Evaluation of Trans-femoral Prosthesis Function Using Finite Element Analysis

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To my parents and my sister, for everything they have given to me.

To my wife and my little daughter, for their love and expectation.

Acknowledgments

I owe a deep sense of gratitude to all kindnesses and supports for my studies. Like once said that no one succeeds all by themselves, the work would not have been completed without the help of many individuals.

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Furthermore, immeasurable appreciation is extended to all members of prosthesis and orthosis group for providing me a chance to get the use of prosthesis devices, do experiments. Last but not least, I am very grateful to my kind friends and colleagues who are one way or another shared their support and understanding spirit, thank you all.

Saitama, September, 2017

Le Van Tuan

Abstract

A transfemoral prosthesis is an artificial limb that replaces a leg missing above the knee. The transfemoral amputee must deal with increased energy consumption for ambulation, balance, and stability; a more complicated prosthetic device; difficulty rising from sitting to standing. Transfemoral amputees can have a very difficult time regaining normal movement. A transfemoral prosthesis includes the following components: a socket, knee part, shank, ankle foor and suspension mechanism. For the transfemoral amputee to achieve the best possible outcome, it is necessary for the prosthetist to understand the prosthetic components and how they work. In this study, the author refers to the understandings about features of transfemoral prosthesis, methods and engineerings used in evaluated and manufactured transfemoral prosthesis. In this study, the author present a method for evaluation the functions of transfemoral prosthesis part by finite element method. The results of this study suggest that this method can used by the designer and prosthetist for design and choose the best comfortable prosthesis for the patient and reduce time for training before use the transfemoral prosthesis. This study includes six chapters were structured as follows.

Chapter 1: Introduction

This chapter provides an outline of the whole work. In the first section, an overview of the amputation situation in over the world and some country are introduced. After that, the defination of amputation levels, prosthesis solution and its component, problem when use the

prosthesis are summarized to high light the necessary of this study. Finally, the contributes and the abstract of all chapters provides a panoramic view of the entire of study.

Chapter 2: Technical Background and Literature Review

This chapter presents an overview of finite element analysis, multibody simulation and review the related studies. In the first section, the fundamental of finite element analysis and multibody simulation are briefly presented. This part provides the most important concepts and theory for the whole work. In the next section, the previous study are reviewed. Some prevailing results of studies are also introduced to clarify the novelty of the contributions in this work.

Chapter 3: Evaluation interface pressure on surface of residual limb in standing posture

In this chapter, a nonlinear finite element model was created and analyzed to determine the pressure distribution between a residual limb and the prosthesis socket of a transfemoral amputee. Besides that, the better approach for using the shape of socket and residual limb was considered. Three-dimensional models of the residual limb and socket were created using magnetic resonance imaging data; the models were composed of 21 layers, each separated by 10 mm. Two types of socket are MCCT (Manual Compression Casting Technique) socket and UCLA socket are used in this study for quantitative evaluation. The interface pressure distribution in the residual limb was observed. The experiment to measure the pressure at eight locations on the surface between socket and residual limb was conducted with the condition correspond with simulation.

Chapter 4: Transfemoral Gait Cycle Analysis and Evaluation Interface Pressure On Surface Of Residual Limb In Gait Cycle

This chapter present the analysis of kinematic transfemoral gait and the method for evaluation interface pressure on surface of residual limb in gait cycle. There are the different between the human normal gait and transfermoral gait. Even, there are very different of individual transfemoral patient. Understand the properties of gait pathology is very important in rehabiliation program. The multibody simulation method was used for analysis the gait cycle of transfemoral prosthesis. After that a method for computation the interface pressure between socket and residual limb during walking of patient with some of the limitation movement of residual limb and socket was presented. The shape of socket was assumed the same with the residual limb. The kinematics data of residual limb with prosthesis were observed by motion analysis system. The total model includes residual limb and all components of transfemoral socket were modeled in real size. The experiment was conducted to measure the value of pressure between socket and residual limb. The results of two methods were compared and disscused.

Chapter 5: Estimation of the ground reaction force and pressure beneath the foot prosthesis during the gait of transfemoral patients

In this chapter, the authors were implemented a finite element (FE) method for computing the GRF, and the pressure beneath the foot prosthesis and its distribution. The finite element model of all components of transfemoral of the prosthesis was created. The ground reaction forces, beneath pressure of foot prosthesis and other parameters were disclosed after solving by explicit solver of LS-Dyna software. The results of the vertical ground reaction forces exhibit consistently similar data between the simulation and the measurement. A correlation coefficient of 0.91 between them denotes their correspondence. The reaction force at knee joint, distribution of beneath pressure of foot prosthesis were included in results and discussion. These results can be used for prosthesis design and optimization; they can assist the prosthetist in selecting a comfortable prosthesis for the patient and in improving the rehabilitation training.

Chapter 6: Conclusion and future work

This chapter conclusions the study about the transfemoral prosthesis. The achievements and the limitation of this research. Furether more, some solution to improve of this work was discussed.

Nomenclature

Roman Symbols

3D Three Dimension

AD Anterior Distal

AKA Above Knee Amputation

AP Anterior Proximal

BKA Below Knee Amputation

CAD Computer Aid Design

CAT-CAM Contour Adducted Trochanteric Controlled Aligment Method

COP Center Of Pressure

FE Finte Element

FEA Finte Element Analysis

FEM Finte Element Method

GRF Ground Reaction Force

HFE high frequency events

IDF International Diabetes Federation

LD Lateral Distal

LP Lateral Proximal

MCCT Manual Compression Casting Technique

MD Medial Distal

MP Medial Proximal

MRI magnetic resonance image

NRCD National Disabled Persons Rehabilitation Center

PD Posterior Distal

PP Posterior Proximal

SACH Solid Ankle Cushion Heel

TSB Total Surface Bearing

UCLA University of California Los Angeles

UK United of Kingdom

US United State

vGRF Vertical Ground Reaction Forces

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Chapter 1

Introduction

This chapter provides an outline of the whole work. In the first section, an overview of the amputation situation in over the world and some country are introduced. After that, the defination of amputation levels, prosthesis solution and its component, problem when use the prosthesis are summarized to high light the necessary of this study. Finally, the contributes and the abstract of all chapters provides a panoramic view of the entire of study.

1.1 Overview

1.1.1 Statement of amputations

The Amputee Coalition of America estimates that there are 185,000 new lower extremity amputations each year just within the United States [1] and an estimated population of 2 million American amputees [100] . It is projected that the amputee population will more than double by the year 2050 to 3.6 million.

According to a survey by Sawamura [2] on amputation based on the physically disabled persons certificate in 20 cities in Hyogo Prefecture in Japan for the 25-year period from 1968 to 1992, the incidence of amputation was 6.2/100,000 population per year, and trauma accounted for 70% of the causes of amputation. Although there were no changes in the total number of amputations during those 25 years, the percentage of amputations due to arteriosclerosis obliterans and diabetes mellitus was increasing. According to a survey on amputation based on the physically disabled persons certificate in Okayama Prefecture for the five-year period from 1984 to 1988, they reported that 58.2% of lower limb amputations were caused by peripheral circulatory disorder [69]. Hayashi et al. conducted a mail survey of lower limb amputees whose prosthetic legs were made during the six-year period from 1992 to 1997, and reported that peripheral circulatory disorder was the cause in approximately 3% of subjects who underwent amputation before the 1960s, but had increased to 37% among the subjects who underwent amputation in the 1990s [5]. These reports from Japan are of surveys conducted from the 1980s to 1990s [2, 46, 69], and recent data are unknown. In addition, the residential areas and details of these subjects are unclear, only amputation due to peripheral vascular disorder has been surveyed, and the incidence of amputation is unclear due to lack of any community-based surveys. An appropriate community-based survey in an area representing an average population of Japan is required to uncover the incidence and causes of amputation in Japan. Kitakyushu City is a local city with a population of one million and is believed to reflect the average condition of Japan [3, 4].

In Vietnam, a major problem is the current traffic situation, remaining of landmines and the effects of the war [5, 35]. This results in a high level of injuries involving amputations and other disabilities in the country, which increases the need of prosthetic devices and services. According to Day [35] there are 200,000 amputees estimated in Vietnam 1996, and is increasing by 3-4% per year.

The Vietnamese people take their agriculture very seriously, and it is significantly important for the economy in Vietnam [6]. Its of high importance for sustainable development and poverty reduction in the country. By getting amputated you cant resume previous occupations such as farming in most cases without a prosthetic device [66, 92]. The social acceptance isnt easy either, especially in the amputees families where they could see them as a burden because of the occupational situation they are in. In Vietnam, the families of the amputees are responsible to take care of them during hospitalization, which also affect the families economy since they need to be absent from work [7, 66, 73]. Even after the hospitalization many amputees cant go back to their previous occupations because of their restrictions, which make them vulnerable. Especially in the urban areas where people with disability get unemployed three times more than persons without disability.

Amputation risk in patients with diabetes has always been a global challenge. The global view, which reveals more than 1 million annual limb amputations, one every 30 seconds, is even more troubling, particularly since the International Diabetes Federation (IDF) predicts that current global prevalence of diabetes will burgeon from 366 million in 2011 to reach 552 million by 2030 [8]. In the U.S., the burden of diabetes is expected to double from its current prevalence, 25.8 million adults and children, or 8.3% of the population, by 2030 [9].

In the most developed nations the annual incidence of foot ulceration, which precedes amputation in 85% of cases, is about 2%. In poorer, developing nations a lack of access to care places about half of all persons with diabetes at risk for foot ulceration, and diabetes-related amputations are very common [25]. Yet, the vast majority of amputations both in the US. and abroad are preventable.

1.1.2 Solution for amputation patients

A prosthesis is a device designed to mimic a missing part of human anatomy, in this case an anatomical leg. Since it is impossible to fully recreate a human leg, the designer should create a prosthesis with the necessary features to satisfy the functional requirements of the leg.

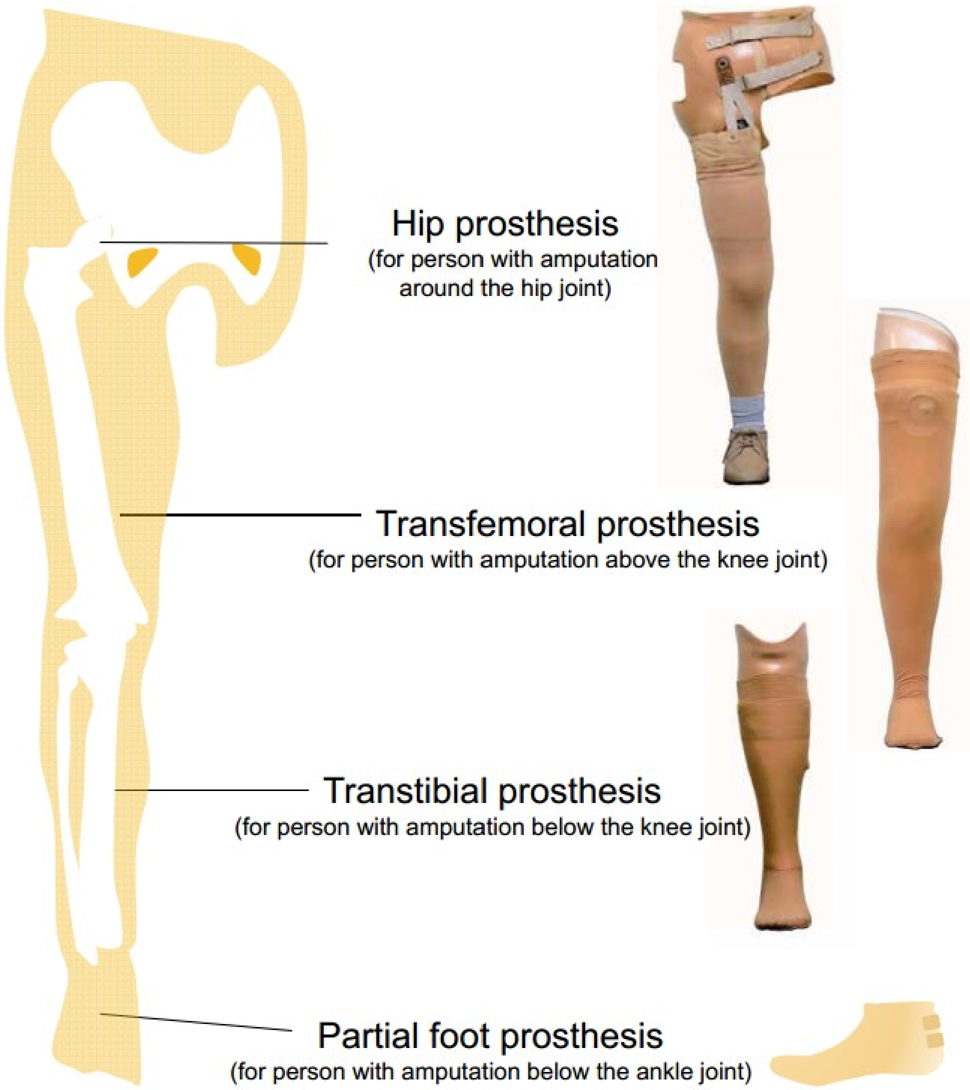


Figure 1.1: Amputation levels (NRCD - Japan)

Ideally, a prosthesis must be comfortable to wear, easy to put on and remove, light weight, durable, and cosmetically pleasing. Furthermore, a prosthesis must function well mechanically and require only reasonable maintenance. Finally, prosthetic use largely depends on the motivation of the individual, as none of the above characteristics matter if the patient will not wear the prosthesis.

Amputation is performed at a number of different levels (Figure 1). The most common continues to be the trans-tibial level, accounting for almost half of all referrals to the prosthetic services in the UK [10]. Determining the ideal level of amputation for a patient depends on a number of factors. An holistic assessment considers factors such as healing potential, rehabilitation potential, prosthetic considerations, the patient's own wishes, discharge arrangements [11], and the extent of non-viable tissue on the affected limb [12]. Consideration must be given to knee and hip function and the presence of joint prostheses. The final choice of the level of amputation is considered to be a compromise between ensuring primary wound healing and maximising the patient's function postoperatively [81]. Successful prosthetic intervention should be judged by patient-specific functional outcomes. A nonambulatory patient may report an improved quality of life with a prosthesis used for transfers (movement from one position or surface to another) as opposed to one employed for ambulation.

A transfemoral prosthesis is an artificial limb that replaces a leg missing above the knee. Transfemoral amputees can have a very difficult time regaining normal movement. In general, a transfemoral amputee must use approximately 80% more energy to walk than a person with two whole legs. This is due to the complexities in movement associated with the knee. In newer and more improved designs, after employing hydraulics, carbon fibre, mechanical linkages, motors, computer microprocessors, and innovative combinations of these technologies to give more control to the user.

1.2 Transfemoral prosthesis components

The major components of a lower extremity prosthesis are the socket (with or without a socket liner), a suspension system, interposed joint components (as needed), a shank (pylon), and a prosthetic foot. The prosthetic foot is typically a component that functions and looks like a foot but that may take other forms or functions for water or other sports activities (Figure 2).

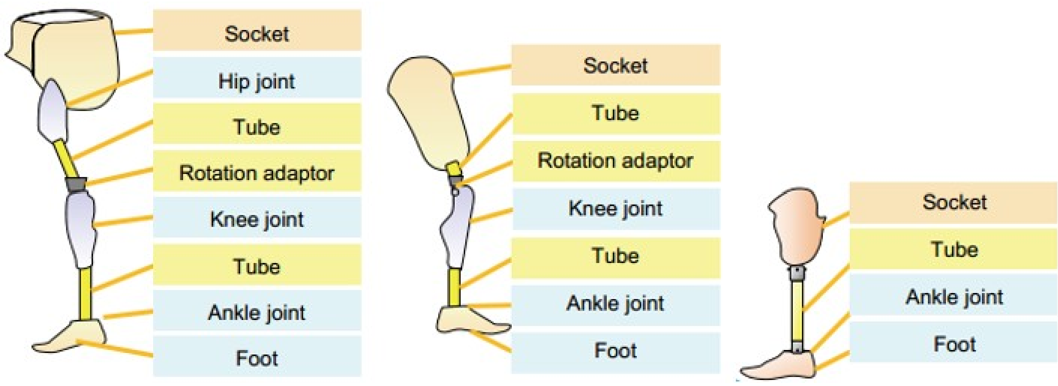


Figure 1.2: Main components of the lower limb prosthesis (NRCD Japan). Hip prosthesis (left); Transfemoral prosthesis (middle) and Transtibial prosthesis (right)

1.2.1 The socket

The socket serves as the interface between the residual limb and the prosthesis (Figure 3). It must not only protect the residual limb but must also appropriately transmit the forces associated with standing and ambulation. The preparatory (temporary) socket will likely need to be adjusted several times as the volume of the residual limb stabilizes. The preparatory socket can be created by using a plaster mold of the residual limb as a template. Some prosthetic manufacturing facilities use computer-assisted technology to map the residual limb, manufacturing a socket directly from that data.

Figure 1.3: Prosthetic socket made of lamination resin (Ottobock))

The most common socket used in a transtibial amputation is a patellar tendon-bearing (PTB)socket. This socket emphasizes increased contact or weight bearing in the area of the patellar tendon, inferior to the patella, but that is not to say that there is not significant contact or weight bearing elsewhere on the residual limb. The concept of total contact is important because prior to the total-contact PTB socket, transtibial sockets often had an open-ended, plug-fit design, which lead to numerous skin problems, chronic choke syndrome, ulceration, and other problems. Total surface bearing (TSB) transtibial socket designs are moving away for the concept of emphasizing patellar tendon weight bearing, but even these require selective loading and selective relief over certain areas of the residual limb. Neither socket will work well for every amputee. The prosthetist still needs to work with an individual patient to fit a socket that meets that particular patient's needs.

1.2.2 Suspension system

Every prosthesis requires some type of suspension system to keep it from falling off the residual limb. Suspension can be achieved by a variety methods, including

Figure 1.4: The UCLA socket type and MCCT socket type. Made by prof. Agarie laboratory.

the following:

- Self-suspension of the socket - This makes use of the anatomic shape of the residual limb (Syme or knee disarticulation).
- Suction suspension - Methods of creating suction suspension include the use of an appropriate suction socket design, of a gel suspension liner.
- Suspension device or harness - Such equipment includes belts, cuffs, wedges, straps, and sleeves.

A combination of these techniques also can be used. Standard suction is a common suspension choice for transfemoral prostheses; it employs a total-contact, form-fitting, rigid or semirigid socket with a 1-way air valve in the distal end that allows air to be expelled after the socket is donned. The socket's intimate fit creates a seal between the skin of the residual limb and the socket. When air is driven out of the end of the socket, a small negative pressurestrong enough to suspend the socket on the residual limbdevelops inside the socket. This form of suspension allows excellent proprioceptive feedback and is lightweight. One disadvantage of the suction socket is its inability to tolerate much weight or volume fluctuation up or down before it requires replacement.

1.2.3 Knee joint

The prosthetic knee must fill the following 3 functions:

- Provide support during the stance phase of ambulation.
- Produce smooth control during the swing phase.
- Maintain unrestricted motion for sitting and kneeling.

The prosthetic knee can have a single axis with a simple hinge and a single pivot point, or it may have a polycentric axis with multiple centers of rotation.

Figure 1.5: Knee joint system (Otto Bock)

Prosthetic science is advancing the types of knees now available. The hydraulic-based Otto Bock C-Leg (Otto Bock Health Care, Minneapolis, Minn) provides several benefits over purely mechanical knee systems. These microprocessor-controlled knees improve upon the timing of the hydraulic and pneumatic knees. The patient can ambulate at greater speeds with optimal, biomechanically correct symmetry while expending less energy. Most importantly, the user can safely walk step over step up and down stairs. The built-in battery lasts anywhere from 25-40 hours, which means that it can support a full day of activity. The recharge can be performed overnight or while traveling in a car (via a cigarette lighter adapter). The magnetorheological-fluidbased Rheo Knee(Ossur, Reykjavic, Iceland; Ossur North America, Aliso Viejo, Calif) is capable of "learning" how the patient walks.

Electronic sensors on the artificial joint measure the joint's angle and the loads it is bearing, 1,000 times per second while a computer chip controls the viscosity of magnetic fluid inside the knee. Tiny metal particles suspended in the fluid form small chains when the magnetic field is turned on, causing the fluid to become thicker. That, in turn, affects the stiffness of the joint, which is modified constantly while the knee is in use, allowing for a smooth swing of the leg. However, the cost of technologically advanced knees is prohibitory for most amputees.

1.2.4 The pylon and ankle

The pylon is a simple tube or shell that attaches the socket to the terminal device. Pylons have progressed from simple, static shells to dynamic devices that allow axial rotation and that absorb, store, and release energy. The pylon can be an exoskeleton (soft foam contoured to match the other limb and covered with a hard, laminated shell) or an endoskeleton (an internal, metal frame with cosmetic soft covering). The ankle function usually is incorporated into the terminal device.

A separate ankle joint can be beneficial in heavy-duty industrial work or in sports such as mountain climbing, swimming, and rowing. However, the additional weight of a separate joint requires more energy expenditure and greater limb strength to control the additional motion.

1.2.5 Prosthetic feet

The 5 basic functions of the prosthetic foot are as follows:

- Provide a stable, weight-bearing surface.
- Absorb shock.
- Replace lost muscle function.
- Replicate the anatomic joint.
- Restore cosmetic appearance.

Prosthetic feet are broadly classified as energy-returning feet or nonenergy-returning feet. Nonenergy-returning feet include the solid-ankle, cushioned-heel (SACH) foot and the single-axis foot. The SACH foot mimics ankle plantar flexion, which allows for a smooth gait. The prosthetic is a low-cost, low-maintenance foot for a sedentary patient who has had a BKA or an AKA. The rigid forefoot provides an anterior lever arm and proprioception. The single-axis foot adds passive plantar flexion and dorsiflexion, which increase stability during the stance phase. They are most commonly used for patients with a transfemoral amputation if knee stability is desired. Energy-returning feet are probably improperly named because, in fact, they do not return energy. They do, however, assist the body's natural biomechanics and allow for greater cadence or less oxygen consumption. The multiaxis foot and the dynamic-response foot are members of this family. The multiaxis foot adds inversion, eversion, and rotation to plantar flexion and dorsiflexion; it handles uneven terrain well and is a good choice for the individual with a minimal-to-moderate activity level.

Figure 1.6: The Triton family of feet (Otto Bock)

The dynamic-response foot is the top-of-the-line foot and is commonly used by young, active persons and by athletic individuals. The forefoot acts like a spring, compressing in the stance phase and rebounding at toe-off. Geriatric patients benefit from the light weight of these feet.

1.3 Common problem

1.3.1 Socket fitting

Following lower limb amputation, quality of life is highly related to the ability to use a prosthetic limb. The conventional way to attach a prosthetic limb to the body is with a socket. Many patients experience serious discomfort wearing a conventional prosthesis because of pain, instability during walking, pressure sores, bad smell or skin irritation. In addition, sitting is uncomfortable and pelvic and lower back pain due to unstable gait is often seen in these patients. The main disadvantage of the current prosthesis is the attachment of a rigid prosthesis socket to a soft and variable body. The socket must fit tightly for stability during walking but should also be comfortable for sitting [41].

When a socket is not a snug fit, the resulting gap allows the residual limb to move more than it should; and the result is often sores, blisters, and ongoing pain. Experienced prosthetic practitioners know that fitting well distributes the weight and pressure evenly over areas of the residual limb that can tolerate regular pressure. Evidence shows that a good fit can also help ease phantom pain. Sometimes prostheses that cause pain or discomfort are too tight. When the socket is too constrictive, it can inhibit circulation and cause swelling or friction that results in skin abrasions. Problems with how well prostheses fit can be related to fluctuations in body weight. If you gain or lose weight, it can have an impact on the fit of your prosthesis.

Design and manufacture a good quality of socket are purpose of many researchers and project. The comfortable socket for individual patient requires the coordination of all steps from the method of surgery for amputation, type of socket used, rehabilitation trainning and medical care conditions of patient.

1.3.2 Dynamics of knee joint

Prosthetic knee designers have used components such as springs and dampers and optimized them with an aim of replicating ideal knee moment required for walking with able-bodied kinematics [65].

Modern transfemoral prostheses knee joint can be classified into three major groups: passive, variable damping, and powered. Passive prosthetic knees do not require a power supply for their operation and are generally less adaptive to environmental disturbances than variable-damping prostheses. Variable-damping knees do require a power source but only to modulate damping levels, whereas powered prosthetic knees are capable of performing nonconservative positive knee work.

However, many challenges for design and choose a good knee joint prosthesis because it depends on individual patient features, finance ability and using purpose. The understand of knee joint operation and load appeared are important parameters for design and improve quality of knee joint. Nowadays, many studies continuing find the solution for study the quality of knee joint by using advanced technologies.

1.3.3 Ground reaction forces and center of preessure

Ground reaction forces (GRF) and pressure beneath the foot prosthesis are the main parameters used in biomechanical analysis to estimate the joint load and evaluate the quality of the prosthesis, especially with transfemoral patient who have amputation that occurs through the femur. The information of ground reaction forces and beneath pressure of foot prosthesis is conventionally achieved using dynamics method or the experimental method. However, these methods have some limitation for a prosthetist and designers to choose the best prosthesis solution for transfemoral patient.

1.4 Objectives

Motivated by the difficult issues for achived a good transfemoral prosthesis, specifially find a convenient method using finite element (FE) analysis for evaluation the function of socket, the knee joint, feet and collected the data for determine quality of transfemoral prosthesis operation, as well as the limitiations of the published researchs, the main ojectives of the dissertation are as follow:

- Improving the overvall method for evaluation the fitting of transfemoral prosthesis socket in all states includes: standing posture and working.

- Developing the three dimension (3D) model and finite element model of residual limb includes: skin, fat, muscle and bone; components of prosthesis includes: knee joint, shank and feet.

- Analysis the GRF and pressure beneath the foot prosthesis during the gait of transfemoral patients.

- The experiments were also conducted for comparison computation results.

With the above objectives, by using the FE approach, this study is expected to helping the prosthetist develop biologically realistic lower-limb assistive devices that improve amputee locomotion. Furthermore, the results of the study can aid the prosthesis designer in the design of the prosthesis parts and the structure of the artificial leg, and in material selection.

1.5 Contributions

The contributions of the dissertation are as follows:
Created the model of residual limb of transfemoral amputatiion with four parts: skin, fat, muscle and bone. This is the first study mentioned this idea for established the 3D model and FE model of residual limb and socket.

- To improve the accuracy the model for computation interface pressure between socket and residual limb, the stress inside residual limb.

- Decribed the behavior of soft tissue layer insided residual limb and the contraints of muscle to the bone.

- The correlation coefficients between results and experiment are larger 0.9 expressed the compatible and effectiveness of FE method.

The total of all transfemoral prosthesis were created and simulation with dynamics software and FE software:

- The 3D model and FE model of all components of transfemoral prosthesis and residual limb were established.

- The operation and material behavior of all components were described and simulated.

- The results of forces at knee joint, vertical GRF and pressure beneath of foot prosthesis were obtained and evaluation with results of experiments.

1.6 Structure of this works

In this study, author proposed three topic that relative with evaluate the function of three parts of transfemoral prosthesis are socket, knee joint and foot. After that the evaluation for total artificial limb was discussed. Three topics are socket evaluation, dynamics of lower limb with prosthesis, GRF and pressure on beneath of foot prosthesis . This works focus on using the FE analysis method by using software for understanding behaviour of residual limb and adaption of transfemoral prosthesis.

In the first topic, the quality of socket was evaluation in two case: stand posture and walking. The pressure on surface of residual limb was considers as the critical for quality of the socket, it described the fitting of socket for the patient used in standing and walking. The results of simulation were confirmed by compare with results of experiment.

The dynamics properties of knee joint in gait cycle were computation by two approach: multibodies dynamics and FE analysis, they are described in the second topic. The residual limb and a trans-femoral prosthesis was designed as a coupled link with two revolution joints at the hip and knee joints. The forces and moments knee joint were calculation by Matlab Simulink and LS-DYNA.

