THE EFFECT OF ALIGNMENT ON THE BALANCE AND CONFIDENCE OF TRANS-FEMORAL PROSTHESIS USERS

by

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‘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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A B S T R A C T

This pilot study aims to assess the effect of prosthetic alignment on the balance and confidence of trans-femoral prosthesis users.

The prosthetic alignment of five non-vascular trans-femoral prosthesis users were recorded using a bench alignment apparatus. The hip range of motion of each participant was assessed using the Thomas Test to establish the recommended socket flexion angle for bench alignment and compared to the socket flexion in the original prosthesis alignment.

The Activities-specific Balance and Confidence Scale (ABC) was used to determine user baseline balance and confidence with the original prosthetic alignment.

Each prosthesis was then re- aligned using two pre-determined angles of initial socket flexion. Dynamic alignment was conducted without adjustment to socket flexion or extension above the knee joint and the effect of compensatory adjustments noted. The resulting dynamic alignment of each configuration was compared using the bench alignment apparatus.

Each participant was assessed using the L-Test and Four Step Square Test (FSST) in the each of the alignment configurations of their everyday prosthesis.

Results showed a high level of balance confidence (Mean ABC = 86.6, s.d. = 8.1), walking ability (L-Test mean = 24.77 seconds) and balance (FSST mean = 12.43 seconds) in all alignment configurations. No statistically significant differences were found in the times recorded for the L-Tests and FSST, for any participant, in any

alignment configuration. The results indicate healthy, active prosthesis users can adapt using compensatory movements to accommodate changes in prosthetic alignment. The clinical significance of these compensatory movements requires further investigation.

Future research to promote understanding of the influence of prosthetic alignment and the effects of compensatory movements on balance and confidence in a lower limb absent population is required. Such work is important to facilitate long-term optimal functional ability of the prosthesis user.

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This thesis is dedicated to Margaret, Suzie and Tiny.

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LIST OF ABBREVIATIONS

2MWT	Two Minute Walk Test
6MWT	Six Minute Walk Test
10MWT	Ten Minute Walk Test
12MWT	Twelve Minute Walk Test
A/P	Anterior/Posterior
AAMPro	Amputee Mobility Predictor with Prosthesis
AAS	Amputee Activity Score
ABC	Activities-specific Balance and Confidence
ADL	Activities of Daily Living
AMP	Amputee Mobility Predictor
BBS	Berg Balance Scale
BESS	Balance Error Scoring System
EMG	Electromyography
FAI	Frenchay Activity Index
FES	Falls Efficacy Scale
FIM	Functional Independence Measure
FMA	Functional Measure for Amputees
FRT	Functional Reach Test
FSST	Four Step Square Test
GARS	Groningen Activity Restriction Scale
GRF	Ground Reaction Force
HD	Hip Disarticulation
ICF	International Classification of Function.
ISPO	International Society of Prosthetics and Orthotics
KD	Knee Disarticulation
LCI	Locomotor Capabilities Index
LLA	Lower Limb Amputee
M/L	Medial/Lateral
MFCS	Medicare Functional Classification System
MPK	Microprocessor Knee Joint
NMPK	Non-Microprocessor Knee Joint
PEQ	Prosthesis Evaluation Questionnaire
PGI	Patient Generated Index
PPA	Prosthetic Profile of the Amputee
QOL	Quality Of Life
RCT	Randomised Controlled Trial
ROM	Range Of Motion

SACH	Solid Ankle Cushion Heel
SF-12/36	Short Form 12/36
SIGAM	Special Interest Group in Amputee Medicine
SIP68	Sickness Impact Profile 36
TAPES	Trinity Amputation and Prosthesis Experience Scales
TF	Trans-femoral
TKA	Trochanter Knee Ankle
TT	Trans-tibial
TUG	Timed Up and Go Test
TWT	Timed Walk Tests
WHO	World Health Organisation

I N T R O D U C T I O N

Prosthetic management and rehabilitation following a trans-femoral amputation involves a complex series of procedures. These include the socket interface and fitting, suspension of the prosthesis and the alignment of modular components such as the prosthetic foot and knee. The individual needs of each prosthesis user and the training and education provided are also important in the overall success of the prosthetic fitting procedure. None of these aspects can be considered in isolation and each will have some effect on the overall outcome.

Prosthetic alignment is an inherent part of fitting a prosthesis and is routinely conducted and individually configured for each user. The individual variables will influence each other; therefore, the design of appropriate research must attempt to control these variables, whilst acknowledging the limitations of results where variables may have an effect.

Current lower limb absent population demographics demonstrate that less than 1% of the general population in the developed world has an amputation, around 75% of which are due to vascular disease and diabetes (1). These issues are mainly seen in the elderly and 70-80% of the limb absent population are over 70 years of age (2, 3). More recently, due to world conflicts, there has been an increase in younger more active, mainly male amputees, who have suffered often multiple injuries in combat. Consequently, this group demand higher quality, more functional prostheses and more

intensive rehabilitation (4). The issues affecting both of these groups however remain the same, to have a comfortable, functional and stable prosthesis to perform the activities of daily living (5-7).

The alignment of a prosthesis is central to a successful prosthetic fitting and can affect the fit of the socket, component function and the stability and gait of the user. Historically, alignment has been approached in a subjective way by practitioners using their clinical experience, manufacturer's guidelines for the set-up of components and feedback from the user (8-12). The individual nature of the feedback gained from each prosthesis user and the customisation of each prosthesis may introduce subjectivity in this process (13). This subjective approach can lead to confusion and a lack of consensus on the most appropriate alignment methods and how best to optimise individual alignment (8, 10, 14, 15). A stable prosthesis can promote comfortable gait (10, 16-18) and function (15, 19-22) for the prosthesis user and may increase user confidence by reducing the risk of falls (23-27).

Balance and confidence has been widely studied in the elderly population and the concept of self-efficacy and fear of falling as described by Bandura (28, 29) has been accepted by professionals in Elderly Care as a valid concept. This has initiated studies of balance, confidence and the relationship to falling in an elderly population and has led to the study of this phenomenon in a lower limb absent population. Falling and fear of falling, is a recognised issue for trans-femoral prosthesis users and can be linked to balance and confidence, which has been shown to be generally low in a lower limb absent population (30-32). A clearer understanding of the effects of prosthetic

alignment on this lower limb absent population could lead to improvements in balance and confidence (8, 10, 11, 14, 15).

The purpose of this investigation was to pilot the effect of the alignment of a trans-femoral prosthesis on the balance and confidence of the prosthesis user.

C H A P T E R 1

BACKGROUND

Amputations have been performed by surgeons since ancient times and the provision of a prosthesis or an artificial limb to replace a missing limb has evolved over centuries. The design and manufacture of a prosthesis is complicated by the individual prescription of each limb. Each prosthesis is custom-made for the individual user and there are a number of component parts that make up the design and construction of such a device.

The interface between the residual limb and the prosthesis, the prosthetic socket, is designed utilising biomechanical principles to facilitate comfortable transmission of forces from the residual limb tissue to the prosthesis. Optimal socket fit is essential, although criteria to determine exactly what constitutes optimal fit is still debated and much time is spent refining and adjusting the socket until the user is satisfied. The method of attaching the socket to the user, socket suspension, may influence the comfort and fit of the socket and affect the ability of the user to control their prosthesis (33).

Along with the socket and suspension method, the level of amputation and the required function of the user determine components that comprise the prosthesis. The individual biomechanical set up of the components, known as the alignment of the prosthesis, is

crucial in the overall function. The higher the level of amputation the more influence alignment has on the function of the user and their ability to control the prosthesis (11).

The alignment of any prosthesis is based on the anatomical position and condition of the residual limb; the anatomy of the sound side; the socket interface and the specific prosthetic components that constitute the prosthesis. There are three stages of alignment:-

1. Bench alignment – The initial set-up of the prosthesis to interconnect and align the components and socket before fitting to the user.

2. Static alignment – The initial assessment and adjustment of the position, angulation and height of the components and socket fit in a weight-bearing situation.

3. Dynamic alignment – The process of aligning the prosthesis during walking, by altering the linear and angular alignment of socket, knee and foot to achieve a safe and comfortable gait pattern for the user.

All of these processes may influence the outcome of a prosthetic fitting. In trans-femoral prosthetic alignment the position and angulation of the socket relative to the prosthetic knee and foot is central in establishing bench alignment. This is achieved through assessment of the anatomy and movement at the hip and pelvis of the prosthesis user. Normal range of passive hip motion is 10-15° of extension and 130° of flexion in the sagittal plane. In general, 6° of hip extension and 35-40° of flexion are required for normal walking (34). This is important when considering the set-up of a

trans-femoral prosthesis as the muscles acting around the hip are compromised following amputation. The hip muscles may not be strong enough or in the optimum position to facilitate the range of motion required for normal walking (35, 36) and this must be accommodated within the alignment of the prosthesis.

Bench alignment is the starting point necessary to facilitate optimal individual prosthetic alignment. This is the set-up initially fitted to the trans-femoral prosthesis user. At this early stage, safety is of inherent importance and a feeling of instability could influence the outcome. Poor balance and fear of falling can lead to a lack of confidence in using the prosthesis and reluctance to bear weight fully on the device. The changes made to the prosthesis during dynamic alignment, as the prosthesis user stands and walks, alter the biomechanics of the prosthesis and can influence these perceptions. The issues of stability and mobility are compounded for trans-femoral or higher level prosthesis users due to the loss of active muscle control over multiple joints and the reduced proprioception a user may experience (10, 11, 37-40).

A trans-femoral prosthesis user must rely on the biomechanical set up of the prosthesis to provide the stability needed in the stance phase of gait to prevent the knee from buckling (10). In normal gait knee joint flexion is controlled by the quadriceps muscles, acting across the knee joint, which eccentrically contract to control unwanted knee flexion in stance (34). Following a trans-femoral amputation, the quadriceps muscles no longer function to control the knee joint. The trans-femoral prosthesis user is dependent on the ability to use their hip extensor muscles to stabilise the prosthetic knee and the biomechanical alignment of the prosthetic knee and foot to maintain stability in stance. Many prosthetic knee joints incorporate a stance control mechanism

that can also assist in improved stability. The loss of functional control of the knee joint, foot and ankle is a challenge for trans-femoral prosthesis users and can lead to falls, lack of confidence and increased energy expenditure even in younger, active prosthesis users (17, 28, 30, 41-47).

Balance and confidence has been assessed in the elderly population (48-52) and the effect of low balance confidence, reported falls and fear of falling has been shown (53-56) to be detrimental to mobility, independence and social participation. In a limb absent population and particularly a trans-femoral prosthesis user population, the effects of low balance and confidence have demonstrated similar results (30, 32, 43).

The introduction of modular prosthetic systems has enabled the Prosthetist to adjust and re-adjust alignment configurations quickly and easily in the clinic to achieve a biomechanically stable alignment. More recently, technology has enabled the Prosthetist to use tools within the clinical setting which simplify and speed up this complex process (8). These tools can also enhance the ability of the Prosthetist to record and repeat certain alignment configurations and may improve the alignment process for user and clinician alike (21). The desire to find a universal procedure to solve what is essentially a biomechanical problem has been approached in a number of different ways, but it has proved difficult to glean any consensus due to the number of variables which make this so much more than a simple biomechanical problem (9-11, 14, 57).

Outcome measurement has become more important and sought after in many areas of healthcare research and clinical practice. This is also true in prosthetic rehabilitation

with measurements such as quality of life, balance and confidence, mobility and functional ability being studied (58-60). These outcome measures have been used to highlight areas of importance to the lower limb absent population and clinical practitioner, such as suitability of fitting and rehabilitation with a prosthesis, choice of prosthetic components (15, 61-64) and psycho-social issues (65, 66). This is especially important in the area of prosthetics where realistic goal setting is essential in the process of rehabilitation. Varieties of tests and questionnaires have been developed to provide clearer evidence in these areas.

To investigate these topics in more detail, a review of the literature was conducted to examine the evidence for a link between balance and confidence and the alignment of a trans-femoral prosthesis. The literature review also investigated current alignment protocols and the most appropriate tools and outcome measures to assess balance and confidence in a lower limb absent population.

CHAPTER 2

A REVIEW OF THE LITERATURE

2.1 INTRODUCTION

The aim of this literature review was to ascertain current protocols for prosthetic alignment and to determine if there is a relationship between prosthetic alignment and balance and confidence of the prosthesis user. The review also examined the tools and equipment used for measuring and recording prosthetic alignment and the clinical measurements of the prosthesis user. The validity of appropriate outcome measures for the assessment of balance and confidence in this population was also investigated.

To address the above questions, four key areas must be evaluated:

- Establishing alignment protocols
- The effects of alignment on the biomechanical function of the prosthesis
- Technical and clinical measurements
- Outcome measurements of balance and confidence

To assess the influence of prosthetic alignment on the balance and confidence of a trans-femoral prosthesis user it is important to understand the biomechanics and basic principles of fitting and aligning such a prosthesis. The instruments and tools, which measure this procedure, must be verified and their reliability, validity and sensitivity

ascertained to determine the most appropriate method of measuring and recording alignment in this population. Evaluation of appropriate and valid outcome measurements is necessary, in order to measure the effect of alignment on balance and confidence.

2.2 METHODS

The review was conducted using the following databases: Medline via Ovid (1966-present), Old Medline 1951 to 1965, Medline in process citations, Embase (1947-present), RECAL and PubMed. A search of the University of Strathclyde E-Library was performed and electronic sources found using the search engine Google. There were no limitations specified in the advanced search of Medline (via Ovid). There were a number of advanced searches conducted in order to cover each of the areas of interest. The main themes and synonyms for the searches are shown in Table 1. The citations of the references retrieved from the searches were exported to Endnote Web (©Thomson Reuters) bibliographic reference software.

Table 1: Main themes and synonyms

TOPIC	MAIN THEMES	SYNONYMS
Prosthetic alignment	prosthetic fitting biomechanics artificial limbs lower extremity amputee	prosthetic gait gait prosthetic alignment dynamic alignment prosthesis design above knee amputation trans-femoral amputation

TOPIC	MAIN THEMES	SYNONYMS
Anatomical measurements	hip range of motion leg length residual limb pelvic motion	hip hip flexion Thomas Test goniometer trans-femoral amputation flexion contracture
Balance and confidence	balance confidence	lower limb prosthetic alignment above knee amputation trans femoral amputation
Outcome measures	outcome measurement	balance and confidence amputee lower extremity prosthetic fitting mobility

Further articles were obtained by manually cross-referencing the references listed in the reviewed papers. There was no limit on the scope of time since publication as this may have excluded some important historical work on these topics.

2.3 STUDY SELECTION

The initial criteria for inclusion in this review were as follows:

1. Studies on trans-femoral prosthetic alignment and clinical procedures.

2. Studies reflecting the importance of prosthetic alignment for trans-femoral prosthesis users.

3. Studies on balance and confidence of trans-femoral prosthesis users.

4. Studies of balance and confidence outcome measures for a lower limb absent population.

Due to these narrow criteria, it was difficult to obtain relevant articles for this review. The prevalence of studies relating to different levels of amputation e.g. trans-tibial resulted in a revision of the inclusion criteria as some of these articles were important and warranted consideration when determining the methodology of this research project.

Therefore, following revision of the inclusion criteria, these areas of study were considered:

1. Studies on prosthetic alignment and clinical procedures.

2. Studies reflecting the importance of prosthetic alignment for trans-femoral prosthesis users.

3. Studies on balance and confidence in a lower limb absent population.

4. Studies of balance and confidence outcome measures for a lower limb absent population.

The abstracts of the articles located in the search were reviewed according to the criteria and the articles which met the inclusion criteria were appraised using the Scottish Intercollegiate Guidelines Network (SIGN) (67). The studies were assigned a level of evidence according to the grading system in Table 2. SIGN develops evidence

based clinical guidelines to improve patient care in the NHS (Scotland) and is recognised worldwide as a grading system.

Table 2: SIGN Grading System – Levels of evidence (www.sign.ac.uk)

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

2.4 RESULTS

Articles were considered from the searches of the literature from 1955 to 2012. The abstracts of 309 articles located in the literature searches were reviewed. From this 116 were excluded initially due to their irrelevance to this specific review. A further 104

articles were also excluded after further consideration of the abstract or reading of the full text. The remaining 89 articles fulfilled the inclusion criteria and are included in this review. Two of the articles required translation into English.

The articles reviewed were divided into Prosthetic Studies and Outcome Studies. The articles relating to Prosthetic Studies specifically deal with prosthetic alignment and clinical procedures and were further sub-divided into:

- Biomechanical Studies - studies assessing the biomechanics of prosthetic alignment using kinematics and kinetics. .
- Specific Intervention Studies - studies in which a single or multiple controlled intervention altered the alignment of a trans-femoral prosthesis to establish a specific protocol.
- Technical Measurements and Equipment Studies - studies demonstrating or describing techniques and equipment for measurement of prosthetic alignment.

The Outcome Studies articles relate to outcome measurement and outcome tests, specifically outcome tests in relation to balance and confidence in a lower limb absent population and were divided into:

- Balance and Confidence Measurement Studies.
- Functional Walking and Balance Test Studies.

The numbers of articles in each category are shown in Table 3. Four of the articles were included in more than one category.

Table 3: Articles reviewed by category

CATEGORY	SUB-CATEGORY	NO. OF ARTICLES
Prosthetic Studies	Biomechanical Studies	15
	Specific Intervention Studies *	21
	Technical Measurements and Equipment Studies *	22
Outcome Studies	Balance and Confidence Measurement Studies	17
	Functional Walking and Balance Test Studies *	14
Total number of articles		89
* Contain articles included in more than one section		

In the Prosthetic Studies category, the majority of articles (n= 25) (9, 16-18, 20, 22-26, 38, 44, 68-80) investigated a trans-femoral population, six articles (6, 11, 15, 21, 62, 81) used a mixed group of trans-tibial and trans-femoral prosthesis users and seven articles (8, 12, 46, 82-85) studied trans-tibial level only. In the articles describing the

technical measurements almost half (n=11) (10, 14, 19, 40, 57, 86-91) did not study a population but described equipment or methods.

The number of subjects varied greatly between studies, the Biomechanical Studies had a range of 1 to 179 participants with 57% using less than 10 participants and in the Specific Intervention Studies, 55% had less than 10 subjects (range= 1-328). The Outcome Studies sample sizes (range =1-435) were larger than the Prosthetic Studies. In the Balance and Confidence Measurement Studies, seven studies (31, 32, 37, 43, 44, 92, 93) used subjects from a lower limb absent population with a range of 1 to 435 subjects and nine studies (48, 49, 51, 52, 94-98) used subjects from a non-amputee population with a range of 31 to 210 participants.

In the Functional Walking and Balance Test Studies (n=16) (58-60, 71, 99-110), nine studies (71, 100, 102, 104-106, 108-110) used subjects from a lower limb absent population with a range of 5 to 93 subjects and five studies (58-60, 99, 101) used subjects from a non-amputee population with a range of 60 to 290 participants. The Biomechanical and Specific Intervention Studies used measurement tools and tests to assess outcomes, these included gait analysis (n=21) (9, 12, 15-18, 22-25, 46, 68-70, 73-75, 82-84, 111), self-assessment questionnaires and outcome tests (n=10) (6, 17, 20, 26, 38, 44, 69-71, 76) and energy expenditure measurements (n=5) (15, 17, 18, 23, 76).

The Balance and Confidence Measurement Studies used 12 different tests, the most frequently used test was the Activity-specific Balance and Confidence Scale (ABC) (n=11) (37, 43, 44, 48, 49, 52, 92-95, 112) and eight studies (43, 44, 48, 49, 51, 52, 92, 95) used more than two outcome tests. In the Functional Walking and Balance Test

Studies, 13 different tests were used with some studies using more than one test. The most frequently used tests from the literature reviewed were the Timed Walk Tests (n=5) (71, 100, 104-106) and the Timed Up and Go Test (n=6) (71, 100, 107-110). The World Health Organization International Classification of Function (ICF) (99) was discussed in five of the studies (59, 99, 101-103).

The studies in this review are outlined in tables that can be found in Appendix A-E:

- Appendix A – Biomechanical Studies
- Appendix B – Specific Intervention Studies
- Appendix C – Technical Measurement and Equipment Studies
- Appendix D – Balance and Confidence Measurement Studies
- Appendix E – Functional Walking and Balance Test Studies

From the literature searches and analysis of the relevant articles, it became apparent that there was considerable literature relating to general prosthetic alignment. The field of prosthetics has changed enormously since the post war period and continues to evolve today with the ever-increasing use of sophisticated mechanical and electronic components and instruments (113). Despite this, basic principles remain and articles published before the modern era of prosthetics are relevant and still considered good practice (57, 86, 91, 114).

2.5 DISCUSSION

From the studies appraised in this literature review, there was a considerable amount of current literature on outcome measurement, as this has become an important tool in recent years. The focus on this area of the literature was balance and confidence and functional tests validated for use with a lower limb absent population. The review also found extensive research on aspects of prosthetic alignment and the effect on prosthesis users, prosthetic componentry and a variety of equipment and measurement techniques.

The purpose of this review of the literature was to assess the current procedures in the initial set-up and stages of prosthetic alignment and to establish if there is a link between the alignment of a trans-femoral prosthesis and balance and confidence of the prosthesis user. The review also ascertained suitable balance and confidence tests and outcome measures, appropriate for use in this pilot study of a lower limb absent population. The articles reviewed are discussed in the following sections described earlier in Table 3.

2.5.1 PROSTHETIC STUDIES:

2.5.1.1 Biomechanical Studies (Appendix A)

The majority of articles assessed various changes in biomechanics, kinetics and kinematics in groups of prosthetic users (9, 12, 15-17, 46, 68, 82-84). Almost all of the articles in the Biomechanical Studies state the importance of alignment but very few describe in detail the alignment configuration or methods used. The methodology of the studies made qualification of how alignment was conducted difficult to establish as

it generally relied on the clinical judgment and experience of the clinician and the feedback of the prosthesis user.

This subjective alignment approach was examined by Zahedi et al (11) using a group of 10 trans-tibial and 10 trans-femoral prosthesis users. Each prosthesis was aligned a number of times on a number of different occasions by three experienced Prosthetists with the objective of establishing an accurate bench alignment criteria and an "optimum" dynamic alignment that could be easily repeated. Results demonstrated that a range of alignment configurations were acceptable to both clinician and user but the authors recommended further work to develop a system to more accurately measure this. This was an extensive study and is one of only a few that examined prosthetic alignment in detail. It is an extremely good example of the apparent variability in prosthetic alignment and lack of clinical criteria of bench alignment or dynamic alignment. A large range of alignment configurations were described for each prosthesis user but there was no information reported regarding the physical characteristics of the subjects such as the length of the residual limb, hip muscle strength or limitation in hip movement. Therefore interpretation of the range of acceptable alignment configurations documented in this study specifically for the trans-femoral prosthesis users is difficult (11).

The introduction of modular prosthetic systems using pyramid adapters has facilitated more controlled and accurate changes to the alignment of modern prostheses and reduced the time involved in adjusting the limb, compared with the traditional exo-skeletal prosthesis. Technological advances may help in the fitting of this complex device but a consensus on alignment has yet to be agreed.

