The Department of Biomedical Engineering

Advanced Tuning of a Trans-Tibial Prosthesis Using Motion Capture and Visualisation

By

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Declaration of Author's Rights

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

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Date:

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Abstract

A transtibial prosthetic alignment is a three dimensions interrelationship between a socket and a prosthetic foot. The prosthetic alignment aims to achieve the most suitable limb position for desired function and comfort. The alignment is tuned through three alignment stages; bench, static and dynamic until achieving the optimal alignment. However, the available instrumentation could not be used for assisting the prosthetist in aligning the prosthesis through all three alignment stages.

This aims of this study were to investigate and develop a new alignment system that can assist the prosthetist in tuning the alignment of a trans-tibial prosthesis and to compare to Conventional Alignment Technique (ConAT).

Four gait analysis protocols: Strathclyde Cluster Model (SCM), Human Body Model (HBM), Human Body Model 2 (HBM2) and Plug-in Gait (PiG) were investigated, and their reliability were explored in able-bodied and trans-tibial amputee (TTA) subjects. The SCM demonstrated good correlation, good repeatability, accuracy, and easy to use in both able-bodied and TTA subjects.

The walking condition was considered as a crucial factor during gait analysis. Three walking conditions, Overground (OG), Fixed speed treadmill (FS TM) and Self-paced treadmill (SP TM), were compared. Results demonstrated no significant difference between OG and SP TM. Therefore, SP TM can be used compatibly with OG.

Furthermore, a Computerised motion capture and Visualisation system for the Assisted Alignment Technique (CVAT) was developed to read-outs of the alignment parameters in real-time. The SCM and prosthetic markers set were used to implement alignment visual feedback scenarios during three alignment stages. SP TM was used to assist alignment in the dynamic stage. Further, the CVAT was compared to the ConAT. Results of the CVAT method showed a positive effect on gait outcomes.

In conclusion, the CVAT allows the prompt and qualitative prosthetic alignment and enables the prosthetist to align prosthesis objectively.

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List of Abbreviation

AJC	Ankle Joint Centre
AL	Anatomical Landmark AVPS
AP	Antero-posterior, from front to back
CVAT	Computerised motion capture and Visualisation system for assisted Alignment Technique
CVBAT	Computer motion capture and Visualisation system for assisted Bench Alignment Technique
CVDAT	Computerised motion capture and Visualisation system for assisted Dynamic Alignment Technique
CAREN	Computerised Assisted Rehabilitation Environment
CVSAT	Static Computerised motion capture and Visualisation system for assisted Static Alignment Technique
CAST	Calibrated Anatomical System Technique
ConAT	Conventional Alignment Technique
ConBAT	Conventional Bench Alignment Technique
ConSAT	Conventional Static Alignment Technique
ConDAT	Conventional Dynamic Alignment Technique
CGM	Conventional Gait Model
DOF	Degree Of Freedom
GCS	Global Coordination System
GRF	Ground Reaction Force
HBM	Human Body Model
HBM2	Human Body Model 2
HJC	Hip Joint Centre
HS	Heel Strike
IC	Initial Contact
ICC	Intra Class Correlation
ISB	International Society of Biomechanics
ISPO	International Society for Prosthetics and Orthotics
JCS	Joint Coordinate System KJC Knee Joint Centre
LCS	Local Coordination System

LLA	Lower Limb Amputation
ML	Medio-lateral, from front to back
MTP	Medial tibial plateau
MS	Mid Stance
OG	Overground
OGA	Observational Gait Analysis
PiG	Plug-in Gait
PTB	Patella Tendon Bearing
ROM	Range of Motion
SACH	solid ankle cushion heel
SCM	Strathclyde Cluster Model
SD	Standard Deviation
SMS	Skin-based marker set
SP	Self-Paced
STA	Soft Tissue Artefact SVA
TC	Terminal Contact
TM	Treadmill Walking
TO	Toe Off
TSB	Total Surface Bearing
TTA	Trans-Tibial Amputation
TTP	Trans-Tibial Prosthesis
VR	Virtual Reality

Glossary

The following definitions are used in this thesis and are listed here to aid the reader. Unless otherwise specified, they represent my own definitions.

Term	Definition
Alignment	Establish the position in the space of the components of the prosthesis or orthosis relative to each other and the patient
Bench alignment	Assembly and alignment of the components of a prosthesis or orthosis in accordance with their characteristics and with previously acquired data regarding the patient
Static alignment	A process whereby the bench alignment is refined while the prosthesis or orthosis is being worn by the stationary patient
Dynamic alignment	A process whereby the alignment of the prosthesis or orthosis is optimized by using observations of the movement pattern of the patient
Cluster	A plastic shell equipped with three or more reflective markers that are used to track a body segment.
Markers	A polystyrene hemisphere, with a minor flat surface, covered with retro-reflective material. These are the objects attached to body segments and/or joints in order to describe the position of the object in relation to some previously determined frame of reference.
Virtual marker	A marker that is created in the software. For example, a virtual marker could be created as the midpoint (50% of the distance of the line between two skin markers). Virtual markers are also referred to as landmarks (Tranberg, 2010).
SACH foot	Unjointed, prosthetic ankle-foot unit
Socket AP shift	Anterior or posterior displacement of the socket with respect to the foot
Socket AP tilt	Tile of the socket in the sagittal plane; i.e. Flexion/extension

Socket ML shift	Medial or lateral displacement of the socket with respect to the foot
Socket ML tilt	Tile of the socket in the coronal plane; i.e. adduction/abduction
Toe out/in angle	Rotational of the foot with respect to the line of progression
Optimal alignment	An alignment provides the patient with an acceptable cosmetic and comfortable gait
Socket	The interface that transmits forces between the residual limb and the prosthesis
Real-time visual feedback	Describes a scenario where, within a real-time system, results from an alignment calculation are used for assisting the alignment tuning.
Observational Gait Analysis	The visual observation of gait that occurs in real-time as the person ambulates. Observational gait analysis does not rely on any other measures or tools and only addresses the motion and movement that is occurring during ambulation.
Quantitative Gait Analysis	This analysis is performed in a formal gait lab setting and provides quantitative information regarding gait which can include kinematics, kinetics, muscle activity, and energetics

Chapter 1. Introduction and background

1.1 Introduction and Background

Lower limb amputation (LLA) is the most common amputation for both civilian and military populations. In Thailand, the prevalence of lower limb amputees is approximately 1 in every 200 people (Thirapatarapong and Dajpratham, 2009). In the United States (US), the prevalence of lower limb amputations is approximately 1 in 3,500 people per year. In the United Kingdom (UK), there are approximately 55,000 amputees, which equates to approximately 1 amputee per 1,000 able-bodied people in the UK (Sewell et al., 2012). The prevalence of lower limb amputation is increasing year by year in all countries around the world. Among the several LLA levels, Trans-tibial amputation (TTA) is the most common lower limb amputation level (Zahedi et al., 1986). In the U.S., it accounts for 40% of all amputation surgeries performed annually (Sun and Voglewede, 2013). In the U.K., the percentage of trans-tibial amputation is 50.6% (Stewart, 2008). There are no data available regarding the number of the trans-tibial amputee in Thailand. However, we can assume a larger proportion.

The prosthesis used by an amputee is described by the International Organization for Standardization ISO 85494 :1989 as “an externally applied device used to substitute wholly, or in part, an absent or deficient limb segment” (ISO, 1989). It can restore and improve function as well as provide a more cosmetic appearance to the residual limb .The prosthetic device for trans-tibial amputees is known as “trans-tibial prosthesis (TTP)” Trans-tibial prostheses commonly have three major components :a socket, a shank, and an ankle foot mechanism .The quality of the rehabilitation achieved for trans-tibial amputees is influenced by several prosthetic and biomechanical factors such as the prosthetic socket, the type of prosthetic foot selected, and the alignment between the two. The alignment of the elements of the prosthesis plays a critical role in producing successful ambulation and comfort and the overall function of the limb .A functional and comfortable trans-tibial prosthesis is essential in restoring the trans-tibial amputee's ability to perform everyday activities (Blumentritt, 1997; Price, 2006; Sanders et al., 2006). Rehabilitation for the trans-tibial amputee is an integral part of helping them to restore optimal gait, achieve an independent lifestyle and return to previous social environments (Chen,

2012). During the multidisciplinary rehabilitation process, the rehabilitation team work together and complement each other's respective roles. A typical amputee rehabilitation process involves physiotherapy, the provision of a prosthesis, as well as gait training. Each member of the clinical team has individual responsibility. However, during the prescription of the prosthesis, the prosthetist takes the main responsibility. The prosthetist evaluates, designs, fabricates and fits a custom prosthetic device to meet a patient's individual functional needs. The prosthetic design process requires knowledge of anatomy, physiology, prosthetics technology, materials properties, biomechanics and fabrication techniques, and hence requires specialised knowledge by the prosthetist (Chen, 2012; KAPP and Miller, 2009).

During the fabrication of a prosthesis, the alignment protocol is an important component of overall prosthetic function and successful fitting (Kobayashi et al., 2013). To be effective, the alignment between the foot and the socket must be finely adjusted until the best alignment is achieved.

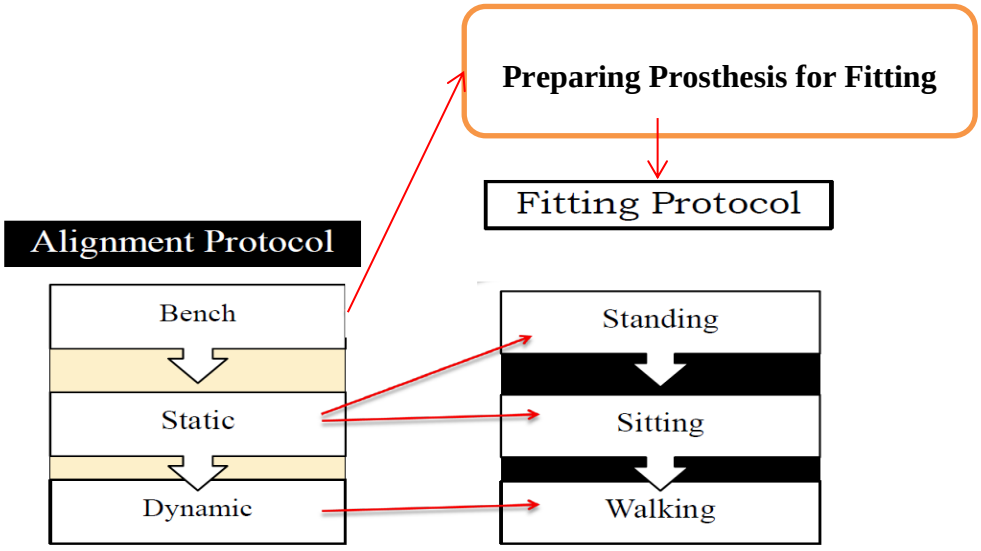


Figure 1.1 Alignment procedures

Trans-tibial prosthetic alignment can be described spatially as a three-dimensional adjustment with six degrees of freedom between the socket and the foot .The process of aligning a prosthesis occurs in three stages, referred to as "bench "alignment, "static "alignment and "dynamic "alignment, as shown in Figure 1.1 (Chen, 2012).

The definition of each process is described by the ISO 85494: 1989 protocol. Bench alignment is the "assembly and alignment of the components of a prosthesis or orthosis in accordance with their characteristics and with previously acquired data regarding the patient". Static alignment is a "process whereby the bench alignment is refined while the prosthesis or orthosis is being worn by the stationary patient". Dynamic alignment is a "process whereby the alignment of the prosthesis or orthosis is optimised by using observations of the movement pattern of the patient" (ISO, 1989). The prosthetic alignment might need to change as the patient's ROM, muscle strength, and balance improve (KAPP and Miller, 2009). Moreover, dynamic alignment is a crucial step in aligning the prosthesis, with the aim of achieving the most suitable limb position to achieve optimal function and comfort. Malalignment may result in walking difficulties, skin abrasions and uneven forces acting on the residual limb within the socket, which could lead to the creation of a blister, a wound, and even more serious skin and joint trauma.

In the Conventional Alignment Technique (ConAT) (Figure 1.2): the dynamic alignment is achieved in response to visual observations made when the patient walks, and feedback from the patient as he/she walks. During dynamic alignment, the prosthetist is adjusting the alignment by using screws, located below the socket or at the ankle level. The screws are used to rotate or translate the socket/foot relationship as required. Conventionally, the prosthetist uses subjective judgment base on visual observation and the history of practice to produce clinically useful insights and understanding. Feedback from the patient is also valuable as the process aims to achieve the most suitable limb geometry for best function and comfort. The prosthetist attempts to observe the patient from all angles while standing and walking and records the patient's comments. Factors such as experience, understanding of the cause of postural deviations and gait deviations, information on zones of overload at the stump-socket interface, and feedback received from the patient are all integrated to assist the prosthetist in altering the geometrical configuration of the prosthesis until the desired alignment is achieved .This conventional alignment technique relies on observational gait analysis to provide information about prosthetic fit, alignment,

and function for the individual patient .However, the literature (Chen, 2012; Fridman et al., 2003; Zahedi et al., 1986) has indicated that visual observation is neither sufficiently reliable nor sensitive to detect anything other than gross deviations .This method of alignment lacks consistency. Clearly, a method of alignment based on visual observation must, therefore, be less than ideal.

Figure 1.2 Conventional Alignment Technique (ConAT)

Using conventional practice, achieving optimal alignment can take from one day to several weeks to achieve the final dynamic alignment. This depends on the prosthetist's skill and experience and the complexity of the user. The optimisation of the alignment can be a very time- consuming process undertaken as it is with a subjective and inconsistent process based on visual observation and feedback from the patient. Furthermore, a prosthesis aligned using this conventional subjective process may fail to include important scientific biomechanical information (Blumentritt, 1997; Blumentritt et al., 1999; Fridman et al., 2003; Zahedi et al., 1986) and may, therefore, be sub-optimal.

Quantitative methods have been used to evaluate prosthetic alignment and have served a purpose in the research of prosthetic practice for many decades (Lusardi et al., 2013). However, the methods are far from ideal for clinical practice. Quantification of prosthetic alignment could provide a method for optimisation and documentation of the prescription and could be achieved by motion capture. This

kind of biomechanical gait analysis goes beyond conventional visual observational methods and can provide in-depth and precise information on amputee gait and amputee performance. Recorded data could include spatial parameters, cadence, kinematic and kinetic measures (Blumentritt, 1997; Rusaw and Ramstrand, 2011; Sanders et al., 2006). Over the past three decades, three-dimensional (3D) motion analysis has been used in research to quantitatively evaluate the gait of trans-tibial amputees (Rusaw and Ramstrand, 2011) and is considered to provide objective measurements for assessing the quality of walking and to characterise walking patterns (Gard, 2006).

The utility and benefits of 3D motion analysis to lower limb prosthetics design and research are well understood. Yet to the author's knowledge following, a comprehensive literature review undertaken as part of this thesis no significant studies are published where capture motion has been used in routine prosthetic clinical practice. The development of a system, which can assist the prosthetist in utilising 3D motion analysis to visualise prosthetic alignment and measure biomechanical outcomes during alignment, would seem to be needed.

This thesis reports the design of a new system based on 3D motion analysis to assist TTP alignment. The new technique is called "A Computerised motion capture and visualisation system for the Assisted Alignment Technique or the CVAT method" In the CVAT method; computer-aided motion analysis is used during clinical fitting to acquire variables as outcome measures. The outcome data are provided by a visualisation application allowing the subject to be an integral part of a real-time feedback loop, in which the measured behaviour of the subject is used to provide visual feedback to prosthetist and subject. The design and development of the system will follow a review of the available literature.

Chapter 2. Literature review

2.1 Introduction

In the current chapter, the background of the study and the relevant literature establishing the study rationale are reported. The first section describes the epidemiology and level of amputation, followed by an overview of lower limb prosthesis and normal gait. Of particular interest to the study is the effect of amputation on gait ability. In this regard, gait deviations following the amputation are described. The next section describes prosthetic alignment tuning and the current clinical practice on the tuning process, followed by a literature review on an instrument-assisted prosthetic alignment. The last section treats 3D motion capture as the main method for developing real-time alignment of a prosthetic by a custom system. To conclude, the considerations of the literature reviewed are made.

2.2 Amputation

Limb amputation is "surgical removal of the whole or part of a limb" (ISO, 2014). In this thesis, the term is used to refer to the removal or absence of a limb. Amputation is performed to remove damaged tissue, to relieve pain and to obtain healing (Silverthorn, 2004).

2.2.1 Epidemiology

Epidemiology of amputation differs from country to country. Amputation occurs for a variety of reasons including Peripheral Vascular Disease (PVD), Tumour and infection (Esquenazi, 2004; McCollum, 2004). The quality of walking with a prosthesis is effected by the cause of amputation (Michael, 2006). Amputees with traumatic amputation have been shown to have more normal gait than amputees with limb loss as a result of vascular insufficiency (Michael, 2006).

In developed countries, the vascular disease accounts for 68% of all amputations performed each year (Esquenazi, 2004). The second most common cause is trauma, accounting for approximately 30% of all amputations (Esquenazi, 2004). The third is congenital limb deformity with up to 3% of all amputations (Esquenazi, 2004). In developed countries, PVD-associated with diabetes mellitus is the most common cause of lower limb amputation and accounts for more than 90% of lower limb amputation undertaken for disease (McCollum, 2004).

In contrast, for developing countries, the most common cause of amputation is trauma (Esquenazi, 2004). Trauma often leads to amputation because of severe fractures, caused by accidents with motor vehicles or other mechanical machinery.

2.2.2 Amputation level

The level of amputation is categorised by the joint or segment at which amputation is performed (ISO, 2014). Lower limb amputations are the most common level of amputations (Powelson, 2011). A trans-tibial level accounts for 39%, trans-femoral level 31% as shown in Figure 2.1 (Esquenazi, 2004).

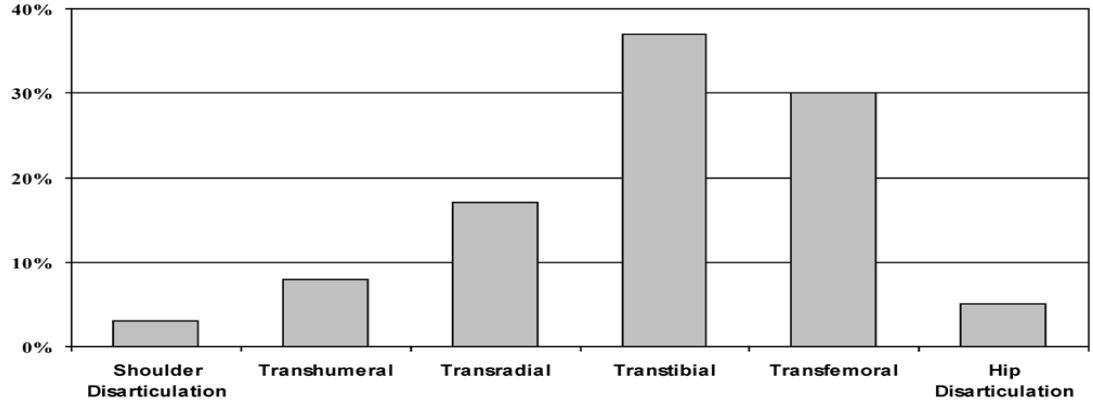


Figure 2.1 Incidence of limb amputation by level (Esquenazi, 2004).

2.2.3 The prevalence of lower limb amputation

The prevalence of lower limb amputation is increasing year-by-year all around the world. In Thailand, based on information available from the National Statistical Office in "The 2007 disability survey" there were approximately 1.9 million people with disabilities in Thailand. This is 2.9 % of the Thai population. Of those people, approximately 27,000 have lower limb amputations. The Amputee Statistical Database for the United Kingdom showed the prevalence of lower limb amputations to be 91% of all amputations (Luff et al., 2009).

2.3 Lower Limb Prosthetics

2.3.1 Prostheses

A prosthetic device is an externally applied device used to replace wholly, or in part, an absent or deficient limb segment (ISO, 1989). The lower limb prosthesis can be

categorised by amputation level into three main groups; Trans-tibial (below knee), Trans-femoral (above knee) and disarticulation (through knee joint).

2.3.2 Trans-Tibial Prostheses

By definition, the residual limb of a trans-tibial amputee includes the tibial tubercle into which the quadriceps tendon inserts, which retains the ability to produce knee extension (Silver-thorn, 2004). The prosthesis for a trans-tibial amputee consists of a socket with an optional insert, adapter hardware to attach the socket to the shank (or pylon) and an artificial foot (Silver-thorn, 2004). Also, the prosthesis may often include some means of auxiliary suspension (Silver-thorn, 2004).

2.3.3 Trans-Tibial Prosthetic Components

The trans-tibial prosthesis is composed of many components that can be configured together based on prosthetic prescription. However, the typical trans-tibial prosthesis is comprised of four major elements: (a) the socket,(b) the suspension system, (c) the pylon (1c) and alignment adapter (2c), and (d) the prosthetic foot (Powelson, 2011), as shown in Figure 2.2.

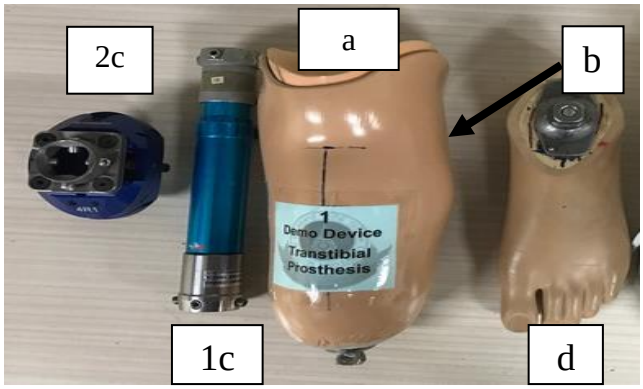


Figure 2.2 Components of a Trans-tibial Prosthesis a**.** Socket, b. Suspension, c**.** Pylon (1c) and Alignment adapter (2c), and d**.** Prosthetic foot

There are a variety of prosthetic components available on the market. The prescription of prosthetic components is based on amputee activity level. The current approach for classifying amputee activity levels is determined using the Medicare Functional Classification Level (MFCL), also known as functional K-levels. The

classification was developed by the Centres for Medicare and Medicaid (CMS). It was created to describe five levels of functional ability (K-0 through K-4) and in turn designates the appropriate prosthetic component for each functional k-level of that patient (Meier and Melton, 2004). Clinical assessments of beneficiary rehabilitation potential must be based on the following classification levels:

Level K-0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility

Level K-1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulatory.

Level K-2: Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

Level K-3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Level K-4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

2.3.3.1 Socket

The first major component of a TTP is the socket. The socket is the interface that transmits forces between the residual limb and the prosthesis (Powelson, 2011). The socket is a central part of the prostheses. Moreover, the socket must provide a good, comfortable, and secure fit to the amputee (Boone et al., 2012; Edelstein and Moroz, 2011; Powelson, 2011). The design of a trans-tibial (TT) socket can be categorised into two basic designs (Murphy, 2013). The first design is called a patellar tendon

bearing (PTB) socket. The PTB design is a pressure specific design allowing pressures in two specific areas: the patellar tendon bar and the posterior wall (Murphy, 2013). The second design is called a total surface bearing (TSB). The TSB socket is based on the true anatomical shape of the residuum with mild, if any, relief to the bony prominences (Murphy, 2013).

2.3.3.2 Suspension

The suspension system is another important consideration when prescribing the prosthetic components. The suspension system is designed to support the prosthesis during the swing phase of the gait cycle by holding the prosthesis (Powelson, 2011) to the limb whenever there is no weight being placed on the prosthesis (Powelson, 2011).

2.3.3.3 Shank and Alignment Adaptor

The shank attaches the socket to the prosthetic foot .In general, the shank can be categorised either as an exoskeletal shank or endoskeleton pylon. An endoskeleton is a type of prosthesis that contains a lightweight metal tube that connects the foot to the socket of the prosthesis (May and Lockard, 2011). An exoskeletal is a type of prosthesis constructed from wood or rigid polyurethane covered with a rigid plastic lamination that connects the foot of the prosthesis to the socket (May and Lockard, 2011) .Most modern prostheses use a pylon so we will focus on this type of device . The pylon is a tube where the forces of the wearer applied to the socket are carried through and transmitted to the foot .The role of the pylon in a trans-tibial prosthesis is to act as the replacement for the length of the tibia that was amputated (Adebayo et al., 2011; Donati et al., 2008; Moroz, 2017).

The alignment adapter allows the prosthetist to perform independent tuning of translation and angulation (Figure 2.3) in the sagittal and coronal planes and rotation in the transverse plane between the socket and pylon (Boone et al., 2013). The primary function of this component is to allow the foot to be properly positioned beneath the leg (Adebayo et al., 2011).

Figure 2.3 Translation adapter

2.3.3.4 Prosthetic foot

The final part of the prosthesis is the prosthetic foot .The five basic functions of prosthetic feet are to provide a weight-bearing surface, absorb shock, replace lost muscle function, replicate the anatomical joints, and restore cosmetic appearance (Adebayo et al., 2011). Prosthetic feet for a transtibial amputee vary with multiple designs that each serves a particular function. The most fundamental prosthetic foot for people with transtibial amputation is the Solid Ankle Cushioned Heel (SACH), as shown in Figure 2.2d (LeMoyne, 2016). The SACH foot is the most basic prosthetic foot still used in practice today.

Rusaw, D. and Ramstrand, N. (2011) conducted a systematic review of motion-analysis studies of transtibial prosthesis users. This literature founded that in total, 34 of the reviewed papers investigated SACH feet, 20 of which were published between the years 2000–2009, with five published in 2006. Rusaw, D. and Ramstrand, N. (2011) concluded that the SACH foot had received the most attention in transtibial amputee research; one could assume that this is the most commonly prescribed foot.

The SACH foot is a non-articulated foot having a wooden keel which acts as a solid ankle as well as a portion of the heel (Adalarasu et al., 2011). For people with lower limb amputations in developing countries such as Thailand, the requirements are logically influenced by the apparent limitations of economic resources (LeMoyne, 2016). The low cost of the SACH makes it an economical choice. So we will focus on this type of foot in this thesis.

2.4 Gait cycle

The understanding normal gait cycle is essential to the evaluation and management of abnormal gait patterns. In this session, the principles of normal gait are introduced. The simplest subdivision of the gait cycle divides the cycle into two periods by floor contact pattern (Baker, 2013). The first period of the gait cycle is the stance phase. The stance phase is about 62% of the gait cycle and refers to the time that foot is in contact with the ground. The second period is the swing phase and is about 38% of the gait cycle. Swing phase is the time when the foot is in the air (Baker, 2013). The Rancho Los Amigos Gait Analysis Committee (Sutherland et al., 1994) subdivided the gait cycle into 8 phases, which are based on the respective events of gait.

The first phase is the initial contact. The interval of initial contact is 0% - 2%. Initial contact is the moment when the ipsilateral foot just touches the floor. Normally, the heel is the first part of the foot to touch the ground. Meanwhile, the contralateral leg is at the end of terminal stance.

The second phase is the loading response, which is from 2% - 10% of the gait cycle. The description of loading response is the period when the ipsilateral forefoot contacts the floor and continuing until the contralateral foot is lifted for the swing. In this period, loading is transferred from one leg to the other.

The time interval for the third phase, Midstance, is 10% - 30% of the gait cycle. This phase begins with the lifting of the contralateral foot and continues until body weight is aligned over the supporting foot. The ipsilateral leg advances pass the ipsilateral foot. Ankle dorsiflexion is present, and the hip and knee extend. The contralateral leg is advancing in its mid-swing phase.

Terminal stance begins when the ipsilateral heel rises and continues until the heel of the contralateral foot hits the ground. Bodyweight progresses beyond the ipsilateral foot. This period is 30% - 50% of the gait cycle.

Pre-swing is the last phase of the time when the foot is in contact with the floor. The time interval is 50% - 60% of the gait cycle. It begins with initial contact of the

contra-lateral foot and ends with toe-off of the ipsilateral foot. Ground contact by the contra-lateral leg causes the ipsilateral leg to increase ankle plantar flexion, increased knee flexion, and decrease hip extension. In this phase, loading is transferred from one limb to the other.

Initial swing, the time interval is 60% - 70% of the gait cycle. It begins when the foot is lifted from the floor and ends when the swinging foot is opposite the stance foot. The ipsilateral leg is advanced by increased hip flexion and increased knee flexion. The ankle is only partially dorsiflexed to ensure ground clearance.

The time interval between 70% - 85% of the gait cycle is mid-swing. This period continues from the end of the initial swing and continues until the swinging limb is in front of the body and the tibia is vertical. Advancement of the ipsilateral leg is accomplished by further hip flexion. The knee is allowed to extend in response to inertia while the ankle continues dorsiflexion to neutral. The contralateral leg is in late mid-stance.

The final phase of gait is terminal swing form 85% - 100% of the gait cycle. It begins when the tibia is vertical and ends when the foot touches the floor. Limb advancement is completed by knee extension. The hip maintains its flexion, and the ankle remains dorsiflexed to neutral.

2.5 Trans-tibial Gait Deviations

A gait deviation is any walking pattern that deviates from a smooth and normal able-bodied gait. While assessing prosthetic gait, it is important to know how gait in the amputee may be affected.

There are several possible causes of gait deviation in the trans-tibial amputee. For example, prosthetic misalignment, improper prosthetic components, restricted range of motion, muscle weakness, fear / insecurity and old habits/patterns. Berger, (2002) stated that to assist in observing gait deviations which are often sometimes-subtle characteristics with complex causes, the phases of the walking cycle (Figure 2.4) in which the deviation occurs are identified (Berger, 2002).

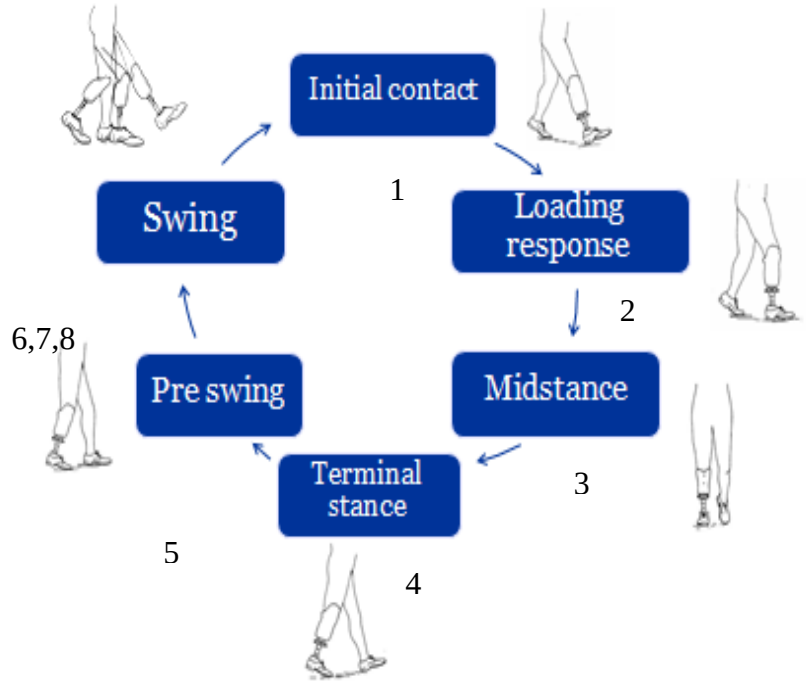


Figure 2.4 Amputee gait during the gait cycle

The process of observational gait analysis involves three important steps (Berger, 2002). The first step is an observation of the amputee's gait from at least two planes; the sagittal plane which views from the side and the frontal plane view from the front or back. The second step is an identification of the gait deviations. In this step, the prosthetist attempts to define any abnormal gait characteristic by comparison to normal gait. The last step is the determination of causes. The prosthetist uses their knowledge of normal locomotion, their observation of the amputee and their knowledge of the cause of gait deviations to identify the cause of the pattern regarding incorrect alignment, socket problem and suspension (Berger, 2002; Smith et al., 2004).

The common gait deviations in trans-tibial amputees are summarised. The most common deviation is excessive knee flexion. The best view to observe excessive knee flexion is from the side of the patient. During walking, the trans-tibial amputee is seen walking with an excessive range of knee motion on the amputated side (Berger, 2002). The possible causes of this gait deviation are too much flexion of the socket, and the prosthetic socket is too anterior to the prosthetic foot (Berger, 2002).

The second most common deviation is absent or insufficient knee flexion. The normal knee shows a peak of extension in the terminal stance of between 0^{o} and 15^{o} of flexion (Hillman et al., 2010). During walking, the trans-tibial amputee is seen walking with no or insufficient knee flexion on the amputated side (Berger, 2002). The possible causes of this gait deviation are insufficient socket flexion, and the prosthetic socket is too anterior to the prosthetic foot (Smith et al., 2004).

Uneven step length leads to asymmetry in the gait cycle. In trans-tibial gait, it is common for uneven step lengths to occur. This gait deviation is a short prosthetic step (Berger, 2002). The possible causes of this gait deviation are insufficient flexion of the socket during bench alignment (Mccollough et al., 1981).

During midstance, the pylon can lean laterally. This derives from the tendency of the prosthesis to rotate around the amputated limb (Berger, 2002). The best view to observe this gait deviation is from the front or back of the patient. The possible causes of this gait deviation are that the socket is set in too much abduction, and the foot is set too much medially (Smith et al., 2004).

Narrow base gait occurs when the amputee's base of walking is less than 50 mm between the feet at midstance. The possible causes of this gait deviation are the foot is too inset (Mccollough et al., 1981).

Fewer gait problems are involved with the swing phase than with the stance phase. The crucial aspect in trans-tibial amputees gait is a failure of toe clearance (Wilken and Martin, 2009) where the foot touches the floor during midswing. It can be observed from the lateral view of the patient. The possible causes of this gait deviation are that the prosthesis is too long (Mccollough et al., 1981).

2.6 Prosthetic Alignment

The definition of alignment as given by ISPO, is to "Establish the position in the space of the components of the prosthesis or orthosis relative to each other and the patient" (ISO, 1989). Moreover, alignment can be considered the optimisation of the

spatial relationship between the prosthetic socket and foot as to produce as near a normal pattern of gait as is possible.

Wen and Chen, (2012) explain how to perform the prosthetic alignment. A trans-tibial prosthetic alignment is performed in three orthogonal planes of the Cartesian system commonly referred to as the anterior/posterior (AP), medial/lateral (ML), and transverse (horizontal) planes as shown in Figure 2.5.

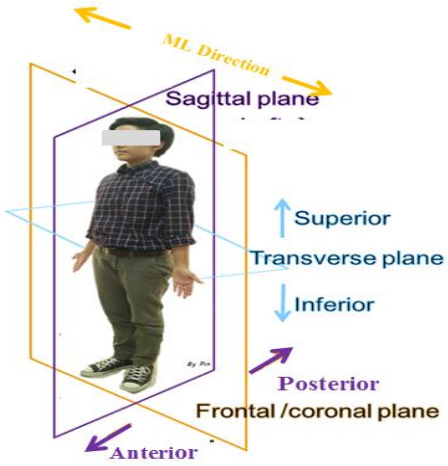


Figure 2.5 Three orthogonal planes of the Cartesian system

2.6.1 Alignment Process

The process of aligning a prosthesis occurs in three stages, referred to as "bench alignment", "static alignment" and "dynamic alignment" (Chen, 2012).

2.6.1.1 Bench Alignment

Prosthetic bench alignment is described as the initial alignment of the components of the prosthesis based on components' characteristics and with previously acquired data regarding the patient individually (ISO, 1989). Bench alignment is taken place on the laboratory bench without any trials by the amputee Figure 2.6.

Figure 2.6 Bench alignment

2.6.1.2 Static Alignment

Static alignment is " a process whereby the bench alignment is refined while the prosthesis is being worn by the stationary patient" (ISO, 1989) as shown in Figure 2.7.

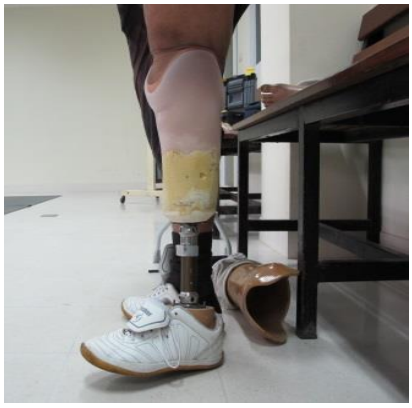


Figure 2.7 Static alignment

2.6.1.3 Dynamic Alignment

Dynamic alignment, which is the final stage in fitting, is described as a process whereby the alignment of the prosthesis is optimised by using observations of the movement pattern of the patient (ISO, 1989).

Dynamic alignment (Figure 2.8) needs to be the most precise alignment stage since it is the final step of the alignment process and determines the final position of the prosthetic components (Chen, 2012). Dynamic alignment aims to achieve the most suitable limb geometry for best function and comfort (Zahedi et al., 1986).

Figure 2.8 Dynamic alignment

2.6.2 Trans-tibial Prosthetic Alignment Changing

During prosthetic assembly and alignment, the prosthetic components are designed to be able to change and adjust the relationship between each component. The structural components (Figure 2.9) allow the prosthetist to adjust the position between the socket and foot correctly. An adjustable alignment system was used in this thesis including a pyramid which is placed underneath the prosthetic socket, a sliding adapter which is placed between the prosthetic socket and pyramid receiver and a pyramid receiver which is placed underneath the sliding adapter.

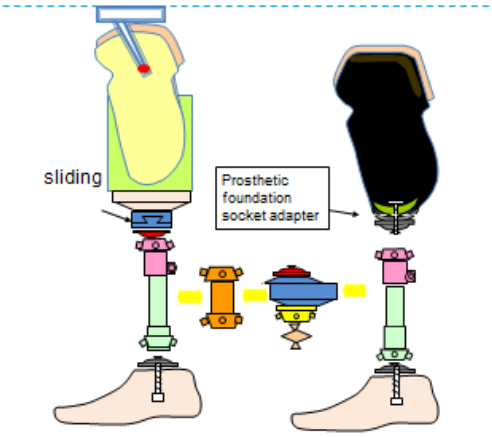


Figure 2.9 Trans-tibial prosthetic strictures

The position between the socket and foot can be adjusted in angular tilt by using the pyramid system. The system is adjusted by Allen keys and allows varying degrees of angular tilt in any direction from a neutral position. The Pyramid System Adapters consist of a concave pyramid receiver with 4 screws a convex contact surface with a pyramid-shaped alignment core. The pyramid is clamped with the 4 alignment

screws of the pyramid receiver. It is a rigid but detachable connection with 7 degrees of tilt in each direction, as shown in Figure 2.10. The adjustments can be changed by turning screws at the below-socket, as shown in Figure 2.11 or by turning screws in the alignment unit itself, as shown in Figure 2.11.

The position between the socket and foot can be adjusted in translation **(**shifts**)** by using a sliding adapter, as shown in Figure 2.3. The adjustments can be changed by turning screws in the sliding adapter unit itself, as shown in Figure 2.11.

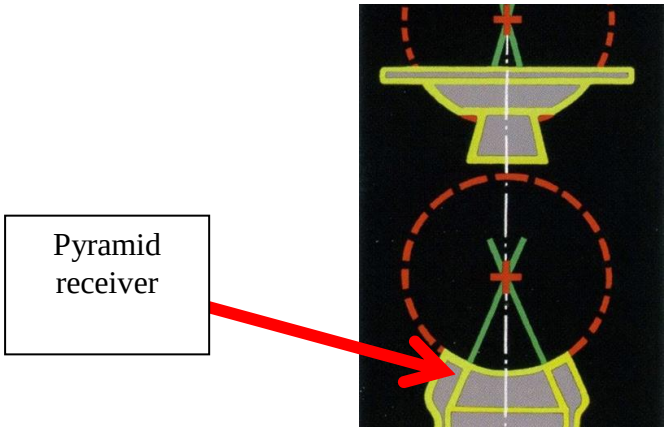


Figure 2.10 The pyramid system

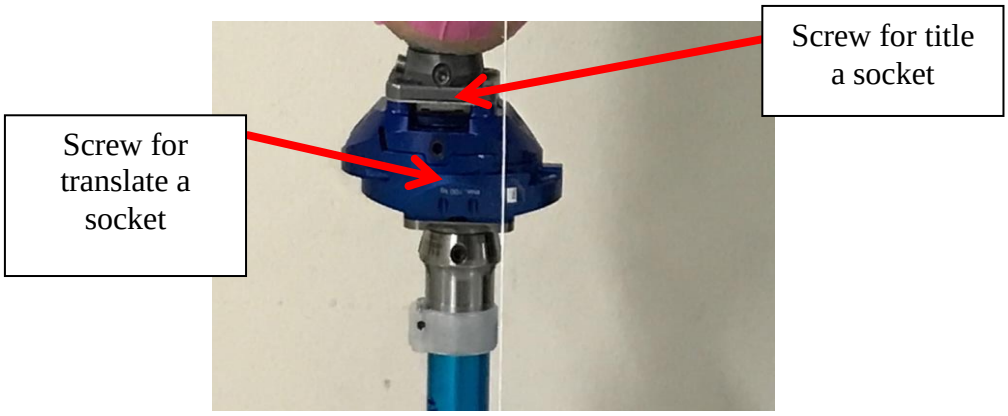


Figure 2.11 Screws at the alignment device

A considerable array of changes can be made, as illustrated in Figure 2.12. There is an ability to change anteroposterior socket positioning (socket AP shift), anteroposterior tilting of the socket (socket AP tilt), mediolateral socket positioning (socket ML shift), mediolateral tilting of the socket (socket ML tilt), foot rotation

(toe out/in angle) with respect to the line of progression and the height of the socket, (Kapp and Cummings, 2002; McCollum, 2004; Zahedi et al., 1986).

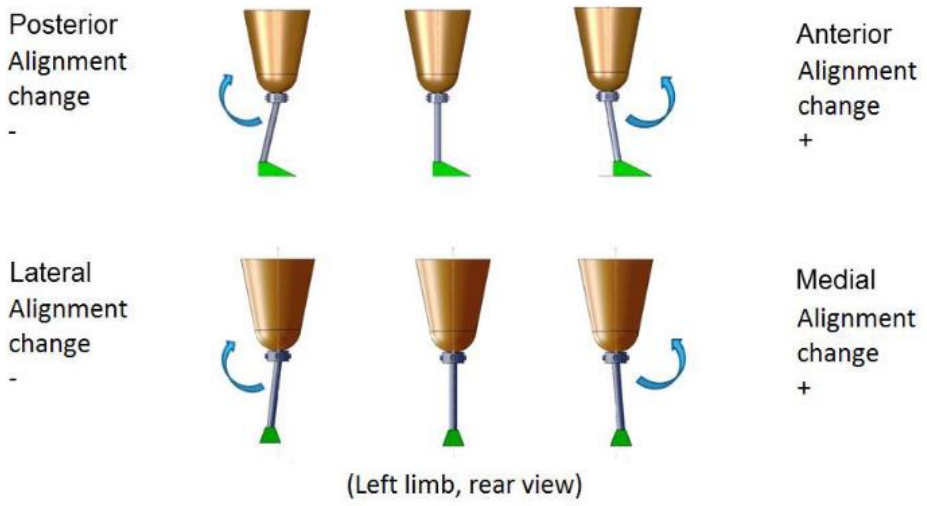


Figure 2.12 Array of alignment changing

In summary, an adjustable alignment unit allows all alignment parameters proposed by Zahedi MS (Zahedi et al., 1986) to be altered. They are

1. Anteroposterior socket positioning (Socket AP shift)

Socket shift can be done by using a sliding adapter (Figure 2.3). Turning the anterior adjustment screws with a 4 mm Allen wrench will make the upper sections slide on the centrepiece. The graduated scales allow for a precise adjustment.

2. Anteroposterior tilting of the socket (Socket AP tilt)

Anteroposterior tilting of the socket can be adjusted by pyramid and connector. Tilt is achieved by loosening one screw and tightening the opposite screw.

3. Mediolateral socket positioning (Socket ML shift)

Socket shift can be done by using a sliding adapter (Figure 2.3). Turning the lateral adjustment screws with a 4 mm Allen wrench will make the upper sections slide on the centrepiece. The graduated scales allow for a precise adjustment.

4. Mediolateral tilting of the socket (Socket ML tilt)

Mediolateral tilting of the socket can be adjusted by pyramid and connector.Tilt is achieved by loosening one screw and tightening the opposite screw.

5. Prosthetic height

Prosthetic height can be adjusted by cutting the pylon or changing a pylon as shown in Figure 2.13. Estimate the pylon length needed and assemble all parts. Measure the height of prosthesis Compare with PTB to ground measurement If the height is longer, the pylon is cut at the end length of the prosthesis is achieved by the correct size of the structural component which connects the two alignment pyramids.

Figure 2.13 Pylon with cutting line.

6. Toe out/in angle (Foot rotation)

A rotational adjustment can be carried out with the socket adapters with rotation (Figure 2.14) or with the tube adapter. A tube clamp exists between socket and shin tube to allow alteration of length and rotation of the foot. The adapters are designed as socket adapters with pyramid receiver. They are provided with various types of distal connection.

Figure 2.14 Rotational adapter.

2.6.3 Conventional Alignment in Practice

In the first stage, conventional bench alignment requires general knowledge about prostheses, clinical skill and limited technology. A plumb line or laser level can be used to visually align the midpoint of the socket with the ankle bolt when viewed in the sagittal plane (Adebayo et al., 2011). In the frontal plane, the line is used to visually match the midpoint of the socket to the centre of the heel, as shown in Figure 2.15a. This plumb line (Figure 2.15a) or laser line (Figure 2.15b) allows the prosthetist to view the alignment from slightly varied angles (Adebayo et al., 2011).

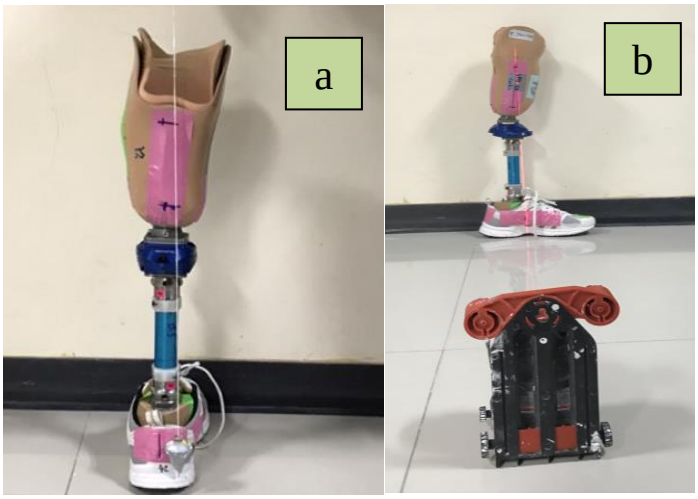


Figure 2.15 A plumb line or laser line used to visually align the midpoint of the socket with the ankle bolt at bench alignment

In static alignment, the prosthetist adjusts a mechanical alignment device placed between the socket and prosthetic foot while the patient is wearing the prosthesis (Boone, 2005). Clinically, the prosthetist observes the patient's balance and prosthesis height (Figure 2.16) by observing if the pelvis is level in the frontal plane and if not adjust the length of the prosthesis as required by adding the compensation board underneath of lower side as shown in Figure 2.17. Stance stability is achieved with balanced foot leverage an equal foot contact during standing.

Figure 2.16 A prosthesis is checked for height during static alignment (Boone, 2005)

Figure 2.17 A compensation plate

In the clinical setting of the final stage, dynamic alignment is performed in response to observations made when the patient walks and feedback from the patient as he/she walks. An Observational Gait Analysis (OGA) is the most common method for gathering gait analysis data during dynamic alignment. Throughout this thesis, OGA is represented in the word of "conventional alignment technique" during the phase of dynamic alignment. In OGA, the procedures (Berger, 2002) are as follows: observation, identification of gait deviations and determination of causes of gait deviation followed by adjusting of the prosthesis. To use OGA requires knowledge and understanding of the biomechanics of gait (Smith et al., 2004). Thus the

definition of an “optimal” alignment becomes relative to each person, adding variability to alignment outcomes.

For conventional alignment technique, the prosthetist uses their eyes, expertise, insight understanding and feedback from the patient to optimise the alignment (Chen et al., 2016). Factors such as previous experience, understanding of the cause of posture deviations, information on zones of overload at the stump-socket interface, and feedback received from the patient assist the prosthetist in making alterations to the geometrical configuration of the prosthesis until the desired alignment is achieved (Fridman et al., 2003).

Failure to provide a correct alignment may result in problems for the amputee (Zahedi et al., 1986). Misalignment may lead to difficulty in walking, skin abrasion and uneven forces acting on the residual limb within the socket, which could lead to discomfort, pain, and even more serious skin and joint trauma such as infection and musculoskeletal complications (Chen et al., 2016; Zahedi et al., 1986). This, in turn, leads to problems for the prosthetist since the patient will inevitably return to the clinic and with a more complex problem to solve. It is therefore important to make every endeavour to provide an acceptable alignment to the patient on every occasion.

During the dynamic phase of prosthetic alignment, the prosthetist is adjusting the alignment in response to the observation by using the Allen keys. The screws are used to perform a tilt by adjusting one pair of screws or a shift by adjusting two pairs of screws at two different locations. A plumbline device is used to define the reference planes (AP and ML). Several instruments are using for achieving the required alignment: permanent marker, goniometer, measuring tape, plumb bob, tape and Allen key, as shown in Figure 2.18.

Figure 2.18 Tools using for conventional alignment changing.

An important limitation of the current prosthetic alignment approach is the subjectivity and the lack of standardized quantifiable baseline values. To achieve optimal alignment using conventional method takes several hours to several weeks to finalise the dynamic alignment (Blumentritt, 1997). The time taken depends on the prosthetist's skill and experience and the complexity of the patient (Blumentritt, 1997). An alignment optimisation can be a very time- consuming process when accomplished by the subjective judgment of the prosthetist based on visual observation of gait and feedback from the patient (Fridman et al., 2003; Zahedi et al., 1986).

Jonkergouw et al., (2016) conducted a systematic review of the effect of alignment changes on unilateral transtibial amputee's gait. The review states that gait deviations are commonly used to help during dynamic alignment tunning. The dynamic alignment is undertaken through iterative adjustments based on observation of the amputee's gait. Jonkergouw et al., (2016) also mentioned that prosthetic alignment is optimized through repetitive optical gait observation and induction of alignment adjustments when gait deviations as described in previous session 2.5 are detected in spatiotemporal and kinematic gait parameters (Jonkergouw et al., 2016). Van Velzen et al., 2005 argued that alignment of transtibial prostheses performed using observation was subjective and unlikely to be the most effective way of producing optimal alignment and with no clear guidelines for the correct alignment (Van Velzen et al., 2005).

From the reviewed literature, it may be suggested that current conventional alignment tuning based on visual observation is neither sufficiently reliable nor sensitive to detect small deviations.

2.7 An instrument-assisted prosthetic alignment technique

An instrument-assisted prosthetic alignment technique for individuals with a transtibial amputation can be used to provide evidence-based practice. The need for the evidence-based practice, a quantitative measure, has become more pertinent to help objectively assess the outcomes of alignment techniques.

For bench alignment stage, one system that could be used was developed by Sin et al., (1999). This system is a mechanical device and could be used to measure and prescribe alignment for trans-tibial prostheses only during bench alignment. This instrument (Figure 2.19) is not convenient and not able to be used during gait testing or static alignment as the patient has to take off his/her prosthesis when using this apparatus.

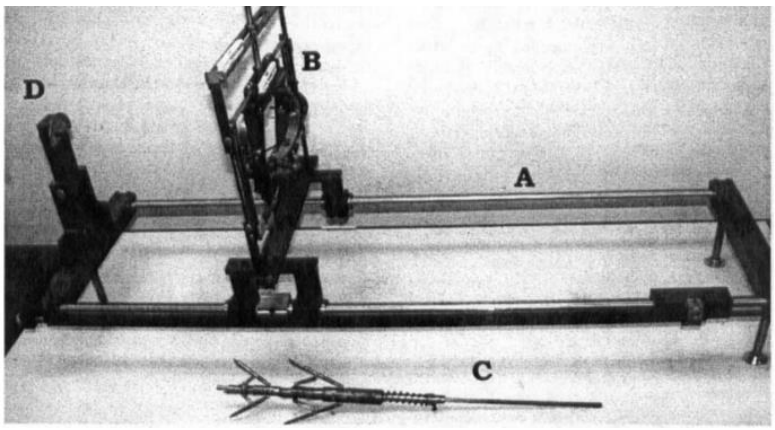


Figure 2.19 The alignment jig. A - The alignment table; B - the vertical mount; C - the socket axis locator; D - the adjustable socket mount with 4 scales. (Sin et al**.,** 1999**)**

For static alignment stage, From the literature, one system used in clinical practice is the "L.A.S.A.R. Posture system" (Figure 2.20; Blumentritt, 1997) which is intended to aid the statistic alignment process by quantifying the standing balance of the amputee in terms of variables such as the centre of pressure (COP) or the weight line (Chen, 2012).

Figure 2.20 Measuring the static alignment of a trans-tibia1 amputee. (Blumentritt, 1997)

For the dynamic alignment stage, a comprehensive literature review found a few studies of the development of devices which provide clinicians with objective measures relative to dynamic prosthetic alignment during gait and some are available on the market. Therefore, in the worldwide clinical setting, a wide range of tools is available to assess amputee gait performance during dynamic tuning. These tools range from the brief informal visual assessment commonly used in the clinic to the application of advanced motion capture technologies (Wilken and Martin, 2009).

Hillman et al., (2010) developed a visual gait score and assessed the repeatability of an observational gait analysis score that was developed specifically for unilateral amputees. The prosthetic observational gait score was constructed to analyse 16 aspects of amputee gait (Table 2.1). The summary score was computed as the sum of the scores for each of the 16 items. The scoring criteria were based on observations made in established practice in clinical prosthetics. These observations took into account anatomical levels of the trunk, hip, knee, ankle and foot. This study has demonstrated good intraobserver repeatability with an average repeatability coefficient of 3 (range 1.5–4.6). Interobserver repeatability was poor with a repeatability coefficient of 5.9. Although this tool showed intraobserver repeatability, it is still based on visual observation. However, there is published evidence that the visual observation was an ‘‘unreliable clinical skill’’ and inadequate for optimizing the gaits of lower-limb amputees. (Blumentritt, 1997; Gard, 2006; Saleh and Murdoch, 1985). The inadequacy of visual observation emphasises the need for objective measurements.

Item	Observation	% agreement 1st observation	% agreement 2nd observation	Average % agreement	Ranking by % agreement	Pooled kappa	Ranking by kappa
1	Arm Swing	55	46	50	15	0.34	7
2	Vaulting in stance	67	74	71	7	0.24	10
3	Lateral trunk lean/side flexion in stance	63	74	68	8	0.16	14
4	Peak sagittal position	53	56	55	14	0.18	13
5	Peak hip extension in stance	63	57	60	11	0.29	8
6	Peak hip flexion in swing	67	76	72	6	0.26	9
7	Peak knee extension in stance	87	87	87	1	0.46	3
8	Knee flexion in terminal stance	63	69	66	10	0.43	4
9	Peak knee flexion/heel rise in swing	65	69	67	9	0.52	2
10	Knee in terminal swing and at initial contact	69	85	77	5	−0.03	16
11	Step symmetry	48	52	50	16	0.21	11
12	1st ankle rocker	87	82	84	2	0.60	1
13	Foot rotation at initial contact	79	80	80	3	0.20	12
14	Width of base/Lateral thrust	52	59	55	13	0.39	6
15	Circumduction in swing	78	80	79	4	0.40	5
16	Swing phase whip	61	55	58	12	0.09	15

Table 2.1 Interobserver agreement for each scoring item developed by Hilman et al., (2010)

One method of augmenting observational analysis is through the use of a 2D video camera. Visual gait analysis, performed by viewing a videotape recording of the subject's gait, can greatly aid with the interpretation of the quantitative gait data (Gard, 2006). The process can generally be facilitated by involving someone who is knowledgeable about the measures and skilled in analyzing and interpreting the data.

The recorded movements can only be considered valid if the movement is in the plane of the camera and the camera is perpendicular to the subject. Further, these methods generally require the user to identify joint centres in the sagittal or coronal planes, thus allowing the software to calculate joint angles in one plane using simple geometry. However, this method is still subject to user variability in the identification of joint centres. Users will often be required to process a gait or functional movement trial on a frame by frame basis, making the processing time consuming and also increasing joint centre location variability.

The Compas™ system is an instrument-assisted dynamic prosthetic alignment technique for individuals with trans-tibial amputation (Chen et al., 2016). The Compas™ Figure 2.21) consists of an instrumented pyramid adaptor that is fitted at the distal end of the socket. It has a built-in load sensor to measure axial forces, flexion and extension moments, and varus and valgus moments, which are all defined in the instrument's local coordinate system. The system also has a module for transmitting the data from the transducer to the computer, where the moment data

are graphically presented (Figure 2.22), and alignment suggestions are provided. Chen et al., (2016) compared an instrument-assisted dynamic alignment technique (Compa™) to conventional methods. The results of the study showed that there were no differences between alignment techniques in global gait measures. The study also conducted questionnaires. From the questionnaire, six amputees had no preference, while three preferred the conventional alignment. Chen et al., (2016) concluded that the use of Compas™ appears to produce similar alignment results as conventional techniques, although with slightly higher moments at the socket.

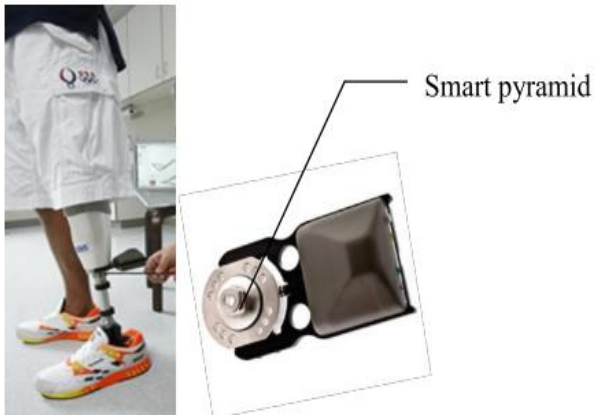


Figure 2.21 Compas™ system (Orthocare Innovations, 2009) used in (Chen, 2012)

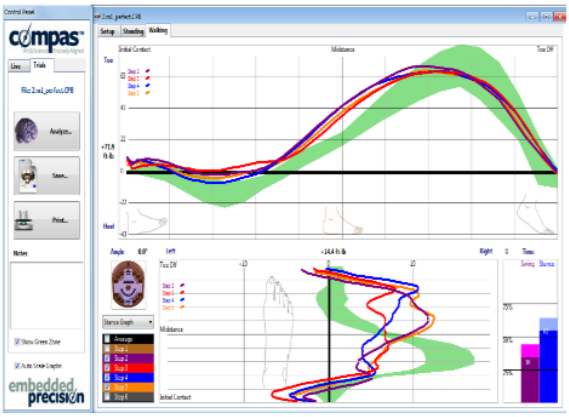


Figure 2.22 Compas™ system trial analysis plot (Chen, 2012)

Kobayashi et al., (2015) reported the possibilities of assisting dynamic alignment of trans-tibial prostheses through visualisation of socket reaction moments. Smart Pyramid™ (currently Europa™) was used to measure the socket reaction moments

under various alignment conditions from an amputee with a trans-tibial prosthesis. There are some limitations associated with the alignment tuning process using the Smart Pyramid. This device was used to assist in dynamic alignment. The report recommended that kinetic and kinematic behaviour are closely linked, and it may not be possible to manipulate one without modifying the other. They concluded the contribution of kinetics and kinematics for optimal prosthetic alignment requires further research (Kobayashi et al., 2015).

Harlaar et al., (2000) developed a new system - called SYBAR. This system consists of video cameras, a force plate, and an EMG recorder used for the lower extremities in gait studies. The outputs from the system are temporal, spatial gait characteristics, the amplitude, direction of the ground reaction force (GRF), muscle activity and a projection of the force vector. (Harlaar et al., 2000). Van Velzen et al., (2005) suggested that the SYBAR system could be used for dynamic alignment in clinical practice (Noldus Information Technology, The Netherlands). Van Velzen et al., (2005) also conducted a study to investigate which systematic effects of prosthetic misalignment could be observed using the SYBAR system. Temporal and spatial characteristics, the magnitude and timing of the ground reaction force (GRF), and the external joint moments were derived from these data. The results from using the SYBAR system in this study revealed little effect of perturbations in prosthetic alignment and were hardly found for the selected parameters. Only the pattern of the GRF in the mediolateral direction and joint moment around the ankle in the frontal plane showed a systematic effect when the alignment changed. It was suggested that the usability of the SYBAR system in clinical settings should be further explored (Van Velzen et al., 2005).

Recent advances in motion capture technology are making it possible for motion capture instruments that are sensitive to prosthetic alignment and would, therefore, be valuable for providing additional information for aligning prostheses (Kobayashi et al., 2015). Three-dimensional motion analysis has been used since the early 1980s to evaluate the gait parameters of trans-tibial amputees gait (Gard, 2006; Rusaw and Ramstrand, 2011). Instrumented gait analysis has been used commonly in clinical research, and there are several methods of capturing three-dimensional data and

interpretation of research findings (Gard, 2006; Rusaw and Ramstrand, 2011). Key advantages of quantitative gait analysis for persons with lower-limb pathologies are that the results allow for easy comparison of a patient's gait characteristics to an able-bodied pattern for a relatively quick determination of abnormal movements (Gard, 2006) .Moreover, Saleh and Murdoch, (1985) compared the observational analysis of prosthetic alignment with a marker based measurement system and concluded that the measurement system used was accurate in recording gait deviations and picked up 3.4 times as many deviations as visual observation (Saleh and Murdoch, 1985). Gait analysis aims to collect quantitative information about joint kinematics, joint kinetics and the body centre of mass during walking (Cappozzo et al., 2005)

Hence, alignment instrumentation has been developed for prosthetic alignment from the bench (Sin et al., 1999), to the static (Blumentritt, 1997) and the dynamic alignment (Chen et al., 2016; Harlaar et al., 2000; Kobayashi et al., 2015). However, the available instrumentation could not be used in all three stages of the alignment processes; most of these systems permit only one stage of alignment. As mentioned previously, an objective way of delivering accurate and reliable prosthetic tuning could be achieved using marker based measurement with motion capture technology. Moreover, it would be possible to use this technology throughout the three stages of the alignment process. However, routine use of motion capture in the clinical environment remains limited.

Therefore, in order to increase the use of motion analysis in routine clinical practice to deliver appropriate alignment feedback, there is a need for a motion analysis protocol which requires minimal technical expertise to operate and is less time consuming than current systems. I have hypothesised that the use of motion analysis would allow real-time feedback of alignment, detection of gait deviations and recommendations for prosthetic tuning.

2.8 3D motion capture

In the previous review section, one method of augmenting observational analysis is quantitative gait analysis using motion capture. Lusardi et al., (2013) also mentioned

that motion analysis had played a crucial role in prosthetic research providing objective outcome measurement of prosthetic technology for many decades (Lusardi et al., 2013). According to Gard, (2006), gait assessment may be useful for evaluating an amputee's prosthesis by providing objective measurements that characterize the walking pattern.

Throughout this study, 3D motion analysis will be the main method for real-time alignment of a prosthetic limb by a custom system and user interface that allows real-time blending of a motion database that contains all the possible alignment errors and enables real-time comparison to alignment baseline.

Instrumented motion analysis allows objective and accurate measurement. In a clinical or research setting, motion analysis refers to the study of the motion of the human body using specialised hardware and software for collecting, processing and analysing biomechanical parameters of patient gait (Gard, 2006; Rusaw and Ramstrand, 2011). In the following section, biomechanical model, hardware and software configurations used throughout the study are detailed, along with definitions for global, anatomical and technical reference frames.

2.8.1 Hardware used in motion analysis

There are a number of commercially available motion capture systems. Recent additions to the hardware available are documented below.

2.8.1.1 Use of an instrumented treadmill for gait analysis

Treadmills have recently been used for objective clinical gait analysis. To replace overground gait analysis which requires much more space (Van der Krogt et al., 2014; Sloot et al., 2014). The use of instrumented treadmills in research has grown in popularity in recent years (Zeni and Higginson, 2010). The benefits of the treadmill to overground gait analysis is described by Sloot et al., (2014) are as follows; they allow for several gait cycles to be recorded and they require a small area of the laboratory. The operation of the treadmill can be categorised into two types. The first is "fixed-speed" mode. Conventionally, biomechanics research has been performed on treadmills operating at a fixed speed (Sinitski et al., 2015). However, Sloot et al.,

(2014) mentioned that "walking on a treadmill is known to affect gait performance, resulting in decreased preferred walking speed and stride length, slightly decreased the joint range of motion and small changes in EMG activation". The second mode is "self-paced". A self-paced (SP) mode is a feedback-controlled treadmill that allows patients to walk at their preferred comfortable speed (Sloot et al., 2014). In SP mode, the treadmill automatically modifies its speed in real-time to match the subject's walking speed. A treadmill with self-paced mode could, therefore, enable a more natural gait than is possible with conventional treadmills operating at a fixed speed (Sinitski et al., 2015).

2.8.1.2 Computer Assisted Rehabilitation Environment

Computer Assisted Rehabilitation Environment (CAREN) (Motekforce Link, Netherlands) is a system that can provide perturbations and dual tasking, capture measurements and provide feedback in several ways, including visualization. In this way, gait analysis becomes easier to objectify and quantify. The systems consist of a motion base, motion capture, a projection screen, force plate and the D-flow software System (Geijtenbeek and Steenbrink, 2011). The CAREN system with D-flow software is available at the University of Strathclyde.

2.8.2 Software used in motion analysis

There are various commercially available software packages used in motion analysis. This section outlines the software available for use in a motion laboratory at the University of Strathclyde.

2.8.2.1 Vicon Nexus and Vicon Tracker

The Vicon motion analysis system is an accurate optoelectronic motion analysis computerised system used for objective gait analysis using Nexus software and single markers (Szczerbik and Kalinowska, 2011). Vicon also provides Tracker 3.2.0 (Vicon Motion Systems, Oxford, UK) which is a real-time system for modelling based on the use of clusters of the markers, which is fast, flexible and precise and used in the animation industrial. This tracker is able to offer low latency real-time modelling of human movement.

2.8.2.2 D-flow

D-Flow (Motekforce Link, Netherlands) is software used with the CAREN and designed for the development of interactive virtual reality applications. The purpose of this system is to enable clinical research and rehabilitation in movement analysis. The D-Flow is a software system designed for the development of interactive and immersive virtual reality applications, for clinical research and rehabilitation. The key concept of the D-Flow software system is that the subject is regarded as an integral part of a real-time feedback loop, in which multi-sensory input devices measure the behaviour of the subject, while output devices return motor-sensory, visual and auditory feedback to the subject. The D-Flow software system allows an operator to define feedback strategies through a flexible and extensible application development framework based on visual programming. The D-flow module for Gait Analysis produces various parameters useful for gait feedback. The module uses both motion capture and force plate data. All parameters are computed in real-time and can be used as part of a training application. the motion data can be streamed into D-flow directly from Vicon Tracker.

2.8.3 Coordinate systems

Description of skeletal system movement involves the definition of specific sets of axes or frames that are either global or local. Those two coordinates system must be defined when conducting a 3D gait analysis.

Global or laboratory coordinate system (GCS) is referred to as the inertial reference system (Figure 2.23). The GCS is determined when calculating the system prior to 3D capture (Robertson et al., 2004). In human movement analysis, orthogonal coordinate systems are used for a global/laboratory reference frame usually defined with the x-axis defined in the direction of progression, y-axis vertical positive upward, and z-axis medio-lateral positive pointing to the right (Right-handed system).

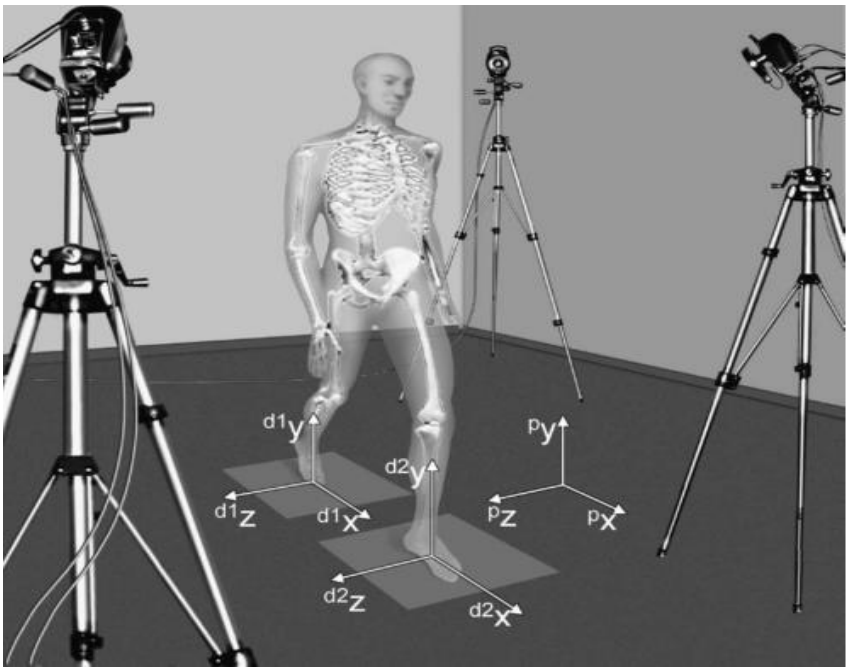


Figure 2.23 Global or laboratory coordinate system (GCS) (Cappozzo et al., 2005)

The local frame rigidly associated with a bony segment is referred to as a Local Coordinate System (LCS) and moves with the body segment (Robertson et al. 2004). These frames are used to describe the location in space, either stationary or time-varying, of the segment under analysis Figure 2.24) (Cappozzo et al., 2005). The Local Coordinate System (LCS) is defined in accordance with the International Society of Biomechanics (ISB) convention of the right-handed orthogonal triad (Papi, 2012).

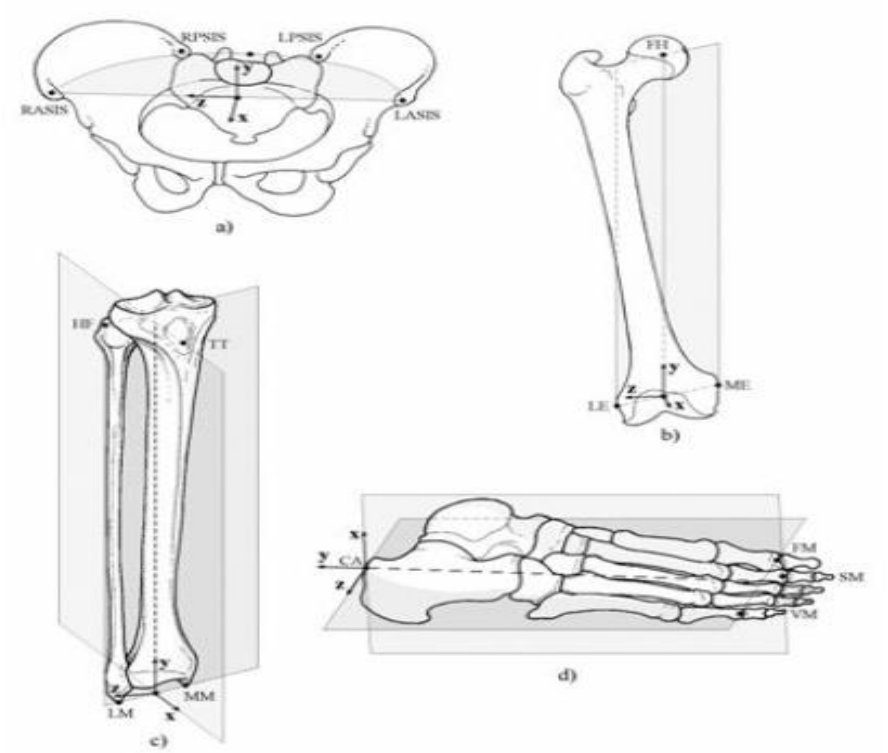


Figure 2.24 Local Coordinate System **(**LCS**) (**Cappozzo et al**.** 1995**)**

2.8.4 Joint Kinematics

Joint kinematics describes the relative movement between two contiguous bony segments in three - dimensional space. Two adjacent bones are the proximal (p) and the distal (d) as shown in Figure 2.25 (Cappozzo et al., 2005; Papi, 2012). Joint motions are described by six degrees of freedom (6 DOF). 3DOF are translational, and 3 DOF are rotational. Joint angles are widely used for clinical decision- making and treatment planning (Papi, 2012). A description of joint attitude in clinical use can be reported in three planes, i.e. the sagittal, coronal, and transverse anatomical planes of the body (Papi, 2012). There are various methods used to calculate the joint angle, as shown in Table 2.2 with definitions and pros and cons noted. The Grood and Suntay method is recommended by ISB (Wu et al., 2002).

Method	**Definitions**	**Pros**	**Cons**
Plane projections	Angles projected onto plane	Simple	Parallax
Direction cosines	Transformation	Complete	Not clinically

		representation	relevant
Euler/Cardan	The sequence of rotations axis	Clinical interpretation	Gimbal locks
Grood and Suntay	Euler with floating	Sequence-independent	Not suitable for kinetics
Helical	Screw axis	Rotation and translation	Sensitive to noise

Table 2.2 Methods of joint angle calculation (Sutherland, 2002)

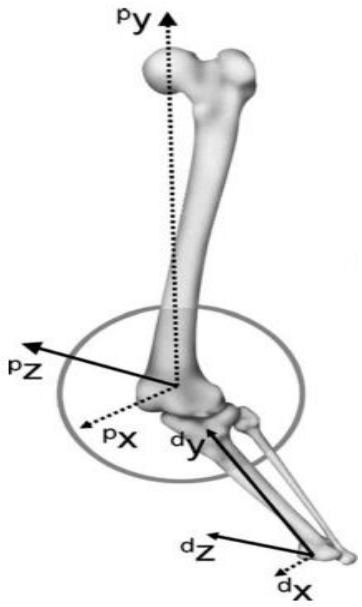


Figure 2.25 Proximal and distal anatomical frames used to describe joint kinematics (Cappozzo et al., 2005)**.**

2.8.5 Associated errors in human movement analysis

The important aspect of assessing the reliability of human movement analysis is the estimation of the effects of different sources of error on joint kinematics (Della Croce et al., 2005). Marker trajectory reconstruction is often affected by errors that can compromise the estimation of joint kinematics and kinetics (Papi, 2012). There are two principal sources of error. Those errors can be attributed to the model calibration and those attributed to soft tissues artefacts (STA) (Baker, 2006).

The model calibration has two aspects. The first aspect is placing accurately markers concerning specific anatomical landmarks. The second aspect is determining the location of the joint centres from these markers (Baker, 2006). The model calibration error can be minimised with the optimal calibration of the system and using appropriate filtering and smoothing techniques. Extensive surveys of these techniques have been provided by Wood, Gazzani, and Woltring (Chiari et al., 2005). One of the most popular filters used is the generalised cross-validation with splines (GCVSPL) method proposed by Woltring (Papi, 2012).

The STA is the degree of movement of the skin, muscle and other soft tissues in relation to the bones that occurs during walking (Baker, 2006). A standard gold method is needed for determining the 'soft tissue shifting' effect of body surface markers during analyses of joint motion (Leardini et al., 2005). The STA is an acceptable error in motion analysis. Baker, (2006) stated that soft tissue movements vary from individual to individual and by mapping of soft tissue movement as a function of joint angle. We can locate areas of low STA suitable for marker location. Optimal placement of markers for each marker sets must be defined by given knowledge of the soft tissue displacements. Cluster methods are known to reduce STA (Cappozzo et al., 2005).

2.8.6 Biomechanical model use in clinical measurement.

Protocols for gait analysis differ. Each one defines a biomechanical model of the subject and the procedures for data collection, processing, analysis and reporting of the results (Ferrari et al., 2008). Modelling strategies using individual marker sets vary in complexity and affect the number of degrees of freedom (DOF) calculated, and so may affect the kinematic data calculated (Kent and Franklyn-Miller, 2011). The following section details a number of commercially available biomechanical

models. A short literature review of comparisons between different biomechanical models and their kinematic outputs is provided.

A number of commercially available marker sets exist, usually developed by motion capture companies. However, some labs may adapt marker sets to suit their specific clinical needs. The most common model used in the clinical environments for gait analysis is Vicon's plug-in gait (PiG; Vicon Motion Systems, Oxford, UK). The PiG is the commercial name for the Vicon implementation of the Conventional Gait Model (CGM) (Kent and Franklyn-Miller, 2011). Plug-in Gait is based on the Newington-Helen Hayes gait model (Ferrari et al., 2008). Plug-in Gait uses a retroreflective marker set (Figure 2.26 and Figure 2.27) and a set of subject measurements to create outputs of the joint kinematics for a gait analysis patient (Davis et al., 1991; Vicon Motion Systems., 2008)

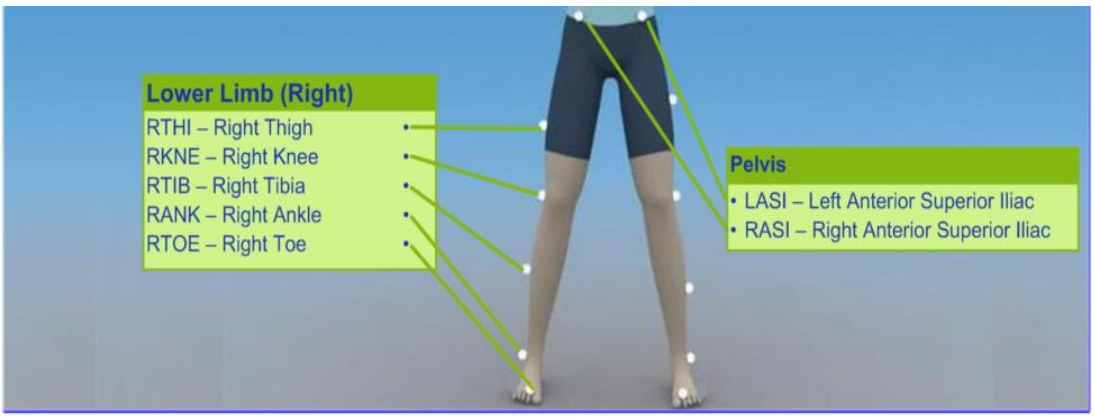


Figure 2.26 Marker Placement for PiG lower Body Model-Front view (Vicon Motion Systems., 2008)

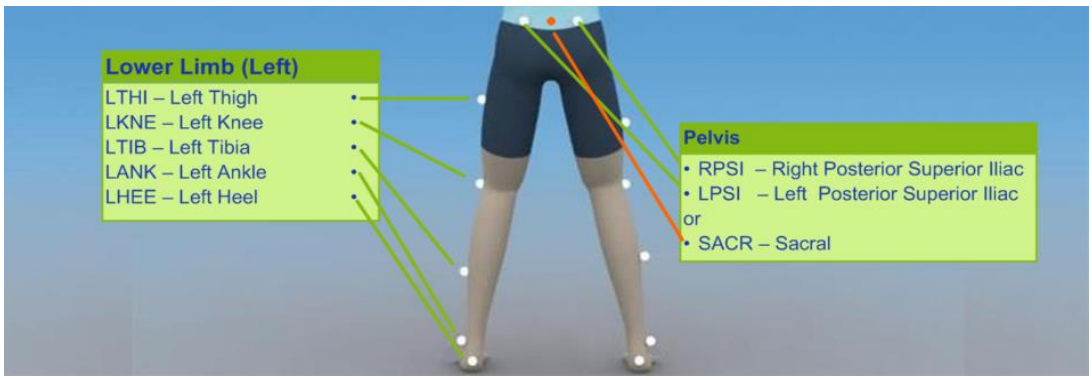


Figure 2.27 Marker Placement for PiG lower Body Model-Rear view (Vicon Motion Systems., 2008)

PiG is a clinical gold standard and most commonly used. However, there are a number of disadvantages associated with the PiG marker set. PiG requires markers placed directly on bony landmarks during dynamic trials. The study deals with the experimental problems related to the reconstruction of the position and orientation of the lower limb bones in space during the execution of locomotion and physical exercises by Cappozzo et al., (1996) suggested that markers placed on bony landmarks are subject to an unacceptable amount of movement during dynamic trials. Further, the precision and accuracy of the determination of the location of palpable anatomical landmarks (ALs) may be introduced into the kinematic output (Della Croce et al., 2005; Ferrari et al., 2008; McGinley et al., 2009). To give an example, the anteroposterior placement of the marker must be placed in very precise locations for correct alignment of the knee flexion axis (Vicon Motion Systems, 2016). Placement of the markers following these directions can be extremely difficult to do visually, and if the thigh markers are not placed correctly, then the definition of the flexion axis of the knee will be incorrect (Millar, 2016). This can often lead to crosstalk which occurs when the anatomical frames (AF) from a segment is out of alignment with the axis about which rotations actually occur and therefore one kinematic output is mistaken for another (Piazza and Cavanagh, 2000). Moreover, PiG is required anthropometric measurements, but Leardini et al., (2007) mentioned that the reliability of some anthropometric measurements seems poor (Leardini et al., 2007).

