaflets, lower pressure drop across the valve, and smaller recirculation zones in the sinus areas. The proposed design may open a new chapter in the conceptual design and hemodynamic improvement of the next generation of MHVs.

### 1.4 Outline of the Thesis:

Chapter 2 of the thesis outlines a summary of variety of MHVs, their hemodynamics and their major mechanical issues. Also, numerical and computational studies on the hemodynamics of bileaflet MHVs are extensively discussed.

In chapter 3, details of the pilot study and the customized numerical method is discussed. The method used in this study is developed to analyze the dynamics of MHVs in the closing phase. The dynamics of MHVs are characterized by regurgitation flow, the velocity of blood, the velocity of leaflets, the closing phase duration, etc.

In chapter 4, the novel computational platform for the analysis of the hemodynamics of MHVs is discussed. This chapter elaborates on the numerical aspects of the developed platform, such as the turbulence model used (Shear Stress Transform (SST) turbulence...
model, and the choice of boundary conditions. Also, the computational domain and geometrical aspects of the platform including the inlet and outlet lengths, anatomic aortic root are extensively discussed.

In chapter 5, more hemodynamics issues with the SJM valve is explored. The proposed numerical platform developed earlier is used for the assessment of the hemodynamics of the SJM valve in the opening phase, but for an elevated heart rate (HR). The hemodynamic issues, such as high shear stress regions for both SJM and native valves in the aortic position, are extensively discussed.

In chapter 6, the developed numerical platform was applied to successfully assess the hemodynamics of the proposed ESJM valve in the opening phase. Results are compared side by side by those of conventional SJM valves.

Finally, chapter 7 summarizes the conclusions and applications of this thesis and future works will be discussed.

Figure 1.7 describes the summary of the goals and objective of thesis.
Figure 1.7. Summary of the thesis objectives

Quick Hemodynamics Assessment of Bileaflet MHVs in the Closing Phase; A Pilot Study
- Introducing features of the new design
- Numerical method of the pilot study
- Hemodynamic improvements of the ESJM valve

Chapter 3

Novel Computational Platform for Hemodynamic Study of MHVs (Opening Phase)
- Controversies in the literature and lack of standard computational platform
- Details of the numerical platform

Chapter 4

Effect of the Heart Rate on the Hemodynamics of Bileaflet MHVs (SJM Valve)
- Change of HR from 60 to 150 bpm
- Effect of HR on SS and WSS and recirculation zones

Chapter 5

The Hemodynamic Study on the Proposed ESJM in the Opening Phase
- Improvements in SS and WSS of the new design compared to SJM
- Less blood complications
- Lower valve pressure drop

Chapter 6
Chapter 2: Literature Review

2.1 Design and Development of Bileaflet MHVs

More than 50 prosthetic heart valve designs have been introduced to the market since the implantation of the first caged-ball valve designed by a Harvard Medical School Professor, Dr. Hufnagel, in 1952 [5]. Earlier generations of MHVs, such as ball and cage, disk and cage, and tilting disk valves are known to have major drawbacks. These include high pressure drop across the valve or low EOA, highly disturbed flow, high regurgitation flow and high shear stress zones [6]. The design of bileaflet MHV, however, addressed some of these issues and improved the hemodynamics of MHVs [15]. The bileaflet SJM valve (Figure 2.1a) was designed and fabricated in 1977. Although, this model provides almost a uniform flow after the valve with lower level of turbulence and flow complications compared to the other MHVs, there is still room for improvement. The main improvements are made around the leaflet opening angle and shape, housing profile or aspect ratio and hinge design. The CarboMedic valve (Figure 2.1b) has curved leaflets compared to flat leaflets in the SJM valve.

![Figure 2.1](image)

**Figure 2.1.** Different types of Bileaflet MHVs, St. Jude Medical valve (a) [14], CarboMedic valve (b) [27], On-X valve (c) [28].

The ATS valve introduced the concept of the open pivot hinge design rather than recessed hinges in the SJM valve as shown in Figure 2.2. The latest generation of bileaflet MHVs is the On-X valve, which was introduced by the Medical Carbon Research Institute in Austin, USA, as shown in
Figure 2.1c. The specific leaflet and hinge design of this valve provides the maximum opening angle of $90^\circ$ and the profile of the valve was designed to be the same as the native aortic valve. Despite the availability of several designs for bileaflet MHVs on the market, the SJM valve has the highest number of implantations around the world. \[16\]

![Figure 2.1c](image)

**Figure 2.2.** Hinge design of two MHVs, the SJM valve with cavity pivot (a) and the ATS valve with open pivot (b). \[29\]

Several studies have been conducted to evaluate the overall hemodynamic performance of the SJM valve compared to other types of bileaflet MHVs. They showed that the simple and reliable design of the SJM valve results in lower level of blood complications with an improved hemodynamic performance. \[17,27,29,30\] In an experimental study, Grigioni et al. \[27\] studied the hemodynamic performance of the SJM and the CarboMedic valves in order to study the effect of leaflet curvature in the CarboMedic valve on the flow field. They utilized the Laser Doppler Anemometry (LDA) method to study the velocity field and Reynolds shear stress downstream of the leaflets in the two models. They reported that curved leaflets do not improve the valve hemodynamics which was due to shear stress zones caused by the leaflets in the CarboMedic valve. Dumont et al. \[30\] compared the hemodynamics and thrombogenicity of the ATS valve (open pivot) with the SJM valve (recessed pivot). In their study, they used the fluid solid interaction (FSI) method to simulate the 3D transient flow around the valves. They reported that the maximum opening angle in the ATS valve is less than that of the SJM valve. Also, they exposed that ATS and SJM valves show the same level of shear stress accumulation in platelet activation during the opening phase. In an *in vitro*
study, Yoganathan et al. [2] showed that the EOA and PI of the SJM valve is higher than bioprosthetic valves, when the valve size is higher than 23 mm (ID>23 mm) (Appendix A).

There are several studies in literature with a focus on the assessment of the hemodynamic performance of the SJM valve in both the opening and the closing phases [8,18,27,30–40]. Dumont el al. [30] studied the shear stress distribution in the leaflet gaps and within the hinges using the FSI method coupled with the DNS method. They reported that during the closing phase, about 80% of the platelets undergo shear stress higher than the threshold of the platelet activation (10 Pa for 3.5 ms [26]). They concluded that the jet flow in the leaflet gaps and within the hinges in the SJM valve leads to high shear stress zones at the contact surface of the jet, causing damage to blood cells. Ge et al. [8] studied the detailed flow structure near peak systole for the SJM valve using the detached eddy simulation (DES) numerical method and the particle image velocimetry (PIV) experimental technique. According to the results, the initiation of the leaflet vortex shedding occurs at the wake of leaflets which turns the stream into a fully disturbed flow and accordingly increases the blood cell residual time. They also reported multiple counters rotating recirculation zone at the sinuses area. Regarding the velocity flow field, they showed that the maximum velocity is approximately four times higher than the upstream flow velocity occurring close to the leaflet leading edges at the central orifice. They also reported a higher maximum velocity for the lateral orifices compared to central orifice downstream of the leaflets at the aortic root.

Problem Statement: Despite several design modifications, the SJM valve still suffers from multiple hemodynamic issues such as blood complications, cavitation, high shear stress zones, highly turbulent flow, high pressure drop, and regurgitation flow compared to the native aortic valve. The aim of this thesis is to address some of these shortcomings.

Our Strategy: In this thesis, a novel design for the SJM valve is proposed. This design modification is characterized by an oval housing and a reduced valve profile compare to the conventional SJM valve. Given the design of the housing, the proposed model is named “Elliptic St. Jude Medical Valve” or the “ESJM” valve. It is suggested that the proposed design delivers an improved hemodynamics by providing lower shear stress zones, lower valve pressure drop across the valve, reduced regurgitation flow volume, and reduced valve
dynamic response time. Two computational platforms are developed: (1) a quick solver platform by which the overall performance of the proposed design is evaluated and compared with that of the conventional SJM valve in the closing phase, using the novel numerical model developed by Mohammadi et al. [22]. In this phase, the valve dynamic response time, the regurgitation flow, etc., are evaluated through a pilot study. Based on the results obtained in this section, (2) a more sophisticated CFD-based computational platform is developed for a more precise assessment of the hemodynamics of the proposed ESJM valve in the opening phase. In the following, a comprehensive literature survey is presented in order to introduce available computational platforms with their advantages and disadvantages.

2.2 Computational Challenges in Hemodynamic Study of MHVs

Numerous experimental and computational studies are available in literature on the study of hemodynamics and the detailed flow structure around bileaflet MHVs. In an in vitro experimental study, Yoganathan et al. [2] reported that the profile of velocity right after the leaflets is non-flat with the peak velocity of 2.2 m/s occurring in the lateral orifices. Also, the peak velocity in the main orifice between the leaflets is 2.0 m/s. In their study, the bileaflet SJM valve was used with an annulus diameter of 27 mm, a cardiac output of 6.0 L/min and a HR of 70 beats/min. Under the same conditions and through a computational study, Nobili et al. [40] reported that the maximum velocity occurs at the lateral orifices with a magnitude of 1.38 m/s. Three symmetric semi-spheres were used for aortic sinuses and a pulsatile flat velocity profile for the inlet boundary condition. Ge et al. [8] considered an axisymmetric model for the SJM valve in steady-state conditions (Re_D=6000). They reported that maximum flow velocities downstream of the valve at the lateral and main orifices are 1.6 m/s and 1.5 m/s, respectively. Tullio et al. [41] applied DNS on a bi-carbon model with a diameter of 27 mm. A time varying mass flow rate boundary condition was used at the inlet with the maximum velocity of 0.81 m/s corresponding to Re_D=7200, with the flat velocity profile at the bulk flow and no-slip condition at the walls. They showed that the peak velocity is about 1.6 m/s in the lateral orifice and 1.5 m/s at the main orifice. There are other studies in literature supporting the idea that the maximum velocity occurs in the lateral orifices [18,34,42].
In contrast, some studies suggest that the peak velocity does not occur at the lateral orifices. Ge et al. [32] conducted a CFD study using axisymmetric geometry and sinuses. The laminar flow was modeled ranging from Re=250 to Re=1200 with a steady-state fully developed condition at the inlet. According to their results, for the Re=750, the maximum velocity downstream of the leaflet occurs at the main orifice with the magnitude of 2.1 m/s and the lateral orifices have the velocity of 1.85 m/s. King et al. [43] performed a 3D numerical study on the CarboMedic valve with a diameter of 25 mm (Re=1500) and their results were validated with the LDA experimental measurement. The maximum velocities at the main and lateral orifices are approximately 1.45 m/s and 1.3 m/s, respectively. Yagi et al. [39] experimentally investigated the effect of the leaflet orientation on the hemodynamics of the SJM valve. An average flow rate and a heart rate of 5 L/min and 75 beats/min, respectively, were assumed (Re=4000). According to their results, the maximum velocities for the main and lateral orifices are the same with the magnitude of 1.5 m/s located 0.25D after the leaflets. There are other studies reinforcing the idea that maximum velocity does not emerge from the lateral orifices [27,36,44].

As to the profile of velocity downstream of the leaflets, some studies reported a semi flat shape velocity profile downstream of the valve at the main and lateral orifices [27,42,44], while other studies showed a curved profile with the maximum at the center [2,8,18,19,41]. The peak velocity in these studies ranges from 1 m/s to 3 m/s. This highly depends on the model’s assumptions and numerical set-ups, such as the geometry of the valve and the aortic root, boundary conditions, regime of flow, etc.

Problem Statement: Even though there are many studies on the hemodynamics of the mechanical heart valves, a standard computational platform through which the hemodynamics of bileaflet MHVs can be analyzed and then compared to other models is yet to be realized.

Our Strategy: In this thesis, a novel computational platform for the analysis of hemodynamics around the SJM valve in the opening phase is proposed (will be discussed in detail in Chapter 4). This novel numerical platform is developed to study the hemodynamics of the SJM valve using realistic geometry for the aortic root [45]. To avoid the effect of
boundary conditions on the flow regime around the leaflets, an inlet and an outlet length are added to the model. Both pressure- and velocity-based boundary conditions at the inlet and outlet are considered \cite{46,47}. The final boundary conditions and the inlet and outlet lengths together ensure that the hemodynamics around the valve is not affected by the inlet and outlet conditions. This is characterized by forming a fully developed flow entering the valve and a fully developed flow adequately far from the valve at the outlet. The flow regime is assumed to be pulsatile in which three identifiable regimes of laminar, transient, and turbulent are formed. To model the salient features of flow around the valve, the shear stress transport (SST) low-Re two-equation turbulence model is applied \cite{48}. This model effectively utilizes the features of k-ω model near the wall and low Reynolds number regions and k−ε at the bulk flow. Wilcox’s k-ω model was chosen to study the regions near the surface and to model stationary transitional flow and also capturing laminar flow at sufficiently low Reynolds regimes \cite{49}. More details are provided in Chapters 3 and 4.

2.3 Thrombogenicity and RBC Lysis

MHVs are associated with thrombogenic complications and RBC lysis. Although the real cause of these complications is still unknown, it is thought that the non-physiological flow abnormalities may result in high shear stress zones triggering the platelet activation and RBC lysis \cite{2,4,5}. Activated platelets can then enter the stagnation and recirculation zones such as hinges, wake of the leaflet and leaflet vortex shedding and increase the residual time and consequently result in clot formation \cite{2,4,5}. Numerous experimental and computational studies have been carried out to assess the effect of the MHVs on the thrombus initiation and RBC damage \cite{35,38,50}. In general, the critical value for the shear stress resulting in RBC lysis is reported to be 400-800 Pa which highly depends on the exposure time (1 to 620 ms) \cite{23,24}. However, this value for the clot formation is reported to be 10 Pa around MHVs with an exposure time of 2.5 to 3.5s \cite{23,24}.

2.4 Turbulent vs. Viscous Stresses

Being influential in RBC lysis and platelet activation, it is thought that viscous shear stresses are more dominant compared to turbulent shear stresses. Ge et al. 2008 \cite{33} reported that the
Reynolds shear stresses (RSS) are not responsible for the actual mechanical forces experienced by the blood cells. In their study, they questioned the notion of contribution of the RSS to the RBC lysis and platelet activation. According to their results, the fluctuating properties in the turbulent flow around MHVs can be a result of cycle to cycle variation and not merely the small scale turbulent fluctuating effects. They showed that even in the acceleration phase and when the flow is laminar, the Reynolds stresses show considerably large numbers compared to the viscous stresses (the maximum turbulent Reynolds stress of 70 Pa versus the maximum viscous stress lower than 15 Pa). They concluded that the Reynolds stresses are not representative of the actual mechanical forces experienced by the blood cells in the hemodynamics of MHVs, it is viscous stresses that are the true reference to assess the real mechanical forces. They also indicated that only those-small-scale eddies with comparable size to the blood cells size can induce destructive mechanical forces. However, in MHVs the dissipation eddy scales, characterized by the Kolmogorov scale, are estimated to be within the range of 20-70 \( \mu \)m while the platelet and RBC scales are about 2 \( \mu \)m and 10 \( \mu \)m, respectively. Here the same concept has been followed to evaluate the shear stress induced by the implantation of MHVs into the blood cells and the threshold for the platelet activation has been considered to be 10 Pa \([23–26,41,51]\).

2.5 Blood as a Newtonian Flow

There are numerous numerical and computational studies in literature in which blood is assumed to be Newtonian \([4,8,18,29,30,32–36,38,39,41,44,52,53]\). Blood is comprised of blood cells floating in a Newtonian fluid known as plasma; therefore, the assumption of Newtonian fluid for blood is correct within arteries with length scale much larger than blood cells \([41,54]\). However, at locations where the length scale is comparable to blood cells, such as hinges of MHVs or flow within the gap of leaflets, the assumption of Newtonian fluid might contribute to numerical errors \([41,54]\). In addition to length scale, shear rate plays an important role in the effective viscosity of the blood \([41]\). Newtonian behavior of the blood is more prominent in arteries and many blood vessels where the shear rate is higher than 100 s\(^{-1}\). In contrast, non-Newtonian fluid behavior is normally considered in narrow blood vessels, such as capillaries and veins where shear rate is as low as 1 s\(^{-1}\) and blood viscosity increases sharply \([41]\).
2.6 Rigid Wall

Numerous computational studies are available in literature in which a rigid wall was assumed for the ascending aorta in the study of the hemodynamics around MHVs \[^{[2,8,18,29–38,40,41,43,44,50,55–58]}\). One of the major challenges in the hemodynamic study of MHVs is whether or not the aortic root should be considered compliant. This aspect of the numerical simulation might affect the turbulence features of the flow and leaflet dynamics by changing the pressure gradient and dynamics of the flow near the surface\[^{[41]}\). Since in this thesis, the focus is on the overall hemodynamic performance of the proposed valve by exploring the advantage and disadvantages of the new design, assuming a rigid geometry for the ascending aorta seems to be reasonable.