A more recent article involved a kinematic study of a single trans-femoral prosthesis user fitted by five Prosthetists with varying levels of experience (9). The results showed there were small differences, which were not specified, in the static alignment by each clinician but these were not significant in the kinematic data results. The authors concluded this could be due to the ability of the prosthesis user to compensate for the small changes made and echoed previous findings (11) that a range of alignments may be acceptable to the prosthesis user rather than an optimum alignment configuration. The study concluded that more research was needed to define optimum alignment and perhaps there was no necessity for automated or computerised alignment tools (9). It would be beneficial to expand this methodology to a larger sample and further analysis of the kinematic measurements may produce useful results regarding the compensatory methods employed by trans-femoral prosthesis users when fitted with different alignment configurations.

Yang et al (16) constructed a model to show the effects of changes in prosthetic alignment on the gait of a trans-femoral prosthesis user. The study involved three alignment changes to the prostheses of four active trans-femoral prosthesis users. Changes were made to the tilt angle of the socket; A/P socket shift; dorsi-flexion and plantar-flexion of the foot and a combination of socket and foot adjustment, all changes were made in the sagittal plane. The subjects were analysed using gait analysis in level walking after adjusting to the changes. Again, it was shown that prosthesis users employ compensatory measures, as the effects of the Ground Reaction Force (GRF) on the foot and knee are altered. The changes made to the socket position and the socket /foot position concurrently had the largest effect on the gait pattern. The

gait patterns were least influenced by dorsi-flexion and plantar-flexion of the foot, but changing the socket flexion angle significantly altered the position of the GRF. The authors concluded this was due to the combined factor of altering the position of the GRF and joint movements on the prosthetic side, which led to an alteration in limb stability. The components in this study were not consistent; therefore, some of the results may be masked or enhanced by the effects of different knee joints and prosthetic feet. In addition, the hip joint positions were difficult to locate, which may have introduced some errors in the measurements of socket tilt.

This area of alignment has been further investigated recently at an American Academy of Prosthetists and Orthotists Scientific Conference (68). Preliminary findings were presented on the effects of changing trans-femoral alignment, testing five trans-femoral prosthesis users in three different alignment configurations. Initial findings showed that in level walking the active trans-femoral prosthesis user could compensate for perturbations in alignment. In this study, the knee joint position was moved from a position of "optimum" alignment to a more stable posterior position and less stable anterior position. Changes had little effect on knee torques and no effect on the hip torques measured on each subject. Future research was proposed to further investigate this in more challenging situations such as stairs and slopes (68).

These studies have shown that the prosthesis user has the ability to alter their gait pattern and adapt to changes in alignment configuration of their prosthesis. The ability of the prosthesis user to compensate for changes in prosthetic alignment was the subject of three further studies (12, 46, 84). Pinzur et al (46) tested 14 active trans-tibial prosthesis users through gait analysis including force plate and stance time data.

He concluded there was a positive relationship between weight transfer to the contra-lateral limb and ‘mal-alignment’, which increased pressure on the residual limb in certain alignment configurations. There was no detailed description of the methods of alignment change and measurement. Another study assessed the influence of prosthetic foot rotation on the gait kinematics of eight trans-tibial prosthesis users (84). The authors concluded that the trans-tibial prosthesis user can adapt to a position of excessive rotation of the foot by compensation mechanisms such as hip rotation and stride length without affecting their gait velocity (84). Isakov et al (12) showed three trans-tibial subjects were able to compensate for the alignment changes by increasing the load on their contra-lateral limb in standing. These compensation mechanisms make the measurement and the definition of optimum alignment more complex and limit the parameters that can be used to measure alignment changes.

The compensatory mechanisms of weight transfer employed by prosthesis users, in response to different alignment conditions can result in asymmetry between limb movements and in joint motions. Gait symmetry has been used as a predictor of optimum alignment and three of the studies reviewed assessed the effect of asymmetry on the prosthesis user (15, 83, 115). The results of these studies showed there are variations in the alignment configurations considered acceptable by individual prosthesis users (83). Alignment changes at the foot had the most influence on gait symmetry and in general, prosthetic alignment changes influenced hip motion in standing and walking (82). According to Schmalz et al (15), plantar-flexion and dorsi-flexion adjustments to the prosthetic foot produced the greatest effect on the GRF position and had the most influence on oxygen consumption of the prosthesis user but

these adjustments did not affect gait speed. All of these studies assessed small samples of a trans-tibial population, there was variation in the detail and measurement of the alignment changes documented in the studies and no consistency in the time given to the prosthesis user to adapt to any changes carried out.

The analysis of gait symmetry may be useful to clinicians in assessing the effect of changes to alignment on parameters such as stride length, step length and velocity. Many of these studies highlighted the range of alignment configurations that may be acceptable to a prosthesis user and the compensatory mechanisms employed to adapt to each configuration. It is this range and variability which creates difficulties in quantifying and qualifying measurement and methods to assess prosthetic alignment (12, 115). A more common anomaly encountered in daily prosthetic practice is the issue of leg length and finding the optimal length of the prosthesis. This tends to be a subjective measure, rather than a scientific measure, by the clinician and prosthesis user, which appears to be unreliable. According to the literature, leg length discrepancy has been shown to have detrimental effect on the prosthesis user resulting in pain, asymmetry and reduced activity levels (81).

Compensatory mechanisms appear to be necessary for the prosthesis user in order to maintain an efficient pattern of gait and as an adaptation to the fact that the biomechanics of a prosthesis do not mirror the biomechanics of the sound limb. This theory has been examined to assess the effect of prosthetic alignment on the gait of trans-femoral prosthesis users, the influence on compensatory movements in the trunk and hips and resultant effect on energy expenditure (15, 17). In a study of 29 non-vascular trans-femoral prosthesis users, gait analysis, energy expenditure and a self-

reporting questionnaire were used to show that the trans-femoral prosthesis users had a lower gait velocity, had less hip movement in gait and used more energy to walk. It appears from this study, increased gait compensations can lead to increased energy expenditure. This could result in loss of function for trans-femoral prosthesis users due to fatigue; the study also suggests gait speed may be associated with hip motion. There were no changes made to the prostheses in this study and therefore it is an assessment of the everyday situation of the subjects (17). These findings were corroborated by Schmalz et al (15) that oxygen consumption was affected when specific changes were made to the components and alignment of 12 trans-femoral prostheses. Small adjustments to the sagittal plane alignment of the prosthetic knee, shifting anterior or posterior from the recommended alignment, produced significant increases in oxygen consumption for this group of trans-femoral prosthesis users.

Increased energy expenditure is an important aspect of ambulation for a lower limb absent population, especially for the elderly, who are most prevalent in this population. From these studies, it appears there is evidence to support previous findings of levels of increased energy expenditure among this population compared with an able-bodied population (41, 42). Although this review is not focused on energy expenditure, it is important to note the multitude of effects that wearing a prosthesis has on the prosthesis user, and therefore also to note the complexity of investigating any alterations to the alignment of the prosthesis.

A survey of a lower limb absent population in North America (6) reported results indicating reduced levels of activity due to prosthetic socket problems, pain, poor suspension, prosthetic alignment and issues with the type of prosthetic foot. This study

highlighted the complexity of fitting and wearing a prosthesis and the effect, issues such as socket fit, suspension and alignment can have on the activity levels of prosthesis users. The importance of socket fit, alignment and an understanding of biomechanics for the clinician is emphasised in many of the articles (6, 11, 15, 16, 39). The biomechanical significance of alignment is well documented but has yet to be fully understood and a procedure for best practice developed (9, 11, 12).

These studies have assessed the effects of biomechanical changes on groups of trans-femoral and trans-tibial prosthesis users. They included general biomechanical investigations and alterations and the effects on the prosthesis user and highlighted the importance of prosthetic alignment and the difficulties in setting standard alignment protocols. The achievement of a single 'optimum' alignment may not be possible or necessary due to the many variables involved in these complex procedures. The sample numbers were small and detail was lacking in some of the study methodology, especially the set-up and measurement of the alignment configurations.

The evidence does suggest there is a link between the compensatory measures employed by prosthesis users to ambulate and biomechanical changes to the prosthesis, which can lead to increased energy expenditure and excessive joint motions, especially at the hip joint. It is also apparent that perhaps the tools used to assess these tasks scientifically are not readily available or are inappropriate for use in an everyday clinical setting. Rietman et al (56) discussed the use and function of gait analysis techniques in the field of prosthetics and concluded that this was a useful tool for scientific research but is not as appropriate in a clinical setting (116, 117). Gait analysis, including electromyography studies (EMG) and energy consumption tests are

widely used in the following studies to assess specific interventions, such as prosthetic component changes and alterations to the prosthetic alignment, in individual and groups of prosthesis users.

2.5.1.2 Specific Intervention Studies (Appendix B)

These studies were selected to ascertain specific protocols in relation to prosthetic alignment and focus on the trans-femoral level. Van Der Linde et al (61) reviewed the literature on the different component selections used to build prostheses. He concluded from the review that there were no scientific protocols for choosing different types of componentry, for example prosthetic knee joints or prosthetic feet. This process was based on clinical experience, consensus of practitioners and subjective opinion of the users. The authors recommended this area required further research to develop prescription criteria for the provision of prosthetic components (61).

The range of prosthetic components on the market can be over-whelming and the assessment of suitability for different patient groups can be an issue for experienced and inexperienced clinicians. A number of studies have specifically looked at the function and comparison of different mechanical knee joints in a trans-femoral prosthesis (22, 69-71). In recent years the development of microprocessor knee (MPK) joints has led to studies comparing these with the more traditional mechanical or non-microprocessor knee (NMPK) joints (15, 18, 24, 25, 38, 44, 47, 62, 72, 118, 119). Many of these studies lack the detail of information on the exact process of static and dynamic alignment and how the optimisation of each prosthetic set up was achieved. This is important as the alignment of the prosthetic components can affect their function.

Four studies (22, 69-71) investigated the influence of different non-microprocessor knee (NMPK) joints on trans-femoral prosthesis users. All of the studies recruited active trans-femoral prosthesis users with sample sizes ranging from five to 28, all used a combination of gait analysis and questionnaires to assess the effect different types of knee joints had on the trans-femoral prosthesis user. Thorn-Silver (69) in 2009 used a small sample of five non-vascular trans-femoral prosthesis users to assess the effects of two NMPK joints on stability in gait. Statistical analysis was conducted within subjects and the authors concluded that each NMPK joint tested had good stability but at different stages of the gait cycle. The methodology of the alignment procedures was not well defined and adjustment time for each knee joint was short. (69).

Boonstra et al (70) studied the effect of two NMPK joints with different swing phase control mechanisms concluding that a pneumatic controlled swing phase knee joint allowed faster walking speeds and the subjects reported more comfort than with a mechanical friction swing phase control knee joint. The alignment procedures and methods of transfer of knees to sockets were not well described.

Blumentritt (22) in 1998 also conducted a study to assess the stability of a NMPK joint with hydraulic stance and swing control, following sagittal alignment changes to the knee joint position and in combination with a variety of prosthetic feet. The alignment protocols were better defined in this study. The results showed that the stability of the prosthetic alignment set-up and primarily, the prosthetic knee joint, influenced the amount of hip movement in flexion and extension. These findings were confirmed in a subsequent study by Schmalz et al (15). The study also discovered there were many

variations between subjects in each of the gait characteristics in the initial test and therefore concluded that between-subject comparison of small changes to the alignment of a prosthesis does not yield conclusive results and it would appear more appropriate to assess within subject comparisons for such investigations. This was verified in the results found by Lythgo et al (71) who compared the effect of three different NMPK joints on five trans-femoral prosthesis users and found no significant differences between the knee joints. This study differed from the others in the use of timed walking tests and will be further discussed in the Functional Walking and Balance Tests.

Eight studies assessed the different effects of using a NMPK joint compared with a MPK joint (15, 23-25, 38, 62, 72, 76). In an extensive survey, Berry et al (38) examined a sample of 328 trans-femoral prosthesis users, initially fitted with a NMPK joint, using a questionnaire for feedback on a variety of areas such as socket fit, gait manoeuvrability, confidence/stability and cosmesis. The subjects were then fitted with a completely new prosthesis with a MPK joint and repeated the questionnaire after 6-9 months. The results show the subjects felt better in all areas especially that of socket fit, confidence and gait manoeuvrability, which could be attributed to the fitting of a new prosthesis rather than the knee joints. This is a subjective study and no relevant conclusions, regarding the effect of different prosthetic knee joints can be drawn from these results (38).

Justification for the provision of prosthetic components, especially where there is a cost implication, such as between a NMPK joint and a MPK joint is an area of focus for clinicians involved in the prescription of prostheses. Klute et al (62) compared a

sample of vascular prosthesis users and non-vascular prosthesis users using a NMPK joint and a MPK joint by measuring step count and concluded that there were no significant differences found between the two knee joints. The methodology in this study may have resulted in this conclusion as the subjects had worn the NMPK joint for a longer period and perhaps step count is not the most appropriate outcome to measure mobility. In two similar studies, Segal et al (24) and Orendurff et al (23) investigated biomechanics and gait efficiency of an active sample of trans-femoral prosthesis users wearing a MPK and a NMPK joint. The prosthetic sockets and feet were changed to accommodate the different knee joints but there is no detail about the alignment procedures for the set-up of the prostheses. Generally both studies reported no significant changes in the parameters measured but some of the findings did not concur with earlier studies (15) as gait speed appeared to improve with the MPK joint. The authors suggested that trials that are more robust might be useful, such as uneven surfaces and negotiation of obstacles. It does appear that level walking may not be sensitive enough to test the more subtle differences between prosthetic components and the effects on the prosthesis user.

A study carried out by Blumentritt (25) in 2009 compared two NMPK joints and a MPK joint and emphasized the importance of safety in stance for the trans-femoral prosthesis user. Knee and hip angles and motions were measured to determine the safety of each knee joint. The alignment and force plate data relating to the set-up of the prosthesis were well defined in this study and the prosthetic feet and sockets were kept constant throughout. The study concluded that the risk of falling was higher for the two non-microprocessor knees compared with the microprocessor knee, due to the

superior stance phase control (25). This concurs with previous research that perceived stability of a trans-femoral prosthesis user may be improved with the fitting of a MPK joint (18, 20, 26, 38, 76, 119).

Meier et al (72) recently carried out a comparison study of three prosthetic knee joints and their function over an "obstacle course" setting. The obstacle course represented many conditions encountered in the outside world during every day walking. The user was timed traversing the course and their heartbeats were recorded, this was then repeated with the participant doing a mental loading exercise and the results recorded. There were no significant differences in performance of the course, but a significant difference was shown in the increased heart beat rate with the microprocessor knee joint when asked to perform a mental loading test, implying the user required more thought to negotiate obstacles with this knee joint (72). The use of an obstacle course to assess the effect of NMPK joints versus a MPK joint on the energy expenditure was examined in a preliminary study by Seymour et al (76). This study found that oxygen consumption was reduced with the MPK and less steps were taken to complete the obstacle course. It is difficult to compare these studies, as there are a number of different outcome measurements used. Although there appears to be some benefits and advantages of a MPK joint over a NMPK joint for a trans-femoral prosthesis user, the evidence is not conclusive.

This is the basis for a study by Bellmann et al (18) using oxygen consumption as a measure of energy expenditure, testing nine active trans-femoral amputees in a number of different walking conditions. The subjects were fitted with four different MPK joints and analysed using gait analysis and oxygen consumption. The conditions

included level walking at three speeds, descending stairs and ramps. The risk of falling was assessed using a sudden stop test, stepping on an obstacle and induced tripping. The bench alignment procedures were described and the prosthetic sockets and feet remained constant for the study. The subjects adjusted for two hours to the new knees, although it should be noted that all of the subjects had been wearing one of the tested knees in their everyday prosthesis for some time. The results showed there were considerable differences in the functions of the knee joints in the kinetic and kinematic analyses but no significant differences in energy consumption between different brands of MPK joints. The results of this study are consistent with some of the findings in the studies discussed previously where certain kinetic and kinematic parameters were found to be different but the overall effect on the subject was not significantly altered (9, 15, 16, 61, 62). This supports the ability of the prosthesis user to compensate and maintain efficient mobility and the difficulty in measuring change in a lower limb absent population.

The use of a prosthesis is an evolving skill and often the time spent in the clinic training with a new limb or components is not a reflection of the actual outcome, due the artificial environment of the clinic and the limitations of time. There has been no consensus reached in the literature regarding the appropriate time required for a prosthesis user to adapt to an intervention. English (111) recommended an adjustment time of one week for clinical purposes and three weeks for research purposes for a subject to acclimatise to a new knee joint. From the literature, the adaptation time varies greatly between studies from a few hours to a number of months (15, 18, 24, 25,

38, 62, 69). There has been little research into the influence of acclimatisation time on study results and this is an area which remains unresolved.

A less common activity for trans-femoral prosthesis user is running. In two case studies, specific interventions were carried out to assess the effect of running on a sample of active trans-femoral prosthesis users (73, 74). The optimal height of the prosthetic knee joint in a sprinting prosthesis was investigated. The results showed that lowering the knee joint centre could enhance the sprinting times and reduce asymmetry in a small group of Paralympic athletes. Although this is an intriguing concept and well defined in this study, it is a very specific intervention to an elite group of prosthesis users (74). In a second study, the same authors investigated the effects of asymmetry on the same group of active amputees in walking and running. This study showed that the group were asymmetrical in normal walking but exhibited better limb symmetry when running (73).

Many of the studies discussed, assessed the properties and effects of different prosthetic knee mechanisms in normal walking and the effects on the users. This may be a reflection of the lack of evidence based prescription criteria for many prosthetic components. This is true for other levels of amputation and the literature search revealed much work on the trans-tibial level and use of different prosthetic feet. Prosthetic alignment is widely mentioned in all of the studies but there is no consistency in the measurement procedures documented or defined protocols in the literature as to how this is carried out or recorded. This is important when comparing or assessing different prosthetic components and the effect the prosthetic alignment will have on the function of these components. Different prosthetic knee joints will

exhibit different mechanical properties depending on the design and control mechanism of the prosthetic knee joint and this may affect the balance and confidence of the prosthesis user.

Several studies (18, 20, 25, 26, 44, 75, 76, 119) have assessed the effect on safety and incidence of falls by incorporating a MPK joint in a trans-femoral prosthesis. The consensus from the literature suggests a MPK joint reduces the risk of falling and promotes increased confidence in the trans-femoral prosthesis user. Again, there is no consistency in the outcome measures used and although some of the reported improved confidence in these samples is a perceived improvement by the user (23, 24, 38), the functional outcome for a prosthesis user can be influenced by perception. The influence of alignment also becomes more difficult to quantify and assess especially when considering MPK joints, which have improved stance phase stability (15, 18, 25, 119) and by definition should remain stable over a wider range of alignment configurations. This has yet to be fully investigated and all of these areas need further and more specific study.

The effects on the prosthesis user of a variety of different prosthetic components and interventions were examined in these studies. The outcomes have been presented using gait analysis techniques, force plate data, oxygen consumption and self-report opinions. The difficulties are emphasised in managing the variables such as the individual prosthesis user, socket fit, different component combinations of prosthetic feet and knees and the alignment of these in a prosthesis. The evidence is not conclusive in defining standard prosthetic alignment protocols due to the different procedures used and the variety of outcomes measured. There is little detail of the

equipment used to bench and dynamically align the prostheses in the studies; these procedures are explained in more detail in the following studies.

2.5.1.3 Technical Measurements and Equipment Studies (Appendix C)

The future development of tools and equipment may improve current techniques enabling clinicians to achieve repeatable, optimum individual prosthetic alignments using clear guidelines. The need to develop a method for consistency and repeatability dates back to the origins of alignment and early prostheses manufacture. There have been various devices over the years to help with the complex task of alignment, such as the development of the Berkeley Jig and the introduction of modular components in the late 1960's which are interchangeable and easier to adjust (14, 57, 86, 87, 91, 120). This is still an area where practices vary between clinicians, geographical locations and the equipment used for the set-up of a prosthesis.

Today there is still no consensus on best practice. This has also become more important especially to trans-femoral prosthesis users as the components available, such as MPK joints, have become more sophisticated. The introduction of the articulating knee unit to replace a straight or locked knee unit prompted the teaching of a biomechanically aligned prosthesis to ensure the safety of the user. Radcliffe in 1955 (57) proposed that the fit of a trans-femoral prosthetic socket and the alignment of the overall prosthesis could not be considered mutually exclusive. He drew from earlier research by Franz Schede who had advocated the adoption of the laws of mechanics to the alignment of a prosthesis (57, 114). This led to the development and use of a plumb line to set up the prosthesis and this is still in use in workshops today, although it has been upgraded to a freestanding laser in many clinics.

Radcliffe (57) outlines the many devices which have been developed over the years to solve the problem of repeatability and consistency in alignment procedures. One of the challenges for the Prosthetist is the transfer of an optimally aligned prosthesis from test stage to definitive prosthesis without changing or 'losing' the alignment. General practice is to fit and align prosthesis in a trial stage where the socket and alignment are adjusted until an optimum situation is agreed by clinician and user. The trial prosthesis is then used as the template for the manufacture of the definitive prosthesis. This is a complex procedure and many of the devices described by Radcliffe (57) and Taylor (86) were designed to enhance and simplify this process. If the socket or alignment is not transferred correctly to the final prosthesis, the user will not be satisfied and the prosthesis may have to be re-made. Obviously this is a time consuming and expensive procedure, hence the range and diversity of these devices. It also highlights the fact that this has been an area of contention and difficulty for clinicians and engineers alike for many years. Modern versions of these devices are still in use in many clinics, but the basic problem still exists today and there is still a need for the development of universal tools and equipment (57, 86, 88).

The development of these tools has made an immeasurable difference to the area of manufacture and alignment of a prosthesis, especially the introduction of the pyramid adjustment system by prosthetic company, Otto Bock (121). Most manufacturers of prosthetic components have adopted this system, reducing the need for lengthy and inaccurate adjustments at fitting stages. Although, some believe the apparent ease of adjusting a prosthesis using this equipment may have led to a move away from basic principles. Stark (19) discussed the possibility that modern components and methods

of suspension of prosthesis may be leading to complacency in the bench alignment procedures and re-emergence of common gait deviations in prosthetic fittings. He emphasized the importance of assessing the anatomical situation of the residual limb to determine the initial socket flexion angle and the importance of adherence to biomechanical principles. The guidelines provided by the manufacturer of modern components, such as prosthetic feet and knees, should be adhered to when aligning a trans-femoral prosthesis.

Some of these observations may be mirrored in previous findings of this literature review where there appears to be no clear consensus on prosthetic alignment procedures or consideration of the physical and anatomical features of the subjects to determine alignment configurations (9, 11, 15, 16, 22, 24, 25, 122).

