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FLUID-STRUCTURE INTERACTION OF COMPUTATIONAL AERODYNAMICS ANALYSIS IN PARAVALVULAR LEAKAGE OF TRANSCATHETER AORTIC VALVE IMPLANTATION PATIENT

ADI AZRIFF BASRI

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By

ADI AZRIFF BIN BASRI

Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

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FLUID-STRUCTURE INTERACTION OF COMPUTATIONAL AERODYNAMICS ANALYSIS IN PARAVALVULAR LEAKAGE OF TRANSCATHETER AORTIC VALVE IMPLANTATION PATIENT

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November 2017

Chairperson: **Kamarul Arifin bin Ahmad, PhD**
Faculty: **Engineering**

Fluid Structure Interaction (FSI) is widely known as superior simulation technique that provide significant outcomes through the interaction between fluid dynamic and structure mechanics. In this research, the computational aerodynamic analysis of FSI is carried out to investigate of behavior of human blood flow and aortic wall response associated to heart valve replacement known as Transcatheter Aortic Valve Implantation (TAVI). Even though TAVI has huge potential in providing better solution, yet a lot of complications has occurred such as the effect of hemodynamic forces on the TAVI, the problem of migration associated with the implanted valve and paravalvular leakage (PVL) have to be addressed. Up-to-date, none of the researcher investigated the flow pattern of PVL after implantation of TAVI valve using FSI. The proposed research consists of MRI-Cardiac work, computational and numerical work, as well as experimental. This study has been approved by Institut Jantung Negara (IJN) and have received preliminary CT-scan data, thus the patient case data can be obtained. PVL is highlighted as one of the major complications for the post-TAVI due to possibility of calcification development. Hence, the computational of FSI is carried out, by which the simulation is based on the opening of TAVI valve represented as calcification. In addition, further study is conducted by determining the severity of PVL due to the undersizing of TAVI valve. The experimental study is carried out to validate the simulation model and result analysis representing the real world perspective. The results proven that the presence of PVL disturb the norm of blood flow distribution and aorta

structure behaviour. In fact, the opening of 20% GOA (geometric orifice area) of TAVI 26 on human aorta proven the significant impact with highest value of velocity 2.74 times higher and displacement of 1.19 times higher than 100% GOA, thus graded as severe PVL. In addition, the undersizing TAVI valve showed that TAVI 23 has higher possibility of valve migration with 55.01% leakage compared to TAVI 26. Hence, this research provides a noteworthy benchmark with the aid of FSI to predict significant impact of PVL complication for TAVI patient. The outcomes of this study also can be practiced to help the medical practitioner to reducing the risk of re-operation, hence lead to the time saving of the standardization of the computational analysis.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

INTERAKSI BENDALIR-STRUKTUR BAGI ANALISIS BERKOMPUTER AERODINAMIK KE ATAS KEBOCORAN PERSEKITARAN INJAP OLEH PESAKIT IMPLANTASI TRANSKATETER INJAP AORTIC

Oleh

ADI AZRIFF BIN BASRI

November 2017

Pengerusi: **Kamarul Arifin bin Ahmad, PhD**
Fakulti: **Kejuruteraan**

Interaksi Bendalir-Struktur (FSI) dikenali dengan meluas sebagai satu teknik yang unggul yang memberikan hasil yang lebih realistik secara fisiologi dan bermakna melalui interaksi antara dinamik bendalir dan mekanik struktur, terutamanya dalam menyelesaikan masalah yang sebenar. Pelbagai kajian berkaitan FSI seperti getaran pesawat, pembengkokan bilah turbin angina, kepakan sayap, denyutan jantung, pembukaan dan penutupan injap jantung dan sebagainya. Dalam kajian ini, analisis berkiraan aerodinamik iaitu FSI telah dijalankan untuk mengkaji perilaku aliran darah dan respon dinding aorta manusia berkaitrapat dengan gantian injap jantung dikenali sebagai Implantasi Transkateter Injap Aortic (TAVI). Walaupun TAVI mempunyai potensi besar dalam memberikan penyelesaian yang baik, namun banyak komplikasi telah berlaku seperti kesan daya tindakan pada hemodinamik ke atas injap TAVI, masalah migrasi berkaitan injap yang diimplankan dan kebocoran persekitaran injap (PVL) perlu ditangani. Sehingga kini, tiada kajian mengenai corak aliran PVL selepas pengimplanan injap TAVI menggunakan FSI. Penyelidikan yang dicadangkan terdiri daripada kerja-kerja MRI-jantung, berkiraan daan berangka serta eksperimen. Kajian ini telah diluluskan oleh Institut Jantung Negara (IJN) dan menerima data awal CT scan, maka data bagi kes pesakit boleh diperolehi. PVL telah diserlahkan sebagai salah satu komplikasi yang major untuk selepas-TAVI disebabkan kemungkinan pembentukan kalsifikasi. Dengan itu, perkiraan FSI telah dijalankan, di mana simulasi ini berdasarkan