The function of feet prosthesis was considered in the third topic. The model of feet with shoe plate with real size were created by laser scanner. They was connected with others part of prosthesis as the real case. The ground reaction force and center of pressure were estimation and discussions. These results were compared with results of experiment.

This dissertation is composed of six chapters.

Chapter 1 has provided the overview about the ampuation and prosthesis, challenges and motivations of this work. It was also show the structure of this works.

Chapter 2 presented the technical background of finite element method and its applied in computation interface pressure, the multibody simulation for analysis human gait cycle. Many related studies about interface pressure between socket and residual limb, the plantar pressure and ground reaction forces are reviewed.

Chaper 3 presented a simulation method for calculation the interface pressure on surface of residual limb in stand posture and walking state. The load was applied to the prosthesis was hypothesis equal the body weight of patient. In the standing posure, the simulation was carried out in two case: one leg and two legs position. The comparison between simulation and experiment results was discussed.

Chapter 4 described the interface pressure on surface of residual limb in the walking state, the movement of transfermoral prosthesis was simulated as the real case with kinematic dynamics got from experiment. The comparison between simulation and experiment results was discussed.

Chapter 5 introduces the analysis of kinematic transfemoral gait and the method for evaluation interface pressure on surface of residual limb in gait cycle. The total 3D model of transfemoral prosthesis was built and meshing. The simulation with very strong method is finite element analysis. By this method, almost the information about the operation of transfemoral prosthesis was disclose. The results considered the ground reaction force and center of pressure. It also compares with the results of experiment.

The dissertation ends with conclusions and future works in chapter 6.

Chapter 2

Technical Background and Literature Review

This chapter presents an overview of finite element analysis, multibody simulation and review the related studies. In the first section, the fundamental of finite element analysis and multibody simulation are briefly presented. This part provides the most important concepts and theory for the whole work. In the next section, the previous study are reviewed. Some prevailing results of studies are also introduced to clarify the novelty of the contributions in this work.

2.1 Technical Background

2.1.1 Finite Element Analysis

The Finite Element Analysis (FEA) originated from the need for a method to solve complex elasticity, and structural analysis problems in both civil engineering and aeronautical engineering. However, it has since been used in many fields. One essential characteristic is the decomposition of a continuous domain into a set of discrete sub-domains. Such a characteristic provides a great advantage to employ local information comprehensively and to describe variation details, while much computation is needed.

The development of the FEA in continuum mechanics is often based on an energy principle, e.g., the virtual work principle or the minimum total potential energy principle, which provides a general, intuitive and physical basis that has a great appeal to engineers. Mathematically, the finite element method is employed to find approximate solutions of partial differential equations as well as solutions of integral equations or their combinations. The solution approach is usually a numerically based simulation.

In the modeling of the mechanical response of a soft tissue, the finite element method has been employed to solve the established constitutive equation which describes the soft tissue behavior. The comprehensive employment of local information makes the FEA efficient in describing the shape changes of the soft tissue. On the other hand, with the increase of the computation power of computers, the finite element based modeling becomes an efficient and accurate technique in many applications.

It is important to remember that the order the nodes and elements are numbered greatly affects the computing time. This is because we get a symmetrical, banded stiffness matrix, which bandwidth is dependent on the difference in the node numbers for each element, and this bandwidth is directly connected width the number of calculations the computer has to do. Computer FEM-programs have internal numbering that optimizes this bandwidth to a minimum by doing some internal renumbering of nodes if they are not optimal.

2.1.2 Finite Element Analysis Theory

The analysis of a structure by the Finite Element Method (FEM) can be divided into several distinctive steps. These steps are to a large extent similar to the steps defined for the matrix method. Here we give a theoretical approach to the method, and its different steps.

2.1.2.1 Discretization

Discretization is the process of dividing your problem into several small elements, connected with nodes. All elements and nodes must be numbered so that we can set up a matrix of connectivity. The picture to the right shows discretization of a transverse frame into beam elements and discretization of a plane stress problem into quadrilateral elements.

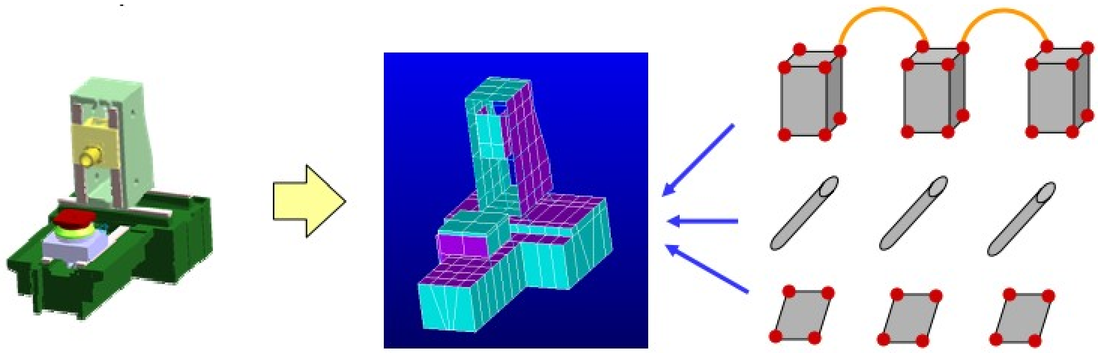


Figure 2.1: Divide the domain into a number of small, simple elements (MIT web)

2.1.2.2 Element Analysis

The element analysis have two key components; Expressing the displacements within the elements, and maintaining equilibrium of the elements. In addition, stress-strain relationships are needed to maintain compatibilty.

The final result is the element stiffness relationship: S = kv. For beam elements this relationship was obtained using the exact relationships between forces and moments and the corresponding displacements.These results could therefore be interpreted as being obtained by the governing differential equation and boundary condition of the beam elements.

For e.g. a plane stress problem it is not possible to use an exact solution. The displacements within the elements are expressed in terms of shape functions scaled by the node displacements. Hence, by assuming expressions for the shape functions, the displacements in an arbitrary point within the element is determined by the nodal point displacement.

The section of the structure that the element is representing is kept in place by the stresses along the edges. In the finite element analysis it is convenient to work with nodal point forces. The edge stresses may in the general case be replaced by equivalent nodal point forces by demanding the element to be in an integrated equilibrium using work or energy considerations. This technique is often reffered to as to "lump" the edge forces to nodal forces.

This requirement result in a relationship between the nodal point displacements and forces to be given as:

$$S = kv + S^0 \tag{2.1}$$

Where:

- S - generalized nodal point forces
- k - element stiffness matrix
- v - nodal point displacements

- S^0 - nodal point forces for external loads

Computer programs usually have many options for types of elements to choose among.

2.1.2.3 System Analysis

A relationship between the load and the nodal point displacements is established by demanding equilibrium for all nodal points in the structure:

$$R = Kr + R^0 \tag{2.2}$$

$$K = \sum_j a_j^T k_j a_j \tag{2.3}$$

$$R^0 = \sum_j a_j^T S_j^o \tag{2.4}$$

The stiffness matrix is established by directly adding the contributions from the element stiffness matrices. Similarly the load vector R is obtained from the known nodal forces.

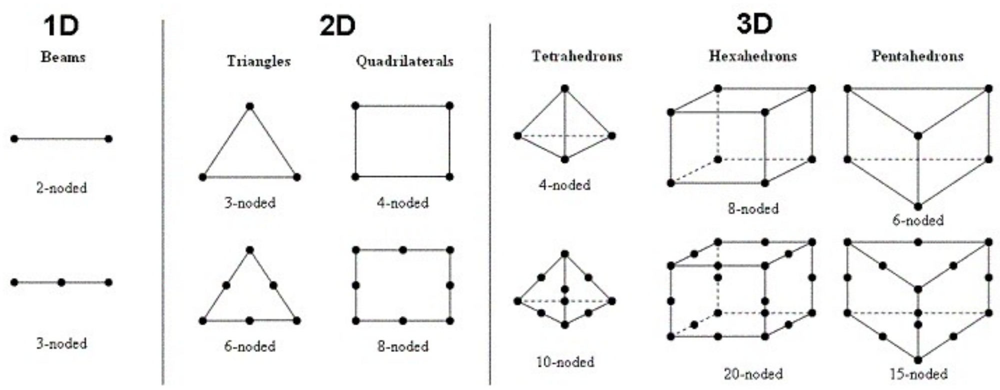


Figure 2.2: Different 1D, 2D and 3D basic elements

2.1.2.4 Boundary conditions

Boundary conditions are introduced by setting nodal displacements to known values or spring stifnesses are added.

2.1.2.5 Finding global displacements

The global displacements are found by solving the linear set of equations stated above:

$$r = K^{-1}(R - R^0) \tag{2.5}$$

2.1.2.6 Calculation of stresses

The stresses are determined from the strains by Hooke's law. Strains are derived from the displacement functions within the element combined with Hooke's law. They may be expressed generally by:

$$\sigma(x, y, z) = D.B(x, y, z).\nu \tag{2.6}$$

Where:

- v = ar
- D - Hooke's law on matrix form
- B - Derived from u(x, y, z)

Output interpretation programs, called postprocessors, help the user sort out the output and display it in graphical form.

2.1.3 Finite Element Analysis Stage

A Finite Element analysis consist of three separated stages; Preprocessing, processing, and postprocessing. A complete finite element analysis is a logical interaction of these three stages.

2.1.3.1 Preprocessing

As the name indicates, preprocessing is something you do before processing your analysis. The Preprocessing involves the preparations of data, such as nodal coordinates, connectivity, boundary conditions and loading and material information.

The preparation of data require considerable effort if all data are to be handled manually. If the model is small, the user can often just write a textfile and feed it into the processor, but as the complexity of the model grows and the number of elememnts increase, writing the data manually can be very time consuming and error-prone. Its therefore neccessary with a computer preprocessor which help with mesh plotting and boundary conditions plotting.

For an example of a simple preprocessor, see the Java-applet on these pages. Her you can change loads, boundary condtitions, mesh and element properties and material. All this is done graphically to minimize the chance of error. The only limitation is that you cannot draw your own geometry, you have to select one of the pregenerated geomtries.

2.1.3.2 Processing

The processing stage involves stiffness generation, stiffness modification, and solution of equations, resulting in the evaluation of nodal variables. This is a typical "black box"-operation, as the user will see little of whats going on. You feed data from the preprocessor, and you get data out.

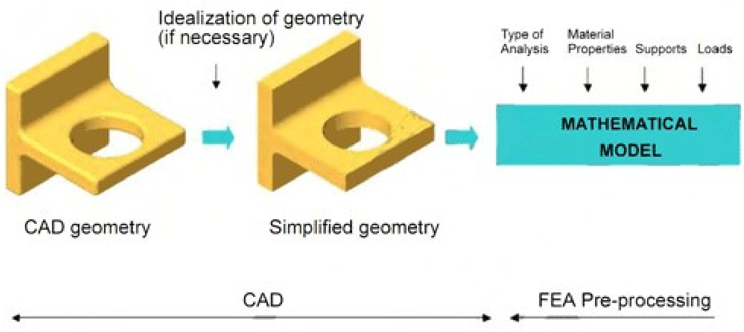


Figure 2.3: FEA Preprocessing (simplan.de)

2.1.3.3 Postprocessing

The postprocessing stage deals with the representation of results. Typically, the deformed configuration, mode shapes, temperature, and stress distribution are computed and displayed at this stage.

For an example of a simple postprocessor, see the Java applet on these pages. Here you can, after analysis of a model, view the deformed model, and inspect stresses and displacements, both in the controid of elements and the nodal values, and see contour plotting of these data.

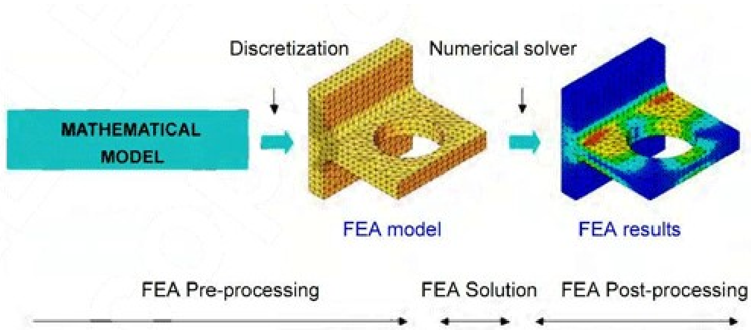


Figure 2.4: FEA Postprocessing (simplan.de)

2.1.4 LS-DYNA Solver

LS-Dyna is advanced general purpose multi-physics simulation software developed by Livermore Software Technology Corporation. LS-Dyna is a Non-linear Explicit Transient Dynamic FE code, originated from the 3-D FEA program DYNA-3D developed by Dr.John.O.Hallquist at Lawrence Livermore National Laboratory, California in 1976.
The main application areas of LS-DYNA are crash simulations, metalforming simulations and the simulation of impact problems and other strongly non-linear tasks. LS-DYNA can also be used to successfully solve complex nonlinear static problems in cases where implicit solution methods cannot be applied due to convergence problems.

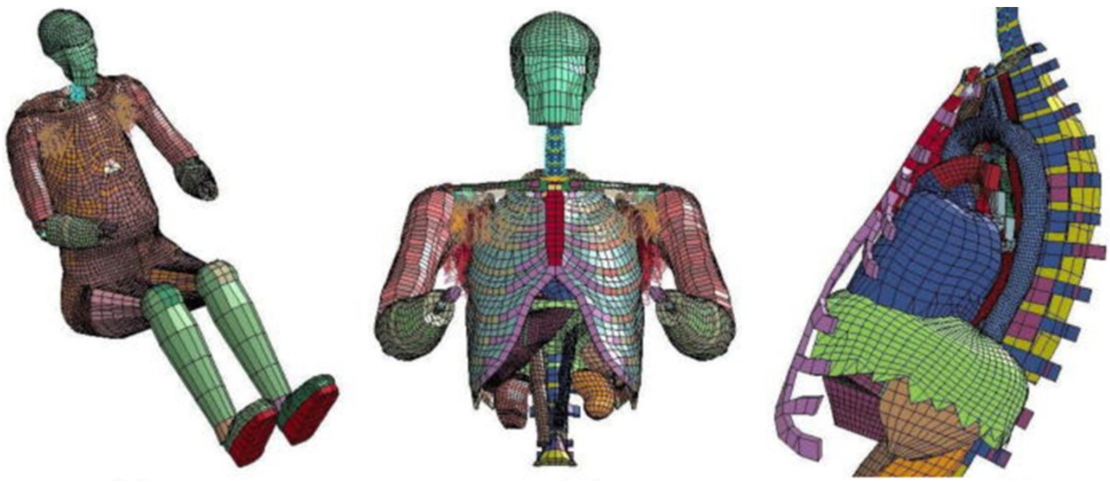


Figure 2.5: Wayne State Human Body Model - II

2.1.5 Multibody Dynamics Simulation

2.1.5.1 Overview

During the last quarter century, rigid body dynamics has received considerable attention due the central role it plays in robot simulation, control, design, computer animation, haptics and virtual reality. A great number and variety of formalisms have been developed for rigid body systems despite the fact that all of them can be derived from a few fundamental principles of mechanics.

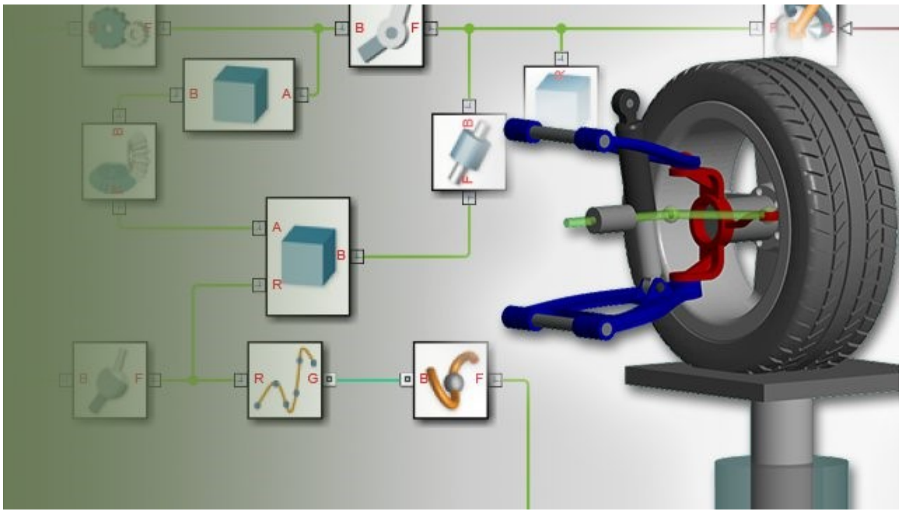


Figure 2.6: Multibody Simulation with Simmechanics (Matworks Inc).

What is commonly known as the Newton-Euler method includes the constraint forces acting on all bodies of the system, which results in redundant equations with more equations than unknowns. In other formulations, such as Lagrange equations, Gibbs-Appell equations [24], and Kanes method [25], the constraint forces are eliminated by use of dAlemberts principle. Efficient simulation algorithms were developed based on these formulations for systems with different structures.

2.1.5.2 Matlab SimMechanics Solution

Matlab SimMechanics provides a multibody simulation environment for 3D mechanical systems, such as robots, vehicle suspensions, construction equipment, and aircraft landing gear. The SimMechanics blocks do not directly model mathematical functions but have a definite physical - mechanical meaning. The block set consists of block libraries for bodies, joints, sensors and actuators, constraints and drivers, and force elements. Besides simple standard blocks there are some blocks with advanced functionality available, which facilitate the modeling of complex systems enormously. An example is the Joint Actuator with event handling for locking and unlocking of the joint. Modeling such a component in traditional ways can become quite difficult. The machine is assembled automatically at the beginning of the simulation [**?**].

All blocks are configurable by the user via graphical user interfaces as known from Simulink. The option to generate or change models from Matlab programs with certain commands is not implemented yet. It might be added in future releases. It is possible to extend the block library with custom blocks, if a problem is not solvable with the provided blocks. These custom blocks can contain other preconfigured blocks or standard Simulink S-functions.

Standard Simulink blocks have distinct input and output ports. The connections between those blocks are called signal lines, and represent inputs to and outputs from the mathematical functions. Due to Newtons third law of action and reaction, this concept is not sensible for mechanical systems. If a body A acts on a body B with a force F, B also acts on A with a force F, so that there is no definite direction of the signal flow. Special connection lines, anchored at both ends to a connector port have been introduced with this toolbox. Unlike signal lines, they cannot be branched, nor can they be connected to standard blocks. To do the latter, SimMechanics provides Sensor and Actuator blocks. They are the interface to standard Simulink models.

Actuator blocks transform input signals in motions, forces or torques. Sensor blocks do the opposite, they transform mechanical variables into signals.

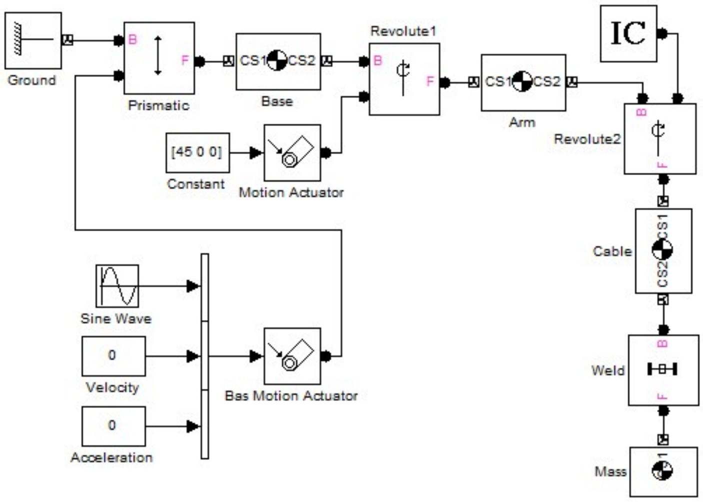


Figure 2.7: Example of Simmechanics Block Diagram (Matworks Inc).

2.2 Literature Review

2.2.1 Interface Pressure Residual Limb and Prosthesis

2.2.1.1 Finite Element Analysis for Socket Pressure Measurement

Socket is an important part of every prosthetic limb as an interface between the residual limb and prosthetic components. Biomechanics of socket-residual limb interface, especially the pressure and force distribution, have effect on patient satisfaction and function.

For years, researchers have used finite element methods to study pressure and stress measurement. The foundations of material and fluid physics, such as hydrostatics and Pascal's law, provide a suitable framework for understanding the residual limb and socket behavior [53]. Another issue is whether mere high pressure causes damage to the tissue [86] or size and intervals (high-frequency events, HFE) are also important. Geometric changes in the muscles and materials are deemed important factors. Findings, such as skin damage caused by a loading cycle (22118 times) of 423kPa with a friction coefficient of 0.5 [85], can support this notion because endurance threshold, peak point, and onset of pain are subjective and vary from one person to another. Remarkable ethnic differences also exist in terms of genetics, race, muscle intensity, and skin endurance, thereby lowering the credibility of such experiment results. Such comparisons are ongoing, and the capability of sensors is further enhanced by technological advances, such as the emergence of chips and ultrasensitive fibers [13]. Aside from sensors, computerized modeling has been also considered since 1996.

Similar to an artificial leg, the residual limb is a complicated system with mechanical and biomechanical behaviors. Parameters, such as force distribution, friction, and tension on residual limb against the socket have been investigated through FEM [99]. Tomographic images have also been used to improve 3D FEM modeling. For instance, liner stiffness and its impact on residual limb-socket friction have been evaluated with the solid model constructed using the automesh function of the CAD system [59]. Understanding these variables helps better in the comprehension of mechanical and biomechanical relationships between the socket and residual limb. However, in several cases of modeling, the displacement during donning the socket is neglected. As such, the automatic contact method was applied to overcome these defects [96] to analyze the magnetic resonance imaging (MRI) and skeletal structure using the Mimics software [56].

Software programs, such as SolidWorks (SolidWorks Corporation, MA, USA), Abaqus (Hibbitt, Karlsson Sorensen, Inc., Pawtucket, RI, USA), magnetic resonance MRI, and XRY Dynamic, have been widely used to understand the biomechanics of suspension systems and residual limb interfaces. After transferring the model and data from Solidworks to Abaqus, FEM assumes that the bones, fat, and muscles are the same elements and form a monolith with different mechanical properties [77]. For the sake of simplicity, the assumption in FEM is that the knee angle does not change with different loadings. Jia et al. studied external and internal parameter and assumed that no motion relationship exists between the residual limb and socket during locomotion [49].

All techniques used for assessing pressure and socket-residual limb tension were aimed at increasing accuracy and producing results approximated to the practical and medical situation. The study on the residual limb-socket interface behavior in a dynamic state has automatically extended the research scope. Some studies have highlighted the mutual effect of the hard and soft tissues of residual limb (e.g., effect of knee movement, changes in the position of residual limb bones, and their function in generating tension and shear forces). The results of these investigations were expected to contribute to practical improvements in socket construction, mainly for the pain management due to socket misfit. Thus, pain perception was evaluated using technical and computerized systems to redesign and rectify the socket prior to actual construction in accordance with the obtained results [57].

2.2.1.2 Experiments for Socket Pressure Measurement

Researchers have examined the defects of measuring instruments, weakness of existing sensors in terms of size and sensitivity and impact of heat, which casted doubt on research results. Lee and Zhang aimed to rectify the socket design in a virtual environment before construction through the pain perception threshold as an evaluation criterion [57]. The oral report of the wearer was used as a credible measure for evaluation, rectification, and actual construction of the socket. Additionally, special sensors were utilized to evaluate the pressure between the socket and residual limb and between the liner and socket. The most commonly used sensors are fluid-filled transducers, pneumatic transducers, printed circuit sheet sensors, and diaphragm deflection strain-gauge sensors. Modern biofeedback has been used to record the pressure in dynamic and static states. Measurement systems include shear stress neuromuscular system, 3D computer modeling, prototype socket sensor matrices, customized pressure vessels, Rincoe socket fitting system, Tekscan F-Socket pressure measurement system, and novel pliance system.

The thickness of these sensors and systems, albeit small, affects the results of studies [30, 76]. The accuracy and response of sensors in curved areas, as well as lumps, have also been compared. The only available system that allows clinical use is smart pyramid called Europa. However, it only provides forces applied below the socket, not the forces or pressure applied inside the prosthetic socket or between the residual limb and liner. Yet, the same technology might be improved to be used inside the socket. The current available pressure mapping systems are complicated and expensive and require laboratory settings. These make it impossible to be used in clinical settings. There is the need to develop portable wireless systems that can be easily used in rehabilitation clinics for objective real-time assessment.

2.2.2 Dynamics of Human Gait Analysis

2.2.2.1 Biomechanical Model for Gait Analysis

The characterization of the human body depends on the intended use of the model. The number of segments, the type of joints, the number of muscles, etc., are decisions that researchers have to make according to the purpose of their study.

The simplest model used to study human gait is the inverted pendulum [29, 47, 50, 51], which is a useful first approach to study the efficient transfer of kinetic and potential energy that takes place when a subject walks. Another simple model is the passive walker, a mechanism vaguely resembling human lower body, that can walk stably down a slight slope without external energy input or control. The pioneering passive dynamic walking work is published by McGeer [90]. Other models based on the same principle mechanisms are used to study highly efficient gaits in bipedal walking exploring the natural dynamics of two-legged machines [14, 91]. Both two-dimensional motion and three-dimensional motion studies are present in the literature. However, these simple models do not provide a realistic representation of the human anatomy.

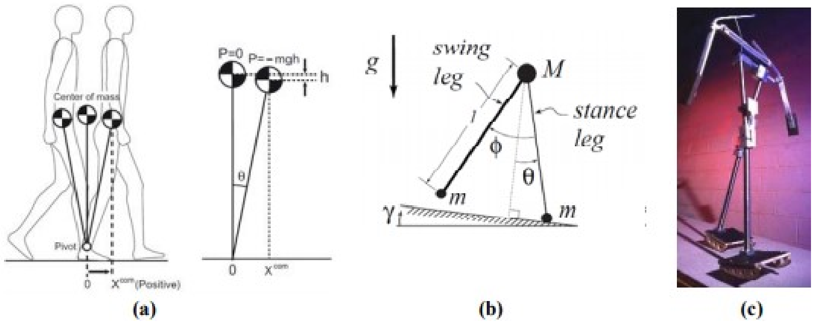


Figure 2.8: Simple models of human gait. (a) Inverted pendulum model [50]. (b) 2D passive walking [43]. (c) Cornell 3D passive biped with arms [33].

2.2.2.2 Model for amputation patient

Many studies have been build model for analysis transfemoral amputee locomotion for design and optimization prosthesis. Zarrugh et al. [97] simulated the swing phase dynamics of an amputee wearing an above knee prosthesis with a simple controlling unit. Mohan et al. [68] developed a mathematical model of an above knee prosthesis to study its function during the swing phase of the gait cycle and determine the optimal location of the prosthesis centre of mass. Bach et al. [15] also investigated the kinematic and dynamic characteristics of the swing phase of the transfemoral amputee gait using computer simulation techniques. Pejhan et al. [16] developed a simple mathematical model to study the influence of alteration of the prosthetic leg design parameters on the kinematics of the amputee gait during the swing phase. In a recent study, Suzuki [94] simulated transfemoral amputee locomotion during the swing phase using a musculoskeletal model and found the optimal knee joint friction that minimized energy expenditure.