2.7 Hemodynamic Study of MHVs with Respect to Heart Rate

To date, in almost all of the hemodynamic computational and experimental studies, the modeling conditions are set based on a fixed heart rate (HR) of 72 beats per minute (bpm) \[^{[2,4–6,22,33,37,59–61]}\). This HR does not comprehensively represent the entire normal hemodynamic conditions. In some cases, such as resting, sleeping, etc., HR could be as low as 60 bpm. In contrast, HR can increase to even 150 bpm while jogging, running, etc. Also, daily emotional conditions such as anxiety and stress may affect our HR. Therefore, a HR range of 60-150 bpm seems to be justifiable as normal HR conditions under which native or prosthetic heart valves function. It is hypothesized that HR would significantly affect the hemodynamic characteristics of bileaflet MHVs, indicating that a computational study to assess the effect of HR on the hemodynamics of MHVs seems to be necessary.

The effect of HR ranging from 60 bpm to 150 bpm on the hemodynamic performance of MHVs is comprehensively discussed in Chapter 5. The high shear stress (SS) and high wall shear stress (WSS) regions, recirculation zones, formation of vortex shedding after leaflet and velocity profiles were comprehensively studied in the opening phase.
Chapter 3: Quick Hemodynamic Assessment of Bileaflet MHVs in the Closing Phase; A Pilot Study

3.1 Overview

The St. Jude Medical valve (SJM) design consists of two semicircular leaflets which pivot on hinges. It provides good central flow, the leaflets open completely, and the pressure drop across the valve is trivial. However, non-physiological hemodynamics around these valves may lead to red blood cells lysis and thrombogenic complications $[60,62]$. Also, the regurgitation-flow in SJM valves is almost twice that of the native valves in the aortic position $[22]$. In this study, a new design has been suggested for the stent (housing) of SJM valves in which 10% ovality is applied to the stent whereas its perimeter remains constant. In this pilot study, the hemodynamic performance of the proposed design is studied to evaluate its regurgitation flow and its velocity and the leaflet tip velocity in the closing phase compared to that of conventional design, SJM valve. The proposed numerical model was first introduced by Mohammadi et al. $[22]$ in 2006 in which unsteady Bernoulli’s equations and equations of motions are coupled in a finite strip method platform.

3.2 Method

The SJM model considered in this study has an inner diameter of 25 mm as shown in Figure 3.1a,b. In the proposed design, the perimeter of the housing remains constant. The housing is elliptic with a major diameter of 27 mm and a minor diameter of 23 mm as shown in Figure 3.1c,d. Due to the leaflet’s rotation, the computational domain is defined as a control volume (CV) with moving boundaries as shown in Figure 3.2a,b. In order to simplify the computational process, the blood flow is assumed to be unidirectional in the direction of the major axis and the projected area between the leaflets and the aortic wall is assumed to be rectangular at various positions during the closing phase $[21]$. The flow is considered inviscid such that velocity is uniform at every cross section in the control volume (CV) and the inlet (Reif et al. $[62]$, Van Steenhoven et al. $[63]$).
Chapter 3: Pilot Study

Elliptic St. Jude Bileaflet Mechanical Heart Valve

Figure 3.1. The conventional SJM valve (a); the engineering drawing the proposed elliptic SJM valve (b); and the fabrication of the proposed elliptic SJM model (c).

Figure 3.2. The control volume used in this study (a), AB is the leaflet, o is the pivot, AD is the inlet, BC is the outlet, $P_v$ is the ventricular pressure, $A_{ao}$ is the aortic pressure, $F_{reac}$ is the force applied on the control volume by the leaflets, $EF$ is an arbitrary section between the inlet and the outlet; and the control volume used for force and momentum balance equations (b).

The regurgitation flow is divided into two regimes through the minor and major orifices at the entrance of each section. When the valve is fully open, it is assumed that the aortic pressure ($P_{ao}$) and the ventricular pressure ($P_v$) are both uniform and equal. This is because
the valve remains fully open during the systole with almost no backflow from aorta to left ventricle. The control volume is $ABCD$, where $AB$ is the leaflet, $O$ is the pivot, and $EF$ is an arbitrary section. $UAD$, $UBC$, and $UEF$ are the velocities of blood at the entrance ($AD$), at the outlet ($BC$) and at the arbitrary section ($EF$), respectively. The distance from the $EF$ section with respect to the inlet section is denoted as $Y$. $lAD$, $lBC$ and $lEF$ are the lengths of the inlet and the outlet and the arbitrary sections which are time dependent. Their widths ($w$) though, remain constant (Figure 3.2). Velocities and pressures vary constantly through the sections $AD$ to $BC$. Mass is conserved within the CV such that the velocity at the $EF$ section ($V_{EF}$) is calculated with respect to the inlet velocity ($U_{AD}$) or the outlet velocity ($U_{BC}$) in the CV. It should be noted that the velocity of blood in the vicinity of the leaflet tips and at the $EF$ section is higher than the axial velocity of the leaflet tip ($U_{iAD}$, $U_{iBC}$) and the axial velocity of the leaflet at the $EF$ section ($V_{iEF}$), respectively.

The unsteady continuity equation on the $CV$ takes the form:

$$A_{AD}(U_{AD} - U_{iAD}) = A_{EF}(U_{EF} - U_{iEF}) + \frac{dV_i}{dt}$$  \hspace{1cm} (3-1)

where $A_{AD}$ ($w l_{AD}$) and $A_{EF}$ ($w l_{EF}$) are cross sectional areas at the sections $AD$ and $EF$, respectively. The axial velocities of the leaflet at $A$ and $E$ are $U_{iAD} = (r - b)\omega\cos\theta$ and $U_{iEF} = (r - b - l)\omega\cos\theta$, where $r$ is the radius of the leaflet in the circular SJM valve and the major radius of the leaflet in the elliptic SJM valve. $b$ is the distance from the pivot to the major leaflet tip, $l$ is the distance from the minor leaflet tip to section $EF$, $\omega$ is the angular velocity of the leaflet and $\theta$ is the angle between the $AD$ and the leaflet. $V_i$ is the volume of the $CV$ which is $V_i = (l_{AD} + l_{EF})/2wY\sin\theta$.

Applying the principle of the conservation of momentum on the $CV$ gives:

$$(A_{AD}P_{ao} - A_{BC}P_v - F_{rec}) - (m_{BC}U_{BC} - \dot{m}_{AD}U_{AD}) = d(MV)/dt$$ \hspace{1cm} (3-2)
Chapter 3: Pilot Study
Elliptic St. Jude Bileaflet Mechanical Heart Valve

where $A_{BC}$ ($w_{BC}$) is the cross sectional area at the outlet, $m_{BC}$ is the mass flow at the outlet which is $m_{BC} = \rho A_{BC}(U_{VC} - U_{iBC})$ where $\rho$ is the density of blood and $U_{iBC} = -b\omega \cos \theta$, $m_{AD}$ is the mass flow in the inlet which is $m_{AD} = \rho A_{AD}(U_{AD} - U_{iAD})$ and $dt$ is the time increment, $F_{rea}$ is the axial force applied on the CV by the leaflet, $M$ is the mass of the CV which is $M = \rho wd(l_{AD} + l_{BC})/2 \cdot \sin \theta$, where $d$ is the axial distance between the inlet and the outlet, and $V$ is the velocity of the CV which is $V = (U_{AD} + U_{BC})/2$. Using the (3-2), $F_{rea}$ is calculated.

Also, the unsteady energy equation between the inlet and the outlet is applied to calculate $F_{rea}$ such that:

$$
\frac{U_{AD}^2 - U_{EF}^2}{2} + \frac{P_{AD} - P_{EF}}{\rho} = \int_0^{Y_{EF}} (dV/dt)dy
$$

(3-3)

where $P_{AD}$ is the aortic pressure and $P_{EF}$ is the pressure at the section $EF$. $Y_{EF}$ is the axial distance between $AD$ and $FE$. It should be noted that in Eq. 3-3 it is assumed that the mass of leaflets compared to the mass of the CV is trivial so it was not accounted for.

Assuming $(dV/dt)$ as:

$$
\frac{\partial V}{\partial t} = [(V_j)_t - (V_j)_{t-\delta t}] / \delta t
$$

(3-4)

Then the term of the right part of equation is expressed:

$$
\int_0^{Y_{EF}} (dV/dt)dy = \sum_{j=1}^{N} [(V_j)_t - (V_j)_{t-\delta t}] \delta l \sin \theta / \delta t
$$

(3-5)

where the subscript “t”, “t-\delta t” represents the value at time $t$, and $t-\delta t$, respectively, $\delta t$ is the time increment and $\delta l = \frac{r}{N}$ where $N$ is the number of strips. The set of equations of (3-3)
to (3-5) gives the pressure at an arbitrary section \((P_{EF})\) which is used to calculate \(F_{\text{reac}}\):

\[
F_{\text{reac}} = \int w P_{EF} \cos \theta dl = \sum_{m=1}^{N} w \delta l \cos \theta P_m.
\]

The two approaches used to calculate \(F_{\text{reac}}\) are solved together simultaneously in order to calculate the inlet velocity \((V_{AD})\). Using \(V_{AD}\) the angular velocity of the leaflets is calculated.

The governing equation of motion for the leaflets takes the form:

\[
T_p + T_g = I_o \left( d^2 \theta / dt^2 \right)
\]

where \(T_p\) is the torque due to pressure, \(T_g\) is the torque due to gravity, and \(I_o\) is the mass momentum of inertia of the leaflets about the pivot. \(T_p\) and \(T_g\) are calculated as such:

\[
T_p = -\int_{N}^{r} (P_{EF} - P_v) w(r - b - l) ds = \sum_{m=1}^{N} (P_{EF} - P_v) w(r - b - l) \delta s
\]

\[
T_g = m_e g (r / 2 - b) \cos \theta,
\]

Where \(m_e = A_o \Delta (\rho_o - \rho)\) is the equivalent mass of the leaflets by taking the buoyant force into account. \(A_o\) and \(\Delta\) are the area and the thickness of each leaflet and \(\rho_o\) is the density of the leaflets. The two necessary initial conditions are based on the maximum opening angle of the SJM valves which is \(\theta(0) = 85^o\) and the velocity at the beginning of the closing phase is considered 0 m/s. The regurgitation flow is calculated by \(Q_{rf} = A_{or} V_f \delta t\) where \(Q_{rf}\) is the regurgitation flow and \(A_{or}\) is the total orifice area.

### 3.3 Results

The hemodynamic performance of proposed design including the velocity of the blood and the velocity of the leaflets and the regurgitation flow volume are calculated with respect to time in the beginning of the diastolic phase, i.e., the closing phase. The time increment \(\delta t\) is chosen to be 0.05 ms. Also, as mentioned above, \(F_{\text{reac}}\) is calculated using the two approaches in order to calculate the inlet velocity. The converging criterion specified is that the calculated \(F_{\text{reac}}\) from the two approaches should be less than or equal to 0.001 (N). When the angle between the housing and the leaflet is less than 1 degree, it is assumed that the leaflet is very close to the final closed position. Time, \(t\), is selected to be zero at the moment where
backflow is initiated and it is assumed that the initial velocity of the fluid is zero. The leaflet is divided into 30 strips of equal width. The governing equations of motion for the leaflet are solved by fourth order Runge-Kutta method. The heart rate and cardiac output were selected to be 70 beats per minute (bmp) and 6 lit/min, respectively\cite{65}. The ventricular pressure is assumed to decrease from a value equal to the aortic pressure (when the valve is fully opened) and the average aortic pressure is considered to be 16.0 kPa, i.e., 120 mmHg in the closing phase and is assumed to be constant all along.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig3a.png}
\caption{The velocity of the leaflet tip in the closing phase for both elliptic and conventional SJM valves (a); The velocity of the regurgitation flow in the vicinity of the leaflet tip in the closing phase for both elliptic and conventional SJM valves (b)}
\end{figure}

The velocity of the leaflet tip, the velocity of the blood flow in the vicinity of the leaflet tip and the regurgitation flow volume of the conventional SJM valves obtained in this study and those reported before (Subramainain et al. \cite{66}) are consistent.

Figure 3.3a shows the velocity of the leaflet tip in the closing phase for both designs. The velocity of the leaflet tip in the elliptic design is higher than that of the conventional design. It also shows that the closing phase in the elliptic design is %9.7 lower.

Figure 3.3b shows the velocity of the regurgitation flow in the vicinity of the leaflet tip for the elliptic and conventional SJM valves. The velocity of the regurgitation flow in the elliptic model shows an average increase of 11% compared to the conventional SJM valve. The
higher velocity of the regurgitation flow in the elliptic SJM model leads to a shorter closing phase. The two effective parameters to calculate the regurgitation flow volume are (1) the closing phase time and (2) the velocity of the blood which is shown in Figure 3.4. Results show that even though the velocity of the regurgitation flow in the elliptic SJM model is higher than that of the conventional SJM model, the backflow volume in the two models is comparable and equal (<0.05% error).

![Figure 3.4. The regurgitation flow volume in the closing phase for both elliptic and conventional SJM valves](image)

As a result, design modification to the SJM conventional valves using the numerical tool that can quickly assess the hemodynamic performance of bileaflet mechanical heart valves, suggest a clear improvement in the hemodynamic performance of elliptic SJM valves over the conventional models.

### 3.4 Summary

In this study, a design modification was proposed to the SJM conventional valves and a numerical tool was developed that can quickly assess the hemodynamic performance of bileaflet mechanical heart valves in general and the elliptic SJM valve proposed in this study in particular. Results of the current study suggest a clear improvement in the hemodynamic performance of elliptic SJM valves over the conventional models. A comprehensive set of experimental and computational studies in the opening and closing phases will further address the hemodynamic performance of the proposed elliptic SJM valve (ESJM).
Chapter 4: A Novel Computational Platform for the Assessment of Hemodynamics of MHVs in the Opening Phase

4.1 Overview

In the first step of this thesis, the hemodynamic performance of the proposed design was evaluated in a pilot study which was extensively discussed in the previous chapter. The results showed a clear improvement of hemodynamics in the elliptic SJM valve (ESJM) compared to the conventional SJM model and that the new design needs further consideration. To do so, I applied the computational fluid dynamics (CFD) method as a powerful and established tool in the assessment of the hemodynamics around bileaflet mechanical heart valves (MHVs). It is well recognized that CFD allows reliable physiological blood flow simulation and measurements of flow parameters.

Problem Statement: A standard computational platform by which the hemodynamic performance of a newly designed valve can be assessed has not yet been developed. Also, in almost all of the modeling studies on the hemodynamics of bileaflet MHVs to date, a velocity (mass flow) based boundary condition and an axisymmetric geometry for the aortic root have been assigned which, to some extent, are erroneous. Moreover, there have been contradictory reports of the profile of velocity downstream of leaflets, i.e., in some studies, it is suggested that the maximum blood velocity occurs in the lateral orifice as shown in Figure 4.1a [2,8,18,34,40,41], and in some other studies it is postulated that the maximum velocity in the main orifice and lateral orifices are identical, Figure 4.1b&c [27,32,36,39,43,44].

The main objective of this step of the thesis is to develop a novel computational platform in order to assess the hemodynamic performance of bileaflet MHVs in the opening phase. This study demonstrates the importance of the exact anatomical model of the aortic root and the realistic boundary conditions in the hemodynamics of the bileaflet MHVs. The model considered in this study is based on the St. Jude Medical (SJM) valve in a novel modeling platform. Through a more realistic geometrical model for the aortic root and the SJM valve, a new set of boundary conditions have been developed in order to assess the hemodynamics of
bileaflet MHVs in the aortic position. The results of the current study are significant for the design improvement of conventional bileaflet MHVs and for the design of the next generation of prosthetic valves.

