Computational Fluid Dynamics (CFD) Simulation for the Extraction of Blood Clot in Middle Cerebral Artery using 'GP' 2 Device

by

NUR NAZEHAH BINTI ABDUL RAHAMAN

Dissertation submitted in partial fulfilment of the requirements for the
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DISSERTATION REPORT

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CERTIFICATION OF APPROVAL

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(CHEMICAL ENGINEERING)

Approved by,

_____

(AP Dr. Ku Zilati Ku Shaari)

UNIVERSITI TEKNOLOGI PETRONAS
TRONOH, PERAK
SEPT 2012

CERTIFICATION OF ORIGINALITY

This is to certify that I am responsible for the work submitted in this project, and the original work is produced on my own except as specified in the references and acknowledgements, and it has not been undertaken or done by unspecified sources or person.

Produced by,

_____

NUR NAZEHAH BINTI ABDUL RAHAMAN

ABSTRACT

Stroke has become the number three killer disease in Malaysia following heart disease and cancer; with 110 of people dying from it every day. The effects of stroke often lead to life-changing, permanent impairment to the patients such as paralysis, speech and logic sequencing. Hence, recent studies are looking into stroke treatments with minimal after surgical effect to patients. One of the alternatives is using mechanical thrombectomy devices. In this project, the simulation for 'GP' 2 device which functions to extract the blood clot in the artery without damaging the arterial wall and causing downstream embolism is presented. The simulation will be carried out using computational fluid dynamics; applying the Volume of Fluid (VOF) model.

In grid size selection, it is clear that finer grids results in higher accuracy calculations i.e. better results. However, this is achieved at the cost of prolonged computational time. From grid sensitivity study in identifying the optimum grid size that is fine enough to generate accurate calculations but large enough to avoid extra computational time; the grid size of 0.2mm is used.

The design for 'GP' 2 Device has to be characterised to identify which of the two proposed designs is efficient for the suction of blood clot for 100% occlusion in the Middle Cerebral Artery. Design for 'GP' 2 Model 1 device is better at clot extraction than the Model 2 device because increase in surface area for suction favours same-suction principle rather than vortex creation to break the clot. Theoretically, higher pressure results in faster clot extraction. However, the value of pressure applied shall be observed closely so that no arterial damage is done and it can be applied for clinical tests. For both models, it can be shown that higher pressure extracts blood clot at lower time whereby the fastest clot extraction occurs at time 0.00498s for Model 1, and 0.01211s for Model 2 both at 60 kPa.

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INTRODUCTION

1.1 Project Background

Millions of people suffer from stroke annually. Stroke, or cerebrovascular accident (CVA), occurs when blood supply to part of the brain is disturbed, causing brain cells to die; because brain cells need constant supply of oxygen and glucose to function(Wedro, 2009). Blood flow can be compromised by a variety of mechanisms such as blockage of the artery or rupture of the artery (Wedro, 2009). Arterial blockage can be caused by several factors such as narrowing of the small arteries inside the brain, hardening of the major arteries supplying blood to the brain and also formation of blood clots from the heart to the brain, called embolism (Wedro, 2009). Arterial rupture on the other hand, is bleeding in the brain due to high blood pressure (Wedro, 2009). There are two main types of stroke, ischemic stroke and haemorrhagic stroke. Ischemic stroke accounts for about 75% of all strokes and occurs when a blood clot (thrombus) forms and blocks blood flow to part of the brain (Crosta, 2009). This wandering clot may be carried through the bloodstream to the brain where it can cause ischemic stroke (Crosta, 2009). A haemorrhagic stroke occurs when a blood vessel on the brain's surface ruptures and fills the space between the brain and skull with blood or when a defective artery in the brain bursts and fills the surrounding tissue with blood (Crosta, 2009).

The blockage of an artery in the brain by a clot (thrombosis) is the most common cause of a stroke (Wedro, 2009). The part of the brain that is supplied by the clotted blood vessel is then deprived of blood and oxygen, and as a result the cells of that part of the brain die and the body part that it controls stop working (Wedro, 2009). Medical institutions nowadays are finding the best possible method to remove the blockage (blood clot) with minimal effect to the brain to reduce the after-surgical effect to the patients. Ideally, removing the blood clot and re-establishing normal flow in the affected artery shall cure patients with stroke with minimal after surgical effect. Such method is called thrombosis. In understanding thrombosis, according to Bernsdorf (2005), a comprehensive understanding of Virchow’s triad must be accomplished. Virchow’s triad discusses the factors thought to cause thrombosis. In

the first triad, alterations in normal blood flow. In the second triad, phenomena associated with irritation of the blood vessel and its vicinity, and the third triad; alterations in the constituents of blood.

Generally, the treatment for stroke depends on what causes stroke for the patient; either by blood clot (ischemic) or bleeding in the brain (haemorrhagic). However, we will refine the research area covering only stroke caused by blood clot which is the common case for stroke. For patients diagnosed soon enough after the show for symptoms, they will be given a clot-dissolving medicine called tissue plasminogen activator (t-PA). t-PA acts to dissolve the blood clot and re-establishing normal blood flow by biochemical reaction. However, the usage of t-PA has their limitations. Due to the risk of haemorrhage (abnormal bleeding) it is contraindicated to patients who have undergone recent surgery (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). In addition, it has to be given at a relatively early time after stroke has occurred and be used up to 4 to 5 hours post-stroke(Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). Hence, with these available limitations, mechanical thrombectomy devices are recently developed as alternative means for clot removal.

In recent years, Mechanical Thrombectomy Devices (MTD) has become widely used as an alternative to remove blood clots. The Gwen Pearce Thrombectomy Aspiration Device (GP TAD) is designed to mechanically remove the blood clot from the artery and re-establish normal blood circulation to the brain. The extraction of the clot by the device is done by means of vacuum suction provided by a pump (Pearce G. , Perkinson, Romero, Martinez, & Felez, 2011). The vacuum suction generates a vortex created by a mathematical design of its internal surface to facilitate suction of the clot. Such characteristic also gives rise to low forces on the periphery of the device; therefore, less risk of arterial collapse (Pearce G. , et al., 2009). Previously, a research was carried out to prove the theoretical hypothesis associated with the ‘GP’ Device. In this project however, two new designs for ‘GP’ device mark 2 are studied using computational fluid dynamics.

The need to study new MTD devices means that a computer pre-modelling may be helpful in the optimization and fine-tuning of the medical devices prior to clinical trials (Pearce G. , Perkinson, Romero, Martinez, & Felez, 2011). One of the subjects

of interest in relation to finding cure for stroke is to study the fluid flow for the blood clot and its behaviour when a mechanical device is used to remove it. Studies comparing the experimental data and simulation data are carried out to prove the theories associated with the designed devices. Simulating the dynamics of fluid flow can be done by Computational Fluid Dynamics (CFD). Users are able to generate the domain geometry in which the desired computations are iterated. This is a virtual way of carrying out the experiments by setting up the necessary boundary conditions and let the software calculate the outcome fluid dynamics parameters.

Computational fluid dynamics (CFD) is branch of fluid mechanics which uses numerical methods to solve and analyse problems related to fluid flows. CFD is a powerful, reliable and efficient tool; carried out using computers to perform required calculations to simulate the interaction of fluids with surfaces predefined by boundary conditions. One of the advantages of using CFD is it provides a platform for low cost but relatively accurate research because it allows the simulation for real time conditions without having to build the equipment to carry out the laboratory experiments. Besides that, using CFD is safe because the research does not involve experiments on human beings. Therefore, it allows for preliminary detection for possibilities of risks when the 'GP' 2 device is applied to patients later on. In this project, ANSYS FLUENT (FLUENT) software will be used to carry out the simulations; and ANSYS DesignModeler (DesignModeler) will be used to generate and mesh the geometry.

1.2 Problem Statement

Mechanical thrombectomy devices are one of the methods to remove blood clot in the artery. However, most mechanical devices have the drawback of using moveable parts, or involve contact with luminal wall (Pearce, Patrick, & Perkinson, A New Device for the Treatment of Thromboembolic Strokes, 2007). The recently invented and patented 'GP' device avoids many potential problems associated with the usage of mechanical devices in removing blood clot such that it has no moving parts and does not need to touch the blood clot to facilitate clot removal(Pearce G. , et al., 2009). The application of suction through a micro-catheter allows removal of blood clot and any subsequent debris without the necessity for direct contact with the clot surface (Pearce, Patrick, & Perkinson, A New Device for the Treatment of Thromboembolic Strokes, 2007). The 'GP' device has a tube of helical spiral design embedded at the last 20mm end of the micro-catheter. The schematic view of the 'GP' clot removal device is as shown below:

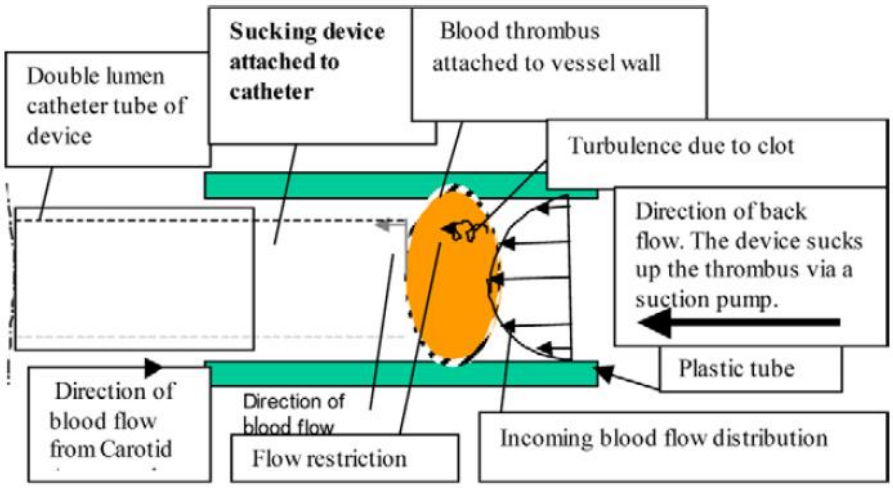


Figure 1: 2D schematic view of GP device (Pearce, Patrick, & Perkinson, A New Device for the Treatment of Thromboembolic Strokes, 2007)

Moreover, a newer design 'GP' 2 device has 9 helical spiral or cylindrical tube around the periphery of the device. With the increase in number of tubes, it is assumed to be more efficient such that blood clot suction can be done with lesser time at the same applied suction force. Hence, 'GP' 2 device is theoretically an improved design of the 'GP' device allowing more efficient clot removal. The mode of operation for 'GP' 2

device is similar to ‘GP’ device. Below is the 2D sketch showing the difference in the geometry designs.