The Human Body Model (HBM; Motek Medical, Amsterdam) is another example of a commercially available marker set. The HBM (Motex forcelink LTD.) is a software system that performs a biomechanical analysis to design for real-time biomechanical analysis of joint kinematics and kinetics, as well as estimation and visualization of muscle function during gait. The standard marker set for the lower limb Human Body Model (HBM) consists of 25 single markers, one of which is a marker placed over the greater trochanter. However, Della Croce et al., (1999) studied the precision of lower limb ALs position determination, its effects on AF orientation determination, and the effects of errors in AF orientation on joint kinematics. The

results showed greater trochanter (GT) variation was the largest (up to 18mm root mean square) among of lower limb anatomical landmarks (Della Croce et al., 1999).

When calibrating the subject in HBM, the subject should stand in a so-called 'T-Pose'. For the HBM T-Pose, the 25 markers positions anatomical landmarks using in static calibration are shown in Figure 2.28 and detailed in Table 2.3 (Van Den Bogert et al., 2013). Currently, HBM was initialised by recording an initialisation pose in which subjects had to stand straight and symmetrically, with feet pointing forward. However, not all subjects will be able to assume this pose due to, for example, spasms or bone deformities. Moreover, the knee joint and the ankle joint are identified by using only lateral epicondyles and the dimension of the knee joint. This will lead to incorrect locations of the knee and ankle joint axis and therefore incorrect data.

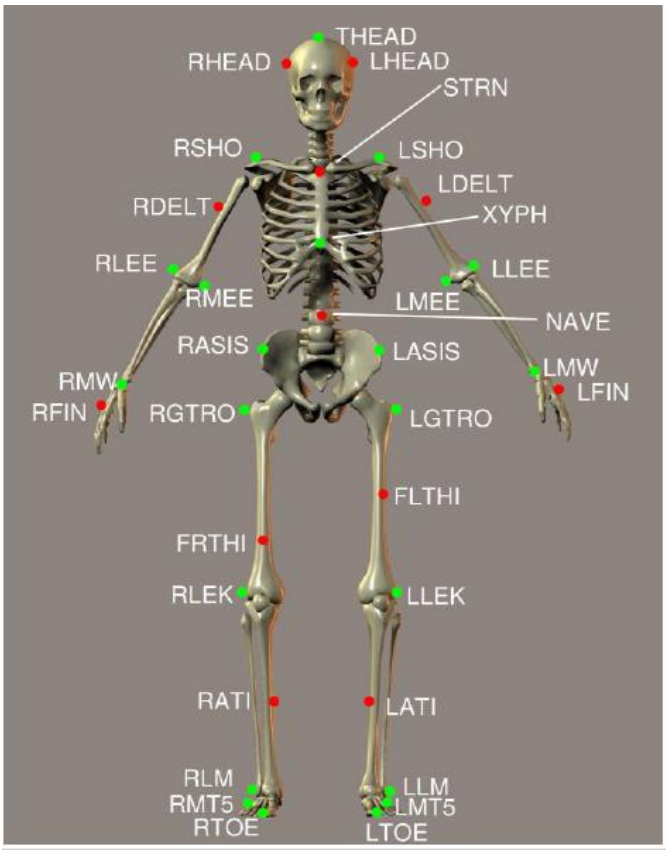


Figure 2.28 Marker placement for Full body Human Body Model (Van Den Bogert et al., 2013)

Name	Position	Remarks
T10	T10	On the 10th thoracic vertebrae.
NAVE	Navel	On the navel.
XYPH	Xiphoid process	Xiphiod process of the sternum.
STRN	Sternum	On the jugular notch of the sternum.
SACR	Sacrum bone	On the sacral bone.
LASIS	Pelvic bone left front	Left anterior superior iliac spine
RASIS	Pelvic bone right front	Right anterior superior iliac spine
LPSIS	Pelvic bone left back	Left posterior superior iliac spine
RPSIS	Pelvic bone right back	Right posterior superior iliac spine

Name	Position	Remarks
LGTRO	Left greater trochanter of the femur	On the centre of the left greater trochanter
FLTHI	Left thigh	1/3 on the line between LGTRO and LLEK.
LLEK	Left lateral epicondyle of the knee	On the lateral side of the joint axis
LATI	Left anterior of the tibia	2/3 on the line between LLEK and LLM.
LLM	Left lateral malleolus of the ankle	The centre of the left lateral malleolus
LHEE	Left Heel	Center of the heel at the same height as the toe
LTOE	Left toe	Tip of the big toe
LMT5	Left 5^{th} metatarsal	Caput of the 5^{th} metatarsal bone, on joint line midfoot/toes
RGTRO	Right trochanter major of the femur	On the centre of the right greater trochanter
FRTHI	Right thigh	2/3 on the line between RGTRO and RLEK.
RLEK	Right lateral epicondyle of the knee	On the lateral side of the joint axis
RATI	Right anterior of the tibia	1/3 on the line between RLEK and RLM.
RLM	Right lateral malleolus of the ankle	The centre of right lateral malleolus

Name	Position	Remarks
RHEE	Right Heel	Center of the heel at the same height as toe
RTOE	Right toe	Tip of the big toe
RMT5	Right 5^{th} metatarsal	Caput of the 5^{th} metatarsal bone, on joint line midfoot/toes

Table 2.3 Anatomical landmarks static calibration markers, name and position using in HBM model (Van Den Bogert et al., 2013)

There was a problem related to the HBM version previously described. So, HBM was updated in 2017 to be HBM2 in order to meet the current state of the art in the field of gait analysis (Motekforce Link, 2017). HBM2 uses a marker set containing 26 markers (Figure 2.29) and detailed in Table 2.4. Green markers are anatomical markers used to define the skeleton during initialisation. Some makers were removed when compared to the HBM. Greater trochanter markers, SACR (sacrum) and NAVE (navel) are removed to avoid soft tissue artefacts associated with these markers. Medial epicondyle and medial malleolus markers are added to make the model initialisation pose independently. The predictive method used in hip joint estimation is changed from Bell's method (Bell et al., 1989) to linear regression equations proposed by (Harrington et al., 2007). The marker position was also moved such as the TOE marker is moved from the tip of the big toe to the caput of the 2^{nd} metatarsal bone.

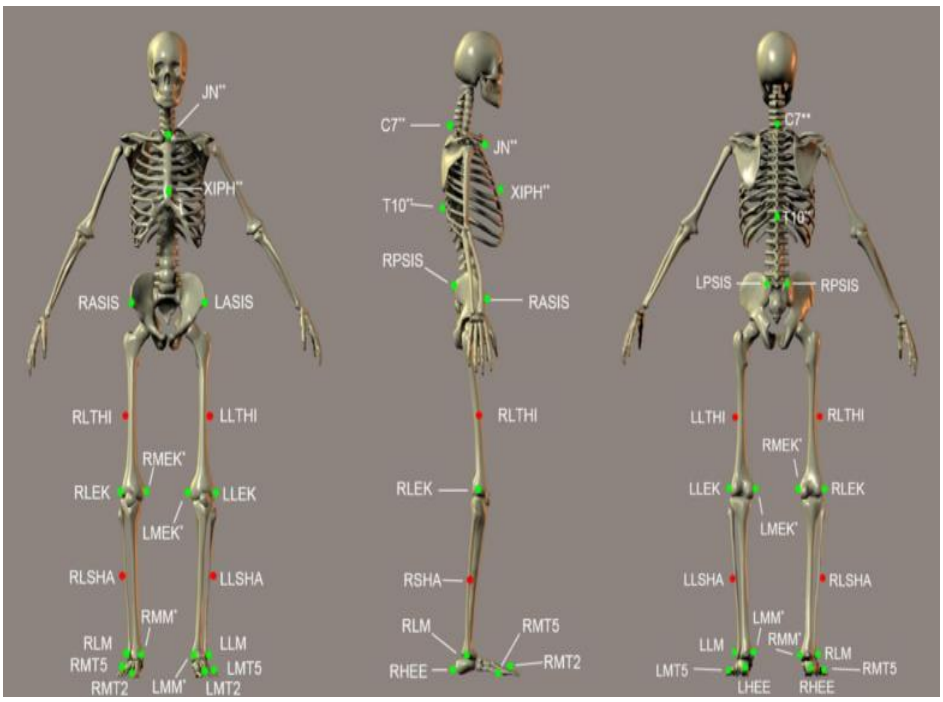


Figure 2.29 Marker placement for HBM2 (Motekforce Link, 2017)

No.	Marker	Position	Placement Remarks
1	C7	C7	On the 7th cervical vertebra
2	T10	T10	On the 10th thoracic vertebra Xiphoid
3	XIPH	Xiphoid process	The xiphoid process of the sternum
4	JN	Jugular notch	On the jugular notch of the sternum
5	LASIS	Pelvic bone left front	Left anterior superior iliac spine
6	RASIS	Pelvic bone right front	Right anterior superior iliac spine
7	LPSIS	Pelvic bone left back	Left posterior superior iliac spine
8	RPSIS	Pelvic bone right back	Right posterior superior iliac spine
9	LLTHI	Left thigh, lateral	1/2 on the line between the left greater trochanter and RLEK
10	LLEK	Left lateral epicondyle of the knee	On the lateral side of the joint axis

No.	Marker	Position	Placement Remarks
11	LMEK	Left medial epicondyle of the knee	On the medial side of the joint axis. Check by holding both points and bending the knee; markers should not/hardly move.
12	LLSHA	Left shank, lateral	1/2 on the line between LLEK and LLM
13	LLM	Left lateral malleolus of the ankle	The centre of the left lateral malleolus
14	LMM	Left medial malleolus of the ankle	Most pronounced part of the left medial malleolus
15	LHEE	Left Heel	Center of the heel at the same height as LMT2
16	LMT2	Left 2nd metatarsal	Caput of the 2nd metatarsal bone, on joint line midfoot/toes
17	LMT5	Left 5^{th} metatarsal	Caput of the 5tf metatarsal bone, on joint line midfoot/toes
18	RLTHI	Right thigh, lateral	1/2 on the line between the right greater trochanter and RLEK
19	RLEK	Right lateral epicondyle	On the lateral side of the joint axis
20	RMEK	Right medial epicondyle	On the medial side of the joint axis.
21	RLSHA	Right shank, lateral	1/2 on the line between RLEK and RLM The
22	RLM	Lateral malleolus of ankle	The centre of right lateral malleolus

No.	Marker	Position	Placement Remarks
23	RMM	Right medial malleolus of the ankle	Most pronounced part of the right medial malleolus
24	RHEE	Right Heel	Center of the heel at the same height as RMT2
25	RMT2	Right 2nd metatarsal	Caput of the 2nd metatarsal bone, on joint line midfoot/toes
26	RMT5	Right 5^{th} metatarsal	Caput of the 5tf metatarsal bone, on joint line midfoot/toes

Table 2.4 Anatomical landmarks static calibration markers, name and position using in HBM2 model (Motekforce Link, Netherlands)

In conjunction with the three markers mentioned, the marker sets employ individual skin surface markers. Several studies that describe patterns and magnitudes of STA have been reported. These studies (Leardini et al., 2005; Peters et al., 2010) shown that single markers located on the skin are not the most accurate way to estimate segment position during dynamic trials as they are subjected to the greatest soft tissue artefact (STA) error due to relative movement between skin and underlying bone. Soft tissue displacements should be minimised to mimic the real skeletal movements as accurately as possible. Millar, (2016) conducted a review of marker displacement and kinematic measurement errors due to STA. The review highlighted that STA could be reduced by using rigid plates of markers (Clusters).

A protocol developed at the Bioengineering Unit at the University of Strathclyde (Glasgow, UK) during the first decade of this century based on cluster marker methods (Papi et al., 2014) is known locally as the Strathclyde Cluster Model (SCM). This SCM is a modification of the method developed by Cappozzo et al., (1995). In this SCM method, a combination of skin markers and clusters consisting of a shell and four markers on a rigid plate are used to implement the model (Papi,

2012). The Strathclyde Cluster Model (SCM), as it has become known, is a combination of skin markers and clusters consisting of a four markers on plastic shell attached on each segment of the lower limb, allowing 6 DOF at each joint (3 rotation and three translation) (Papi, 2012; Zuk and Pexowicz, 2015). The advantages of the Strathclyde Cluster Model (SCM) was mentioned by Papi, (2012) as follows:

Fast subject preparation; Easy marker positioning; Soft tissue artefacts minimised; Biomechanical model based on accessible identifiable anatomical landmarks; Segmental and Joint coordinate system consistent with standards (ISB); Joint angles which agree with their common anatomical meaning; Repeatability; Fully 3D, including the foot and ankle and finally, cross-talk errors can be minimised at the knee using the optimisation technique.

Table 2.5 detailed anatomical landmarks used in static calibration are shown, and Figure 2.30 shows where the SCM markers and SCM clusters should be placed on the subject in the front and lateral views.

Marker	**Marker placement**
RASI/LASI	Left/Right anterior superior iliac spine
RPSI/LPSI	Left/Right posterior superior iliac spine
RLEPI/LLEPI	Left/Right lateral epicondyle
RMEPI/LMEPI	Left/Right medial epicondyle
RLMAL/LLMAL	Left/Right lateral malleolus
RMMAL/LMMAL	Left/Right medial malleolus

Table 2.5 Anatomical landmarks static calibration markers, name and position using in SCM model (Papi, 2012)

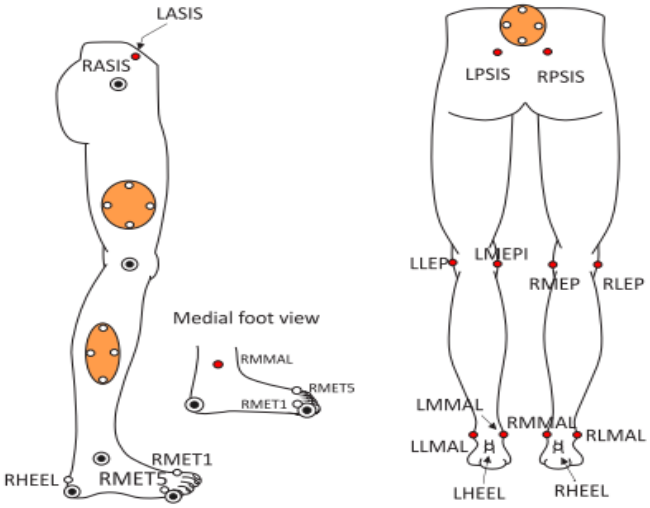


Figure 2.30 Lower limb marker set and rigid cluster for SCM (Papi, 2012)

The available marker sets described previously were usually developed based on able-bodied lower limb models. Therefore, Rigney et al., (2016) stated that the amputee subjects, joint kinematics are typically defined using able-bodied gait analysis techniques, despite the inherent differences of the lower limb. Inaccurate data is likely to be produced when selecting a rigid-link segment model developed from able-bodied gait and applying it to amputee gait.

Kent and Franklyn-Miller, (2011) conducted the review of biomechanical models in the study of lower limb amputee kinematics. The study aimed to investigate the use of motion capture, biomechanical models and marker sets for the motion of individuals with lower limb loss. The clinical relevance of this study stated that standard modelling techniques might not consistently represent the body and prosthesis adequately to produce valid results for the analysis of the function of persons with lower limb loss.

Moreover, Rusaw, (2011) mentioned that the position of the markers on the prosthetic limb during gait analysis of prosthesis users has to be made through approximation and sometimes through a direct measurement from the remaining foot. This creates a source of error at both the knee and the ankle.

The review presented an insight into the state of art of motion analysis highlighting the more critical aspects involved. It is concluded that motion capture systems can be used to quantify alignment and for recording the amputee's gait. Biomechanical gait analysis is the main technique used in qualitative gait assessment. It has played a crucial role in objective outcome measurement for many decades. However, there are several methods of capturing three-dimensional data and interpretation of research findings and protocols for gait analysis differ. Each one defines a biomechanical model of the subject, and the procedures for data collection, processing, analysis and reporting of the results. It is unclear which protocol is best to analyse amputees gait and which one could be used to calculate prosthetic alignment feedback in real-time during alignment tuning.

2.9 Summarise of Literature Review

TTA is one-third of amputation levels and is the most common level among several amputation levels in all populations. The high prevalence of TTA, particularly in Thailand currently represents a significant global problem. A properly constructed and adjusted prosthetic device is key to the reintegration of these patients into their family, social, and working environments. Therefore, TTA was chosen to be the population for this thesis, which constitutes the majority of the amputation level.

After amputation, the trans-tibial amputee requires a prosthesis to replace the lost limb. The prosthesis can improve mobility function and restore cosmesis. A functional and comfortable trans-tibial prosthesis is crucial to help trans-tibial amputees return to their everyday activities. During the construction of the prosthesis, the alignment protocol plays an important role in the prosthetic function and successful fitting.

Conventionally, prosthetic alignment is performed by prosthetists and accomplished by the subjective judgment of the prosthetist based on subjective methods of gait analysis and feedback from the patient. Those processes seem to lack any scientific biomechanical data and have been shown to lack reliability. Moreover, when is performed on an individual basis, the alignment that results in a perfect fit is unknown and only lose guidelines and available.

Conventional alignment techniques are slow and maybe inadequate for optimizing the gait of lower-limb amputees. Using motion capture to provide outcome data which is responsive to prosthetic alignment quality could help to improve prosthetic alignment (Tafti et al., 2018).

Based on the evidence presented in this chapter, this thesis explores the possibility of applying 3D motion capture for measuring alignment by measuring the position in the space of the prosthetic socket relative to the prosthetic foot and the kinematics of the gait pattern to the process of prosthetic alignment. It is hypothesised that a system based on kinematics data could provide real-time biomechanical measures and serve as an objective tool and aid alignment of a trans-tibial prosthesis from initial bench alignment to the final dynamic alignment during gait.

Chapter 3. Aims and Objectives

Based on the information obtained from the literature review, the overall aim of the thesis was to develop a new alignment system based on kinematics data which can help the prosthetist to optimise and tune the alignment of a trans-tibial prosthesis.

The following specific objectives were addressed through this study:

Research Objectives:

1. To access the within-subject variability, between-subject variability and between protocol variability of four different gait measurement marker. Protocols found in the literature and to select an appropriate one for the application.
2. To validate the selected 3-D gait analysis protocol to be used for kinematic data collection in trans-tibial amputee gait;
3. To determine an appropriate walking condition for gait performance assessment with this system;
4. To develop a real-time tuning feedback application integrated into the D-flow system for a real-time alignment protocol based on a trans-tibial prosthetic fitting standard; and
5. To evaluate this real-time tuning feedback application and its usefulness in the trans-tibial prosthetic fitting.

The flow of the study was to identify optimal methods to address the research objectives 1 to 4 before using the findings from these studies to design and carry out the feasibility study in subjects with trans-tibial amputation (Study objective 5**).** The aims and objectives of each step are described below.

Chapter 4: This chapter outlines the first steps undertaken to compare a 3-D gait analysis protocol from among available protocols. In order to see whether they agree sufficiently for the new protocol (SCM, HBM, NHBM) to replace a well-established one (PiG) for assessing the gait performance in the clinic. Data from kinematic biomechanical parameters obtained from different models were assessed the within-

subject variability, between-subject variability and between protocol variability of four different protocols. The within-subject variability, between-subject variability and between protocol variability has to be evaluated and compared to a commonly used clinical gait model (e.g. Plug-in-Gait model) which was the purpose of this study.

Chapter 5: Subjects with a trans-tibial amputation (TTA) show gait differences from normal gait. Three-dimensional motion analysis was used to evaluate several aspects of trans-tibial amputees' gait. However, there are large variability across the methods of capturing three-dimensional data. This chapter outlines the steps undertaken to finalise a 3-D gait analysis protocol that is simple, accurate, and repeatable for the assessment of gait performance, and the 3-D gait biomechanical model that could be applied for the assessment of trans-tibial amputees in a clinical environment.

Chapter 6: In this chapter, we determine a walking condition which is suitable for the assessment of gait performance in the clinical environment. Data from kinematic biomechanical parameters were compared in different walking conditions

Chapter 7: This chapter focuses on the introduction of a method for measuring the alignment of the prosthesis and detail of developing and calculating the prosthetic alignment outcome. Moreover, the chapter outlines the steps undertaken to determine if the Computer motion capture and Visualisation system for assisted Bench Alignment Technique (CVBAT) is able to produce a more repeatability aligned prosthesis than the conventional bench alignment process (ConBAT), and which one is less time-consuming.

Chapter 8: This chapter describes the development of a real-time tuning feedback application integrated into the D-flow system, which produces various parameters used for a real-time alignment protocol based on a trans-tibial prosthetic fitting standard.

Chapter 9: This chapter details the design and experimental procedures of a feasibility study involving a single trans-tibial amputee with multiple prosthetists to

investigate the effect of the real-time tuning application integrated into D-flow. In this study, two alignment techniques were compared. The first was the conventional dynamic alignment technique, the alignment of a trans-tibial prosthesis done by the prosthetist based on visual observation and the history of the practice. The second method was the Computerised motion capture and visualisation system for the Assisted Alignment Technique or the CVAT method, when the alignment of the same prosthesis was undertaken by the prosthetist with the help of real-time outcome information provided by the D-flow application.

Chapter 10: This chapter critically discusses the findings reported in this thesis including the methods introduced and utilised. Clinical implications are also discussed as to their future work. This chapter also provides the thesis conclusions

Chapter 4. Comparison of kinematic parameters of healthy adult gait using four marker based models

4.1 Introduction

Biomechanical gait analysis is the systematic scientific measurement of walking ability and is an important tool for documenting, evaluating and quantifying walking performance in both normal and pathological gait patterns. Fully describing gait through quantitative analysis typically involves a combination of measurements, including temporal-spatial parameters, kinematics, kinetics and energy transfer (Van Den Bogert et al., 2013)

Gait analysis requires specialised hardware and software for collecting, processing and analysing biomedical parameters of human locomotion. A common tool for tracking and describing the kinematics of human gait in three dimensions is marker-based motion capture (Kent and Franklyn-Miller, 2011; Pitkin, 2006). This tool uses a set of calibrated cameras, a linked segment model and usually a set of retro-reflective markers. Such models can be skin-based marker sets (SMS) such as Plug-in Gait (PiG), or a combination of skin markers and clusters of markers on a rigid shell (Calibrated Anatomical Systems Technique calibrated; CAST). Four markers on a cluster shell have been suggested as the best cluster solution. The placement of each marker or marker cluster is specific to each model. The placement depends on the protocol of the model and how the model identifies certain key anatomical characteristic points on the body (Papi et al., 2014; Szczerbik and Kalinowska, 2011).

In order to develop a system to aid prosthetic tuning, one must first select a suitable marker protocol for the motion capture. However, from the evidence presented in the literature review it is known that different protocols present different degrees of assigned freedom to joints, use different data processing techniques and produce different results (Duffell et al., 2014; Ferrari et al., 2008). The biomechanics laboratory of the department of biomedical engineering at the University of Strathclyde used different marker sets to suit specific clinical needs. Four marker models were in use.

The first available marker model is the current clinical gold standard which is known as Plug-in Gait (PiG; Vicon Motion Systems, Oxford, UK). This has been widely

adopted. PiG is a well- established model and has been developed over several years. Although PiG has been validated, it is not without problems, this conventional marker set is thought to provide less repeatable results than cluster-based marker sets (Leardini et al., 2007) is prone to errors arising from inconsistent anatomical landmark identification (Stief et al., 2013), and also requires a lot of preparation time of the subjects. Moreover, the thigh and calf marker positions are critical for correct alignment of the knee joint axis (Ceseracciu et al., 2014; Duffell et al., 2014; Ferrari et al., 2008; Papi et al., 2014).

The Human Body Model (HBM; Motek Medical, Amsterdam) was another available marker set. HBM is the plugin biomechanical model in the D-flow application. The D-flow application is the software available to use in the Strathclyde motion analysis laboratory for visualisation as a result it might be easier to use this model as a protocol to develop the TTA alignment tuning system. However, the author found no studies in the literature that compared differences between HBM and the current clinical gold standard (PiG) to determine if the kinematic output calculated by HBM was acceptable for clinical use. Further, evidence in the literature reviews that there were suggested problems related to the substantially of data from HBM.

HBM was updated in 2017 as a result of the problems to be HBM2 in order to meet the current state of the art in the field of gait analysis used in clinical practice and biomechanical research (Motekforce Link, 2017). Apart from the information provided from Motekforce Link, there was no publication to prove that HBM2 have advantages over HBM.

Finally, a new cluster protocol based on the cluster marker set proposed by Cappottzo (Donati et al., 2007) was evaluated and used by Papi and colleagues with good repeatability (Papi et al., 2014). Papi, (2012) and Millar, (2016) claimed that the cluster protocol had a lot of benefits as mention previously in the literature review.

The aim of the study in this chapter was therefore to access the within-subject variability, between-subject variability and between protocol variability of four different protocols Four biomechanical models have included: the Strathclyde cluster

model (Papi et al., 2014), the Human Body Model (van den Bogert et al., 2013) and the Human Body Model 2 (Motekforce Link, 2017) and the conventional Plug-in Gait model (Vicon Motion Systems., 2008). Therefore, the purpose of this assessment is to assure that the other three protocols are capable of producing meaningful kinematic output. In order to select a suitable marker protocol based on a comparison. It is proposed that a good marker protocol would show low values of variance within and between normal subjects.

4.2 Methods

4.2.1 Participation

The participants were selected using the following criteria: between 18-50 years old, a good current condition of health, the normal range of motion (ROM) in all joints of the lower limbs, capable of walking for 30 minutes without becoming tired or feeling pain. This study was approved by the Department of Biomedical Engineering Research Ethics Committee. Written informed consent was obtained prior to participation. The study was conducted in the Biomechanics Laboratory, Department of Biomedical Engineering, and University of Strathclyde. A total of 10 able-bodied adult participants were recruited. They were in good health with a normal ROM in all lower limb joints (ages 29.16 ± 4.16 years, weight 54.62 ± 7.53 kg, height 1.61 ± 0.083 m.). All participants provided written informed consent to participate in the study.

4.2.2 Protocols and Data Collection

Simultaneous data capture of all four marker sets (Figure 4.1) was accomplished by designing a marker-set which combined the protocols of the Plug-in Gait model (PiG), the Human Body Model (HBM), the Human Body Model 2 (HBM2) and the Strathclyde Cluster Model (SCM). Table 4.1 shows the combined marker sets where individual markers and marker clusters were attached. All landmark identifications and anthropometric measurements were carried out by one expert, and all body landmarks necessary for the combined marker-set of each of the four protocols were recorded by using a single static T-Pose posture. The subjects were then asked to

walk at a self-selected speed with an average walking speed 1.26(0.1) m/s (Ranged from 1.1 – 1.36 m/s) along a walkway while being recorded by a 3-dimensional motion analysis system (Vicon MX Giganet, Motion Systems, Oxford, UK) at 100 samples per second. The 3-D marker trajectories were captured synchronously, and joint angles were calculated using the protocols for the four different marker models.

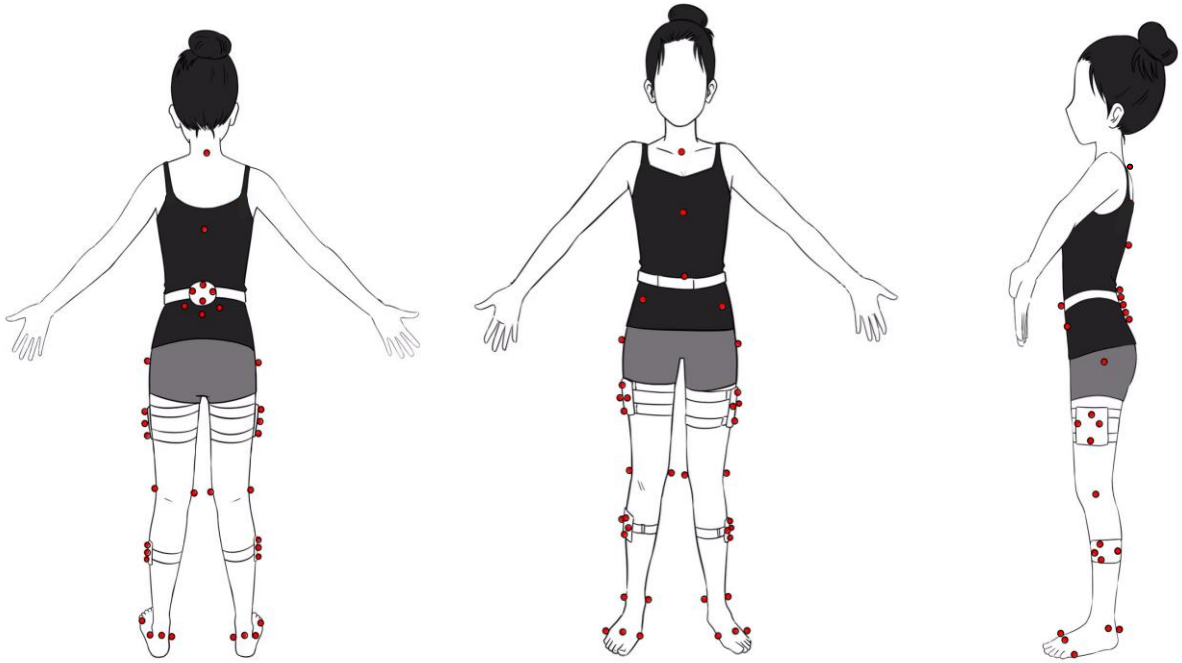


Figure 4.1 A single marker set for four marker models. The makers indicated by red circles are part of the combination mode

Maker	Model	Marker Placement
C7	HBM2	On the 7th cervical vertebra.
T10	HBM/HBM2	On the 10th thoracic vertebrae.
NAVE	HBM	On the navel.
XYPH	HBM/HBM2	Xiphiod process of the sternum.
STRN	HBM/HBM2	On the jugular notch of the sternum.
LASI	PiG/SCM/ HBM/HBM2	Placed directly over the left anterior superior iliac spine
RASI	PiG/SCM/ HBM/HBM2	Placed directly over the right anterior superior iliac spine
LPSIS	PiG/SCM/ HBM/HBM2	Placed directly over the left posterior superior iliac spine
RPSIS	PiG/SCM/ HBM/HBM2	Placed directly over the Right posterior superior iliac spine
SACR	HBM	Placed on the skin mid-way between the posterior superior iliac spines *(*PSIS*).* An alternative to LPSIS and RPSIS.
LGTRO	HBM	On the centre of the left greater trochanter
RGTRO	HBM	On the centre of the Right greater trochanter
LTHI	PiG/HBM/HBM2	Place the marker over the lower lateral 1⁄3 surface of the thigh, just below the swing of the hand, although the height is not critical.
RTHI	PiG/HBM/HBM2	Place the marker over the lower lateral 2⁄3 surface of the thigh, just below the swing of the hand, although the height is not critical.
LLEK	PIG/SCM/ HBM/HBM2	On the lateral side of the joint axis
LMEK	SCM/ HBM2	At the similar height of the LLEK. Check by holding both points and bending the knee; markers should not⁄hardly move.
RLEK	PIG/SCM/ HBM/HBM2	On the lateral side of the joint axis

Maker	Model	Marker Placement
RMEK	SCM/ HBM2	At the similar height of the RLEK. Check by holding both points and bending the knee; markers should not/hardly move.
LTIB	PiG/HBM/HBM2	Similar to the thigh markers, these are placed over the lower 1/3 of the shank to determine the alignment of the ankle flexion axis
RIIB	PiG/HBM/HBM2	Similar to the thigh markers, these are placed over the lower 2/3 of the shank to determine the alignment of the ankle flexion axis
LLM	PiG/SCM/HBM/ HBM2	Placed on the lateral malleolus along an imaginary line that passes through the transmalleolar axis
RLM	PiG/SCM/HBM/ HBM2	Placed on the lateral malleolus along an imaginary line that passes through the transmalleolar axis
LMM	SCM/HBM2	Most pronounced part of the left medial malleolus
RMM	SCM/HBM2	Most pronounced part of the right medial malleolus
LMT2	PiG/HBM2	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot
LHEE	PiG/SCM/ HBM/HBM2	Placed on the calcaneus at the same height above the plantar surface of the foot as the toe marker
LTOE	HBM/SCM	Tip of the big toe
LMT5	HBM/SCM	Head of the 5^{th} metatarsal bone, on joint line midfoot/toes
RMT2	PiG/HBM2	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot
RHEE	PiG/SCM/ HBM/HBM2	Placed on the calcaneus at the same height above the plantar surface of the foot as the toe marker

Maker	Model	Marker Placement
RTOE	HBM/SCM	Tip of the big toe
RMT5	HBM/SCM	Head of the 5th metatarsal bone, on joint line midfoot/toes
WAIST Cluster	SCM	On the back close to the sacrum.
Thigh Cluster	SCM	A lateral and distal aspect of the thigh
Shank Cluster	SCM	A lateral and distal aspect of the shank

Table 4.1 Single marker and clusters used during data collection**.** The name of each marker and its position is reported relative to the body segment they are referred to**.**

4.2.3 Data processing

Data processing was carried out by one rater for all protocols. 3D marker trajectories were reconstructed. Heel strike (HS) detection was based on the vertical displacement of the heel marker. The minimum vertical position of the distal heel marker was used to identify HS (Fellin et al., 2010; O'Connor et al., 2007; Segal et al., 2011; Zeni et al., 2008). One right gait cycle was extracted from each of three good trials. The trial was selected based on a good quality reconstruction of all marker trajectories without a missing marker coordinates. . All data were filtered used a second-order low pass Butterworth filter with a cut-off frequency of 6Hz. The marker trajectory data were then processed. The same gait cycles were analysed for each protocol to allow consistency in the comparisons. The gait data were calculated separately for each data set according to the gait analysis software package for that post-processing marker-set model.

Gait data were further processed using Excel VBA including joint angle normalisation to 101 points (0 -100) per gait cycle. The VBA code for joint angle normalisation is provided in appendix 1. In total, the data consisted of 3 trials of self –selected comfortable overground walking for 10 participants, analysed using four different biomechanics protocols making a total of 120 gait cycles in all. The mean value and standard deviations of hip flexion, hip abduction, hip rotation, knee flexion

and ankle dorsiflexion were calculated from the four protocols. The mean value and standard deviations of knee abduction, knee rotation, ankle abduction and ankle eversion were calculated from PiG and SCM that are not available from HBM and HBM2. The values of joint rotation across the gait cycle were plotted for visual comparison.

4.2.4 Data analysis and statistic

Descriptive statistics were applied to the experimental data to assess the variability of the measurements. Within-subject variability was obtained by analyzing 3 gait trials for each subject and reported by standard deviation over 10 subjects (McGinley et al., 2009; Schwartz et al., 2004). The standard deviation was calculated using the averages of the 3 walking trials among the 10 participants, and then between-subject variability was defined by standard deviation across the gait cycle (McGinley et al., 2009; Schwartz et al., 2004). Intraclass correlation coefficients (ICCs) with their 95 % confidence intervals were calculated using a two-way mixed effect method, an absolute agreement measure analysis for each protocol. The ICCs (McGinley et al., 2009) were calculated between two possible protocols over average from10 subjects using SPSS 24 (IBM Corporation, Amonk, NY). In addition, values of the ICC were rated as excellent between 0.9 to 1, good between 0.74 to 0.89, moderate between 0.4 to 0.73) and less than 0.39 as poor (Donath et al., 2016) .

4.3 Results

4.3.1 Within-Subject variability

The standard deviation (SD) was calculated at each time point between the three gait cycles and then averaged across the gait cycle to give the mean SD for each gait parameter for each subject. These represent the within-subject variability (Table 4.2 - 4.5). These were then averaged to give the mean within-subjects SD for each parameter (The bottom line of the table) and a mean of means to represent the overall within-subject variability for that model (Right hand lower corner of the table). The small standard deviations are indicative of good repeatability of the protocols outcomes.

The mean of standard deviations (mSD) for all parameters calculated by all four protocols ranged from 0.6° to 3.5°. The least within-subject variability was for ankle abduction/adduction for the PiG protocol (0.6°). The highest within-subject variability was observed for ankle inversion/eversion for the PiG protocol (3.5°). The highest overall within-subject variability was observed for the HBM protocol (2.4°). The lowest variability was observed for the SCM protocol (1.6°). There is one remarkable value shown in subject 3 for HMB protocol as shown in Table 4.4 (10°).

Within-subject variability was low for all four protocols and similar to data from previous biomechanics protocol studies using these protocols (Zak 2015; Manca et al. 2010; Schwartz et al. 2004).

	Hip flex/ext	**Hip abd/add**	**Hip int/ext**	**Knee flex/ext**	**Knee Abb/Add**	**Knee int/ext**	**AnkleDorsi/pla**	**Ankle Ab/ad**	**Ankle inver/ever**	**Mean**
Subject 1	5.9	1.0	2.9	4.5	2.0	1.7	2.4	0.5	1.9	
Subject 2	0.9	0.6	0.7	1.3	0.4	0.8	0.9	2.1	14.3	
Subject 3	3.2	1.1	2.1	6.6	1.2	1.5	2.6	0.3	2.5	
Subject 4	2.7	1.7	1.8	3.5	1.6	1.9	3.5	0.8	3.8	
Subject 5	0.9	0.7	1.7	1.4	0.5	1.0	0.9	0.3	2.1	
Subject 6	0.7	0.5	1.2	1.8	0.7	0.5	0.7	0.1	1.1	
Subject 7	2.7	1.0	2.2	3.9	1.1	1.1	1.9	0.3	1.7	
Subject 8	1.2	0.6	0.6	1.7	0.6	0.8	1.0	0.2	1.8	
Subject 9	1.1	0.5	0.7	1.8	1.0	1.1	1.1	0.5	2.1	
Subject 10	5.8	1.3	2.5	4.6	1.2	1.6	2.4	0.8	3.9	
Mean	2.5	0.9	1.6	3.1	1.0	1.2	1.7	0.6	3.5	1.8

Table 4.2 Within-Subject variability over the right gait cycle across 3 trials per subjects as calculating by PiG as shown by the standard deviation.

	Hip flex/ext	Hip abd/add	Hip int/ext	Knee flex/ext	Knee Abb/Add	Knee int/ext	AnkleDorsi/pla	Ankle Ab/ad	Ankle ever/ever	Mean
Subject 1	3.4	1.1	1.0	4.8	0.9	0.9	2.7	1.0	1.4	
Subject 2	1.2	0.6	1.0	1.6	0.5	1.0	0.9	1.0	0.6	
Subject 3	3.6	1.1	1.7	7.0	1.4	1.7	3.0	1.5	1.4	
Subject 4	3.9	3.6	2.2	3.9	1.8	2.1	3.1	2.7	1.4	
Subject 5	2.1	1.1	1.4	1.5	0.5	1.4	0.9	1.5	0.6	
Subject 6	1.3	0.7	1.1	2.0	0.6	0.8	0.8	0.6	0.9	
Subject 7	2.9	1.0	1.3	4.2	0.9	1.3	2.1	1.0	0.5	
Subject 8	3.1	1.0	0.6	2.0	0.5	1.2	1.0	0.8	1.3	
Subject 9	1.5	0.5	0.8	1.9	0.6	1.5	0.9	1.3	1.0	
Subject 10	3.4	1.3	1.7	4.4	1.0	1.3	2.4	1.9	1.6	
Mean	2.6	1.2	1.3	3.3	0.9	1.3	1.8	1.3	1.1	1.6

Table 4.3 Within-Subject variability over the right gait cycle across 3 trials per subjects as calculating by SCM as shown by the standard deviation.

	Hip flex/ext	Hip abd/add	Hip int/ext	Knee flex/ext	Knee Abb/Add	Knee int/ext	AnkleDorsi/pla	Ankle Ab/ad	Ankle ever/ever	Mean
Subject 1	2.2	1.2	1.2	3.1	-	-	1.6	-	-	
Subject 2	1.4	0.8	0.7	2.9	-	-	1.2	-	-	
Subject 3	3.5	5.6	12.2	7.4	-	-	10.0	-	-	
Subject 4	2.8	2.0	2.6	3.7	-	-	2.8	-	-	
Subject 5	1.4	0.7	2.5	1.9	-	-	2.2	-	-	
Subject 6	1.1	0.6	1.1	2.4	-	-	1.6	-	-	
Subject 7	1.2	0.7	0.9	2.5	-	-	1.2	-	-	
Subject 8	1.2	0.7	1.3	1.8	-	-	2.9	-	-	
Subject 9	1.0	0.7	0.7	1.8	-	-	1.1	-	-	
Subject 10	2.7	1.9	2.0	4.3	-	-	2.5	-	-	
Mean	1.9	1.5	2.5	3.2	-	-	2.7	-	-	2.4

Table 4.4 Within-Subject variability over the right gait cycle across 3 trials per subjects as calculating by HBM as shown by the standard deviation.

	Hip flex/ext	Hip abd/add	Hip int/ext	Knee flex/ext	Knee Abb/Add	Knee int/ext	AnkleDorsi/pla	Ankle Ab/ad	Ankle ever/ever	Mean
Subject 1	2.4	0.8	1.7	1.2	-	-	0.9	-	-	
Subject 2	0.8	0.6	0.6	1.1	-	-	0.8	-	-	
Subject 3	3.4	1.4	1.9	7.1	-	-	2.8	-	-	
Subject 4	2.8	1.9	2.6	3.3	-	-	2.8	-	-	
Subject 5	2.0	1.1	2.4	2.6	-	-	3.1	-	-	
Subject 6	1.2	0.6	0.9	2.3	-	-	1.3	-	-	
Subject 7	1.3	0.7	1.3	2.5	-	-	1.1	-	-	
Subject 8	1.3	0.7	1.6	1.6	-	-	3.5	-	-	
Subject 9	1.1	0.6	1.0	2.3	-	-	0.9	-	-	
Subject 10	3.0	1.7	1.9	4.4	-	-	2.3	-	-	
Mean	1.9	1.0	1.6	2.9	-	-	1.9	-	-	1.9

Table 4.5 Within-Subject variability over the right gait cycle across 3 trials per subjects as calculating by HBM2 as shown by the standard deviation

4.3.2 Between-subject variability

Between -subjects variability was calculated by taking the average gait curve of the 10 subjects and calculating the SD for the group of 10 at each gait cycle point and then averaging these SD values across the cycle for each gait parameter (Table 4.6). These values were then averaged across all parameters in the model to give an overall value for between-subject variability for each model. The gait cycle for each individual was across the 10 subjects to give the average cycle for each parameter for each model. This produced four sets of data which are fully reported in appendix 12.

Overall greater between-subject variability was observed among the measured variables for each protocol than for within-subject variability. The between-subject variability ranged from 2.7^{o} to 15.2^{o} in the PiG (Table 4.6). The between-subject variability was highest for hip internal/external rotation angle and lowest for hip abduction/adduction angle. The highest mean of all parameters was found for PiG (8.0^{o}). The lowest mean of all parameters was found for SCM (5.3^{o}). The overall between-subject variability of all four models is 6.25^{o}.

Parameters	Between subject PiG	Between subject SCM	Between subject HBM	Between subject HBM2	Mean
Rotation(^{0})					
Ankle Dorsi/pla	3.9	4.8	5.7	5.3	
Ankle Ab/ad	2.7	4.3	-	-	
Ankle In/Ever	13.9	4.5	-	-	
Knee flex/ext	6.6	6.4	5.5	6.2	
Knee Ab/ad	8.5	3.8	-	-	
Knee int/ext	12.0	7.5	-	-	
Hip flex/ext	6.3	7.9	7.0	9.1	
Hip abd/add	2.8	2.8	3.9	2.8	
Hip int/ext	15.2	5.9	8.9	4.1	
Mean	8.0	5.3	6.2	5.5	6.25

Table 4.6 Between-subject variability over the right gait cycle across ten subjects as shown by the standard deviation

4.3.3 Between protocol variability

The average gait cycle for each individual was averaged across the 10 subjects to give the group the average cycle for each parameter for each model. These are illustrated in (Figure 4.2 - 4.4) and provide a visual interpretation of variability between models. Blue lines represent kinematic data for PiG; red lines represent kinematic data for SCM and green lines represent kinematic data for HBM. Finally, purple lines represent kinematic data for HBM2. High consistencies of joint angle curves for the four protocols were observed for the sagittal plane, particularly for knee flexion/extension. The PiG gait showed an approximately 12^{o} offset in the hip flexion/extension curve compared to the other models. The greater difference was observed in the coronal plane and the largest difference in the transverse plane particularly for the knee and ankle.

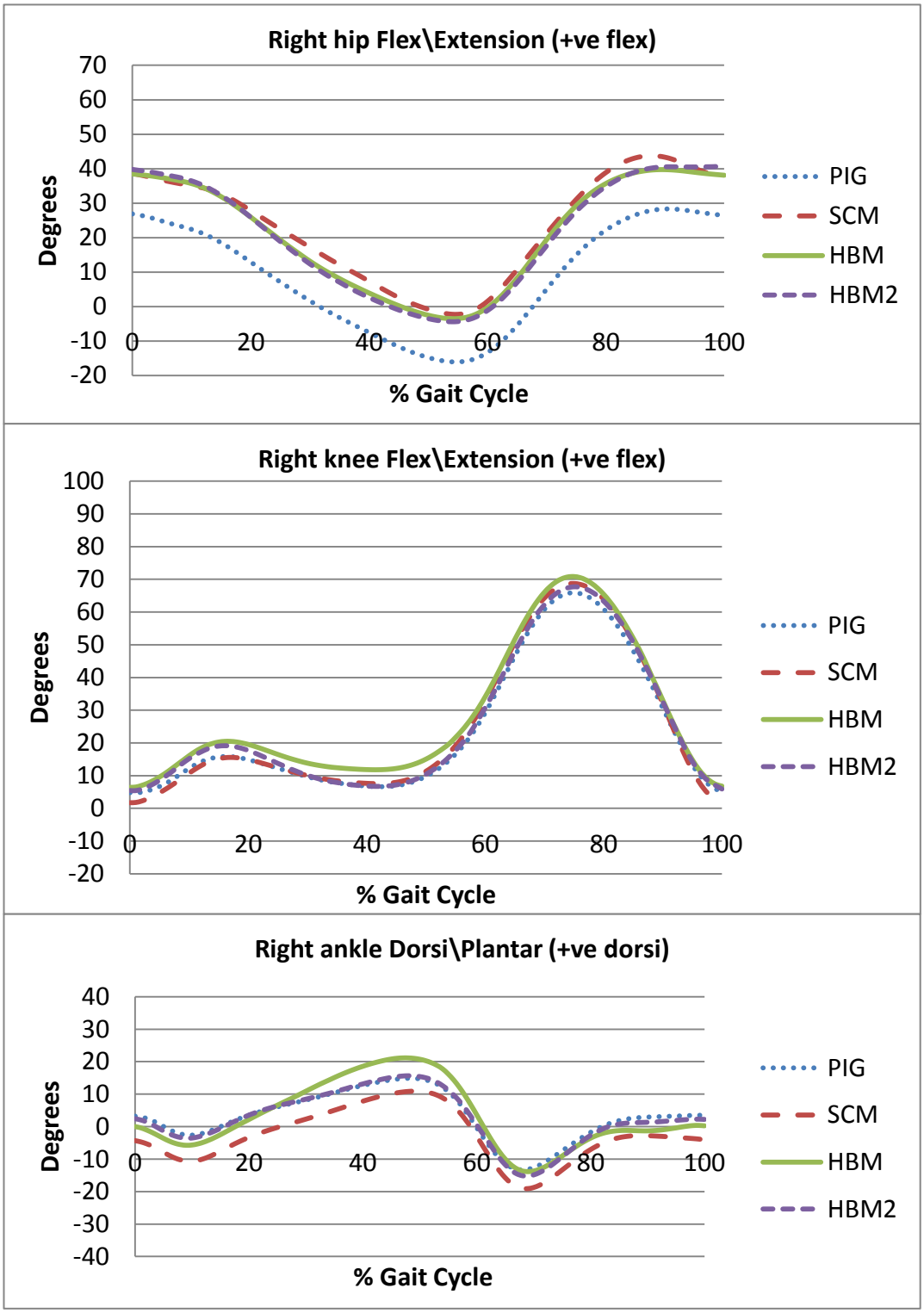


Figure 4.2 Sagittal kinematic parameters at the right gait cycle over 10 subjects as calculating by PiG **(**blue **round dot)**, SCM **(**red **dashed)**, HBM **(**green solid**)** and HBM2 **(**purple **square dot)** for three trial repetitions

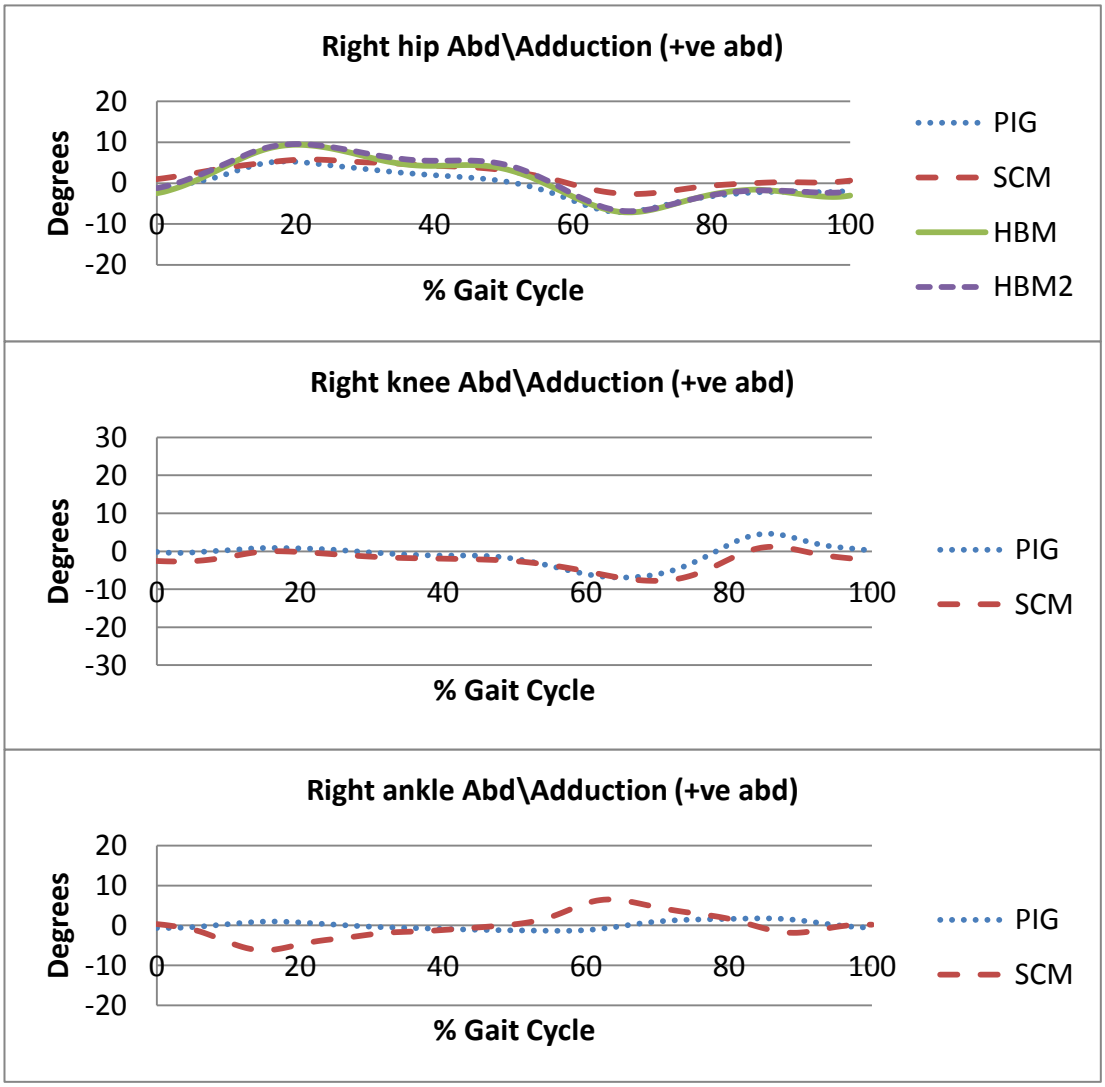


Figure 4.3 Coronal kinematic parameters at the right gait cycle over 10 subjects as calculating by PiG **(**blue **round dot)**, SCM **(**red **dashed)**, HBM **(**green solid**)** and HBM2 **(**purple **square dot)** for three trial repetitions

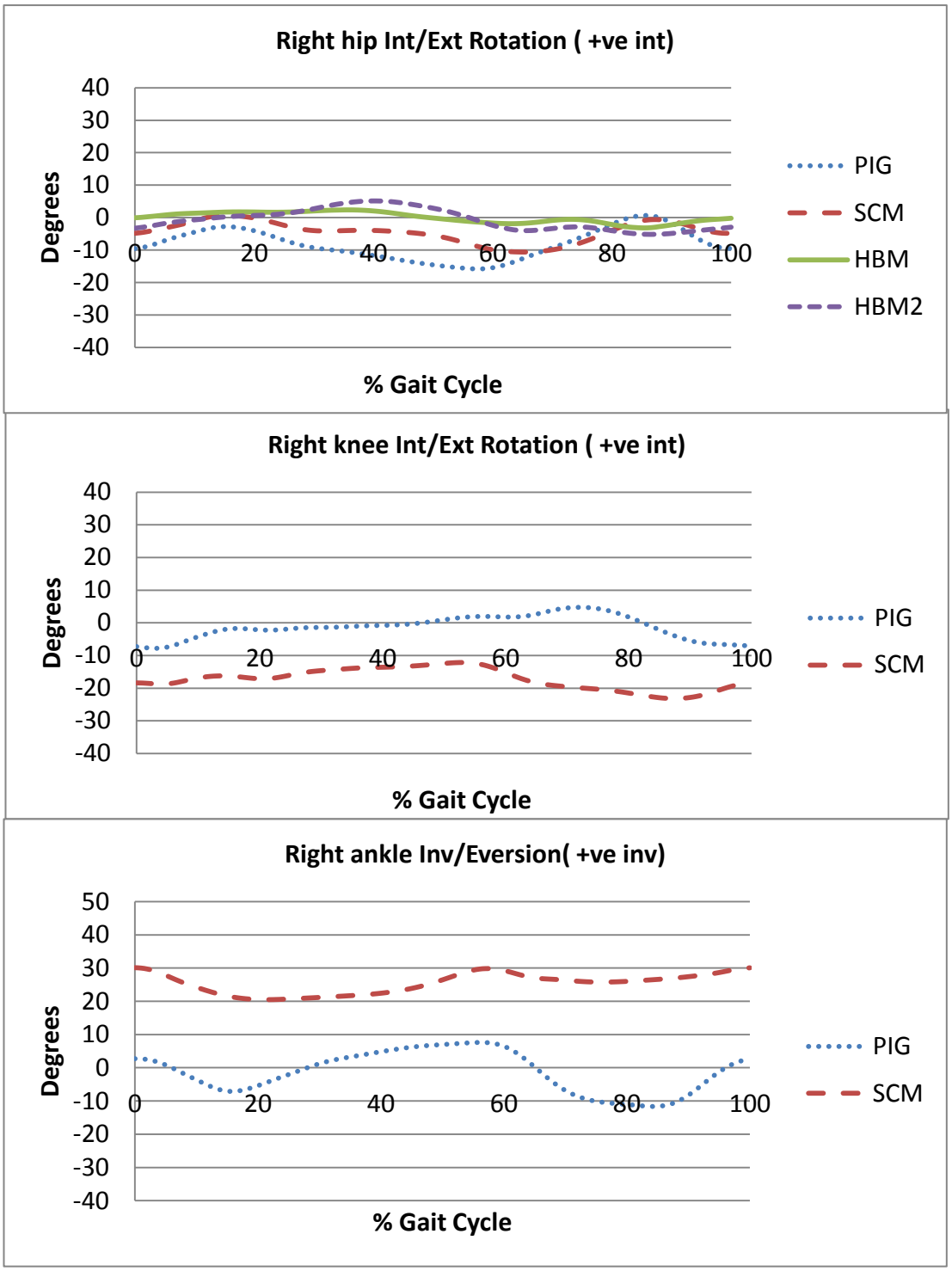


Figure 4.4 Transverse kinematic parameters at the right gait cycle over 10 subjects as calculating by PiG **(**blue **round dot)**, SCM **(**red **dashed)**, HBM **(**green solid**)** and HBM2 **(**purple **square dot)** for three trial repetitions

	PiG vs SCM	PiG vs HBM	PiG vs HBM2	SCM vs HBM	SCM vs HBM2	HBM vs HBM2
Joint Rotation(°)						
Ankle Dorsi/pla	0.876	0.956	0.996	0.882	0.903	0.972
Ankle Ab/ad	-0.143	-	-	-	-	-
Ankle ever/ever	0.018	-	-	-	-	-
Knee flex/ext	0.997	0.989	0.998	0.993	0.997	0.994
Knee Ab/ad	0.897	-	-	-	-	-
Knee int/ext	0.043	-	-	-	-	-
Hip flex/ext	0.819	0.862	0.873	0.994	0.990	0.999
Hip abd/add	0.848	0.936	0.906	0.888	0.898	0.994
Hip int/ext	0.627	-0.053	-0.394	0.213	0.161	0.771

Table 4.7 Between-protocol reliability reported by Intraclass correlation coefficients **(**ICC value**)** obtained by comparison of each of the protocols and pooled over 10 subjects

The calculation between models was investigated using intraclass correlation coefficients (ICC). Good and excellent correlations were found (Table 4.7) in most parameters among the 4 protocols in the sagittal plane parameters ($r > 0.74$). The largest correlations were hip flex/ext ($r = 0.999$) and knee flex/ext ($r = 0.998$). Smaller correlations were found for out-of-sagittal planes than for sagittal plane. One negative value was found in ankle abduction/adduction ICC indicating opposite trends of the gait curve, but the ICC was very low (-0.143).

4.4 Discussion and Conclusion

This study aimed to access the within-subject variability, between-subject variability and between protocol variability of four different protocols in healthy adults. The study procedures were repeated in ten healthy adults. A single marker set created by using four different protocols was attached to each patient and all landmark identification, and anthropometric measurement was carried out by one expert. Consistency within the four protocols with regards to marker positioning and biomechanical processing was ensured by being performed by one expert. The four protocols differed in degrees of assigned freedom, data processing and results. Plug-in Gait and HBM models required both the attachment of a single reflective marker on the skin at anatomical landmarks and anthropometric measurements. According to Schwartz M, Dixon PC (2018), accurate subject measurements are required for protocol and these measurements should be considered as possible sources of angular error (Schwartz and Dixon, 2018).

HBM2 also required single markers attached to the skin at anatomical landmarks. However, HBM2 did not require anthropometric measurements for joint centre estimation. For the SCM, the clusters were attached to the segments, and a single reflective marker was required for anatomical calibration. In the issue of subject preparation and a practical point of view, the SCM is more rapidly implemented compare to skin marker models such as PiG and HBM. The PiG and HBM associated anatomical landmark calibration and anthropometric measurement procedures. It is less skin exposure and less use of double-sided tape. Finally, it is required less

positioning the reflective markers. So, it provides more bearable for subjects with difficulties in prolonged standing tasks ((Papi, 2012) and in severe musculoskeletal deformities (Leardini et al., 2007).

In clinical gait analysis, the total variability affects how results can be interpreted. With greater variability in the data, comes greater uncertainty when interpreting the data. Measurement variability may arise from motion capture system error (extrinsic) or from the patient (intrinsic) due to gait variation (Schwartz et al., 2004; Yavuzer et al., 2008). The variability which a proposed method calculates kinematic variables during walking can be used as an indication of the protocol reliability (Papi, 2012).Good repeatability for kinematic variables is indicated by low standard deviation values. The within-subject variability for kinematic results was observed and ranged from 0.6° to 3.5° across all four protocols. The within-subject variability from all four protocols was considered reasonable and did not exceed 5° (McGinley et al., 2009). Previous literature also confirmed similar findings (Duffell et al., 2014; Ferrari et al., 2008; Gorton et al., 2009; Papi et al., 2014; Zuk and Pexowicz, 2015). The SCM showed the lowest within-subject variability of the four protocols. This was indicated by the small standard deviation (Table 4.2 - Table 4.5).

For HBM protocol in Table 4.4, HBM showed higher variability in subject 3. It was suspected that the high variability resulted from the consistent offset value in 1 trial resulting in the highest within-subject variability. It is likely to be because calculation or post-processing error.

The SCM model was the only one to use rigid clusters of markers. It would appear that the skin movement artefact was minimised by the use of rigid clusters firmly attached to the distal part of the segment. Previously conducted studies (Cappozzo et al., 2005; Papi et al., 2014) also stated that the use of rigid clusters of markers and attachment at the distal part of the anatomical segment was associated with reduced errors due to soft tissues movement. The evidence presented suggests that cluster-based models are subject to reduced STA when compared to skin surface marker models but there is insufficient evidence to draw conclusions. However, Millar,

(2016) argue that without comparison to a bone fixated device, it is not possible to determine which model is producing the most accurate measure of kinematics.

Between-subject variability was higher than within-subject variability by approximately 3°. This is also reported in previously conducted studies (Ferrari et al., 2008; Papi et al., 2014; Zuk and Pexowicz, 2015). These results are due to the natural variation between humans but are still relatively small. The SCM shows the least between-subject variability of the four protocols. Overall, variability was found to be lower in sagittal plane kinematics followed by the coronal plane and then the transverse plane. This follows the rotation sequence used were the first calculated rotation has least error and the final one in the sequence most error.

Between protocol variabilities were higher than within subject and between subject variabilities for most gait kinematics and this also agrees with previously reported studies (Duffell et al., 2014; Ferrari et al., 2008; Papi et al., 2014; Zuk and Pexowicz, 2015). The between protocol variation measures extrinsic repeatability with error arising from various sources, such as joint centre location and anthropometric measurements (Schwartz et al., 2004). Comparison of patterns of the kinematic graphs is a method used to compare and interpret quantitative 3D gait data (Kainz et al., 2017). Visually comparing all four kinematic waveforms showed that all four protocols showed good waveform agreement, in the sagittal plane and this was particularly so in the knee joint. The PiG showed an approximately 12^{o} offset in the hip flexion/extension curve compared to the other models. However, the excursion and variability were similar for the four models. It may therefore be the hip joint centre (HJC) is calculated by different regression equations in the models (Papi, 2012). Having different HJC coordinates influences, in fact, both hip and knee anatomical frames and thus the relative kinematics (Papi, 2012). It is therefore likely that the SCM, HBM and HBM 2 model also aligns all axes to zero during calibration.

In the coronal plane, similar patterns of hip abduction/adduction were seen across all four models for the knee, and the ankle coronal plane rotations were not given by HBM and HBM2. The ankle patterns were similar between the PiG and the SCM, but for the knee, the PiG abduction/adduction during swing was notably variable

with 4 out of 10 showing adduction to 15^{o} while 6 showed the opposite. This is a classic problem with PiG and related to malalignment of the knee axis. For the transverse plane, the hip kinematics were similar for each model but showed a large variation between subjects. Knee and ankle kinematics were not available from the HBM and The HBM2 in the transverse plane. The PiG and the SCM showed similar results but again with a large variation between subjects. There are two protocols (PIG and SCM) provides 3 degrees of freedom of angular kinematics for all three lower limb joints. Therefore, the SCM aligns the knee joint axis so that crosstalk and large amounts of abduction/adduction angulation in either direction are not seen at the knee during the swing, suggesting improved accuracy of knee axis alignment compared with the PiG protocol.

In summary, the comparisons of kinematic results from the three available protocol (SCM, HBM and HBM2) used in Strathclyde Laboratory with a widely used clinical gait analysis protocol, Plug-in Gait, showed good within-subject variability with reasonable error, as suggested by McGinley et al., (2009) in common clinical situations. The between protocol variability results were much larger than within subject and between subject variability. Good and acceptable correlations were found for sagittal plane rotations of the hip, knee and ankle particularly between PiG and SCM. Poor consistencies were observed in knee and ankle out-of-sagittal plane rotations. From these results, it can be concluded that first of all good within-subject variability to describe the joint kinematics as the PiG (clinical gold standard) when used for the gait analysis of able-bodied subjects. Despite the known large differences among the techniques, good correlations were observed for most of the gait variables. The overall the gait variables are comparable among protocols.

This study has some potential limitations. First, the issue of errors derived by skin movement artefact was minimised by the use of rigid clusters still unclear. Although, the evidence (Holden et al., 1997; Leardini et al., 2005; Manal et al., 2000) suggests that cluster-based models are subject to reduced STA when compared to skin surface marker models. However, without an accuracy method such as bone pins, external fixator devices, skeletal trackers, or medical imaging (Bonci, 2015; Leardini et al.,

2005) to assess soft tissue artefact between each model, it is not possible to determine which model is minimising STA.

A further limitation of the current study is that only healthy individuals were tested; therefore, the results cannot be generalized to other populations, especially not to amputees for clinical use in this manner. So, it important to note that this has only been demonstrated with healthy subjects and remains to be shown in amputees. This will be the focus of the next chapter in the thesis.

Chapter 5. Kinematic analysis of the Strathclyde Cluster Model when used to measure trans-tibial amputee subjects: a quantitative comparison with Plug-in Gait protocol

5.1 Introduction

A trans-tibial amputee is a person with lower limb loss and hence some loss of the typical anatomical reference used in gait analysis. When describing the kinematics of lower limb amputees, Kent & Franklyn-Miller, (2011) recommended that motion analysis of an amputee must take this issue into account. Differences in the marker positioning, in joint behaviour, non-anatomical movement of prosthetic components and the introduction of an additional segmental interface between the socket and residual limb may increase the scope for misrepresentation and subsequent misinterpretation.

The available biomechanical models used in clinical gait analysis vary in complexity and the number of degrees of freedom (DOF). The PiG is a clinical gold standard. However, A literature review by Kent & Franklyn-Miller (Kent and Franklyn-Miller, 2011) concluded that the standard biomechanical model use in clinical gait assessment (PiG) might not work properly for the analysis of trans-tibial amputee gait. The model may not consistently represent the body and prosthesis adequately to produce valid results for the analysis of the function of trans-tibial amputee. Moreover, as shown in the previous Chapter, PiG is far from ideal. The HBM and HBM 2 are other examples of a commercially available marker set as mentioned in chapter 2 and compared to PiG in chapter 4. In conjunction with the three marker sets mentioned, those three marker sets employ individual skin surface markers. Therefore, the researcher was excluded use of HBM and HBM2 in this study.

As the results in Chapter 4 showed, the SCM kinematic output was an equally reliable method to describe the joint kinematics as PiG when used for the gait analysis of able-bodied subjects. It was presumed to be the best option for a routine clinical marker based motion tracking tool. However, the previous chapter described protocol was used with healthy subjects. Limited work has been carried out to investigate differences between cluster based models and models which employ skin surface markers in a transtibial amputee population who focus of this thesis.

The aims of this study were to compare two marker sets (PiG and SCM) and to validate this 3-D gait analysis protocol to be used for kinematic data collection in

trans-tibial amputee gait. In order to find a marker set capable of producing a meaningful kinematic output and which adequately represents both natural and prosthetic segments and joints.

5.2 Methods

5.2.1 Participants

This study was approved by the Siriraj Institutional Review Board (SIRB) of Thailand. The certificate of approval for this study is given in appendix 3. An advertisement was posted on the information board at the Sirindhorn School of Prosthetics and Orthotics (SSPO), Bangkok. The information included the main contact person. The information asked interested amputees to contact the email provided in the advertisement. The researcher sent out a Participant Information Sheet discussed the study with the potential participants and arranged a session date. Written informed consent was obtained before participation. The study was conducted in the three-dimensional motion analysis laboratory, Sirindhorn National Medical Rehabilitation Centre (SNMRC). A total of 7 trans-tibial amputee participants were recruited.

They were in good health and walking without an assistive device. The prostheses used by the participants' varied only in the side of the amputated limb. Table 5.1 indicates the specific components used by each trans-tibial amputee who completed the study. The participants were selected using the criteria listing in the inclusion and exclusion Table 5.3 and Table 5.3.

Patient Code	Amputated side	Socket Design	Suspension	Foot
EP201	Left	PTB	Self-suspension	SACH
EP202	Left	PTB	Self-suspension	SACH
EP203	Left	PTB	Self-suspension	SACH
EP204	Left	PTB	Self-suspension	SACH
EP205	Right	PTB	Self-suspension	SACH
EP206	Left	PTB	Self-suspension	SACH
EP207	Right	PTB	Self-suspension	SACH

Table 5.1 The prostheses used by participants

Inclusion criteria
Functional K level 3, 4 Able to walk for 60 minutes,
A good current condition of health without other diseases,
Between 18-60 years old,
Normal ROM in all joints in the lower limb,
Patients who had worn the prosthesis for more than six months,
Residents with easy access to the rehabilitation centre,
Muscles strength grade 4 – 5 according to Oxford scale,
Able to comply with directions and comprehend written and spoken in Thai,
Unilateral trans-tibial amputation performed more than one year with medium/long stump length.

Table 5.2 Inclusion criteria for participants

Exclusion criteria
Pain or neuroma at the stump,
A residual limb with wounds, congestion & extreme volume changes,
Patients with diabetic, hypertension & other severe medical conditions,
Patients who have problems with the sound side which can influence the gait,
Patients with joint or muscle contractures either on stump side or sound side.

Table 5.3 Exclusion criteria for participants

5.2.2 Protocols and Data collection

Simultaneous data capture was accomplished by designing a marker-set which combined the protocols of the Plug-in Gait model (PiG) and the Strathclyde Cluster Model (SCM) as shown in Figure 5.1. All landmark identification and anthropometric measurements were carried out by one expert. Calibration of the participants for PiG and SCM used a single static T-Pose posture with some additional skin surface markers. The details of the reflective markers and clusters used in this study are explained in Table 5.4. The subjects were then asked to walk at a self-selected speed along a walkway while being recorded by a 3-dimensional motion analysis system (Vicon MX Giganet, Motion Systems, Oxford, UK) at 100 samples per second. The 3-D marker trajectories for the two different marker models were then processed.

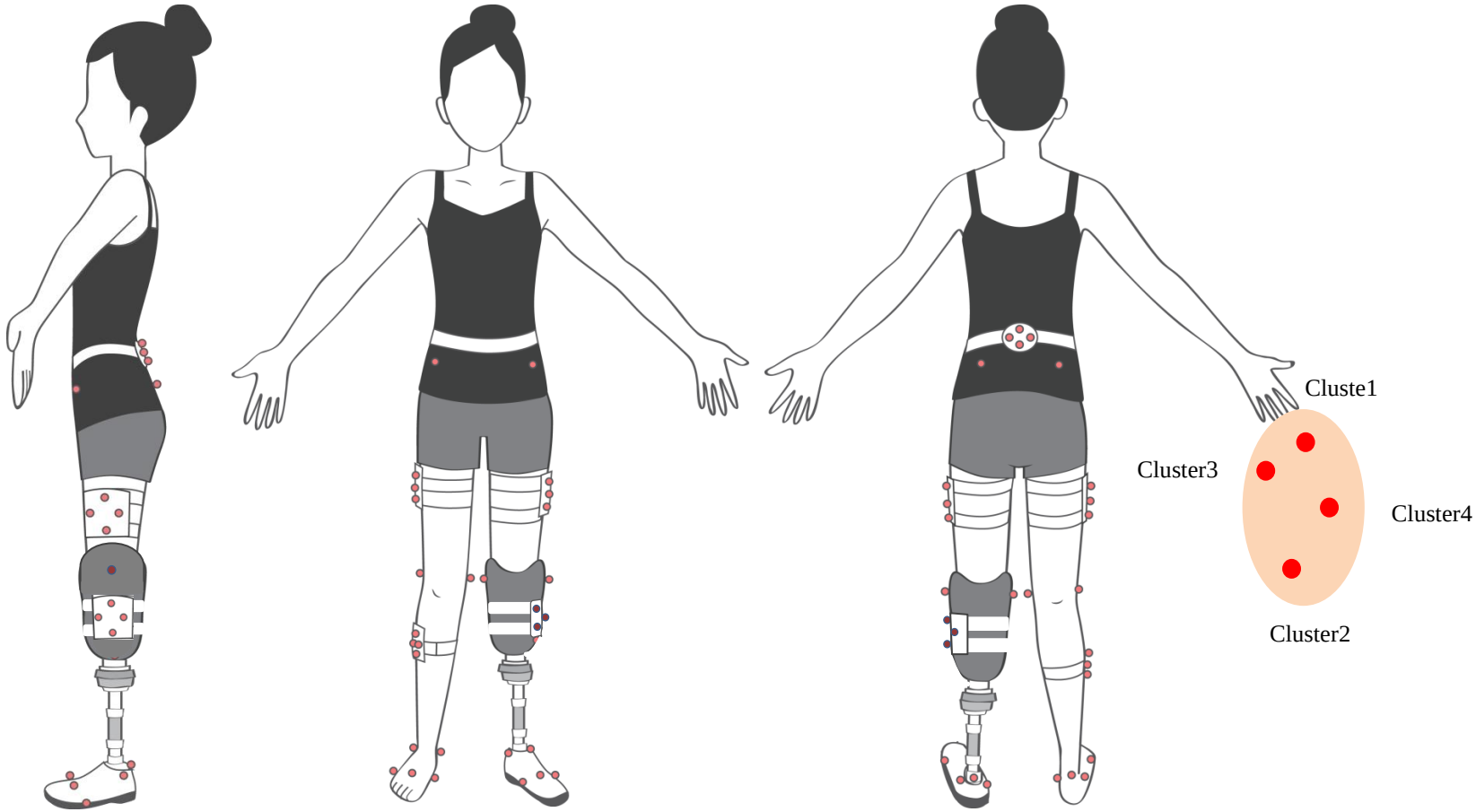


Figure 5.1 A single comprehensive marker set for two marker models **(**SCM and PiG) and the cluster

Marker	Definitions	Model	Marker Placement
LASI	Left ASIS	PIG/SCM	Placed directly over the left anterior superior iliac spine
RASI	Right ASIS	PIG/SCM	Placed directly over the right anterior superior iliac spine
LPSIS	Left PSIS	PIG/SCM	Placed directly over the left posterior superior iliac spine
RPSIS	Right PSIS	PIG/SCM	Placed directly over the Right posterior superior iliac spine
Pelvic Cluster	Pelvic Cluster	SCM	On anterior pelvic
TCluster1/	Thigh Cluster	PIG/SCM	On the superior thigh cluster and
TCluster2		SCM	On the inferior thigh cluster
TCluster3		SCM	On anterior thigh cluster
TCluster4		SCM	On posterior thigh cluster
SCluster1	Shank Cluster	PIG/SCM	On the superior shank cluster and
SCluster2		SCM	On the inferior shank t cluster
SCluster3		SCM	On anterior shank cluster
SCluster 4		SCM	On posterior shank cluster

Marker	Definitions	Model	Marker Placement
LLEK	Left lateral epicondyle of the knee	PIG/SCM	On the lateral side of the joint axis
LMEK	Left medial epicondyle	SCM	At the similar height of the LLEK. Check by holding both points and bending the knee; markers should not/hardly move.
RLEK	Right lateral epicondyle	PIG/SCM	On the lateral side of the joint axis
RMEK	Right medial epicondyle of the knee	SCM	At the similar height of the RLEK. Check by holding both points and bending the knee; markers should not/hardly move.
LLM	Left ankle/ Left lateral malleolus of the ankle	PIG/SCM	Placed on the lateral malleolus along an imaginary line that passes through the transmalleolar axis
RLM	Right ankle/ Right lateral malleolus of the ankle	PIG/SCM	Placed on the lateral malleolus along an imaginary line that passes through the transmalleolar axis

Marker	Definitions	Model	Marker Placement
LMM	Left medial malleolus of the ankle	SCM	Most pronounced part of the left medial malleolus
RMM	Right medial malleolus of the ankle	SCM	Most pronounced part of the right medial malleolus
LTOE	Left toe	PiG	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot
LTOE	Left Heel	PiG/SCM	Placed on the calcaneus at the same height above the plantar surface of the foot as the toe marker
LHEE	Left 1st metatarsal	SCM	Head of the 1st metatarsal bone, on joint line midfoot/toes
LMET1	Left 5th metatarsal	SCM	Head of the 5th metatarsal bone, on joint line midfoot/toes
LMET5	Right toe/ Right 2nd metatarsal	PiG	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot

Marker	Definitions	Model	Marker Placement
RTOE	Right Heel	PiG/SCM	Placed on the calcaneus at the same height above the plantar surface of the foot as the toe marker
RHEE	Right 1st metatarsal	SCM	Head of the 1st metatarsal bone, on joint line midfoot/toes
RMET1	Right 5th metatarsal	SCM	Head of the 5th metatarsal bone, on joint line midfoot/toes
RMET5	Left toe	PiG	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot

Table 5.4 Marker set used during the study with the name of each marker, and its position is reported relative to the segment

5.2.3 Data processing

Data processing was carried out by one expert rater for both protocols. 3D marker trajectories were reconstructed. During post-processing, 3D marker trajectories were reconstructed, labelled, and gap filling was performed for each marker set shown in Figure 5.2. Gaps were filled manually in all trial data by using the appropriate fill tools (Spline Fil, Pattern Fill and Rigid Body Fill**)** to generate data to fill the selected trajectory gap.

