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Al-Nahrain University
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Analysis and manufacturing of above knee prosthesis socket by using revo fit solution

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prosthetics and orthotics Engineering**

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تحليل وتصنيع وقب صناعي لبتر فوق الركبة باستخدام (REVO FIT SOLUTION)

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الإهداء

الى صاحب الفضل الأول والأخير الى الهادي الى
سواء السبيل...الله عز وجل

ثم الى والدتي العزيزه والى والدي العزيز اطل الله
في عمرهما...

اهدي بحثي المتواضع...

واتقدم بالشكر الجزيل والأمتان العظيم والتقدير
العميق الى أستاذي واخي الكبير سيف محمد لما
منحه لي من وقت وتوجيه وجهد وإرشاد كما لا
يفوتني ان اتقدم بشكري وأمتاني للدكتور وجدي
صادق لما قدمه لي من نصح وإرشاد كما لا انسى
زميلتي المهندسة مريم عبد السلام لما قدمته لي من
مساعده في بحث التخرج وأشكر كل من وقف معي
وساعدني من زملائي واخوتي في القسم الداخلي

Abstract

The large numbers of terrorist attacks and the difficulty of the situations in Iraq led to the rise of the amputees numbers. However, typically a large number of the amputations are trans-femoral or above knee (AK).

In this work, manufacturing a socket by using new method (REVO FIT SOLUTION) for manufacturing trans-femoral prosthetic socket by two molding, first mold used (2 layers) of carbon fiber after that we fixing the revo fit device and artificial fiber then we do a second molding also by (2 layers) of carbon fiber, finally open the socket from several part. The main objectives of this work is to design and manufacturing of above knee prosthetic socket by revo fit solution method to increase suspension, decrease weight of socket and easier to donning and doffing especially for the elderly.

The experimental work included subjecting the socket materials to tensile and fatigue testing. The results show that the mechanical properties for (4 layers of carbon fiber) are $\sigma_{ult} = 213\text{MPa}$, $\sigma_y = 135\text{MPa}$ and $E = 3.5\text{GPa}$. The Fatigue life equation for carbon fiber are $\bar{\sigma} = 739.6 (N_f)^{-0.13}$ and The fatigue limit are 90 MPa The data of gait cycle (Ground Reaction Force (GRF), Center of Pressure (COP) by using force plate and Interface pressure between the socket and the residual limb was calculated using F-Socket device, the pressure in anterior region equal to (222Kpa) between the socket and the residual limb for patient (male) suffering from above knee right leg amputation and age (42) year.

The finite element technique (ANSYS) is used to analyze and evaluate fatigue characteristics by observing the safety factor, equivalent (Von Mises) stress, and total deformation. The obtained results from ANSYS gave the profile of safety factor of fatigue, for AK with carbon fiber (1.26).

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Notations

Symbols	Notations	Units
A	Area	mm ²
a	Center of Mass's Vertical Acceleration	m/s ²
E	Young's modulus	GPa
L	Length	mm
M	Body Mass	Kg
N	Number of Cycles
T	Thickness	mm
σ_y	Yield strength	MPa
σ_{ult}	Ultimate strength	MPa

Abbreviations

AK	Above knee
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing

COM	Center of Mass
COP	Center Of Pressure
DOF	Degree Of Freedom
FE	Finite Element
FEM	Finite Element Method
FES	Functional Electrical Stimulation
GRF	Ground Reaction Force
PTB	Patellar Tendon Bearing
PVA	Polyvinyl Acetate
ROM	Range of Motion

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CHAPTER ONE

1.1 INTRODUCTION

Introduction In this chapter a brief introduction on the prosthetic limb and amputation as well as the gait cycle for the above knee amputee.

1.2 General Prosthesis

Prosthesis is an artificial device extension that replaces a missing body part. Prostheses are generally used to replace parts lost by injury (traumatic) or missing from birth (congenital) or to supplement defective body parts. Prostheses are specifically not orthotics, although given certain circumstances prosthesis might end up performing some or all of the same functional benefits as an orthotics. Prostheses are technically the complete finished item. For instance, a C-Leg knee alone is not prosthesis, but only a prosthetic component. The complete prosthesis would consist of the attachment system to the residual limb - usually a "socket", and all the attachment hardware components all the way down to and including the terminal device. A long-standing goal in engineering is to exploit the unique designs of the body to guide the development of anthropomorphic artificial appendages that exhibit human-like stability, strength and speed in a variety of natural environments. Although tremendous technological progress has been made since the days of the wooden peg leg, contemporary orthotic and prosthetic (O&P) limbs cannot yet perform as well as their biological counterparts, whether in terms of stability, fatigue-life or speed.[1] Lower limb prostheses can be exoskeletal (prosthesis with the peripheral weight-bearing capacity, the use of which facilitates the transfer of a patient's weight to the ground along the device's circumference) or currently most frequently used endoskeletal – modular (prosthesis with the central weight-bearing capacity, the use of which facilitates the transfer of a patient's weight to the ground a tubular structure in the prosthesis centre) [2].

1.3 Types of Lower Limb Prosthetic Lower limb prosthesis is an artificial replacement for any or all parts of the lower leg extremity. There are seven

main categories of lower extremity prosthetic devices (lower limb prosthesis), which are:

1-Partial-Foot Amputations: any amputation through foot.

2-Symes: this is an ankle disarticulation while preserving the heel pad.

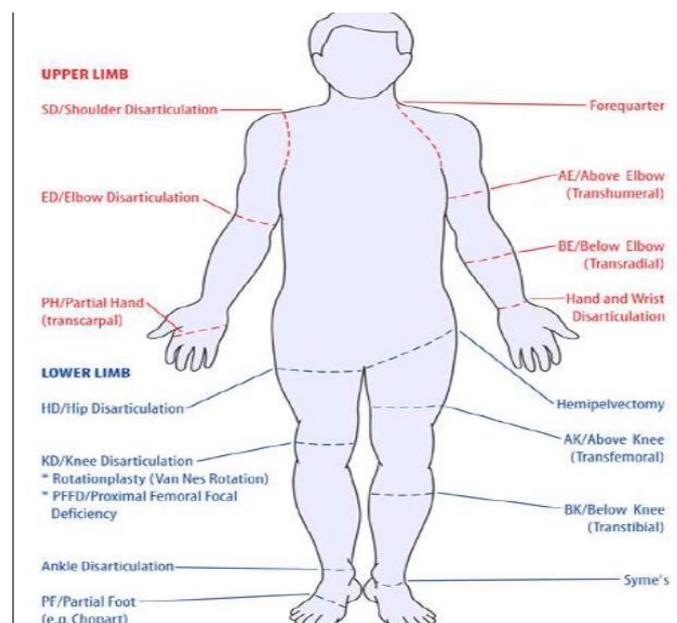
3-Trans-tibial: (any amputation transecting the tibia bone or a congenital anomaly resulting in a tibial deficiency).

4-Trans-femoral: any amputation transecting the femur bone or a congenital anomaly resulting in a femoral deficiency.

5-Knee disarticulations: this usually refers to an amputation through the knee disarticulating the femur from the tibia.

6-Hip disarticulations: this usually refers to when an amputee or a congenitally challenged patient has either an amputation or anomaly at or in close proximity to the hip joint.

7-Hemipelvectomy: Although the anatomic differences between hip disarticulation and transpelvic (hemipelvectomy) amputations are considerable, prosthetic component selection and alignment for both levels are quite similar. The major differences are in socket design[3].



Figure(1-1) Type of amputations[3]

1.4 Transfemoral Amputation

Transfemoral amputation is the amputation of the leg above the knee. This type of amputation is usually performed as a result of trauma, accidents, or due to disease, like diabetes, vascular disease etc. With this type of amputation a person loses two of the most versatile joints in the human body, knee and ankle. The knee joint is important to human gait because it serves as a junction for the thigh and shank muscles. The knee locks and unlocks during heel strike and toe off respectively. Knee locking can be caused either by contraction of muscles (voluntary) or a slight overextension of the knee (involuntary). Without locking of the knee, human legs would buckle and walking would not be possible. Ankle joints are important in gait because the joint offers stiffness to avoid collapse of the leg at dorsiflexion or heel strike; at plantarflexion or toe off it provides control and power to propel the body forward. The loss of function of these muscles results in variation of gait, usually as age progresses [13].

1.5 COMPONENTS OF AN ABOVE KNEE PROSTHETIC LIMB

1.5.1 Socket

The socket is the most critical component of the prosthesis. If it doesn't fit correctly, the patient can experience pain, sores and blisters, and the prosthesis will feel heavy and cumbersome. Mobility may be compromised, or the prosthesis may even end up in the back. Socket design technology has come a long way from the days of hard plastic and wooden sockets. With the emergence of contoured sockets that fit every aspect of the residual limb, amputees are more comfortable and mobile than ever before, fitting a socket is an art form that continues to evolve.

The prosthetist's goal used to be to create a socket from softer materials; now the goal is to make the prosthesis as stable as possible while maintaining comfort. However, although today's materials are much lighter, it's difficult to create an inanimate prosthetic socket to comfortably contain a part of the body that is living and constantly changing[4].

1.5.2 Prosthetic Knee

For the above-knee amputee, the prosthetic knee joint is one of the most critical components of the prosthesis. Replacing the amazingly complex human knee has been an ongoing challenge since the beginning of modern prosthetics. A prosthetic knee has to mimic the function of the normal knee while providing stability and safety at a reasonable weight and cost. A prosthetic knee that produces the most functional outcomes is needed.

Developing such a knee requires familiarity with normal gait, because that is the basis for understanding an above-knee amputee's gait.[5]

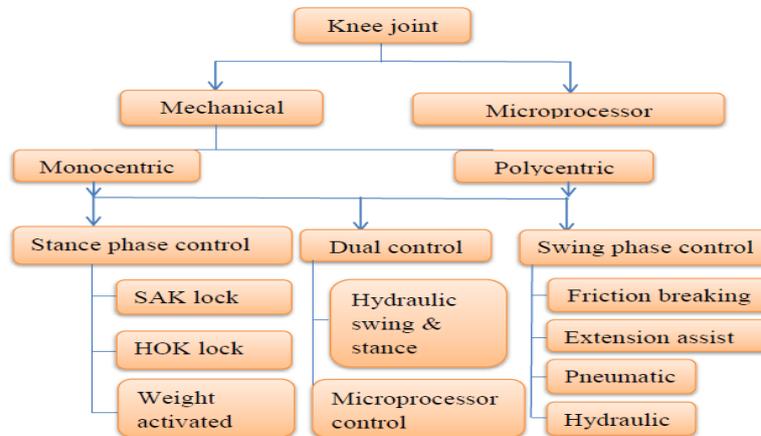


Fig. 1.2: calcification of prosthetic knee type [6].

1.5.3 Shank (shin)

The primary purpose of the shank is to transfer the vertical loads caused by the weight of the amputee to the foot and on to the floor. Two types are available: Crustacean, or exoskeleton, where the forces are carried through the outside walls of the hollow shank which is shaped like a leg; and endoskeletal, or pylon, where the forces are carried through a central structure, usually a tube and the shape of the leg is provided by a foam covering (fig 1.3) .The endoskeletal systems offer the most life-like appearance, but require more care to maintain[7] .

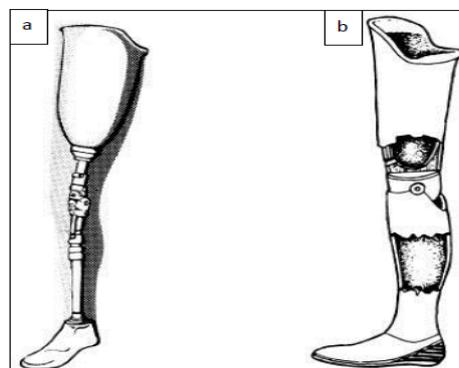


Fig. 1.3: a: endoskeletal, b: exoskeletal transfemoral prosthesis [8].