4.1 Method

4.1.1 Governing Equations and Turbulence Model

The model is considered three dimensional (3D), the blood flow is Newtonian, turbulent and has a viscosity and density of 0.0035 Pa.s and 1060 kg/m³, respectively [57,67]. The flow is transient and pulsatile with the heart rate (HR) of 72 beat per minutes (bpm). The geometrical model is made up of an anatomic aortic root with asymmetric sinuses, with inlet and outlet lengths of 5R and 17R, respectively. The solver is commercial finite volume based software, ANSYS CFX 14.5 [68], which was run on a desktop PC equipped with Intel 8 cores 3.40 GHz processor with 12 GB of RAM.

The continuity equation (Eq.(4-1)) and the Reynolds Averaging Navier Stokes (RANS) equations (Eq. (4-2)) were numerically solved for the distribution of pressure $P$ and velocity components $u_i$ ($i = 1,2,3$) in the flow field.

$$\frac{\partial u_i}{\partial x_i} = 0 \quad (4-1)$$
\[ \frac{\partial u_i}{\partial t} + \frac{\partial u_i u_j}{\partial x_j} = -\frac{1}{\rho} \frac{\partial P}{\partial x_i} + \frac{1}{\rho} \frac{\partial}{\partial x_j} \left( \mu \left( \frac{\partial u_i}{\partial x_j} + \frac{\partial u_j}{\partial x_i} \right) - \rho u_i u_j \right) \]  

(4-2)

where \(\rho\) and \(\mu\) are the fluid density and viscosity.

\[ u_i = U_i + u'_i \]  

(4-3)

In this method, all of the spontaneous variables are decomposed into mean and fluctuating components, as shown in Equation (4-3). By substituting this equation in the Navier-Stokes (NS) equations, all of the fluctuating components are averaged and the only remaining part is \(\rho u_i u_j\). This term is known as the Reynolds stress tensor, which adds six unknown to the NS equations [69]. The two-equation method was applied, which is a combination of the k-\(\omega\) and the k-\(\varepsilon\) turbulent models, known as shear stress transport model (SST) [48,70]. In this model, the k-\(\varepsilon\) model is applied for the regions where the Reynolds number is high, i.e., central flow, and the k-\(\omega\) model is implemented for regions where the Reynolds number is low, i.e., the vicinity of the vessel wall.

On Baseline (BSL) k-\(\omega\) model, the blending function \(F_1\) is multiplied on \(k-\omega\) equation and \(1-F_1\) to k-\(\varepsilon\) equation [48,68].

**k-\(\omega\) Model:**

\[ \frac{\partial (\rho k)}{\partial t} + \frac{\partial (\rho U_j k)}{\partial x_j} = \frac{\partial}{\partial x_j} \left[ \left( \mu + \frac{\mu_l}{\sigma_{k1}} \right) \frac{\partial k}{\partial x_j} \right] + P_k - \beta \rho k \omega \]  

(4-4)

\[ \frac{\partial (\rho \omega)}{\partial t} + \frac{\partial (\rho U_j \omega)}{\partial x_j} = \frac{\partial}{\partial x_j} \left[ \left( \mu + \frac{\mu_l}{\sigma_{\omega1}} \right) \frac{\partial \omega}{\partial x_j} \right] + \alpha_1 \frac{\omega}{k} P_k - \rho \beta_1 \omega^2 \]  

(4-5)

**Transformed k-\(\varepsilon\) model:**

\[ \frac{\partial (\rho k)}{\partial t} + \frac{\partial (\rho U_j k)}{\partial x_j} = \frac{\partial}{\partial x_j} \left[ \left( \mu + \frac{\mu_l}{\sigma_{k2}} \right) \frac{\partial k}{\partial x_j} \right] + P_k - \beta \rho k \omega \]  

(4-6)
\[
\frac{\partial (\rho \omega)}{\partial t} + \frac{\partial}{\partial x_j} (\rho U_j \omega) = \frac{\partial}{\partial x_j} \left[ \left( \mu + \frac{\mu_t}{\sigma_{\omega 2}} \right) \frac{\partial \omega}{\partial x_j} \right] + 2\rho \frac{1}{\sigma_{\omega 2} \omega} \frac{\partial k}{\partial x_j} \frac{\partial \omega}{\partial x_j} + \alpha_2 \frac{\omega}{k} P_k - \beta_2 \rho \omega^2
\]

(4-7)

and BSL model:

\[
\frac{\partial (\rho k)}{\partial t} + \frac{\partial}{\partial x_j} (\rho U_j k) = \frac{\partial}{\partial x_j} \left[ \left( \mu + \frac{\mu_t}{\sigma_{k 3}} \right) \frac{\partial k}{\partial x_j} \right] + P_k - \beta' \rho k \omega + P_{kb}
\]

(4-8)

\[
\frac{\partial (\rho \omega)}{\partial t} + \frac{\partial}{\partial x_j} (\rho U_j \omega) = \frac{\partial}{\partial x_j} \left[ \left( \mu + \frac{\mu_t}{\sigma_{\omega 2}} \right) \frac{\partial \omega}{\partial x_j} \right] + (1 - F_1)2\rho \frac{1}{\sigma_{\omega 2} \omega} \frac{\partial k}{\partial x_j} \frac{\partial \omega}{\partial x_j} + \alpha_3 \frac{\omega}{k} P_k - \beta_3 \rho \omega^2 + P_{eb}
\]

(4-9)

The same blending function is applied to the new coefficients.

\[
\Phi_3 = F_3 \Phi_1 + (1 - F_3) \Phi_2
\]

(4-10)

In the BSL equation, the coefficients are defined as \[68\].

\[\beta' = 0.09, \quad \alpha_1 = \frac{5}{9}, \quad \beta_1 = 0.075, \quad \sigma_{k 1} = 2, \quad \sigma_{\omega 1} = 2, \quad \alpha_2 = 0.44, \quad \beta_2 = 0.0828, \quad \sigma_{k 2} = 1, \quad \sigma_{\omega 2} = \frac{1}{0.856}\]

Although this method combines the advantageous of \[k-\omega\] and \[k-\varepsilon\], it over predicts the eddy viscosity and shows some problems on detecting the separation flow. A better equation for eddy viscosity is to use a limitation on the eddy viscosity equation, leading to better transport in shear stress suggesting SST model.

\[
\nu_i = \frac{a_i k}{\max(a_i \omega, SF_2)}
\]

(4-11)

where S stands for shear strain rate and \(F_2\) is blending function like \(F_1\).
\[ F_1 = \tanh(\arg_1^4) \]  
\[ \arg_1 = \min\{\max\left(\frac{\sqrt{k}}{\beta\omega y}, \frac{500\nu}{y^2\omega}, \frac{4\rho k}{CD_{ko}\sigma\omega y^2}\right) \} \]  
\[ CD_{ko} = \max(2\rho \frac{1}{\sigma_{\omega_2\omega}} \frac{\partial k}{\partial x_j} \frac{\partial \omega}{\partial x_j}, 1.0 \times 10^{-10}) \]  
\[ F_2 = \tanh(\arg_2^2) \]  
\[ \arg_2 = \max(2\sqrt{k} \frac{500\nu}{\beta\omega y}, \frac{\sigma\omega y^2}{y^2\omega}) \]  

4.1.2 Geometry

The geometry of the computational domain used in this study includes the SJM valve (D=27 mm) and an anatomic aortic root with three asymmetric sinuses, as shown in Figure 4.2 [45]. The inlet length of 5R and outlet length of 17R were incorporated to the geometry in order to ensure a fully developed velocity profile at the valve inlet in all time phases and to minimize the effect of outlet boundary conditions on the flow around the leaflets [45].

The opening and closing phases of the leaflets (30-40 ms) are considerably shorter than the period when the leaflets are fully open (150-250ms) [2,18,22]; therefore, leaflets were assumed to be fixed at the maximum opening angle of 85 degrees [8,29,32,37,57,71,72].

4.1.3 Temporal Boundary Conditions

A HR of 72 bpm and cardiac output (CO) of 5.1 L/min was chosen for this study. The peak flow velocity is 830 mm/s, which results in the maximum Reynolds number of 7000 in the valve section. The systolic time period is assumed to be 250 ms, corresponding to approximately one third of the cardiac cycle [2,33]. The time dependent velocity boundary condition is given as Equation (4-17), Figure 4.3.
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\[ U(t) = \left( \frac{U(t)_{\text{max}}}{2} \right) \left[ 1 - \cos \left( \frac{2\pi t}{T} \right) \right] \]  \hspace{1cm} (4-17)

where here \( U(t)_{\text{max}} = 0.83 \text{ m/s} \) and \( T = 250 \text{ ms} \).

Figure 4.2. (a) schematic geometry of the valved conduit model and sections in streamwise (Z) direction; (b) Front view of the aortic root with asymmetric and realistic sinuses, (c) a close view of the unstructured mesh near the leaflet region and structured mesh used for the rest of the geometry with total number of \( 2 \times 10^6 \) elements.

Figure 4.3. Temporal boundary conditions showing the mass flow rate ratio versus cardiac cycle.
The flow is transient and pulsatile and a sinusoidal waveform was chosen for the systolic flow that changes from zero mass flow at early systole to the maximum mass flow at the peak. It again drops to zero at the end of systole and remains unchanged during diastole, as shown in Figure 4.3.

### 4.1.4 Spatial Boundary Conditions

Three different boundary conditions have been considered in this study: (1) uniform velocity inlet with pressure outlet (MP), (2) turbulent fully developed profile velocity inlet with pressure outlet ($U_{turbulent P}$), and (3) pressure inlet with mass flow outlet (PM). The laminar and turbulent fully developed velocity profiles are defined as Equations (4-18 and 4-19, respectively).

\[
U = U_{\text{max}} \left[ 1 - \left( \frac{r}{R} \right)^2 \right] \quad (4-18)
\]

\[
U = U_{\text{max}} \left[ 1 - \left( \frac{r}{R} \right)^6 \right] \quad (4-19)
\]

where $R=D/2, \; r=x^2+y^2$ and $U_{\text{max}} = 2U(t)$ for the laminar fully developed profile and $U_{\text{max}} = 4/3U(t)$ for the turbulent fully developed profile.

![Figure 4.4. Spatial Laminar and Turbulent velocity profile at the inlet.](image)

### 4.1.5 Convergence Criteria

In order to achieve high accuracy and better convergence, the adaptive time stepping method was used with the maximum and minimum values of 1 ms and 0.01 ms, respectively, to meet the target residual values of $1 \times 10^{-5}$. The minimum and maximum iterations per time step are 2 and 15, respectively, and results were saved every 5 ms. To attain the pulse cycle and
initial guess independence, the simulation was run for four consecutive cycles and the results were extracted from the fifth cycle\textsuperscript{[53,73]}.\par

4.1.6 Mesh Independency

The y+ for this study is set to 1 with 12 numbers of prism layers in the regions close to the surfaces. The total number of mesh is approximately $2 \times 10^{-6}$ with more than 70% tetrahedral elements used near the valve and aortic root where the geometry is complicated. The rest are modeled by hexahedral elements. To achieve mesh independency, three simulations were performed at the maximum flow by setting the y+ value to 0.7, 1.0 and 2.0, corresponding to total number of elements of $3.3 \times 10^{-6}$, $2.01 \times 10^{-6}$ and $1.51 \times 10^{-6}$, respectively. Table 4.1 shows the pressure drop between inlet and outlet of the domain, for three mesh density. According to the results, there is $\sim$2% discrepancy between y+ of 1.0 and 2.0 and this value reduces to $\sim$0.5% discrepancy for y+ of 1.0 and 0.7.

<table>
<thead>
<tr>
<th>Y+</th>
<th>Number of elements</th>
<th>Δp (Inlet-Outlet) [Pa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7</td>
<td>$3.3 \times 10^{-6}$</td>
<td>553</td>
</tr>
<tr>
<td>1.0</td>
<td>$2.01 \times 10^{-6}$</td>
<td>551</td>
</tr>
<tr>
<td>2.0</td>
<td>$1.5 \times 10^{-6}$</td>
<td>543</td>
</tr>
</tbody>
</table>

The mesh sensitivity study also indicates that there is a good conformity between y+ of 1.0 and 0.7 for the shear stress distribution at the midline downstream of leaflets as shown in Figure 4.5a,b. Figure 4.5c&d demonstrate the SS distribution at midline downstream of the leaflets at normal and parallel to leaflets for three cases. It shows that the discrepancy between y+ of 1.0 and 0.7 is less than 2% in most regions, in particular regions near the surfaces with high density prism layer mesh. Results also indicate that there are some discrepancies between y+ of 1.0 and 2.0, i.e., $\sim$5%.\par

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4.1.7 Calculating Shear Stress in the Domain

The stress in every point of the fluid is a tensor with three normal stress components \((\sigma_{xx}, \sigma_{yy}, \sigma_{zz})\) and three shear stress components \((\tau_{xy}, \tau_{yz}, \tau_{xz})\) in three dimensional (3D) fluid flow. The maximum shear stress is calculated according to components of the stress tensor. In two dimensional (2D) approximations, the Mohr’s circle is employed to calculate the maximum
shear stress in the assumed plane. By knowing the normal stresses ($\sigma_{xx}, \sigma_{yy}$) and shear stress ($\tau_{xy}$) in a 2D XY plane, the maximum shear stress ($\tau_{xy}^{\text{max}}$) is calculated by \cite{26}:

$$
(\tau_{xy})_{\text{max}} = \sqrt{\frac{(\sigma_{xx} + \sigma_{yy})^2}{4} + \tau_{xy}^2}
$$

(4-20)

This method may be used in 3D models as long as the velocity vector shows a dominant component in one direction and the other two vector components are negligible. If not, a 3D approximation is used instead. In our study the scalar approximation of the shear stress was employed according to the Von Mises criterion. In this method, the scalar shear stress ($\tau_{\text{sca}}$) is calculated based on the 6 components of the stress tensor calculated by Equation (4-21) \cite{51}:

$$
\tau_{\text{sca}} = \frac{1}{\sqrt{3}} \times \sqrt{\sigma_{xx}^2 + \sigma_{yy}^2 + \sigma_{zz}^2 - \sigma_{xx}\sigma_{yy} - \sigma_{yy}\sigma_{zz} - \sigma_{xx}\sigma_{zz} + 3(\tau_{xy}^2 + \tau_{yz}^2 + \tau_{zx}^2)}
$$

(4-21)

Figure 4.6 demonstrates the viscous shear stress calculated by the 2D approximation and the scalar shear stress. It is clear that the 2D approach is valid in regions with the axial unidirectional flow, but in a more complicated flow pattern, the 3D approximation should be used instead \cite{45,51,71,74}.

**Figure 4.6.** Maximum viscous shear stress at peak flow for the HR of 60 bmp, (a) ($\tau_{yz}$)$_{\text{max}}$ ; (b) $\tau_{\text{sca}}$
4.1.8 Validation

The numerical method used in this thesis has been validated using two different approaches: (1) applying the numerical method on a stenosis which was studied by Ahmed et al. [75] experimentally, and by Ryval et al. [76] computationally. (2) Validating the numerical platform with the results of a study about the hemodynamics of the SJM valve conducted by Liang Ge et al. [8]

4.1.8.1 Study of the Flow in a Stenosis

The proposed model was applied on a standard computational platform of an eccentric stenosis as performed previously by Ahmed et al. [75] experimentally, and by Ryval et al. [76] numerically. The model includes a constricted channel with 75% area reduction in which the inlet- and outlet- lengths are 4D and 16D and the length of the stenosis is 2D (D=25mm) (Figure 4.7a). The fluid specification is the same as used in the current study, Newtonian fluid with the blood density and viscosity are considered as 1060 kg/m3 and 0.0035 Pa.s, respectively. A Reynolds number of 500 and the SST turbulence model, capable of modeling the low Reynolds number turbulent regions, were used in this study.