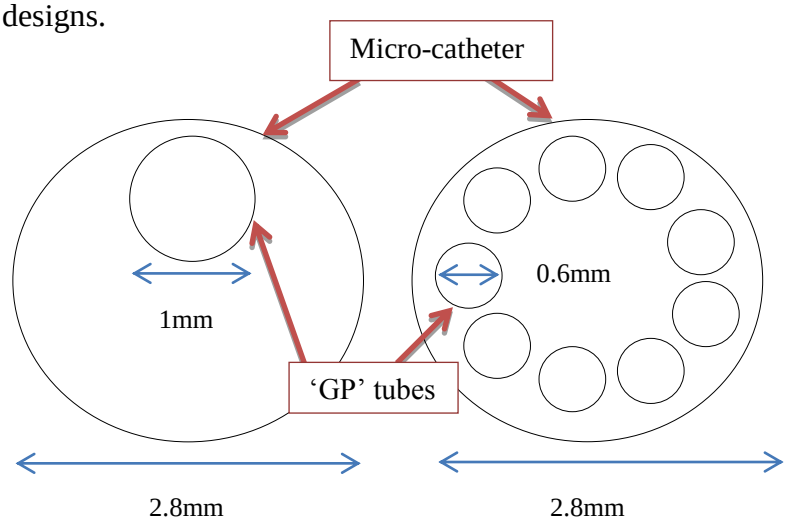


Figure 2: 2D sketch for the geometry of ‘GP’ device (left) and ‘GP’ 2 device (right)

Implementing these devices on human beings is the ultimate goal. It is invented to be used to cure for stroke in humans. However, testing for the feasibility to use this device to cure for stroke in human beings can be very risky. Since the device is small and the operating conditions severe, instrumentation for making necessary flow measurements is extremely difficult to design; therefore it became necessary to look at the flow by computational means (Kiris & Kwak, 2007). Hence, an alternative method to experiment and to testify if these devices can be used to cure stroke for human beings is by using CFD simulation. This is because, CFD allows for real time simulation at lower risk and cost. CFD also offers reliable results.

1.3 Objectives and Scope of Study

The objective of this study is to carry out 3D FLUENT simulations to compare the two proposed designs of 'GP' 2 device for the treatment of thromboembolic strokes in Middle Cerebral Artery (MCA); an artery where blood clot in stroke patients most commonly occur. Model specifications are as tabulated below:

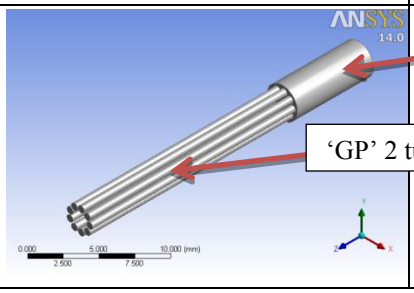
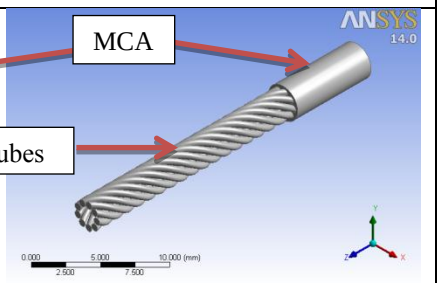
Model type / Description	**Model 1**	**Model 2**
Number of tubes	9	9
Tube Diameter (mm)	0.6	0.6
Tube Shape	Cylindrical	Helical spiral
Horizontal Length (mm)	20	20
Diagram		

Table 1: Geometry specification for the two proposed designs for 'GP' 2 device

The scope of this research is outlined as follows:

- Create and mesh the geometry domains using DesignModeler
- Carry out grid sensitivity study to identify the most accurate but coarse grid to minimize computational time without jeopardizing the accuracy of the results.
- Carry out the simulation using FLUEN for a range of pressures
- Compare the two designs to identify the best geometry for clot removal.

This research will useful to Dr. Gillian Pearce of Kiel University, United Kingdom and her team of collaborators, for preliminary results to compare between the two models of 'GP' 2 device. Deeper and more insightful research on this device to determine its potential and applicability for clinical trials will be beneficial for stroke patients worldwide.

CHAPTER 2

LITERATURE REVIEW

This section emphasizes on the previous studies carried out which are related to the subject matter and its relation to the development of this study. In the first section, current available methods to remove blood clot are discussed. In the second section, theories and studies related to the modelling of blood clot are discussed. Finally, in the last section, the theories related to the computational methods used in the software FLUENT are discussed.

2.1 Methods to Remove Blood Clot in Artery

Treatment efforts to clear blood clot causing stroke has been made directly by surgery, with clot-dissolving drugs (thrombolysis), or by inserting a mechanical thrombectomy device (MTD) (Pearce, Perkinson & Patrick, 2007). The drawback of thrombolysis is the short therapeutic time window of 3 hours after stroke onset and the contraindication effects it has on some patients, making the range of patients suitable to receive cure treatment smaller.

A study carried out by Tennuci et al (2011), a comparison for the effectiveness of three methods of recanalization in a model of the Middle Cerebral Artery; comparing i) thrombus aspiration via a 4F catheter, ii) thrombus aspiration via the 'GP' thrombo-aspiration device, and iii) mechanical thrombectomy using the solitaire thrombectomy device shows that thrombus aspiration is faster with the usage of mechanical thrombectomy. The three methods of recanalization of an occluded vessel were tested in a pulsatile model of the cerebral circulation. The pulsatile environment is created using a peristaltic pump creating the pulse in a Hartmann's solution placed in a beaker in a 37° C water bath (Tennuci, et al., 2011). A silicone model with 3mm internal diameter is used as Middle Cerebral Artery (MCA). The main finding of this study shows that all three devices successfully removed majority of clots in the MCA. Recanalization rate is 15% higher with the 'GP' TAD than with the 4F catheter; and a further 8% higher with the Solitaire than the 'GP'TAD (Tennuci, et al., 2011). In this study, the GPTAD appeared to grasp the clot better than the 4F catheter, with more

successful first-attempt removals, and this may have caused less fragmentation (Tennuci, et al., 2011). However, once the clot was grasped, clot removal was smooth. Both devices appeared to stretch the clot on removal (Tennuci, et al., 2011). The GPTAD creates a vortex with suction and does not touch the clot during removal thus reducing the risk of fragmentation compared to the 4F catheter (Tennuci, et al., 2011). The Solitaire device uses an open-slit, closed cell design which interacts with the thrombus, giving an optimal radial force, increasing the chance of clot trapping (Tennuci, et al., 2011). In this study, it ensnared clots up to 45mm of length within the struts of the device (Tennuci, et al., 2011). From this study, it shows that extraction of blood clot via mechanical thrombectomy ('GP' TAD and Solitaire) is more efficient.

One of the established mechanical thrombectomy devices is the Mechanical Embolus Removal in Cerebral Ischemia (MERCI). Gobin et al (2004) reports the result of MERCI 1 study, a phase 1 trial to evaluate the safety and efficacy of mechanical embolectomy in the cerebral vasculature to 28 patients in 7 US centres. Using standard cerebral catheterization techniques, the micro-catheter was guided into the occluded vessel and pass beyond the thrombus (Gobin, et al., 2004). A selective angiogram was performed distal to the thrombus to evaluate the size and tortuosity of the distal arteries, where the Merci Retriever was to be deployed (Gobin, et al., 2004). The Merci Retriever was then advanced through the micro-catheter and 2 to 3 helical loops were deployed beyond the thrombus (Gobin, et al., 2004). The Merci Retriever was then retracted at the contact of the thrombus, and proximal loops were then deployed within the thrombus (Gobin, et al., 2004). The balloon guide catheter (BGC) was inflated to control intracranial blood flow during removal of the thrombus and 5 clockwise rotations were applied to the Merci Retriever to further ensnare the thrombus(Gobin, et al., 2004). The Merci Retriever, with the ensnared thrombus, and the microcatheter, were withdrawn together into the BGC lumen (Gobin, et al., 2004). Continuous aspiration was applied to the BGC to ensure complete evacuation of the thrombus (Gobin, et al., 2004). The balloon of the BGC was deflated to re-establish flow; and upon confirmation of complete evacuation of thrombus, a repeat angiogram was performed (Gobin, et al., 2004).

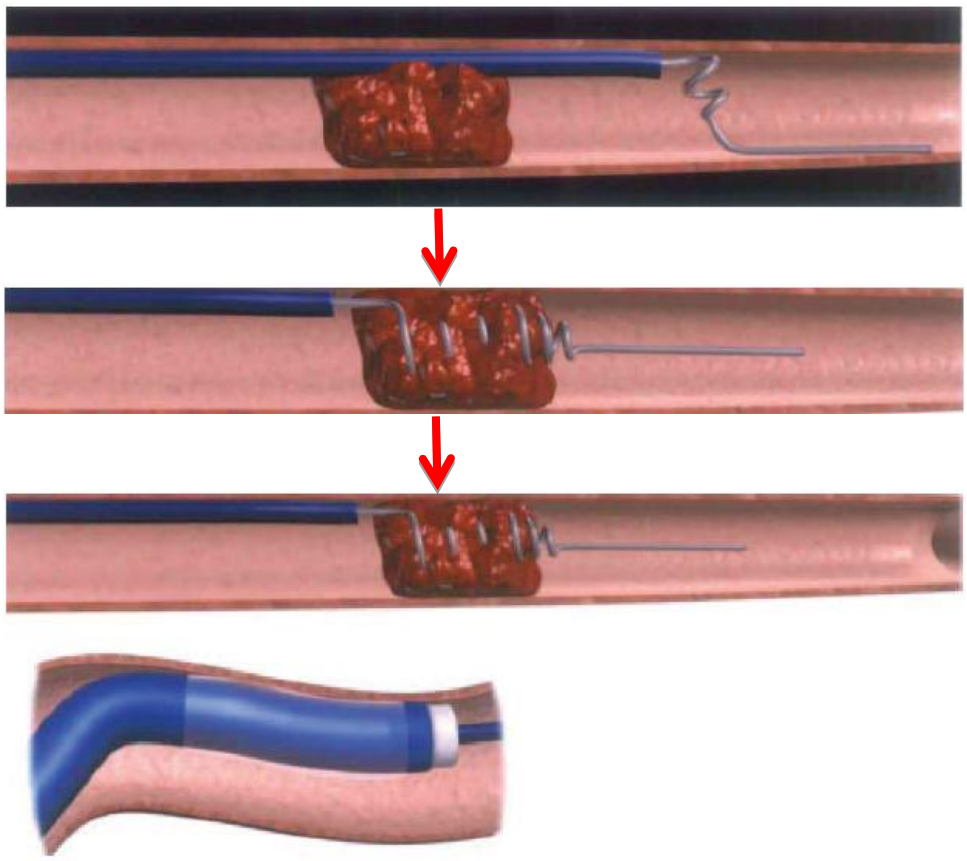


Figure 3: Steps for thrombus removal using MERCI (Gobin, et al., 2004)

The result of this study shows 43% of successful recanalization in the patients and an additional 21% of the patients had successful recanalization with the aid of a thrombolytic agent (Gobin, et al., 2004). However, most mechanical devices have the drawback of using moveable parts, or involve contact with the luminal wall; which could cause downstream embolization of clot pieces or even broken catheter tips (Pearce, Perkinson& Patrick, 2007). In the case of MERCI, there was one complication when the tip of the Merci Retriever detached from the device (Gobin, et al., 2004). Another Merci Retriever was used to ensnare the detached tip and successfully remove it from the vasculature; and had no clinical consequence (Gobin, et al., 2004). The recently invented and patented 'GP' MTD avoids many potential problems associated with the usage of mechanical devices in removing blood clot such that it has no moving parts and does not need to touch the blood clot to facilitate clot removal(Pearce G. , et al., 2009).