From previous research, one of the factors that may affect alignment and function of a trans-femoral prosthesis is hip movement (11, 17, 68). This has been examined in gait analysis and studies of muscles acting around the hip in the affected limb and contralateral limb, but there has been very little investigation of the initial angles of flexion in the prosthetic socket in relation to measurement of hip movement of the residual limb (16). Biomechanical guidelines have been documented by Radcliffe (10) where the Trochanter-Knee-Ankle (TKA) method of bench alignment is described. This method of alignment advocates the trans-femoral prosthetic socket should be set up at an angle of five degrees of initial flexion in bench alignment. Radcliffe (10, 14) noted in a lecture to the International Society of Prosthetics and Orthotics (ISPO) that the fitting of a prosthesis should encompass a complete procedure including the fit and shape of the socket, the components to be used and the alignment of the socket to these

components. From the literature, current practices in bench alignment procedures are not clear.

The Atlas of Limb Prosthetics (123) describes the recommended current processes of prosthetic practice and emphasises the importance of clinical measurement of the trans-femoral amputee especially in range of motion, to determine the socket design and configuration of an individual prosthesis. The importance of initial flexion in the socket is also discussed, stating that the presence of a hip flexion contracture or weakness in hip extensors often found in a lower limb absent population can influence knee stability in a trans-femoral prosthesis. The recommended practice appears to be setting the initial socket flexion angle to equal to the minimum angle of flexion measured in the residual limb plus five degrees, with the prosthetic knee and foot aligned below according to manufacturer's guidelines (40). This concurs with the previous research by Radcliffe (10) describing the 'zone of voluntary stability' and the importance of hip extensor muscle power for the amputee to create an extensor moment at heel strike to prevent prosthetic knee instability.

There is little quantification of this procedure in the literature and this may be due to the variables encountered, as each prosthesis user will have individual needs and unique anatomy. Perhaps this is assumed to be common practice but this may not always be the case (19). In addition, the setting of initial socket flexion is generally addressed at bench alignment stage, due to the process of dynamic alignment this is often altered as the prosthesis user walks, and may change over time and with additional training. In an article describing techniques for the design of an ischial containment trans-femoral socket, Stark (89) describes the importance of pre-flexion in

the alignment of the trans-femoral socket to facilitate normal stride length and knee stability. He comments that a common error in clinical practice is the inaccurate measurement of hip flexion contracture in the residual limb and the resultant incorrect angle of pre-flexion in the trans-femoral prosthetic set up. These observations are supported by the results found by Zahedi et al (11) discussed earlier (Biomechanical Studies), where the mean flexion angle of the trans-femoral sockets aligned in this study was less than one degree but there is no information on the anatomical measurements of the subjects.

Generally measurement of hip extension motion is carried out clinically using the Thomas Test or modified Thomas Test (124). The Thomas Test is described as a clinical examination of the hip to determine if there is a flexion contracture of the iliopsoas muscle. This test is widely used by clinicians in many disciplines to assess hip range of motion and is the most commonly used test among prosthetic and rehabilitation clinicians to assess for a hip flexion contracture in the residual limb (78, 125). There have been a number of studies carried out to assess the reliability and repeatability of the Thomas Test (126-135). Boone et al (135) tested intra-tester and inter-tester reliability of four Physical Therapists measuring range of motion on normal subjects. The study found that inter-tester variability was lower for upper limb measurements than lower limb and suggested that the same tester should measure joint motion and changes of 3-4° were necessary to show a minimal detectable clinical change in joint motion. None of these studies relates directly to the measurement of hip motion in the residual limb of a trans-femoral amputee and there is little reference to this procedure in the current literature.

Clinical measurement of hip motion is usually performed using a goniometer. Nussbaumer et al (125) carried out a study of the validity and test re-test reliability of manual goniometers. In a sample of 15 adults with femoro-acetabular impingement, hip range of motion measurements were taken using a manual goniometer and an electromagnetic tracking system. The results showed good test re-test reliability especially when measuring hip flexion. Goniometer measurements were greater than electromagnetic tracking measurements for all ranges of motion measured. The authors concluded that measurement of hip motion is not easily executed due to the number of motions that can occur simultaneously in this joint, such as pelvic tilt and rotation. Manual goniometer measures are adequate for longitudinal studies of a group but further studies to improve measurement techniques will lead to more accurate and repeatable measurements.

In a similar study to assess the reliability of goniometer measures with visual estimates of hip range of motion, twenty five patients with osteo-arthritis were measured using a goniometer by two clinicians and the results were compared with the visual estimates of movement of the same group by an Orthopaedic Surgeon. The results showed there was test re-test reliability especially for hip flexion measurements and interestingly the visual estimates and actual measures showed good agreement (133, 134). This has relevance to the subject of this pilot study as many clinicians will rely on their experience to estimate the angle of limitation in a joint and may over or under estimate the amount of hip flexion contracture in a residual limb, which will directly affect the set-up of the bench alignment of the prosthesis.

In a study by Gaunaurd et al (78) into postural asymmetries in trans-femoral prosthesis users, clinical evaluation techniques including the modified Thomas Test using a manual goniometer were carried out. The purpose was to establish baseline values for assessment and treatment of this population. The results showed there were discrepancies found in leg length, hip extension and pelvic rotation in this group. The leg length differences corresponded with a previous study (81) finding more than 60% of the group had a difference in the length of their prosthesis to clinically measured sound limb length. Pelvic rotation was found to be higher in this group than in previously measured groups of trans-tibial prosthesis users and non-amputee populations and was correlated with a shorter prosthetic limb length but not with hip extension. Hip extension was found to be significantly lower on the amputated side than the sound side and this concurs with previous studies (15, 17). The authors acknowledged the limitations of the clinical evaluation methods and noted that there is conflicting opinion as to the reliability and validity of these techniques.

Some work has been carried out on the effects of hip motion in trans-femoral prosthetic gait. Rabuffetti et al (79) found that a sample of trans-femoral prosthesis users had increased pelvic tilt, reduced hip flexion and extension in gait. Some of this reduced movement was attributed to mechanical factors of wearing a prosthetic socket. They concluded that although the hip motions were reduced and pelvic tilt increased they were necessary adjustments to enable the user to have a functional gait pattern, despite the possibility of damage to other structures.

Hip and pelvis motion has also been investigated in relation to osseo-integration, a relatively new method of attaching the trans-femoral prosthesis directly to the femur,

negating the need for a prosthetic socket. Two studies assessed the effect of this process of attaching a trans-femoral prosthesis on hip flexion movement and comfort for the user. Hagberg et al (80) investigated hip motion and sitting comfort in osseo-integrated prostheses compared with conventional socket interface prostheses. Passive ranges of motion were measured using a goniometer with and without the prosthesis, and a questionnaire (Q-TFA) for trans-femoral prosthesis users was administered. This study found there was no significant difference between the affected side hip movements without prosthesis and the contra-lateral limb in either group but there were significant differences in all motions when wearing the prosthesis, with the osseo-integration group having increased movement especially in flexion of the residual limb. This can be explained by the limiting anterior brim of a prosthetic socket and in turn, the higher level of discomfort reported by the socket interface group in this study. These findings were confirmed by Tranberg et al (77) using gait analysis to measure hip and pelvis motion, pre and post osseo-integration. Following fitting with an osseo-integration prostheses, the range of motion in hip extension was improved and pelvic tilt reduced but the overall range of motion at the hip was still found to be less than that of an able-bodied population (77). The use of different methods to take measurements of the hip joint motion in these studies precludes comparison of the results.

This selection of literature relating to hip motion in trans-femoral prosthesis users introduces a number of variables to the alignment configuration of a trans-femoral prosthesis. There are many conflicting opinions and methods of comparing these

variables but there are distinct gaps in the evidence as to the influence of hip motion and position on prosthetic alignment (90).

Recently, new alignment equipment has been developed which may offer the possibility of a more standardised procedure for achieving a better alignment and fitting result. Blumentritt (8) described the development of the Laser Assisted Static Alignment Reference Device (L.A.S.A.R. Posture Assembly; Otto Bock) (136, 137). This device uses a laser line to project the vertical component of the GRF when a person stands on the force sensor platform. This line can be used to measure the distance from the GRF to specific points on the body, such as joints, and could be useful in establishing the static weight bearing alignment of a prosthesis. Further studies have shown this device can be used to optimise static alignment, in accordance with the guidelines established from research and manufacturer's instructions (8, 15, 85). The developer of this equipment has done much of this research and further independent studies are needed to clarify and corroborate these findings.

Blumentritt (8) proposed using the load line of the individual as a reference for static alignment of a prosthesis. The static standing posture of 18 trans-tibial amputees was compared to 20 non-amputee subjects using a force plate system. There were significant differences in the standing postures between the two groups at the position of the hip, knee and foot. The author suggested that the optimisation of alignment of a trans-tibial prosthesis through the generally accepted procedure of dynamic alignment, observation and adjustments by the clinician and feedback from the user, was time consuming and inefficient and did not always result in a satisfactory outcome. The results showed a range of acceptable standing postures in the sagittal and frontal planes

for the two groups, with the biggest differences occurring at the hip joint. The author concluded that the device allows visualisation of the individual load line and incorporation of the effect of the body mass and posture of the amputee on the initial set up of static alignment. He proposed a recommended range of static alignment configurations in the set-up of a trans-tibial prosthesis.

A further study by the same author in 2001 (85) assessed the effect of prosthetic foot alignment on gait kinetics and kinematics and electromyography studies (EMG). The study recommended an optimum static alignment position for the foot and knee with reference to the load line for trans-tibial prosthetic alignment. These findings concurred with observations by Isakov et al (12) discussed in the Biomechanical Studies (Appendix A). To date there have been no published recommendations for trans-femoral prosthetic static alignment. Although, the manufacturer of the L.A.S.A.R. Posture provides guidelines with their own componentry and recommends to use the equipment for static alignment for all levels of prostheses (136, 137). (Appendix P)

These studies introduce the L.A.S.A.R. Posture in a concise manner. This equipment is an excellent visual tool for the clinician and following some of the recommendations discussed in the literature, the L.A.S.A.R. Posture may be an invaluable tool in the process of prosthetic alignment. It is a portable machine that can be used in any clinical environment and has been used in a number of research studies. Although the sensitivity and reliability of this device has not yet been tested in any current studies and therefore it may not be suitable for scientific research.

The L.A.S.A.R. Posture was used to assess the prosthetic alignment of 21 prosthesis users wearing a microprocessor controlled knee joint (C-Leg®) in their prostheses (138). The results revealed a wide variation of static alignments were present in the assessed prostheses and only one of the 21 prosthesis was aligned within the recommended range according to the manufacturer's guidelines. There is no detail on the use of the L.A.S.A.R. Posture or the repeatability and reliability of this device to measure the alignment configurations in this study. Closer examination of the results of this study shows that there was an error in the reporting of the measured alignments. The recommended bench alignment configuration for this microprocessor knee joint is the knee joint centre should be positioned 0-5mm anterior to the static laser line of the bench alignment jig, but the recommendation for the static alignment with L.A.S.A.R. Posture is the knee joint centre should be positioned 30mm posterior to the projected laser line. In this study, the bench alignment guidelines were used to assess the static alignment positions. This error may indicate confusion regarding the processes of bench and dynamic alignment by the authors.

Breakey (21) has utilized the L.A.S.A.R. Posture to present the 'Theory of Integrated Balance' in which he suggests that consideration of the centre of balance line or GRF of the user with both feet on the force sensor platform should be compared to the GRF of the user with only the prosthetic limb on the force sensor platform. The closer these two lines become the more integrated the balance of the user. This article addressed a number of the issues surrounding alignment and made some suggestions as to how these could be resolved. Due to the lack of scientific data in this article, there is scope

for further development of these theories and research into new equipment to establish better protocols.

Over the last 60 years there have been a number of tools developed to assist in the set-up of a prosthesis, some of these have become part of the everyday equipment in workshops and clinics around the world and some have been designed for specific research studies (57, 86). Solomonidis et al (139) defined a unique axis system for both trans-tibial and trans-femoral sockets to allow location of the position of the socket relative to the rest of the body. From this research, Berme et al (91) designed a socket axis device to accurately define the socket axis in a much more efficient way. This device has been used in more recent research (83), but locating the axes of a prosthetic socket is still not well defined and there is no clear protocol on how this should be achieved.

It is clear from the literature that the subject of alignment is of great interest and importance to clinicians and researchers in the field of prosthetic rehabilitation. The number of subjects assessed and tested in each of these prosthetic studies varied from large long-term studies to small controlled trials and the parameters measured varied among the articles. The variety of tests and equipment available to assess prosthetic alignment in a lower limb absent population is vast. There appears to be no gold standard or agreed current protocols for the procedures of alignment in an everyday clinic. The determination of the initial position of socket flexion in relation to the array of different components available to build a prosthesis has not been clarified. The measurement of range of motion, specifically at the hip joint, has been shown to be of importance in the initial set up of a trans-femoral prosthesis. It appears from the

current literature that there are a number of techniques for this assessment but there does seem to be a consensus that the Thomas Test, where the pelvis is secured to prevent rotation and using a manual goniometer to measure hip angle, is reliable with single observer measurement. There is scope for future research in all of these areas to verify the results of these studies and to continue to improve clinical practices.

2.5.2 Outcome Studies

The articles reviewed in the area of outcome measurement are listed in Appendix D and E. The SIGN grading system has been used to evaluate each paper. They are divided into two categories, Balance and Confidence Measurement Studies and Functional Walking and Balance Test Studies. There is a significant amount of literature regarding outcome measurement and in turn a significant number of tests and questionnaires to assess these outcomes. The focus of this review was to ascertain the validity of these measures in the specific area of balance and confidence in a lower limb absent population.

2.5.2.1 Balance and Confidence Measurement Studies (Appendix D)

Condie et al (58) carried out a comprehensive review of the literature from 1995-2005 on outcome measures in lower limb prosthetics. They found that there were a myriad of outcome measures available, but not all of these were suitable or validated for use with a limb absent population. Although some had good reliability and validity, they were not necessarily useful in a clinical setting. Table 4 outlines the most commonly used tests and outcome measurements in the assessment of a lower limb absent population according to this study.

Table 4: Outcome measures frequently used in assessment of a lower limb absent population

OUTCOME	AMPUTEE SPECIFIC	GENERIC
MOBILITY	Locomotor Capabilities Index (LCI)	Timed walk tests (TWT)
	Amputee Mobility Predictor with Prosthesis (AAMPro)	Timed-up and Go Test (TUG)
	Russecks Code	L-Test
	Special Interest Group in Amputee Medicine (SIGAM)	
FUNCTION	Amputee Activity Score (AAS)	Barthel Index
	Functional Measure for Amputees (FMA)	Functional Independence Measure (FIM)
	Houghton Score	Frenchay Activity Index (FAI)
	Prosthetic Profile of the Amputee (PPA)	
QUALITY OF LIFE	Prosthesis Evaluation Questionnaire (PEQ)	Short Form 12 /36 (SF-12,SF-36)
	Trinity Amputation and Prosthesis Experience Scales (TAPES)	Patient Generated Index (PGI)
BALANCE		Berg Balance Scale (BBS)
		Balance Error Scoring System (BESS)
		Activities-specific Balance Confidence Scale (ABC)

From the table it is apparent there are a number of tests and questionnaires that are specific to a lower limb absent population and a number of generic tests, which have been applied to this population.

The functional ability of a trans-femoral prosthesis user can be greatly influenced by their ability to balance when using their prosthesis. This is especially important when negotiating obstacles such as slopes, stairs and uneven ground. Basic tasks such as sitting, standing and turning which the able bodied population may find easy, can

prove challenging for this group regardless of their age or co-morbidities. In order to predict levels of function following an amputation and develop methods to improve or maintain mobility it is important to be able to assess the balance of an amputee in the clinical setting.

The Activities-specific Balance Confidence Scale (ABC) (48) was developed to assess balance and confidence in the elderly population but this has been successfully used to determine the balance and confidence of a limb absent population (92). This scale is a 16-item self-assessment questionnaire to assess levels of confidence of the individual in performing a task without becoming unsteady or losing their balance. It is rated on a scale of 0-100. Myers et al (94) reported that a score of less than 50 indicates poor balance confidence and corresponds with poor functioning and institutionalised elders, an ABC score between 50 and 80 corresponded with moderately functioning elders in retirement homes with some balance confidence issues and a score above 80 indicated good balance confidence and high functioning elders. The ABC Scale has good test re-test reliability and good construct validity. The ABC Scale is amenable to change and can detect differences in elders with different levels of mobility. Further comparison tests have been carried out comparing the ABC with the Falls Efficacy Scale (FES) (97), the Timed Up and Go Test (TUG) and Timed Walk Tests (TWT) (31, 37, 38, 43, 44, 49, 92, 94).

The ABC Scale has been used in a number of studies to assess fall risk in an elderly population. Myers et al (49) in 1996 administered the ABC questionnaire and FES (97) to sixty elderly home care individuals, thirty who considered themselves to be high mobility and thirty with perceived low mobility. Each subject was asked about their

falls history, the need for assistance in outdoor mobility and avoidance of activities and a walking speed test and postural sway measurement were conducted. The authors concluded that psychological indicators should be used in tandem with efficacy tests when determining rehabilitation goals. The ABC Scale appears to be a useful indicator of balance confidence in medium to high activity older adults.

A number of studies on balance confidence in a lower limb absent population have been conducted (30, 31, 37, 43, 92). Balance and confidence in prostheses users can also be a predictor to the level of participation in social activity and the effect of falling or fear of falling in this population (31, 44, 52). Similar to the elderly population, falling or fear of falling can lead to a reduced level of confidence among the lower limb absent population. Miller et al (30) investigated the levels of social activity, mobility capability and mobility performance of a group with different levels of amputation and abilities and related this to levels of balance confidence. Four hundred and thirty-five subjects were assessed using the Prosthesis Evaluation Questionnaire (PEQ), Houghton Scale, Frenchay Activities Index (FAI) and a specially developed questionnaire. The results showed that low balance and confidence levels corresponded with reduced mobility capability and performance and recommended this should be a consideration for rehabilitation. Low balance and confidence also reflected the lower participation in social activities of this population (140).

Fear of falling and falls, in the lower limb absent population, are a significant issue particularly for trans-femoral prosthesis users. Gauthier-Gagnon et al (32) reported that the trans-femoral prosthesis user had a significantly increased rate of reported falls and Miller et al (30) have shown almost 50% of trans-femoral prosthesis users report a fear

of falling. In a prospective study, Miller et al (31) carried out a follow up of 245 individuals with lower limb amputations. Baseline ABC scores and two year follow up ABC scores were compared with age, gender, general health, socio-demographics and fear of falling. They concluded that balance confidence was a major issue for this group and age, health, gender and fear of falling could predict low balance confidence and changes in balance confidence. In a further study (43), sixty-five primary amputees were assessed for balance confidence, walking ability and social activity at discharge and one month and three months post discharge from rehabilitation. Balance and confidence was assessed using the ABC Scale, the L-Test (a form of the TUG Test) to assess walking ability or mobility and the FAI was used to assess social participation. The balance confidence scores remained similar at one and three months, but walking ability of the sample had improved between discharge and three-month follow up. This infers balance confidence is independent of walking ability and can be used as a predictor to social activity levels after amputation. Again it was recommended this should be considered when rehabilitating this population (43).

Miller et al in 2003 (92) carried out psychometric testing of the ABC Scale using the Two Minute Walk Test (2MWT) and the Timed Up and Go Test (TUG) in a sample of 329 individuals with trans-femoral and trans-tibial amputations. They assessed the re-test reliability, construct validity and internal consistency of the ABC Scale in this population and found it to be a useful tool that was reliable and valid and may be considered in the assessment of this group of individuals for rehabilitation needs.

The level of balance and confidence has been shown to be less for the lower limb absent population in comparison to the able-bodied population and especially for those

with amputation due to vascular problems as they tend to be of an older age group and therefore less physically able. The ABC does not discriminate well between different levels of amputation and therefore may not be best suited to assessing outcomes across different levels of amputation and it may exhibit a ceiling effect for the more active and mobile prosthesis user (37).

The field of prosthetics has grown in recent years with many companies now manufacturing a variety of components for prostheses. This choice of components can be daunting to the clinician and user alike and as mentioned earlier, although some study has been done in this area there remains an array of prosthetic feet and knee joints for which there are no clear guidelines as to the optimum choice for the user (61). Balance, confidence and stability as primary considerations may be useful in assisting with component choice. Two case studies have used the ABC Scale as an outcome measure to compare the effect of wearing a NMPK joint and a MPK joint (44, 93). Wong et al (44) assessed the balance confidence and fall incidence of one vascular trans-femoral prosthesis user using the Berg Balance Scale (BBS), ABC and TUG and reported an increase in all three test scores from baseline with the NMPK joint and everyday prosthesis to initial fitting with a MPK joint and at one year follow up.

In a targeted intervention, Stevens (93) tested one non-vascular trans-femoral prosthesis user using the ABC Scale six weeks after initial prosthetic fitting with a NMPK joint. The ABC Scale was re-administered to the same subject nine days after fitting with a MPK joint and at a six-month follow up. The results showed there was a 30% change in the balance confidence of the subject after initial fitting with the MPK joint and this was maintained at six-month follow up. He recommended there is good

evidence to encourage the use of tests in evaluating clinical interventions (93). Similar to many of the Prosthetic Studies in this review, there is little detail regarding the alignment procedures in these studies. No clear conclusions can be drawn from these two case studies due to uncontrolled variables that may have affected the outcomes. The use of balance tests are encouraged for this group but further investigation of the sensitivity of tests are required and study design must account for individual variables.

From the literature, it is apparent there are a number of balance tests currently used by healthcare professionals. This review has focused on specific balance tests that are relevant to a lower limb absent population, but to date much of the balance assessment research and development of tests has been carried out on an elderly non-amputee population. The following articles were reviewed to assess the suitability of generic balance tests specifically for use in this study.

Berg et al assessed 31 elderly subjects using the BBS (96). The test involves completing 14 tasks of increasing difficulty and assessing balance using a method of timing and ability in each task. The scores achieved in the BBS were compared with measurement of postural sway and to Tinetti's FES (49, 97), the Barthel Index and the TUG. The BBS was shown to have good validity and sensitivity to the use of walking aids (51). The BBS has also been used to assess balance in the elderly population to predict risk of falling. Muir et al (98) in 2008, studied a sample of 210 elderly subjects to determine their fall status. A baseline assessment was conducted including the administration of the BBS and information on the fall rate and frequency of the sample was collected every month for one year. The results suggest that the BBS is not a good predictor of falls in the elderly. The predictive ability of balance tests has been further

investigated. Lajoie et al used reaction time testing along with ABC, BBS and postural sway in two studies to construct a model for prediction of falls in the elderly population and concluded that in combination their model was a good predictor of falls (52, 95).

The BBS and ABC have been used in a number of studies to assess the balance and confidence of the elderly and a lower limb absent population. The BBS may not be sensitive enough to assess small changes in an active non- vascular lower limb absent population and may exhibit a ceiling effect, it is also a time consuming test to administer. The ABC Scale appears to be more sensitive to change and less prone to ceiling effect. It is relatively easy to understand and administer but again may not be sensitive enough to detect small changes in an active trans-femoral prosthesis user group. The ABC Scale may be a useful tool to assess the baseline balance and confidence of this population.