The inlet boundary condition is pressure-based and outlet is mass flow rate-based in which the inlet pressure boundary condition considers the zero gradient velocity. As shown in Figure 4.7b and c, the results of the current studies are in agreement with the experimental results, such that the accuracy offered in the proposed model leads to more accurate results in accordance with the experimental ones comparing to those obtained by Ryval et al. [76]. Figure 4.7b & c show the normalized mean axial velocities at the throat and at Z=1D downstream of the throat obtained from different numerical models. The results obtained in this study hold less discrepancy to those obtained experimentally as compared to the standard and transient $k-\omega$ model specifically in the areas close to the wall. Moving toward the center, the current model shows the same amount of axial velocity as reported in the experiment while the result of the transient $\kappa-\omega$ model [76], shows 8% and 7% discrepancies close to the center in Figure 4.7b & c, respectively.
Figure 4.7. Schematic view of the stenosis model with 75% area constriction and generated mesh (a), Velocity profile at different locations downstream of the throat, at the throat (b), 1D from throat (c), and 5D from throat (d)

4.1.8.2 Hemodynamic Study of the SJM Valve

The experimental model reported by Liang Ge et al. \[8\] was reproduced by the computational platform developed in this study for validation. In their study, they used a simplified geometry with an axisymmetric aortic root, and utilized the particle image velocimetry (PIV) measurement method to calculate the profile of velocity near the leaflets at Re = 6000.

Figure 4.8c & d show the profile of velocity at the center line and 0.3R distance from the center line, (Figure 4.8b), along the surface Z3 of Figure 4.8a. The results obtained offer a good consistency with those reported by Ge et al.\[8\] with less than 5% discrepancy. This discrepancy in the profile of velocity at the sinuses regions might be due to the difference of the anatomic aortic root applied in this study (asymmetric sinuses) versus that of used in their study (axisymmetric sinus).
4.2 Results and Discussion

During the acceleration phase, the flow regime evolves from laminar to transient and turbulent. Accordingly, the velocity profile of the valve inlet changes from fully developed laminar to fully-developed turbulent. Fixing the profile of the velocity to the specific profile at the inlet, as used in most of the studies, can lead to unrealistic results. In addition, an accurate BC should be capable of taking the effect of the downstream geometry into consideration, but by specifying the profile at the inlet, the effect of the valve and any constriction on the housing becomes minimal. As such, in this study instead of fixing the
spatial inlet profile at all phases of time, the pressure boundary condition has been applied to the inlet.

Figure 4.9 shows the velocity profile at section Z2 upstream of the leaflet housing, for three possible boundary conditions, uniform velocity inlet with pressure outlet (MP), turbulent fully developed profile velocity inlet with pressure outlet \( U_{\text{turbulent}P} \), and pressure inlet with mass flow outlet (PM).

Figure 4.9a shows the axial velocity at \( \text{Re} = 2000 \) during the acceleration phase. As it can be seen, the only BC that can give the fully developed laminar profile correctly is the pressure inlet condition (red line). On the other hand, other BCs (dash green and blue lines) show significant deviations from the laminar fully developed boundary condition which can cause unrealistic velocity profile, shear stress, and other hemodynamic properties. Figure 4.9b demonstrates the axial velocity profile at the same section while the regime of the flow is turbulent with \( \text{Re} = 7000 \). As shown, the inlet uniform velocity profile fails to present the correct behavior of the flow. The turbulent inlet flow and pressure boundary conditions show the correct behavior especially close to the walls and with about 3\% discrepancy at the center.

![Figure 4.9](image)

**Figure 4.9.** (a) Velocity profile upstream of the valve inlet at location Z2 (a) \( \text{Re} = 2000 \); (b) and \( \text{Re} = 7000 \); MP: Mass flow inlet Pressure outlet, PM: Pressure inlet Mass flow outlet, \( U_{\text{turbulent}P} \): Turbulent velocity profile inlet & pressure outlet
In Figure 4.10a to f, the comparison between the velocity profiles of the current study and the study carried out by Ge et al. \cite{8}, and Nguyen et al. \cite{36}, are shown at section Z5 downstream of the valve normal and parallel to the leaflets. Different boundary conditions at three time phases of acceleration, maximum flow and deceleration have been examined here. As discussed, the right BC should be capable of simulating the correct inlet velocity profile at different time phases corresponding to laminar or turbulent regimes. The pressure inlet and turbulent profile inlet have very similar results as the regime of flow is turbulent, while uniform velocity inlet shows a different pattern. Results from Ge et al. \cite{8} show the maximum velocity at the lateral orifices while Nguyen et al. \cite{36} reported these velocities approximately the same level and pattern as the uniform velocity inlet did. Both of these studies have considered an axisymmetric sinus while the current study considers physiological sinuses with the long inlet and outlet lengths far enough from the leaflets to let the flow develop a zero gradient velocity and pressure at the inlet and/or outlet boundaries. Uniform velocity inlet follows the maximum velocity at the lateral orifice, but pressure inlet and turbulent velocity profile inlet show approximately the same maximum velocity as the main orifice does.

The maximum velocity field orientation changes at different sections downstream of the valve, Figure 4.11a. The maximum velocity field orientation is parallel to the valve direction at the section close to the valve (section P1), but as the flow travels further downstream, the pattern of maximum velocity changes from parallel to normal to the valve direction at section P4. The maximum velocity field orientation change agrees with the numerical and experimental results of Ge et al. \cite{8}. Further of this section, the velocity profile shows an approximately even distribution at section P5, and as the flow travels downstream toward the outlet, the velocity pattern becomes more even. It shows that the outlet length is long enough to let the flow develop the zero gradient condition.
Figure 4.10. Velocity profiles downstream of the valve normal to the leaflet and at maximum area location (Z5), (a) Re=4600 at t=0.3T; (b) Re=7000 at t=0.5T; (c) Re=4600 at t=0.7T; at systolic phase. Velocity profiles downstream of the valve parallel to the leaflet and at maximum area location (Z5), (d) Re=4600 at t=0.3T; (e) Re=7000 at t=0.5T; (f) Re=4600 at t=0.7T; at systolic phase.

As the flow reaches the leaflets, it will be divided into the main orifice and two lateral orifice areas. The main orifice consists of two diverging leaflets forming a diffuser with a positive pressure gradient. The lateral orifices are confined between one leaflet and housing forming a nozzle with negative pressure gradient. Then at the entrance section of the leaflets, the central orifice has higher velocity comparing to the lateral orifices. However, because of the effect of the diffuser, the flow decelerates within the main orifice along with the increase of pressure. The same scenario makes the pressure decrease within the lateral orifices. Then at the tip of the leaflet, there is a pressure difference between the main and lateral orifices, with higher pressure at the main one. This causes the flow to escape from the main orifice towards the lateral one at the tip of the leaflet as shown in Figure 4.11b. Figure 4.11c shows the velocity vectors normal to the valve at section Z5 and at maximum flow. Two counter rotating zones
can be detected in the left and right sinuses. The top sinus involves more complications because of the effects of the leaflets, Figure 4.11c.

Figure 4.11. Contour of axial velocity at five sections showing (a) the maximum velocity directions changes from horizontal at P1 to vertical at P4; (b) velocity vectors at a section within the leaflets; (c) and front view at a section downstream of the valve at peak systole.
As the flow reaches the leaflets, it will be divided into the main orifice and two lateral orifice areas. The main orifice consists of two diverging leaflets forming a diffuser with a positive pressure gradient. The lateral orifices are confined between one leaflet and housing forming a nozzle with negative pressure gradient. Then at the entrance section of the leaflets, the central orifice has higher velocity comparing to the lateral orifices. However, because of the effect of the diffuser, the flow decelerates within the main orifice along with the increase of pressure. The same scenario makes the pressure decrease within the lateral orifices. Then at the tip of the leaflet, there is a pressure difference between the main and lateral orifices, with higher pressure at the main one. This causes the flow to escape from the main orifice towards the lateral one at the tip of the leaflet as shown in Figure 4.11b. Figure 4.11c shows the velocity vectors normal to the valve at section Z5 and at maximum flow. Two counter rotating zones can be detected in the left and right sinuses. The top sinus involves more complications because of the effects of the leaflets, Figure 4.11c.

In the hemodynamics study of MHVs, recirculation zones and stagnation points should be closely studied. The recirculation regions especially in areas close to the hinges and the contact areas of the leaflets and housing, increase the residual time of the blood cells and can activate platelets which could lead to thrombus formation. The initiation of the recirculation zones in the left and right sinuses normal to the valve direction and close to the valve housing starts at early stage of systole as shown in Figure 4.12a,b. As they grow in area with respect to time, they move toward downstream (Figure 4.12 c&d). With further traveling downstream of the valve, a new recirculation area forms after the housing with the same direction and it will last until the end of systole. During the deceleration phase, the first recirculation area starts growing in space while the center of the rotation remains virtually unchanged. It grows continuously until it becomes dominant at the sinus region at the late deceleration phase. The same pattern has been reported by Nguyen et al.\textsuperscript{[35]} and Dasi et al.\textsuperscript{[30]} (Figure 4.12e-h).
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(a) \( t=0.1T \) systolic period

(b) \( t=0.2T \) systolic period
(c) $t=0.3T$ systolic period

(d) $t=0.4T$ systolic period
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(e) $t=0.5$ systolic period

(f) $t=0.6$ systolic period
Figure 4.12. Velocity vector and recirculation zones in the sinus region and within the leaflet at different time phases
Figure 4.13. Time varying velocity profile in different sections from 0.1 to 0.9 systolic periods, every 0.1 period time step
Figure 4.13 demonstrates the side view of the velocity vectors in respect to time at locations from the inlet to outlet. It can be seen that the outlet of the domain is far enough from the leaflets. This will let the flow develop the zero gradient velocity profile. During the acceleration phase, maximum velocity at the section near the leaflet emerges from the side orifice. However, when the acceleration phase reaches its peak, the maximum flow at the main and lateral orifices are approximately equal. This pattern is maintained during the deceleration phase. At the section near the leaflet entrance, the maximum velocity emerges at the main orifice for all of the phases of time.

Shear stress study is one of the main aspects of MHV hemodynamic analysis. High shear can cause blood cell lysis and platelet activation initiation that requires the patient to need lifetime anticoagulant therapy. Any design improvement to reduce the shear stress of MHVs can significantly enhance the hemodynamics of the valve. Figure 4.14 a & b show the shear stress normal to the valve plane, also the vortices in y direction.

It can be seen that there are three regions with higher shear stress: after the sinuses and reattachment areas where the separated flow attaches to the wall, near the valve housing with sudden constriction, and finally around the leaflets in the middle of the flow field with highest velocity where the presence of a leaflet with no slip condition can cause a high velocity gradient.

![Shear Stress and Vorticity](image)

(a) Mid plane shear stress  
(b) Mid plane vorticity Y

**Figure 4.14.** Mid plane shear stress and vortices Y, showing the regions with high shear stress near the wall and just after the sinuses, at peak systole
The maximum shear stress which is 15 Pa is shown to be at the structure wall after each sinus. Although this value of shear stress can not affect the RBCs, but platelets may be activated in those regions because they are exposed to higher than 10 Pa shear stress. Also, RBCs are exposed to high residual time in sinus regions and leaflet wakes, because of recirculation zones in the sinuses and vortex shedding after the leaflets. As a result, the chance of platelet activation is increased. Our results are consistent with those reported by Dumont et al. [17]. It should be noted that until 2008, the RSS (Reynolds Shear Stress) used to be assumed to be the dominant mechanical force experienced by RBCs and the hypothesis of the role of these stresses on the RBC lysis and platelet activation has been used in many studies. In 2008, Ge et al. [33] performed a comprehensive set of experimental and numerical studies in order to assess the real mechanical forces induced by the implanted aortic MHV into the blood cells. They concluded that the RSS is not the representative of the actual mechanical forces experienced by the blood cells and instead it is the viscous stresses that are the true reference to assess the real mechanical forces. In this study, I followed the same concept to evaluate the shear stress induced by the St. Jude MHV into the RBCs and the threshold for the platelet activation has been considered to be 10 Pa as mentioned earlier.

The wall shear stress (WSS) at the leaflets and walls downstream of the valves are demonstrated in Figure 4.15a,b. Two regions with the highest magnitude can be seen just after the right and left sinuses while there are two smaller areas of high WSS downstream of the top sinus. These locations with high WSS are directly related to the strength and extension of the recirculation zones at the sinus regions. In Figure 4.15c the highest WSS can be detected at the tip of the leading edge where there is a high velocity gradient and near the trailing edge where the tip recirculation happens. Due to the effect of diverging leaflets and higher flow exposure, the lateral orifice side of the leaflet shows a higher magnitude of WSS than the main orifice side. This is addressed in studies conducted by Nguyen et al. [36] and Dumont et al. [30].
Figure 4.15. Wall Shear Stress on the wall and on the leaflet at the maximum flow systole

The wall shear stress (WSS) at the leaflets and walls downstream of the valves are demonstrated in Figure 4.15a,b. Two regions with the highest magnitude can be seen just after the right and left sinuses while there are two smaller areas of high WSS downstream of the top sinus. These locations with high WSS are directly related to the strength and extension of the recirculation zones at the sinus regions. In Figure 4.15c the highest WSS can be detected at the tip of the leading edge where there is a high velocity gradient and near the trailing edge where the tip recirculation happens. Due to the effect of diverging leaflets and higher flow exposure, the lateral orifice side of the leaflet shows a higher magnitude of WSS than the main orifice side. This is addressed in studies conducted by Nguyen et al. [36] and Dumont et al. [30].

There are many studies on the effect of the turbulent and laminar wall shear stress on the endothelial cell performance in arteries, permeability of lipoprotein and atherosclerosis [54,77–
For many years, it had been hypothesized that the high shear stress can promote atherosclerosis in arteries \[^81\], however, recent findings show that low positive average turbulent shear stress with disturbed flow in arteries, can significantly increase the lipoprotein permeability and causes atherosclerosis \[^50\]. Laminar shear stress even in the elevated magnitude cause the endothelial streamwise reorientation and consequently reducing the cell resistance to the flow and shear stress. However, regions with bifurcation can experience flow separation and time average low shear stress causing endothelial cell misalignment and consequently further increasing shear stress \[^82\]. Despite many studies around the assessment of the shear stress on the endothelial cells and further complications in arteries, there are lacks of studies on the effect of induced high wall shear stress by the MHVs on the aortic root endothelia cells.

### 4.1 Summary

Numerical simulation of SJM bileaflet MHVs with realistic three asymmetric sinuses has been studied here. First, three different possible boundary conditions are studied and velocity profile downstream of the valve were compared with those reported by Nguyen et al. \[^36\] on the ATS valve, and Ge et al. \[^8\] on the St. Jude valve. Both studies considered steady state conditions and one axisymmetric sinus in their simulations. Most of the studies in literature considered a turbulent fully developed fixed velocity or uniform velocity profile at the inlet of the computational domain which can be a source of error. Because the flow regime is either laminar or turbulent during a cycle, then the valve inlet profile of velocity changes accordingly. In this study, we showed that the pressure inlet BC with mass flow outlet, can give a more realistic profile at different time phases, taking the effects of both flow regime and geometry into consideration. It is expected to be more important when regurgitation flow or fluid/solid interaction (FSI) with moving leaflets studies being considered.

There are controversies in the literature regarding the location of the maximum velocity downstream of the valve with some reporting at the lateral orifices and some at the same level while a few reported at the main orifice. These controversies originate from many aspects of numerical simulation. Any compromise in geometry, especially in the aortic root, turbulent modeling, mesh independency and suitable y+, inlet length and outlet length,
boundary conditions, pulsatile or steady flow and FSI with moving leaflet study, are the possible sources of the different reports. During the acceleration phase, the maximum velocity is at the lateral orifice for all of the boundary conditions. At the maximum flow, the pressure inlet and turbulent profile inlet fairly give the same results with the same maximum velocity at the main and lateral orifices downstream of the valve, while at the uniform profile inlet, the maximum velocity emerges from the lateral orifices. This trend continues until the end of the deceleration phase, while within the leaflet at the section near the inlet, the maximum velocity emerges from the main orifice for all of the time phases. Studying recirculation zones at the left and right sinuses shows a small zone appears after the leaflet housing at the early stage of systole and continues to grow while moving down. Another recirculation area forms right after the housing during the acceleration phase. During the deceleration phase, the bigger zone continues to grow until it fairly occupies the whole region. There are three main regions with higher WSS near the leaflets, at regions where the separated flow reattaches to the wall after sinuses, at the housing, leading edge, and trailing edges of the leaflets. Some new and innovative ideas have been discussed in this study that can provide more insight as to modeling of hemodynamics of MHVs.
Chapter 5: More explorations into the hemodynamics of the SJM valve

Elliptic St. Jude Bileaflet Mechanical Heart Valve

Chapter 5: Effect of the Heart Rate on the Hemodynamics of Bileaflet MHVs (SJM Valve)

5.1 Overview

The advent of SJM valves was regarded as an achievement as they soon became a major substitute for the replacement of diseased valves. They have been implanted in millions of patients in both the aortic and the mitral positions. However, they are associated with hemodynamic complications, such as high shear stress zones, turbulent flow, leaflet vortex shedding and leaflet gap jet flow during regurgitation flow. These non-physiological blood flow conditions may lead to red blood cell (RBC) lysis and thromboembolic complications for which the patients would need to take a lifelong anticoagulation therapy. To date, in almost all of the studies performed around the hemodynamics of bileaflet MHVs, a heart rate (HR) of 70-72 beats per minute (bpm) has been considered. In fact, the HR of ~72 bpm does not represent the entire normal physiological conditions under which the aortic or prosthetic valves function. The HRs of 120 bpm or 50 bpm may lead to hemodynamic complications such as plaque formation and/or thromboembolism in patients.