kepada pembukaan injap TAVI yang diwakili sebagai kalsifikasi. Tambahan pula, kajian selanjutnya telah dijalankan untuk mengetahui tahap keseriusan PVL disebabkan pengurangan injap TAVI. Kajian eksperimen dilakukan bagi mengesahkan model simulasi dan hasil analisis menggambarkan perspektif yang sebenar. Hasil kajian membuktikan bahawa kehadiran PVL mengganggu norma peredaran aliran darah dan perilaku struktur aorta. Sebenarnya, pembukaan 20% GOA (kawasan orifis geometri) bagi TAVI 26 ke atas aorta manusia telah membuktikan impak yang bermakna dengan nilai yang terbesar pada halaju sebanyak 2.74 kali ganda dan anjakan sebanyak 1.19 kali ganda daripada 100% GOA, justeru digredkan sebagai PVL yang serius. Tambahan pula, pengurangan injap TAVI menunjukkan TAVI 23 mempunyai kebarangkalian yang tinggi bagi pergerakan injap dengan kebocoran sebanyak 55.01% berbanding dengan TAVI 26. Justeru itu, kajian ini menyediakan satu tanda aras yang bermakna dengan bantuan FSI untuk meramal impak komplikasi PVL yang signifkan bagi pesakit TAVI. Hasil kajian ini juga boleh dipraktikkan bagi membantu pengamal perubatan dalam mengurangkan risiko pembedahan semula, justeru membawa kepada penjimatan masa dalam pemiawaian analisis perkiraan.

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I certify that a Thesis Examination Committee has met on 7th November 2017 to conduct the final examination of Adi Azriff bin Basri on his thesis entitled "Fluid-Structure Interaction of Computational Aerodynamics Analysis in Paravalvular Leakage of Transcatheter Aortic Valve Implantation Patient" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the (insert the name of relevant degree).

Members of the Thesis Examination Committee were as follows:

Azmin Shakrine bin Mohd Rafie, PhD
Associate Professor Ir.
Faculty of Engineering
Universiti Putra Malaysia
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Mohd Khairol Anuar bin Mohd Ariffin, PhD
Professor Ir.
Faculty of Engineering
Universiti Putra Malaysia
(Internal Examiner)

Faizal bin Mustapha, PhD
Professor Ir.
Faculty of Engineering
Universiti Putra Malaysia
(Internal Examiner)

Ng Yin Kwee, PhD
Associate Professor
School of Mechanical and Aerospace Engineering
Nanyang Technological University
Singapore
(External Examiner)

NOR AINI AB. SHUKOR, PhD
Professor and Deputy Dean
School of Graduate Studies
Universiti Putra Malaysia

Date: 29 January 2018

This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

Kamarul Arifin bin Ahmad, PhD
Associate Professor Ir.
Faculty of Engineering
Universiti Putra Malaysia
(Chairman)

Mohammed Zuber, PhD
Senior Lecturer
Faculty of Engineering
Universiti Putra Malaysia
(Member)

Ahmad Fazli Abdul Aziz, MD
Associate Professor,
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Member)

Masaaki Tamagawa, PhD
Professor
Kyushu Institute of Technology
Japan
(Member)

Rosli Mohd Ali, MD
Medical Doctor
Department of Cardiology
National Heart Institute (IJN) Malaysia
(Member)

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ROBIAH BINTI YUNUS, PhD
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Signature:
Name of Chairman of Supervisory Committee: Associate Professor Ir. Dr. Kamarul Arifin bin Ahmad

