# A Mechatronic System for Achieving Optimum Alignment of Lower Limb Prosthesis

**by**

## Kian Sek TEE

**Submitted in accordance with the requirements**
**for the degree of Doctor of Philosophy**

**The University of Leeds**
**School of Mechanical Engineering**

**November 2011**

The candidate confirms that the work submitted is his own and that appropriate credit has been given where reference has been made to the work of others.

# Abstract

Misalignment in the lower limb prosthesis can cause great discomfort in the stump-socket interface and disturbance to gait function. In the long run, it could deteriorate the musculoskeletal system. In practice, the assessment still depends heavily on the verbal feedback of an amputee and experiences of a prosthetist. Moreover it is inconsistent amongst the prosthetists.

Prosthetic alignment involves the adjustment of the prosthetic components relative to the gait quality. Some methods were proposed, including symmetry index, variation in a step-to-step transition, stability within the zone of integrated balance, matching roll-over shape (ROS) to an ideal ROS and etc. It is not clear if the optimum alignment could be achieved. These methods exhibit a few limitations, i.e. limited use of gait variables in a single comparison and non-uniform results when different gait variables are applied. There is a need to provide an objective assessment method that processes high dimensional gait variables and presents them in a simple form. In addition, it could be impractical and expensive clinically to spend excessive time on a patient. An ambulatory gait measurement system could achieve this objective to a certain extent.

This research investigates a potential engineering solution that is able to provide an assistive and objective assessment of the lower limb prosthetic alignment that provides optimal gait quality.

The effort includes a development of a low-cost ambulatory gait measurement system which could be reliably used during indoor and outdoor trials. Human walking trials using the designed ambulatory system are designed and performed to justify the proposed solution. A novel gait analysis method using Principle Component Analysis and Self-Organizing Feature Map is proposed to process high dimensional gait data into a simple plot and a decision guide. The proposed methodology could help to collect sufficient gait data during indoor and outdoor gaits and could provide an objective gait assessment during the application of lower limb prosthetic alignments.

# Acknowledgement

I would like to thank the people who have helped me through my study and supported me all the way along the project.

Special thanks to Dr. D. Moser and Prof. S. Zahedi from Chas A Blatchford & Sons Ltd., whom have shown me the door of biomechanics especially lower limb prosthetics. Great thanks to my supervisor, Dr. A. Dehghani for guiding me with great patience throughout the period of the study.

I would like to thank my colleagues especially Mohammed Awad and Mojtapa Khazravi. Many thanks to all technical staffs in the School of Mechanical Engineering for their advices and supports, especially David Readman and Tony Wiese.

My greatest gratitude must forward to my financial support, University Tun Hussein Onn Malaysia.

I must thank my family especially my parent for continual love and support. Last but not least, my thanks to my beloved wife, Soon Chin Fhong and my daughter, Chloe Tee, for sharing the happiness and hardship together.

# Content

# List of Abbreviations

| | |
|---|---|
| **2D** | 2 Dimension |
| **3D** | 3 Dimension |
| **A/D** | Analog to Digital |
| **AK** | Above Knee |
| **AP** | Anterior Posterior |
| **ASYM** | Asymmetry |
| **BCOM** | Body Centre of Mass |
| **BK** | Below Knee |
| **BMB** | Bisector of Medial Brim |
| **BMU** | Best Matching Unit |
| **CA** | Cronbach's Alpha |
| **CAD** | Computer Aided Design |
| **CW** | Clockwise |
| **CCW** | Counter Clockwise |
| **COM** | Centre of Mass |
| **COP** | Centre of Pressure |
| **CSV** | Comma-Separated Values |
| **D/A** | Digital to Analog |
| **dof** | Degree of Freedom |
| **FO** | Foot Off |
| **FS** | Foot Strike |
| **FSR** | Force Sensitive Resistor |
| **GC** | Gait Cycle |
| **GCI** | Gait Cycle Index |
| **GRF** | Ground Reaction Force |
| **vGRF** | Vertical Ground Reaction Force |
| **HC** | Heel Contact |
| **HPF** | High Pass Filter |
| **HS** | Heel Strike |
| **IC** | Initial Contact |