In this chapter we assess the hemodynamic performance of the SJM bileaflet MHV with an inner diameter of 27 mm in a HR range of 60 to 150 bpm in the opening phase. In chapter 4 of the thesis \cite{45}, an idealized computational platform was developed. It can be used to assess the hemodynamic performance of MHVs and was used for this study. The developed platform includes a computational domain, such as inlet and outlet lengths, anatomic aortic root and pressure inlet with mass flow outlet boundary conditions. Also, a similar model was developed for benchmarking of our results in which the SJM valve was replaced by a native aortic valve. The regions with high shear stress (SS) and wall shear stress (WSS), the recirculation zones, vortex shedding and velocity profiles were specifically studied. The flow field around the SJM valve was considered pulsatile, with three regimes i.e laminar, transient, and turbulent flow. To analyze the salient features of flow around the SJM valve, the shear stress transport (SST) low-Re two-equation turbulence models were implemented. Results clearly indicated that considering a HR of 70-72 bpm for hemodynamic analysis of
MHVs is not a safe assumption. More HR studies should be conducted in the opening and closing phase in order to assess the hemodynamic complications of an existing valve and new design.

5.2 Geometry

The current study is based on a bileaflet SJM valve with an inner diameter of 27mm (2R). The computational domain consists of an inlet length (5R), an outlet length (17R) and an aortic root which precisely follows the anatomy of the human aortic root. The inlet and outlet lengths provide a fully developed velocity profile at the section upstream of the leaflet and a zero gradient condition at the outlet of the domain (Figure 5.1a&b). The valve is considered fully open mainly because the opening and closing phases are considerably shorter (30-40 ms) than the period during which the valve remains open\(^\text{[22,83]}\). Also, since we are concerned with the peak values of the flow conditions in this study, this assumption seems to be reasonable. In the benchmark model, the SJM valve is replaced by the natural aortic valve as shown in Figure 5.1c.

![Figure 5.1](image)

**Figure 5.1.** (a) the SJM bileaflet mechanical valve and our design used in this study; (b) The aortic root with asymmetric and realistic sinuses viewed from the front; (c) The geometry of the aortic root including the aortic valve in the opening phase.

5.3 Temporal Boundary Condition

The key features are the values of the cardiac output (CO) and the stroke volume (SV) such that CO is calculated by knowing the HR and the SV. The end diastole volume (EDV) and the end systole volume (ESV) are also influential on the SV. It is important to relate the CO and the HR because the corresponding CO to a particular HR is used to define the boundary
conditions (BCs). In an experimental study on a dog’s heart, it was reported that as the HR increases, the CO initially increases and then remains constant and eventually decreases. However, the SV decreases as the HR increases. The increase rate of the HR and the decrease rate of SV are both important because if the rate of decrease of the SV is lower than the rate of increase of the HR, then the CO increases otherwise it decreases. The former happens when the HR is in the range of 50-110 bpm, and the latter happens when the HR is 200 bpm or higher. For the range of HR 90 to 200 bpm, when the HR increases the CO remains constant. This is because the increase in the HR cancels out the decrease in the SV within that range. In the case of human heart, however, experimental studies indicate that the CO and the SV show the same behavior as the HR increases [84–89]. Figure 5.2a, shows the values of SV with respect to HR reported by Stohr et al. [90] and Ekblom et al. [84] which was used to estimate the maximum velocity with respect to HR and determine the BCs. The temporal BC was set by deriving the peak systolic velocity and the time period according to the HR as shown in Figure 5.2b.

![Figure 5.2](image)

**Figure 5.2** (a) The change of stroke volume (SV) with the heart rate (HR) increase; (b) Temporal BC in the systolic phase

### 5.4 Results and Discussion

#### 5.4.1 Velocity Flow Field

The color-map of the velocity vectors and vortices at the sinuses regions and also downstream of the leaflets for two selected HRs (60 and 150 bpm) were shown in a plane
perpendicular to the leaflets in Figure 5.3. In both cases, the pattern of the recirculation zone development is similar during the acceleration phase. Vortices start from the valve housing and while they grow in size, they propagate and move downstream in the sinuses until the mid-systole. The recirculation zones at the sinuses region are more extended at higher HRs during the maximum flow, Figure 5.3c. The flow regime shows laminar behavior before mid-systole, but after mid-systole during the deceleration phase, it becomes turbulent [8]. The vortex shedding then occurs after the leaflet wake and subsequently affects the recirculation zones at the sinuses region [37]. The formation of the vortex pairs occurs after the sinuses and earlier for higher HRs as shown in Figure 5.3d&e. Recirculation zones in the sinuses are similar and have asymmetric growth pattern during the deceleration zone when the HR is low. However, for the high HR, under the effect of asymmetric complex 3-D flow and a stronger vortex shedding after the leaflets, the vortex at the left coronary sinus grows but the vortex at the right coronary sinus becomes considerably small at the end of the deceleration phase, Figure 5.3e&g.

Heart Rate of 60 bmp

Heart Rate of 150 bmp

(a) At time step 0.3T
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Elliptic St. Jude Bileaflet Mechanical Heart Valve

(b) At time step 0.4T

(c) At time step 0.5T

(d) At time step 0.6T

(e) At time step 0.7T
Figure 5.3. Velocity vectors for the low (60 bpm) and high (150 bpm) HRs demonstrated at seven time steps in a plane perpendicular to the leaflets.

Figure 5.4 shows the velocity vectors for the low (60 bpm) and high (150 bpm) HRs in different time phases viewed in a plane parallel to the leaflets. Two vortices are originated from the valve housing: one from the non-coronary sinus, which is stronger, and one across the non-coronary sinus on the housing. The vortex of the non-coronary sinus grows and moves downstream during the early stages of the acceleration phase, Figure 5.4a&b. As it moves away from the housing, it becomes bigger and affects the main stream flow, similar to the other vortex. This process continues until the end of the systolic phase for both high and low HRs. The other vortex is weaker such that when it collides with the main stream flow, strong shear layers are developed. In fact, the frequency of initiation, propagation and growth of the vortices downstream of the housing for the high HRs is larger than that for the low HRs as shown in Figure 5.4b to e. For the case HR = 150 bpm, the first vortex is initiated in the time-step of 0.4T (T is the total systolic time). In the next time step (t = 0.5T), it propagates, collides with the main stream, causes turbulent flow, and then is followed by the
next vortex, Figure 5.4b. At the low HR (60 bmp), the initiation and propagation of the first vortex is significantly slower than that in the high HR (150 bpm).

Heart Rate of 60 bmp

Heart Rate of 150 bmp

(a) At time step 0.3T

(b) At time step 0.4T

(c) At time step 0.5T
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(d) At time step 0.6T

(e) At time step 0.7T

(f) At time step 0.8T
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Elliptic St. Jude Bileaflet Mechanical Heart Valve

Figure 5.4. Velocity vectors for the low (60bpm) and high (150bpm) HRs demonstrated at seven time steps in a plane parallel to the leaflets. More details on the flow pattern at the center and sinuses are shown in Figure 5.5 by considering the profiles of velocity downstream of the valve in a plane normal and parallel to the leaflets for the four selected HRs, i.e., 60, 90, 130, 150 bpm. In low HRs, the maximum velocities of the main and side orifices are almost the same [45], but in high HRs, the maximum velocity emerges from the lateral orifices.

Figure 5.5a also shows an asymmetric flow pattern in the right and left coronary sinuses. The higher the HR, the stronger the vortex is at the right coronary sinus. However, the flow pattern in the left coronary sinus is different such that the formation of the regurgitation areas is observed as the HR increases. In the non-coronary sinus, the velocity profile almost
remains the same but higher values of HR lead to higher negative velocity of the regurgitation flow. In the region across the non-coronary sinus, the recirculation zone is limited to a considerably small zone as shown in Figure 5.5b.

5.4.2 Shear Stresses Distribution

The shear stress induced by the SJM valve into the blood cells was evaluated and compared to the threshold for the platelet activation, considered to be 10 Pa \([25,26]\). The maximum viscous shear stress in a plane normal and parallel to the leaflets for low and high HRs, i.e., 60 and 150 bpm, at three selected time-steps are shown in Figure 5.6 and Figure 5.7, respectively. Time-wise, results show the maximum shear stress happens at peak flow regardless of the HR (Figure 5.6b and Figure 5.7b). For the case HR = 60 bpm, the maximum shear stress is lower than 10 Pa except for some locations such as the leaflet leading edge, the housing and the regions after the sinuses near the wall at peak flow (time-wise). In other time phases other than peak flow, the shear stress is even lower, and the maximum viscous shear stress is 15 Pa at the leading edge of the leaflets at the peak flow. In other time phases, the same region is under the stress higher than 10 Pa which suggests that there is risk of platelet activation even at low HRs. Dumont et al. \([17]\) compared the risk of thrombogenicity in SJM and ATS valves using the Lagrangian particle tracking technique for the HR = 72 bpm in order to assess the accumulative shear stress, during the opening and closing phases. According to their results, about 1% of the platelets are subject to shear stress higher than the platelet activation threshold of 35 Pa.s (10 Pa for 3.5 s) for the both valves, which is consistent with our results.

The current study shows that at high HRs, e.g., 150 bpm, there are multiple locations downstream of the leaflets which are prone to thrombogenicity. Figure 5.6 and Figure 5.7 show that even during the acceleration phase, there are some regions exceeding the shear stress threshold, such as the valve housing and the hinges, the leaflet leading edges, and the regions after the sinuses with the shear stress of 70 Pa, Figure 5.8. During the acceleration phase, platelets are activated within these zones that will continue to experience a high shear stress downstream of the housing within the sinuses downstream of the leaflets, and downstream of leaflet vortex shedding regions at the following deceleration phase. In fact,
applying high shear stresses to the platelets in the acceleration phase followed by further exposure to the wake or vortex shedding regions in the deceleration phase may lead to thrombogenic complications.

Figure 5.6 and Figure 5.7 show that the maximum viscous shear stress increases by a factor of 5 as the HR increases from 60 to 150 bpm at the leading edge of leaflets, which in turn increases the risk of thrombogenicity in those regions. Given that in previous studies, only a fixed HR of 70-72 bpm was considered for analysis of the thrombogenicity or the RBC lysis, results justify that considering a fixed HR is inadequate for a precise evaluation of the hemodynamics of the MHVs. In fact, results suggest a higher risk of thrombogenicity for patients who have received a bileaflet MHV when the HR is high.
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Elliptic St. Jude Bileaflet Mechanical Heart Valve

(c) At time step 0.7T

Figure 5.6. The maximum shear stress at the mid-plane normal to the leaflets for low (60bpm) and high (150bpm) HRs at three selected time-steps

(a) At time step 0.3T

(b) At time step 0.5T
Elliptic St. Jude Bileaflet Mechanical Heart Valve

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Figure 5.7. The maximum shear stress at the mid-plane parallel to the leaflets for low (60bpm) and high (150bpm) HRs at three selected time steps

Figure 5.8. The maximum shear stress on blood at the leaflet leading edge with respect to the HR

5.4.3 Wall Shear Stress Study

In this study, two models were considered for comparison, (1) the platform including the SJM valve, and (2) the platform with no valve at all, which resembles the native aortic valve when the leaflets are wide open and attached to the aortic wall. Results show that there are two regions of high shear stress located after each sinus for both models with the native and the SJM valves, Figure 5.9a-d. For the case HR = 130 bpm, the highest wall shear stress appears to be on the left and right coronary sinuses which is 125 Pa in the model with the SJM valve and 90 Pa in the model with the native valve, Figure 5.9. The non-coronary sinus shows a lower WSS with the value of 90 Pa for the model with the SJM valve. This is
thought to be due to the effect of the leaflet on the flow near the walls, the association of the leaflet vortex shedding, and the sinuses recirculation zones.

**Figure 5.9.** (a) Wall shear stress at maximum flow for the HR of 130bpm in the model with the native aortic valve (left and right coronary sinuses are viewed); (b) in the model with the SJM valve (the left and right coronary sinuses are viewed); (c) in the model with the native valve (the non-coronary sinus is viewed); (d) in the model with the SJM valve (the Non coronary sinus is viewed); (e) WSS in the leaflets of the SJM valve.
Comparing the maximum WSS after the sinuses in the model with the SJM valve and the native valve shows minor differences (<5%) in the low HRs, but as the HR increases this discrepancy (~40%) increases significantly, Figure 5.10. Results indicate that the maximum WSS is 166 Pa in the model with the SJM valve at the HR of 150 bpm and 20 Pa in the model with the native valve. Results also show the WSS at the leaflets are higher at the side orifices compared to the main orifice which seems to be reasonable, Figure 5.9e. Also, for the case HR = 130 bpm, the maximum WSS is around 230 Pa as shown in Figure 5.10.

![Maximum WSS after sinuses](image)

**Figure 5.10.** Maximum wall shear stress with respect to the HR at region after the sinuses for the SJM valve and the native valves

### 5.5 Summary

Lack of adequate studies in the hemodynamic assessment of the MHVs at a variety of normal and physiological HRs was the motivation for this step of the thesis. Results suggest a high risk of thrombogenicity associated with the hemodynamic performance of MHVs when the HR is high (90-150 bpm). The high value of SS in the areas around the valve housing and leaflet leading edges and wakes, meets the threshold of platelet activation. As the blood flow around these zones during the acceleration phase, platelets are activated and will be exposed to even higher shear stress in the following deceleration phase. This issue is less severe in low HRs (60-90 bpm) but is significant in high HRs. Even though it was suggested that thromboembolic complications are mostly associated with the closing phase rather than the opening phase \[17,30\], results of the current study suggest that even the opening phase when HR is high may lead to thrombogenicity. More importantly, results of this study indicate that considering a HR of 70-72 bpm for hemodynamic analysis of MHVs is not a safe assumption.
to evaluate their hemodynamic performance. In fact, HR should increase up to 150 bpm in order to assess the hemodynamic complications of the heart valve during both the opening and the closing phases.
Chapter 6: The Hemodynamic Study on the Proposed ESJM in the Opening Phase

6.1 Overview

Bileaflet mechanical heart valves (MHVs), such as the St. Jude Medical (SJM) valve, are widely used due to their great hemodynamic performance compared to other MHVs. However, thrombogenicity and red blood cell (RBC) lysis still remain the potential issues associated with SJM valves [4,6,22,59–61]. The main objective of this thesis is to propose a new design for the housing of the SJM valves by applying 10% ovality to the housing. Using a customized computational model, the overall hemodynamic performance of the proposed elliptic SJM (ESJM) valve was studied [91]. As discussed in Chapter 3 of this thesis, results of the pilot study show clear hemodynamic improvements of the new design compared to the SJM valve. Results also indicate that the proposed design requires a more detailed hemodynamic study. To do so, a standard numerical platform was developed which enables us to study the details of the valve fluid dynamics in the opening phase, using the CFD method (Chapter 4 of the thesis) [45].

Here, the hemodynamics of the proposed design are assessed more in detail and compared with that of the SJM valve using the computational platform developed in Chapter 4. Flow features such as the valve pressure drop, the recirculation zone pattern and extension, areas of critical shear stress, flow field behavior during different time phases of acceleration and deceleration, and wall shear stress (WSS) of the two models (i.e., the proposed ESJM valve and the conventional SJM valve) were extensively discussed and hemodynamic improvements of the ESJM valve were reported against the SJM valve.