Signature:
Name of Member of Supervisory Committee: Dr. Mohammed Zuber

Signature:
Name of Member of Supervisory Committee: Professor Masaaki Tamagawa

Signature:
Name of Member of Supervisory Committee: Associate Professor Dr. Ahmad Fazli Abdul Aziz

Signature: b/p
Name of Member of Supervisory Committee: Dr. Rosli Mohd Ali

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LIST OF ABBREVIATIONS

ACC/AHA	American College of Cardiology/ American Heart Association
AHA	American Heart Association
ALE	Arbitrary Lagrange-Euler
AR	Aortic Regurgitation
AS	Aortic Stenosis
AVA	Aortic Valve Area
AW	Ascending Wall
AWoV	Aorta Without Valve
AWT	Aorta With TAVI26 100% GOA
BA	Brachiocephalic Artery
CAD	Computer Aided Design
CCA	Common Carotid Artery
CCD	Charged-coupled device
CE	Conformité Européene
CEP	Carpentier-Edwards Perimount
CFD	Computational Fluid Dynamic
CT	Computed Tomography
CVD	Cardiovascular Disease
DA	Descending Aorta
DSE	Digitized Shape Editor
DVI	Doppler Velocity Index
ED	Early Diastole
EOA	Effective Orifice Area
ES	Early Systole
ESV	Edward Sapien™ Valve
FDA	Food Drug Administration
FEA	Finite Element Analysis
FIM	First-In-Man
FSI	Fluid-Structure Interaction
GGI	General Grid Interface

GOA	Geometric Orifice Area
HU	Hounsfield Units
IJN	National Heart Institute
ISO	International Organization for Standardization
LD	Late diastole
LSA	Left Subclavian Artery
LVOT	Left Ventricle Outflow Tract
MCV	Medtronic CoreValve®
MIMICS	Materialise Interactive Medical Image Control Systems
MPG	Mean Pressure Gradient
MPS	Maximum Principal Stress
MRI	Magnetic Resonance Imaging
PG	Peak Gradient
PIV	Particle Image Velocimetry
PS	Peak Systole
PVL	Paravalvular Leakage
RMS	Root Mean Square
RSS	Reynolds Shear Stress
SAVR	Surgical Aortic Valve Replacement
SST	Shear stress transport
TA	Transapical
TAo	Transaortic
TAV	Transcatheter Aortic Valve
TAVI	Transcatheter Aortic Valve Implantation
TEE	Transesophageal Echocardiography
TF	Transfemoral
TKE	Turbulent Kinetic Energy
TPG	Transvalvular Pressure Gradient
TTE	Transthoracic Echocardiography
VSS	Viscous Shear Stress
WSS	Wall Shear Stress

LIST OF SYMBOLS

3D	Three-dimensional
Fr.	French
θ	Valvular aperture angle
v	Velocity
ρ	Density
P	Pressure
τ	Deviatoric stress tensor
μ	Viscosity
$\dot{\gamma}$	Strain rate
$\mathbf{k}_e$	Element stiffness matrix
$\mathbf{m}_e$	Element mass matrix
$\mathbf{u}_e$	Displacement for the element
$\ddot{u}_e$	Acceleration vector for the element
A	Operator responsible for assembly process
N	Number of elements
$\mathbf{p}\ (t)$	Force vector in a function of time
rpm	Revolutions per minute
L/min	Liter per minute
M	Structural mass matrix
$\ddot{U}$	Acceleration vector
C	Structural damping matrix
$\dot{U}$ / v	Velocity vector
K	Structural stiffness matrix
U	Displacement vector
v_b	Grid velocity
b	Body force given at time t
$\partial\Omega$	Fluid domain
∂S	Solid domain
^{F}d	Displacement at the interface for fluid domain

${}^{S}d$	Displacement at the interface for solid domain
${}^{S}f$	Force acting at the interface of solid domain
${}^{F}f$,	Force acting at the interface of fluid domain
∇	Vector differential operator
γ	Diffusion coefficient
$\vec{u}$	Mesh displacement velocity

CHAPTER 1

INTRODUCTION

1.1 Overview

The first chapter is structured into five sections as to provide the general idea of this research has been conducted. First, the theoretical foundations of this research are presented in research background and further elaborated in second section discussing on transcatheter aortic valve implantation (TAVI). Then, in the problem statement section, the current situation in TAVI is discussed. Discussion research objective is included in the fourth section. The overview of thesis structure is prepared in the final section.