2.5.2.2 Functional Walking and Balance Test Studies (Appendix E)

Functional walking tests are widely used in areas of rehabilitation to assess ability and function. In 2001, the World Health Organization (WHO) developed a framework for measuring health and disability, the International Classification of Functioning, Disability and Health (ICF) (99). Many areas of healthcare have introduced the use of ICF to assist in clinical practice, sharing of knowledge and research. Recently work has been carried out with reference to the lower limb absent population and the use of the ICF, which may lead to a more universal and comprehensive outcome measurement tool. A number of studies (59, 101-103) have been carried out in the area

of prosthetics to assess the use and feasibility of the ICF in classification and outcomes of a lower limb absent population.

Deathe et al (59) studied the use of the ICF and outcome measures in a lower limb absent population to assist clinicians in choosing the correct method of assessment in conjunction with the ICF categories of mobility. A systematic review of the literature produced seventeen tests that corresponded to the ICF guidelines and concluded that although there are a number of instruments available to the clinician; many require further study to determine their usefulness. In a similar study, Xu et al (101) conducted a systematic review of the literature of functional measures in assessment of a lower limb absent population, in an effort to relate these to ICF categories and create a core set for this population which is clinically useful. Burger et al (103) asked if the ICF could be used in Prosthetic and Orthotics clinics to detect a change in function in a lower limb population and found the categories to be useful but further qualifiers were necessary for use in demonstrating changes in function. In another study of the use of ICF in a lower limb absent population, Kohler et al (102) evaluated the use of an ICF checklist specific to this group testing 20 subjects pre and post amputation. A 25 item amputee-specific checklist was established which needs further study and verification. The ICF is a system that appears to have potential for clinical use in classifying a lower limb absent population but requires further research to establish 'user-friendly' protocols and verify the sensitivity of such an instrument.

The WHO has recognized that the ability to walk is a primary component for mobility (99). Generally, the main goal in prosthetic rehabilitation is to enable the user to ambulate safely and comfortably when physically possible. Rommers et al (60)

conducted a systematic review of the literature to compare mobility scales used to assess a lower limb absent population. He concluded there are a number of scales and questionnaires which have been used to assess mobility in this group but there is no consensus on which is the most appropriate or valid measure.

One of the most commonly used tests are functional walking tests. These are relatively easy and inexpensive to conduct and have been used to measure the ability of the prosthetic user. The following tests were used in some of the studies, the 2 Minute Walk Test (2MWT), 6 Minute Walk Test (6MWT), 12 Minute Walk Test (12MWT), Timed Up and Go Test (TUG), 10 Meter Walk Test (10MWT), gait speed tests and the Four Square Step Test (FSST) (71, 100, 104-110).

The 2MWT and 6MWT are variations of the 12MWTdeveloped by Cooper et al (141). These tests have been shown to be a useful mobility assessment tool in a number of areas such as neurological conditions and respiratory conditions and have been shown to be reliable as a mobility assessment for a lower limb absent population. Two studies (104, 105), investigated the use of timed walk tests (TWT) to measure improvements in function and mobility. Datta et al (104) used the 10MWT to compared the FAI and the Barthel Index and Brooks et al (105) compared the 2MWT with the Houghton Scale and SF-36 function sub-scale. Both concluded the tests were suitable to measure mobility and limited changes in function in this population.

The TWT has been used to predict limitations in the mobility of individuals and they have been shown to be sensitive to multi-variance outcomes within a lower limb absent population, such as level of amputation, muscle strength and balance. Raya et al

(106) used the Amputee Mobility Predictor (AMP), a series of muscle tests and history assessment to determine the ability of impairment measures to predict performance in the 6MWT. They concluded the 6MWT was impacted by multiple factors, the most significant being hip strength and balance. There were a number of limitations to this study, including the method of hip strength testing.

The TUG Test has also been used in the wider population to measure mobility. It is similar to the TWT but involves a turn and a sit to stand movement, which may be a more accurate assessment of functional mobility for the elderly population. Podsiadlo et al (107) investigated the use of the TUG Test on 60 geriatric patients and found it had good reliability and correlated well with the BBS, gait speed and Barthel's Index. The reliability and validity of the TUG Test has been assessed by a number of authors and compared to the various TWT (58, 100, 108). Schoppen et al (108) assessed the validity of the TUG Test with 32 elderly trans-tibial and trans-femoral prosthesis users. The TUG Test was found to be easily administered to this population and showed good inter-rater reliability ($p= 0.31$). The average times recorded for this study group were higher compared to previous studies in elderly non-amputees and the authors encouraged further validity testing. In a review of the literature of outcome measures, Condie et al (58) found the TUG Test had been shown to be a reliable test for assessment but perhaps not sensitive enough for the amputee population. This was an observation by Deathe and Miller (100) who found there was a ceiling effect with the younger and more active elderly prosthesis users. This led to the development of the modified TUG Test or L-Test. This test covers a longer distance and incorporates two sit to stand movements and four turns. The L-Test, 2MWT, TUG and 10MWT were

performed by 93 trans-tibial and trans-femoral prosthesis users. The ABC Scale, FAI and PEQ self-report questionnaires were administered and a re-test was carried out on 27 of the subjects after two weeks. The results showed the L-Test had sound validity and reliability, was easily administered to this group and was better able to distinguish between levels of amputation than the TUG Test.

From the observations of previous studies in this review, assessment of level walking may not be sensitive enough to assess changes in mobility in an active lower limb absent population (18, 25, 72, 142). This has led to the development a more challenging functional walking test, the FSST (110). The FSST differs from many of the other tests of mobility in that it involves stepping in different directions over low obstacles and recording the time taken to complete the test. It is a simple clinical test, which is easy to set up and administer and has been shown to have reliability and validity in testing physical mobility when compared with the TUG Test, Step Test and Functional Reach Test (FRT) in a group of healthy elderly adults. The FSST was able to distinguish between the different groups and had good sensitivity and specificity and further study was recommended for different populations (110). In another study by the same authors, 47 trans-tibial prosthesis users were assessed using the TUG, FSST, LCI and 180° turn to discriminate between fallers and non-fallers in this population. The results showed the FSST to have the highest sensitivity in classifying fallers from non-fallers. The authors conclude that the FSST and TUG Test are easily administered walking tests, which test for movements found in activities of daily living. They recommended further testing with larger lower limb absent populations (109). More recently Lythgo et al (71) conducted a study of five trans-femoral non-vascular

prosthesis users to assess the function of two NMPK joints. The study investigated the physical function, gait and dynamic balance of the amputees using the different knee joints. The alignment procedures are well documented and the subjects are assessed using an instrumented mat to assess their ability to stop suddenly and turn at self-selected speeds. The FSST, TUG Test, 6MWT and a sudden stop and turn test were administered and a modified version of the PEQ carried out. The results showed no significant difference for either of the knees in any of the walking tests and a slight improvement in physical function for one of the knee joints which the authors attributed to the different swing control mechanisms in the knees.

From the literature, there are a number of tests to assess balance, confidence and stability in the able-bodied population. With careful consideration of the information required and perhaps in combination with one another, these tests can be used for the assessment of a lower limb absent population in a research or clinical environment.

The TUG Test and the longer version L-Test appear to have good reliability and validity in testing the mobility and function of a lower limb absent population. In performing the L-Test, the subject completes many of the basic requirements for walking and it may be suitable for assessing a trans-femoral population. The inclusion of obstacle courses and slopes and stairs, in some studies, suggests that perhaps normal walking is not rigorous enough in an active lower limb absent population to detect small changes and their effects. The FSST is a more complex stepping test and requires the subject to stand, turn and cross obstacles at speed. These are tasks that active trans-femoral prosthesis users may find challenging and are likely to be more sensitive to the effects of changes.

2.6 FURTHER DISCUSSION

The review of the literature has shown that balance and confidence is an important factor in function and mobility. It has been widely researched in a non-amputee population and impaired balance and confidence has been linked to reduced function in the elderly and populations with neurological and muscular conditions. The use of balance and confidence outcome measurement is recognised as part of the assessment of rehabilitation. Balance and confidence has been shown to be generally low in a limb absent population and this has been attributed to a number of factors such as age, health and level of amputation. There has also been some investigation of the effects of low balance and confidence on mobility and social participation in this group.

Many studies have investigated the effect of different prosthetic components on a lower limb absent population and assessed the influence of different prosthetic knee joints on the function, stability and balance confidence of the trans-femoral prosthesis user. Almost all studies mention the importance of the alignment of prosthetic components within the prosthesis and the possible effects on stability and function. However, there is little detail describing the process or protocol of prosthetic alignment. A range of tools is available to measure prosthetic alignment with varying accuracy. Some equipment is readily available in prosthetic clinics and some more appropriate for research purposes. From the literature, accepted practice is variable and unclear. There does appear to be a gap in the literature regarding the processes involved in measuring prosthetic alignment and the effect of prosthetic alignment on the prosthesis user, specifically in the area of balance and confidence. This is the focus of this pilot study.

From this review, there is no doubt about the significance and importance of the alignment of a trans-femoral prosthesis. There are a number of methods to align a prosthetic limb using biomechanics and most manufacturers will provide guidelines on specific components to assist clinicians in setting up a prosthesis. It also appears that due to the individual nature of each prosthesis, prosthesis user and the Prosthetist, the standardization of alignment should not be the goal but the individual optimisation of each alignment configuration, using sound biomechanical principles. The assessment of the individual user is key and anatomical information such as hip range of motion and limb length should be an integral part of the initial set-up of the prosthetic alignment as a starting point for a stable and functional prosthesis. Initial impressions of a prosthesis, at fitting stage, with regard to comfort, stability and suspension will influence the prosthesis user and may affect their overall confidence in this process.

It appears stability is a major issue especially for trans-femoral prosthesis users and the literature has shown that, regardless of age and level of amputation, the general lower limb absent population has low balance and confidence compared with an able-bodied population. Further investigation of the link between individual trans-femoral prosthetic alignment and balance and confidence in this lower limb absent group could benefit this population, by improved prosthetic fitting, enhanced function of componentry and general rehabilitation. This is a complex issue with many variables to contend with but technology has provided better equipment, with which we can approach this procedure every day in our clinics, and the careful use of validated and reliable tests can assist in improving outcomes.

The current evidence from this review of the literature indicates static and dynamic prosthetic alignment should be carried out using the appropriate tools available for example, a static bench alignment jig and the L.A.S.A.R. Posture device. Sound biomechanical principles and clinical experience are required to optimise the function of the prosthesis for the user. Some of the processes of prosthetic alignment are well defined in the literature but there are areas that need further investigation and clarification, such as the anatomical assessment of the prosthesis user and the range of motion of the residual limb. The Thomas Test (124) appears to be the most commonly used test among prosthetic and rehabilitation clinicians to assess for a hip flexion contracture, in the residual limb, and has been shown to have good reliability with a single tester, using a manual goniometer. Careful assessment of the physical and anatomical situation and individual needs of the trans-femoral prosthesis user is necessary, to determine the initial flexion angle of the socket for bench alignment and establish a bench alignment protocol which is the starting point for the dynamic alignment process.

Due to the inherent ability of a prosthesis user to compensate for any changes made to their prosthesis it is extremely difficult to assess the effects of such changes. In order to assess the effect of changing the alignment configuration of a trans-femoral prosthesis it is necessary to have a starting point which can be measured and repeated, such as the initial angle of socket flexion and the bench alignment of the components. Assessment of different initial socket flexion angles and the effect on the dynamic alignment process, may improve the understanding of the compensatory movements of the prosthesis user and the functional effects of these changes.

The literature review of outcome measures has shown there are many tests and questionnaires suitable for assessing this population. It does appear that the ABC Scale is appropriate to assess a baseline level of balance and confidence in a lower limb absent population and is an extremely useful indicator for rehabilitation. Due to the possible ceiling effect and the broad nature of the questions, this test may not be sensitive enough to detect the effect of small changes such as different components or alignment changes in a particular group. Therefore, tests to detect small perturbations, that are part of the clinical process of fitting a prosthesis, are required. A study of this nature should assess changes within subjects rather than between subjects, as the number of variables are difficult to control and may ultimately affect the results. From the literature, functional tests of mobility such as the L-Test and the more challenging mobility test such as the FSST have been shown to be applicable to this population.

2.7 CONCLUSIONS

Based on this extensive review of the literature, the aim of this study was to pilot the methods and feasibility of assessing the effect of prosthetic alignment on the balance and confidence of a group of active trans-femoral prosthesis users. From the literature, it has been established there are numerous variables to contend with when assessing a lower limb absent population and there is little evidence-based practice in the procedures to set up and align a trans-femoral prosthesis. In order to determine the suitability and sensitivity of outcome measures to assess balance and confidence in a sample of trans-femoral prosthesis users and establish a protocol for alignment configuration, the following methodology was derived.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

A sample of clients was selected from a population who attend an independently operated Prosthetic Clinic in Cappagh National Orthopaedic Hospital, Dublin, Ireland. The participants were asked to complete a questionnaire (ABC) to establish their baseline balance and confidence level and an assessment of the hip range of motion on the affected side was carried out. The participants attended wearing their everyday prosthesis and the original definitive alignment of this prosthesis was recorded using the Bench Alignment Apparatus (137). Each participant completed a timed walking test (L-Test) and a timed stepping test (FSST) to assess their mobility and balance and confidence with their current prosthesis.

Each participant was assessed with two new alignment configurations, based on two pre-determined angles of initial socket flexion. In order to assess the effect of the alignment changes it was necessary to establish a starting point for the process, which was achieved by setting the socket in 20 degrees and 30 degrees of initial socket flexion at bench alignment. This provided a foundation to ensure continuity at the start of each test and provide a point of reference from the bench alignment to assess the changes carried out to the overall alignment of each prosthesis. The pre-determined initial socket flexion angles of 20° and 30° were chosen to allow for a perceived

change in the prosthetic alignment for the participant and to create a large enough difference between angles to perhaps see an effect from the alignment changes in each test.

Each prosthesis, using the original socket, prosthetic foot and knee joint, was bench aligned with the two angles of initial socket flexion. The re-aligned prostheses were fitted to the participants and the process of dynamic alignment was carried out. The participants then repeated the walking test and stepping test for each alignment configuration to determine the effects of the alignment changes on their performance. The prosthesis was removed and put in the Bench Alignment Apparatus (137), using the prosthetic foot as the reference point. For the purpose of this investigation, the Bench Alignment Apparatus was used to measure changes made to the alignment of each prosthesis. The marker positions following testing, were recorded and compared to the original bench alignment measurements, to determine any changes made during the dynamic alignment process.

3.2 STUDY GROUP

A search of the local database elicited 520 clients with a lower limb absence. The inclusion criteria for this study are listed in Table 5.

Table 5: Inclusion Criteria

Reason for Amputation	Non-vascular
Level of Amputation	Unilateral trans femoral
Age Range	18-65 years
Mobility Level	Independently ambulant
Prosthetic Status	Current user
Time since amputation	1 year post surgery

The inclusion criteria are further explained in the following sections:

3.2.1 Reason for Amputation

Figure 1 shows the demographics of the study population.

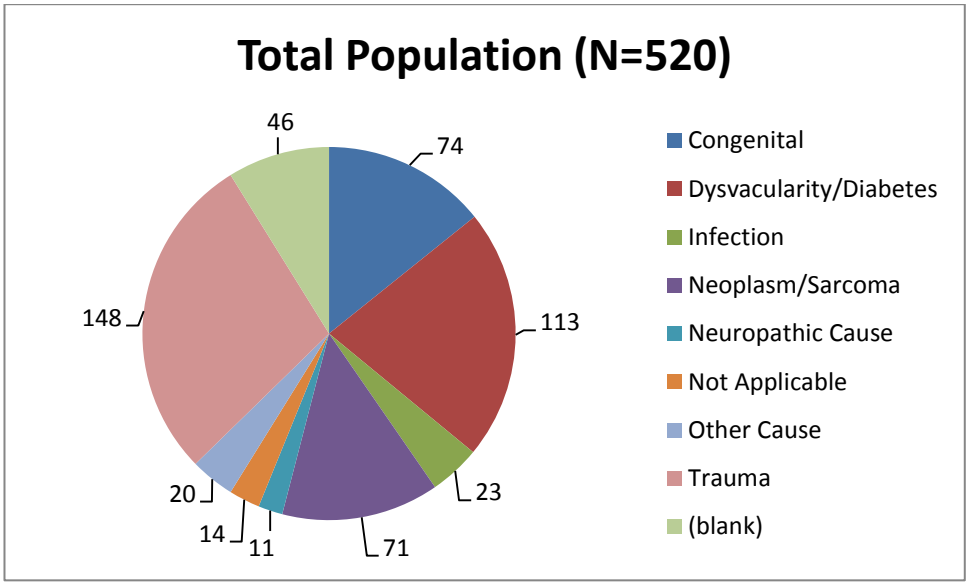

Figure 1: Demographics of study population

From the database, 22% of the population had an amputation due to dysvascular reasons with 56% recorded as having amputation due to trauma, tumour or congenital issues. These are unusual statistics in relation to most Prosthetic/Rehabilitation Centres in the developed world. According to the latest statistics from the United States and United Kingdom on average 75% of all amputations are due to dysvascular causes and affect mainly elderly persons (1, 2). This may be explained by the type of facility this population attends, where the specialisation is in rehabilitation of a younger, more active lower limb absent population. Therefore, this study focused on a non-vascular group of prosthesis users.

3.2.2 Level of Amputation

Men and women with a unilateral trans-femoral absence who currently use a prosthesis were considered for this study.

3.2.3 Age Range

The unusual demographics of this facility are also reflected in the age of this lower limb absent population. The mean age of the trans-femoral population on the local database was 55 years; generally, this population would be expected to be a more elderly group. The age range of 18-65 years excludes children or older adults who may be less able to complete the questionnaire or the tests required and reflects the population of the study facility.

3.2.4 Level of Mobility

There are a number of different scales and methods for categorizing mobility levels of a lower limb absent population but there is currently no consensus on the use of mobility scales within a clinical environment. From the literature, there has been much work in this area but to date there is no universally accepted model for the assessment of mobility level (58, 60, 64, 101-103).

In this study the participants were assessed using the MOBIS® Scale, which is a measure of mobility developed by Otto Bock (143). By assessing the weight and activity level of the user, a grading of MOBIS® Level 1-4 can be assigned. It is based on the profiling questionnaires of the German Association of Medical Services for the National Health Insurance Companies and is similar in description to the K-level classification or Medicare Functional Classification System (MFCS) (144) widely used

in the United States. The MOBIS® Scale is in daily use within the clinic of this study and is further described in Appendix F.

The purpose of the inclusion criteria of mobility level in selecting the participants was to ensure that the participants were independently mobile with their prosthesis and therefore would be capable of completing the tests required for this study. Only participants assessed as MOBIS® Level 2 or 3 were considered for the study. The balance and confidence of these participants was the major interest in this study and the assessment of their mobility is another study in itself.

3.2.5 Prosthetic Status

The participants were all trans-femoral prosthesis users who reported no problems with their prosthesis that they wore on a regular daily basis.

3.2.6 Time since Amputation

Only individuals who were more than 12 months post-amputation surgery were considered. This was in an attempt to reduce the effect of the steep learning curve which most, previously active individuals experience when undertaking their primary rehabilitation following an amputation (145). At this stage, they should be established in their walking pattern. During initial rehabilitation following amputation, these otherwise healthy individuals function well physically and quickly master the basic skills of walking and standing with their prosthesis (93). This learning process gradually levels off after some months as an acceptable level of activity and mobility is reached. The new prosthesis user may experience problems with their residual limb and this is compounded in the early stages of rehabilitation by changes in shape and

volume of the residuum (146). It is generally accepted that the residual limb is more stable 12 months after surgery, in a regular prosthesis user (147). Psychological and emotional issues can take longer to deal with but one year after amputation an individual may be in a more stable situation physically and emotionally (148-150).

3.3 SELECTION PROCEDURES

The process of selection of the participants is outlined in Figure 2. In accordance with the inclusion criteria, the database was filtered by age, level of amputation and reason for amputation.

Figure 2- Selection Process

Due to some limitations in the information stored in the database, it was not possible to filter for all of the inclusion criteria. Therefore, the prosthetic records of the filter group were independently screened by a certified clinician for the remaining inclusion criteria, current use of a prosthesis, mobility level and the time since they had surgery. The resulting group then received a written invitation to participate in the study (Appendix G). The procedure to be undertaken was explained fully, in writing, and they were requested to accept by signing and returning the enclosed consent form (Appendix H & I) before the closing date. Five clients returned consent forms within the time period and were sent notification to attend the clinical facility to take part in the study. Anonymity of the clients was maintained in the selection process by appointing an administrator in the clinic to distribute the letters and contact the participants regarding attendance times. All data collected was kept secure and confidential and only the investigator had access to this information.

Ethical approval was obtained from the University of Strathclyde, Glasgow, Scotland and Cappagh National Orthopaedic Hospital, Dublin, Ireland before conducting any trials. The ethical application forms and approval forms are in Appendix J & K.

3.4 TESTS/QUESTIONNAIRES

Two functional tests and a questionnaire were used to assess the balance and confidence of the participants, the L-Test (100) which is a modified version of the TUG Test (107), the FSST (110, 151) and the ABC Scale (48). These tests have been used with a lower limb absent population and have been shown to be valid and reliable (30, 31, 48, 92, 100, 110).

3.4.1 ABC Scale

The participants were given the ABC Questionnaire on arrival at the clinic and were asked to complete the form and hand it to the investigator at the end of the trial. This scale was developed to assess balance and confidence in the elderly population (48). It has also been found to be useful in assessing the balance and confidence in a lower limb absent population and there is evidence to support the reliability and validity of this questionnaire (92). Due to the nature of the questions it may not be sensitive enough to detect the influence of small changes in prosthetic alignment over a short period of time. Therefore, the ABC Scale was used to gather baseline information on the balance and confidence of the participants.

The ABC Scale is a 16-item self-assessment questionnaire that assesses the level of confidence of an individual in performing a task without becoming unstable or losing their balance. It is rated on a scale of 0 (no confidence) to 100 (full confidence). The mean score is calculated, with a score of less than 80 indicating low balance and confidence and perhaps a need for intervention. (94)

The ABC Scale and scoring system is detailed in Appendix L.

3.4.2 L-Test

The L-Test is a modified version of the TUG Test (107) to measure physical mobility. The TUG Test is widely used to assess mobility in rehabilitation but this test may not be challenging or sensitive enough to detect the effect of changes in prosthetic alignment in an active group of trans-femoral prosthesis users. The L-Test is a longer version of the TUG Test and incorporates three turns and two sit to stand movements.

This test has been shown to have excellent reliability and validity when testing the mobility of a lower limb absent population (100, 108, 109). The participant is required to stand up from a standard height chair, walk three meters, make a 90-degree turn, walk seven meters and then turn around and retrace their path. The time it takes in seconds to complete the 20-meter circuit from the time the individual starts to stand to the point that they sit down again is recorded. This is a self-selected walking speed test and reflects the basic skills required for normal walking. The instructions given to the participants for the L-Test are in Appendix M.