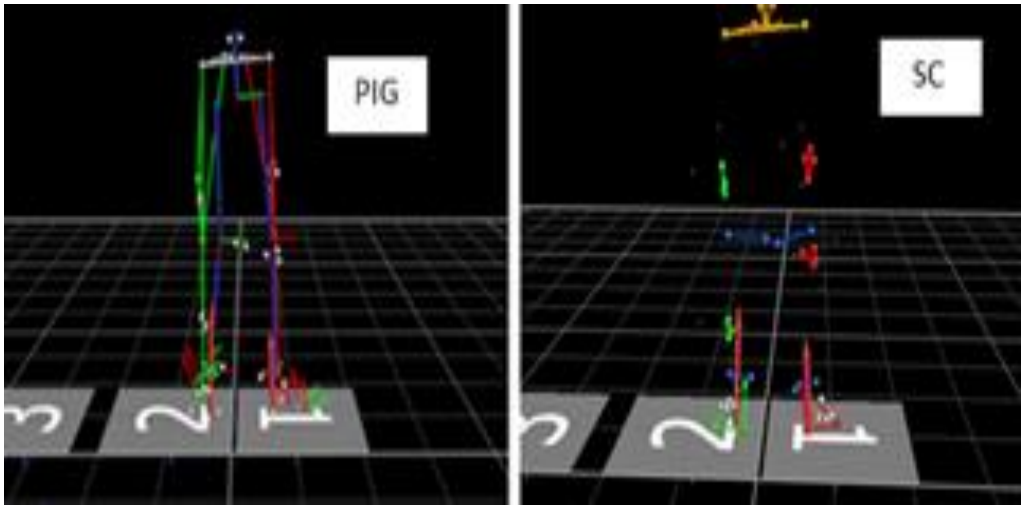


Figure 5.2 A single marker set for two marker models

Force plate data were used to determine Heel strike and Toe Off. Heel Strike was calculated at the first frame at which the vertical GRF was greater than 20 Newtons and Toe Off as the last frame at which it exceeded 20 N (Zeni et al., 2008). Heel Strike and Toe Off detection were also performed using the "detect events" operation from the pipeline in Nexus. The auto correlates event in the pipeline was used to determine these heel contacts force plate.

All data were time normalised to the gait cycle. The amputated limb and contralateral limb gait cycles were extracted from each of three good trials. The trial was selected based on a good quality reconstruction of all marker trajectories without a missing marker coordinates. Both models used the same gate cycle to compared the difference between model to allow consistency in the comparisons.

Different filters will have different effects on the gait parameters calculated (Tabakin, 2000). Hence, all data were filtered using a second-order low pass Butterworth filter with a cut-off frequency of 6Hz. The marker trajectory data were then processed and gait data calculated separately for each data set according to the gait analysis software package for that marker model.

To calculate the kinematic parameters of the gait for the SCM model a custom BodyLanguage Model was used (Papi, 2012), PiG using the plug-in model available in the Vicon pipeline. Gait data were further processed using Excel VBA including gait cycle normalisation to 101 points (0 -100) per cycle. The VBA code for joint angle normalisation is provided in appendix 1. In total, the data consisted of three trials of self –selected comfortable overground walking for seven participants, analysed using two different biomechanics protocols making a total of 42 gait cycles in all. The mean values of joint rotation (± 1SD) were plotted for visual comparison. Key kinematic parameters (Tables 5.4-5.6) were compared. Paired t-test with a significance level of $\alpha = 0.05$ was used to test the difference between PiG and SCM protocols. Then, key kinematic parameters were compared using Bonferroni corrected t-tests ($\alpha = 0.005$).

For variability the standard deviation, (SD) and the average of the standard deviation throughout the gait cycle were used. Within-subject variability was obtained by looking at three repetitions of the gait cycle. The SD was calculated for each percentage point of the gait cycle and then averaged over the cycle to give the average SD within that subject for that kinematic variable. Between-subject variability was defined by taking the mean cycle for each participant and calculating the within-group standard deviation. This was then averaged across the gait cycle to give the between-subject variability (Zuk and Pexowicz, 2015).

5.3 Results

All subjects walked at a self-selected comfortable speed in all conditions. All subjects were able to walk independently on the overground. Walking's speed are shown in Table 5.5

Participant	OG walking speed (m/s)
Participant 1	0.86
Participant 2	0.82
Participant 3	0.82
Participant 4	0.76
Participant 5	0.96
Participant 6	0.86
Participant 7	0.90
Mean (SD)	**0.85 (0.08)**

Table 5.5 Walking speed

5.3.1 PiG and cluster protocols comparison (Within-subject and between-subject variability)

To allow an overall analysis of within-subject variability, repeatability of joint angles calculation for each subject was summarised in the value of the standard deviation of each joint angle throughout the gait cycle. The gait cycle for each individual was across the 7 subjects to give the cycle for each parameter for each model. This produced two sets of data which are fully reported in appendix 13. These values are reported in Table 5.6 and Table 5.7 for hip rotations, in Table 5.8 and Table 5.9 for knee rotations and Table 5.10 and Table 5.11 for ankle rotation.

Subject	Hip joint rotation					
	Flex/Extension		Ab/Adduction		Int/External	
	PiG	SCM	PiG	SCM	PiG	SCM
Subject 1	1.6	2.4	1.1	1.0	2.0	1.5
Subject 2	1.3	1.0	0.8	1.6	1.8	1.8
Subject 3	1.0	1.8	1.3	2.7	3.6	2.7
Subject 4	1.9	2.6	1.3	2.6	5.6	2.2
Subject 5	2.0	1.8	1.2	2.0	1.7	2.5
Subject 6	2.5	5.6	1.6	2.4	3.0	2.9
Subject 7	3.1	3.0	1.2	3.1	4.4	4.6
Mean(^{o})	1.9	2.6	1.2	2.2	3.2	2.6

Table 5.6 Within-Subject variability of hip joint rotation over the amputee gait cycle across three trials per subjects as calculating by PiG and SCM is shown by the standard deviation **(**SD**)**

In Table 5.6, the within-subjects variability as reported by the average SD (in degrees) was below 5.6° for all rotations of the hip on the amputated side for all subjects for both methods and averaged 2.1° for PiG and 2.5° for SCM. Table 5.7which shows the same data for the sound hip the maximum value was 4.7° and the average value was 1.9° for PiG and 2.1° for SCM. Overall, good within-subject repeatability was observed among the measured variables for both methods in the assessment of hip joint kinematics on both sides.

Subject	Hip joint rotation					
	Flex/Extension		Ab/Adduction		Int/External	
	PiG	SCM	PiG	SCM	PiG	SCM
Subject 1	1.0	1.9	0.4	0.6	1.6	1.6
Subject 2	1.3	1.3	0.6	1.1	1.3	1.8
Subject 3	3.1	4.3	0.7	2.8	2.5	1.3
Subject 4	2.0	4.1	1.1	2.7	2.9	3.9
Subject 5	3.3	3.4	1.1	1.8	2.7	2.7
Subject 6	2.5	3.9	0.8	1.8	2.7	4.3
Subject 7	2.2	2.5	1.0	1.8	4.7	1.5
Mean(^{o})	2.2	3.0	0.8	1.8	2.6	2.4

Table 5.7 Within-Subject variability of hip joint rotation over the sound gait cycle across three trials per subjects as calculating by PiG and SCM is shown by the standard deviation (SD)

Subject	Knee joint rotation					
	Flex/Extension		Ab/Adduction		Int/External	
	PiG	SCM	PiG	SCM	PiG	SCM
Subject 1	2.0	4.5	1.8	2.7	1.0	2.2
Subject 2	2.1	1.6	1.1	1.4	0.7	1.6
Subject 3	1.1	1.8	1.6	1.4	0.3	2.3
Subject 4	2.2	3.9	3.2	2.4	1.4	2.2
Subject 5	2.4	3.4	2.0	1.4	2.9	2.0
Subject 6	4.9	6.5	3.4	1.7	0.7	2.6
Subject 7	5.3	3.9	3.2	2.9	9.8	4.4
Mean(^{o})	2.9	3.7	2.3	2.0	2.4	2.5

Table 5.8 Within-Subject variability of knee joint rotation over the amputated gait cycle across three trials per subjects as calculating by PiG and SCM is shown by the standard deviation (SD)

Subject	Knee joint rotation					
	Flex/Extension		Ab/Adduction		Int/External	
	PiG	SCM	PiG	SCM	PiG	SCM
Subject 1	0.8	2.8	0.5	0.8	1.0	1.8
Subject 2	1.3	2.1	1.5	0.8	1.6	1.5
Subject 3	4.1	6.1	2.5	1.9	2.4	3.9
Subject 4	2.3	3.0	1.4	2.6	2.0	2.5
Subject 5	3.2	7.3	1.9	1.9	2.8	2.3
Subject 6	2.0	2.3	1.7	1.3	3.9	1.8
Subject 7	2.4	4.7	3.3	2.0	2.8	2.3
Mean(^{o})	2.3	4.1	1.8	1.6	2.4	2.3

Table 5.9 Within-Subject variability of knee joint rotation over the sound gait cycle across three trials per subjects as calculating by PiG and SCM is shown by the standard deviation (SD)

Table 5.8 shows the average SD obtained for the knee joint on the amputated side. Average standard deviation values (in degree) were limited to 6.5° for all knee rotations on the amputated side for the SCM and to 9.8° for PiG. Table 5.9shows the average SD obtained for the sound knee. Average standard deviation values (in degree) were limited to 7.3° for all knee rotations on the sound side for the SCM and to 4.1°for PiG.

For PiG, the average SD for all knee joint kinematics on the amputated side was 2.5° while for SCM, it was 2.7° (Table 5.8). On the sound side. These average SD were 1.9° for PiG and 2.4 ° for SCM (Table 5.9).

Subject	Ankle joint rotation (SD)					
	Dorsi/Plantar		Ab/Adduction		Inv/Eversion	
	PiG	SCM	PiG	SCM	PiG	SCM
Subject 1	1.1	0.9	1.2	2.9	5.5	1.4
Subject 2	0.3	0.5	0.2	0.8	1.5	0.7
Subject 3	0.5	0.5	0.9	0.8	3.6	0.8
Subject 4	1.0	0.8	3.7	1.1	2.2	0.8
Subject 5	6.4	0.6	6.9	0.7	1.7	0.6
Subject 6	1.1	1.5	0.4	1.0	2.4	1.3
Subject 7	11.1	1.6	3.3	1.2	15.7	1.4
Mean(^{o})	3.1	0.9	2.3	1.2	4.6	1.0

Table 5.10 Within-Subject variability of ankle joint rotation over the amputated gait across three trials per subjects as calculating by PiG and SCM is shown by the standard deviation (SD)

Subject	Ankle joint rotation (SD)					
	Dorsi/Plantar		Ab/Adduction		Inv/Eversion	
	PiG	SCM	PiG	SCM	PiG	SCM
Subject 1	1.7	2.4	0.9	1.9	1.3	1.1
Subject 2	6.4	1.5	3.6	1.7	1.5	1.0
Subject 3	8.2	2.8	8.0	5.6	1.1	1.4
Subject 4	1.8	2.0	0.8	2.5	3.4	1.4
Subject 5	4.1	6.0	1.5	4.1	4.5	2.5
Subject 6	1.8	14.2	1.8	12.2	4.2	1.5
Subject 7	1.8	1.7	1.1	2.5	5.0	1.3
Mean(°)	3.7	4.4	2.5	4.4	3.0	1.5

Table 5.11 Within-Subject variability of ankle joint rotation over the sound gait cycle across three trials per subjects as calculating by PiG and SCM is shown by the standard deviation (SD)

Table 5.10 shows the average SD obtained for the ankle joint on the amputated side. Average standard deviation values (in degree) were limited to 2.9° for all ankle rotations on the amputated side for the SCM and to 15.7° for PiG. Table 5.11 shows the average SD obtained for the ankle joint on the sound side. The average standard deviation values for the sound side ankle were limited to 14.2° for SCM and to 8.2° for PiG.

The average SD for the ankle kinematics on the amputated side was 3.3° for PiG and 1° for the SCM and on the sound side 3.1 ° for the PiG and 3.4° for the SCM.

Overall all three joints, the average SD for within-subjects variability was 2.5° for the PiG and 2.4° for the SCM. Both protocols showed good within-subject repeatability across all degrees of freedom for all joints.

Between-Subject variability was illustrated the mean by used mean (°) of angle standard deviation over the sound gait cycle among the seven participants for both protocols and is shown in Table 5.12 and Table 5.13

Amputated side										
	Hip joint			**Knee joint**			**Ankle joint**			
Protocol	Flex/Ext	Ab/ Ad	In/ Ex	Flex/Ext	Ab/Ad	In/Ex	Dorsi/Plntar	Ab/Ad	Inv/ Evr	Mean (°)
PiG	9.6	3.8	38.3	10.0	11.1	12.7	14.0	18.3	40.7	17.6
SCM	10.6	4.6	22.4	8.2	9.3	15.5	3.5	5.2	4.4	9.3

Table 5.12 Between-Subject variability illustrated by the mean standard deviation over the amputee gait cycle among the seven participants for both protocols

Sound side										
	Hip joint			**Knee joint**			**Ankle joint**			
Protocol	Flex/Ext	Ab/ Ad	In/ Ex	Flex/Ext	Ab/Ad	In/Ex	Dorsi/Plntar	Ab/Ad	Inv/ Evr	Mean (°)
PiG	11.4	5.7	19.0	10.5	8.1	22.6	17.6	22.0	21.4	15.4
SCM	11.8	3.8	19.3	7.4	10.3	14.7	6.7	6.6	6.5	9.7

Table 5.13 Between-Subject variability illustrated by the mean standard deviation over the sound gait cycle among the seven participants for both protocols

Between-subject variability for the two limbs across the 9 kinematic variabilities is shown in Table 5.12 and Table 5.13 .The between-subject variability ranged on the amputated side from 3.8^{o} to 40.7^{o} for PiG with an average of 17.6° and from 3.5° to 22.6° for SCM with an average of 9.3°. For the sound side PiG ranged from 5.7° to 22.6° with an average of 15.4° while the SCM ranges from 3.8° to 19.3° with an average of 9.7°. The mean standard deviation for the PiG was larger than SCM on both amputated and sound limb. The overall between-subject variability of the SCM was similar on both the amputated limb (9.3^{o}) and sound limb (9.7^{o}).

5.3.2 Agreement between PiG and SCM protocols

The Nine kinematics variables were analysed from the two protocols by plotting the mean gait cycle plus or minus one standard deviation, and these are illustrated in Figure 5.3 - Figure 5.8. The kinematic waveforms were visually inspected in the sagittal plane, coronal plane and transverse plane for the sound side and amputated side. This allows visual comparisons of kinematic data for 100% of the gait cycle between protocols.

Figure 5.3 - Figure 5.8. show joint angles for hip, knee and ankle in each plane as obtained by PiG and SCM are shown. The shaded black area represented mean ± 1SD from SCM and shaded purple area represent mean ± 1SD from PiG. Significant differences ($p < 0.05$) between PiG and SCM kinematic variables are highlighted by red bars in a point by point basis at the bottom of each graph.

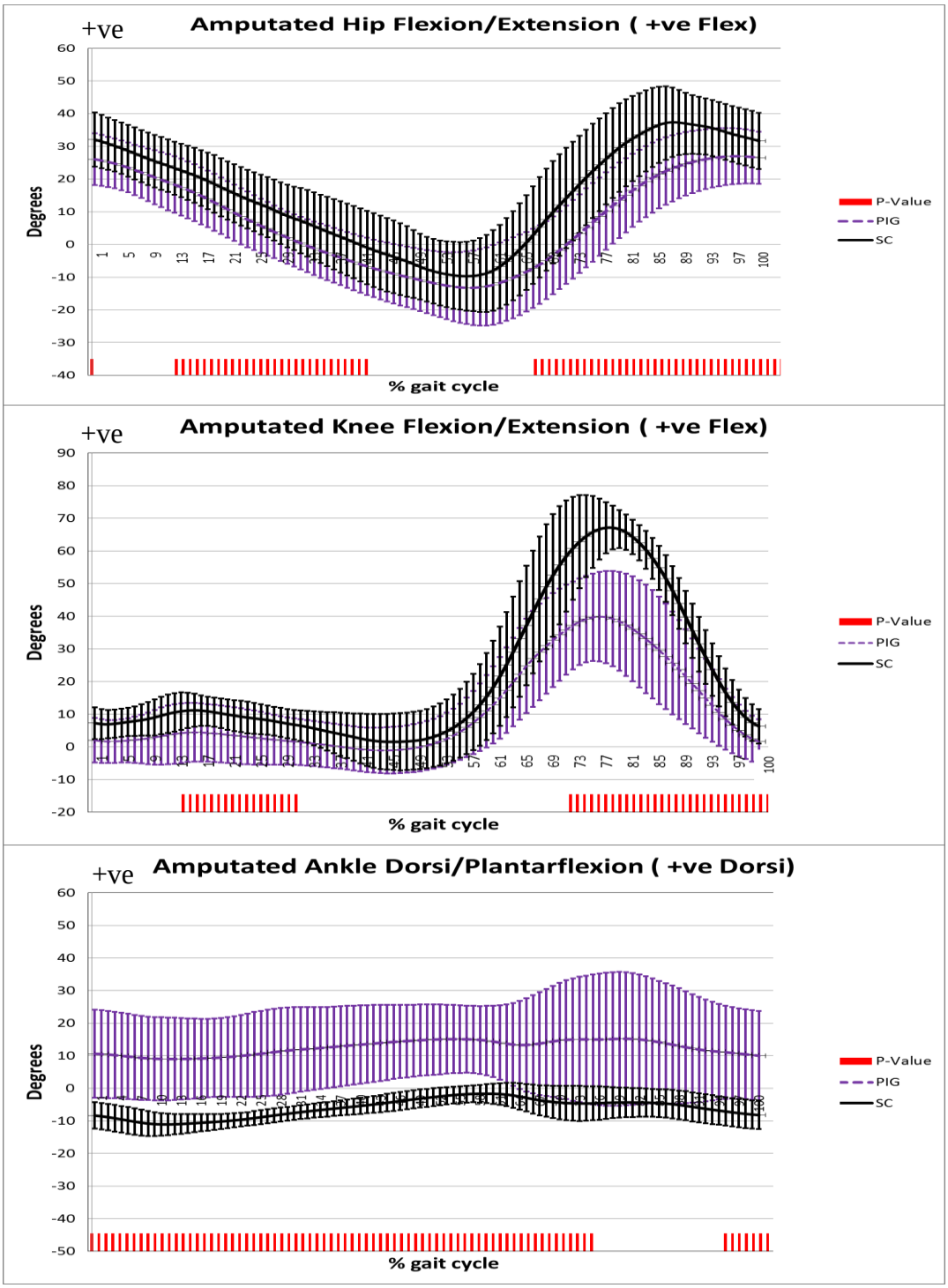


Figure 5.3 Sagittal Kinematic gait graph with Standard Deviation Bar at the amputated gait cycle over 7 amputees as calculate by PiG **(**Purple dash**)** and SCM **(**Black Solid**)** for three trial repetitions**.** T-test significant differences **(**p-value bar**)** throughout the gait cycle are reported at the bottom as red bars.

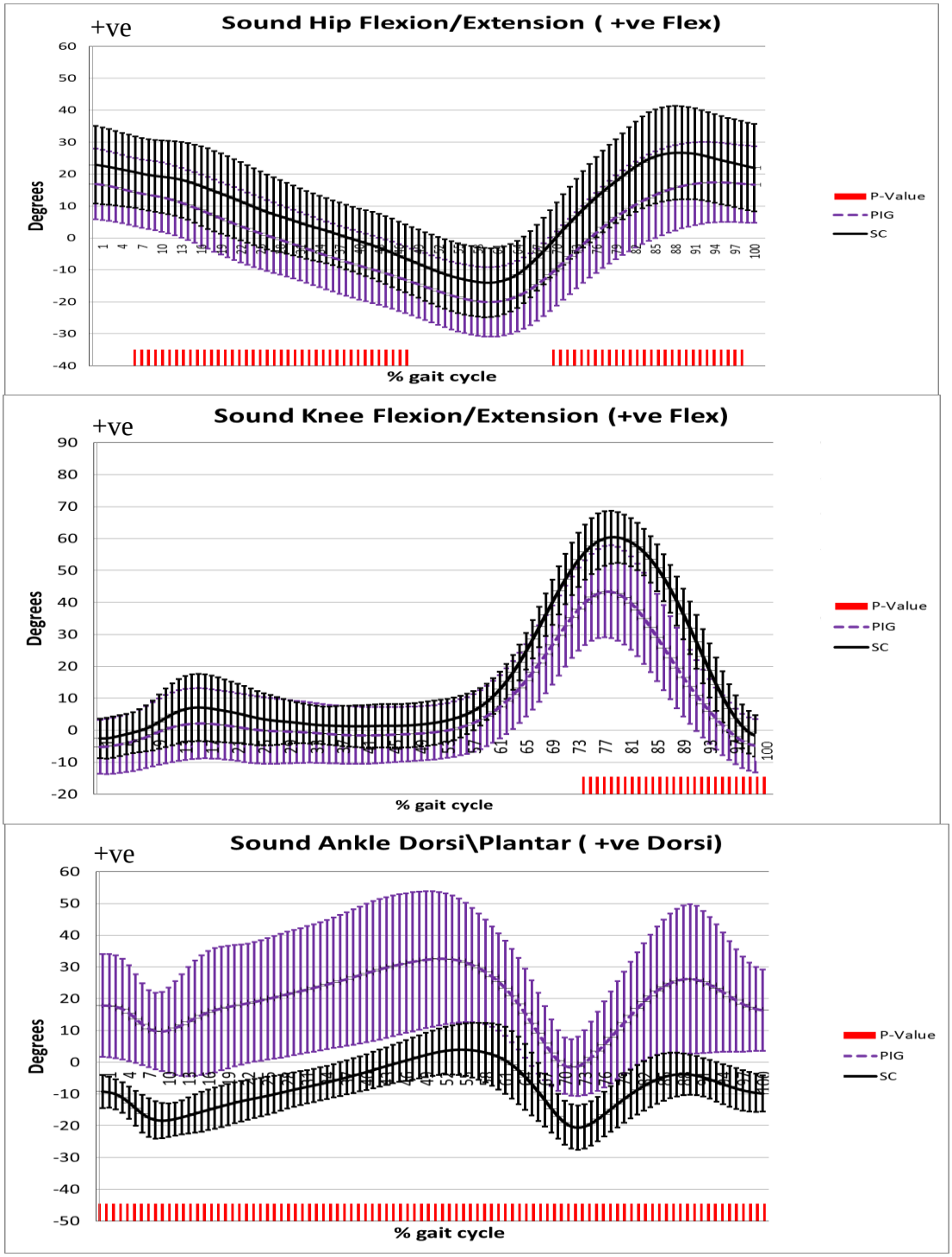


Figure 5.4 Sagittal Kinematic gait graph with Standard Deviation Bar at the sound gait cycle over 7 amputees as calculate by PiG **(**Purple dash**)** and SCM **(**Black Solid**)** for three trial repetitions**.** T-test significant differences **(**p-value bar**)** throughout the gait cycle are reported at the bottom as red bars

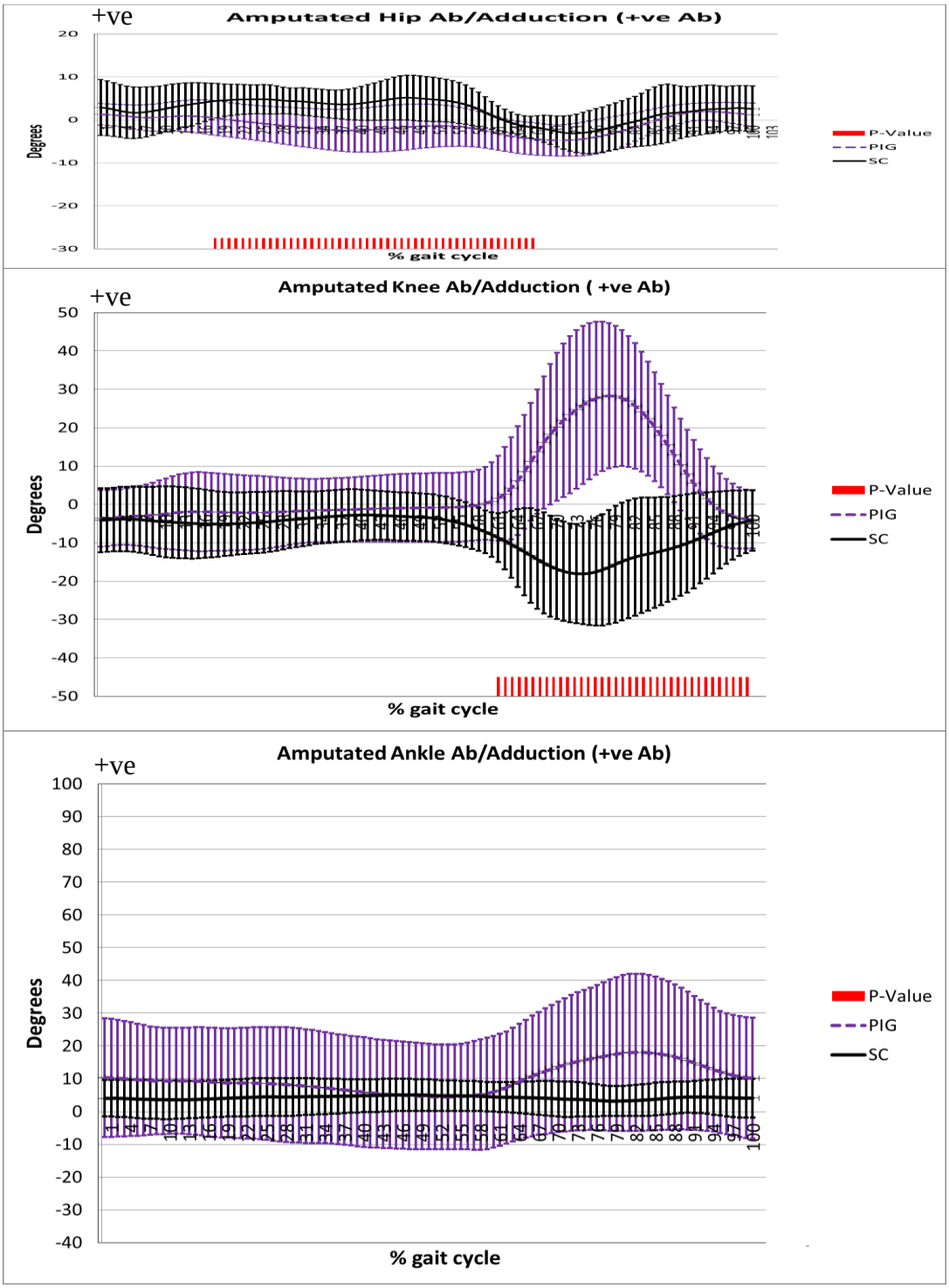


Figure 5.5 Coronal Kinematic gait graph with Standard Deviation Bar at the amputated gait cycle over 7 amputees as calculate by PiG **(**Purple dash**)** and SCM **(**Black Solid**)** for three trial repetitions**.** T-test significant differences **(**p-value bar**)** throughout the gait cycle are reported at the bottom as red bars

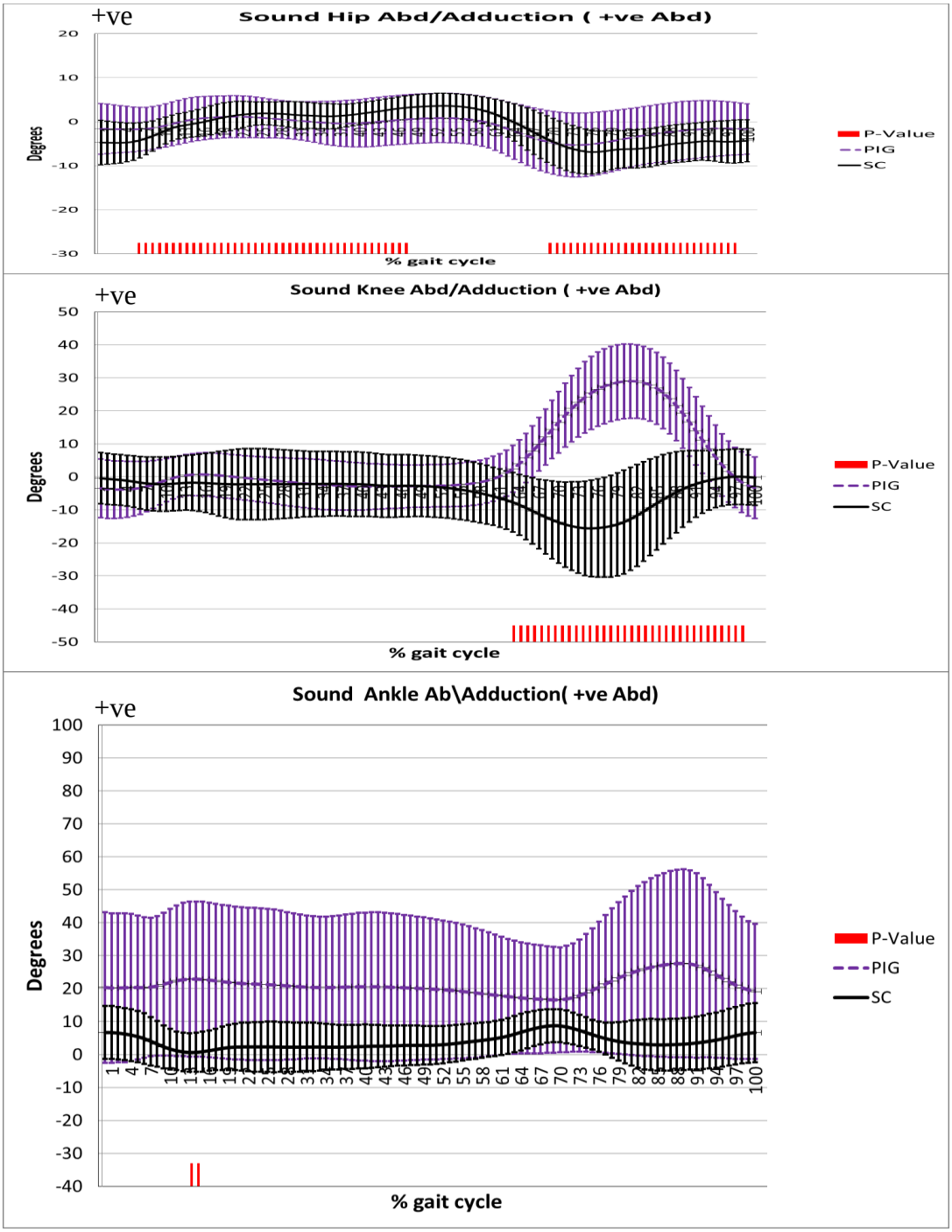


Figure 5.6 Coronal Kinematic gait graph with Standard Deviation Bar at the sound gait cycle over 7 amputees as calculate by PiG **(**Purple dash**)** and SCM **(**Black Solid**)** for three trial repetitions**.** T-test significant differences **(**p-value bar**)** throughout the gait cycle are reported at the bottom as red bars

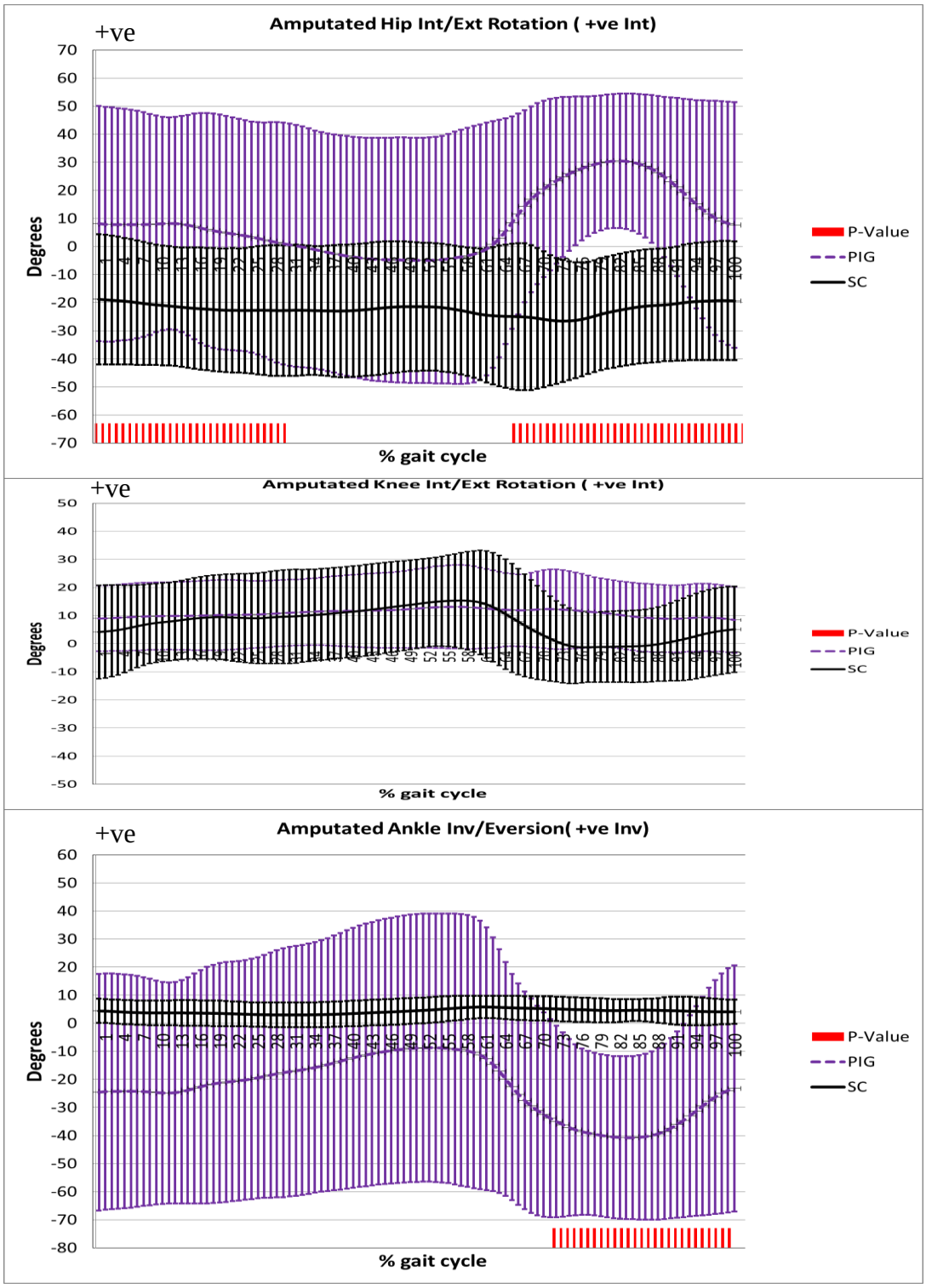


Figure 5.7 Transverse Kinematic gait graph with Standard Deviation Bar at the amputated gait cycle over 7 amputees as calculate by PiG **(**Purple dash**)** and SCM **(**Black Solid**)** for three trial repetitions**.** T-test significant differences **(**p-value bar**)** throughout the gait cycle are reported at the bottom as red bars

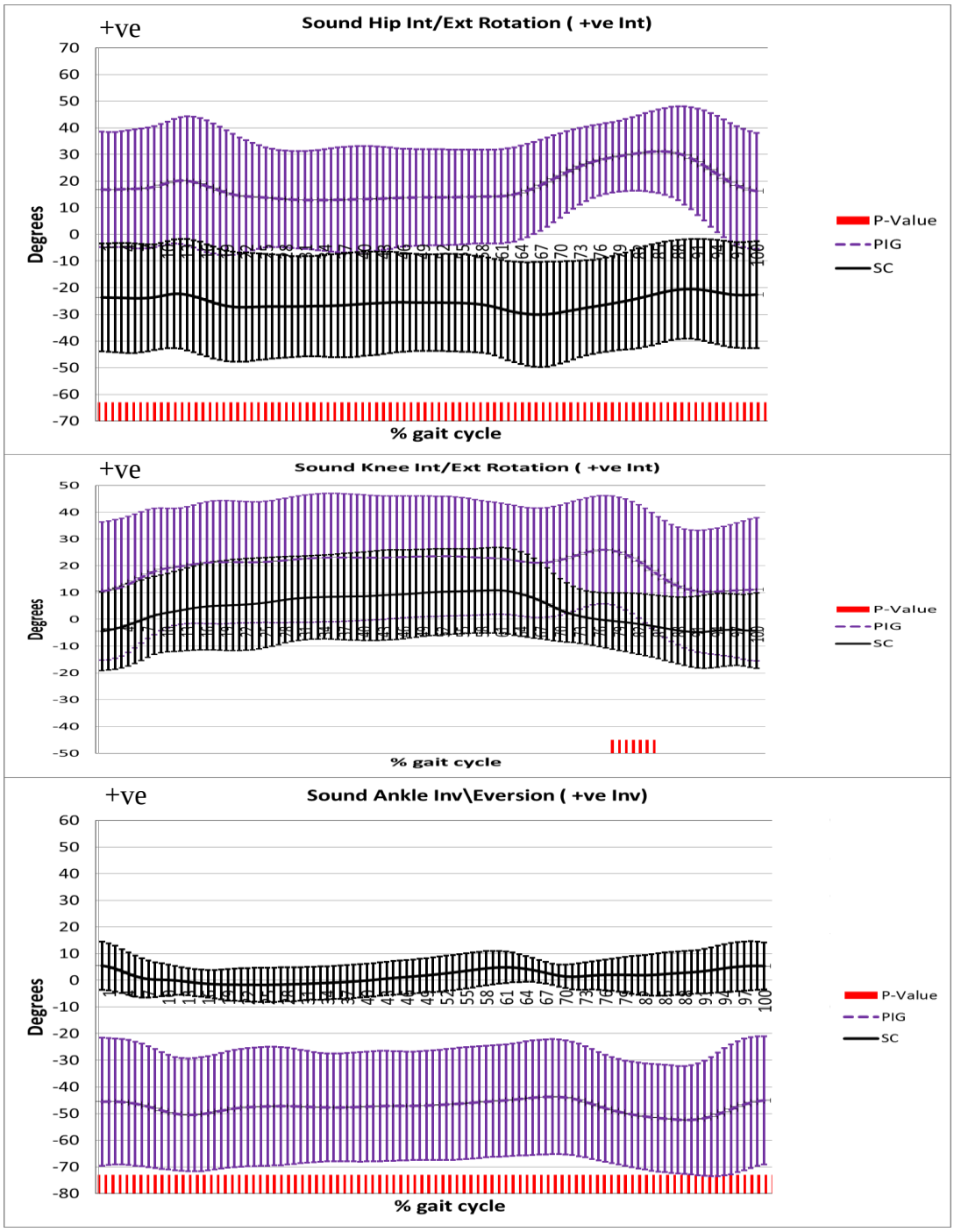


Figure 5.8 Transverse Kinematic gait graph with Standard Deviation Bar at the sound gait cycle over 7 amputees as calculate by PiG **(**Purple dash**)** and SCM **(**Black Solid**)** for three trial repetitions**.** T-test significant differences **(**p-value bar**)** throughout the gait cycle are reported at the bottom as red bars

The least agreement between the two protocols was observed in ankle inversion/eversion on the sound side, with curves being far apart and with different trends (Figure 5.8). Moreover, there was an offset between the two curves of approximately 50° in ankle inversion/eversion on the sound side. However, the graph pattern appeared similar for the two models. For ankle dorsiflexion hip internal-external rotation and ankle inversion/eversion on the sound side, there were significant differences between the two protocols for the entire gait cycle as shown by the red p-value bar ($p < 0.05$). Ankle abduction/adduction on both sides showed the best agreement.

The question still remains on what are the differences in kinematic output between the two models affect the calculated gait parameters needed for quantification of gait and to provide real-time visual feedback during the tuning application to be developed.

Key kinematic parameters (Table 5.14 - Table 5.16) were investigated and a paired t-test with a significance level of $\alpha = 0.05$ was used to test the difference between PiG and SCM protocol over the gait cycle. There are reported in Table 5.17, Table 5.18 and Table 5.19.

Hip Joint Parameters	
SH1	Hip flex/extension ROM at sound side
SH2	Peak Stance Extension at sound side
SH3	Peak Swing Flexion at sound side
SH4	Hip Ab/Ad ROM at sound side
SH5	Hip Int/Ext Rotation ROM at sound side
AH1	Hip flex/extension ROM at amputated side
AH2	Peak Stance Extension at amputated side
AH3	Peak Swing Flexion at amputated side
AH4	Hip Ab/Ad ROM at amputated side
AH5	Hip Int/Ext Rotation ROM at amputated side

Table 5.14 Hip joint angle parameters**.** Acronyms and corresponding definitions are reported

Knee Joint Parameters	
SK1	Knee flex/extension ROM at sound side
SK2	Peak Stance Flexion at the sound side
SK3	Peak Swing Flexion at sound side
SK4	Knee Ab/Ad ROM at sound side
SK5	Knee Int/Ext Rotation ROM at sound side
AK1	Knee flex/extension ROM at amputated side
AK2	Peak Stance Flexion at amputated side
AK3	Peak Swing Flexion at amputated side
AK4	Knee Ab/Ad ROM at amputated side
AK5	Knee Int/Ext Rotation ROM at amputated side

Table 5.15 Knee joint angle parameters. Acronyms and corresponding definitions are reported

Ankle Joint Parameters	
SA1	Ankle Plantar/dorsiflexion ROM at sound side
SA2	Peak Stance dorsiflexion at sound side
SA3	Peak Swing plantarflexion at sound side
SA4	Ankle Ab/Adduction ROM at sound side
SA5	Ankle Inv/Eversion ROM at sound side
AA1	Ankle Plantar/dorsiflexion ROM at amputated side
AA2	Peak Stance dorsiflexion at amputated side
AA3	Peak Swing plantarflexion at amputated side
AA4	Ankle Ab/Adduction ROM at amputated side
AA5	Ankle Inv/Eversion ROM at amputated side

Table 5.16 Ankle joint angle parameters. Acronyms and corresponding definitions are reported

Table 5.17 shows typical gait parameters and their SD calculated from 7 patients average gait cycles. The highest standard deviation values were observed for hip Int/Ext Rotation ROM on the amputated side calculated by the PiG (32.3^{o}). Statistical significant differences in joint parameters caused by a difference in the protocol were evident in the sagittal plane ($p < 0.05$) on the amputated side (AH1 and AH3). For the hip rotation on the sound side, there was a significant difference between AH3 and AH5. However, all other parameters exhibited no significant differences.

Parameters	**PiG (SD)**	**SCM (SD)**	**p-Value**	**P<0.05**	**P<0.005**
Sound side					
Hip flex/extension ROM	38.4(4.7)	42.1(7.0)	0.12		
Peak Stance Extension	-15.3(10.5)	-8.9(10.0)	0.06	*	
Peak Swing Flexion	17.9(12.4)	27.2(13.5)	0.02		
Hip Ab/Ad ROM	9.1(3.2)	12.3(3.3)	0.11	*	
Hip Int/Ext Rotation ROM	24.6(5.3)	12.1(4.0)	0.01		
Amputated side					
Hip flex/extension ROM	42.1(7.6)	49.0(5.6)	0.00	*	**
Peak Stance Extension	-11.4(9.6)	-7.6(9.2)	0.22		
Peak Swing Flexion	27.5(8.8)	38.5(9.7)	0.01	*	
Hip Ab/Ad ROM	8.9(3.8)	11.6(3.3)	0.32		
Hip Int/Ext Rotation ROM	37.6(32.3)	12.3(3.0)	0.09		

*Significant difference ($\alpha = 0.05$),

* *Indicates significance level of $p < 0.005$ after Bonferroni correction (0.05/10)

Table 5.17 Hip joint angle parameters of seven amputees subject on sound and amputated side as mean **(**SD**)** over three gait cycles calculated by the PiG and SCM

Parameters	PiG (SD)	SCM (SD)	p-Value	P<0.05	P<0.005
Sound side					
Knee flex/extension ROM	48.8(10.0)	63.4(7.7)	0.01	*	
Peak Stance Extension	3.2(11.4)	8.6(8.4)	0.18		
Peak Swing Flexion	43.6(14.3)	60.8(7.5)	0.02	*	
Knee Ab/Ad ROM	34.1(12.6)	21.3(9.4)	0.08		
Knee Int/Ext Rotation ROM	20.7(8.1)	19.5(5.2)	0.71		
Amputated side					
Knee flex/extension ROM	45.3(12.8)	70.6(8.9)	0.01	*	
Peak Stance Extension	6.8(7.2)	12.2(4.4)	0.03	*	
Peak Swing Flexion	41.9(14.6)	69.3(5.4)	0.01	*	
Knee Ab/Ad ROM	38.7(15.1)	22.5(10.0)	0.10		
Knee Int/Ext Rotation ROM	9.8(6.9)	22.5(10.0)	0.01	*	

*Significant difference ($\alpha = 0.05$),

* *Indicates significance level of $p < 0.005$ after Bonferroni correction (0.05/10)

Table 5.18 Knee joint angle parameters of 7 amputees subject on sound and amputated side as mean (SD) over three gait cycles calculated by the PiG and SCM

For the knee in Table 5.18, SCM estimated a higher angle for sagittal plane joint angle parameters (AK1, AK2, AK3, SK1, SK2 and SK3). The variability was higher for PiG than SCM for all parameters. Statistically significant differences in joint parameters with a change in the protocol were evident in almost all parameters on the amputated side ($p < 0.05$) except knee parameter in the coronal plane (AK4) were no significant differences between the two protocols were found.

Parameters	PiG (SD)	SCM (SD)	p-Value	P<0.05	P<0.005
Sound side					
Ankle Plantar/dorsiflexion	37.3(16.1)	25.7(3.5)	0.12		
Peak Stance dorsiflexion	32.8(21.8)	2.8(6.6)	0.02	*	
Peak Swing plantarflexion	-2.3(8.5)	-21.1(6.6)	0.01	*	
Ankle Ab/Adduction	13.5(13.7)	11.6(3.9)	0.76		
Ankle Inv/Eversion ROM	11.5(5.0)	10.6(3.6)	0.66		
Amputated side					
Ankle Plantar/dorsiflexion	10.5(6.0)	8.2(2.8)	0.43		
Peak Stance dorsiflexion	15.2(11.8)	-3.0(2.6)	0.01	*	
Peak Swing plantarflexion	9.0(13.3)	-8.2(4.0)	0.02	*	
Ankle Ab/Adduction	14.4(11.5)	3.2(0.8)	0.04	*	
Ankle Inv/Eversion ROM	34.7(30.5)	4.0(1.3)	0.04	*	

*Significant difference ($\alpha = 0.05$),

* *Indicates significance level of $p < 0.005$ after Bonferroni correction (0.05/10)

Table 5.19 Ankle joint angle parameters of seven amputees subject on sound and amputated side as mean **(**SD**)** over three gait cycles calculated by the PiG and SCM

All transverse and coronal plane parameters extracted from the gait on the amputated side in Table 5.19, AK3, AK4 and AK5 were significantly different between PiG and SCM ($p < 0.05$). Differences in Stance dorsiflexion on the amputated side were significant ($p < 0.01$). Further, variability was lower for SCM in all parameters.

5.4 Discussion and Conclusion

This study aimed to compare the differences between the two marker protocols as well as to compare the kinematic output of those protocols in trans-tibial amputee's gait. The study procedures were repeated in seven trans-tibial amputees who had been using the prosthesis for more than one year. A single marker set created by using two different protocols PiG and SCM was used. Those two protocols had previously been shown to have good validity and reliability when used for the gait analysis of able-bodied subjects. The single markers set was attached to each patient, and all landmark identification and anthropometric measurement were carried out. Consistency within the two protocols with regards to marker positioning and biomechanical processing was ensured by being performed by one expert.

The two protocols differed in degrees of assigned freedom, data processing and calculated the results. Plug-in Gait required both, the attachment of the single reflective markers on the skin at anatomical landmarks as well as anthropometric measurements. The Strathclyde Cluster protocol, the clusters were attached to the segments, and a single reflective marker was required for anatomical calibration.

The simple method used to compare and interpret quantitative 3D gait data is to compare the patterns of the kinematic graphs (Baker, 2013). Visually comparing both kinematic waveforms showed that the protocols had good waveform correlation, especially in the sagittal plane. The lowest consistency of general patterns was observed for the transverse plane kinematic parameters on the amputated and sound gait cycle as calculate by PiG, especially for knee rotation and ankle rotation.

The differences in joint angle pattern may be due to differences in the positioning of relevant functional landmarks, differences in joint behaviour, non-anatomical movement of prosthetic components and the introduction of an additional segmental interface between the socket and residual limb, amongst other factors, and there may increase the scope for misrepresentation and subsequent misinterpretation (Kent and Franklyn-Miller, 2011).

Both protocols behaved well in terms of within-subject variability, although slightly higher values of standard deviation were observed in SCM protocol. The within-subject variability for kinematic results was observed and ranged from 0.8^0 to 4.6^0

across the two protocols. Although slightly higher values of standard deviation were observed in the SCM protocol showed, but it was considered reasonable and did not exceed 5° (McGinley et al., 2009).

Between-subject variability was higher for the PiG protocol than for the SCM protocol in most parameters. The most remarkable result in the current study was the high standard deviation for PiG protocols particularly in coronal and transverse planes. The SCM showed the lowest between-subject variability. The SCM model used rigid clusters of markers. It would appear that the skin movement artefact was minimised by the use of rigid clusters more firmly attached than PiG to the distal part of the segment. Previously conducted studies (Papi et al., 2014) also stated that the use of rigid clusters of markers and attachment at the distal part of the anatomical segment was associated with reduced errors due to soft tissue movement.

Visually comparing all the kinematic waveforms with plus and minus standard deviation showed that the two protocols showed poor waveform correlation particularly so in the coronal and transverse planes. Overall, variability was found to be lower in sagittal plane kinematics followed by the coronal plane and then the transverse plane. Differences in gait parameters with a change in the two protocols were most evident in ankle parameters ($p < 0.05$). The significant differences between the two protocols were observed in the entire gait cycle as shown by the red p-value bar ($p < 0.05$) in sound side ankle except for ankle abduction/adduction. Different anatomical frames are used in the two methods to define the ankle-foot complex movement explaining the large differences between ankle transverse and coronal plane rotations given by the two methods.

For the knee, PiG estimated lower flexion in the swing than SCM both on the amputated side and sound side. Additionally, PiG estimated higher abduction in the swing than SCM. PiG measured up to approximately 50° of abduction which is abnormal for a healthy participant (Ferrari et al., 2008). In normal knee adduction/abduction angle, the value was expected to be zero. This phenomenon has been reported elsewhere regarding PiG data (McGinley et al., 2009; Millar, 2016).

This might be explained by the crosstalk between flexion and abduction due to an incorrect marker location resulting in an incorrect alignment of the axis of rotation, relatively large in that phase, to abduction/adduction. (Ferrari et al., 2008). This follows the rotation sequence used were the first calculated rotation has least error and the final one in the sequence most error. For the SCM aligns the knee joint axis so that crosstalk and large amounts of abduction/adduction angulation in either direction not seen at the knee during the swing. Therefore crosstalk is likely to be the reason for the higher knee abduction angles measured by PiG in this study.

Another possible cause might be the limb movement between the residuum and socket. PiG is a skin-marker model (SMS) which requires attaching the markers to the anatomical landmarks. In TT amputees, the attachment of reflective markers cannot attach directly to the skin either because it has been amputated or because it is covered by the prosthesis. It is, therefore, necessary to attach markers to the outside of the prosthetic socket then it covers the lateral epicondyles and to the prosthesis itself. As there is a degree of relative movement between the prosthetic socket and the residual limb, the calculation of joint kinematics does not necessarily reflect the true motion, and this presents an additional source of error (Rusaw, 2011). This assumption supported by the research of Childers and Siebert, (2015) which looked at motion between the residuum and the prosthesis during gait. The results of this study showed that the residuum movement relative to the socket went through ~30 mm, 18 mm, and 15° range of motion. Root mean squared errors were 5.47 mm, 1.86 mm, and 0.75° when considering the modelled bone–skin movement in the proximal or distal, anterior or posterior, and angular directions, respectively. PiG showed the largest variability in most gait parameters. The use of skin markers leading to high level of error (Cappozzo et al., 1996; Leardini et al., 2005). Moreover, the study by Cappozzo et al., (1996) suggested that the placement of markers on bony landmarks should be avoided where possible as this can lead to high levels of error due to STA.

For the ankle, PiG showed an offset of approximately 50° in ankle inversion/eversion on the sound side when compared to SCM. The least agreement between the two

protocols was observed in ankle inversion/eversion on the sound side, with curves being far apart and with different trends.

There were some limitations associated with the comparison study. The results of this study can observe some difference but cannot conclude which model correct. It is not possible from these results to determine which model is most accurate, as it was not possible to compare PiG and SCM to a true measure of segment movement. The fact that a motion analysis protocol which has not yet been clinically validated was used for gait assessments may be viewed as a limitation to this study.

Furthermore, this study only concerns the comparison of kinematic data. Therefore it cannot be concluded from this study, that the entire protocol are valid, only whether or not it is valid for measuring hip, knee and ankle angles. Further studies should be carried out in order to compare the remaining of the other parameters such as spatiotemporal parameter and kinetics.

Based on the comparisons of the kinematic results from the two available protocols (SCM and PiG), it can be concluded that the SCM kinematic output is comparable to the PiG. However, the SCM protocol seems to provide kinematic measurements with a smaller variability than that of the PiG. The results from this study showed that SCM is more practical for measuring amputee gait without losing accuracy when comparing to PiG. These findings have enabled us to select the SCM to analyse walking performance in trans-tibial amputees and to use this protocol to develop the tuning application for trans-tibial prosthetic alignment.

Chapter 6. A kinematic comparison of overground walking to fixed speed treadmill walking and self-paced treadmill walking on a split-belt treadmill

6.1 Introduction

Dynamic alignment is the final stage and can be an essential part during the fitting process of a transtibial prosthesis. The walking condition during the alignment process was also a crucial issue that warranted consideration. During dynamic tuning, the amputee is asked to walk many times during an alignment session.

In the current routine, the prosthetist performs dynamic tuning by observing amputee gait walking during overground conditions to evaluate and improve the alignment. However, overground gait analysis has limitations in requiring a large walking space to mobilise in and only catching a few cycles of gait data per walk.

Treadmills have been utilised for objective clinical gait analysis as opposed to the conventional method of gait analysis involving overground walking (Van der Krogt et al., 2014; Sloot et al., 2014). Treadmill gait analysis allows for continuous capture of walking cycles with a variety of gait analysis protocols (Riley et al., 2007; Sloot et al., 2014; Zeni and Higginson, 2010). Recently, treadmills capable of self-paced (SP) modes have been developed and used for clinical gait analysis and research (Van der Krogt et al., 2014; Plotnik et al., 2015; Sloot et al., 2014).

It is believed that using a treadmill with a self-paced (SP) mode during gait analysis can mimic a more natural human walking behaviour than fixed paced treadmill walking (Van der Krogt et al., 2014). SP walking uses a feedback-controlled treadmill that adapts treadmill speed to the user. Consequently, it would offer a natural way of controlling and varying the walking speed, leading to a more natural gait, resulting in long-term stride fluctuations that resemble those as seen during overground walking compared to FS treadmill walking (Sloot et al., 2014). The self-paced mode works by detecting the anterior-posterior position in 3D space of the iliac spines (ASIS, PSIS) and using this data to control the treadmill speed. The subject can speed up or slow down, and the treadmill will adapt making it a more similar experience to that of overground walking (Van der Krogt et al., 2014; Sinitski et al., 2015; Sloot et al., 2014).

There is some literature that has compared the kinematic differences between fixed speed treadmill walking and overground walking, showing statically significant (P=0.05) but small differences (Alton et al., 1998; Riley et al., 2007; Sloot et al., 2014). During fixed speed treadmill walking gait decreases in the stance time, walking speed and stride length when compared to overground walking (Alton et al., 1998; Van der Krogt et al., 2014). Step width tends to be wider when using a split-belt fixed paced treadmill (Van der Krogt et al., 2014; Zeni and Higginson, 2010) and higher knee sagittal plane rotation (flexion-extension) has been observed during treadmill walking (Van der Krogt et al., 2014; Matsas et al., 2000; Plotnik et al., 2015; Sloot et al., 2015).

Treadmill walking would therefore be valuable as tools for dynamic tuning. It allows long distance walking in limited space. So, the prosthetist can have more time to observe any gait deviations. This raises the question of which walking conditions would be most suitable for TT amputees during dynamic alignment tuning. However, it remains unclear as to whether self-paced walking is a viable alternative and if it produces greater similarity to overground walking than fixed speed walking in gait analysis. In relation to lower limb kinematics, the effect of self-paced walking on hip, knee and ankle joint sagittal plane rotations has yet to be established.

The purpose of this study was to compare the self-selected gait speed of overground walking with that of a fixed speed treadmill walking and self-paced treadmill walking on a split-belt treadmill and to look for differences in lower limb angular kinematics. We hypothesized that an SP walking is capable of producing a similar kinematic output compared to overground walking. This research is important for guiding methodological decisions related to walking conditions when tuning prosthetic alignment in new instrumentation technique and to see whether treadmill walking could replace overground walking for clinical gait analysis.

6.2 Methods

6.2.1 Participants

A total of 6 healthy adult subjects were recruited. The participants were selected using the following criteria: between 18-50 years old, a good current condition of health, a normal Range of Motion (ROM) in all joints of the lower limbs, and the ability to walk for 30 minutes without fatigue or pain. The participants were in good health with a normal Range of Motion (ROM) in all lower limb joints. A summary of subject demographics and physical characteristics is provided in Table 6.1. All subjects consented to participate in the study. The Department of Biomedical Engineering Research Ethics Committee approved the study and written informed consent was obtained before participating. The study was conducted in the Biomechanics Laboratory, Department of Biomedical Engineering, University of Strathclyde.

	Healthy subjects (n = 6) (Male 1 , Female 5)	
	mean	**SD**
Age (years)	28.42	5.29
Body weight (kg)	56.28	6.28
Height (m)	1.62	0.06

***Table 6.1** Subject characteristics*

6.2.2 Biomechanics protocol

The Strathclyde Cluster Model (SCM) developed at the Bioengineering Unit of the University of Strathclyde was used for this study (Papi et al., 2014). A cluster of 4 markers attached to a rigid shell was used to track each segment in a lower limb

model (Papi, 2012)The clusters were attached to the pelvis, thighs and shanks and individual markers were attached to foot segments. Prior to walking a set of single reflective markers were attached to key anatomical landmarks and a T-pose used for static calibration (Millar, 2016).

6.2.3 Data Capture and Walking Conditions

Three-dimensional marker data was collected for the three walking conditions using a Vicon motion capture system. Markers were attached to each participant as per the Strathclyde Cluster Model (SCM) (Papi, 2012) and remained in place unaltered during all 3 walking test conditions.

6.2.3.1 Overground walking (OG)

The participants were asked to walk back and forward at a self-selected comfortable walking speed across a 15 m long section of a conventional gait lab (CGL). Each subject performed three consecutive walking trials while data was recorded in a central 3 m cubed capture volume by a 12 camera Vicon motion analysis system (Vicon MX Giganet, Motion Systems, Oxford, UK) at 100 Hz.

6.2.3.2 Treadmill Walking(TM)

TM walking was performed after completion of the OG walking. The CAREN-Extended virtual environment (Motek Medical, Amsterdam, NL) was used for this study. The system consists of a split-belt treadmill with a belt surface 2.5 m long and 0.5 m wide for each belt and a virtual reality system comprising a 180° projection screen. The system was controlled by D-flow software (Motek Medical, Amsterdam, NL). The participants were acclimatised to the treadmill and the virtual environment system. This was done by asking the subject to warm up by walking on a treadmill for 5 minutes before data collection began (Zeni and Higginson, 2010).

Two types of TM walking conditions were tested in this study, self-paced treadmill walking (SP TM) and fixed speed treadmill walking (FS TM) Participants were randomly allocated to undertake either the SP or FS treadmill walking condition first. Before walking, a safety harness was fastened to the participant to prevent any unexpected falls. Each study participant performed three consecutive walking trials while being recorded by a 12 camera Vicon motion analysis system (Vicon Bonita, Motion Systems, Oxford, UK) at 100Hz.

a) Self-Paced TM walking (SP TM)

During SP TM walking on the CAREN system, participants were asked to walk at a comfortable self-selected walking speed continuously on the treadmill. This self-paced treadmill walking used the average position of the left and right ASIS and PSIS on the pelvis to pace the treadmill if the pelvis moved forwards on the belt then the belt speed would increase and vice versa so keeping the participant in the middle of the treadmill (Sinitski et al., 2015; Sloot et al., 2014). After recording 2 minutes of the data, participants were asked to reduce their walking speed steadily until coming to rest.

b) Fixed Speed TM walking (FS TM)

Fixed speed TM walking speed was determined by asking participants to steadily increase up to their desired walking speed until reaching an initial comfortable speed. Then, the treadmill speed was increased and then decreased until the participant reported a second preferred comfortable speed. The initial preferred comfortable speed and second comfortable speed was then averaged to determine a final comfortable fixed speed (Adopted from Plotnik et al., 2015). Again 2 minutes of walking data was recorded, and the treadmill was slowed and stopped.

6.2.4 Data Processing

One expert carried out all data processing. Data processing of overground walking and treadmill walking was performed using Vicon Nexus 2.1.1 and Vicon BodyLanguage programs (Vicon, Oxford Metrics Ltd., UK). Three-dimensional marker trajectories were reconstructed. Heel strike detection was based on the vertical displacement of the heel. The minimum vertical position of the distal heel marker was used to identify HS (O'Connor et al., 2007; Zeni et al., 2008). Marker trajectory data was then processed and gait data calculated. All data were time normalised to the gait cycle, for overground gait, one right gait cycle was extracted from each of three good trials The trial was selected based on a good quality reconstruction of all marker trajectories without a missing marker coordinates. For the treadmill data, 3 cycles were extracted from the central portion of the recorded data. All data was filtered using a second-order low pass Butterworth filter with a cut-off frequency of 6Hz (Sloot et al., 2014).

6.2.5 Data analysis

All angular kinematics of gait cycles were further processed using Excel VBA and joint angle's received normalisation to 101 points (0% - 100%) per cycle. In total, the data consisted of 3 trials of self – selected comfortable OG walking, 3 of SP TM walking and 3 of FS TM walking for 6 participants (n = 54). The mean value and standard deviations of joint kinematics were calculated from the 3 walking conditions and the average kinematic curves for each walking condition were calculated and were plotted to allow comparisons of kinematic data across the gait cycle.

6.2.6 Statistical analyses

All statistical tests were performed using SPSS statistics 18.0 (SPSS Inc., Chicago, Il, USA). Descriptive statistics were used to describe demographics and physical characteristics of subjects. Mean and standard deviation (SD) were calculated for

kinematics in the three walking conditions. A repeated-measures analysis of variance (ANOVA) was performed to test the mean difference of angular kinematics among the three conditions (OG, SP TM and FS TM) followed by post-hoc t-test to highlight the differences between two conditions if the ANOVA was significant ($\alpha = 0.05$).

6.3 Results

All subjects walked at a self-selected comfortable speed in all conditions. All subjects were able to walk independently on the treadmill in both fixed speed and self-paced walking modes with the safety harness on.

Walking speed was available in two walking conditions: FS TM walking and OG walking and these data are shown in Table 6.2. The data showed that there is no significant difference between the two walking speeds ($p = 0.09$). Indicating that the overground and treadmill walking were compatible.

Participant	**FS TM walking speed (m/s)**	**OG walking speed (m/s)**	
Participant 1	1.36	1.33	
Participant 2	1.19	1.23	
Participant 3	1.35	1.40	***p*-value**
Participant 4	1.30	1.41	
Participant 5	1.25	1.32	
Participant 6	1.15	1.18	
Mean	**1.26**	**1.31**	**0.09**

Table 6.2 Walking speed *significant difference ($\alpha = 0.05$)

The majority of average kinematic curves were visually similar between the three walking conditions: FS TM, SP TM and OG, although some small but significant differences were found Figure 6.1 trough Figure 6.3 , Table 6.3). Kinematic curve pattern analysis was undertaken visually and confirmed similarity on the three

walking conditions. However, the graphs showed that coronal and transverse planes were slightly less similar regarding kinematic curves.

Table 6.3 shows means, standard deviations and the results of repeated measure ANOVA of the gait parameters in fixed speed treadmill walking, self-paced treadmill walking and overground walking. The statistics used confirmed the visual observation that the kinematics of fixed speed treadmill walking, self-paced treadmill walking and overground gait was almost identical. When comparing the mean range-of-motion only one degree of freedom from nine showed a statistically significant difference using the ANOVA analysis as shown in Table 6.3. This was the mean of knee flexion across three conditions ($p = 0.019$). Post hoc t-tests revealed that there was a significant difference between FS TM walking and OG walking ($p = 0.037$), while no significant difference between the other walking conditions was found.

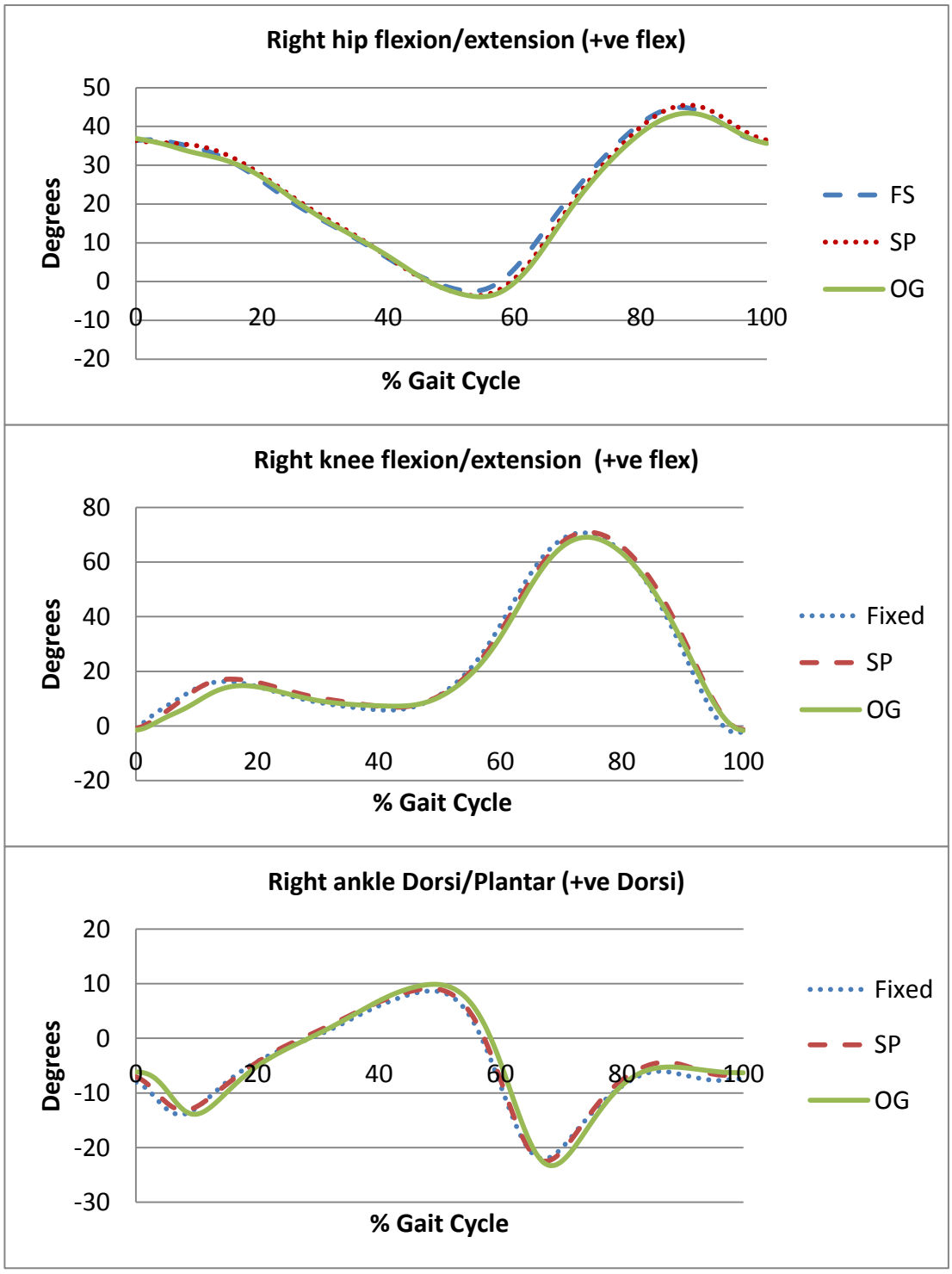


Figure 6.1 Sagittal plane kinematic at the right cycle for six subjects as calculated for FS (Blue round dot), SP (Red dash) and OG (Green solid)

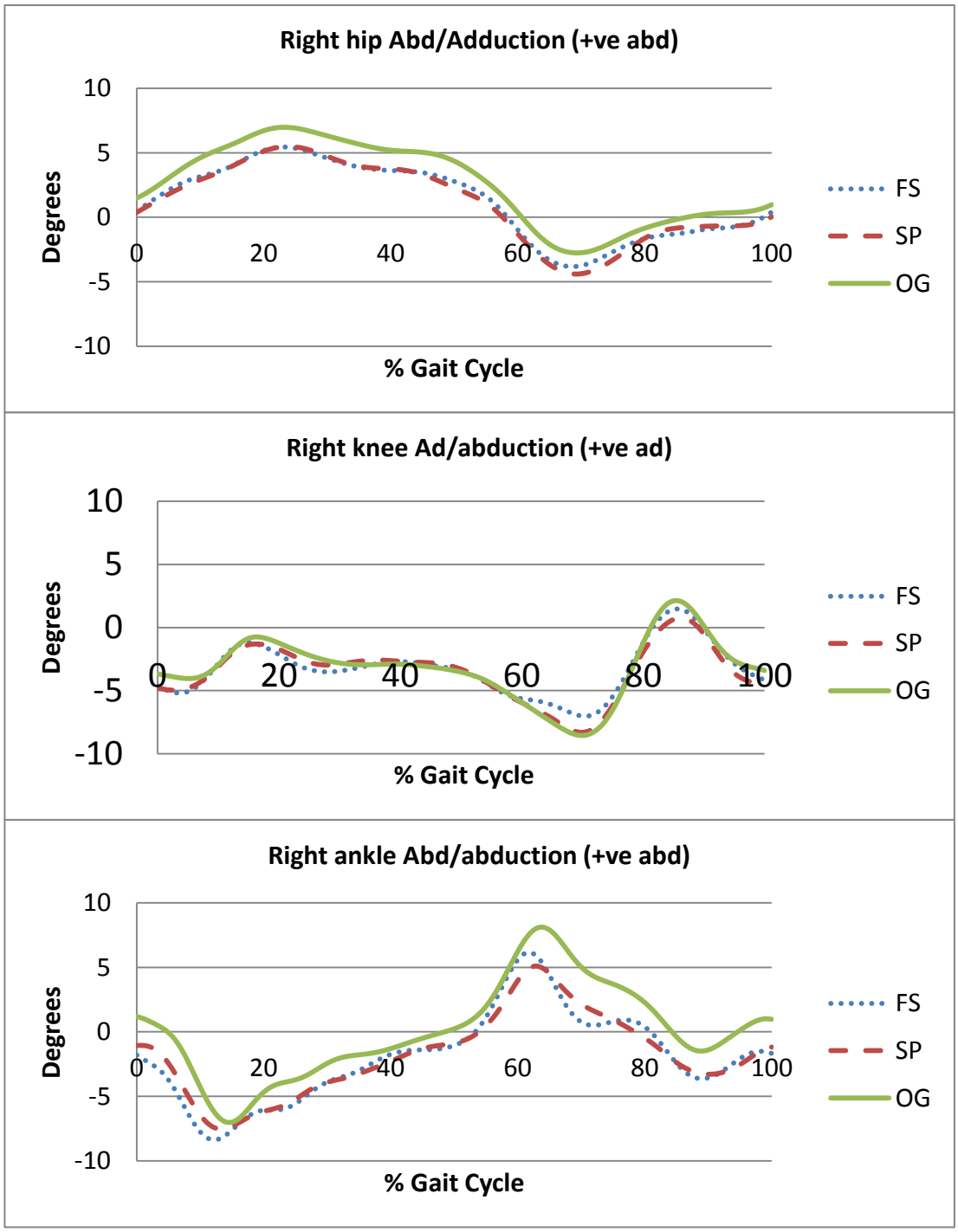


Figure 6.2 Coronal plane kinematic at the right cycle for six subjects as calculated for FS (Blue round dot), SP (Red dash) and OG (Green solid).

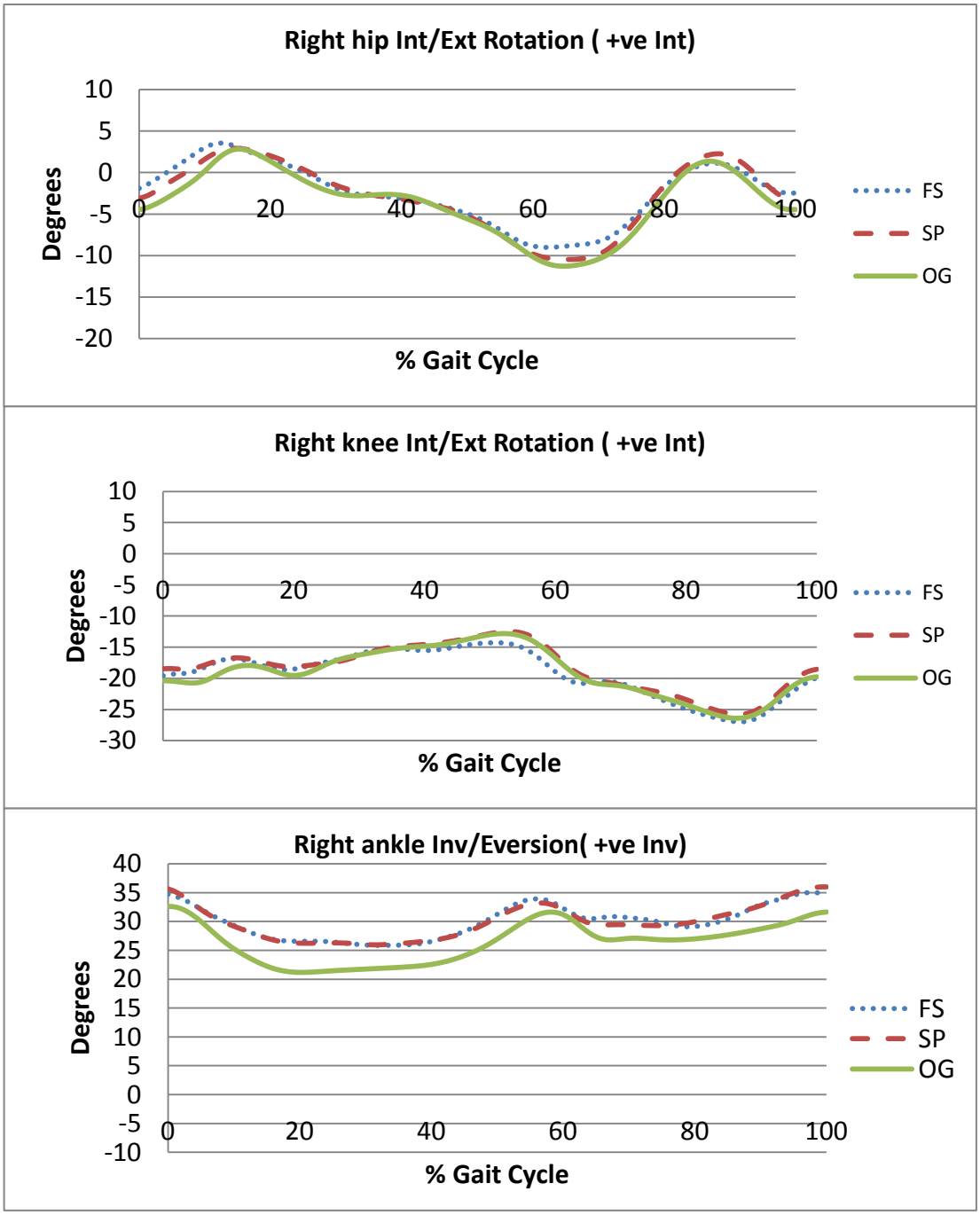


Figure 6.3 Transverse plane kinematic at the right cycle for six subjects as calculated for FS (Blue round dot), SP (Red dash) and OG (Green solid).

Parameters	FS TM	SP TM	OG		The absolute difference between mean		
	Mean ±SD	Mean ±SD	Mean ±SD	*p*-value	FS TM and SP TM	FS TM and OG	SP TM and OG
Hip Flexion ROM (°)	47.6±3.1	49.6±3.2	47.7±2.2	0.690	2.0	1.1	1.9
Hip Abduction ROM (°)	10.4±1.8	10.6±3.1	10.9±2.5	0.894	0.2	0.5	0.3
Hip Rotation ROM (°)	14.6±3.1	15.7±4.0	15.2±2.7	0.823	1.1	0.6	0.5
Knee Flexion ROM (°)	75.5±7.3	73.8±6.2	72.3±8.9	**0.019***	1.7	3.2	1.5
Knee Abduction ROM (°)	11.5±3.2	12.6±5.0	12.6±3.7	0.227	1.1	1.1	0
Knee Rotation ROM (°)	15.4±5.3	14.8±6.2	15.5 ±5.1	0.833	0.6	0.1	0.7
Ankle PF/DF ROM (°)	31.8±5.2	32.3±7.0	33.8±5.2	0.385	0.5	2	1.5
Ankle Abduction ROM (°)	15.5±4.3	14.1±3.9	16.1±4.0	0.635	1.4	0.6	2
Ankle Rotation ROM (°)	13.9±3.8	14.1±4.1	14.3±3.2	0.907	0.2	0.4	0.2
			Mean Absolute difference between mean		0.98	1.1	0.96

Table 6.3 Kinematic ROM in three different walking conditions *significant difference **(α = 0.05)**

6.4 Discussion and Conclusion

This study aimed to compare self-selected gait speed and kinematics during overground walking, fixed speed treadmill walking, and self-paced treadmill walking on a treadmill for possible differences in lower limb angular kinematics and to compare angular kinematics of our study to those previously reported. Moreover, there were no previous studies that compared out –of –sagittal plane motion in the knee and ankle joints between self-selected gait speeds –overground walking, fixed speed treadmill walking and self-paced treadmill walking on a split-belt treadmill.

Numerous studies have compared fixed paced treadmill walking and overground walking (Alton et al., 1998; Fellin et al., 2010; Lee and Hidler, 2008; Warabi et al., 2005; Watt et al., 2010), however to our knowledge, there is no literature comparing the three walking conditions to each other in the same subjects. Using SCM, there are only small differences in joint motions recorded between FS TM, SP TM and OG in all kinematic parameters and these differences would not be considered as being clinically relevant. The difference in the three walking conditions was on average less than 1° and in the worst case less than 3.2. The difference would not affect clinical decision making in typical clinical situations as suggested by McGinley et al.(2009).