1.2 Research Background

Cardiovascular disease (CVD) is generally known as the major cause of deaths in many countries around the world (Jamuna and Abnurajan, 2011). The American Heart Association (AHA) reported that more than five millions Americans are diagnosed with heart valve disease each year (Nkomo et al., 2006). It is a common condition of CVD, which affects hundreds of thousands of individuals, particularly the heart valve disease. This type of disease occurs due to the disorder function of heart valve; either a single valve or a combination of four valves, which mostly are the diseases of aortic and mitral valves. Hence, these cause the disruption of normal blood flow through the heart.

Fundamentally, the anatomy of the normal heart consists of four valves, where the tricuspid and pulmonary valves are located on the right side of the heart while the mitral and aortic valves are on the left side. Blood is pumped out from the left heart ventricle into the aorta, passes through the aortic valve to the rest of the human body. The heart valves are made up of tissues that form the leaflets of three half-moon-shaped pocket-like flaps (Maleki, 2010). These leaflets located at the lower part of the aorta are able to move in the valves, whereas the sinuses at the upper part attached to aorta are the cavities. The anatomy of the heart valve is depicted in Figure 1.1.

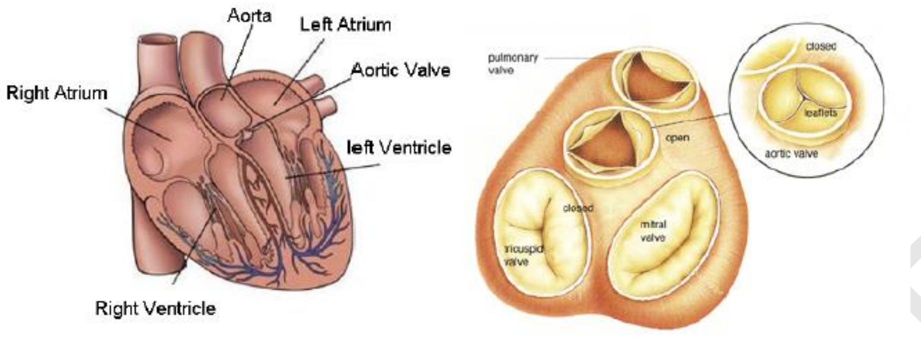

Figure 1.1. Heart valve from front view and above view
(Sources: Maleki, 2010)

The physiology of the aortic valve mainly serves to provide a pathway for blood leaving the heart and it is also hampers backflow for blood from re-entering the heart. However, the performance of the aortic valve can be affected as subjected to the calcium deposition that develops on the aortic valve leaflets (Maleki, 2010). This deposition causes the valve structure to gradually harden where the valves have an opening problem, leading to less volume of blood forcing out from the left ventricle. Thus, heart performance is decreased. Heart valve disease can be caused by two basic kinds of problems or defects, which are stenosis and regurgitation (Leon et al., 1998). One of the most common heart valve diseases that occur to elderly heart disease patients, is aortic stenosis (AS). The prevalence in populations older than 75 years is up to 5% and 25% has been found with aortic sclerosis, which is the precursor of AS (Lindroos et al., 1993; Yoganathan et al., 2004; Nkomo et al., 2006). It occurs due to the narrowing of the aortic valve during the systole by which it increases the resistance of blood flow from left ventricular to the ascending aorta due to the calcium deposition on the aortic leaflets or congenital abnormality of the valve. Hence, it will generate a larger pressure drop across the valve. On the other hand, aortic regurgitation (AR) occurs due to the failure of the valve leaflet to close firmly, which leads to backward blood leak, referred to as retrograde blood flow (regurgitation) when the valve is closed during diastolic phase (Yacoub and Takkenberg, 2005). The problems of heart valve disease are depicted in Figure 1.2.