3.4.3 FSST

The FSST (151) is a clinical test which has been shown to have reliability and validity in testing physical mobility and balance (110, 151-153). It has been used to assess a lower limb absent population (71, 109) and differs from many of the other tests of mobility in that it involves stepping in different directions over low obstacles at speed. It is a relatively simple test to set up and administer, using four standard walking sticks placed on the floor to form four squares. The squares are numbered from 1 to 4 and the participant is instructed to start in square 1 and move in the sequence 1, 2, 3, 4, 1, 4, 3, 2, 1 as quickly as possible, without disturbing the sticks. The most efficient way to complete the test is to face in the same direction, side step and step back and forward over the obstacles but as long as both feet make contact with each square, the participant is free to use their preferred method to negotiate the test. These types of movement are present in everyday activities but can be challenging for a trans-femoral prosthesis user and any perturbations to the alignment configuration of the prosthesis

may affect the difficulty of this test. A full description of the FSST and the instructions given to the participants are in Appendix N.

3.5 PROCEDURES

On arrival at the clinical facility the participants were given an information pack (Appendix O), outlining the procedures for the trials and describing the tests and the ABC Questionnaire. General information was gathered such as height; weight; activity level, number of hours per day the participant wore their prosthesis and details of any problems they were experiencing. The participants were asked to read and complete the ABC Questionnaire and return it at the end of the trial. They were encouraged to ask the investigator if there were any ambiguities in the questionnaire.

Cosmetic coverings, if present, were removed from the prosthesis. In order to locate the position for the hip marker, the lateral brim edge of the socket was marked on the participant in standing, the prosthesis was then removed and the location of the greater trochanter marked on the participant. The distance between these two points was measured and transferred to the socket as a reference point for the level of the hip marker, to allow positioning of the 50:50 Socket Gauge (Otto Bock 743A80) designed to determine the lateral centre line of a prosthetic socket (154). This gauge has moveable legs to conform to the shape of the socket, and was positioned on the socket 40mm from the distal end and 40mm below the level of the trochanter and marked through the centre of the gauge. These two points were joined to mark the centre line on the socket. The same prosthetic socket was used throughout the trial and the reference lines were maintained. The knee centre of rotation, as defined by the

manufacturer (Appendix R and S), was marked as the knee reference point and the middle of the foot was marked as the foot reference point, the same components were used for all three tests.

Each participant was initially assessed with their current prosthesis for weight-bearing static alignment using the L.A.S.A.R. Posture device (136). The L.A.S.A.R. Posture (Appendix P) is used to adjust the static alignment of modular limb prostheses during trial fitting. The L.A.S.A.R. Posture consists of a force sensor platform (*Inelta Sensorsysteme, Munich, Germany*) (Appendix Q) and a laser line projection which allows visualisation of the position of the GRF while standing on the force sensor platform (Figure 3).

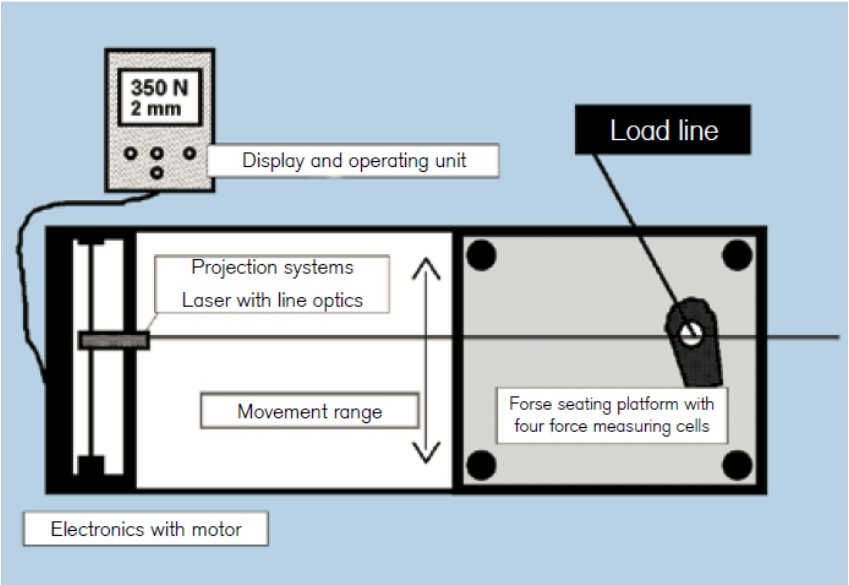

Figure 3: L.A.S.A.R. Posture

Extensive studies to develop this equipment have produced guidelines for the static alignment of various levels of prostheses (8, 85, 155), in combination with bench

alignment recommendations (Appendix S) and the manufacturers' guidelines for prosthetic components (Appendix R). This methodology has been used for the purpose of discussion in this pilot study. The L.A.S.A.R Posture was not used to optimise the alignment, as the goal of this study was to test the effect of different prosthetic alignments on the balance and confidence of the user. The alignment configurations were recorded on the Bench Alignment Apparatus before and after each test, and these results have been statistically analysed in this study. The measurements of the L.A.S.A.R. Posture are documented in the Results section and are described in the Discussion section, as they may be of clinical interest and provide a comparison to previous work. The L.A.S.A.R. Posture has been used in previous similar studies and is available in many prosthetic clinics, to assess a variety of conditions such as changes in componentry and alignment (15, 21, 22, 25, 85, 138, 155).

Each participant stood on the force sensor platform, the laser line projected in the sagittal plane was moved, using the control panel of the device, to each of the markers, and the position recorded. This was carried out with both feet on the force sensor platform and with the prosthesis on the force sensor platform and the contralateral foot on a height block. The markers for the hip, knee and foot were kept in the same position throughout for each prosthesis. The foot marker was different to the one used for the Bench Alignment Apparatus, as this was concealed by the participants' footwear and previous studies using the L.A.S.A.R. Posture have utilized the shin tube of the prosthesis as a reference point. These measurements were documented as L.A.S.A.R. Posture A.

Following the assessment of the static alignment, the participant was given instructions on the L-Test and performed the test twice with a two-minute break between each test. The time was recorded in seconds using a stopwatch and the mean time documented as L-Test A. The FSST was explained to the participant and they completed one trial of the test. The test was then performed twice with a two-minute break between each test and the time recorded in seconds using a stop watch; the mean time was documented as FSST A.

The prosthesis was then removed and the participant was asked to lie supine on a plinth and a physical assessment of the participant was conducted. The investigator and a qualified assistant assessed the range of motion at the hip joint on the affected side, the Thomas Test was carried out to determine the presence of a hip flexion contracture and maximum range of flexion was measured. The same clinicians repeated this test prior to each intervention to ensure consistency.

The participant's pelvis was secured with a stabilizing strap to limit pelvic rotation, a reference line was marked bisecting the residual limb from greater trochanter to end of femur, and the midline of the trunk was marked. The qualified assistant placed their hand under the lumbar spine and flexed the sound side hip and knee until the lumbar lordosis became flattened. The investigator flexed the residual limb to maximum and the degree of hip flexion was measured, using the midline of the trunk and the midline of the residual limb. The participant was then asked to relax and allow the residual limb to be extended. The angle of the midline of the residual limb and the trunk was measured when the assistant felt the lumbar lordosis increase indicating pelvic

movement due to limitation in the hip flexor muscles or the residual limb reached the plinth with no change in the lumbar lordosis.

The measurements were taken using a long arm manual goniometer and documented as the angle of hip flexion contracture, with 0° indicating neutral flexion/extension or no flexion contracture. Each participant was measured three times and the mean angles recorded for hip flexion contracture (Thomas Test) and maximum hip flexion movement.

The participant's prosthesis was then assessed for the original dynamic alignment configuration. The prosthesis was placed in the Bench Alignment Apparatus (Otto Bock 743A100=3) (137) as shown in Figure 4.

Figure 4: Bench Alignment Apparatus

The apparatus consisted of a clamp for the socket, knee and foot components. The prosthesis was secured in the current aligned position and a static laser set up to project a line in the sagittal and frontal planes to record the original alignment. This apparatus is routinely used in the clinic to set up or bench align the prosthesis before fitting to a patient. This is a crucial part of the manufacture and fitting of a prosthesis and is achieved by following the alignment recommendations from the manufacturer of the specific components and the position of the socket according to the position of the residual limb (137). This process is further explained in Appendix S.

The Bench Alignment Apparatus was used to set up each prosthesis with the test angles of socket flexion and to measure the original definitive alignment. The changes made to the alignment of the prosthesis during each test were measured by recording the initial bench alignment for each angle of flexion and then recording the alignment of the prosthesis after it had been fitted and dynamically aligned to the participant and the tests completed.

After completion of the first walking tests, the sagittal alignment of the prosthesis was recorded using a laser line on the Bench Alignment Apparatus. This projected to show the distance from the reference line of the socket, reference point of the knee joint and the middle of the foot. The measurements were recorded from the alignment jig for the foot position, heel height and knee joint position. The socket flexion angle was measured by placing the vertical laser line on the hip marker and using a manual goniometer measuring the angle between the laser line and the socket bisecting reference line. This was documented as Alignment A. This was the original dynamic

or definitive alignment of the prosthesis as it was fitted and delivered to the participant. The original bench alignment could not be recorded as this was established during the fitting of the prosthesis and subsequently changed during the alignment procedure. The height and alignment of the prosthesis was recorded using the sagittal and frontal laser lines on the Bench Alignment Apparatus to ensure the prosthesis was returned to the participant in the original alignment after the completion of the tests.

The prosthesis was then dismantled and the components set up in the Bench Alignment Apparatus according to the manufacturers' guidelines for the components. The starting point for the bench alignment process was achieved by using two pre-determined initial socket flexion angles. The socket was set up in 20 degrees of initial socket flexion for Test B and 30 degrees of initial socket flexion in Test C. This provided a point of reference from the bench alignment to assess the changes carried out to the overall alignment of each prosthesis. The pre-determined angles of socket flexion were not based on any assumption of the original alignment of the prosthesis, as the original socket flexion angles were unknown until testing began, but generally the initial socket flexion angles would be expected to be lower than these values.

The order in which the socket angle was set up for each participant was randomised by the flip of a coin, to avoid the effect of learning during the functional walking tests. Each participant undertook Test A first with the original alignment, three participants performed the test sequence with 20 degrees initial socket flexion (Test B) as the second test and with 30 degrees initial socket flexion (Test C) as the final test, the remaining two participants undertook the sequence Test A, Test C and Test B. The prosthetic knee and foot were clamped into the apparatus at the recommended

positions and the socket was lowered into position and connected using the necessary adapters. These alignment configurations were documented as Bench Alignment B (20° initial socket flexion) and Bench Alignment C (30° initial socket flexion).

The prosthesis was re-fitted to the participant and they were asked to walk with the prosthesis within the walking bars. Limited dynamic alignment adjustments were carried out, to allow the user to function and adjust to the new configuration, using clinical observation and participant feedback.

The goal was not to "optimise" the alignment, as it was the effect of the initial angle of socket flexion and the resultant changes in alignment that was being assessed, therefore the adjustment of socket flexion or extension, above the knee joint, was not carried out. The length of the prosthesis and rotation of the knee and foot were adjusted as necessary. The range of adjustments were anterior and posterior shift of the knee position in relation to the socket and dorsi-flexion and plantar-flexion adjustment of the foot. These adjustments would have an overall effect on the socket alignment and the resulting dynamic alignment represented the effect of the initial angle of flexion of the socket and the compensations made to the rest of the system to accommodate for this when fitted to the participants.

This procedure was conducted within the clinic walking room and involved level walking, stairs and ramps. The weight-bearing static alignment of each configuration was documented, using the L.A.S.A.R. Posture (136), as L.A.S.A.R. Posture B and L.A.S.A.R. Posture C. Each participant repeated the L-Test and FSST with the new alignment configurations and these were documented as L-Test B and C and FSST B

and C, respectively. The final alignments were measured in the Bench Alignment Apparatus, after completion of each test, and documented as Alignment B and C, respectively. The individual assessments were carried out in one visit and the necessary time to rest between tests was consistent for each participant.

Within-subject comparisons of the times of the L-Tests and FSST were carried out. In order to assess if changing the alignment of a trans-femoral prosthesis had any effect on the self-selected walking speed (L-Test) or the speed of completing a stepping test (FSST) of an active trans-femoral prosthesis user. It was hoped to establish a possible relationship between the socket flexion angle and the Thomas Test to re-affirm the protocols of bench alignment and to assess the clinical effect of different socket flexion angles on the alignment of the participant.

During this study, no changes were made to the fit or shape of the socket and the participant used their original prosthetic knee and foot. All of these processes are part of standard clinical practice during prosthetic fitting, where clinical observations and prosthesis user feedback initiate any changes made to the alignment or socket fit, in order to reach an agreed acceptable fitting. Each participant had a minimum of one hour to adapt to the new alignment configuration. It is general practice to allow the user to become familiar with a new prosthesis or changes to a prosthesis, in their own environment for a longer period, before finalising a decision or completing the prosthesis, therefore the participants had no permanent changes made to their prosthesis during this study.

The prosthesis was returned to the participant in the original alignment configuration using the Bench Alignment Apparatus to re-create the original alignment as recorded at the beginning of the trial. The participants were informed that if they felt they might benefit from a review of their prosthesis, due to the findings in the study, this would be carried out after the completion of the tests.

3.6 DATA ANALYSIS

The data collected was analysed using the statistical package Minitab©v16 (*Minitab Inc., Pennsylvania, USA*). Descriptive statistics were obtained for the demographics of the participants, ABC Questionnaire results, socket flexion angles and Thomas Test results. Correlation between the Thomas Test measurements, socket flexion angle and hip range of motion was calculated using Pearson's Product Moment. The results of the L-Tests and FSST were analysed by participant and for the sample. A Repeated Measures ANOVA was used to assess if the changes in alignment had a statistical effect on the results of the L-Test and FSST of the individual participants. A power calculation was carried out to estimate sample numbers for possible future studies in this area and was calculated using a one factor repeated measures ANOVA design through nQuery v7 software (*Statistical Solutions Ltd., Ireland*).

CHAPTER 4

RESULTS

4.1 DEMOGRAPHICS

The demographics of the study group participants (P1-5) are shown in Table 6.

Table 6: Demographics of Study Group

Participant	Gender	Age (yrs)	Reason for amputation	Time since amputation (yrs)	Length of residuum (mm)	Activity level (MOBIS ® Scale)
P1	M	45	Tumour	26	110	2/3
P2	F	36	Tumour	4	350	3
P3	M	34	Tumour	5	190	3
P4	M	41	Trauma	25	240	3
P5	M	40	Tumour	1.5	250	3

The mean age of the participants was 39.2 years (SD = 4.3) with mean time since amputation 12.3 years (SD = 12.1). The large standard deviation was not unexpected given the small sample. Four of the five participants had their amputation following diagnosis of a tumour.

A summary of prosthetic socket type, suspension method and foot and knee components for each participant is outlined in Table 7. A description of the components can be found in Appendix T.

Table 7: Prosthetic prescription

Participant	Socket Design	Prosthetic Foot	Prosthetic Knee Joint	Suspension Method	Walking Stick or Crutch
P1	ICS laminated	C-Walk (1C40)	3R80	Suction	1 crutch
P2	ICS laminated, flexible inner	Dynamic SACH (1D35)	C-Leg®	Seal-in liner	None
P3	ICS laminated	Trias (1C30)	C-Leg®	Seal-in liner	None
P4	ICS laminated	Trias (1C30)	3R60	TES belt	None
P5	ICS laminated	Trias (1C30)	3R60	Pin locking liner	None
ICS – Ischial containment socket SACH – Solid ankle cushion heel					

One of the participants used a crutch for outdoor walking, but chose not to use it for any of the tests in this study.

4.2 ACTIVITIES-SPECIFIC BALANCE AND CONFIDENCE SCALE

Each participant, based on their experience with their everyday prosthesis, completed the ABC Questionnaire. The results of the 16 questions on that scale, scored out of 100, are shown in Figure 5.

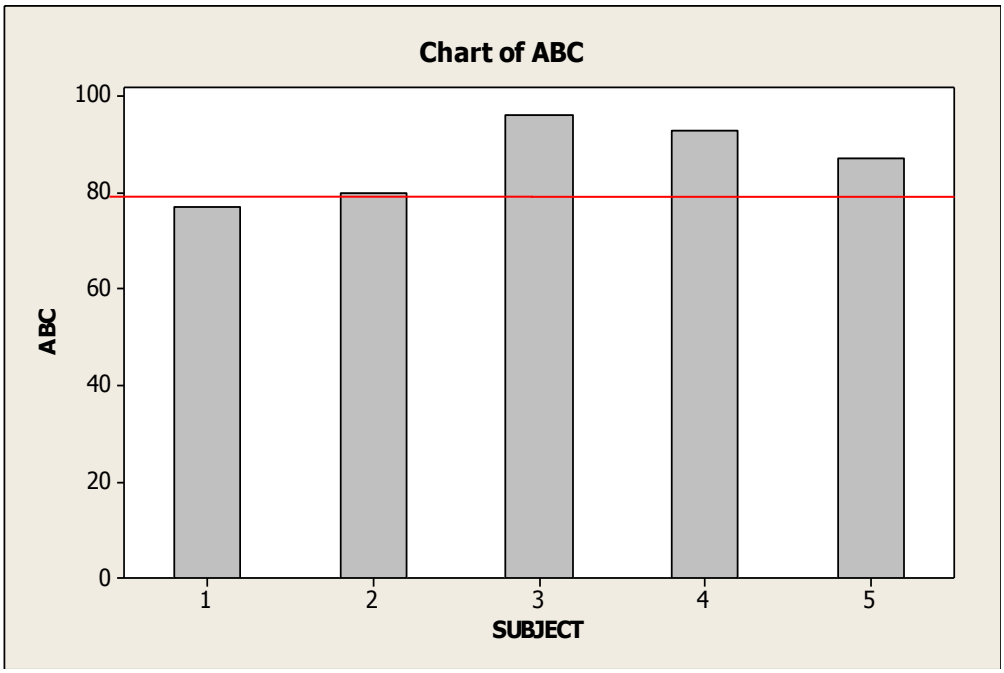

Figure 5: ABC Scale Scores

The mean ABC was 86.6 (S.D. = 8.1, Median = 87, Range 77-96). This test was used to establish a baseline balance confidence score for this sample of trans-femoral prosthesis users. Figure 5 illustrates the high scores achieved by this sample with scores over 80 showing a high level of balance and confidence, only one of the participants scored below 80 on the ABC Scale. This is a self-assessment questionnaire and the results demonstrate a high level of perceived balance and confidence in this group.

4.3 HIP RANGE OF MOTION RESULTS

The mean angles from the Thomas Tests and the measurements of maximum flexion of the residual limb are shown in Table 8. The results show the degree of hip flexion contracture for each participant and the range of flexion motion at the affected hip. All measurements were passive ranges of motion.

Table 8: Hip Range of Flexion Motion

Participant	Thomas Test – Hip flexion contracture (degrees)	Maximum hip flexion (degrees)	Range of flexion (degrees)
P1	8	110	102
P2	0	130	130
P3	18	80	62
P4	14	55	41
P5	17	110	93

Hip flexion contractures ranged from 0 degrees, or no hip flexion contracture present, to 18° of hip flexion contracture of the residual limb (Mean = 11.4, S.D. = 7.5, Median = 14). The participants' maximum flexion movement was also assessed and resulted in a range from almost normal values of 130° of hip flexion to considerably reduced motion of 55° of hip flexion (Mean = 97.0, S.D. = 29.5, Median = 110). Participants 3 and 4 had fixed flexion contractures.

The alignment of each prosthesis was initially recorded on the Bench Alignment Apparatus and the angle of flexion of the socket measured. This was the original alignment of the prosthesis, which the participants had been wearing for more than one year prior to the study. Table 9 shows the flexion angle of the socket in the original alignment configuration of the prosthesis for each participant and the results of the Thomas Test conducted during the study.

Table 9: Original Socket Flexion Angles

	P1	**P2**	**P3**	**P4**	**P5**
Original socket flexion angle (degrees)	18	4	3	6	7
Flexion Contracture (Thomas Test) (degrees)	8	0	18	14	17

From the correlation results for the original socket flexion angle and the Thomas Test r = -0.179, p = 0.773, socket flexion angle and hip range of flexion movement, r = 0.222, p = 0.720 and hip range of flexion movement and Thomas Test r = -0.762, p = 0.134. There appears to be no significant correlation between the angle of socket flexion in the prosthesis, the Thomas Test results and hip range of flexion movement for each participant.

4.4 WALKING TESTS RESULTS

The results of the L-Test and FSST for each participant with each of the alignment configurations are shown in Table 10.

Table 10: Results of L-Test and FSST

Test	P1	P2	P3	P4	P5
L-Test A	23.36	23.13	22.19	24.47	26.44
L-Test B	21.04	27.08	20.97	25.16	25.80
L-Test C	23.11	34.79	21.58	24.63	28.87
Mean	22.50	28.33	21.58	24.75	27.04
S.D.	1.27	5.93	0.61	0.36	1.62

Test	P1	P2	P3	P4	P5
FSST A	10.98	13.34	9.28	14.58	10.71
FSST B	9.98	15.42	9.55	12.94	11.10
FSST C	10.41	24.24	10.68	10.89	12.39
Mean	10.46	17.67	9.84	12.80	11.40
S.D.	0.50	5.79	0.74	1.85	0.88
Times in Seconds A- Original alignment, B- Initial socket flexion 20°, C- Initial socket flexion 30°					

The boxplots in Figures 6 and 7 show the overall variation for each participant in the times recorded for the L-Tests and the FSST.

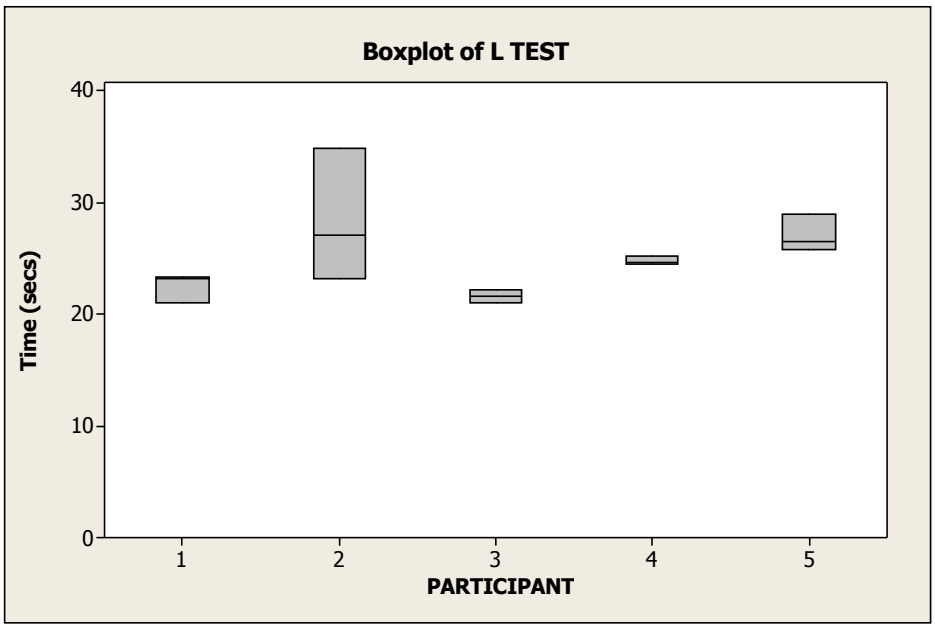

Figure 6: Boxplot of mean L-Test results by participant

The box plots show the range of the overall mean times for each participant in the L-Tests and *FSST.*

These figures illustrate the consistent performance of Participants 1, 3, 4 and 5 and highlight the variation in times for Participant 2 in both the L-Tests and FSST.