Results suggested both lower shear stress (SS) and wall shear stress (WSS) values and an overall improved hemodynamic performance in the proposed design. This improvement is characterized by lower values of SS and WSS in the regions downstream of the leaflets, a lower pressure drop across the valve, and smaller recirculation zones in the sinuses areas.
The proposed design may open a new chapter in the concept of design and hemodynamic improvement of the next generation of MHVs.

6.2 Method

6.2.1 Geometry

The geometry of the computational domain used in this study consists of an anatomic aortic root with three asymmetric sinuses, as shown in Figure 6.1 [45]. The inlet length of 5R and outlet length of 17R were incorporated to the geometry in order to ensure a fully developed velocity profile at the valve inlet in all time phases and to minimize the effect of the outlet boundary conditions on the flow around the leaflets [45]. An SJM valve with an inner diameter of 25 mm was chosen for the benchmark model, as shown in Figure 6.1b. The proposed ESJM model has an elliptical stent with a major diameter of 27 mm and a minor diameter of 23 mm (Figure 6.1c), corresponding to ~10% ovality of the housing [91]. Since the valve diameter was reduced from 25 mm in the SJM model to 23 mm in the ESJM model (minor axis), the leaflet length and valve profile were consequently reduced from 12.8 and 11 mm in the SJM model [18] to 11.2 and 9.5 mm in the proposed model, respectively, as shown in Figure 6.1d and e.

6.2.2 Temporal Boundary Conditions (BCs)

An HR of 70 bpm and cardiac output (CO) of 4.75 L/min was chosen for this study. The peak flow velocity is 97 mm/s, which results in the maximum Reynolds number of 7300 in the valve section. The systolic time period is assumed to be 288 ms, corresponding to approximately one third of the cardiac cycle [2,33]. The flow is transient and pulsatile and a sinusoidal waveform was chosen for the systolic flow that changes from zero mass flow at early systole to the maximum mass flow at the peak. It again drops to zero at the end of systole and remains unchanged during diastole, as shown in Figure 6.2.
Figure 6.1. An overview of the geometrical model, including the valve, (a) Aortic root inlet and outlet lengths, (b) 25 mm St. Jude Medical valve with three asymmetric sinuses, (c) Elliptic St. Jude Medical valve with three asymmetric sinuses, (d) and (e) Side view of the valve and leaflets in SJM and ESJM, respectively, with the view of the sections from inlet to outlet of the valve (Z1-Z5).
Figure 6.2. Temporal boundary conditions showing the mass flow rate ratio versus cardiac cycle.

6.2.3 Spatial Boundary Conditions

As it was discussed in Chapter 4, an inlet mass flow/outlet pressure BC, which is conventionally used for similar hemodynamic studies, may lead to an unrealistic profile of velocity, flow misbehavior near the leaflets and incorrect shear stress values [45]. It was also indicated that an inlet pressure/outlet mass flow BC (used in this study) may result in a more realistic velocity profile at the inlet and regions near the leaflets at different time phases, corresponding to laminar or turbulent regimes of the flow [45].

For more detail information about the numerical method used here please refer to chapter 4 of the thesis.

6.3 Results and Discussion

6.3.1 Velocity Flow Field

Figure 6.3a to l and Figure 6.4a to l show velocity vectors at different sections of the domain with respect to time. The velocity planes are located at the center of the model in normal and parallel directions to the leaflets. As expected, flow is laminar during the acceleration phase (0.3T to 0.4T) [33] and the flow pattern during this phase is similar in both SJM and ESJM models (Figure 6.3a to d and Figure 6.4a to d). Differences between the two models become apparent at the peak systole and during the deceleration phase (0.5T to 0.9T) when flow is turbulent. It occurs specifically at the sinuses region, which is well characterized by the presence of recirculation zones as shown in Figure 6.3e to l and Figure 6.4e to l.
Figure 6.3. Colored view of velocity vectors at different sections of the domain, moving in the normal direction to the leaflets at varying time phases, (a) to (d) the acceleration phase and the peak flow (e) and (f), and (g) to (l) the deceleration phase, for both SJM and ESJM models, respectively.
Figure 6.4. Colored view of velocity vectors in different sections of the domain parallel to leaflet direction at varying time phases i.e., (a) to (d) the acceleration phase and the peak flow (e) and (f), and (g) to (l) the deceleration phase, for both SJM and ESJM models, respectively.

In the proposed model, the main flow pattern and recirculation zones in the sinuses region appear to be different during the deceleration phase at both planes. The recirculation zones in the sinuses region are extended to the main flow area at the plane normal to the leaflets (Figure 6.3e to l), but these extensions are relatively smaller in the plane parallel to the leaflets (Figure 6.4e to l). Phase-wise, this trend becomes more apparent close to the end of systole. The recirculation zones in the left and right coronary sinuses are even more extended.
to the centerline in the ESJM model whereas they are smaller in the SJM model (Figure 6.3k to l). Furthermore, the recirculation zone in the non-coronary sinus is smaller in the ESJM model compared to that of the SJM model (Figure 6.4k to l).

At the normal view to the leaflets, the main flow has been narrowed downstream of the leaflets in the ESJM valve in which caused the main flow and shear layer at the wake of leaflets to orient towards the wall of the aortic root at the end of sinus region, Figure 6.3e to j. Conversely, this pattern is toward the center of the flow in the lateral view resulting in wider main flow area, Figure 6.4e to j. The characterization of the main flow is important for the estimation of shear stress (SS) and wall shear stress (WSS) in the regions downstream of the leaflets, which will be discussed later.

Figure 6.5 demonstrates the profile of velocity in section Z4 (Figure 6.1d) with respect to time in the sinus regions in the normal and parallel directions to the leaflets for both models. During the acceleration phase and the peak flow phase, the profile of velocity seems similar for both models (Figure 6.5a,b & Figure 6.5e,f), except for the areas close to the wall at peak flow (Figure 6.5b). In this region, the direction and the magnitude of the velocity are significantly different. The values of velocity in the regions close to the wall and in the sinuses region show a 50% difference, which in turn might significantly affect the shear stresses and WSS in those regions (Figure 6.5c,d,g and h). The recirculation zone in the left coronary sinus is reversed in the ESJM model, unlike to that of the right coronary sinus.

### 6.3.2 Valve Pressure Drop

As mentioned before, the proposed model results in 12.5% and 13% reduction in the leaflet length and the valve profile, respectively. Results indicate that the pressure drop between section Z1 and section Z5 of (Figure 6.1d), are ~ 260 Pa and ~210 Pa for SJM and ESJM models, respectively, which corresponds to ~20% improvement in pressure drop improvement in the proposed design.
6.3.3 Shear Stress Study

The exposure of blood cells to high shear stress zones plays a significant role in hemodynamic complications caused by a non-physiological flow in an implanted MHV. These complications are usually referred to as RBC lysis and thrombogenic complications. The critical values for RBC lysis and platelet activations were assumed to be 400 Pa and 10 Pa, respectively [23–26]. Results show that in the proposed model, the maximum shear stress during the opening phase does not exceed the critical value for RBC lysis but they do meet the threshold of the platelet activation. At the plane normal to the leaflets, the values of shear stresses are improved during both the acceleration and deceleration phases for the ESJM valve (Figure 6.6). The peak SS values at the leaflet leading edges of the ESJM valve are 17...
Pa and 21 Pa at 0.4T (Figure 6.6a and e) and 0.7T (Figure 6.6c and g), respectively, showing 10% improvement in the SS values in those regions compared to the SJM valve. Close to the valve housing, the peak SS is the SJM model is 9 Pa at 0.4T during the deceleration phase, whereas this value in the same location is 8 Pa in the proposed model (11% improvement). It should be noted that reported peak shear stress values are higher than 10 Pa and meet the threshold of the platelet activation for both models; however, the improved hemodynamics in the proposed design might lead to more hemodynamic improvements at higher heart rates and reduce the risk of thrombogenic complications\(^\text{[74]}\).

Figure 6.6. Shear stress distribution in the plane normal to the leaflets with respect to time phases, i.e., the acceleration phases (a) and (e), the peak flow phase (b) and (f), and the deceleration phase (c), (d), (g), and (h) for the ESJM model.
Figure 6.7 shows the contour of the SS distribution at the plane parallel to the leaflets at several selected phases. Results show that maximum SS values are lower in the proposed design compared to that of the SJM model in almost all time phases. In addition, downstream of the leaflets in the sinuses region, the ESJM valve offers a wider zero SS region compared to the SJM model. Downstream of the aortic root, however, the SS distribution shows similar behavior for all time phases in both models.

Figure 6.7. Shear stress distribution at different locations in the plane parallel to leaflets with respect to time, i.e., the acceleration phases (a) and (b), the peak flow phase (c) and (d), and the deceleration phase (e) to (f), for both SJM and ESJM models, respectively.

Figure 6.8 shows the profile of SS downstream of the leaflets and at section Z4 (Figure 6.1d) in the plane parallel to the leaflets for both models. During the acceleration phase, peak SS
near the wall and within the domain show noticeable improvements in the ESJM model (~30% improvement), (Figure 6.8a). At peak systole, in addition to lower SS values within the domain (~25% improvement), the ESJM model shows a wider area of the zero SS at the central flow in all time phases (Figure 6.8b). During the deceleration phase, the proposed model shows clear improvements in SS values near the wall and within the domain away from the wall. Results show ~25% improvements in reported SS values at the main flow and 40% improvement near the wall at this time phase.

![Image](https://via.placeholder.com/150)

**Figure 6.8.** Shear stress distribution downstream of leaflets at section Z4 of Figure 6.1d in the plane parallel to the leaflets with respect to time phases, i.e., the acceleration phases (a), the peak flow phase (b), and the deceleration phase (c), (d) for both SJM and ESJM models, respectively.

### 6.3.4 Wall Shear Stress (WSS)

Figure 6.9 shows the contour of WSS distribution with respect to time for the two models. During the acceleration phase, both valves show almost similar WSS distribution, as shown in Figure 6.9a and b. At peak systole, results display a region of maximum WSS after each sinus as shown in zone A of Figure 6.9c,d. In the ESJM valve, these zones move upstream toward the sinus region while in the SJM valve, they are close to the end of the sinus region. The maximum value of the WSS at this region is around 25 Pa for both valves. During the deceleration phase (0.7T), the pattern of WSS distribution changes drastically for both cases (Figure 6.9e to h), with the maximum SS of 14 Pa for the proposed design (5% improvement). At the end of the systole, the WSS distribution in the proposed model is 8.5
Pa in which shows up to 30% improvement, as shown in Figure 6.9g and Figure 6.9h. WSS results show a clear improvement on the maximum SS values at the sinuses areas and downstream of the sinuses.

Figure 6.9. Wall shear stress distribution near valve and aortic root with respect to time phases, i.e., the acceleration phases (a) and (b), the peak flow phase (c) and (d), and the deceleration phase (e) to (h) for both SJM and ESJM models, respectively.
6.4 Summary

A new design was proposed to the SJM bileaflet MHVs by applying ~10% ovality to the housing. In the previous study, the performance of the new design was compared with the conventional SJM valve using a customized numerical method, and showed a clear improvement in the regurgitation volume flow during the closing phase\(^\text{[91]}\). Here, the hemodynamic performance of the ESJM model was extensively studied in the opening phase using a more sophisticated numerical platform that is based on CFD\(^\text{[45]}\). Results show clear improved hemodynamics in the proposed design, including up to 40% improvement in the shear stress values and up to 30% in wall shear stress valves. This may result in less thrombogenic complications and RBC lysis associated with SJM valves. In addition, geometrical changes to the valve housing, caused 12.5% and 13% reduction on the leaflet length and valve profile respectively, which can reduce the exposure of blood cells to valve artificial materials and consequently reduce blood flow complications, as well as improvements in the valve pressure drop. Results indicate that there is ~20% pressure drop improvement for the new design compared to the SJM valve. The results of the current study suggest that the proposed design could be taken to the next level for further hemodynamic assessment.
Chapter 7: Summary, Conclusions and Future Work

7.1 Summary

Bileaflet mechanical heart valves (MHVs), such as the St. Jude Medical (SJM) valve, are widely used due to their great hemodynamic performance compared to other types of MHVs. Numerous studies can be found in literature in which the overall hemodynamic performance of the SJM valve has been evaluated and compared to other types of bileaflet MHVs. They showed that the simple and reliable design of the SJM valve results in a lower level of blood complications with an improved hemodynamic performance. However, despite several design modifications to the SJM valve, it still suffers from multiple hemodynamic issues such as blood complications, cavitation, high shear stress zones, highly turbulent flow, high pressure drop, and regurgitation flow compared to the native valve. Such hemodynamic complications may lead to thrombogenicity and red blood cell (RBC) lysis, which still remain the main issues associated with SJM valves and necessitate that the patient goes under lifetime anticoagulation therapy.

The main objective of this thesis was to propose a novel design for the SJM valve in order to improve its hemodynamic performance. This design modification is characterized by an oval housing and a reduced valve profile compared to the conventional SJM valve in which 10% ovality is applied to the stent whereas its perimeter remains constant. It was hypothesized that the proposed design delivers improved hemodynamics by providing lower shear stress zones, lower pressure drop across the valve, reduced regurgitation flow volume, and reduced valve dynamic response time.

First, the overall performance of the proposed design was evaluated and compared with that of the conventional SJM valve in the closing phase, using the novel numerical model (chapter 3). The proposed numerical model was first introduced by Mohammadi et al. in 2006 where unsteady Bernoulli’s equations and equations of motion are coupled in a finite strip method platform. The valve dynamic response time, the regurgitation flow, etc., were evaluated through a pilot study.
Results of the pilot study indicated that the new design needs a more detailed study of the flow in order to assess its hemodynamic specifications compared to the SJM valve. To do so, computational fluid dynamics (CFD) method was used, a powerful and established method in the hemodynamic assessment of bileaflet mechanical heart valves (MHVs). It is well recognized that CFD allows reliable physiological blood flow simulation and measurements of flow parameters. However, there is no standard computational platform in literature that can be used for the detail hemodynamic assessment of the new design. For example, in almost all of the modeling studies to date on the hemodynamics of bileaflet MHVs, a velocity (mass flow) based boundary condition and an axisymmetric geometry for the aortic root have been assigned which, to some extent, are erroneous. Also, there have been contradictory reports of the profile of velocity in downstream of leaflets, i.e., in some studies, it is suggested that the maximum blood velocity occurs in the lateral orifice while other studies postulated that the maximum velocity in the main orifice and lateral orifices are identical.

Chapter 4 explains the development of a novel computational platform in order to assess the hemodynamic performance of bileaflet MHVs during the opening phase using CFD method. This study demonstrates the importance of the exact anatomical model of the aortic root and the realistic boundary conditions in the hemodynamics of bileaflet MHVs. The model considered in this study is based on the St. Jude Medical (SJM) valve in a novel modeling platform. Through a more realistic geometrical model for the aortic root and the SJM valve, a new set of boundary conditions were developed in order to be used for the assessment of the hemodynamics of aortic bileaflet MHVs. The results of the current study are significant for the design improvement of conventional bileaflet MHVs and for the design of the next generation of prosthetic valves. The designed numerical platform was used as a standard numerical platform.

To date, in almost all of the studies performed around the hemodynamics of the bileaflet MHVs, a heart rate (HR) of 70-72 beats per minute (bpm) has been considered. In fact, the HR of ~72 bpm does not represent the entire normal physiological conditions under which the aortic or prosthetic valves function. The HRs of 120 bpm or 50 bpm may lead to hemodynamic complications, such as plaque formation and/or thromboembolism in patients.
The objective of the chapter 5 was to assess the hemodynamic performance of a SJM bileaflet MHV with an inner diameter of 27 mm in a HR range of 60 to 150 bpm in the forward flow phase. In addition to the SJM valve model, a similar model was developed for benchmarking of our results in which the SJM valve was replaced by a native aortic valve. The regions with high shear stress (SS) and wall shear stress (WSS), the recirculation zones, vortex shedding and velocity profiles were specifically studied.

Finally (Chapter 6), the hemodynamics of the proposed design was assessed more in detail and compared with that of the SJM valve using the computational platform developed at the previous step of the thesis (chapter 4). Flow features such as the valve pressure drop, the recirculation zone pattern and extension, areas of critical shear stress, flow field behavior during different time phases of acceleration and deceleration, and wall shear stress (WSS) of the two models (i.e., the proposed ESJM valve and the conventional SJM valve) were extensively discussed and hemodynamic improvements of the ESJM valve were reported against the SJM valve.