In exoskeletal prostheses, the shank is most often rigid urethane foam or wood and the shank is tubular, usually aluminum or graphite with either stainless steel or titanium connectors at the foot and socket or knee. The connectors generally have alignment capability, even after the prosthesis is fabricated and finished [9].

1.5.4 Prosthetic Feet

The prosthetic foot is an important, multifaceted component of the transfemoral prosthesis. The primary purpose of the prosthetic foot is to serve in place of the anatomic foot and ankle.

There are essentially four different designs of prosthetic feet available for use prostheses in general (SACH feet, single-axis feet, multi-axis feet, and flexible-keel-dynamic-response feet). There is one special consideration for the transfemoral amputee. Since heel strike though midstance on the transfemoral prosthesis is the Most difficult period for knee control, an ankle-foot combination that dampens the knee flexion torque moment generated at heel strike can be an important consideration. This is particularly true for the elderly or otherwise debilitated amputee. Use of an ankle-foot combination that allows true plantar flexion within the ankle mechanism single-axis foot as in(fig 1.5) , multi-axis foot opposed to simulated plantar flexion (solid-ankle feet), provides better absorption of shock and torque generated at heel strike, thereby decreasing potential knee instability[10].

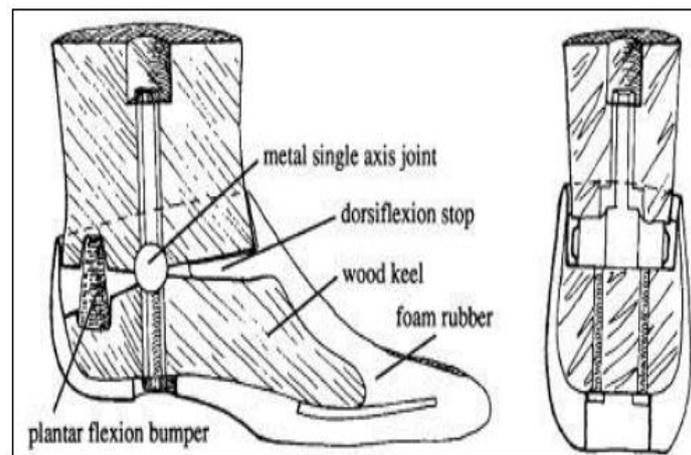


Fig. 1.4: Single-axis foot [11].

1.6 Gait Cycle

Human gait is a cyclic walking pattern created by putting one leg in front of the other to move forward with a leg trajectory from back to front. During healthy human gait, legs move in a symmetric fashion that is always 180 degrees out of phase. Gait is a result of various complex movements occurring in synchronization [12]. a walking cycle is typically broken down into two phases; the stance phase (60%) and the swing phase (40%) as shown in (Fig. 1.5) .

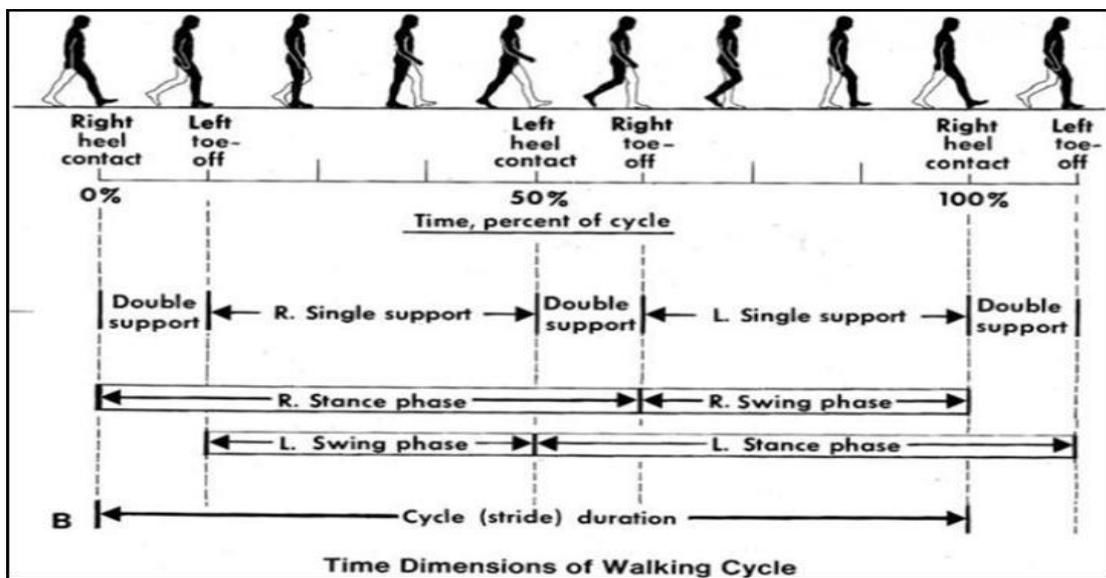


Fig. 1.5: The descriptive stages of the gait cycle [13].

The gait cycle for the right side begins with heel strike of the right foot. At this point, both feet are on the ground.

This is known as the initial double support phase. This sub-phase of the gait cycle is also known as weight acceptance as the body weight is shifted to one leg. Forward advancement begins when the left foot leaves the ground (i.e. Left toe-off).

During the single support phase of stance, the right leg supports the body weight while the left leg advances forward. When the left foot hits the ground, it is the beginning of a second double support phase. As the right leg comes off the ground (toe-off), the body transitions into swing phase. During

this phase, the limb advances forward in preparation for the next contact with the ground [13].

1.7 Objective

This work is intended to provide:

1- Measuring the maximum ground reaction force and pressure that will be subjected on patient leg during gait cycle walking for each joint.

2- Measuring the interface pressure distribution between the residual limb and prosthetic socket.

3- Measuring the mechanical properties of the AK prosthetic material including tensile test and (S-N) curve of fatigue to determine the best result of materials.

4-

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

The purpose of this section is to have a brief review of the history of lower limb prosthetic devices and the previous researches in this subject.

2.2 Brief History of Prosthetics

“Prosthetic history begins with humankind’s spiritual and functional need for wholeness. Prosthetics were developed for function, cosmetic appearance, and a psycho-spiritual sense of wholeness but not necessarily in that order.” There are records that show that the use of prosthetics began in the ancient cultures. People used peg legs or simple crutches made from wood and leather, pictures of which were often depicted in pottery. Thought the Dark Ages knights had iron prosthetics made for use in battle. Advances in prosthetic design and manufacture did not really begin until the period between 1600 and 1800. Advances in medicine during this time including the invention of the tourniquet, anaesthesia and disease fighting drugs meant that the residual limbs had greater function. This allowed the prosthetist to design more functional prosthetics. In 1800 James Potts constructed a leg with a wooden shank and socket, a steel knee joint and an articulated foot controlled by catgut tendons attached to the knee and ankle. Large-scale wars such as the American Civil War and World War I saw a great increase in the number of amputees and the introduction of the use of aluminium and rubber. These wars as well as World War II saw an increase in the interest of governments. This meant funding and research which in turn produced more advanced designs and more advanced materials. This research and development continues till this day[14].

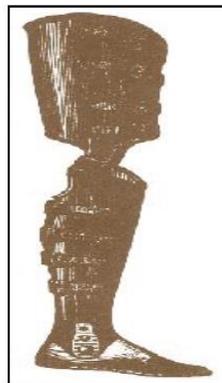


Fig. 2.1 Paré’s above-knee device [14].

2.3 Literature Review on Prosthetic Socket.

Tyagi Ramakrishnan, 2014 [15] Transfemoral amputees develop a physical asymmetry because of their amputation, which includes reduced force generation at the knee and ankle, reduced control of the leg, and different mass properties relative to their intact leg. The physical change in the prosthetic leg leads to gait asymmetries that include spatial, temporal, or force differences. This altered gait can lead to an increase in energy consumption and pain due to compensating forces and torques. The asymmetric prosthesis demonstrated in this research aims to find a balance between the different types of asymmetries to provide a gait that is more symmetric and to make it overall easier for an amputee to walk

The study showed that there is symmetry in step lengths for all the cases in overground walking. The knee at the lowest setting was the closest in emulating a normal symmetric step length. The swing times for overground walking showed that the healthy leg swings at almost the same rate in every trial and the leg with the prosthetic simulator can either be symmetric, like the healthy leg or has a higher swing time. Step lengths on the treadmill also showed a similar pattern, and step length of the low knee setting were the closest to the step length of normal walking.

Michael Telwak, B.S. May 2013 [16] Transfemoral amputees suffer the loss of the knee and ankle joints, as well as partial or complete loss of many of the lower extremity muscle groups involved in ambulation. Recent advances in lower limb prostheses have involved the design of active, powered prosthetic knee and ankle-foot components capable of generating knee and ankle torques similar to that of normal gait. The associated onboard motors, conditioning/processing, and battery units of these active components result in increased mass of the respective prosthesis. While not an issue during stance, this increased mass of the prosthesis affects swing. The goal of this study is to develop and validate mathematical models of the transfemoral residual limb and prosthesis, expand these models to include an active ankle-foot, and investigate counter-mass magnitude(s) and location(s) via model optimization that might improve kinematic symmetry during swing.

Single- (thigh only, shank only) and multi-segment (combined thigh and shank) optimization of counter-mass magnitudes and locations indicated that a 2.0 kg counter-mass added 8 cm distal and 10 cm posterior to the distal end of knee unit within the shank segment approximated knee kinematics of able-

bodied subjects. This location, however, induced artificial hip torques that reduced hip flexion during swing.

Casey Michael Barbarino June, 2013[17] Transfemoral amputees around the world experience increased difficulty in climbing stairs due to lack of muscle, balance, and other factors. The loss of a lower limb greatly diminishes the amount of natural force generation provided that is necessary to propel oneself up stairs. This study investigated possible solutions to the problem of stair ascension for transfemoral amputees by the means of designing and developing an externally attachable device to a prosthesis. The number of amputations from military service has greatly increased since 2008, which shows there is a clear need for assistive devices (Wenke, Krueger, & Ficke, 2012). With the number of amputations rising and no current externally attachable products on the market to aid in stair ascension for transfemoral amputees, the need for this specific device has become more prominent. Research, previous work, and preliminary testing provided a basis for design and development of a new prototype. Bench top testing was conducted to review concepts in the prototype and provide data for further modifications. Results from testing of previous work, as well as testing of new concepts and modifications, provided a framework for designing a new externally attachable device for assistance in stair ascension. A new prototype was then designed, manufactured, and tested with bench models as well as realtime testing with amputees.

GARRETT C. WAYCASTER,2010 [18] This paper describes the mechanical design for both a one and two degree of freedom above-knee (AK) prosthesis actuated by pneumatic artificial muscles. Powered prosthetics aim to improve the quality of life of the 50% of AK amputees who never regain the ability to walk. Pneumatic artificial muscle (PAM) provides great potential in prosthetics, since this type of actuator features a high power density and similar characteristics to human muscles. Currently, commercially available AK prosthetics are largely passive devices, and no research has been conducted on PAM actuators in AK prosthetics. In this thesis, the design requirements of an above knee prosthesis using PAM are discussed and a prototype one degree of freedom prosthesis with a PAM actuated knee joint is constructed. This prototype is then tested, and based on the results a new actuator is developed. This new actuator uses a flexible tendon and an elliptical pulley to improve torque, adding more functionality and increasing the maximum mass of a user by 25 kilograms. This actuator is also tested and compared to the initial prototype design. Finally, this new

actuator is incorporated into the design of a two degree of freedom prosthesis with an actuated ankle as well as the knee joint.

