Computational Design of Thrombectomy Device for Blood Clot Removal: A Study on Suction Pressure and Clot Hardness

By:

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CERTIFICATION OF APPROVAL

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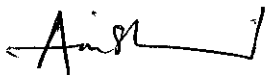

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UNIVERSITI TEKNOLOGI PETRONAS

TRONOH PERAK

SEPT 2011

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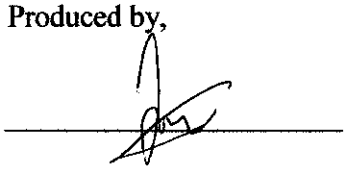

MUHAMMAD AMINUDDIN BIN ISHAK

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ABSTRACT

According to World Health Organization (WHO), in 2008, an estimated 17.3million people died from Cardiovascular Disease, representing 30% of all global death. About 6.2 million of it was due to stroke. In Malaysia, stroke becomes the third killer after heart disease and cancer with an average 110 people dying of it every day. Stroke occurs because of the interruption of blood supply to the brain due to the blood clot formation in blood vessel and to be specific, the artery in the crane. There are several techniques that have been developed to overcome the problem and one of the techniques developed was "GP" Mechanical Thrombectomy Device(GPMTD).The concept used by the device is to remove the blood clot from the artery. This device was mechanically proven suitable for soft clot while in acute cerebrovascular stroke, the whole blood clot is firm and hard. This shows that the clot is formed at different hardness. Besides, from the literature review, the clot can be removed by applying suction pressure within the range of 40kPa to 60kPa. Therefore; Navier Stokes equation will be used in ANSYS FLUENT simulation software which is Fluent 6.3.26 to simulate the blood clot extraction from the blood artery with different hardness of blood clot and under different suction pressure. By performing the simulation, the effect of suction pressure and clot hardness on blood clot removal process can be studied. By this understanding, it will help to increase the effectiveness of the blood clot removal system.

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LIST OF ABBREVIATIONS

CVD	Cardiovascular Disease
CFD	Computational Fluid Dynamics
WHO	World Health Organization
CAD	Computer Aided Design

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND STUDY

1.1.1 Cardiovascular disease

The modern style of living nowadays which full of technology is really helping to decrease the burden of people. However, too much dependence on technology will also contribute to the unhealthy lifestyle. For example, spend too much time indoor instead of going out, physical inactivity, consumptions of foods with high sugar and fat and also unhealthy diet. These are the main factors that contribute to one of the major diseases that cause death globally, which is cardiovascular disease (CVD).

According to World Health Organization (WHO) (2011), in 2008, there are 17.3million people died due to CVD which represents about 30% of all global deaths. From this 17.3million people, an estimated 7.3 million died due to coronary heart disease and 6.2 million were due to stroke. If this trend continues, experts expecting that by 2030, there are will be 23.6 million people will die from CVD, mainly from heart disease and stroke. Figure 1.1 below shows the division of causes of deaths worldwide.

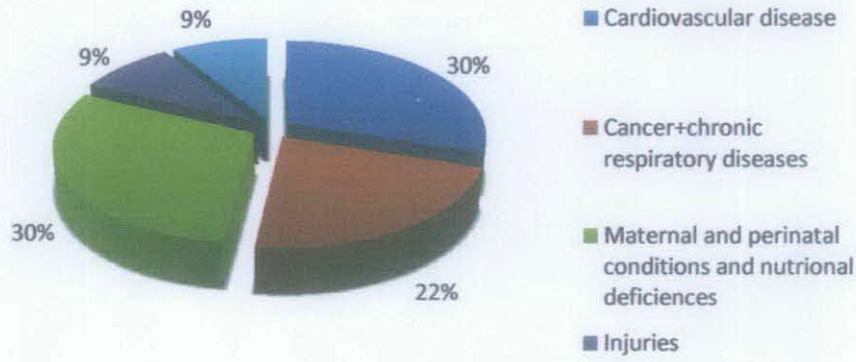


Figure 1.1: Causes of deaths worldwide

1.1.2 CVD in Malaysia

CVD in Malaysia is still on the rise despite the improvement of health services and facilities. In 2006, CVD is the second leading causes of death and in 2010, CVD become the leading cause of death in Malaysia, According to Dr Robaayah Zambahari, the senior consultant of National Heart Institute of Malaysia (NHI), the heart disease were also the main cause of death among women in Malaysia which is even more compared to cancer. Of the 15,880 women died in 2006, 4152 of them died of heart disease while 1898 died because of cancer.

While according to the Malaysia Noncommunicable Disease Surveillance 2005/2006, the prevalence of risk factors are physical inactivity, smoking, obesity, hypertension, raised blood glucose and also hypercholesterolemia. Figure 1.2 shows the factors of CVD with percentage.

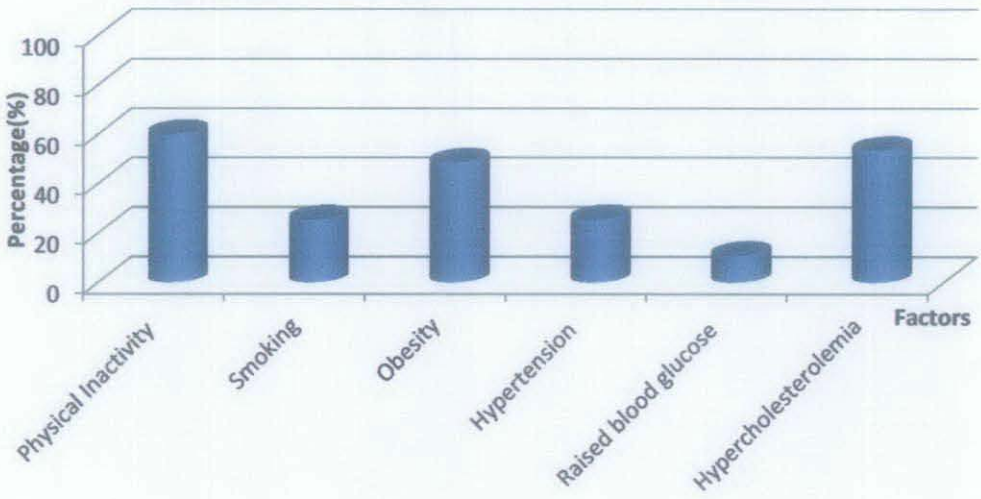


Figure 1.2: Factors of CVD with percentage

From the trend, it can be seen that, in the future, the number of people die from CVD can be increased dramatically. This prediction is even supported by the recent publication from Datuk Rosnah Abdul Rashid Shirlin,the Deputy Health Minister, Malaysia has the highest obesity rate among Southeast Asian countries and ranked sixth in the Asia Pacific Region.

1.1.3 Types of CVD

There are a few types of cardiovascular disease which are a group of disorders of the heart and blood vessel.

- Coronary heart disease
- Cerebrovascular disease
- Peripheral arterial disease
- Rheumatic heart disease
- Congenital heart disease
- Deep vein thrombosis and pulmonary embolism

Heart attack and stroke are usually an acute event and these attacks are occurred due to the blockage of blood flow to the heart or brain. Both attacks are due to the existence of fatty deposit in blood artery wall that can interfere with the steadiness of blood flow. Thus, in order to have a specific and detail research, this project will focus more on **stroke disease.**

1.1.4 Stroke

Stroke can be defined as the interruption of blood supply to the brain or usually called as "*brain attack*'. This is due to the blockage or usually called as blood clot or thrombosis formed in the blood vessel where it will prevent the supply of blood to our brain. Brain is the main organ in a body which it supports central body function and it is the one that control the bodies' activities, to think and also to control automatic function such as breathing or producing hormone in the body. The main function of blood is to carry oxygen to all cells in body. When the blood flow is interrupted, thus the oxygen is unable to be supplied to the cell. Oxygen is essential for all cells especially brain. Without oxygen supply, the brain cannot work efficiently and probably the will damage the brain cell and then cells and tissues will die. Figure 1.3 below shows the comparison between normal and blocked blood vessel

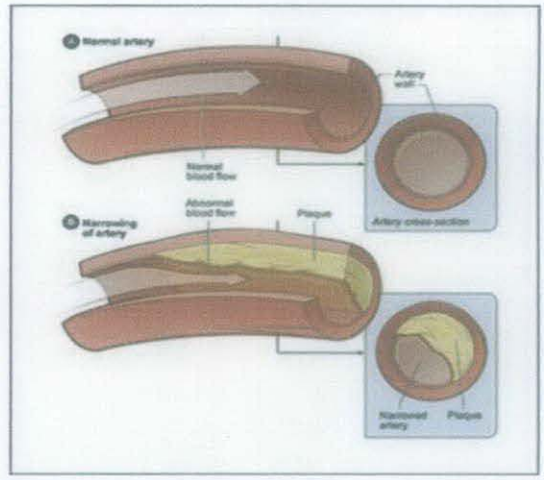


Figure 1.3: The diagram of normal and blocked blood artery

Blood is a liquid that flows within the blood vessel where it consistently flowing to whole body due to the pumping of hearts. Blood consists of:

- Red blood cell(containing hemoglobin to carry oxygen to cells and remove carbon dioxide)
- White blood cell(fight infection)
- Platelets(part of the clotting process of the body)
- Blood plasma(contains fluid, chemicals and protein required by the body)

Blood clotting is an essential mechanism to repair the blood vessel that injured. Whenever blood vessels are damage, platelets are gathered to the injured area to form an initial plug. These activated platelets will release chemicals that start the clotting cascade. When, the fibrin is formed, the protein that crosslinks with itself to form a mesh that makes up the final blood clot or medically called thrombus.