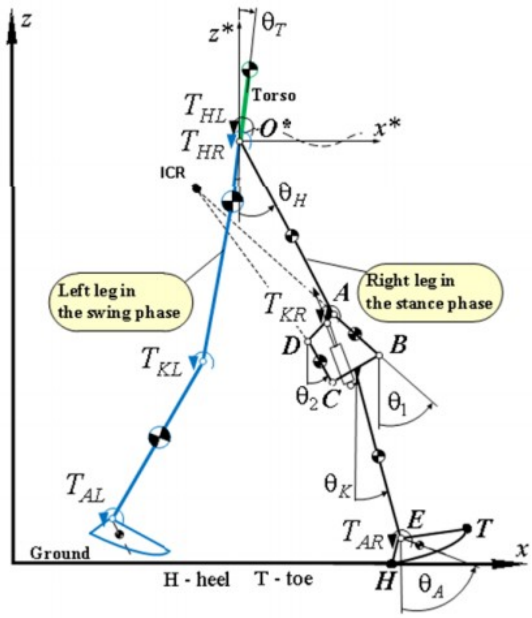


Figure 2.9: Kinematic scheme of human walking with prosthesis with the polycentric artificial knee joint mechanism [72].

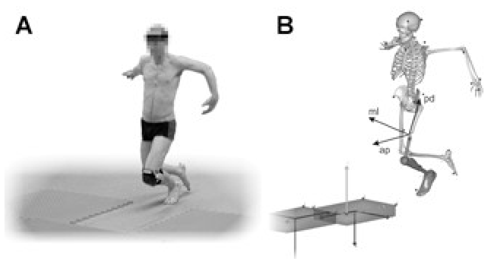


Figure 2.10: Volunteer protected by kneepads falling from gait onto one knee. B: Numerical model of the subject with the coordinate system, where the loads are simulated [27].

2.2.3 Ground reaction force and feet pressure

2.2.3.1 Ground reaction force

The ground reaction force (GRF) is the force exerted by the ground on a body in contact with it. For example, a person standing motionless on the ground exerts a contact force on it (equal to the persons weight) and at the same time an equal and opposite ground reaction force is exerted by the ground on the person.

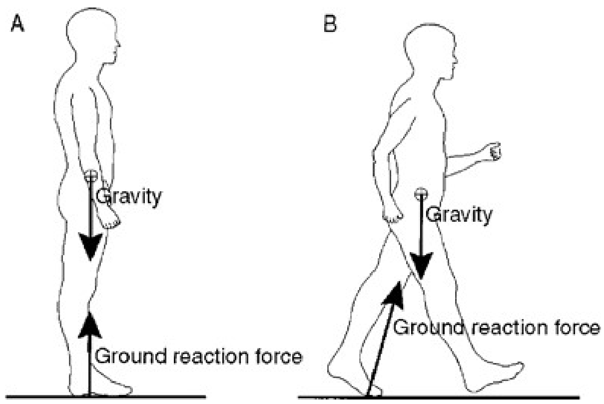


Figure 2.11: Ground reaction force (spartascience.com)

The GRF has been used in previous studies [36, 38, 70, 71, 82] for evaluating the success of the prosthesis and the rehabilitation training. The GRF and the moments in both the prosthesis and sound limb sides were measured and calculated. At the sound limb-side, the GRF and the moments affect the capacity of the musculoskeletal system in absorbing the body load during gait [45]; consequently, there is an increased likelihood of developing overuse injuries [28]. The joint load provides insights into the development of pathological conditions such as back pain and osteoarthritis [74]. On the prosthetic-side, the GRF and the moments are critical parameters for evaluating the quality of the prosthesis, the effect of the load on the prosthetic knee and ankle joints, and the method for controlling its operation. The GRF provides more information regarding the gait balance, friction between the sole and the floor, and the tendency to slip.

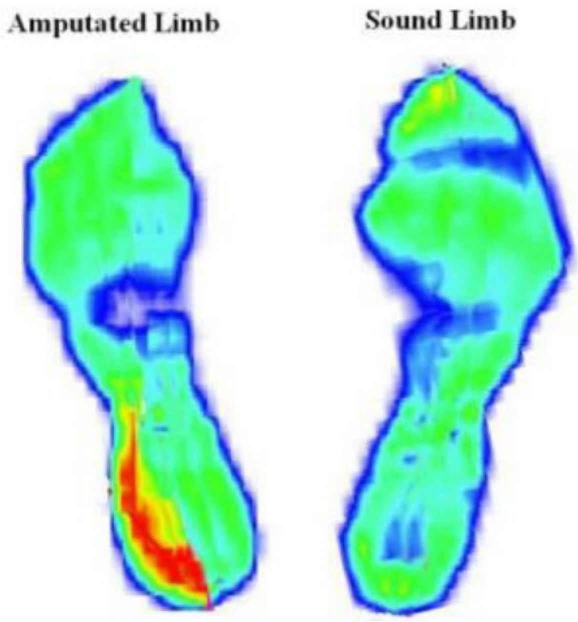


Figure 2.12: Distribution of the plantar pressures [32].

2.2.3.2 Feet pressure

Feet provide the primary surface of interaction with the environment during locomotion. Thus, it is important to diagnose foot problems at an early stage for injury prevention, risk management and general wellbeing. One approach to measuring foot health, widely used in various applications, is examining foot plantar pressure characteristics. It is, therefore, important that accurate and reliable foot plantar pressure measurement systems are developed.

The plantar pressure beneath the foot is considered to be clinically useful in evaluating the prosthesis and the results of the rehabilitation training. It can be used to identify anatomical foot deformities for guiding the diagnosis and treatment of gait disorders, and in preventing pressure ulcers [48, 61]. The pressure beneath the foot prosthesis and its center trajectory, during gait, control the forward progression of the entire body center mass [34]. Impaired center of pressure displacements in amputees may cause difficulties in the adequate control of the dynamic equilibrium [54, 62].

2.3 Conclusion

In this chapter, the author has presented the fundamentals of finite element analysis, multibody simulation and its applied for computation interface pressure, ground reaction force, dynamics gait analysis. Simultaneously, many related studies have been reviewed to complement a panoramic view of the background. The concepts, terminologies, and equations in this chapter are very important for the subsequent chapters.

Chapter 3

Evaluation interface pressure on surface of residual limb in standing posture

The socket of a prosthesis is an important part that serves as the interface between the residual limb and the prosthesis. The soft tissue around a residual limb is not well suited to load bearing and an improper load distribution may cause pain and skin damage. Correct shaping of the socket for appropriate load distribution is a critical process in the design of lower limb prosthesis sockets.

In this chapter, a nonlinear finite element model was created and analyzed to determine the pressure distribution between a residual limb and the prosthesis socket of a transfemoral amputee. Besides that, the better approach for using the shape of socket and residual limb was considered. Three-dimensional models of the residual limb and socket were created using magnetic resonance imaging data; the models were composed of 21 layers, each separated by 10 mm.

Two types of socket are MCCT (Manual Compression Casting Technique) socket and UCLA socket are used in this study for quantitative evaluation. The interface pressure distribution in the residual limb was observed. The experiment to measure the pressure at eight locations on the surface between socket and residual limb was conducted with the condition correspond with simulation. The value of pressure from experiment and simulation is high coefficient of correlation (>0.817). This analysis allows health care providers and engineers to simulate the fit and comfort of transfemoral prostheses in order to evaluate the fit of socket shape [26].

3.1 Introduction

A lower limb prosthesis is an artificial limb designed to mimic the natural function, structure and aesthetics of the limb being replaces. There are some types of lower limb prosthesis depend levels of lower limb extremity amputations. transfemoral or above knee prosthetics refers to an artificial limb replacement where the knee joint has been removed and the individual still has part of the femur or thigh bone intact. One of the most important parts of transfemoral prosthesis is a socket, it serves as the interface between the residual limb and the prosthesis. It must not only protect the residual limb, but must also appropriately transmit the forces associated with standing and ambulation. The skin and the soft tissue of the residual limb experiences severe stress and excessive distortion during gait positioning [64]. Especial with transfemoral prosthesis, the residual limb with complex soft tissue and volume change when using sockets. It makes the prosthesis instability and difficult for patient get acquainted. For evaluate quality in socket design and fit, the pressure distribution at the interface between the residual limb and the prosthetic socket is considered as a main critical. The abnormal effective transfer of force from socket to residual limb is cause of instability of patient gait, pressure ulcers and deep tissue injury.

Many studies have been conducted to quantify the stress distribution at the interface between the residual limb and the socket. Usually, the method used in these study are by either experimental measurements or finite element analyses as the review by Mark et al. [88], Silver-Thorn et al. [95], Zachariah and Sanders [93], Winson C.C. Lee et al. [98] and Zhang et al.[52, 55]. Almost of these studies focus on the transtibial or below knee prosthesis. The features of residual limb are more convenient to measure or finite element analysis cause the less changing of soft tissue volume, the shape of socket nearly the same with residual limb and the simple displacement in human gait. Damien Lacroix et al. [60] was model the actual donning procedure of socket in five transfemoral amputees and used finite element analysis to observe the stress distribution on the surface of stumps and bone. Linlin Zhang et al. [84] was built a nonlinear finite element model to investigate the interface pressure between the above-knee residual limb and its prosthetic socket. The model of residual limb includes bone and soft tissue and the length of model quite full, along with above hip joint. Portnoy et al [80] was to characterize the mechanical conditions in a muscle flap of trans-tibia patient during static load-bearing. Another study of Portnoy et al. [77] focus on quantifying internal strains in trans-tibia prosthetic user during load-bearing with a variation of residual limb length. It gave more understanding about internal stress and strain of tran-tibia patient and help the prosthetist and patient prevent risk of developing a pressure ulcer and deep tissue injury. Juan Fernando Ramirez and Jaime Andrs Vles [81] were identified the contact boundary condition between bone and soft tissues in a transfemoral amputee affects the stress and strain state of the residual limb.

In this chapter, the authors proposal an overall approach to enhance the evaluation of the transfemoral prosthesis socket by finite element analysis.

First step, the comparison between two approachs for using the shape of socket and residual limb was evaluated. Two models of residual limb: same and different with the shape of the socket were created. After that, the FE models were generated with appropriate conditions of the donning process. The experimental procedure was conducted for comparison and discussion with the results of simulation. The results in case of different shape of socket and residual limb suggest that it is the better model for evaluating the interface pressure. The procedure developed through this work can be used by future researchers and prosthesis designers in understanding how to better design the socket and transfemoral prostheses.

After the previous step shown that the approach using different shape of socket get the better results, in this next step, the model of residual limb and socket were created separately. In the model of residual limb includes four parts are bone, muscle, fat and skin. Two types of socket are UCLA and MCCT socket with real size were obtained. The shape of the socket and residual limb are quite different, it makes the computation more complex and spend much more time to complete. Furthermore, the experiment was setting-up to measurement pressure on the interface between socket and residual limb. Eight three dimension sensors were positioned on the surface of the socket for measurement the forces that generate on the skin of the residual limb. The results of simulation and experimental as well as the results of two types of socket were compared and discussed.

3.2 Finite element analysis procedures

The subject in this study was a male (age 35) with a left-side transfemoral amputation. He had a height of 169 cm and weighed 63 kg without his prosthesis. The prosthesis incorporated two types of socket are UCLA [17] and MCCT [63] socket, a Nabco prosthesis, and an Ottobock foot.

The UCLA socket is a type of socket that was created by UCLA technique. This technique is known as CAT-CAM (Contour Adducted Trochanteric Controlled Aligment Method), based on work by John Sabolich, C.P.O. and inspired by Ivan A.Long, C.P. Based on the theory of UCLA type IRC (Ischial Ramal Containment) socket, the new IRC socket that originated in Japanese MCCT method has been developed. The socket incorporate the modelling method of suction socket with quadrilateral shape developed by Iida [63]. At first, the shape of the socket was designed to aim the same shape of the cross sectional shape of

UCLA socket while casting. However, the stability in the anterolateral direction was not satisfactory. By applying the force directly to the residual limb while casting that compete with the force generated inside of the socket during gait, it was able to design the IRC socket by which the stability in the anterolateral direction was improved.

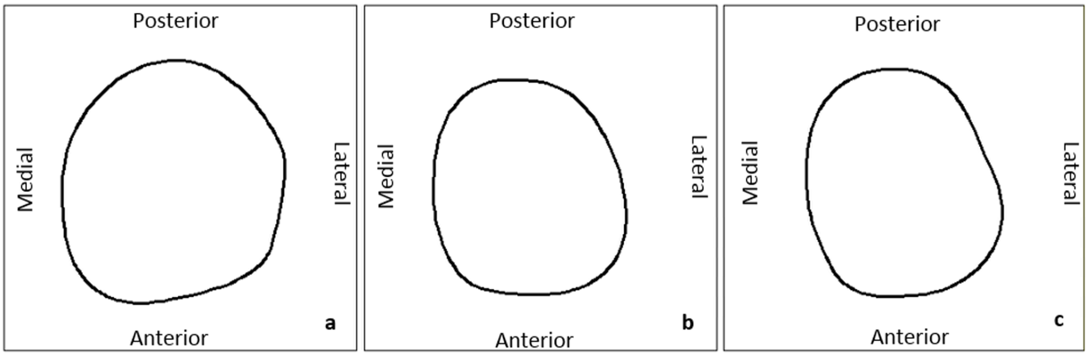


Figure 3.1: Profile at the cross section from distal end of (a) residual limb, (b) UCLA socket, and (c) MCCT socket at 180 mm

3.2.1 Geometry Modeling

Cause the quiet different shape of the socket and residual limb, the geometry of socket and residual limb was created separately. Magnetic resonance imaging (MRI) was used to obtain data of the residual limb within and without socket prosthesis. Which were captured as 21 layers with 10 mm separation perpendicular to the sagittal plane. The MRI machine used in this study is Siemens Magneton Symphony Maestro class 1.5T. Some marks were made to the socket and residual limb for specified location of them. The data of residual limb without socket continue the process with Matlab software to distinguish individual parts. After that the spline of every MRI slice of bone, muscle, fat, and skin was obtained by CAD software. These files were loaded into parallel planes and contours manually drawn per slice and lofted into the 3D body by means of a

Figure 3.2: Posture of patient (a), MRI process (b), MRI image (c).

solid modeling software (PTC Creo Parametric). The model of two type sockets was offset from the skin shape of the residual limb within the socket.

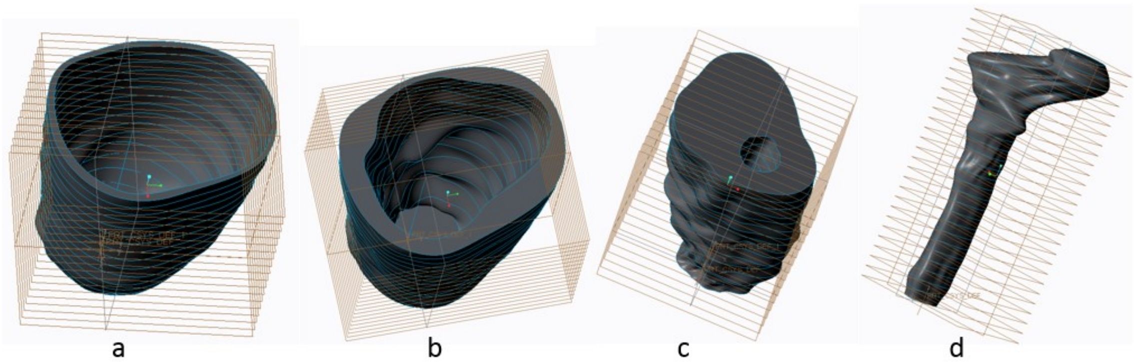


Figure 3.3: 3D model of parts of residual limb. (a. Skin; b. Fat; c. Muscle; d. Bone).

3.2.2 Finite element model

3.2.2.1 Element Types

The three dimensional model of all models were meshing with Hypermesh software (Altair Engineering). The socket was meshing as a shell element with thickness about 3 mm. The bone and soft tissue include skin, fat, muscle were meshing with the solid element size of element about 6 mm. The tetrahedral element was used with the type of a solid element. The finite element model of all part was shown on Figure 3.4.

3.2.2.2 Material Model

The mechanical properties of bone and socket were assumed to be linearly elastic, and therefore obey Hookes law in which strain varies linearly with stresses developed in an elastic body. The materials of the parts were modeled as isotropic,

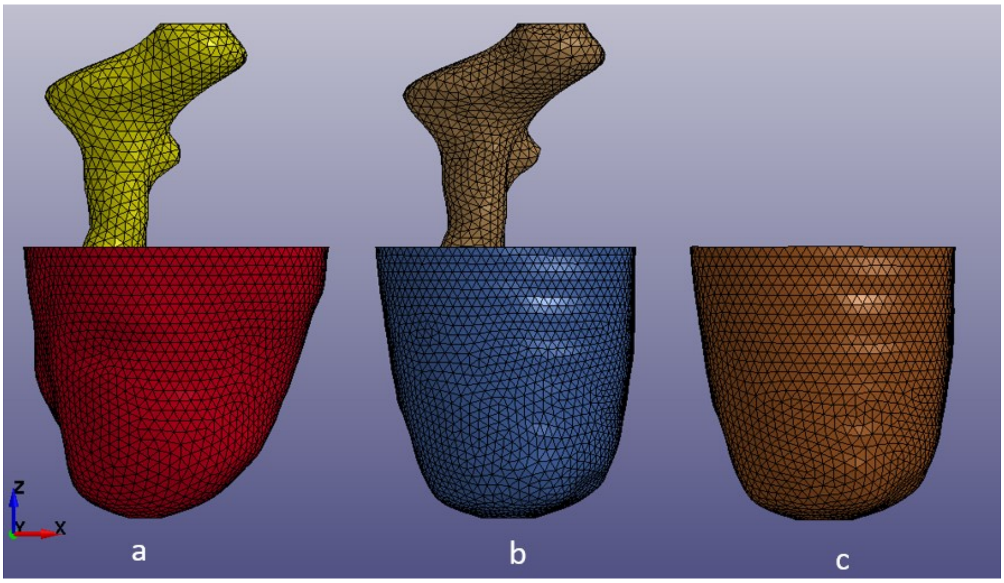


Figure 3.4: The FE model of residual limb in case of different shape with MCCT socket (a); same shape with MCCT socket (b) and the socket (c).

with all uniform elastic properties in all directions. Finally, these volumes were assumed to be homogenous with consistent material properties throughout. The femur bone was modeled with a Youngs modulus of 17,700 MPa and a Poissons ratio of 0.3. The prosthesis socket was modeled with a Youngs modulus of 1886 MPa and a Poissons ratio of 0.39 [52].The soft tissue exhibited time-dependent behavior. Fung [22] proposed the quasi-linear viscoelasticity theory that is widely used in mechanics to describe soft tissue behavior. The main assumption of the theory corresponds to the convolution integral representation of the stress as shown in the following expression with respect to an uniaxial loading condition:

$$\sigma(t) = \int_0^t G(t)\frac{\partial\sigma^e[\lambda(\tau)]}{\partial\tau}d\tau \tag{3.1}$$

Where σ^e denotes elastic response, $G(t)$ denotes relaxation function, and $\lambda(\tau)$ denotes stretch ratio time history. The soft tissue was considered a composite material that was comprised of collagen fibers embedded in a softer isotropic material referred to as the ground. Weiss formulated the strain-energy function of the soft tissue material with terms W_1, W_2, and W_3 as expressed in equation

(3.2) given below:

$$W = W_1 + W_2 + W_3 \tag{3.2}$$

The first term W1 aids in modeling the ground substance matrix as a MooneyRivlin material as follows:

$$W_1 = C_1(I_1 - 3) + C_2(I_2 - 3) \tag{3.3}$$

Where C_1 and C_2 denote invariants of the right Cauchy deformation tensor. The second term W_2 is defined to incorporate the behavior of the crimped collagen in tension, which works only in the fiber direction as defined in the model given below:

$$W_2 = F(\lambda) \tag{3.4}$$

The role of the last term in the strain-energy function is to ensure that the material behaves in an incompressible manner to a significant extent, as given by the following.

$$W_3 = \frac{1}{2}K[ln(J)]^2 \tag{3.5}$$

where $J = detF$ denotes the third invariant of the deformation tensor, which changes based on the volume, and K denotes the bulk modulus. The reduced relaxation function *G(t)* represented by the Prony series is as follows:

$$G(t) = \sum_{i=1}^{2} S_i exp(\frac{-t}{T_i}) \tag{3.6}$$

Here, S_i and T_i denote the spectral strength and characteristic time, respectively. In the study, W_1 and W_3 were used for skin, fat, and muscle [**? ?**]. Table 1 lists the material properties of the skin, fat, and muscle.

Table 3.1: Material properties of soft tissues

Name	Density (kg/m^3)	C_1 (kPa)	C_2 (kPa)	S_1	S_2	T_1 (ms)	T_2 (ms)	K (kPa)
Skin	906	0.186	0.178	0.968	0.864	10.43	84.1	20000
Fat	906	0.19	0.18	1	0.9	10	84	20000
Muscle	1051	0.12	0.25	1.2	0.8	23	63	20000

3.2.2.3 Contact definitions

The first contact definition between the residual limb and the socket was a surface-to-surface contact. A coefficient of friction of 0.5 was assigned as an interaction property for the contact surfaces, as was justified in the previous study [98]. The second contact definition applied a tie contact between bone and muscle. It provides a simple way to bond surfaces together permanently, which prevents slave nodes from separating or sliding relative to the master surface. This contact was suggested from study of Juan Fernando Ramirez and Jaime Andrs Vles [40]. Based on the hypothesis about the connection between skin and fat, fat and muscle which there is no movement relation.

3.2.2.4 Loads and boundary condition

The analysis was carried out in two cases with 50 percent and 100 percent of body weight corresponded with in two state of patient: stand with two and one leg. At the end of the analysis, the shape of residual limb changing and fitting with the shape of the socket. The stresses developed and the deformation in the first case of 50 percent body weight was retained and propagated to the next analysis case with full body weight.

3.3 Interface Pressure Experiment Procedures

3.3.1 Experiment Setup

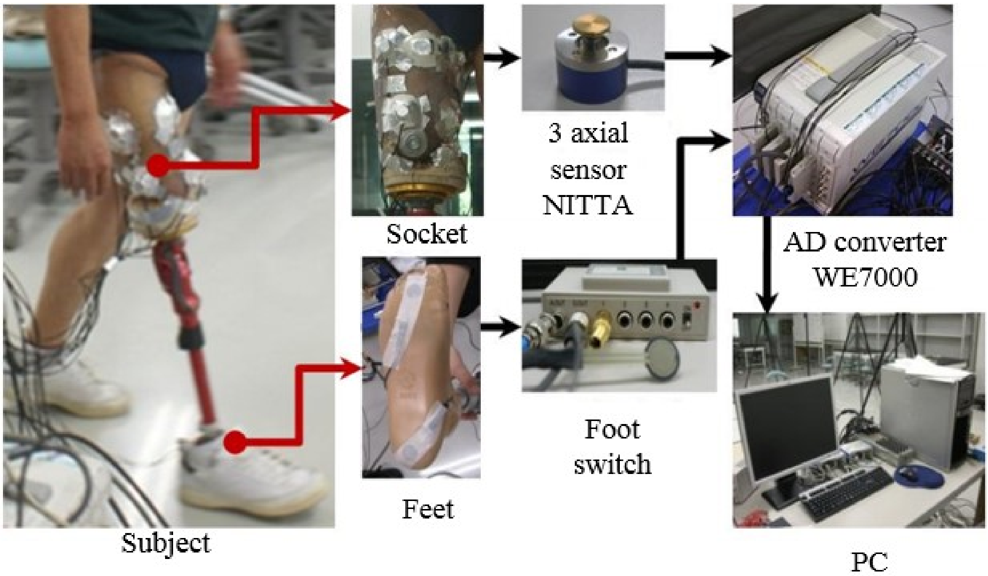


Figure 3.5: Experiment diagram

The triaxial force sensors NITTA PD 3-32-05-015 [18] were used in experiments. These force sensors can resolve the force applied to their surface into three components, two shear components in orthogonal directions (in this study tangential to the skin surface) and one normal stress component (in this study normal to the skin). The schema of place which installed the sensors was shown on Figure 3.6. There are eight sensors correspond with eight areas of the socket were measured. Four sensors were defined on four directions are anterior, posterior, medial and lateral. The schema experiment was described in Figure 3.5 which include sensors on the socket of patient, analogue-to-digital converter, data acquisition software and computer. The direction of force along three axis of the sensor were described in Figure. The sampling frequency was 1000 [Hz]. After measuring the value of forces, the value of pressure was calculated by the equation as below:

$$[kPa] = \frac{V}{C}\frac{g}{4.5^2\pi 10^{-12}} \tag{3.7}$$

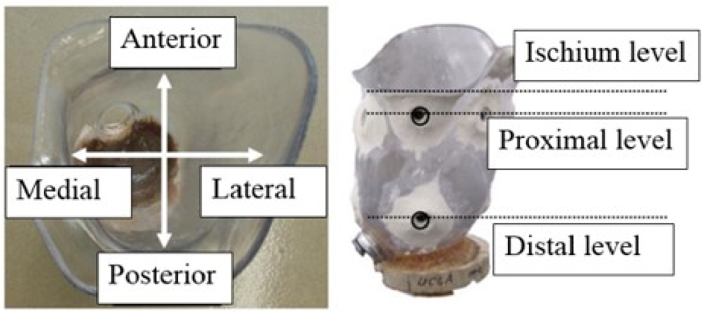


Figure 3.6: The position of eight sensors on socket

where g denotes the acceleration due to gravity, 4.5 denotes the radius of the sensor surface, V denotes the voltage generated, and C denotes the calibration coefficient.

3.3.2 Experiment Results

The Table 3.2 and Table 3.3 were shown the value of stress along three axis of sensors in two cases: 50 percent and 100 percent of body weight, which corresponding with the stand of patient by one leg and two legs. The results also shown with two types of socket.

In the case of 50% body weight, the position of maximum of normal stress (stress along z axis) is different with two types of socket. The maximum of normal stress with MCCT socket reached 39.22 kPa at the lateral distal position, with UCLA socket reached 33.33 kPa at the anterior proximal. The total of normal stress and resultant stress with MCCT socket is larger than UCLA socket 14.87% and 14.73% respectively. The direction and magnitude of shear stress

Table 3.2: Stress along the axes of sensor in case of 50% body weight (Unit: kPa)

kPa	Axis	AP	PP	MP	LP	AD	PD	MD	LD	Total
MCCT	X	-7.66	-11.39	-12.56	-7.16	-4.57	-5.37	-7.21	-8.09	-64
	Y	-14.81	-17.11	4.38	-14.93	-5.74	-12.58	-8.76	-13.37	-82.92
	Z	29.11	12.37	24.84	26.91	13.53	20.37	16.76	39.22	183.1
	Resultant	33.54	23.99	28.18	31.59	15.39	24.54	20.23	42.22	219.69
UCLA	X	-6.25	-8.54	-11.17	-6.98	-4.61	-4.88	-6.59	-3.19	-52.21
	Y	-19.56	-11.86	3.42	-14.79	-5.64	-12.28	-6.24	-10.43	-77.38
	Z	33.33	15.33	21.06	22.11	11.8	14.48	13.75	27.55	159.4
	Resultant	39.15	21.18	24.09	27.5	13.87	19.6	16.48	29.63	191.48

(stress along x and y axis) in two cases of socket are similar.

In the case of 100% body weight, the maximum normal stress (stress along z axis) is the same with two types of socket. The maximum of normal stress with MCCT socket reached 66.06 kPa at the lateral distal position, with UCLA socket reached 57.28 kPa at the same position in case of MCCT socket, lateral distal. The total of normal stress with MCCT socket is the same with UCLA socket, 298.19 kPa in comparison with 299.23 kPa. The total of resultant stress of MCCT socket is only larger than UCLA socket 1.7%. The direction and magnitude of shear stress (stress along x and y axis) in two cases of socket are nearly the same, except in lateral distal position, the direction of shear stress along x-axis are opposite.

The load applied to the residual limb in second case increase by double, but the normal stresses are not corresponding rise, total normal stress increases 62.84% in the case of MCCT socket and 88.05% in case of UCLA socket, total resultant stress increase 45.61% in the case of MCCT socket and 64.27% in the case of UCLA socket.

In case of 100 percent body weight the value of pressure, which distribute

Table 3.3: Stress along the axis of sensor in case of 100% body weight (Unit: kPa).