In our study, we found slight increases in mean hip and knee flexion ROM with both treadmill gaits. Alton et al. (Alton et al., 1998) also reported an increase in hip ROM due to increased peak hip flexion when walking on a treadmill. However, our results were not statistically significant and amounted to less than 2^{o}.

Overall, FS TM, SP TM and overground walking are similar. Sagittal plane kinematics was most similar and frontal and transverse planes had slightly less similar kinematic curves. (Fellin et al., 2010) reported similar findings for kinematic curves in running conditions overground and on treadmills.

Based on lower limb angular kinematic analysis, the results support that both SP TM and FS TM are similar to overground walking and that no statistically significant

differences existed between SP TM walking and overground walking in our sample (n = 6). However, for fixed paced walking, knee flexion was significantly increased by 3.2^{o}. The similarities observed in the gait patterns provide evidence to support FS TM and particularly SP TM as a suitable alternative to overground walking in angular kinematic gait analysis.

In the current study, between-walking conditions variability was measured at two laboratories between overground walking in a conventional gait lab and treadmill walking in the CAREN motion lab (Motek Medical, Amsterdam, NL). It is possible that there were still some minor differences in camera setting and positioning. In multi-laboratory research designs, the source and magnitude of measurement error and variability are of concern, especially optical distortion occurring from differences in the camera set-up (Chiari et al., 2005). Therefore, Gorton et al., (2009) mentioned that the error could be compensated through an optimal calibration of the system, ensuring that each marker is seen by at least two cameras. It was expected and confirmed that the two commercial systems produce accurate and reliable 3D marker locations. Moreover, Gorton et al., (2009) also investigated the variability of kinematic measurements among 12 motion analysis laboratories. Four sources of variability were evaluated between: (1) examiners, (2) trials, (3) systems, and (4) days. The results showed that marker placement differences between examiners are shown to be the most likely source of between site variability.

In conclusion, there are similarities in angular kinematic output between the three tested walking conditions. Therefore, one condition could be used as an alternative to the other conditions during clinical angular kinematic gait analysis. As the results from the study show, no angular kinematic gait parameters between overground and SP TM walking showed significant differences and average difference were less than a degree and in the worst case less than 2^{o}. Self-paced treadmill walking can be used instead of overground walking and could be a powerful tool to study the patient's gait. There are many advantages to collecting gait data by SP TM walking. First, natural walking under SP TM provides a more natural gait and better resembles

overground gait as compared to FS TM walking (Sloot et al., 2014). Walkers are able to select and identify their specific comfortable walking speed (Sloot et al., 2014). SP TM walking has the ability to acquire full gait kinematic data over longer distances and multiple strides (Plotnik et al., 2015; Sloot et al., 2014). In clinical gait analysis, most of the patients with disabilities have walking difficulty and fatigue. Walking with SP TM permits more freedom to select and change walking speed than FS TM walking. If these findings are replicable in the disabled SP TM walking may permit a safer and more space-saving method of gait analysis than does overground walking in a conventional gait laboratory.

There are a number of limitations in the present study design that should be considered in future investigations. First, Self-Paced TM walking speed should be mentioned, however, that was not employed in this study. Therefore it cannot be concluded from this study, that the entire program is valid,

In this study we only focused on kinematic gait variability measures. However, one of the main concerns when assessing gait on the treadmill, is related to kinetic gait variability measures. Hence, further studies comparing kinetics between three walking conditions are mandatory.

Further, the system accuracy and variability of the subject between walking conditions in different laboratories are excluded as factors that may consider as an error. Moreover, the calibration data was not employed in this study, therefore it cannot be concluded from this study, that the different camera setup wasn't the cause by a small difference. Hence, further studies should take this point in to account.

Chapter 7. Development of measurement of prosthetic alignment using three-dimensional motion capture for trans-tibial prosthesis

7.1 Introduction

This chapter deals with the theoretical design of the biomechanical model, marker design and the anatomical landmarks identification. This chapter will explain the generation of the 3D coordinates of the body markers from of the three-dimensional motion capture, definition of the joint centres, prosthetic segment centres and frames of reference.

Based on the evidence presented in the previous chapter, a based marker set using rigid plastic plates was presumed to be the best option for an angular kinematic gait analysis based on marker based motion tracking tool. Further the method of obtaining the alignment variables for measuring of three-dimensional alignment for the trans-tibia1 prosthesis used in this study is also detailed

7.2 Development of measuring bench alignment parameters

Although the alignment of the prosthesis is most clinical during dynamic tasks like walking, the bench alignment is also important to get the best initial alignment. A method of three-dimensional motion capture alignment using real-time feedback was designed and developed.

7.2.1 Marker placement set on the prosthesis

The prosthesis reference frames (PRFs) were built using prosthesis landmarks associated with various components. The marker models for measurement of the bench alignment was based on a set of single reflective markers attached to the prosthesis. These markers were selected to define the shank and foot segments of the prosthetic limb.

The prosthetic marker placement (Figure 7.1) was designed to allow the definition of the prosthetic frame of reference based on the work of Berme et al., (1978). The marker set consisted of 12 markers (Table 7.1). First, 4 markers were placed on a transverse plane at a proximal level on the socket at a position 25 mm distal to the patellar bar as the posterior brims of sockets do not reach the patellar bar level. The 4 proximal level markers were; Anterior Proximal Socket, Posterior Proximal Socket, Medial Proximal Socket and Lateral Proximal Socket (Berme et al., 1978). A second

marker set of 4 markers were placed on the distal aspect of the socket and located 25 mm from the distal end of the socket. Those markers are the Anterior Distal Socket, Posterior Distal Socket, Medial Distal Socket and Lateral Proximal Socket (Berme et al., 1978). For the SACH foot, Berme et al., (1978) suggest the ankle markers are placed at the same level as the centre of the bolt hole. Those two markers are the lateral ankle marker and the medial ankle marker. One marker was also placed posteriorly on the heel and one marker placed at a position equivalent to the tip of the second toe. These heel and toe markers were placed on the shoe, not the foot itself.

Marker	**Definitions**	**Marker Placement**
APS	Anterior Proximal Socket	On the anterior side of the socket located at 25 mm distal to the patellar bar and mid-point between LPS and MPS.
PPS	Posterior Proximal Socket	On the posterior side of the socket located at 25 mm distal to the patellar bar and mid-point between LPS and MPS.
MPS	Medial Proximal Socket	On the medial side of the socket located at 25 mm distal to the patellar bar and mid-point between APS and PPS.
LPS	Lateral Proximal Socket	On the lateral side of the socket located at 25 mm distal to the patellar bar and mid-point between APS and PPS.
ADS	Anterior Distal Socket	On the anterior side of the socket located 25 mm from the distal end of the socket and midpoint of LDS and MDS.
PDS	Anterior Distal Socket	On the posterior side of the socket located 25 mm from the distal end of the socket and mid-point between LDS and MDS.
MDS	Anterior Distal Socket	On the medial side of the socket located 25 mm from the distal end of the socket and mid-point between ADS and PDS.
LDS	Anterior Distal Socket	On the lateral side of the socket located 25 mm from the distal end of the socket and mid-point between ADS and PDS.
TOE	Toe	At place equivalent to the tip of the second toe at SACH foot.
HEEL	Heel	Mid of Prosthetic heel
LAM	Lateral ankle marker	At most prominent of lateral SACH foot
MAM	Medial ankle marker	At most prominent of lateral SACH foot

Table 7.1 The name of the marker and its position reported relative to the prosthesis

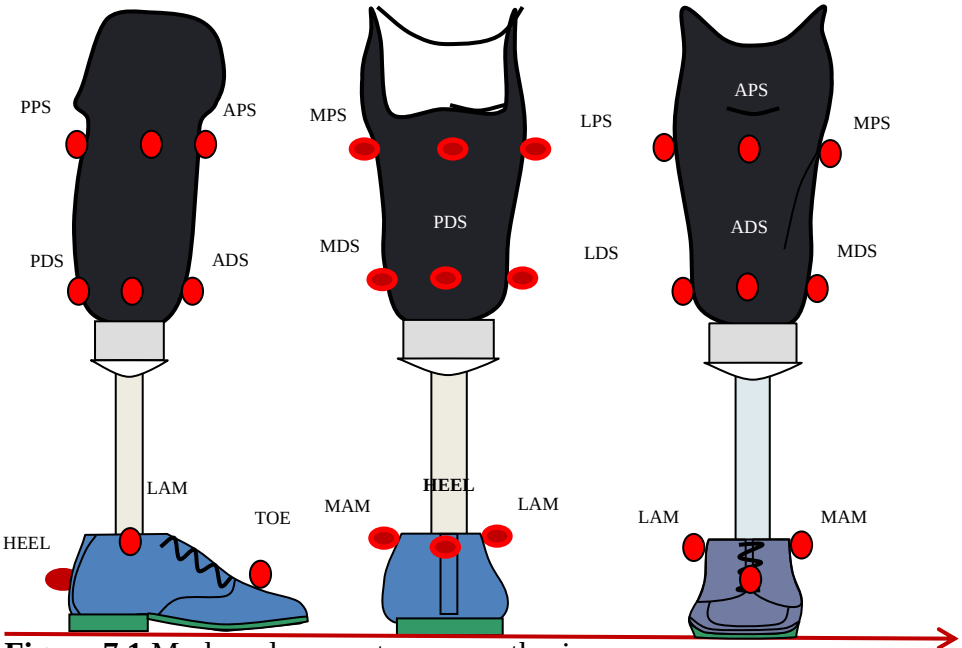


Figure 7.1 Marker placement on a prosthesis

7.2.2 Coordinate system and frame in bench alignment

A frame of reference or coordinate system is required to specify the orientation and position in the space of the components of the prosthesis in three dimensions and to characterise locomotion performance. Figure 7.2 shows the Cartesian coordinates system which was used for the analysis of the work presented in this thesis.

To specify the position and orientation of the components of the prosthesis in three dimensions, it is necessary to have a frame of reference to which all measurements may be referred. The frame used to describe the prosthesis reference frame (PRF) is the Cartesian coordinate system (X, Y and Z axes) describe by Zahedi et al., (1986). The PRF of the socket segment was used as it forms the basis for all alignment parameters calculated in the application. For a trans-tibial prosthesis, there are two main segments. The socket and foot segment separated by the ankle. In this application, general direction axes based on the Cartesian coordinate system were used (Berme et al., 1978). All three Cartesian axes and directions are mutually perpendicular.

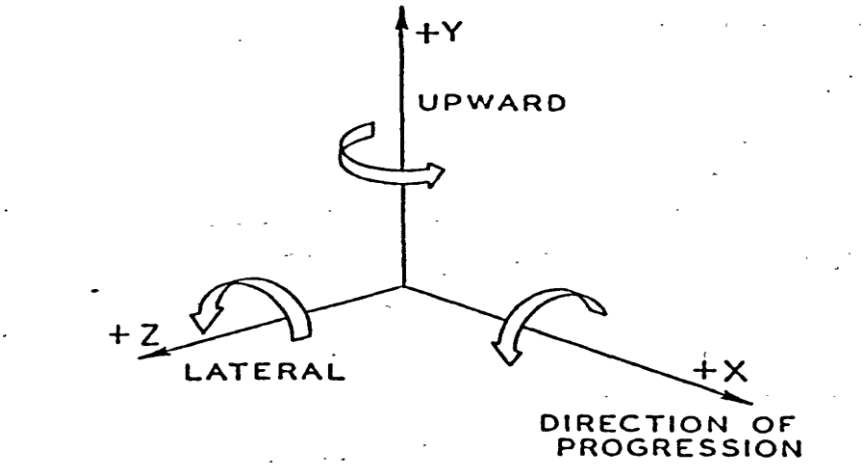


Figure 7.2 The Cartesian coordinates system used for Global or laboratory coordinate system (GCS) for the static reference standard (Zahedi et al., 1986)

The first axis is the x-axis and defined as positive forward along the direction of progression, and this is taken to be perpendicular to the posterior part of the socket;

The y-axis is defined as positive upwards, and perpendicular to the x-axis;

The z-axis is perpendicular to both x and y-axes.

The PRF as constructed from the specified prosthetic landmarks and prosthetic centres is given for the socket and foot in Table 7.2.

This reference offers the advantages that the anterior-posterior plane of the prosthetic foot coincides with the XY plane, and the mediolateral plane coincides with the YZ plane (Zahedi et al., 1986).

The stages necessary to use these prosthetic centre coordinate systems to describe alignment consistently using conventional segment clinical terminology are outlined here for the proximal socket, distal socket and prosthetic ankle centre. The generalised socket segment coordinate systems (Figure 7.3) used for alignment measuring as described and implemented by Berme et al., (1978)

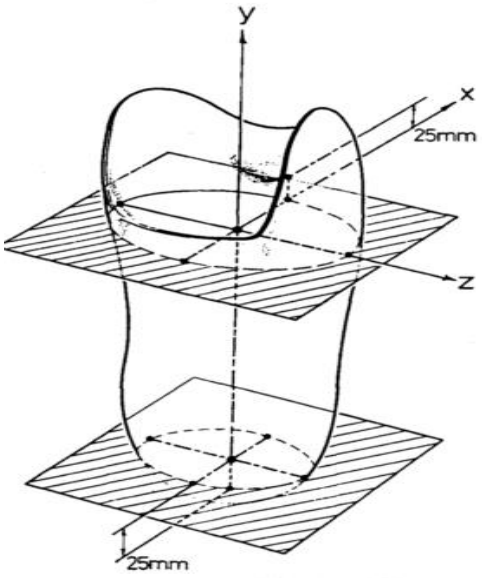


Figure 7.3 Illustration of the generalised segment embedded coordinate systems used by Berme et al., (1978)

Proximal socket segment centre (PSSC) in the anterior-posterior plane (the XY plane) is estimated as the midpoint between the APS and PPS markers. Proximal socket segment centre (PSSC) in the mediolateral plane coincides (the zy plan) is estimated as the midpoint between the MPS and LPS markers as shown in Table 7.2 (Berme et al., 1978).

Distal socket segment centre (DSSC) in the anterior-posterior plane (the xy plane) is estimated as the midpoint between the ADS and PDS markers. Distal socket segment centre (DSSC) in the mediolateral plane coincides (the zy plan) is estimated as the midpoint between the MDS and LDS markers as shown in Table 7.2 (Berme et al., 1978).

The prosthetic ankle segment centre is arbitrarily defined as the centre of the bolt hole on the top surface of the SACH foot (Berme et al., 1978). Prosthetic ankle segment centre (PASC) is the midpoint between LML and MML markers (Berme et al., 1978). A coordinate system of reference was defined so that the origin of the system is at the centre of the bolt hole (Marmar, 1993). However, the heel was used to define the referent angle for segment angle calculation as shown in Table 7.2.

The two centre points (PSSC and DSSC) defined a line that was a unique axis for the socket. This unique axis for the socket makes a line within the socket when viewed in the ML and AP planes (Berme et al., 1978).

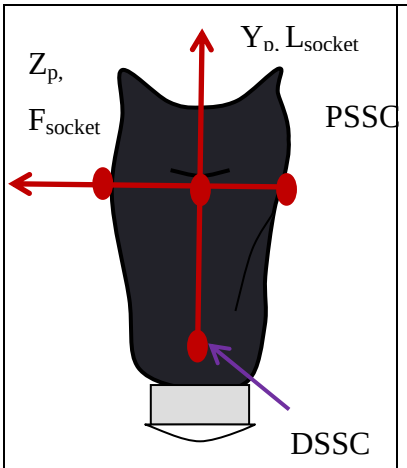
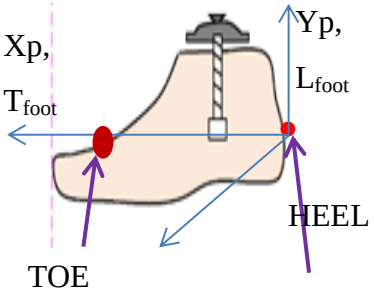
	**Socket** Proximal centre Mid-point between LPS and MPS Distal Origin Mid-point between LDS and MDS Y-axis In the direction from DSSC to PSSC X-axis Mutually perpendicular to Y-axis Z-axis Mutually perpendicular to other two axes
	**Prosthetic foot** Origin Heel Y-axis Mutually perpendicular to X-axis X-axis In the direction from Heel to Toe Z-axis Mutually perpendicular to other two axes

Table 7.2 Prosthetic reference frame definitions for socket and prosthesis foot

The Prosthetic frame (PRF) was constructed from the specified markers and prosthetic joint centres as shown for socket and foot inTable 7.2. PRFs were defined in such a way that the y-axis always represents the longitudinal axis of the relative components.

7.2.3 Calculation of the bench alignment parameters

The PRF of each segment was the basis for alignment calculation. After defining PRFs of the socket and the prosthetic foot, the parameters needed to be specified which completely defined the relationship between the socket and the foot for the trans-tibial prostheses. These parameters were selected to represent the angular tilts and linear shifts that most alignment units embody and are employed by the prosthetist (Table 7.3) (Zahedi et al., 1986).

Bench alignment Parameters	Nomenclature
Prosthesis height(mm)	Prosthetic Height (PH)
Socket AP tilt (Degrees)	Socket Flexion (SFLX)
Socket ML tilt(Degrees)	Socket Adduction (SADD)
Socket AP shift(mm)	Socket Forwards Set (SFS)
Socket ML shift(mm)	Socket Set Out (SAO)
Toe-out(degrees)	Toe-out angle (TOUT)

Table 7.3 Bench alignment Parameters

Berme et al., (1978) and Zahedi et al., (1986) stated that tuning depended on the calculation of 6 alignment parameters, i.e. the anteroposterior (AP) linear shift, anteroposterior (AP) angular tilt, mediolateral (ML) linear shift and mediolateral (ML) angular tilt of the socket relative to the foot, length of the prosthesis and the toe-out angle (Berme et al., 1978; Zahedi et al., 1986). These parameters can be used for measuring as well as prescribing three - dimensional prosthetic alignment with 6 degrees of freedom. The application, therefore, carried out the calculation of those parameters in real-time. Table 7.4 details actual direction in positive and negative values in three planes.

Alignment Parameters	Actual Alignment Direction
Coronal Plane	
Mediolateral tilting of the socket	Abduction -
	Adduction +
Mediolateral socket positioning	Medial translation -
	Lateral translation +
Sagittal	
Anteroposterior tilting of the socket	Extension -
	Flexion +
Anteroposterior socket positioning	Posterior translation -
	Anterior translation +
Vertical Plane	
Prosthetic height	Upward translation +
	Downward translation -
Transverse Plane	
Foot rotation	Toe in – (Internal rotation)
	Toe out + (External Rotation)

Table 7.4 Actual Alignment Direction

7.2.3.1 Prosthetic height

Prosthetic height (PH) was the length of the prosthesis and was measured as the position of the proximal socket segment centre in the Y-axis (PSSCy) with the additional 25 mm. Equation 7.1 was applied to give prosthetic height.

Prosthetic Height (PH) = PSSCy +2.5 mm **Equation 7.1**

Where:

PSSCy is socket segment centre in a vertically upward direction defined as a position of PSSC in the y-axis.

7.2.3.2 Socket AP tilt (Degrees)

The second optimal bench alignment parameter is Socket AP tilt. The socket AP tilt is the spatial relationship between the prosthetic socket and foot in AP angulation. Equation 7.2 was then applied to give of the socket flexion\extension.

Socket Flexion (SFLX) = arctan $\left(\frac{PSSCx-DSSCx}{PSSCy-DSSCy}\right)$ **Equation 7.2**

Where:

PSSCy was socket segment centre in the vertical upward vertically defined as a position of the PSSC in the y-axis. PSSCx was the socket segment centre in the forward direction defined as a position of PSSC in the x-axis. DSSCy was the distal socket segment centre in the vertical upward vertically defined as a position of DSSC in the y-axis. DSSCx was the distal socket segment centre in the forward direction defined as a position of PSSC in the x-axis.

7.2.3.3 Socket ML tilt (Degrees)

The third optimal bench alignment parameter is the Socket ML tilt. Equation 7.3 was then applied to give an estimation of the socket Adduction\Abduction. (Code in appendix 2)

Mediolateral tilting of the socket	Abduction -
	Adduction +

Socket Adduction (SADD) = arctan $\left(\frac{PSSCz-DSSCz}{PSSCy-DSSCy}\right)$ **Equation 7.3**

Where:

PSSCy was the socket segment socket segment centre in the vertical upward direction defined as the position of the PSSC in the y-axis. SACz was the socket segment socket segment centre in the forward direction defined as the position of the

PSSC in the z-axis. DSSCy was the distal socket segment socket segment centre in the vertical direction defined the position of the DSSC in the y-axis. DSSCz was the distal socket segment centre in the forward direction defined as the position of the PSSC in the z-axis.

7.2.3.4 Socket AP shift (mm)

The fourth optimal bench alignment parameter was the socket AP shift or anteroposterior socket positioning (Figure 7.4). After measuring the prosthesis on the coordinate measuring system, the measured coordinates were related to the ankle segment centre (PASC) by subtracting the coordinate of the PASC from all other measures. This was done in order to allow calculation of the alignment parameters from a consistent part on the prosthesis (Marmar, 1993). Equation 7.1 was then applied to give an estimation of the location of the prosthetic socket centre related to prosthetic foot centre.

Anteroposterior socket positioning	Posterior translation -
	Anterior translation +

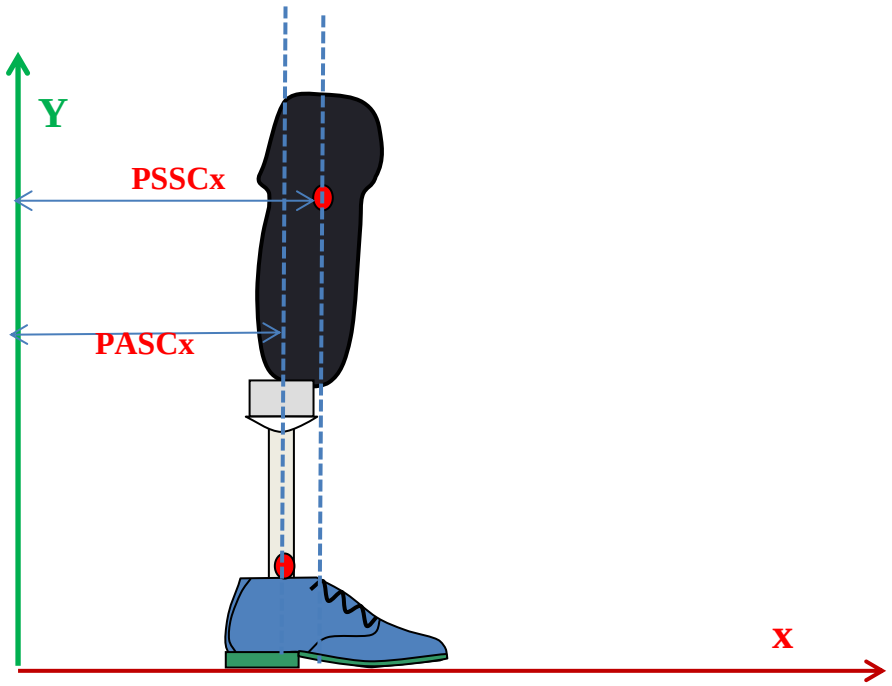


Figure 7.4 Diagrams Socket AP shift or anteroposterior socket positioning

Socket Forwards Set (SFS) = PSSCx - PASCx **Equation 7.4**

Where:

PSSCx was the socket segment centre in the anterior-posterior direction relates to the ankle joint centre in the x-axis. PASCx was the ankle segment centre position in the anterior-posterior position direction in the x-axis.

7.2.3.5 Socket ML shift (mm)

The fifth optimal bench alignment parameter was socket ML shift (Figure 7.5). The centre of the heel may be inset medially from 0 to 12 mm to the posterior line of centre rotation of the socket (Boone, 2005b). Socket Set Out (SAO) was to mediolateral socket positioning. Equation 7.5 was then applied to give a calculation of SAO. (Code in appendix 2)

Mediolateral socket positioning	Medial translation -
	Lateral translation +

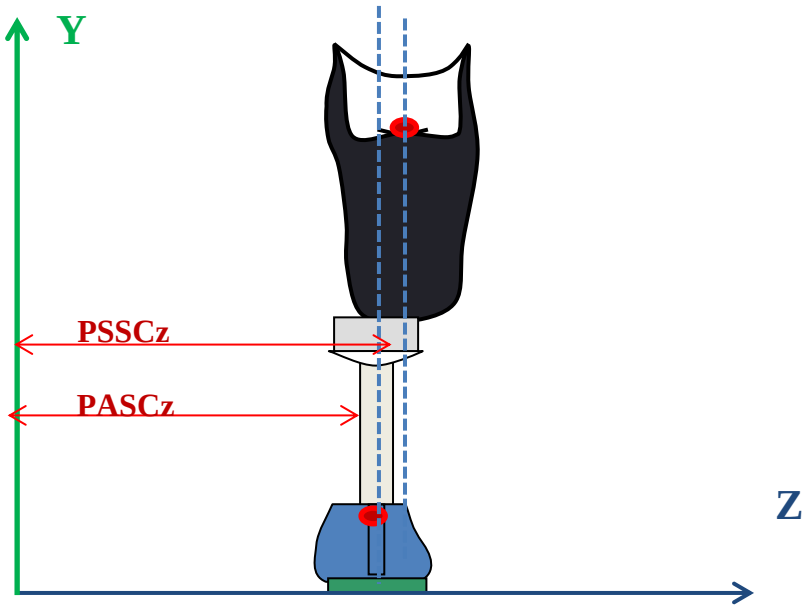


Figure 7.5 Diagrams Socket ML shift or Mediolateral socket positioning

Socket Set Out (SAO) = (PSSCz –PASCz)*AS **Equation 7.5**

Where:

PSSCz was the socket segment centre in the medio-lateral direction in the z-axis. PASCxz was the ankle segment centre position in the medio-lateral direction in the z-axis. AS = 1 for the right amputee and -1 for the left amputee.

7.2.3.6 Calculation of toe-out angle

Toe out was defined as "the angle formed by the heel of the foot and the x-axis of the socket of the below-knee prostheses. The foot toe-out angle was calculated using the coordinates of the Toe of the foot TOEx, TOEy and TOEz (Figure 7.6).

Foot rotation	Toe in – (Internal rotation)
	Toe out +(External Rotation)

Toe-out angle (TOUT) = $\arctan\frac{TOEZ}{TOEx}$ **Equation 7.6**

Where

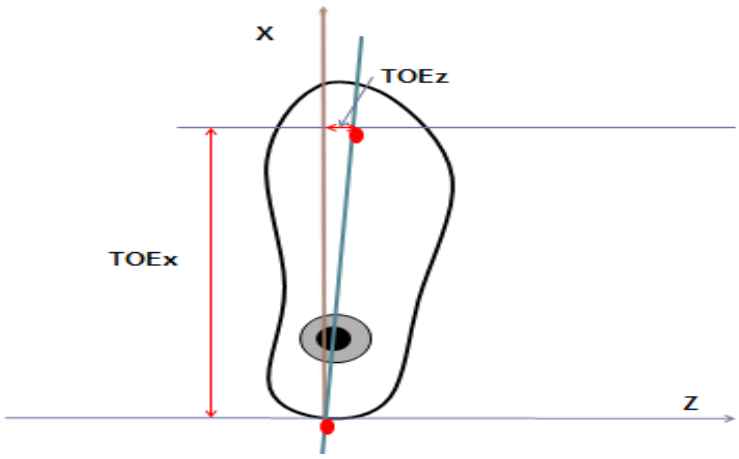


Figure 7.6 Calculation of the foot toe-out angle (TOUT)

The code which was used to construct frames of reference, the definition of joint angles, calculate components angles, and bench alignment parameters are presented in appendix 1.

7.3 Repeatability of a new alignment method for measuring and prescription of three-dimensional bench alignment for trans-tibial prosthesis

7.3.1 Introduction

In clinical service, bench alignment is the initial process for preparing the prosthesis for prosthetic fitting and prescribed by geometry (Berme et al., 1978).

The "prosthetic bench alignment" was the initial alignment of the components of the prosthesis based on the components' characteristics and with previously acquired data regarding the patient (ISO, 1989). It is a starting point and is done at the workbench before the patient arrives.

Trans-tibial prosthetic alignment parameters have been proposed (Sin et al., 1999; Zahedi et al., 1986) which are a series of angular tilts and linear shifts. Those parameters are Prosthetic Height, AP tilt, ML tilt, AP shift, ML shift and toe out the angle.

The overall objective of this study was to design and develop an instrument-assisted alignment using the new system produces repeatability measurement when compared to conventional techniques. We hypothesized that it could be used to measure and prescribe alignment for trans-tibial prostheses with good reliability.

7.3.2 Methods

7.3.2.1 Prosthetist

Two experienced prosthetists with 10 and 11 years of experience were involved in this investigation; Prosthetists were responsible for alignments setting. The alignment units used by the prosthetists consisted of the 4R1 Adjustment Adapter, Otto Bock.

7.3.2.2 Prostheses

Five trans-tibial prostheses used in this study as listed in Table 7.5 and as shown in Figure 7.7.

Prosthesis	Amputated side	Socket Design	Suspension	Foot	Alignment unit
EP201	Left	PTB	Self-suspension	SACH	The 4R1 Adjustment Adapter, Otto Bock
EP202	Left	PTB	Cuff suspension	SACH	The 4R1 Adjustment Adapter, Otto Bock
EP203	Left	PTB	Self-suspension	SACH	The 4R1 Adjustment Adapter, Otto Bock
EP204	Left	PTB	Self-suspension	SACH	The 4R1 Adjustment Adapter, Otto Bock
EP205	Right	PTB	Self-suspension	SACH	The 4R1 Adjustment Adapter, Otto Bock

Table 7.5 Information of prosthesis used in the study

Figure 7.7 Five prostheses used in the study Procedure

Each session contained two parts.

Session 1: two prosthetists performed the bench alignment set up three times (5 prostheses) using Conventional Bench Alignment Technique (ConBAT) as shown in Figure 7.8. The results of the three bench alignment setting, five prostheses and two prosthetists were averaged. The means and standard deviations of the averaged prosthetic alignment for the five subjects measured by a prosthetist were determined.

Figure 7.8 Bench alignment set up using Conventional Bench Alignment Technique

Session 2: two prosthetists performed the bench alignment set up three times (5 prostheses). The five alignment parameters except prosthetic height were aligned by using the Computer motion capture and Visualisation system for assisted Bench Alignment Technique (CVBAT) method. The results of the three trials, five prostheses and two prosthetists were averaged. The means and standard deviations of the averaged prosthetic alignment for the five subjects measured by a prosthetist were determined.

In both sessions of this study, the repeatability of prosthetic height could not be measured due to the limited adjustment in height available for this component. So, five alignment parameters were measured.

7.3.2.3 Data Analysis and Statistic

In order to study the repeatability of the CVBAT method and ConBAT method, the five alignment parameters of 5 selected PTB trans-tibial prostheses were repeatedly measured three times by two prosthetists. The repeatability of the measured

parameters was checked by measuring the alignment of the prosthesis three times by the two prosthetists. The prosthesis was reset between each test. The mean and standard deviation (SD) were then calculated for all the trails (Table 7.6). Simple alignment parameters were designed and developed.

7.3.3 Results

Prosthetic alignment parameter	Mean (SD)		Indicated Alignment
	ConBAT	CVBAT	
Socket AP tilt (Degrees)*	7.3 ± 2.2	5.3 ± 0.9	5
Socket ML tilt (Degrees)**	5.4 ± 10.6	5.7 ± 0.9	5
Socket AP shift (mm)*	17.8 ± 9.8	2.7 ± 3.7	0
Socket ML shift (mm)**	10.9 ± 9.8	0.2 ± 3.9	0
Toe-out (degrees)***	4.6 ± 4.9	7.0 ± 1.1	7
Time (minutes)	11.3 ± 6.2	4.0 ± 2.01	-

*Positive for anterior tilt/shift, negative for posterior tilt/ shift

**Positive for lateral tilt/shift, negative for medial tilt/shift

***Positive for toe-out, negative for toe-in

Table 7.6 Means and the standard deviation **(**SD**)** of the repeatability test of the five prostheses measured by the two prosthetists using the conventional method and the new 3D instrumentation method

For the rotational alignment parameter, the maximum mean SD for the ConBAT was of 10.6° for Socket ML tilt, whereas for the CVBAT method the highest mean standard deviation corresponded to 1.1° found for Toe-out measurement. Minimum mean SD was 2.2° for Socket AP tilt of the ConBAT and 0.9° for the Socket AP tilt and Socket ML tilt of the CVBAT method.

In translation alignment parameter, the mean SD for the ConBAT was of 9.8 mm for both Socket AP shift, and Socket ML shift, whereas for the CVBAT method the highest mean standard deviation corresponded to 3.9 mm found for Socket ML shift measurement. The maximum mean SD in the alignment parameters was higher in the

ConBAT method than the CVBAT method. Minimum mean SD was 3.7 mm for Socket AP shift of the CVBAT method.

The ConBAT method took an average of 11 minutes to set bench alignment following the prescription. The CVBAT method took average less than 4 minutes to set bench alignment following the prescription with including 10 minutes for the setup and calibration time at the beginning of the CVBT session.

7.3.4 Discussion and conclusion

The aim of this study was to determine the repeatability of the aligned prosthesis when using the Computer motion capture and Visualisation system for assisted Bench Alignment Technique (CVBAT) and when using Conventional Bench Alignment Technique (ConBAT) with less time-consuming.

The comparison means, and SD between two alignment methods revealed that alignment from The CVBAT method was more repeatable than the one obtained by the ConBAT method. It was observed that for all five alignment parameters of the prostheses. The CVBAT method fell within a relatively narrow range whereas the ConBAT method did not. The results showed that it took less time when using the new method compared to the conventional method to prescribe or measure a prosthetic alignment for a skilled operator.

The study is not without limitations. First, this study was specific to subjects with trans-tibial prostheses using SACH foot. Second, training on the operation of the alignment application was required. Third, there were only 2 raters was conducted the alignment.

In conclusion, a bench alignment application was designed and developed. It could be used to measure and prescribe bench alignment for trans-tibial prostheses with good reliability. It could provide the direct standard bench alignment required for the individual patient according to the components' characteristics and with previously acquired data regarding the patient individual. Moreover, this application could record an individual's prosthetic alignment in a digital file for future reference and comparison, and the recorded alignment could then be reproduced whenever was

necessary. Moreover, this application could be useful for any research related to prosthetic alignment.

This scientific record keeping could benefit those amputees who need to change their prosthesis frequently. Moreover, the application could also be used for static and recorded optimal dynamic alignment. The application could provide a systematic and objective means for the setup of individual prosthetic alignment and consequently to facilitate the follow-up evaluation.

7.4 Design of Static and Dynamic tuning and alignment analysis

The Biomechanical Model used in the static and dynamic measurement was the combination of two markers set.

The first set was the prosthetic alignment marker set as detailed previously for measuring the six prosthetic alignment parameters.

The second set was the SCM protocol for kinematic gait analysis. The protocol was designed to measure lower limb kinematic parameters during tests of trans-tibial amputee's gait. In this study, the biomechanical protocol was adapted from the methods of Papi (Papi, 2012) and Millar (Millar, 2016). Chapter 5 provided a 3-D gait analysis protocol that was simple, accurate, and repeatable for the assessment of gait performance and a 3-D gait biomechanical model that could be applied for the assessment of trans-tibial amputees in the clinical environment. The results showed that the SCM model had validity and reliability when used to analyse trans-tibial kinematic gait. The methods in Chapter 5 enabled us to use the SCM to analyse the walking performance of amputee when walking on a treadmill.

7.4.1 Marker set to define the anatomical and prosthetic segment during static and dynamic tuning

The following section details the marker set used for the data capture. Two marker sets and one anatomical landmarks pointer were used during static and dynamic tuning. Marker models in this study combined both a set of single reflective markers and clusters including anatomical landmark needed.

First, the prosthetic marker set (Table 7.1) which was previously explained in this chapter. It was applied to the prosthetic limb. A second marker set was the SCM. The SCM was chosen due to several reasons. It allows for the possibility of automatic marker recognition and labelling so speeding up data processing and allowing real-time feedback. It shows less variability in chapter 5. Secondly, cluster based marker set using rigid plastic plates was presumed to be the best option for a routine clinical marker based motion tracking tool.

The SCM consist of 7 clusters was attached to the lower limb (Table 7.7). Each cluster was designed with a unique marker arrangement, thus allowing each individual cluster to be labelled and tracked individually and the three-dimensional position and orientation of each lower limb segment to be calculated. Each cluster of four retro-reflective markers was firmly adhered to be segmented using tape and straps. One cluster was positioned inferior to the PSIS anatomical landmarks (Millar, 2016). Four were placed on the distal part of the thigh and shank segments of both legs using a Velcro attachment on elastic bands (Papi, 2012). The last two clusters were attached to the dorsum of each forefoot. Once the cluster object was created, the tracker software determined which marker was which, then individual markers were automatically labelled. All four markers in each cluster were labelled as described in

Figure 7.9.

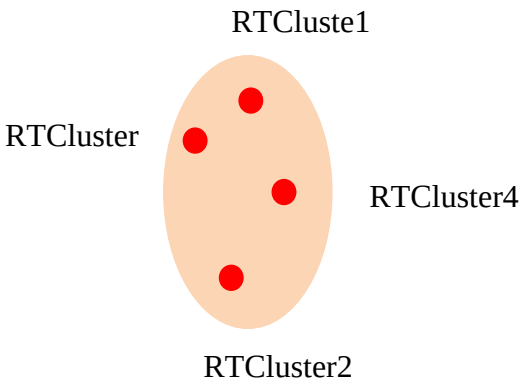


Figure 7.9 Example of how the RTCluster was constructed based on the position of the markers in each cluster

7.4.2 Participant anatomical landmark calibration

Participant calibration is an extremely important aspect of the measurement of human kinematics. Initially, skin surface markers were used to locate the anatomical bony landmarks. Skin surface markers require a time consuming process to apply a number of skin surface markers for the purpose of collecting only a few frames of data (Millar, 2016). Further, skin surface markers require participants to wear tight or minimal clothing, which is not ideal in the clinical environment (Millar, 2016). The evidence by Cappozzo et al., 1996 and Leardini et al., 2005 suggests that placement of markers on bony landmarks should be avoided where possible as this can lead to high levels of error due to STA. Therefore, the use of the pointer for calibration was to replace the need for skin surface markers during participant calibration. Moreover, the cluster of 4 markers allowed tracking and labelling in the real-time and same way as was done for the SCM clusters.

A total of eighteen points (Table 7.7) must be identified by the examiner. Each anatomical landmark with identified with the pointer. A pointer is a device used for creating landmarks.

Segment	**Name**	**Definitions**
Pelvic	LASI	The left anterior superior iliac spine
	RASI	The right anterior superior iliac spine
	LPSIS	The left posterior superior iliac spine
	RPSIS	The right posterior superior iliac spine
Sound Lower limb	SHEEL	Sound heel
	SMET5	Sound 5th metatarsal
	SMET1	Sound 1st metatarsal
	SLM	Sound lateral malleolus of the ankle
	SMM	Sound medial malleolus of the ankle
	SLE	Sound lateral epicondyle of the knee
	SME	Sound medial epicondyle of the knee

Segment	Name	Definitions
Prosthetic Lower limb	PHEEL	Mid of prosthetic heel
	PMET5	At place equivalent to a ball of 5th metatarsal at SACH foot
	PMET1	At place equivalent to a ball of 1st metatarsal at SACH foot.
	PLM	At most prominent of lateral SACH foot equivalent to the lateral malleolus
	PMM	At most prominent of lateral SACH foot equivalent to the lateral malleolus
	PLE	On the lateral side of the socket located 10 mm superior to the level of the patellar bar
	PME	On the medial side of the socket located 10 mm superior to the level of the patellar bar

Table 7.7 Anatomical landmarks pointer name and position are reported

In this study, Tracker was used to creating an ‘object' for the pointer object. The pointer in this study was developed as a cluster of 4 markers (Figure 7.10). A red dot indicates marker one which was labelled as "PC1" and was placed on the anatomical landmark of interest and the position of the anatomical landmark. A yellow dot indicates marker two which was labelled as "PC2". The green dot indicates marker three which was labelled as "PC3". The purple dot indicates marker four which was labelled as "PC4". Participant calibration was conducted when beginning static alignment tuning; the prosthetist palpates the anatomical landmark of interest and uses the pointer to store its position and the position of the four corresponding cluster markers on that segment. The stored data in a file is then used both during static and dynamic alignment tuning to produce virtual markers which they are used to define the anatomical joint centres, the ARFs, PRFs and TRFs and calculate the outcome variables during static and dynamic alignment tuning.

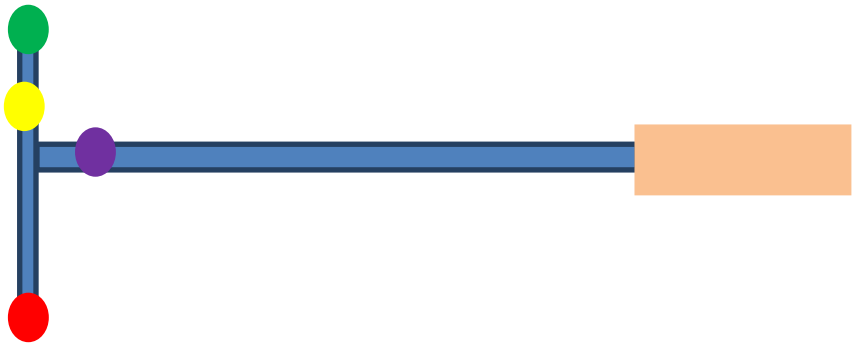


Figure 7.10 Pointer used to locate anatomical landmarks**.** A red dot indicates a marker **(**PC1**)** which is placed on the anatomical landmark of interest

7.4.3 Reference axes and coordinate system in static and dynamic alignment

In the static and dynamic applications the reference axes and kinematics of each segment on the prosthetic side and the sound side were based on the same protocol the detail of which follows;

Prosthetic reference frames (PRFs) in this study these refer to the segment of the trans-tibial prosthesis on the amputated side as in Table 7.8. Prosthetic reference frames can thus be constructed in each sampled instant of time of the prosthesis tuning concerning the laboratory axes, and the translation and rotation of one component relative to another (alignment parameters) can be determined (Figure 7.11). On the prosthetics side, the knee joint is estimated as the midpoint on the line between the mid lateral side of the socket located 10 mm superior to the level of the patellar bar on (PLE) and the mid medial side of the socket located 10 mm superior to the level of the patellar bar (PME) as mentioned previously in table 7.8. Prosthetic ankle joint centre is estimated as the midpoint between the most prominent of lateral SACH foot equivalent to lateral malleolus and the most prominent of medial SACH foot equivalent to medial malleolus (PLM and PMM).

Anatomical reference frames (ARFs) were constructed from the specified anatomical landmarks and joint centres as shown for each segment in Table 7.8. Anatomical knee joint centre was estimated as the midpoint between the lateral femoral epicondyles and medial femoral epicondyles (SLE and SME). The anatomical ankle

joint centre was the midpoint between the lateral malleoli and malleoli (SLM and SMM).

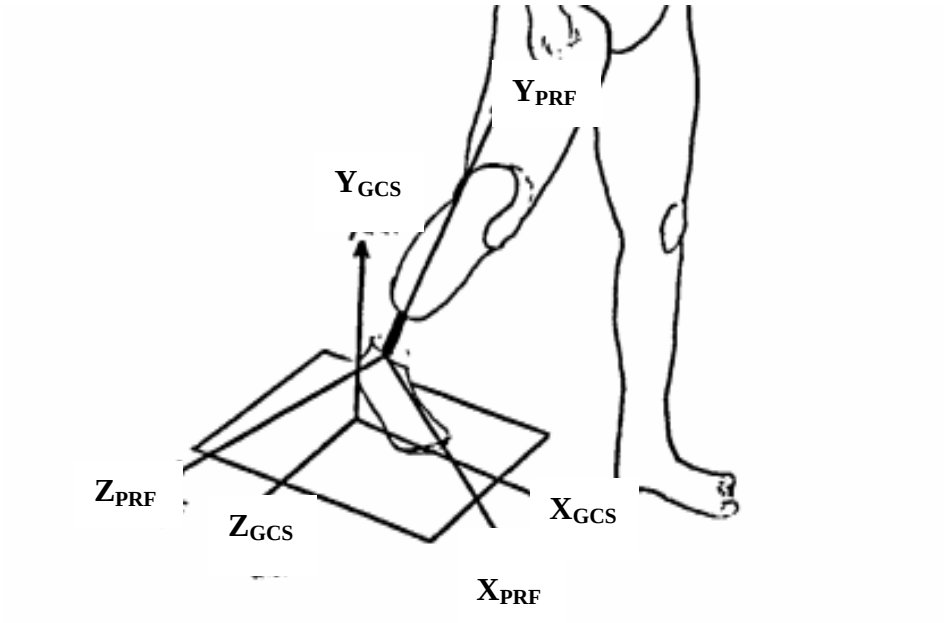
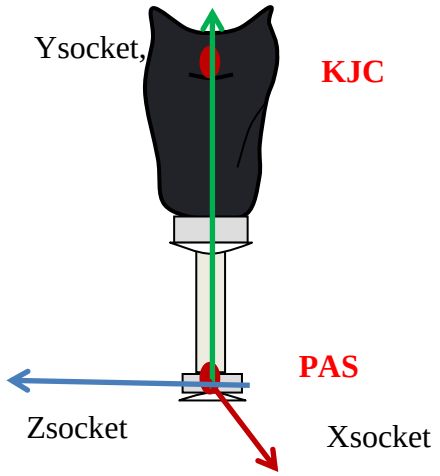
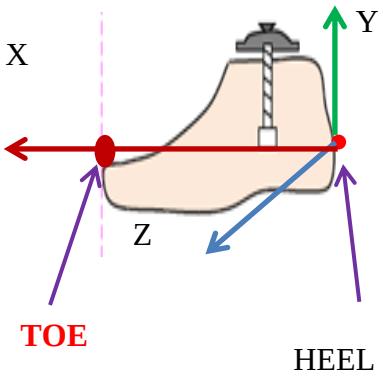
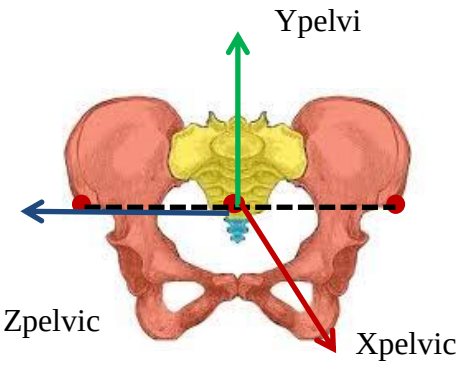
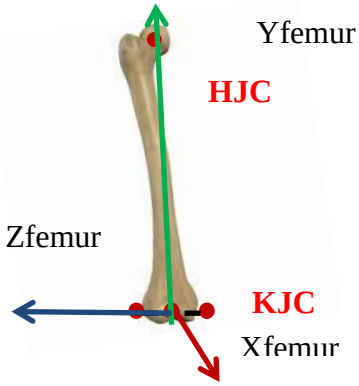


Figure 7.11 Prosthesis coordinate system

	**Knee joint on the prosthetic side** Origin prosthetic ankle segment centre (PASC) (Mid-point between PLE and PME) Y-axis In the direction from PASC to KJC X-axis Mutually perpendicular to Y-axis Z-axis Mutually perpendicular to other two axes

	**Prosthetic ankle centre** Origin Heel Y-axis Mutually perpendicular to X-axis X-axis In the direction from Heel to Toe Z-axis Mutually perpendicular to other two axes
	**Pelvic** Origin Midpoint between the LASIS and RASIS X-axis Line between the midpoint of the RASIS and LASIS and the midpoint of the RPSIS and LPSIS Y-axis Mutually perpendicular to X and Z Z-axis Mutually perpendicular to other two axes
	**Femur** Origin KJC (midpoint between ME and LE) Y-axis In the direction from KJC to HJC X-axis Mutually perpendicular to Y-axis and the line in lateral direction joining LE and ME Z-axis Mutually perpendicular to other two axes

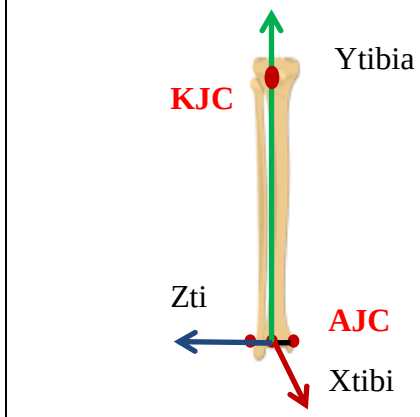
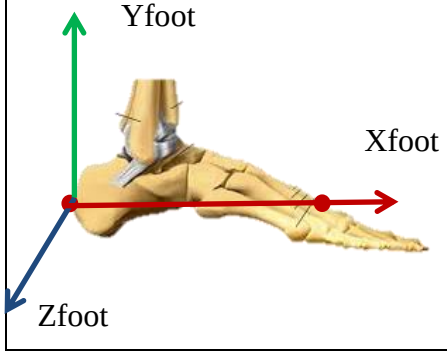
	**Tibia** Origin AJC (midpoint between MM and LM) Y-axis In the direction from AJC to KJC X-axis Mutually perpendicular to Y-axis and the line in lateral direction joining LM and MM Z-axis Mutually perpendicular to other two axes
	**Foot** Origin Heel Y-axis Mutually perpendicular to X and Z X-axis In the direction from MidFoot to HEEL Z-axis Mutually perpendicular to other two axes

Table 7.8 Prosthetic and anatomical reference frame definitions for the socket and prosthesis foot

7.4.4 Calculation of static, dynamic gait analysis

The ARFs and PRFs of each segment were the basis for kinematic calculation. The kinematic calculation in this study was performed using the SCM model (Cole et al., 1993; Grood and Suntay, 1983), The code for kinematic calculation is presented in appendix 1. A fuller description of kinematic calculation can be found in the thesis, Visual Feedback in Orthopaedic Rehabilitation by Millar.,(2016) and An investigation of the methodologies for biomechanical assessment of stroke rehabilitation Papi., (2012).

To calculate the joint angles, the axes from the segment proximal and distal to the joint the position of one segment must be expressed relative to the other (Figure 7.12). Grood and Suntay (1983) proposed a way of doing this with clinical meaning that has been widely accepted. This was modified by Cole et al. (1993) to apply to prosthetic and anatomical joints (Cole et al., 1993).

They proposed a generalised algorithm which could apply to all joints in the lower limb (Cole et al., 1993). The method uses a set of embedded axes for each segment as outlined previously in Table 7.9.

Nomenclature	
X, Y, Z	The three axes of a body segment fixed the Cartesian coordinate system
i, j, k	Unit vectors that describe the attitude of the X, Y, and Z axes, respectively, in an inertial reference system
F, L, T	breakdown of the axes of a body segment coordinate system into an axis of flexion, a longitudinal axis, and a third axis
f, I, t	Unit vectors that describe the attitude of the F, L, and T axes, respectively, in an inertial reference system
ê1, ê2, ê3	Unit vectors that describe the attitude of the first, second, and third axes of the nonorthogonal joint coordinate system between two body segments, relative to an inertial reference system
$\hat{e}k_{ij}$	the unit vector describing the attitude of the high axis of the joint coordinate system between the reference segment (i) and the target segment (j), relative to an inertial reference system
t_i	The third axis of the proximal segment
l_i	The proximal longitudinal axis.
i	the proximal segment
j	the distal segment
f	the longitudinal segment
fi	proximal flexion axis
f x l	the cross product of two vectors
f ·l	the dot product of two vectors
$f_1 * l_2$	multiplication
A	A is a correction factor that allows angle calculations about ê2 to be continuous between $-\pi$ and $+\pi$.
B	Determines the sign of the angle, which is positive if the angle between the floating axis and the proximal longitudinal axis is greater than zero and negative otherwise.

Nomenclature	
C	Determines the sign of the angle, and is positive if the angle between the proximal flexion axis and the distal longitudinal axis is greater than zero and negative otherwise.
D	Determines the sign of the angle and is positive if the angle between the floating axis and the distal flexion axis is greater than zero and negative otherwise

Table 7.9 Nomenclature used for creating a set of 3 joint axes by Cole et al**.**, **(**1993**)**

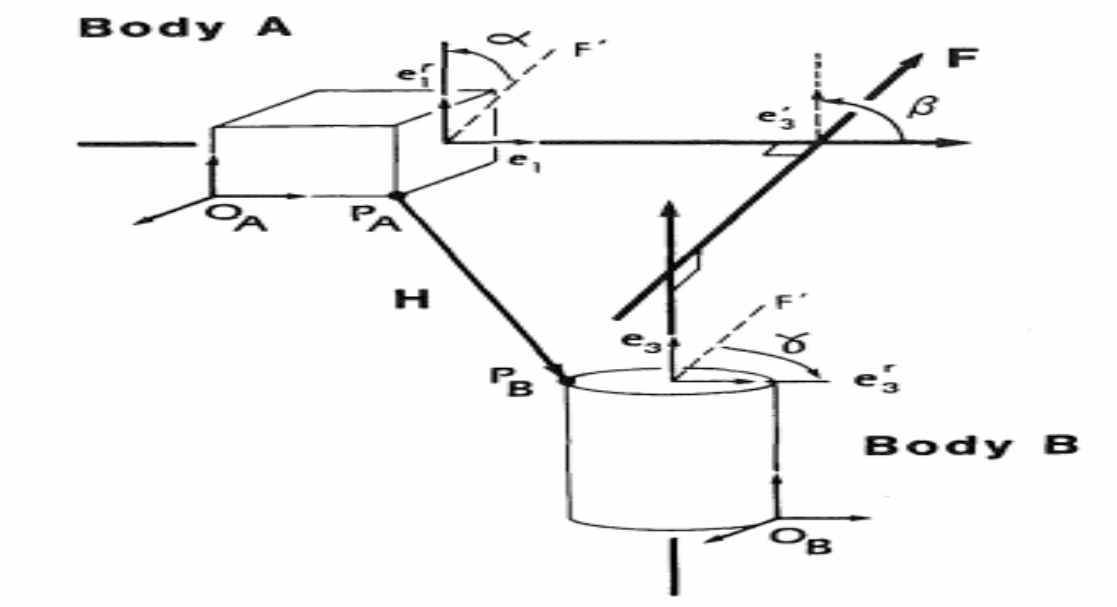


Figure 7.12 The generalised joint coordinate system composed of three axes by Grood and Suntay (1983)

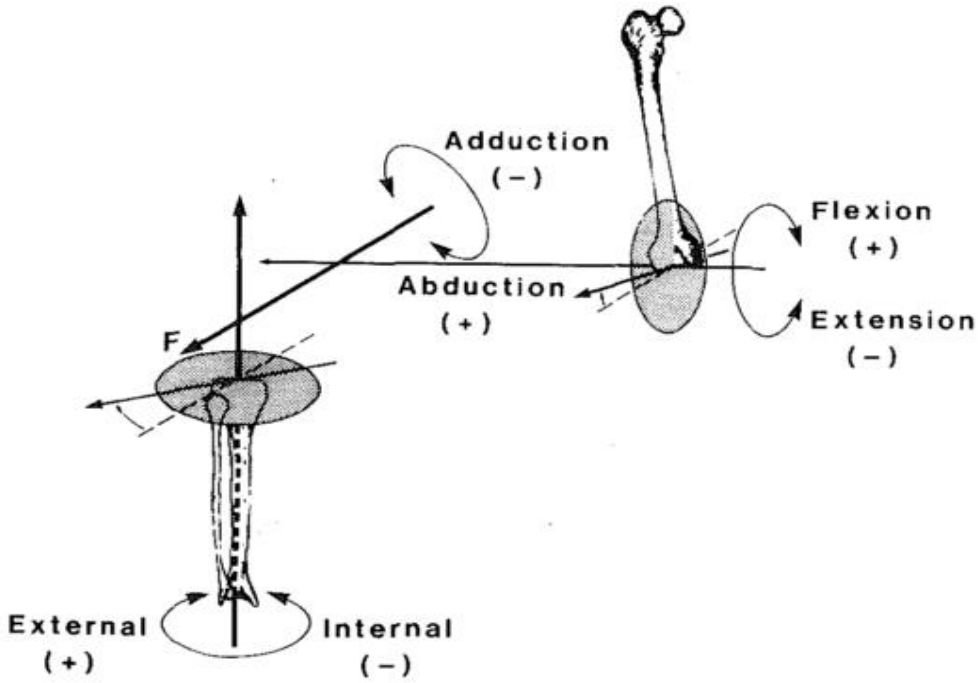


Figure 7.13 Joint angles are defined by rotations occurring about the three joint coordinate axes for the right knee as described by Grood and Suntay, (1983)

In two connected segments, proximal and distal (Figure 7.13), the 3-D rotations of the joint interconnecting the two segments are defined by Baker, (2003) Flexion/Extension is a rotation in the sagittal plane of the proximal segment, Ab/Adduction is a rotation out of the sagittal plane of the proximal segment, Internal/External rotation is the rotation about the longitudinal axis of the distal segment

The method of kinematic calculation by Grood and Suntay (1983) was implemented. This involves creating a set of 3 axes about which the above-described movements can occur. The nonorthogonal unit base vectors of the coordinate systems which define the axes are denoted as ê1, ê2 and ê3 where two of the axes are described as body fixed axes and are embedded in the segments whose movement is to be described.

ê1 is proximal fixed axis and embedded in the socket and proximal segment. ê1 is the z-axis (medio-lateral) of the socket and proximal segment coordinate system.

ê3 is the long axis of the distal segment. As previously shown (Table 7.10) it is named y-axis, but it is not vertically (proximally) oriented, it lies on the transverse plane of the prosthetic foot and foot (conventionally speaking x-axis direction, anteroposterior axis).

ê2 is the floating axis mutually perpendicular to ê1 and ê3 and given by Equation 7.7 (Cole et al., 1993). A rotation around ê2 identifies a rotation out of the sagittal plane of the socket component and thus defined ab/adduction of the ankle complex.

$$e2 = \left(\frac{\text{e1 x e3}}{|\text{e1 x e3}|}\right) * A$$

$$\text{A} = \begin{cases} -1, & \text{if } ((\hat{e}3 \text{ x } \hat{e}2) \cdot t_j < 0 \text{and } ((\hat{e}3 \text{ x } \hat{e}1)\text{x } \hat{e}3) \cdot f_j > 0 \\ 1, & \text{Otherwise} \end{cases}$$

Equation 7.7

The next section will describe the body fixed axes of the joint coordinate system and the reference axes which will be used to describe relative motion needed for construction of each the joint axis system. Figure 7.14 through Figure 7.17 describe the definition of the joint axis systems for the socket and prosthetic foot, the hip, knee and ankle respectively.

Applying the method from Grood and Suntay (1983) as modified by Cole et al. (1993) joint coordinate systems comprises the axes shown in Figures 7.14 -7.17.

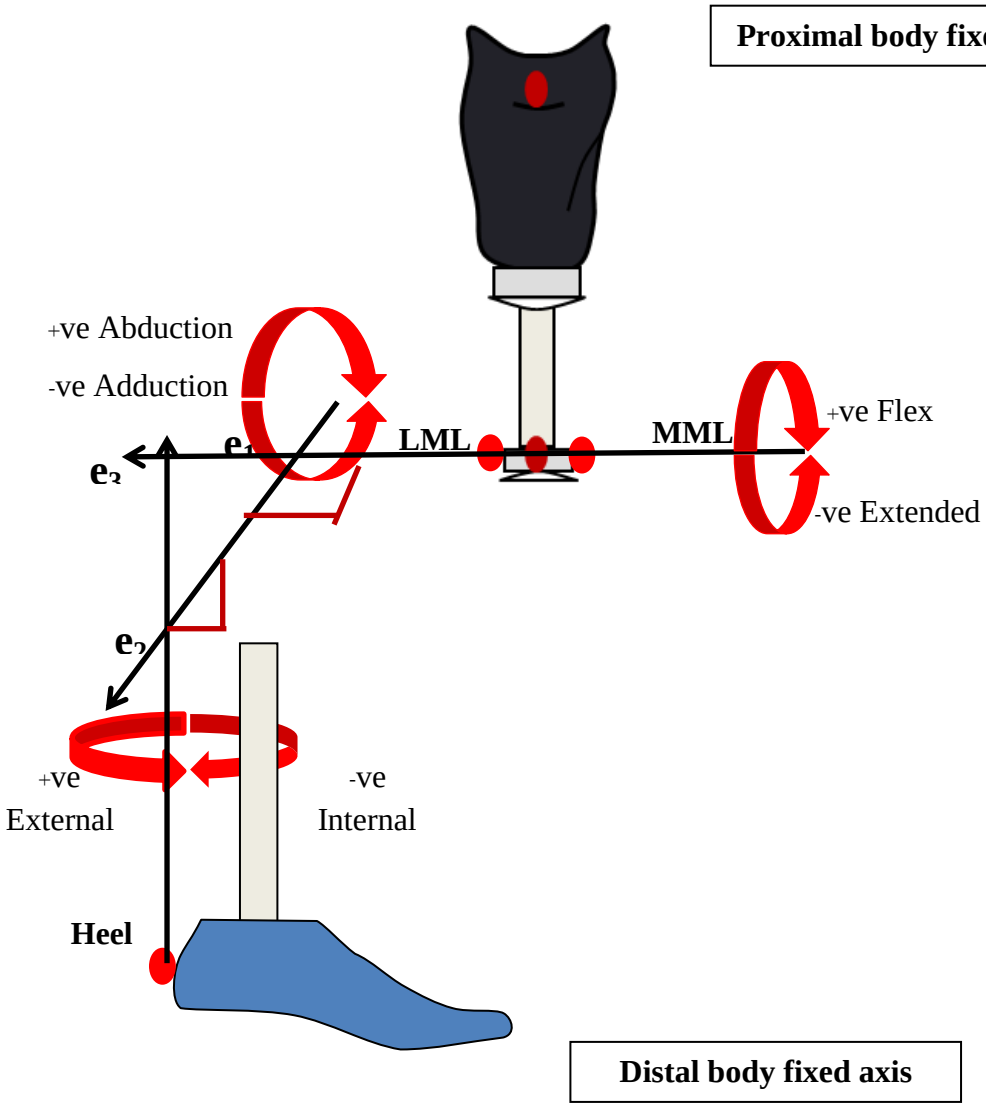


Figure 7.14 Prosthesis Coordination

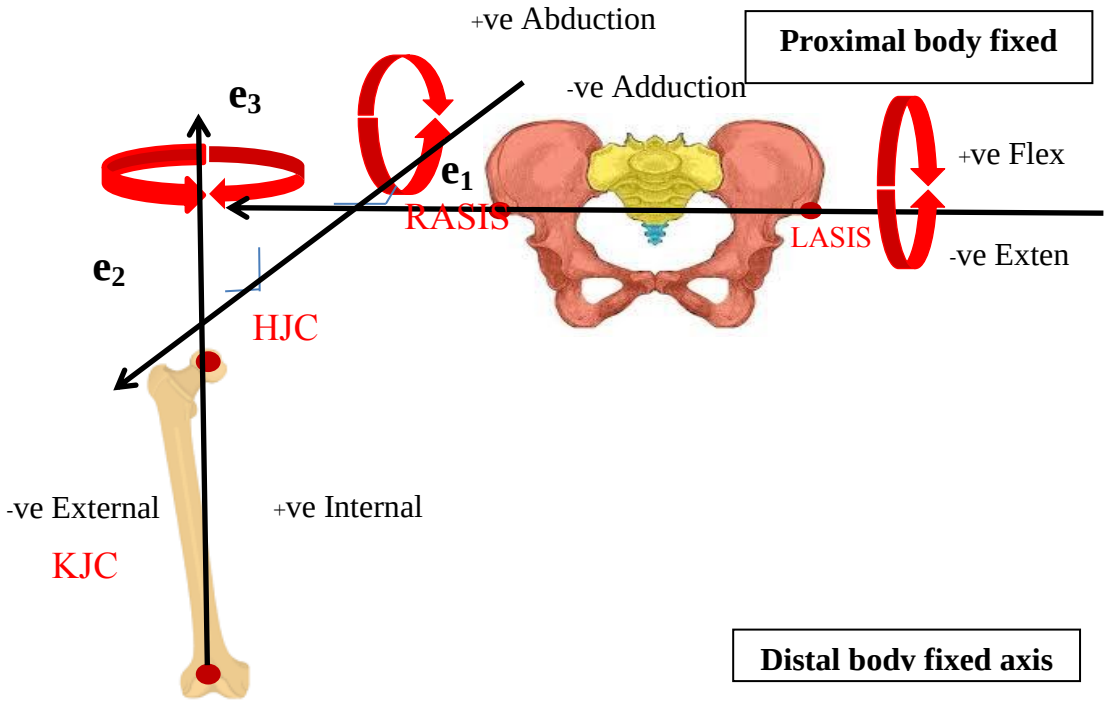


Figure 7.15 Hip Joint Coordinate System

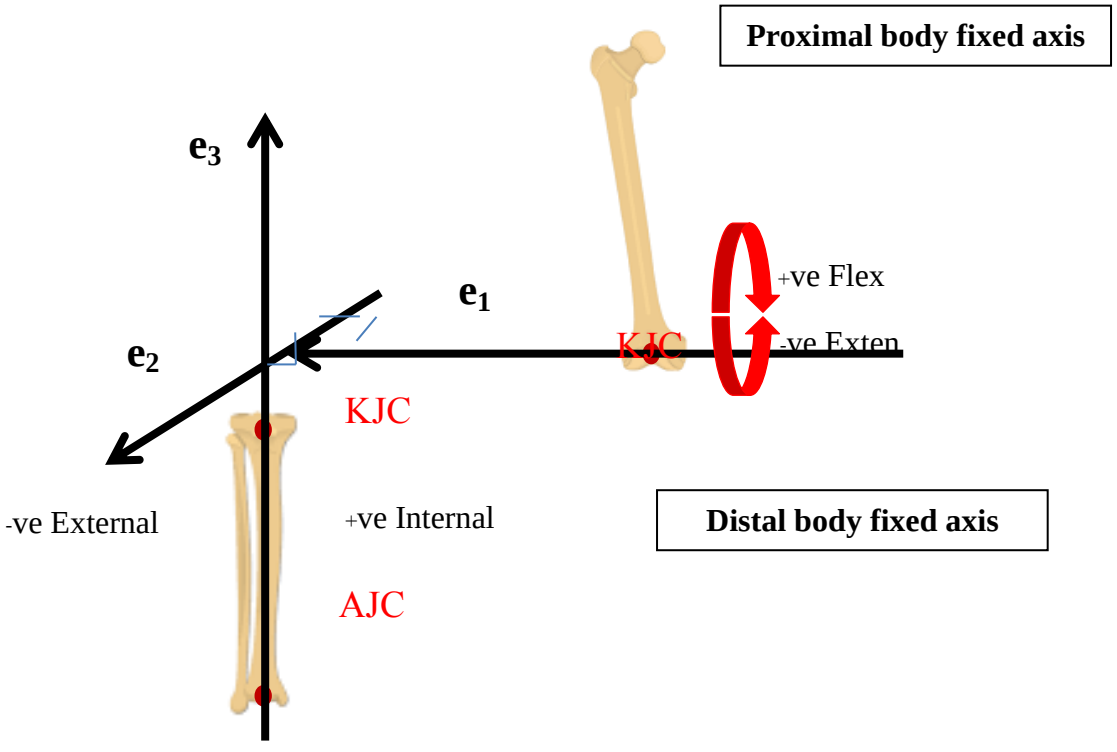


Figure 7.16 Knee Joint Coordinate system

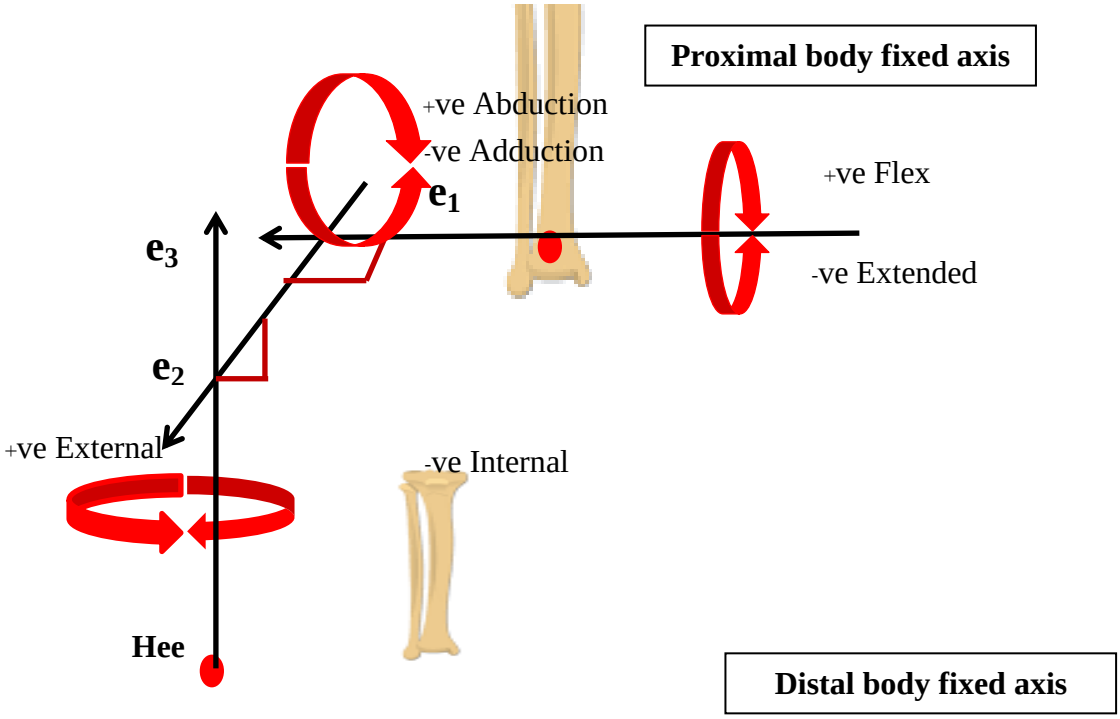


Figure 7.17 Ankle Joint Coordinate system

The prosthesis and sound side joint angles of flexion/extension (α), ab/adduction (β), and internal/external rotation (γ) were derived from a geometrical analysis of the two rotating components. The subscripts in Equation 7.8 through Equation 7.10 describe the calculation of each clinical movement used to indicate the axis of those components. Subscript i refers to axes which are part of the proximal segment. Subscript j refers to axes which are part of the distal segment. Subscript ij refers to axes which are part of the working axis system.

α is the angle of flexion/extension a rotation about ê1, Rotation about ê1 describes a rotation in the sagittal plane of the joint and thus flexion/extension and counterclockwise rotations about each axis is considered positive. Equation 7.8 was used to calculate the angle of flexion/extension

$\alpha = \cos^{-1}(\hat{e}2 \cdot t_i) * B$

$B = 1$ if $(\hat{e}2 \cdot l_i) > 0$ elsewise $B = -1$ **Equation 7.8**

β is rotation about the floating axis describes the abduction/adduction rotation, angle, rotation about ê2.

$\beta = \cos^{-1}(r \cdot l_j) * C$, where $r = (\frac{f_i \, x \, \hat{e}2}{f_i \, x \, \hat{e}2})$

$C = 1$ if $^{1}(f_i \cdot l_j) > 0$ elsewise $C = -1$ **Equation 7.9**

γ is an angle of internal/external, rotation about ê3, Rotation about ê3 describes the internal/external rotation of the joint. These are also referred to internal and external rotation about the y-axis of the foot.

$\beta = \cos^{-1}(\hat{e}2 * t_j) * D$

$D = 1$ if $^{1}(\hat{e}2 * f_j) > 0$ elsewise $D = -1$ **Equation 7.10**

7.4.4.1 Gait Even Detection

In the dynamic gait analysis, the dynamic alignment outcome measurement is summarising based on the phase of gait (stance phase and swing phase). The timing of heel strike (HS) and toe-off (TO), the events that mark the transitions between stance and swing phase of gait, is essential when analysing gait (O'Connor et al., 2007). In the dynamic application, A Coordinate-Based Algorithm was used to detect gait events during treadmill walking (Zeni et al., 2008). Horizontal heel and toe position relative to the pelvis was used to detect the gait event in this application. The code which was used to detect the gait event is presented in appendix 1.

The peaks deference between the two correlation to the point in time when the position of the foot marker is most advanced relates to the sacral marker, and this

coincides with the initiation of stance phase or heel strike. The minimum difference between the two coincides with the initiation of the swing phase or toe off. The mean value of this difference is used to set a threshold beyond which the peaks (HS) and valleys (TO) (Figure 7.18) can be detected (Hendershot et al., 2016; Zeni et al., 2008).

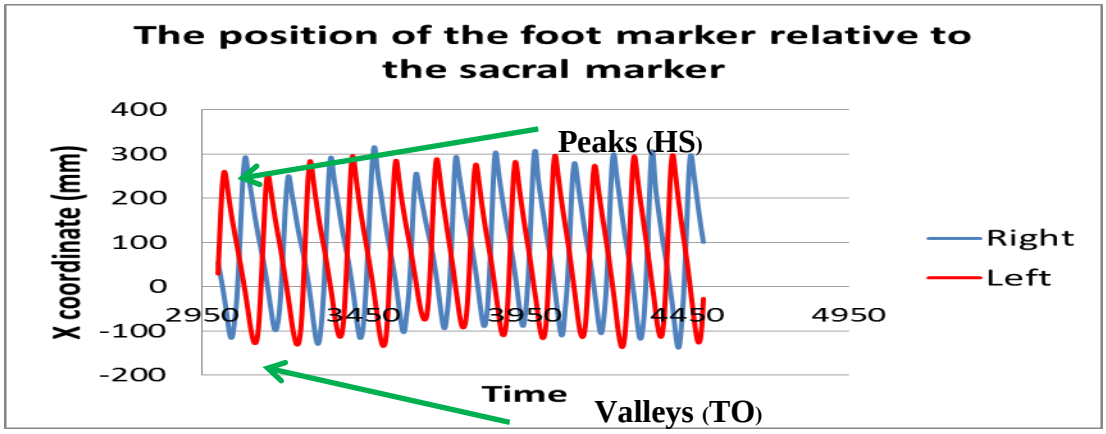


Figure 7.18 The position of the foot marker is graphed relative to the sacral marker, the peaks (HS) and valleys (TO)

Having established the biomechanical model for static and dynamic alignment the next chapter will explain how this model was implemented in D-flow software to show the static and dynamic data to the user during tuning.

Chapter 8. Assessment of a new alignment method for quantification and prescription of three-dimensional alignment for trans-tibial prosthesis

8.1 Introduction

A new system was designed and developed to facilitate quantification and prescription of prosthetic alignment for trans-tibia1 prostheses. This chapter introduces the new system, details the concept of feedback, the importance of feedback in the form of the alignment measurements used and details how this feedback was given to the prosthetists as visual feedback in real-time.

8.2 Overview of the Computerised motion capture and visualisation system for the Assisted Alignment Technique (CVAT)

Based on a comprehensive literature review undertaken as part of this thesis in Chapter 2, researcher found alignment instrumentation has been developed for helping in the prosthetic alignment process for the bench (Sin et al., 1999), the static (Blumentritt, 1997) and the dynamic alignment (Chen et al., 2016; Harlaar et al., 2000; Kobayashi et al., 2015). However, the available instrumentation could not be used in all of the alignment processes; most of these systems permit only one stage of alignment. Moreover, the majority of instrument alignment techniques available in the market are used to perform dynamic alignment; most of that instrument based on kinetic data. It could be hypothesised that the instruments are based on kinematic data, which could provide real-time biomechanical measures and serve as an objective tool which could be use for aiding prosthetists conducting the alignment of a trans-tibial prosthesis from initial alignment until the final gait alignment.The development of a system, which can assist the prosthetist in utilising 3D motion analysis data to visualise prosthetic alignment and measure biomechanical outcomes during gait would therefore be valuable as additional information for aligning prostheses.

The researcher designed the CVAT method which focused on tuning using 3D motion analysis which assists in setting alignment in three scenarios: the bench, static standing and dynamic gait. This was achieved using D-flow software from Motek Forcelink a software package designed for the development of interactive and immersive virtual reality applications.

In this chapter, the specific hardware and software used in these applications are detailed including each of the applications.

8.3 Software and hardware used in the CVAT method

The hardware used in the system consisted of a self-paced treadmill, retro-reflective markers (both single and clusters) and a Vicon Bonita system. The software used in the system was Vicon Tracker and Motek's D-flow.

8.3.1 Software configuration

Marker trajectories were identified using Vicon Tracker 3.2.0 (Vicon Motion Systems, Oxford, UK). Marker trajectories were then streamed into D-Flow (Motekforce Link, Netherlands) for calculation and visualisation.

8.3.1.1 Vicon Tracker

The Vicon motion system is an accurate optoelectronic motion analysis system used for objective gait analysis (Szczerbik and Kalinowska, 2011). For this application, the researcher used Vicon Tracker 3.2.0 (Vicon Motion Systems, Oxford, UK) as the tool to capture marker trajectories. Tracker is used in the animation industry as a real-time system for modelling (Figure 8.1). Each of the seven clusters and a pointer were defined in Tracker by creating an object or a Vicon Skeleton Template (VSK). Each cluster and the pointer contained 4 markers, asymmetrically arranged on the object and all different from one another. Each VSK was, therefore, unique and allowed Tracker to automatically locate and label each object. Thus, the clusters and pointer were automatically tracked when in the field of view. Once clusters were located, individual markers were automatically labelled from pre-identified templates (VSKs) by Tracker. Clusters would continue to be tracked while in the capture volume. The creation of the VSK objects only needs to be done once at the beginning of the development. The same clusters were used to capture the data throughout the study. Clusters were recognised and labelled by Tracker and streamed into D-Flow in the background.

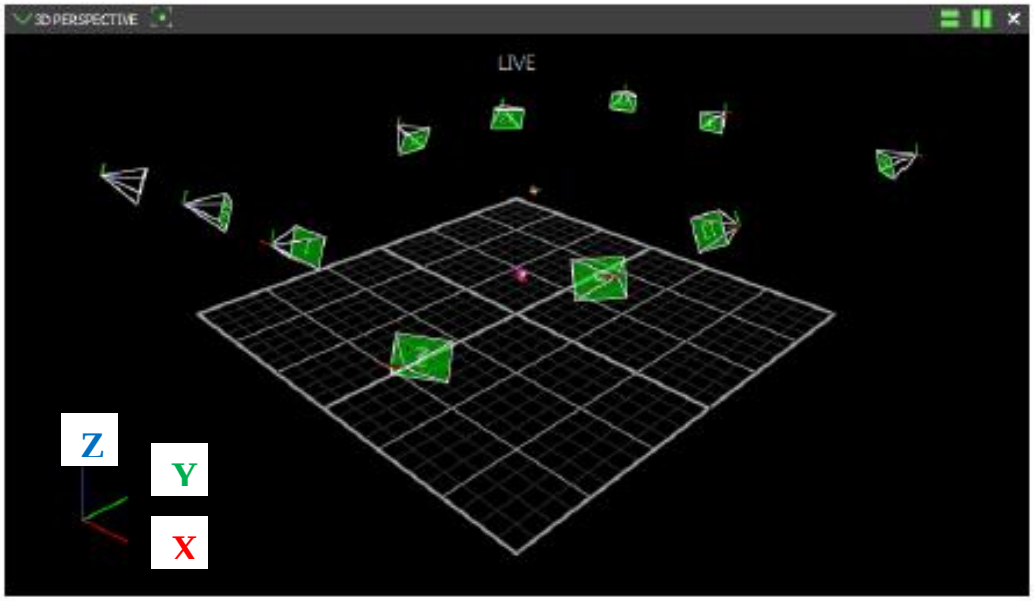


Figure 8.1 3D Perspective view pane in the Vicon Tracker

8.3.1.2 D-flow

The data from the Vicon tracker was automatically steamed into D-Flow using the MOCAP module (Motekforce Link, Netherlands). This is a quick and easy way to provide live data to the application. In D-flow motion, data can be manipulated using other available modules or by using a script written in Lua code.