J. A. Campbell, 2002 [19] The materials choices for the components of an above knee prosthetic leg are dependant on the physical needs of the amputee and the functional requirements for the component. For a sprint athlete the weight, performance and durability are of great importance. For a landmine victim the simplicity of the design, the cost of the materials, the method and cost of manufacture are of greater importance. High performance components use lightweight, strong material such as titanium, carbon fibre, aluminium alloys, silicone and Kevlar. In less fortunate circumstances cheaper alternatives are used including wood, leather, steel and thermoplastics.

F. A. GOTTSCHALK and M. STILLS, 1994[20] The biomechanics of trans-femoral amputations has not been previously described. Little attention has been paid to the importance of adductor magnus in holding the femur in its normal anatomical axis. Loss of function of adductor magnus leads to abduction of the residual femur, in a trans-femoral amputation. A cadaver study of the adductor group of thigh muscles has been done and the biomechanical importance of these muscles is documented. The moment arms of the three adductor muscles have been determined, based on muscle attachments and muscle size, relative to each other. Adductor magnus has a major mechanical advantage in holding the thigh in its normal anatomical position. Loss of the distal third of its attachment results in a 70% loss of the effective moment arm of the muscle, which contributes to the abducted femur in standard trans-femoral amputations. A muscle preserving trans-femoral amputation, which keeps adductor magnus intact, prevents abduction of the residual femur and may allow for easier walking with a prosthesis. The conflicting reports about adductor magnus activity during the gait cycle can be explained by this muscle's dual innervation by the sciatic and obturator nerves and its dual function as a hip adductor and extensor.

Kerstin Hagberg, RPT, PhD; Rickard Brånemark, MD, PhD, 2009[21]

Treatment with osseointegrated transfemoral prostheses has been shown to improve quality of life. The treatment has been performed in Sweden since 1990 and consists of two surgical procedures followed by rehabilitation. During the first years, the rehabilitation process was not standardized. In 1999, a treatment protocol called OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) was established. This article describes the current rehabilitation protocol and illustrates the overall results. The OPRA rehabilitation protocol is graded to stimulate the process of osseointegration

and prepare the patient for unrestricted prosthetic use. It includes initial training with a short training prosthesis followed by gradually increased prosthetic activity. Between May 1990 and June 2008, we treated 100 patients with 106 implants (6 bilaterally; 61% males, 39% females; mean age 43 years; mean time since amputation 11.5 years.) The majority had amputations due to trauma (67%) or tumor (21%) (other = 12%). Currently, 68 patients are using their prostheses (follow-up: 3 months– 17.5 years) and 32 are not (4 are deceased, 7 are before second surgery, 6 are in initial training, 4 are not using prosthesis, and 11 had the implant removed). The majority of treatment failures occurred in patients before we established the OPRA protocol. The implementation of graded rehabilitation is considered to be of utmost importance for improved results.

CHAPTER THREE

THEORETICAL CONSIDERATION

3.1 Introduction

The locomotion biomechanics study provides very extensive and interesting material for investigating the physiological process involved and the neural mechanisms controlling the systems. Gait analysis – the systematic analysis of locomotion – is used today for pre-treatment assessment, surgical decision making, postoperative follow-up, and management of both adult and young patients.

In this chapter, the gait cycle, Prosthesis Alignment, biomechanics, Suspension methods and ground reaction force are studied to know the problems of the pathological gait parameters.

3.2 Biomechanical Requirement

The magnitude of pressure between the stump and socket imposes major determinants of comfort, stability and any function . Prosthesis biomechanics studies the relationship between the socket and the stump such as the socket shape and alignment [22]. Also, the pressure from the weight bearing of the amputee on the socket or on each component of prosthesis and the reaction forces from the ground at heel strike, foot flat and push off Pressure is directly proportional to the forces applied. It is expressed in formula($\sigma = F/A$) which represents the average stress and **F,A** represents the force and the area over which the force is applied respectively.The comfort stability and function of prosthesis are achieved primarily by the application of certain biomechanical stress [23].

The diagram in **Fig.(3-1a)** illustrates a schematic representation of stump that has essentially circular cross section encased in a socket that accurately matches the periphery of the stump .If the stumps were of uniform firmness, the stump – Socket pressure would also be uniform .The diagrams in **Fig.(3-1b)** and **Fig.(3-1c)** are similar to that in **Fig.(3-1a)** except that there is no uniform firmness. The areas indicated by the letter “**F**” are relatively firm, while softer areas are indicated by the letter “**S**”. This, of course, is a schematic diagram and the indicated areas represent, but do not designate, specific firm and soft areas on the actual stump. If the socket is shaped to match the stump accurately the pressure on the stump would not

be evenly distributed. A more even distribution of pressure could be obtained by purposely modifying the socket.

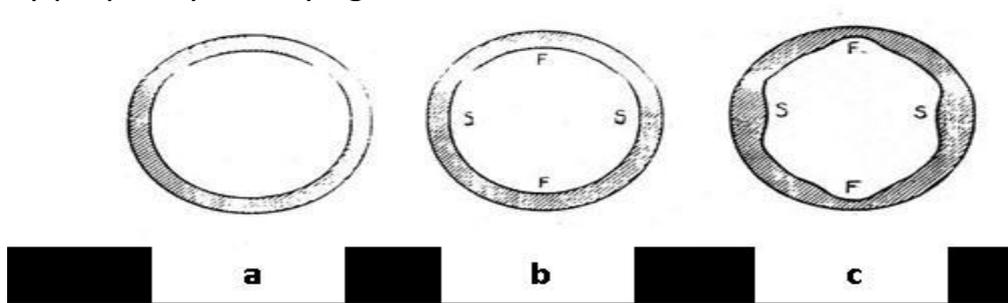


Figure (3-1) Top view of Trans -Femral socket[23]

a) **a-Top** view as circle with thickness **t**.

b) **b-Top** view with uniform distribution load **S** and **F**.

c) **c-Top** view with non-uniform distribution load **S** and **F**.

Socket shape is important in determining the load distribution and how to distribute the load which depends on the tolerant ability of the limb tissues. For prosthetic socket design, the optimal load distribution should be proper to the ability of body to sustain stresses. Stresses at the interface of a residual limb and prosthetic socket are important aspect of prosthetic fitting. If the pressure (stresses perpendicular to the interface) and **shear stresses** (stresses in the plane of the interface) are not properly distributed then pain, discomfort and residual limb soft tissue break down occur [24].

3.3Socket design

The two most common types of TFA sockets are the quadrilateral and ischial containment sockets. The objective of both designs is to use femoral flexion and adduction so as to have the hip extensors and abductors at a functional length. The design choice depends on the length of the patient's residual limb, functional strength of the remaining. musculature, ability to balance, and prosthetist preference

The quadrilateral socket, as the name implies, consists of four walls: posterior, anterior, medial, and lateral .The posterior wall contains a small, horizontal shelf used as a weight bearing surface for the ischial tuberosity. The anterior wall extends superiorly to the ischial seat and provides pressure needed to maintain contact with the posterior wall. The medial wall of the socket provides a counterforce for the remnant tissues and musculature, while

the lateral wall places the femur in adduction. This type of socket is typically recommended for patient with a long residual limb and strong remnant musculature.

The ischial-containment socket is typically prescribed for active TFAs with short, fleshy residual limbs. This socket contains a wide anterior-posterior and narrow mediolateral dimensions to maintain adduction of the femur. Unlike the quadrilateral design, high posterior and medial walls encase the ischial tuberosity within the socket. This containment provides a mechanical lock between the ischium, trochanter, and lateral femur, preventing mediolateral translation and more effective distribution of forces on the residual limb[25][26].

3.4 The Gait cycle

Gait is the medical term to describe human locomotion, or the way that we walk. Interestingly, every individual has a unique gait pattern as shown in Fig.3-2.

3.4.1 Phases of Gait Cycle

The gait cycle is mainly divided into two phases which are in turn sorted into sub phases, the two gait phases and their stages will be described in detail.

3.4.1.1 The Stance Phase

Start from initial contact (Heel strike) to toe off, nearly which represents about 60 % gait cycle, in two periods of double stance 10 % each the body's center of gravity is at its lowest. The stance phase is divided into five sub-phases.

A. Initial Contact (Heel Strike)

At initial contact, the knee is extended and the ankle neutral (or slightly plantar flexed) normally, the heel contacts the ground first (in patients with pathological gait patterns, the entire foot or the toes contact the ground initially).

B. Loading Response

The loading response corresponds to the gait cycle's first period of double limb support and ends with contra lateral toe off, when the opposite extremity leaves the ground.

C. Mid Stance

The next phase is the mid stance phase which represents 30 percent of the cycle, in this phase the body weight passes over foot as the body comes forward. This is where foot (in this case the right foot) supports the body weight.

D. Terminal Stance

Terminal stance is the second half of the single support from 30 to 50 % of the gait cycle and is defined as the time from heel rise until the other limb makes contact with the floor. During this phase body weight moves ahead of the forefoot.

E. Pre-Swing

Pre-swing is the final double support stance period which is defined from the time of initial contact with the contra lateral limb to ipsilateral toe-off. [27],[28].

3.4.1.2 The Swing Phase

Swing phase called the “non- weight bearing” phase begins as soon as the big toe of one limb leaves the ground (after toe off), and finishes just prior to heel strike or contact of the same limb.

A. Initial Swing

The initial swing(acceleration) from 60 to73 % of the gait cycle as defined from toe-off to when the swing limb foot is opposite the stance limb. Forward momentum is provided by the ground reaction to the push off action (when the heel is off the ground but the toes are in strong contact with the ground).

B. Mid Swing

Mid swing is the middle third of the swing phase from 73 to 87 % of the gait cycle as defined from the time the swing foot is opposite the stance limb to when the tibia is vertical.

C. Terminal Swing

Terminal swing is the final third of the swing phase from78to100% of the gait cycle as defined from the time when the tibia is vertical to initial contact. The momentum slows down as the limb moves into the stance phase again.

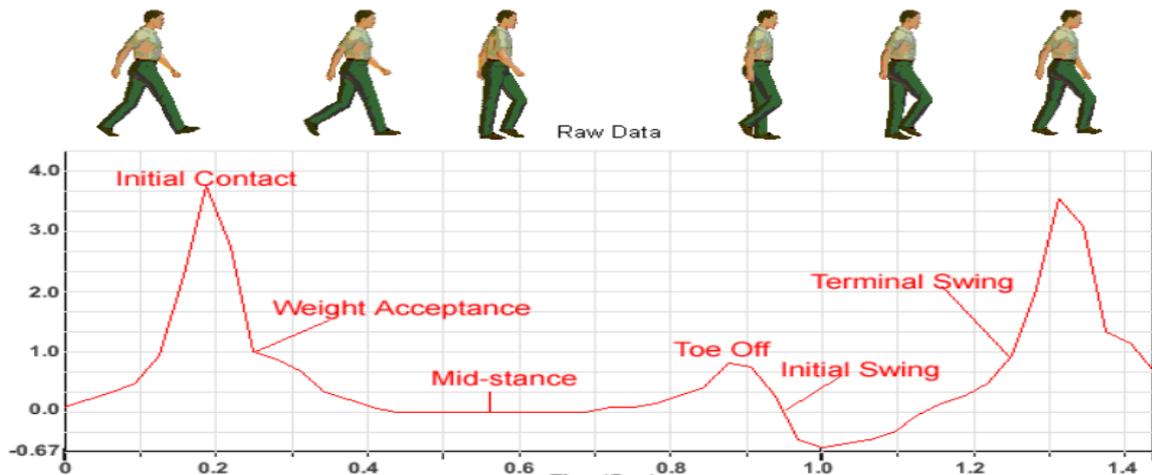


Figure 3-2 Gait Cycle Measured by the Sensor from Right Foot[27]

3.5 The Ground Reaction Force

Ground reaction forces (GRF) develops during gait as a result of the force applied to the ground when the foot is in contact with it. GRF is equal and opposite to the force that the foot applies on the ground. Since GRF is external force acting on the body during locomotion, it is of great interest in gait analysis.