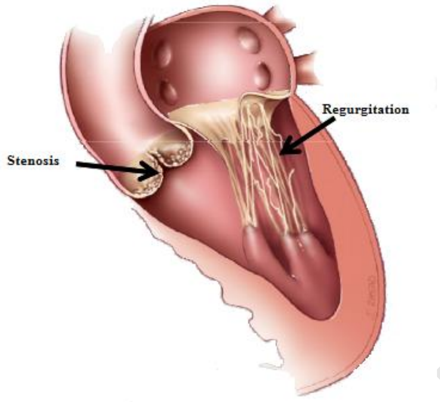

Figure 1.2. Heart valve disease of stenosis and regurgitation

Nowadays, aortic valve damages can be treated. It is based on the grading of the aortic valve damage level depending on the hemodynamic parameters, whether mild, moderate or severe. For mild and moderate levels, the aortic valve can be treated by suitable interventions. However, repairing or replacing the diseased valve is required for severe AS. Generally, the diseased valve is replaced by prosthetic heart valves instead of repairing due to the severity of damage of the native valves. To date, over 290 000 heart valve procedures are performed annually worldwide and it is estimated to triple over to 850 000 by 2050 (Yacoub and Takkenberg, 2005). Therefore, the demand for prosthetic heart valve is increasing at a rate of 10%–12% per year (Black and Drury, 1994; Pibarot and Dumesnil, 2009). Basically, prosthetic heart valves are divided in two major types, namely mechanical heart valves and bioprosthetic heart valves. The mechanical heart valves are made up of pyrolytic carbon, whereas the bioprosthetic heart valves known as tissue heart valves are made of human-derived or animal-derived tissue (Butany et al., 2003; Dasi et al., 2009).

Operative treatment of native heart valve that has remained fairly consistent for more than forty years is the Surgical Aortic Valve Replacement (SAVR). The aortic valve is removed through an open-heart procedure and a new valve (mechanical or bioprosthesis) is sewn to the annulus of the native valve (Carrel et al., 2013; Cho et al., 2013; Osnabrugge et al., 2013; Yankah and Hetzer, 2010). However, the indication for this type of procedure includes symptomatic severe aortic stenosis, severe aortic stenosis with ejection fraction less than 50%, and severe aortic stenosis that needs for any other heart surgery. Age, degree of valve disease, general health, specific medical condition, and heart function are the important factors that needs to be identified prior to performing SAVR associated to the increase risk of surgery (Carrel et al., 2013). Hence, Transcatheter Aortic Valve Implantation (TAVI) has been developed as a good alternative to surgical approach for elderly patients and patients with very high or prohibitive surgical risk (Wu et al., 2013). Even though this technique is still in its commencement stage, its proliferating evidence has evolved through clinical trials and observational studies.

1.3 Transcatheter Aortic Valve Implantation (TAVI)

Implantation means the insertion or grafting of an organ or tissue of biological material into the body. In the treatment of native heart valve perspective, TAVI is the deployment of bioprosthetic valve via delivery of catheter and implanted within the diseased native aortic valve (Leon et al., 2010; Wu et al., 2013). The indication for TAVI includes symptomatic patients with severe aortic stenosis, patients with severe aortic stenosis undergoing other heart operations, and patients with severe aortic stenosis and left ventricular systolic dysfunction (Ye et al., 2012). The benefits of TAVI include a shorter procedure, less pain, and shorter stay in the hospital after the implantation for recovery. Due to its minimally invasive procedure, recovery time is significantly shorter than aortic valve replacement surgery, which takes only two to four weeks instead of six to eight weeks (Clavel et al., 2010; D'Errigo et al., 2013).

TAVI has been increasingly performed in many countries with the evidence of over 9000 procedures worldwide to date, due to its less invasive procedure, yet significant concerns are also increasing due some severe complications that could risk patients' future (Loeser et al., 2013). There are several clinical trials and observational studies regarding potential complications after TAVI such as procedure-related incidence of paravalvular leakage (PVL). Vasa-Nicotera et al. (2012) studied the impact of PVL on the outcome in patients after undergoing TAVI. The authors proved the occurrence of PVL after TAVI through patient clinical studies according to its severity level. The authors also highlighted the occurrence of PVL that may be due to heavily calcified cups, annulus-prosthesis valve size mismatch, and the placement of prosthesis valve. The widespread and novel technology of TAVI raised significant concerns to perform TAVI on the elderly and inoperable patients in respect to the safety, durability, and effectiveness of the TAVI devices.