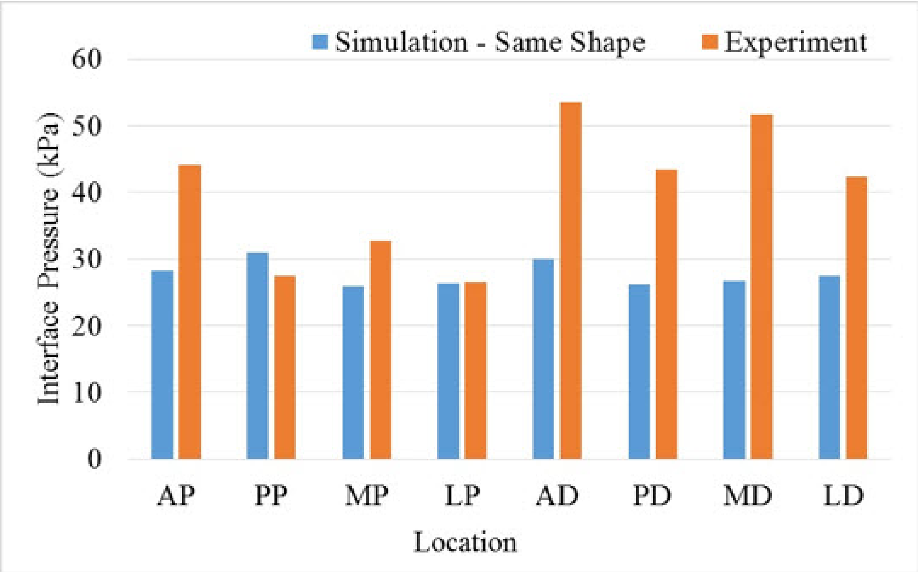
kPa	Axis	AP	PP	MP	LP	AD	PD	MD	LD	Total
MCCT	X	-7.07	-12.19	-11.65	-7.07	-4.37	-4.25	-6.49	-2.48	-55.58
	Y	-15.72	-14.85	4.66	-16.25	-4.49	-11.02	-7.81	-4.53	-70.02
	Z	42.17	18.92	39.38	40.89	27.96	32.7	30.11	66.06	298.19
	Resultant	45.56	26.96	41.33	44.57	28.65	34.77	31.78	66.26	319.88
UCLA	X	-4.81	-8.58	-8.98	-7.17	-3.92	-2.74	-6.11	3.6	-38.72
	Y	-19.59	-6.87	7.01	-16.61	-3.23	-10.97	-3.95	-2.79	-57
	Z	47.3	32.41	40.43	37.44	26.56	29.59	28.22	57.27	299.23
	Resultant	51.42	34.22	42.01	41.58	27.04	31.68	29.15	57.46	314.55

on eight positions of surface between socket and residual limb is not so different compare with in case of 50 percent body weight. The reason of this is the shape of UCLA more fitting than the shape of MCCT socket. In case of 50 percent body weight, the contact area between socket and residual limb with UCLA socket is more than MCCT socket. This will be clear with the results of simulation.

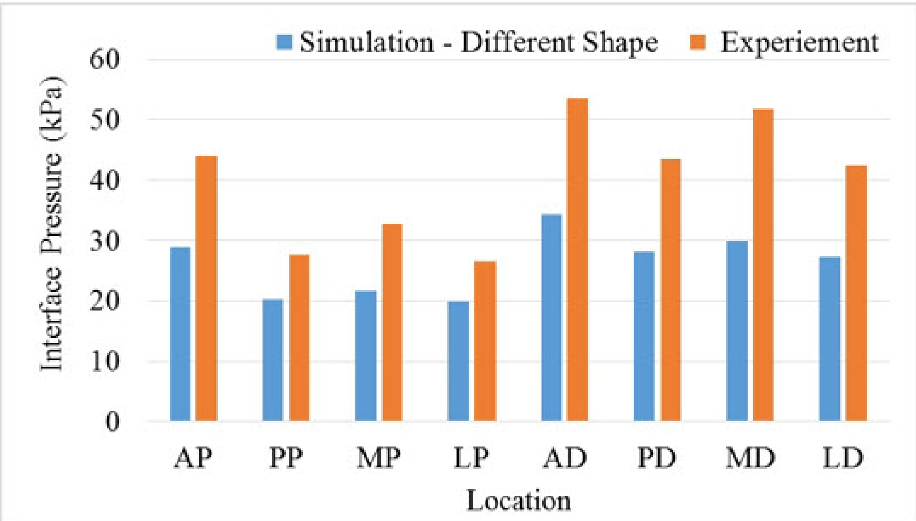
3.4 Discussion

3.4.1 The comparison of two case residual limb shape

The results of the interface pressure of the experiment and simulation in the case of the shape of the socket and residual limb are the same were shown in Figure 3.7a. The results of the experiment are ranging from 26.504 kPa at PD location to 53.508 kPa at AD location. However, the interface pressure of simulation in the case of the shape of the socket and residual limb is the same nearly the same with all locations. The minimum value about 25.850 kPa at MP location and maximum value about 30.980 kPa at PP location. The value of interface



(a)



(b)

Figure 3.7: Comparison of interface pressure between experiment and simulation in the case of the shape of the socket and residual limb are the same and different.

pressure at correspond locations doesn't correlate, the correlation coefficient between the results of experiment and simulation about 0.053.

The comparison of interface pressure between experiment and simulation in the case of the shape of the socket and residual limb are different was shown in Figure 3.7b. The results of simulation distribution from 19.920 kPa at LP location to 34.290 kPa at AD location. The value of experiment always larger than value of simulation from 33.10% at LP location to 73.40% at MD location. However, the results of experiment and simulation have a strong correlation, the correlation coefficient about 0.978. The Figure 3.8 shows the relation between experimental results and two cases of simulation results.

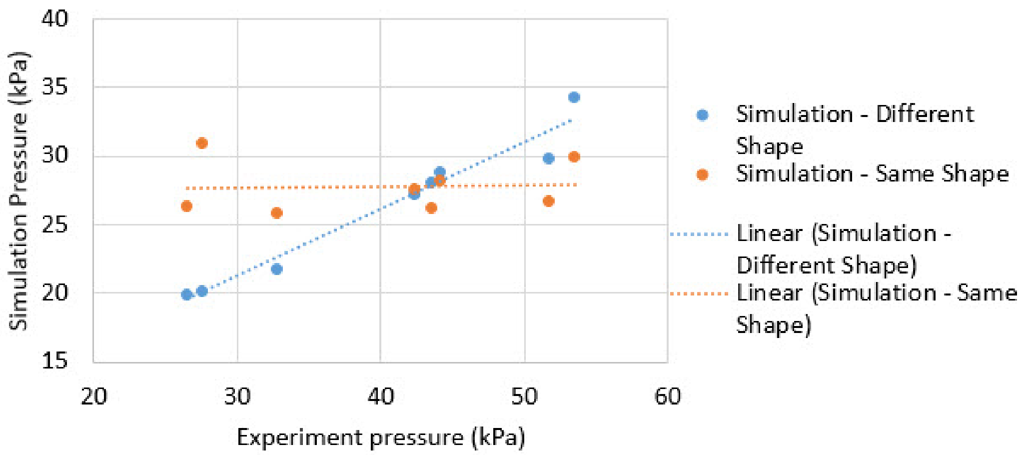


Figure 3.8: The scatter diagram shows the relation between experimental results and two cases of simulation results.

The results of the experiment shown that the interface pressure generated on the surface between socket and residual limb are different, which depend on the location on the residual limb. The cause of it can come for two reasons. First, the changing of residual limb shape is not the same when wore the socket. In some areas, the shape of the residual limb is compressed, in other areas, it is extruded to fit with the shape of the socket. Second, the residual limb includes the skin tissue, fat adipose tissue, muscle tissue and bone. The thickness of tissue layers in residual limb is various and complex. It leads to behavior of residual limb soft tissue is not homogeneous in all volumes.

In case of the shape of the socket and residual limb are the same, the simulation shown the value of interface pressure, which is the result of the same distortion of the residual limb in all surfaces. The behavior of the residual limb is not strong affect to the value of interface pressure. The interface pressure is not describing the actual change of the shape of residual limb when wore the socket.

In case of the shape of the socket and residual limb are different, the results of simulation and experiment have strong correlate. Although the value of experiment larger than the value of simulation, which express pretty accuracy the behavior of the residual limb in each area.

3.4.2 Evaluation Interface Pressure Two Type Of Socket

The value of pressure at eights sensors position in two case MCCT and UCLA socket was shown on Figure 3.9 and Figure 3.10 include the value of experimentation. The distribution of pressure on the surface of skin in two case MCCT and UCLA socket was shown in Figure and Figure at 50 percent and 100 percent of body weight.

The distribution of pressure on the surface of the skin was clearly observed. The value of pressure as well as its position easy to define. The maximum of pressure on MCCT socket and UCLA socket with full of body weight are 52.14 kPa and 48.83 kPa respectively. The results of pressure on the surface of skin shown that the shape of MCCT socket and UCLA socket nearly the same.

The value of pressure at eights sensors location in simulation gets high correlation. The value of coefficient correlation larger 0.8 means that the simulation results quite corresponding to the value of the experiment. In this study, the value of pressure in experiment always higher than the value of simulation, especially at AP (anterior proximal) an LD (lateral distal) location. The pressure levels observed are significantly lower than the pain threshold limit of 690 kPa [63].

There are some reasons for the difference between simulation and experiment. The real surface of residual limb had the wound and scars uneven, by MRI with 10 mm separate slices very difficult to describe the fulfil the profile of it. This is cause of differences between simulation and experiment in some locations. There are some materials models for soft tissue and even now it has continued to develop. The mechanical properties of soft tissue are changing in large range depend on age, sex, health, etc. So the value of mechanical properties for simulation was not accuracy value for specific patients. The accuracy of the sensor, the method to position the sensor to the location of the socket are considered.

3.5 Conclusion

3.5.1 The comparison of two case residual limb shape

In this study, the FE model of the residual limb and socket were established. The residual limb includes four parts are skin, fat, muscle and bone. Two cases with two shapes of residual limb were built and simulated in donning socket process. The experiment with sensors for measure interface pressure between socket and residual limb was conducted. The interface pressure of experiment, simulation in two cases was compared and evaluated. The results of the this analysis, along with previous research studies, indicate that finite element modeling of prosthetics must be tailored to the specific individual for whom a prosthetic device is being developed.

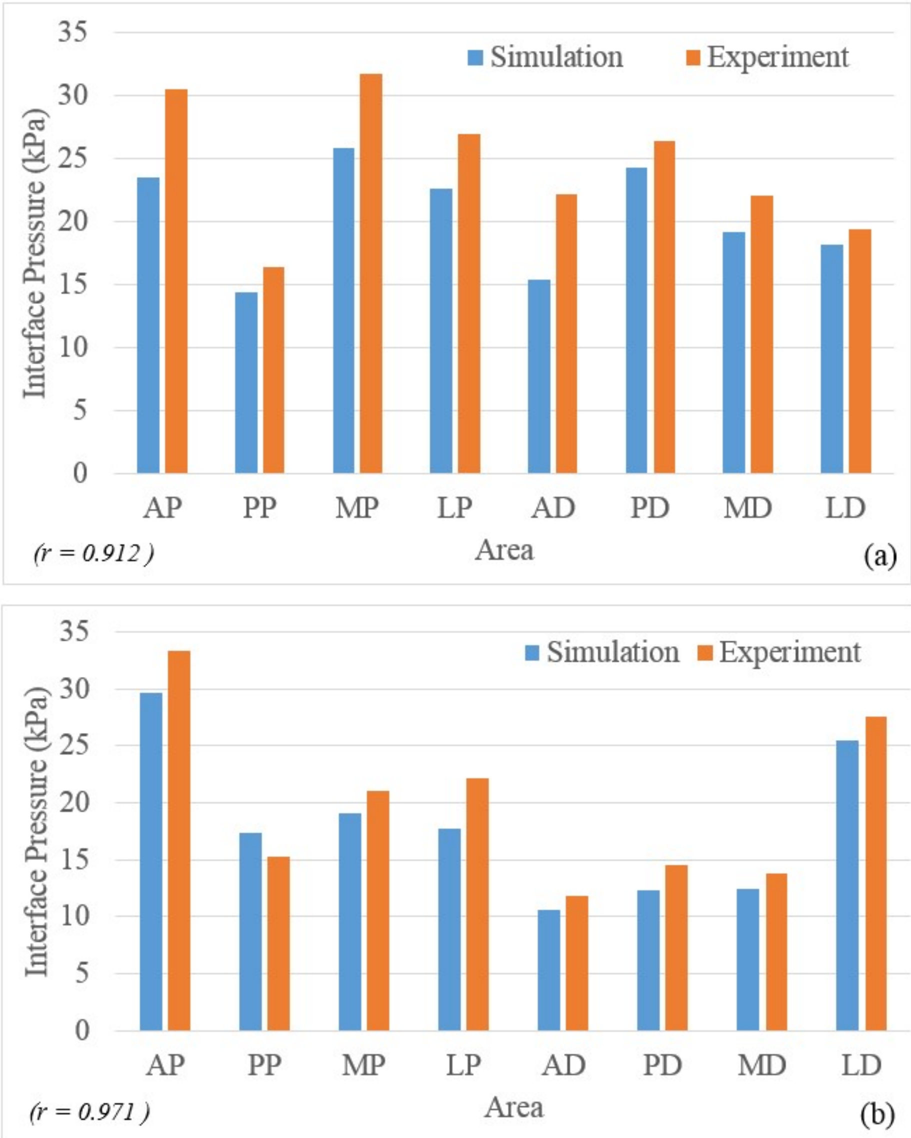


Figure 3.9: The value of pressure at sensors location in the experiment and simulation in case of MCCT (a) and UCLA (b) socket with 50 percent body weight.

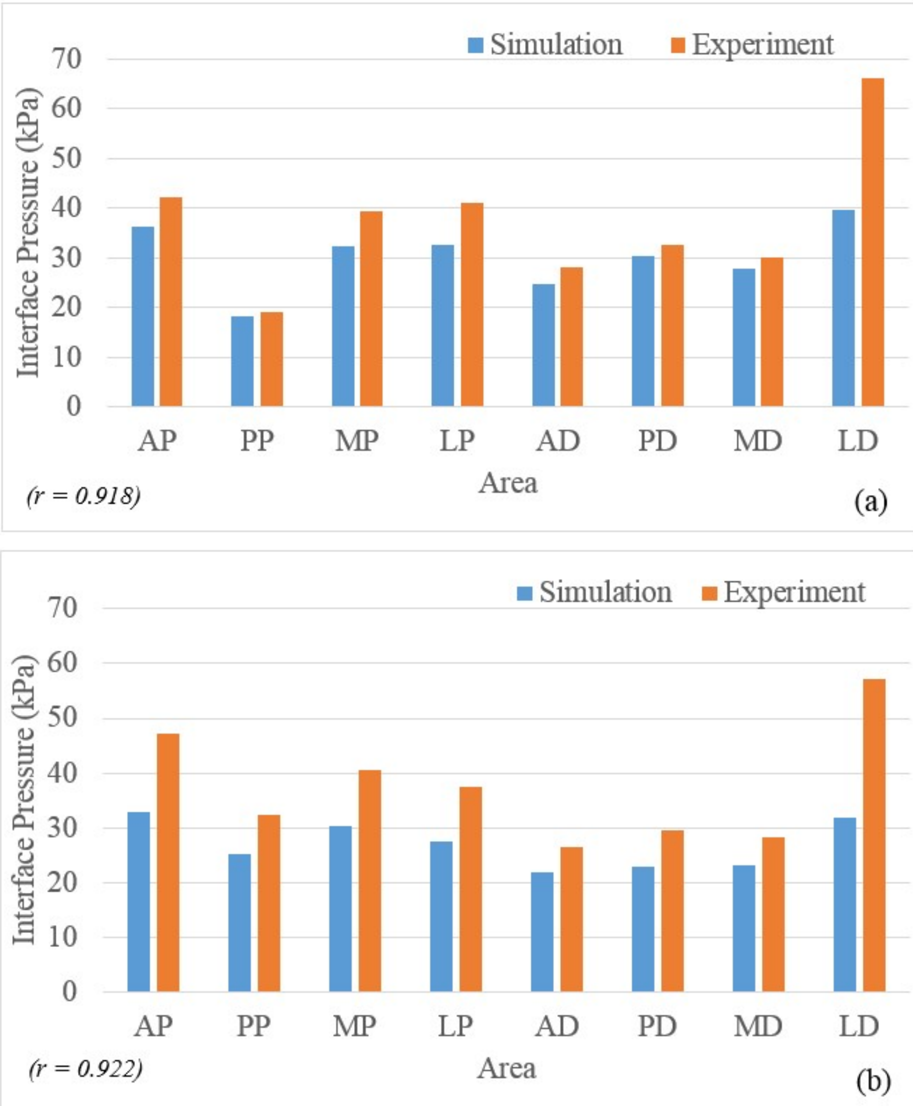


Figure 3.10: The value of pressure at sensors location in the experiment and simulation in case of MCCT (a) and UCLA (b) socket with 50 percent body weight.

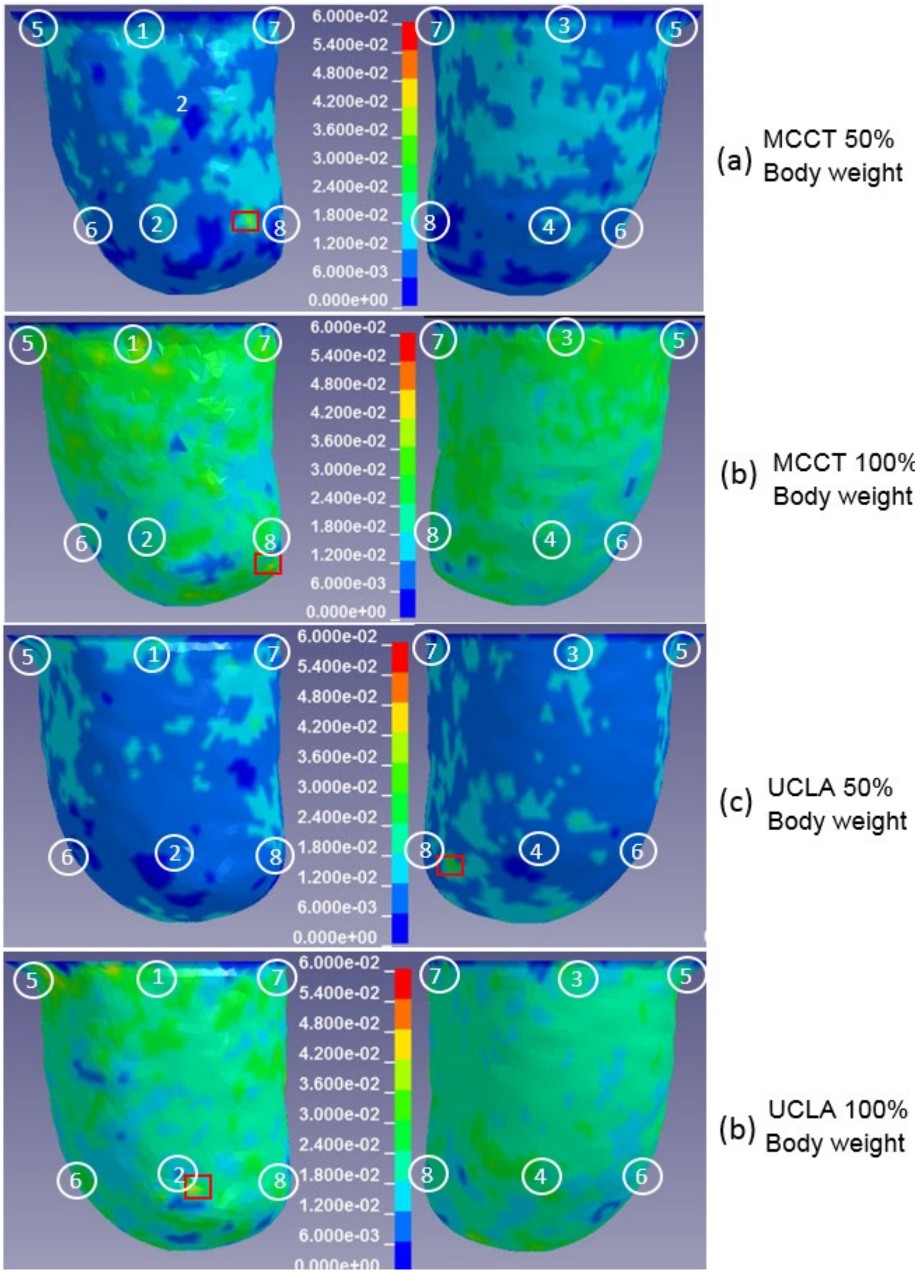


Figure 3.11: Distribution of interface pressure (Unit: MPa). Anterior (left side) and posterior (right side) view. Red rectangles show positions where the maximum pressure is observed on residual limb. White circles 1, 2, 3, 4, 5, 6, 7, and 8 show the position of sensors at AP, AD, PP, PD, MP, MD, LP, and LD, respectively.

The results of this study suggested that using the different shape more better than using the same shape of socket and residual limb for evaluating the interface pressure. Through this work, a new approach has been developed that can be used by others in modeling and analyzing the transfemoral prosthetic fit. The process starts with scanning of the amputee leg and socket, followed by developing separate CAD models for the parts of residual limb, bone, and prosthetic socket. The CAD models, then import into FE software and assembled properly. Preprocessing operations are completed by meshing the volumes with appropriate element size and element type, assigning correct material properties, and applying contact definitions where appropriate. The results of allowing health care providers and engineers to simulate the fit and comfort of transfemoral prosthetics in order to reduce the number of refits needed for amputees.

In developing more advanced FE models of the transfemoral prosthetic-limb interface, the experiment needs to conduct for confirming the material properties of residual limb. The experimental studies on frictional coefficients can provide insight into how to better model the contact analytically. Because of the complexity of the shape of residual limb parts, the accuracy of their 3D CAD model needs to be improved.

3.5.2 Evaluation Interface Pressure Two Type Of Socket

The primary objective of this work was to enhance the method using finite element analysis that allows health care providers and engineers to simulate the fit and comfort of transfemoral prosthetics. The advance of this work was expressed in two points. First, the model of residual limb was built with four parts includes skin, fat, muscle and bone. This represents more real the model of soft tissue in the residual limb. So it makes more difficult in creating models and simulation process. Second, the real shape of two types of socket was considered in this method. In almost the previous studies, the model of socket was hypothesized the same with the model of residual limb or unreal socket model created by software. This study uses the real model of two types of socket. So the shape of residual limb quite different from the shape of socket. It makes the simulation more complexity cause the large deformation of residual limb when it puts on the socket.

Furthermore, the experiment was conducted to confirm the correctness of the method. Two levels and four positions in the socket was selected to add the sensors. These positions can be representation of the distribution of pressure on the surface of skin.

The results of experiment and simulation got the high correlation (correlation coefficients > 0.9). The correlation coefficients between experiment and simulation quite high show the corresponding of them. It is suggested that if the material properties of soft tissue more suitable for patient in this study, the results of simulation will more approach to the results of the experiment. In this study, the value of pressure in experiment always higher than the value of simulation, especially at LD (lateral distal) location. The pressure levels observed are significantly lower than the pain threshold limit of 690 kPa [63].

The quite large difference (66.64% with MCCT socket; 80.52% with UCLA socket) at the lateral distal (LD) area appeared in case of full body weight but in case of half of body weight it is not so different. The cause of this can be explained by incorrection in creating process the shape of the socket and residual limb at LD area or some abnormality of soft tissue due to the scars or uneven.

The comparison in results between two types of socket: UCLA and MCCT socket show that the distribution of pressure on surface of residual limb in case of MCCT socket was nearly the same in case of UCLA socket. The method for creating MCCT socket shape with less than time for repair and edit the shape of positive models of socket is convenient for prosthetist with limited experience.

This study had built the detail method for evaluation socket prosthesis. The process starts with scanning of the amputee leg and socket, followed by developing separate CAD models for the parts of residual limb, bone, and prosthetic socket. The CAD models, then import into FE software and assembled properly. Preprocessing operations are completed by meshing the volumes with appropriate element size and element type, assigning correct material properties, and applying contact definitions where appropriate.

The nonlinear analysis was used to simulate the weight bearing process of the residual limb with the socket. The shape of residual limb changing to the shape of the socket and under the load of body weight, the pressure generated on the surface of skin. The maximum value, position, direction of pressure is easily observed.

The results of the current analysis, along with previous research studies, indicate that finite element analysis is the strong method for evaluation prosthesis. In developing more advanced FE models of the transfemoral prosthetic-limb interface, the material model need to consider for a specific subject, the accuracy of the 3D model of residual limb needs to be improved cause the complexity of the residual limb shape.

Chapter 4

Transfemoral Gait Cycle Analysis and Evaluation Interface Pressure On Surface Of Residual Limb In Gait Cycle

This chapter present the analysis of kinematic transfemoral gait and the method for evaluation interface pressure on surface of residual limb in gait cycle. There are the different between the human normal gait and transfermoral gait. Even, there are very different of individual transfemoral patient. Understand the properties of gait pathology is very important in rehabiliation program. The multibody simulation method was used for analysis the gait cycle of transfemoral prosthesis.

There is a little of studies about the interface pressure between socket and residial limb. Since 2000, there have been three publications implemented the displacement of socket as free rigid body with six deegree of freedom. This chapter present a method for computation the interface pressure between socket and residual limb during walking of patient with some of the limitation movement of residual limb and socket. The shape of socket was assumed the same with the residual limb. The kinematics data of residual limb with prosthesis were observed by motion analysis system. The total model includes residual limb and all components of transfemoral socket were modeled in real size. The experiment was conducted to measure the value of pressure between socket and residual limb. The results of two methods were compared and disscused.

4.1 Introduction

4.1.1 Human nomal gait

Gait is a term used to describe a walking pattern. Normal gait is used to define a pattern which has been generalised from the general public across many variables, including age and sex [19].

A complete cycle of gait begins at initial contact of one limb and ends at the repeated initial contact of the same limb, performing all phases of gait in doing so. This full cycle can be described as a stride. A step is sometimes incorrectly used to describe this cycle. A step however, is different; it is described as the distance of heel strike from one leg to the heel strike of the opposite leg [20].

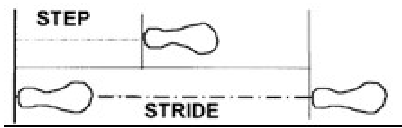


Figure 4.1: Step and stride in human gait.

The gait cycle can be split into 2 stages:

- Stance Phase -Time the foot is in contact with the floor, weight acceptance and single leg stance, which makes up 60% of the cycle.

- Swing Phase The period of time where the limb is lifted from the floor, limb advancement. This makes up 40% of the cycle.

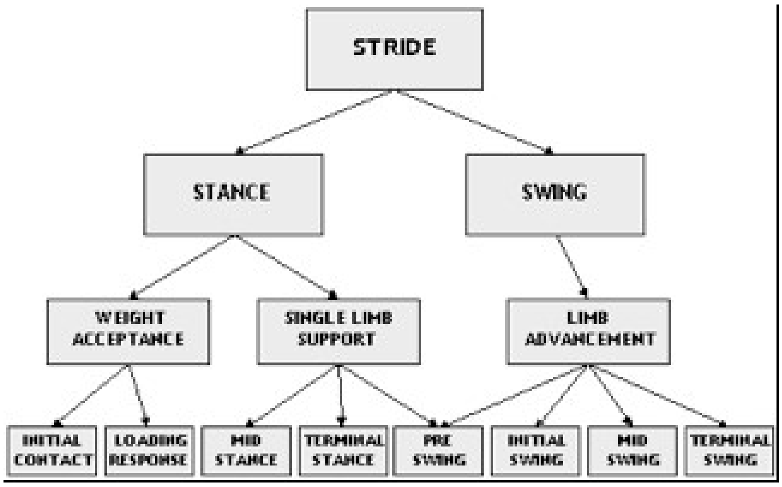


Figure 4.2: Divisions of Gait Cycle.