A typical plot of the vertical ground reaction force through one gait cycle is sometimes called the M curve because it resembles the shape of that letter refer to Figure 3-3. F_z Reaches a maximum of 120% body weight during the double stance phase and drops to about 80% body weight during single stance.

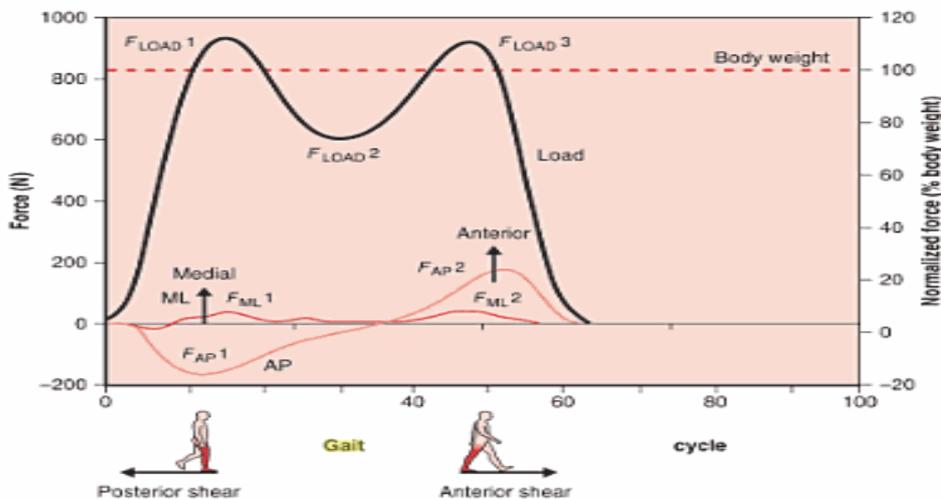


Figure 3-3The three components of GRF

Figure 3-3The three components of GRF during normal gait. F_z , the vertical component of GRF, is here referred to as F_{LOAD} . F_{AP} represents the anterior/posterior force component of GRF, and F_{ML} its medial [29].

3.6 Prosthesis Alignment

The alignment of a lower-limb prosthesis depends on the spatial relationship of the socket relative to other components of the prosthesis, such as the knee joint and foot unit, and these alignments are critical to the successful utilization by the user. Optimal prosthetic alignment is achieved in three steps: bench, static, and dynamic alignment.

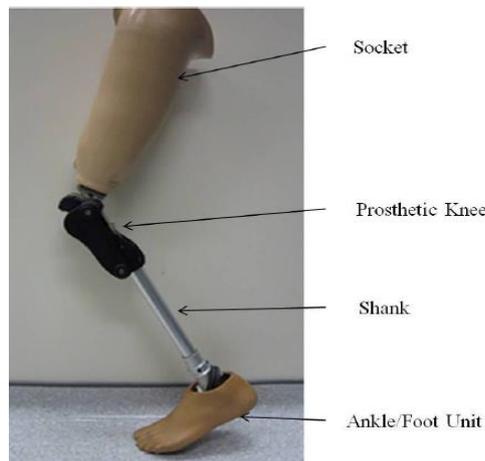


Figure 3-4 Lower-limb prosthesis[30]

3.6.1 Bench alignment: is the process of configuring the prosthetic components without the patient. Typically, manufacturers of prosthetic components such as knees and feet provide recommendations for how they should be attached together and to the prosthetic socket. The prosthetist will use this information in conjunction with his or her experience and knowledge of the patient to make an initial estimate of a well-aligned prosthesis.

3.6.2 Static alignment: is done with the patient standing in the prosthesis with the body weight distributed equally on both extremities. An alignment Common types of alignment reference line include the Trochanter, Knee, and Ankle (TKA) line and the weight bearing (WB) line. Generally, the more posterior the knee center is to the reference line, the more stable the prosthesis will be. However, the more posterior the knee is with respect to the reference line, the more difficult the knee will be to flex in terminal stance. A suitable balance between safety, stability, and control is desired.

3.6.3 Dynamic alignment is the process of aligning the prosthesis based on observing the amputee walk while wearing the prosthesis. One main goal of dynamic alignment is to identify how the prosthetic limb is used and controlled by the amputee. Gait deviations that may be a result of malalignment are identified and addressed. The position and orientation of the knee, foot, and pylon are adjusted to achieve a more normal gait pattern.[30]

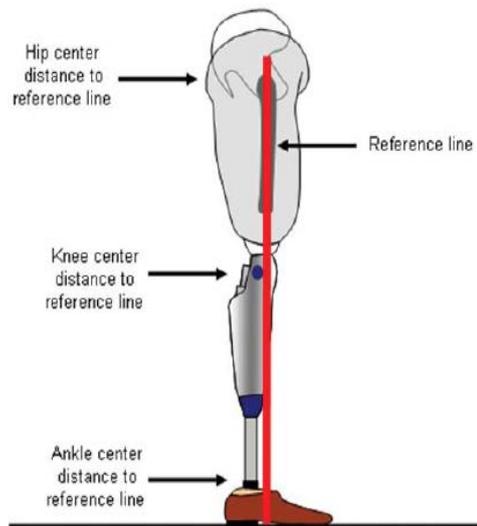


Figure 3-5 – Alignment reference line[30]

Although the basic socket alignment has been established during fabrication of the prosthesis, minor adjustments should be made during the dynamic alignment process. The most common of these is the AP and ML placement (placement of the socket relative to the knee, shin, and foot components). This adjustment is often made when the amputee is able to ambulate for longer periods of time and has established a “normal” pattern of prosthetic gait. This process of dynamic alignment may require several sessions and should incorporate navigating community barriers such as uneven terrain, stairs, and inclines.

The physical therapist can conduct an evaluation of alignment during rehabilitation activities and provide feedback to the prosthetist to assist in dynamic alignment. This is the best time for the physical therapist and the prosthetist to interact to help the amputee achieve optimal gait and function. Often it is difficult to determine the cause of the gait deviation, which may be poor prosthetic fit, malalignment, muscle weakness, limb length or patient habit [31].

3.7 Suspension System

The prosthetic suspension system keeps the prosthesis securely attached to the residual limb, maintaining the prosthesis in an optimal functional position while supporting the weight of the knee and ankle-foot components. Proper suspension assists in minimizing movement of the residual limb within the socket to achieve stable and efficient gait. The five types of suspension systems prescribed for TFAs include an external hip joint and pelvic band, supplemental Silesian belt, supplemental total elastic suspension (TES) belt, suction suspension with expulsion valve, and liner suction with locking pin[33][34].

3.7.1 The hip joint and pelvic band suspension consists of a metal pin joint positioned over the anatomic hip joint and attached to a leather-lined pelvic band resting on the iliac crest. Fixation of the joint in the sagittal plane provides rotational control and increases medial-lateral stability of the residual limb within the socket. This form of suspension is typically prescribed for TFAs with short residual limbs. Poor cosmetic appearance, increased weight, and potential discomfort in the seated position do not make this form of suspension highly favored

3.7.2 A Silesian belt is another method of suspension which wraps around the pelvis and is anchored to the socket. This configuration provides supplemental rotational control of the residual limb within the socket. A Silesian belt is commonly used in combination with suction suspension for active TFAs with short residual limbs.

3.7.3 The TES belt is made of an elastic neoprene material. This method of suspension fits around the proximal socket and encircles the waist. The TES belt prevents excessive limb pistoning by distributing pressure over a greater area. This form of suspension may be comfortable for low activity levels, but the associated heat retention can be problematic for active TFAs. TES belts are typically used as a supplemental means of suspension as it provides easy donning and doffing of the prosthesis

3.7.4 Suction suspension is the most frequently used form of suspension, providing total contact of the residual limb with the socket, improving prosthetic limb control, and enhancing proprioception during ambulation. The two types of suction suspension include the traditional suction with expulsion valve and more recent gel liner with locking pin. In traditional TF suction suspension, the residual limb is wrapped with an ace bandage or pull sock and placed into the socket. The bandage or sock is then removed through a hole located at the distal end of the socket. A one way air expulsion valve is then screwed into place, sealing the hole. Loading of the prosthesis allows additional air to escape, securing the residual limb within the socket. This suspension method requires that the residual limb volume is stable. For liner suction suspension system, a silicone liner with a distal locking pin provides a stable mechanical lock between the residual limb and prosthesis. The liner is rolled over the residual limb, creating a suction fit between the residual limb and silicone liner. The locking pin is then inserted into the socket, locking the residual limb in place via a mechanical linkage[32][33][34].

3.8 The Numerical Analysis

The finite element method (FEM) is now widely used in a variety of fields of engineering and science. Taking the advantage of the rapid development of digital computers with large memory capacity, as well as, fast computation. The method is recognized as one of the most powerful numerical methods because of its capabilities which include complex geometrical boundaries and non-linear material properties. In this work, FEM with aid of ANSYS Workbench 15 software is used as a numerical tool to illustrate the effect of the fatigue performance in a structure element. It is used to determine the behavior of maximum stress, total deformation, fatigue life and safety factor [48].

The general analysis used by ANSYS has three distinct steps which are;

- Building the geometry as a model.
- Applying the boundary conditions load and obtaining the solution.
- Reviewing the results.

3.8.1 Building up The Geometry

The ultimate purpose of a finite element analysis is to re-create mathematically the behavior of an actual engineering system. In other words, the analysis must be an accurate mathematical model of a physical prototype. In the broadest sense, the model comprises all the nodes, elements, material properties, real constants/boundary conditions, and other features that are used to represent the physical system [49].

With solid modeling, the geometric boundaries can describe the model, with established controls over the size and desired shape of the elements automatically. By contrast with the direct generation method, the location can be determined for every node, size, shape, and connectivity of every element

prior to defining these entities in the model. The solid modeling is usually more powerful and versatile than direct generation .It is commonly the preferred method for generating models. Alternatively, the model can be created via SOLIDWORKS in which the model is drawn in details then exported to ANSYS easily. Mainly, ANSYS Workbench 15 deals with ACIS (.sat), Mechanical desktop (.dwg), solid works (.SLDPRT, .SLDASM) ...etc. Therefore the ACIS with extension (.sat) was selected for exporting process as a command in SOLIDWORKS system. finally, the model can be imported from SOLIDWORKS system to ANSYS Workbench 15 according to its extension (.sat).

3.8.2 Determination of The Geometry

In this thesis, types of above knee prosthesis (AK) models, are used as it will be explained in chapter four. The procedure of using ANSYS Workbench program. for above knee prosthesis (AK) model, is illustrate in the Fig. 3-6.

This model was drawn by using SOLIDWORKS system, which fabricated according to an original prototype in three dimensions. Most of the small details in were taken into account at drawing this model.