Further, a number of inbuilt objects are available which allow simple object-based programming for the development of the visualisations for visual feedback. The SCM model has been shown previously in this thesis (Chapters 4 and 5) to reliably produce gait variables for use as outcome measures for the CVAT application. All parameters could be computed in real-time, displayed in a visual environment window (Figure 8.2), and therefore used as part of a tuning application based on motion analysis.

A consistent global reference frame (GRF) for the system was needed. A standard rigid wand with infrared LEDs on it used to define the GRF within the capture volume. The wand was placed on the treadmill in the geometric centre of the capture volume. A spirit level embedded in the wand was used, to ensure the wand was truly in line with the treadmill. As previously mentioned, two software platforms were used during the tuning process; Tracker and D-flow. There was a difference in the

GRF axes definition between the two programs. In Tracker (Figure 8.1), Z is the vertical axis (positive upwards) whereas in D-Flow (Figure 8.2), Y is the vertical axis (positive upwards). Likewise in Tracker, the axis to the side is the Y-axis, and for D-flow this is the Z-axis. The X-axes are both forward in the two systems. When calculating the kinematic and alignment parameters, these difference need to be taken into account.

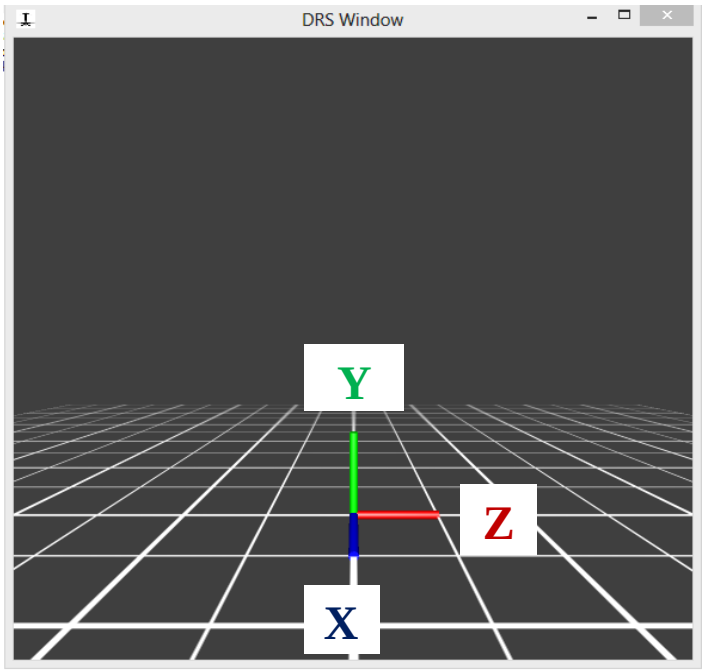


Figure 8.2 Virtual environment within D-Flow.

8.3.2 Treadmill

The results from Chapter 6 showed there were no significant differences between overground and self-paced treadmill (SP TM) walking on the recorded lower limb kinematics. Hence self-paced treadmill walking can be used instead of overground walking and could be a powerful tool to study the patient's gait. Walking on an SP TM (Figure 8.3) permits more freedom for the participant to select and change walking speed than fixed paced treadmill walking. The treadmill method facilitates recording many gait cycles in a short period of time in a fixed capture volume. On the treadmill, there is an emergency stop button which provides a harness for clinical gait analysis. For these reasons, we chose to use self-paced treadmill walking in the CVAT method.

Figure 8.3 Shows the single bell self-paced treadmill used to develop the system. (Motekforce Link, Netherlands)

8.4 Alignment Feedback Scenarios and Avatar

Alignment feedback scenarios were then developed for three alignment applications. Further, a user-friendly graphical user interface (GUI) was developed to allow operators with the limited technical expertise of three-dimensional motion analysis to use the system.

8.4.1 Bench alignment feedback scenarios

An adjustable prosthesis is assembled with endoskeletal components in bench alignment according to a range of standard variables.

The first bench alignment variable is prosthetic height. The height of a trans-tibial prosthesis is correct when the patellar bar (Figure 8.4) of the socket is at the same height as the medial tibial plateau (MTP) on the sound side (Boone, 2005b).

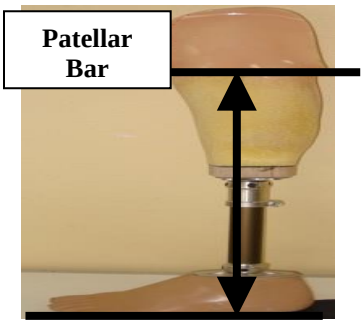


Figure 8.4 Prosthesis Height

Ruder (2009) and Murphy (2013) describe the recommended starting configuration for a standard bench alignment. In the sagittal plane, the socket is placed in 5 to 10 degrees of flexion (Figure 8.5) to facilitate heel strike and to place the quadriceps complex on stretch (Murphy, 2013). In the sagittal plane, the centre of rotation of the socket lies at the intersection of the line representing the mid-point between the anterior-posterior aspects of the socket and the patellar bar. The ankle centre in the sagittal plane is defined as the centre of the bolt hole on the top surface of SACH foot (Berme et al., 1978). A vertical reference line dropped from the socket centre of rotation in the sagittal plane should fall approximately 0 to 30 mm anterior to the ankle centre for a SACH foot as shown in Figure 8.5 (Ruder, 2009).

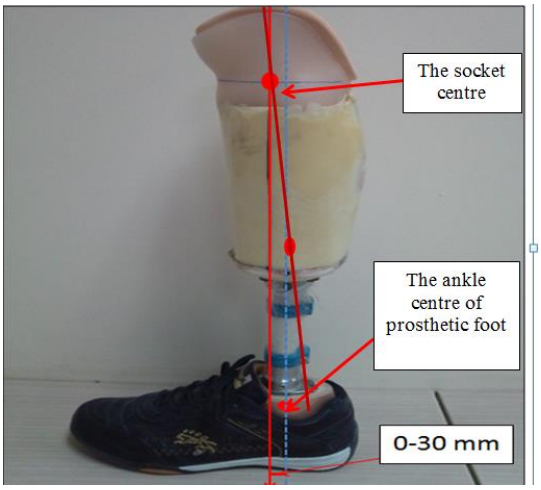


Figure 8.5 Bench alignment in the sagittal plane

KAPP & Miller (2009) also recommended a standard bench alignment in the coronal plane (Figure 8.6). The adduction of the socket is set to follow the adduction angle of the patient's residual limb. That angle can be determined by evaluating the residual limb during the casting procedure. On average, sockets are set at 5° - 10° adduction. The proper socket flexion/extension angle and adduction angle should result in a vertical pylon and a foot that is flat on the floor at midstance (KAPP and Miller, 2009). The centre of the heel may be inset medially from 0 to 12 mm to the centre of rotation of the socket (Red line in Figure 8.6) (Boone, 2005b).

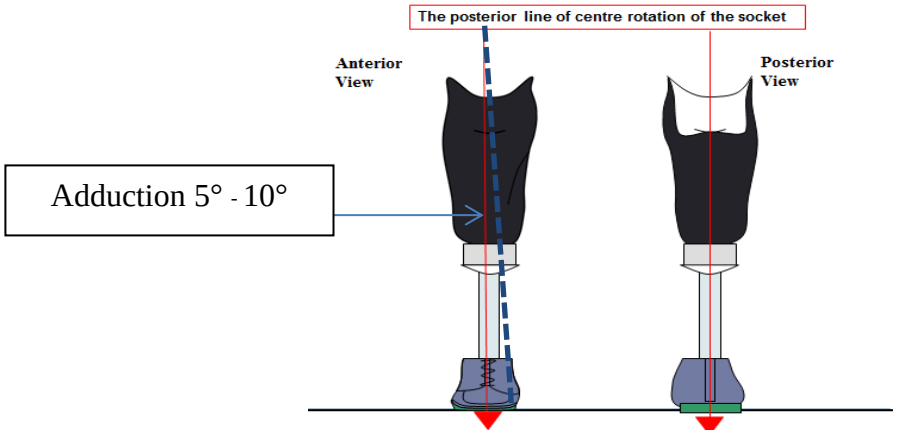


Figure 8.6 Bench alignment in the coronal plane

According to Susan and Cummings 2002, a standard bench alignment in the transverse plane (Figure 8.7) is produced by setting the medial border of the foot parallel to the line of progression. This gives approximately 5° to 7° of toe out from the line of progression (Kapp and Cummings, 2002). However, the standard bench alignment must be adjusted when there are joint contractures, or deformity is present (McCollum, 2004).

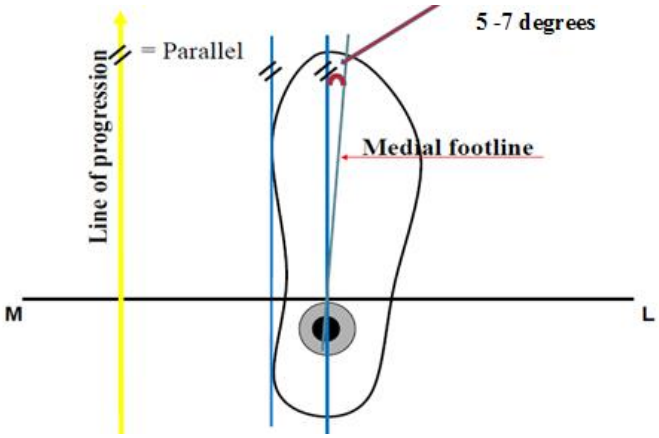


Figure 8.7 Bench alignment in the transverse plane

8.4.2 Bench Alignment Feedback Scenarios Calculation and Avatar

During tuning, each alignment measurement was calculated following the detail in Chapter 7. All the code used to calculate the alignment are presented in appendix 1. Green and red spheres objects (Figure 8.8) were used alongside the data to visualise the outcome. Green spheres indicated that the parameter was within the prescribed

limits while red spheres indicated the contrary. The system also showed written feedback to the prosthetist for correcting the alignment. Moreover, the system could be used as a recording tool to capture the current alignment. The example of data recorded from the application in appendix 11.

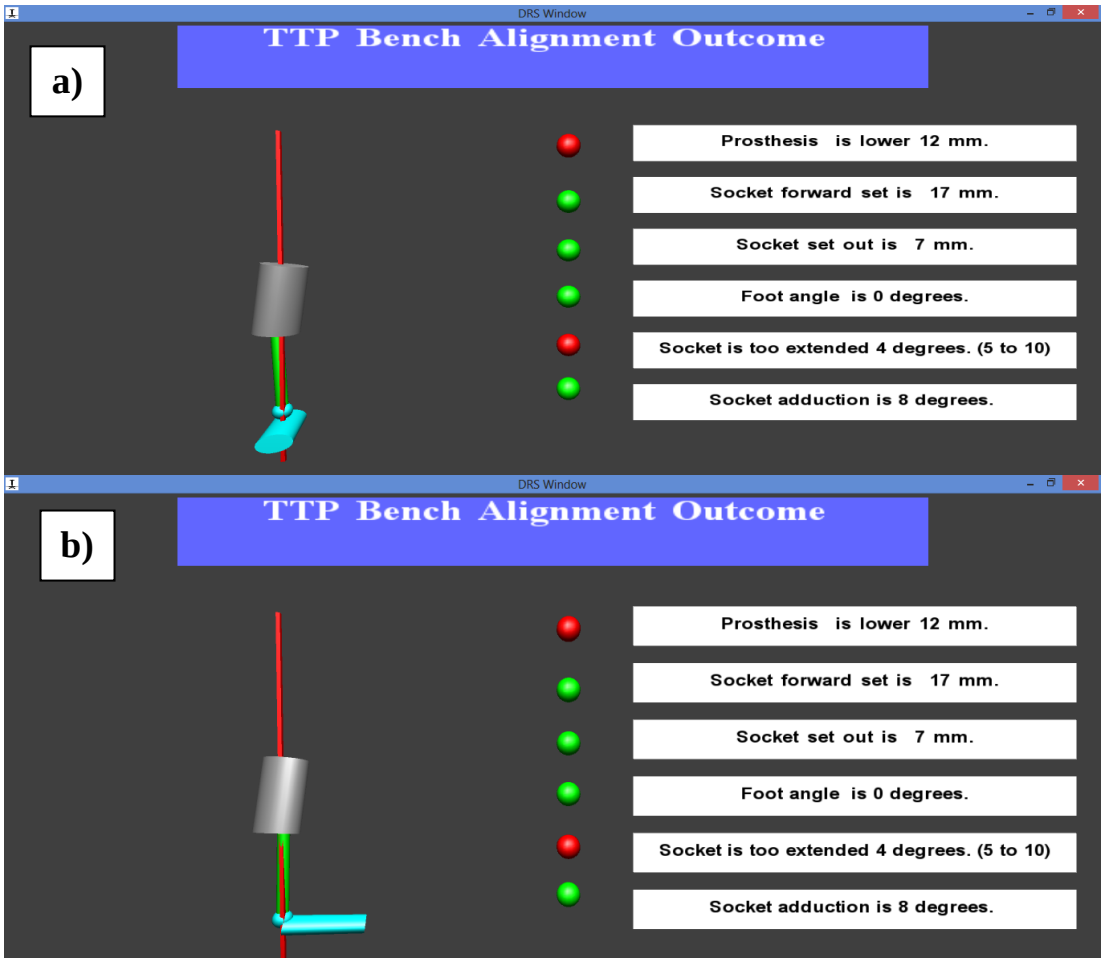


Figure 8.**8** Real-time visual display of feedback scenarios during bench alignment a) Avatar Frontal b) Avatar Sagittal

The system also provided written feedback of optimal initial alignment needed. The optimal initial alignment varied based on the components' characteristics and with previously acquired data regarding the individual. This information was entered into the GUI or capture console by the prosthetist. The markers were used to create and drive an avatar of the prosthesis (Figure 8.9) by linking components between component centres. (Code in appendix 1)

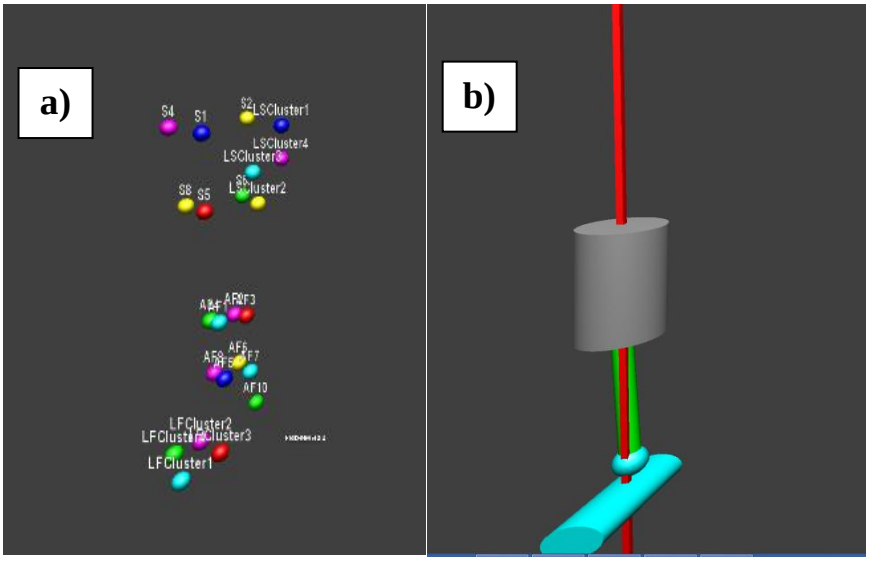
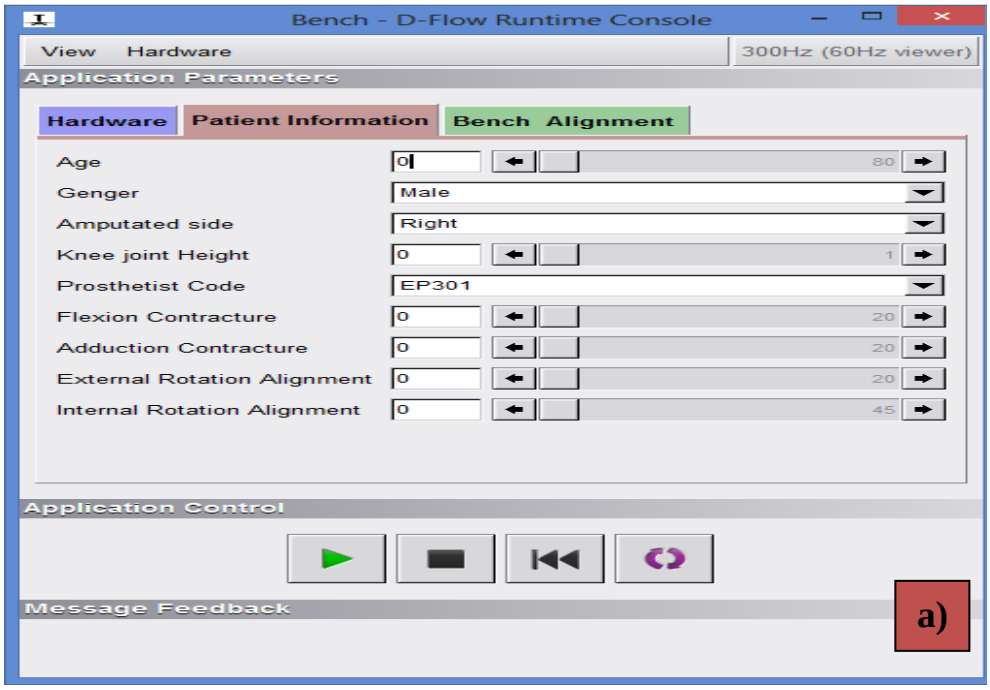


Figure 8.9 a) The prosthesis is driven by the marker placed on the prosthesis b) Avatar of TTP movements

During tuning, each parameter was measured and used to define the angle and position of the socket relating to the foot. The written feedback provided to the prosthetist for adjusting the alignment was determined by thresholds as indicated in Table 8.1. The code to implement feedback scenarios is presented in appendix 1.



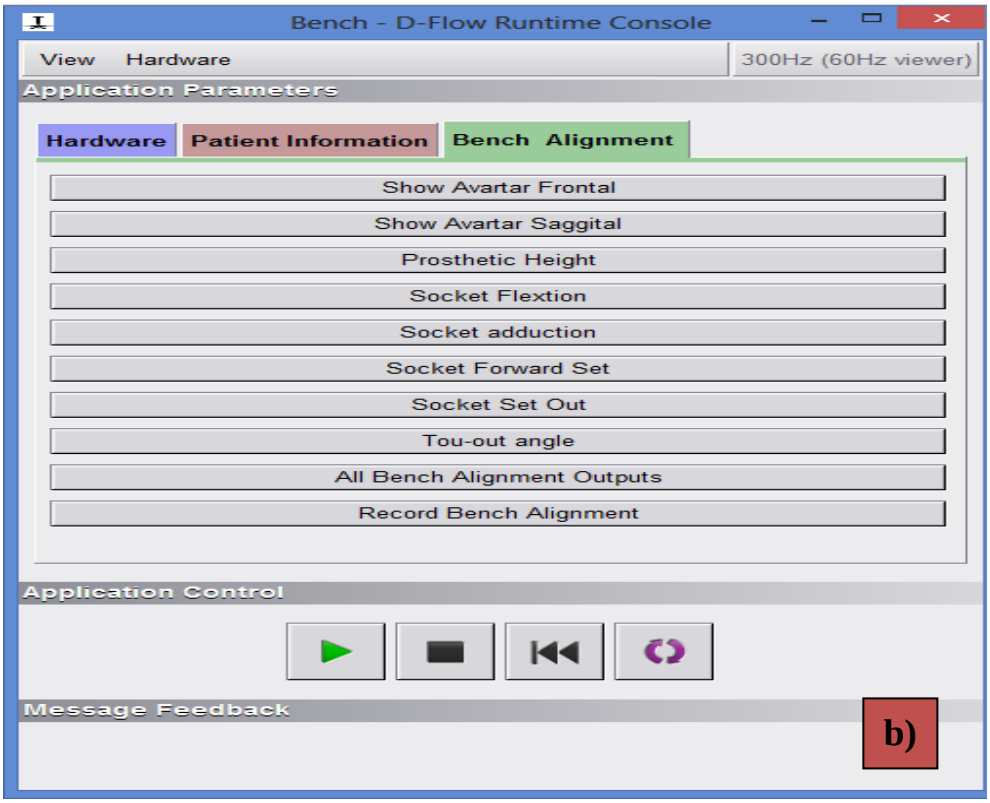


Figure 8.10 Graphical user interface for the Bench Alignment a) the patient information tab b) Bench Alignment tab

Within the Graphical user interface **(**GUI) otherwise known as the runtime console was the patient information tab (Figure 8.10a) and the bench alignment tab. (Figure 8.10b). The patient information tab requests important data for setting bench alignment. The valuables are the participant's age, gender, prosthetist code, amputated side; Knee joint height (KH), flexion contracture (FC), adduction contracture (AC) and knee rotation (KR).

Bench alignment was conducted according to information provided previously in guidelines established and provided by the manufacturers of prosthetic feet and knees (Adebayo et al., 2011; Neumann, 2009). Moreover, The bench alignment was also established based on the amputees' residual limb requirement, e.g. magnitude of contractures of the knee (Kobayashi et al., 2015).

The feedback enabled the prosthetist to get the optimal bench alignment based on the amputees' data and the guidelines. The goal for optimal bench alignment was to set the orientation of the prosthetic components in the middle of the anticipated range of

adjustments prior to subsequent static and dynamic alignment (Kobayashi et al., 2015).

From the review of guidance of bench alignment in Chapter 2, the parameters for bench alignment were the six parameters shown in Table 8.1.

Bench alignment Parameters	Nomenclature
Prosthesis height **(**mm**)**	Prosthetic Height (PH)
Socket AP tilt (Degrees)	Socket Flexion (SFLX)
Socket ML tilt (Degrees)	Socket Adduction (SADD)
Socket AP shift (mm)	Socket Forwards Set (SFS)
Socket ML shift (mm)	Socket Set Out (SAO)
Toe-out (degrees)	Toe-out angle (TOUT)

Table 8.1 Six alignment parameter

The aim was for the prosthetist to tune the prosthesis, aiming to achieve the optimal alignment with six green spheres in the feedback view.

The first alignment setting was prosthetic height. Optimal Length of the prosthesis was equal to the height of the sound side. The length of a trans-tibial prosthesis is correct when the medial tibial plateau (MTP) of the residual limb is maintained at the same height as MTP on the sound side (Boone, 2005b) as shown in Figure 8.4. In the bench application, this was called DifHeight (the height difference between the prosthetic and sound side). Equation 8.1 shows how to calculate DifHeight.

$$DifHeight = PH - KH \qquad \textbf{Equation 8.1}$$

Where:

KH was knee height on the sound side as measured from the height of the medial tibial plateau (MTP) on the sound side. PH is prosthetic height (PH) which was calculated by the system using equation 7.1 from Chapter 7.

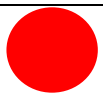
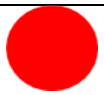
Prosthesis height (PH)			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
DifHeight > 5 mm		Too height	Prosthesis is higher < DifHeight > mm
-5> DifHeight < 5		Proper	Prosthesis Height is <PH> mm.
DifHeight <– 5 mm		Too low	Prosthesis is lower < DifHeight > mm

Table 8.2 Details limits for Prosthesis height parameter

The second bench alignment parameter was socket AP tilt as shown in Figure 8.11and detailed in Table 8.2. Ruder, (2009) and Murphy, (2013) describe the recommended starting configuration for a standard bench alignment. In the sagittal plane, the socket was placed in 5 to 10 degrees of flexion with the addition of the magnitude of any contractures of the knee. Socket flexion (SFLX) is socket AP tilt, which was calculated by using equation 7.2 from Chapter 7.

BF1 = 5^{o} + magnitude of AP contractures of the knee **Equation 8.2**

BF2 = 10^{o} + magnitude of AP contractures of the knee **Equation 8.3**

Where:

The threshold for socket AP tilt was the minimum optimal socket AP tilt **(**BF1**)** and maximum optimal socket AP tilt **(**BF2**)** as detailed in Table 8.3. The magnitude of AP contractures of the knee was input in the patient information tab as a flexion contracture.

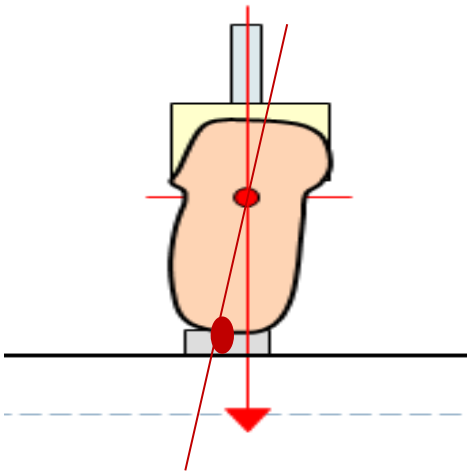


Figure 8.11 The second alignment setting is Socket AP tilt

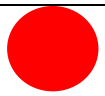
Socket AP tilt			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
SFLX > BF2		Too flexed	Socket is too flexed < SFLX> degrees. (BF1 to BF2)
BF1 < SFLX < BF2		Proper	Socket AP tilt is < SFLX> degrees.
SFLX < BF2		Too extended	The socket is too extended <SFLX> degrees. (BF1 to BF2)

Table 8.3 Details limits for Socket AP tilt parameter

The third bench alignment parameter was socket AP shift or socket AP translation relative to the position of the ankle bolt as detailed in Table 8.4. The reference line dropped from the centre of the socket in the sagittal plane on the socket should fall approximately 0 to 30 mm anterior to the ankle centre for a SACH foot as shown in Figure 8.5 (Ruder, 2009). Socket Forwards Set (SFS) is socket AP translation, which was calculated by using equation 7.4 from Chapter 7.

Socket AP shift			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
BAP > 30 mm		Too anterior	Foot is too anterior < BAP > mm. (0 – 30 mm)
O mm> BAP < 30 mm		Proper	Foot position is < BAP > mm.
BAP < 0 mm		Too posterior	Foot is too posterior < BAP > mm. (0 – 30 mm)

Table 8.4 Details limits for Socket AP shift parameter

The fourth bench alignment parameter was socket ML tilt as shown in Figure 8.12 and detailed in Table 8.5. A standard bench alignment of socket ML tilt in the coronal plane was based on setting the adduction angle of the patient's residual limb. This angle determined during the casting procedure. On average, sockets are at 5° - 10° adduction (KAPP and Miller, 2009).

BAP1 = 5^{o} + magnitude of ML contractures of the knee. **Equation 8.4**

BAP2 = 10^{o} + magnitude of ML contractures of the knee. **Equation 8.5**

Where:

The threshold for socket ML tilt was the minimum optimal socket ML tilt **(**BAP1**)** and maximum optimal socket ML tilt **(**BAP2**)**. The magnitude of ML contractures of the knee was input in the patient information tab as adduction contracture. Socket Adduction (SADD) is socket ML tilt which calculated by using equation 7.3 from Chapter 7.

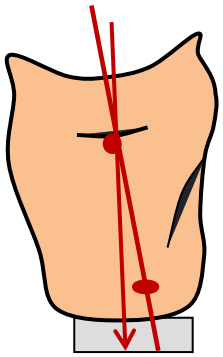


Figure 8.12 The fourth alignment setting is Socket ML tilt

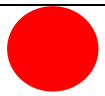
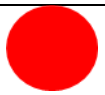
Socket ML tilt			
Threshold	**Visual Feedback**	**Quality**	**Wording feedback**
Socket AP tilt > BAP2		Too adducted	Socket is too adducted < SADD > degrees. (BAP1 to BAP2)
BAP1< Socket AP tilt < BAP2		Proper	Socket ML tilt is < SADD > degrees.
Socket AP tilt < BAP1		Too abducted	Socket is too abducted < SAD > degrees. (BAP1 to BAP2)

Table 8.5 Details limits for Socket ML tilt s parameter

The fifth bench alignment parameter was socket ML shift as detailed in Table 8.6**.** The centre of the heel may be inset medially from 0 to 12 mm to the posterior line of centre rotation of the socket (Red line in Figure 8.5 (Boone, 2005b). The optimal positioning of mediolateral foot positioning (BML) is between 0 - 12 mm in medial translation. Socket Set Out (SAO) is socket ML translation which was calculated by using equation 7.5 from Chapter 7.

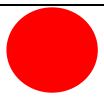
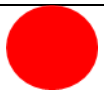
Socket ML shift			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
BML > 12 mm		Too inset	Foot is too inset < SAO > mm. (0 – 12 mm**)**
O mm > BAP < 12 mm		Proper	Foot position is < SAO > mm.
BAP < 0 mm		Too outset	Foot is too outset < SAO > mm. (0 – 12 mm**)**

Table 8.6 Details limits for Socket ML shift parameter

The sixth optimal bench alignment parameter was foot angle as detailed in Table 8.7. Prosthetic foot internal-external rotation angle describes the degrees of in-toeing or out-toeing of the foot relative to the forward line of progression during the stance phase (Shores, 1980). A standard bench alignment in the transverse plane is 5° to 7° of toe out from the line of progression as shown in Figure 8.7 (Kapp and Cummings,

2002). However, the standard bench alignment must adjust when joint contracture or deformity is present (McCollum, 2004).

BTO1 = 5^{o} + magnitude of stump rotation of the knee. **Equation 8.6**

BTO2 = 7^{o} + magnitude of stump rotation of the knee. **Equation 8.7**

Where:

The threshold for foot rotation was the minimum optimal foot rotation **(**BTO1**)** and maximum optimal foot rotation **(**BTO2**).** The magnitude of transverse plane rotation of the knee was the input in the patient information tab as rotation alignment.

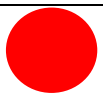
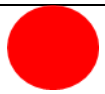
Toe out (Foot angle)			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
TOUT > BTO2		Toe out	Prosthetic foot is toe out < TOUT > degree (BTO1 – BTO2)
BTO1> TOUT > BTO2		Proper	Prosthetic foot is < TOUT > degree
TOUT < BTO1		Toe in	The prosthetic foot is toe out < TOUT > degree (BTO1 – BTO2)

Table 8.7 Details limits for Toe out (Foot angle) parameter

8.4.3 Static Alignment Feedback Scenarios

During static alignment, the patient is in a quiet, erect standing with equal weight on each leg and the feet approximately 100 mm apart at the heel (Mccollough et al., 1981). The prosthetist observes the standing posture of the stationary patient to observe quiet balance (Chen, 2012).

To determine any misalignment during static alignment, the inclination of the pylon and position of the socket relating to the foot are marked (Blumentritt, 1997; Mccollough et al., 1981). In the coronal plane, the anterior superior iliac spine (ASIS) should be at the same level as shown in Figure 8.13 (KAPP and Miller, 2009).

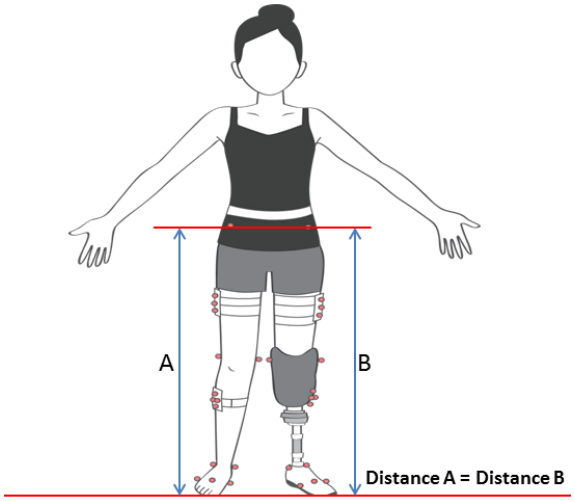


Figure 8.13 Static alignment in the coronal plane

When the socket was insufficiently adducted (Figure 8.14), the patient stood with the foot supinated, and the pylon laterally inclined. The socket was adducted less than the initial socket ML tilt in the bench alignment (Radcliffe and Foort, 1961).

When the socket was excessively adducted, the patient stood with the foot pronated and the pylon medially inclined. The socket was adducted more than the initial socket ML tilt in the bench alignment (Radcliffe and Foort, 1961).

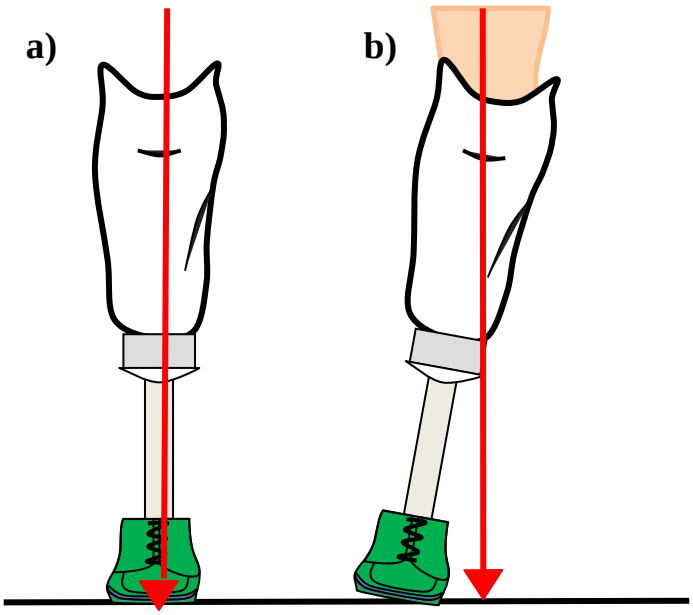


Figure 8.14 The static alignment setting in coronal plane is Socket ML tilt**. a)** socket ML tilt in a bench setting b) socket ML tilt in the static setting

For static prosthetic alignment in the sagittal plane, when the socket had insufficient flexion, (Figure 8.15) the patient stood with the heel raised. The pylon would be anteriorly inclined. The socket would be flex more than the socket AP tilt in the bench alignment (Radcliffe and Foort, 1961).

When the socket had excessive flexion, the patient stood with the toe raised, and the pylon would be posteriorly inclined. The socket would be extended more than the socket AP tilt in bench alignment (Radcliffe and Foort, 1961)

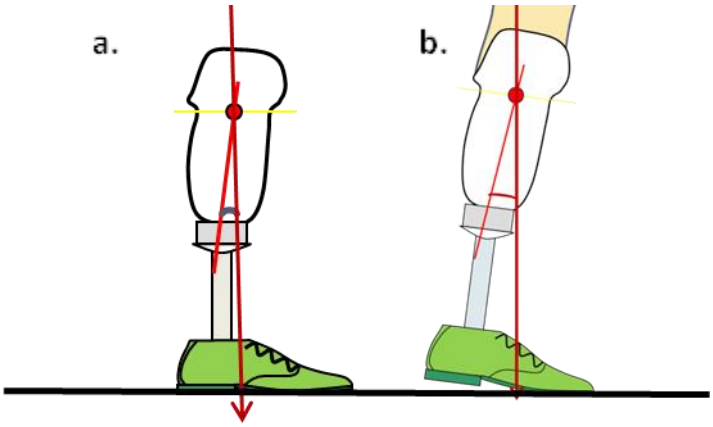


Figure 8.15 The static alignment setting in sagittal plane is Socket AP tilt **a)** socket AP tilt in bench setting b) socket AP tilt in the static setting

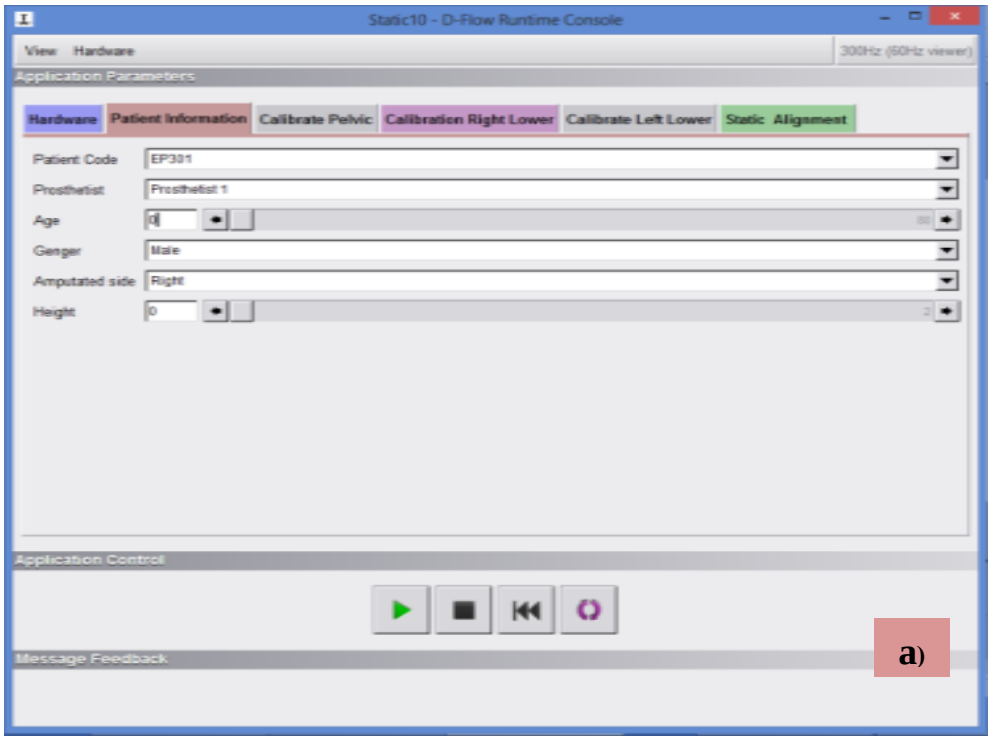
8.4.4 Static Alignment Feedback Scenarios Calculation and Avatar

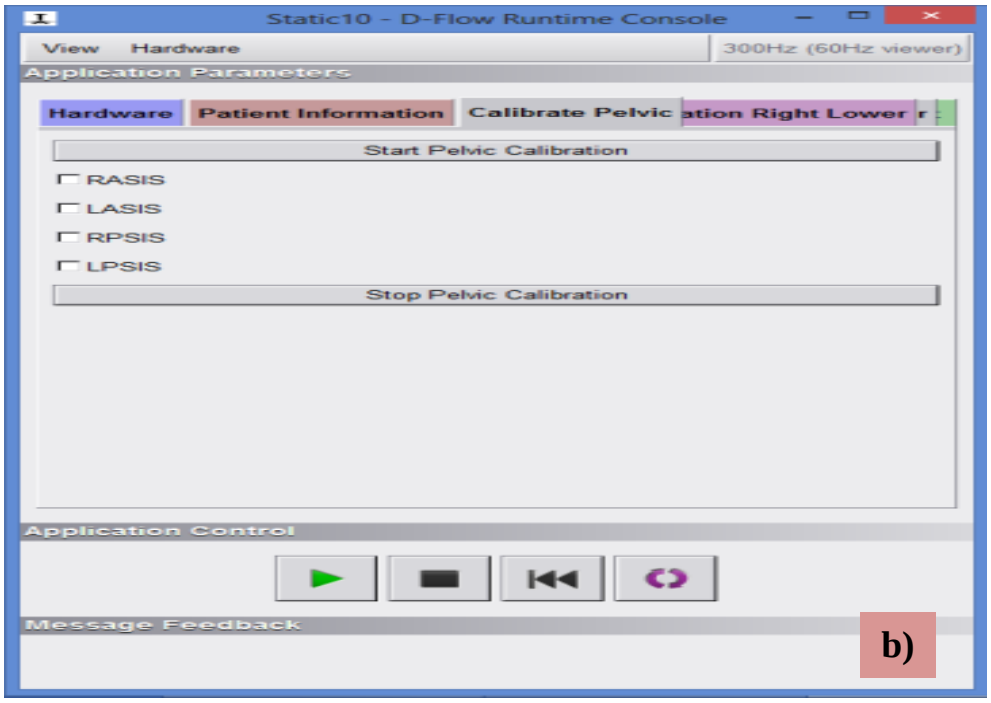
In the static application which was termed the Computer motion capture and Visualisation system for assisted Static Alignment Technique (CVSAT), a user-friendly graphical user interface **(**GUI**)** was developed to allow operators with limited technical expertise to calibrate a patient and run a session to calculate the optimal alignment feedback**.** To calibrate the patient, the anatomical landmarks of the SCM model were recorded using a pointer.

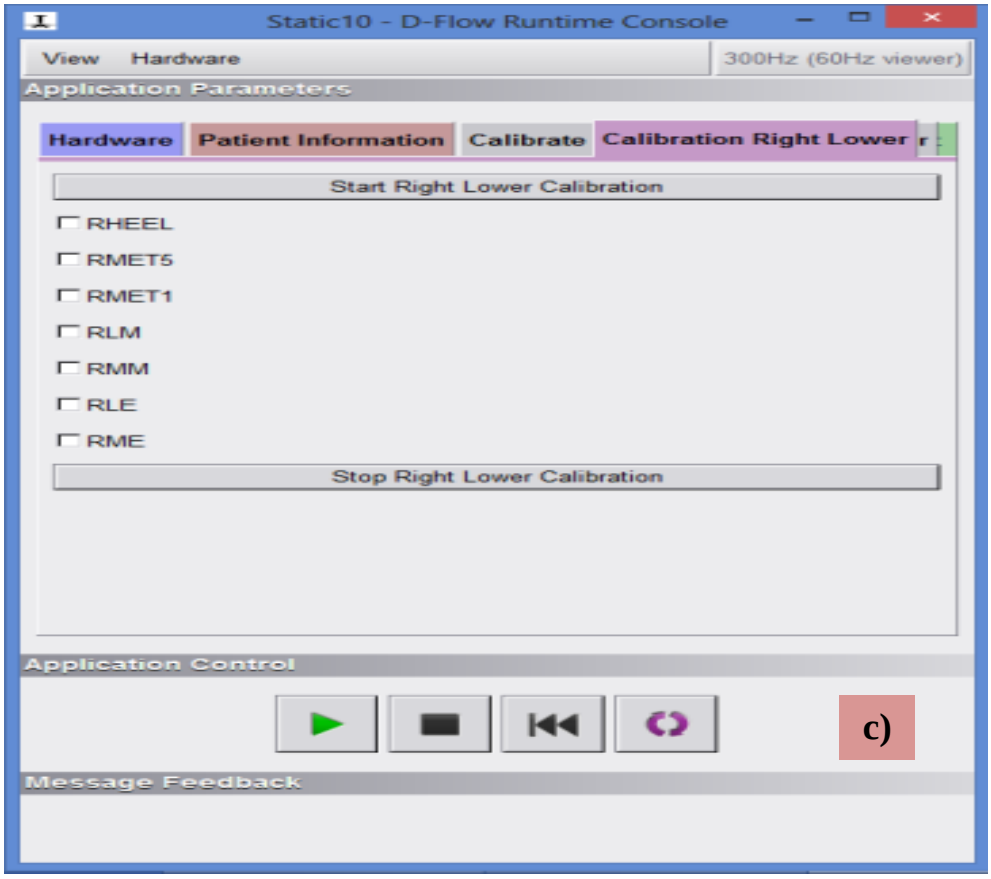
The GUI in the CVSAT application was made up of five tabs which allow the operator to control the software **(**Figure 8.16**).** The first tab was patient information **(**Figure 8.16a**).** The next three tabs were calibration tabs**.** The sequence of participant calibration started with pelvic calibration (Figure 8.16b). The second calibration tab was right lower limb (Figure 8.16c). The last calibration tab was left lower limb (Figure 8.16d). After calibration, the x, y and z positions of each anatomical marker relative to the adjacent segment cluster were stored. Once calibration was completed, the x, y and z position of each marker and relative to the cluster on the adjacent segment saved using the **'**Record calibration file**'** button**.** This recorded file was also used later in the dynamic alignment tuning**.**

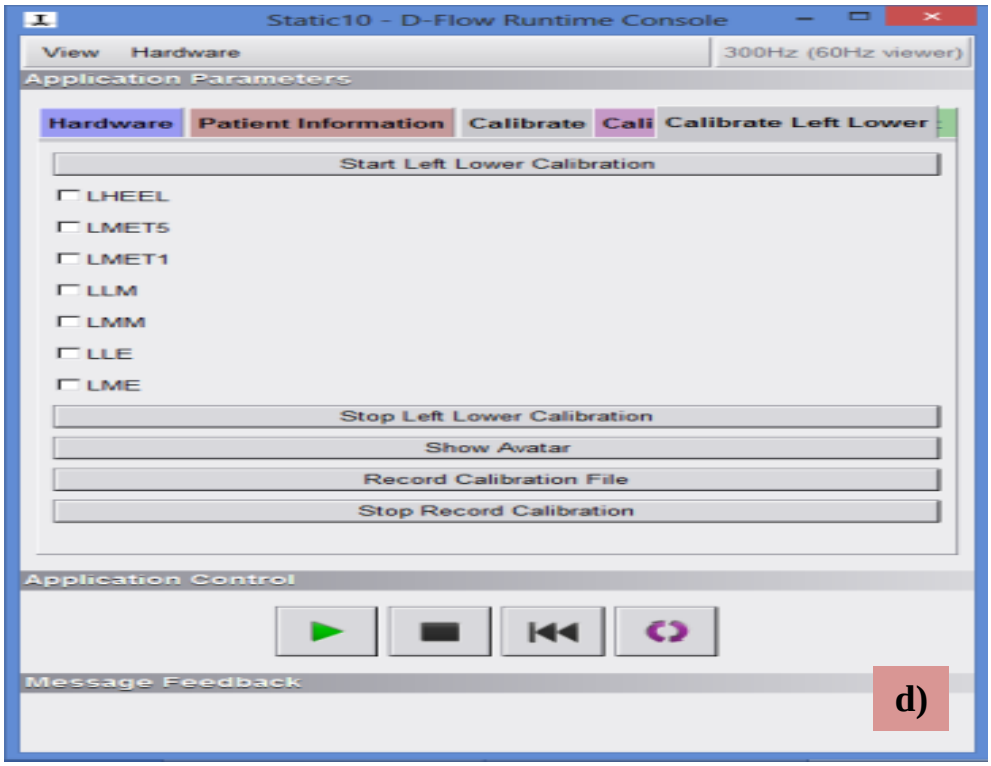
The calibration data created the biomechanical model and displayed a body avatar**.** The last calibration tab **(**Figure 8.16d**)** controlled the way in which the avatar was shown**.** The avatar could be used to check if all cluster markers were visible and also that virtual (anatomical) markers had been reconstructed correctly**.**

The static alignment tab **(**Figure 8.16e**)** allows setup and control of all the static alignment feedback parameters**.** The code for the subject calibration is presented in appendix 1.


Static10 - D-Flow Runtime Console
View Hardware
300Hz (60Hz viewer)
Application Parameters
Hardware
Patient Information
Calibrate Pelvic
Calibration Right Lower
Calibrate Left Lower
Static Alignment
Patient Code
EP301
Prosthetist
Prosthetist 1
Age
Genger
Male
Amputated side
Right
Height
Application Control
Message Feedback
a)


Static10 - D-Flow Runtime Console
View Hardware
300Hz (60Hz viewer)
Application Parameters
Hardware
Patient Information
Calibrate Pelvic
ation Right Lower
Start Pelvic Calibration
RASIS
LASIS
RPSIS
LPSIS
Stop Pelvic Calibration
Application Control
Message Feedback
b)


Static10 - D-Flow Runtime Console
View
Hardware
300Hz (60Hz viewer)
Application Parameters
Hardware
Patient Information
Calibrate
Calibration Right Lower
Start Right Lower Calibration
RHEEL
RMET5
RMET1
RLM
RMM
RLE
RME
Stop Right Lower Calibration
Application Control
Message Feedback
c)


Static10 - D-Flow Runtime Console
View
Hardware
300Hz (60Hz viewer)
Application Parameters
Hardware
Patient Information
Calibrate
Cali
Calibrate Left Lower
Start Left Lower Calibration
LHEEL
LMET5
LMET1
LLM
LMM
LLE
LME
Stop Left Lower Calibration
Show Avatar
Record Calibration File
Stop Record Calibration
Application Control
Message Feedback
d)

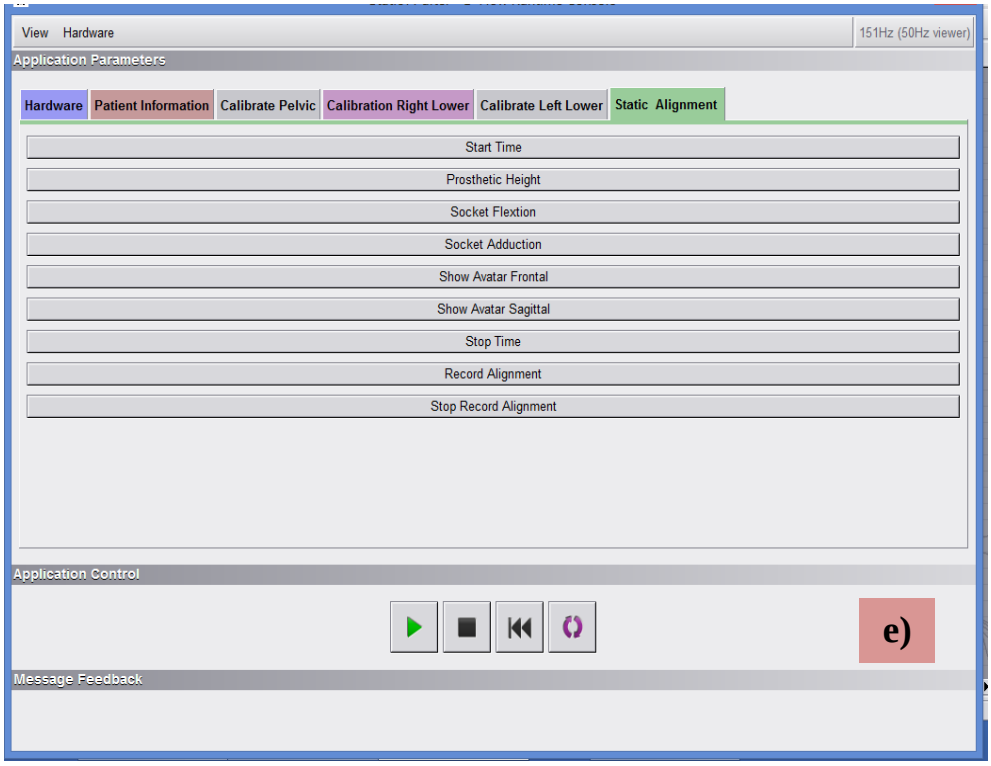


Figure 8.16 The GUI in the CVSAT application is made up of five tabs a) Patient information b) Pelvic calibration tab c) Right lower limb calibration tab d) Left lower limb calibration tab e) Static alignment tab

In the static alignment application, with the patient standing upright wearing a prosthesis, the alignment was changed by tilting the pylon in the anterior, posterior, medial, and lateral directions. During static tuning, the trans-tibial amputee will adapt himself to the prosthetic alignment through accommodation at the contralateral limb. The alignment tuning procedures must consider both limbs. The measurement of both limbs simultaneously was, therefore, essential to determine the combined effect of static alignment (Isakov et al., 1994). The goal was to deliver appropriate socket height and orientation so that the amputee could balance the body well while standing (Kobayashi et al., 2015).

The code which was used to track segments and calculate kinematics is presented in appendix 1. The following section details how the TTP alignment was calculated. The parameters for static alignment are indicated in Table 8.8. In this application optimal

static alignment was again based on thresholds. The visual feedback and written feedback given to the prosthetist for adjusting the alignment are indicated in Table 8.11 and provided in the system as the writing feedback of optimal initial alignment needed as shown in Figure 8.14.

Optimal static alignment parameters	Nomenclature
Prosthetic Height (mm)	SP1
Socket AP tilt in static (Degrees)	SF1
Socket ML tilt in static (Degrees)	SA1

Table 8.8 Optimal static alignment parameters

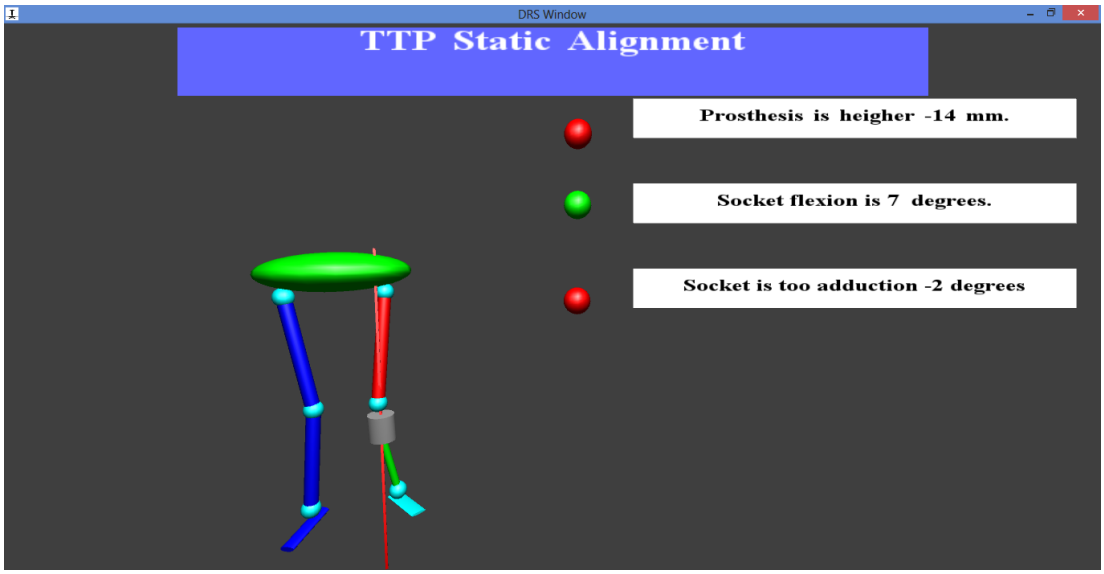


Figure 8.17 Real-time visual display of feedback scenarios during static alignment

The first static alignment parameter was to correct pylon height (Neumann, 2009) as given by the height in the coronal plane, the anterior superior iliac spine (ASIS) should be at the same height (KAPP and Miller, 2009) as shown in Figure 8.13 and detailed in . In the static application, DifPelvic gave the height difference between the ASIS on the sound side and the ASIS on the amputated side (Equation 8.8).

DifPelvic = AASISy - SASISy **Equation 8.8**

Where:

DifPelvic was the height difference between the ASIS on the sound side and the ASIS on the amputated side. AASISy was the height of the anterior superior iliac spine in the vertical direction on the amputated limb. SASISy was the anterior superior iliac spine height in the vertical position on the sound limb. PH is Prosthetic height (PH) which was calculated by the system using equation 7.1 from Chapter 7.

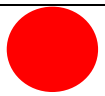
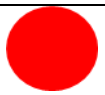
Pelvic Level			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
DifPelvic > 10 mm		Too height	Prosthesis is higher < DifPelvic > mm
-10 < DifPelvic < 10		Proper	Prosthesis Height is <PH> mm.
DifPelvic <– 10 mm		Too low	Prosthesis is lower < DifPelvic > mm

Table 8.9 Shows the limits used for Pelvic Level alignment parameter

The second optimal static alignment parameter was socket AP tilt as detailed in Table 8.10. During static alignment, if the patient stands with a flexed or extended socket along with a non-vertical pylon, the socket is not properly aligned (Radcliffe and Foort, 1961).

The static socket flexion minus the bench, socket flexion would indicate if the socket flexion was correct during stance.

DSF = SocketFlexionS - SocketFlexionB **Equation 8.9**

Where:

DSF was the difference in angle between the socket AP tilt in the bench setting and the socket AP tilt in the static setting. SocketFlexionB was socket AP tilt in the bench setting. SocketFlexionS was the socket AP tilt in the static setting.

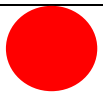
Socket AP tilt in static			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
DSF > 2		Too flexed	The socket is too flexed < DSF > degrees.
-2 < DSF < 2		Proper	Socket AP tilt is < SocketFlexionS > degrees.
DSF < -2		Too extended	The socket is too extended < DSF > degrees.

Table 8.10 Shows the limits used for Socket AP tilt in static alignment parameter

The third optimal static alignment parameter was Socket ML tilt as detailed in Table 8.11. During static alignment, if the patient stood with the socket abducted or adducted along with a non-vertical pylon, then the socket was not properly aligned (Radcliffe and Foort, 1961).

DSML = SocketAdductionS - SocketAdductionB **Equation 8.10**

Where:

DSML was the difference in angle between the socket ML tilt in the static setting and socket ML tilt in bench set. SocketAdductionS was socket ML tilt in the static setting. SocketAdductionB was socket ML tilt in the bench setting.

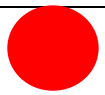
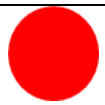
Socket ML tilt in static			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
DSML > 2		Too abducted	Socket is too abducted < DSML > degrees.
-2 < DSML < 2		Proper	Socket AP tilt is < SocketAdductionS > degrees.
DSML < -2		Too adducted	The socket is too adducted < DSML > degrees.

Table 8.11 Shows the limits used for Socket ML tilt in static alignment parameter

8.4.5 Dynamic alignment feedback scenarios

At present, there is no gold standard to achieve an optimal prosthetic alignment. It is performed on an individual basis, where the end-point resulting in a perfect fit is unknown. There is confusion in the literature as to what is an optimal alignment. A review of trans-tibial prosthetic alignment by Neumann, (2009) stated that there is insufficient evidence to make a statement about how to define an optimal alignment.

In this thesis, the dynamic alignment feedbacks were adopted from Prosthetic Observational Gait Score (POGS) by Hilman et al., (2010) as explained previously in Chapter 2 with the application of information of common joint kinematics used to analyse TTP gait. The criteria were also based on kinematic pattern of body segments by observations made in established practice in clinical prosthetics. Hilman et al., (2010) believed that kinematic pattern of body segments would represent the most important pathological features of a TT amputees' gait pattern that could be seen easily. According to (Griškevičius et al., 2018), the kinematic parameters can be objective criteria when deciding on choice of the prosthesis. Kinematic data allow optimal prosthesis adjustment, particularly for bringing the lower limb forward during the swing phase and, at the knee, for providing shock absorbance during the heel-strike phase (Griffet, 2016).

The dynamic alignment feedbacks chose six items out of 16 items. Dynamic alignment feedback scenarios took into account anatomical levels of the trunk, hip and knee. Ankle and foot domain was removed from this alignment feedback due to absence of ankle joint motion in TT amputees using SACH feet. According to a summary by (Nielsen, 2008), Sagittal plane kinematics are more reliable than frontal and transverse, particularly angle measurements for the larger joints such as hip and knee, compared to the measurements for the ankle.

Moreover, symmetry items were also excluded, such as step symmetry and arm swing. However, an indication of correct prosthetic alignment may be provided by an increase in symmetry between the prosthetic side and sound side. Therefore, increasing gait symmetry for TTA does not necessarily result in an improvement of gait (Jonkergouw et al., 2016). When comparing the prosthetic limb with the unaffected side various asymmetries are apparent (Hillman et al., 2010). So, it may be argued that kinematic and spatiotemporal symmetry should not be the goal of dynamic alignment of the prosthesis.

Generally, kinematics of body segments are used to guide optimal dynamic alignment in stance and swing phases (Smith et al., 2004). As mentioned previously in Chapter 2, the tuning feedback was designed for TT amputee using SACH foot. Therefore, with regards to various transtibial prostheses, the phases and subphases of gait are contextually relevant to the design objectives of the prosthesis. For the conventional SACH prosthesis, gait may be reduced to the basic stance and swing phases of gait (Lemoyne, 2016). So, the feedback items were based on only stance and swing. The items which defined which sub phases were excluded due to the sensitivity to determine sub-phase. Therefore, the items in the knee domain were chosen two items out of 4 items.

Therefore, six dynamic alignment feedbacks were selected based on the above statement. Dynamic alignment feedback scenarios were constructed to analyse six aspects of prosthetic alignment as shown in Table 8.12 below.

Dynamic alignment feedback scenarios	Application of information of common joint kinematics used to analyse TTP gait.
Vaulting	The first alignment feedback is Vaulting. Hilman et al., (2010) stated that in normal gait, the total vertical displacement of the head and trunk is around 2% of body height. Vaulting presents an increased vertical motion of the head and trunk affected by plantar flexor activity of the soundside. Correct prosthesis' height must be achieved to obtain a smooth and symmetrical gait with no excessive trunk lean to either side (Kapp and Cummings, 2002).
Peak hip extension in the stance	Hilman et al., (2010) stated the normal hip extension is range 0° - 20°. The severe abnormal hip flexion in the stance shows up as more than 15^{o} of flexion or extension more than 35^{o} (Hillman et al., 2010)
Peak hip Flexion in Swing	Peak hip flexion in the swing is one of the POGS. The normal hip in the swing was between 25^{o} and 45^{o} of flexion (Hillman et al., 2010). Hilman et al., (2010) stated hip motion for flexion in the swing was more than 60^{o} of flexion are indicated as markedly increased and hip flexion less than 10^{o} is indicated as severely reduced (Hillman et al., 2010).
Peak knee extension in the stance	The goals of dynamic alignment (Smith et al., 2004) is to get smooth knee flexion throughout stance (Hillman et al., 2010). At initial contact and during the period of loading response, the knee is maintained in 5^{o} to 10^{o} of flexion (Smith et al., 2004). The normal knee shows a peak of extension in the terminal stance of between 0^{o} and 15^{o} of flexion and is stable with the ground reaction force vector anterior to the knee (Hillman et al., 2010). Hilman et al., (2010) stated knee motion for flexion in the stance is more than 20^{o} is indicated as severe flexion. Knee motion for extension in the stance is more more than 10^{o} is indicated as severe hyperextension (Hillman et al., 2010).

Dynamic alignment feedback scenarios	Application of information of common joint kinematics used to analyse TTP gait.
Peak knee Flexion in Swing	During mid-swing, heel and toe of the foot should swing smoothly without touching the floor (Smith et al., 2004). Hilman et al., (2010) stated normal knee shows a peak of flexion in initial swing should be between 50^{o} - 70^{o} (Hillman et al., 2010). Abnormal knee motion for flexion in the swing was therefore set as more than 70^{o} or less than 35^{o}.
Base of support	During the initial double support period (from stance to swing), the goal is to get a smooth transfer of body weight from amputated side to the sound side (Smith et al., 2004) and to achieve a gait as near normal walking gait as possible (Mccollough et al., 1981). The base of support is the width between the centres of the two heels in successive steps and should be less than 0.5 of the width of the pelvis as shown in (Hillman et al., 2010).

Table 8.12 Six dynamic alignment parameters

8.4.6 Dynamic alignment feedback scenarios Calculation and avatar

Six gait deviations are common in TT amputee gait and can be quantified using the parameters given in Table 8.13 and shown in Figure 8.18.

Optimal dynamic alignment Parameters	Nomenclature
Vaulting	V1
Peak hip extension in the stance (Degrees)	HF1
Peak hip Flexion during Swing (Degrees)	HF2
Peak knee extension in the stance (Degrees)	KF1
Peak knee Flexion during Swing (Degrees)	KF2
Base of support (mm)	SW1

Table 8.13 Optimal dynamic alignment Parameters

The GUI in the CVAT dynamic application was made up of two tabs which allowed the operator to control the software (Figure 8.18). The first tab was patient information (Figure 8.19a). The second tab was the dynamic alignment tab (Figure 8.19b) which allowed setup and control of all dynamic alignment feedback scenarios.

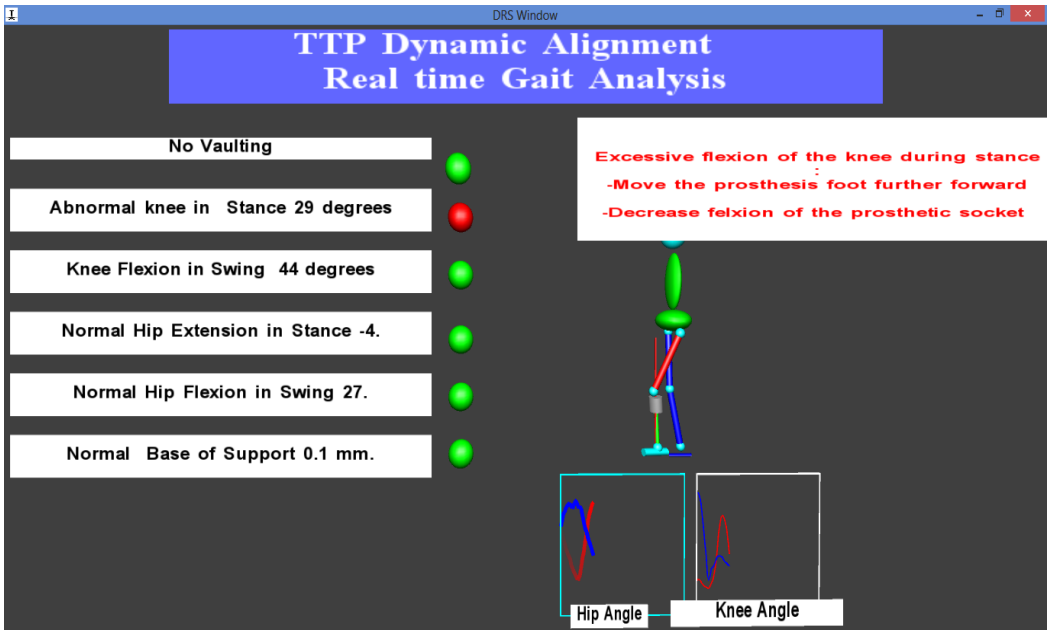


Figure 8.18 Real-time visual display of feedback scenarios during dynamic alignment

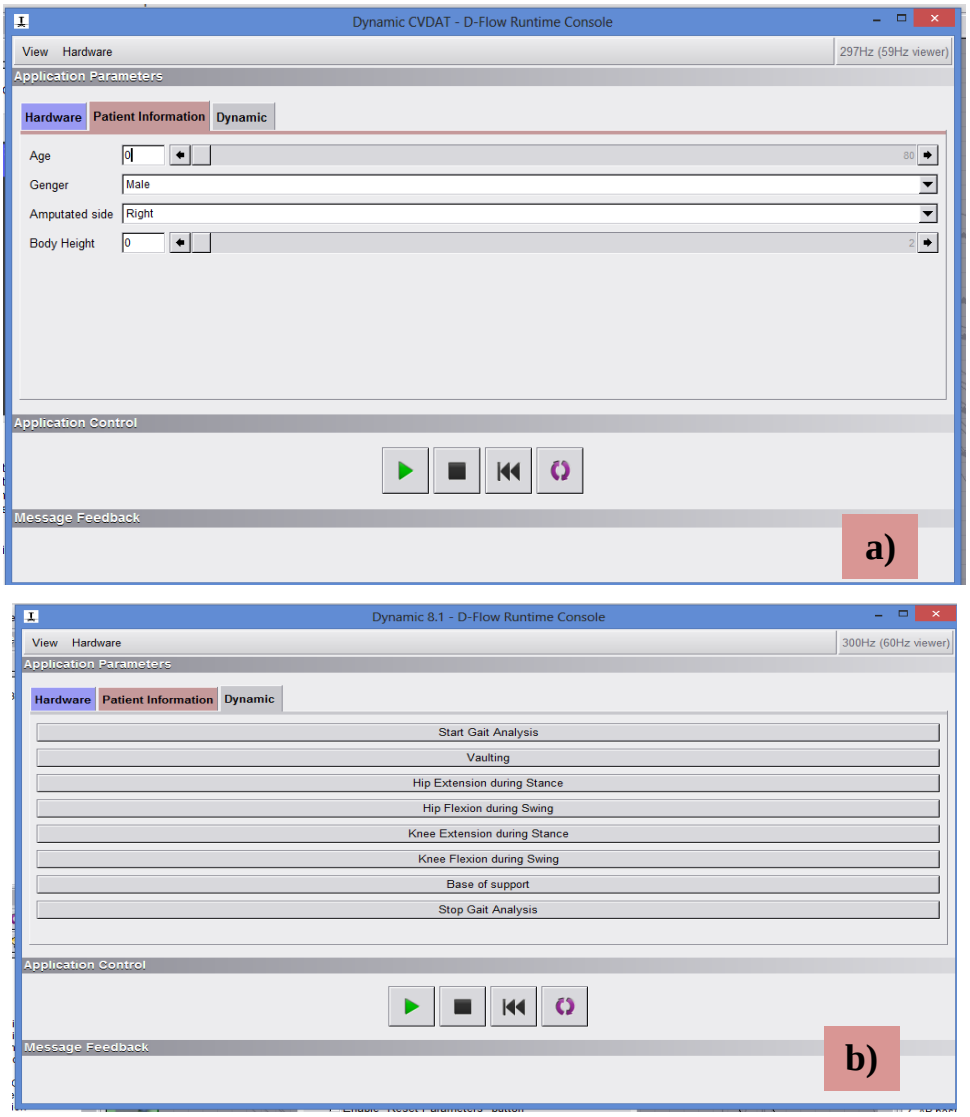


Figure 8.19 The GUI in the CVDAT application is made up of five tabs
a) Patient information b**)** Static alignment tab

Table 8.14 trough Table 8.19 detail the limits for the dynamic alignment parameter used. The written feedback also gave prosthetists feedback on whether each prosthetic alignment was correct or incorrect. Moreover, a sphere in the virtual environment also gave the prosthetists feedback on if the alignment they achieved was “proper or “improper” by turning green or red, respectively.

The first optimal dynamic alignment parameter was vaulting as detailed in Table 8.14. In the dynamic application, the mean of the total vertical displacement of the body (AverageVaulting) was calculated using Equation 8.11A vaulting threshold (VT1) of 2% of body height was applied as shown below.

As the marker was not included head marker. In the algorithm, pelvic markers were used instead of the head marker (Vaulting is happening by used the plantar flexion of the contract side to evaluate the length). Vaulting was calculated as follows:

CM = ((RPSISY + LPSISY + RASISY + LASISY)/4)*1000 (height of pelvic in mm when static) **Equation 8.11a**

CMW = ((gRPSISY + LPSISY + gRASISY + gLASISY)/4)*1000 (height of pelvic in mm during gait) **Equation 8.11b**

Where:

RPSISY, LPSISY, RASISY and LASISY were the marker positions of the iliac spines in the vertical direction during static**.** gRPSISY, gLPSISY, gRASISY and gLASISY were the marker positions of the iliac spines in the vertical direction during dynamic data capture.

$$AverageVaulting = (BodyHeight * 0.02) * 1000 \quad \textbf{Equation 8.11c}$$

$$VT = CM + AverageVaulting \quad \textbf{Equation 8.11d}$$

$$VT1 = CMW - (CM + AverageVaulting) \quad \textbf{Equation 8.11e}$$

Where:

BodyHeight was the patient**'**s height from the patient information tab. CM was the estimated centre of mass in the vertical direction during static alignment**.** CMW was the estimated centre of mass in the vertical direction during the dynamic application**.**

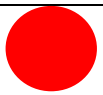
Vaulting			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
VT1 > 0		Too height	Prosthesis too long < VT 1 > mm
VT1 < 0		Proper	No Vaulting.

Table 8.14 Shows the limits for the Vaulting parameter used

The second parameter was peak hip extension in the stance HF1 as detailed in Table 8.15. HF1 was quantified using the centre line of the thigh segment.

The average value of peak hip extension in the stance (HF1) was calculated using the average minimum hip angle during stance phase. (Code in appendix 1)

Peak hip extension in the stance			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
-35 < HF1 > 15		Abnormal	Abnormal Hip Extension < HF1 > degree.
-35 < HF1 < 15		Normal	Normal Hip Extension in Stance < HF1 > degree.

Table 8.15 Shows the limits for Peak hip extension in the stance parameter used

The third parameter was Peak Hip Flexion during Swing HF2 as detailed in Table 8.16. HF2 was calculated from the centre line of the thigh segment and the pelvis.

The average value of peak hip flexion in swing (HF2) was calculated using the average maximum hip angle during swing phase. (Code in appendix 1)

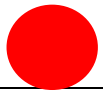
Peak hip flexion in swing			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
HF2 > 60 or <10		Abnormal	Abnormal Hip Extension < HF2 > degree.
10 < HF2 < 60		Normal	Normal Hip Extension in Stance < HF2> degree.

Table 8.16 Shows the limits for Peak hip flexion in swing parameter used

The fourth optimal dynamic alignment parameter was peak knee extension in the stance as detailed in Table 8.17.

The average value of the peak knee extension in the stance (KF1) was calculated using the average maximum knee angle during stance (Code in appendix 1).

Peak knee extension in the stance				
Threshold	**Visual Feedback**	**Result**	**Wording feedback**	**Broadcast the Causes of deviation**
KF1 > 20		Abnormal	Abnormal knee flexion in Stance <KF1> degrees	Excessive flexion of the knee during stance: -Move the prosthesis foot further forward -Decrease flexion of the prosthetic socket
-10 < KF1 < 20		Normal	Knee Flexion in Stance < KF1 > degrees.	-
KF1 < 0		Abnormal	Abnormal knee flexion in Stance <KF1> degrees	Insufficient Knee Flexion during Stance: ----Move the prosthesis foot further back ----Increase flexion of the prosthetic socket

Table 8.17 Shows the limits for Peak knee extension in the stance parameter used

The fifth optimal dynamic alignment parameter was peak knee flexion in the swing as detailed in Table 8.18.

The average value of peak knee flexion in swing (KF2) was calculated using the average maximum knee angle during the swing phase (code in appendix 1).

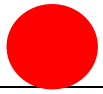
Peak knee flexion in swing			
Threshold	**Visual Feedback**	**Result**	**Wording feedback**
35 > KF2 > 70		Abnormal	Abnormal knee flexion in Stance < KF2 > degrees
35< KF2 < 70		Normal	Knee Flexion in Stance < KF2 > degrees.

Table 8.18 Shows the limits for Peak knee flexion in swing parameter used

The sixth and final optimal dynamic alignment parameter was base of support (SW1) as detailed in Table 8.19. The step width was calculated as follows.

g_AstepWidth= math.abs (g_storeAHeelPosZ - g_storeSHeelPosZ) **Equation 8.12a**

g_SstepWidth= math.abs (g_storeSHeelPosZ - g_storeAHeelPosZ) **Equation 8.12b**

Where:

g_AstepWidth was the width between the centres of the heels on the amputated and sound side calculated using equation 8.12a. g_SstepWidth was the width between the centre of the heels on amputated and sound side calculated using equation 8.12b. g_storeAHeelPosZ was the heel marker position in the coronal plane on the amputated limb at initial contact. g_storeSHeelPosZ was the heel position marker in the coronal plane on sound at initial contact.

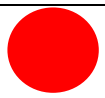
Base of support				
Threshold	**Visual Feedback**	**Result**	**Wording feedback**	**Broadcast the Causes of deviation**
BOSDif > 0		Too wide	Width of base < BOSDif > mm.	Width base gait: -Prosthesis too long -Foot position too far medially -Socket set in an abduction
DifPelvic < 0		Proper	Normal Base of Support	-

Table 8.19 Shows the limits for Base of support parameter used

BOS = **(**math**.**abs **(**g_AstepWidth**)**+ math**.**abs**(**g_SstepWidth**))**/2 **Equation 8.12c**

BOSStatic = math**.**abs **(**RASISZ - LASISZ**)***0.5 **Equation 8.12d**

BOSDif = (BOS - BOSStatic) **Equation 8.12e**

Where:

BOS was the average width between the centre of the heels during the gait analysis.

BOSStatic was the width between RASIS and LASIS during static capture. RASISy was the anterior superior iliac spine position in the coronal plane. LASISy was the anterior superior iliac spine position in the coronal plane.

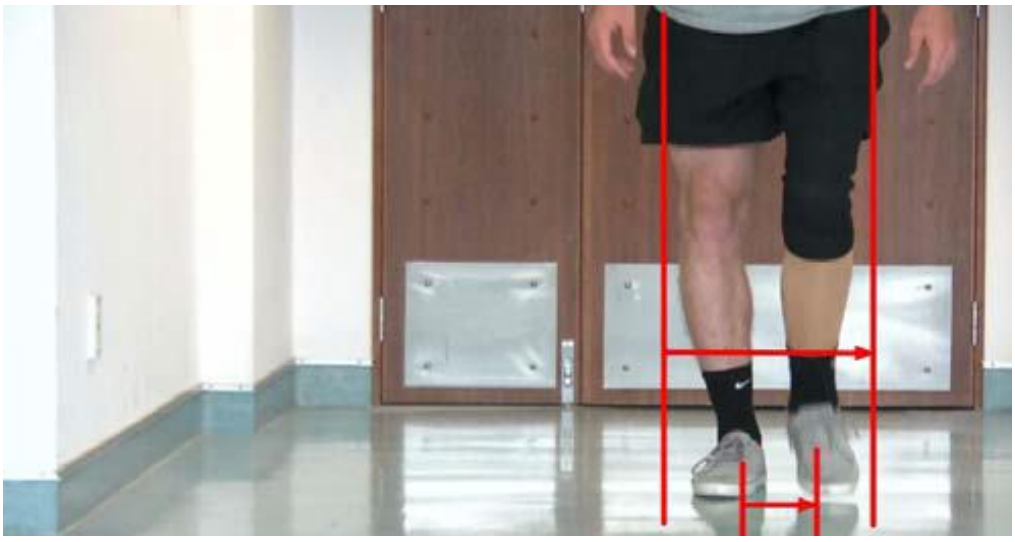


Figure 8.20 Base of support by Hillaman et al., (2010)

The development of interactive virtual reality dynamic feedback using the D-flow environment allowed feedback of the body segments and prosthesis as shown in Figure 8.21. The application also drew in real-time graphs of hip and knee flexion during each gait cycle (Figure 8.22). The avatar of amputee movement (Code appendix 1) was developed based on Millar, (2016). The patient segments and the prosthesis avatar were developed for this dynamic application (Figure 8.21). The work of MacDonald et al., (2009) discussed how patients were comfortable viewing only the segments of interest when performing movement tasks and hence the movement of the arms was not included. The trunk and head were modelled as a single segment using the pelvic markers.