As a matter of fact, Singhal et al., (2013) highlighted on the possibility of calcification development related to PVL after undergone TAVI. This may lead to serious complications for post-implantation due to biomaterial components of the tissue valve. Therefore, it is a must to have a simulation analysis to assess the interaction between the fluid-flow pattern of blood and biomechanical structure stresses of aortic wall due to PVL.

1.4 Problem Statement

The PVL occurrence is a serious complication. The risk of PVL following TAVI may increase due to the irregular and heavily calcified leaflet of the native aortic valve, thereby preventing the sealing between the prosthesis and the annulus (Neragi-Miandoab and Michler, 2013; Panayiotides and Nikolaides, 2014). Tamburino et al. (2010) reported that there is mild insufficiency of the prosthetic valves found in about 70% of patients after undergoing TAVI. Hence, this serious complication will lead to implication issues related to PVL following TAVI.

From the clinical impacts of the occurrence of PVL post-TAVI, several drawbacks can be highlighted, which are:

i. The problem of valve sizing will definitely exist due to different valve size of Asian and European patients, hence lead to the consequences of undersizing or oversizing of TAVI valve.
ii. The complication after performing TAVI on the patients is clinically limited. The follow-up period by patients, more studies with a longer follow-up are required to further understand and investigate the time-course of changes and the effects of TAVI.
iii. Less clinical practice of TAVI and small number of patients in Malaysia restricted the clinical trials to assess the durability of results after performing TAVI.

Therefore, the current and develop FSI technique provide superior performance of TAVI under various cases. In addition, the drawbacks of clinical trials can be technically solve without the need to access the patient. On top of that, FSI can provides PVL behaviour in technical perspectives such as patient specific assessment flow patterns and related biomechanical stresses in order to observe the complications of post-TAVI, which overcome the shortcoming of clinical trials.

The simulation based on the opening of TAVI valve represented as calcification may provide better understanding on the after-effects of post-implantation of TAVI, thus better decision making can help to reduce the risk of complications on the patients. Literally, the novelty of the current research work is the application of fluid-structure interaction (FSI) on critical study of leaflet calcification of TAVI valve in terms of fluid flow behaviour and structure deformation. On top of that, the highlighted complication of post-TAVI is important as the subject of simulation which contribute to critical findings in terms of engineering perspectives.

1.5 Research Objective

The main objective of this research is to investigate the pattern of blood flow and biomechanical stresses on the aortic wall due to the TAVI implant using the applications of Fluid-Structure Interaction (FSI). Specifically, the objectives of this research are to:

1. Conduct two validations of numerical computational fluid dynamics with *in vitro* experiment and FSI with other research papers for the adequacy of further FSI studies based on the developed realistic human aorta from computed tomography (CT) images into the 3D model using Materialise Interactive Medical Image Control Systems (MIMICs) software
2. Perform 3D numerical studies of FSI to investigate the effect of paravalvular after TAVI implantation on two conditions of aorta; aorta without valve (AWoV) and aorta with TAVI (AWT) prior to be validated with the experiment using particle image velocimetry (PIV).
3. Carry out further FSI numerical simulations to investigate the impact of different valve openings and undersizing TAVI valve represented the severity of PVL

1.6 Scope of thesis

The thesis contains eight chapters.

- Chapter 1 provides the overview of aortic stenosis, transcatheter aortic valve implantation (TAVI), and objectives of the research.
- Chapter 2 is exclusively dedicated to previous works describing problems with TAVI. Additional information on statistical data of Malaysian TAVI implants is also provided in this chapter.
- Chapter 3 discusses the methodology adopted in this work. The conversion of raw CT data from the patient to 3D model is described. The governing equations for solving the 3D numerical model and the fluid-structure interaction (FSI) are explained in detail. Besides that, this chapter also explains the experimental setup development and PIV study procedure.
- Chapter 4 discusses the validation of aorta arch using computational fluid dynamic with the experimental study are explained. The validation of FSI simulation with existing research paper is also included in this chapter.
- Chapter 5 describes the details on paravalvular effects of TAVI using FSI for two conditions; aorta without valve (AWoV) and aorta with TAVI (AWT).
- Chapter 6 presents the parametric studies on the effects of calcification in PVL and undersized towards PVL.
- Chapter 7 presents the experimental works of PIV on two aorta conditions of AWoV and AWT.
- Chapter 8 represents the discussion and conclusions as well as the recommendations for future works.

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