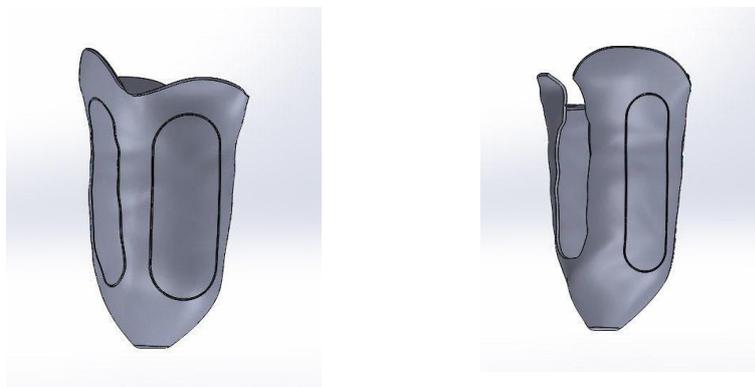


Figure 3-6 AK models which used in this work.

3.8.3 Creation of Mesh in The Model

The meshing process has been done by choosing the volume, and then the shape of element was selected as tetrahedron (Automatic meshing), as shown in Fig. 3-7. The total number of elements was (21848 elements) with total a number of nodes of (41504 nodes).

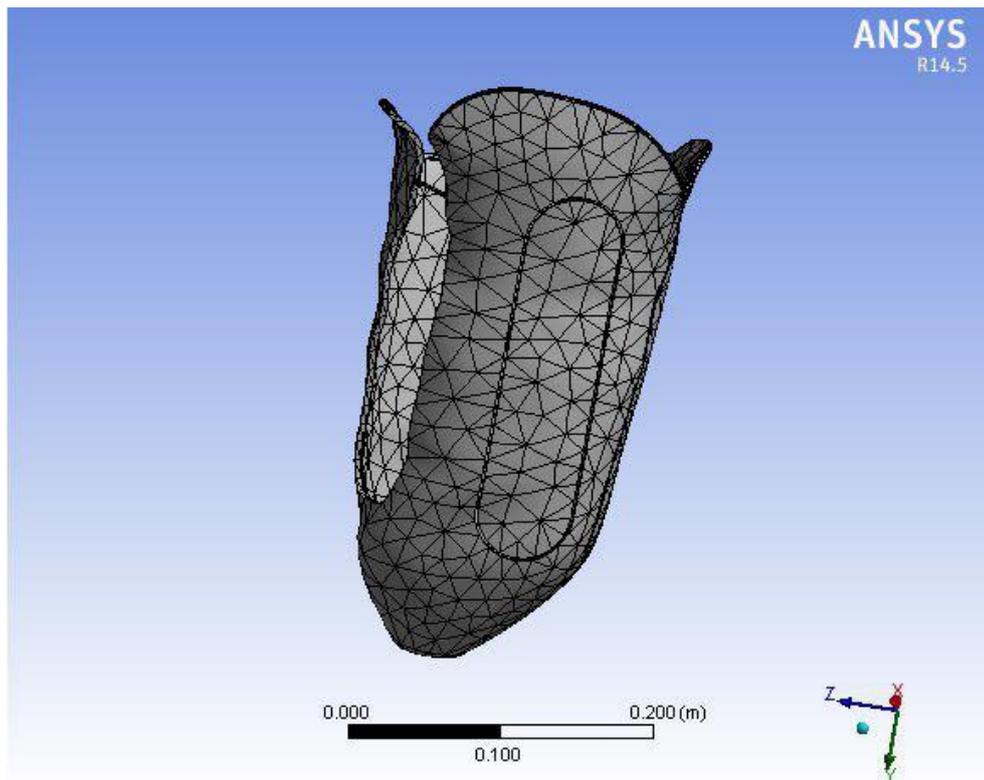


Figure 3-7, The model of AK with meshing.

3.8.4 Defining The Analysis Type and Applying Load

The term 'load' includes the boundary conditions (constraints, supports, or boundary field specification), as well as other externally and internally applied loads. The load used in the ANSYS Workbench software will be fixed support at the sides of the anterior AK segments. While, the interface pressure was distributed according to the particular positions, as shown in Figure 3-8.

For fatigue solution, the fatigue tool is used to find the equivalent stress, maximum shear stress, total deformation, safety factor, and life at particular loads.

The ANSYS workbench consists of the following sequence:

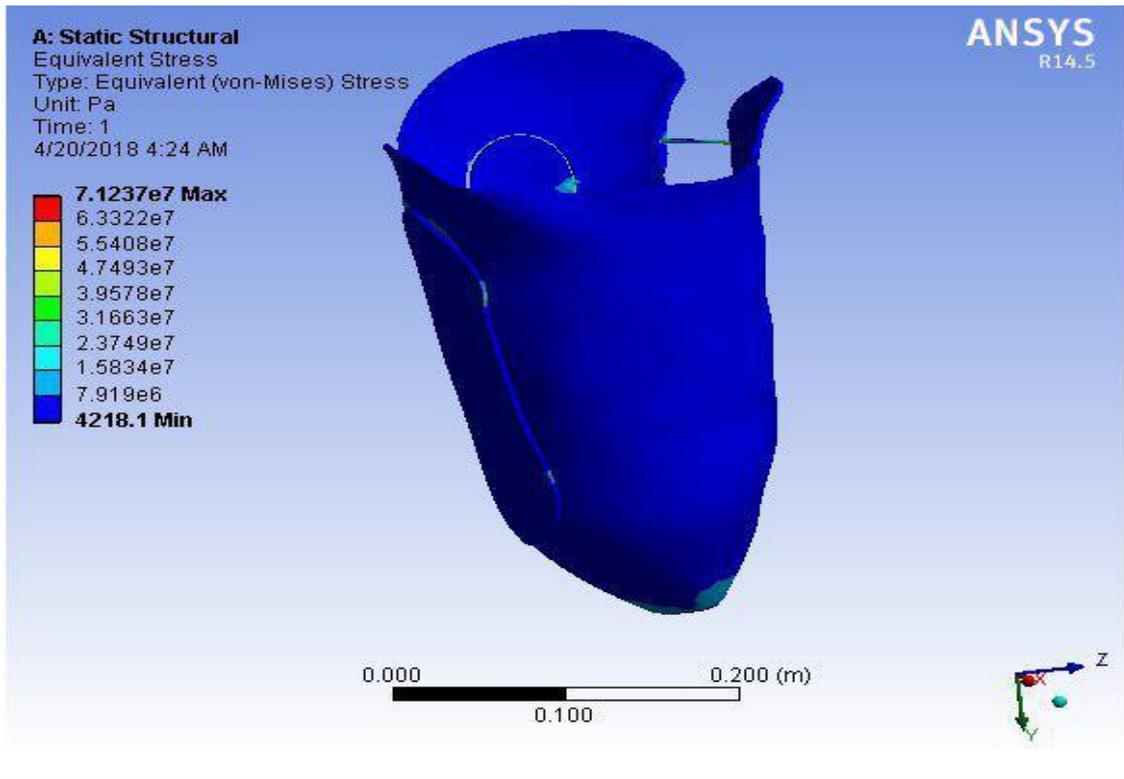
The first is the drawing of the geometry (AK model), then transforming into meshing options (mesh generation), and finally by using the map of analysis types option the fatigue analysis can be selected. In order to complete the total solution of this case, many important parameters are added, such as Young's modulus, Poisson ratio, tensile yield stress, ultimate stress, and alternating stress. It is important to mention that, the fatigue analysis used in the present work is based on Soderberg theory. The main relation for fatigue safety factor are:

$$S_a = S \left[1 - \left(\frac{S_m}{S_y} \right) \right] \quad \text{Soderberg's law}$$

Where: S_y ; static yield strength, S_m ; the mean stress, S_a ; is the alternating stress, and S ; is the alternating fatigue strength.

The life for the fatigue failure which used for the numerical analysis is based on the 10^6 cycle's life which is used in the ANSYS package.

After providing all the required parameters mentioned above followed by running ANSYS software, the theory of failure of all the materials used in this



thesis will be assumed according to Von Mises theory.

Figure 3-8 The model subjected to pressure load.

CHAPTER FOUR

EXPERIMENTAL WORK

4.1 Introduction

This chapter deals with materials and apparatus used in this research work as well as the experimental procedure , The main outline of the experimental work is as follows;

- 1- Selection of materials from which prostheses are made.
- 2- Evaluation the Mechanical properties of the AK materials.
- 3- Investigating the (S-N) curve of fatigue for the AK materials.
- 4- Designing and manufacturing procedure of the AK prosthetic socket by revo fit solution.
- 5- Comparing gait cycle and the ground reaction force testing with the other parameters by using force plate.
- 6- Determining the interface pressure between the leg and the brace by using F-socket.

4.2 The Materials Used in The Research

The materials that used in the manufacturing of different types of AK in this thesis are as follows and shown in Fig. 4-1.[35]

- 1- Carbon fiber (ottobock health care 616G15).
- 2- C-orthocryl lamination resin for use with carbon fiber.
- 3- Hardening powder (ottobock health care 617P37).
- 4- Polyvinyalcohol PVA bag (ottobock health care 99B71).
- 5- Materials for Jepson.

Table 4-1 The mechanical properties of some material used in this study [36].

Materials	Ultimate strength(MPa)	Modulus of elasticity (GPa)	Strain to failure%
Carbon fiber	2070-2750	10-380	1.6-2



Figure 4-1 Materials used for AK Manufactured

4.3 Specimens Preparing For Mechanical Properties

To measure the mechanical properties, specimens were prepared according to the steps shown in Fig. 4-2. The method of preparation of composite specimen is called vacuum method which prevents cavities or defects and it is as follows:

- 1- Mounting the positive mold (Jepson manufactured with size 10*15*25 cm³) at the laminating stand and completing the connection with the vacuum forming system through the pressure tubes and pulling the inner (PVA)bag in the positive mold and opening the pressure valves to value of approximately 30 mm Hg at room temperature.
- 2- Putting the carbon fiber(4 carbon fiber)layers and pulling the outer (PVA) keeping the smaller end positioned over the value area using cotton string to tie off the (PVA) bag.
- 3- Mixing the C-orthocryl lamination resin for using with carbon fiber with the hardener about(500-600)ml of resin mixed with(1-2) part of hardener and then putting the resulting matrix mixture inside the outside (PVA)bag and distributing the matrix homogeneously over all area of lamination.
- 4- Maintaining constant vacuum until the carbon fiber materials becomes cold and then lifting the resulting lamination.
- 5- Cutting the carbon fiber materials sheet after cold by special tool (vibrational cutter) to manufacturing samples for tensile and fatigue testing.



A. Vacuum device

B. Carbon fiber block

Figure 4-2 Stages of preparing the specimens of carbon fiber material

4.4 Mechanical Properties Tests

Testing the samples is implemented by using the Testometric machine (Al-Nahrain University / mechanical Engineering). the tensile and Fatigue test was carried out by Hi-TECH device.

4.4.1 Tensile Test

All tensile test samples tested using the universal testing instrument (testometric). For the carbon fiber pice the cross head speed is 5mm/min. Fig. 4-3 shows samples under tensile test. Therefore, the specifications of the tensile test have been restricted according to the American Society for Testing and Materials specifications (ASTM); the tensile specimen's geometry and dimensions for standard (D638) [37] was specified for carbon fiber, as shown in Fig. 4-3.



Figure 4-3 Tensile test device.