As presented in Appendix C, we further applied the proposed computational platform for the assessment of the effect of the HR changes on the hemodynamics of our new design. Results of this study shows a clear hemodynamic improvement of the proposed design, particularly at the elevated HRs (>90bpm).

7.2 Conclusions

7.2.1 Pilot study

A novel design was proposed to the SJM conventional valve by applying 10% ovality to the housing while its perimeter remains constant. Results of the pilot study suggest a clear improvement in the hemodynamic performance of elliptic SJM valves over the conventional models. The velocity of the regurgitation flow in the elliptic model show an average increase of 11% compared to the conventional SJM valve. The higher velocity of the regurgitation flow in the elliptic SJM model leads to a shorter closing phase. The two effective parameters to calculate the regurgitation flow volume are (1) the closing phase time and (2) the velocity of the blood. Results show that even though the velocity of the regurgitation flow in the
Elliptic SJM model is higher than that of the conventional SJM model, the backflow volume in the two models is comparable.

### 7.2.2 The Novel Computational Platform

Numerical simulation of St. Jude Medical bileaflet mechanical heart valves with realistic three asymmetric sinuses were studied at this step of the thesis. First, three different possible boundary conditions were studied and the velocity profile downstream of the valve was compared with reports from other studies. Most of the studies in literature considered a turbulent fully developed fixed velocity or uniform velocity profile at the inlet of the computational domain which can be a source of error. Since the flow regime is either laminar or turbulent during a cycle, then the valve inlet profile of velocity changes accordingly. Here it was shown that pressure inlet BC with mass flow outlet, can give more realistic profile at different time phases, taking the effects of both flow regime and geometry into consideration. This is more important when regurgitation flow or fluid/solid interaction (FSI) with moving leaflets studies being considered.

According to results, during the acceleration phase, the maximum velocity is at the lateral orifice for all of the boundary conditions. At the maximum flow, the pressure inlet and turbulent profile inlet give fairly the same results with the same maximum velocity at the main and lateral orifices downstream of the valve, while at the uniform profile inlet, the maximum velocity emerges from the lateral orifices. This trend continued until the end of the deceleration phase, while within the leaflet at the section near the inlet, maximum velocity emerges from the main orifice for all of the time phases. Studying recirculation zones at the left and right sinuses shows a small zone appears after the leaflet housing at the early stage of systole and continues to grow while moving down. Another recirculation area forms right after the housing during the acceleration phase. During the deceleration phase, the bigger zone continues to grow until it occupies almost the whole region. There are three main regions with higher WSS near the leaflets, at regions where the separated flow reattaches to the wall after sinuses, at the housing and leading edge and trailing edges of the leaflets. Some new and innovative ideas have been discussed in this study that can provide more insight as to modeling of hemodynamics of MHVs.
7.2.3 Effect of HR on the Hemodynamics of the SJM Valve

Lack of adequate studies in the hemodynamic assessment of the MHVs at a variety of normal and physiological HRs was the motivation for this step of the thesis. Results suggested a high risk of thrombogenicity associated with the hemodynamic performance of MHVs when the HR is high (90-150 bpm). The high value of SS in the areas around the valve housing, leaflet leading edges and wakes, meets the threshold of the platelet activation. As the blood flows around these zones during the acceleration phase, platelets are activated and will be exposed to even higher shear stress in the following deceleration phase. This issue is less severe in low HRs (60-90 bpm) but is significant in high HRs. Even though it was suggested that thromboembolic complications are mostly associated with the closing phase rather than the opening phase\cite{17,30}, results of the current study suggest that when the HR is high even forward flow may lead to thrombogenic complications. More importantly, results of this study indicates that considering HR of 70-72 bpm for hemodynamic analysis of MHVs, is not a safe assumption to evaluate the hemodynamic performance of MHVs. In fact, HR should increase up to 150 bpm in order to assess the hemodynamic complications of the heart valve during both the opening and closing phases.

7.2.4 Hemodynamic Study of the New Design (ESJM Valve)

The hemodynamic performance of the ESJM model was extensively studied in the opening phase using a more sophisticated numerical platform that is based on CFD\cite{45}. Results show clear improved hemodynamics in the proposed design, including up to 40% improvement in the shear stress values and up to 30% in wall shear stress valves. This may result in less thrombogenic complications and RBC lysis associated with SJM valves. In addition, geometrical changes to the valve housing, caused 12.5% and 13% reduction on the leaflet length and valve profile respectively. This can reduce the exposure of blood cells to valve artificial materials and consequently reduce blood flow complications, as well as improvements in the valve pressure drop. Results indicate that there is ~20% pressure drop improvement for the new design compared to the SJM valve. The results of the current study suggested that the proposed design could be taken to the next level for further hemodynamic assessment including closing phase study, leaflet shape design and hinge design. In addition,
the hemodynamic study of the proposed design at high HRs (>90 bpm) indicate that our
design is less prone to the hemodynamic complications than the SJM valve (Appendix C).

7.3 Recommendations for the Future Work

7.3.1 New Design Features

In this thesis, a new design was introduced to the SJM valve and its hemodynamic
advantages against the conventional design were discussed in details. The main feature of the
new design is the oval housing of the valve; however, there are other design aspects that need
to be done such as housing shape, leaflet shape design, hinge design and location of the
hinges. The shape of the new design housing is similar to the conventional SJM valve and
has a flat shape; however, considering a converging diverging profile can improve the
dynamics of the flow around the housing and provide a smooth converging flow with a no
separation diverging flow. In addition, this design can compensate a portion of the pressure
loss caused by the friction and flow separation. Leaflets of the current design are flat, but
they can have curved shape similar to that of CarmoMedic valve in order to provide better
forward flow. In addition, the hinges can have an open pivot similar to the ATS valve instead
of recessed pivot in SJM valve to minimize the shear stress values during the closing phase
and reduce the risk of RBC lysis and thrombogenic complications. Moreover, changing the
location of the hinges and moving the leaflets away from each other can provide more central
flow, lower valve pressure drop and less shear stress at the tip of the leaflets.

7.3.2 Numerical Study

Since the leaflets are fully open in a major portion of time during systole, fixed leaflets were
assumed at the maximum opening angle for the forward flow analysis and it showed some
hemodynamic improvement for the ESJM valve. However, a detailed fluid-solid interaction
study can results in more insights into fluid dynamics for the forward flow as well as the
regurgitation flow. In addition, modeling the whole ventricle to generate the physiological
inlet flow to the valve and modeling flexible aortic root with aortic arc at the outlet can be a
huge advantageous in assessing the hemodynamic performance of the implanted valve;
however, this cannot be achieved just by CFD simulation and requires FSI simulation which consequently needs huge RAM with clustered CPUs.

In this thesis the SST turbulence model was employed which is a two equation RANS model. This model is effective in modeling boundary layer near the surface using the k-ω model and the bulk flow using k-e model. Using more accurate numerical methods such as LES and DNS, the spontaneous values for flow variable can be estimated rather than average values obtained by RANS method. These models can provide more flow details around the implanted MHV and in particular the flow in the hinges area and the gap between the leaflet and the housing.

7.3.3 Experimental Study

After the phase of design optimization, the prototype of the new design can be fabricated and tested in a series of experimental studies in order to evaluate the performance of the valve under physiological conditions. Design features such as the oval housing, leaflet shape and hinge design can be experimentally studied and results can be compared with those of the computational study.
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References
Elliptic St. Jude Bileaflet Mechanical Heart Valve


Appendices

Appendix A : Hemodynamic Performance of PHVs

The first PHV was implanted as early as 1952. Since then, more than 50 different artificial heart valve designs have been introduced to the market \[5\]. There are around 300,000 heart valve replacements annually around the world, in which more than half of them are MHVs \[4,60,74\]. It is estimated that the rate of PHV implantation is increasing by the rate of 10-12% annually, in which can result in an approximate of 850 000 PHV annual implantation by 2050 \[5,92,93\].

PHVs come with different types (i.e. MHVs and bioprosthetic valve) and sizes from 19 cm for younger patients up to 27mm for adults. shows results of the in vitro study for the hemodynamic performance of different types and sizes of PHVs at the aortic position \[2,94\]. Results show that independent from the valve type, the bigger valve size show higher regurgitation volume. Results also indicate that MHVs have higher regurgitation volume (i.e. 6.2 to 10.8 ml/beat depending of the valve type) compared to that of boiprosthetic valves (i.e. lower than 4 ml/beat). However, the effective orifice area and performance index of MHVs are far better than bioprosthetic valves, in particular, stented valves which impose higher pressure drop to the passing blood flow compared to nonstented valves. Moreover, St. Jude Medical valve (Figure 1.3e) represents higher EOA and PI compared to all other types of valves. This valve has EOA and PI of 4.09 and 0.71 respectively, for the 27 mm size.
**Table A.2. Hemodynamic performance of different types of PHVs in the Aortic position (In-Vitro study)** [2,94].

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Valve</th>
<th>Size</th>
<th>Regurgitation Volume (ml/beat)</th>
<th>EOA(cm²)</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caged Ball</td>
<td><em>Starr-Edwards 1260</em></td>
<td>27</td>
<td>5.5</td>
<td>1.75</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>4.3</td>
<td>1.62</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21</td>
<td>2.5</td>
<td>1.23</td>
<td>0.36</td>
</tr>
<tr>
<td>Tilting Disk</td>
<td><em>Medtronic-Hall</em></td>
<td>27</td>
<td>9.6</td>
<td>3.64</td>
<td>0.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>8.4</td>
<td>3.07</td>
<td>0.62</td>
</tr>
<tr>
<td></td>
<td></td>
<td>23</td>
<td>7.3</td>
<td>2.26</td>
<td>0.54</td>
</tr>
<tr>
<td>Bileaflet</td>
<td><em>St. Jude Medical Standard</em></td>
<td>27</td>
<td>10.8</td>
<td>4.09</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>9.9</td>
<td>3.23</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td></td>
<td>23</td>
<td>8.3</td>
<td>2.24</td>
<td>0.54</td>
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<td></td>
<td></td>
<td>21</td>
<td>6.8</td>
<td>1.81</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19</td>
<td>6.8</td>
<td>1.21</td>
<td>0.43</td>
</tr>
<tr>
<td>Stented Bioprosthesis</td>
<td><em>Carpentier-Edwards Porcine</em></td>
<td>27</td>
<td>&lt;3</td>
<td>1.95</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>&lt;2</td>
<td>1.52</td>
<td>0.31</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21</td>
<td>&lt;2</td>
<td>1.28</td>
<td>0.37</td>
</tr>
<tr>
<td>Nonstented Bioprosthesis</td>
<td><em>Freestyle Medtronic Porcine</em></td>
<td>27</td>
<td>&lt;4</td>
<td>3.75</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>&lt;4</td>
<td>3.41</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td></td>
<td>23</td>
<td>&lt;3</td>
<td>2.69</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21</td>
<td>&lt;2</td>
<td>2.17</td>
<td>0.63</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19</td>
<td>&lt;2</td>
<td>1.84</td>
<td>0.65</td>
</tr>
</tbody>
</table>

HR = 70 bpm; CO = 5 L/min typical; 120/80 mm Hg aortic pressure
EOA: Effective orifice area, PI: Performance index
Appendix B: Fluid Mechanics of Heart Valves

The heart valve function is controlled by the fluid motion and pressure gradient caused by the contraction and relaxation of heart muscles; therefore, understanding details of fluid mechanics of heart valves and governing equations (i.e. conservation of mass, momentum and energy), is crucial for explaining the complicated function of heart valves. In addition, Computational Fluid Dynamics (CFD) can be used in predicting the function of diseases heart valve and improving the performance of the implantation PHV\textsuperscript{[8,95,96]}. The basic governing equations in fluid mechanics consist of conservation of mass, momentum and energy and all other equations such as Bernoulli’s equation or Goline formula for EOA, are derived from these principal equations which will be discussed later.

The continuity equation expresses that mass cannot be either created or destroyed. In the other word, the sum of all of the passing masses through control surfaces (CS) is equal to the change of the mass within the control volume (CV). In case of incompressible flow such as blood flow in which the density is constant, the conservation of mass can be expressed as the conservation of volume, Equation (B-1).

$$\oint_{c,s} \overrightarrow{U} \cdot d\overrightarrow{A} + \frac{\partial}{\partial t} \iiint_{c,v} dv = 0$$

Where $\overrightarrow{U}$ is the fluid velocity on the control surface, $A$ is the surface area and $dv$ is the element of volume inside the CV. This equation can be simplified to Equation (B-2) in case that there is only one inlet and one outlet and flow is steady, such as aortic valve where during the forward flow the inlet of the valve is on the ventricle side and outlet is on the aortic root, Figure 1.5, and flow is nearly steady at mid systole\textsuperscript{[87]}.

$$u_{in}A_{in} = u_{out}A_{out}$$

Where $u$ is the valve instantaneous inlet/outlet velocity at peak flow or average velocity during systole, normal to the inlet/outlet cross section area ($A$). Equation (B-2) can be utilized
to calculate the area at the desired location (i.e EOA) where velocity is measured by using echocardiographic technique $[^{87}]$.

Another principal equation which is frequently used in fluid mechanics of heart valves is the Bernoulli’s equation. This equation is a simplified form of the energy or momentum equation when the flow is steady, incompressible, frictionless (inviscid), in the absence of mechanical work or heat transfer. It states that in an idealized flow condition, the total mechanical energy at each point of the domain is constant; therefore, the sum of pressure energy, kinetic energy and potential energy is constant, Equation (B-3).

\[ p + \frac{1}{2} \rho u^2 + \rho gh = P_{\text{total}} = \text{Constant} \]  

(B-3)

Where \( p \) is the pressure energy per unit volume, \( \frac{1}{2} \rho u^2 \) is the kinetic energy per unit volume and \( \rho gh \) is the gravitational potential energy per unit volume.

The change in the potential energy is negligible in heart valves since the change in the level of the flow from inlet to outlet is ignorable; therefore, the Bernoulli’s equation is simplified into the exchange of kinetic and pressure energies, meaning that any increase/decrease in the velocity within the valve leads to decrease/increase in the static pressure and vice versa.

Left ventricle provides the required mechanical energy for the blood circulation in body by increasing the blood pressure. This pressure is converted to the kinetic and gravitational energy downstream in the circulation. Figure B.1 demonstrates changes in the left ventricle pressure during one cardiac cycle $[^{12,97}]$. During diastole, process A in the figure, the mitral valve is open and the left ventricle (LV) volume increases with low pressure rise when it is filled with the blood (diastole). After mitral valve closure until aortic valve opening, isovolumetric contraction, the pressure rises considerably while the LV volume is almost constant. Aortic valve opens at point 3 by the contraction of the LV when the ventricle pressure exceeds that of aorta and remains open until when the valve pressure gradient becomes positive (systole). During isovolumetric relaxation, LV pressure decreases significantly while its volume is not changing. The area enclosed in the left ventricle P_V
diagram, Figure B.1, represents the mechanical energy generated by LF during one cardiac cycle\cite{98}.

The generated energy in the form of pressure rise at the LV, has to overcome the energy losses in the circulation. The main sources of energy losses in the circulation are viscous loss, turbulent loss and flow separation loss. Regurgitation flow is considered another form of mechanical energy loss since it imposes more work to LV in order to provide the desired cardiac output. In order to incorporate energy losses in the Bernoulli’s equation, the modified equation is used in which considers the effect of unsteadiness and losses in the circulation, Equation (B-4)\cite{94,97}.

\[
p_1 + \frac{1}{2} \rho u_1^2 + \rho g h_1 = p_2 + \frac{1}{2} \rho u_2^2 + \rho g h_2 + \int_1^2 \rho \frac{\partial V}{\partial t} ds + \varphi \quad (B-4)
\]

Where S is the distance between point 1 and 2, and \( \varphi \) represents the energy losses in forms of pressure losses. Equation (B-4) also infers that the pressure drop cannot always be considered as pressure loss since the gravitational or kinetic energy changes contribute into pressure changes. To be more accurate, the velocity and level of the section 1 and 2 of the
flow should be the same and flow should be steady or at peak flow, in order to consider the pressure drop as same as the pressure loss.

**Viscous Losses:** Viscous energy losses originate from the friction between the adjacent fluid particles with different speeds and friction between the wall and the flow proximal to its surface. This form of energy loss depends on the viscosity and density of the fluid, surface roughness, flow rate and diameter and length of the vessel [94].