2.2 Blood Clot Simulation

Blood clotting usually occurs when the blood vessel is damaged. This causes platelets to adhere to the broken wall and release chemicals which attract more platelets. Upon formation of a platelet plug, the external bleeding is stopped. Then, clotting factors cause strands of blood-borne materials (fibrin) to stick together and seal the inner wound (Wedro, 2011). Bernsdorf (2005) in his study for the concurrent numerical simulation of the unsteady flow within an idealised stenosed artery and a simplified blood clotting process based on a residence time model claims that a comprehensive understanding of thrombosis requires full consideration of the three entities of Virchow's' triad; blood chemistry, vessel wall properties and fluid mechanics. This simulation utilises the lattice Boltzmann method; which is based on the numerical simulation of time, space and velocity-discrete Boltzmann-type equation. The propagation and interaction of the particles of an 'artificial computer fluid' is calculated in terms of the time evolution of a density distribution function, representing and ensemble average of the particle distribution (Bernsdorf, 2005). In this study, the residence time model refers to the aging of the blood clot. Assuming that clotting occurs after a certain elapsed period since the 'activation' of blood; the residence time of the activated fluid is the most important variable for the clotting process because it indicates the likelihood of clot formation (Bernsdorf, 2005). A passive scalar is used as a tracer to estimate the residence time of activated fluid in this model (Bernsdorf, 2005). This tracer is transported by advection-diffusion and a small, constant quantity is injected at every lattice node each time step (Bernsdorf, 2005). The local concentration of the tracer is therefore proportional to the average 'age' of the fluid (blood) which can be used as a threshold parameter within the clotting model(Bernsdorf, 2005). The 2D simulation results obtained from Bernsdorf's study (2005) shows good agreement for the simulation of clot formation, comparable to results of milk clotting experiments using comparable flows. However, for better accuracy and representation of blood clot formation, a 3D model should be simulated.

An important parameter to study in blood clot simulation is the adhesion forces between blood clot and the artery wall. In a study carried out by G. Romero, I. Higuera, M.L. Martinez, G. Pearce, and N.D. Perkinson (2010), simulation using

Bond Graph technique is carried out to analyse the adhesion forces between clot and artery wall for the GP device applied to the Middle Cerebral Artery. The main objective of this simulation is to analyse the minimum pressure required to perform the blood clot extraction with varying adhesion forces between clot and the artery wall, and to check that both the pressure and time required to complete the clot extraction are reasonable for use in clinical situations, and are consistent with any experimentally obtained data. To generate a correct model, assimilation of the catheter, 'GP' device and artery as pipes of different materials are done and inertance due to mass of fluid, the compressibility that the blood and artery are subjected, and finally the resistances that appear when fluid and blood clot flow into the pipe(Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). The phenomena preventing clot movement is the difference in diameter between the clot and the artery where it is located. In order to decide when to begin the movement of the obstructive element, firstly a spring needs to be inserted into the model to measure the force supported by the beginning of the clot and its deformation (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). To obtain the value of this spring the phenomenon of surface tension must be taken into account, since it is this that joins the clot to the artery. This surface tension γcomes about from the attraction forces between molecules and is defined as force by unit length (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010).

$$\gamma = \frac{F}{l} \tag{2.2.1}$$

If we take the sphere in figure 3, the surface tension would act on the circumference of the contact between the clot and the artery (marked with a blue ellipse).

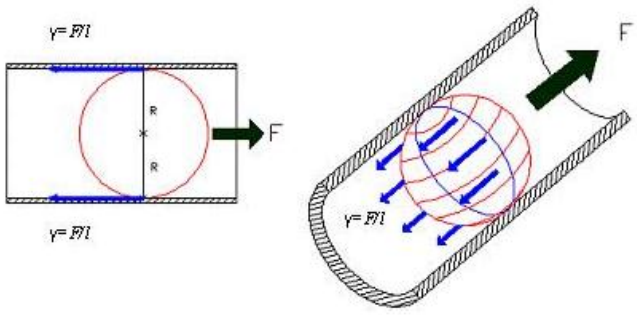


Figure 4: Model for surface tension (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010)

Bearing in mind the previous, if the value of the length of contact from the radius r of the artery is taken into account, the value for the surface tension can be obtained and, in turn, the value for the spring coefficient as:

$$K = \gamma = F / l = 1{,}061\,\mathrm{N/m} \tag{2.2.2}$$

The clot is between [3-5] cm long, which means it can be broken down into the union of several spheres, all with the same constant. Since over the whole surface of the clot there are adhesion forces, to obtain a correct approximation it is necessary to consider the existence of a sphere for every 0.1 mm (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). This means that between 300 and 500 spheres located in parallel, with each sphere in contact at 2 diametrical opposite points with the artery wall, would need to be included in the model. On the other hand, since the clot behaves like a rigid body, the fact that all the spheres are located in parallel must be taken into account, so that until the resultant adhesion force is overcome in all of the spheres, the clot will not begin to move (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). Therefore, since all the individual springs are equal, the equivalent spring for a 5 cm clot can be had from the form appearing in the following expression:

$$K_{eq} = \frac{K}{n} = \frac{1{,}061}{500} = 0{,}002122\,\mathrm{N/m} \tag{2.2.3}$$

To know when the force will be reached in this equivalent spring and, therefore, when the clot movement will begin, it is essential to calculate the displacement of the spring when it is subjected to 0.01 N (i.e.) through a typical spring equation(Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). Therefore, only when the spring undergoes this displacement should the clot be allowed to move; to the contrary it would be prevented.

$$x = \frac{F}{K_{eq}} = \frac{0{,}01N}{0{,}002122N/m} = 4{,}7124m \tag{2.2.4}$$

Secondly, in Romero's (2010) study the friction between the clot and the arterial wall creates another resistance factor. The value of this parameter is variable, depending on whether the clot has begun its movement, (dynamic fraction) or is still motionless

(static friction). This value is obtained starting from the Stokes equation and can be given a value of $2.5x10^{-6}$ N.s/m for static friction and an order of magnitude lower for dynamic friction (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010). So, when the displacement undergone by this spring is less than that calculated, static friction rules, but when greater, the friction will be dynamic.

To ensure that the clot remains at rest while the force existing at its beginning is less than the adhesion force, a spring-damper system joined to a wall (zero flow source) must be used. In this system, while the clot does not receive the force of minimum suction, it has zero speed (no movement by the clot), but when it begins to move, the spring-damper system is cancelled to allow extraction by the 'GP' device (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010).

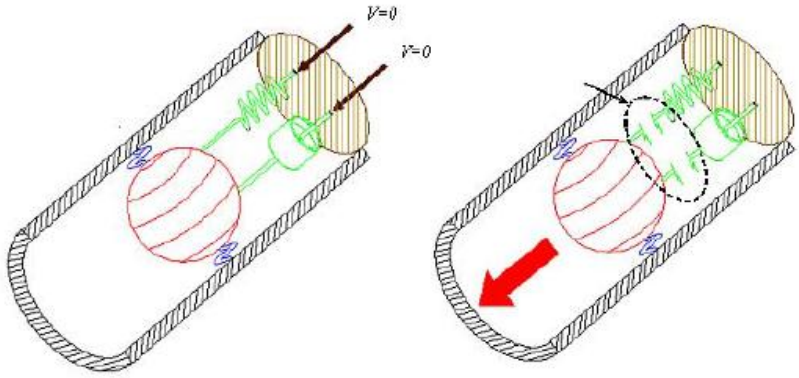


Figure 5: Left figure shows the spring-damper system when force exerted is lower than the adhesion force; and the figure on the right shows when force exerted is equal or greater than the adhesion force (Romero, Higuera, Martinez, Pearce, & Perkinson, 2010)

Romero's (2010) study concludes that lower adhesion force requires lesser pressure and time for the extraction of blood clot in Middle Cerebral Artery. His study is one of the basis theory for the development of the blood clot extraction simulation by the 'GP' 2 device which will be carried out in this research.

A study carried out by KuShaari, A. Rahman and Pearce (2012) on blood clot behaviour upon extraction by 'GP' device by CFD Simulation states that blood does not exhibit a constant viscosity at all flow rates compared to water and is non-Newtonian in the microcirculatory system (in small branches and capillaries). The normal blood flow is laminar with secondary flows generated at curves or branches(KuShaari, A.Rahman, & Pearce, 2012). The Reynolds number varies from 1 in small arterioles to approximately 4000 in the largest artery (KuShaari, A.Rahman, & Pearce, 2012). The heart creates pulsating conditions in all arteries, making the blood flow and pressure unsteady. A grid sensitivity study was also conducted by assessing the effect of the grid size on pressure and laminar properties (KuShaari, A.Rahman, & Pearce, 2012). In each case, the grid density was varied from coarse to fine by increasing the number of cells in the whole device generally, including the wall. Grid independency is said to be achieved when any further increase in the number of cells did not adversely affect the simulation results; the optimum grid size avoided any unnecessary prolonged computational effort required for the simulations with large number of cells (KuShaari, A.Rahman, & Pearce, 2012). Their study concludes that finer grid size results in higher accuracy result. Besides that, it is found that the fastest time to remove the blood clot of 0.6-1g weight at 0.0035Pa.s viscosity is 0.006s, when 60kPa pressure is applied. The findings of this study will also be the basis for the research works on 'GP' 2 device.

A study carried out by Serza, Tratar & Blinc (2005) states that the rate of thrombolysis, i.e, the progression rate of lysing front dr/dt is proportional to the average mechanical power of the flowing blood to the surface of the flow channel. The power, P is equal to the force F of the flowing blood to the clot surface multiplied by the average blood velocity in the flow channel v. The force F is also equal to the product of pressure drop Δp across the flow channel multiplied by the cross-section area of the flow channel, S (Serza, Tratar, & Blinc, 2005). The pressure drops for laminar and turbulent flow are governed by different set of equations.

$$P = Fv = \Delta pSv \tag{2.2.5}$$

Thus, the study carried out by Serza (2008) concludes that blood clot deformation is governed by both biochemical reactions of the thrombolytic agents and mechanical forces by the blood flow in non-occlusive clots.

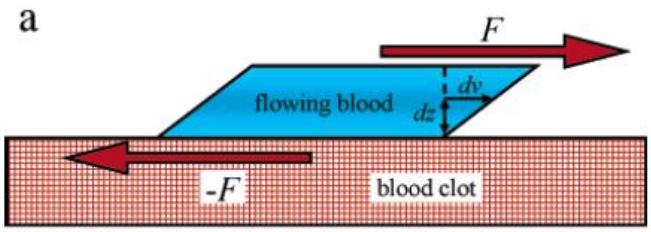


Figure 6: Viscous forces to dissolve blood clot when blood flow is laminar (Serza, Tratar, & Blinc, 2005)

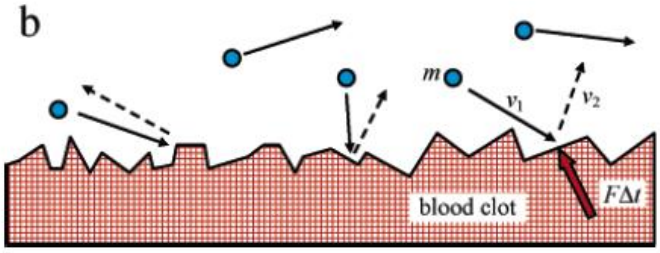


Figure 7: Kinematic forces to dissolve blood clot when blood flow is turbulent (Serza, Tratar, & Blinc, 2005)

In a different study carried out by Pearce et al (2010), an in vitro testing was carried out for the new 'GP' aspiration thrombus device. In the first experiment, relationship between clot weight and pressure required for clot extraction is carried out. The clots used are in the range of 0.03g – 0.13g with needed pressure of the range 30 and 34 kPa. The results obtained shows linear relationship between size of clot and pressure applied; with larger clots requiring higher extraction pressures. After the experiments, sections of the porcine arteries were taken for examination. It showed no arterial damage for extraction pressure applied between 30kPa – 40kPa. From this study, it shows that laboratory experimental results show positive outcome in using the 'GP' device to extract blood clot in the porcine artery.