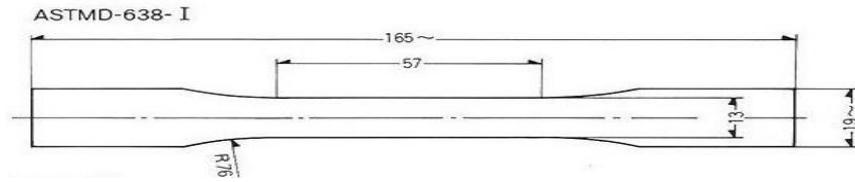


Figure 4-4 The general shape and dimensions of tensile specimens.

4.4.2 Fatigue Test

The type of fatigue testing machine is alternating bending fatigue with constant amplitude as shown in Fig 4-5. The specimens were subjected to deflection perpendicular to the axis of specimens on one side of the specimens, and the other side was fixed to develop the bending stresses. So, the surfaces of the specimens are under tension and compression stresses when the machine rotates. The fatigue specimens have the geometry as described in Appendix A. The dimensions of samples are length 100mm and width 10mm according to the fatigue device test while thickness varies with the type of lay up. Fig 4-6 shows the shape and dimensions of fatigue samples.

A dial gauge was used to measure the deflection; their values were used to determine the maximum alternating bending stress. The S-N curves were obtained with and without temperature effect.

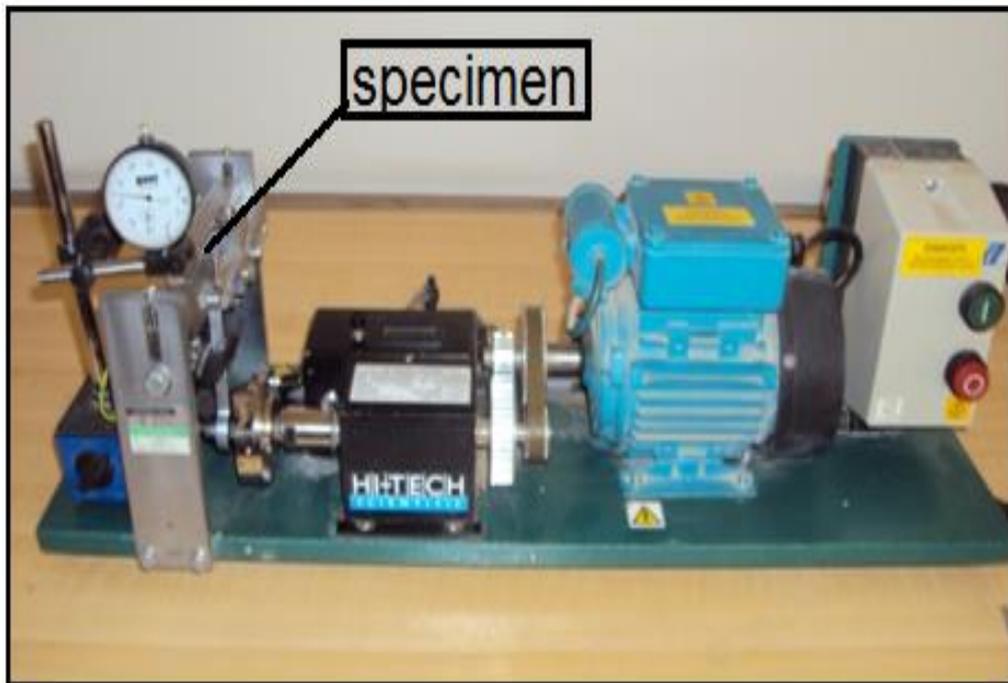


Figure 4-5 Fatigue test device.

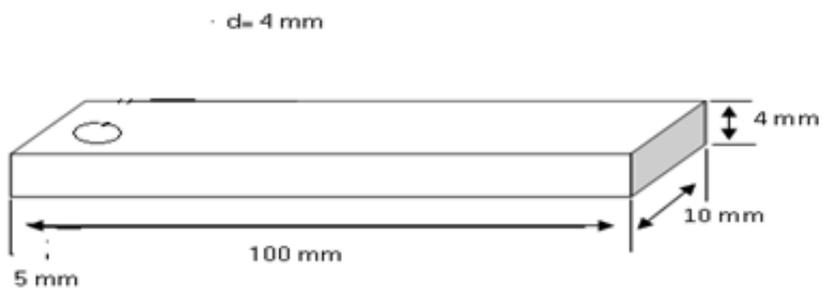




Figure 4-6 The general shape and dimensions of fatigue specimens.

4.5 Case Study

Measurement were collected for patient is about (42)year old suffered from right leg above knee amputation due to explosion, as shown in Fig 4-7.



Figure 4-7 The case study

4.6 Manufacturing Procedure of above knee prosthetics

After previewing the patient by the prosthtist,take measurement and knowing the ability of the patient to rehabilitation, the description of the prosthtist will limit the type of prosthesis that is to say, AK.

The manufacturing process for AK will be explained in the following steps:

- 1- Mounting the positive mold at the laminating stand according to the dimensions of the patients suffering from above knee amputation and completing the connection with the vacuum forming system through the pressure tubes, Fig 4-8a. pulling the inner (PVA) bag in the positive mold, Fig 4-8b. and opening the pressure valves to value Fig 4-8 shows the mold of AK prosthetics.



(a)



(b)

Figure 4-8 Positive mold of (AK).

2- Putting the 2 layers of carbon fiber as shown Fig. 4-9a.pulling the outer (PVA) keeping the smaller end positioned over the valve area by using cotton string to tie off the (PVA) bag as shown Fig. 4-9b.



(a)



(b)

Figure 4-9 manufacturing of (AK).

3- Mixing the C-orthocryl lamination resin for using with carbon fiber with the hardener about(800-900)ml of resin mixed with(2-3) part of hardener and then putting the resulting matrix mixture inside the outside (PVA)bag and distributing the matrix homogeneously over all area of lamination Fig. 4-1 shown lamination used for manufacturing above knee prosthesis(AK).



Figure 4-10 Lamination used for manufacturing (AK).

- 4- Maintaining constant vacuum until the carbon fiber material becomes cold and then left the resulting lamination and cutting the increase that will not required and will the wedge smooth as shown in Fig. 4-11.



Figure 4-11 cutting and smoothing for manufacturing (AK).

- 5- Drawing the place of revo fit solution, fixing this device and draw the place of cutting in several part of the socket as shown in figure 4-12.

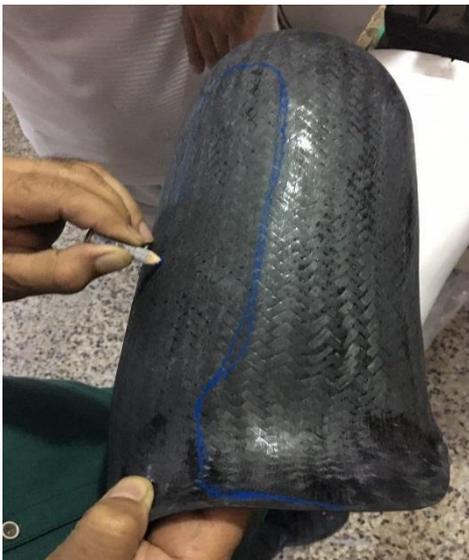


Figure 4-12 drawing and fixing for REVO FIT device.

- 6- Fixing the socket adapter and Close the cavity of the socket adapter and fix with carbon straps as shown in figure 4-13.



Figure 4-13 fixing for socket adapter.

- 7- Putting the 3 layers of carbon fiber on first mold also putting the outer PVA to keeping lamination resin and operating the vacuum to pulling any air, bubbles to get good socket and smooth as shown in figure4-14.



Figure 4-14 secondary operation molding.

- 8- Cut through the laminate around the proximal brim leaving a margin of approx 2 cm using electric cast cutter and remove the dummy from the socket adapter.
- 9- After secondary molding socket drawing the cutting region as shown in figure 4-15a, and we drilling a circle hole to putting the valve device to outflow the air that between stump and socket as shown in figure 4-15b.



(a)



(b)

Figure 4-15secondary manufacturing of (AK).

10- Finally Assembly of AK Prosthesis after smoothing the socket.



Figure 4-16 final socket of (AK).

4.7 Gait Cycle and Ground Reaction Force Testing (GRF)

Gait cycle analysis was done in the laboratories of the P&O department of Al-Nahrain University on force plate (Tekscan's Walkway Pressure Assessment Systems) .

The Walkway system provides static and dynamic gait data and barefoot pressure and force measurements over several steps using a low profile floor walkway. It is ideal for capturing multiple foot strikes during natural or perturbed gait, the Walkway system is the essential tool for plantar pressures and gait studies for adult and pediatric patients, as well as the animal research as shown in the Fig. 4-17.

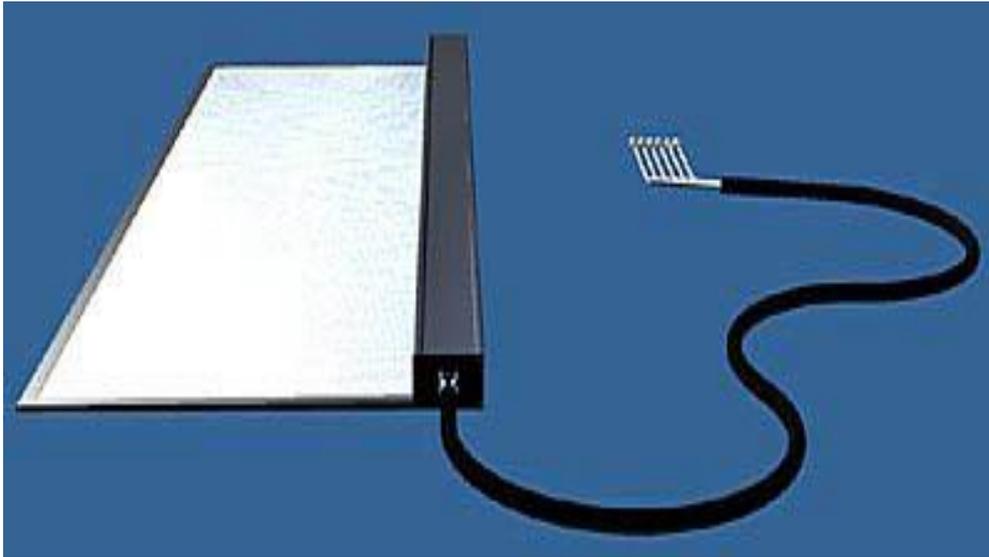


Figure 4-17 The force plate (Walkway).

The ground reaction force (GRF) introduced under sole, due to biomechanical effects on leg during gait and stance cases. The obtained data were compared between the defectived right leg (drop foot) with the normal left leg. Stance and swing phase were giving the behavior of gait cycle. The GRF exhibited the difference between the gait pattern for both right and left leg, and this added to these data. The pressure distribution under the insole when the subject wearing his shoes for both feet. The stride length, cadence and the center of pressure (COP) were collected too. All these data are compared with a standard gait cycle by using normal subject data. Fig. 4-18 show the patients walking on force plate with and with AK.



(a)



(b)

Figure 4-18 The patient with and with AK.

4.8 The Interface Pressure By Sensor of F -Socket Testing

The alternating load between the calf and patient's leg, who was wearing the AFO, was measured as pressure. The sensor type (MatScan) is more acceptable for this type of dynamic load, as shown in Fig. 4-19.



Figure. 4-19 The MatScan sensor.

The MatScan sensor detects subject's plantar pressure. This sensor is made of over 2,000 individual pressure-sensing locations, which are referred to as "sensing elements" or "sensels." The sensels are arranged in matrix on the sensor. Each sensel can be seen as an individual square on the computer screen by selecting the "2-D" display mode. The output of each sensel is divided into 256 increments, and displayed as a value in the range of 0 to 255 by the software. The "map" number (3150) identifies the sensor type. The software uses a "map" to convert the pressure detected by the hardware to the pressure data displayed in the Real-time window. For more information, refer to the MatScan Sensor section.

