SIMULATION OF BLOOD FLOW THROUGH TRANSCATHETER HEART VALVE (THV) USING ANSYS FLUID STRUCTURE INTERACTION

By:
MOHAMAD HAZIQ BIN JUMA'AT
(Matrix no: 131459)

Supervisor:
Dr. Mohamad Aizat Abas

May 2019

This dissertation is submitted to
Universiti Sains Malaysia
As partial fulfilment of the requirements to graduate with honors degree in
BACHELOR OF ENGINEERING (MECHANICAL ENGINEERING)

School of Mechanical Engineering
Engineering Campus
Universiti Sains Malaysia

DECLARATION

I hereby certify that this thesis which I now submitted for assessment is entirely my own work, that I have exercised reasonable care to ensure that the work is original and does not to the best of my knowledge breach any law of copyright and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

Name of student	:	Mohamad Haziq Bin Juma'at	Signature:
Date	:	29 May 2019	
Witnessed by	:	Dr. Mohamad Aizat Abas	Signature:
Date	:	29 May 2019	

ACKNOWLEDGEMENT

All praise to the God the Al-Mighty that allow me with His blessings and guidance to finally finish my final year project. First and foremost, I would like to express my deepest appreciation to everyone whom directly or indirectly involved throughout the period of completing this project especially my beloved parents for the prayers and continuous support in my whole life.

Next, I would like to deeply express my gratitude to my supervisor Dr. Mohamad Aizat Abas. Thank you for accepting me as one of his FYP's students. This project was really hard for me and this dissertation would not be possible without his continuous guidance, encouragement and endless suggestions proposed by him for me to continue my research for this project. I really thankful and enjoyed this project as it is something new for me. Also, a big thanks to Dr. Norizham Bin Abdul Razak for his guide and help during the PIV experiment.

I also wish to express my sincere thanks to Dr. Aizat's master students Muhammad Haziq Abu Bakar and Aqil Azman, whom step by step helped and guide me from the start until the end of this project. There are tons of knowledge that I gained starting from designing, simulation and PIV experiment and more. When I with them, I always feel that there are lots room of improvement that can be applied in this study, it helps to develop my critical thinking.

Lastly, I would like to thank you all of the technician Mr. Zaimi, Mr. Norijas, Mr. Kamarul, Mr. Zafril, Mr. Hashim, Mr. Mahmud, Mr. Zulkhairi and all of my friends who helped me doing this project. Again, thank you very much, I wouldn't able to complete it on my own. I hope everything will end well for everyone.

TABLE OF CONTENTS

Declaration ..... **i**

Acknowledgement ..... **ii**

Table of Contents ..... **iii**

List of Tables ..... **v**

List of Figures ..... **vi**

List of Abbreviation ..... **x**

Abstrak ..... **xi**

Abstract ..... **xii**

CHAPTER 1 INTRODUCTION **1**

1.1 Overview 1

1.2 Research Background 1

1.3 Problem Statement 5

1.4 Objectives 6

1.5 Research Scope 6

1.6 Thesis Outline 6

CHAPTER 2 LITERATURE REVIEW **7**

2.1 TAVI First Human Implantation 7

2.2 History Review of Transcatheter Heart Valve Implantation 8

2.3 Current Transcatheter Heart Valve 12

2.4 Deployment Approaches 14

2.5 Particle Image Velocimetry (PIV) 16

CHAPTER 3 METHODOLOGY **19**

3.1 Establishment of CAD Model 19

3.2 Simulation 29

3.3 Experiment 39

CHAPTER 4 RESULTS AND DISCUSSION 47

4.1 Verification of Simulation Model 47

4.2 Velocity Contour 52

4.3 Doppler Velocity Index (DVI) 55

4.4 Pressure Contour 58

4.5 Vectors 61

4.6 Wall Shear Stress 64

CHAPTER 5 CONCLUSION 68

5.1 Future Work 69

CHAPTER 6 REFERENCES 70

APPENDICES 74

LIST OF TABLES

Table 1. 1 shows the recommended device and aortic annulus diameter pairings [5]. 4

Table 2. 1 shows the Hemodynamic Results and Doppler Gradient at the Last Follow-Up [9] 8

Table 3. 1: Parameters and assumed values to describe 26 mm SAPIEN XT frame [21]. 23

Table 4. 1 shows the maximum wall shear stress for different curvature and proximity minimum size 49

Table 4. 2: Comparison of velocity contour and vector between simulation and experiment 50

Table 4. 3: Velocity contour development over a cardiac cycle 52

Table 4. 4 shows the coordinates of the 10 selected points 56

Table 4. 5 shows the each points velocity at the valve's inlet and outlet from simulation and experiment 57

Table 4. 6 shows the average velocity and DVI at the valve inlet and outlet 57

Table 4. 7 shows the pressure contour development over a cardiac cycle 59

Table 4. 8 shows the blood flow direction over a cardiac cycle in simulation 61

Table 4. 9 shows the blood flow direction over a cardiac cycle in PIV experiment . 64

LIST OF FIGURES

Figure 1. 1 shows (A) The location of the heart in the body. (B) Cross-section of a healthy heart and its inside structure 1

Figure 1. 2 illustrates the normal and diseased aortic valve due to calcification thickening during open and closed 3

Figure 1. 3 shows (A) a normal mitral valve. The valve separates the left atrium from the left ventricle. (B) a mitral valve prolapse (C) a closeup view of mitral valve prolapse (D) a mitral valve that allows blood to flow back into the left atrium. 3

Figure 2. 1 shows the Carpenter-Edwards porcine tented xenograft valves conduit ... 7

Figure 2. 2 shows the conduit repair for ccTGA pulmonary atresia 7

Figure 2. 3 illustrates the lateral still-frame angiograms. Abolition of stenosis and regurgitation after pulmonary valve implantation[10] 9

Figure 2. 4 shows the Cribier-Edwards percutaneous valve. An equine pericardial valve is sewn within a stainless-steel frame. A fabric skirt covers the bottom third of the stent [11] 10

Figure 2. 5 illustrates the (A) Balloon-mounted prosthetic valve positioned adjacent to native valve calcification. (B) Partial inflation of the deployment balloon. (C) Full inflation of the deployment balloon [11] 11

Figure 2. 6 shows the 23, 26 and 29 mm Edwards SAPIEN XT [13] 12

Figure 2. 7 shows the Edwards SAPIEN 3 13

Figure 2. 8 shows the Edwards SAPIEN 3 Ultra 13

Figure 2. 9 illustrates the transfemoral approach through an incision in leg [15] 14

Figure 2. 10 illustrates the transfemoral, transaortic and transapical procedure approaches [17] 16

Figure 2. 11 illustrates the divided section at the aortic sinus by TAVI. The two spaces are (1) a diminished native sinus and (2) neo-sinus . The neo-sinus is a region between the native and transcatheter aortic valve leaflets where thrombus has been observed [19] 17

Figure 2. 12 illustrates the local flow stagnation and neo-sinus washout results from in-vitro model. (A) Local maximum velocity fields by each spatial location over 9 cardiac cycles. (B) Neo-sinus washout curves for 2 transparent TAVR (GT-TAVR) models and surgical control valve at 5L/min cardiac output [19] 18

Figure 3. 1 shows the Perspex model. (a) Right side Perspex. (b) Left side Perspex.19

Figure 3. 2 illustrates the 3D model constructed in Solid Work 2018 software 20

Figure 3. 3 shows the actual 29 mm SAPIEN XT. [21] 21

Figure 3. 4 illustrates the SAPIEN XT additional labelled parameters [21] 22

Figure 3. 5 illustrates the SAPIEX XT parameterized geometry [21] 22

Figure 3. 6 shows the 3D model of 29 mm SAPIEN XT frame 24

Figure 3. 7 shows the SAPIEN XT frame with cuff attached. 25

Figure 3. 8 illustrates the triple leaflet model presented in open isometric view (A) open top view (B) open side view (C) closed side view (D) and closed top view (E) prosthetic valve in closed top view for comparison purpose. [22] 26

Figure 3. 9 shows the isometric view of tri-leaflet 3D model. 27

Figure 3. 10 shows the top view of the tri-leaflet 3D model. 27

Figure 3. 11 shows the 3D model of 29 mm SAPIEN XT 28

Figure 3. 12 shows the drawing details for a complete 29 mm SAPIEN XT. 28

Figure 3. 13 shows the inlet velocity profile in two periods. [24] 31

Figure 3. 14 shows the tree outline of the Design Modeler 32

Figure 3. 15 shows the symmetric view of the lefts side heart and SAPIEN XT imported design 33