Thrombus is formed in a normal repair process in the body. However, there is little consequence. There are times when a thrombus will form when it is not required and this can contribute something significant. For example, Arterial thrombi .It is the blood clots in an artery. For those with atherosclerotic disease, plague deposits form along the lining of the artery and grow to cause narrowing of the vessel. This is the process that can cause disease such as heart attack, stroke or peripheral artery disease. Figure 1.5 shows how the blood clot is formed.

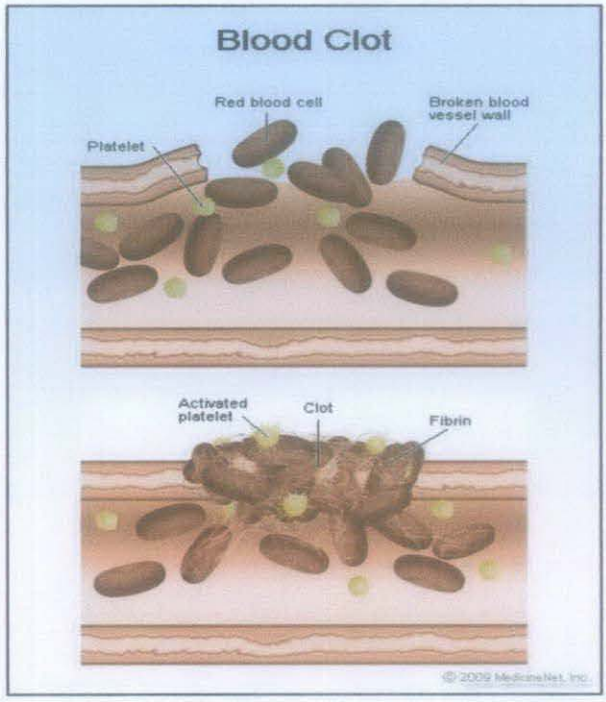


Figure 1.4: The diagram on how the blood clot is formed.

When the thrombus is growing bigger and bigger in blood vessel, the blood vessels is getting narrower. In this condition, a person is exposed to have the severe disease which is stroke.

There are a few symptoms of stroke that can be observed to the patient and it depends on what part of brain is damaged. The symptoms are usually occurring suddenly and without warning and it is the most severe when the stroke first happens. However, it also may slowly get worse. A few symptoms that may be faced by stroke patients are headache, change in alertness and taste, difficulty in swallowing, loss of balance, and muscle weakness in the face, arm or leg. Other symptoms include trouble speaking and walking (PubMed Health, 2011):

1.1.5 Types of Stroke

There are two types of stroke (Hoch, 2010). The first type is Ischemic stroke. Ischemic stroke is the stroke that caused by the interruption of the blood supply. This is because of the existence of blood clots in the artery. The blood clots will stuck in the artery and then will blocks the blood flow to the brain. According to Latchaw(2007), this type of stroke occurs because of the existence of embolus to an intracranial artery rather than *in-situ* thrombosis. Below are the three possibilities of ischemic stroke:

- **A cerebral thrombosis** (The blood clots forms in a main artery leading to the brain, and then cutting off body supply)
- **A cerebral embolism** (The blood clots forms in a blood vessel elsewhere, and is carried in the bloodstream to the brain)
- **A lacunar stroke** (The blockage is in the small blood vessels deep within the brain)

Figure 1.5 shows the graphical picture of ischemic stroke

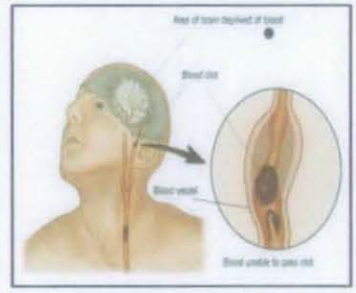


Figure 1.5: Ischemic Stroke

The second type of stroke is known as Hemorrhagic Stroke It occurs when a blood vessel in or around brain burst causing a bleed or hemorrhage. This is because high blood pressure that left untreated gives a strain on the artery walls that finally can increase the risk of bursting and bleeding. When an artery bursts, blood is forced into the brain tissue, and it will damage the cells .Therefore, the area of the brain is malfunction.

There are two types of Hemorrhagic stroke which are:

- An **intracerebral haemorrhage**, in which a blood vessel bursts within the brain itself
- A **subarachnoid haemorrhage**, in which a blood vessel on the surface of the brain bleed into the area between the brain and the skull, known as the subarachnoid space

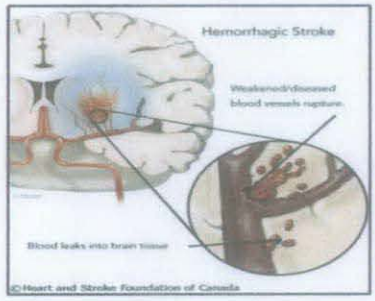


Figure 1.6: Hemmorhagic stroke

1.1.6 Treatment of Stroke

There are two methods used in removing the blood clot (Pearce, 2009) and both methods are using the same of treatment which is to remove the blood clot from the artery. The first method of treatment is known as thrombolysis. This method is to remove the blood clot by breaking the clot down. One type of drug which is tissue plasminogen activator (tPA) is used to dissolve the clot and make the artery unblocked. However, this treatment is only for acute stroke within three hours of onset of symptoms and it cannot be used to the patients have undergone recent surgery and also it may cause bleeding at the site of the clot in some instances. (Pearce, et al., 2009).Besides,thrombolysis is a lengthy procedure,require hours to achieve.In the meantime,cells are dying and the endothelium is becoming more porous,allowing hemorrhage to occur. (Latchaw, 2007)

The second method of treatment is by using mechanical thrombectomy device (MTD). During the last decade, MTD have become more widely used and have been developed into an alternative mean for clot removal (Romero et.al, 2010). The concept used by MTD is to remove the thrombus directly from the artery. Catheter is inserted into the femoral artery, directing it into the cerebral circulation and deploying a corkscrew-like device to ensnare the clot and then withdrawn from the body. The advantage of this method is it is effective in restoring blood flow in patients who are not suit with the first method. It is approximately one-third of massive pulmonary embolism are not suitable for thrombolytic therapy because of contraindications (Haude, 2007).Therefore, the best alternative for them is to use the MTD in order to remove the blood clot. Besides that, this method is not fixed for use up to 3hours post stroke just like thrombolysis .MTD also can be used in many conditions nevertheless somebody who has undergone recent surgery, allergic and etc. It makes the MTD is more flexible. Figure 1.7 below shows the example of MTD.

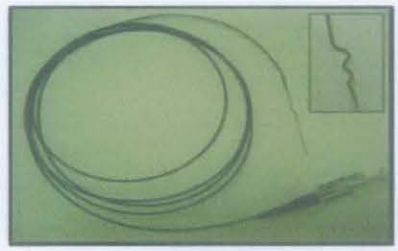


Figure 1.7: The example of MTD.

Both methods have advantages and disadvantages, and MTD is the treatment that has gained much ground in the last few years (Pearce, 2009). There are development and improvement on MTD nowadays. Among the improved MTD are GP Mechanical Thrombectomy Device (GP MTD) and novel Mechanical Thrombectomy Device as proposed by Monsky et.al, (2010).These two devices are using the same concept which is to remove blood clots away from blood vessel.

For GP MTD, there is an attachment to the head of the catheter, namely GP device or a helical spiral. The helical spiral can be inserted up to the blockage with a gap of about 3mm.The gap produced is important to make sure the catheter will not pushing the blood clot further in the blood clots and make it harder to remove it away from the artery. The blood flow direction is parallel to the catheter movement. This can produces a vortex of liquid pushed swirling in the direction of blockage and creating sort of suction to enable extraction of the blockage. The operating pressures have been found within 40kPa to 60kPa in order to remove the blockage (Ali Rahman, 2011) (Romero, et al., 2010). The helical vortex mode of action of this GP device means that there is less risk of collapse or damage in the arterial wall and less risk of downstream embolization (Pearce, et.al, 2007) .Figure 1.8 shows the actual GP MTD.

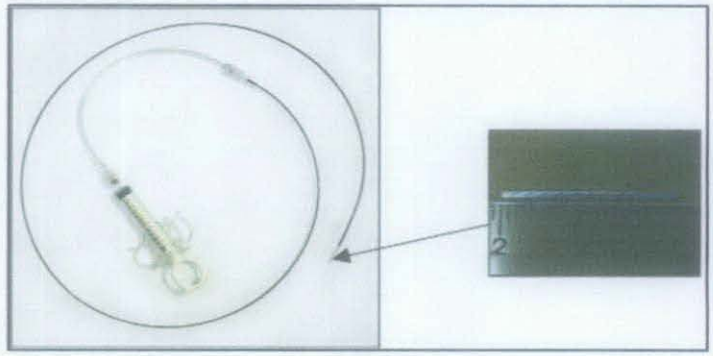


Figure 1.8: The actual GP device attached to catheter

1.2 Problem Statement

The usage of MTD in the last few years has gained much ground in biomedical application (Pearce , 2009). This is because of the significant advantages offered by MTD. Therefore, this project will focus more to the MTD and to be specific the recently invented 'GP' MTD. In Figure 1.9 below shows the illustration of GP MTD. The major difference between GP MTD and common MTD is GP MTD avoids many of potential problems such as breakage of moving parts, penetration of the arterial wall and downstream embolization (Pearce et.al, 2009). This is because the GP MTD has no moving parts and does not need to touch the clot to facilitate clot removal. The tip of the device can be inserted up to the blockage with a gap of about 3mm.By this features; GP MTD is able to remove blood clot from artery without having any risks. This device was mechanically proven suitable for soft clot. However, generally the blood clots exist with a different hardness. It can be hard or soft (Latchaw, 2007). It is due to the time of clot formed and also the location of the clot. In acute cerebrovascular stroke, whole blood thrombus or 'red thrombus" which predominate in the occluded vessel is firm and hard (Pearce,et al., 2009)Besides,the device also can used by applying different suction pressure to remove the blood clot. Therefore, the effect of the clot hardness and suction pressure to the blood clot removal by using GP device must be studied. The Computational Fluid Dynamics (CFD) is chosen to be used in order to simulate the GP device model and to predict the efficiency of the thrombectomy device before being accepted for clinical treatment. In the simulation, different blood clot hardness is simulated by varying the value of blood surface tension.