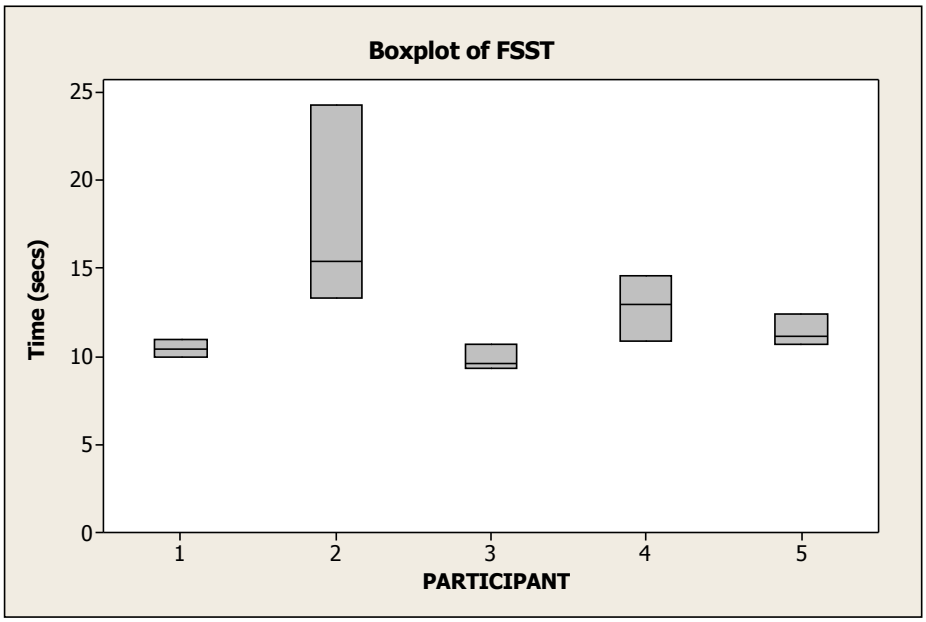

Figure 7: Boxplot of mean FSST results for each participant

The mean times for the L-Test and FSST, for each participant with the three alignment configurations (A- Original Alignment, B- Initial socket flexion angle 20°, C- Initial socket flexion angle 30°), are shown in Figures 8 and 9.

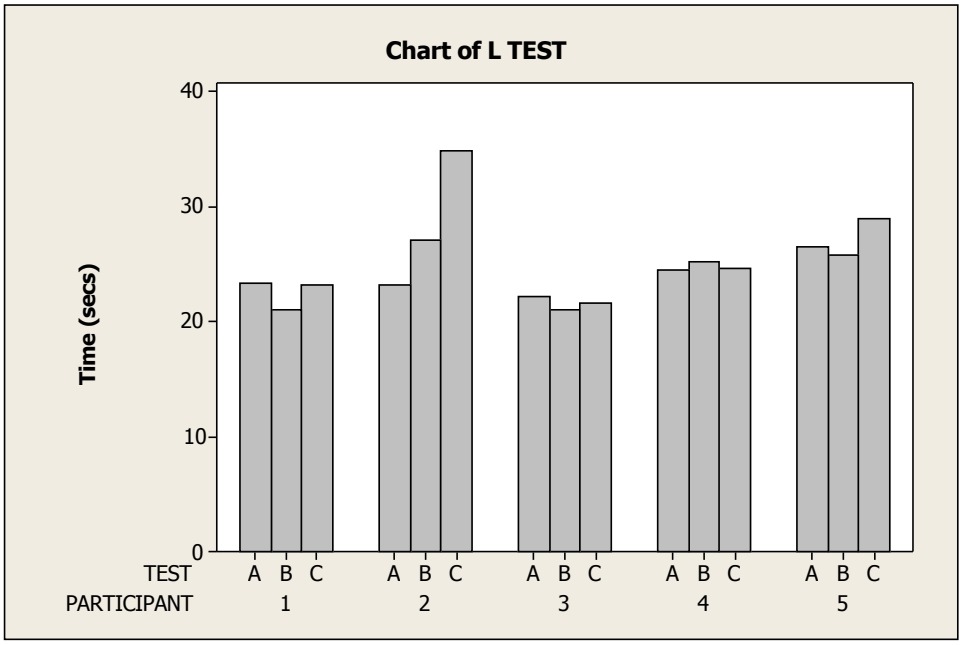

Figure 8: Mean Times of L-Tests by participant

The standard deviations (Table 10) of the individual L-Tests and the illustration in Figure 8 show Participants 3 and 4 performed most consistently in the L-Test with each of the alignment configurations. From the boxplot (Figure 6) Participant 2 had the largest variation in overall mean time for the L-Test, Figure 8 shows Participant 2 recorded a considerably slower time for Test C (initial socket flexion 30°) than in Test A (original socket flexion) or Test B (initial socket flexion 20°).

The mean times for each participant with each alignment configuration in the FSST are shown in Figure 9. The standard deviations for the FSST (Table 10) and the illustration in Figure 9 show Participant 1 and 3 were most consistent in the times recorded with each alignment configuration. Participant 2 showed the least consistency and recorded a much slower time for Test C (initial socket flexion 30°)

and this may indicate this alignment configuration was more challenging in both of the walking tests for this participant. Participant 4 appears to have improved times between FSST A and FSST C and Participants 2, 3 and 5 performed slower times from FSST A to FSST C.

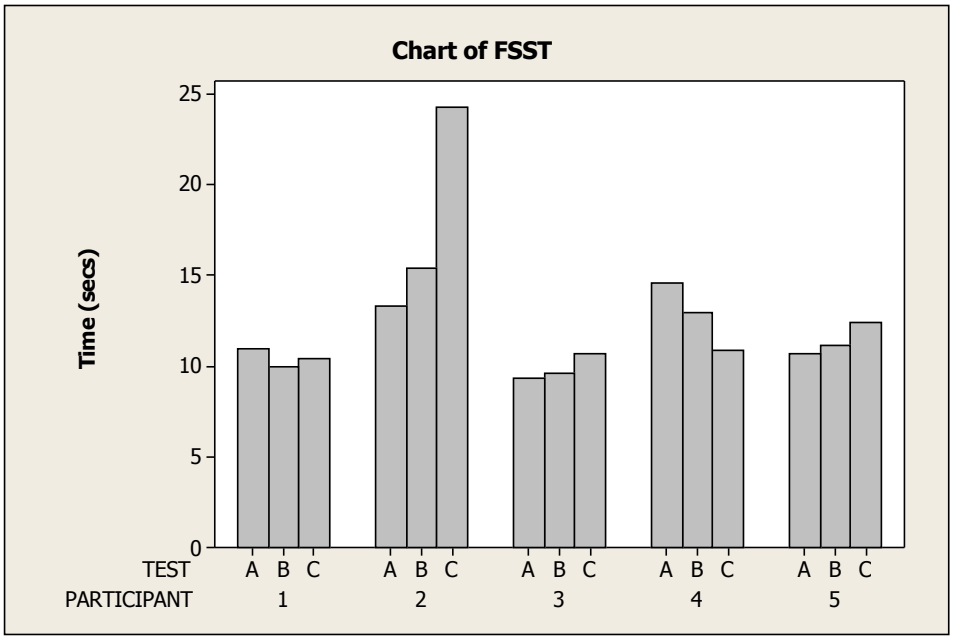

Figure 9: Mean times of FSST by Participant

In order to assess if changing the alignment of the prosthesis had a significant effect on the timed tests of balance and confidence a Repeated Measures ANOVA was used to analyse the data.

Table 11 shows the results from the ANOVA across the three alignment configurations. For the L Test, $p = 0.255$ and for the FSST $p = 0.493$, therefore the results show there was not a significant change in either of the timed tests for the

each of the alignment configurations. This, however, may simply be due to the small sample and large variation between the participants.

Table 11: Analysis of Variance for L Test and FSST.

Measurement	Degrees of freedom (DF)	F Value	P
L Test	2	1.63	0.255
FSST	2	0.77	0.493

The plots of residuals, checking the Normality assumption of the ANOVA models, are in Appendix U.

4.5 BENCH AND DYNAMIC ALIGNMENT

Each prosthesis was bench aligned for the new angle of socket flexion in Tests B and C. The measurements from the Bench Alignment Apparatus are in Table 12. Measurements are from the markers on socket, prosthetic knee and foot to the laser alignment line on the Bench Alignment Apparatus. A positive (+) measurement indicates the marker was positioned ahead of the projected alignment line and a negative (-) measurement indicates the marker was positioned behind the projected alignment line.

Table 12: Bench Alignment Measurements

	Socket flexion angle (degrees)	**Hip (mm)**	**Knee (mm)**	**Mid-foot (mm)**	**Heel height (mm)**
P1					
TEST B	20	0	0	+30	15
TEST C	30	0	0	+30	15
P2					
TEST B	20	0	0	+30	13
TEST C	30	-10*	0	+30	13
P3					
TEST B	20	0	0	+30	10
TEST C	30	0	0	+30	10
P4					
TEST B	20	0	0	+35	10
TEST C	30	0	0	+35	10
P5					
TEST B	20	0	0	+40	15
TEST C	30	0	0	+40	15
+ Denotes marker ahead of the laser reference line					
- Denotes marker behind the laser reference line					
* Unable to achieve laser line through hip marker					

There are no measurements for the original bench alignment (Test A) as this would have been established during the original set-up of the prosthesis and may have been altered during dynamic alignment.

The measurements taken, on the Bench Alignment Apparatus, after the dynamic alignment process and testing was completed, are shown in Table 13. The results show the position of the static markers at the hip, knee and foot, in relation to the

laser line on the Bench Alignment Apparatus. The dynamic alignment changes made to each prosthesis are highlighted in green, the colour coding of the measurements indicates the type of adjustments carried out.

Table 13: Dynamic Alignment Measurements

	Socket flexion angle (degrees)	Hip (mm)	Knee (mm)	Mid-foot (mm)	Heel Height (mm)
P1					
TEST A	**18**	**0**	**-5**	**+30**	**15**
TEST B	**20**	**0**	**0**	**+30**	**15**
TEST C	**30**	**-5**	**-10**	**+30**	**15**
P2					
TEST A	**4**	**+3**	**+11**	**+30**	**13**
TEST B	**19**	**+2**	**+5**	**+30**	**13**
TEST C	**23**	**-81**	**+9**	**+30**	**13**
P3					
TEST A	**3**	**+7**	**-8**	**+30**	**10**
TEST B	**22**	**-24**	**-10**	**+30**	**10**
TEST C	**32**	**-28**	**-15**	**+30**	**10**
P4					
TEST A	**6**	**-19**	**-5**	**+35**	**10**
TEST B	**20**	**0**	**0**	**+35**	**10**
TEST C	**32**	**-18**	**-10**	**+35**	**10**
P5					
TEST A	**7**	**0**	**-18**	**+40**	**15**
TEST B	**23**	**-15**	**-5**	**+40**	**15**
TEST C	**30**	**0**	**0**	**+40**	**15**
+ Denotes marker ahead of the laser reference line					
- Denotes marker behind the laser reference line					
Socket flexion increased **Socket flexion decreased**		**Change from plantar-flexion adjustment**		**Change from combination of shift and dorsiflexion**	

During dynamic alignment, no adjustments were made to the actual flexion angle at the socket in relation to the knee joint. Rotation adjustments of the foot and knee joint were carried out where necessary and anterior-posterior shift of the knee joint and plantar-flexion and dorsi-flexion adjustments of the foot were made, through clinical observation and participant feedback. This resulted in an effective change to the initial socket flexion angle. The amount of adjustment varied among participants as can be seen from the differences between the bench and dynamic alignment measurements in Tables 12 and 13.

The position of the foot in the alignment jig remained constant for all tests at the recommended position for the individual prosthetic foot type (Appendix T). From Table 13, Participants 1 and 4 had small adjustments to the plantar-flexion angle of the foot during dynamic alignment in Test C. Participants 3 and 5 also had plantar-flexion adjustments carried out which resulted in a small increase in the angle of socket flexion. The largest dynamic alignment adjustments were conducted on Participant 2, with anterior slide of the knee joint and dorsi-flexion of the foot resulting in a decrease in the socket flexion angle in both Tests B and C. No changes were made to the alignment for Participant 1 in Test B, Participant 4 in Test B and Participant 5 in Test C.

During dynamic alignment the position of the centre of pressure of the GRF, in relation to the static markers for each alignment configuration, was measured using the L.A.S.A.R. Posture (136). The results are based on the recommendations of the component manufacturers for the hip, knee and foot position on the L.A.S.A.R. Posture (Appendix P).

These results are documented in Table 14. The individual measurements at hip, knee and foot are colour coded. Green denotes an optimum position of the markers in relation to the laser line of the L.A.S.A.R. Posture, purple results denote an acceptable position (within a range of 10-15mm to the optimum) and the red results indicate the marker position is outside the recommended position. The overall alignment configurations are colour coded, green as optimum, orange as acceptable and blue as out of the recommended range. These comparisons are based on the manufacturer's recommendations for use of the L.A.S.A.R. Posture and guidelines for the set-up of prosthetic components (8, 85, 136, 155) (Appendix P).

A positive (+) measurement indicates the marker was positioned ahead of the projected alignment line and a negative (-) measurement indicates the marker was positioned behind the projected alignment line.

The fitting guidelines provided by the manufacturer for each of the components provide the recommended range (Appendix P) for static alignment with the L.A.S.A.R. Posture, shown in columns 2-4 of Table 14. The weight-bearing static alignment configurations, closest to the optimum for each participant, are highlighted in Table 14. The results show for Participant 1, none of the alignment configurations were within the recommended range for static alignment. Participant 2 had an acceptable weight-bearing static alignment in L.A.S.A.R. Posture A (original alignment) and Participant 3 in L.A.S.A.R. Posture B (initial socket flexion 20°). Participants 4 and 5 had a good weight-bearing static alignment positions on the L.A.S.A.R. Posture, according to the recommendations, in Test B (initial socket flexion 20°).

Table 14: L.A.S.A.R. Posture measurements of weight-bearing static alignment

Recommended values (Appendix P)			+10 to -30 (mm)	-30 to -40 (mm) (Depending on knee joint type)	-45 to -65 (mm) (Depending on the foot size and type)
+ Denotes marker ahead of the laser reference line					
- Denotes marker behind the laser reference line					
Good			Acceptable		out of range
Participant/ Test/ Socket flexion angle	**Weight-bearing position**	**Weight (kg)**	**Hip (mm)**	**Knee (mm)**	**Foot (mm)**
P1					
Test A	Both feet	81.5	**+23**	**-6**	**-40**
18°	Prosthesis	34.5	**+22**	**-2**	**-39**
Test B	Both feet	81.5	**+44**	**-6**	**-29**
20°	Prosthesis	37	**+40**	**-8**	**-40**
Test C	Both feet	81.5	**+26**	**-32**	**-69**
30°	Prosthesis	32	**0**	**-58**	**-89**
P2					
Test A	Both feet	68.5	**-30**	**-17**	**-47**
4°	Prosthesis	33.5	**-37**	**-31**	**-61**
Test B	Both feet	68.5	**-26**	**-35**	**-81**
19°	Prosthesis	33	**-3**	**-15**	**-76**
Test C	Both feet	68.5	**-60**	**+18**	**-28**
23°	Prosthesis	30	**-97**	**-29**	**-76**
P3					
Test A	Both feet	73	**+5**	**-2**	**-23**
3°	Prosthesis	35	**+8**	**-12**	**-35**
Test B	Both feet	73	**0**	**-15**	**-43**
22°	Prosthesis	30	**0**	**-26**	**-38**
Test C	Both feet	73	**-2**	**-14**	**-44**
32°	Prosthesis	28	**-37**	**-56**	**-83**

Participant/ Test/ Socket flexion angle	Weight-bearing position	Weight (kg)	Hip (mm)	Knee (mm)	Foot (mm)
P4					
Test A	Both feet	71.5	**0**	**+3**	**-25**
6°	Prosthesis	28	**-28**	**-30**	**-64**
Test B	Both feet	71.5	**-8**	**-12**	**-36**
20°	Prosthesis	28	**-19**	**-32**	**-64**
Test C	Both feet	71.5	**0**	**-10**	**-47**
30°	Prosthesis	28	**-21**	**-36**	**-69**
P5					
Test A	Both feet	90	**+19**	**-4**	**-4**
7°	Prosthesis	47.5	**+22**	**-23**	**-27**
Test B	Both feet	90	**0**	**-18**	**-41**
23°	Prosthesis	46	**0**	**-29**	**-60**
Test C	Both feet	90	**+8**	**-12**	**-45**
30°	Prosthesis	45	**0**	**-21**	**-56**
+ Denotes marker ahead of the laser reference line					
- Denotes marker behind the laser reference line					
Good			**Acceptable**		**out of range**

Each participant was measured in standing, with both feet on the force plate and with only the prosthesis on the force plate and the contralateral limb on a height block. The total body weight and the weight borne through the prosthesis only for each test are shown in Table 14. All of these measurements compare the effect of posture on the standing balance of a trans-femoral prosthesis user and are used to assess the concept of the ‘theory of integrated balance’ (21). This theory recommends the difference between these two measurements should be within 10mm for an optimally aligned prosthesis. From the results in Table 14, a difference of less than 10mm between these

two measurements does not equate to an optimum static alignment, where a prosthesis is not optimally aligned in the first instance.

4.6 POWER CALCULATION

In order to determine from this pilot study the number of participants required for a fully powered study, a power calculation was carried out, using a One Factor Repeated Measures ANOVA design.

Making use of estimates of between and within angle variation it was estimated that at the 5% level of significance, a Power of 80% would be achievable if a sample of 17 was used for the L-Test and a sample of 23 was used for the FSST (nQuery v7 software, Statistical Solutions Ltd., Ireland,). From these results, a fully powered study with 25 subjects would be required to detect differences that may exist.

CHAPTER 5

DISCUSSION

The purpose of this pilot study was to assess the effects of alignment on the balance and confidence of a trans-femoral lower limb absent population. The primary objectives were to verify the methodology for use with this population and calculate the number of participants required for a larger study.

The tests used in the study are validated for use in this population (30, 31, 37, 48, 49, 59, 71, 92, 100, 109, 110, 156) and the equipment is widely accepted as routinely used in clinical situations (8, 15, 18, 21, 22, 85, 125).

5.1 DEMOGRAPHICS

The demographics of this sample show a young, moderately active group of trans-femoral prosthesis users (Table 6). The range of time since amputation surgery varied from a relatively new prosthesis user to two experienced prosthesis users, wearing a prosthesis for more than 20 years. There appears to be no link between length of time since amputation surgery and the level of balance confidence, as the participant with the longest time since amputation scored lowest in the baseline ABC (Figure 5).

There does not appear to be a link between length of the residual limb (Table 6) and the balance and confidence scores for this sample. Participant 1 had the shortest residual limb of 110mm and scored lowest in the baseline ABC with 77, Participant 2

had the longest residual limb of 350mm and had the second lowest ABC score of 80 (Figure 5).

A lower limb absent population is diverse; hence, a specific group of non-vascular, moderately active trans-femoral prosthesis users was selected from a lower limb absent population for this pilot study (Table 6). The range of prosthetic components and suspension methods in Table 7 is evidence of this variability, even within a specific group. It reinforces the individual nature of each prosthesis and the set-up of the component parts. Although prosthetic componentry was not the focus of this study and the components for each participant remained the same, the effect of the different characteristics of the prosthetic knees and feet must be considered, as they may have influenced the ability of the user to perform the tests. There is a description of the individual components in Appendix T.

5.2 ABC SCALE

The ABC Scale (48) has been used to assess the balance and confidence of a lower limb absent population and the results of studies compared to the elderly non-amputee population. Myers et al (49, 94) (Appendix D) have shown that scores on the ABC Scale of 50-80 represent a moderate level of functioning elderly adults in homecare, with chronic health issues, who may benefit from interventions. Scores of over 80 represent an independent and fit group of elderly adults. From the results of this study, all but one of the participants scored 80 or over in the baseline ABC Scale (Figure 5).

The ABC Questionnaire was completed by the participants as a reflection of their perceived balance and confidence with their current prosthesis and provides a baseline

to gauge the level of balance and confidence in this group. Analysis of the 16 questions associated with the ABC Questionnaire (Appendix L) revealed all five participants felt 100% confident to walk around their house, sweep the floor and walk to a car in the driveway. The most challenging activity was walking on an icy pathway, with three participants recording they were less than 50% confident. These observations concur with the results from a previous study of a lower limb absent population (37) (Appendix D).

The reason for such high scoring in this group may be due to the activity level of these participants, who were classified according to the MOBIS® Scale (143) (Appendix F). The inclusion criteria (Table 5) specified only participants classified as restricted outdoor walkers (MOBIS® 2) or unrestricted outdoor walkers (MOBIS® 3) would be eligible to take part in the study. Only Participant 1 was classified as MOBIS® 2 (Table 6) and reported using a crutch for outdoor walking (Table 7). Participant 1 also had the lowest ABC score, which may indicate the ABC Scale, can discriminate between mobility levels.

The ABC scores are discussed with consideration of the demographics of each participant and the Bench Alignment Apparatus and L.A.S.A.R. Posture measurements of the original alignments configurations (Test A). These measurements reflect the biomechanical set-up of their current prosthesis, which had been worn every day for more than one year, and the ABC Questionnaire responses were based on this situation.

The L.A.S.A.R. Posture results for Test A (Table 14) represent the position of the markers in relation to the projected centre of pressure of the GRF line. The participants were assessed with prosthesis only on the force sensor platform and both feet on force sensor platform, to test the 'theory of integrated balance' (21). The 'theory of integrated balance' was introduced by Breakey (21) in 1998 and used the L.A.S.A.R. Posture to assess the standing or static alignment of 115 trans-tibial and 42 trans-femoral prosthesis users. He determined that the use of compensatory movements were an expected trait when wearing a prosthesis. The degree of compensation required to adjust to wearing a prosthesis is dependent on the individual range of joint motion, muscle power and control. He suggested using the L.A.S.A.R. Posture to assess the GRF or load line of the user, with only the prosthetic limb on the force sensor platform (Limb Load Line) and with both feet on the force sensor platform (Total Weight Line). The closer these two lines become or the narrower the 'zone of integrated balance', the more integrated the balance of the prosthesis user. He recommended a zone of 10mm, in either direction, indicated reduced compensatory movements and a balanced alignment (21).

Generally, in clinical practice, the L.A.S.A.R. Posture is used to 'optimise' prosthetic alignment in relation to the projected GRF line. As the methodology of this study prevented actual flexion and extension adjustments of the socket, the goal was not to use the L.A.S.A.R. Posture to optimise the alignment of the prosthesis but to assess the effect of different socket flexion angles on the static alignment of the prosthesis user. The L.A.S.A.R. Posture device is described in Appendix P.