Figure 3. 16 shows the symmetric view of fluid domain created 33

Figure 3. 17 shows the faces selected (a) Inlet, (b) Outlet, (c) Heart wall, and body selected (d) fluid zone for named selection. 34

Figure 3. 18 shows the skewness and orthogonal quality mesh metrics spectrum 35

Figure 3. 19 shows the meshed fluid domain 35

Figure 3. 20 shows the close up views of the mesh at THV section..... 36

Figure 3. 21 shows the Carreau model setup 37

Figure 3. 22 shows inlet boundary condition..... 38

Figure 3. 23 shows the fully opened rapid prototyped SAPIEN XT 39

Figure 3. 24 shows the two Perspex blocks of the left side heart 40

Figure 3. 25 shows the experimental model for PIV measurement..... 40

Figure 3. 26 illustrates the schematic diagrams of the flow system 41

Figure 3. 27 shows the PIV experimental setup 42

Figure 3. 28 shows the real-time instantaneous flow rate of the experiment 43

Figure 3. 29 illustrates the measurement principle of PIV flow diagram [26] 44

Figure 3. 30 illustrates the correlation of the two interrogation areas, I1 and I2, results in the particle displacement DX, represented by a signal peak in the correlation C(DX). [26]..... 45

Figure 3. 31 shows the region of interest (ROI) and masks applied using PIVlab.... 46

Figure 4. 1 shows the net mass flow rate (kg/s) of inlet and outlet 48

Figure 4. 2 shows the velocity profile at inlet..... 48

Figure 4. 3 illustrates the maximum wall shear stress for different mesh model 49

Figure 4. 4 illustrates the position of V_{LVO} and V_{jet} in a prosthetic mitral valve [29]55

Figure 4. 5 shows the selected 10 points (A-J) for velocity data extraction..... 56

Figure 4. 6 shows the doppler parameters of prosthetic (Pr) mitral valve function [28] 57

Figure 4. 7 shows the isometric and top views of wall shear stress..... 65

Figure 4. 8 shows the wall shear stress along the boundary intersection of left side heart and 29 mm SAPIEN XT. 66

Figure 4. 9 shows the distribution of wall shear stress at 0.1 s..... 67

LIST OF ABBREVIATION

THVR	Transcatheter Heart Valve Replacement
SHV	Surgical Heart Valve
THV	Transcatheter Heart Valve
FSI	Fluid Stucture Interface
PIV	Particle Imnage Velocimetry
DVI	Doppler velocity index
SE	Self-expandable
BE	Balloon expandable
PET	Polyethylene terephthalate
TAVI/TAVR	Transcatheter Aortic Valve Implantation/Replacement
SAVR	Surgical Aortic Valve Replacement
CAD	Computer Aided Drawing
RVSP	Right Ventricular Systolic Pressure
RVOT	Right Ventricle Outflow Tract
AHV	Artificial Heart Valve
CT	Computed Tomography
CFD	Computational Fluid Dynamics
UDF	User Defined Function
LVOT	Left Ventricle Outflow Tract
VTI	Velocity Time Integral

ABSTRAK

Semenjak kaedah angioplasti menjadi alternatif kepada kaedah pembedahan untuk mengantikan injap jantung yang berpenyakit selepas pertama kali ia diuji dengan manusia pada tahun 2000. Pelbagai kajian dan modifikasi telah dijalankan untuk menambah baik kaedah angioplsti ini sehingga kini. Namun demikian, memandangkan kaedah ini masih baru, adakah keberkesanan kaedah angioplasti ini setanding dengan kaedah pembedahan untuk menggantikan injap jantung yang berpenyakit.

Justeru itu, di dalam projek ini, 29 mm SAPIEN XT model bersifat tiga dimensi (3D) telah direka bentuk untuk simulasi dengan menggunakan perisisan Pengkomputeran Dinamik Bendalir (PDB). Simulasi injap jantung angioplasti ini dilakukan semasa injap tersebut berada didalam jantung. Hal ini kerana, dengan cara tersebut corak aliran darah didalam jantung dapat dilihat mirip seperti kehidupan sebenar. Data-data seperti aliran darah, halalaju, tekanan dan vortex direkod untuk dianalisa. Simulasi yang telah dijalankan selepas itu disahkan dengan menjalankan ujian Particle Image Velocimetry (PIV) untuk membandingkan Doppler Velocity Index (DVI) injap jantung.

ABSTRACT

As transcatheter heart valve replacement (THVR) progressively became an alternative to surgical heart valve (SHV) from it first implantation in 2000, numerous research and lots of improvement has been made and still on going until now. However, does the effectiveness of the transcatheter heart valve (THV) is on par with the mechanical heart valve and other prosthetic heart valves.

In this research project, the three-dimensional 29 mm SAPIEN XT inside the left side heart is designed and simulated using computational fluid dynamics software. The simulation is carried out by using ANSYS Fluid Structural Interaction (FSI) to analyse the fluid field, velocity, pressure, vortices and wall shear stress obtained. The simulation is validated by Particle Image Velocimetry (PIV) experiment by comparing the prosthetic mitral valve inlet velocity, outlet velocity and Doppler Velocity Index (DVI) of the THV.

CHAPTER 1 INTRODUCTION

1.1 Overview

In this chapter, the common heart valve diseases occurred in human heart will be discussed. The objectives, problem statements and research scope of the project are presented in 1.5 until 1.6.

1.2 Research Background

1.2.1 Heart Valve

Heart has four main valves which are mitral, tricuspid, aortic and pulmonary valves. Mitral valve and tricuspid valve located at lower chamber controlling blood flow from atria to the ventricles, while aortic valve and pulmonary valve located at upper chamber control blood flow out from ventricles. The atria consist of left or right atrium act as receiving chamber of heart by receiving blood flowing back to the heart. The ventricles that consist of left or right ventricles pump the blood out from the heart, respectively.

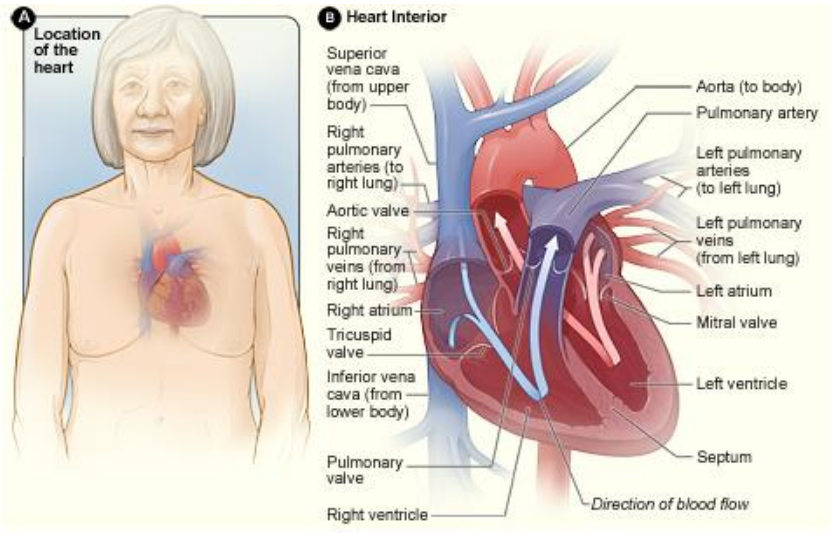

Figure 1. 1 shows (A) The location of the heart in the body. (B) Cross-section of a healthy heart and its inside structure

1.2.2 How the Heart Valves Work

The blood flows in human body in form of pulse or heartbeat. At the start of each heartbeat, the body and lungs fill the two heart's upper chamber atria. The mitral and tricuspid valves are located at the bottom of the chambers interconnecting the atriums and ventricles. When the blood builds up in the atria, these valves (mitral and tricuspid) open to allow the blood to flow into the ventricles.

After a brief of delay, as the ventricles begin to contract, the mitral and tricuspid valves will shut tightly. This is to prevent the blood from flowing back to atria. As the ventricles contract, the blood will be pumped through the pulmonary and aortic valves. The pulmonary valve opens to allow blood to flow from the right ventricle into the lungs to be oxygenated.

At the same time, the aortic valve opens to allow the oxygenated blood from the pulmonary arteries to flow into the aorta. The aorta carries oxygen-rich blood to the whole body. After that, as the ventricles relax, the pulmonary and aortic valves shut tightly to prevent blood from flowing back into the ventricles and the cycles continue.

1.2.3 Heart Valve Disease

Heart valve disease occurred when one of the valves does not function properly, either the valve is not opened or closed correctly. This will disturb the flow of the blood through the heart. There are several diseases that can cause the heart to be malfunction such as stenosis, regurgitation, atresia, rheumatic valve disease, infective endocarditis and congenital heart valve [1].