The interface pressure was obtained by recording the output signal of the sensor through a multi-meter instrument which is interface with the computer and recording the data with the time. Fig. 4-20 shows the patients walking with MatScan and AK.



Figure 4-20 Patients walking with MatScan and AK.

CHAPTER FIVE

RESULT AND DISCUSSION

5.1 Introduction

In this chapter, the results of the experimental work for the AK prosthetic material will be shown for the tensile and fatigue test. The results of the gait cycle (GRF, Pressure distribution, force distribution, peak contact area , peak contact pressure Center of Pressure (COP), Gait analysis , step-stride , gait cycle tables and foot print analysis) and From F-socket device measure the interface pressure by sensor between the stump and the socket of AK prosthetic. will show the major difference between the pathological subject (amputee for above knee), who AK prosthetic. The analysis of the kinematics data will indicate the differences of the behavior for the gait cycle between the normal and pathological subject.

5.2 Mechanical Properties Results

The results of the mechanical properties (tensile and fatigue test) for the AK prosthetic materials will be presented separately:

1. Tensile properties results

The results of the mechanical properties (tensile test) of the socket materials are shown in Table(5-1), The specimens for carbon fiber were tested to get stress-strain curve. Fig. 5-1 show the stress-strain curve for a sample of the carbon fiber.

Table 5-1 Mechanical properties of socket materials

Material of socket	Thickness(mm)	σ_y (MPa)	σ_{ult} (MPa)	E (GPa)
Carbon fiber(4-layer)	3.6	135	213	3.5

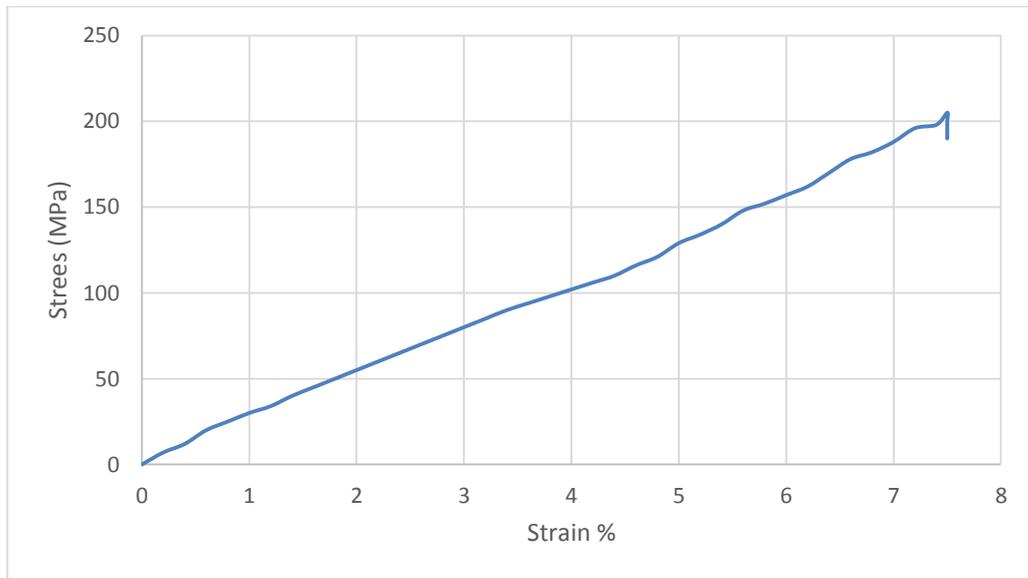


Figure 5-1 Stress-strain curve for carbon fiber.

2. Fatigue test result

Table 5-2, as shows the test fatigue readings obtained from the process have been presented in the chapter fourth, which contains the number of cycles failure per sample by fixed of the length (dimension you install the sample for a free edge) of each sample model with the change in the output of the stress samples per model by relationships deformity and the laws based on the obtained results of tensile testing and figure 5-2, show the S-N curves for sample of carbon fiber.

Table 5-2 Fatigue readings and results for carbon fiber materials.

Sample NO	Stress MPa	N of cycle	Log N
1	225	3529	3.547
2	210	5617	3.749
3	195	18445	4.265
4	180	35607	4.551
5	165	69927	4.844
6	150	217500	5.337
7	135	453618	5.656
8	120	652148	5.814
9	105	794514	5.9
10	90	1000597	6

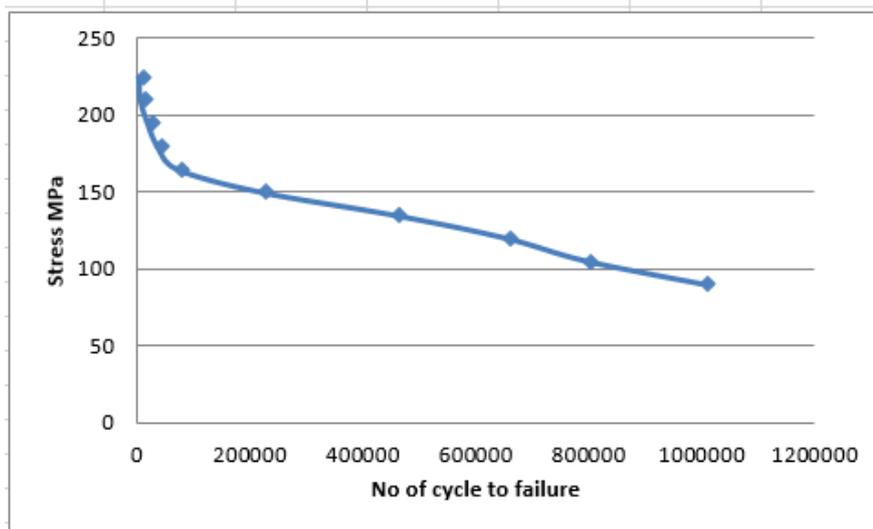


Figure 5-2 S-N curve for carbon fiber.

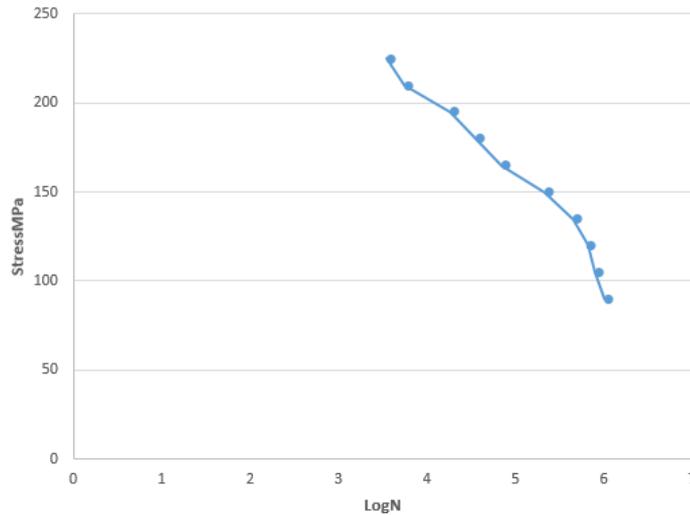


Figure 5-3 S-Log N curve for carbon fiber.

5.3 Interface Pressure between the Stump of Patient and Socket

The pressures are only considered over the gait cycle by contact method between the stump and socket. The data are normalized to 100 percent of gait cycle. The pressure for subjects are different at weight acceptance from one patient to another. The experimental part of case study with transfemoral amputee wearing AK prosthetic. The results show that the maximum value of interface pressure between the stump and socket, The figure(5-4) as showing the pressure distribution in socket material and relation between force and time ,table (5-3) showing the magnitude of pressure about socket region.

Table 5-3 readings and results for **IP**

Socket regions	Anterior	Lateral	Posterior	Medial
IP(Kpa)	222	204	193	170

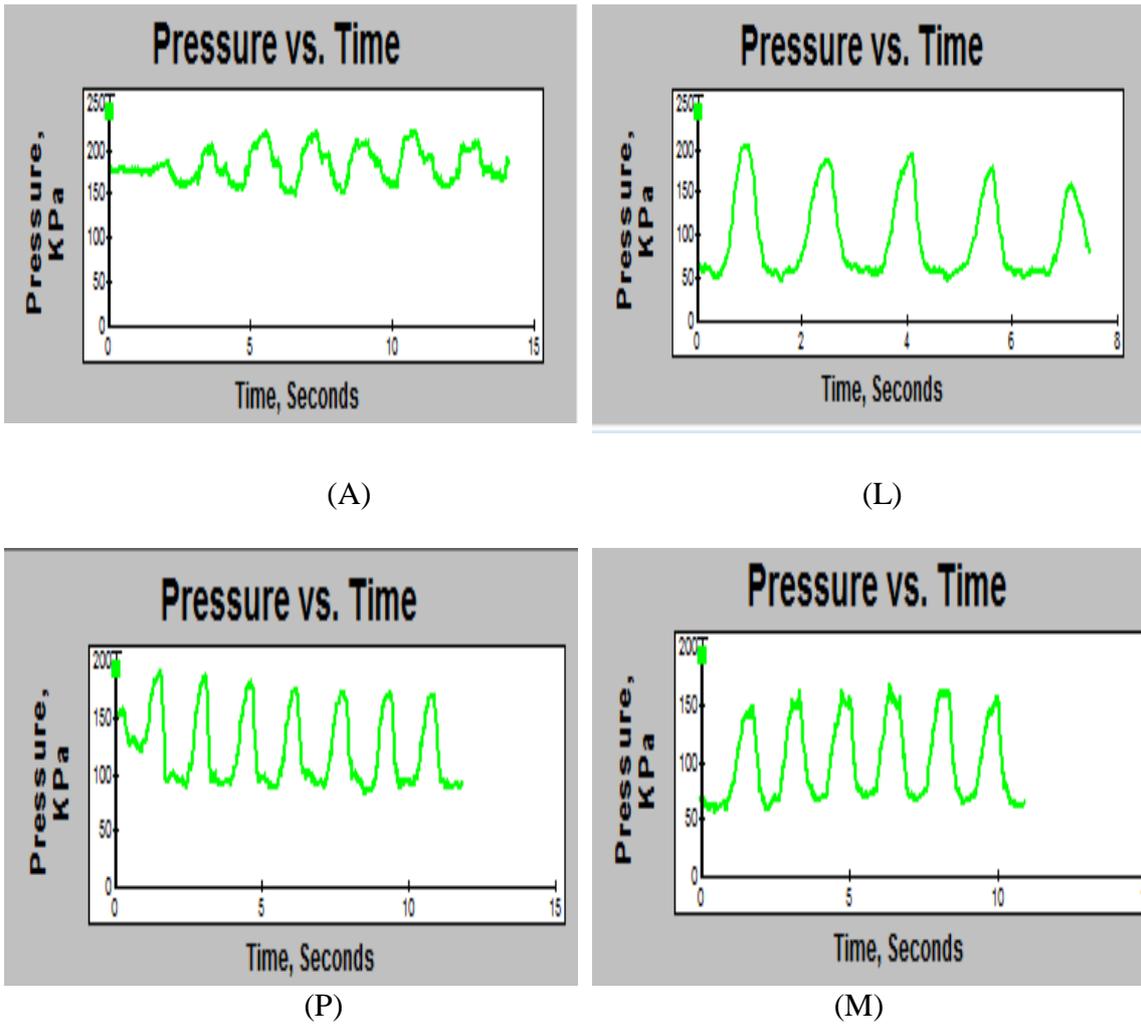


Figure (5-4) as showing the pressure vs. time.