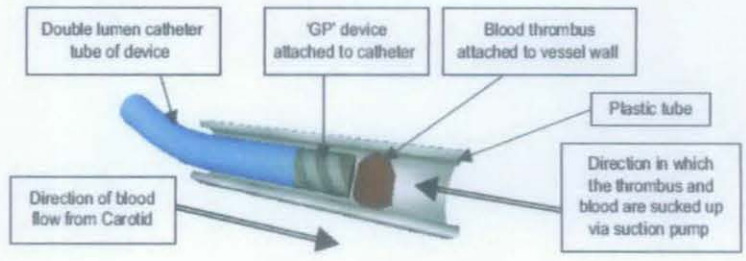


Figure 1.9: The illustration of GP MTD.

1.3 Objectives

From the problem statement, a few objectives have been outlined to be achieved in this project. The objectives of this project are:

- To simulate the blood and blood clot in Fluent
- To study the effect of suction pressure during blood clot removal
- To study the effect of blood clot hardness on blood clot removal process

1.4 Scope of Study

Computational Fluid Dynamics (CFD) method is used in this project and Navier Stoke equation will be the governing equation that is employed in the software during the execution steps. The model of the GP MTD is generated by using preprocessor software which is Gambit and then the geometry is exported to and simulated in Fluent 6.3.26.The main finding in this project is the effect of blood clot hardness on blood clot removal process. Clot hardness is varied by manipulating the surface tension coefficient of the blood in Fluent. The removal process of blood clot under different pressure is also monitored. Therefore, the scope of study is to see the effect of blood clot hardness on blood clot removal process under different pressure. The multiphase model used in the project is Volume of Fluid (VOF) to simulate both materials involved which are blood and blood clot. The movement of the clot in GP MTD model will be observed.

CHAPTER 2

LITERATURE REVIEW

2.1 Literature Review

2.1.1 Stroke

Stroke is a major cause of morbidity and mortality worldwide. The disease that affects the arteries leading to and within the brain is the no 3 cause death in United States (American Heart Association, 2011) and also Malaysia after heart disease and cancer. While in United Kingdom alone, there are 130000 strokes cases each year (Romero, 2011). For the patients that survive from the initial insult of the disease, they are always left with residual disability resulting in profound impact of their life and life expectancy.

Table 2.1: Top 10 causes of death globally (WHO, 2011)

World	Deaths in millions	% of deaths
Ischaemic heart disease	7.25	12.8%
Stroke and other cerebrovascular disease	6.15	10.8%
Lower respiratory infections	3.46	6.1%
Chronic obstructive pulmonary disease	3.28	5.8%
Diarrhoeal diseases	2.46	4.3%
HIV/AIDS	1.78	3.1%
Trachea, bronchus, lung cancers	1.39	2.4%
Tuberculosis	1.34	2.4%
Diabetes mellitus	1.26	2.2%
Road traffic accidents	1.21	2.1%

2.1.2 Latest MTD development

A novel MTD was proposed by Monsky et.al. (2010).This method consisted of a core wire, which usually made of platinum or stainless steel coil element and a stainless steel hypotube via a polyamide.This MTD is inserted into a microcatheter positioned distal to the obstruction using conventional over-the-wire coaxial angiographic technique. The device will advances the blood clots and will be actuated to produce the distal loops. This loop is required to act as a cap over the distal aspect of the thrombus. Then, the preshape coil are advanced out of the microcatheter around the midportion of the thrombus and then the proximal portion of the clot to ensure the retrieval of the intact clot as the catheter is progressively pulled back to unsheathe the device. Figure 2.1 shows the principle of operation of this MTD.

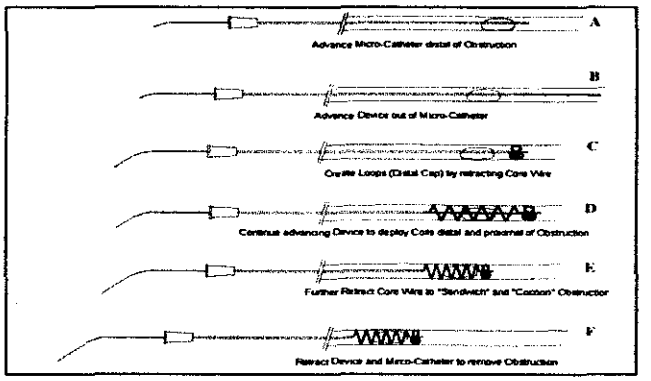


Figure 2.1: Principle of operation of Novel MTD

Compared to the GP MTD, the difference between these two devices is the way how the blood clot is removed. For GP MTD, it does not touch the blood clot in order to suck the blood clots into the catheter while for the novel MTD, it has to pass or advance through the blood clot. Besides, the clot removed by using GP MTD, is about 1cm to 5 cm in size while for the novel MTD, it is capable of removing clots with the size of up to 6cm.The direct comparison of the parameters studied could not be obtained because the MTD is still at preliminary design stage.

2.1.3 Modeling of MTD

CFD is widely used to study the liquids which in motion and is largely used in engineering. Some studies focus more on the flow through pipes, blood vessel and over various obstacles. The movement of fluid would be visualized and the related forces acting on it could be specified. To study the movement, several equations are used to explain about the conservation laws of mass, energy, momentum apply to liquids and etc.

A mathematical model that used Bond Graph, (Romero et al., 2010) technique has been established to investigate the effect of pressure on the clot extraction. The pressure is varied from zero to a non-determined value to find the suitable pressure for carrying out the extraction. In the mathematical model, the parameters studied are the minimum pressure required to extract the blood clot out from the blood vessel, depending on the clot size while the time taken to extract the blood clot is measured.

To obtain the simulation of the developed model, *Bondin* software will be used. The simulation produces block diagram to model the artery. Figure 2.2 shows the modeling artery, blood and clot components by Bond Graph technique.

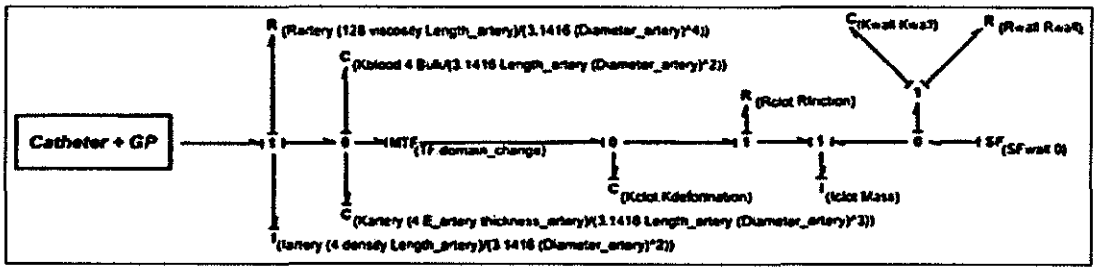


Figure 2.2: Modeling artery, blood and clot components by Bond Graph technique

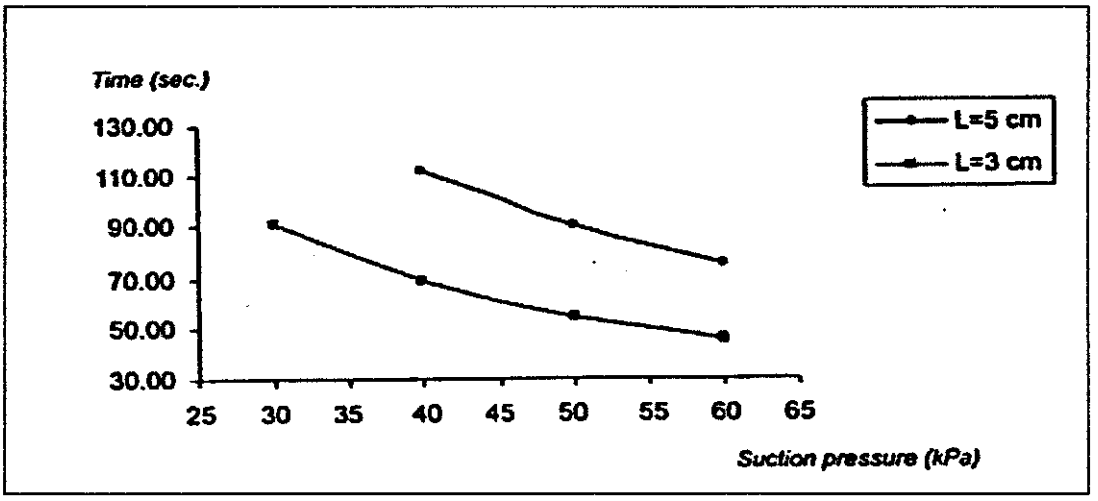


Figure 2.3: Time to begin clot movement with different sizes and suction pressure

From the data obtained, the minimum pressure to remove the blood clot for 5cm clots is 40kPa and 30kPa for 3cm in the range of 60-120seconds.

One of disadvantages of Bond Graph technique is it is unable to visualize the finding such as the velocity, flow field, vector and etc. Bond Graph technique is all about the representation of block diagram. Therefore, in order to overcome the disadvantage, the Computational Fluid Dynamic software can be used which is Fluent. Fluent provides the prediction of fluid flow by the means of mathematical modeling, numerical methods and software tools.