However, the three-basic kind of problems are regurgitation, stenosis and atresia. Regurgitation or backflow occurs if a valve doesn't close tightly. The blood will leak back into the previous chambers rather than flowing forward through the heart or into an artery. Next, stenosis occurs if the flaps of a valve thicken, stiffen or fuse together. This prevents the heart valve from fully open thus there is not enough blood flows through the valve.

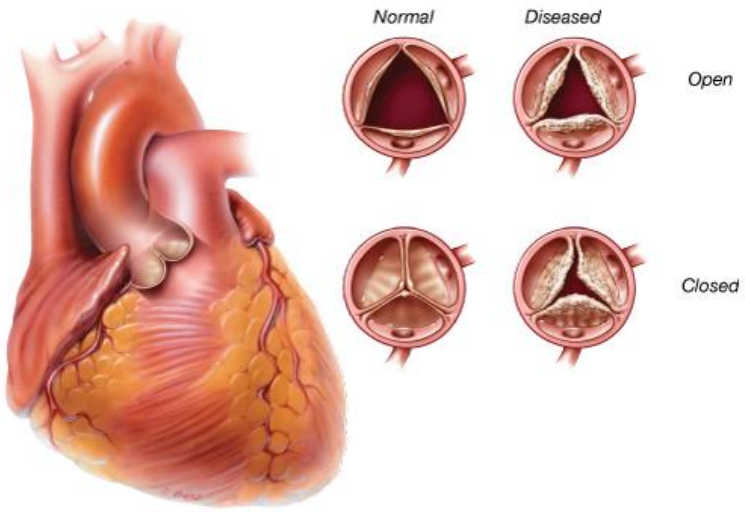

Figure 1. 2 illustrates the normal and diseased aortic valve due to calcification thickening during open and closed

For mitral regurgitation, it is often due to prolapse when the soft flaps of the mitral valve fail to close together smoothly. Instead of closing properly, the part of the valve bulges into the upper chamber, allowing blood to flow in the wrong direction and causes regurgitation.

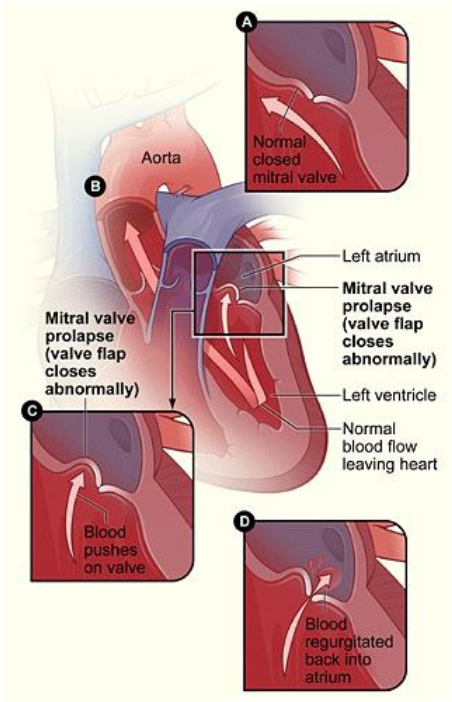

Figure 1. 3 shows (A) a normal mitral valve. The valve separates the left atrium from the left ventricle. (B) a mitral valve prolapse (C) a closeup view of mitral valve prolapse (D) a mitral valve that allows blood to flow back into the left atrium.

1.2.4 Transcatheter Aortic Valve Implantation (TAVI)

In normal circumstances, surgical method is the method used for heart disease problems. The patient will undergo open heart surgery to replace the diseased valve. However, if the patient's risk to undergo surgery is too high due to medical or anatomical reasons and considered inoperable, the treatment option will be percutaneous catheter-based method (TAVI).

The minimally invasive procedure where a bioprosthetic valve is inserted through a catheter and implanted within the diseased native valves. There are two main options for deploying a TAVI device which are (1) self-expandable (SE) and (2) balloon-expandable (BE). SE devices rely on the super-elastic material properties of the frame to expand, as opposed to BE devices which are deployed using balloon inflation [2].

There are advantages to both types of devices where the BE devices are guaranteed to reach full expansion while SE devices generally have a lower delivery profile allowing for safer delivery of the device. In a further study, the SE devices can be retracted after being semi-sheathed if the device is incorrectly positioned during deployment [3].

The size of the aortic root and valve are vary for every patient, so there a different diameter sizes of valve available. Besides that, there are only four well-known companies selling TAVI devices commercially in UK (CE mark approved): Medtronic, Edward Lifesciences, Boston Scientific and Direct Flow. The focused TAVI in this thesis is balloon expandable (Edwards Lifesciences SAPIEN XT) since it can transfemorally deployed in the mitral valve [4].

Table 1. 1 shows the recommended device and aortic annulus diameter pairings [5]

SAPIEN XT diameter	Recommended annulus diameter
23 mm	18-21 mm
26 mm	22-24 mm
29 mm	25-28 mm

1.2.5 Fluid-structure Interaction

Fluid-structure interaction (FSI) is a multiphysics coupling between the laws that describe fluid dynamics and structural mechanics. This phenomenon is characterized by interactions – which can be stable or oscillatory – between a deformable or moving structure and a surrounding or internal fluid flow.

When a fluid flow encounters a structure, stresses and strains are exerted on the solid objects that can lead to deformations. These deformations can be quite large or very small, depending on the pressure and velocity of the flow and the material properties of the actual structure.

A lot of scientific and industrial area in which interaction between different substances act as important role, like airflow along an aircraft, particle flow, deformation of artery, heart and also heart valve had been done by researchers from different fields. FSI method approach also has been done using computational method such as finite element.

1.3 Problem Statement

Heart valve disease occurs when one or more of the valves in your heart do not work correctly. Normally, the heart valves help control the flow of blood through the chambers of the heart. With heart valve diseases usually aortic stenosis and regurgitation, a valve may not close properly or may not open fully. This affects blood flow and may require your heart to work harder with each heartbeat. In many cases, the symptoms of heart valve disease can be managed with drugs, but eventually the valves may need to be repaired or replaced.

For many years surgical aortic valve replacement (SAVR) was the standard treatment for the heart valve disease before transcatheter aortic valve replacement (TAVR) being introduced. Nowadays, TAVR or TAVI are comparable to SAVR in terms of choice since it doesn't require incision of the chest to access the heart, it's just needed a minimally invasive catheter-based procedure inserted through a blood vessel. Nevertheless, there are still questions regarding the effectiveness and durability of the TAVI compared to mechanical valve and bioprosthetic valve.

1.4 Objectives

The objectives of this research are as follow:

- To simulate real scale transcatheter heart valve (THV) on mitral valve using ANSYS.
- To validate the simulation findings with particle image velocimetry (PIV).
- To observe the regions and vortices formation which can lead to thrombus formation.

1.5 Research Scope

The three main parts of this project are design, simulation and experiment. In the design part, the TAVI are composed of three parts which are frames, cuff and leaflet. The geometries of the frame are obtained by previous research [6] from 29mm actual model SAPIEN XT.the model are designed using SolidWorks to be fitted in the damaged heart valve. Next, the model is used to undergo simulation part. The software used for this project is ANSYS Fluent. Finally, the particle image velocimetry (PIV) experiment is conducted for validation with the simulation results.

1.6 Thesis Outline

This thesis is divided into five main chapters, introduction, literature review, methodology, result and discussion and conclusion. Chapter 1 describes the general overview and the motivation for the work performed in this thesis. It explains about human heart valve, heart valve disease, transcatheter heart valve and computational method used in this research. Chapter 2 describes the histology of transcatheter heart valve and studies that related to this research topics. Chapter 3 describes the procedures and technique used to develop the left side heart and transcatheter heart valve model using computer aided drawing (CAD) software. Then, the process to simulate left side heart and heart valve model using numerical simulation will be shown in this chapter. The experimental procedure used to validate simulation results is also presented. In Chapter 4, the results obtained from the numerical simulation and experiments are presented and discussed. Chapter 5 summarizes this research and recommends an outlook for future work. Finally, a list of publication contribution is given to end this chapter.

CHAPTER 2 LITERATURE REVIEW

2.1 TAVI First Human Implantation

Before the TAVI became well known, the first percutaneous heart valve (PHV) was developed by (Percutaneous Valve Technologies Inc). The method was introduced and reported by Bonhoeffer et al. [7] in 2002. The main objective of his research is to invent a new nonsurgical technique instead of open-heart surgery for valve replacement. The research was performed by using bovine jugular vein trimmed to the delivery system mounted within a stent, the device is then being inserted in 11 lambs via internal jugular approach. The result was 7 out of devices were successfully implanted deducing that implantation can be done instead of open-heart surgery.