In order to describe the elements of gait, the cycle can be broken down further into 8 sub factors:

- Initial Contact
  Also known as heel strike. This is the first moment the foot comes into contact with the floor. The hip is flexed approximately to 30 degrees , knee extended between 0-5 degrees and ankle dorsiflexed to a neutral position, giving contact with the floor at approximately a 25 degree angle. This is the first phase of double limb support. The aim of initial contact is to stabilise the limb in preparation for it to take the impending forward translation of body weight.

- Loading Response
  The foot flattens on the floor through pronation. The hip begins to extend

and propels the body forwards and over the foot, using the heel as a rocker. The knee then flexes to allow shock absorption. The aim of this phase is shock absorption, weight bearing stability and preservation of progression.

- Midstance
  This is the first half of single limb support. Weight is aligned fully over the supporting foot through ankle dorsiflexion, while the hip and knee extend, as the other foot lifts off the floor. The body weight is fully supported on one leg.

- Terminal Stance
  This is the second half of single leg support; it begins as the other leg lifts off the floor. The heel of the loaded limb lifts off the floor and the body weight moves forward past the forefoot, as the hip increases in extension. The knee gains full extension and begins to flex again. This phase is completed when the non-loaded limb makes contact with the floor.

- Preswing
  Also known as toe off and is the final phase of stance. The other limb has now begun a new stance phase and is in the initial contact phase. The limb is rapidly off loaded with a forward push to transfer the weight onto the opposite limb. The knee is flexed and the ankle plantarflexes as the toe leaves the ground.

- Initial Swing The foot is lifted off the floor by hip and knee flexion, as the ankle begins to dorsiflex. The other foot will be in midstance phase. When the off loading limb is level with the leg in stance phase the initial swing phase is complete.

- Midswing The limb swings forward of the body through hip flexion as the knee begins to extend. The foot is clear of the floor.

- Terminal Swing Also known as late swing, the knee becomes fully extended and the ankle dorsiflexes to neutral as the foot prepares to make contact with the floor.

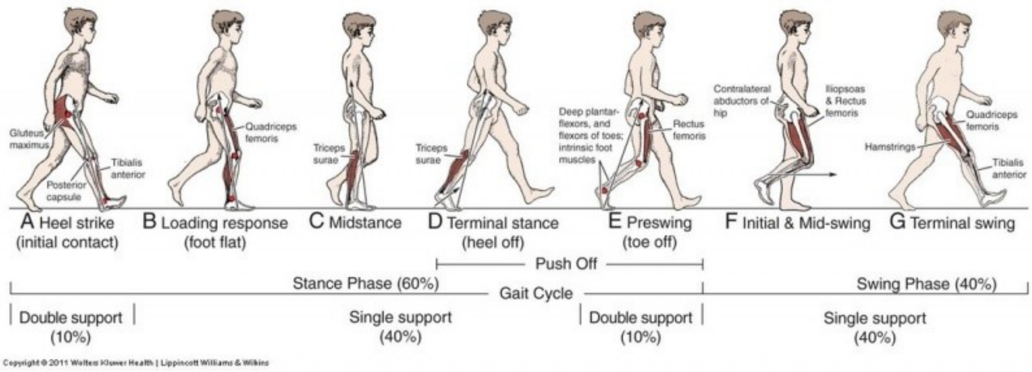


Figure 4.3: The diagram demonstrates this division of gait cycle.

4.1.2 Prosthetic Gait

After an amputation the amputee uses different muscle groups in order to create a smoother gait pattern. Overall energy consumption required is higher, due to the increased effort required to compensate for the lose of the limb. The amount of metabolic oxygen consumption in a non amputee correlates directly to increased walking distance and speeds. In the amputees, however, this metabolic cost is higher even at normal speed. On average these increased requirements are [21]:

- Traumatic Transtibial Gait - 25% increased energy requirement
- Vascular Transtibial Gait - 40 % increased energy requiremeny
- Traumatic Transfemoral Gait - 68% increased energy requirement
- Vascular Transfemoral Gait -100% increased energy requirement

4.1.3 Transfemoral Gait

A person with a transfemoral amputation has to compensate for the loss of both the knee and ankle joint [91]. The gait cycle is affected by the quality of the surgery, the type and alignment of prosthesis, the condition of the stump and the length of the remaining muscular structure and how well these are reattached [22]. The main focus of the gait cycle is to prevent the knee from buckling during stance phase. A fixed knee prosthesis will counteract this issue. A free knee will need to remain in extension for longer throughout the stance phase approx 30-40% to ensure buckling does not occur. This extension causes prolonged heel strike and the body will move forward over the prosthetic leg as one unit for stance phase. The hip extensors on the prosthetic side will work to stabilise the limb in During swing phase of the prosthetic limb the hip extensors and calf muscles on the non prosthetic side help to generate force for the non prosthetic limb to gain swing forwards. Hip flexors on the prosthetic limb must generate the same force required during normal gait. Although the prosthesis is generally 30% lighter than the limb would be, speed generated by the hip flexors is required in order to snap the prosthesis of a free knee into extension for heel strike. General control and strength is reduced in a transfemoral amputation due to the shortened lever length of the thigh muscles, which reduces the force of contraction. For amputees with a fixed knee prosthesis floor clearance is reduced during swing phase, due to the lack of knee flexion and ankle dorsi flexion. Elevation of the hip using trunk and hip muscles is required to prevent dragging on the floor known as hip hitching or hip hiking [23]. Stance time on the non prosthetic limb is increased as it is for transtibial amputees, because of the instability resulting from the prosthesis and the reduced range of motion available. Overall energy expenditure is higher than is required for a transtibial amputee due to the energy which is lost through the prosthesis over two joints and not one. Greater compensation is required by the hip and trunk muscles and the contra lateral limb to generate the energy required for stability and movement throughout the gait cycle [21] prosthetic weight bearing.

4.1.4 Summary

While assessing amputee gait it is important to be aware of normal gait and how normal gait in the amputee is affected. Furthermore there may be deviations which an amputee will adopt to compensate for the prosthesis, muscle weakness or tightening, lack of balance and fear. These deviations create an altered gait pattern and it is important that these are recognised, as rehabilitation of the gait will need to encompass corrections of these deviations.

Amputees should have a full functional and physical assessment and rehabilitation should be based around personalised functional goals. Individualised exercise programmes are developed thorough assessment. An awareness of normal gait and the deviations and their cause formulates the basis of the correct rehabilitation of the individual. There are numerous techniques that can be used during rehabilitation and not all of them will be appropriate for each individual, therefore the programme and technique must be applied to each individual and reviewed regularly to ensure it remains adequate. The amputees previous level of activity, overall health and potential to improve needs to be taken into consideration when formulating a rehabilitation programme and should aim at translating the function gained in a controlled environment into their own home functional environment [24, 79].

4.2 Transfemoral Gait Analysis

4.2.1 Kinematics Gait Analysis

4.2.1.1 Experiment procedures

The subject in this study was a man with a right-side trans-femoral amputation. He was aged 47, 167 cm in height, and weighed 61 kg without his prosthesis. His prosthesis incorporated a UCLA socket, a Nabco prosthesis, and an Ottobock foot. The kinematic data for the lower-limb and prosthesis, as well as the reaction forces applied to the prosthesis foot while walking were measured using a Mac3D system (Motion Analysis Corporation). Data was recorded at a sampling rate of 200 Hz while the subject was walking. The model was considered on the sagittal plane and the socket of the prosthesis and the residual limb were assumed as one block.

Figure 4.4: Experiment with Mac3D System.

The position of markers on lower limb prosthesis was shown on Figure. There are four markers were posted on the prosthesis. The first sensor was on the big toe of foot prosthesis, others three sensors was defined at position of the ankle joint, the knee joint and the hip joint. The Mac 3D system (Motion Analysis Corp) was used to captured the gait cycle of patient. The position data of markers were analyzed with Mathlab (Mathworks). The trajectories of marker were shown on Figure.

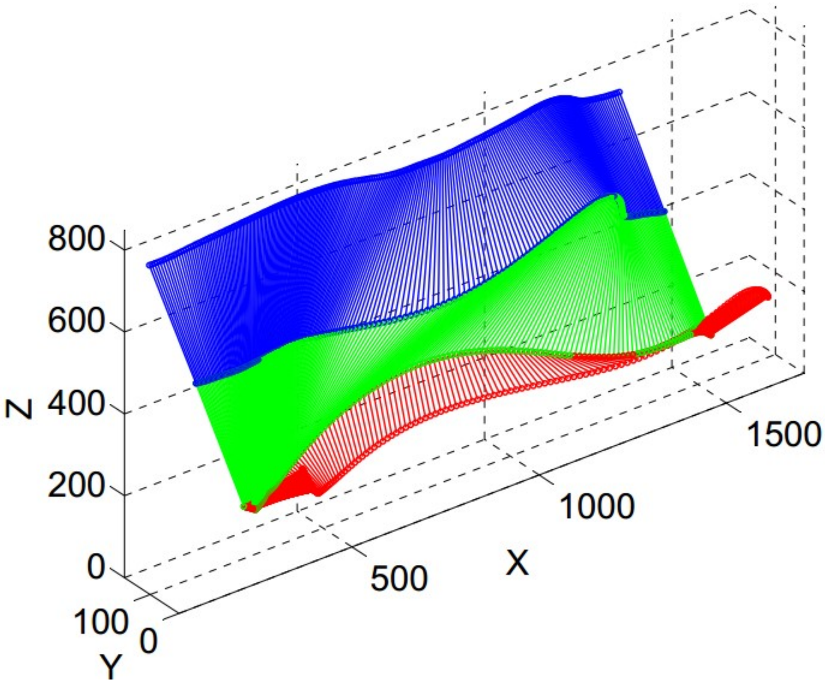


Figure 4.5: Schema movement of lower limb with prosthesis (mm).

4.2.1.2 Results

The angular rotations of the hip (θ_1) and knee ($\theta 2$) joints are defined as shown in the diagram. Matlab (Mathworks Inc.) was used to calculate the angle, angular velocity, and angular acceleration at the hip and knee joints based on the time difference between the coordinate data of the markers, using cosine

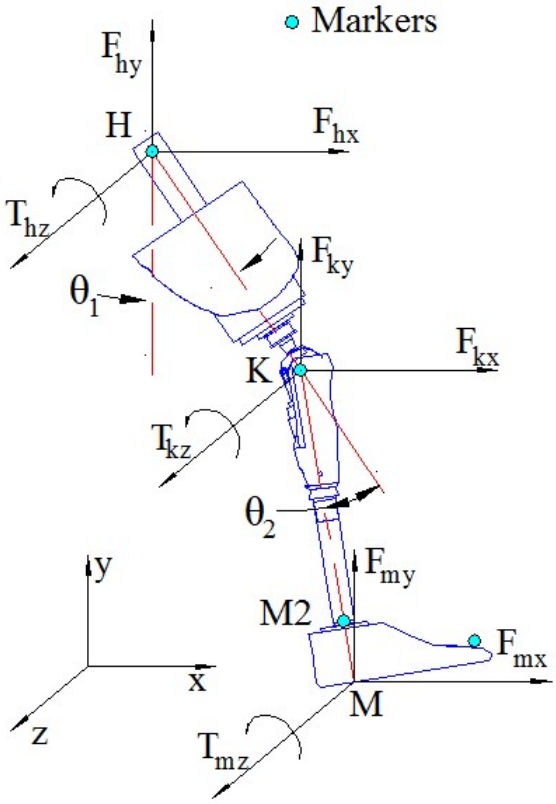


Figure 4.6: Position of markers and angles on lower limb.

rule. The schema movement of the trans-femoral prosthesis recognized by the markers is shown in Figure 4.5 and Figure 4.6, and the results of the kinematic parameters are shown in Figure 4.7 and Figure 4.8 The speed of the subject in the gait cycle was calculated from the position data of the marker at the hip joint.

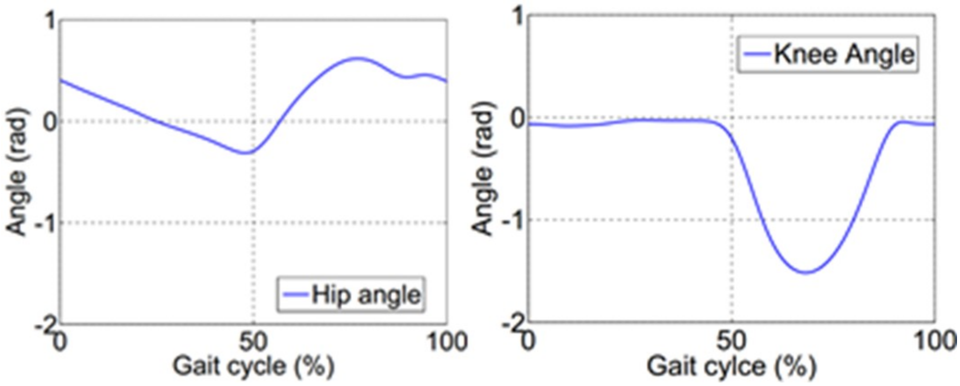


Figure 4.7: Rotation Angle at Hip and Knee Joint.

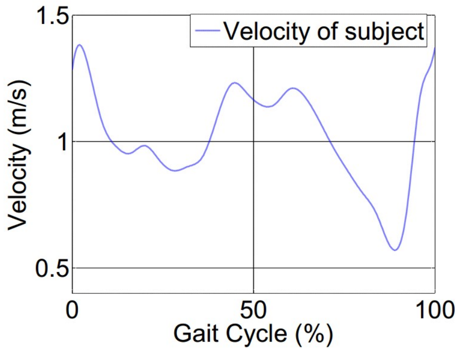


Figure 4.8: Velocity of Patient.

4.3 Dynamics joints of transfemoral prosthesis

4.3.1 Established model

Figure 4.9 shows the actual lower limb with the prosthesis and the 3D model. The 3D model was created using Creo software. The modeling parts of the first link above the knee included the connected part, socket, and residual limb. An assumption was made that there was no relative motion between the residual limb and socket during walking. This link was connected to the hip part by a revolution joint, which describes the rotation of the hip joint. The modeling parts of the second link below the knee including the foot, shank, and knee joint system. This link was connected to the first link by a revolution joint, which describes the rotation of the knee joint.

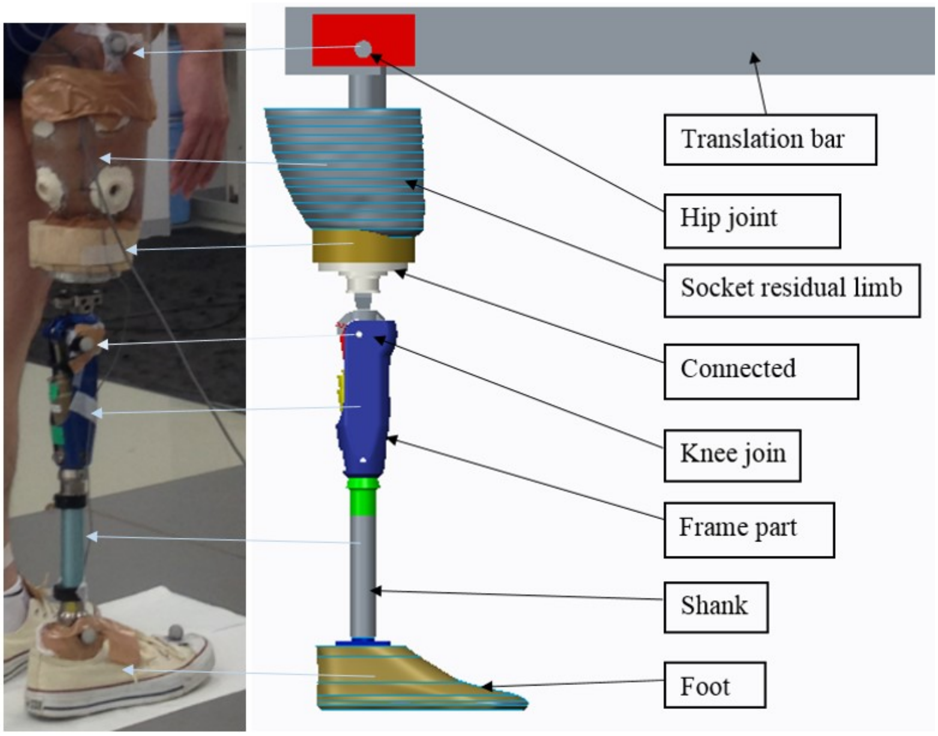


Figure 4.9: The actual and 3D model of lower limb with prosthesis.

In the first link, the 3D surfaces of the residual limb with the socket, which includes bone, muscle, fat, skin and the socket, were obtained from MRI scans. The MRI scans, which consisted of 17 layers with each layer separated by 10 mm, were loaded into parallel and contours. After that which were manually drawn per each slice and lofted into 3D body by means of a solid modeling software

(Creo Parametric 2.0 PTC Inc.).

The density of the residual limb was obtained by averaging the density of the bone, muscle, fat, skin, and socket. The dimensions of the parts were taken from the actual prosthesis. The material density of each part was calculated from the following equation :

$$d = \frac{m}{V} \tag{4.1}$$

Where d is the density, m is the mass, and V is the volume of each part.

After that, all the parts were connected to the translation bar by a prismatic joint at the hip part. The movement of this joint represents the distance walked by the subject and the speed of the subject in the gait cycle.

4.3.2 Input parameters

The reaction force acts on the foot of the prosthesis at the COP. The position of the COP in the first force plate coordinate system, which corresponds to the right-side trans-femoral amputation, is shown in Figure. The position of the COP changed along the bottom surface of the feet and the COP moved to a fixed point. Figure 4.10 shows the method to calculate the position and move the load from the COP to point M.

The load that moved to point M, as shown in Figure 4.11 and 4.12, has two components. The first component is a force (Fx, Fy) that has the same magnitude and direction as the reaction force (Fx, Fy) at A (COP). The second component is a moment with a defined magnitude that depends on the positions of A and

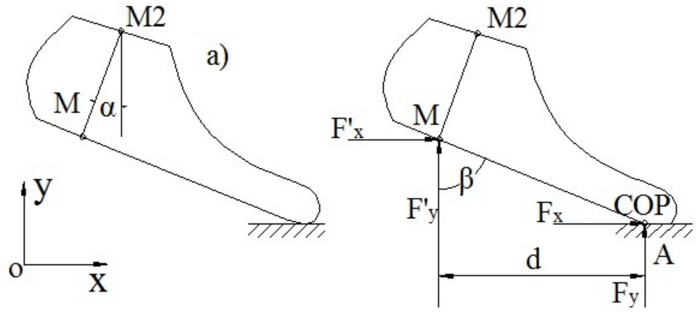


Figure 4.10: Schema for calculating position and load at M point.

M, as represented by the following equation:

$$T_M = \begin{cases} F_y.d - F_x.MM_2 & (When x_A > x_M) \\ -F_y.d - F_x.MM_2 & (When x_A > x_M) \end{cases} \tag{4.2}$$

The coordinates of M (M_x, M_y) were calculated using equations as below:

$$Mx = M_{2x} - MM_2(\cos()) \tag{4.3}$$

$$My = M_{2y} - MM_2(\sin()) \tag{4.4}$$

Here, (M_{2x}, M_{2y}) and MM_2 denote the coordinates of M_2 and the distance between M and M_2, respectively.

4.3.3 Simulation with SimMechanics

The physical data determined using Creo, including the material density, inertia moment, geometrical data, and constraints, were exported to SimMechanics First Generation (MathWorks). The initial simulation parameters consisted of the angle, angular velocity, and the angular acceleration at the hip and knee joints. The

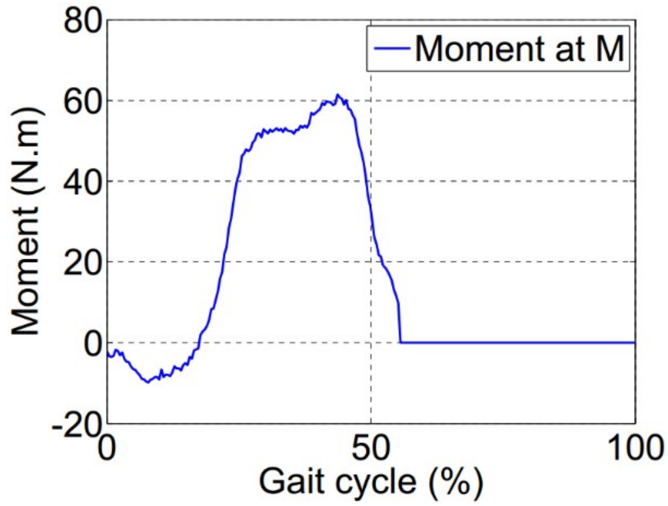


Figure 4.11: Moment at M point.

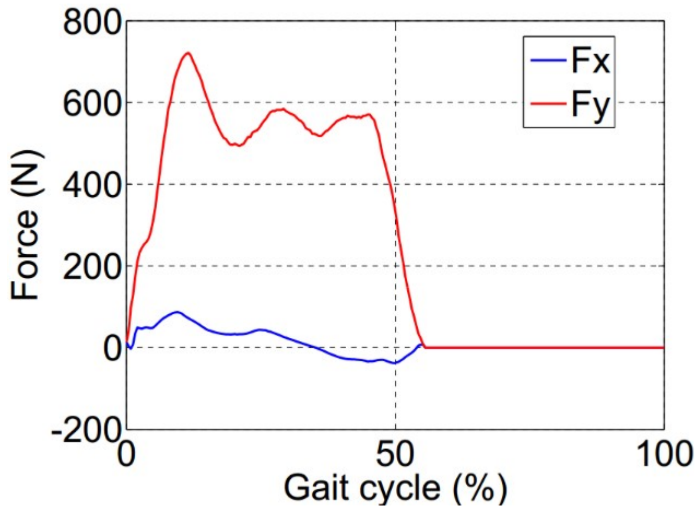


Figure 4.12: Forces at M point.

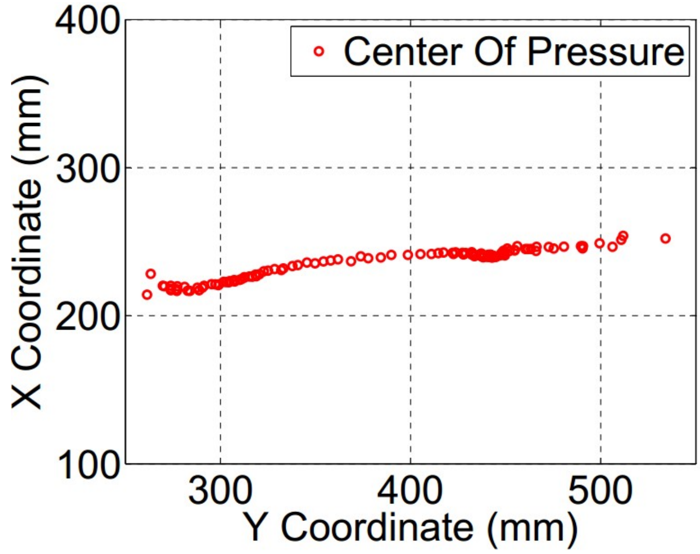


Figure 4.13: Center of Pressure.

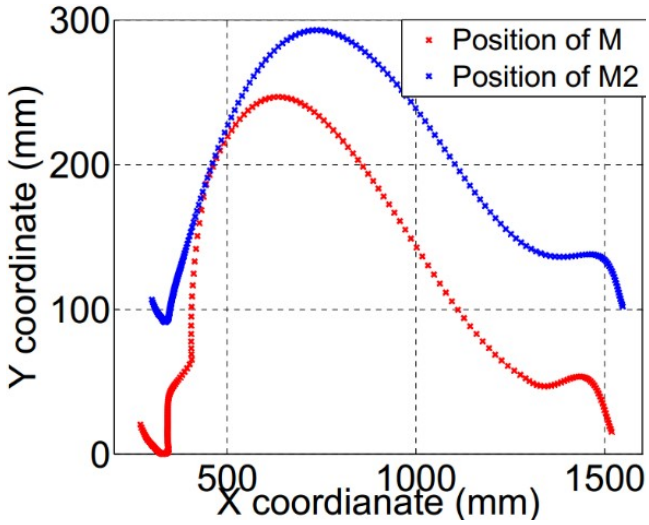


Figure 4.14: Position of M and M_2.

reaction force and moments at the foot were calculated from the measured data.

The block diagram in SimMechanics is shown in Figure 4.15. The input data (I) includes 5 blocks: distance traveled, velocity, and acceleration of prismatic joint (Id1), which represents the distance walked by the subject; angle, velocity, and acceleration, (Id2) which describes the rotation of the hip joint; angle, velocity, and acceleration (Id3), which represents the rotation of the knee joint; reaction moment at point M (Id4); reaction force at point M (Id5). They were connected to a joint by a joint actuator block (II). The joint actuators supply the kinematic parameters to the joints.

The 14 physical models of the parts and joints that are exported from Creo assembly were in group (III). The blocks express the parts assembly Creo in sequence. The physical, geometrical, and joint and constrain properties of the parts were determined in Creo. The joint sensors (JS) block (IV) that received the output signal consists of reaction forces and moments at the joints and supply them to the scope. The results can be observed in the scope or exported to the workspace of Matlab.

4.3.4 Results

The simulation in SimMechanics environment is shown in Figure 4.16. The gait cycle can be divided into two phases: stand phase and swing phase.

The stance phase of the gait can be assumed to start from the point of initial contact of the foot on the ground (heel strike-HS), the point when the full foot is on the ground (mid stance), and to the point where the stance phase ends (toe off-TO). The movement of the lower limb with the trans-femoral prosthesis was observed in the simulation process. The time and position of the prosthesis can

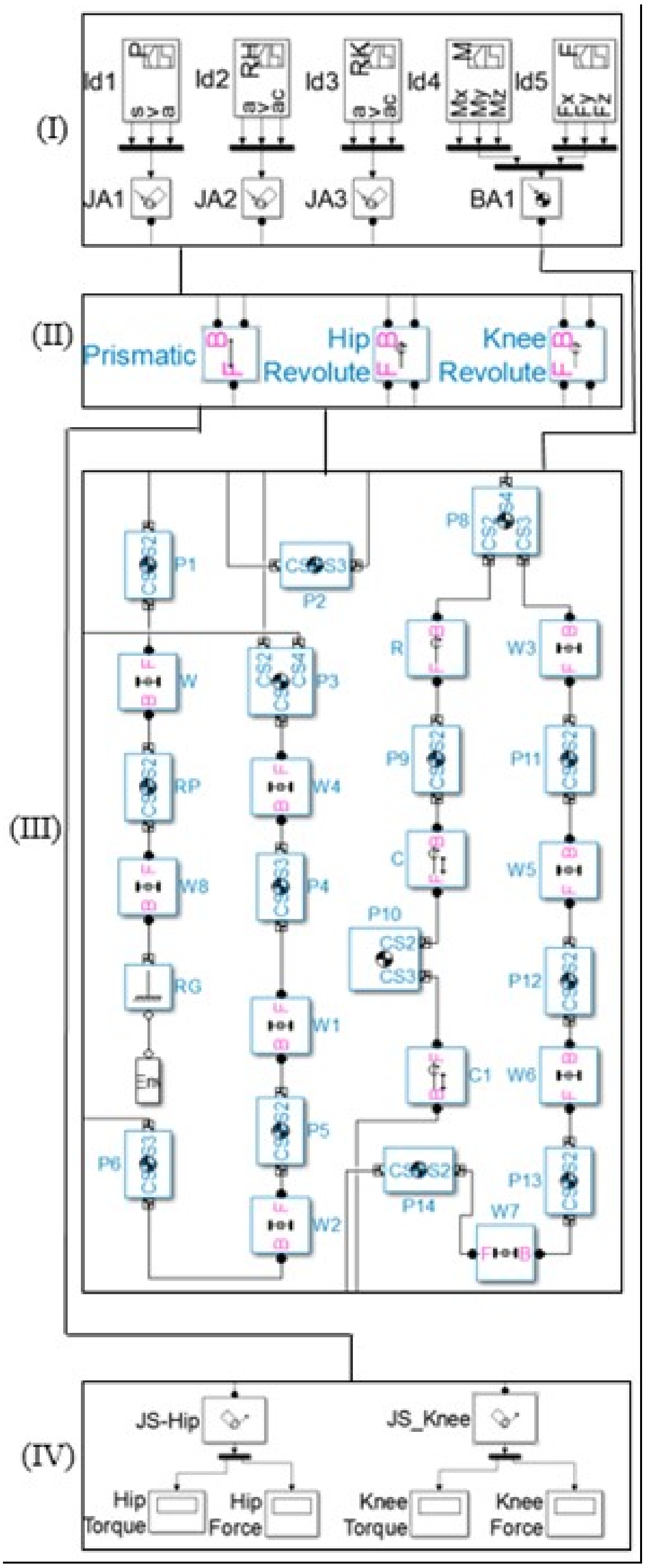


Figure 4.15: Block diagram in SimMechanics.