2.1.4 Clot hardness

The factor that affects the blood clot removal system is blood clot hardness. Generally, most of the clots formed are intracranial. Intracranial is the part within the cranium, the bone that houses and protects the brain and also gives shape to the head. Most ischemic stroke is because of the occlusion of intracranial arteries, such as the middle cerebral artery or the basilar artery (Latchaw, 2007).The blood clot formed in the intracranial arteries come in both hard and soft. Approximately, according to Latchaw (2007), 40% of the time, the clot formed in the intracranial artery is the firm-to-rock hard clot. There are MTDs that proven in removing soft clot from the artery.GP MTD also mechanically proven has the ability to remove soft blood clot. For the time being, there is no way for interventionist to predict the clot's consistency in the artery since the artery diameter is quite small which about 3mm. Therefore, any device that can remove both soft and hard

clot can be said as the first device which able to do it. In this project, the different clot hardness is simulated by varying the surface tension coefficient. Blood surface tension is one of the most crucial and important blood parameters as it will affects many vital functions of human body. Surface tension is the strong intermolecular attractive forces that experienced by molecules of liquid. When those forces are acted between similar, identical molecules, the forces are referred as cohesive forces and the strong cohesive forces at the surface are the forces that constitute surface tension. In a volume of liquid, each molecule is pulled equally in all direction by neighboring liquid molecules and produces a net force of zero. While at the surface of liquid, the molecules are pulled inward by other molecules deeper inside the liquid but there are no other liquid to balance the force. Thus, the surface molecules are subjected to an inward force of molecular. Surface tension is measured in newton per meter (N/m) and defined as the force along a line of unit length perpendicular to the surface or simply said work done per unit area (Rosina et.al, 2007).According to American Society for Testing Material (ASTM),(2011), the surface tension range for blood and body fluids is approximately between 0.040 to 0.060 N/m All surface tension coefficients are equal to 0 by default, representing no surface tension along the interface between two phases (ANSYS, 2009). Therefore, in the simulation, the soft clot is represented by the clot with low blood surface tension coefficient while the harder clot is represented by the clot with higher blood surface tension coefficient. Since there is variation in blood clot hardness, the effect of this factor must be studied and considered while designing GP MTD.

2.2 Theory

2.2.1 Computational Fluid Dynamics (CFD)

CFD is a computational technology that enables the study of the dynamics of things that flow. By using CFD, a computational model can be built which represents a system or device that want to be studied and then, the fluid flow physics and chemistry is applied to this virtual model. The CFD software will produce output which is the prediction of the fluid dynamics and related physical phenomena.

2.2.2 Navier Stokes Equation

Applying the fundamental laws of mechanics to a fluid gives the governing equations for a fluid. It is the Navier Stokes equations. This equation can be said as the basis to almost all CFD problems. The equations are time –dependent and consist of continuity equation for conservation of mass, conservation of momentum and also conversation of energy.

The law of conservation of mass which is also known as Continuity Equation states that, the mass of fluid that enters the volume minus the mass that exit must be equal to the any change in mass within the control volume.

(Rate of Mass In) - (Rate of Mass Out) = Rate of Change of Mass within the tube

Rate of Mass in = $\int_{A1} \rho v_{1n} dA$ (1)

Rate of Mass out = $\int_{A2} \rho v_{2n} dA$ (2)

For fluid and blood in particular, a good assumption that can be made is that the fluid is incompressible, where its density, ρ is constant. This assumption causes the time rate of change of mass within the control volume to be zero.

$$\frac{\partial \rho}{\partial t} + \nabla \cdot (\rho \mathbf{v}) = 0 \quad (3)$$

where ρ is the mass density (mass per unit volume), and **v** is the velocity of the fluid. This equation is the mass continuity equation.

If the equation written in Cartesian coordinates, (x, y, z)

$$\frac{\partial \rho}{\partial x} + \frac{\partial(\rho Vx)}{\partial x} + \frac{\partial(\rho Vy)}{\partial y} + \frac{\partial(\rho Vz)}{\partial z} = 0 \qquad (4)$$

The principle of conservation of momentum is formulated from Newton's Second Law of motion where it states that the sum of the forces acting on an object is equal to its mass (m) times its acceleration or

$$\sum F = ma \qquad (5)$$

Rewriting a as $\frac{dv}{dt}$ and bringing m inside the differential result in the time rate of change of momentum

$$\sum F = m\left(\frac{dv}{dt}\right) = d\left(\frac{mv}{dt}\right) \qquad (6)$$

$$\frac{\rho Dv}{Dt} = -\nabla p - [\nabla . \tau] + \rho g$$

If the equation written in Cartesian coordinates, (x, y, z)

$$\rho\left(\frac{\partial Vx}{\partial t} + Vx\frac{\partial Vx}{\partial x} + Vy\frac{\partial Vy}{\partial y} + Vz\frac{\partial Vz}{\partial z}\right) = -\frac{\partial p}{\partial x} - \left[\frac{\partial}{\partial x}\tau_{xx} + \frac{\partial}{\partial x}\tau_{yx} + \frac{\partial}{\partial x}\tau_{zx}\right] + \rho g_x$$

$$\rho\left(\frac{\partial Vx}{\partial t} + Vx\frac{\partial Vx}{\partial x} + Vy\frac{\partial Vy}{\partial y} + Vz\frac{\partial Vz}{\partial z}\right) = -\frac{\partial p}{\partial y} - \left[\frac{\partial}{\partial x}\tau_{xy} + \frac{\partial}{\partial x}\tau_{yy} + \frac{\partial}{\partial x}\tau_{zy}\right] + \rho g_y$$

$$\rho\left(\frac{\partial Vx}{\partial t} + Vx\frac{\partial Vx}{\partial x} + Vy\frac{\partial Vy}{\partial y} + Vz\frac{\partial Vz}{\partial z}\right) = -\frac{\partial p}{\partial z} - \left[\frac{\partial}{\partial x}\tau_{xz} + \frac{\partial}{\partial x}\tau_{yz} + \frac{\partial}{\partial x}\tau_{zz}\right] + \rho g_z$$

2.2.3 CFD method

Analysis begins with a mathematical model of a physical problem. The conservation of mass, momentum and energy if applicable must be satisfied throughout the region of interest. Some assumptions have to be made in order to make the problem is tractable. The examples of assumptions are steady-state, incompressible and etc. Few inputs have to be inserted in the software such as appropriate initial and boundary conditions to solve the problem. CFD applies numerical methods which usually called as discretization to develop approximation of the governing equations of fluid mechanics in the fluid region of interest. Domain is discretized into a finite set of control volumes or cells. The discretized domain is called the "grid" or the "mesh" All equation are solved to render flow field. Figure 2.4 shows the fluid region of pipe flow discretized into finite set of control volumes

.

Figure 2.4: Fluid region of pipe flow discretized into finite set of control volumes

2.2.4 Application of CFD

CFD is used in various disciplines and sector .For example, aerospace industry, automotive, power generation, chemical manufacturing, polymer processing, petroleum exploration, medical research, meteorology, and effect analysis of missiles. (Kunwar, 2009)

2.2.5 Advantages of CFD

There are a lot of advantages of CFD. CFD has the ability to simulate velocity and pressure fields in the virtual model of the system (Silva et.al, 2010). Other advantage of CFD is CFD is relatively low cost compared to experimental work. The costs are likely to decrease as computers become more powerful. If the experimental works need to be done, it will involve a lot of cost which are equipment cost, and a lot of side cost. CFD also requires short period of time to be executed.

CHAPTER 3

METHODOLOGY

3.1 Computational Fluid Dynamics (CFD)

As stated above, this project will be dealing with Computational Fluid Dynamics (CFD). CFD is a science that uses numerical methods and also algorithm to analyze and to solve problem that related to flows. The fundamental basis of almost all CFD problems is the Navier-Stokes equations. CFD incorporates empirical models for modeling turbulence based on experimentation, as well as the solution of heat, mass and other transport and field equation.

3.2 Fluent

The FLUENT software is a well-known and popular commercial CFD package. It is a powerful and flexible computational fluid dynamics packaged that contains physical models for a wide range of application which are to model the flow, turbulence, heat transfer and also reactions for industrial application.

The result of FLUENT analysis is relevant to conceptual studies of new design, detailed product development, troubleshooting and also redesign process. The application of CFD Fluent in industries absolutely can eliminate the taxing and tedious work of doing experimental works. It is also saves a lot of time since the simulation can be executed in a short period of time compared to experimental works.

Fluent solvers generally based on the finite volume method. A domain is discretized in a finite set of cell or usually called as control volume. General conservation equation for mass, momentum, energy, species and etc are solved within the control volume as shown below:

$$\frac{\partial \rho \phi}{\partial t} + \nabla.(\rho u \phi) = \nabla.(\Gamma \nabla \phi) + S\phi$$

Transient term Convection term Diffusion term Source term

3.3 Basic step in CFD

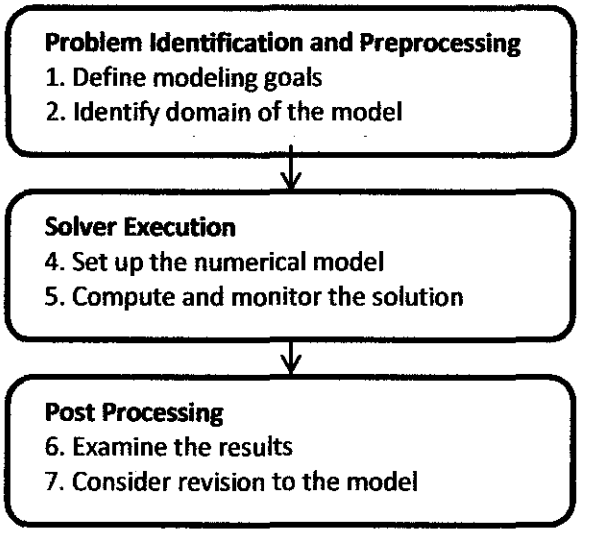


Figure 3.1: Basic steps in CFD

Figure 3.1 above shows the basic steps in CFD. There are three major steps in CFD. First step in CFD modeling is the problem identification and preprocessing. In this phase, the modeling goals should be identified. The goals of the project are to study the effect of the clot hardness on blood clot removal process and to study the effect of pressure in extracting the blood clot from artery. Therefore, to start the modeling, a solid geometry is modeled by using a CAD tool which is GAMBIT. Next, the domain of the model should be identified where the model is determined whether should be generated in 3D or 2D.In this project, the GP device is modeled in 3D.After the model is completed, it is put into a mesh generator to generate and divide the domain into a finite set of control volume.