2.3 Theory on Computational Methods using FLUENT

In a research carried out by C. Kiris and D. Kwak (2007), the applicability of the DeBakey heart assist device (a type of ventricular assist device, VAD) is studied using space technology and CFD for its usage in human implantation to increase blood circulation in heart-failure patients awaiting transplant. Because blood is the operating fluid, the design of a VAD requires that it propel the blood gently, minimizing damage to the red blood cells (Kiris & Kwak, 2007). In order to reduce red blood cell damage, the pumping device must be designed to avoid regions of high shear stress and separated flow in the pump (Kiris & Kwak, 2007). In addition, the blood must be properly washed out of the pump since the formation of blood clots may appear within stagnation regions as a result of previously damaged blood cells. Since the device is small and the operating conditions severe, instrumentation for making necessary flow measurements is extremely difficult to design; therefore it became necessary to look at the flow by computational means (Kiris & Kwak, 2007). This study shows the reliability of CFD in the optimisation of devices needing high accuracy to be implemented in humans.

Simulation for the suction of the blood clot in the artery using CFD utilises the Navier-Stokes equation. This set of equation describes fluid substances' motion. It originates by applying Newton's Second Law of Motion (*F=ma*) into fluid motion and assuming that the fluid stress is a sum of diffusing viscous term and a pressure term. Romero et al (2011) stated that blood is deemed to be an incompressible fluid. Hence, Navier-Stokes equation for incompressible flow, assuming constant viscosity is used throughout the simulation and takes the following form:

$$\overbrace{\rho\Big(\underbrace{\frac{\partial \mathbf{v}}{\partial t}}_{\text{Unsteady acceleration}} + \underbrace{\mathbf{v}\cdot\nabla\mathbf{v}}_{\text{Convective acceleration}}\Big)}^{\text{Inertia (per volume)}} = \overbrace{\underbrace{-\nabla p}_{\text{Pressure gradient}} + \underbrace{\mu\nabla^2\mathbf{v}}_{\text{Viscosity}}}^{\text{Divergence of stress}} + \underbrace{\mathbf{f}}_{\text{Other body forces}} \qquad (2.3.1)$$

Where v = flow velocity, ρ = density of blood plasma, p = pressure, μ = viscosity. The term *f,* or other body forces represents gravity or centrifugal force. The

divergence of stress terms, or shear stress is the useful quantity when fluids are assumed incompressible, Newtonian and homogeneous.

In running this simulation, CFD multiphase flow is observed. The concept of multiphase flows in CFD is not limited to only physical mixture of phases, but refers to an identifiable class of material which has a particular inertial response to and interaction with the flow and the potential field in which it is immersed. In this case, the blood and blood clot are 2 different phases involved. As mentioned earlier, the main objective of this study is to identify the interaction and behaviour of the blood clot upon suction by the 'GP' device. Hence, the multiphase model to be applied in this situation is the Volume of Fluid (VOF) Model. The VOF model isa surface-tracking technique applied to a fixed Eulerian mesh (Fluent 6.3 User Guide , 2006). It is designed for two ormore immiscible fluids where the position of the interface between the fluids is of interest (Fluent 6.3 User Guide , 2006). In the VOF model, a single set of momentum equations is shared by the fluids, and the volume fraction of each of the fluids in each computational cell is tracked throughout the domain (Fluent 6.3 User Guide , 2006). Applications of the VOF model include stratified flows, free-surface flows, falling, sloshing, the motion of large bubbles in a liquid, the motion of liquid after a dam break, the prediction of jet breakup (surface tension), and the steady or transient tracking of any liquid-gas interface (Fluent 6.3 User Guide , 2006).

The VOF formulation relies on the fact that two or more fluids (or phases) are not interpenetrating. For each additional phase added to the model, a variable is introduced; the volume fraction of the phase in the computational cell (Fluent 6.3 User Guide , 2006). In each control volume, the volume fractions of all phases sum to unity. The fields for all variables and properties are shared by the phases and represent volume-averaged values, as long as the volume fraction of each of the phases is known at each location (Fluent 6.3 User Guide , 2006). Thus the variables and properties in any given cell are either purely representative of one of the phases, or representative of a mixture of the phases, depending upon the volume fraction values(Fluent 6.3 User Guide , 2006).In other words, if the q^{th} fluid's volume fraction in the cell is denoted asα_q; then the following three conditions are possible:

- $\alpha_q = 0$: The cell is empty for the q^{th}fluid

- $\alpha_q = 1$: The cell is full for the q[th]fluid
- $0 < \alpha_q < 1$: The cell contains the interface between the q[th]fluid and one or more other fluids

Based on the local value for α_q, the corresponding properties and variables will be assigned to each computational cell. The tracking of the interfaces between the phases is accomplished by the solution of a continuity equation for the volume fraction of one or more of the phases (Fluent 6.3 User Guide , 2006). For the q[th] phase, this equation has the following form:

$$\frac{1}{\rho_q}\left[\frac{\partial}{\partial t}(\alpha_q \rho_q) + \nabla \cdot (\alpha_q \rho_q \vec{v}_q) = S_{\alpha_q} + \sum_{p=1}^{n}(\dot{m}_{pq} - \dot{m}_{qp})\right] \quad (2.3.2)$$

Where m_{qp} is the mass transfer from phase q to phase p and m_{pq} is the mass transfer from phase p to phase q; by default, the source term on the right-hand side of Equation 3.1.1.1, S_q, is zero, but a constant or user-defined mass source can be specified for each phase(Fluent 6.3 User Guide , 2006). The volume of fraction equation will not be solved for the primary phase, because the primary phase will be computed with the following constraint:

$$\sum_{q=1}^{n} \alpha_q = 1 \quad (2.3.3)$$

Generally, simulation using CFD utilises the concept of interpolating the values for every desired properties and variables from one control volume (computational cell) to another. In using the VOF model, the constraint shall be the interpolation at the interface between phases; whereby it uses two schemes; the geometric reconstruction scheme and the donor-acceptor scheme.

The geometric reconstruction scheme is the most accurate and applicable for general unstructured meshes. This type of scheme utilises the piecewise linear approach whereby it assumes that the interface between the two phases has a linear slope within each cell and uses this linear shape for calculation of the advection of fluid through the cell faces.

The donor-acceptor scheme identifies one cell as a donor of an amount of fluid from one phase and another (neighbour) cell as the acceptor of that same amount of fluid, and is used to prevent numerical diffusion at the interface(Fluent 6.3 User Guide , 2006). The amount of fluid from one phase that can be convected across a cell boundary is limited by the minimum of two values: the filled volume in the donor cell or the free volume in the acceptor cell (Fluent 6.3 User Guide , 2006). The orientation of the interface is also used in determining the face fluxes. The interface orientation is either horizontal or vertical, depending on the direction of the volume fraction gradient of the q^{th} phase within the cell, and that of the neighbour cell that shares the face in question(Fluent 6.3 User Guide , 2006).

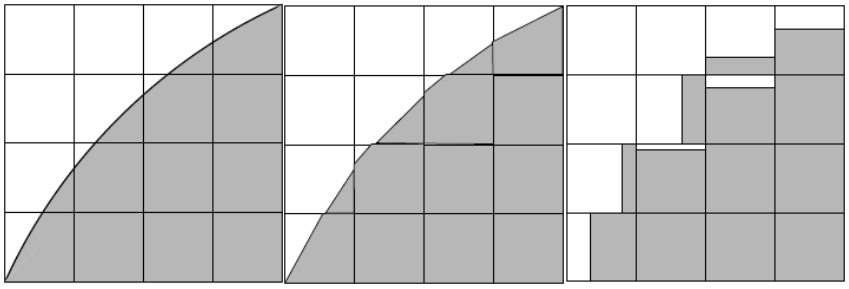


Figure 8: (a) Actual interpolation shape between phases; (b) interpolation by geometric reconstruction scheme; (c) interpolation by donor-acceptor scheme (Fluent 6.3 User Guide , 2006)

In simulating the behaviour of the blood clot upon extraction, the effects of surface tension and wall adhesion are important. Surface tension is a result of attractive forces between the molecules in a fluid. It is a force which acts to balance the radially inward intermolecular attractive forces with the radially outward pressure gradient force across the surface. The surface tension can be written in terms of the pressure jump across the surface (Fluent 6.3 User Guide , 2006). The force at the surface can be expressed as a volume force using the divergence theorem (Fluent 6.3 User Guide , 2006). It is this volume force that is the source term which is added to the momentum equation (Fluent 6.3 User Guide , 2006). It has the following form:

$$F_{\text{vol}} = \sum_{\text{pairs } ij,\ i<j} \sigma_{ij} \frac{\alpha_i \rho_i \kappa_j \nabla \alpha_j + \alpha_j \rho_j \kappa_i \nabla \alpha_i}{\frac{1}{2}(\rho_i + \rho_j)} \tag{2.3.4}$$

where $K_{i,j}$ is surface curvature, dependent on divergence of the unit normal, $K_{i,j} = \nabla n$ and σ is surface tension coefficient

In the VOF model, wall adhesion calculation is assumed to be the contact angle between the fluid and the adjacent wall to adjust the calculated value for curvature (K) of the surface near the wall. With the adjustments made from the calculation of curvature, the surface tension is also affected. Adjustment to the curvature results from the direct proportionality of the surface normal (n) to the contact angle; given by the following equation:

$$\hat{n} = \hat{n}_w \cos\theta_w + \hat{t}_w \sin\theta_w \tag{2.3.5}$$

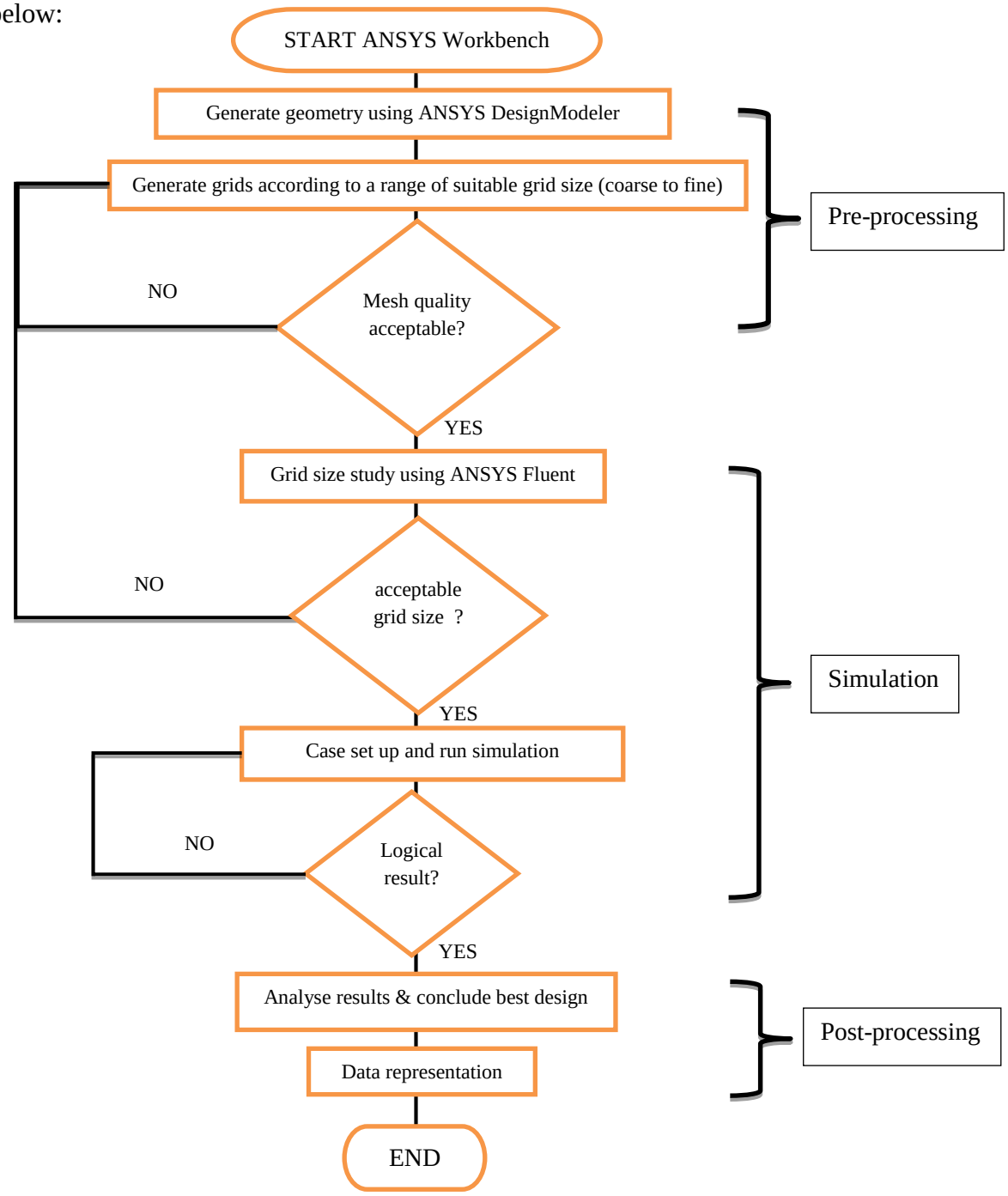
where t_w is tangential unit vector to the wall.