| | |
|---|---|
| **IMU** | Inertial Measurement Unit |
| **ISw** | Initial Swing |
| **L.A.S.A.R.** | Laser Assisted Static Alignment Reference |
| **LiNo GC** | Linear Interpolated Normalized Gait Cycle |
| **LPF** | Low Pass Filter |
| **LR** | Load Response |
| **KAF** | Knee, Ankle and Foot |
| **MEMS** | Micro-Electro-Mechanical Systems |
| **MISO** | Master In Slave Out |
| **ML** | Medial Lateral |
| **MOSI** | Master Out Slave In |
| **MSt** | Mid Stance |
| **MSw** | Mid Swing |
| **PC** | Principle Component |
| **PCA** | Principle Component Analysis |
| **PCB** | Printed Circuit Board |
| **PSw** | Pre-Swing |
| **RHR** | Right Hand Rule |
| **RMS** | Root Mean Square |
| **ROS** | Roll Over Shape |
| **RSD** | Relative Standard Deviation |
| **SCLK** | Serial Clock |
| **RVCG** | Rotational Vibratory Coriolis Gyroscope |
| **s** | Standard Deviation |
| **SD** | Secure Digital |
| **SE** | Standard Error |
| **SOFM** | Self-Organizing Feature Map |
| **SPI** | Serial Peripheral Interface |
| **SS** | Slave Select |
| **TF** | Transfemoral |
| **TO** | Toe Off |
| **TSA** | Total Sway Activity |
| **TSt** | Terminal Stance |
| **TSw** | Terminal Swing |

| | |
|---|---|
| **TT** | Transtibial |
| **WBI** | Weight-bearing Imbalance |
| **ZPLP** | Zero Phase Low Pass Filter |

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# CHAPTER 1

# INTRODUCTION

## 1.1 Background

Misalignment in lower limb prostheses could cause serious skin issues and damages to the musculoskeletal system if not corrected. Undesired pressure distribution in the stump/socket interface [1-7] would result in great discomfort, and continuous mechanical abrasion will eventually cause tissue breakdown, bruise, irritation, stump pain and skin problems. Stump skin damages are serious and should be avoided. Furthermore, heavy and consistent dependency on the sound limb would cause undesired pressure distribution to the rest of musculoskeletal system [8] and hence increase in the prevalence of degenerative changes in the lumbar spines and knee.

Currently, there is no agreement amongst practitioners and researchers regarding the parameters and objective methodologies of gait performance assessment to identify the optimum alignment for lower limb prosthesis. Some researchers believe that symmetry [3, 9] is the key in searching for the optimum alignment. They tried to look for the symmetry between the sound leg and the prosthetic leg. Others [10] believe that the assessment should look into the variation in between steps. Meanwhile, another group of researchers believes in stability and minimum energy expedition [11-13]. Recently some researchers [14, 15] have proposed that matching roll over shape (ROS) as close as possible to an ideal ROS shape of the foot is the key to a priori alignment. Somehow none of the researchers have claimed confidently that they have found the key of the optimum alignments. Above all, Zahedi [1] proved that the amputees are highly capable to adapt themselves to a broad range of optimum alignments in level walking. He also suggested a set of alignment definitions for both transtibial and transfemoral prosthesis. Later, Sin [16] re-examined the accepted range and found that a non-level walking test could constraint the acceptable range into a smaller set.