For the next step which is solver execution which is run the simulation by using Fluent. For this project, Volume of Fluid (VOF) multiphase model is selected to be used. The VOF model can model two or more immiscible fluids by a solving a single set of momentum equations and tracking the volume fraction of each of the fluids throughout the domain. Application of the VOF model includes stratified flows, free surface flow, the motion of large bubbles in a liquid and etc. Basically, in VOF, it uses the interface tracking scheme which associated with the volume fraction of each fluid throughout the domain. There are 3 possible conditions which are:

- $\varepsilon_k = 0$ if cell is empty (of the k^{th} fluid).
- $\varepsilon_k = 1$ if cell is full (of the k^{th} fluid).
- $0 < \varepsilon_k < 1$ if cell contains the interface between the fluids

where ε_k is the volume fraction at time k .The tracking interface between the phases is accomplished by the solution of a continuity equation of one or more phases:

$$\frac{\partial \varepsilon k}{\partial t} + uj\frac{\partial \varepsilon k}{\partial xi} = S\varepsilon k$$

Mass transfer between phases can be modeled by using a user-defined subroutine to specify a nonzero value for $S_{\varepsilon k}$. The solver will continue the computation by taking into the consideration the transport equations, the operation conditions, initial solution, and also material properties after getting the input from user. The operation is simplified in the Figure 3.2 below.

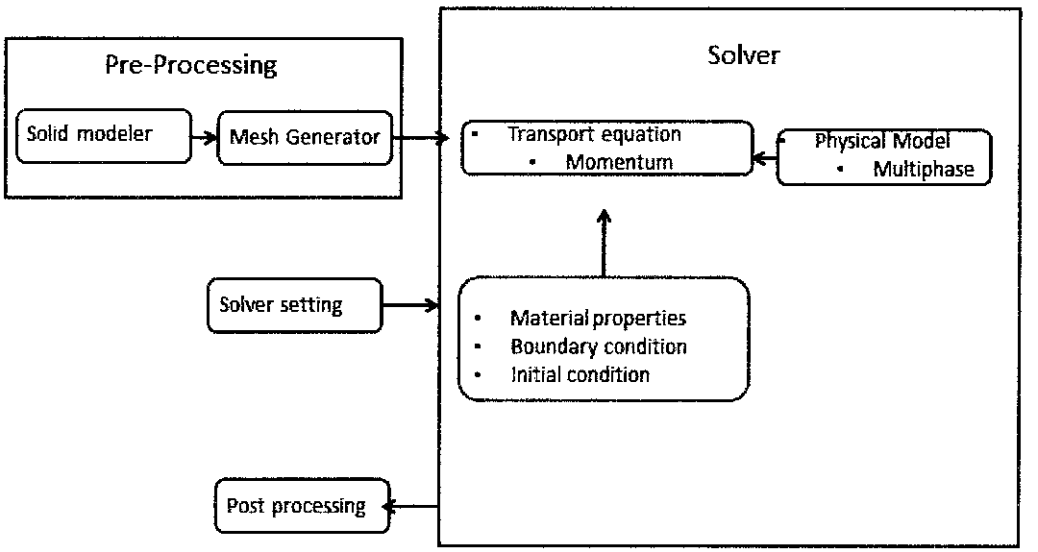


Figure 3.2: FLUENT operation system

The last step in the CFD is post processing step. In this step, the result obtained from the simulation will be studied and examined. After that, some modifications can be made in order to improve the models.

3.4 Performing Simulation

3.4.1 Problem Description

GP device is modeled by using Gambit software. Then, the geometry model will be meshed and the mesh file is simulated in Fluent with the interval size of 0.5. In this case, the GP Device is designed with the helical spiral and this represents the idealized geometry of GP Device with the length of 20mm and diameter 1mm. The domain will be modeled in 3D. Below is the schematic diagram of GP device modeled in Gambit.

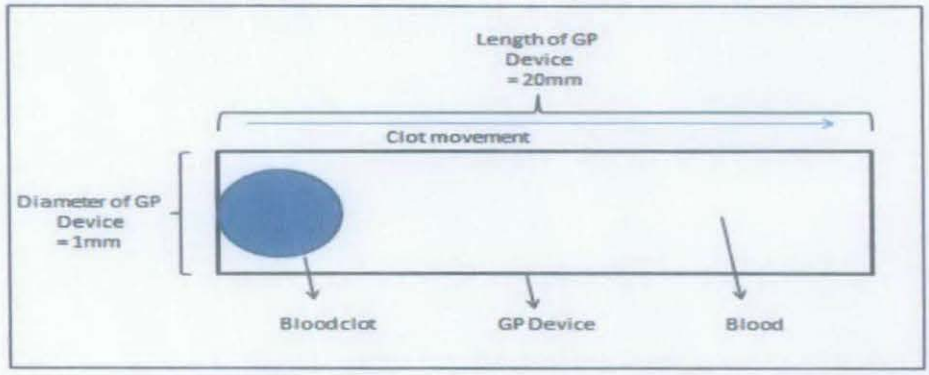


Figure 3.3: Schematic diagram of GP device

To carry out the model validation, the values of parameters used in the simulation are listed in the following table. (Romero, *et.al*, 2010)

Table 3.1: Parameters values

Pressure	0-[-30-60] kPa
Catheter length	1.10m
Catheter diameter	0.001m
'GP' length	0.02m
'GP' diameter	0.001m
Blood viscosity	0.0035Pa.s
Blood density	1060kg/m^3
Clot weight	0.001kg

3.4.2 Simulation development

After completing the meshing of model geometry, the project proceeds to the second phase of CFD modeling which is solver execution or simulation development. As stated before, the multiphase model used in this project is VOF model with laminar and unsteady state of flow (Bernard et.al, 2005). To start simulating the device in Fluent, the geometry model must be ready with the correct unit and measurement. Then, the mesh file is read and scaled according to the problem. Next step, the material properties, operating condition, boundary condition, convergence monitors have to be defined. Then, start the iteration where the computer will start calculating and computing the monitor.

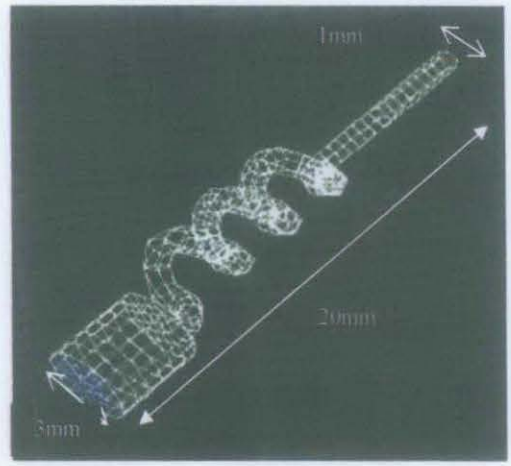


Figure 3.4: Model of GP device (Ali Rahman, 2011)

There are two materials involve in the simulation which are blood and blood clot. Both materials are in fluid phase. However, for the blood clot, it is assumed to be gel-like phase .The blood clot is located at the inlet of the GP device. The properties of the materials which are blood and blood clot are specified in the software. The properties of blood and blood clot are as stated in Table 3.2 below.

Table 3.2: The properties of blood and blood clot

Properties	Blood	Blood Clot
Density(kg/m^3)	1060	1080
Viscosity(kg/m.s)	0.0035	0.05

Since there are two materials, each of the materials must be specified as primary or secondary phases. Thus, blood is the primary phases and blood clot as the secondary phases. Blood clot is specified as secondary phase as it will be patched in the pipe. The next item that must be specified is the surface tension between molecules in fluid. Surface tension is a property of the surface that allows it to resist an external force. This property is caused by cohesion of molecules, and is responsible for many of the behaviors of liquid. In this project, the value of surface tension coefficient for blood clot-blood will be varied in order to have the variation in clot hardness. The range of surface tension is between 0.040 until 0.060 N/m (ASTM, 2011). Next, the boundary conditions at the inlet, outlet and also wall are specified. For inlet and outlet, the specification is in pressure. The pressure is also will be varied until it is able to remove the blood clot from the GP device. Some other inputs have to be inserted into the solver setting in order to solve the problem. The setting is shown below.

Equations	Flow, Volume Fraction
Pressure-velocity coupling	PISO
Pressure	PRESTO!
Momentum	QUICK
Volume Fraction	Geo-Reconstruct

The blood clot in the vessel has to be defined in the geometry. This can be done by the process of adaptation. A region which represents the secondary phase which is blood clot is patched inside the blood vessel. Below is the figure of the blood clot in the blood vessel.