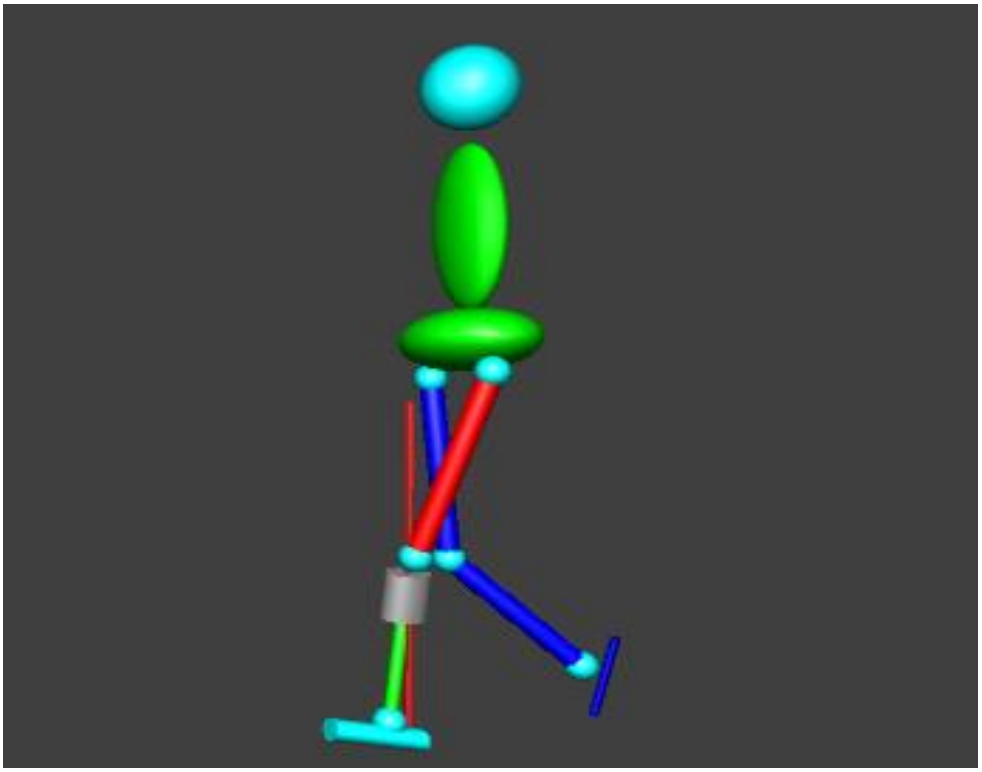


Figure 8.21 Visualisation screenshots are showing an avatar from one patient**:** an avatar of the amputee with TTP movements within D-flow**.** The prosthesis and patient**'** segments are driven by the marker placed on the prosthesis

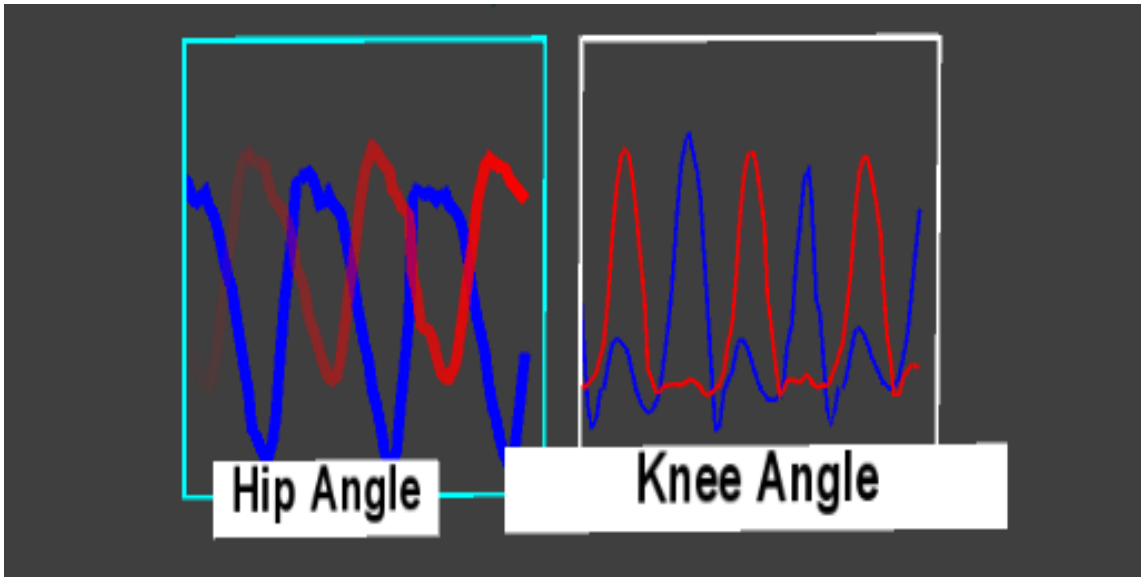


Figure 8.22 visualisation screenshots are showing real-time hip and knee angles from one amputee during dynamic tuning**.** The solid red line indicated the joint motion on the amputated side**.** Blue solid line indicated the joint motion on the sound side.

Having established the biomechanical model (Chapter 7) and the feedback parameters for successful bench, static and dynamic alignment and tuning (Chapter 8), in order to complete the aims of this study it was necessary to complete a clinical trial of the CVAT system.

Chapter 9. The alignment of a trans-tibial prosthesis using the "Conventional" and "CVAT system" when used by prosthetists and the effect on the subject's gait

9.1 Introduction

As discussed in Chapter 1 and summarised in Chapter 2, lower limb amputation (LLA) is the most common amputation among several amputation levels in both normal people and military populations (Thirapatarapong and Dajpratham, 2009). Among the several LLA levels, trans-tibial amputation (TTA) is recorded as the most common lower limb amputation level (Zahedi et al., 1986).

The prosthesis used by an amputee can restore and improve function as well as providing a more cosmetic appearance of the residual limb. During the construction of a prosthesis, the alignment protocol plays an essential role in the prosthetic function and successful fitting (Kobayashi et al., 2013). To be effective, the alignment between the foot and the socket must be finely adjusted. A trans-tibial prosthetic alignment can be described as six degrees of freedom interrelationship between socket and foot. Moreover, dynamic alignment is a crucial step in aligning the prosthesis, aiming to achieve the most suitable limb position to achieve the desired function and comfort. Particularly during gait, misalignment may result in walking difficulty, skin abrasion and uneven forces acting on the residual limb within the socket, which can lead to the creation of wounds and more severe skin and joint trauma (Blumentritt, 1997; Fridman et al., 2003; Zahedi et al., 1986).

Previous studies have shown that final optimal alignment may considerably vary (Reisinger et al., 2007; Zahedi et al., 1986). In current clinical practice, prosthetists greatly rely on their personal experiences and skills (Kobayashi et al., 2015), but unfortunately, both skill and time are frequently lacking in the developing world. Thus, it is necessary to develop tools and techniques that will allow prosthetists or prosthetic technicians with little experience to properly align prostheses in less time.

These observations provided the encouragement for developing a alignment techniques that might result in prostheses offering acceptable alignment for patient, without requiring the time- consuming alignment process or the skill of an experienced prosthetist.

Previously in this research, we have designed, developed and piloted a system called “Computerised motion capture and Visualisation system for assisted Alignment Technique (CVAT)”. The study reported in this chapter was designed to evaluate the

usability of the new motion capture tuning system which provides visual data on the alignment of the prosthesis and the resulting gait of the amputee to the prosthetist at the time of prosthetic alignment.

In this study, two alignment techniques were compared. The first was the conventional alignment technique – alignment of a trans-tibial prosthesis performed by a prosthetist based on visual observation and their history of the practice. The second method was CVAT – alignment with the help of real-time outcome information provided by the D-flow application (Chapters 7 and 8).

The objective of this final study was to look at the usability of the system when used by a variety of trained prosthetists with a variety of experience levels, to gather their opinions and comments on the system, to compare the kinematic biomechanical outcomes in terms of gait from the two methods, and finally to gauge any increase in dynamic alignment efficiency and effectiveness brought about by the CVAT system when performing alignment.

9.2 Method

9.2.1 Participants

One trans-tibial unilateral amputee was recruited along with 14 prosthetists. Only one amputee was included in this study. This is because there were a number of participants' characteristic factors effects on alignment when assessing alignment outcomes. These factors were foot and suspension types, toe-in/toe-out positions of the prosthetic foot, shoe designs, participants' weights, and residual limb lengths.

The prosthetists were selected using the criteria in Table 9.1. This study was approved by the University of Strathclyde Research Ethics Committee. Participants (both amputee and prosthetists) were provided with information about the study (appendixes 4 and 7). Written informed consent (appendixes 5 and 8) was obtained before participation. The study was conducted in the Biomechanics Laboratory, Department of Biomedical Engineering, University of Strathclyde and in the West of Scotland Mobility and Rehabilitation Centre (WestMARC). The 14 prosthetists recruited consisted of students (n = 3), prosthetic lecturers (n = 1) and practising prosthetists from the local prosthetics service (n = 10). The student was included to investigate the effect of using the system in the less experience in tuning prostheses. One trans-tibial amputee was recruited for the study, selected using the criteria in Table 9.2. This study did not use the amputee's actual prosthesis but fabricated an identical socket and used this. An identical socket adapter, pylon, and prosthetic foot were used for the copy prosthesis in all experiments. This copy prosthesis was only in use during the test sessions.

Inclusion Criteria
A practising prosthetist or in the 3rd and 4th year of a prosthetics course in the UK,
Capable of giving informed consent
Exclusion Criteria
Unable to comply with directions and comprehend written and spoken English,

Table 9.1 Inclusion and exclusion criteria for the participating prosthetists

Inclusion Criteria
Unilateral trans-tibial amputation performed more than one year with medium/long stump length,
Functional level 3, 4
Able to walk for a long time,
A good current condition of health,
Between 18-65 years old
Normal ROM in all joints in the lower limb,
Amputees who had worn the prosthesis for more than six months,
Resident within Glasgow
Muscles strength grade 4 – 5 according to Oxford scale,
Able to comply with directions and comprehend written and spoken English,

Exclusion Criteria
Pain or neuroma at the stump
A residual limb with wounds, congestion or extreme volume changes,
An amputee with diabetic, hypertension or other severe medical conditions,
An amputee who have problems with the sound side which can influence the gait,
An amputee with joint or muscle contractures either on stump side or sound side.
Pain or neuroma at the stump

Table 9.2 Inclusion and exclusion criteria for the participating amputee

9.2.2 Data collection procedures

Before experimentation, all participants were asked to read the Participant Information Sheet and sign the Consent Form. The 14 eligible prosthetists who met the inclusion criteria were booked in for two sessions, one for each alignment method. Each prosthetist was asked to fit the limb both without and with the visualisation software (CVAT). The first intervention was tuning the TTP by using the conventional method and the second intervention was tuning the TTP by using the CVAT system (Figure 9.1) to assist and give the alignment recommendation back to the prosthetists. During the tuning of the TTP by using the CVAT system, the

marker on prosthetic was permanently attached on the prosthesis as we used only one prosthesis in this study. There was no requirement for individual markers to be attached to patients.. Only the cluster was attached to patients' segment by the researcher (The prosthetist was done only calibration marker by using the pointer). The prosthetist was asked to use the pointer to point at the bony prominence which was indicated by system. During calibration, the prosthetists just need to follow indications on the screen as shown in figure 8.11. The study scheme of this study is shown in Figure 9.2.

Figure 9.1 Intervention is tuning the TTP by using the CVAT system

After the two experimental sessions, the prosthetist was asked to fill in a questionnaire (appendix 6). In one session, the amputee walked with the copy prosthesis, and this was aligned using conventional methods. Gait analysis was performed after the prosthetist conducted the alignment. Markers were attached to the amputee by the researcher, using the SCM model previously described. The same biomechanical protocol was used to collect data for both techniques. The same motion capture system was also used to minimise calculation and system errors (Chiari et al., 2005; Schwartz et al., 2004).

During data collection, the amputee walked on a self-paced treadmill. This is a treadmill that paces itself to the movement of the subject; if they speed up or slow

down so does the treadmill. The amputee was given plenty of time to get used to this system before the testing began.

In the other session, the amputee walked with the copy prosthesis, which was aligned using the new CVAT method including the purpose-written D-flow application. The CVAT method required the prosthetist to attach the marker to the amputee, using the TTP marker model protocol (Chapter 8). The data collection for the gait outcome was performed after a settled alignment was achieved.

The self-paced treadmill (Motex Forcelink N-mill), motion capture system (Vicon Bonita Tracker software) and D-flow software (Motek Medical Ltd of Amsterdam) were all CE marked as medical devices and were used within their typical mode of operation.

9.2.3 Data Processing

One expert carried out all gait analysis data processing. Data processing of both sessions was performed using Vicon Nexus 2.1.1 and Vicon BodyLanguage programs (Vicon, Oxford Metrics Ltd., UK). Three-dimensional marker trajectories were reconstructed. A coordinate-based treadmill algorithm was used to identify heel strike (HS). The algorithm was developed for determining events on the treadmill by Zeni et al., (2008). The algorithm was based on the value of the X coordinates of a heel marker over time. The algorithm uses the peak X values which correspond to the time at which the foot comes into contact with the treadmill belt. Peaks caused by HS were found by identifying the time of the maximum value of the difference in the X position of the foot marker and the sacral marker (Zeni et al., 2008). Marker trajectory data was then processed for each detected gait cycle with the movement of the treadmill factored in and gait cycle kinematic data calculated for the identified cycle. Five cycles in which a good quality set of marker trajectories was exhibited were extracted for analyses. All marker data was filtered using a second-order low pass Butterworth filter with a cut-off frequency of 6Hz (Sloot et al., 2014).

9.2.4 Data analysis

9.2.4.1 Quantitative analysis

Gait data was further processed using Microsoft Excel VBA (Microsoft Corp., Washington, DC, USA) including joint angle calculation and normalisation to 101 points (0 -100) per gait cycle (Code in appendix 1). The amputated limb and contralateral limb gait cycle were extracted from each of the five good cycles (i.e., ones in which there was a good quality set of marker trajectories). Next, data from the two dynamic alignment techniques was compared to address the research question. The primary outcome measurement for this study was the kinematic data of the hip and knee joint in the sagittal plane.

9.2.4.2 Qualitative analysis

In order to determine the acceptability of the new CVAT system to the practitioner, a questionnaire was developed (Appendix 5) to determine the "user experience" of the practitioner with the system. The questionnaire aimed to assess the usability of the system, how the system could be improved, and what was beneficial or an obstruction to the use of the system.

9.2.5 Statistical considerations

After data collection, qualitative analysis was used to describe the participants' responses to the questions. This qualitative data was presented in term of themes and categories. The gait data obtained at the end of each test session was compared and contrasted. Differences in alignment and gait between the two methods of alignment were quantified using key kinematic parameters (Table 9.3 and Table 9.4). Key kinematic parameters were decided based on the fact that human locomotion entails movement primarily in the sagittal plane (Neumann, 2009). Moreover, the sagittal plane kinematics have been suggested to be more reliable than frontal and transverse, particularly angle measurements for the larger joints such as hip and knee, compared to the measurements for the ankle (Nielsen, 2008).

Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0. The kinematic gait parameters for the two alignment techniques (Conventional vs CVAT) were compared. Nonparametric statistics were tested for significance using Wilcoxon signed rank test and Mann–Whitney U test ($\alpha = 0.05$) for comparing alignment tuning by inexperience prosthetists ($n = 4$). Parametric statistics were tested for significance using t-tests ($\alpha = 0.05$) for comparing alignment tuned by experience prosthetists ($n = 10$).

Bonferroni correction was applied to multiple t-test ($\alpha = 0.05/3=0.017$). The t-tests were carried out to determine any significant difference between normal and outcome for each outcome measure. The normal gait data from the study of the able-bodied subjects from Chapter 4 was used as the comparison. The kinematics was calculated using the SCM method. Quantitative gait analysis is considered to be an objective means that can be used to measure walking performance (Gard, 2006). Key advantages of quantitative gait analysis for persons with lower-limb pathologies are that the results allow for easy comparison of a patient's gait characteristics with those from an able-bodied person and give a relatively quick determination of abnormal movements (Gard, 2006).

Hip Joint Parameters	
H1	Hip flex/extension ROM
H2	Peak Stance Extension
H3	Peak Swing Flexion

Table 9.3 Hip joint angle parameters.

Knee Joint Parameters	
K1	Knee flex/extension ROM
K2	Peak Stance Flexion
K3	Peak Swing Flexion

Table 9.4 Knee joint angle parameters.

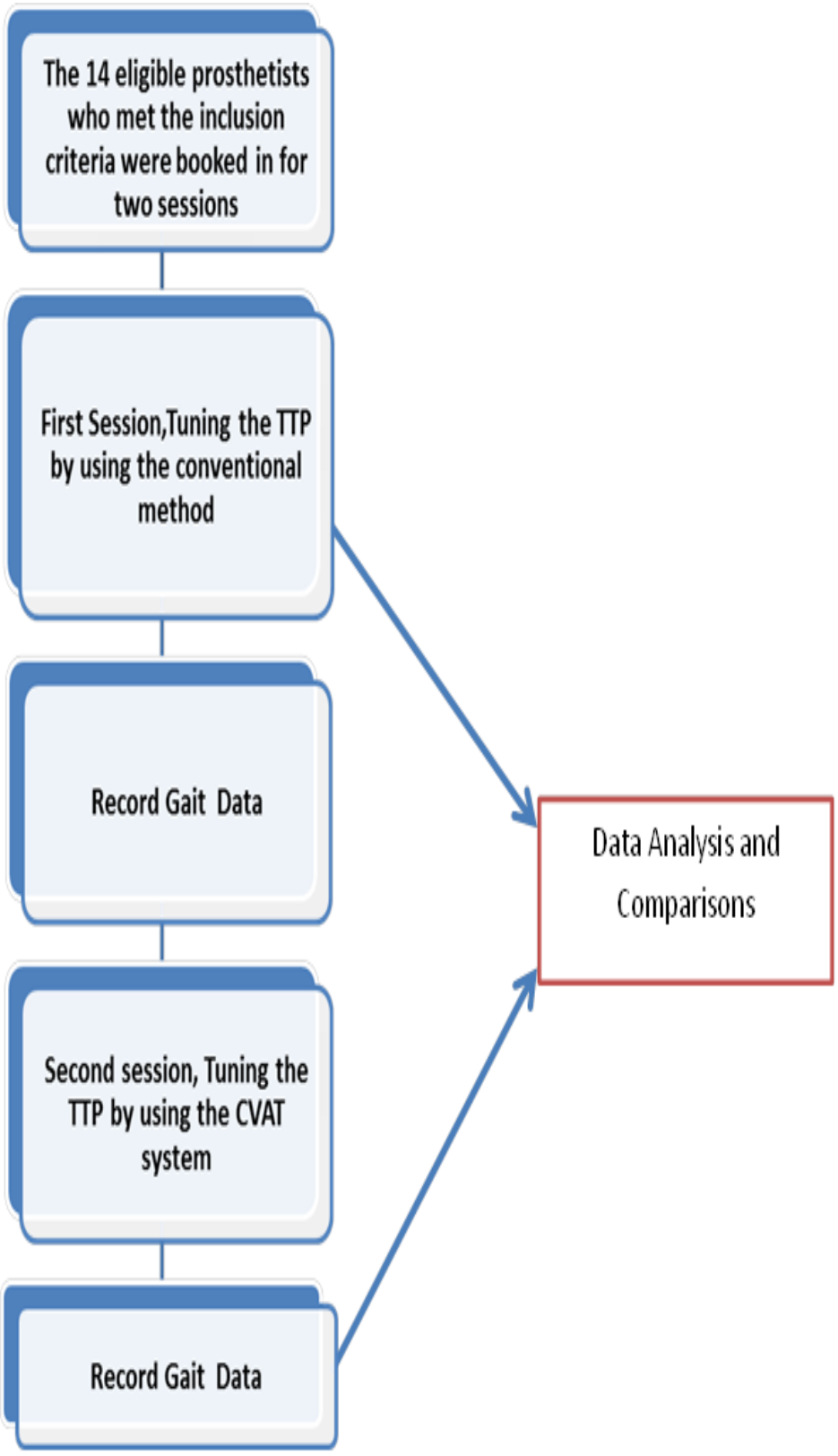


Figure 9.2 The study scheme

9.3 Results

9.3.1 Comparisons of kinematic data

Kinematics of the group gait data were calculated when the alignment was performed by inexperience and practising prosthetists and when using the conventional and the CVAT method. This produced four sets of data which are fully reported in appendix 9. All fourteen visual observations of plotted data by cycle and participant showed that a consistent gait pattern was produced. Although there were noticeable differences in the data, no outliers or inconsistencies were observed. Hence summary data for each individual at each test point were calculated and are included in appendix 9 (six tables; one for each parameter calculated).

In this chapter, the outcome data are presented according to the experience of prosthetists.

The first group is the four inexperienced prosthetists. The second group is the ten expert clinical staff.

9.3.1.1 Data from inexperience prosthetists (student and lecturer)

Figures 9.3-9.6 present hip and knee joint sagittal plane rotations from the SCM model of gait produced when the amputee walked with a prosthesis tuned by the four inexperienced prosthetists using both methods compared to normal data. The graphs in Figure 9.3 and Figure 9.5 show mean normal, sound side and amputated side gait data. Figure 9.4 and Figure 9.6 show the same mean data but with ± 1SD for knee and hip kinematics in the sagittal plane.

Good similarity of joint angle pattern was observed between the CVAT method and normal (Figure 9.3 and Figure 9.5), for both amputated and sound side processed data. It can be seen that the kinematic curves for the CVAT method showed less variability (Figure 9.5) than the kinematic curves for the conventional method.

Standard deviation bars of hip and knee sagittal plane rotation (Figure 9.4 and Figure 9.6) showed the amputee's kinematic gait data when the prosthetic was tuned

using the CVAT method were closer to normal data than when tuning was performed with the conventional method.

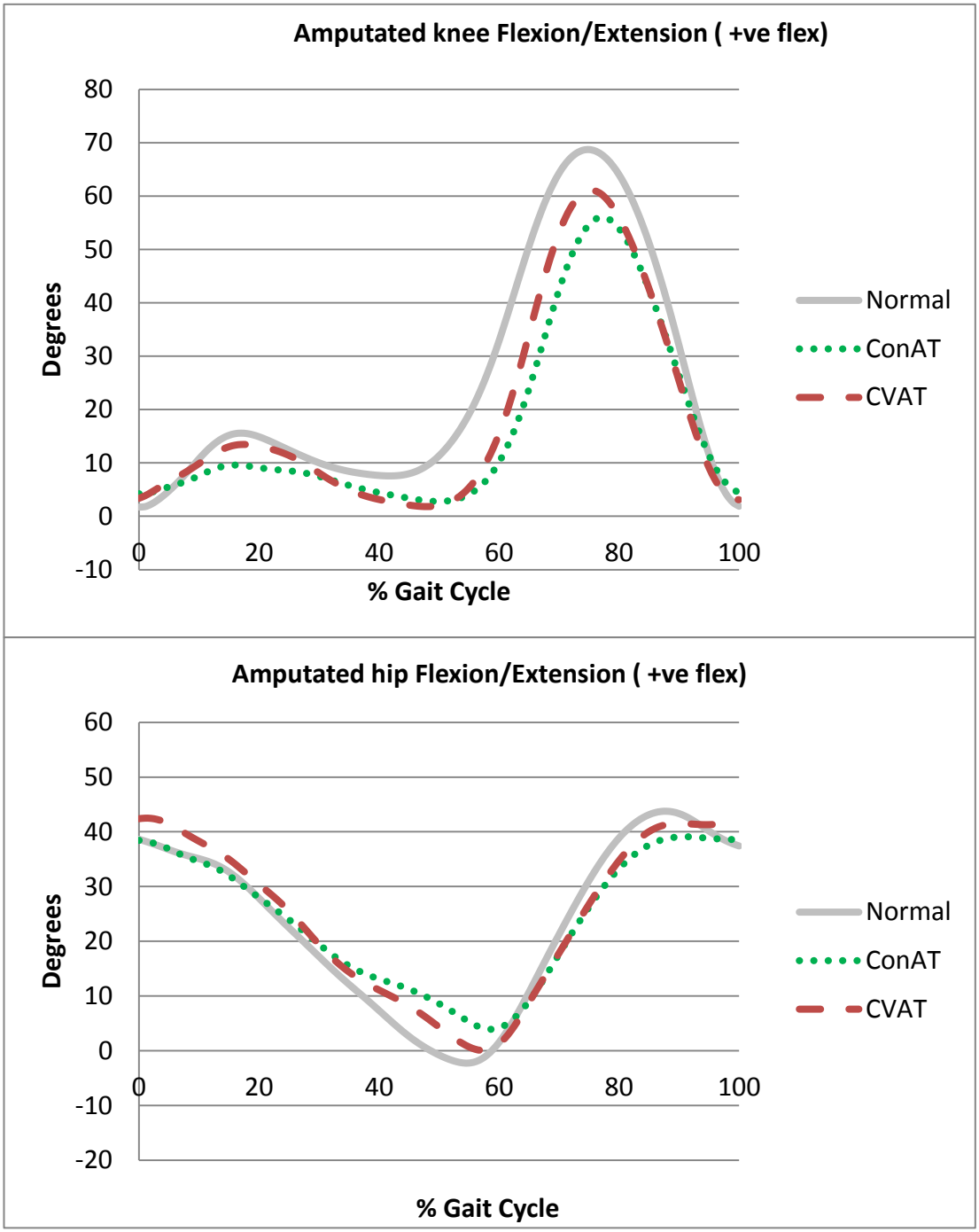


Figure 9.3 The mean normal and amputee gait data for knee and hip kinematics on the sagittal plane when walking with prosthesis tuned by four inexperienced prosthetists.

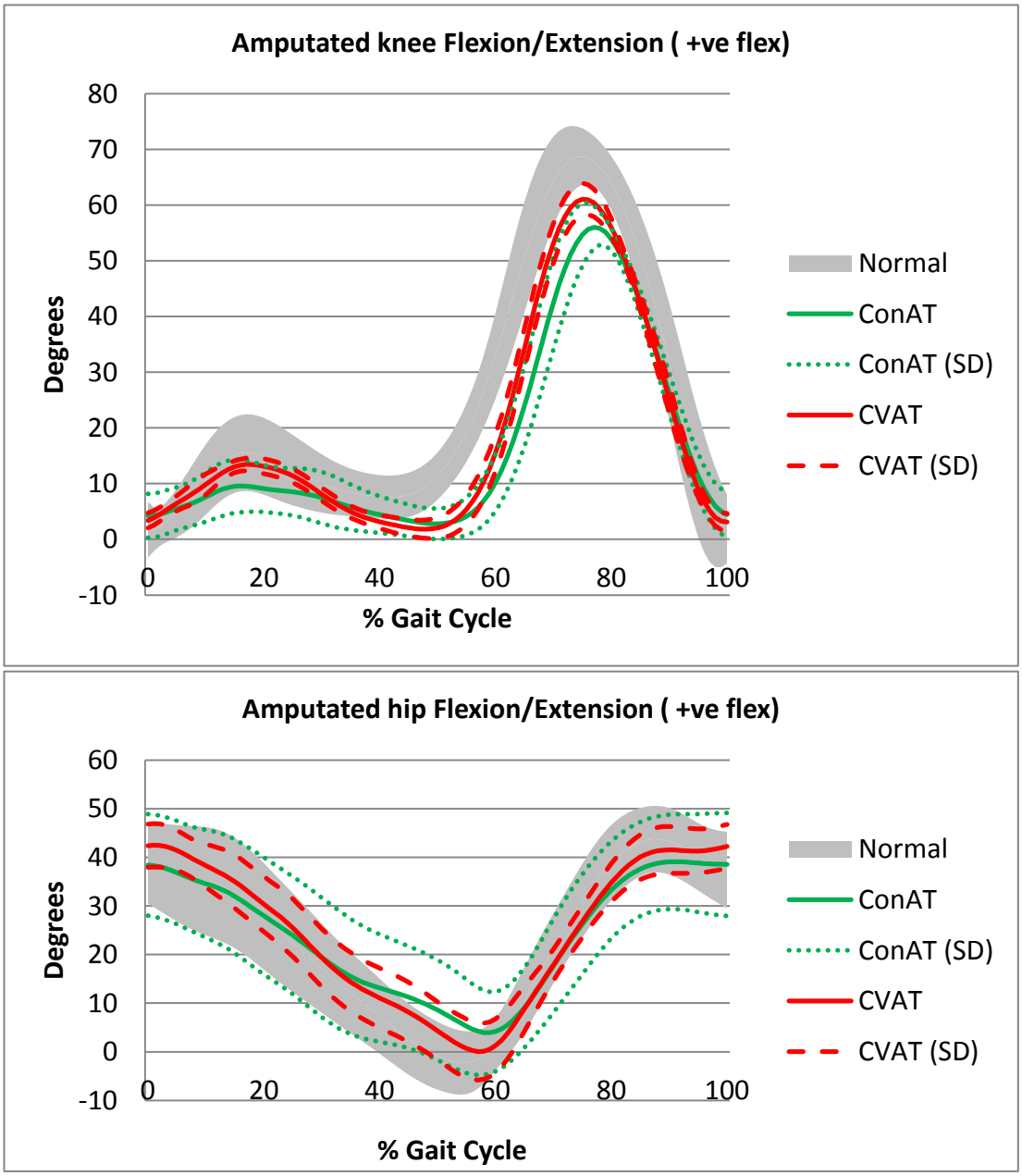


Figure 9.4 The mean normal and amputee gait data ± 1SD for knee and hip kinematics on the sagittal plane when walking with prosthesis tuned by four inexperience prosthetists.

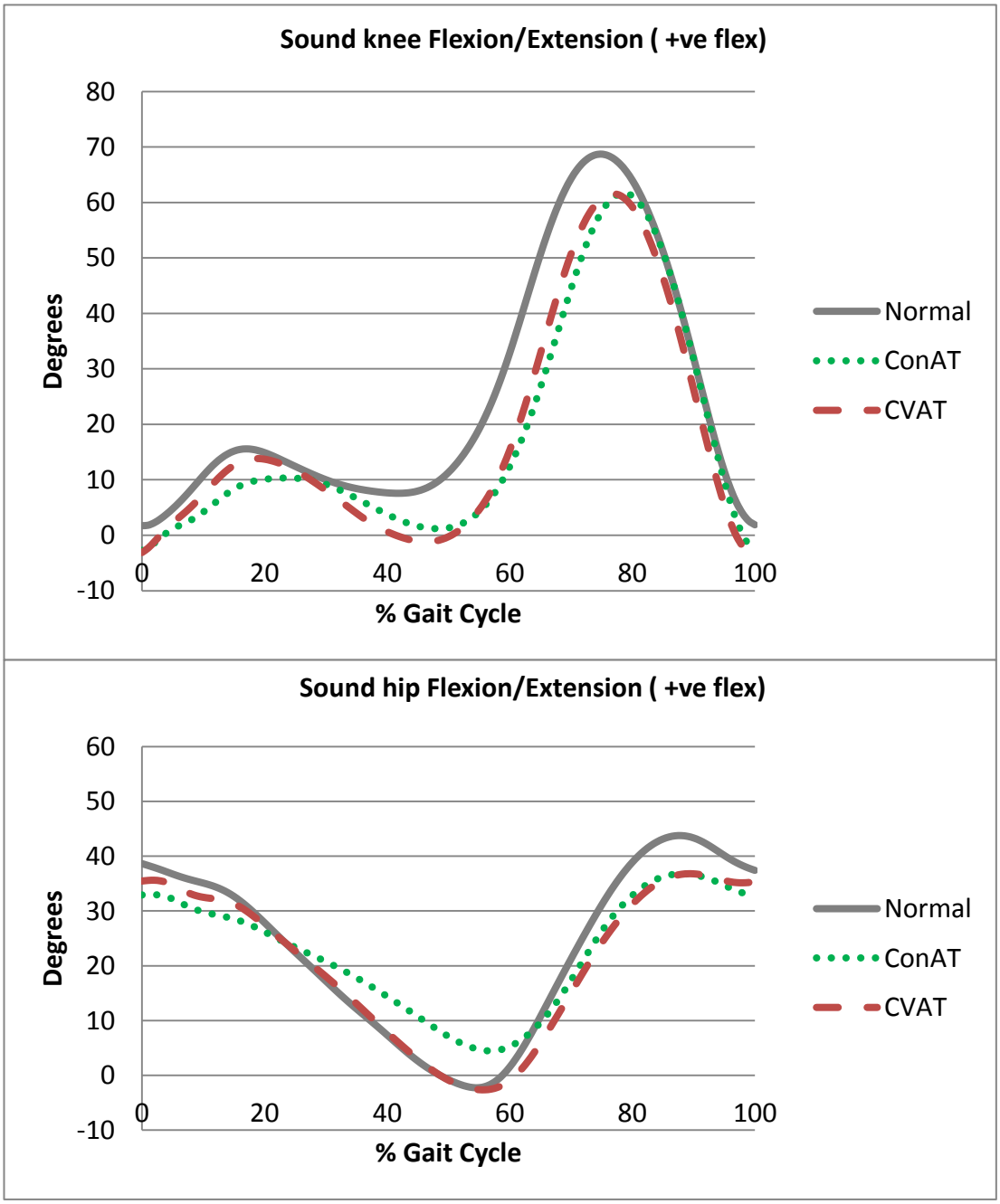


Figure 9.5 The mean normal and sound gait data for knee and hip kinematics on the sagittal plane when walking with prosthesis tuned by four inexperience prosthetists.

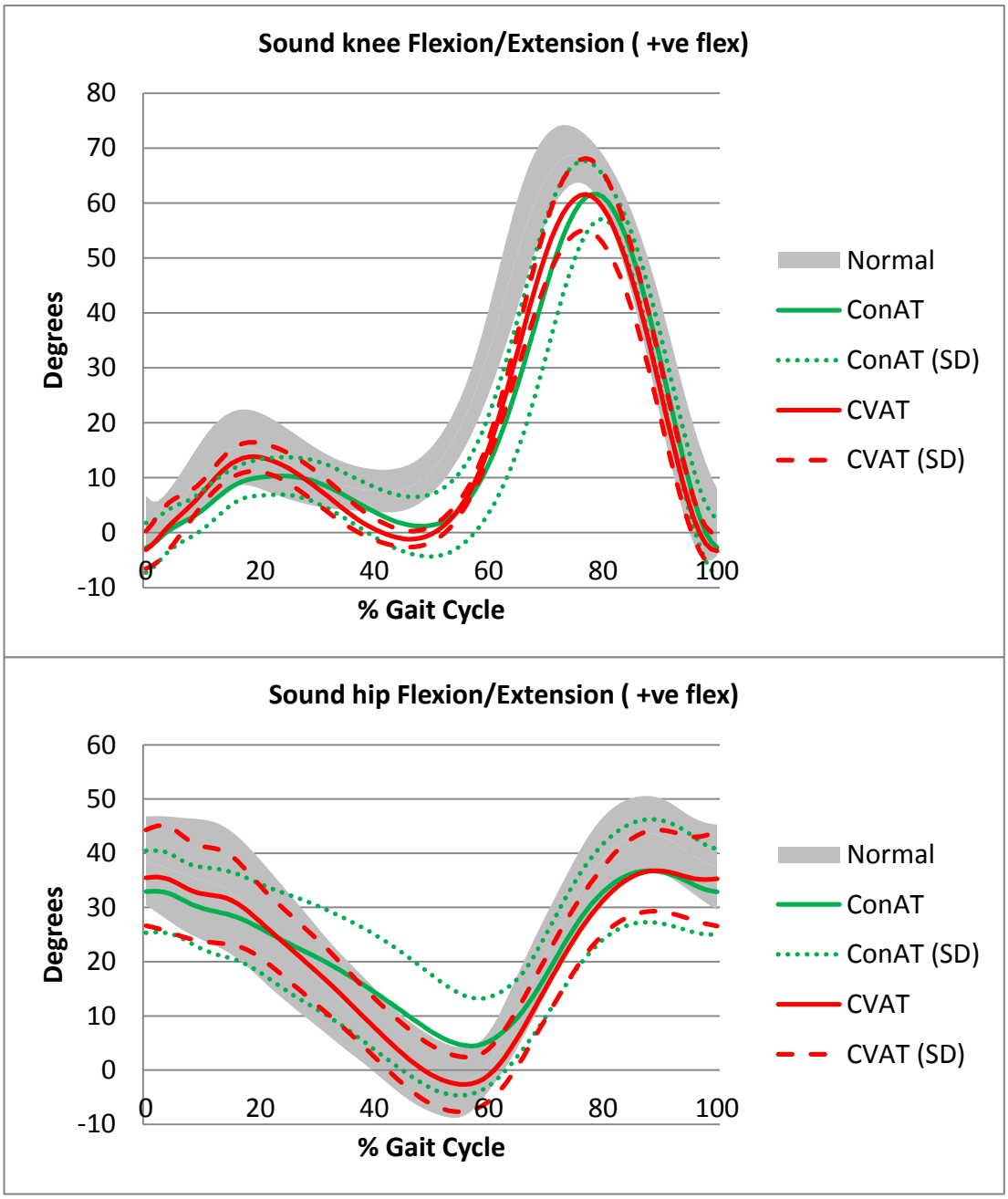


Figure 9.6 The mean normal and sound gait data ± 1SD for knee and hip kinematics on the sagittal plane when walking with prosthesis tuned by four less experience prosthetists.

Parameters	Conventional (ConAT)	CVAT	Normal	P-value		
	Mean ±SD	Mean ±SD	Mean ±SD	ConAT & Normal	CVAT & Normal	CVAT & ConAT
Hip Flexion ROM(°); H1	35.7±2.6	42.6±3.2	47.4±5.9	**0.004***	0.106	0.068
Hip Peak Stance Extension(°); H2	3.8±8.6	0.0±5.0	-2.9±6.0	0.106	0.454	0.715
Hip Peak Swing Flexion(°); H3;	39.5±10.2	42.3±4.0	44.4±6.9	0.454	0.539	0.715
Knee Flexion ROM(°); K1	55.2±2.5	59.5±2.0	70.6±7.4	**0.002****	**0.014****	0.144
Knee Peak Stance Flexion (°); K2	14.1±5.0	18.5±3.0	39.9±8.9	**0.002****	**0.004****	0.068
Knee Peak Swing Flexion (°); K3	56.6±3.3	61.1±2.5	69.7±4.9	**0.002****	**0.008****	0.068

Table 9.5 Mean kinematic output ± 1SD for the amputated side walked with prosthesis tuning by four inexperience prosthetists.
* Indicates significance level of $\alpha = 0.05$

** Indicates significance level of $\alpha = 0.017$ after Bonferroni correction (0.05/3)

The mean values and SD for gait data when tuning was performed by the four inexperience prosthetists were summarised and compared using Wilcoxon signed rank test and Mann–Whitney U test ($\alpha = 0.05$) (Table 9.5 and Table 9.6).

The results in Table 9.5 showed that all kinematic output for the amputated side when the prosthesis was tuned using the CVAT method was improved and close to normal data. Smaller standard deviations were observed when the amputee walked with a prosthesis tuned by the CVAT method. The knee parameters in the sagittal plane (K1, K2 and K3) for the amputated side with the prosthesis tuned by four inexperience prosthetists were significantly different between the conventional and normal, as they were for the CVAT and normal.

For the hip, there was a statistically significant difference in hip parameter (H1) between the conventional and normal. However, there was no such significant difference between the CVAT method and normal. None of the CVAT methods demonstrated a significant difference when compared to the conventional method ($\alpha = 0.017$). For the hip, there was a statistically significant difference in hip parameter (H1) between the conventional and normal. However, there was no such significant difference between the CVAT method and normal. None of the CVAT methods demonstrated a significant difference when compared to the conventional method ($\alpha = 0.017$).

Parameters	Conventional (ConAT)	CVAT	Normal	P-value		
	Mean ±SD	Mean ±SD	Mean ±SD	ConAT & Normal	CVAT & Normal	CVAT & ConAT
Hip Flexion ROM (°); H1	32.7±5.3	39.8±3.5	47.4±5.9	**0.004****	**0.024***	0.068
Hip Peak Stance Extension (°); H2	4.1±8.6	-2.7±4.4	-2.9±6.0	0.240	1.000	0.273
Hip Peak Swing Flexion (°); H3	36.8±9.5	36.8±6.5	44.4±6.9	0.142	0.142	1.000
Knee Flexion ROM (°); K1	65.5±6.7	65.0±6	70.6±7.4	0.454	0.374	0.715
Knee Peak Stance Flexion (°); K2	15.5±8.7	18.4±1.6	39.9±8.9	**0.009****	**0.003****	0.715
Knee Peak Swing Flexion (°); K3	62.6±4.7	70.6±2.9	69.7±4.9	0.076	0.050	0.465

Table 9.6 Mean kinematic output ± 1SD for the sound side walked with prosthesis tuning by four inexperience prosthetists.

* Indicates significance level of $\alpha = 0.05$

** Indicates significance level of $\alpha = 0.017$ after Bonferroni correction (0.05/3)

Table 9.6 showed that four of the six kinematic outputs (H1, K2 and K3) for the sound side with the prosthesis tuning using the CVAT method were improved and closer to normal data than for the conventional method, with the other two being the same. All kinematic outputs for the sound side with the prosthesis tuned using the CVAT method showed a low standard deviation which indicates that there is less variability when using CVAT.

When the kinematic output of the conventional tuning was compared to CVAT and normal groups, the hip and knee parameters in the sagittal plane (H1 and K2) for the sound side tuning by four inexperience prosthetists were significantly different (Table 9.6). There was a significant difference in two of the six parameters (H1 and K2) between the CVAT and normal ($p < 0.017$).

In general, the CVAT method showed a better gait, less variability and an objectively more normal gait for both the amputated and sound sides compared to the conventional method, indicating that this system leads to some improvement in outcome when used by this inexperienced group of prosthetists.

9.3.1.2 Data from practising prosthetists

The hip and knee joint sagittal plane kinematics from the SCM model of gait produced when the amputee walked with a prosthesis tuned by ten practising prosthetists are illustrated in Figure 9.7 through Figure 9.10 for both methods so as to allow comparisons between the two alignment techniques performed and with healthy subject gait data.

The graphs in Figure 9.7 and Figure 9.9 showed mean normal, sound side and amputated side gait data and Figure 9.8 and Figure 9.10 showed these same mean curves with ± 1SD for knee and hip kinematics on the sagittal plane.

A high degree of similarity in joint angle patterns were again observed from both methods (the CVAT and conventional method) and normal data (Figure 9.7 and Figure 9.9), for both the amputated and sound side data. It can be seen that the kinematic curves for the CVAT and conventional method provided similar results when practising prosthetists were involved. The hip and knee ROM data for both

sides in the sagittal plane of the amputee, with prosthesis tuning performed using either method, were lower than the knee ROM data of healthy gait.

Comparison of the CVAT and conventional methods to normal data revealed that tuning with the CVAT method, as visualised in Figure 9.8 and Figure 9.10, showed the amputee's kinematic gait data to be slightly closer to normal data with the CVAT than when tuning with the conventional method by inexperienced prosthetists, but to a lesser degree than for experienced prosthetists.

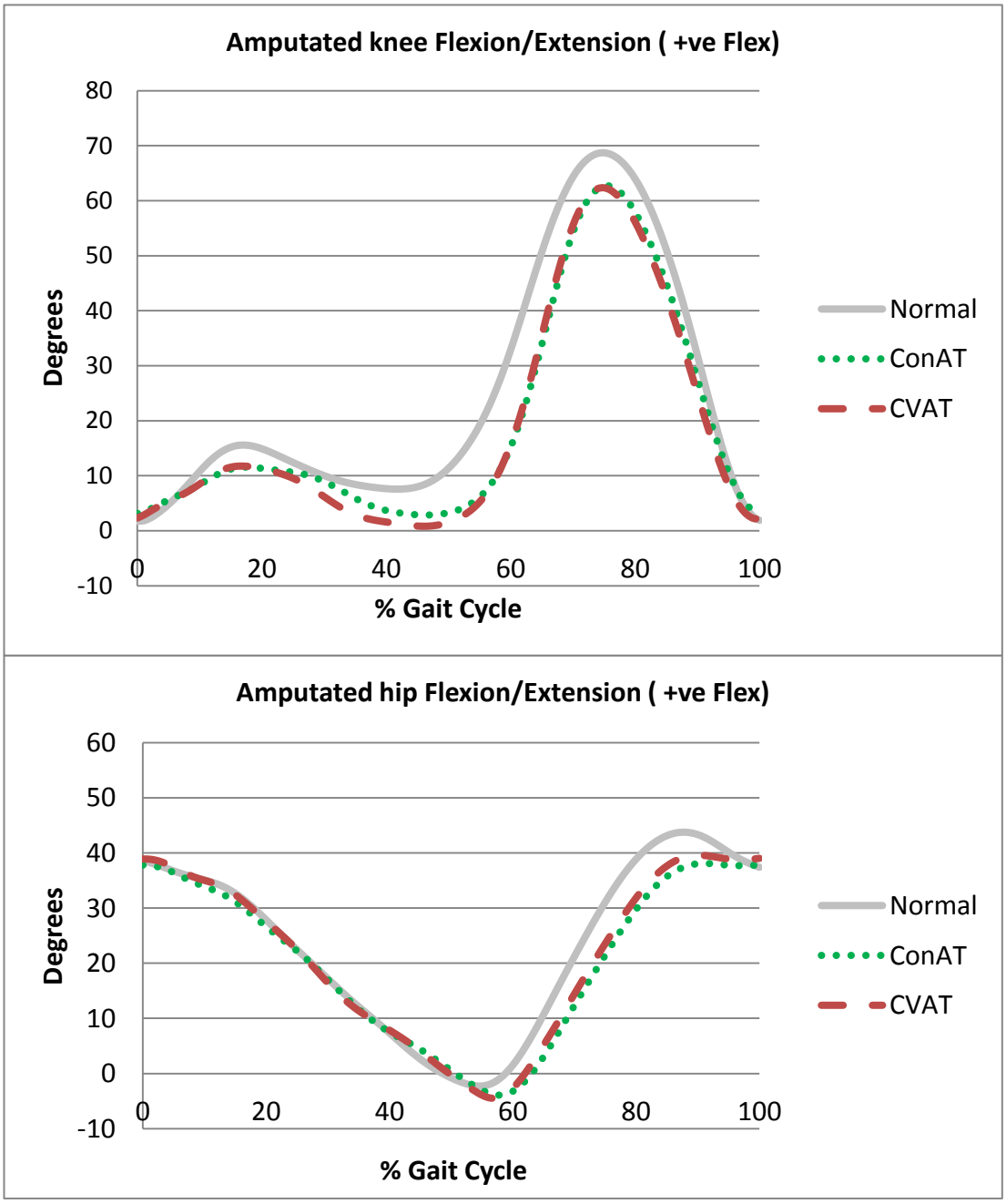


Figure 9.7 The mean normal and amputated gait data for knee and hip kinematics in the sagittal plane when walking with prosthesis tuned by ten practising prosthetists.

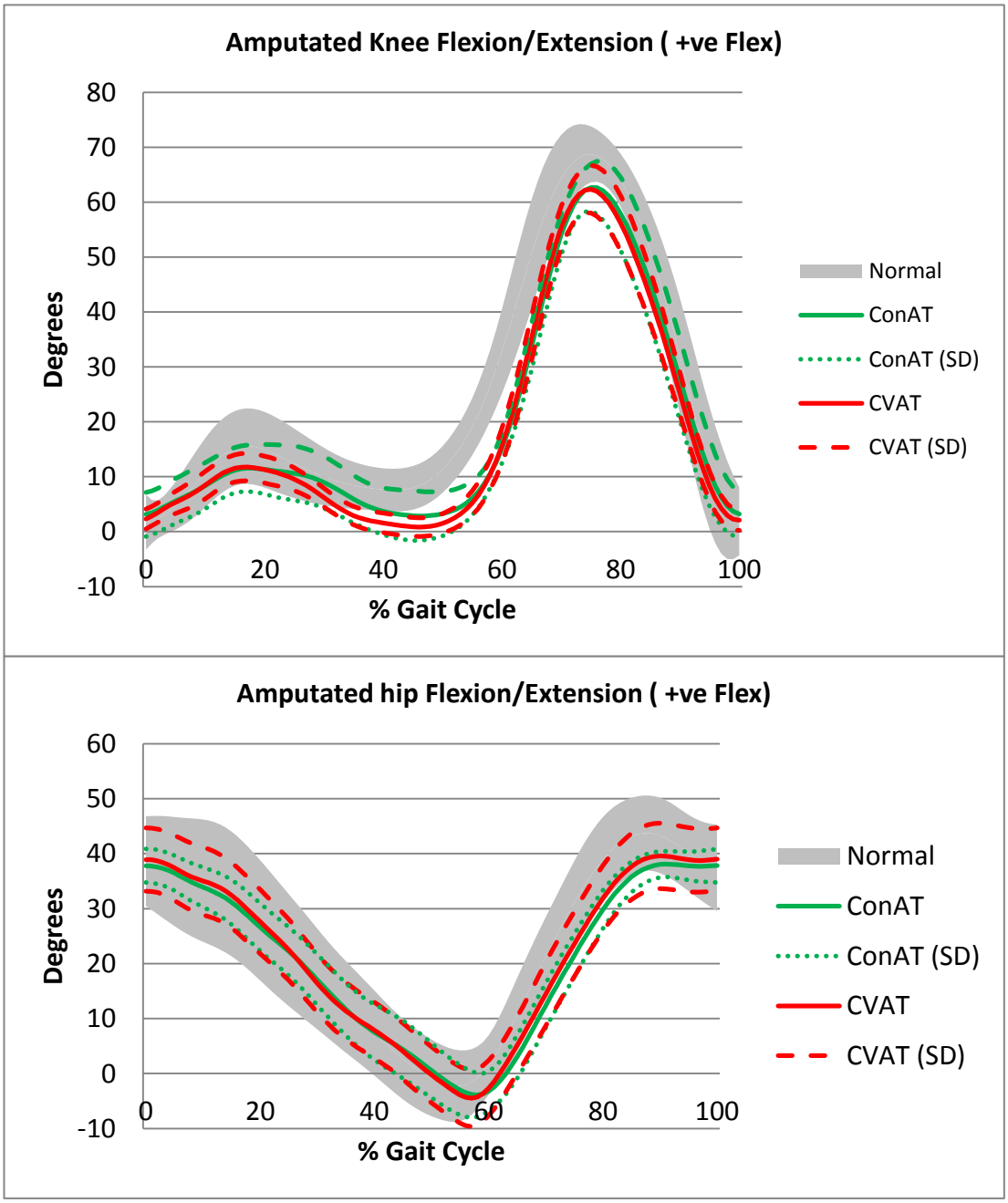


Figure 9.8 The mean normal and amputated gait data ± 1SD for knee and hip kinematics in the sagittal plane when walking with prosthesis tuned by ten practising prosthetists.

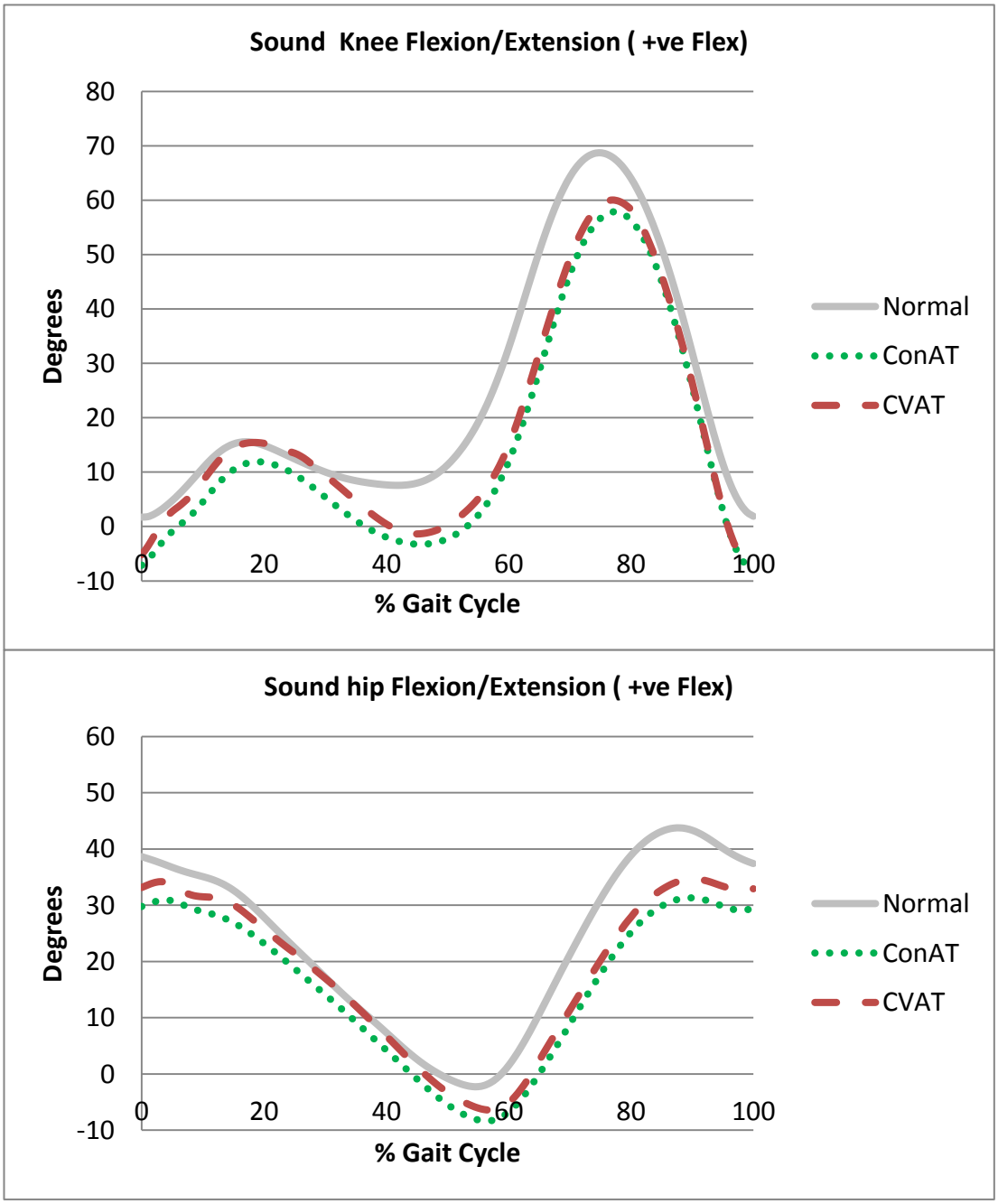


Figure 9.9 The mean normal and sound gait data for knee and hip kinematics in the sagittal plane when walking with prosthesis tuned by ten practising prosthetists.

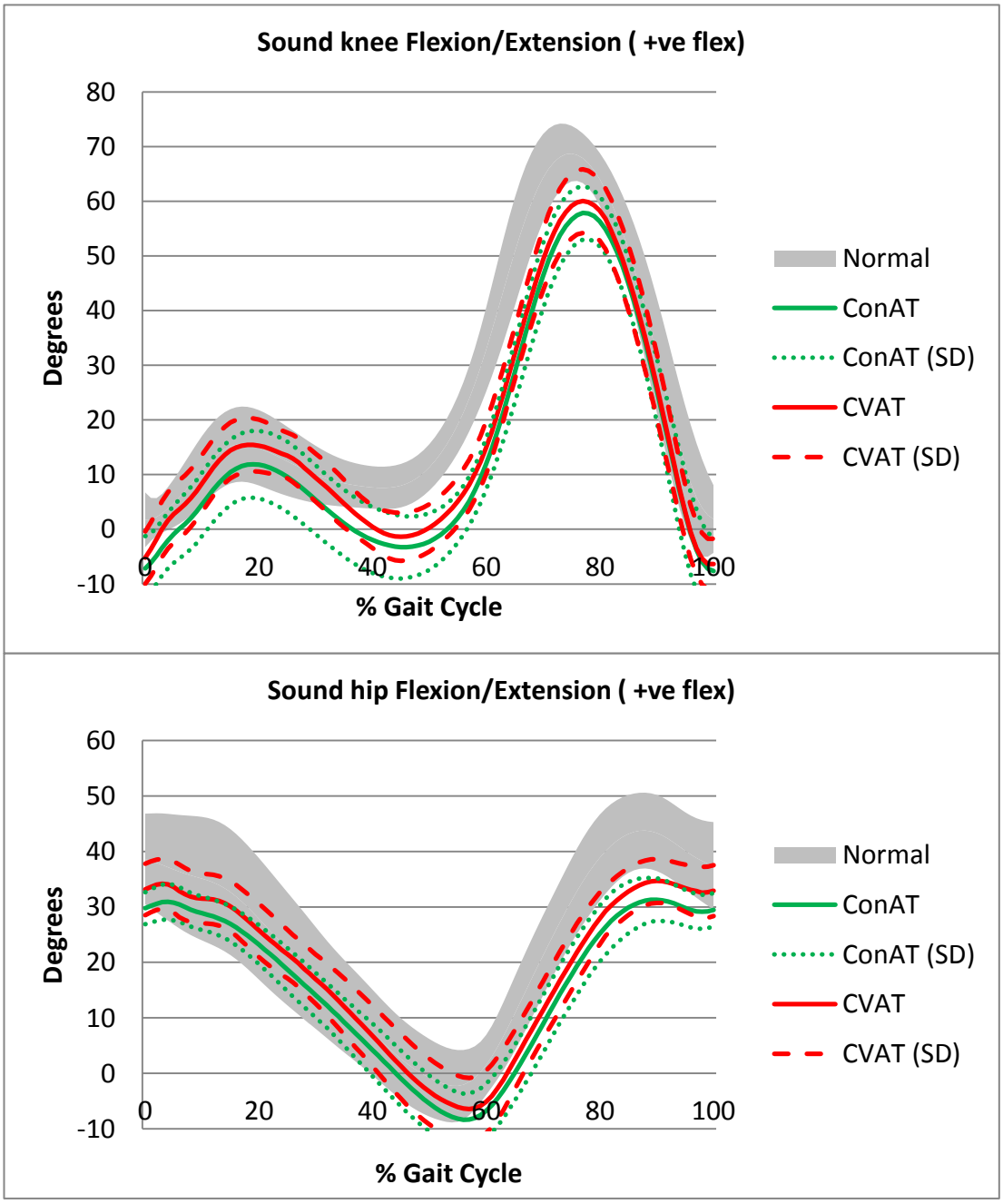


Figure 9.10 The mean normal and sound gait data ± 1SD for knee and hip kinematics on the sagittal plane when walking with prosthesis tuned by ten practising prosthetist

Parameters	Conventional (ConAT)	CVAT	Normal	P-value		
	Mean ±SD	Mean ±SD	Mean ±SD	ConAT & Normal	CVAT & Normal	CVAT & ConAT
Hip Flexion ROM(°); H1	40.2±8.6	44.5±2.0	47.4±5.9	**0.043***	0.167	0.121
Hip Peak Stance Extension(°); H2	-4.3±4.1	-0.2±4.8	-2.9±6.0	0.568	0.294	0.093
Hip Peak Swing Flexion(°); H3	35.9±6.7	40.0±5.3	44.4±6.9	**0.012****	0.130	0.270
Knee Flexion ROM(°); K1	57.2±11.8	61.9±3.4	70.6±7.4	**0.007****	**0.003****	0.311
Knee Peak Stance Flexion(°); K2	20.1±4.1	22.6±3.4	39.9±8.9	**0.000****	**0.000****	0.259
Knee Peak Swing Flexion(°); K3	58.9±11.2	62.4±4.0	69.7±4.9	**0.011****	**0.002****	0.428

Table 9.7 Mean kinematic output ± 1SD for the amputated side walked with prosthesis tuning by ten practising prosthetists.

* Indicates significance level of $\alpha = 0.05$

** Indicates significance level of $\alpha = 0.017$ after Bonferroni correction (0.05/3)

The mean values and SD for gait data when tuning was performed by the four inexperience prosthetists were summarised and compared using the T-test (Table 9.7 9.7 and Table 9.8).

Table 9.7 shows that all kinematic output for the amputated side with the prosthesis tuning performed using the CVAT method were higher than using the conventional method. All kinematic outputs for the amputated side with the prosthesis tuning performed using the CVAT method were closer to normal data than the conventional method. In exception, H2 measured with the conventional method of prosthetic alignment showed hip extension exceeding normal. All kinematic outputs for the amputated side with the prosthesis tuned using the CVAT method showed a lower standard deviation (ranged from 2.0° to 5.3°) than when using the conventional method (4.1° to 11.8°).

Table 9.7 shows that all the hip and knee parameters in the sagittal plane for the amputated side with the prosthetic tuned by ten practising prosthetists were significantly different between the conventional tuning and normal groups, except H2 ($p < 0.017$). There was a significant difference in three knee parameters (K1, K2 and K3) between the CVAT tuning method and normal ($p < 0.017$). However, there was no significant difference in the hip parameters between the CVAT and normal groups. There were, however, no significant differences in all of the six parameters between the CVAT and the conventional methods when applied by experienced prosthetists.

Parameters	Conventional (ConAT)	CVAT	Normal	P-value		
	Mean ±SD	Mean ±SD	Mean ±SD	ConAT & Normal	CVAT & Normal	CVAT & ConAT
Hip Flexion ROM(°); H1	40.4±2.8	41.6±3.0	47.4±5.9	**0.004****	**0.014****	0.444
Hip Peak Stance Extension(°); H2	-8.5±4.7	-3.3±5.6	-2.9±6.0	**0.033****	0.893	0.070
Hip Peak Swing Flexion(°); H3	31.5±3.7	34.8±3.7	44.4±6.9	**0.000****	**0.001****	0.091
Knee Flexion ROM(°); K1	65.8±6.0	67.1±1.4	70.6±7.4	0.131	0.156	0.571
Knee Peak Stance Flexion(°); K2	18.7±4.2	21.2±4.5	39.9±8.9	**0.000****	**0.000****	0.217
Knee Peak Swing Flexion(°); K3	58.2±4.5	60.6±4.9	69.7±4.9	**0.000****	**0.001****	0.328

Table 9.8 Mean kinematic output ± 1SD for the sound side walked with prosthesis tuning by ten practising prosthetists.

* Indicates significance level of $\alpha = 0.05$

** Indicates significance level of $\alpha = 0.017$ after Bonferroni correction (0.05/3)

Table 9.8 shows that all kinematic outputs for the sound side with the prosthesis tuning performed using the CVAT method were closer to normal data than for the conventional method. All kinematic outputs for the sound side with the prosthesis tuning performed using the CVAT method was higher than when using the conventional method. All kinematic outputs for the sound side with the prosthesis tuned using the CVAT method showed a low standard deviation (less than 6°). Four of the six parameters, when the prosthesis was tuned with the CVAT method, were significantly different from normal on the sound side.

Table 9.8 also shows that there were significant differences in the sound side with a prosthesis tuned by ten practising prosthetists when using the conventional method compared to normal healthy walking, with the exception being the K1 parameter. There were, however, no significant differences in any kinematic parameter between the CVAT method and the conventional method.

In general, positive effects on lower limb joint kinematics were observed when using the CVAT method. This approach more repeatable generated a closer to normal gait for both the amputated and sound sides compared to the conventional method, indicating that the CVAT system leads to some improvement in outcome when used by this experienced group, although less than that seen in the inexperienced group.

9.3.2 Results from Subjective Questionnaires

Questionnaires were given to the fourteen prosthetist participants. Eleven questionnaires were sent back to the researcher. Thus a response rate was approximately 79 % of all participants was achieved. Two experienced prosthetists and one inexperienced prosthetist failed to return the completed questionnaire. Table 9.10 showed the response of the rating scale questionnaires. The response of the open end questionnaires was summarized in Tables 9.11 through Table 9.16.

All prosthetists had experienced using the CVAT system at the time of answering the questionnaire. They had used it only once for this study but not on a day-to-day basis as part of their regular clinical practice.

9.3.2.1 Participants' Characteristics

Participant No.	Gender	Age	Experience	Qualification
EP301	Male	26	< 5 years	Student
EP302	Female	32	< 5 years	Student
EP303	Female	29	5 – 10 years	Student
EP304	Female	34	10 - 15 years	Prosthetic Practitioner
EP305	Female	59	> 15years	Prosthetic Practitioner
EP306	Male	38	> 15years	Prosthetic Practitioner
EP307	Female	27	< 5 years	Prosthetic Practitioner
EP308	Female	30	5 – 10 years	Prosthetic Practitioner
EP309	Female	46	> 15years	Prosthetic Practitioner
EP310	Female	51	> 15years	Prosthetic Practitioner
EP311	Female	29	10 - 15 years	Prosthetic Practitioner

Table 9.9 Prosthetists' characteristics who returned the questionnaire

Table 9.9 presents the demographics of the participants (n = 11) who returned the questionnaire, including gender, age, their experience of tuning prosthesis and their qualification. Approximately 80 % of participants were female. The median age from these participants was 32 (SD = 10.4). Eight of the eleven participants were active prosthetic practitioners who had been working in the field for more than five years.

9.3.2.2 Summary of the questionnaire (Rating scale and Open-end)

	Totally Disagree	Disagree	Neutral	Agree	Strongly Agree	Unable to rate
1. The new method is easy to use	-	45.45%	18.18%	18.18%	18.18%	-
2. The new method is useful	-	18.18%	9.09%	45.45%	27.27%	-

	Not at All Interested	Not Very Interested	Neither Interested nor Uninterested	Somewhat Interested	Very Interested
3. Overall, how interested are you in using this method if it were available?	-	27.27%	9.09%	45.45%	18.18%

Table 9.10 The rating scale the questionnaire

The response of the rating scale questionnaires was summarised in Table 9.10. Forty-five percent of the responding participant prosthetists agreed that the new method was useful and 27% strongly agreed. There were also 45 % who answered that they did not think the new method was easy to use, while 36% felt it was easy to use. All of the prosthetists had only one-time experience with using the new system and did not receive any training before using the new system. This might be the reason why nearly half of prosthetists thought it was not easy to use. However, despite this, three out of four participants felt it was useful.

Participants	Comments
Student	It is a very advanced way to help a P&O to do a proper fitting.
Student	Easy to apply
Student	The application assists in the real-time situation. The suggestion about the range of angle for alignment
Lecturer	No Comment
Practitioner	The ease of using a colour indicator to see if the alignment is correct
Practitioner	No Comment
Practitioner	Can be completed before goes on the computer
Practitioner	It is a way to verify that your alignment is correct
Practitioner	Easy to see red/green dots when things wrong aligned.
Practitioner	Straightforward and achieves a nice gait
Practitioner	The green lights were reasonably easy to understand, but the value one did confuse me.
Practitioner	No Comment

Table 9.11 Point 1: what do you like most about our new method?

When asked the question "what do you like most about our new method?" prosthetists identified that the CVAT method is an advanced way to verify that prosthetic alignment is correct. Most of the prosthetists liked the visualisation with coloured objects (green and red) to identify the correct alignment. The green lights were reasonably easy to see.

Participants	Comments
Student	Need more skills
Student	The difference in motion was not easy to follow
Student	There were quite a lots of markers need in the initial process. The practitioner may need to understand how to read the value or number to adjust the prosthesis alignment appropriately.
Lecturer	No Comment
Practitioner	Feel there is no one correct alignment so unsure if its reliable
Practitioner	A bit sensitive should get better with practice
Practitioner	When the alignment was set up following the computer the patient could not walk
Practitioner	It is difficult to understand at first. Time-consuming.
Practitioner	Terminology-I found this confusing. Relies on initial assessment measuring heavily. Bench alignments were different. Variability of marker placement.
Practitioner	Difficult to use a wand to identify anatomical landmarks- wand shape not easy to get into position while the patient on the treadmill
Practitioner	There seemed to be a bit of range between the options, e.g. The green light appears on the screen just after 10 and up to 30 how do you know where best to start.
Practitioner	The system was very confusing due to the range the limb could be set in& and could still achieve a green light. The alignment still had to be adjusted after the green lights had been achieved.

Table 9.12 Point 2: what do you like least about our new method?

When asked "what you do like least about our new method?" prosthetists identified that the alignment indicators used in the CVAT method turned green within too wide a range. This parameter was set to the range specified in the literature. Some prosthetists felt this was too wide a range and wanted to know a narrower range for optimal alignment. Additionally, they found it difficult to use the motion capture system and felt that too many markers were needed.

Participants	Comments
Student	Quite accurate, tells you what need to be done.
Student	Give direct instructions for an unexperienced prosthetist
Student	Convenience for practice, once a patient's information fills in the application, the computers automatically calculate and display on the screen in a few seconds. An application provides reliable, accurate data, I try to recheck, and it quite satisfies me.
Lecturer	No Comment
Practitioner	could be helpful for those aligning limbs with very little experience
Practitioner	No comment
Practitioner	appeared to be accurate
Practitioner	You can check that alignment is in an optimal range.
Practitioner	Potential to record alignment. Confirmation it alignment is correct after setting up
Practitioner	I like the real-time gait analysis
Practitioner	Not sure would have to use it again a least a few time to understand it more.
Practitioner	No comment

Table 9.13 Point 3: what are strong points of the new method?

When asked about the strong points of the new method, prosthetists identified that the CVAT method provided a real-time gait analysis with reliable, accurate and objective measurement. It also could give direct instructions for an inexperienced prosthetist.

Participants	Comments
Student	Can it be used in the busy clinic? Time-consuming. Highly dependent on the skill of the P&O. Any wrong placement of marker gives wrong results
Student	Should consider patient comfort
Student	To simplify the marker attach to the patient's stump & prosthesis. For dynamic alignment evaluation, the graphs demonstrate kinematically (Hip & Knee) can add the indicator to compare the normal range and the current situation.
Lecturer	No Comment
Practitioner	the sensitivity of computer feel a wider range of alignment would be better
Practitioner	I found the wand difficult
Practitioner	When turning grab screws, lost values. Notice system led to being recalculated after
Practitioner	The system does not take patient account preference. An instruction sheet could be issued to explain how the system works.
Practitioner	Terminology. Variability of marker placement
Practitioner	Narrow the range of bench alignment variables.
Practitioner	Not sure would have to use it again a least a few time to understand it more.
Practitioner	Greenlight system not reliable

Table 9.14 Point 4: what are the weak points of the new method?

When asked about the weak points of the new method, prosthetists identified that the CVAT method did not take patient preference into account. A lot of markers were needed, which should be simplified for the next version. The sensitivity of the system meant that as the parameter was on the edge of the range, the alignment indicator light flickered between red and green, making the system seem unreliable. The marker occlusion added to this unreliability in that the light would go red if one of the markers was occluded.

Participants	Comments
Student	The methods. Which model should I use? And the skill of calibration.
Student	no
Student	Up to date reviews on the optimal alignment in static/dynamic of TTP
Lecturer	No Comment
Practitioner	none
Practitioner	not much computer knowledge
Practitioner	No straightforward enough
Practitioner	No
Practitioner	I did not understand how the method worked. Perhaps easy access/ reference to normal parameters and special manufacturer recommendations
Practitioner	I don't think so.
Practitioner	Very possibly I completely understand how to bench alignment a limb, but I am less confident with gait alignment and computer programs
Practitioner	Did not fully understand the purpose of the new system

Table 9.15 Point 5: were there any gaps in your knowledge that made using the new method difficult?

When asked “were there any gaps in your knowledge that made using the new method difficult?” prosthetists generally identified that training/reference manual is required to learn how the system works.

Participants	Comments
Student	no
Student	no
Student	no
Lecturer	No Comment
Practitioner	No
Practitioner	I just found the system confusing
Practitioner	Still would end up with different alignment if was aligning Conventional prosthesis approach now. To allow the patient to stand with feet together
Practitioner	No
Practitioner	Components were awkward to use, e.g. Rotation and flexion. Any new socket would potentially have different adapters position so copying alignment might not be useful. Marker placement seemed quite random unreliability. Therefore, any resulting information might not be accurate.
Practitioner	I don't think this is viable in my own clinic but has great potential for countries with less qualify staff.
Practitioner	Would have been good to get feedback on how good initial bench alignment had been the first visit how close it was to the alignment one.
Practitioner	Difficult to use & understand. Not fully reliable as alignment required adjustment following achieving the green light system.

Table 9.16 Point 6: are there any other comments you wish to make about the system or study?

When asked for any other comments that they wished to make about the system or study, prosthetists mentioned that the CVAT system was difficult to use the first time and not suitable for a busy clinic, however, it has great potential for countries with less qualified staff.

9.4 Discussion and Conclusion

The aim of this part of the feasibility study was to look at the usability of the system when used by a variety of trained prosthetists, to gather their opinions and comments on the system, to compare the kinematic biomechanical outcomes in terms of gait from the two methods. For outcome measures in this study, both quantitative and qualitative parameters were used. The kinematic variables used as quantitative parameters. The questionnaires were used as qualitative parameters.

According to the fitting process in this study design, the order of alignment techniques was not randomised. The conventional alignment technique was performed before the CVAT technique because in this way, prosthetists would not be influenced by the CVAT technique when performing the conventional alignment technique. Chen, (2012) suggested that influencing optimal alignment from assistive technology may alter the performance of the conventional technique. Therefore, the study protocol was designed so that the conventional alignment technique was applied before the assisted technique to mitigate this potential bias.

Findings for quantitative outcome measures when kinematic data from the amputee wearing the prosthesis tuned using the CVAT method and the conventional method were compared; some improvement was indicated by the data from the CVAT method. The CVAT method typically produced higher values for most outcome measures compared with the conventional method (Table 9.5 - Table 9.8). More than 90 % of kinematics when using the CVAT method was closer to normal data. Grad (2006) stated that intervention is considered beneficial if improvement in the gait pattern is observed, evident by a reduction in abnormal movements with an evolution toward patterns that are more like those of able-bodied individuals. From these studies, it can be concluded that the CVAT method had a positive effect on amputee gait.

A low SD for kinematic results was observed in the CVAT method that did not exceed 5° for most parameters. The SD of most outputs from all protocols was between 2° - 5°, which is considered clinical reasonable (McGinley et al., 2009).

Grad (2006) recommended that kinematic data acquired from pathological gaits should be typically analysed by utilising a type of differential analysis, plotting able-bodied curves onto the same graphs as amputee data so that deviations from normal can be readily determined. The graphs in this study showed that using the CVAT system, kinematic curves closer to a normal able-bodied kinematics pattern were also observed in the sagittal plane when compared to data from the conventional method. In general, there was good agreement between the CVAT methods and normal data.

The qualitative data from the questionnaire were used to determine the "user experience" of the practitioner with the system. The questionnaire was designed to assess the usability of the system, how the system could be improved, and what was beneficial or an obstruction to the use of the system. For the vast majority of statements, prosthetists stated firstly that the CVAT system is a very advanced way to help prosthetists to produce correct tuning for a patient especially for those aligning limbs with minimal experience. Chen et al., (2016) also suggested that the alignment instrumentation system may be a useful tool especially when a prosthetist may be having difficulties achieving optimal alignment with maximum patient comfort, or for inexperienced prosthetists who are still developing their skills in performing dynamic alignments (Chen et al., 2016). Secondly, the visual feedback was helpful. It was easy to apply due to using a colour indicator to see if the alignment was correct. It was easy to see red dots when things were incorrect. Lastly, it could be a way to verify that your alignment was correct and achieves an optimum gait pattern as the system shows the data in real-time.

Therefore, the prosthetists also mentioned the weak point of the system. The negative comments can be summarised in two main points. The first limitation is the marker issue. There were quite a lot of markers needed in the initial process. In the bench alignment application, single markers were attached to the prosthesis, and these may be lost in the camera view which causes a calculation error during real-time tuning alignment. To avoid this, each marker should be within the field of view of at least two cameras at any given time. During the prosthetist tuning alignment, some markers could become occluded due to the person in the capture volume and by the prosthetists' hand. Moreover, a single marker attached to the landmark increased the

number of markers to be identified during calculation which had to be applied and which could be knocked off during testing. So, in hindsight, a cluster with pointer calibration would be the best model to use tracking the prosthesis and for calculating the six initial alignment parameters. This would reduce the calculating error and further reducing alignment process time.

- The second limitation relates to the experience of the prosthetists in using the CVAT. The practitioners may need to practice and get training in using the system and to understand how to read the value and adjust the prosthesis alignment appropriately. Therefore, it is highly recommended that the prosthetists receive the training of application system prior to the testing of any further development of visual feedback scenarios application.

Additional suggestions from the prosthetists may be summarised in the following points:

1) The system has great potential for countries with less qualified staff.
2) To simplify the marker system attached to the patient's stump and prosthesis. For dynamic alignment evaluation, the graphs could demonstrate kinematically (hip and knee) the normal range and the current situation with the amputee.
3) There were a number of comments that the initial starting alignment criteria were too wide. For example, when setting the position of the centre of the socket in relation to the centre of the foot in a sagittal plane, the criteria were that the socket centre should be between 0 mm and 30 mm anterior to the foot centre. However, the prosthetists asked, “how do you know where best to start”. The system would benefit from more guidelines as to the initial starting position to use.

4) The system does not take patient preference into account. Taking patient preference into account by asking how they feel before and after each alignment would be helpful to interpret the optimal alignment. This should be a foremost consideration.
5) An instruction sheet could be issued to explain how the system works.

There was some limitations associated with this study. This work was only carried out using a small number of participants. Thus, future studies should be validated in a study with a larger sample size. Considering the nature of this field, 10 amputees would be a reasonable sample size, the evidence from past studies where only three of 34 alignment studies over the past 35 years recruited more than 10 amputee participants (Neumann, 2009).

The limitations should be noted when interpreting the current findings. We did not systematically evaluate the effects of walking speed (or its variation) within a self-paced treadmill application. Although we did not visually observe any noticeable changes in gait speed and Boone et al., (2013) stated that the maximum difference in cadence among different alignment conditions was less than 10% in the same group of amputees (Boone et al., 2013). The results should, therefore, be generalizable to self-paced walking for each population, and relatively wide ranges of speed (0.48–1.64 m/s) (Hendershot et al., 2016).

There was also a lack of instructions on how to read the verbal feedback when using the CVAT technique. Consequently, prosthetists were unclear about how to follow the instructions to make alignment changes during the clinical assessments.

A further limitation of the current study is that the primary outcome measure was sagittal plane hip and knee kinematics. Kinetic and kinematic behaviour is closely linked, and it may not be possible to manipulate one without modifying the other. Therefore it cannot be concluded from this study, that which method is better, only whether or not it is valid for measuring sagittal plane hip and knee angles.

Contribution of kinetics and kinematics for optimal prosthetic alignment requires further research.

Finally, the fact that all aspects of this study were carried out by one researcher may be viewed as a limitation to this study. One researcher may have led to bias during analysis. However, this could not be avoided as there wasn't an adequate resource to train a prosthetist in use of the system. Throughout all stages of the study, the researcher was careful to avoid bias, and all raw data and results were reviewed by the principal investigator to reduce any chance of researcher bias during analysis.

In conclusion, an LLA prosthetic alignment tool was designed, developed and clinically evaluated. It can provide a real-time read-out of six alignment parameters for the trans-tibial prosthesis with alignment recommendations in the bench application. It could be used to measure and prescribe initial alignment for trans-tibial prostheses. The initial alignment set during the bench application was further tuned using static and dynamic applications. Using the CVAT system appeared to have a positive overall effect on gait outcomes. The findings from this study imply that the CVAT method had a positive effect of producing a better gait outcome for the amputee gait compared with the conventional approach. This study presented a new method to measure, visualise, and interpret the various alignment conditions collected from a trans-tibial amputee in real-time, in order to provide optimal alignment recommendation to the prosthetist.