After a while, the technique was further studied and first human transcatheter implantation in pulmonary valve [8]. The valve was implanted in a 12 years old boy with pulmonary atresia and ventricular septal defect, who had severe stenosis and insufficiency of prosthetic conduit from the right ventricle to the pulmonary artery. The prosthetic bovine jugular mounted on a specially designed balloon-expandable stent was inserted via transfemoral approach replacing the degenerated valve conduit. The attempt of the first human percutaneous replacement result was a success where the pulmonary insufficiency was almost eliminated with subsequent reduction in the right ventricular dimension.

Figure 2. 1 shows the Carpenter-Edwards porcine tented xenograft valves conduit

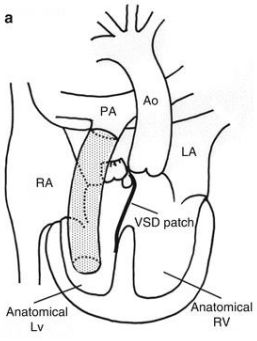

Figure 2. 2 shows the conduit repair for ccTGA [1]pulmonary atresia

[1] ccTGA congenitally corrected transposition of the great arteries

2.2 History Review of Transcatheter Heart Valve Implantation

2.2.1 Clinical Experience

After the successful implantation on the first human, the method was further tested on eight patients by Bonhoeffer et al. [9] two years later. Seven of them were children age between 10 to 17 years old and one adult age 38 years old. All of the implantation was successful and the follow up shows that pulmonary insufficiency significantly improved even though two stent fracture were reported.

Table 2. 1 shows the Hemodynamic Results and Doppler Gradient at the Last Follow-Up [9]

Patients	Conduit or Valve Type	Systolic Pressure Ratio Between Right Ventricle and Aorta (RV Peak Systolic Pressure)		Pulmonary Artery Pressures Distal to Conduit (Systolic/Diastolic/Mean)		Doppler Gradient at Last Follow-Up (m/2)
		Before	After	Before	After	
1	18-mm Carpentier-Edward valved conduit	85% (80 mm Hg)	66% (50 mm Hg)	30/8/16	30/16/20	3
2	18-mm GoreTex non-valved conduit	71% (70 mm Hg)	33% (40 mm Hg)	22/6/16	28/14/20	3
3	18-mm Hancock valved conduit	71% (65 mm Hg)	33% (40 mm Hg)	25/8/15	30/14/18	3
4	RVOT reconstruction with Dacron patch	70% (90 mm Hg)	60% (50 mm Hg)	60/10/18	40/10/22	3.3
5	27-mm Hancock valve	33% (35 mm Hg)	33% (32 mm Hg)	28/12/16	32/16/20	2
6	16-mm Carpentier-Edward valved conduit	90% (95 mm Hg)	50% (54 mm Hg)	31/8/15	32/14/19	3
7	20-mm Hancock valved conduit	85% (85 mm Hg)	60% (55 mm Hg)	30/8/16	30/16/20	3.5
8	18-mm Carpentier-Edward valved conduit	90% (72 mm Hg)	38% (32 mm Hg)	28/16/20	16/8/20	2.5

RV = right ventricular; RVOT = right ventricular outflow tract.

From the table above, we can see that the Right Ventricular Systolic Pressure (RVSP) overall decreases. Even though the pressure is quite high, the RSVP of the patients generally decrease with the highest 55 mmHg.

RVSP is a term used to estimate that the pressure inside the artery that being supplied by the right ventricle. The pressure was measured by inserting a small tubes catheter into the heart chamber or echocardiography.

In our lungs, the blood picks up the oxygen and releases carbon dioxide. This oxygen-rich blood then flows through blood vessels in our lungs to the left side of our heart. So, normally the blood pressure in our lungs is much lower since the blood flows easily through the vessels in the lungs.

The normal mean pulmonary artery is 12 to 25 mmHg. If the pulmonary artery pressure 40 mmHg from the echocardiogram, it means that the mean pulmonary artery pressure is greater than 25 mmHg and therefore considered pulmonary hypertension.

The valve design was then acquired by Medtronic from Bonhoeffer who was a specialist in medical technology. The Bonhoeffer's valve design and method were evaluated in 59 patients[10]. The method was deduced a success after being implanted in 58 out of 59 patients with pulmonary regurgitation with or without stenosis.

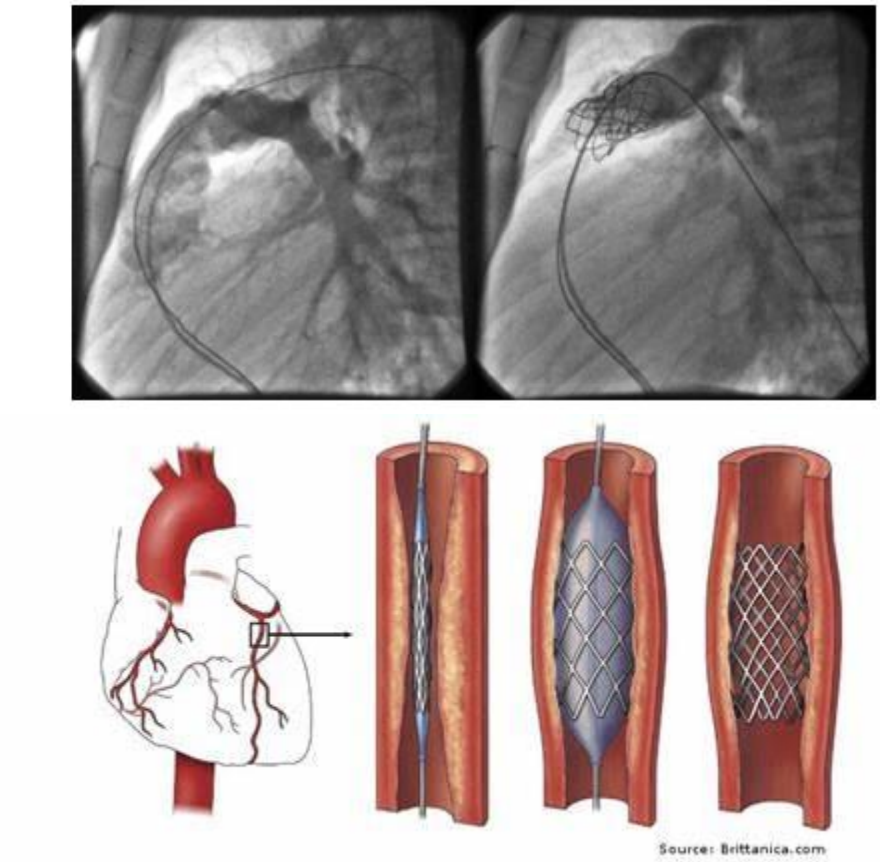

Figure 2. 3 illustrates the lateral still-frame angiograms. Abolition of stenosis and regurgitation after pulmonary valve implantation[10]

There were several complications during the implantation process and 2 stent cases during the follow-up. One was the increase of RVOT[2] gradient and another was stent embolization in pulmonary artery. Both of them were resolved by second valve implantation and valve conduit implantation respectively. There was no mortality reported at 12 moths flow up and the freedom of explantation deduced was 83% [10]. Even though this method was deduced success, the effectiveness, safety and longevity of the valve still need to be further assessed.

As the percutaneous method progressively became known, Edwards Lifesciences Inc developed a new type which can be used by transfemoral approach. The Cribier valve as shown in Figure 2.4 was constructed from a tubular, slotted, stainless steel stent with an attached equine pericardial tri- leaflet valve [11]. The valve was mechanically crimp onto a specially constructed valvuloplasty balloon catheter.