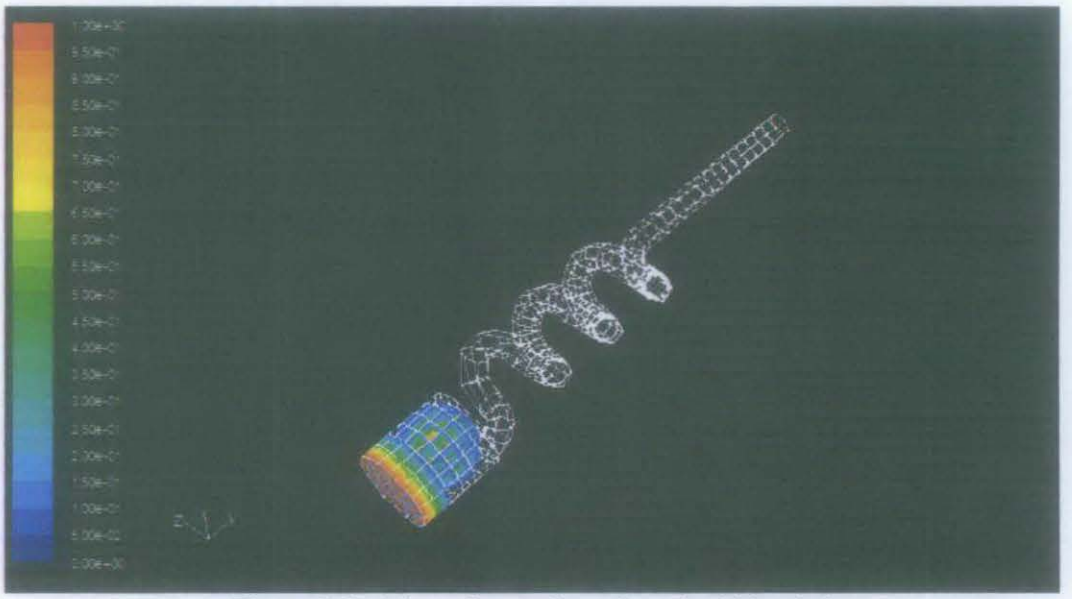
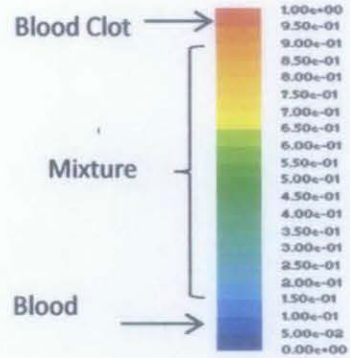


Figure 3.5: Adaptation region of patched blood clot

The last part which is post-processing part comes after all the required value and data are inserted into the software. The time step used in this project is 1.0e-6s.Small time step is required in order to capture every small detail during the blood clot removal process. It is also to avoid differences in results between platforms. After the software finish iterating, the data can be viewed by displaying the contour of blood clot volume fraction.

The calculation is finish and considered as reliable when the solution is converged. The convergence plot can be obtained while simulating the problem. The scaled residual provides a mechanism to monitor the trend. Basically, the solution is converged when the residual is below than the convergence limit defined by user.

The success of blood clot removal process can be seen on the contour display. It can be said as success whenever there is no more blood clot fraction left in the model. Figure 3.6 below shows the scale of range of volume fraction.



. Figure 3.6: Scale of Range of Volume Fraction

The processing step is one of the most important steps in the simulation work. In this part, the deformation of blood clot in the blood vessel is observed when it is subjected to certain pressure. After the solving stages are done, a data file (*.dat*) is created by FLUENT at each specified time steps. The animation sequence will help to observe the clot deformation. Therefore, from the animation sequence, the effect of clot hardness during the blood clot removal process can be observed.

The simulation is repeated by using different suction pressure and blood surface tension in order to study the effect of the clot hardness on blood removal process. Table 3.3 shows the parameters:

Table 3.3: Parameters of the project

Case	Pressure	Surface Tension(N/m)
1	40kPa	=0.040 =0.050 =0.060
2	50kPa	=0.040 =0.050 =0.060
3	60kPa	=0.040 =0.050 =0.060

CHAPTER 4

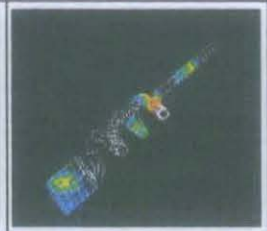
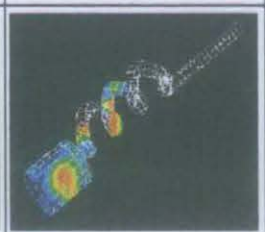
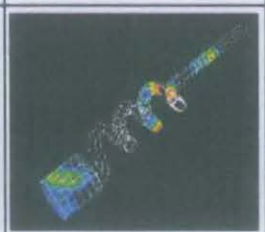
RESULT AND DISCUSSION

In this chapter, the result for the effect of suction pressure and clot hardness on blood clot removal is discussed

4.1 Effect of suction pressure on blood clot removal

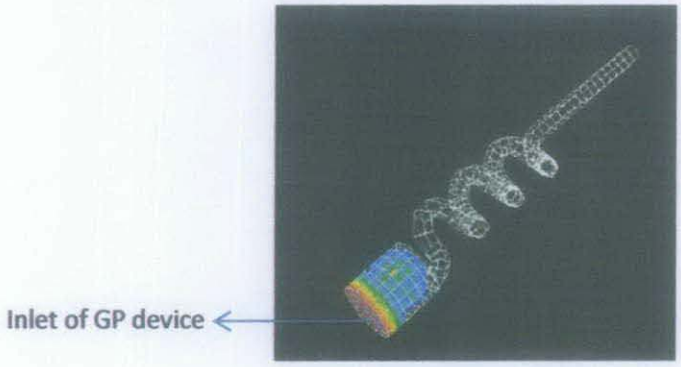
In the simulation by using FLUENT, different pressures have been applied to the system. This study is basically to see the effect of the pressure applied to the GP device on blood clot removal process. The pressure used is the suction pressure where it is applied at the outlet of the catheter and will remove the blood clot from blood vessel. The pressure range is 40-60kPa (Ali Rahman, 2011; Romero, et al., 2010).Thus, in the simulation, three different pressures which are 40kPa, 50kPa and 60kPa are applied. Once the pressure is applied, the deformation of the blood clot can be seen. Table 4.1 below shows the image of blood clot in the helical spiral device at time, t with different pressures which are 40kPa, 50kPa and also 60kPa.

Table 4.1: Image of Blood Clot in the Helical Spiral Device at Time, t with suction pressure, ΔP=40kPa, 50kPa, 60kPa

Pressure\Time	0.00 x10^{-3}s	1.00 x10^{-3}s	2.00 x10^{-3}s	3.00 x10^{-3}s	4.00 x10^{-3}s	5.00 x10^{-3}s
40kPa						
50kPa						
60kPa						

n Table 4.1 it shows the image of blood clot in the helical spiral device at time, t with suction ressure, ΔP=40kPa, 50kPa, and 60kPa .The animations which generated by FLUENT portrays he deformation of the blood clot in GP device. Thus, the deformation can be observed according o the suction time. When the pressure is applied, the deformation will start. The volume of lood clot for each suction pressure at 0.001s, 0.002s, 0.003s, 0.004s, and 0.005s is monitored. or all suction pressure applied, there is no clot removal observed after 0.004s.It means even hough the process is continued, no clot will be removed after 0.004s for any suction pressure pplied.

n order to evaluate the deformation, the volume fraction of blood clot at inlet is measured.



elow is the plot of volume fraction of blood clot at inlet against the suction time at different ressure.

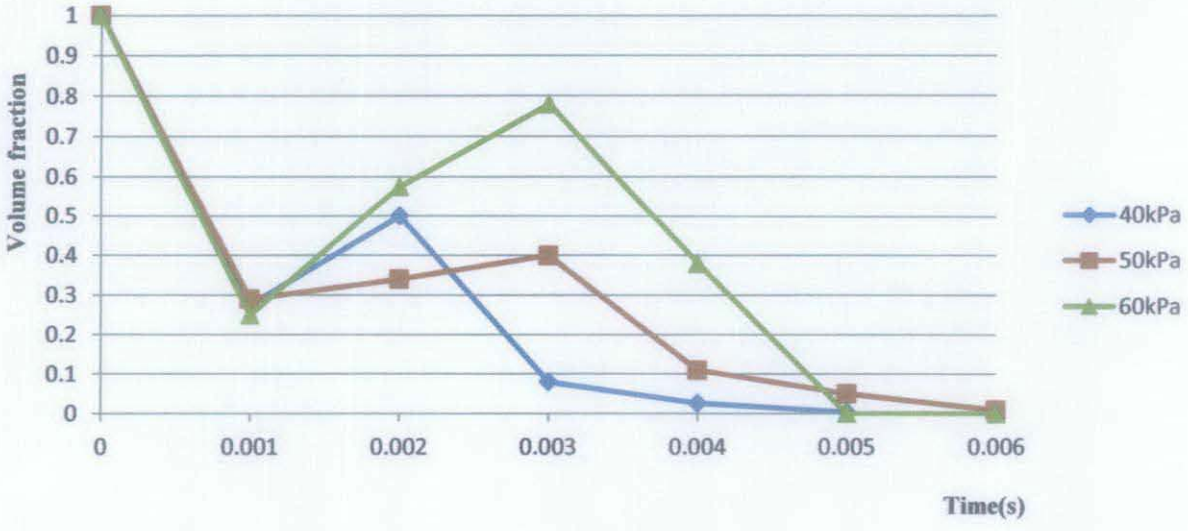


Figure 4.1: Graph of volume fraction of blood clot at inlet versus suction time

From the Figure 4.1, it shows that, the volume fraction of blood clot is reduced when comparing at the beginning and the ending of the removal process. Basically, the volume fraction initially starts from 1 and will decrease to 0 for a complete clot removal. Three different pressure has been applied which are 40kPa, 50kPa and also 60kPa.It is proven from the literature that, the blood clot can be sucked out gently using a minimum pressure of 40kPa.To compare the effect of the pressure to the blood clot removal process, the above graph is analyzed. For 40kPa and 50kPa, it reaches 0 volume fraction after 0.006s while for pressure at 60kPa, the volume fraction of blood clot at inlet reaches 0 after 0.005s.It is the shortest time taken to remove blood clot completely from the inlet of the device. The pressure of 60kPa removes the blood clot at the fastest rate compared to other pressures. It can be considered true as higher pressure tends to suck out the clot with greater force within less time.