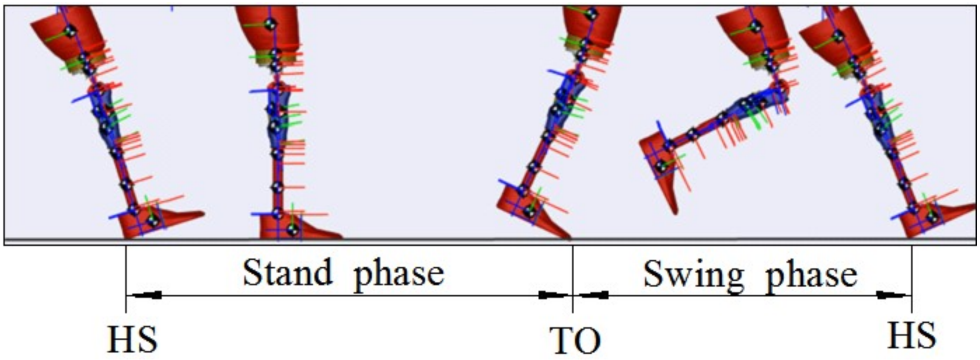


Figure 4.16: Gait cycle in simulation .

be easily obtained from it.

The forces (F_x, F_y) and moments (M_z) at the hip and knee joints are determined using SimMechanics and are shown in Figure 4.19 and 4.20; Figure 4.17 and 4.18, separately. They changed according to the gait cycle. The forces start to increase at HS and decrease to a minimum at the end of the stand phase (TO).

The graphs of the reaction forces at the hip and knee joints are almost the same as the ground reaction force. Especially, the magnitude of the reaction force at the knee joint is almost the same as that on the ground.

The direction of the moment at point M, the hip joint, and the knee joint is reversed in the stand phase. This is caused by changing the position of the COP at the foot. The position of the COP at the foot was distributed from the heel to the toe. The COP determined where ground reaction force impact to prosthesis. In the swing phase, the forces and moments at the hip and knee joints are almost negligible.

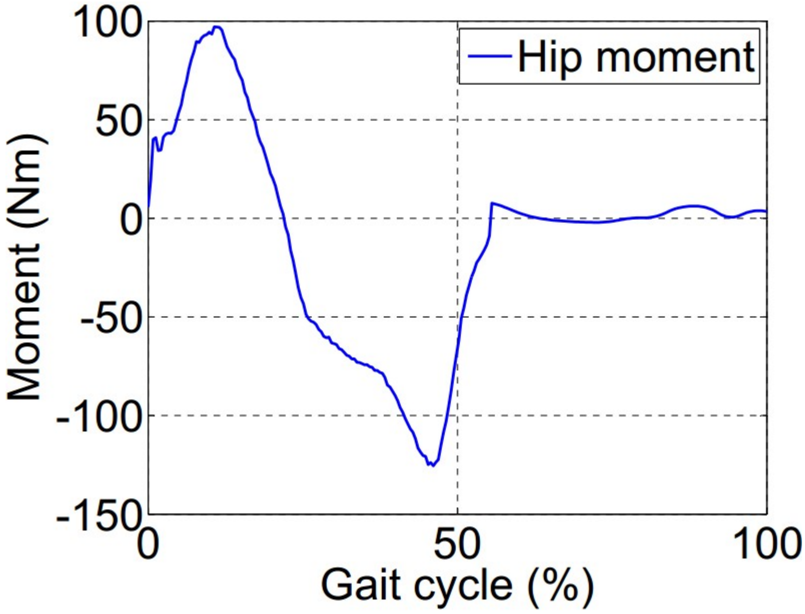


Figure 4.17: Moment at Hip Joint.

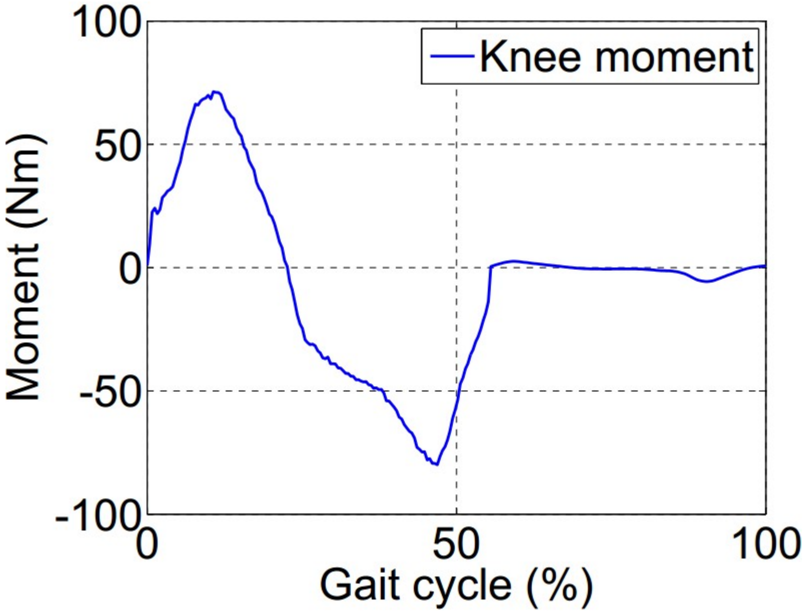


Figure 4.18: Moment at Knee Joint.

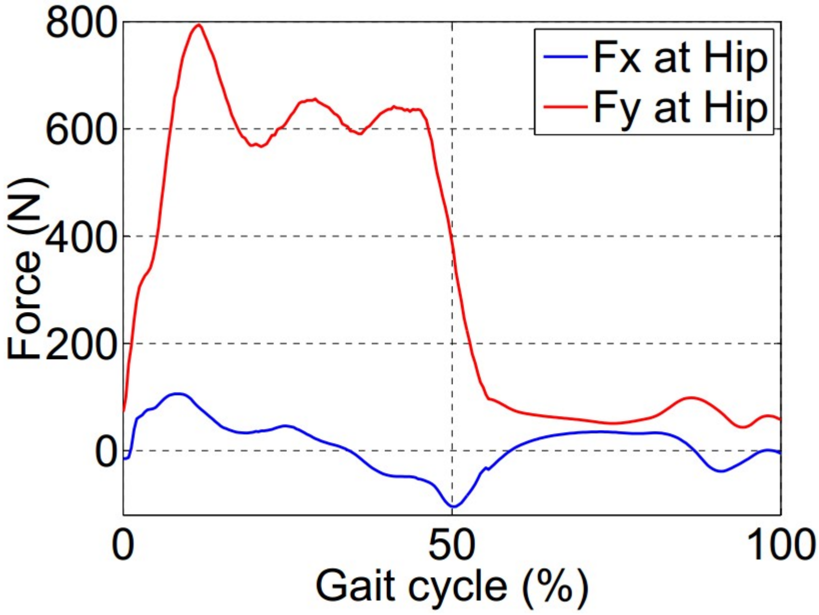


Figure 4.19: Force at Hip Joint.

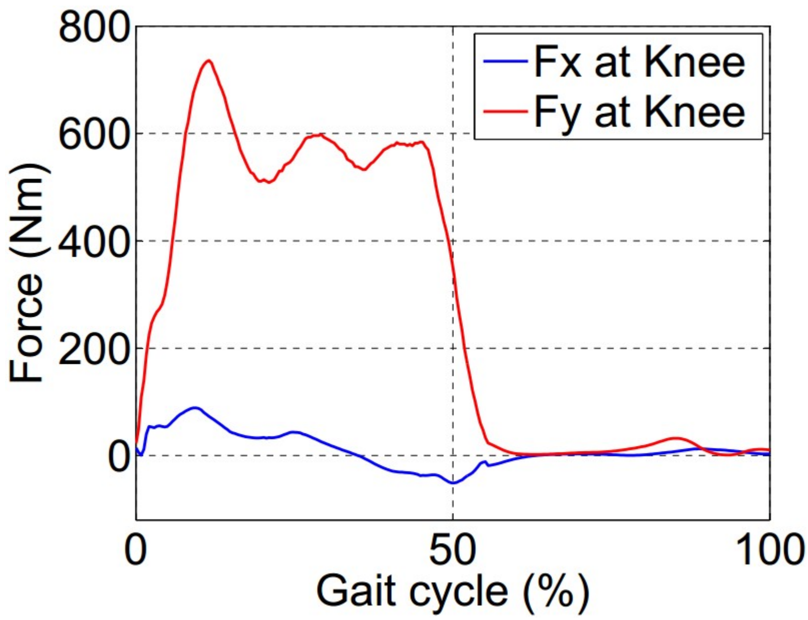


Figure 4.20: Force at Knee Joint.

4.3.5 Discussions

A method was proposed to calculate the forces and moments acting on the hip and knee joints for one gait cycle. This method was based on a 3D model that described the movement of a lower limb with a trans-femoral prosthesis nearly in real state and considered three movements: distance walked by the subject, and rotation of the hip and knee joints. The method also considered the ground reaction force and its position in walking.

By applying the proposed method, we can easily obtain the values of the forces and moments acting on the hip and knee joints despite changing the various parameters of any part in the prosthesis. In addition, we can easily change the shape, material properties, joint type, structure of the knee joint, and type of foot of the prosthesis. This method can be used to compute the load between the socket and the residual limb.

This model can be used to analyze the knee joint prosthesis, and it enables the quantitative evaluation and optimization of the structure of the lower limb prosthesis and improves the prosthetic design and fitting. It can be combined with other module of Matlab, for example, Simulink, SimHydraulic, and Control System Toolbox with various component.

To obtain more accurate results, this model should be build more precise with the shape, material and joint feature. Especially, the shape and material of residual limb is important because determining the shape and material of the residual limb is very difficult.

In the future, this study will be enhanced to observe the dynamics properties in three planes : sagittal plane, transverse plane, and frontal plane. The ankle joint will be added to the model. A knee joint with a pneumatic cylinder will be considered to build a more realistic model.

4.4 Interface Pressure Simulations Procedures

4.4.1 Finite Element Analysis Procedures

4.4.1.1 Geometry Modeling

The residual limb with prosthesis was modeled as the structure with two revolute joint at hip and knee joint. The angle rotation at hip and knee joint around x-axis were defined on Figure. Magnetic resonance imaging (MRI) was used to obtain images of the residual limb with the socket prosthesis. The patient wore the socket prosthesis during the MRI. The residual limb with socket prosthesis was captured using 17 images with 10 mm separation perpendicular to the sagittal plane. Subsequently, the three-dimensional (3D) surfaces of bone and soft tissue were obtained. The MRI data were loaded as a 3D stack, contours were manually drawn in each slice, and lofted into a 3D body structure using a solid modeling software (PTC Creo Parametric). The model of the socket was offset from the surface of the residual limb within the socket. The model of the parts of the prosthesis were measured, and subsequently manufactured in real size dimensions using CAD software. After the modeling, all parts were imported to Hypermesh for meshing.

4.4.1.2 Element type and Material Properties

Tetrahedral meshes were generated for soft tissue, bone, and foot parts. These types of meshes are generally preferred over hexahedral meshes for free-form complex geometries, as the former are computationally more cost-effective and easier to apply [58]. The socket, frame, and shank parts were meshed with triangular elements. The other parts of the prosthesis include the wood circle and the knee part, which were meshed with hexahedral elements. The results of meshing are shown in Figure.

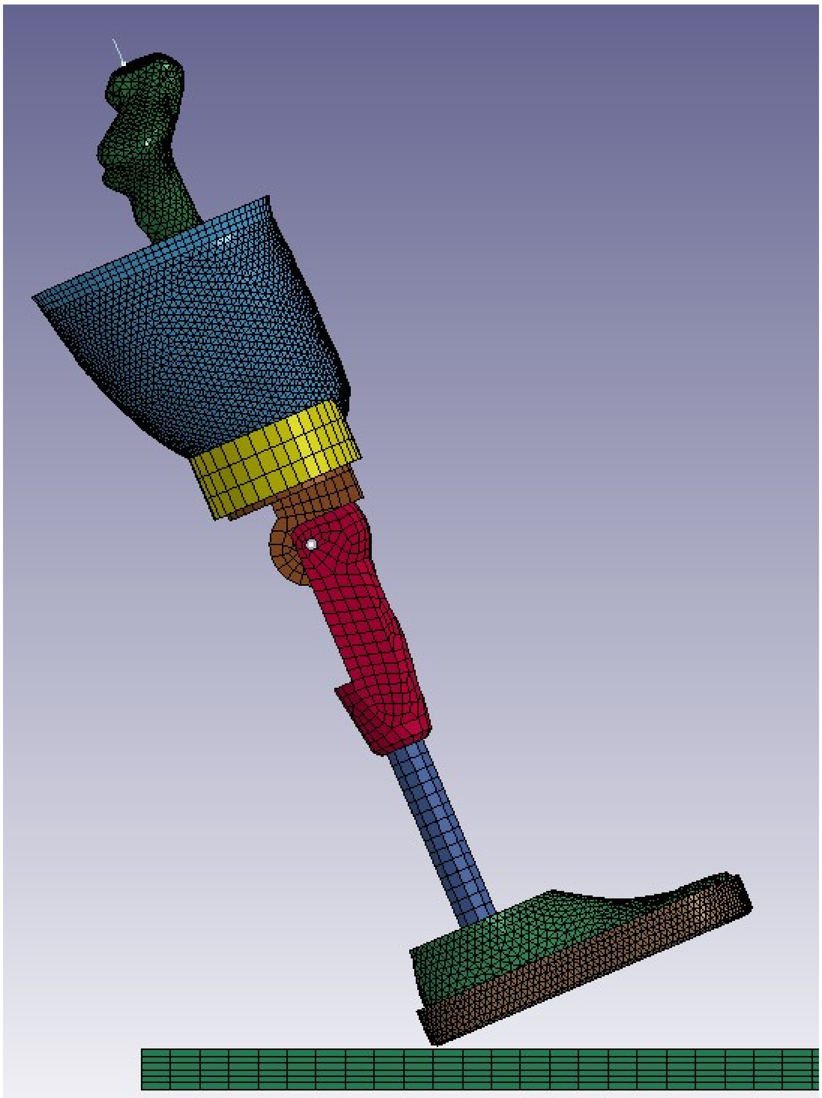


Figure 4.21: The finite model of the prosthesis.

Table 4.1: Material Properties

Name	Material	Density (Ton/mm^3)	Young Modulus	Poisson ratio
Soft tissue	Soft tissue	1.00E-09	0.06	0.45
Socket	Acrylic	1.18E-09	1886	0.39
Wood circle	Wood	5.00E-10	1.00E+04	0.4
Knee circle	Steel	7.80E-09	2.10E+05	0.29
Bone	Bone	1.75E-09	17700	0.3
Wood feet	Wood	5.00E-10	1.00E+04	0.4
Feet	Polyurethane	1.20E-09	25	0.5
Frame	Steel	7.80E-09	2.10E+05	0.29
Shank	Aluminum	2.70E-09	7.00E+04	0.34

The mechanical properties of all parts were assumed to be linearly elastic. Therefore, they obey Hookes law, in which strain varies linearly with stresses developed in an elastic body. The materials of the parts were modeled as isotropic, with all of them possessing uniform elastic properties in all directions. Finally, these volumes were assumed to be homogenous with consistent material properties. Table lists details of the material properties of all parts used in the finite element model.

After determining the element type and material model, the four parts (bone, muscle, fat, and skin) were meshed with tetrahedral elements in LS-Prepost. The total number of nodes and elements for the parts is specified in Table.

4.4.1.3 Contact definition

Two contact conditions were defined in the current FE model to perform nonlinear analyses. The first contact definition was a surface-to-surface contact between the feet and the floor. Generally, the stiffer and more rigid surface of the contact pair is defined as the master surface, while the deformable surface with softer material is selected as the slave surface. Hence, the outer surface of the feet

Table 4.2: Finite element properties of model

Name	Element	Number of nodes	Number of elements	Element
Tissue	Elastic solid	9915	54805	13
Socket	Elastic solid	251	472	13
Wood circle	Elastic solid	728	489	1
Knee	Elastic solid	580	328	1
circle				
Bone	Elastic solid	121	271	13
Wood	Elastic solid	497	348	13
feet				
Feet	Elastic solid	941	2983	13
Frame	Rigid shell	460	388	16
Shank	Rigid shell	150	140	16

was defined as the slave surface, and the sockets inner surface was defined as the master surface. The contact definition requires that the slave surface conforms to the master surface. Therefore, it is recommended that a finer mesh is applied over the slave surface and a coarser mesh over the master surface. A coefficient of friction equal to unity was assigned to model the interaction property for the contact surfaces, and limit the relative sliding between the feet and the floor. The second contact definition applied a tie contact between the tissue and the socket. It provided a simple way to couple the tissue and the surface of the socket together permanently, which prevented nodes from separating or sliding relative to each other. The connection between the muscle and the bone was the set of the constrained extra nodes. The inner face of the muscle was constrained by the bone to limit all the degrees of motion between muscle and bone.

4.4.1.4 Boundary Condition

An equivalent load of 61 kg was applied on the hip joint. It is described as the human body weight. The analysis was carried out during one gait cycle that spanned a total time duration of 1.2 s. The starting time of the gait cycle is the time at which the heel strikes the floor, and the end-time is at the next heel strike. A finite element (FE) model was developed and solved using the nonlinear dynamic explicit method in LS-DYNA.

4.4.2 Simulation Results

The interface pressure between socket and residual limb was shown on four phases of gait: heel strike, mid-stance, toe off and middle of swing phase. The figure from 4.22 to 4.25 shown the distribution of pressure on surface of resdual limb in four view direction: anterior, posterior, lateral and medial.

4.5 Interface Pressure Experiment Procedures

4.5.0.1 Experiment Setup

The triaxial force sensors NITTA PD 3-32-05-015 [18] were used in experiments. These force sensors can resolve the force applied to their surface into three components, two shear components in orthogonal directions (in this study tangential to the skin surface) and one normal stress component (in this study normal to the skin). The schema of place which installed the sensors was shown on Figure 3.6.