CHAPTER 3
METHODOLOGY

In this chapter, the methodology used achieve the desired results will be further explained. Simulation algorithm will be shown and explained to help understand the work method used.

3.1 Research Methodology & Project Activities

The framework for carrying out the research can best be shown in the algorithm below:



Geometry generated using ANSYS DesignModeler which is developed by ANSYS Inc. will be used as a pre-processor for this study. DesignModeler is a state-of-the-art pre-processor suitable for engineering analysis. It is equipped with an advanced geometry tools, which are highly flexible, systematic and allows for parametric study. Complex models can be generated directly using DesignModeler or can be imported from any major CAD/CAE system. This geometry can then be read into the meshing tool embedded within ANSYS Workbench. The meshing function in Workbench is highly-automated and equipped with predefined size function which allows faster, systematic and appropriate meshing.

Then, the mesh file (*.msh*) is imported into the simulation software, ANSYS Fluent. Fluent allows for calculation for various types of physical models and fluid flows such as steady-state or transient flow, compressible and incompressible flows, laminar or turbulent flows, Newtonian or non-Newtonian flows, etc. The case and data files (*.cas*& *.dat*) from Fluent are generated upon setting of boundary conditions prior to running the simulation. Once the simulation has stopped (converged), post-processing is done. In post-processing, the related data are extracted and required calculations are carried out to obtain the desired parameter. Once all calculations and data processing are complete, the results are documented for bookkeeping.

3.1.1 Pre-processing

In pre-processing, the geometry domains are generated, with dimensions as shown in the figures below:

3.1.1.1 Geometry

MODEL 1: Consist of 9 cylindrical tubes at 0.6mm diameter each.

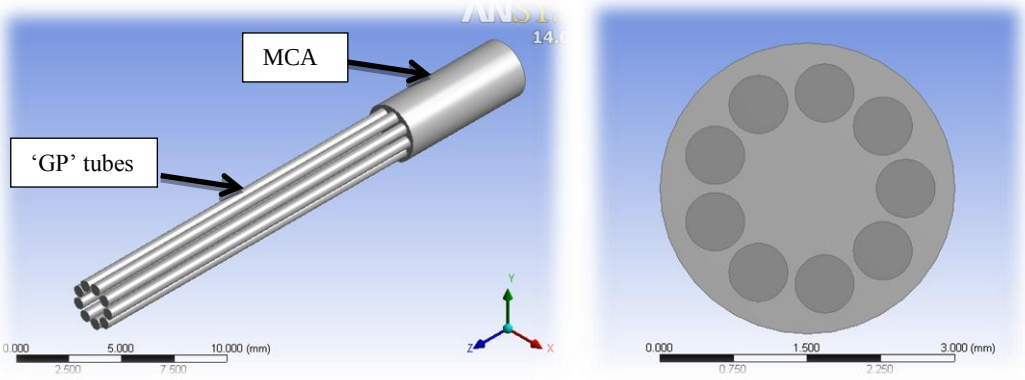


Figure 8: Isometric view (left) front view (right) of 'GP' 2 model 1

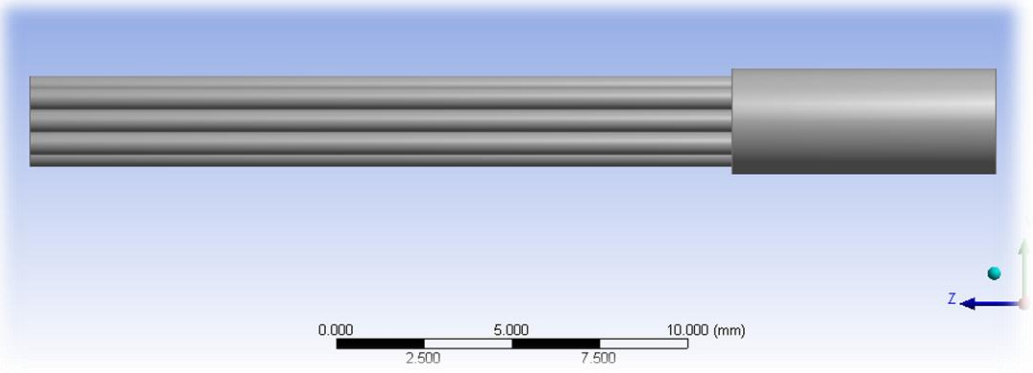


Figure 9: Side view of 'GP' 2 device, model 1

MODEL 2: Consist of 9 helical spiral tubes of 0.6mm diameter each

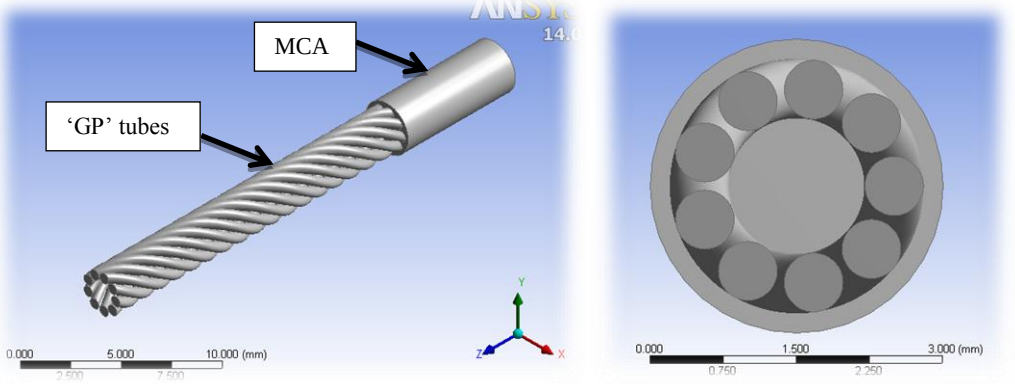


Figure 10: Isometric view (left) and front view (right) of 'GP' 2 device model 2

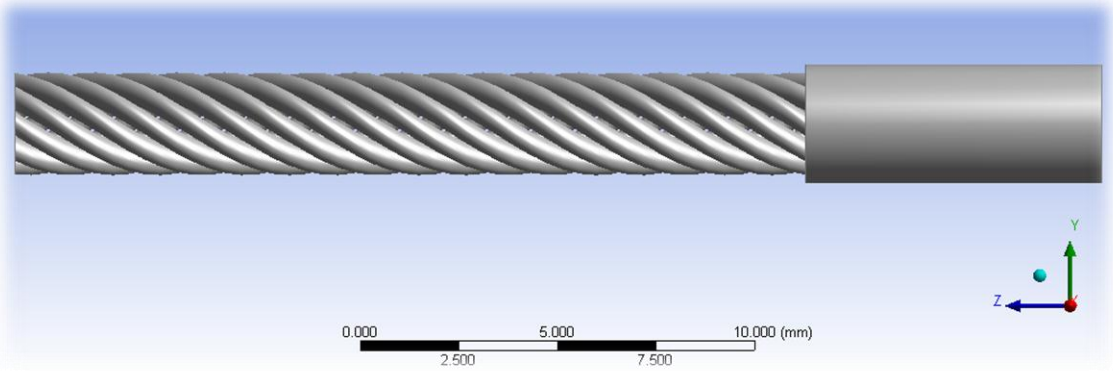


Figure 11: Side view of 'GP' 2 device model 2

3.1.1.2 Meshing

Once the 3D geometries are generated, the next step is to adapt appropriate grid sizes i.e. meshing. The mesh sizes are adapted such that it fits the range of appropriately coarse to appropriately fine meshes. The size range of mesh is set to be between 0.4mm to 0.1mm range referring to the mesh size range done by KuZilati, A.Rahman

& Pearce (2012) whereby their study was based on the original 'GP' device. A mesh is said to be appropriate if the mesh quality check is within the suggested quality range. Mesh skewness (range from 0-1) is one aspect that determines mesh quality. From standard practices, the mesh skewness should be kept lower than 0.8 or 0.7 at best. The diagram below shows an example of coarse mesh and fine mesh.

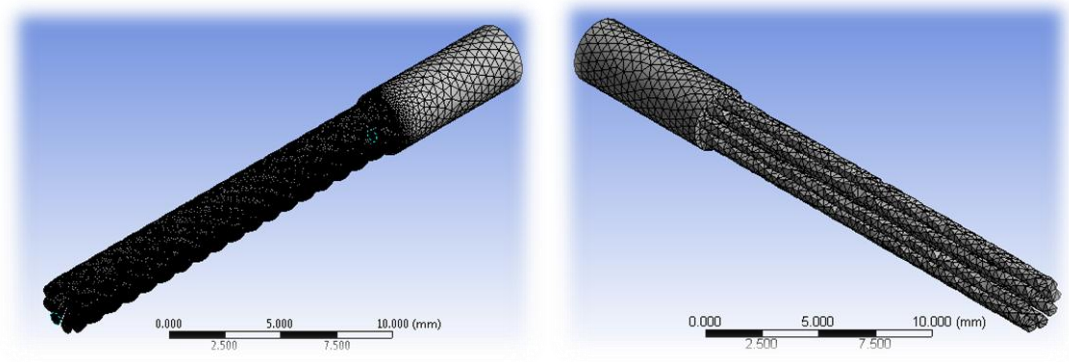


Figure 12: Fine mesh (left) and coarse mesh (right)

When meshing is complete, the geometry shall be labelled accordingly to allow boundary conditions to be defined in the simulation software later. In a later stage, a grid sensitivity study will be carried out to determine which grid size is the best to carry out the simulation. The choice of grid size shall be one that is large enough to cut computation time but small enough to provide accurate results.

3.1.2 Simulation

The next step is to run the simulation. The solver type used is pressure-based, with transient time setup. The multiphase, Volume of Fluid (VOF) model is selected in the model stage which allows the blood clot behaviour upon suction by the ‘GP’ device at various pressures to be visualized clearly. The default settings for VOF in FLUENT are used; i.e. Explicit parameter scheme and 0.25 Courant number. The number of Eulerian phases are set to two namely for blood and blood clot.

Next, appropriate material properties, boundary conditions and operating conditions are specified. The material properties of blood and blood clot are as shown in the table below:

Parameter / Phase	Blood	Blood Clot
Density (g/cm^3)	1.06	1.08
Viscosity (poise)	0.035	0.35

Table 2: Material properties table (Soleimani, Pennati, & Dubini, 2011) (Nohirnyak, Suk, & Holland, 2006)

The phases are set; with blood as primary phase and blood clot as secondary phase. A phase interaction in the form of surface tension is set; with constant surface tension coefficient value of 0.1N/m (Soleimani, Pennati, & Dubini, 2011).