From the observation of the graph, the suction of the blood clot is continuously occurs from time to time. Generally, the trend of the graph is decreasing, and at some time, it is increasing and then decreasing again. At the beginning, the volume fraction of blood clot drop rapidly where the volume fraction drops from 1 to 0.3.After that, there is fluctuation in volume fraction at inlet occur for every pressure applied in the system at 0.001s. The volume fraction increases for a while with the biggest increase is for the system with 60kPa of pressure. The fluctuation occurs because of the backflow of the blood in the device. When backflow occurs, it will bring the blood clot back to the inlet and thus causes the volume fraction to increase. The fluctuation for 60kPa is the largest because 60kPa is the highest pressure applied. Higher pressure will causes more backflow to the system.

From the animation generated by FLUENT, the deformation of the blood clot can be observed clearly. When the pressure is applied, the deformation will start. Blood clot, initially, in the form of sphere, and when it is sucked into the spiral part, the clot becomes fragmented into smaller pieces. The existence of the spiral part helps the 'cutting' process of the clots. Smaller clots are easier to be removed from the device. Therefore, the spiral part can be said as safety precaution for the GP device while removing the blood clot.

.2 Effect of blood clot hardness on blood clot removal

'or this study, basically the observation will be on the deformation of the clot when the pressure pplied on the system. The pressures applied are 40kPa, 50kPa and 60kPa.In order to study the lot hardness effect on blood clot removal, the surface tension coefficient is varied for each ressure applied. The surface tension coefficients are 0.04N/m, 0.05 N/m and 0.06 N/m. The clot vith the surface tension of 0.04 N/m is considered as the softest clot while the clot with the urface tension of 0.06 N/m is considered as the hardest clot. Table 4.2, 4.3 and 4.4 show the nage of blood clot in the helical spiral at certain time, t with different pressure and different urface tension coefficients.

Table 4.2: Image of Blood Clot in the Helical Spiral Device at Time, t with pressure, ΔP=40kPa

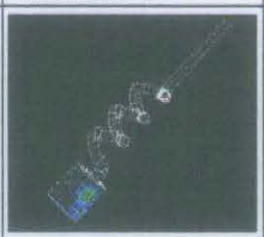
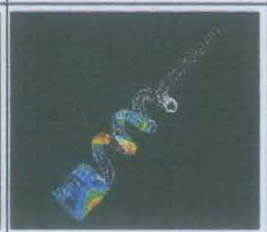
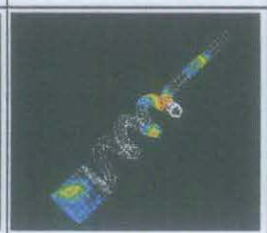
Parameter\Time	0.00 x10^{-3}s	1.00 x10^{-3}s	2.00 x10^{-3}s	3.00 x10^{-3}s	4.00 x10^{-3}s	5.00 x10^{-3}s
0.04 N/m						
0.05 N/m						
0.06 N/m						

Table 4.3: Image of Blood Clot in the Helical Spiral Device at Time, t with pressure, ΔP=50kPa

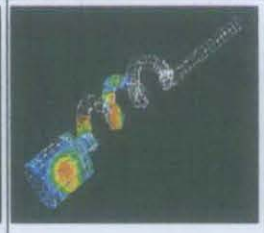
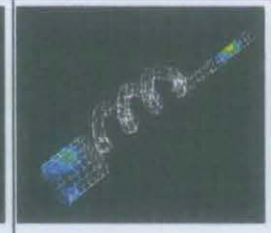
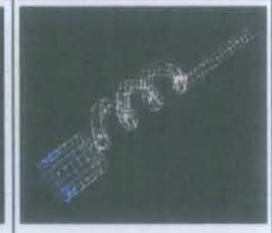
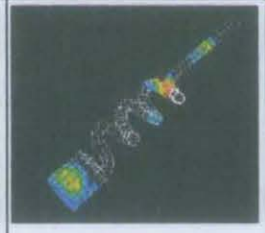
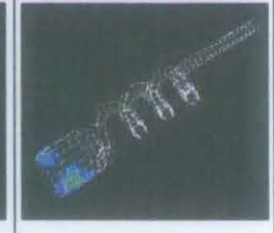
Parameter\Time	0.00 x10^{-3}s	1.00 x10^{-3}s	2.00 x10^{-3}s	3.00 x10^{-3}s	4.00 x10^{-3}s	5.00 x10^{-3}s
0.04 N/m						
0.05 N/m						
0.06 N/m						

Table 4.4: Image of Blood Clot in the Helical Spiral Device at Time, t with pressure, ΔP=60kPa

Parameter\Time	0.00 x10^{-3}s	1.00 x10^{-3}s	2.00 x10^{-3}s	3.00 x10^{-3}s	4.00 x10^{-3}s	5.00 x10^{-3}s
0.04 N/m						
0.05 N/m						
0.06 N/m						

From Table 4.2, Table 4.3, and Table 4.4, the deformation of blood clot can be seen for all clots with different surface tension coefficients for 40kPa, 50kPa and 60kPa. Just like for the study on suction pressure effect on blood clot removal process, the volume of blood clot for each suction pressure at 0.001s, 0.002s, 0.003s, 0.004s, and 0.005s is monitored. Therefore, for the observation, basically, for all suction pressure applied, there is no clot removal observed after 0.004s.It means even though the process is continued, no clot will be removed after 0.004s for any suction pressure applied at different surface tension.

From the animation also, it can be said the deformation is differing from each other depending on the surface tension coefficients and the pressure applied to the system. Therefore, in order to evaluate the effect of clot hardness, the volume fraction of blood clot at inlet is plotted against suction time. Below is the plot of volume fraction of blood clot at inlet versus suction time for 40kPa.

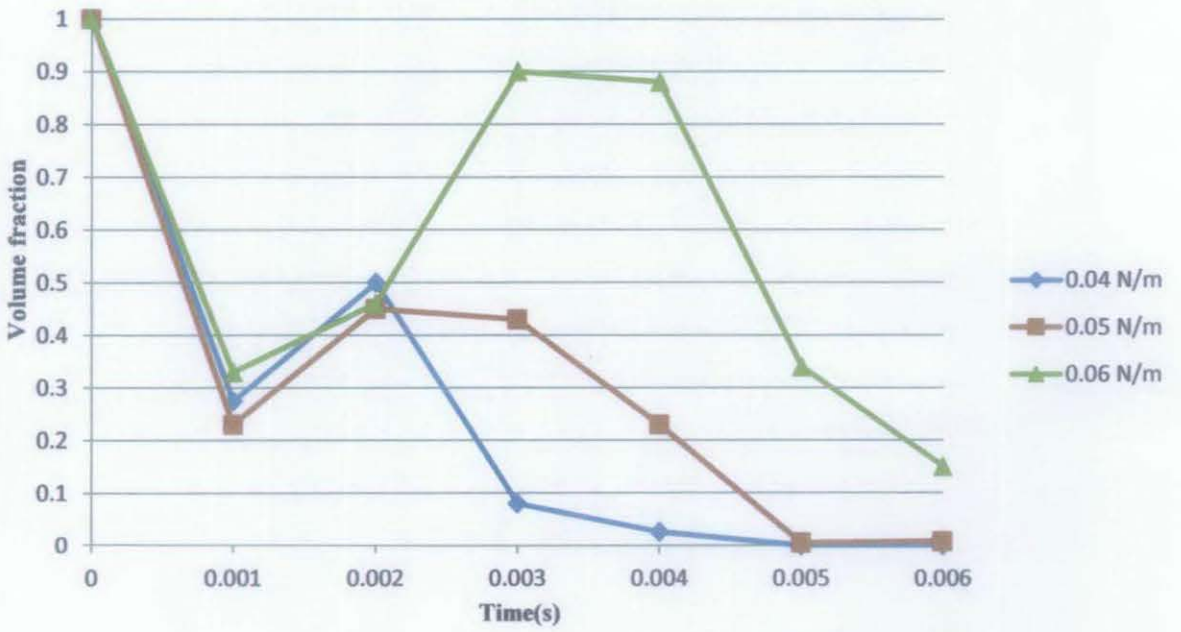


Figure 4.2: Graph of volume fraction of clot at inlet versus suction time for pressure=40kPa

igure 4.2 above shows the volume fraction of blood clot at inlet versus suction time when 0kPa pressure is applied for different surface tension coefficients. The volume fraction of blood lot is reduced when comparing at the beginning and the ending of the removal process. From ıe observation, basically as time increases, the volume fraction will decrease. Except at several oints which is at 0.001s where the volume fraction increases as it is the effect of the backflow. ıfter 0.006s, the blood clots with surface tension coefficients of 0.04 N/m and 0.05 N/m, which epresent soft and medium hard clot, are completely removed from the inlet of the device. lowever, for the clot with surface tension coefficient of 0.06N/m which represents the hard clot, ıere is remaining clot available at the inlet. It is generally true as harder clot is more difficult to e removed since the force from the pressure applied which is 40kPa not enough to suck the clot ut from the device.