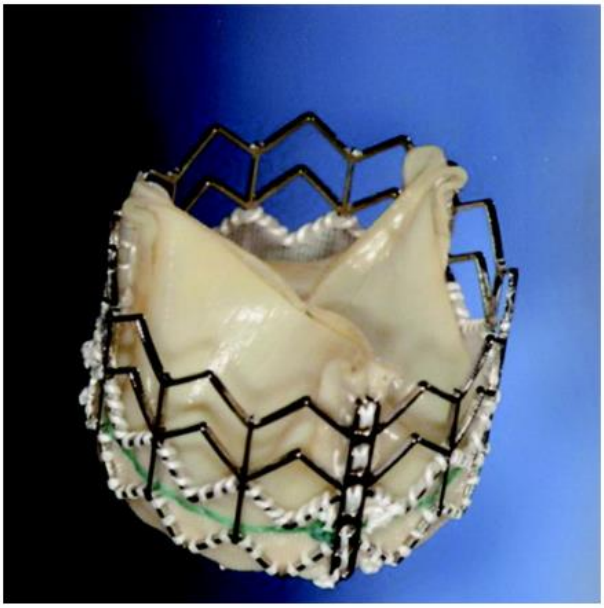

Figure 2. 4 shows the Cribier-Edwards percutaneous valve. An equine pericardial valve is sewn within a stainless-steel frame. A fabric skirt covers the bottom third of the stent [11]

[2] RVOT: Right Ventricular Outflow Tract

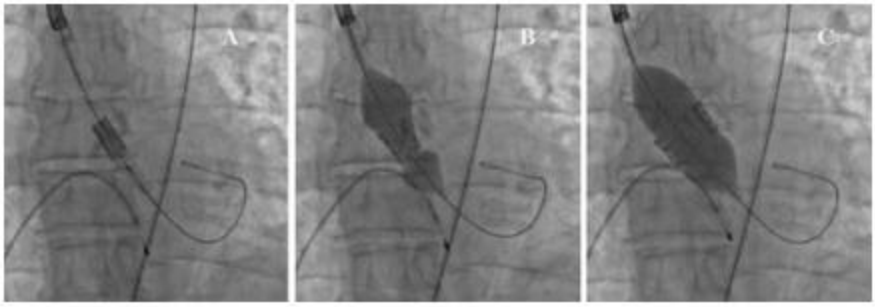

Figure 2. 5 illustrates the (A) Balloon-mounted prosthetic valve positioned adjacent to native valve calcification. (B) Partial inflation of the deployment balloon. (C) Full inflation of the deployment balloon [11]

In the experiment by Edwards Lifesciences Inc, the patients selected are patients that were unsuitable for surgery. Patients that were diagnosed with severe symptomatic aortic stenosis because of multiple comorbidities and excessive surgical risk. The clinical follow-up and echocardiograms were conducted within 24 hours after the procedure and at 1,6 and 12 months after the procedure.

As a result of the procedure conducted, 16 patients out of 18 patients' valve were successful implanted. The patients average age was 81±6 years. Even though 2 of the patients had iliac artery injury, subsequent actions were taken and no intraprocedural death reported. However, one of the iliac artery injury patients died due to multisystem failure 2 weeks later. In the end, at the follow-up of 73±49 days, 16 of the 18 patients remained alive.

However, in this experiment, several problems are discussed for further improvement of the percutaneous valve implantation. One of the problems is the competence of antegrade to retrograde approach [12]. Next is the optimal position of the deployment. This is deployment position is critical to avoid embolization, paravalvular insufficiency and coronary obstruction. The size of the prosthesis sizing due to variation of the annulus diameter.

The design of Edwards TAVI is then further developed to SAPIEN XT, SAPIEN 3 and the latest is SAPIEN 3 Ultra to reduce the paravalvular leak. The material of the frames and leaflet are being researched for improvement in terms of expansion limit, strength and stresses. The delivery system is also progressively being improved to obtain a lower profile access and different approaches.

2.3 Current Transcatheter Heart Valve

2.3.1 Edwards Lifesciences SAPIEN XT

The SAPIEN XT is the second-generation THV designed and manufacture by Edward Lifesciences. The bioprosthetic leaflets were produced from three-equal size bovine pericardium that are hand-sewn to the frame. The stainless-steel frame was changed to cobalt-chromium alloy frame and a polyethylene terephthalate (PET) cuff. The delivery catheter depends on the valve size with the lowest profile access 16 F[3] with NOVAFLEX+ delivery system. There are several approaches delivery method available which are transfemoral, transapical and transaortic approaches. The SAPIEN XT size is available in 3 sizes, 23mm, 26mm and 29mm dimeter as shown in Figure 2.6. The 29 mm device is unique asit has addition cells frame.

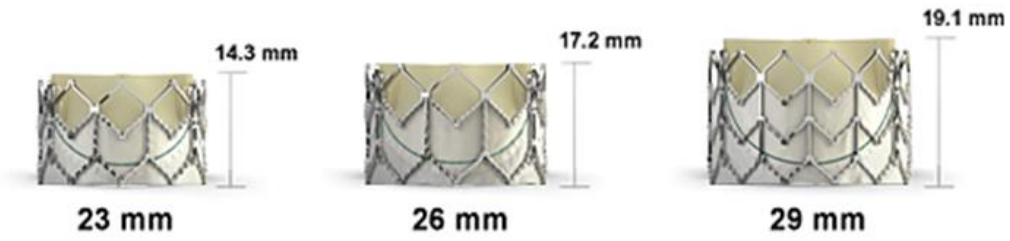

Figure 2. 6 shows the 23, 26 and 29 mm Edwards SAPIEN XT [13]

2.3.2 Edwards Lifesciences SAPIEN 3

The Edwards Lifesciences SAPIEN 3 is the net model of the SAPIEN XT. The design was modified to reduce the paravalvular aortic regurgitation (PAR). The cuff of the model covered both interior and exterior of the frame. The catheter sizes in this model is smaller than the previous (14F and 16F) with improved positioning delivery system (Edwards COMMANDER and Certitude delivery system). Other than that, the frame geometry was optimized by lowering the frame height and open cell geometry. The SAPIEN 3 size available in 4 sizes, 20mm. 23mm, 26mm and 29mm diameter.

[3] F is the abbreviation of French, the unit used to measure the diameter of a catheter. 1 F is 0.33mm.

Figure 2. 7 shows the Edwards SAPIEN 3

2.3.3 Edwards Lifesciences SAPIEN 3 Ultra

The new SAPIEN 3 is the improved version of the previous SAPIEN 3. The exterior cuff of the model was increased 40% with textured polyethylene terephthalate (PET) material. The frame and leaflet were designed with ultra-low delivery profile with high radial strength. Due to the difficulty of coronary re-engagement of post-TAVR [14], the frame height has been designed to minimize the interactions between TAVI and coronary ostia. The sizes available are 20mm, 23mm and 26mm diameter. Besides that, the sheath size Edwards Axela is seamless and expandable 14F with smooth tip-to-valve transition SAPIEN 3 Ultra delivery system.

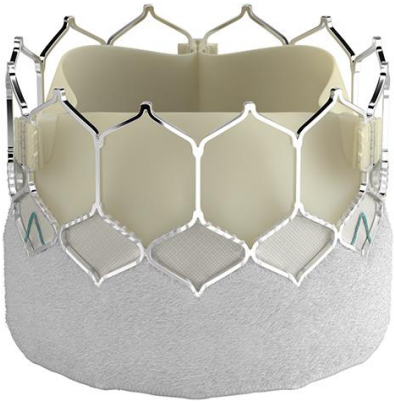

Figure 2. 8 shows the Edwards SAPIEN 3 Ultra

2.4 Deployment Approaches

2.4.1 Transfemoral

Transfemoral retrograde is the most approach used access site to implant TAVI. As the name indicated, a small incision is made to access the femoral artery. The TAVI device inserted from the groin will travels up the femoral artery until the device pass through the aortic valve. The catheter delivery system has a shunted nose to aid passage through the native valve. After the position of the deployment confirmed, the device is expanded under pacing to stall the heart and reduce blood pressure. After being deployed, the catheters are being removed and the incision at the groin is sutured [11].

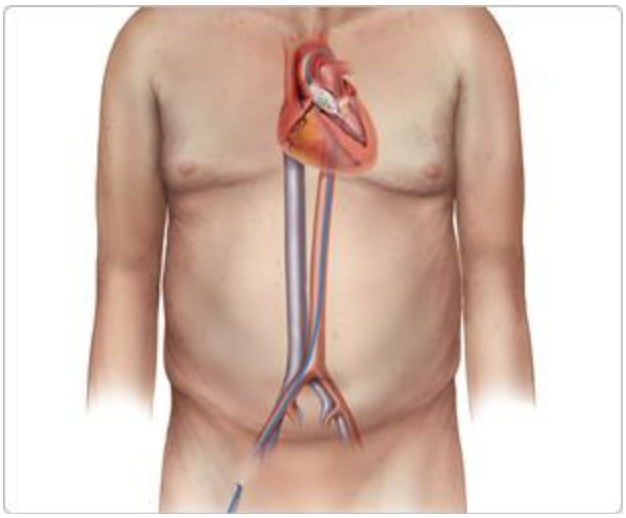

Figure 2. 9 illustrates the transfemoral approach through an incision in leg [15]

2.4.2 Transaortic

For transaortic, three requirements must be met before considering this approach. The requirements are the aorta is not calcified, the anatomy allows the sheath to be inserted in a direct line to the deployment and the aorta is long enough to allow the balloon to expand without interference [16]. In order to ascend the aorta, a mini J-shaped sternotomy is performed through the right third intercostal spacing. The sternum can be divided by means of an automatic sternal saw, revealing the pericardium incised to give a direct route to the aorta. Purse string sutures are used to secure the aorta for the catheter. A needle is then punctured the aorta and a soft guide wire and catheter are inserted. The initial guide wire is retracted for stiffer wire followed by the valve loader into the deployment position in the aortic root. The deployment position is guided by radio opaque markers. Rapid pacing is then administrated to stall the heart lowering the pressure until the balloon is expanded. The catheters are removed, and aorta is closed the purse strings.