Instrumental gait analysis is crucial for providing a scientific view of walking performance with reported error margins. These instruments provide measurements in temporal, kinematic or kinetic properties of the gait. A gait analysis laboratory may consist of commercial gait measurement instruments such as a vision motion capture system to acquire temporal and kinematic gait data, while using a force plate to measure the ground reaction force within a step. Examples of a vision motion capture system and a force plate are Vicon and Kistler respectively. The commercial motion capture systems provide reliable measurement consistency and accuracy which are reported in their datasheets. In practice, they are expensive and stationary in a confined room.

On the other hand, an ambulatory gait measurement system provides a choice for portable and continuous gait measurements outside a gait laboratory. A number of sensory units that feature light-weight and small in size could be used for direct measurements. A Micro-Electro-Mechanical System (MEMS) type Inertial Measurement Unit (IMU) is light-weight and small in size, relatively cheap, reliable and accurate. An IMU could measure kinematic properties of the limb segments in multiple axes. Commercial MEMS IMUs from Xsens, MEMSense, MicroStrain, MotionNode etc. for example, give a broad range of selections such as types and number of transducers (accelerometer, gyroscope and magnetometer) incorporated, number of degree of freedom (dof) per transducer, signal choices (USB, SPI, I2C, RS232 or analogue voltage) as well as the calibration and analytical software. Off-the-shelf IMUs for gait measurement are rather expensive as compared to their electronic components. An example of MEMS IMU is the integration of ADXL335 (3-axis accelerometer, Analog Devices, Inc.) and IDG500 (2-axis gyroscope, InvenSence, Inc.). However, skilled circuitry development to assemble these ICs is required. The IMU needs to be calibrated before applying it for motion data acquisition.

Controversy on the lower limb alignment might be due to disagreements in gait-alignments assessments. The disagreements could be categorized in two major groups. Firstly the algorithms of assessment and secondly choices of measured gait parameters. Many algorithms are suggested, including symmetry index, variation in a step-to-step transition and ROS as explained above. However limited choices of gait parameters are suggested to be weighted via these algorithms since these algorithms are mathematically incapable to handle high dimensional data at once. Nowadays, gait data are easily available in high dimensions. It may be an irrational sense just to limit to a number of choices. Since walking is a series of voluntary controlled motions, the gait data should map to a distribution with a centre tendency. The gait data are postulated to form the gait patterns as the results of alignments and other restrictions. Next, the challenge would be to present the multi-dimensional data in a simple form that displays the centre tendency. In practice, a prosthetist spends limited time in monitoring the patient's gait. Short gait monitoring time might possibly result in insufficient observation as the patient leaves the clinic. It is envisaged that an ambulatory system instead of a stationary system would provide a longer observation and collect sufficient gait data.

## 1.2 Motivation

Some methods were proposed, including symmetry index [5, 9, 16, 17], variation in a step-to-step transition [10, 18], stability within zone of integrated balance [11] and matching roll-ever shape (ROS) to an ideal ROS [14, 15] (see arguments of these methods in Chapter 2). These reported methods for lower limb prosthetic alignment assessment still exhibit a few limitations as listed.

1. The first limitation is the limited use of gait variables in a single comparison. For example, a symmetry index would compare the stride speed of the left leg and the right leg. In another example, variations of thigh moments in a step-to-step transition are calculated and plotted to justify the quality of an alignment.
2. The second limitation is the non-uniform sensitivity of the methods when different gait variables are applied. Non uniform results could be produced when different gait variables are applied in the reported methods. This is especially true for the symmetry index and variation in a step-to-step transition. The above methods do not consider compound gait variables at a time. If there are n-sets of gait parameters, there could be n-sets of unequal assessment results. Certain gait parameters are sensitive to the changes of the alignment while certain are not.

3. The third limitation is inadequate observation time during an alignment session. From the prescription point of view, it could be impractical and costly in clinical practices to spend excessive time on a patient. Gait observation during a schedule gait trial could be insufficient to provide adequate gait data for analysis. The amputee would adapt to a new gait pattern over the long run upon any alignment updates. An ambulatory gait measurement system which could continuously collect sufficient amount of gait data out of the clinic could achieve this objective to a certain extent.