The boundary conditions set are as below (KuShaari, A.Rahman, & Pearce, 2012):

Boundary Condition	Value
Mixture Pressure Inlet	40, 50 & 60 kPa
Mixture Pressure Outlet	-40, -50 & -60 kPa

Table 3: boundary conditions table

The solution method is set to PISO; and Non-Iterative-Time-Advancement is chosen to speed up the calculation. Surface and volume monitors are also set to monitor for velocity at pressure-outlet; and also blood clot volume fraction at the artery cell zone. Upon initialization; the clot region is adapted and patched. The blood clot is patched with cylindrical shape of radius 1.35mm, and length 4mm. The location of patched clot is 3mm from the periphery of 'GP' device.

With varying inlet pressure set up for each simulation case and two models, this made a total of 6 simulation cases to be run and studied.

3.1.3 Post-Processing

Once the simulation cases are solved, post-processing to extract and analyse the data obtained are done. Contours for blood clot volume of fraction are observed for selected flow times are displayed and animated. A graph to represent the fraction of clot suction against time is also plotted to deduce the best design for blood clot suction using 'GP' 2 device.

3.2 Tools/Software

The tools/software used to carry out this research is listed:

- ANSYS DesignModeler™
- ANSYS FLUENT™ 14.0

For detailed view of the Gantt Chart during the commencement of this project, kindly refer to Appendix C.

CHAPTER 4

RESULTS

4.1 Grid Sensitivity Study

The idea behind meshing and simulation is breaking down a physical domain into small discrete control volumes whereby calculations of the set of equations are done. The variables are iterated to every adjacent cell until a certain tolerance value is reached and the iteration/calculation is stopped and deemed to have converged. The accuracy of the variables/parameters calculated is fully dependent upon the size of the discrete control volumes (cells). Ideally, smaller cells results in more accurate calculation, but at the risk of higher computation time. Hence, grid sensitivity study is carried out to compare the accuracy of the calculation for a range of grid sizes. The best grid size shall be the largest grid which is adequately accurate. In each case, the grid density was varied from coarse to fine by increasing the number of cells in the whole device generally, including the wall. Grid independency is said to be achieved when any further increase in the number of cells did not adversely affect the simulation results; the optimum grid size avoided any unnecessary prolonged computational effort required for the simulations with large number of cells (KuShaari, A.Rahman, & Pearce, 2012).

To carry out the grid size study, a surface monitor at pressure outlet was selected, to monitor for the velocity at every flow time. Then, a graph showing the velocity at different flow times for each of the grids is plotted.

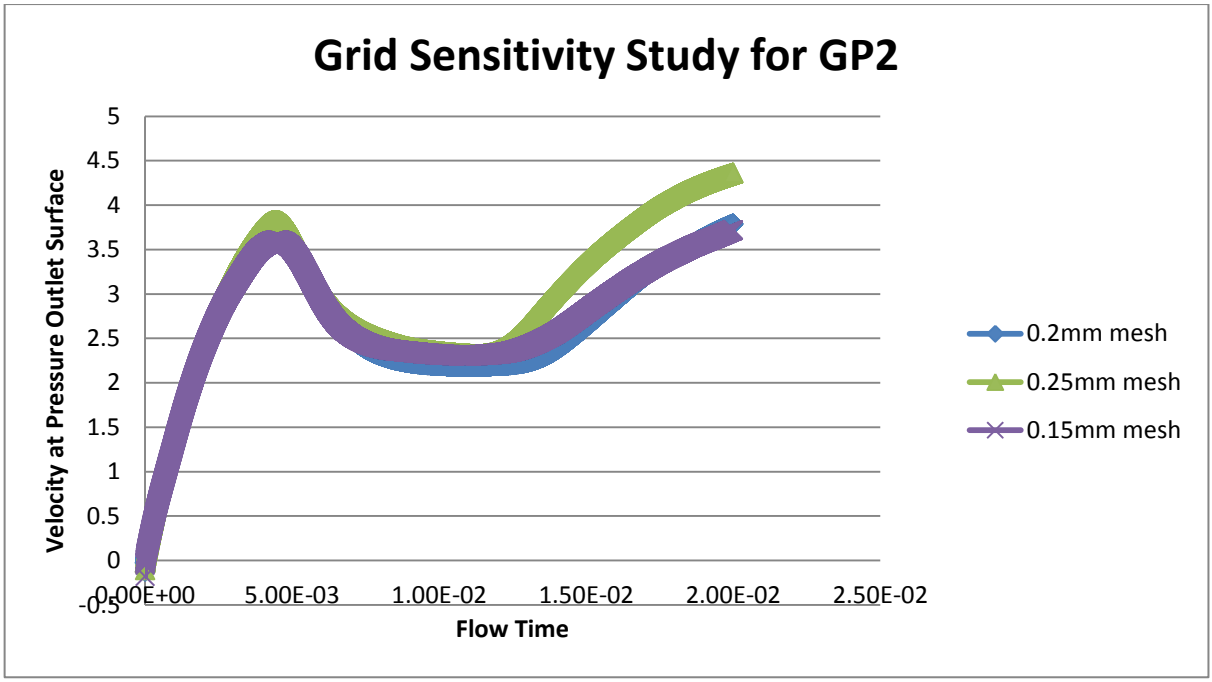


Figure 14: Graph of velocity against flow time for each of the grid sizes

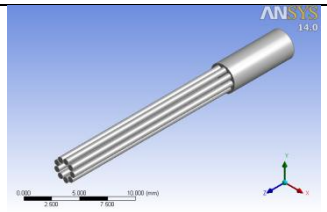
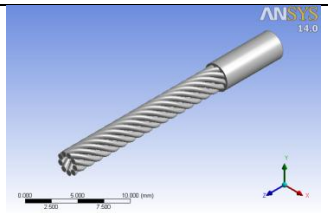
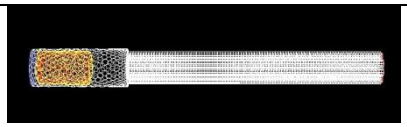
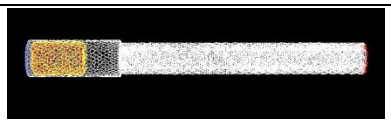
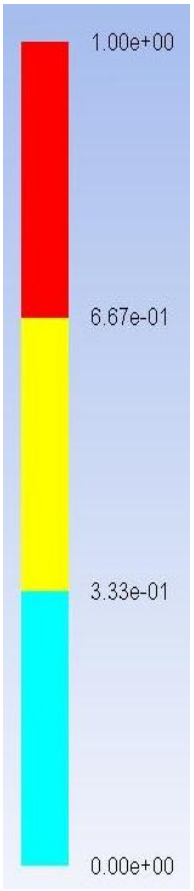
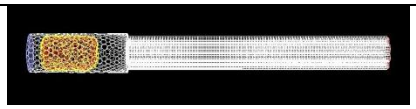
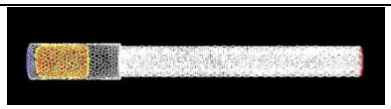
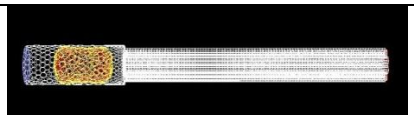
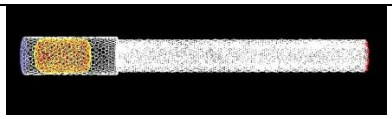
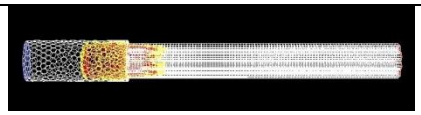
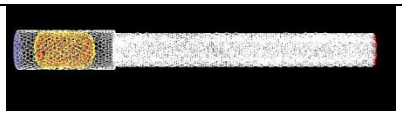
The velocity against flow time pattern for 0.25mm and 0.2mm size is relatively similar, and since the largest of the chosen grids are chosen to cut computation time, 0.25mm grid size should be chosen. However, to obtain better clot shape upon patching, a finer grid size is preferred. To fit this purpose, 0.2mm is chosen because it is relatively fine, with reasonable amount of computational cells to avoid unnecessary, extra computation time.

4.2 Clot Behaviour Study

In this section, the qualitative and quantitative behaviour of blood clot upon extraction by 'GP' 2 devices at different pressures are analysed and compared to determine which of the two proposed designs are better.

4.2.1 Qualitative Visualization of Clot Behaviour at 40, 50 and 60kPa

In this section, the clot behaviour upon extraction is visualised for both proposed designs at 3 different pressures. The results are as tabulated below:

40kPa			
	'GP' 2 Model 1	**'GP' 2 Model 2**	
Design			
Time (s)			**Clot Volume Fraction**
0			
0.001			
0.002			
0.003			
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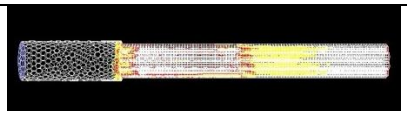
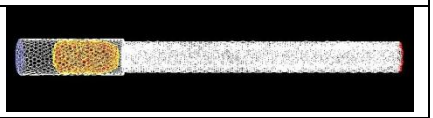
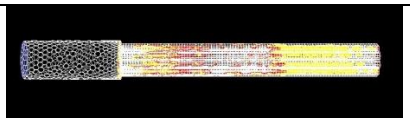
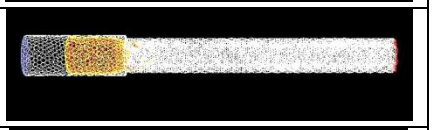
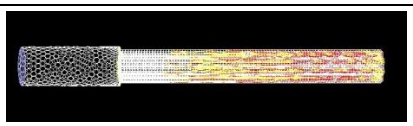
0.005			
0.006			
0.009			