2.4.3 Transapical

Due to the limited length of the delivery system and elderly patients' poor circulation, a retrograde approach through the femoral artery was no suitable, a transapical approach was developed. An incision is made in the chest between 5^{th} and 6^{th} intercostal space where a soft tissue retractor easy accessed. An incision then is made in the pericardium revealing the apex of the heart. A needle is then pushed through the aortic valve into the ascending aorta. After that, a catheter is inserted along the initial guide wire which is retracted followed by the valve loader into the deployment position in the aortic root. Rapid pacing is then administrated to stall the heart lowering the pressure until the balloon is expanded.

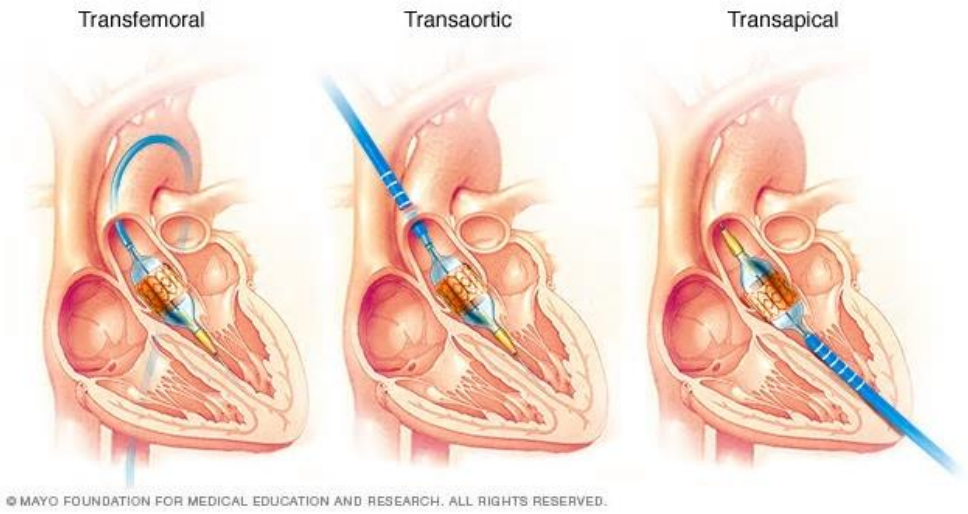

Figure 2. 10 illustrates the transfemoral, transaortic and transapical procedure approaches [17]

2.5 Particle Image Velocimetry (PIV)

In a healthy heart, the one-way blood flow is maintained by the four heart valves in every cardiac cycle. However, extra pressure or flow induced heart failure in the long term due to diseased conditions such as endocarditis and stenosis. This is why the native heart valves are replaced with artificial heart valves (AHV). Hence, experimental and numerical studies of hemodynamic performance of both healthy heart valve and AHV are being investigated extensively.

For experimental studies, the investigation was conducted in vitro by mimicking the flow in human's heart. The blood flows are observed by using Particle Image Velocimetry (PIV) method. PIV is a method to captures the instantaneous velocity distribution on a selected plane in the flow field that is illuminated by the laser. In PIV application, tracer particles are added to the fluid, these particles when selected plane in the flow field is illuminated by the laser sheet, allows the camera to capture and recorded the light scattered by the tracer particles on the plane.

After the image being captured and recorded, the image is further processed in post-processing. In the post-processing, the image is divided into small sub-areas called "interrogation areas". The mean local displacement vector of the tracer particles in the images are determined for each interrogation area by means of statistical methods (auto-correction or cross-correction method) [18]. The process is repeated for all the images recorded.

2.5.1 PIV on Transcatheter Heart Valve

As the TAVI progressively emerging as a safe and effective method of treatment for stenosis, the improved 4-dimensional volume-rendered computed tomography (4DCT) has raised concerns about reduced sub-clinical leaflet thrombosis and reduced leaflet mobility in both surgical and transcatheter aortic bio prostheses [19]. We can see from Figure 2.11 sections observed for the potential thrombus formation at the ascending aorta.

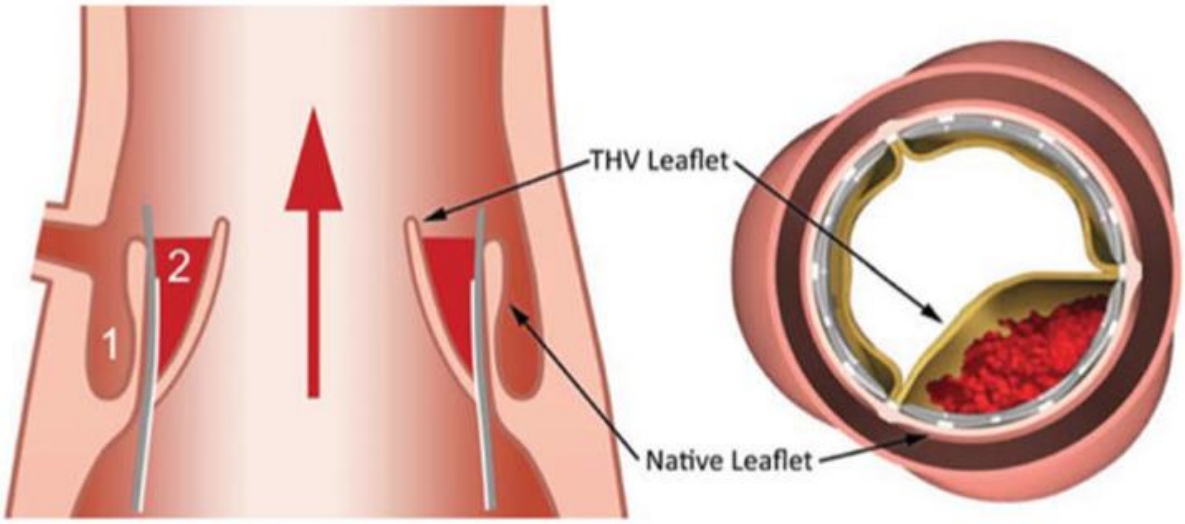

Figure 2. 11 illustrates the divided section at the aortic sinus by TAVI. The two spaces are (1) a diminished native sinus and (2) neo-sinus . The neo-sinus is a region between the native and transcatheter aortic valve leaflets where thrombus has been observed [19]

The in-vitro PIV conducted was to analyze the potential mechanism that may contribute to the transcatheter heart valve thrombosis. The hemodynamics of the in-vitro loop was tuned to 70 beats/min, cardiac output conditions 2.5, 5.0, 6.5 L/min, and blood pressure of 120/80 mmHg [20]. Different valves were tested which are balloon expanding SAPIEN 3 and self-expanding CoreValve/Evolute R with blood mimicking kinematic viscosity working fluid 3.5-cSt saline-glycerin solution [20].