It is arguable that the lower limb prosthetic assignment and its assessment must be limited to a pre-scheduled clinical session and must be confined within a certain types of gait variables and must investigate the sensitivity of certain gait variables with regard to the alignment. To date, a typical instrumental gait measurement would easily generate many gait variables. Simple plots and statistical analysis focused on a limited number of gait variables may be insufficient to reveal the 'true' gait quality. It could be a waste of information by discarding part of the gait variables without proper justification. Since human walking involves a high synchronization of falling and supporting of the body controlled by the lower limbs, repeated gait variables measured from predefined body segments could possibly reveal crucial gait patterns due to the alignment. There is a need to provide an objective assessment method for the application of lower limb prosthetic alignment, that acquires sufficient amount of gait data and processes high dimensional gait variables and presents them in a simple form.

## 1.3 Aims and Objectives

### 1.3.1 Aims

1. To design a low cost portable mechatronic system that is able to monitor gait in lower limb segments during normal walking.
2. To propose a simple gait analysis solution as an objective assessment during lower limb prosthetic alignments.

### 1.3.2 Objectives

1. To develop an ambulatory system for gait data collection. The system should be portable and low cost.
2. To calibrate the ambulatory system including the datalogger and the sensors. The efforts should specify the system and provide margin of errors.
3. To collect gait data using the ambulatory system under several walking restrictions.
4. To propose a procedure of gait data processing. The procedure involves multi-stages of signal processing and conditioning.
5. To propose a simple presentation of gait data that could provide essential visual aids and guides during lower limb prosthetic alignments.

## 1.4 The Scope of this Research

The project could cover many stages of research and development phases before reaching a clinically proven solution. However, at this early stage, this project is intended to provide a potential solution to the problem and is limited into these scopes.

1. To develop a low-cost ambulatory gait measurement system that could be used indoors and outdoors.
2. To propose a novel assessment method that consider a compound set of gait variables
3. To use healthy subjects to validate the proposed solution

## 1.5 Contributions of this research

As a contribution to the body of knowledge, part of the thesis are published in peer-reviewed conferences. The development of the ambulatory system as reported in Chapter 3 is published in *The 2011 International Conference of Mechanical Engineering, July 6-8*, London, UK, 2011. Different techniques of static calibration of an triaxial accelerometer and the comparison of these techniques as reported in Chapter 4 are published in:

- *The Eighth IASTED International Conference on Biomedical Engineering, February 16 – 18*, Innsbruck, Austria, 2011.

- *The 2011 International Conference of Mechanical Engineering, July 6-8*, London, UK, 2011.

From the same chapter, the dynamic calibration of a gyroscope using a simple pendulous rig and a statistical method is published in *The 14th International Conference on Climbing and Walking Robots and the Support Technologies for Mobile Machines (CLAWAR2011), September 6-8*, Paris, France, 2011. Further works and findings from the research will be published in peer-reviewed journals. The citations of the publications are listed in Appendix D.

Further contributions of this research work can be summarized as:

1. Proposing the development consideration of an ambulatory system. This includes the embedded system design and the recommendation of IMU sensory axes conversion according to the body axes at predefined body landmarks.
2. Revising and comparing several IMU static calibration methods. The comparison reveals the advantages and disadvantages of each method. An innovative procedure using 6/12 known positions and the iterative mathematical solution proves to be useful and easy to apply.
3. Proposing an innovative dynamic calibration for a gyroscope using a pendulous system.
4. Proposing a validation method for IMU dynamic performance using a pendulous system. The IMU actual outputs are compared with the theoretical models formulated from the principle of circular motions.
5. Proposing a novel set of cross-designed experiments to investigate the effect of a crucial alignment factor (ankles) and the walking level to the gait quality.
6. Proposing an innovative procedure to systematically process the collected gait data into a structure of normalized and linear interpolated gait cycles.
7. Proposing a novel gait assessment algorithm that provides a visual aid and a decision guide using PCA and SOFM. The solution is envisaged to serve as an easy-to-use gait assessment tool for the prosthetists during dynamic alignment or more generally, for normal and pathological gait analysis.