Table 4: Summary of clot behaviour visualization for both models at 40kPa

50kPa			
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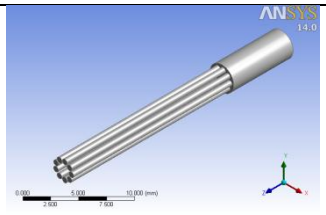
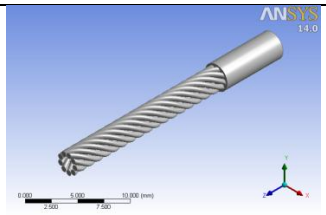
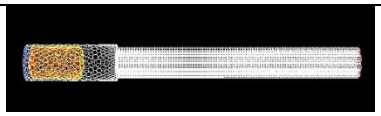
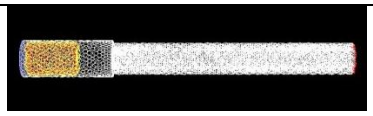
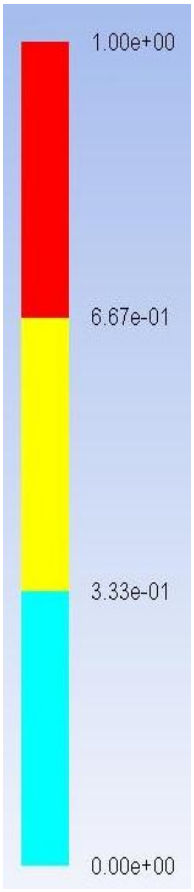
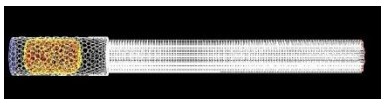
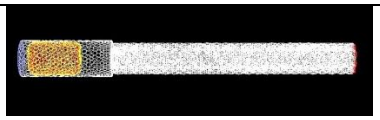
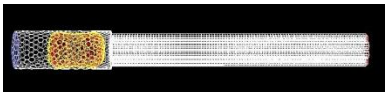
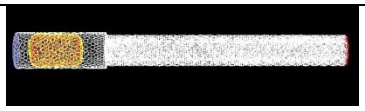
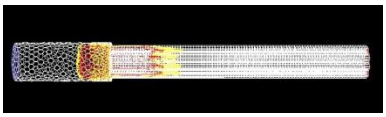
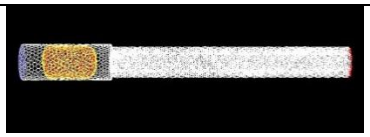
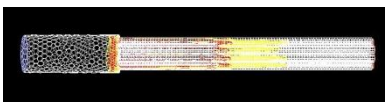
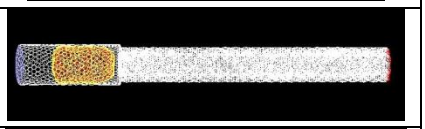
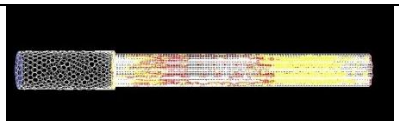
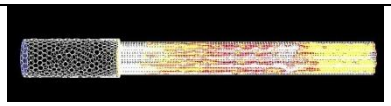
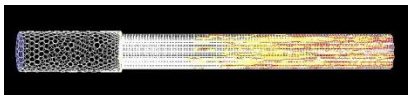
Design			
Time (s)			**Clot Volume Fraction**
0			
0.001			
0.002			
0.003			
0.004			
0.005			
0.006			
0.009			

Table 5: Summary of clot behaviour visualization for both models at 50kPa

60kPa			
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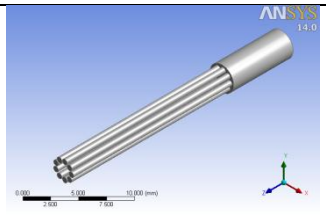
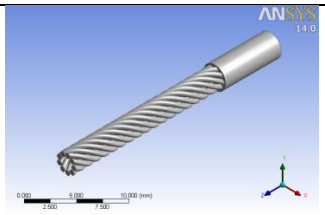
Design			
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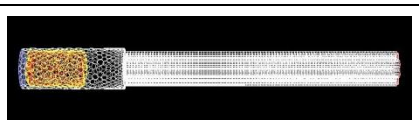
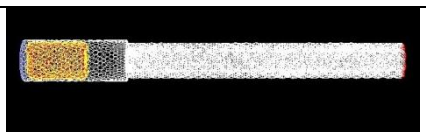
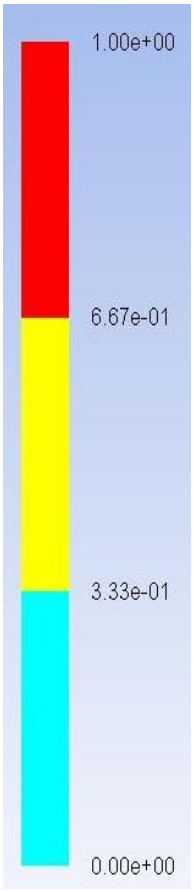
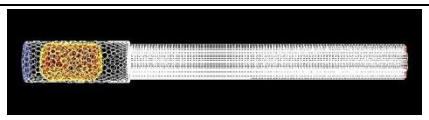
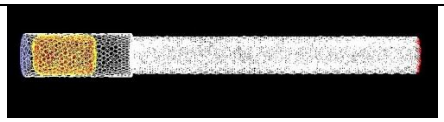
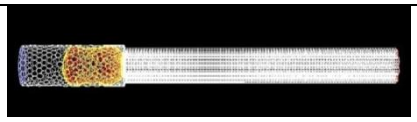
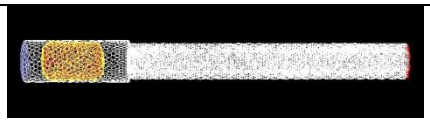
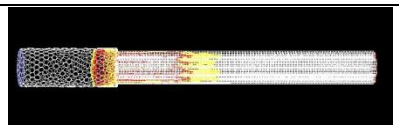
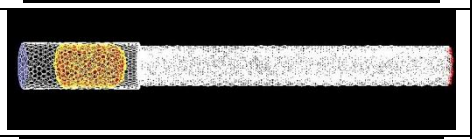
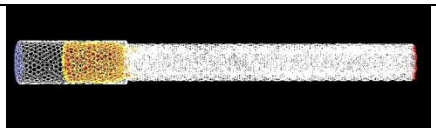
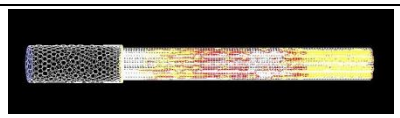
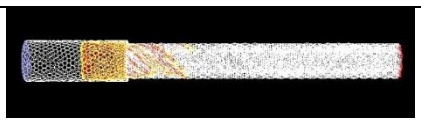
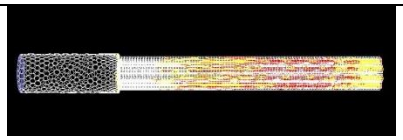
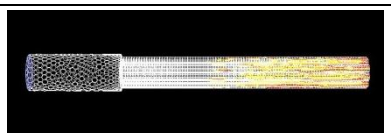
0			
0.001			
0.002			
0.003			
0.004			
0.005			
0.006			
0.009			

Table 6: Summary of clot behaviour visualization for both models at 40kPa

From the visualization shown, an early conclusion could be drawn. It is clear that qualitatively, 'GP'2 Model 1 which has cylindrical tube design is much more efficient (faster) in extracting blood clot than the helical spiral design for all three pressures. Besides that, as pressure increases, the time for removal of blood clot decreases. Further analysis will be done to prove this conclusion.

4.2.2 Quantitative Analysis of Clot Behaviour at 40, 50 and 60 kPa

A graph showing the volume fraction of blood clot in the artery region is plotted against time for both models at different pressures.

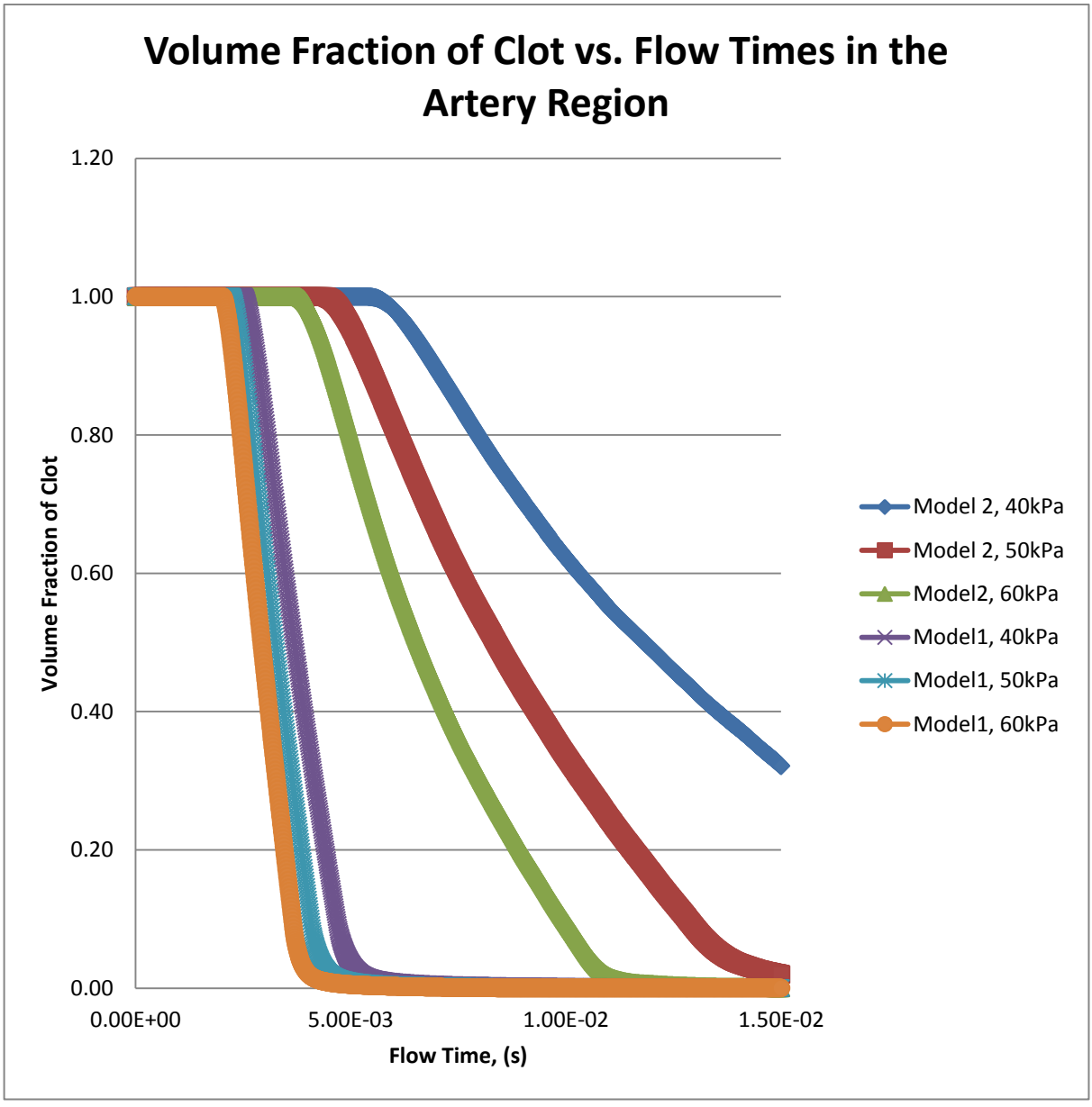


Figure 15: Graph showing the clot volume fraction in the artery region

The table below summarizes the time taken for complete clot extraction for both model at three different pressures.

Pressure / Model	Extraction time for 'GP' 2 Model 1	Extraction time for 'GP' 2 Model 2
40 kPa	6.92µs	27.97µs
50 kPa	5.75µs	17.28µs
60 kPa	4.98µs	12.11µs

Table 7: Summary of extraction time for complete blood clot removal

From the data extraction carried out qualitatively and quantitatively, it can be proven that 'GP' 2 Model 1 is a better design as compared to 'GP' 2 Model 2; because it allows blood clot extraction at shorter time for all three pressures. The cylindrical shaped tubes are more efficient in the suction process as compared to the helical spiral design because with cylindrical shapes, the air suction travels at shorter distance thus reaching the clot quicker, to allow extraction to occur. With 9 cylindrical tubes, i.e. 9 sources of suction, it facilitates in breaking up the clot into smaller fragments. When the source for suction (i.e. number of tubes) is increased, cylindrical shapes are better in clot extraction because the cylindrical-shaped geometry works by the same-suction principle allowing more suction power. This type of phenomena is normally found in nature; e.g. the stomata found in leaves. The vortex creation process which is observed upon suction by the helical spiral design, compared to the same-suction principle process is less efficient (requires more time) in clot extraction at the same applied pressure.

In the earlier studies for the invention of 'GP' device, a model of one cylinder and one helical spiral tube are compared. In this study, the helical spiral model proves to be better at clot extraction because the helical spiral design a vortex flow in the artery between the clot and catheter, thus motivates the fragmentation (breaking up) of the clots to allow recanalization. However, when the number of tubes (both cylindrical and helical spiral) is increased in amount, the result shows contradicting findings. This is because the same-suction principle works best when surface area of suction is increased.