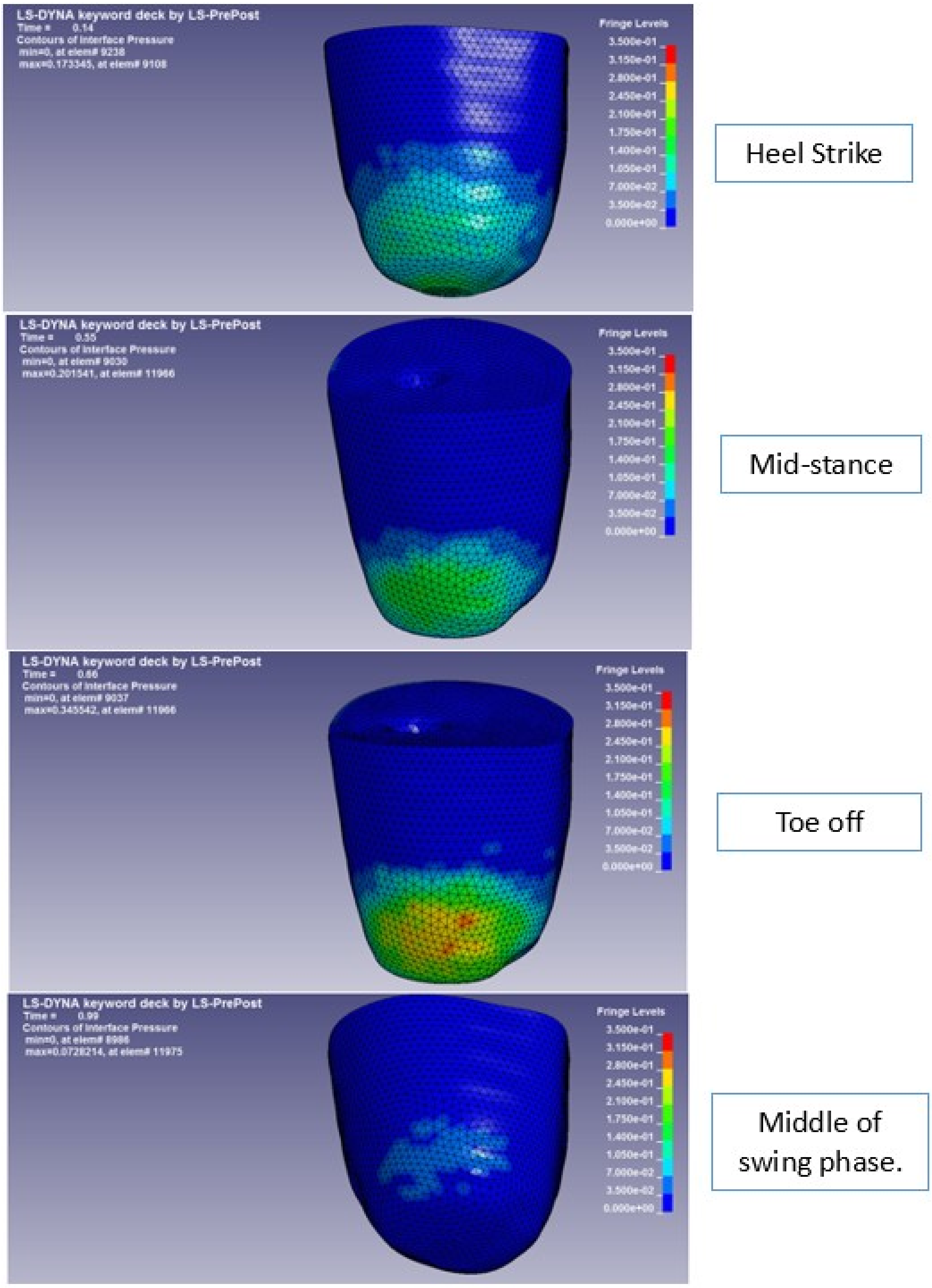


Figure 4.22: Anterior View

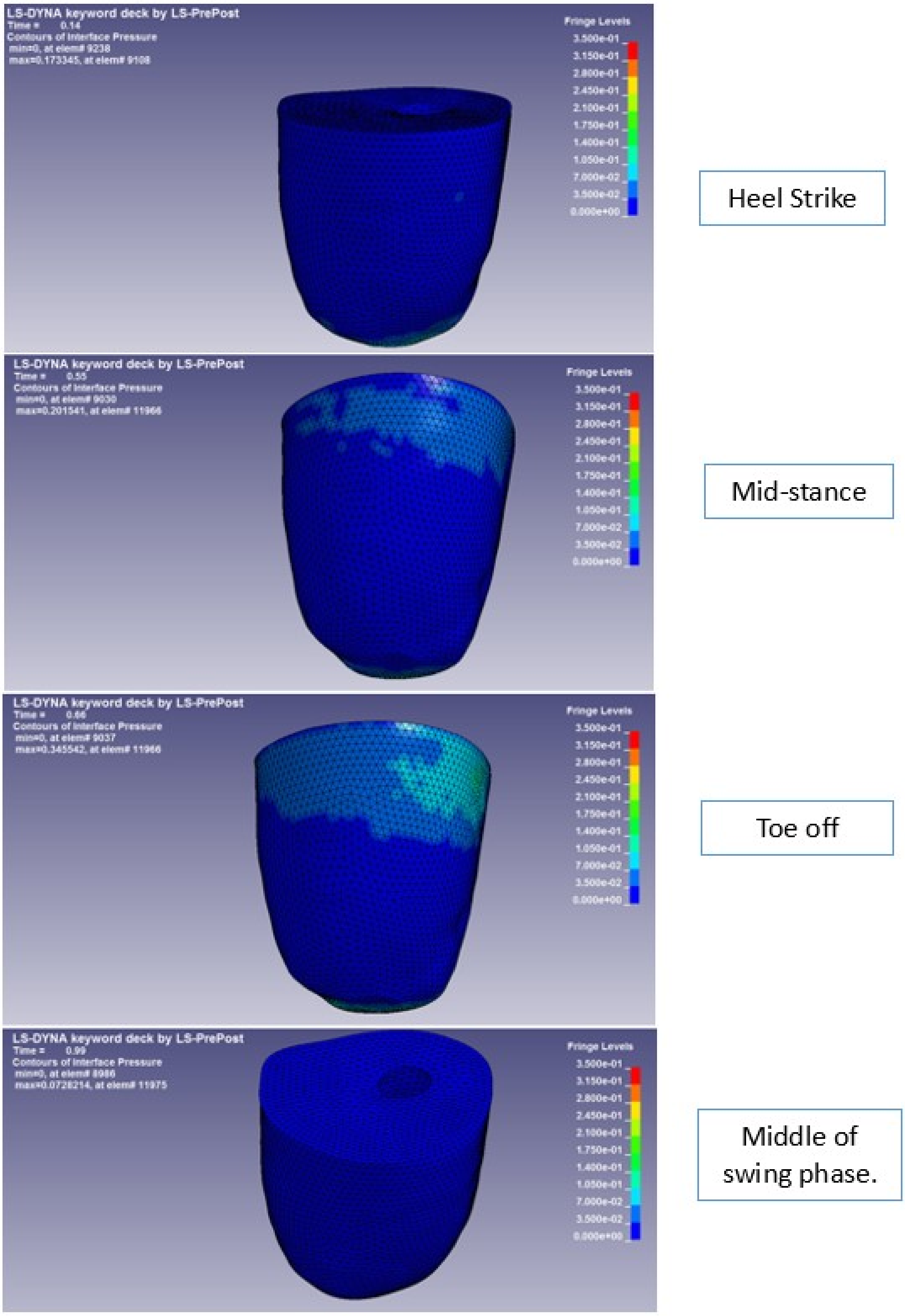


Figure 4.23: Posterior View

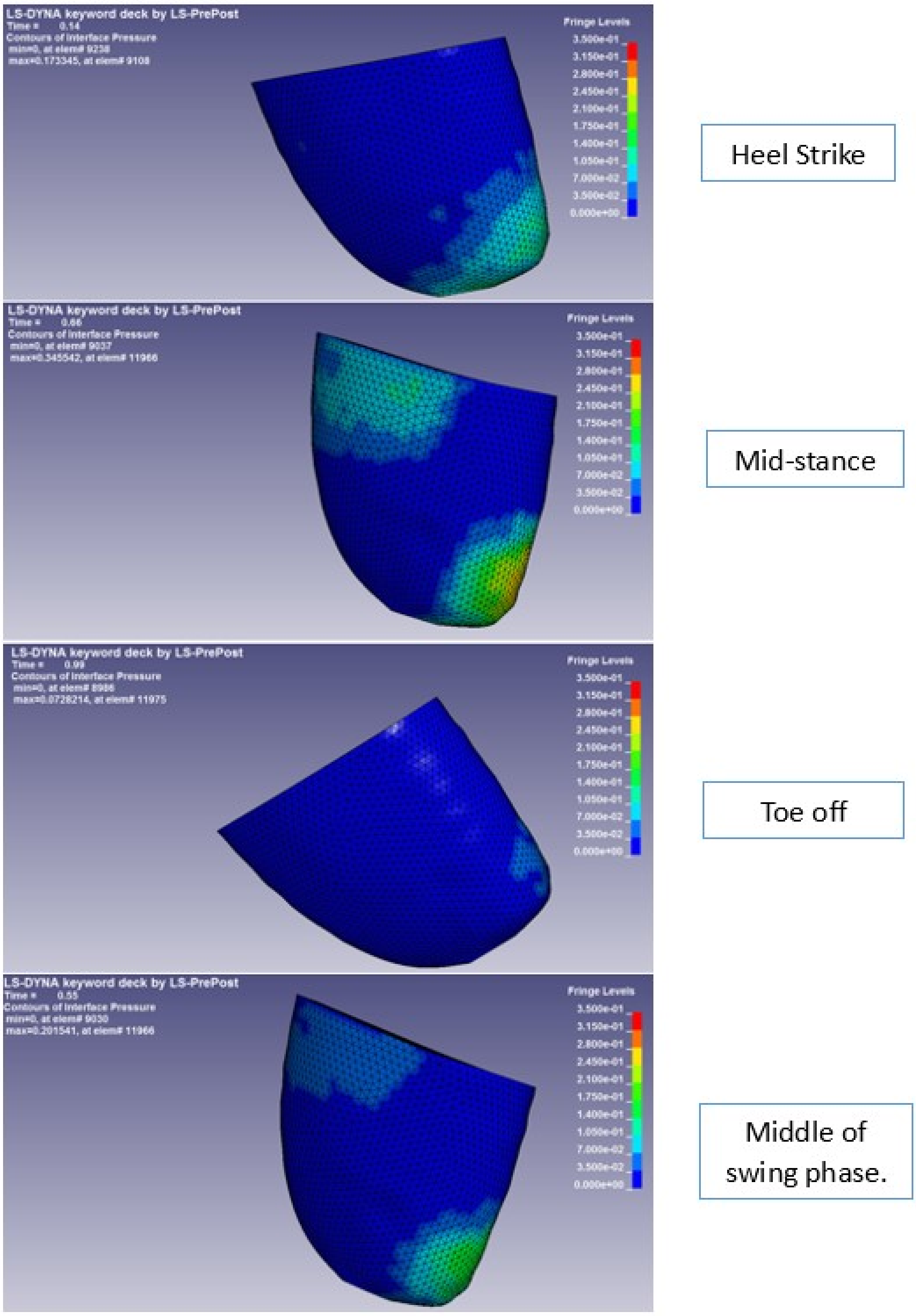


Figure 4.24: Lateral View

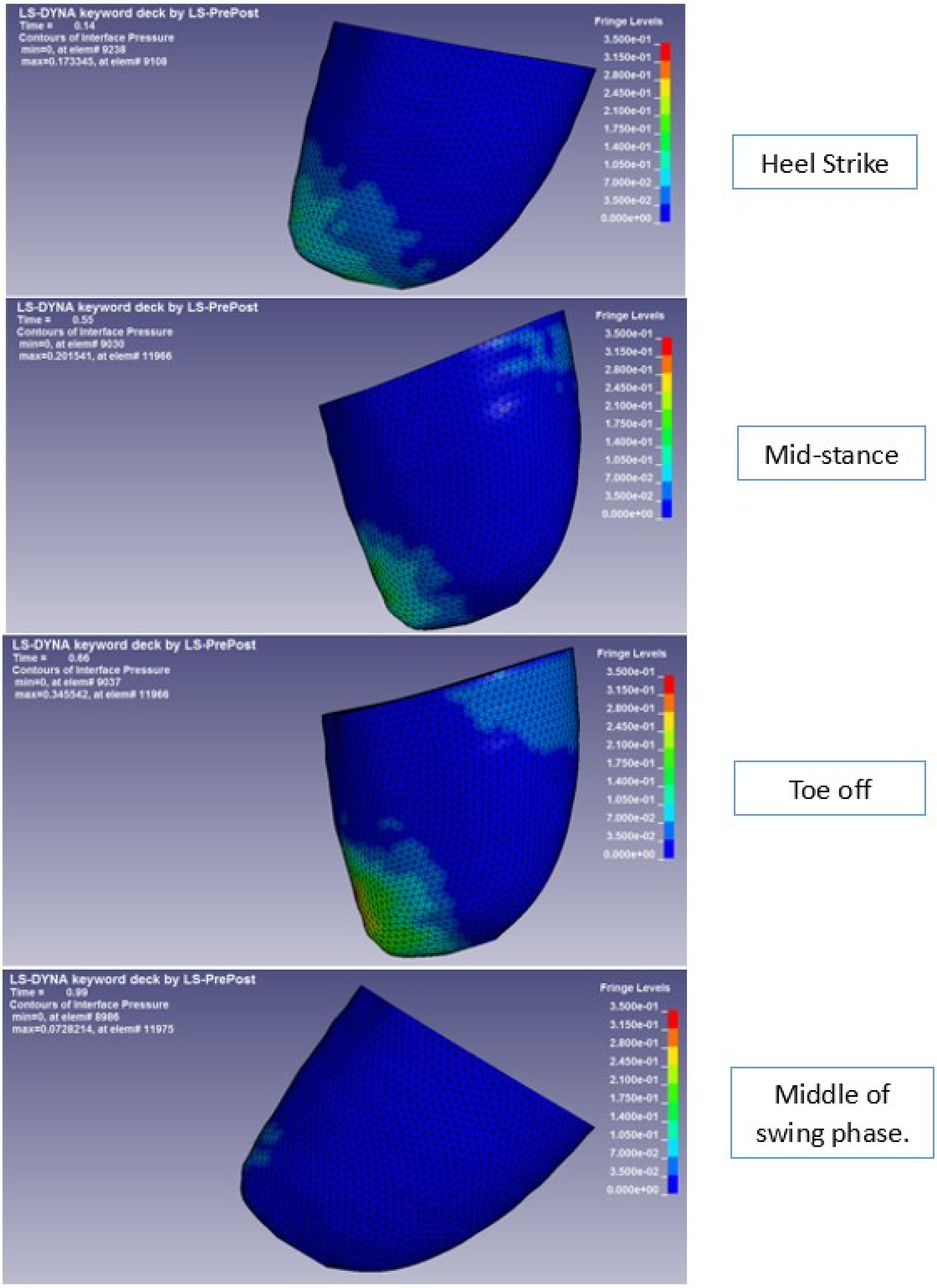


Figure 4.25: Medial View

4.5.0.2 Experiment Results

The results of pressure on eight sensors were shown on from Figure 4.26 to Figure 4.33 .

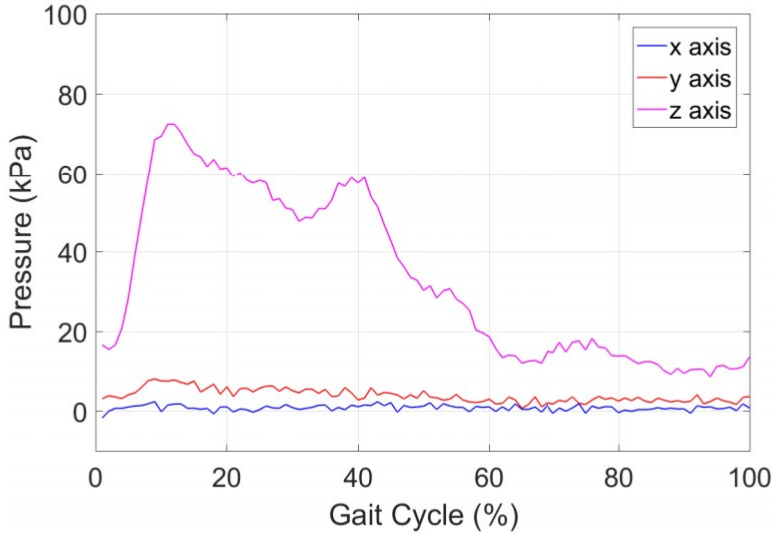


Figure 4.26: Proximal Anterior Position

4.5.1 Discussions

In two case of experiment and simulation, the interface pressure on suface of residual limb appear appreciate in stance phase. The value of pressure on surface of residual limb is not significant in swing phase.

The pressure on surface of residual limb is the critical to evaluate the quality of socket. It is significantly effect to the patient who wore the socket. The experiment for measure the pressure spent so much time and cost. By the simulation, the pressure is easy to observe and evaluation. The model of socket, structure of prosthesis, properties of patient gait can be change for various evaluation.

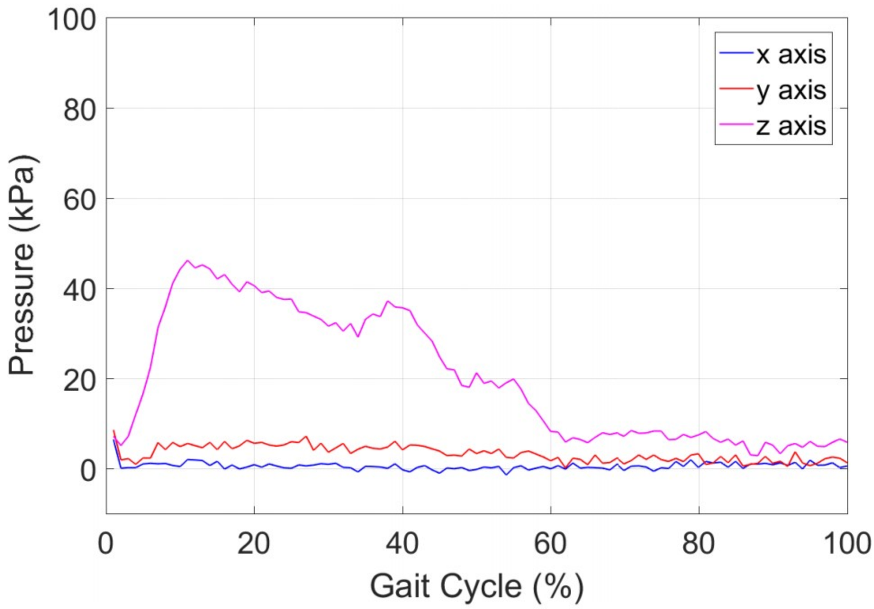


Figure 4.27: Proximal Lateral Position

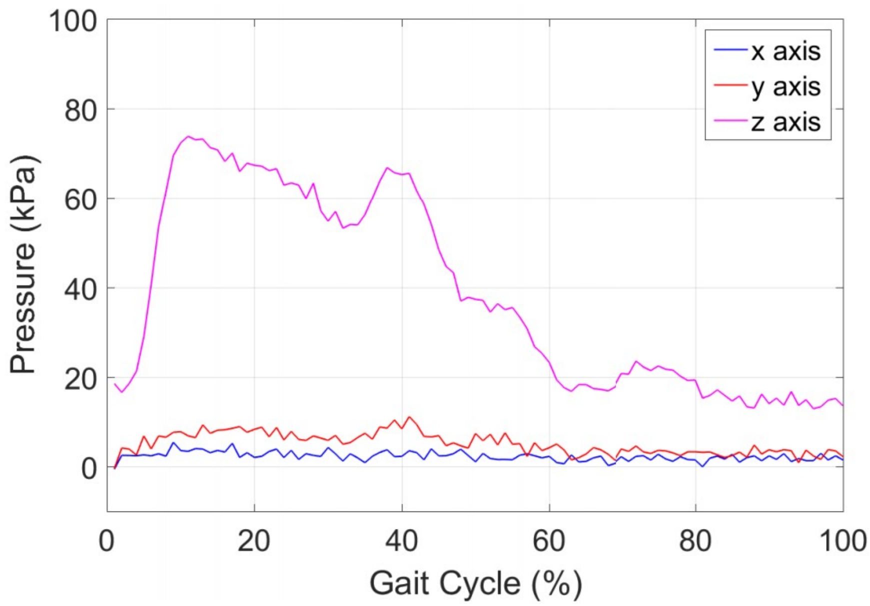


Figure 4.28: Proximal Medial Position

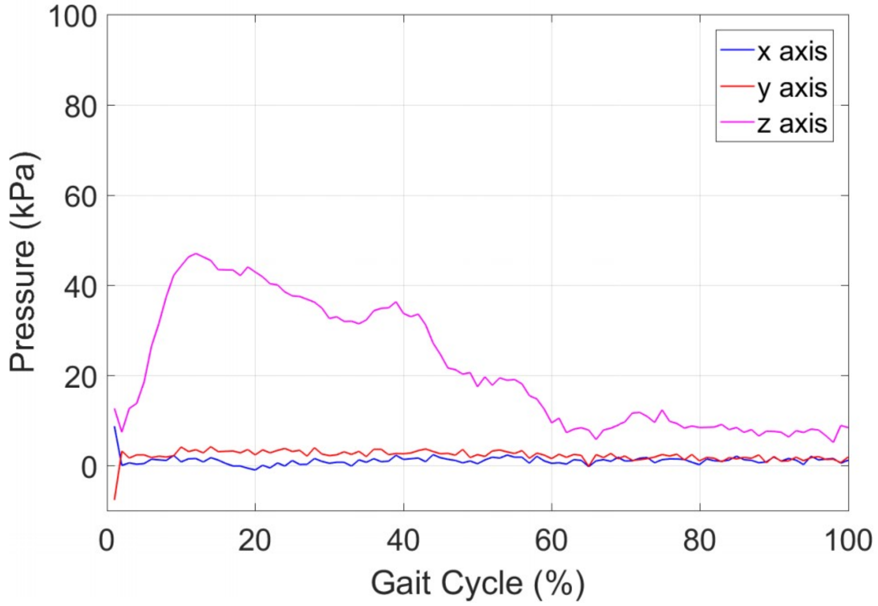


Figure 4.29: Proximal Posterior Position

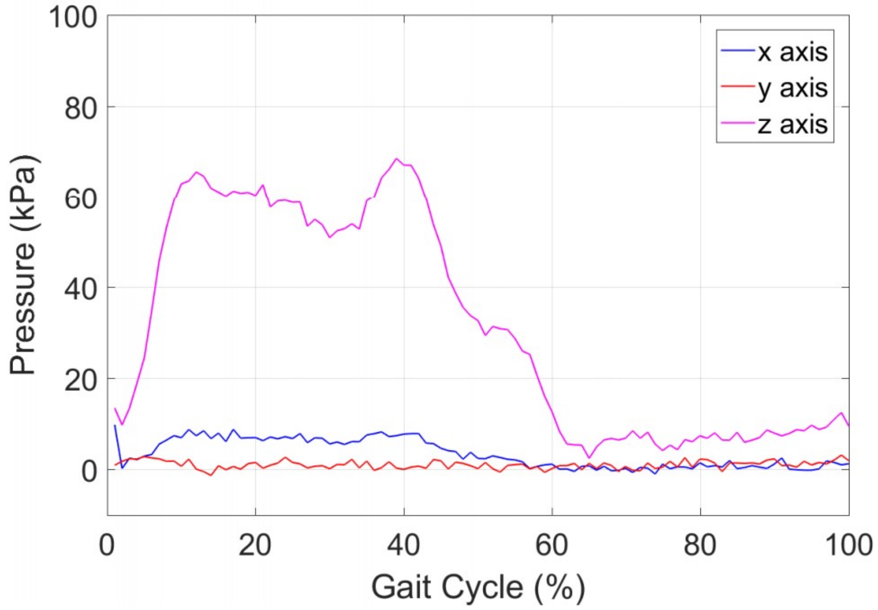


Figure 4.30: Distal Anterior Position

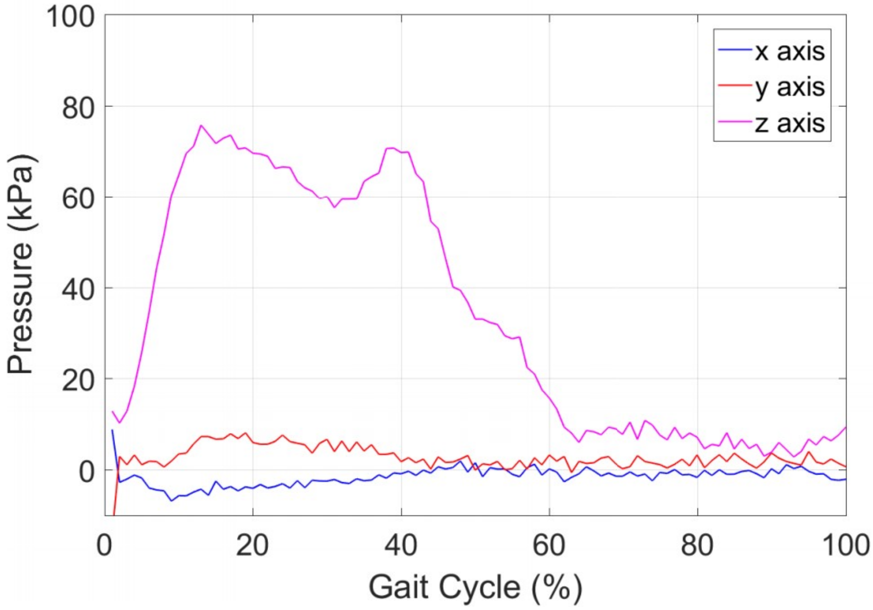


Figure 4.31: Distal Lateral Position

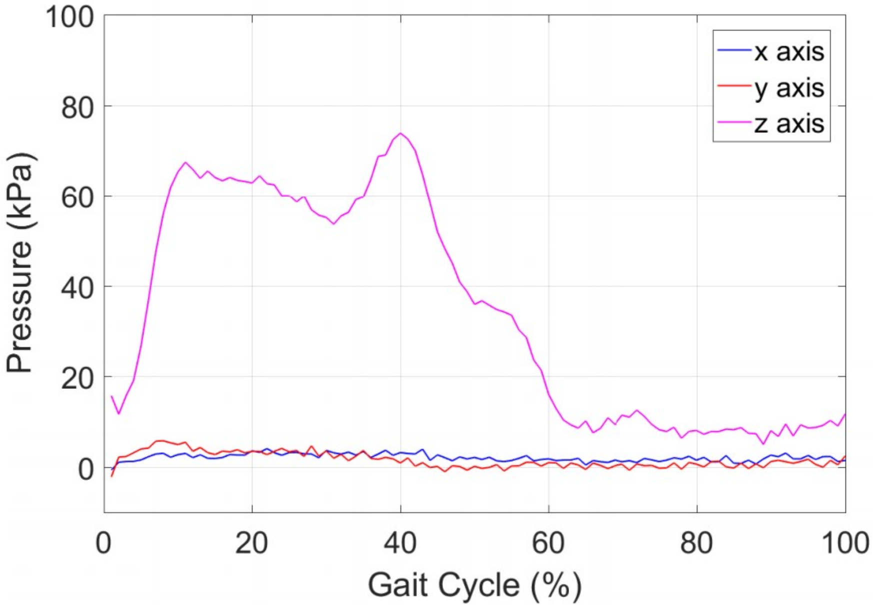


Figure 4.32: Distal Medial Position

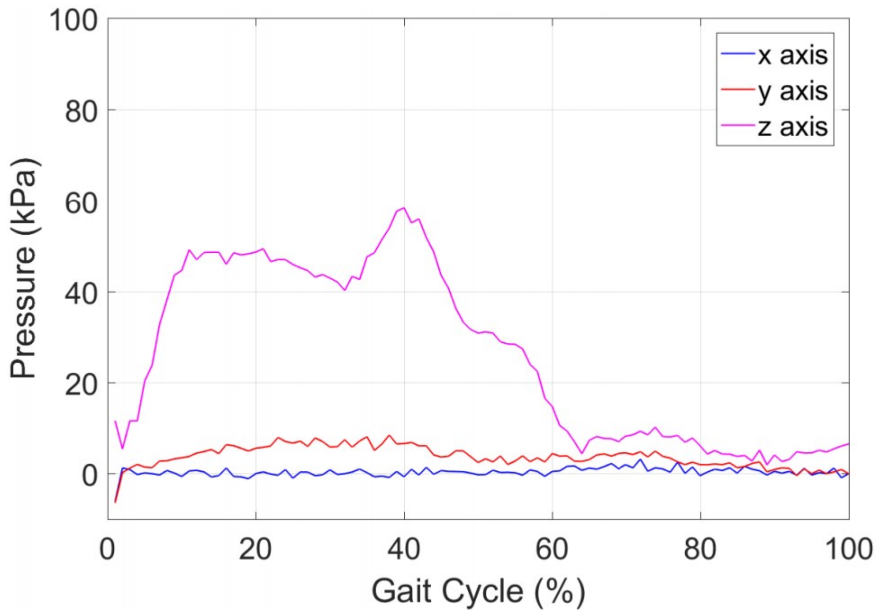


Figure 4.33: Distal Posterior Position

4.6 Conclusions

In this chapter, the analysis of kinematic transfemoral gait and the method for evaluation interface pressure on surface of residual limb in gait cycle were described. Both experiment procedures and simulation processes were conducted and discussed.

In the future works, the model of residual limb need to be improved. The nonlinear material of soft tissue need to consider.

Chapter 5

Estimation of the ground reaction force and pressure beneath the foot prosthesis during the gait of transfemoral patients

Ground reaction forces (GRF) and pressure beneath the foot prosthesis are the main parameters used in biomechanical analysis to estimate the joint load and evaluate the quality of the prosthesis, especially with transfemoral patient who have amputation that occurs through the femur. The information of ground reaction forces and beneath pressure of foot prosthesis is conventionally achieved using dynamics method or the experimental method. However, these methods have some limitation for a prosthetist and designers to choose the best prosthesis solution for transfemoral patient. In the dynamics method, the deformation of the foot prosthesis and the variation in the shape of the residual limb in the socket is neglected and the center of gravity of the prosthesis component is estimated; thus, the method is less accurate because the prosthesis consists of several parts with different materials and shapes. The experimental method involves time and cost in setting-up the device. Data can be acquired only after the patient wears the prosthesis.

In this chapter, the authors were implemented a finite element (FE) method for computing the GRF, and the pressure beneath the foot prosthesis and its distribution. The finite element model of all components of transfemoral of the prosthesis was created. The ground reaction forces, beneath pressure of foot prosthesis and other parameters were disclosed after solving by explicit solver of LS-Dyna software. The results of the vertical ground reaction forces exhibit consistently similar data between the simulation and the measurement. A correlation coefficient of 0.91 between them denotes their correspondence. The reaction force at knee joint, distribution of beneath pressure of foot prosthesis were included in results and discussion. These results can be used for prosthesis design and optimization; they can assist the prosthetist in selecting a comfortable prosthesis for the patient and in improving the rehabilitation training.

5.1 Introduction

Limb amputation is one of the most physically and psychologically devastating events that can occur; however, a lower-limb prosthetic can be considered as a solution. The main function of the lower-limb prosthesis is to support the body weight, while walking. Although it tries to support the patient such that the gait is almost natural and the balance is maintained with the intact limb, the use of the prosthesis affects the patients health. The energy consumption for a unilateral transfemoral patient increases up to 60% [58], with frequent pain in the sound limb, lower-back and lumbar[37]; previous studies indicate a longer stance phase, higher ankle, knee, and hip joint moments, and vertical ground reaction forces (vGRF) in the sound limb. The loading asymmetry between the intact and prosthetic limbs may be expressed in terms of the vGRF and impulse acting on the limbs. A unilateral amputee is subject to a force asymmetry of up to 23%, depending on the type of prosthesis used [89] [83] [39]. Higher values for the step width [67] and displacement of the center of pressure (COP) were applied to both the limbs of individuals with lower limb amputation. However, these alterations in the load distribution between the lower limbs increase the risk of injuries. Over several years, asymmetry in walking, with a greater loading on the intact limb, may cause degenerative changes in the weight bearing joints [31].

The prosthesis is limited in its mechanical functionality, in the patient gait cycle [87]. Gait-feature alterations, promoted by the adaptation to a prosthetic limb may cause health risks for patients. During the prosthesis alignment process and gait training in subjects with lower extremity amputation, a prosthetic foot rollover as close as possible to the physiological foot is required. This process is highly subjective and variable, leading to the need for instruments, which can easily and reliably provide quantitative measurements of the gait of individuals with limb loss, to help and improve the rehabilitation process [87].

The ground reaction force (GRF) has been used in previous studies for evaluating the success of the prosthesis and the rehabilitation training. The GRF and the moments in both the prosthesis and sound limb sides were measured and calculated. At the sound limb-side, the GRF and the moments affect the capacity of the musculoskeletal system in absorbing the body load during gait [75]; consequently, there is an increased likelihood of developing overuse injuries. The joint load provides insights into the development of pathological conditions such as back pain and osteoarthritis [44]. On the prosthetic-side, the GRF and the moments are critical parameters for evaluating the quality of the prosthesis, the effect of the load on the prosthetic knee and ankle joints, and the method for controlling its operation. The GRF provides more information regarding the gait balance, friction between the sole and the floor, and the tendency to slip.

The plantar pressure beneath the foot is considered to be clinically useful in evaluating the prosthesis and the results of the rehabilitation training. It can be used to identify anatomical foot deformities for guiding the diagnosis and treatment of gait disorders, and in preventing pressure ulcers. The pressure beneath the foot prosthesis and its center trajectory, during gait, control the forward progression of the entire body center mass. Impaired COP displacements in amputees may cause difficulties in the adequate control of the dynamic equilibrium.

In most studies, the GRF and the plantar pressure beneath the foot prosthesis are calculated using the dynamics method or the experimental method. In the dynamics method, the deformation of the foot prosthesis and the variation in the shape of the residual limb in the socket is neglected and the center of gravity of the prosthesis component is estimated; thus, the method is less accurate because the prosthesis consists of several parts with different materials and shapes. The experimental method involves time and cost in setting-up the device. Data can be acquired only after the patient wears the prosthesis. The objective of this study is to implement a finite element (FE) method for computing the GRF, and the pressure beneath the foot prosthesis and its distribution. The novelty of this study is that the developed model employs all the parts of a lower limb with a prosthesis, including the residual limb, socket, knee joint, shank, and foot, and the total standing phase of the gait is dynamically simulated. The gait cycle parameters are measured and incorporated in the simulation. The combination of these analyses provides more detailed and complementary information regarding the specific features of the forces acting on the prosthetic limb and can be applied to sound limbs also. In this study, the authors hope to further contribute to the development of biologically realistic lower-limb assistive devices that improve amputee locomotion. Furthermore, the results of the study can aid the prosthesis designer in the design of the prosthesis parts and the structure of the artificial leg, and in material selection.

5.2 Method

The subject of this study is a male (aged 35) with right-side transfemoral amputation. His height was 169 cm and he weighed 63 kg, without the prosthesis. The prosthesis incorporated a manual compression casting technique (MCCT) IRC socket developed by Professor Agarie [17], a Nabtesco prosthesis knee, and an Ottobock foot.

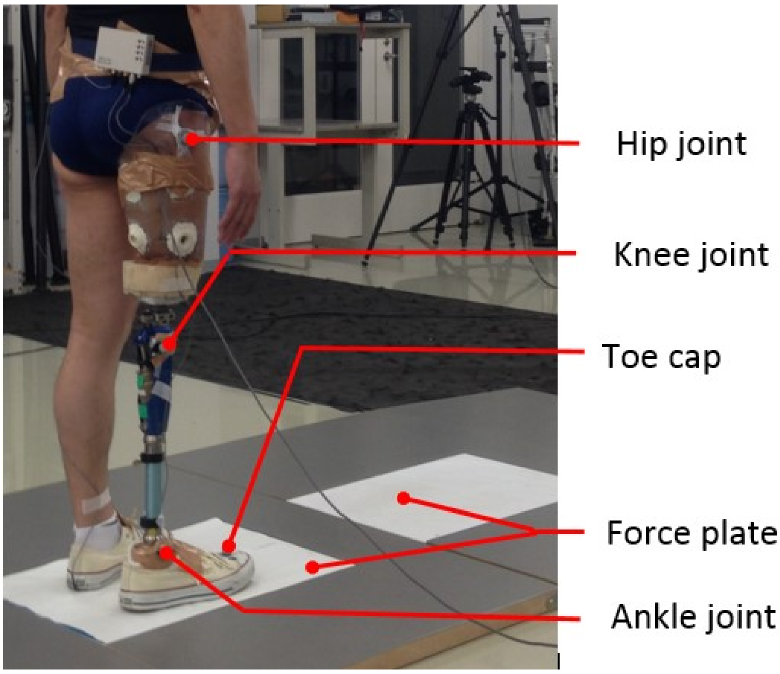


Figure 5.1: Marker positions on the subject and force plates during the experiment.