The main benefits of using the CVAT system are:

1) It allows automated real-time monitoring of functional/biomechanical outcomes.
2) This system can assist prosthetists to adjust and measure dynamic alignments based on objective evidence.
3) It is suitable for prosthetic students as a visual teaching tool.

Chapter 10. General Discussion and Conclusions

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10.1 Discussion

The primary aim of this PhD thesis was to develop a new system which can help the prosthetist to optimise and tune the alignment of the TTP by using real-time feedback during TTP tuning, and to test the effectiveness of the feedback on alignment. The hypotheses were that motion capture and applications which had been designed for the purpose would become more feasible and deliver appropriate alignment feedback, which requires minimal technical expertise to operate and is less time consuming than current systems. This would allow real-time feedback of alignment recommendation.

This project involved many different aspects of methodology consideration, and these were addressed in the chapters throughout this thesis. This involved finding a suitable biomechanic model, walking conditions and development of a new system to implement real-time feedback during alignment tuning and testing of the effectiveness of the feedback on patient gait.

At various points in time during the completion of this thesis, additional methodological considerations came to the author's attention. The methodological considerations of this work would benefit from further discussion.

10.1.1 Biomechanic model

The first aspect involved finding a suitable biomechanics model. In order to be able to obtain valuable, meaningful and reliable 3-D gait data. A suitable protocol needed to be selected from available protocols.

When four biomechanics models were compared, PiG, HBM and HBM2 were commercially available marker sets which employ individually placed skin surface markers. The kinematic calculation based on the data from markers attached to the skin may include skin movement artefacts which may lead to significant errors (Tranberg, 2010). The Strathclyde Cluster Model (SCM) was the only model which

used clusters. Each cluster was attached to a segment, and single markers were required only for anatomical calibration during static registration and were removed.

When the accuracy of different models was investigated, results demonstrated that the SCM showed the lowest within-subject variability and low between-subject variability in the able body population (Chapter 4) and, therefore, the decision was made to use such protocols to investigate TT amputees' gait compared to PiG (Chapter 5). In TT amputees, the PiG estimated higher knee abduction during swing than the SCM. The PiG indicated peak knee adduction of approximately 50° during the swing, which is abnormal for a healthy participant and unlikely in an amputee (Ferrari et al., 2008). Knee abduction during swing recorded with the cluster method was much smaller. The possible cause of this result might be incorrect marker positioning in the PiG protocol, leading to poor knee axis alignment, or significant movement of the knee markers during walking; especially the marker attached on the outside of the socket.

From a more practical point of view, the SCM has advantages over the other available protocols. The SCM is more rapidly implemented by fastening the cluster to the limb using Velcro straps. Therefore, no individual markers need to be attached to the participant's skin. Consequently, it is more acceptable to the subject, requiring less skin exposure than other marker-based models.

According to clinical experience, the most important source of error in kinematics is soft tissue artefact (STA). As mentioned by Kent and Franklyn-Miller, 2011, STA caused by the uncontrolled movement of skin and subcutaneous tissue is one of the primary sources of error (Kent and Franklyn-Miller, 2011). Reducing the number of individual markers attached to the skin by using the clusters is likely to reduce the soft tissue artefact error. It also showed the least within-subject variability of the four protocols. Furthermore, it also showed the least between-subject variability of the four protocols. It provides 3 degrees of freedom for all three lower limb joints. It aligns the knee joint axis so that crosstalk and large amounts of abduction/adduction angulation in either direction are not seen at the knee during the swing.

As stated previously, it was clear that the SCM has advantages over the other available protocols; it can be advised that the SCM is much more suitable for analysing walking performance in trans-tibial amputees in a tuning application, when compared to other motion analysis protocols. Notably, the SCM model using clusters can be applied using VICON Tracker software that allows processing of data in real-time including automatic marker labelling and real-time feedback.

From these results, it may be confirmed that the SCM is more practical for measuring amputee gait without loss of accuracy when compared to PiG. The SCM is capable of providing accurate data with a setup which is much more suitable when used for rapid, real-time gait analysis.

10.1.2 Walking condition during dynamic alignment process

In addition to the biomechanical model, the walking condition during the alignment process was also a crucial issue that warranted consideration. During dynamic tuning, the amputee is asked to walk many times during an alignment session. This raises the question of which walking conditions would be most suitable for TT amputees during dynamic alignment tuning.

When the differences between walking conditions were compared for gait performance in the able-bodied group, there were no significant differences observed between overground (OG) walking, fixed-speed treadmill (FS TM) walking, and self-paced treadmill walking. The results from Chapter 6 showed that between OG and self-paced treadmill (SP TM) walking, the average difference was less than one degree in joint motion and in the worst case less than 2^{o}. SP TM walking is a suitable alternative to OG walking in gait analysis.

Treadmill walking has considerable benefits compared to overground walking for the purposes of gait analysis. The subject remains in a fixed and relatively small capture volume. Each marker remains within the field of view of at least two cameras at any given time. Moreover, Rusaw and Ramstrad, (2011) determined this after they

conducted a review of motion-analysis studies of transtibial prosthesis users. It was suggested that level walking at a self-selected velocity was the most common activity investigated in kinematic studies of transtibial amputees. Self-paced treadmill walking could be a powerful tool to study the patient's gait. There are many advantages to collecting gait data by SP TM walking. First, natural walking under SP TM provides a more natural gait and better resembles overground gait as compared to FS TM walking (Sloot et al., 2014). Walkers can select and identify their specific comfortable walking speed (Sloot et al., 2014). SP TM walking can acquire full gait kinematic data over longer distances and many strides (Plotnik et al., 2015; Sloot et al., 2014).

In dynamic alignment tuning, real-time gait analysis can be conducted and analysed with immediate feedback, allowing the potential for the amputee to keep walking during tuning of the prosthesis. Walking with SP TM permits more freedom to select and change walking speed than FS TM walking and more freedom to stop walking at any time. SP TM also permits a safer, more adaptable, more efficient and more space-saving process for dynamic alignment tuning. Therefore, it must be noted that the finding reported here are based on flat walking.

10.1.3 Parameter for Alignment Feedback Scenarios

When parameter needs for alignment feedback, dynamic alignments have always been regarded as the most challenging area of transtibial prosthetics (Staats, 1985). Several factors can cause the need for repeat alignment and should be taken into consideration when assessing alignment outcomes. Therefore, the CVAT system may help improve alignment by making their factor visual in real-time and hence to assist the prosthetist in achieving optimum alignment.

In this thesis, the dynamic alignment feedbacks were adopted from Prosthetic Observational Gait Score (POGS) by Hilman et al., (2010). Six dynamic alignment feedback scenarios were selected based on anatomical levels of the trunk, hip and knee. Sagittal plane kinematics were taken into account, as they are more reliable

than frontal and transverse kinematics, particularly angle measurements for the larger joints such as hip and knee, compared to the measurements for the ankle.

However, the parameters of kinematic analysis of the lower limb may not be sufficient to assist with tuning alignment in TTA. From the author's point of view, biomechanics data and patient satisfaction are closely linked, and it may not be possible to manipulate one without modifying the other for optimal prosthetic alignment. Alignment is a comprehensive process which can be best achieved using the combination of scientific justification, prosthetists' expertise, and amputees' satisfaction level (Chen, 2012). Some factors could, however, be added.

Prosthetists could use kinetic information for various purposes in the alignment process. First, they could use them to prevent excessive loading on the sensitive areas of the residual limb (Kobayashi et al., 2015). Second, they could use them to improve gait stability. Third, they could use the socket reaction moments as a tool to communicate with their patients and visually explain the effect of alignment tuning and how that may potentially benefit them. This tool may also help build more confidence in their prostheses (Boone et al., 2013).

A single quantitative biomechanical measure will never determine the success of the outcomes of alignment. There are not only kinetic but also kinematic behaviours, which help to achieve optimal alignment. These behaviours are closely linked, and to manipulate both for optimal prosthetic alignment is the ideal (Kobayashi et al., 2015).

The contribution of kinetics and kinematics for optimal prosthetic alignment requires further research. The magnitude and timing of the ground reaction force (GRF), a projection of the force vector on to the three-dimensional motion, which captures the external joint moments, could be used (Harlaar et al., 2000). Moreover, using the projection of the GRF (dynamic plumb line) to visualise the distance between the centre of rotation of the joints and the ground reaction force vector assists with the alignment of trans-tibial prostheses (Van Velzen et al., 2005). The GRF, as well as the position of the joint centre of rotation, must be measured to estimate the net moment of a force about knee joints (Harlaar et al., 2000).

The true net moments of force are calculated by using additional inverse dynamics of segments distal to the joint combing with accurate kinematics, as measured by a motion capture system (Harlaar et al., 2000). To do so, a force plate is necessary. Structures of a force platform-instrumented treadmills need to be highly rigid in order to ensure that the resultant force measured by these force sensors closely approximates the actual GRF applied to the track surface (Hong et al., 2017). These requirements inevitably increase the manufacturing cost. Consequently, the high cost of the force platform-instrumented treadmills has limited their adoption to use.

This CVAT system was designed based on objective kinematic data without the subjective feedback of the individual. When prosthetist opinions were evaluated, it was noted that the system does not take patient account preference. It was, therefore, suggested that perception of the person with amputation by taking verbal feedback of amputee's satisfaction regarding the prosthetic fit and comfort is also an essential aspect of determining the best alignment (Boone et al., 2012) .A further version of the CVAT method could include feedback of the individual amputee using the prosthesis. But it is difficult to see how this could be combined with objective data. There is published evidence by Boone et al., (2012) that the subject's perception was not accurate enough to detect small (<6 angulation, <20 mm translation) yet potentially clinically important malalignments. Sin et al., (2001) also demonstrated that the wide range of acceptable alignments was -5° to +13° in sagittal angulation and -15 mm to +35 mm in anterior translation.

10.1.4 Marker design for calculating alignment feedback

In these applications, two sets of markers positioned over the amputee's lower limb and prosthesis were used to calculate the required alignment parameters in real-time and to provide visual feedback. The first marker set was the prosthetic market set which was used to calculate six initial bench alignment parameters in the bench alignment application and two of three static alignment parameters in the static application. The second set was the SCM model with pointer calibration. It was used

to calculate one of three static alignment parameters (prosthetic height) in the static application and to calculate kinematic parameters in the dynamic application.

Furthermore, another issue is the number of markers needed in the CVAT method, in the bench alignment application, single markers were attached to the prosthesis, and these may be lost in the camera view which causes a calculation error during real-time tuning alignment. To avoid this, each marker should be within the field of view of at least two cameras at any given time. During prosthetist tuning alignment, some markers could become occluded due to the person in the capture volume and by the prosthetists' hand. Moreover, a single marker attached to the landmark increased the number of markers to be identified during calculation which had to be applied and which could be knocked off during testing. So, in hindsight, a cluster with pointer calibration would be the best model to use to track the prosthesis and for calculating the six initial alignment parameters. This would reduce the calculating error and further reducing alignment process time.

10.1.5 Experience and perceptions with the new technology in the clinical practice

Further, the field of prosthetics is advancing rapidly regarding technology. Even the terms robotics, bionics, and biomimetics are becoming more commonly used by prosthetists. Challenges in making sense of new technology in the clinical practice of the field of prosthetics are the main issue. The number of new scientific and technological advances for assisting with alignment optimisation available in the prosthetic field is increasing. However, previous evidence has suggested that it has also been shown that health professionals find it difficult to integrate technology into their work practices (Pals et al., 2015). According to the author's experiences, the fact that the prosthetic practitioners were familiar with the conventional method to perform alignment meant they resisted the use of technology for this purpose. They did not perceive an increase in efficiency or effectiveness the technology could achieve, nor its benefits to the less experienced practitioner.

From the author's point of view as a prosthetist, a prosthetic lecturer and PhD student in biomedical engineering, it is crucial for the technology to provide adequate and accurate scientific evidence. Implementing the new technologies to help in assisting transtibial prosthetic fitting in making decisions about care and intervention options based on objective data are crucial but also a challenge.

10.1.6 Number of participants

A small number of sample size needed to be considered, the primary study was the usability studies of the system and the user survey of the opinion of the prosthetists using the system. The main participants in the feasibility study were prosthetists. The final testing of the system involved a single trans-tibial amputee with multiple prosthetists to investigate the effect of the real-time tuning application integrated into the D-flow. In the future, the developed version of the CVAT system requires evaluation with a larger sample size of amputees. Kinematic data and alignment changes should be recorded to verify the findings of this thesis. Usability studies to examine the accuracy and validity of these innovative technologies are needed. However, previous evidence has suggested that the nature of this field is such that the data in this thesis represents reasonable sample size compared to past studies where only three of 34 alignment studies over the past 35 years recruited more than 10 participants (Chen, 2012; Neumann, 2009).

10.1.7Definition of an "optimal" initial alignment

Finally, in terms of quantifying "Optimal alignment", Zahedi et al., (1986) conducted a study to achieve the most suitable prosthetic alignment for best function and comfort. The prostheses used in their study of trans-tibial amputees were initially bench aligned to the settings recommended by Radcliffe and Foort., (1961) and the results showed that those alignment parameters cover a large range. For example, AP shift ranges from 12 to 28 mm, while ML shift ranges from -15 to 28 mm.

Moreover, according to the literature review conducted in this thesis, initial alignment setting remained that a board range of acceptable alignments was 0° to 10° in sagittal angulation and 0 mm to 30 mm in anterior translation.

A few prosthetists responded to our survey that "in an initial alignment, a starting configuration for a standard bench alignment was set in too wide a range." Therefore, the scopes of the initial setting need to be narrowed down. According to that, a narrowed optimum initial alignment for simplifying the process of alignment methods shall rapidly increase the alignment tuning time and increase service provision.

10.2 Future work

There are some considerations associated with the alignment tuning process using the CVAT method which would benefit from further investigation. A summary of some of the future research related to each study are:

- A further version of the CVAT system should be designed based on objective kinematic and kinetic data and include the subjective feedback of the individual. The inclusion of objective information, in conjunction with the subjective input of patients in the system, could provide assistance in the optimisation of prosthetic alignment.
- Although dynamic fitting is generally tuning based on the flat walking surface. It may not represent the problems for everyday walking environment. A further version of the CVAT system should be designed based on difference walking surface.
- The future development of a cluster with pointer calibration points for tracking the prosthesis and calculating the six initial alignment parameters is warranted

and aims to reduce the number of markers needed and reduce the markers occluded during real-time alignment tuning.

- The information from the application output recorded using the CVAT system in bench application could be used to establish the new initial alignment recommendation, which can be narrower than the current alignment range. So, more work may be needed to refine the databases that are used to drive the alignment process and narrow the initial alignment setting range. The means achieving a "single blueprint optimum alignment" will also require a rapid alignment tunning.
- An automated robot alignment device using the application to control the alignment automatically rather than stopping partially and using Allen keys would lead to further efficiency gaits. Further research may use information from the CVAT application to find the ranges required for the specific alignment parameters and allow incorporation of these ranges into the design criteria for the new alignment device.
- Although the CVAT application is specifically designed for the transtibial prostheses, which constitutes the majority of lower-limb prostheses, it does not account for the significant differences one would expect at either higher or lower levels of amputation. Further research may apply the methods of developing the CVAT application to use for trans-femoral prostheses.
- Finally, further testing of the system is also required, as this work was only carried out using a small number of participants (pilot study). Also, further

testing regarding the effectiveness of visual feedback should be carried out with a greater number of TT amputees. For that purpose, it is highly recommended that the prosthetists receive training of the application system prior to the testing of any further development of visual feedback scenarios application.

10.3 Conclusion

In terms of the analysis carried out in this study, the accuracy of SCM used in amputee gait and the repeatability of the aligned prosthesis during bench using assisted bench alignment application was deemed acceptable. It was noted there was a benefit of using SP TM during visual dynamic alignment feedback, as this provides effective walking conditions in clinical gait analysis. Those found were used to develop real-time visual feedback scenarios in the form of the CVAT method.

After developing the new instrumentation to assist the TTP tuning, a feasibility study of the system was needed and involved a single trans-tibial amputee with multiple prosthetists to investigate the effect of the real-time tuning application integrated into the D-flow. The results of using the CVAT method had a positive effect on amputee gait.

The CVAT method is a prosthetic alignment technology that provides alignment recommendations based on the optimum geometry of the prosthesis and kinematic data throughout all three stages of alignment setting. The application developed proved feasible for tuning of a TTP and capable of producing reliable results. In this way, it addressed the research aims of this thesis by investigating the effect of alignment technology to help clinicians to tune the alignment in a trans-tibial amputee population based on objective gait analysis.

The current version of the CVAT system is the first edited version and considered preliminary, and further investigation of the new version would help determine the feasibility of using it in the field. The current version of the CVAT system provides

clinicians with objective measures relative to prosthetic functioning. However, it is not clinically feasible, as prosthetists would not use it due to lack of clinical time and difficulty with the biomechanical setup. At the present stage, the CVAT system can serve as an evidence-based teaching or justification tool to amputees. It may be a useful tool for prosthetic students with less to moderate experience who are still developing their skills to align prostheses in less time properly and may be used when a prosthetist may be having difficulties achieving a satisfactory alignment for their client. Findings from this work indicate that this system can be used to assist prosthetists in adjusting and measuring alignments based on objective evidence without experience trained staff and move toward a more evidence-based model of practice.

Major conclusions are as follows:

1) The SCM kinematic output is an equal model to describe joint kinematics as the PiG when used for gait analysis of the able-bodied subjects and TTP.
2) Walking with SP TM can be used compatibly with OG. SP TM is more suitable in TTP alignment tuning process. SP TM permits more freedom to select and change walking speed when compared to FS TM walking.
3) Using the CVAT system has a positive effect on hip and knee kinematic gait.
4) Benefits of using the CVAT system:

1. It allows automated real-time monitoring of biomechanical outcomes.
2. This system can assist prosthetists to adjust and measure dynamic alignments based on objective evidence.
3. This system is suitable for prosthetic students as a visual teaching tool.

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Appendix

Appendix 1 Electronic files for Video and Application

Dynamic Tuning using the CVAT

Video of dynamic feedback scenario

CVBAT_Foot Segment

Code, which calculates foot segment in Bench Alignment application, described in Chapters 7

CVBAT_Socket Segment

Code, which calculates socket segment in Bench Alignment application described in Chapters 7

CVBAT_PH and SFS and SFLX

Code which calculates Bench Alignment Parameter on Prosthetic Height (PH) and Socket Forwards Set (SFS) and Socket Flexion (SFLX) described in Chapters 7- 8

CVBAT_Socket Set Out (SAO) and Socket Adduction (SADD)

Code which calculates Bench Alignment Parameter on Socket Set Out (SAO) and Socket Adduction (SADD) described in Chapters 7 and 8

CVBAT_ Toe-out angle (TOUT)

Code, which calculates Bench Alignment Parameter on Toe-out angle (TOUT), described in Chapters 7 and 8

CVBAT_Show Prosthetic Height in Bench_ Visual Feedback and Wording feedback

Code, which indicates the condition for Prosthetic Height in the bench, described in Chapters 7 and 8

CVBAT_Show Socket Adduction (SADD)_Visual Feedback and Wording feedback

Code, which indicates the condition for the SADD in the bench, described in Chapters 7 and 8

CVBAT_Show Socket Forward Set (SFS)_Visual Feedback and Wording feedback

Code, which indicates the condition for the SFS in the bench, described in Chapters 7 and 8

CVBAT_Show Socket set out (SAO)_Visual Feedback and Wording feedback

Code, which indicates the condition for the SAO in the bench, described in Chapters 7 and 8

CVBAT_Show Toe-out angle(TOUT)_Visual Feedback and Wording feedback

Code, which indicates the condition for the TOUT in the bench, described in Chapters 7 and 8

CVBAT_Avatar Frontal

Code, which generates the avatar on frontal plane, described in bench application

CVBAT_Avatar Sagittal

Code, which generates the avatar on the sagittal plane, described in bench application

CVSAT_Pointer Calibration

Code, which places a marker at the tip of the calibration pointer

CVSAT_PelvicCalibration

Code which labels a marker in pelvic at the tip of the calibration pointer for anatomical point

CVSAT_LeftLowerCalibration

Code, which labels a marker in the left lower limb at the tip of the calibration pointer for anatomical point

CVSAT_RightLowerCalibration

Code, which labels a marker in the right lower limb at the tip of the calibration pointer for anatomical point

CVSAT_SP1 and SF1

Code which calculates Static Alignment Parameter on Prosthetic Height (SP1) and Socket AP tilt in static (SF1) described in Chapters 7 and 8

CVSAT_SA1

Code which calculates Static Alignment Parameter on Socket ML tilt in static (SA1) described in Chapters 7 and 8

CVSAT_Show Prosthetic Height in static_ Visual Feedback and Wording feedback

Code, which indicates the condition for Static Prosthetic Height in static, described in Chapters 7 and 8

CVSAT_Show Socket AP tilt in static_Visual Feedback and Wording feedback

Code, which indicates the condition for Socket AP tilt in static, described in Chapters 7 and 8

CVSAT_Show Socket ML tilt in static_Visual Feedback and Wording feedback

Code, which indicates the condition for Socket ML tilt in static, described in Chapters 7 and 8

CVDAT_Pelvic segment

Code, which calculates the pelvic segment, described in Chapter 7

CVDAT_LeftThigh segment

Code, which calculates LeftThigh segment, described in Chapter 7

CVDAT_RightThigh segment

Code, which calculates RightThigh segment, described in Chapter 7

CVDAT_LeftShank segment

Code, which calculates LeftShank segment, described in Chapter 7

CVDAT_RightShank segment

Code, which calculates RightShank segment, described in Chapter 7

CVDAT_LeftFoot segment

Code, which calculates the LeftFoot segment, described in Chapter 7

CVDAT_RightFoot segment

Code, which calculates right foot segment, described in Chapter 7

CVDAT_Lower Limb Kinematics

Code, which calculates lower limb kinematics, described in Chapter 7

CVDAT_Gait detection event

Code, which used to detect gait event described in Chapter 8

CVDAT_ Vaulting

Code, which calculates Dynamic Alignment Parameter on Vaulting, described in Chapter 8

CVDAT_ Peak Hip Extension in Stance

Code, which calculates Dynamic Alignment Parameter on Peak Hip Extension in Stance, described in Chapter 8

CVDAT_ Peak Hip Flexion in swing

Code, which calculates Dynamic Alignment Parameter on Peak Hip Flexion in swing, described in Chapter 8

CVDAT_ Peak Knee Extension in Stance

Code, which calculates Dynamic Alignment Parameter on Peak Knee Extension in Stance, described in Chapter 8

CVDAT_ Peak Knee Flexion in swing

Code, which calculates Dynamic Alignment Parameter on Peak Knee Flexion in swing, described in Chapter 8

CVDAT_ Base of support

Code, which calculates Dynamic Alignment Parameter on Base of support, described in Chapter 8

CVDAT_Show Vaulting_Visual Feedback and Wording feedback

Code, which indicates the condition for Vaulting in dynamic, described in Chapter 8

CVDAT_Show Peak Hip Extension in Stance_Visual Feedback and Wording feedback

Code, which indicates the condition for Peak Hip Extension in Stance in dynamic, described in Chapter 8

CVDAT_Show Peak Hip Flexion in Swing Visual Feedback and Wording feedback

Code, which indicates the condition for Peak Hip Flexion in Swing in dynamic, described in Chapter 8

CVDAT_Show Peak Knee Extension in Stance_Visual Feedback and Wording feedback

Code, which indicates the condition for Peak Knee Extension in Stance in dynamic, described in Chapter 8

CVDAT_Show Peak Knee Flexion in Swing Visual Feedback and Wording feedback

Code, which indicates the condition for Peak Knee Flexion in Swing in dynamic, described in Chapter 8

CVDAT_Show Base of support_Visual Feedback and Wording feedback

Code, which indicates the condition for Base of support in dynamic, described in Chapter 8

Kinematics_AND NormalliseCycles

VBA Code which extracts the data from each participant and normalizes cycles

Appendix 2 Example of D-flow Code for the alignment and visual feedback

Code for calculating Bench Alignment Parameters

```
- __D_FLOW inputs: AmputatedSide, KneeHeight, SAC.PosX, SAC.PosY,
SAC.PosZ, DSACDSAC.PosX, DSAC.PosY, DSAC.PosZ, LML.PosX,
AJC.PosX, AJC.PosY, AJC.PosZ
-- __D_FLOW outputs: SAO, Adduction
-----Right AmputatedSide = 1 ---
------Left AmputatedSide = 2 ---
--Initilisation of varables
AmputatedSide = AmputatedSide or 0
KneeHeight = KneeHeightX or 0
SACx = SACx or 0
SACy = SACy  or 0
SACz = SACxz or 0
SACx = SACx or 0
SACy = SACy  or 0
SACz = SACxz or 0

----CVBAT_Socket Set Out (SAO) and  Socket Adduction (SADD)-----



outputs.setchannels("SAO", "Adduction")

-- inputs set
inputs.setchannels("AmputatedSide",  "KneeHeight", "SAC.PosX",
"SAC.PosY", "SAC.PosZ", "DSAC.PosX", "DSAC.PosY", "DSAC.PosZ",
"LML.PosX","AJC.PosX", "AJC.PosY", "AJC.PosZ")

--  input

AmputatedSide  = inputs.get("AmputatedSide")
KneeHeight  = inputs.get("KneeHeight")
SACx  = inputs.get("SAC.PosX")
SACy  = inputs.get("SAC.PosY")
SACz  = inputs.get("SAC.PosZ")
DSACx  = inputs.get("DSAC.PosX")
DSACy  = inputs.get("DSAC.PosY")
DSACz  = inputs.get("DSAC.PosZ")
LMLx = inputs.get("LML.PosX")
```

```
if AmputatedSide == 1 then


----------------------------Socket Set Out (SAO)---------------------------


SAO= (SACxSJCx - AJCx)*1000* -1

 outputs.set("SAO", SAO)

-----Socket Adduction (SADD)----------

Dy = math.abs(SACy - DSACySJCy - DSJCy)
Dx = math.abs(SACx - DSACxSJCx - DSJCx)

ATAN = math.atan(Dx/Dy)
AdductionTemp = math.deg(ATAN)

   if SACx < DSACxSJCx < DSJCx then

        Adduction = AdductionTemp
      else

        Adduction = AdductionTemp * -1
   end

outputs.set("Adduction", Adduction)
```

```
else AmputatedSide = 2

----------------------------Socket Set Out (SAO)----------------------------

SAO = (SACxSJCx - AJCx)*1000

outputs.set("SAO", SAO)


-----Socket Adduction (SADD)----------


Dy = math.abs(SACy - DSACySJCy - DSJCy)
Dx = math.abs(SACx - DSACxSJCx - DSJCx)

ATAN = math.atan(Dx/Dy)
AdductionTemp = math.deg(ATAN)

  if SACx > DSACxSJCx > DSJCx then

      Adduction = AdductionTemp
    else

     Adduction = AdductionTemp * -1
  end
```

Socket Adduction (SADD) visual feedback events handled in this script

```
-- __D_FLOW inputs: Channel1, Channel2, Channel3

-- __D_FLOW outputs: Adduction, Goalmin, Goalmax

--All events handled in this script

--Initilisation of variables

ini = ini or 0

allinputs = allinputs or {}

input = input or {}

--Initilisation code

if ini == 0 then

for i = 1, 3 do

        allinputs[i] = "Channel"..i

end

inputs.setchannels(unpack(allinputs))

ini = 1

end

for i = 1, 3 do

        input[i] = inputs.get("Channel"..i)

end
```

```
outputs.setchannels("Adduction", "Goalmin","Goalmax")

--Show socket adduction—

--- input[2] = Adduction contracture (AC)

Adduction = input[1]

Goalmin = 5 + input[2]

Goalmax = 10 + input[2]



if Adduction > Goalmax  then

    broadcast("Socket too adduction")



elseif Adduction < Goalmin  then

    broadcast("Socket too abduction")



else broadcast("Socket adduction OK")

end

outputs.set("Adduction", Adduction)

outputs.set("Goalmin", Goalmin)

outputs.set("Goalmax", Goalmax)
```

Code that generates the avatar in the bench application

```
-- __D_FLOW inputs: AmputatedSide, SAC.PosX, SAC.PosY, SAC.PosZ, DSAC.PosX, DSAC.PosY, DSAC.PosZ, Pylon.PosX, Pylon.PosY, Pylon.PosZ, AJC.PosX, AJC.PosY, AJC.PosZ, TOE.PosX, TOE.PosY, TOE.PosZ, Heel.PosX, Heel.PosY, Heel.PosZ

-- __D_FLOW outputs: Output1, Output2, Output3, Output4, Output5, Output6

--In this script the avatar is created and controlled

--Initialisation code

ini = ini or 0

shapes = shapes or {"Sphere", "Cylinder", "Cube", "Cone"}

colours = colours or {"Red", "Green", "Blue", "White", "Gray", "Cyan"}

--Initialisation code

inputs.setchannels("AmputatedSide",

                "SAC.PosX", "SAC.PosY", "SAC.PosZ",

                "DSAC.PosX", "DSAC.PosY", "DSAC.PosZ",

                "Pylon.PosX", "Pylon.PosY", "Pylon.PosZ",

                "AJC.PosX", "AJC.PosY", "AJC.PosZ",

                "TOE.PosX", "TOE.PosY","TOE.PosZ",

                "Heel.PosX", "Heel.PosY", "Heel.PosZ")
```

```
-- inputs

AmputatedSide = inputs.get("AmputatedSide")

Footlength = inputs.get("AmputatedSide")

SACxSJCx  = inputs.get("SAC.PosX")

SACySJCy  = inputs.get("SAC.PosY")

SACzSJCz = inputs.get("SAC.PosZ")

DSACxDSJCx  = inputs.get("DSAC.PosX")

DSACyDSJCy  = inputs.get("DSAC.PosY")

DSACzDSJCz = inputs.get("DSAC.PosZ")

AJCx  = inputs.get("AJC.PosX")

AJCy  = inputs.get("AJC.PosY")

AJCz = inputs.get("AJC.PosZ")

Pylonx  = inputs.get("Pylon.PosX")

Pylony  = inputs.get("Pylon.PosY")

Pylonz = inputs.get("Pylon.PosZ")

TOEx  = inputs.get("TOE.PosX")

TOEy  = inputs.get("TOE.PosY")

TOEz  = inputs.get("TOE.PosZ")

Heelx  = inputs.get("Heel.PosX")

Heely  = inputs.get("Heel.PosY")

Heelz  = inputs.get("Heel.PosZ")
```

```
if ini == 0 then

--Joint centres
object.create(shapes[1], colours[6]):setscaling(0.003, 0.003, 0.003) --1;Socket
object.create(shapes[1], colours[6]):setscaling(0.003, 0.003, 0.003) --2; Connector
object.create(shapes[1], colours[6]):setscaling(0.05, 0.05, 0.05) --3;ankle


--Segments

object.create(shapes[2], colours[5]) --4; Socket
object.create(shapes[2], colours[2]) --5; shank
object.create(shapes[2], colours[6]) --6; foot
object.create(shapes[3], colours[1]):setscaling(0.001, 0.001, 0.001) --7; Line




ini = 1
end

----------Socket----------

objects.get(1):setposition(SACx, SACy, SACzSJCx, SJCy, SJCz)

objects.get(2):setposition(Pylonx, Pylony, Pylonz)

--Distances
distance1x = SACx - DSACxSJCx - DSJCx
distance1y = SACy - DSACySJCy - DSJCy
distance1z = SACz - DSACzSJCz - DSJCz


distance1 = math.sqrt((distance1x^2)+(distance1y^2)+(distance1z^2))
distance1xz = math.sqrt((distance1x^2) + (distance1z^2))
```

```
--Rotations
if distance1x == 0 then
	distance1x = 0.001
else
	distance1x = distance1x
end

if distance1z == 0 then
	distance1z = 0.001
else
	distance1z = distance1z
end
rot1y = math.atan(-distance1z/distance1x) * 180/math.pi
if distance1x < 0 then
	rot1y = rot1y + 180
else
	rot1y = rot1y
end
if distance1xz == 0 then
	rot1z = 90
else
	rot1z = math.atan(distance1y/distance1xz) * 180/math.pi
end

objects.get(4):setposition(DSACx, DSACy, DSACzDSJCx, DSJCy, DSJCz)

objects.get(4):setscaling(distance1+0.1 ,0.10, 0.12)

objects.get(4):setrotation(0, rot1y+90, rot1z)

objects.get(7):setposition(SACx, SACy, SACzSJCx, SJCy, SJCz)

objects.get(7):setscaling(0.01, 1.0, 0.01)
```

```
------------SHANK-------------

objects.get(3):setposition(AJCx, AJCy, AJCz)

--Distances
distance2x = DSACx - AJCx
distance2y = DSACy - AJCy
distance2z = DSACz - AJCz

distance2 = math.sqrt((distance2x^2)+(distance2y^2)+(distance2z^2))
distance2xz = math.sqrt((distance2x^2) + (distance2z^2))

--Rotations
if distance2x == 0 then
        distance2x = 0.001
else
        distance2x = distance2x
end

if distance2z == 0 then
        distance2z = 0.001
else
        distance2z = distance2z
end

rot2y = math.atan(-distance2z/distance2x) * 180/math.pi

if distance2x < 0 then
        rot2y = rot2y + 180
else
        rot2y = rot2y
end

if distance2xz == 0 then
        rot2z = 90
else
        rot2z = math.atan(distance2y/distance2xz) * 180/math.pi
end

objects.get(5):setposition(AJCx, AJCy, AJCz)
objects.get(5):setscaling(distance2,0.03 , 0.03)
objects.get(5):setrotation(0, rot2y+90, rot2z)
```

```
----------FOOT----------

--Distances
distance3x = TOEx - Heelx
distance3y = TOEy - Heely
distance3z = TOEz - Heelz

distance3 = math.sqrt((distance3x^2)+(distance3y^2)+(distance3z^2))
distance3xz = math.sqrt((distance3x^2) + (distance3z^2))


--Rotations
if distance3x == 0 then
	distance3x = 0.001
else
	distance3x = distance3x
end

if distance3z == 0 then
	distance3z = 0.001
else
	distance3z = distance3z
end

rot3y = math.atan(-distance3z/distance3x) * 180/math.pi

if distance3x < 0 then
	rot3y = rot3y + 180
else
	rot3y = rot3y
end

if distance3xz == 0 then
	rot3z = 90
else
	rot3z = math.atan(distance3y/distance3xz) * 180/math.pi
end

objects.get(6):setposition(Heelx+(distance3x/4), Heely+0.04, Heelz+0.07)
objects.get(6):setscaling(distance3, 0.05,0.08)
objects.get(6):setrotation(0, rot3y+90, rot3z-10)
```

Appendix 3 Certificate of Approval by Siriraj Institutional Review Board

2 WANGLANG Rd. BANGKOKNOI
BANGKOK 10700

Tel. +66 2419 2667-72
Fax. +66 2411 9162

Siriraj Institutional Review Board

Certificate of Approval

COA no. Si 754/2016

Protocol Title(English) : Pilot study: Comparison of Biomechanical Outcomes in Transtibial Amputee Gait between Using Traditional Alignment and The CAREN- Assisted Alignment Technique

Protocol Title(Thai) : การศึกษานำร่อง: การเปรียบเทียบผลการเดินทางชีวกลศาสตร์ในผู้พิการใส่ขาเทียมระดับใต้เข่าที่ได้รับการจัดแนวขาเทียมแบบดั้งเดิมและการจัดแนวขาเทียมโดยใช้ระบบคาเรน

Protocol number : 665/2559(EC3)

Principal Investigator/Affiliation : Miss Manunchaya Samala / Faculty of Engineering, University of Strathclyde

Research site : Faculty of Medicine Siriraj Hospital

Approval includes :

1. SIRB submission form
2. Proposal
3. Participant information sheet
4. Informed consent form
5. Case record form
6. Advertisement for recruitment
7. Curriculum vitae

Approval date : November 25, 2016
Expired date : November 24, 2017

This is to certify that Siriraj Institutional Review Board is in full compliance with international guidelines for human research protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

(Prof. Chairat Shayakul, M.D.)
Chairperson

- 8 DEC 2016
date

(Prof.Dr. Prasit Watanapa, M.D., Ph.D.)
Dean of Faculty of Medicine Siriraj Hospital

- 8 DEC 2016
date

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Appendix 4 Participant Information Sheet (Prosthetists)

Title of study:

The alignment of a trans-tibial prosthesis using a "Conventional" and "motion capture enhanced method" when used by practising prosthetists and the outcome on the subject's gait.

Introduction

In this study we are interested in the usability of a new motion capture system which provides data on the alignment of a trans-tibial prosthesis to the prosthetist visually at the time of prosthetic alignment. Professor Philip Rowe, Dr Craig Childs and Manunchaya Samala are running this project. The researchers work in the Biomedical Engineering Department at the University of Strathclyde. Miss Manunchaya Samala is a PhD student in Biomedical Engineering at Strathclyde and a Lecturer in Prosthetics in Thailand.

What is the purpose of this investigation?

We have made a new system using motion capture technology to help the prosthetist optimally align a trans-tibial prosthesis. In this study we would like to look at the usability of the system with trained prosthetists, to gather your opinions and comment on the system and its usefulness and to compare the biomechanical outcomes as seen in the amputee's gait between the Conventional and the new alignment method.

Do you have to take part?

It is your choice whether to take part or not. You have the right to withdraw from the project at any time without giving advance notice or reason. If you do decide to take part but later change your mind, this is entirely up to you, and this decision will not

have any consequences for you. Participation in this study will not adversely affect you in any way.

What will you do in the project?

If you decide to take part in the research, the steps of research will be as follows:

You will be asked to attend twice with each session last a maximum of 2 hours. We will arrange a suitable appointment date and time for you to come to Biomechanics 3 laboratory at the BME department of the University of Strathclyde or if more convenient for you the Westmarc gait analysis laboratory. We will check you are suitably qualified and still happy to participate. We will ask you for your informed consent to carry out the assessments. An amputee will be present, and you will be provided with the prosthetic socket, socket adaptor, pylon and prosthetic foot and suitable anthropometric and clinical data about the amputee. This will not be their actual prosthesis, but a dis-assembled copy and they will not use this copy outside of the experimental session. Instead, they will retain their original and NHS prescribed prosthesis.

During the first visit, you will be asked to sign the consent form. You will then align the prosthesis using Conventional methods and the alignment achieved, and the amputee's gait will be recorded. You will first set up the prosthesis on the bench to the starting alignment. The amputee will then put on the prosthesis, and static alignment will be undertaken. Finally, the amputee will get on the treadmill and start walking in self-paced mode. You can ask the amputee to stop walking and make corrections to the alignment as required. Once you have achieved what you consider to be an acceptable alignment or within one hour of commencement of the alignment of the prosthesis we will ask you to stop. We will then record the alignment of the prosthesis and the gait of the amputee over 20 gait cycles.

For the second visit, approximately one week after the first visit, we will ask you to repeat the process. Again we will provide you with the prosthetic socket, socket

adaptor, pylon and prosthetic foot and suitable anthropometric and clinical data about the amputee. You will then repeat the alignment process but this time assisted by the new visualization system which will show you the current alignment and the gait of the amputee. Again once you have achieved an acceptable alignment, or within one hour of commencement of the alignment of the prosthesis, we will ask you to stop. We will record the alignment and the gait of the amputee over 20 gait cycles for the second time. Finally, we will ask you to fill in a questionnaire about the new alignment method and what you thought of it.

Why have you been invited to take part?

You are invited to take part in the research because of the following reasons;

- You are a practising prosthetist or in the 3rd and 4th year of a prosthetics course in the UK,

You should be able to

- give informed consent
- follow the directions and comprehend written and spoken English.
- attend for two, 120-minute appointments between 9am and 5pm Monday to Friday.

What are the potential risks to you in taking part?

The only risk to you is the normal work-related risk of injury for a prosthetist aligning prosthesis, and these are as you know very slight.

What happens to the information in the project?

The researcher will use a unique code for each individual who participates in the study so that the results of the tests will be kept anonymous. No personal information will be stored in any form either paper or computer-based. The anonymised motion data will be stored on the Strathclyde University network.

What happens next?

If you are happy to be involved in this project, please e-mail Manunchaya Samala using the details below. She will arrange suitable appointment dates and times.

If you do not want to participate, thank you for taking the time to read this information.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

Thank you for reading this information – please ask any questions if you are unsure about what is written here.

This investigation was granted ethical approval by the University of Strathclyde Ethics Committee.

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed, or further information may be sought from, please contact:

Secretary to the University Ethics Committee
Research & Knowledge Exchange Services
University of Strathclyde
Graham Hills Building
50 George Street
Glasgow
G1 1QE
Telephone: 0141 548 3707

Email: ethics@strath.ac.uk

Researcher Contact Details:

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Chief Investigator Contact Details:

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Glasgow G4 ONW

Telephone: 0141 548 3032

E-mail: philip.rowe@strath.ac.uk

Appendix 5 Consent Form (Prosthetists)

Title of study:

The alignment of a trans-tibial prosthesis using a "Conventional" and "motion capture enhanced method" when used by practising prosthetists and the outcome on the subject's gait.

- I confirm that I have read and understood the information sheet for the above project
- I confirm the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.
- I understand that I can withdraw my data from the study at any time.
- I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project

I hereby agree to take part in the above project

Print Name of Participant	
Signature of Participant	Date

Appendix 6 Questionnaire for Prosthetists

Title of study:

The alignment of a trans-tibial prosthesis using a "Conventional" and "motion capture enhanced method" when used by practising prosthetists and the outcome on the subject's gait.

Part 1: Personal information

Instruction: Please put □ into the in□ront of the best answer to each question and fill in any blanks.

1. Gender

1. ☐ Male 2. ☐ Female

2. Your age: .....

3. Qualification

1. ☐ Certificate or lower
2. ☐ Undergraduate or equal qualification
3. ☐ Postgraduate

4. Position

1. ☐ Lecturer 2. ☐ Student
3. ☐ Prosthetic Practitioner

5. Your working experience

1. ☐ No more than 5 years
2. ☐ More than 5 years to 10 years
2. ☐ More than 10 years to 15 years
4. ☐ More than 15 years

<u>Part 2</u>: Opinion on motion capture enhanced method.

<u>Instruction</u>: Please put □ in the best answer to each question and fill in your opinions on your experience regarding the new Computer-assisted method.

Please answer the following questions drawing on your experience in using the computer-assisted tuning applications:

3. What do you like most about our new method?

.....

.....

4. What do you like least about our new method?

.....

.....

5. What are the strong points of the new method?

.....

.....

6. What are the weak points or what could be improved for the new method?

.....

.....

7. Were there any gaps in your knowledge that made using the new method difficult?

.....

.....

Please rate the following questions in regards to your opinion

	Totally Disagree	Disagree	Neutral	Agree	Strongly Agree	Unable to rate
8. The new method is easy to use						
9. The new method is useful						

10. Overall, how interested are you in using this method if it were available?

_____Not at All Interested

_____Not Very Interested

_____Neither Interested nor Uninterested

_____Somewhat Interested

_____Very Interested

11. Are there any other comments you wish to make about the system or study?

.....

.....

Thank you for completing this questionnaire.

Appendix 7 Amputee Information Sheet

Title of study:

The alignment of a trans-tibial prosthesis using a "Conventional" and "motion capture enhanced method" when used by practising prosthetists and the outcome on the subject's gait.

Introduction

In this study we are interested in the usability of a new motion capture system which provides data on the alignment of a trans-tibial prosthesis to the prosthetist visually at the time of prosthetic alignment. Professor Philip Rowe, Dr Craig Childs and Manunchaya Samala are running this project. The researchers work in the Biomedical Engineering Department at the University of Strathclyde. Miss Manunchaya Samala is a PhD student in Biomedical Engineering at Strathclyde and a Lecturer in Prosthetics in Thailand.

What is the purpose of this investigation?

We have made a new system using motion capture technology to help the prosthetist optimally align a trans-tibial prosthesis. In this study we would like to look at the usability of the system with trained prosthetists, to gather their opinions and comments on the system and its usefulness and to compare the biomechanical outcomes as seen in your walking between the Conventional and the new alignment method.

Do you have to take part?

It is your choice whether to take part or not. You have the right to withdraw from the project at any time without giving advance notice or reason. If you do decide to take part but later change your mind, this is entirely up to you, and this decision will not have any consequences for you. Participation in this study will not adversely affect you in any way.

What will you do in the project?

If you decide to take part in the research, the steps of research will be as follows:

Initially, you will be asked to attend for two or three sessions in which we manufacture a copy socket of your current prosthesis and ensure it fits correctly. You will also show what is expected of you and the software we have developed and how it works. You will be introduced to the treadmill and get used to walking on it in a self-paced mode where it paces itself to your walking speed. Once all materials, education training and acclimatisation have been carried out, we will begin the subject testing.

You will be asked to attend up to 30 times. We intend to recruit 15 prosthetists, and each will tune the prosthesis twice, once without the new feedback system and once with it. Each session will last a maximum of 2 hours. We will arrange a suitable appointment date and time for you to come to Biomechanics 3 laboratory at the BME department of the University of Strathclyde or if more convenient for the prosthetists the Westmarc gait analysis laboratory. We will ask you for your informed consent to carry out the assessments during your first visit and will check you remain willing to participate at each subsequent visit. At each visit will examine your stump to make sure there are no signs of possible trauma to the tissue which may be made worse by the testing. We will repeat this at the end of each visit. Should you experience any discomfort during a session, we will halt the session, and if required we will stop the testing. You are free to withdraw from the study at any point without needing to explain why and without any detrimental effects to you of your subsequent relationship with the university or NHS service provision. We will be grateful for any data collected so far and thank you for helping us.

For the sessions, we will provide a replica of your socket, socket adaptor pylon and foot along with suitable anthropometric and clinical data about you to allow the prosthetists to tune the alignment of the prosthesis. You will retain your original and

NHS prescribed prosthesis unaltered and will use this as normal outside the experimental sessions. A prosthetist or student prosthetist will then align the experimental prosthesis using conventional methods and the alignment achieved, and your gait will be recorded. They will first set up the prosthesis in the workshop to determine the starting alignment. You will then put on the prosthesis and alignment changes while you are standing will be undertaken. Finally, you will be asked to get on a treadmill and start walking in self-paced mode. In this mode, the treadmill paces itself to your speed so as you start to walk so the treadmill begins to move and if you slow down and stop then the treadmill will also slow down and stop. You will be asked to stop at various points so the prosthetist or student prosthetist can make corrections to the alignment as required. Once they have achieved what they consider to be an acceptable alignment or within one hour of commencement of the alignment of the prosthesis, we will ask you and them to stop. We will then record the alignment of the experimental prosthesis and your gait over 20 gait cycles.

For the prosthetists second visit, approximately one week after their first visit, we will ask you to repeat the process with them. They will repeat the alignment process but this time assisted by the new visualization system which will show them the current alignment and your gait. Again once they have achieved an acceptable alignment, or within one hour of commencement of the alignment of the prosthesis, we will ask you and them to stop. We will record the alignment of the experimental prosthesis and your walking over 20 gait cycles for the second time.

In all, we hope to recruit 15 prosthetists giving 30 sessions in all. We appreciate this is a lot of your time and we will reimburse all travel costs. We will also compensate you for your travel and experimental time at the rate of £10.00 per hour. We are aware that walking on a prosthesis which is being tuned may until it is tuned properly, place extra loading and unusual loading on your stump. This may place the tissue on your stump at risk. We will space out the appointments in order to reduce any risk to your stump. We will ask you about any discomfort before during and after

the sessions. We will examine your stump before and after and if necessary during each session. We will ask you if you are willing to continue before, during and after each session. There is no requirement for you to finish the study. You are free to withdraw at any time you chose without consequence. If you do withdraw, we will be grateful to you for all the help you have offered us so far and will simply thank you for your help.

Why have you been invited to take part?

You are invited to take part in the research because of the following reasons;

- You are a well-established, trans-tibial prosthetic user who is used to the university and clinical environments, to giving feedback to prosthetists and able to be part of our research team
- Unilateral trans-tibial amputation performed more than 1 year with medium/long stump length,
- Functional level 3, 4
- Able to walk for a long time,
- A good current condition of health,
- Between 18-65 years old
- Normal ROM in all joints in the lower limb,
- Amputees who had worn the prosthesis for more than 6 months,
- Resident within Glasgow or adjacent areas
- Muscles strength grade 4 – 5 according to Oxford scale,
- Able to comply with directions and comprehend written and spoken English,
- give informed consent
- follow the directions and comprehend written and spoken English.
- attend for up to 30, 120-minute appointments between 9am and 5pm Monday to Friday.

And because you do not have

- pain or neuroma at the stump
- A residual limb with wounds, congestion or extreme volume changes,
- Amputee with diabetic, hypertension or other severe medical conditions,

- Amputee who have problems with the sound side which can influence the gait,
- An amputee with joint or muscle contractures either on stump side or sound side.

What are the potential risks to you in taking part?

The main risk to you in taking part is that the procedure may cause damage to the tissue over you to stump. As explained above we will take every precaution to prevent this and should you, or we see any signs of this we will discontinue the experiment either temporarily or permanently. We will use hypo-allergenic double sided tape to stick lightweight markers to your skin for the gait assessment. Despite being Hypo-allergenic, this tape can in rare cases cause irritation to the skin in which case we will stop the experiment and remove the tape. The reaction is mild and local and will usually resolve in a few hours. While moving around in the laboratory, there is a chance you could slip trip or fall so we will chaperone you and make sure the laboratory is clear, dry and free from hazards. When on the treadmill you may feel some motion sickness but this is rare and usually goes away after a minute or so but if it does not we will stop the experiment. You will walk in self-paced mode on the treadmill which is inherently safe in that if you stop so will the treadmill, and if you start to go towards the rear of the treadmill, then the treadmill will slow down to allow you to catch up. The treadmill has handrails. There is an emergency stop button on the treadmill. A falls mat will be placed at the rear of the treadmill.

What happens to the information in the project?

The researcher will use a unique code for each individual prosthetist who participates in the study so that the results of the tests will be kept anonymous both for them and you. No personal information about you will be stored in any computer-based system. We will need the shape of your current socket and details of the components used in you current leg. We will also need clinical details required for the tuning such as your

leg length and height from the floor to your knee but these will be kept on a paper sheet for the prosthetists to refer to and the sheet will be anonymised. The anonymised motion data will be stored on the Strathclyde University network.

What happens next?

If you are happy to be involved in this project, please e-mail Manunchaya Samala using the details below. She will arrange suitable appointment dates and times.

If you do not want to participate, thank you for taking the time to read this information and please email Manunchaya to tell us this.

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

Thank you for reading this information – please ask any questions if you are unsure about what is written here.

This investigation was granted ethical approval by the University of Strathclyde Ethics Committee.

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed, or further information may be sought from, please contact:

Secretary to the University Ethics Committee
Research & Knowledge Exchange Services
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50 George Street

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G1 1QE

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Email: ethics@strath.ac.uk

Researcher Contact Details:

Manunchaya Samala

Biomedical Engineering Department

University of Strathclyde

Wolfson centre

106 Rottenrow

Glasgow G4 ONW

Telephone: 07481809165

E-mail: manunchaya.samala@strath.ac.uk

Chief Investigator Contact Details:

Professor Philip Rowe

Biomedical Engineering Department

University of Strathclyde

Wolfson centre

106 Rottenrow

Glasgow G4 ONW

Telephone: 0141 548 3032

E-mail: philip.rowe@strath.ac.uk

Appendix 8 Consent Form (Amputee)

Title of study:

The alignment of a trans-tibial prosthesis using a "Conventional" and "motion capture enhanced method" when used by practising prosthetists and the outcome on the subject's gait.

- I confirm that I have read and understood the information sheet for the above project
- I confirm the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.
- I understand that I can withdraw my data from the study at any time.
- I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project

I hereby agree to take part in the above project

Print Name of Participant	
Signature of Participant	Date

Appendix 9 Conference Proceedings

Samala M, Childs C, McGarry A, Rowe P J (2015), Comparison of biomechanical parameters of healthy adult gait using three marker models**.** Paper presented at The 25th Congress of the International Society of Biomechanics (ISB 2015), Glasgow, United Kingdom.

Samala M, Rowe P J, Childs C, (2016), Advanced tuning of below knee prosthesis using the MOTEK CAREN system. ISPO European Congress, Rotterdam, (Netherlands)

Appendix 10 Kinematics of gait data performed alignment by all prosthetist both inexperience and practising prosthetists

Hip Flexion ROM (°)					
	Sound		**Amputated**		
	Con	**CVAT**	**Con**	**CVAT**	**Normal**
Four inexperience prosthetists					47.4
Subject 1	25.9	34.0	34.4	46.8	
Subject 2	38.8	42.5	39.5	44.0	
Subject 3	32.6	42.8	34.8	41.4	
Subject 4	33.6	39.8	34	38.1	
Mean	32.7	39.8	34.7	42.6	
Ten practising prosthetists					
Subject 5	38.7	41.8	41.7	44.9	
Subject 6	44.1	38.9	46.6	47.3	
Subject 7	41.0	40.5	45.5	47.0	
Subject 8	40.8	38.5	17.0	43.1	
Subject 9	35.9	39.0	39.1	46.3	
Subject 10	37.0	40.9	44.3	43.2	
Subject 11	38.3	49.7	42.9	43.5	
Subject 12	43.8	43.1	39.9	43.6	
Subject 13	42.2	41.8	39.2	40.5	
Subject 14	42.2	41.2	45.4	45.5	
Mean	40.4	41.6	40.2	44.5	

Table A.1 The mean normal and amputee gait data for Hip Flexion ROM on the sagittal plane

Hip Peak Stance Extension (°)					
	Sound		**Amputated**		
	Con	**CVAT**	**Con**	**CVAT**	**Normal**
Four inexperience prosthetists					-2.9
Subject 1	12.2	-3.8	7.1	-7.1	
Subject 2	10.8	-3.3	11.8	-0.3	
Subject 3	-4.7	4.2	-8.3	7.0	
Subject 4	-1.9	-8	4.5	0.3	
Mean	4.1	-2.7	3.8	0.0	
Ten practising prosthetists					
Subject 5	-3.1	-8.3	-1.5	-6.3	
Subject 6	-16.0	-2.7	-11.4	-0.3	
Subject 7	-12.4	1.6	-8.4	5.9	
Subject 8	-6.4	4.1	0.5	9.0	
Subject 9	-4.2	-0.3	-0.7	-1.2	
Subject 10	-9.7	3.6	-6.9	4.2	
Subject 11	-2.0	-11.4	-3.2	-3.5	
Subject 12	-13.4	-11.4	-4.2	-6.1	
Subject 13	-6.4	-0.9	0.5	-1.0	
Subject 14	-11.2	-7.3	-7.2	-3.0	
Mean	-8.5	-3.3	-4.3	-0.2	

Table A.2 The mean normal and amputee gait data for Hip Peak Stance Extension on the sagittal plane

Hip Peak Swing Flexion(°)					
	Sound		**Amputated**		
	Con	**CVAT**	**Con**	**CVAT**	**Normal**
Four inexperience prosthetists					44.4
Subject 1	38.0	30.2	41.5	39.3	
Subject 2	49.6	38.6	54.3	43.2	
Subject 3	27.9	46.7	26.5	48.4	
Subject 4	31.7	31.9	38.5	38.3	
Mean	36.8	36.8	39.5	42.3	
Ten practising prosthetists					
Subject 5	35.6	31.6	40.2	35.7	
Subject 6	27.7	32.6	35.2	41.9	
Subject 7	28.6	37.7	37.1	48.6	
Subject 8	34.4	39.4	17.4	48.4	
Subject 9	31.7	34.5	38.4	41.3	
Subject 10	27.3	41.4	37.3	42.8	
Subject 11	36.3	34.1	39.7	35.4	
Subject 12	30.3	29.2	35.7	32.4	
Subject 13	35.8	36.4	39.6	35.3	
Subject 14	27.7	31.1	38.2	37.9	
Mean	31.5	34.8	35.9	40.0	

Table A.3 The mean normal and amputee gait data for Hip Peak Swing Extension on the sagittal plane

Knee Flexion ROM(°)					
	Sound		**Amputated**		
	Con	**CVAT**	**Con**	**CVAT**	**Normal**
Four inexperience prosthetists					70.6
Subject 1	55.9	68.6	51.5	60.9	
Subject 2	54.7	67.4	56.1	61.1	
Subject 3	69.0	68.4	56.9	56.2	
Subject 4	66.5	69.4	56.2	59.7	
Mean	70.8	65	55.2	59.5	
Ten practising prosthetists					
Subject 5	65.8	68.2	59.0	63.4	
Subject 6	68.1	66.8	62.2	62.2	
Subject 7	68.0	65.7	67.2	65.8	
Subject 8	68.5	68.1	24.5	68.1	
Subject 9	63.6	65.3	61.1	63.2	
Subject 10	50.3	68.2	62.9	60.9	
Subject 11	65.8	69.5	59.8	58.2	
Subject 12	72.6	65.9	58.2	55.7	
Subject 13	69.6	65.4	58.5	59.4	
Subject 14	66.0	67.7	58.2	61.7	
Mean	65.8	67.1	57.2	61.9	

Table A.4 The mean normal and amputee gait data for Knee Flexion ROM on the sagittal plane

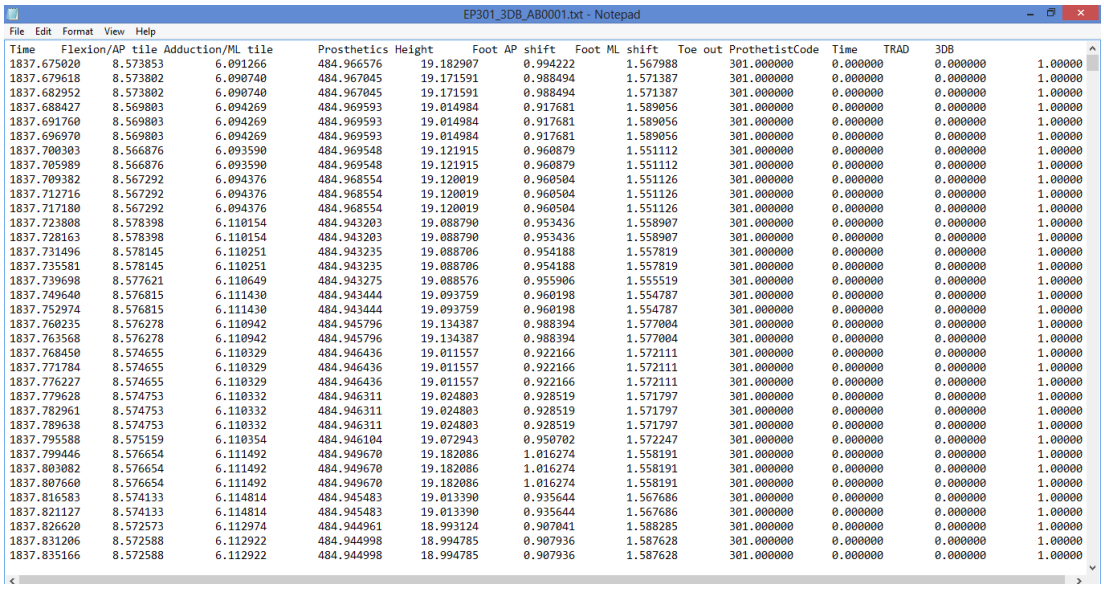
Knee Peak Stance Extension (°)					
	Sound		**Amputated**		
	Con	**CVAT**	**Con**	**CVAT**	**Normal**
Four inexperience prosthetists					39.9
Subject 1	9.5	15.7	7.2	15.7	
Subject 2	12.9	19.6	15.9	20.2	
Subject 3	28.4	19.4	14.6	15.7	
Subject 4	11.1	18.7	18.9	22.5	
Mean	15.5	18.4	14.1	18.5	
Ten practising prosthetists					
Subject 5	22.2	19.9	22.0	24.4	
Subject 6	14.2	18.4	21.4	25.1	
Subject 7	19.6	18.3	23.3	19.5	
Subject 8	19.9	19.0	11.0	24.2	
Subject 9	17.0	18.4	19.2	28.3	
Subject 10	18.1	34.0	17.3	20.8	
Subject 11	28.0	23.0	17.6	26.7	
Subject 12	14.4	20.5	21.8	20.7	
Subject 13	18.6	21.6	26.1	17.8	
Subject 14	15.2	18.8	20.9	18.3	
Mean	18.7	21.2	20.1	22.6	

Table A.5 The mean normal and amputee gait data for Knee Peak Stance Extension on the sagittal plane

Knee Peak Swing Flexion (°)					
	Sound		**Amputated**		
	Con	**CVAT**	**Con**	**CVAT**	**Normal**
Four inexperience prosthetists					69.7
Subject 1	56.5	52.3	52.8	60.6	
Subject 2	65.4	67.8	57.7	63.1	
Subject 3	67.1	63.5	55.5	57.3	
Subject 4	61.3	62.6	60.5	63.4	
Mean	62.6	61.6	56.6	61.1	
Ten practising prosthetists					
Subject 5	62.8	59.9	63.0	62.1	
Subject 6	53.0	56.4	57.2	63.8	
Subject 7	56.5	55.9	66.3	64.9	
Subject 8	60.7	58.2	28.8	69.5	
Subject 9	59.9	57.2	62.4	66.1	
Subject 10	51.0	73.2	69.5	62.0	
Subject 11	66.3	64.8	61.8	62.1	
Subject 12	56.1	59.0	59.6	54.1	
Subject 13	57.6	62.4	61.1	58.7	
Subject 14	57.6	59.2	58.9	61.3	
Mean	58.2	60.6	58.9	62.4	

Table A.6 The mean normal and amputee gait data for Knee Peak Swing Extension on the sagittal plane

Appendix 11 Data recorded by CVBAT application and using by CVSAT application



EP301_3DB_AB0001.txt - Notepad

File Edit Format View Help

Time	Flexion/AP tile	Adduction/ML tile	Prosthetics Height	Foot AP shift	Foot ML shift	Toe out	ProthetistCode	Time	TRAD	3DB	
1837.675020	8.573853	6.091266	484.966576	19.182907	0.994222	1.567988	301.000000	0.000000		0.000000	1.00000
1837.679618	8.573802	6.090740	484.967045	19.171591	0.988494	1.571387	301.000000	0.000000		0.000000	1.00000
1837.682952	8.573802	6.090740	484.967045	19.171591	0.988494	1.571387	301.000000	0.000000		0.000000	1.00000
1837.688427	8.569803	6.094269	484.969593	19.014984	0.917681	1.589056	301.000000	0.000000		0.000000	1.00000
1837.691760	8.569803	6.094269	484.969593	19.014984	0.917681	1.589056	301.000000	0.000000		0.000000	1.00000
1837.696970	8.569803	6.094269	484.969593	19.014984	0.917681	1.589056	301.000000	0.000000		0.000000	1.00000
1837.700303	8.566876	6.093590	484.969548	19.121915	0.960879	1.551112	301.000000	0.000000		0.000000	1.00000
1837.705989	8.566876	6.093590	484.969548	19.121915	0.960879	1.551112	301.000000	0.000000		0.000000	1.00000
1837.709382	8.567292	6.094376	484.968554	19.120019	0.960504	1.551126	301.000000	0.000000		0.000000	1.00000
1837.712716	8.567292	6.094376	484.968554	19.120019	0.960504	1.551126	301.000000	0.000000		0.000000	1.00000
1837.717180	8.567292	6.094376	484.968554	19.120019	0.960504	1.551126	301.000000	0.000000		0.000000	1.00000
1837.723808	8.578398	6.110154	484.943203	19.088790	0.953436	1.558907	301.000000	0.000000		0.000000	1.00000
1837.728163	8.578398	6.110154	484.943203	19.088790	0.953436	1.558907	301.000000	0.000000		0.000000	1.00000
1837.731496	8.578145	6.110251	484.943235	19.088706	0.954188	1.557819	301.000000	0.000000		0.000000	1.00000
1837.735581	8.578145	6.110251	484.943235	19.088706	0.954188	1.557819	301.000000	0.000000		0.000000	1.00000
1837.739698	8.577621	6.110649	484.943275	19.088576	0.955906	1.555519	301.000000	0.000000		0.000000	1.00000
1837.749640	8.576815	6.111430	484.943444	19.093759	0.960198	1.554787	301.000000	0.000000		0.000000	1.00000
1837.752974	8.576815	6.111430	484.943444	19.093759	0.960198	1.554787	301.000000	0.000000		0.000000	1.00000
1837.760235	8.576278	6.110942	484.945796	19.134387	0.988394	1.577004	301.000000	0.000000		0.000000	1.00000
1837.763568	8.576278	6.110942	484.945796	19.134387	0.988394	1.577004	301.000000	0.000000		0.000000	1.00000
1837.768450	8.574655	6.110329	484.946436	19.011557	0.922166	1.572111	301.000000	0.000000		0.000000	1.00000
1837.771784	8.574655	6.110329	484.946436	19.011557	0.922166	1.572111	301.000000	0.000000		0.000000	1.00000
1837.776227	8.574655	6.110329	484.946436	19.011557	0.922166	1.572111	301.000000	0.000000		0.000000	1.00000
1837.779628	8.574753	6.110332	484.946311	19.024803	0.928519	1.571797	301.000000	0.000000		0.000000	1.00000
1837.782961	8.574753	6.110332	484.946311	19.024803	0.928519	1.571797	301.000000	0.000000		0.000000	1.00000
1837.789638	8.574753	6.110332	484.946311	19.024803	0.928519	1.571797	301.000000	0.000000		0.000000	1.00000
1837.795588	8.575159	6.110354	484.946104	19.072943	0.950702	1.572247	301.000000	0.000000		0.000000	1.00000
1837.799446	8.576654	6.111492	484.949670	19.182086	1.016274	1.558191	301.000000	0.000000		0.000000	1.00000
1837.803082	8.576654	6.111492	484.949670	19.182086	1.016274	1.558191	301.000000	0.000000		0.000000	1.00000
1837.807660	8.576654	6.111492	484.949670	19.182086	1.016274	1.558191	301.000000	0.000000		0.000000	1.00000
1837.816583	8.574133	6.114814	484.945483	19.013390	0.935644	1.567686	301.000000	0.000000		0.000000	1.00000
1837.821127	8.574133	6.114814	484.945483	19.013390	0.935644	1.567686	301.000000	0.000000		0.000000	1.00000
1837.826620	8.572573	6.112974	484.944961	18.993124	0.907041	1.588285	301.000000	0.000000		0.000000	1.00000
1837.831206	8.572588	6.112922	484.944998	18.994785	0.907936	1.587628	301.000000	0.000000		0.000000	1.00000
1837.835166	8.572588	6.112922	484.944998	18.994785	0.907936	1.587628	301.000000	0.000000		0.000000	1.00000

Appendix 12 Additional data of Chapter 4

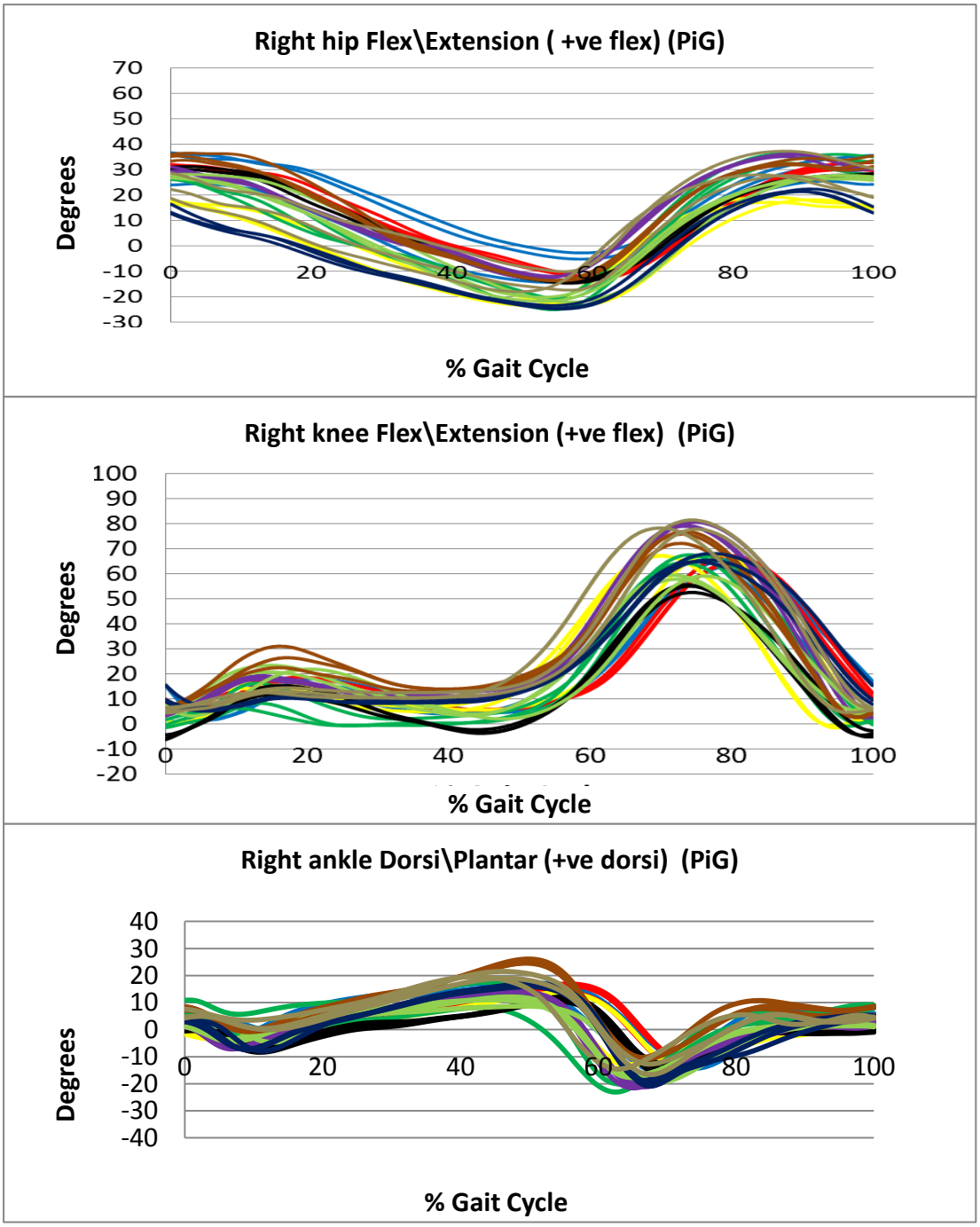


Figure A12.1 Sagittal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated PiG

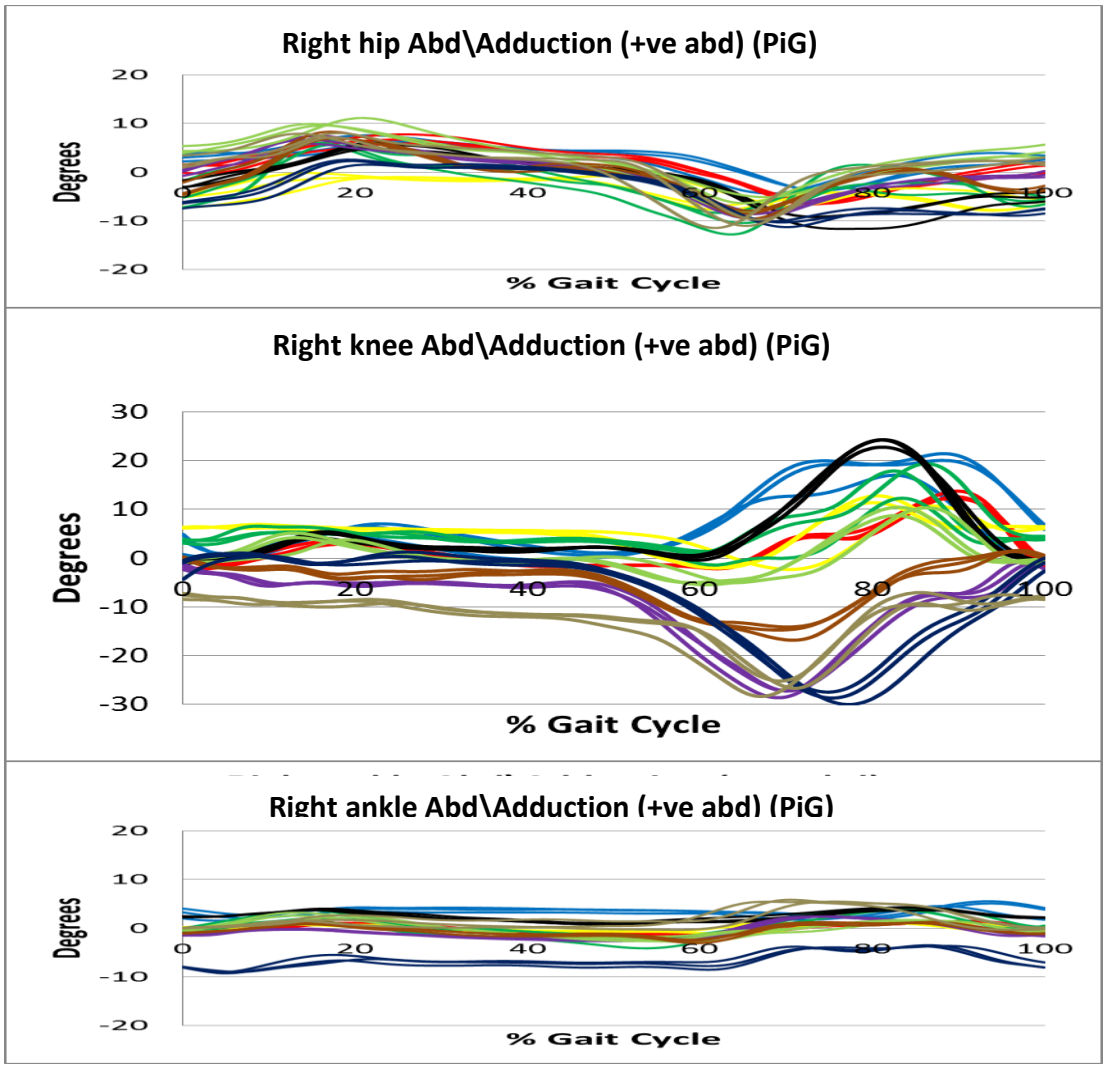


Figure A12.2 Coronal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by PiG

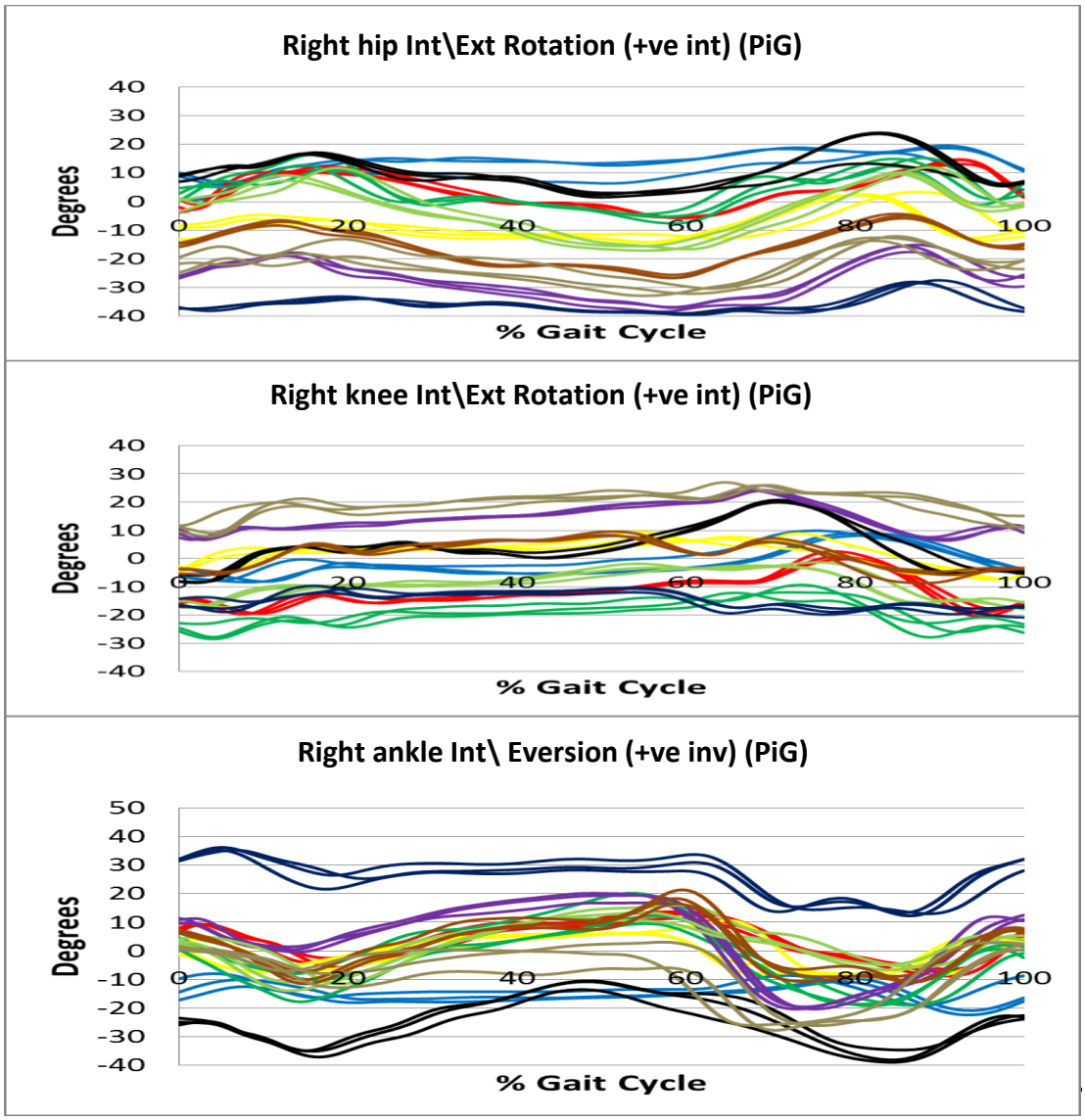


Figure A12.3 Transverse plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by PiG