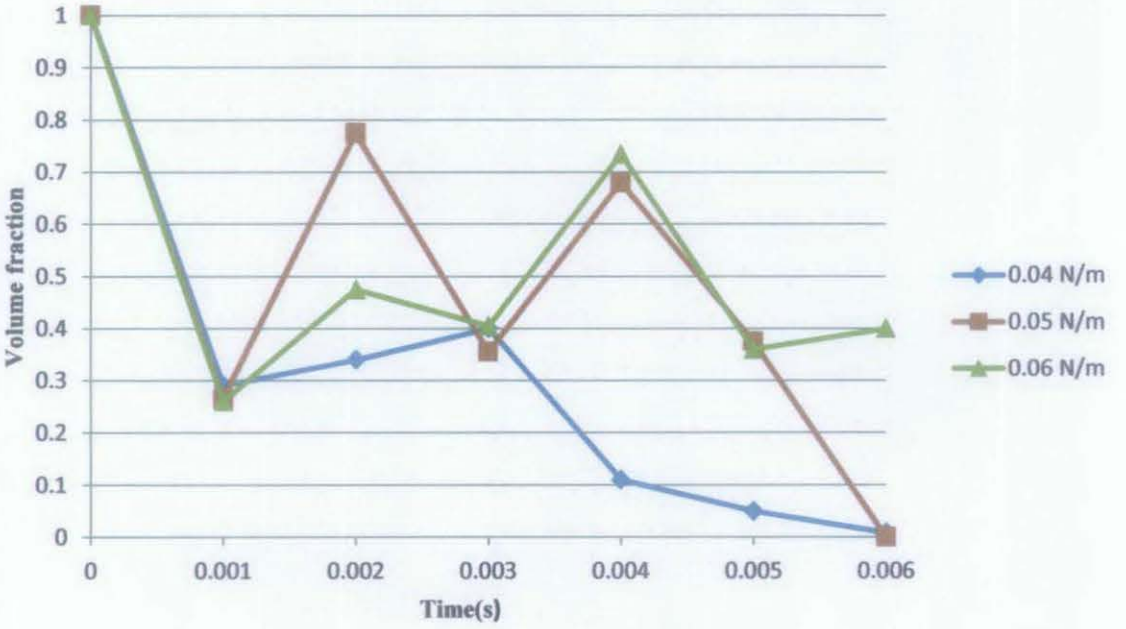


Figure 4.3: Graph of volume fraction of clot at inlet versus suction time for pressure=50kPa

he graph in Figure 4.3 above shows the volume fraction of blood clot at inlet versus the suction me when the suction pressure of 50kPa is applied. The trend is just the same with the Figure 4.2 fter 0.006s, there is still blood clot remaining at the inlet for the clot with surface tension oefficient of 0.06N/m. The remaining blood clot cannot be removed by applying 50kPa pressure nce the suction force is still not enough to suck the clot out. For the clot with the surface

ension coefficient of 0.04 N/m and 0.05N/m , it can be removed easily since it is considered soft nough to be removed with low force resulted from the pressure applied.

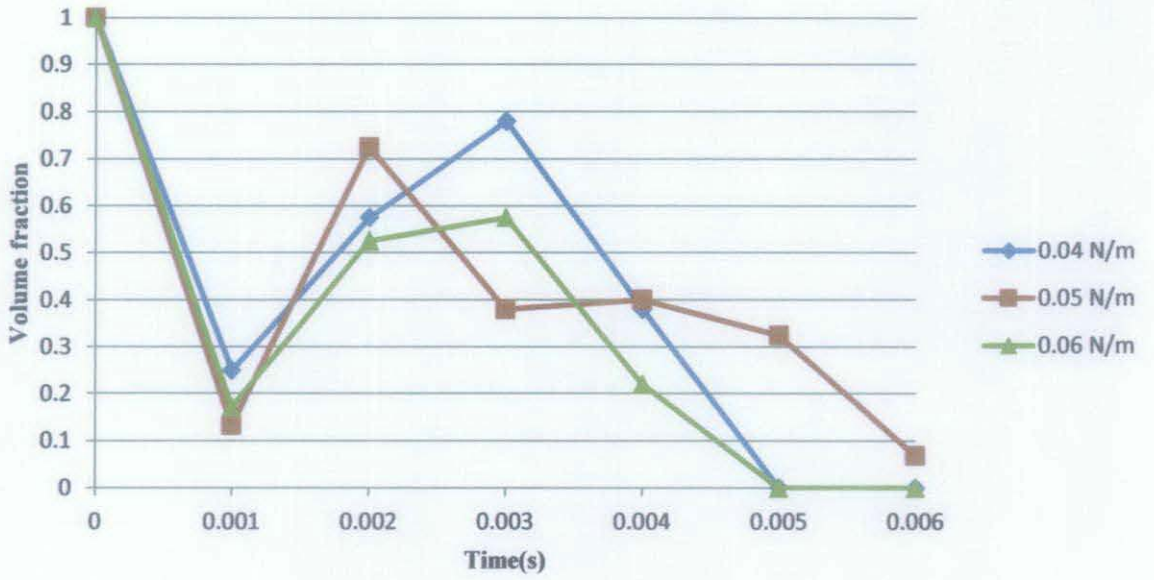


Figure 4.4: Graph of volume fraction of clot at inlet versus suction time for pressure=60kPa

igure 4.4 above shows the volume fraction of blood clot at inlet versus suction time when 0kPa of suction pressure is applied .Basically, the hardest clot with the surface tension oefficient of 0.06N/m found the be removed completely from the inlet of GP device when 0kPa suction pressure is applied. It is different with the result of the application of 40kPa and 0kPa to the system where it is found that there is still remaining blood clot in the system. esides, the blood clot with the surface tension of 0.04 N/m and 0.05 N/m which represent soft nd medium hard clot are completely removed from the inlet of the GP device. It is removed at me is 0.005s.It can be considered the fastest compared to the pressure of 40kPa and 50kPa.This because of the force produced when the pressure of 60kPa is applied is strong enough to move the clot with shorter time. From the graph also, the fluctuation of the graph can be seen early occurs to the clot with surface tension of 0.04 N/m at time 0.001s. The fluctuation is igger compared with the fluctuation occurred when 40kPa and 50kPa pressures are applied. It is ecause when 60kPa of pressure is applied, the resulted force will cause the soft clot is back owed more into the system. That is why the volume fraction increase higher compared to hers.

CHAPTER 5

CONCLUSION AND RECOMMENDATION

.1 Conclusion

.fter studying the concept of GP device invented by Pearce (2009) and some application of CFD
ı this project, finally, the simulation of the model are successfully done. The blood and blood
lot in GP device is simulated and there are also the animations to show how the blood clot is
:moved from the device by applying suction pressure.

or the study of suction pressure effect on blood clot removal process, three different pressures
ıat are recommended by the literature review and previous works which are 40kPa, 50kPa, and
!so 60kPa are applied to the system. Based on the removal process of the blood clot in
LUENT, it shows that, the blood clot is removed faster when higher pressure is applied. In this
roject, the pressure of 60kPa removes the blood clot from the inlet is the fastest .Besides, it is
)und that, the backflow occurs in the system is bigger when higher pressure is applied. From the
ıimation produced, it can be said that, there is no more blood clot removal for any pressure
ter 0.004s of the removal process.

/hile for the study of the effect of clot hardness on blood clot removal process, three different
ırface tension coefficients are used to represent different hardness of the clot. The surface
nsion coefficients are 0.04N/m, 0.05N/m and also 0.06 N/m and the simulation is simulated
ıder three different pressures .From the animation generated by FLUENT, the deformation of
ood clot in the removal process can be observed. Thus, from the observation, it can be said
at, the hardest clot which represented by surface tension of 0.06N/m can be removed by
)plying 60kPa of suction pressure. Besides, the time to remove the blood clot is also vary,
:pending on the hardness of the clot.

.2 Recommendation

or further improvement of the project in the future, several recommendations are made. The rst recommendation is to model the device in artery. For now, the model is without the artery. If ıe artery can be modeled in FLUENT, it is much better since it is closer to the real condition.

esides that, the study can be further enhanced by studying the vortex produced during the ıction process. The gap between clot and GP device will create sort of vortex flow that assist ıe suction of the blood clot. Therefore, by studying the vortex, the condition at the inlet of the P device can be known.

ast but not least, artery could withstand a certain range of pressure or else it will cause injury to tery wall. Therefore, further investigation can be made to look the pressure effect on the artery all.

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FYP 1 Gantt Chart

No	Detail/Week	1	2	3	4	5	6	7		8	9	10	11	12	13	14
1	Selection of topic – Topic related to Biomedical Device-MTD	*	*						#							
2	Literature review on stroke and treatment(MTD and GP MTD)		*	*	*	*			B							
3	FYP1 Briefing given by FYP Coordinator		*	*					R							
4	Submission of Extended Proposal						*		E							
5	Proposal Defence								A	*	*					
6	Familiarization with software ,Preparation of Interim report								K			*	*	*		
7	Submission of Interim Draft Report								#						*	
8	Submission of Interim Report								#							*

No	Detail/Week	1	2	3	4	5	6	7		8	9	10	11	12	13	14
1	Project work continue(Doing tutorial-Gambit and Fluent,)	*	*						#							
2	FYP II Briefing			*					#							
3	Project work continue(Start doing model according to problem)		*	*	*	*			M							
4	Running simulation				*	*	*	*	I							
5	Submission of Progress Report								D	*						
6	Project work continue(Different surface tension, Different size,3D)								B	*	*	*	*			
7	Pre SEDEX								R				*			
8	Submission of draft report								E					*		
9	Submission of Dissertation(softbound)								A						*	
10	Submission of Technical Paper								K						*	
11	Oral Presentation								#							*
12	Submission of Dissertation(hardbound)								#							*