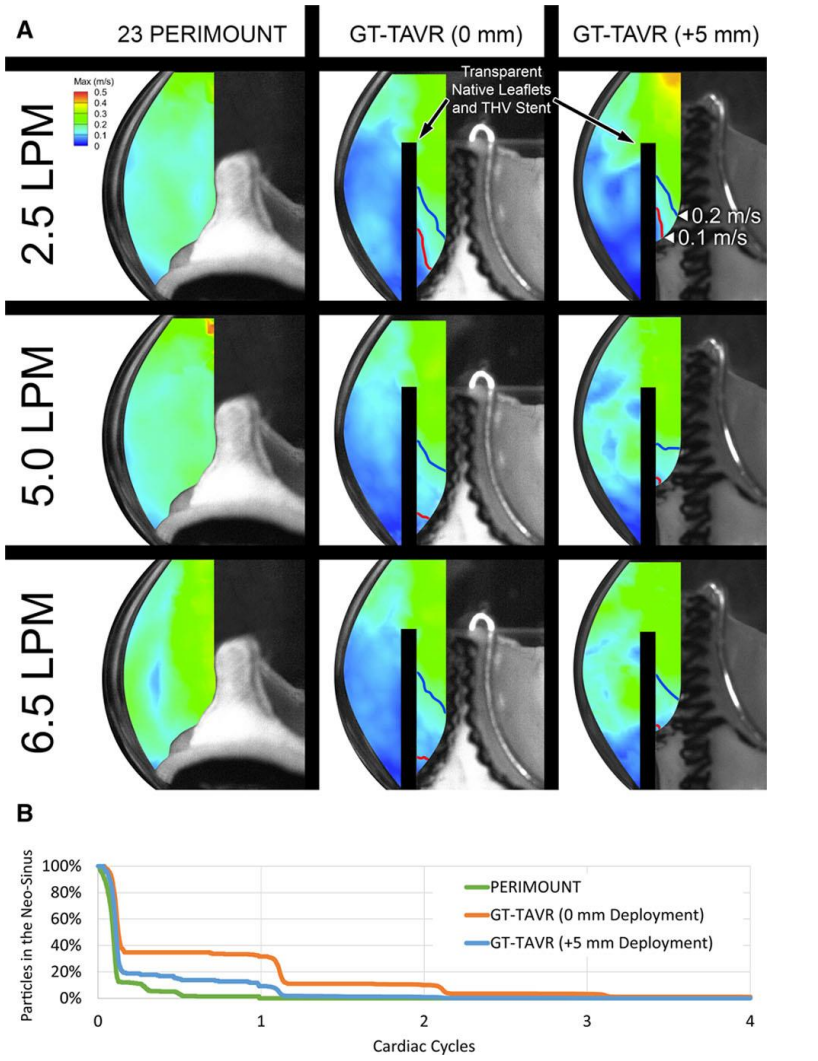

Figure 2. 12 illustrates the local flow stagnation and neo-sinus washout results from in-vitro model. (A) Local maximum velocity fields by each spatial location over 9 cardiac cycles. (B) Neo-sinus washout curves for 2 transparent TAVR (GT-TAVR) models and surgical control valve at 5L/min cardiac output [19]

The results show that the deployed THV geometry may have implication on the occurrence of thrombosis. This is because the data shows that the area of low maximum velocity increased with the depth of the implantation as we can observed between GT-TAVR (0mm and +5mm) in Figure 2.12(A) . The 23 PERIMOUNT doesn't have stagnation zones since the native valve has been removed.

CHAPTER 3 METHODOLOGY

The research focus on the application of the transcatheter heart valve as alternative solution to mechanical heart valve due to native valve dysfunction. The research is conducted by develop three-dimensional model, evaluate using engineering simulation software and validate experimentally using PIV. The model chosen in this research the model that already available in the market.

3.1 Establishment of CAD Model

In this project, there are two parts involved, the left heart and Edwards Lifesciences SAPIEN XT. All of the 3D models were designed by using Solid Work 2018 The left heart model was designed from the left side heart Perspex model. The left side heart Perspex model segmentation measurement details previously were obtained from and actual left heart. The medical imaging data collected from a Computed Tomography (CT) given by medical team from Radiology Hospital Universiti Sains Malaysia after obtaining approval from Jawatankuasa Etika Penyelidikan Manusia (JEPEM).

Left Side Heart

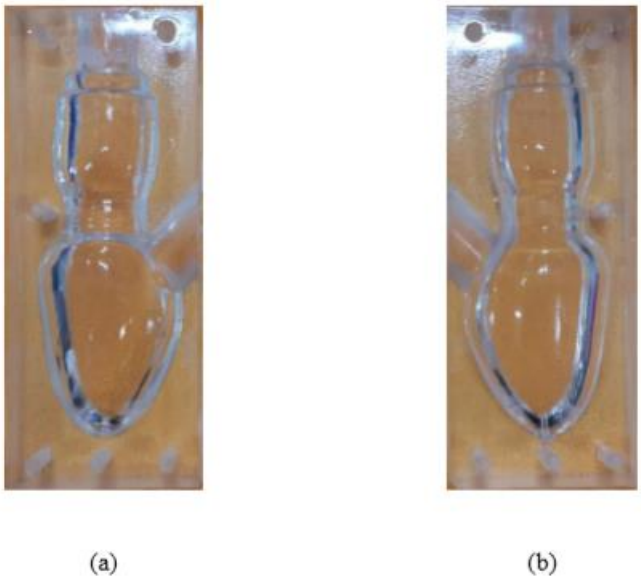

Figure 3. 1 shows the Perspex model. (a) Right side Perspex. (b) Left side Perspex.

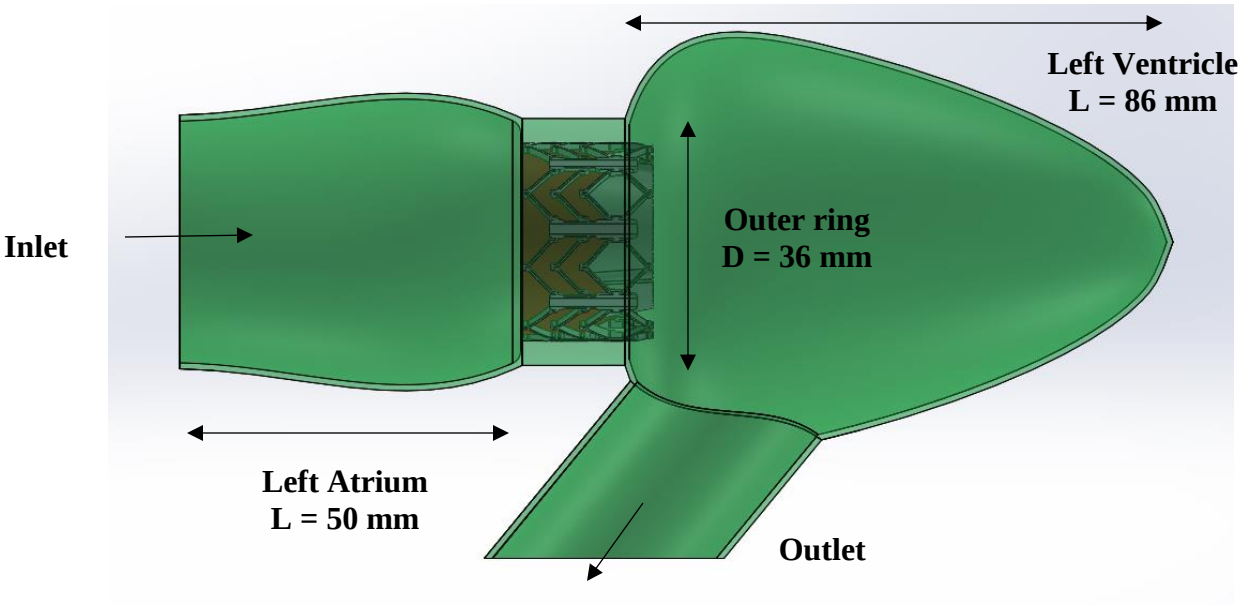

Figure 3. 2 illustrates the 3D model constructed in Solid Work 2018 software

Since there are lots of irregular geometries of the left heart, loft surface features are used to construct the model. The left heart model consists of one inlet, one outlet, left atrium and right atrium. The inlet and outlet are 35 mm. The length of left atrium and left ventricle are 50 mm and 86 mm with the mitral outer ring dimeter and length at 36mm and 16 mm respectively.

Another part is the SAPIEN XT shown in Figure 3.11, the model has 3 sub-parts which are the frame, cuff and leaflet. The model chosen was 29 mm Edwards Lifesciences XT since the model can be implanted on mitral valve which is the focus of our research project.

3.1.1 Edwards Lifesciences SAPIEN XT (29 mm)

3.1.1(a) The Frame

The model developed at full diameter. Geometries of the SAPIEN XT frame were obtained from an actual parameters identical to the 26 mm SAPIEN XT actual device by Bailey's project [21].

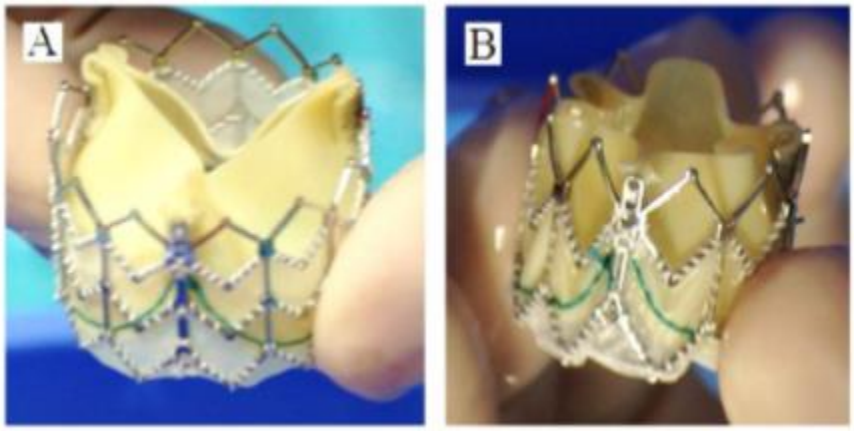

Figure 3. 3 shows the actual 29 mm SAPIEN XT. [21]

In general, the diameter and the height of the frame are 29 mm and 19.1 mm respectively. The frame's thickness in the actual model is 0.4 mm. However, due to the limitation of rapid prototyping, the thickness of the frame increased to 1 mm. The other parameters of the design are as followed below.