5.2.1 Experimental protocol

A motion capture system (MAC3D - Motion Analysis) with seven cameras was used in this experiment. Four markers were mounted at the hip, knee, and ankle joints, and on the toe cap of the prosthesis foot. The position of the markers on the transfemoral prosthesis is shown in Figure . Two force plate platforms (Kistler Corporation) were embedded in the floor, placed such that both the subjects feet contacted with them, during the gait cycle. Data was recorded at a sampling rate of 200 Hz, when the subject was walking.

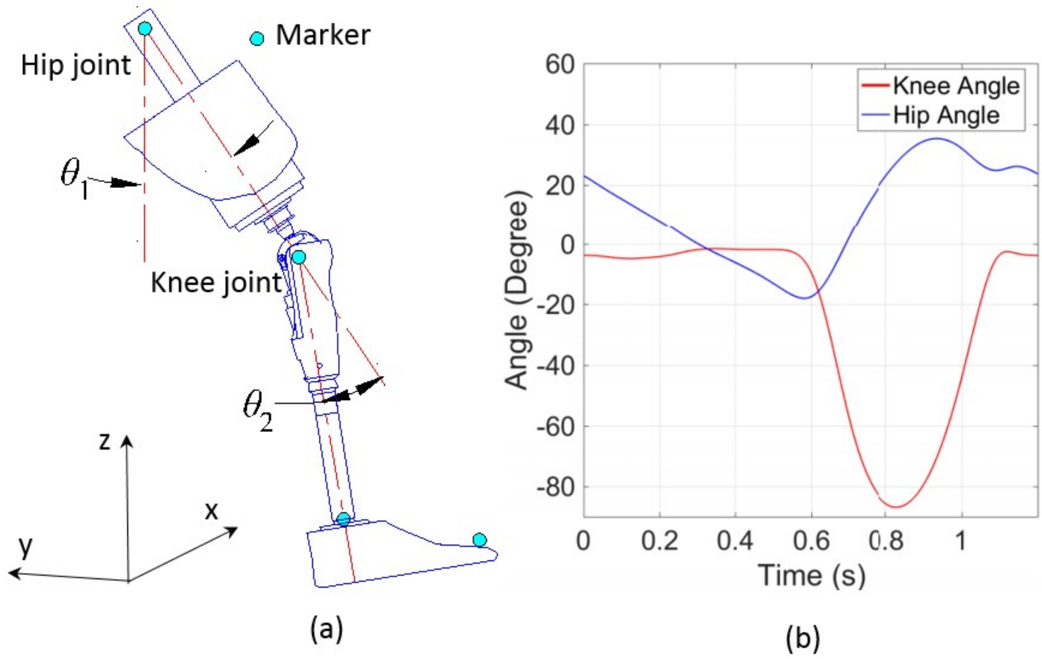


Figure 5.2: (a) Diagram of the rotation of the hip and knee joints and (b) rotational angles of the hip and knee joints.

The rotational angles of the hip and knee joints defined, as shown in the diagram (Figure 5.2). Matlab (Mathworks Inc.), were used to calculate the angle at the hip and knee joints, based on the time variation between the coordinate data of the markers, using the cosine rule. The angles at the hip and knee joints of the transfemoral prosthesis, calculated by the markers, are shown in Figure . The vGRF was recorded by the force plates and calculated during the gait cycle.

5.2.2 Established three-dimensional model

Magnetic resonance imaging (MRI) was used to obtain the images of the residual limb with the socket prosthesis, worn by the patient. 21 images with a 10-mm separation, perpendicular to the sagittal plane, were captured. Subsequently, the three-dimensional (3D) surfaces of the bone and soft tissue were obtained. Each slice of MRI data was loaded as a 3D stack; contours were manually drawn in each slice and loaded as a 3D body structure using a solid modeling software (PTC Creo Parametric). The model of the socket that does not appear on the MRI image was offset from the surface of the residual limb within the socket. A laser scanner (Konica Minolta Vivid 910) was used to create a 3D model of the foot. The parts of the prosthesis were measured and modeled in real-sized dimensions using CAD software. The overall model of the residual limb and transfemoral prosthesis was designed as a coupled link with two revolution joints at the hip and knee joints. The model parts above the knee joint included the knee cylinder, wooden cylinder, socket, and the residual limb. This part was connected to the hip by a rotational joint, representing the rotation of the hip joint. The model parts below the knee included the foot, the wooden foot, shank, and the knee-joint system. This part was connected to the knee-part above by a rotational joint, representing the rotation of the knee joint.

5.3 Finite element procedure

5.3.1 Meshing

An FE residual limb was developed, including the femur and the soft tissue surrounding the femur. Tetrahedral meshes were generated for the soft tissue, bone, and the foot parts. Generally, these types of meshes are preferred, compared to the hexahedral meshes, for free-form complex geometries because they are computationally more cost-effective [96] and easier to apply. The socket, frame, and shank parts were meshed with triangular shell elements. The other parts of the prosthesis, including the wooden cylinder and the knee part, were meshed with hexahedral elements. The results, after meshing, are shown in Figure 5.3.

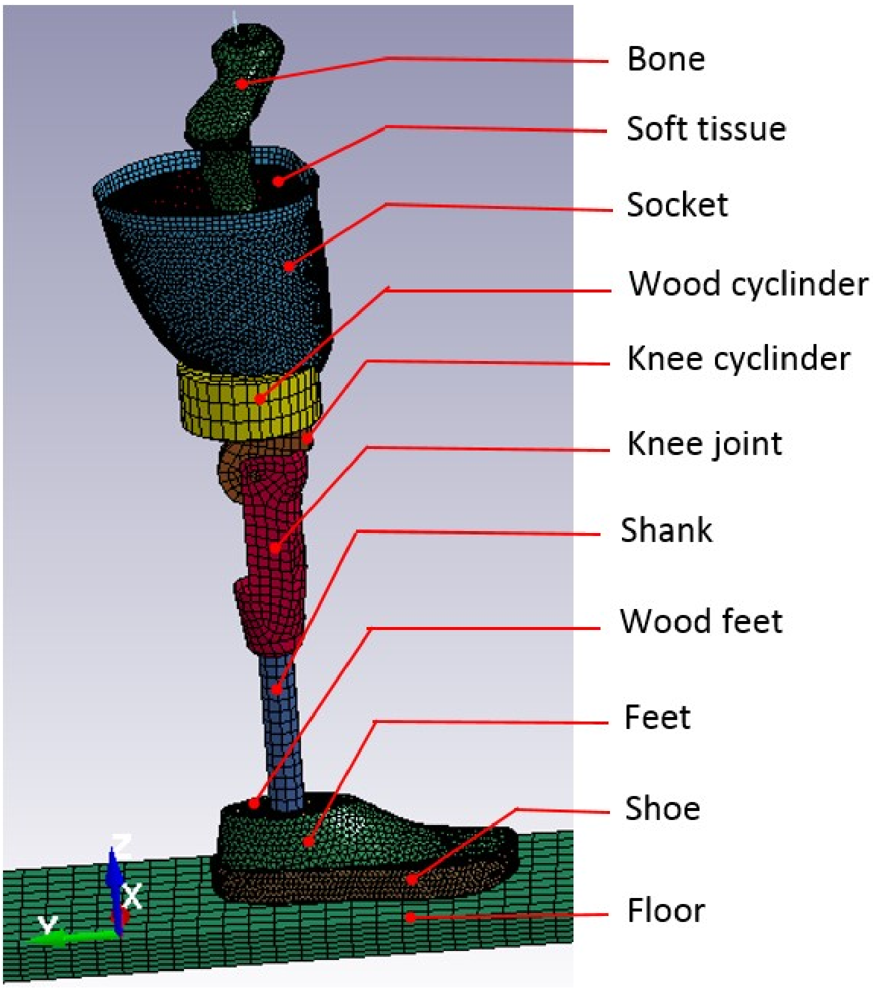


Figure 5.3: Finite element model of the residual limb with a transfemoral prosthesis.

5.3.2 Material Properties

The material properties of all the parts were assumed to be linearly elastic. Therefore, they obey Hookes law, in which the stress varies linearly with a strain increase, in an elastic body. The part materials were modeled as isotropic, with uniform elastic properties in all directions. Finally, these volumes were assumed homogenous with consistent material properties. The Youngs modulus of the soft tissue was estimated to be approximatley 1000 kPa, based on experimental data, for strains above 35% from McElhaney . The femur bone was modeled as an element with a Youngs modulus of 17,700 MPa and a Poissons ratio of 0.3. Table lists the details of the material properties of all the parts used in the FE model.

5.3.3 Contact Definitions

Two contact conditions were defined in the current FE model to perform nonlinear dynamic analyses. The first was the surface-to-surface contact between the foot and the floor, and the second was between the socket and the soft tissue. In the FEA software used, the stiffer and more rigid surface of the contact pair was defined as the master surface, whereas the deformable surface with softer material was defined as the slave surface; so the outer surface of the foot and soft tissue were defined as the slave surface, and the floor and the sockets inner surface were defined as the master surface. The contact definition of the slave surface should conform to that of the master surface. Therefore, a finer mesh is necessary for the slave surface than that of the master surface.

An equal coefficient of friction was assigned to model the interaction property of the contact surface and limit the relative sliding between the foot and the floor. For the second contact definition, a tie contact was applied between the soft tissue and the socket. This is a simple method for coupling the tissue and the surface of the socket permanently and preventing the nodes from separating or sliding, relative to each other. The inner face of the muscle was constrained by the bone to limit all the degrees of relative motion between the muscle and the bone.

5.3.4 Boundary condition

An equivalent load of 63 kg was applied to the hip joint to represent the human body weight. The rotation of the hip and knee joint movements were defined by the measurement result of the rotational angles of the revolute joints (Figure 5.2). The movement of the patient, with respect to the floor, was represented by the translational movement of the hip joint, following the y-axis. The analysis was carried out during a gait cycle that spanned a total time duration of 1.2 s. The starting time of the gait cycle is the time, when the heel strikes the floor and the time, when the next heel strikes is the end-time. The total number of nodes and elements of each part are specified in Table . The FE model was solved using the nonlinear dynamic explicit method in LS-DYNA.

5.4 Results

5.4.1 Ground reaction force and moment

The graphs of the vGRF forces for two cases, the simulation and measurement, were complied with their general human gait properties (Figure). There are two peaks in the simulation, corresponding to the heel strike and toe-off phase in the gait cycle. For the measurement, the two peaks are not very clear and a third peak seems to appear at mid-stance. This is caused by the gait of the individual patient using the transfemoral prosthesis, and the features of the shoe sole and sock.

The first peaks of the simulation (PS1) and measurement (PE1) appeared at almost the same time, at 10% of the gait cycle. The second peak of the simula-

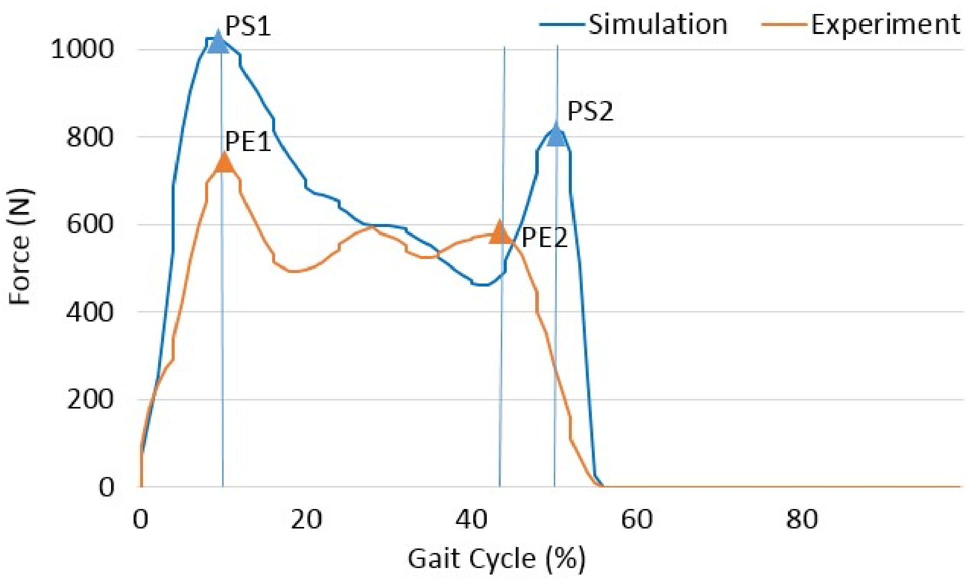


Figure 5.4: Vertical ground reaction force by simulation and measurement.

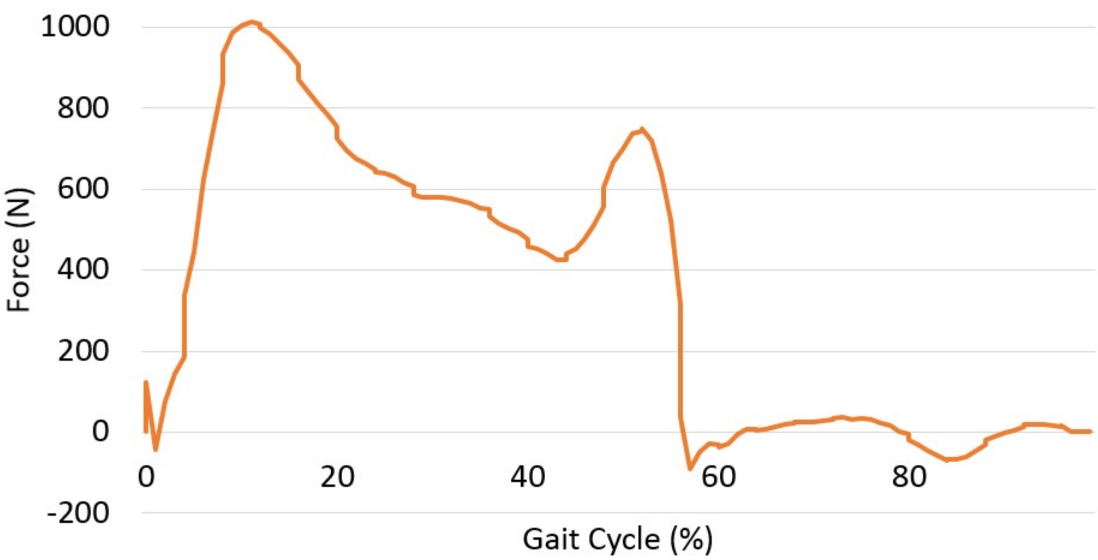


Figure 5.5: Vertical reaction forces at the knee joint.

tion (PS2) appeared at 44% of the gait cycle, whereas that of the measurement appeared at 50%.

The vertical reaction force at the knee joint was also computed by the FE method, as shown in Figure 5. . The graph of the vertical reaction force at the knee joint was almost the same as that of the vGRF. This result was compatible with others previous studies [42, 78].

5.4.2 Pressure beneath the foot prosthesis

The pressure distribution beneath the foot prosthesis depends on the contact condition between the foot and the floor. It varies spatially throughout the foot, from the heel to the toes. Figure shows the movement of the transfemoral with prosthesis at the first (a) and second (b) vGRF peaks and at midstance (b). The results of interface pressure between the shoe sole and the floor corresponds with the movement of the transfemoral with prosthesis were shown in Figure a,b,c and at the sum of all states in the stance phase. The contour around the distribution of the interface pressure describes the shape of the shoe sole. There were two high pressure areas corresponding to the two peaks of the GRF.

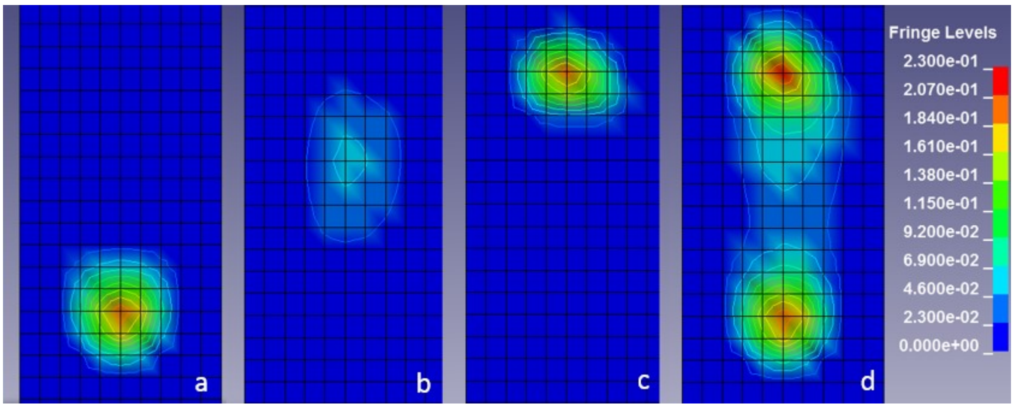


Figure 5.6: Distribution of the interface pressure between the shoe sole and floor at the (a and c) first and second vGRF peaks, (b) midstance, and (d) at the sum of all the states in the stance phase.

5.5 Discussion

The results of the vGRF exhibit consistently similar data between the simulation and the measurement. A correlation coefficient of 0.91 between them denotes their correspondence. The time variation of the vGRF by both the methods was consistently similar. However, there were some differences; the highest value of the vGRF was approximately 1025 N at PS1, whereas it was 737 N at PE1. At the second peak, the value was 818 N at PS2 and 581 N at PE2. The differences may be owing to the material behavior and contact condition between the shoe sole and the simulation floor.

In the results of the reaction force at the knee joint, the position of the 1011 N and 747 N peaks were almost the same as that of the GRF. The reaction force of the knee joint continued to exist, after foot lift-off from the floor. This simulation only considers the vertical force at the knee joint; however, the forces and moments from the other directions can be included in the simulation results by the condition setup. Information on the forces and moments at the knee joint are crucial for the design and control of the knee joint.

The distribution of the interface pressure depicts the reaction of the floor, when the patient walks. The maximum interface pressure in these areas was approximately 230.3 kPa at the toe-off phase. This information is valuable in identifying anatomical deformities in the foot, guiding the diagnosis and treatment of gait disorders. As the CoP affects the balance of the patient in the gait cycle, it can be used as the main parameter for evaluating the quality of the prosthesis. During the gait cycle, the pressure beneath the foot prosthesis transfers between the lateral and medial foot regions. This is also a feasible tool that can enable clinicians to quantify the gait parameters, as they are influenced by prosthetic alignment.

5.6 Conclusion

In this study, the authors have developed a method to estimate the vGRF, the force exerted on the knee joint, and the pressure distribution on the sole of the foot, during the gait cycle of patients with transfemoral prosthesis, using FE analysis. The feature of this FE model is that all the transfemoral prosthesis components and the residual limb were composeded with the actual condition. Patient gait cycle data, which was input to the FE analysis, was computed from clinical experiments. A complex model including the movements of the hip and knee joints, deformation of the residual limb, and contact between the sole of the foot and floor was considered for the simulation process. The simulation was processed through the total gait cycle and the parameters were obtained, as expected. The simulated results of the vGRF were compared with the measured results. The high correlation coefficient of 0.91 proves the effectiveness of the simulation method. Furthermore, the distribution of pressure beneath the foot was determined by the simulation method.

The reaction force of the knee joint can be observed from the simulation results. The moment and power at the knee joint can be also calculated using the simulation result. The mechanical behavior of the prosthetic parts, such as the stress and strain, can be also analyzed.

A significant advantage of the simulation method is that it can conduct the evaluation, before the prosthesis is made or used by the patient. Also, the input data can be changed depending upon the conditions applied, for example, the gait cycle characteristics, the body weight of the patient, and the type and material of the prosthesis. The simulation results can be used for prosthesis design and optimization; they can assist the prosthetist in selecting a comfortable prosthesis for the patient and in improving the rehabilitation training.

This study has certain limitations. First, experiments for measuring the knee reaction force and pressure distribution were not conducted because of the limitation of the equipment used and the simulation results were unable to evaluate the same. However, the most important parameter, vGRF, that affects the characteristic of the knee reaction force and the pressure beneath foot could be evaluated with the measurement results. Second, movement is defined on the sagittal plane only, in the simulation and the movements in the transverse and frontal planes are not considered. Although the movements in the frontal and transverse planes are not significant, they will be considered in the next study for a more accurate analysis. Finally, the forces and moments in the frontal and transverse planes are also not determined. In the next study, it is intended to simulate using a full model, considering all the degrees of freedom and compute all the necessary parameters.

Chapter 6

Conclusions and Future Works

6.1 Conclusions

Finite element analysis is a very strong method for applications engineering. Especially, in design and simulate the product which relate to the human. Because, it is difficult to have experimented or test with subjects are human. The best solution is designed and simulation with the support of computer (CAD-CAM-CAE technology). In this work, the author has proposed, developed and validate the method using FEA for evaluating the function of transfemoral prosthesis. In the first topic, the interface pressure between socket and residual limb was computed by finite element method, the experiment was also conducted for confirming the results of simulation. The successful results of simulation shown that the finite element analysis is reliable enough for the evaluation shape of the socket. This means that, the prosthetist and the designer can use the results of the simulation for observing the behavior of residual limb when it was put to the socket. The interface pressure generated on the surface between socket and residual limb can use to evaluate the quality of socket. The results of simulation continue to simulate in the gait cycle in the next topic. The gait of transfemoral patient was captured by MAC 3D system and analyzed by Matlab software. The movement of the lower limb with prosthesis was observed and discussed. The angular rotation at the hip joint and knee joint were disclosed and it is the valuable data for prosthetist and therapist for evaluation the gait of patients when they used the prosthesis. These results will be the suggestion to choose the comfortable method for a rehabilitation program.

The functions of the knee joint were observed and its properties were shown in results of gait analysis. The angle of the knee joint in gait cycle and the load appeared in knee joint are important data for design and computation the knee joint. On the last topic, the feet prosthesis and relate parameters were considered and evaluation. The feet prosthesis is an important part of transfemoral prosthesis. It is a part impact to ground and the forces generated in feet significant effect to the gait of patients. The center of pressure as well as zero moment point were calculated from the foot prosthesis work. The operation of feet prosthesis was consequence of its material properties and structure. Both material and structure of feet prosthesis and ankle joint can be easily changed with finite element analysis to find which comfortable for individual cases.

However, some limitations are set cause the study conditions and devices. First, the experiment was used three subjects. Usually, with the larger subject, the results of the experiment will be more valuable and more reliable. Furthermore, the data of subject with classified about the age, sex, amputation levels and so on will help the results study more detail and accuracy. Second, the study only considers the movement of the transfemoral prosthesis in sagittal plane. So the forces appeared on hip and knee joint, ground reaction forces, the moment is inadequate all directions. Third, in the study of interface pressure in the gait cycle, the shape of residual limb was considered the same with the socket. So the interface pressure almost distribution on the bottom of socket and residual limb.

6.2 Future Works

The studies of this work would be more valuable and their applicability could be expanded if the following works can be supplemented:
In the evaluation of interface pressure, the works which need to perform or should be solved for the better results are: (1) the material of soft tissue, (2) the shape of the residual limb, and (3) the type and quantity of sensor. The improvements could be:

- In (1), the experiment for evaluating the soft tissue material need to conduct. As we know, the behavior of human tissue depends on the age, sex and health of the patient. The range of parameters of soft tissue material is long and difficult to choose the comfortable value. By the experiment for human soft tissue, the value of material properties will confirm and the input parameters of finite analysis will approach with the real value.
- In (2), the shape of the residual limb in the evaluation interface pressure in gait cycle is the same with the shape of the socket. This is the limitation of the study. This is because if use the different shape, the movement of the transfemoral prosthesis can not as expected of idea. However, it can be overcome if the study gets full the model of socket and residual limb.
- In (3), this study used eight sensors, which were posted on four directions and two levels of the socket. So the value of sensors is inadequate for all surfaces between socket and residual limb. The type and the quantity of sensor should be to enhance for getting the best results of interface pressure on all surfaces of residual limb.

In the analysis the dynamics of transfemoral prosthesis in the gait cycle, the results will valuable and useful for designer and health supporter if it improved: (1) the quantity of patient, (2) the detail of knee joint, and (3) full model of the human body. The improvements could be:

- In (1), more quantity of patient with classified of type as age, sex, amputation levels will help the data of study more valuable and reliable. Because the data of patient are very different with individual cases. By classifying the patient into groups, the data are easy to evaluate and get the helpful conclusions.

- In (2), the knee joint need to describe in fully model, include joint properties. The fully model of knee joint helps the movement of the transfemoral prosthesis more reality and get the accuracy results. Furthermore, the dynamics of the knee joint can be disclosed for the calculation and optimization the knee joint.

- In (3), the full model of the human body which include all parts of the human body are intact limb, upper limb, head and chest abdomen. By using all human body parts in computation, almost the parameters which were considered in the design and optimization the structure of the transfemoral prosthesis can be disclosed by simulation.

If the above works are conducted in further studies and desired results are obtained, the finite element analysis of evaluation functions of the transfemoral prosthesis will be effective for many applications. The prosthetist and designer will have convenient and flexible tools for their work. The patient will reduce the time for the comfort of the prosthesis and rehabilitation program.

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List of Publications

[P.1] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa, "Dynamic Analysis of Hip and Knee Joints of Lower Limb with Trans-Femoral Prosthesis," *Life support Medical Welfare Engineering Association Conference 2014*,(LIFE September 2014), Hokkaido, Japan.

[P.2] Le Van Tuan, Shinichiro Yamamoto, Akihiko Hanafusa, "Functional 3D modeling of transfemoral prosthesis for dynamics analysis," *Prosthetics and Orthotics International Journal*, Volume 39, Issue 1 suppl, June 2015.

[P.3] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa, "A method to analyze dynamics properties of transfemoral prosthesis," *2015 International Conference on Mechanical Engineering and Electrical Systems*, ICMES 2015 Singapore.
DOI: 10.1051/matecconf/20164002026

[P.4] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa, "Finite Element method for evaluation of transfemoral prosthesis sockets," *10th South East Asian Technical University Consortium (SEATUC) Symposium*, Tokyo, Japan, February 2016.

[P.5] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa, "A Method for Evaluating the Quality of a Transfemoral Prosthetic Socket," *38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, August 2016, Florida, US.

[P.6] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa, “Evaluates the shape-changing of residual limb with trans-femoral socket by finite element method,” *Asian Prosthetic and Orthotic Scientific Meeting 2016*, (APOSM November 2016), Seoul, Korea.

[P.7] Le Van Tuan, Shinichiro Yamamoto, Akihiko Hanafusa, “Estimation of ground reaction force of patient with trans-femoral prosthesis during walking by finite element method,” *11th South East Asian Technical University Consortium Symposium*, March 2017, Hochiminh, Vietnam.

[P.8] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa,Finite element analysis of residual limb of transfemoral patient with socket prosthesis in stance phase, ISPO 16th World Congress 2017, Cape Town South Africa.

[P.9] Le Van Tuan, Shinichiroh Yamamoto and Akihiko Hanafusa, Finite Element Analysis for Quantitative Evaluation of a Transfemoral Prosthesis Socket for standing Posture, International Journal of Computer Applications (IJCA) July 2017 Edition. DOI:10.5120/ijca2017914658

[P.10] Le Van Tuan, Kengo Ohnishi, Hiroshi Otsuka, Yukio Agarie, Shinichiro Yamamoto, Akihiko Hanafusa,inite Element Analysis for the Estimation of the Ground Reaction Force and Pressure Beneath the Foot Prosthesis during the Gait of Transfemoral Patients, Journal of Biomimetics, Biomaterials and Biomedical Engineering Vol. 33,Pages:1-11.
DOI:10.4028/www.scientific.net/JBBBE.33.1.