## 1.6 Organization of the Thesis

The thesis is divided into seven chapters. Chapter 2 reviews the problem background of the research. A general knowledge on human waking and biomechanics is reviewed. This includes essential definitions regarding walking and crucial concepts for gait analysis. The review also investigates specially on the issues regarding lower limb prosthetic alignments. These issues include the importance and the need for the alignments, reviews on many alignment methodologies, tools and their arguments. Lastly, contribution of this research to the body of knowledge are mentioned.

Chapter 3 presents the design and development of an ambulatory system which consists of a customized embedded datalogger, five units of inertial measurement units (IMUs) and straps to hold the devices.

Chapter 4 describes the procedures for both static calibration and dynamic calibration of an IMU. The accelerometers are calibrated using several static calibration techniques and these techniques are compared. A pendulous system is recommended for the dynamic calibration. A frequency distribution method is proposed to calibrate the gyroscope. Finally dynamic performances of an IMU are verified by comparing its theoretical models and the actual measurements in the pendulous system.

Chapter 5 reports the procedures of human walking trials and their results. The experiments are cross-designed using two walking restriction factors that influence the gait. The factors are the ankle and the walking level. The experiments received an ethical approval from the Research Support Unit of the University of Leeds and consents from the participants. The procedure for gait feature extraction is demonstrated. It includes multi-stages of signal processing and conditioning techniques, gait events identification, gait features selection and extraction out of processed gait data. The reliability of the ambulatory system (see Chapter 3) is justified using a statistical method called test-retest reliability.

Chapter 6 proposes a potential objective assessment for the lower limb alignments. Correlation and dimensionality are emphasized to be the issues in multi-variants gait data processing. The proposed solution applies Principle Component Analysis (PCA) and Self-Organizing Feature Map (SOFM) to resolve the above issues. The algorithms generates visual aids and guides that map the gait patterns in low dimensional plots. By means of a 2D or 3D plot, both PCA and trained SOFM are able to show clear clusters of gait performances under different walking restrictions. A trained SOFM could determine the class of a gait pattern in future applications.

Chapter 7 summarizes the work reported in this thesis, highlights the main findings and outlines future works.

# CHAPTER 2

# LITERATURE REVIEW

## 2.1 Introduction

This chapter reviews the background knowledge regarding the study of human locomotion and lower limb prosthetic alignments. In a broader view, the review would give a general understanding about the studies of human locomotion and their relevant discoveries. In specific, the review would provide a deeper understanding regarding the researches in the lower limb prosthetic alignments and their relevant discoveries. Lastly, the contributions of this research to the body of knowledge are mentioned.

The review starts with fundamental concepts and terminologies in the study of human locomotion. They include formal definitions of walking, anatomical geometry, motions in lower limbs in kinematic and kinetic terms. These definitions form the background knowledge necessary for gait analysis. All studies in human locomotion cannot leave without gait data collection with reliable gait measurement instruments. A review of these instruments and their limitations are provided.

Next, a few human walking models are reported. Each model emphasizes on different key variants that determine gait quality. The classical human walking model, the six determinants, has gone through several challenges and is seriously questioned. However, it still describes well about human walking. The model, dynamic walking, utilizes the law of conservation of energy to model the walking actions. Meanwhile, the model, rocker based inverted pendulum, utilizes the geometry of roll-over shape (ROS) to anticipate the virtual leg length. Optimal values of ROS radius and virtual leg length are suggested.

It is a great clinical concern to provide optimal prosthetic alignments. The concerns include both dermatological and musculoskeletal reasons. The alignment must at least provide a certain extent of proper gait function and comfort. Key

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