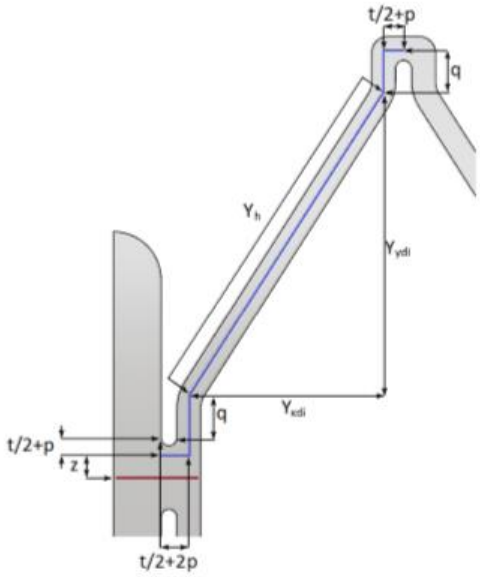

Figure 3. 4 illustrates the SAPIEN XT additional labelled parameters [21]

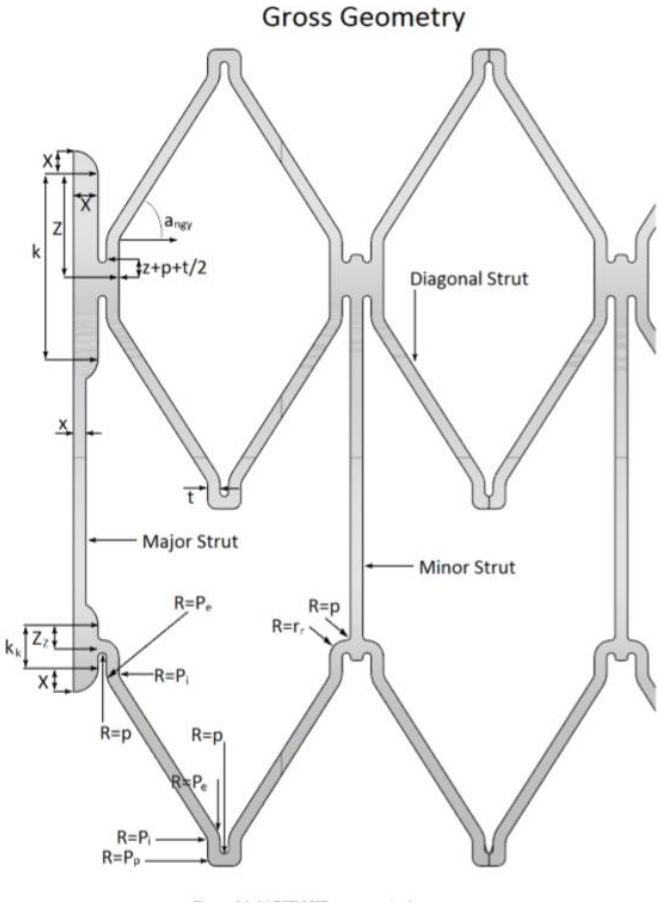

Figure 3. 5 illustrates the SAPIEX XT parameterized geometry [21]

Table 3. 1 shows the parameters and assumed values to describe 26 mm SAPIEN XT frame [21].

Parameter	Description	Value
d	Diameter	26 mm
d_i	Initial or tube diameter	26 mm
t	Strut thickness - circumferentially	0.3 mm
T	Strut thickness - radially	0.4 mm
a_{ngx}	Pitch of the diagonal struts	42.5 degrees
h	Height of the frame (expanded)	17.2 mm
X	Half the width of the major struts at the widest point	0.6 mm
x	Half the width of the major struts at the thinnest point	0.3 mm
Z	Vertical offset of the upper rings of diagonal struts	2.5 mm
z	Vertical offset of the upper rings from Z	0.25 mm
Z_Z	Vertical offset of the lower rings of the diagonal struts	0.5 mm
p	Internal radius of the arcs associated with the diagonal struts at the crowns	0.1 mm
P_p	External radius of the arcs associated with the diagonal struts at the crowns	0.2 mm
P_e	External radius of the arcs associated with the diagonal struts	0.6 mm
P_i	Internal radius of the arcs associated with the diagonal struts	0.3 mm
q	Vertical offset associated with the crowns	0.065 mm
k	Upper hoop length excluding the arcs	5 mm
k_k	Lower hoop length excluding the arcs	1 mm

With the given parameters, the remaining unknown components values such Y_x,Yh, Y_y and r_r can be calculated by the equations given.

$$Y_x = \frac{d\pi - 6X - 54p - 24t}{18}$$

$$Y_{h=\frac{Y_x}{\cos(a_{ngx})}}$$

$$Y_y = ({Y_h}^2 - {Y_x}^2)^{0.5}$$

$$r_r = t = p$$

Then, the a_{ngy} angle can be determined by the following equations:

$$Y_{xdi} = \frac{d_i\pi - 6X - 54p - 24t}{18}$$

$$Y_{ydi} = ({Y_h}^2 - {Y_{xdi}}^2)^{0.5}$$

$$a_{ngy=\cos(\frac{Y_{xdi}}{Y_h})}$$

Although the parameters are based on 26 mm SAPIEN XT, it can be applied by a bit modification to design 29 mm SAPIEN XT since it is the same model generation but with an extra diagonal strut. The 29 mm SAPIEN XT model after being designed by Solid Work 2018 shown in the Figure 3.6.

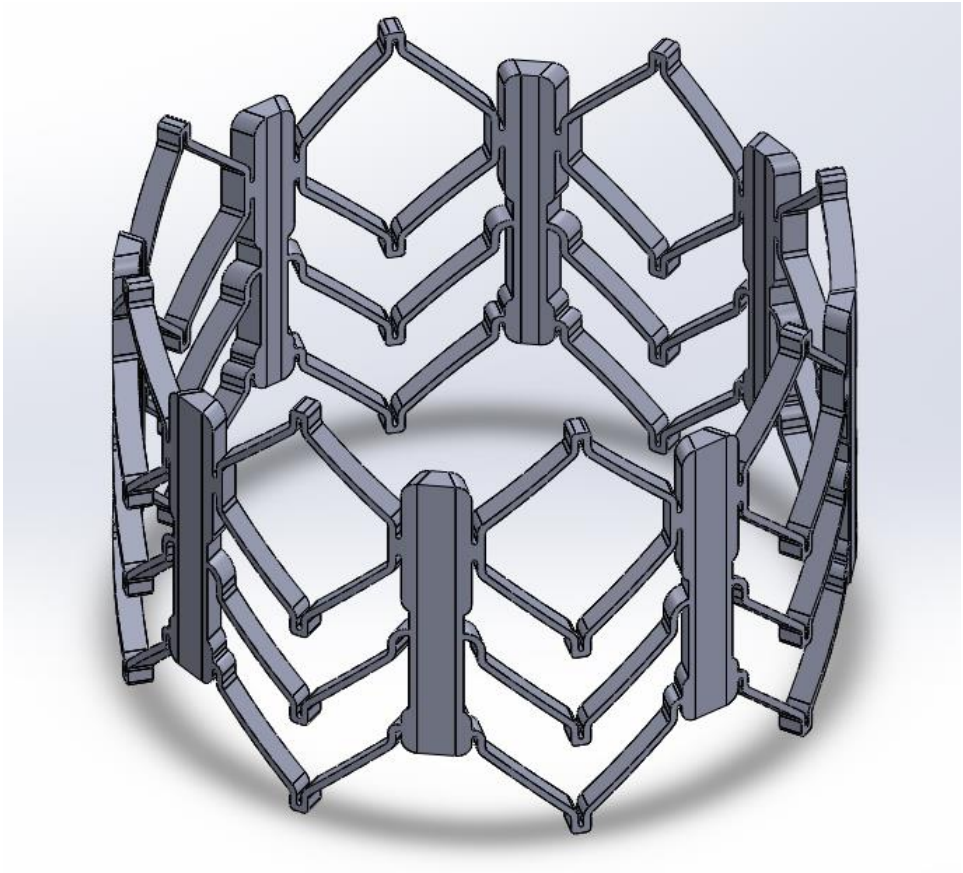

Figure 3. 6 shows the 3D model of 29 mm SAPIEN XT frame