5.2.1 ABC AND L.A.S.A.R. POSTURE

5.2.1.1 Participant 1

Participant 1 had the lowest ABC score of the group and exhibited the most unstable static alignment according to the L.A.S.A.R. Posture Test A results (Table 14). Participant 1 measured 190cm in height and had a residual limb length of 110mm, resulting in a long prosthesis to control with a short residual limb (Table 6). The suspension system was suction and a good fitting suction socket should enhance control of the prosthesis. Participant 1 had a range of hip flexion motion of 102° and a Thomas Test measurement of 8° (Table 8). From Table 9, Participant 1 had an original socket flexion angle of 18°, indicating this prosthesis may have been aligned with excessive socket flexion. The Bench Alignment Apparatus measurements (Table 13) show the prosthetic knee joint was aligned slightly behind the laser line with the hip and foot markers within bench alignment recommendations. The L.A.S.A.R. Posture results indicate Participant 1 tried to extend his residual limb, to compensate for the excessive flexion, producing a dorsiflexion moment at the foot, moving the GRF posterior and reducing the stability at the knee joint.

All measurements were within the 'zone of integrated balance' as defined by Breakey (21), indicating the participant did not change his pattern of trying to extend the socket when using his contralateral limb for more support. Participant 1 also used a crutch for outdoor walking (Table 7) indicating he was not fully confident to walk unaided with his prosthesis. A combination of these factors is reflected in his ABC score of 77.

5.2.1.2 Participant 2

Participant 2 had a high score on the ABC Scale and had the closest to optimum static alignment on the L.A.S.A.R. Posture Test A (Table 14). She had a Thomas Test measurement of 0° indicating no hip flexion contracture and had a full range of hip flexion motion, the original socket flexion angle measured 4° (Table 9) which was within the accepted recommendations (10, 40).

Participant 2 had the longest residual limb and a well-suspended socket with a valve and Seal-in Liner® (Ossur). These factors would indicate Participant 2 should have been able to control the prosthesis due to the long lever arm and minimal socket movement. None of the measurements were within the 'zone of integrated balance' perhaps indicating decreased loading of the prosthetic limb with both feet on the force plate, moving the GRF posterior, as there was less pressure on the prosthetic foot (1C30). This resulted in a slightly less stable knee joint (C-Leg®) and moved the GRF closer to the hip marker. It appears she was not exerting a stabilising extensor moment at the hip in standing but allowing the residual limb to remain slightly flexed and extending the trunk by increasing her lumbar lordosis. This acceptable alignment configuration and use of a MPK joint are reflected in the high score of 80 on the ABC Scale.

5.2.1.3 Participant 3

Participant 3 had the highest ABC score of the group and the L.A.S.A.R. Posture Test A results (Table 14) show a stable position of the prosthetic knee joint (C-Leg®). Participant 3 had limited range of motion at the hip joint, a flexion contracture of 18° (Table 8) and the original angle of socket flexion measured in the prosthesis was 3°

(Table 9). This may explain the position of the hip and knee markers, as he must increase his lumbar lordosis to accommodate for the insufficient socket flexion angle, shifting the load line posterior and effectively producing a less stable alignment. Due to the limitation in hip motion, he was unable to maintain the extended position of the socket, resulting in an unstable anterior position of the knee and foot. All measurements were close to the 'zone of integrated balance' at 12mm and the compensatory movements remained consistent with both feet on the force plate.

Participant 3 is well adapted to the limitations in hip motion, which he has had for many years and he did not have a normal gait pattern for many years before the amputation. He has learned to adapt using compensatory movements to this alignment set-up and has expressed preference to having a more extended socket as he felt a more flexed initial set-up limited his stride length. The increased stability of the MPK joint (C Leg®) may also contribute to his ability to function in a slightly unstable biomechanical position and perhaps these are reasons for the high ABC score of 96 (Figure 5).

5.2.1.4 Participant 4

Participant 4 also scored highly in the ABC Questionnaire (Figure 5). From the results of L.A.S.A.R. Posture Test A (Table 14), he had a stable knee position in line with the recommendations for the knee joint (3R60) (Appendix T) and an acceptable foot position. From Table 8, Participant 4 has the least range of motion, only reaching 55° of flexion and had a fixed flexion contracture of 14° at the hip joint. The original angle of socket flexion measured in this prosthesis was 6° (Table 9) and this may explain the posterior position of the hip marker in standing in Test A. He is unable to extend his

hip to accommodate for the insufficient flexion set in the socket. Therefore, he increased his lumbar lordosis to accommodate for the fixed flexion contracture of his hip, effectively extending the socket and moving the GRF ahead of the hip and knee stabilising the system.

None of the measurements fell within the 'zone of integrated balance' on his current prosthesis (Table 14). With both feet on the force sensor platform his hip was flexed, lumbar lordosis reduced and the GRF passed through the hip marker and posterior to the prosthetic knee joint (3R60) (Appendix T). This concurs with the above analysis demonstrating the compensatory movements employed to accommodate for too little flexion in the socket. This also highlights the pattern of reliance on the contralateral limb for stability in standing and reinforces the concept of the 'theory of integrated balance' (21) to assess the static weight bearing position. Participant 4 had an ABC score of 93 (Figure 5) which infers he was confident to use this set-up, reflecting the relative stability of the alignment achieved by his compensatory movements.

5.2.1.5 Participant 5

Participant 5 scored high on the ABC Scale and the L.A.S.A.R. Posture Test A results show a stable, posterior position of his knee joint (3R60) in standing. Participant 5 had a flexion contracture at the hip joint of 17° and the flexion angle measured in the original set-up of his prosthesis was 7° (Table 9). This would explain the position of the hip and knee markers as he increased his lumbar lordosis to accommodate for the extended angle of the socket, shifting the load line posteriorly. Similar to Participant 3, this participant expressed a preference for this alignment configuration as he felt more energy was required to walk with an increased initial angle of socket flexion, this could

be attributed to the habit of many years of walking with an abnormal gait pattern before amputation.

Only the hip measures were within the 'zone of integrated balance', his position with both feet on the force sensor platform shows he had more of a forward trunk lean to accommodate for the tightness in the hip flexors. This resulted in decreased stability at the knee and increased loading of the contra-lateral limb, to allow the natural position of the hip to be assumed. This alignment configuration did not appear to affect perceived balance and confidence for this participant with an ABC score of 87, possibly due to the fact he was relatively stable using the compensations he had adopted.

It appears from the ABC scores (Figure 5) and analysis of the static alignment of their everyday prosthesis, that prosthetic alignment is only one factor influencing perceived balance and confidence. It does appear that if the prosthesis user can adapt to the alignment configuration and stabilise their hip and prosthetic knee joint, they can maintain their balance and confidence in walking and activities of daily living. However, the long-term effects of using compensatory movements to adapt to prosthetic alignment configurations are unknown; physiotherapy and gait re-training may assist in this reducing these compensations with an optimally aligned prosthesis. The 'theory of integrated balance' may indicate the presence of compensatory movements in a less than optimal alignment configuration. It also may indicate a lack of confidence in the prosthesis if there is a tendency for the prosthesis user to increase the weight borne through the contralateral limb with both feet on the plate. This may result in a greater difference between the two measurements, as with the prosthesis

only on the force sensor platform the prosthesis user is actively encouraged to bear at least 35% of body weight through the prosthesis.

5.3 HIP RANGE OF MOTION

The results of the Thomas Test measurements and range of flexion motion show a range of measurements within the group (Table 8). Participant 2 had no hip flexion contracture and measured closest to normal range of motion into flexion. Participant 1 had a good range of movement into flexion but his residual limb was limited into extension with a flexion contracture of 8°. Participant 1 had the shortest residual limb of 110mm and had been a prosthesis user for 26 years (Table 6). Therefore, these results would not be unexpected, as the mechanics of maintaining a full range of hip motion over a long period of time following amputation is challenging, as the hip extensors are shortened and cannot function to optimum, especially in a short residual limb.

Participant 3 and 5 had Thomas Test measurements of 18° and 17°, respectively, due to complications pre-surgery. Participant 3 also had limitation in movement into flexion of his affected hip but Participant 5 had close to a normal maximum flexion. Both had amputations secondary to tumour (Table 6) and a failed endo-prosthesis following excision of an osteo-sarcoma resulted in a many years of walking with a flexed hip and knee before amputation. This may have contributed to the flexion contracture measured at their hip joints.

Participant 4 also presented with a reduced range of motion in his affected hip (Table 8) with only 41° of overall hip movement. Participant 4 had his amputation due to a traumatic injury, 25 years ago, (Table 6) and has significant soft tissue scarring that

affects the movement of his residual limb and limits the methods of suspension (Table 7) of the prosthesis.

It is unlikely these results are reflective of a wider non-vascular, trans-femoral population but this area has not been widely studied and there is little published data to compare these findings. The small sample allowed a full assessment of the history of the participants and this provides valid explanations for these anomalous findings. Although this appears to be a less than average sample of non-vascular active prosthesis users, the Thomas Test results in combination with the nature of this study investigating the effect of alignment, serve to make this a more valid topic.

5.4 BENCH AND DYNAMIC ALIGNMENT

It is important to discuss the analysis of the bench and dynamic alignments in conjunction with the results of the timed tests. Each prosthesis was bench aligned for Test B and C (Table 12); these were all standard bench alignment configurations except in Test C for Participant 2. It was not possible to set the socket at 30° initial flexion and position the laser reference line through the hip joint marker and maintain the other components in the correct alignment; therefore, the bench alignment was accepted. From the results in Tables 13 and 14, there were a number of changes carried out to the alignment of the prostheses during the dynamic alignment process. It is the dynamic alignment and the effects on the participants that are reflected in the results of the L-Tests and FSST.

5.4.1 L-TESTS

The L-Test was instructed as a self-selected walking speed test of 20 metres (Appendix M). As may be expected from the results of the ABC for this sample, the results of the L-Tests (Table 10) were higher than in previous studies for a lower limb absent population (43, 100).

5.4.1.1 Participant 1

Participant 1 performed his best time in L-Test B (20° initial socket flexion angle). The results of the L.A.S.A.R. Posture measurements (Table 14) for Test A show that Participant 1 had a relatively unstable static alignment configuration with the original alignment (socket flexion angle 18°) with the GRF passing slightly behind the hip joint and only slightly ahead of the knee joint. The initial angle of socket flexion was adjusted to 20° and the prosthesis bench aligned (Table 12), no changes were made at the dynamic alignment stage in Test B (Table 13). The corresponding measurements on the L.A.S.A.R. Posture show the knee was slightly more posterior, the foot measurements were almost identical to Test A but the GRF had moved further behind the hip marker compared with the Test A configuration. The knee joint was in a more stable position but was less than the recommended distance (40mm) posterior to the GRF (Appendix T). The L-Test results in Table 10 reflect this, with an improvement of more than two seconds from L-Test A to L-Test B.

The L-Test C was slower than L-Test B but slightly quicker than in L-Test A (Figure 8). A small adjustment to the plantar-flexion angle of the foot was carried out during dynamic alignment in Test C, which resulted in posterior movement of the knee, by 5mm and effective 2° increase in flexion of the socket measured on the Bench

Alignment Apparatus (Table 13). The L.A.S.A.R Posture results for Test C (Table 14) show the GRF line passing through the hip marker, the knee joint (3R80) was excessively stable at 58mm posterior to the GRF and the foot position was more posterior than for the other alignment configurations. These results would indicate that this was the most stable alignment, from the position of the knee and hip, but the increased angle of flexion in the socket increased the compensations required to function with this set-up.

The increased stability at the knee may explain the slight improvement in the L-Test C to L-Test A but the increased compensation and effort required are better reflected in the slower time compared with L-Test B. None of the measurements in Test C were within the 'zone of integrated balance' indicating this alignment configuration increased the compensation movements required.

5.4.1.2 Participant 2

From Table 10, Participant 2 produced the best time for their individual L-Test with the original alignment configuration (Test A). The original socket flexion angle (4°) was close to the recommended socket angle alignment protocols (10, 19, 40). The alignment set-up measured on the Bench Alignment Apparatus in Table 13, show the hip marker is slightly ahead of the laser line and the knee joint centre is 11mm anterior to the laser line. The results from the L.A.S.A.R. Posture Test A (Table 14) show the GRF ahead of the hip marker, the knee joint (C Leg®) was optimally aligned according to manufacturer's guidelines (Appendix T) at 31mm behind the GRF and the foot was a little posterior, suggesting the alignment configuration in Test A was close to optimal alignment. This is reflected in the results for L-Test A.

In Test B (initial socket flexion angle 20°), the foot was dorsi-flexed during dynamic alignment. The resulting alignment, from the Bench Alignment Apparatus (Table 13), shows a small decrease in the flexion angle of 1° and slight anterior position of the hip and the knee joint (Table 13). This alignment may be deemed to be stable due to the characteristics of the prosthetic knee joint (C Leg®), a MPK joint, as it is acceptable to have a slight anterior position of the prosthetic knee joint centre due to the increased resistance to stance phase flexion in a MPK joint.

In order to accommodate for the excessive initial angle of socket flexion (20°) Participant 2 tried to extend the socket, moving the GRF anterior to stabilise the prosthetic knee joint, due to the flexion at the hip she had an increased anterior trunk bend and reduced lumbar lordosis. These compensations are reflected in the L-Test B score, which was almost 4 seconds slower than L-Test A.

Participant 2 had the most extensive alignment changes during dynamic alignment in Test C (30° initial socket flexion). From Table 12 and 13, the foot was dorsi-flexed and the knee joint was moved anteriorly. From the resulting alignment measurements in Table 13, the prosthetic knee joint centre was 9mm anterior to the laser line and the hip marker 81mm posterior to the laser line. These adjustments had the overall effect of decreasing the initial socket flexion angle from 30° to a socket flexion angle of 23°. From the L.A.S.A.R. Posture results, in order to accommodate for the excessive angle of socket flexion, Participant 2 had a flexed hip and increased anterior trunk lean. The GRF was anterior to the hip marker, the prosthetic knee joint slightly posterior to the GRF and the foot slightly posterior. The extensor moment exerted at the hip produced a flexor moment at the foot moving the GRF slightly ahead of the knee.

Again, these major compensations are reflected in the L-Test scores with L-Test C more than 10 seconds slower than L-Test A and almost 8 seconds slower than L-Test B (Table 7). This participant reported the most difficulties with the changes in alignment configurations and had the least amount of hip flexion contracture in the group. The difference between both feet and prosthesis only on the force plate was 7mm-14mm in Test A, which was close to the "zone of integrated balance" for each marker. In Test B and Test C the margins were much greater, increasing with the increase in angle of socket flexion. The results show these configurations were not optimal for this participant and affected the scores in the functional walking tests. Although her functionality was affected by the changes to the alignment, due to the characteristics of the C Leg® MPK knee joint (Appendix T), she was able to use the increased stance control to complete the tests.

5.4.1.3 Participant 3

Participant 3 had consistent times for each of the L-Tests (Figure 8), with a Thomas Test of 18° and an original socket flexion angle of 3°, from the L.A.S.A.R. Posture results (Table 14) the optimum alignment appears to be in Test B. The increased angle of socket flexion accommodated for the flexion contracture and reduced the forward trunk bend required with the alignment in Test A (socket flexion angle 3°). The GRF line passed through the hip marker, ahead of the prosthetic knee joint centre (C Leg®) by 26mm, close to the recommended 30mm (Appendix T) and slightly posterior to the foot (Table 13).

Comparison of the results from the Bench Alignment Apparatus (Tables 12 and 13) show Participant 3 had a plantar-flexion adjustment carried out in Test B resulting in

an increased socket flexion angle of 22°. The prosthetic knee joint marker moved posteriorly by 10mm and the hip marker moved posteriorly by 24mm, indicating a more stable alignment configuration than for Test A. It could be argued, the influence of the MPK joint (C-Leg®) in this prosthesis enabled Participant 3 to perform consistently in the tests, despite the position of the prosthetic knee joint. The alignment measurements on the L.A.S.A.R. Posture (Table 14), with both feet and single prosthetic stance on the force sensor platform, were within the "zone of integrated balance" for both Test A and Test B and the L-Test times reflect this with L-Test B only one second faster than L-Test A (Table 10). Although Participant 3 did not verbally report Alignment B was a better alignment compared with the original configuration in Test A, as he felt the stride length was shorter and it was more effort to walk.

In Test C (initial socket flexion angle 30°), a plantar-flexion adjustment was carried out during dynamic alignment, resulting in a slight increase in the angle of socket flexion of 2°, a posterior shift of the prosthetic knee joint marker by 15mm and the hip marker by 28mm, resulting in a more stable alignment set-up (Table 13). In Test C the L.A.S.A.R. Posture results show the hip was flexed but the lumbar lordosis had increased, perhaps in order to extend the hip, resulting in an excessively stable position of the prosthetic knee joint. There was a much larger difference between both feet and prosthesis only standing on the force sensor platform. This may be explained by the reduced weight borne on the prosthesis from 50% in Test A to 38% in Test C (Table 14), perhaps indicating less confidence in the alignment of Test C. This is not apparent in the results of the L-Test, as L-Test C is slightly faster than L-Test A. Perhaps with a

longer period of acclimatisation to the alignment changes this participant would have verbally reported a more satisfactory outcome with Alignment B.

5.4.1.4 Participant 4

Participant 4 performed the best time in L-Test A (Socket flexion angle 6°) with the original alignment configuration (Table 10). He had a Thomas Test measurement of 14° (Table 9) but despite the extended position of the socket, the L.A.S.A.R. Posture results (Table 14) show Alignment A was stable due to the compensatory changes by the participant. No changes were made during dynamic alignment in Test B (Initial socket flexion angle 20°). In Test C (Initial socket flexion angle 30°), the alignment measurements on the Bench Alignment Apparatus (Table 13) show the foot was plantar-flexed, moving the hip marker posterior by 18mm and the prosthetic knee joint marker posterior by 10mm and increasing the flexion of the socket by 2°.

The results of the L.A.S.A.R. Posture measurements (Table 14) for Participant 4 showed none of the tests were within the "zone of integrated balance". The hip marker was consistently behind the GRF line indicating perhaps more pelvic tilt, due to the overall limitation in hip range of motion of 41° and the necessity to compensate for this. Participant 4 consistently maintained 39% of body weight in standing (Table 14) with the prosthesis only on the plate and surprisingly, there was very little difference between the L.A.S.A.R. Posture measurements for each test. Again, this may indicate the use of compensatory movement to accommodate for different alignment situations.

The prosthetic knee joint (3R60) (Appendix T) was consistently around 30mm posterior to the GRF in standing which was in line with the recommendations for this

knee joint and the foot position was also consistent. With both feet on the force sensor platform the results show all the markers were less posterior, perhaps indicating less weight going through the prosthesis in this situation. The lordotic position of the lumbar spine was present in all tests, regardless of the socket flexion, perhaps indicating a habitual lordotic posture.

Participant 4 performed the L-Test with very consistent times (Mean = 24.75, S.D. = 0.36) (Figure 8). Perhaps these results are indicative of an experienced prosthesis user (time since amputation = 25 years), with limitations in hip joint motion, who has learned to adapt well to different alignment configurations. Again, gait re-training over an extended period may allow this participant to function with a more optimal alignment and with less compensatory movements.

5.4.1.5 Participant 5

Participant 5 recorded his best time in the L-Test B (Initial socket flexion angle 20°) (Table 10). From the dynamic alignment measurements in Table 13, Participant 5 had a plantar-flexion adjustment to the foot in Test B resulting in an increased flexion angle of the socket to 23°. This was the closest configuration to the recommended alignment with a Thomas Test of 17°.

In L-Test A (socket flexion angle 7°), the measurements on the L.A.S.A.R. Posture (Table 14) show the knee was slightly posterior but close to the recommended position. The hip was slightly flexed and the hip marker was anterior to the GRF, suggesting some compensation at the pelvis for the alignment configuration and indicating too little socket flexion in Alignment A.

In Test B (socket flexion angle 23°) and C (socket flexion angle 30°), L.A.S.A.R. Posture measurements were close to the recommended measurements for the components and were both close to the "zone of integrated balance". There were no adjustments made to the prosthesis in Test C but L-Test C was 3 seconds slower than L-Test B. Despite the apparently more stable alignment conditions in Test B and C Participant 5 verbally commented the prosthetic alignment set-up in Test C required more effort and expressed a preference for the original alignment configuration in Test A.

5.4.2 FSST

5.4.2.1 Participant 1

The FSST was instructed to be completed as quickly as possible without disturbing the obstacles (Appendix L). This is perhaps a more challenging test of balance and confidence for a trans-femoral prosthesis user as they are required to step over obstacles; change direction; concentrate on the sequence and the added dimension of having to complete the task as quickly as possible, increases the difficulty.

Participant 1 had the most consistent times for the FSST (Figure 9) with only one second separating the results and the fastest time in FSST B (Socket flexion angle 20°). According to the L.A.S.A.R. Posture results (Table 14), Participant 1 had the most stable alignment configuration in Tests B but none of the angles of socket flexion in any of the tests were optimum. The excessive flexion angle in each of the alignment configurations did not appear to affect the performance of this participant. This may be explained by the ability of Participant 1 to almost fully extend his hip and move the socket to a position maintaining the stability at the prosthetic knee joint. Comparison

of the results of FSST A, L-Test A (Table 10) and the ABC scores (Figure 5) show Participant 1 had the third fastest L-Test A and FSST A but the lowest ABC score of 77, indicating perhaps his perceived balance and confidence was lower than his actual ability.

5.4.2.2 Participant 2

Participant 2 had the fastest time for their individual FSST in Test A with the recommended alignment configuration. As the flexion angle of the socket was increased the times for the FSST increased, with FSST C (initial socket flexion angle 30°) almost 11 seconds slower than FSST A (initial socket flexion angle 4°). This indicates that, as Participant 2 attempted to compensate for the excessive flexion in socket angle, she was unable to maintain stability at the prosthetic knee joint reducing her balance and confidence. Comparison of the results of FSST A, L-Test A (Table 10), and the ABC scores (Figure 5) show Participant 2 had the second fastest self-selected walking speed in L-Test A, the fourth quickest FSST A time and had a corresponding fourth highest ABC score of 80.

5.4.2.3 Participant 3

Participant 3 also performed his fastest times in FSST A (Table 10) with the original alignment configuration, despite the recommended initial angle of socket flexion being closer to the alignment of Test B (socket flexion angle 22°). There was almost no difference in the times of the FSST A and FSST B, indicating he was stable and confident with both alignment configurations. The results of the L.A.S.A.R. Posture measurements (Table 14) would indicate the prosthetic knee joint (C Leg®) was slightly less stable in Test A than in Tests B and C and that perhaps the use of a MPK

joint may have reduced the feeling of instability and increased the balance and confidence of the participant. Comparison of the results of FSST A, L-Test A (Table 10) and the ABC scores (Figure 5) show Participant 3 had the best scores of the sample for L-Test A and FSST A and the highest ABC score of 96. This participant also had limitation in hip joint movement and the largest measured hip flexion contracture of the sample.