**Turbulent Losses:** Another form of the energy loss in circulation is turbulent losses. Turbulent flow presents where inertia forces are higher than viscous forces; therefore, disturbances caused by the surface roughness or irregularities near the surface, initiate changes in the inertia of the adjacent flow in which cannot be damped by the viscous forces. The disturbances near the surface then propagate and affect the flow elsewhere in the flow. The collision and friction of the fluid components with different speeds at the turbulent flow, eventually is wasted by converting the kinetic energy into heat. The initiation and propagation of turbulent flow depend on the geometry and ratio of fluid inertia forcer to the friction forces, known as Reynolds number, Equation (B-5).

\[
Re = \frac{\rho ud}{\mu}
\]  

(B-5)

Where \( \rho \) and \( \mu \) are fluid density and viscosity, \( u \) is the velocity and \( d \) here is the vessel diameter. The transient Re number for steady flow in a pipe is approximately 2000 and for the fully turbulent flow is considered around 6000 [94,99]. In the pulsatile flow condition however, the transient to the turbulent flow not only depends on Re and geometry, but the ratio of the local acceleration to friction forces in the flow, known as Womersley number (Wo), Equation (B-6).

\[
w_o = \frac{d}{2} \sqrt{\frac{\rho \omega}{\mu}}
\]  

(B-6)

Where \( \omega \) is the angular frequency of the pulsatile flow.
In an in vivo study of aortic flow disturbances, Nerem et al.\textsuperscript{[100]} showed that the transient Re number for the pulsatile flow is around 8000 in which is higher than that of steady flow. Turbulent losses can be avoided by keeping the Re number below the transient Re number, removing the sharp edges that can initiate disturbances in the flow and decreasing the surface roughness \textsuperscript{[94]}.

**Flow Separation Losses:** This form of energy loss plays a major role in the mechanical energy loss in circulation, in particular, stented heart valves and MHVs. Flow separation happens when the positive pressure gradient in the flow overcomes the low inertia flow near the surface and cause the reverse flow at these regions. The sharp edges in the geometry or sudden expansion in the flow are the major causes of flow separation and usually are accompanied with vortices downstream of the separation point. Such losses in the flow can be minimized by avoiding sharp edges in the geometry, providing gradual expansion in the flow and initiating turbulent flow since it increases the inertia of the flow and delays the separation \textsuperscript{[94]}.

Figure B.2 shows the schematic view of the pressure and kinetic energy conversions and energy loss at the flow within the stented geometry such as MHVs. Flow goes under contraction before the stenosis (1-2) and experiences a sudden expansion after the stenosis (3-4). During the contraction, the major source of the energy loss is the viscous friction loss. At this section flow does not undergo separation since the pressure gradient is negative; however, in case of sudden contraction, flow separation can happen after the contraction since the momentum of the flow tends to continue convergence. At this section, flow goes under considerable pressure decreases while velocity increases remarkably \textsuperscript{[94,97]}.

The velocity of the flow within the stenosis does not change since the area is constant (Continuity Equation); however, the pressure decreases as viscous friction losses dissipate a portion of the total energy.
**Figure B. 4.** View of the pressure, kinetic and total energy changes at a converging diverging geometry (stenosis), with flow contraction (1-2), flow within the stented geometry (2-3) and sudden expansion with flow separation after the throat (3-4).

Flow eventually experiences a sudden expansion with flow separations after the stenosis (3-4). At this section, there is a considerable energy loss due to flow separation in form of kinetic energy loss. As it can be seen from Figure B.4, the velocity decreases significantly from section 3 to 4 with flow separation while the pressure increases slightly (pressure recovery phenomena)\(^{10,94}\). In an ideal condition with no friction losses and mild expansion where there is no flow separations, the total energy is conserved at this section and flow experiences expansion with velocity decrease due to increase in the area and pressure increase according to the Bernoulli’s equation (Equation B-4), this has been shown with dashed line from section 3 to 4 in the Figure B-2.
Appendix C : Effect of the Heart Rate on Hemodynamics of the Elliptic St. Jude Medical Valve; A computational Study

C.1 Overview

In this thesis, a new design was proposed for the housing of the SJM valve (elliptic SJM valve or ESJM valve) and a comparison was conducted of its hemodynamic performance with the conventional valve using a customized numerical method in the closing phase (Chapter 3) and using the CFD method during the opening phase (Chapter 6) at the HR of 70 bpm. Results clearly indicated hemodynamic improvements in the proposed design over the SJM valve. The improvements were characterized by lower SS and WSS distributions around the valve and leaflets, and lower valve pressure drop compared to that of the SJM design.

In chapter 5, the hemodynamic performance of the SJM valve was numerically assessed at the elevated HRs (70-150 bpm), and showed that the hemodynamic complications considerably aggregate at higher HRs (>90 bpm). Here, the hemodynamics of the proposed design will be compared with the SJM and Native valves at a range of HRs, i.e. 70, 90 and 130 bpm, during the forward flow. The numerical method is based on the computational platform which was developed for the hemodynamic assessment of MHVs using the CFD method (Chapter 4). Results clearly indicate hemodynamic improvements of the new design compared to the conventional valve even at the elevated HRs (>90 bpm). The improvements are characterized by lower SS and WSS distributions near the valve and leaflets. Therefore, the proposed design provides better hemodynamics compared to the SJM valve which may result in a lower level of blood complications.

C.2 Method

Geometry

The geometrical model consists of an anatomic aortic root with three asymmetric sinuses, as shown in Figure C. 8. An inlet length of 5R was incorporated into the geometry in order to ensure a fully developed flow entering the valve. In addition, an outlet length of 17R was considered to minimize the effect of the outlet boundary condition on the flow field around
the valve \[^{45}\]. The SJM and native valve with an inner diameter of 25 mm were chosen for the benchmark model, Figure C. 8b,d. The new design (ESJM valve) is proposed by applying a 10% ovality to the housing of the SJM valve, which results in a major diameter of 27 mm and a minor diameter of 23 mm as shown in Figure C. 8c \[^{20}\].

**Figure C. 8.** The geometrical model, including the valve, Aortic root inlet and outlet lengths (a); 25 mm St. Jude Medical valve with three asymmetric sinuses (b); Elliptic St. Jude Medical valve with three asymmetric sinuses(c); Native valve from the ventricle view (d); side view of the valve and leaflets in SJM , with the view of the sections from inlet to outlet of the valve (Z1-Z5) (e); side view of ESJM and Native valves (f, g)

Since the opening and closing time of the leaflets (20-30 ms for 70 bpm) are considerably shorter than the fully open phase (200-300 ms), leaflets have been fixed at the maximum
opening angels of 85° for SJM and ESJM valves \cite{2}. In the case of the native valve, no leaflets have been considered at the center of the flow since they are attached to the wall of the aorta in the maximum opening position, Figure C. 8d \cite{101}.

**Boundary Conditions (BCs)**

**Temporal Boundary Condition**

In order to calculate the mass flow rate at each HR, the function of the stroke volume (SV) with respect to HR needs to be derived from the literature. According to the clinical studies, the performance of the left ventricle in ejecting the blood increases up to the HR of 160-170 bpm, then reaches a maximum at 170-190 bpm, and eventually decreases after 190 bpm \cite{84–89}. The left ventricle function results in a similar trend for the SV-HR function as shown in Figure C. 9a. By knowing the SV for each HR, the peak systolic velocity and the systolic time period can be calculated accordingly, Figure C. 9b \cite{101}.

![SV-HR](image)

**Figure C. 9.** Trend of the SV-HR (a); Temporal BC in the systolic phase for 70 bpm (b)

**Spatial Boundary Conditions**

The BCs are based on the numerical platformer which was previously developed for hemodynamic studies \cite{45}. In that study it was shown that the mass flow/velocity inlet BC which has been used in most of computational studies about the MHVs may results in flow
misbehavior near the valve and incorrect SS and WSS values \cite{45}. It was also indicated that the pressure inlet BC with mass flow outlet may result in a more realistic flow behavior near the valve. The same BC has been used in this study.

*Turbulence modeling*

In this study, the shear stress transport model (SST) was used for turbulence modeling. SST is a two equation RANS model which utilizes the advantages of the low Reynolds number k-\( \omega \) near the solid surface and high Reynolds number k-\( \varepsilon \) and the bulk flow \cite{101,45}. The solver is commercial finite volume based software, ANSYS CFX 14.5 \cite{68}.

*Mesh generation*

In order to have better accuracy in the k-\( \omega \) model and to capture the viscous sublayer accurately, the y+ of “1” with 12 number of inflation layer has been used here \cite{45}.

*Criteria for Thrombogenicity and RBC lysis*

There are plenty of studies in the literature that have assessed the effect of the MHVs on the thrombus initiation and RBC damage \cite{50,38,35}. They report that the general criteria for the hemodynamic complication induced by the implanted artificial valve is the viscous shear stress and residual time \cite{33}. The critical shear stress value for the RBC lysis was reported to be 400 Pa for 1 to 620 ms, and for the platelet activation is 10 Pa for 2.5-3.5 ms \cite{23,24}.

*C.3 Results*

*Velocity flow filed*

Figure C. 10 shows the peak flow velocity field near the valve in parallel to the leaflet view for both the SJM and ESJM valve. It indicates that sinus recirculation zones have been limited in the non-coronary sinus for the proposed design compared to the conventional valve in which these zones have been extended to the main flow area \cite{20}. This is more obvious at higher HRs, i.e. 90 and 130 bpm, Figure C. 10c-f. In addition, there is more interaction of the leaflet vortex shedding and sinus recirculation zones in the SJM valve which may cause higher SS distribution at shear layers downstream of the valve, Figure C. 10e,f. Results of the flow filed study also indicate that strong interaction of the sinus recirculation zones and the
leaflet vortex shedding in the conventional design, not only increase the SS values at these regions but also increase the blood cell exposure time which may enhance the risk of RBC lysis and clot formation.

Figure C. 10. Peak flow velocity flow filed in colored view for the SJM and ESJM valves from the side view for 70, 90 and 13 bpm

**Shear stress distribution**

Figure C. 11 shows the distribution of the SS at selected sections downstream of leaflets for both SJM and ESJM valves at mid-systole. Results indicate a clear reduction in SS distribution for the proposed design compared to the SJM valve. For instance, maximum SSs at a section downstream of the leaflet tips are 5.1, 7.2, and 12.8 Pa for the SJM valve while they are 4.9 Pa (4% decrease), 6.9 Pa (4.2% decrease), and 12.1 Pa (5.4% decrease) for the
proposed design at 70, 90, and 130 bpm, respectively. Downstream of the sinus regions and close to the outlet, maximum SSs near to the aortic wall are 4.8, 6.9, and 17.8 Pa for the conventional valve while they are 4.5 Pa (6.2% decrease), 6.4 Pa (7.2% decrease), and 16 Pa (10.1% decrease), for the ESJM valve at 70, 90, and 130 bpm, respectively. Results clearly confirm a trend of an increase in maximum SS discrepancies between two cases with respect to HR increase. In addition, the proposed design shows a wider range of the zero SS distribution downstream of the leaflets compared to the SJM valve [20].

![Shear Stress Distribution](image)

**Figure C. 11.** Peak flow SS distribution at different locations in the plane parallel to leaflets for SJM and ESJM valves at 70 bpm (a,b); 90 bpm (c,d) and 130 bpm (e,f)

Figure C. 12 demonstrates the profile of peak flow SS distribution downstream of the leaflets and at the midline of the plane parallel to the leaflets (at section Z4 of Figure C. 8e) for both models at 70, 90, and 130 bpm. It shows lower maximum SS distributions at this section for
the proposed design compared to the SJM valve; particularly close to the wall of the sinus region. The maximum SS in vicinity to the sinus wall at this section is reported to be 6.9, 9.9, and 9.8 Pa for the SJM valve while they are 4.7 Pa (32% decrease), 4.3 Pa (56% decrease), and 8.2 Pa (20% decrease) for the proposed design at 70, 90, and 130 bpm, respectively.

![Graphs showing SS distribution](image)

**Figure C. 12.** Peak flow shear stress distribution downstream of leaflets at section Z4 of Figure C. 8e in the plane parallel to the leaflets for 70, 90 and 130 bpm for both SJM and ESJM models.

Results of the SS study indicate that there is high risk of thrombogenicity at elevated HRs (>90 bpm) for the SJM valve \[^{20,101}\]. Results also confirm that there is a considerable SS decrease for the proposed design compared to the SJM valve, which reduces the risk of platelet activation, particularly for high HRs.

**Wall shear stress study**

The distribution of WSS close to the valve and aortic root has been shown in Figure C. 13. There are regions of maximum WSS after each sinus (Zone A at Figure C. 13 a-d) for both valves at HRs lower than 90 bpm \[^{20}\]. In the ESJM valve, these zones move upstream of the aortic root while moving away from each other, Figure C. 13 b,d \[^{20}\]. These concentrated zones tend to become a distributed strip after sinus the region rather than concentrated zones for higher HRs (>90 bpm), Figure C. 13 e,f.
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Figure C. 13. Wall shear stress distribution near valve and aortic at 70 bpm for SJM valve (a) and ESJM valve (b), 90 bpm for SJM valve (c) and ESJM valve (d), 130 bpm for SJM valve (e) and ESJM valve (f)
Figure C. 14 shows the maximum WSS after sinus regions (zone A of Figure C. 13) for Native, SJM, and ESJM valves at selected HRs. Results indicate that there is low discrepancy between the three cases for the maximum WSS at these regions at 70 bpm, i.e. 23 Pa for the Native valve and 24 Pa for the proposed design, which shows 4% improvement compared to the conventional valve. At 90 bpm, the maximum WSS discrepancy increases between the three cases, i.e. 48 Pa for the Native valve and 53 Pa for the proposed design, which shows 11.6% improvement compared to the conventional valve. And at 130 bpm, the maximum WSS is 98 Pa for the Native valve and 125 Pa for the proposed design, which shows 11.6% improvement compared to the conventional valve.

Results of the WSS study indicate a clear hemodynamic improvement in the proposed design compared to the SJM valve. They show that the maximum WSS discrepancy between the proposed design and SJM valve increase from 4% at 70 bpm to 9-11% at higher HRs (>90 bpm). Results also confirm a low discrepancy in the three cases (~4%) with respect to the maximum WSS after sinus regions at low HRs, i.e. 70-72 bpm, which have been considered as a standard HR in hemodynamic studies. However, at higher HRs (>90 bpm) the discrepancy increases up to 20% between the Native valve and proposed design.

**Figure C. 14.** Maximum wall shear stress with respect to the HR at regions after the sinuses (Zone A of Figure C. 12) for Native, SJM and ESJM valves
C.4 Summary

In this thesis, a new design was proposed for the housing of the St. Jude Medical valve [91,20]. The hemodynamic performance of the proposed design was assessed during the closing phases and forward flow and showed its hemodynamic improvements at a HR of 70 bpm. Here, the hemodynamics of the proposed design were compared with the conventional valve and Native valve at elevated HRs, i.e. 70,90, 130 bpm.

Results of the flow field study confirm that the sinus recirculation zones have been limited to the sinus region in the proposed design while they have been extended to the main flow for the SJM valve, particularly at HRs higher than 90 bpm. In addition, at higher HRs, there are more interactions between the sinus recirculation zones and leaflet vortex shedding for the conventional valve, which not only increase the SS values at these regions but also increase the blood cell exposure time and may enhance the risk of clot formation.

Results of the SS study indicate that there is high risk of thrombogenicity at elevated HRs (>90 bpm) in the SJM valve [20,101]. Results also confirm a lower risk of platelet activation for the proposed design since there is a considerable SS decrease in the ESJM valve compared to the conventional valve.

There are three regions after each sinus with maximum WSS for all three cases. Results show that the maximum WSS at these regions is higher for the SJM valve compared to the proposed design and Native valve for all of the HR ranges. Results indicate that the maximum WSS discrepancy between the proposed design and SJM valve increase from 4% at 70 bpm to 9-11% at higher HRs (>90 bpm).

The findings of this study indicate a clear hemodynamic improvement for the proposed design compared to the conventional valve. In addition, results show that considering the HR of 70-72 bpm for the hemodynamic assessment of MHVs is not a safe assumption since the risk of blood cell damage considerably increases at elevated HRs (>90 bpm) [101].