5.4 The Results and Discussion of the Gait Cycle Parameters.

The ground reaction force (GRF) introduced under sole, due to biomechanical effects on leg during swing and stance phases, can be done for patient with AK amputation in right leg by using force plate. walk over force plate where the force distribution is developed under sole due to patient gait cycle. The obtained data from the gait cycle test recognize the major differences for the parameters of the right leg. The results will be discussed in detailed for each case as follows: The results of gait as shown in table 5-4.

The results of gait are shown in table 5-4.

Table 5-4 Gait Table.

Gait Table	Patient
Number of Strikes	7
Cadence (steps/min)	100.3
Gait Time (sec)	2.99
Gait Distance (m)	1.914
Gait Velocity (m/sec)	0.640

The main parameters which are shown in Tables 5-5 & 5-6 describe the behavior of the gait cycle for patient wearing AK socket data for one complete gait cycle from heel to heel strike.

Table 5-5 Gait Cycle Table (sec).

Gait Cycle Table (sec)	Patient		
	Left	Right	Difference
Gait Cycle Time	1.23	1.19	-0.04
Stance Time	0.79	0.74	-0.08
Swing Time	0.44	0.48	0.04
Single Support Time	0.46	0.45	-0.01
Initial Double Support Time	0.17	0.18	0.01
Terminal Double Support Time	0.18	0.17	-0.01
Total Double Support Time	0.34	0.34	0.00
Heel Contact Time	0.64	0.45	-0.19
Foot Flat Time	0.58	0.17	-0.41
Mid stance Time	0.45	0.27	-0.18
Propulsion Time	0.15	0.24	0.08
Active Propulsion Time	0.03	0.06	0.03

Table 5-6 Step-Stride Table.

Step-Stride Table	Patient		
	Left	Right	Difference
Step Time (sec)	0.57	0.62	0.05
Step Length (m)	0.373	0.383	0.01
Step Velocity (m/sec)	0.657	0.620	-0.037
Step Width (m)	0.117	0.103	-0.014
Stride Time (sec)	1.23	1.19	-0.04
Stride Length (m)	0.740	0.805	0.065
Stride Velocity (m/sec)	0.600	0.676	0.076
RMS Force (N)	639.08	431.08	-208
Impulse (N*sec)	334.55	195.82	-139.27
RMS Pressure (KPa)	214	350	136
Foot Angle (degree)	4	1	-3

The force distribution under sole due to patient gait for two feet is shown in Fig. 5-5.

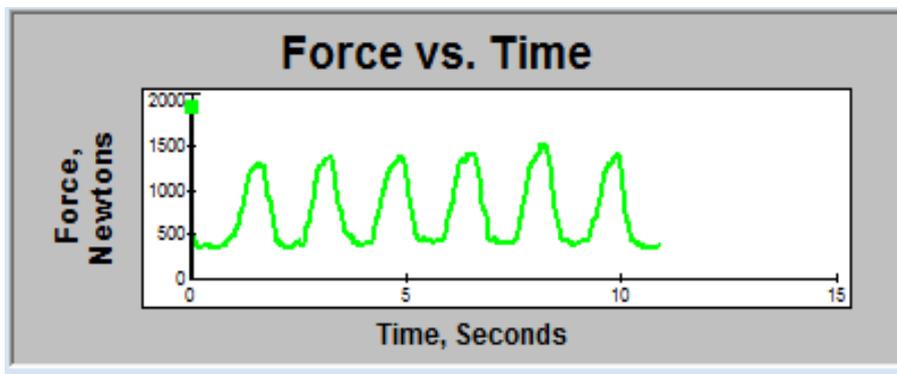


Figure (5-5) force vs. time.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. The lamination above knee prosthesis gave good results in equivalent Von-Mises stress and the safety factor for fatigue, and this led to the longer life design.
2. Manufacturing of the new lamination of above knee socket made from (carbon fiber – C-orthocryl lamination resin),
3. Higher in friction between above knee socket and stump by rovo fit solution and prevent dislocation of stump by increasing suspension.
4. Provide comfortable for patient of easier donning and doffing of adjustable socket especially elderly.
5. The matscan sensor, which is used to measure the interface pressure, was suitable for the alternating load between the socket and the stump. The interface pressure between patients and AK follows a wave pattern and reaches its maximum value(222KPa) at the moment of toe off and heel contact.
6. The gait cycle time for patients wearing above knee prosthetic socket(AK) equal to 14.99sec and gait velocity 0.68m/sec.
7. The model of AK socket showed that the fatigue safety factor for (4 carbon fiber) layers equal to (1.26), which are safe in design.

LIST OF REFERENCES

- [1]. Popovic D., and Sinkjaer T. “Control of movement for the physically disabled” , Springer-Verlag London.2000
- [2] LEE, R.Y.; TURNER - SMITH, A.: The influence of the length of lower-limb prosthesis on spinal kinematics. Arch Phys Med Rehabil 2003, vol. 84. 1357-62
- [3]. Rosalam C. Me, Rahinah I. and Paridah Md. Tahir“ Natural Based Bio Composite Material For Prosthetic Socket Fabrication” University Putra Malaysia, AlamCipta ,Vol. 5 (1), June 2012.
- [4] Scott Sabolich, **Prosthetic Sockets Striking a Fine Balance between Form and Function**, inMotion journal, Volume 16, Issue 5 September/October 2006.
- [5] Bill Dupes, **A publication of the Amputee Coalition of America in partnership with the U.S: Prosthetic Knee Systems**, Army Amputee Patient Care Program, 2005.
- [6] Vicky jarvis, Tim varrall, **prosthetic best practice: guidelines**, steeper UK center, 2010.
- [7] Alvin L. Muilenburg and A. Bennett Wilson, **A Manual for Above-Knee (Trans-Femoral) Amputees**, - 0andp journal, 1996.
- [8] Wilson AB Jr. **Limb Prostheses**, New York, Demos Publications, 1989, Ed 6, p 63. Used by permission.
- [9] C. Michael Schuch, **Consumer Guide for Amputees: A Guide to Lower Limb Prosthetics: Part I -- Prosthetic Design: Basic Concepts**, Volume 8, Issue 2, March/April 1998.
- [10] Michael Schuch, **Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles: Transfemoral Amputation: Prosthetic Management**, second edition, American academy of orthotics & prosthetics, 2002.

- [11] Burgess EM, Hittenberger DA, Forsgren SM, **The Seattle prosthetic foot-A design for active sports: Preliminary studies**. Orthot Prosthet 1983; 13:25-32.
- [12] Tyagi Ramakrishnan, **Asymmetric Unilateral Transfemoral Prosthetic Simulator**, Graduate Theses and Dissertations, 2014.
- [13] Wong Zhen Yang, **Wearable Power Assisted Pneumatic-Based Ankle Foot Orthosis (AFO)**, Biomedical Engineering, University Tunku Abdul Rahman, 2012.
- [13] James Oat JudgeRoy, B Davis, and Sylvia Öunpuu. Step length reductions in advanced age: the role of ankle and hip kinetics. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 51(6):M303–M312, 1996.
- [14] “Prosthetics History”, Northwestern University Prosthetics-Orthotics Centre,
<http://www.nupoc.northwestern.edu/prosHistory.shtml>
- [15] Tyagi Ramakrishnan, **Asymmetric Unilateral Transfemoral Prosthetic Simulator**, Graduate Theses and Dissertations, 2014.
- [16] **Michael Telwak, B.S," DETERMINATION OF OPTIMAL COUNTER-MASS LOCATION IN ACTIVE PROSTHESES FOR TRANSFEMORAL AMPUTEES TO REPLICATE NORMAL SWING",2013.**
- [17] **Casey Michael Barbarino," Design and Development of a Stair Ascension Assistive Device for Transfemoral Amputees",2013.**
- [18] **GARRETT C. WAYCASTER," DESIGN OF A POWERED ABOVE KNEE PROSTHESIS USING PNEUMATIC ARTIFICIAL MUSCLES "2010.**
- [19] **J. A. Campbell," MATERIAL SELECTION IN AN ABOVE KNEE PROSTHETIC LEG",Department of Engineering, Australian National University,2002.**

[20] **F. A. GOTTSCHALK and M. STILLS,** " The biomechanics of trans-femoral amputation", *Department of Orthopaedic Surgery, University of Texas Southwestern Medical Centre, Dallas, USA*, 1994.

[21] **Kerstin Hagberg, RPT, PhD; Rickard Brånemark, MD, PhD,** " One hundred patients treated with osseointegrated transfemoral amputation prostheses Rehabilitation perspective" *Journal of Rehabilitation Research & Development*, 2009.

[22]. Appoldt, F. , Bennett, L., and Contini, R . “ Stump Socket Pressure in Lower Extremity Prostheses” *J .Biomechanics*, Vol.1, No.4, Dec.1968, PP(247 –257) .

[23]. Pearson, J. R.&Grevsten, S. & Almby, B. & Marsh,L“ Pressure Variation in the Below – Knee Patellar Tendon Bearing Suction Socket Prosthesis,” *J Biomechanics* , Vol. 7, No. 6 , Nov. 1974, PP(487-496).

[24]Pritham , E. F. & Welson , A . B “Limb Prosthetics & Orthotics” , In Clynes , M . & Milsum , J.H.(eds).*Biomechanical Engineering Systems*, McGraw – Hill book Co ., 1970 PP:(749-549) .

[25] M. Lusardi, *Orthotics and Prosthetics in Rehabilitation*, 3rd ed., Philadelphia, Pa.:Saunders, 2012.

[26] R. Seymour, *Prosthetics and Orthotics Lower Limb and Spinal*, New York: Lippincott Williams & Wilkins, 2002.

[27]Dr. Amaal Hassan Mohammed Ebrahim “The Gait Cycle”, available at <http://faculty.ksu.edu.sa/68417/RHS%203411/THE%20GAIT%20CYCLE>. Pdf, [Lecture IX](#).

[28]Perry, J. *Gait Analysis : Normal and Pathological Function*. Thorofare, NJ,SLACK. 1992.

[29]Kirtley, C. *Clinical gait analysis : theory and practice*. Edinburgh ; New York, Elsevier. 2006.

[30] T. Kobayashi, M. S. Orendurff, and D. A. Boone, "Effect of alignment changes on socket reaction moments during gait in transfemoral and knee-disarticulation prostheses: Case series," *Journal of Biomechanics*, vol. 46, pp. 2539-2545, Sep 2013.

[31] L. Yang, S. E. Solomonidis, W. D. Spence, and J. P. Paul, "THE INFLUENCE OF LIMB ALIGNMENT ON THE GAIT OF ABOVE-KNEE AMPUTEES," *Journal of Biomechanics*, vol. 24, pp. 981-997, 1991.

[32] D. G. Shurr and T. M. Cook, *Prosthetics & Orthotics*, Norwalk, CN: Appleton & Lange, 1990.

[33] M. Lusardi, *Orthotics and Prosthetics in Rehabilitation*, 3rd ed., Philadelphia, Pa.:Saunders, 2012.

[34] R. Seymour, *Prosthetics and Orthotics Lower Limb and Spinal*, New York: Lippincott Williams & Wilkins, 2002.

[35].Ottobock quality for life " **orthotic- prosthetic materials catalog**",2007.

[36].C.P. Saml Phillips, William Craelius "**material properties of selected prosthetic lamination** "journal of prosthetic and orthotic JPO,vol17,No.1,2005.

[37].American society for testing and materials information ,Handing series "**standard test method for Tensile properties**" 2000.