In this research we found out that these 9 cylindrical tubes are able to break the clot, (fits the function of vortex creating design) at lower time because distance travelled is shorter for both air suction and clot extraction. Hence, we conclude that 'GP'2 Model 1 is more efficient than 'GP' 2 Model 2 design.

CHAPTER 5

CONCLUSION

As a conclusion, the simulation for the extraction of blood clot using ‘GP’ 2 Device is essential for the development for the cure of stroke. Not only it can be used for patients of stroke, but any diseases associated with blood clot such as peripheral vascular disease can also benefit if this device is approved for clinical use. The objectives of this project are in line with the ultimate goal for developing this device whereby it identifies other potential design the best determines its applicability in clinical use.

For the case of selecting the grid size, it is clear that finer grids results in higher accuracy calculations i.e. better results. However, this is achieved at the cost of prolonged computational time. Therefore, from grid sensitivity study to identify the optimum grid size that is fine enough to generate accurate calculations but large enough to avoid extra computational time; the grid size of 0.2mm is used.

The design for ‘GP’ 2 Model 1 device is better at clot extraction than the Model 2 device because the distance travelled for air suction and clot extraction is shorter, in cylindrical tubes. For both models, it can be shown that higher pressure extracts blood clot at lower time whereby the fastest clot extraction occurs at time 0.00498s for Model 1, and 0.01211s for Model 2 both occurring at 60 kPa.

For future work continuation, experimental data shall be compared with the simulation outcomes for model validation. This will further prove the findings obtained in this research work. In terms of model development, it is suggested that smaller diameter tubes but higher in number could facilitate faster clot breaking process.

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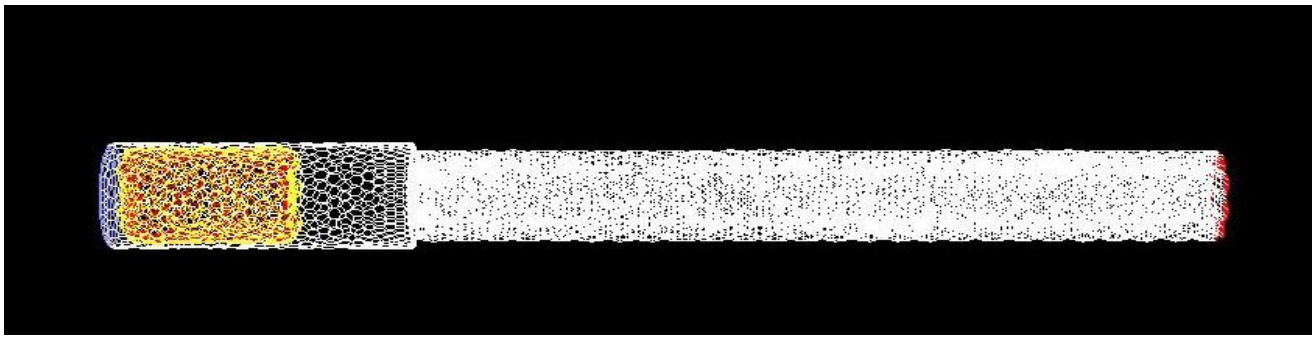
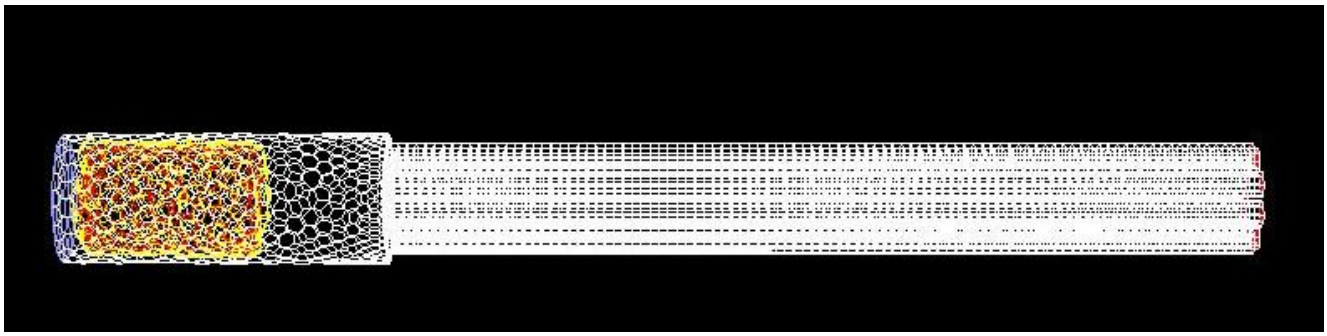
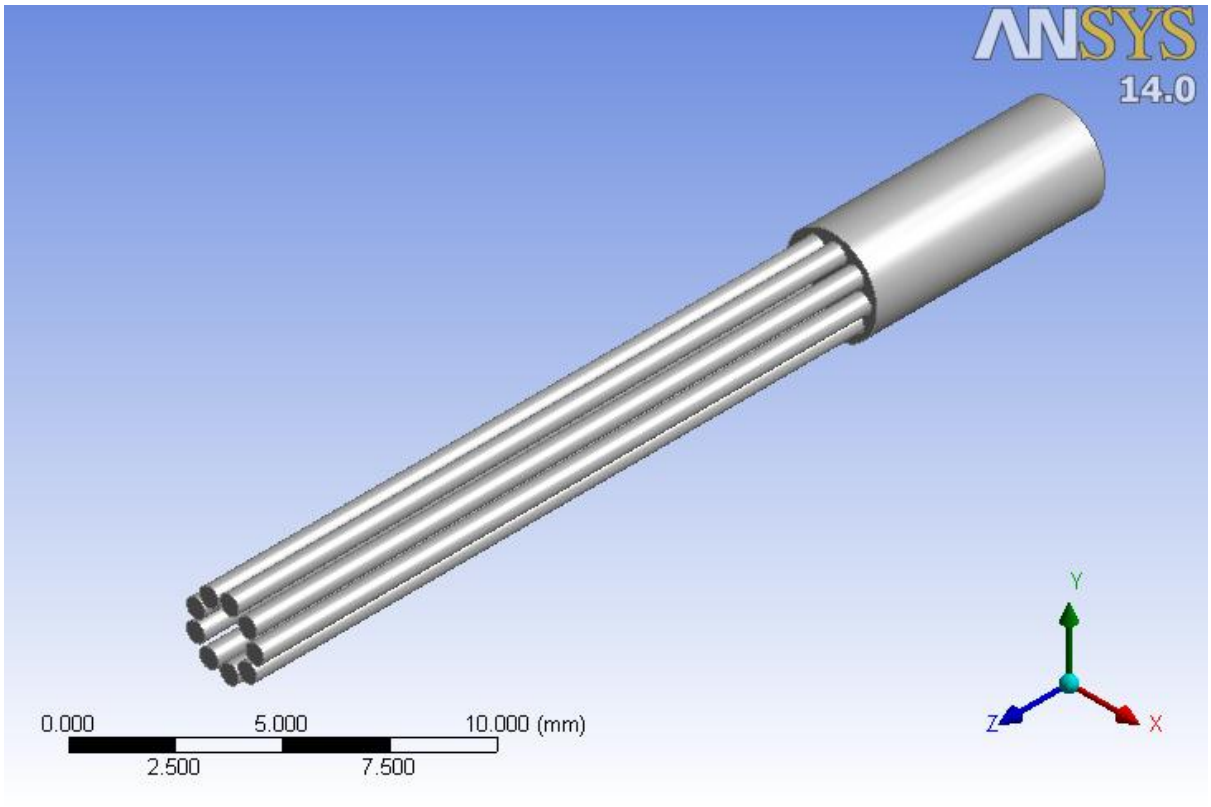
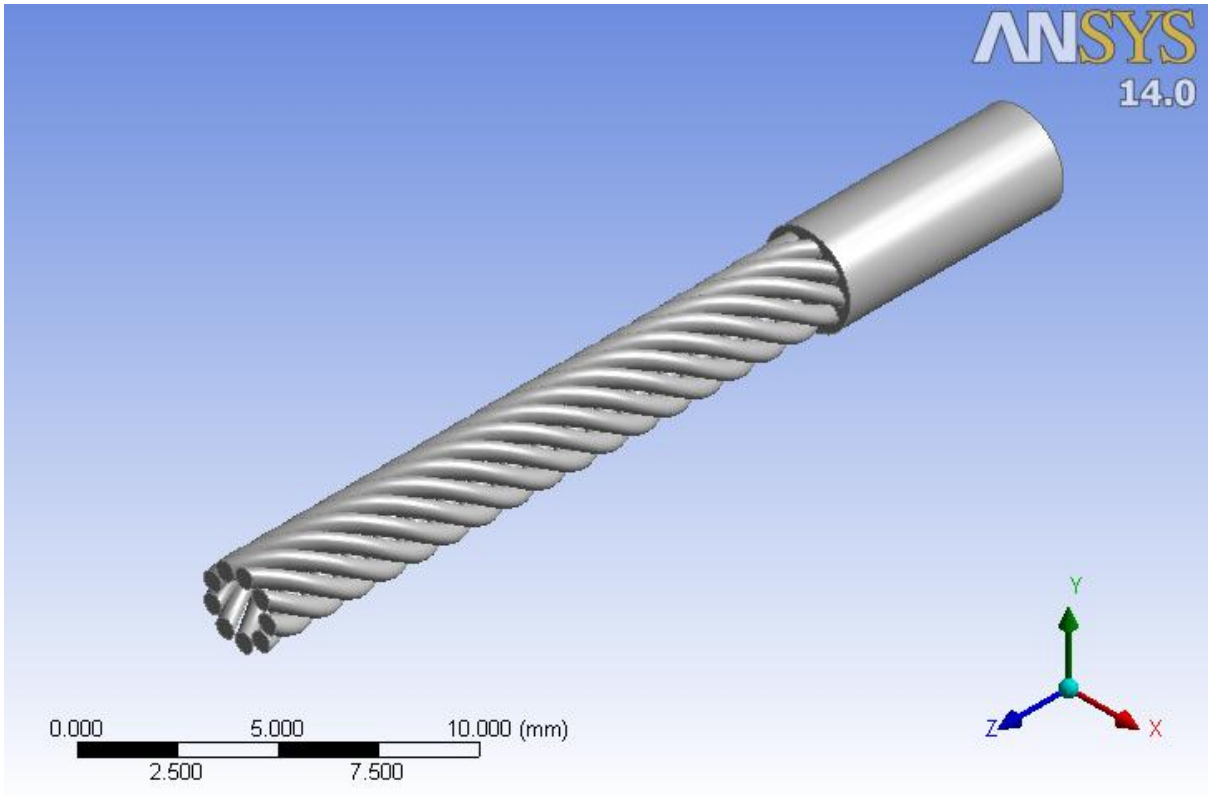
APPENDIX A: PATCHED BLOOD CLOT IN DOMAIN GEOMETRY





APPENDIX B: GEOMETRY DOMAINS 'GP'2 MODEL 1 & MODEL 2





APPENDIX C: FYP 2 Gantt Chart

No	Details / Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1	Continuation of Project Work															
	Create Geometry Domain															
	Meshing															
	Grid Sensitivity Study															
	Case Simulation															
	Post Processing															
2	Submit Progress Report															
3	Pre-EDX															
4	Submit Draft Report															
5	Submit Dissertation (soft bound)															
6	Submit Technical Paper															
7	Viva															
8	Submit Dissertation (hard bound)															