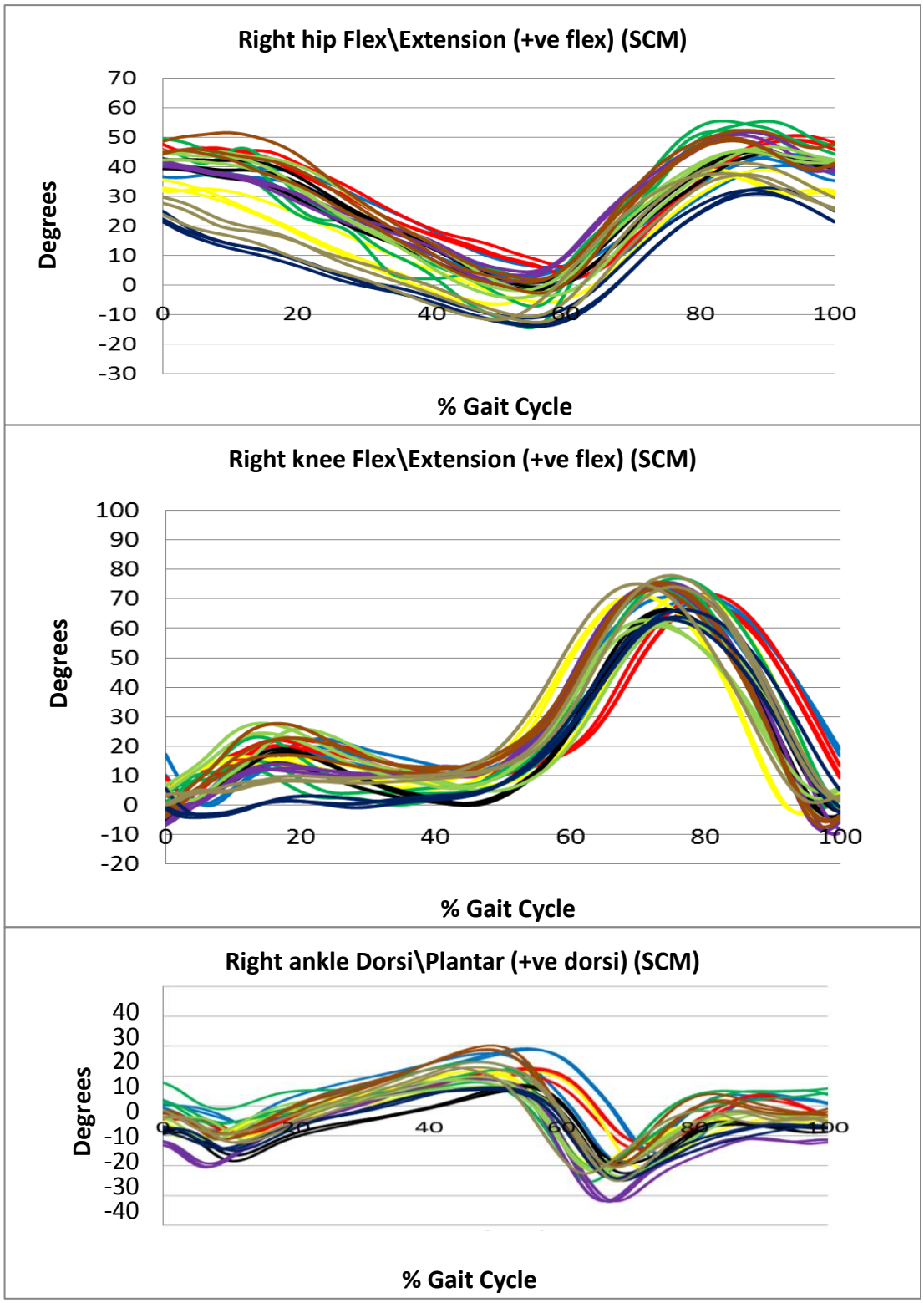


Figure A12.4 Sagittal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by SCM

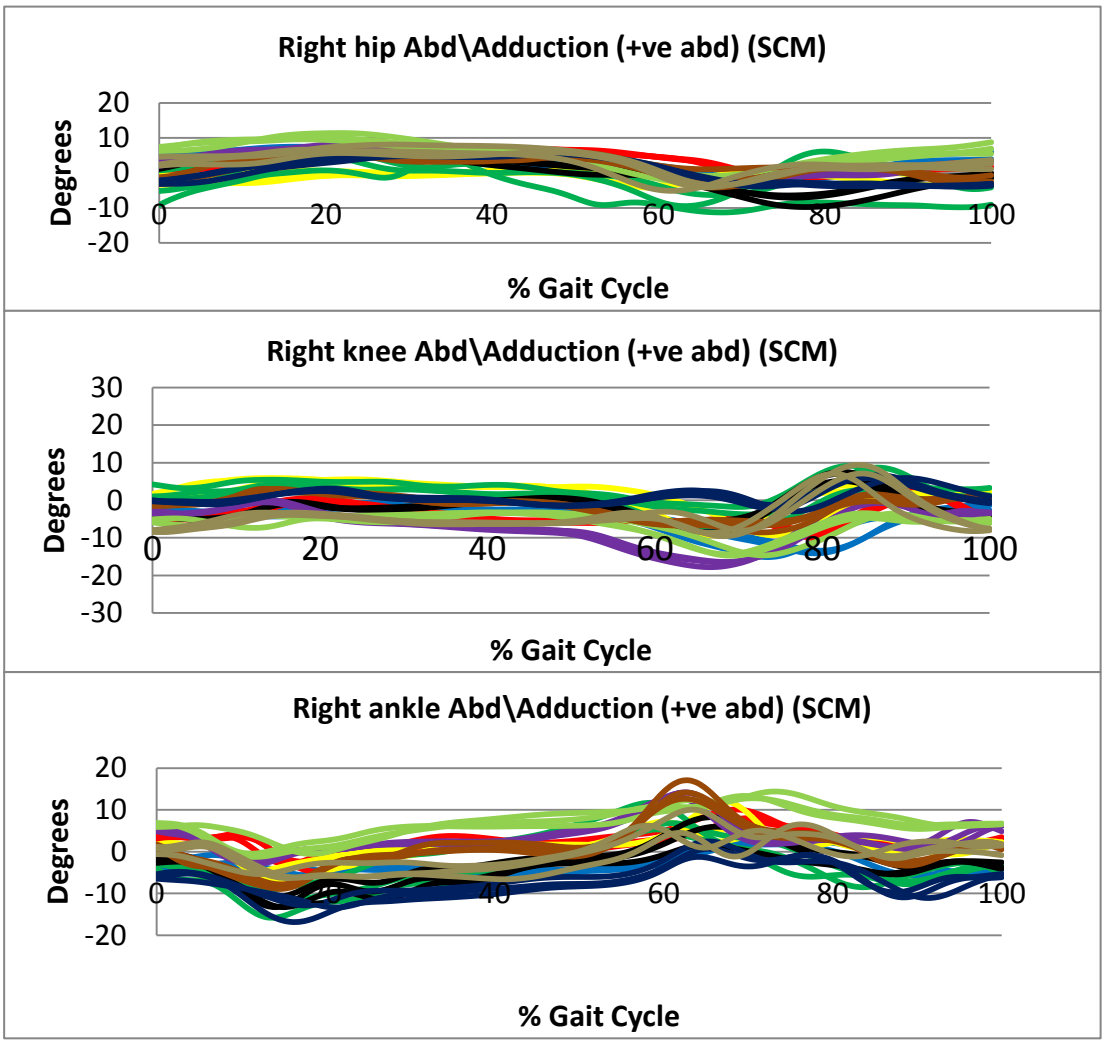


Figure A12.5 Coronal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by SCM

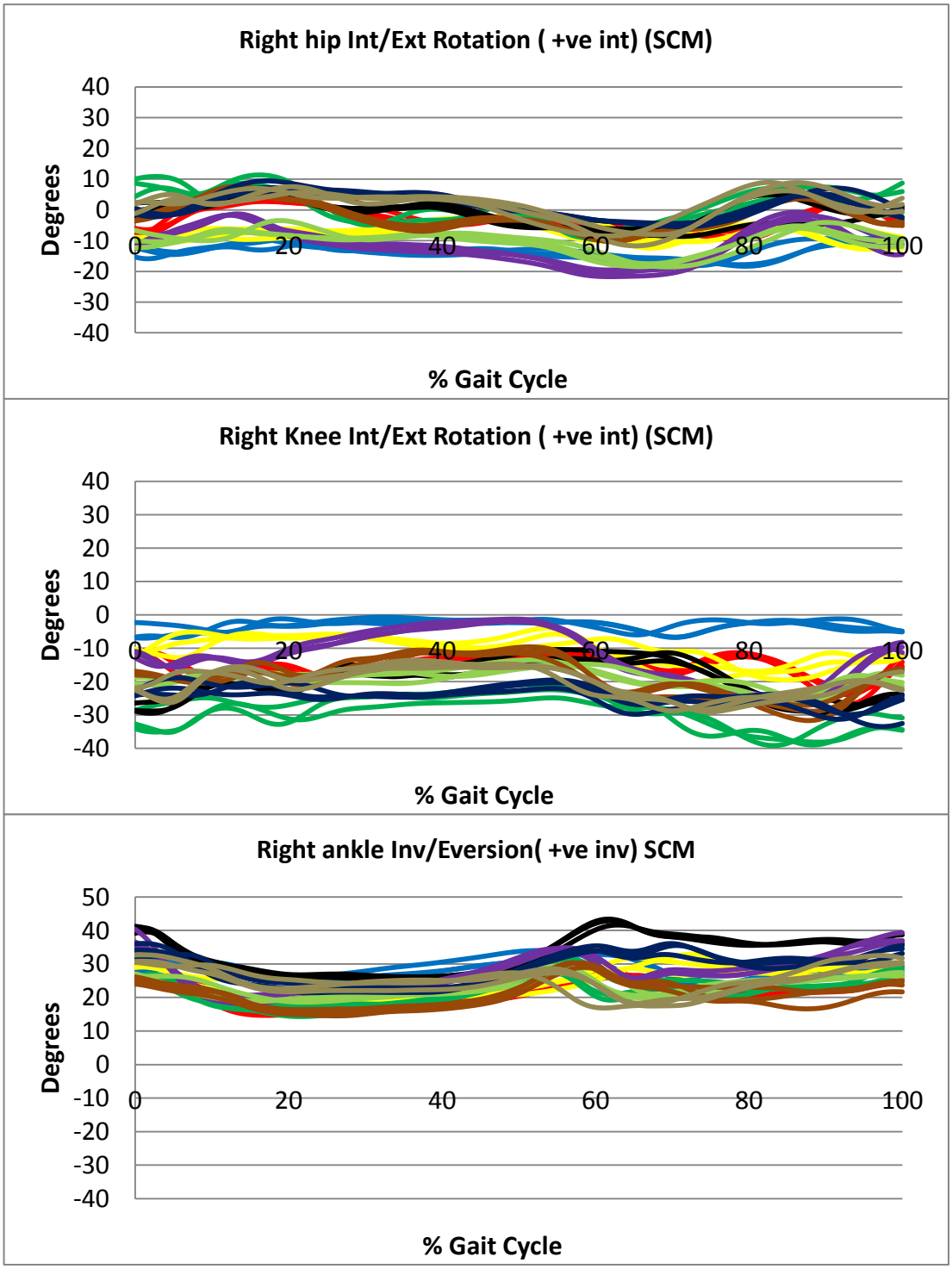


Figure A12.6 Transverse plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by SCM

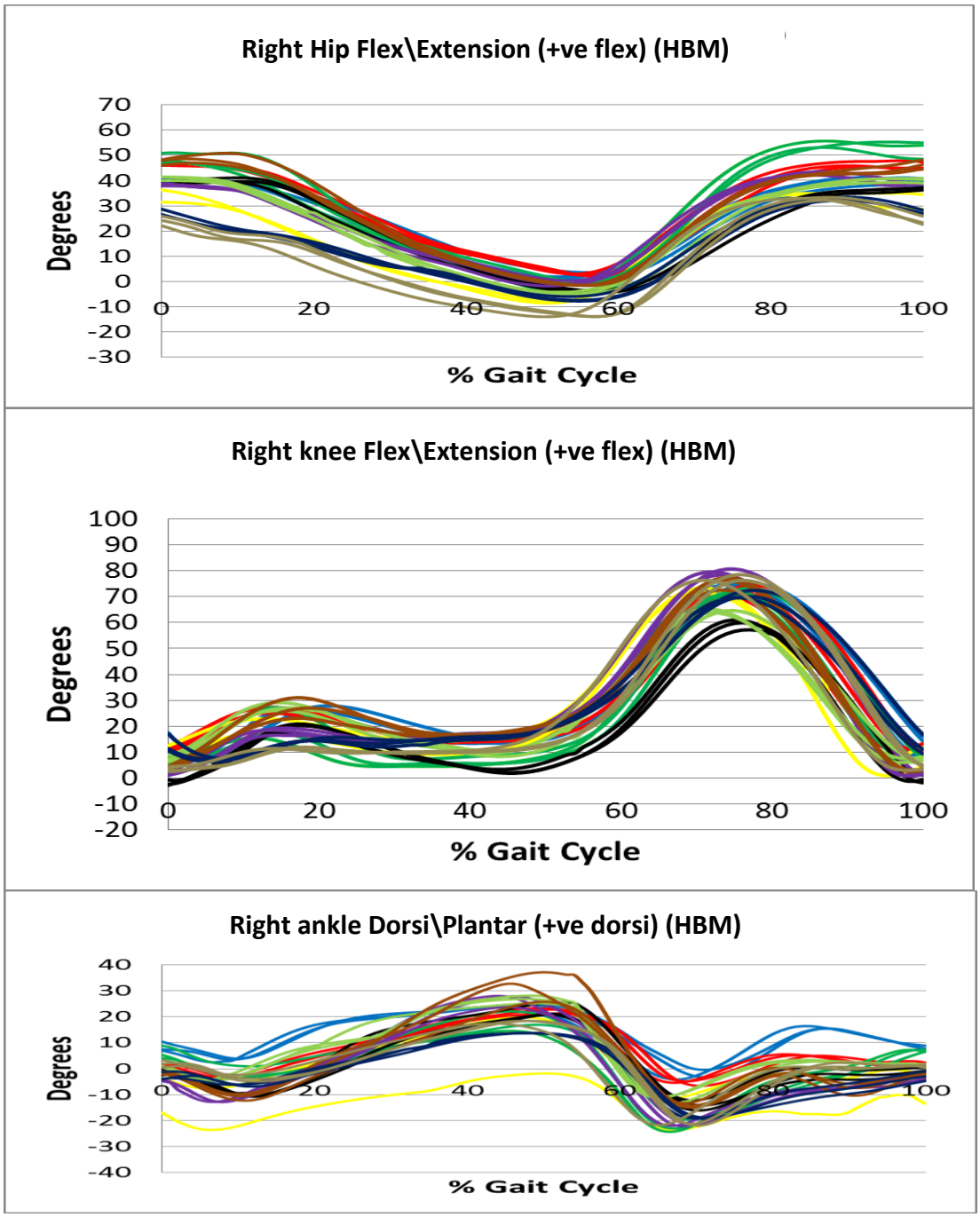


Figure A12.7 Sagittal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by HBM

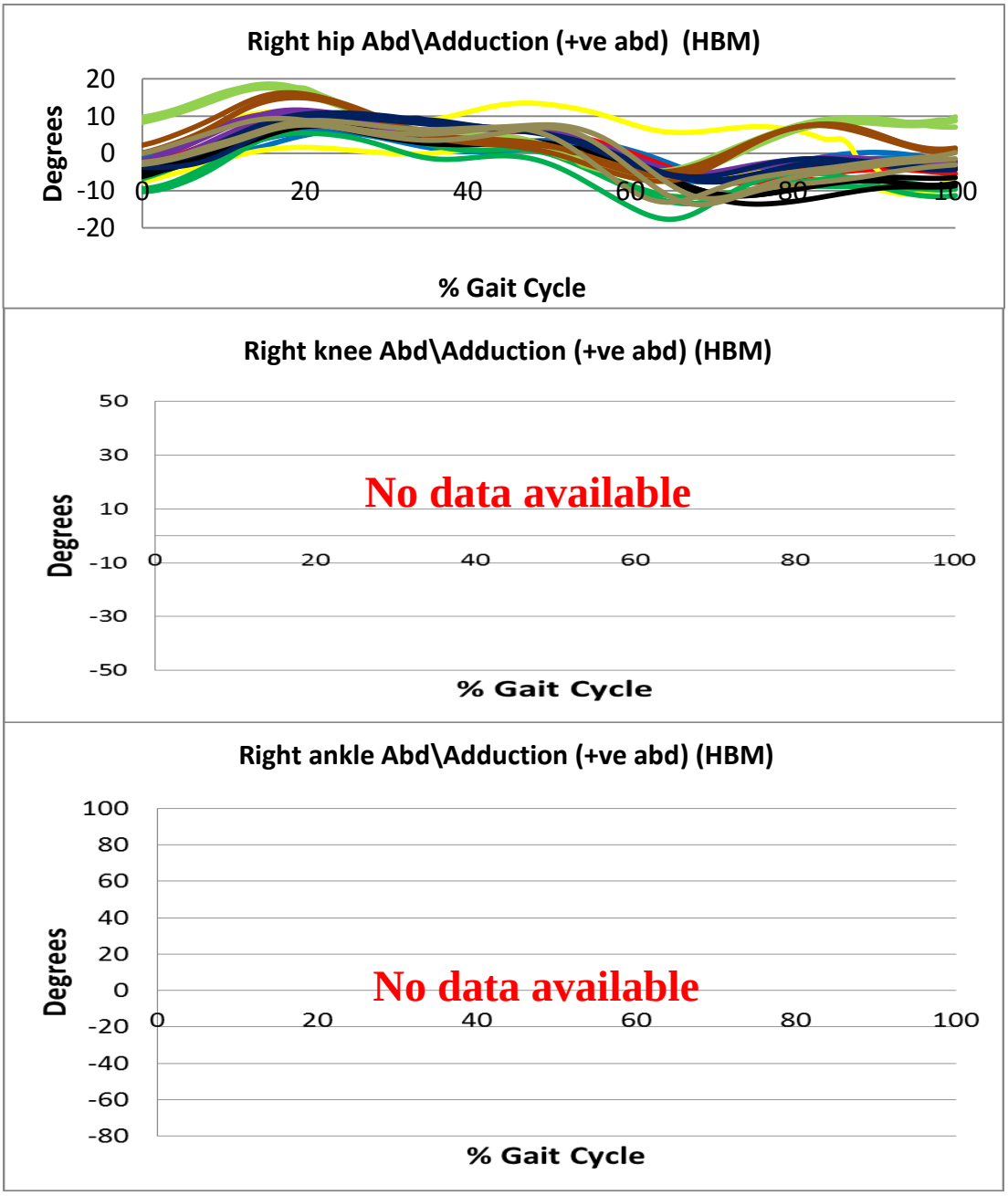


Figure A12.8 Coronal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by HBM

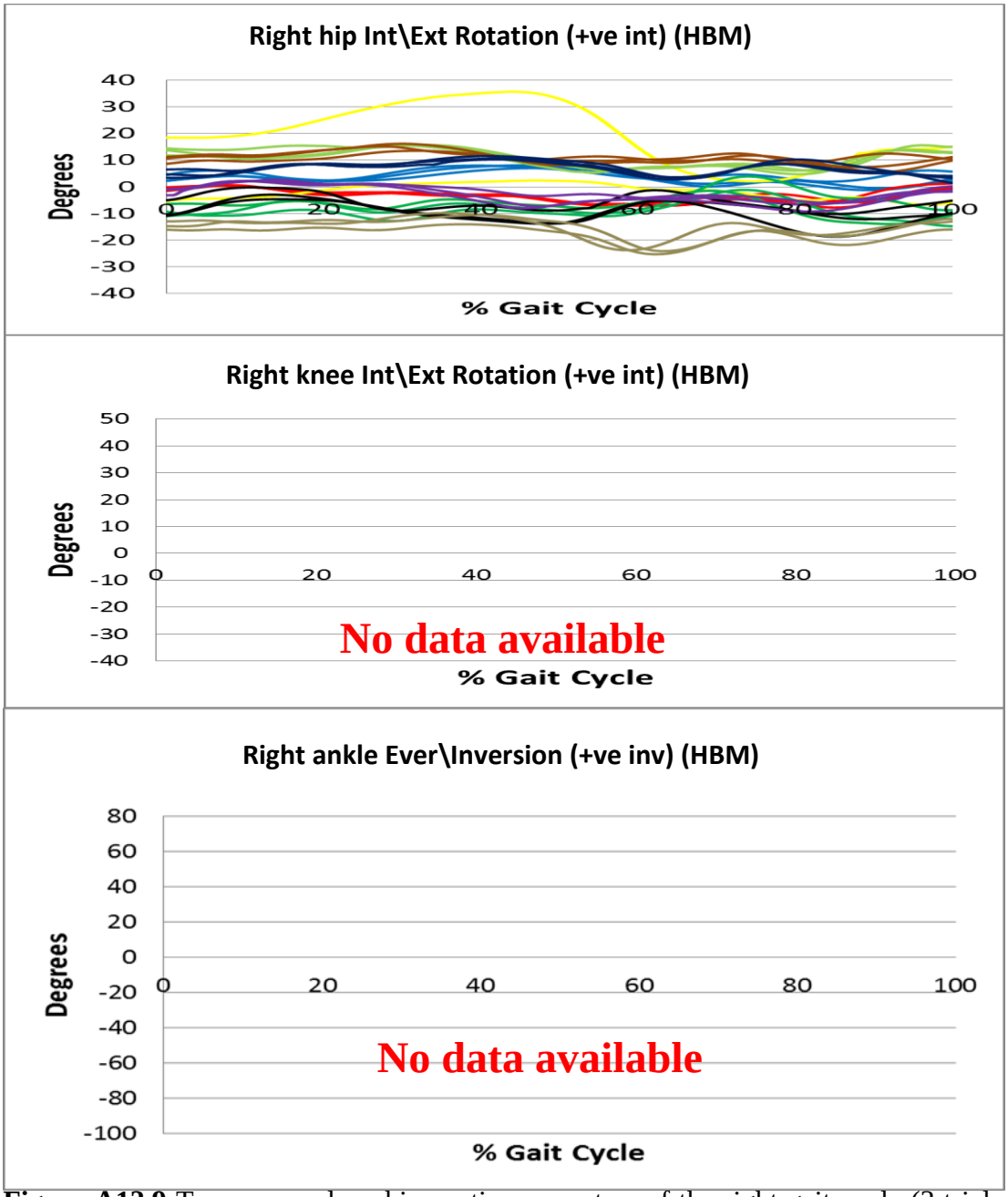


Figure A12.9 Transverse plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by HBM

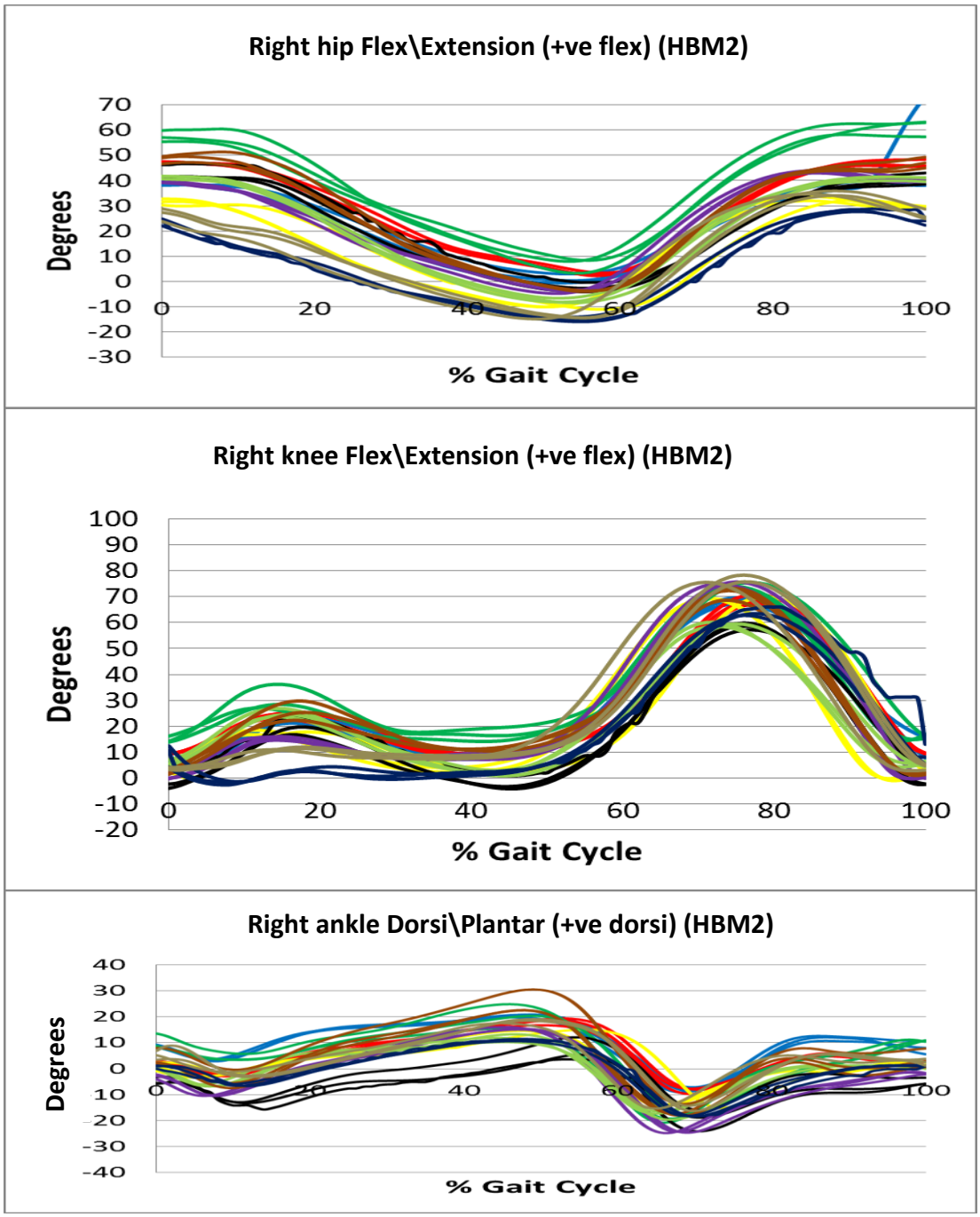


Figure A12.10 Sagittal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by HBM2

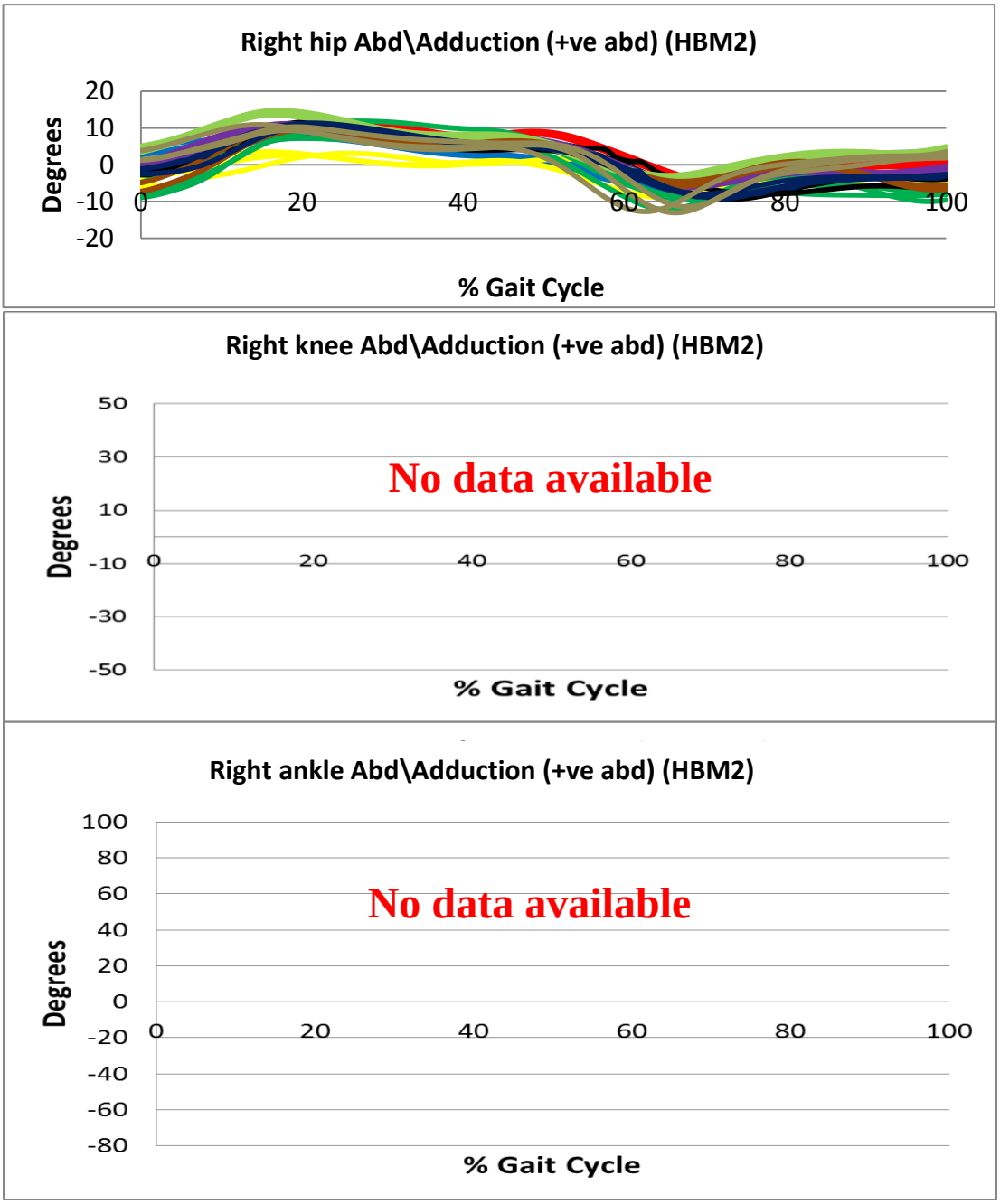


Figure A12.11 Coronal plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by HBM2

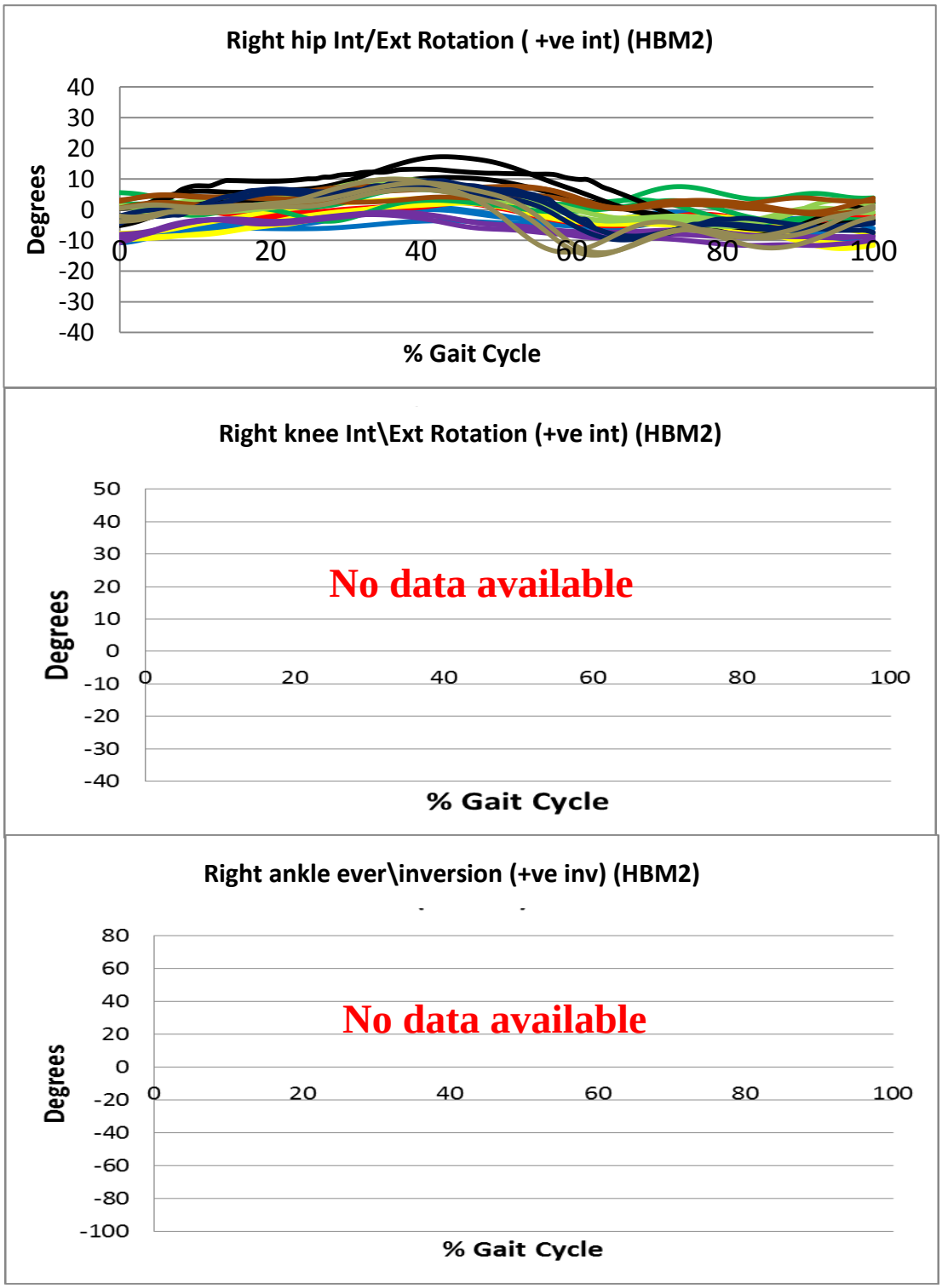


Figure A12.12 Transverse plane kinematic parameters of the right gait cycle (3 trials from 10 subjects) as calculated by HBM

Appendix 13 Additional data of Chapter 5

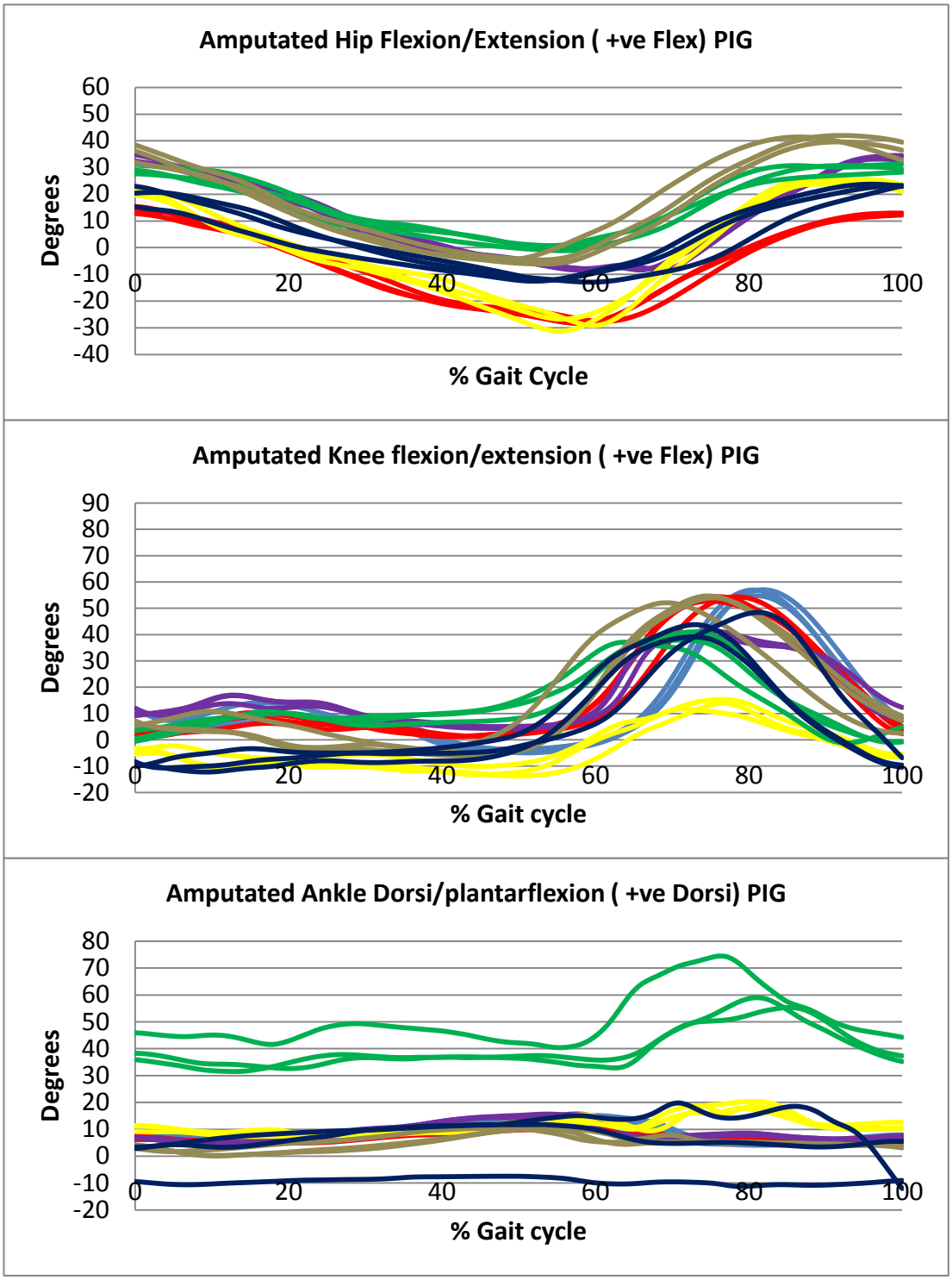


Figure A13.1 Sagittal plane kinematic parameters of the amputated side gait cycle (3 trials from 7 subjects) as calculated by PiG

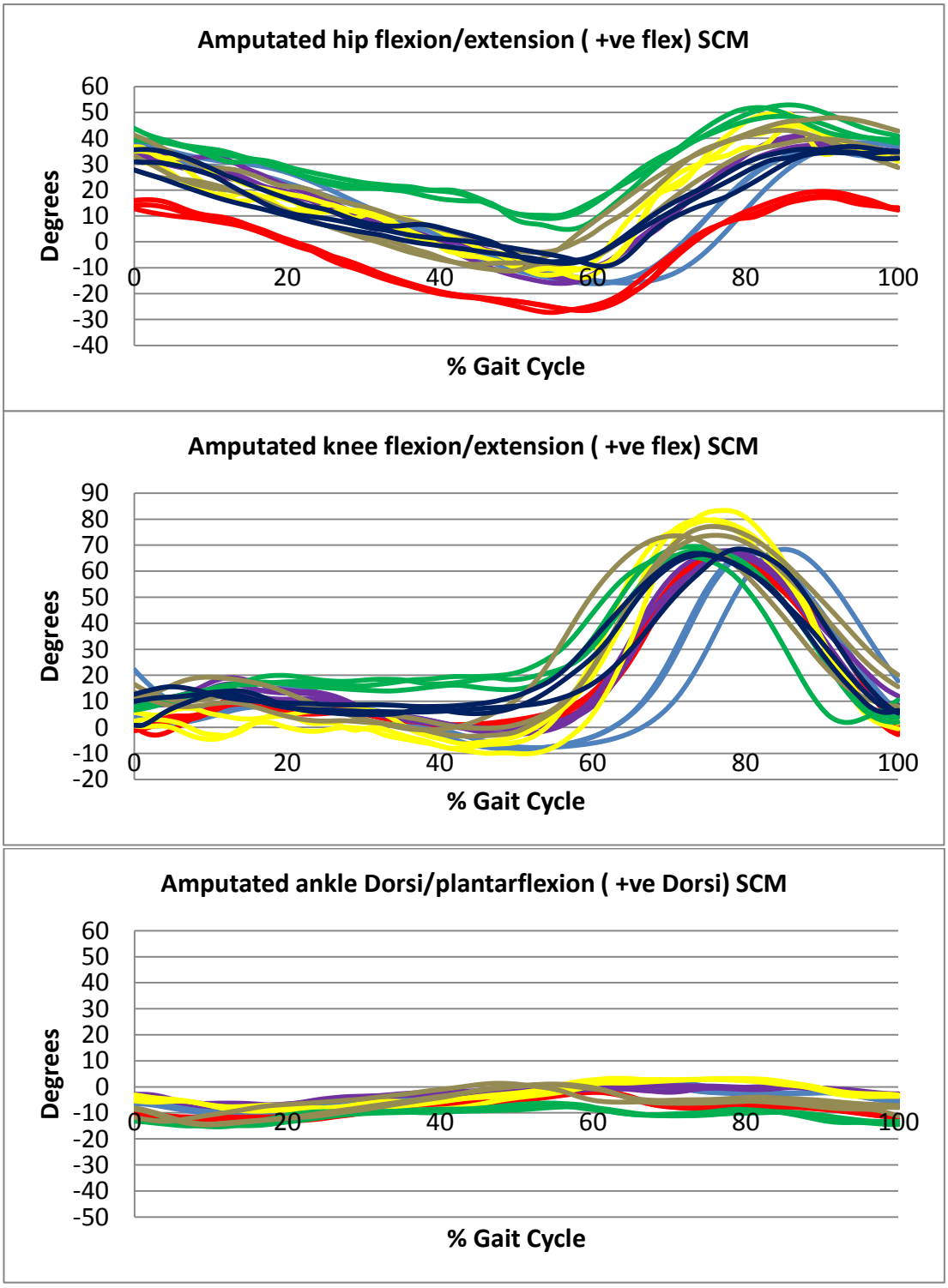


Figure A13.2 Sagittal plane kinematic parameters of the amputated side gait cycle (3 trials from 7 subjects) as calculated by SCM

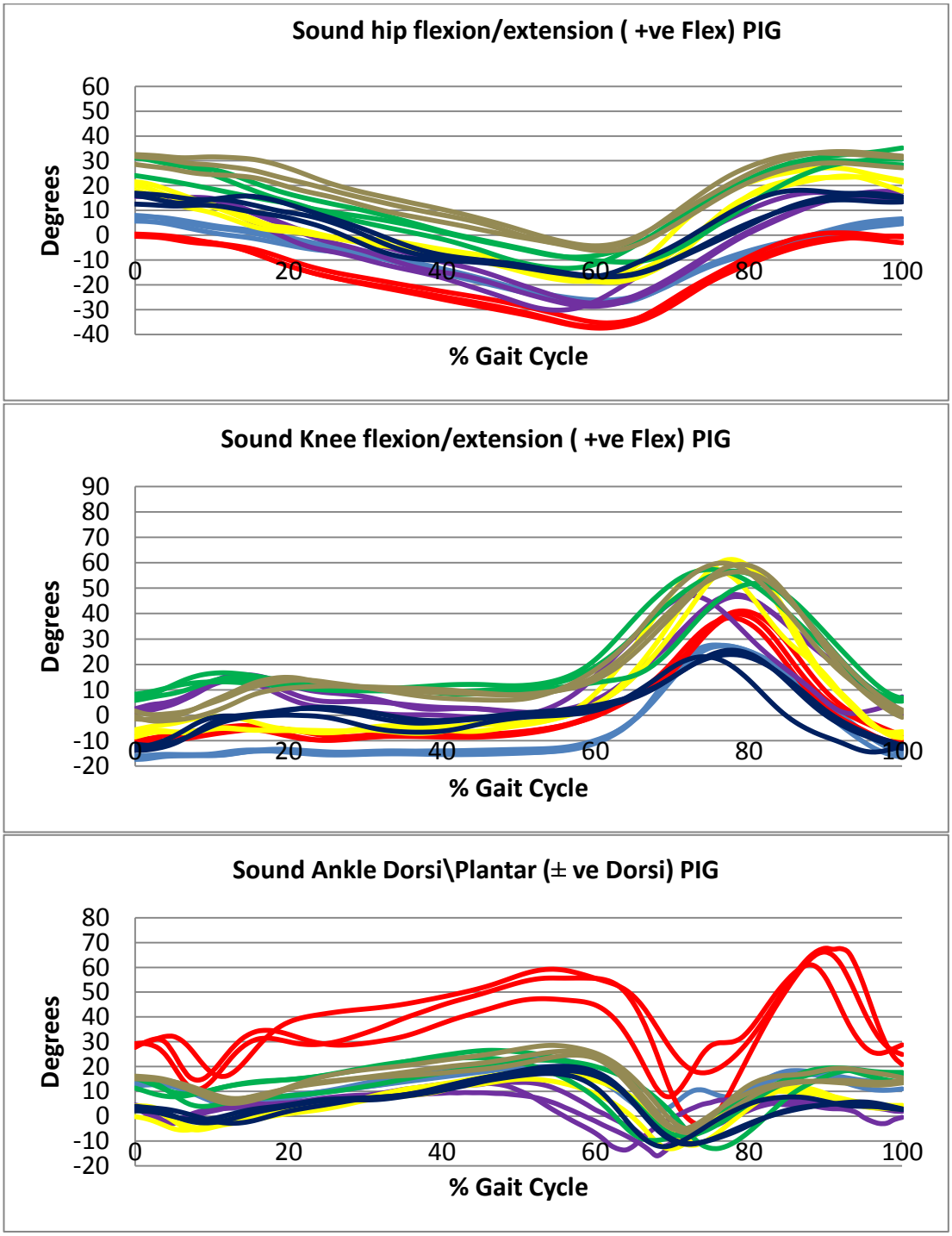


Figure A13.3 Sagittal plane kinematic parameters of the sound side gait cycle (3 trials from 7 subjects) as calculated by PiG

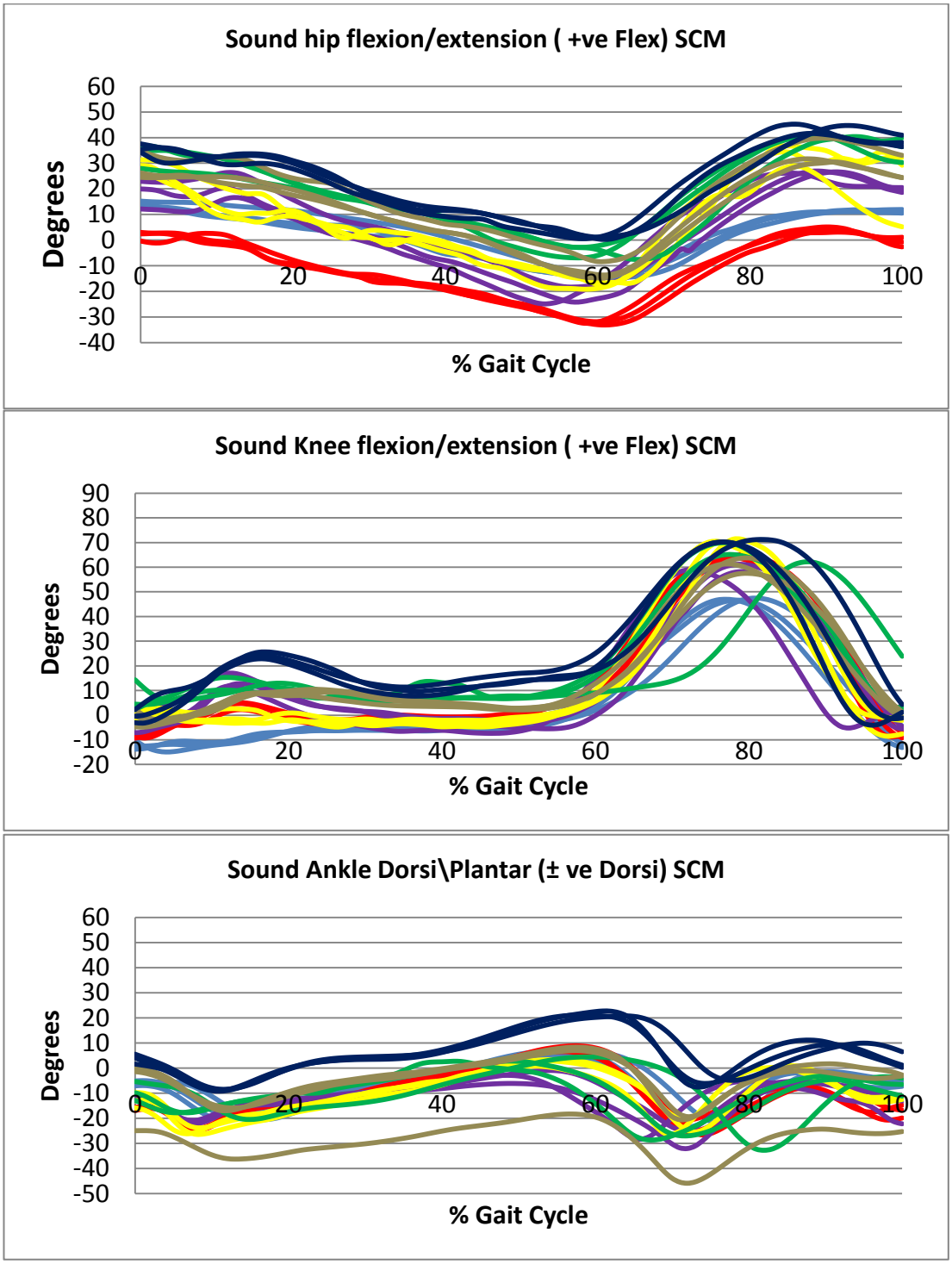


Figure A13.4 Sagittal plane kinematic parameters of the sound side gait cycle (3 trials from 7 subjects) as calculated by SCM

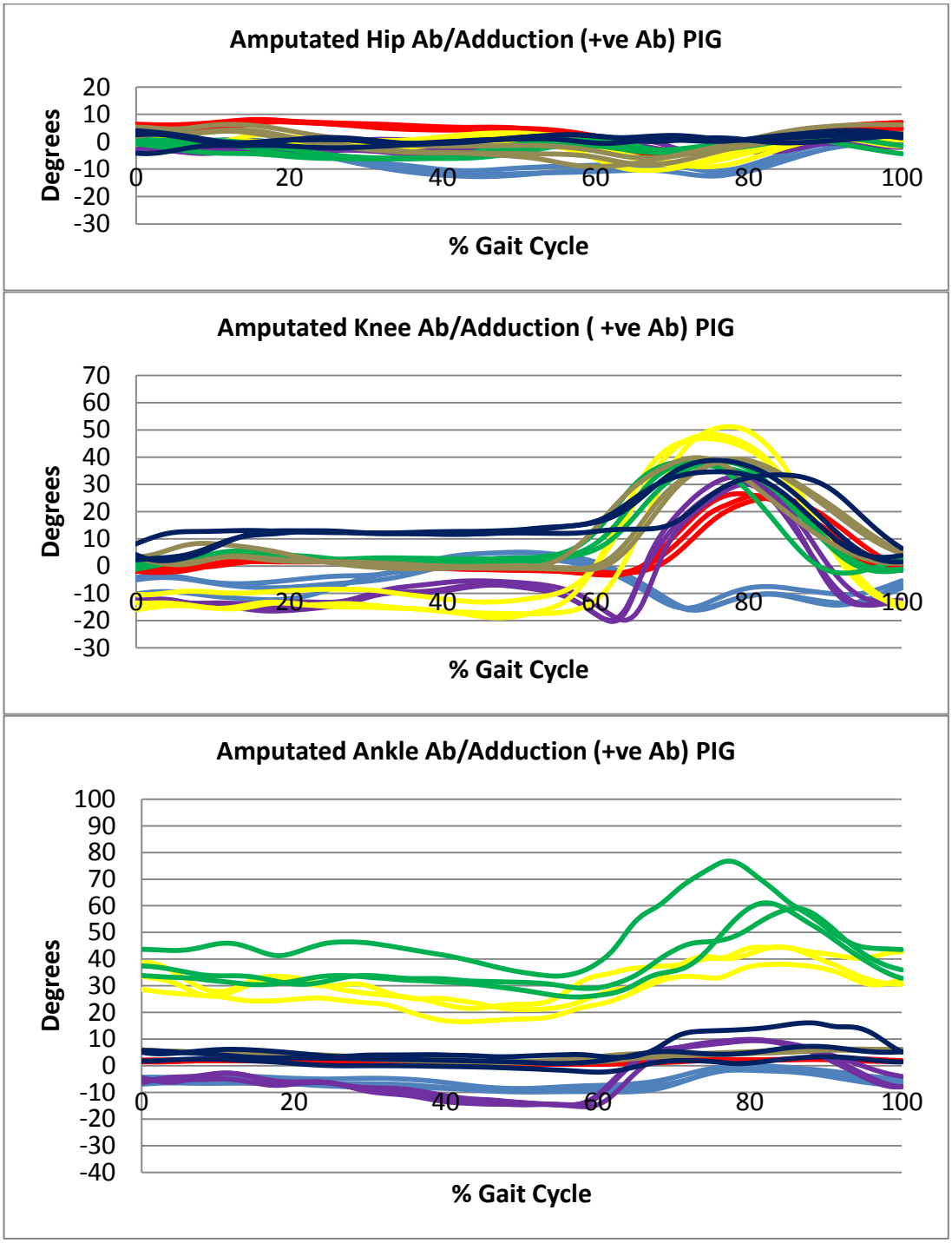


Figure A13.5 Coronal plane kinematic parameters of the amputated gait cycle (3 trials from 7 subjects) as calculated by PiG

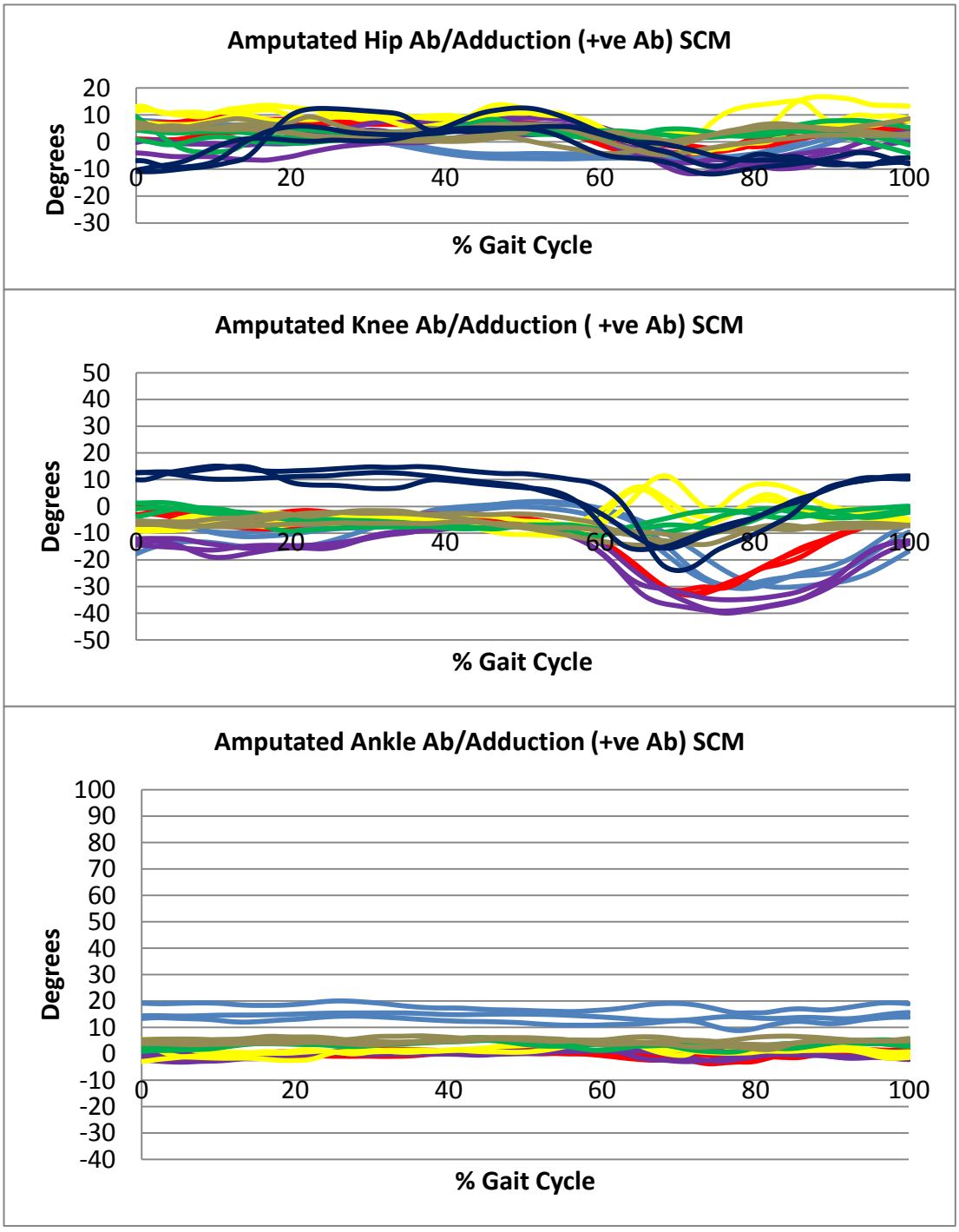


Figure A13.6 Coronal plane kinematic parameters of the amputated gait cycle (3 trials from 7 subjects) as calculated by SCM

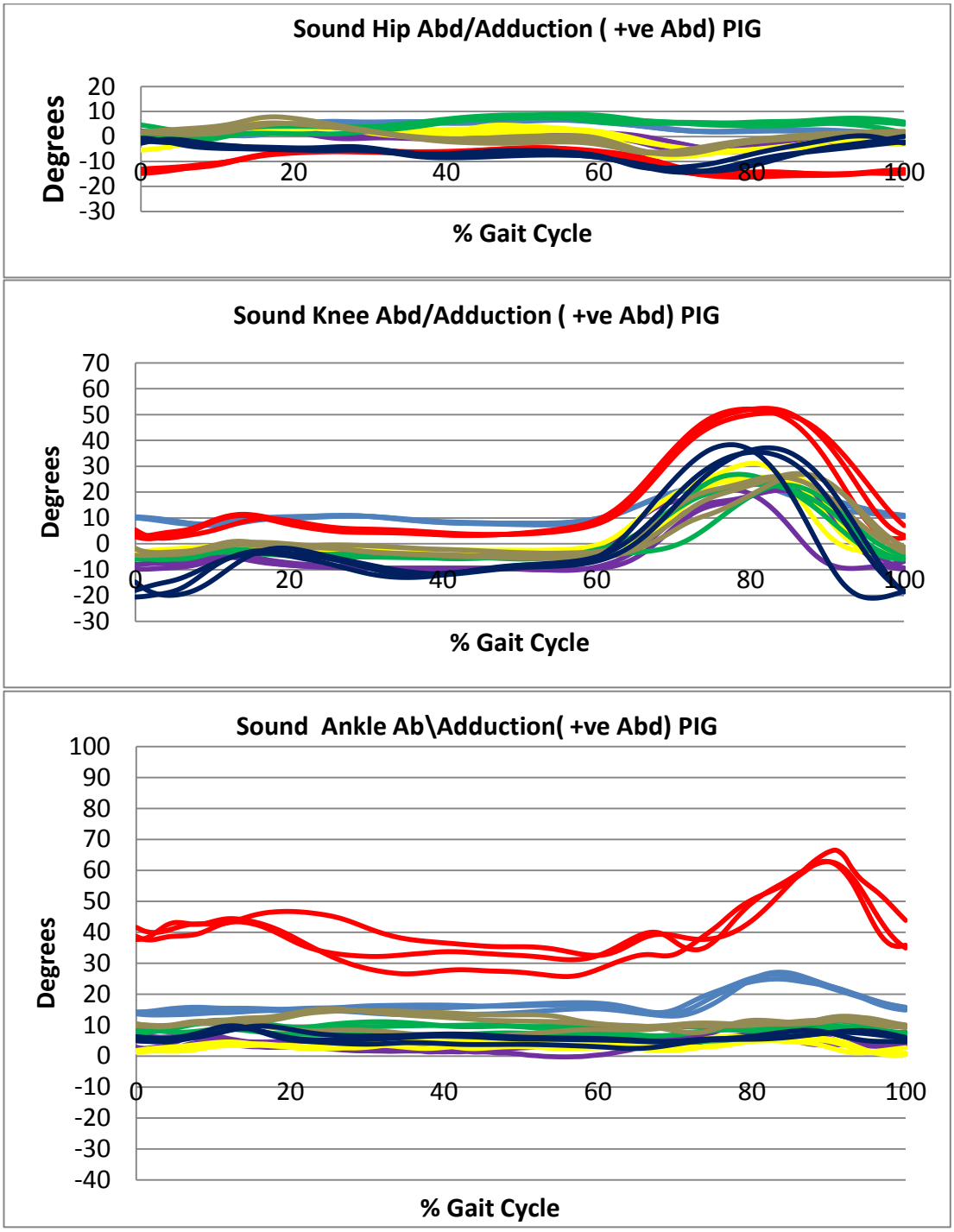


Figure A13.7 Coronal plane kinematic parameters of the sound side gait cycle (3 trials from 7 subjects) as calculated by PiG

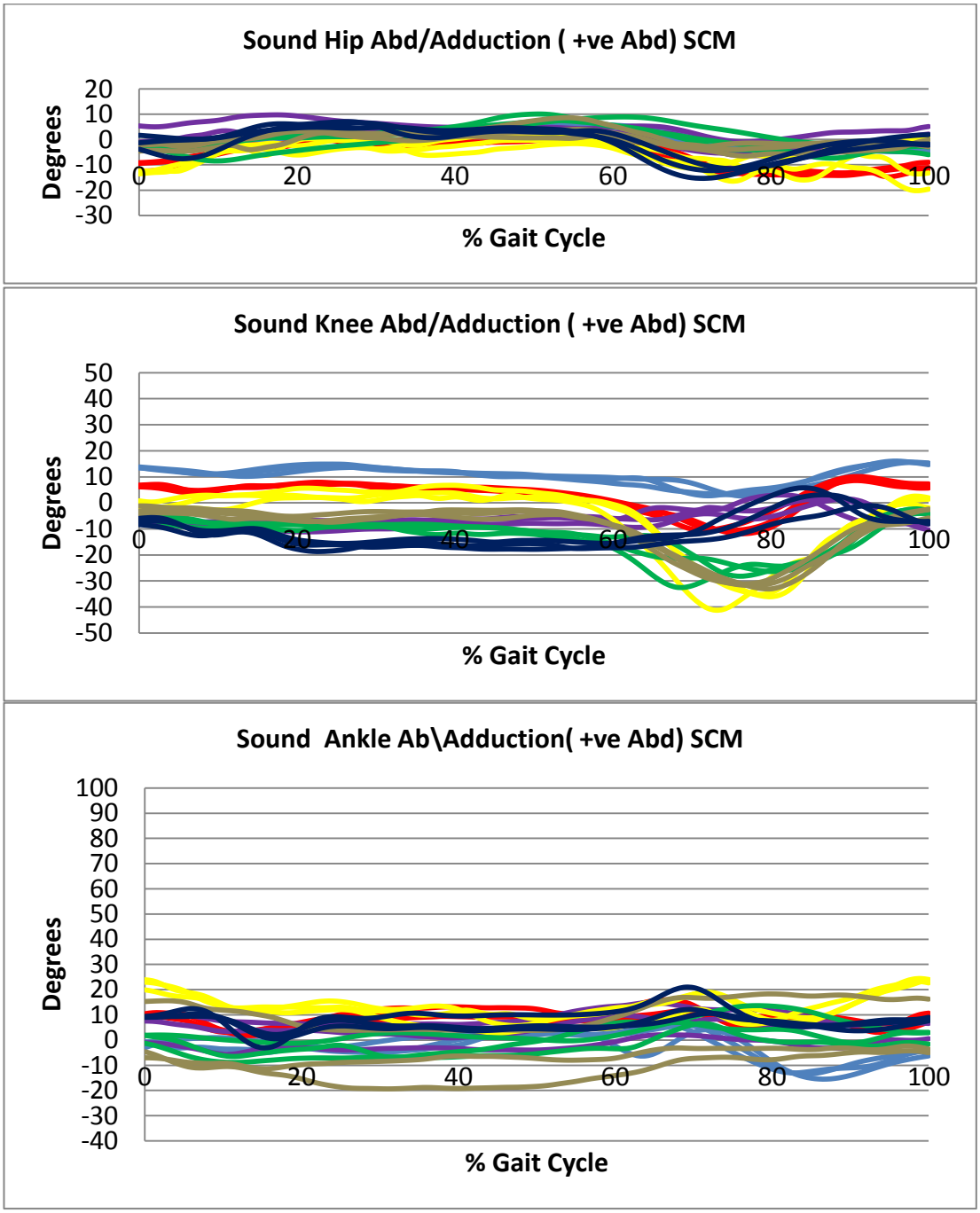


Figure A13.8 Coronal plane kinematic parameters of the sound side gait cycle (3 trials from 7 subjects) as calculated by SCM

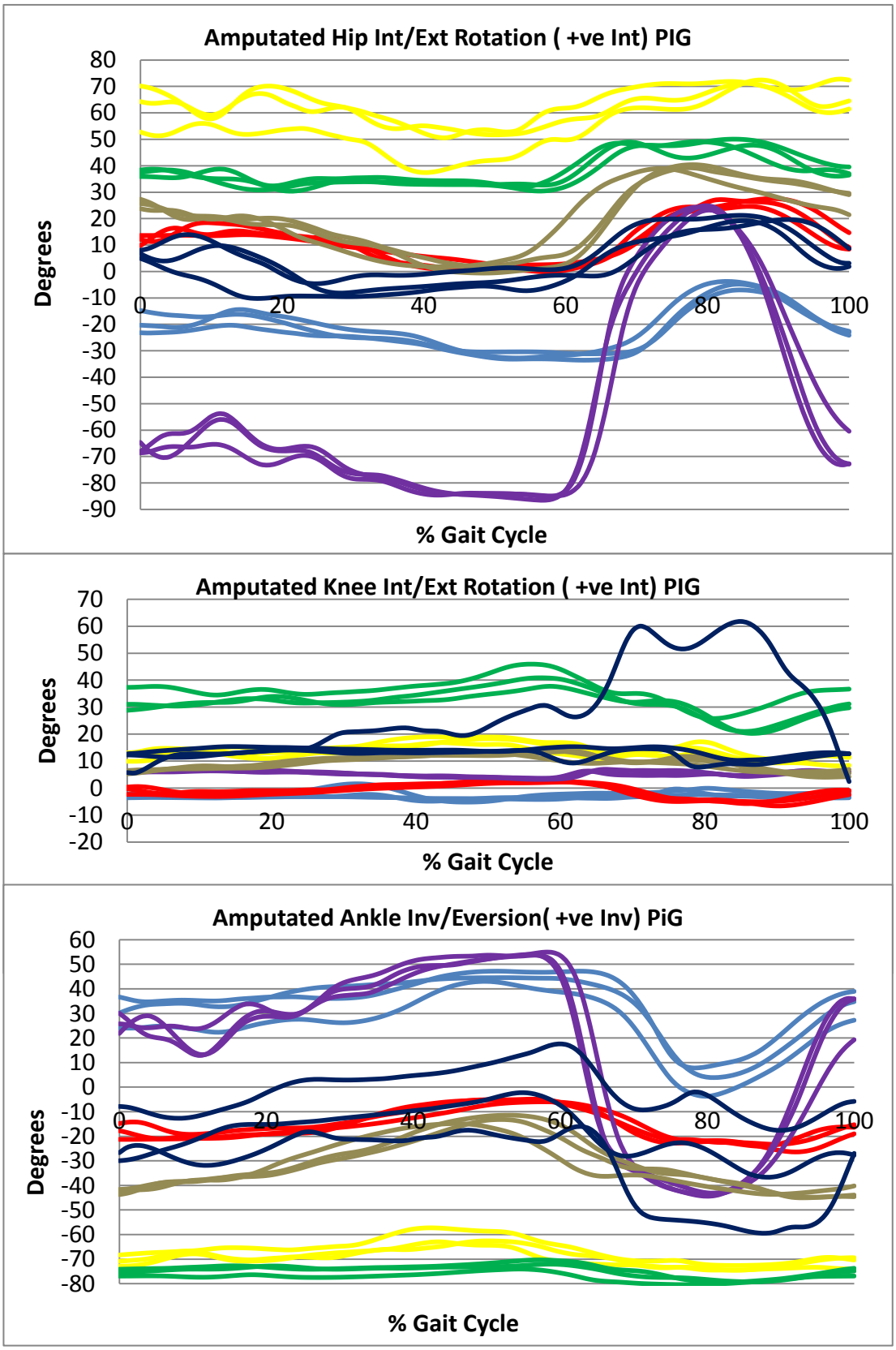


Figure A13.9 Transverse plane kinematic parameters of the amputated side gait cycle (3 trials from 7 subjects) as calculated by PiG

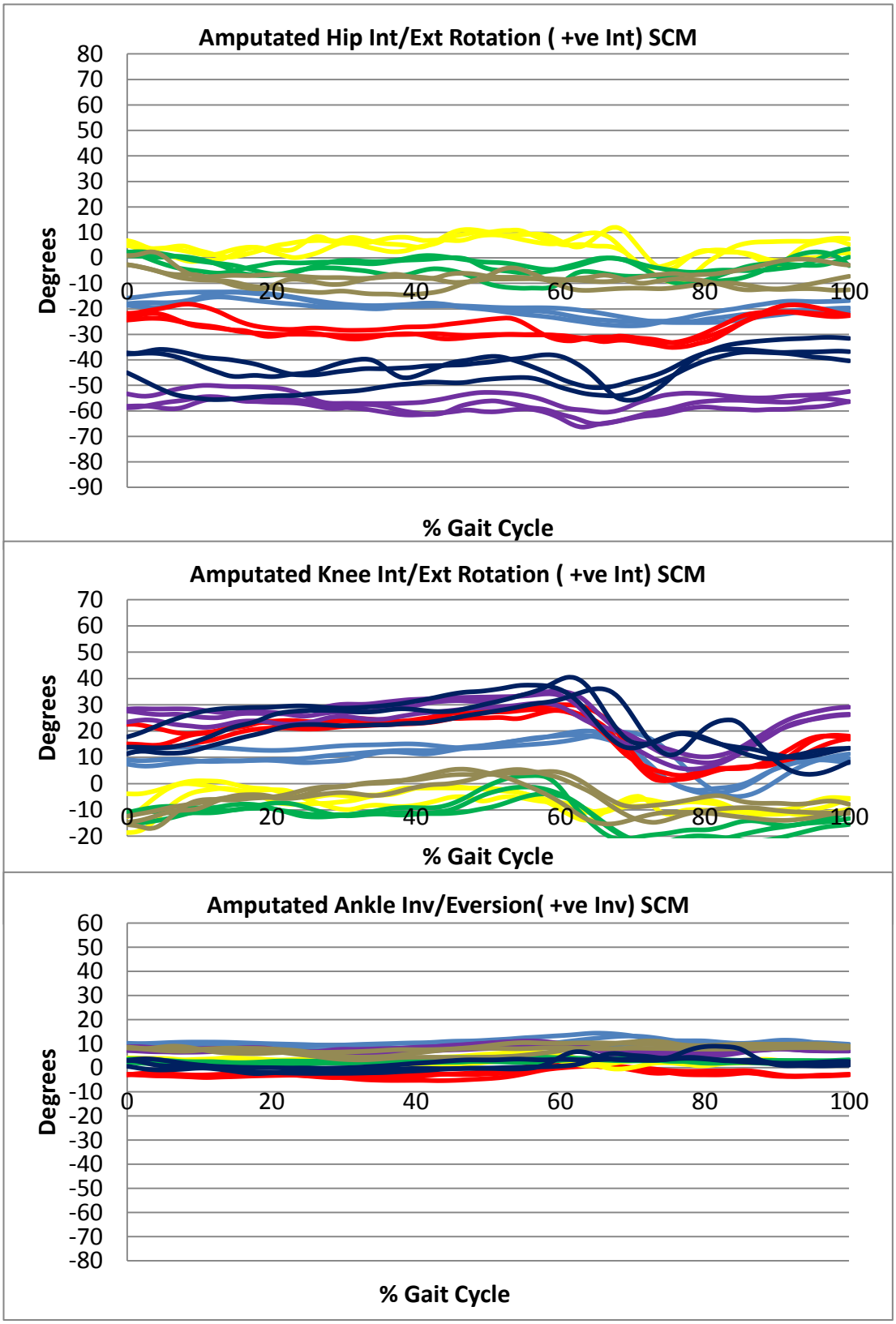


Figure A13.10 Transverse plane kinematic parameters of the amputated side gait cycle (3 trials from 7 subjects) as calculated by SCM

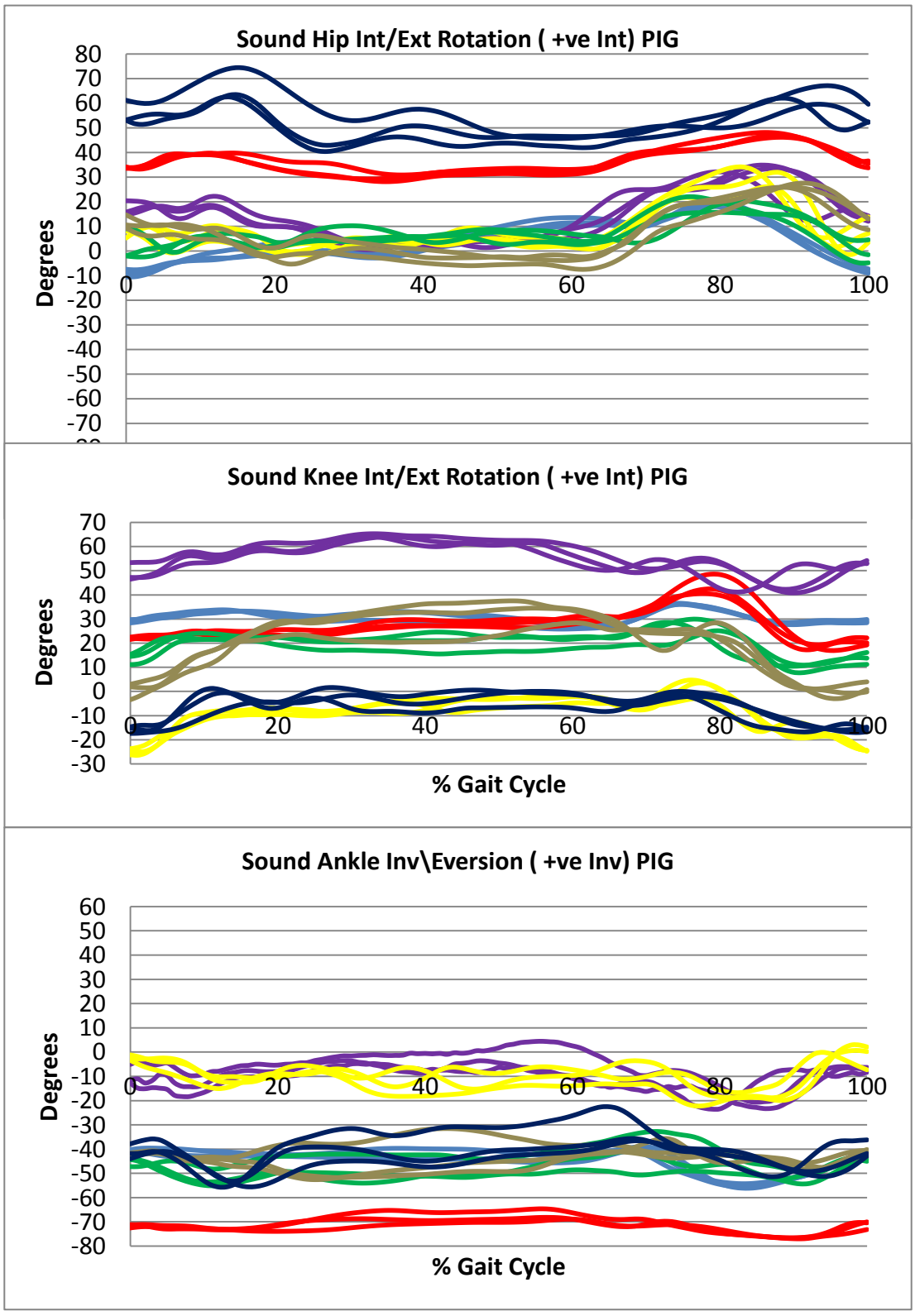


Figure A13.11 Transverse plane kinematic parameters of the sound side gait cycle (3 trials from 7 subjects) as calculated by PiG

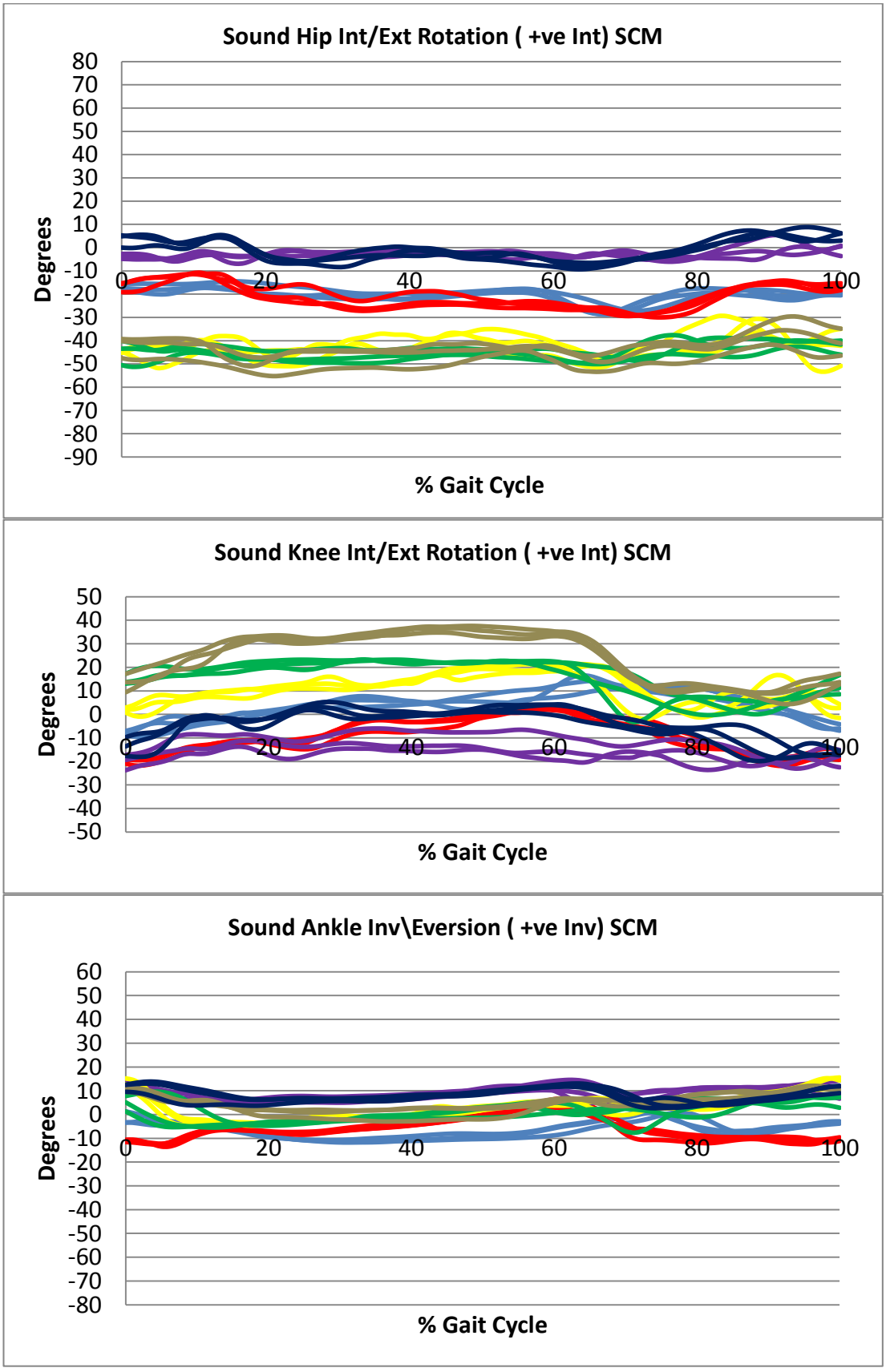


Figure A13.12 Transverse plane kinematic parameters of the sound side gait cycle (3 trials from 7 subjects) as calculated by SCM