5.4.2.4 Participant 4

Participant 4 adapted well to all the alignment configurations. In Test A (socket flexion 6°) he maintained stability of the prosthetic knee joint through compensatory pelvic tilt to accommodate for the insufficient flexion in the socket. These compensatory movements were reduced in Test B (Socket flexion angle 20°) and C (Socket flexion angle 32°) as the socket flexion angle was increased. Perhaps this is reflected in the improved times for FSST B and FSST C. Participant 4 recorded the fastest time for the FSST in Test C but he had difficulty clearing the sticks, perhaps due to his reduced range of hip movement. The test was repeated four times rather than only twice and this may have resulted in a better final time for this test.

Comparison of the results of the FSST A, the L-Test A (Table 10) and the ABC scores (Figure 5) show, Participant 4 had the second highest ABC score of 93 and the slowest time in FSST A. This suggests a high, perceived balance and confidence but the test results indicate this may not be the case, when faced with a difficult challenge.

5.4.2.5 Participant 5

Participant 5 had his fastest FSST time in Test A with the original alignment configuration but his times were consistent for all of the tests (Figure 9). There was a small difference between FSST A and B and less than 2 seconds separating all three test times (Table 10). These results indicate the ability of Participant 5 to compensate for the insufficient flexion in the original alignment configuration and maintain stability at the prosthetic knee joint. Test B with a socket flexion angle of 22° appears from the L.A.S.A.R. Posture measurements to be the optimum set-up for this participant with the knee in a more stable position and requiring less compensatory movements. Comparison of the results of FSST A, L-Test A (Table 10) and the ABC scores (Figure 5) show Participant 5 had the fourth slowest self-selected walking speed and appears to have a naturally deliberate pace of walking but he scored the second fastest time in the FSST A and the third highest ABC score of 87.

According to the literature (109, 110), the most efficient method of completing the FSST is facing forwards and side-stepping, Participants 2 and 4 chose to complete the FSST by pivoting or turning which may have contributed to the slower mean times for these participants (Figure 9).

5.5 FURTHER DISCUSSION

This pilot study was designed to assess the effect of prosthetic alignment on balance and confidence in a sample of healthy, active trans-femoral prosthesis users within a clinical environment. The results show that even with significant changes in the initial angle of flexion of the prosthetic socket, the participants were still able to function to a relatively high degree, as the times of the tests were not significantly different.

These findings concur with previous research. Geil (9) showed that small differences in alignment did not significantly affect the gait pattern of one experienced trans-femoral prosthesis user. The study also found that the alignments perceived as optimal, by the prosthesis user and a number of practitioners who aligned the prosthesis, were not significantly different in gait analysis. The differences between the alignment configurations were not specified in the published study, therefore it is not possible to quantify what is considered a small difference, nor can the results be compared with the measurements in this study.

Zahedi et al (11) found similar results with a number of prosthesis users and practitioners accepting a range of alignments as optimal. The results of the present study concur with these findings, as all the participants expressed a preference for their original alignment configuration (Test A), despite only Participant 2 having an optimum alignment, according to the measurements. The effect of alignment change on various parameters of trans-femoral gait and energy expenditure has been investigated. The results have shown that certain alignment changes, such as anterior-posterior shift of the knee joint can affect the gait pattern and increase energy expenditure (15, 22).

Yang et al (16) also studied the effect of changing the alignment of a trans-femoral prosthesis. They concluded that the prosthesis user only endeavoured to compensate for a combination of changes in alignment of the prosthetic foot and socket angle, by altering the movement of the prosthetic thigh. The results in this study appear to confirm this, where altering the angle of the prosthetic thigh by changing the socket flexion angle and subsequent bench and dynamic alignment changes, induced

compensation movements by all participants. It appears that optimum prosthetic alignment can be measured, but the influence of the human factor of both prosthesis user and clinician will influence the outcome. Perhaps this reinforces the necessity for clear guidelines and protocols for bench and dynamic alignment, to establish a standard starting point that can be repeated for each alignment configuration.

This pilot study investigated the influence of bench and dynamic alignment. Each prosthesis was bench aligned, according to the component specifications, for each initial socket flexion angle, which according to previous research should result in a stable prosthetic set-up at initial fitting (10). The initial angles of socket flexion, for Test B and C, in this study were not based on any anatomical or clinical measurements, such as hip range of motion and muscle power but were randomly chosen in order to assess their effect on the user and to measure the changes from bench alignment to dynamic alignment.

The assessment of hip range of motion in the design and alignment of a trans-femoral prosthesis has not been extensively researched. According to the literature, the hip extensor muscles assist in stabilising the prosthetic knee joint by creating a moment to keep the knee extended during stance (10, 14, 40). This is of utmost importance to the trans-femoral prosthesis user as instability in stance phase can result in the knee buckling and the user may stumble or fall. The main hip extensor and only remaining extensor at the hip following amputation is gluteus maximus, it functions optimally when it is stretched or when the hip is flexed, hence initial flexion in the prosthetic socket allows positioning of the hip extensor in its most powerful position. This position of initial socket flexion can also reduce the compensatory movement of the

pelvis to accommodate for weakness in the hip extensors or tightness in the hip flexors. Radcliffe (10) recommended that the prosthetic socket should be set-up with an initial socket flexion angle of 5° and the prosthetic knee and foot aligned according to the individual characteristics. The chapter addressing trans-femoral alignment in The Atlas of Limb Prosthetics (40) recommends the initial angle of socket flexion should be based on the ability of the prosthesis user to extend their hip and Stark (19) suggested the initial socket flexion should be the hip flexion contracture measurement plus 5°.

It is worth mentioning that it is widely recognised that hip flexion contractures are more prevalent in the elderly, vascular limb absent population secondary to slower rehabilitation due to co-morbidities, weakness and prolonged sitting (157-159). Therefore, the results of hip range of motion measurements for this sample of moderately active non-vascular prosthesis users are somewhat unusual. There have been few studies of hip range of motion in trans-femoral prosthesis users and these studies (78, 80) have measured the range of extension in similar samples of trans-femoral prosthesis users rather than measuring the presence of a flexion contracture or hip flexion range which was the protocol for this study. Comparison of the results is difficult due to different approaches in measuring hip range of motion, although the recommended methods of measurement using the Thomas Test technique, a long arm goniometer and a single tester (160) were similar. Active hip movement was measured in one study (80) and resting and end-range of hip extension was measured in the other study (78), but passive range of hip movement was assessed in this study. The use of different techniques, variation in the movements and the position of the subjects and the possible errors incurred in measuring joint motion reported in the literature (133,

135, 161) present difficulties, when drawing comparisons. With three out of five participants presenting with a considerable hip flexion contractures in this study, it would not be appropriate to generalise these findings and there appears to be no data with which to make comparisons. A larger sample would perhaps have provided more information but this does not detract from the results of the study.

The results of the angles of socket flexion measured for the original alignment configuration (Table 9) show some differences when compared to the Thomas Test measures. It is generally accepted that the initial angle of socket flexion in a trans-femoral prosthesis should be the measurement of hip extension (Thomas Test) plus 5° to allow the required extension movement in gait (10, 19, 40). The results of this study show there is a discrepancy in this group when considering these guidelines. Participant 2 appeared to have an acceptable angle of socket flexion in the original alignment configuration, Participant 1 had an excessively flexed socket position and Participants 3, 4 and 5 appeared to have insufficient socket flexion angles when compared to the Thomas Test results. These alignment configurations were established using traditional techniques of clinical observation and patient feedback and had been deemed satisfactory. The prostheses were used on a daily basis for over one year by each participant with no reported issues.

These socket flexion angles can be compared with the study by Zahedi et al (11), who reported that a mean socket flexion angle of 1° was found across all the test trans-femoral alignment configurations deemed acceptable by user and clinician. There is no accompanying information on hip range of motion of the subjects and no study appears

to address the relationship between hip movement and socket flexion angle on prosthetic alignment.

All of these recommendations complicate the process of alignment. The result of compensatory adjustments, such as shift of the knee joint and flexion and extension of the socket and foot, can produce what appears to be an acceptable alignment set-up. This was the case in the original alignments of three of the prostheses in this study, where the angle of socket flexion in the original alignment was less than would be expected from the measurements of the range of motion at the hip.

The results of this are clearly shown from comparison of the bench and dynamic alignment measurements in this study (Tables 12 and 13). For Participant 1, Alignment A measured on the Bench Alignment Apparatus could be considered to be bench aligned for the socket flexion angle of 18°. No changes were made to the bench alignment in Test B (initial socket flexion angle 20°) and Bench Alignment C (initial socket flexion angle 30°) was altered moving the hip and knee markers posterior to the alignment line. The corresponding measurements on the L.A.S.A.R. Posture show that none of these alignment configurations was optimum. If it is assumed that the recommended angle of socket flexion is the Thomas Test +5° (19, 40), the angle of optimum socket flexion for Participant 1 would be 13°. As the angle of socket flexion was not optimum in any of the tests, the prosthesis was set-up in a slightly unstable alignment, with the prosthetic knee joint more likely to flex. This may explain the lower ABC score for this participant, but the increase in socket flexion angle did not affect the times for the L-Test or FSST (Figures 5 and 6) for this participant, despite the unstable position of the prosthetic knee joint. The consistency of the results in the

walking tests indicates the participant's ability to accommodate for instability in the alignment set-up.

For Participant 2, the results of the dynamic alignment show the bench alignment was altered in all three tests. Assuming an initial bench alignment in Test A, with a socket flexion angle of 4°, this would have been an acceptable alignment with no flexion contracture present. The initial angles of socket flexion of 20° (Test B) and 30° (Test C) for Participant 2 were so extreme it was necessary to make adjustments during dynamic alignment. The adjustments did not optimise the alignment and the L.A.S.A.R. Posture results confirm the effect of an excessive angle of socket flexion on the position of the hip, knee and foot. The effect of the different prosthetic alignments on this participant was to increase the times in the L-Tests and the FSST's for each of the angles of flexion. This suggests the alignment of the prosthesis did have an effect on the balance and confidence of this competent prosthesis user, with an ABC score of 80 with an acceptable original alignment. This suggests the recommendations of 5°of initial socket flexion are appropriate for this user.

For Participant 3, the dynamic alignment results show that for both test situations the bench alignment was altered. If the recommended angle of socket flexion is the Thomas Test +5° (19, 40), the recommended initial angle of socket flexion for Participant 3 would be 23°. Alignment A measured a socket flexion angle of 3°, which was 20° less than the recommended set-up. The L.A.S.A.R. Posture measurements for Test A indicate compensation for a slightly unstable position of the knee joint and anterior position of the foot. The results (Tables 13 and 14) show that Alignment B was closest to optimum with a socket flexion angle of 22°. Participant 3 had consistent

times in the L-Test and the FSST (Figures 5and 6) and from the results the changes in alignment did not affect his balance and confidence. Participant 3 had the highest ABC score of 96 and used a MPK joint. Perhaps the combination of these factors allowed him to accommodate for an over-extended socket position in Test A and the change to 30° of initial socket flexion in Test C was not so excessive assuming an angle of 23° to be optimum.

For Participant 4, the dynamic alignment results show the bench alignment was altered in Test C. If the recommended angle of socket flexion is the Thomas Test +5° (19, 40), the angle of socket flexion for Participant 4 should be 19°. The results (Tables 13 and 14) show Alignment B was closest to optimum with a socket flexion angle of 20°, but the L.A.S.A.R. Posture results for this participant were consistently close to the recommended parameters, regardless of socket flexion angle. Participant 4 was consistent with the times in the L-Test (Figure 6) but improved in the FSST (Figure 9), as the socket flexion angle increased. It may be construed that the increased angle of socket flexion did improve the alignment and his balance and confidence. Participant 4 had a high ABC score of 93. Perhaps his familiarity over time with the alignment configuration in Test A allowed him to accommodate for the over-extended socket position and the test changes of initial socket flexion were not so excessive, assuming an angle of 19° to be optimum.

For Participant 5, the dynamic alignment results show that the bench alignment was altered in Test B. If the recommended angle of socket flexion is the Thomas Test +5° (19, 40), the angle of socket flexion for Participant 5 would be 22°. The L.A.S.A.R. Posture A measurements indicates compensation for a slightly unstable position of the

knee joint and anterior position of the foot due to the extended position of the socket. From the results, (Tables 13 and 14) Alignment B was closest to optimum with a socket flexion angle of 23°. Participant 5 was consistent with the times in the L-Test and FSST (Figures 5 and 6) with his best time in L-Test B and similar times in FSST A and B but the times for Test C were slower (Table 10) and show that perhaps this increase in socket flexion angle did affect his balance and confidence. Participant 5 had a high ABC score of 87 and perhaps his familiarity with the original set-up allowed him to accommodate for the insufficient flexion in the socket in Test A.

From analysis of the alignment changes made to each prosthesis (Table 13) and the recommendations (136) for optimisation of the alignment configurations (Table 14), the correct combination of socket angle and prosthetic foot and knee position are required to achieve a stable and functional prosthesis. The purpose of this study was not to optimise the alignments of these trans-femoral prostheses, but to assess the effect of the combination of adjustments and different resulting dynamic alignments on the balance and confidence of this sample.

Due to the variety of different prosthetic components available to clinicians, an understanding of the effect of these components on the biomechanics of gait is essential in order to correctly align a trans-femoral prosthesis. Many manufacturers provide general alignment information with their products but perhaps the importance of the condition of the residuum and hip movement and strength of the user has not been fully researched. The guidelines such as 3-5° of initial socket flexion (10, 14, 137) is integrated into the bench alignment procedure but is then altered during dynamic alignment, using a combination of adjustments, such as flexion or extension

of the socket and dorsi-flexion and plantar-flexion of the prosthetic foot. Perhaps the ease of changing modular prosthetic systems allows this combination of adjustments to be made without due consideration to the basic principles of alignment. This may result in an acceptable alignment for the user and practitioner but may not be the optimum alignment and may lead to increased energy expenditure; residuum pain; long term back pain; premature wear of componentry; poor gait pattern and may affect balance and confidence.

The use of the ABC to assess the effect of alignment on this group of trans-femoral prosthesis users resulted in an extremely high baseline ABC score (mean = 86.6) compared with previous research (37, 43). The mean ABC score for this group was higher than reported by Miller et al (37) for non-vascular amputees. From further comparison of the results, it is possible to conclude that health status may be a contributor to perceived ability and confidence, as Miller et al (37) reported a mean score of 86 for their study of a lower limb absent population, for those who considered themselves to be in excellent health.

These results should be taken in context, although this is a high average score for a small sample of non-vascular, moderately active, healthy trans-femoral prosthesis users with a mean age of 39 years (Table 6). It is comparable with a group of high functioning, physically active older adults, according to Myers et al (94). The ABC Scale appears to be a useful tool in assessing baseline balance and confidence in active trans-femoral prosthesis users.

The use of the walking tests used in this study was designed to assess walking ability (L-Test) and balance/confidence (FSST) and to compare with previous research findings for this specific group of trans-femoral prosthesis users. It does appear that the results can be compared with previous studies, but perhaps for assessing the effects of small changes in prosthetic alignment, these tests are not sensitive enough to detect differences in such a well-adapted small sample of prostheses users.

The L-test results in this study can be related to previous research with the overall mean times comparable to times recorded by Deathe et al (100) in a sample of non-vascular, active trans-tibial and trans-femoral prosthesis users. Deathe et al suggested that from their sample of 102 trans-tibial and trans-femoral prosthesis users, a statistically relevant change could be seen with a difference of +/- 6.2 seconds for an individual L-Test score (100). From the results of this study (Table 10) only Participant 2 (Mean = 28.33, S.D. = 5.93) had more than a six second difference between tests, with increasingly slower times as the flexion angle was increased. The reduced effect of the alignment changes on the times for the other participants may be reflective of the smaller differences between the recommended flexion angle of the socket and the test angles of socket flexion.

Previous research has shown that self-selected walking speed is affected by hip range of motion (17) and the results of this study may concur with this finding, as Participant 4 had the least range of hip motion and the second slowest L-Test time for the original alignment configuration. The influence of componentry cannot be ignored in this study, and from previous research, it appears the use of an MPK joint can increase the

gait velocity of the user (18, 24). This may account for the faster mean times in L-Test A for Participant 2 and Participant 3, who were both using a MPK joint (C-Leg®).

In comparing the results of the FSST from this study (Figure 9) to previous research, the mean times for this sample were lower than a group of primary trans-tibial prosthesis users classified as non-multiple fallers (109). The mean FSST scores, for all but Participant 2, were lower than the mean FSST scores of five experienced trans-femoral prosthesis users, in a study comparing two NMPK joints (71). Again, this perhaps shows that the large discrepancy between the angle of socket flexion and hip range of extension affected Participant 2, more than the smaller discrepancies between socket flexion angles and hip range of extension for the other participants. In this previous study (71), acclimatisation time of 14-47 days was allowed for each knee joint but the times recorded at re-testing were not significantly different. The results from this pilot study for the mean FSST (Table 10) are comparable to results obtained in studies of elderly persons classified as non-fallers with vestibular disorders and recovering from stroke (110, 151, 156). Again, this is an interesting comparison when considering the demographics of this sample.

5.6 STUDY LIMITATIONS

There are several limitations in this study, which must be taken into account when discussing the outcomes. Due to the nature of the pilot study, the sample size is small, recruiting a less specific group of trans-femoral prosthesis users, regarding level of activity and aetiology, would widen the population and perhaps yield a bigger sample. The use of such a specific group limits the generalisability of the results to a wider

population. The purpose of this study was to test the methodology and determine if the tests would be sensitive enough for a higher activity level of user or appropriate and suitable for a lower level of activity trans-femoral prosthesis.

The number of variables encountered in assessing and examining any prosthetic interventions, such as the socket design and fitting, suspension methods and componentry must be considered. The study design attempted to limit the effects of these variables for each participant, by using the same socket, suspension and components for each test. The variability of the individual must also be considered, this limitation was reduced by using within subject comparison of the results rather than between subject comparisons (22).

Each participant had one hour of adjustment time, which involved walking in the clinic training room and outdoor walking. No changes were made to the socket fit or to any of the components. Generally, in local clinical practice the prosthesis user has a 2-3 week home trial after fitting of a new prosthesis. Due to lack of evidence in relation to the detrimental effects of such alignment changes on function and balance and the temporary nature of the alignment set-up, it was considered unethical to send the participants home with a potential risk to their safety. Therefore, it was not possible to allow for a longer period of acclimatisation. This period of adjustment may be an important factor in assessing the effects of changes in prosthetic alignment. There is no consensus in the literature on the most appropriate length of time needed to adjust to changes to a prosthesis but the ability of the prosthesis user to adapt to a specific change has an influence on the outcome of measurements. English et al (111) suggested that three weeks is a minimum requirement to allow sufficient time to adapt

to a new situation, yet many previous studies have given subjects less time to adjust to component and alignment changes (15, 18, 20, 25, 69, 71, 83).

The use of the L.A.S.A.R. Posture as a scientific measurement tool has not been validated or tested for reliability. This pilot study utilised the L.A.S.A.R. Posture to assess the suitability of such a device, for use in a larger study and to evaluate previous recommendations and theories using the L.A.S.A.R. Posture. It appears this is a useful clinical tool but requires reliability testing and further investigation for future scientific research.

The Thomas Test, although well documented, has been modified and there appears to be no consensus on the correct method for measuring hip motion in trans-femoral prosthesis users (78, 80). A manual goniometer for measuring hip motion introduces further margin for error, although the literature shows that single tester measurement of hip motion is reliable (132, 135, 160, 161).

Bias was controlled, to an extent, by randomising the sequence of the L-Test B and C and FSST B and C. Further bias related to the order of testing may be reduced, by completely randomising the test order, rather than testing the original alignment configuration (Test A) first.

In summary, despite these limitations, the results from this pilot study have shown that the ABC Questionnaire is a useful guide to assess baseline balance and confidence in a specific group of prosthesis users. It confirms previous findings that there may be ceiling effects with higher activity levels and healthy subjects and the ABC Questionnaire may not be sensitive enough to detect changes within specific groups.

This may also be the case with the L-Test and FSST, which may produce better results across different groups rather than within such a specific group. The use of the Thomas Test with such a small group of participants produced a large range of results and should encourage future research in this area, in order to include this as an inherent part of the prosthetic assessment procedure. Further investigation into the relationship of pelvic motion and hip range of motion, should also be considered when assessing socket flexion angles.

This raises the question of the long-term effects of compensatory movements and adjustments for incorrect angles of socket flexion. There are studies in the current literature, which have assessed the prevalence of low back pain among prosthesis users (34, 90, 162-164), but perhaps further study of pelvic movement and hip motion (77-79) would be more informative to assess the effect of compensations, due to reduced hip extension in non-vascular trans-femoral prosthesis users. The measurement of motion at the pelvis, to assess the effects of initial socket flexion, would be a worthwhile addition to this study protocol.

It appears that alignment is only one factor affecting balance and confidence and in this small sample of active trans-femoral prosthesis users, the baseline ABC scores were extremely high indicating a well-adapted and confident group. Although the results did not show any statistically significant differences between the tests, there are clinically significant outcomes that may be useful in future studies in this field.

CHAPTER 6

CONCLUSIONS

The effect of alignment on the balance and confidence of trans-femoral prosthesis users is an important concept. Balance and confidence are essential factors in promoting normal walking in a lower limb absent population. Low levels of balance and confidence can affect mobility, stability and social participation. Prosthetic alignment is an inherent part of the manufacture and fitting of a prosthesis and is particularly important to the trans-femoral prosthesis user, due to the lack of active muscle control of the prosthetic knee joint. The alignment of a prosthesis is a complex series of processes involving the clinician and prosthesis user. It requires an understanding of biomechanics and gait and generally involves feedback from the prosthesis user. In order to achieve an optimum alignment the prosthetic socket, prosthetic knee and foot, and the anatomical position of the user must be considered. The correct combination of these facets should result in the optimum outcome for the prosthesis user but there is little consensus in the literature on what defines optimum alignment and the possible effects on balance and confidence in this population.

Much of the research highlights the importance of alignment but there is little detail on the measurement of prosthetic alignment or the protocols for carrying out this process. The subjective nature of the alignment procedure and the individual outcomes for each user has made developing what is best practice and defining optimum alignment

difficult to achieve. There have been advances in technology, which have enhanced and changed the approach to the process of alignment, but due the individuality of each prosthesis user, repeatability of alignment is difficult and the literature suggests this may not be an appropriate or achievable goal.

This pilot study has investigated the effect of alignment on balance and confidence in a small sample of trans-femoral prosthesis users. The narrow inclusion criteria chosen limited the variability of the prosthesis user within the sample. The participants were all healthy, moderately active, non-vascular prosthesis users who were independent ambulators and had been wearing a prosthesis for more than one year. To further control the variables, there were no changes made to the prosthetic components or the individual sockets. The balance and confidence of the participants was assessed using a validated questionnaire, walking and stepping tests, which had previously been used with a lower limb absent population. The prosthetic alignment and joint range of motion was assessed and measured using equipment that is widely used and available in everyday clinical practice. The prosthetic alignment was altered by changing the initial angle of socket flexion and aligning the prosthesis, according to standard protocols of bench and dynamic alignment. The effects of the changes to the prosthetic alignment were assessed, by comparing the performance of the participants in each of the tests.

From the results of this study, the sample presented with a high level of perceived balance and confidence. There is evidence of the ability of healthy adults to adapt to the use of a prosthesis and gain a high level of function and quality of life following limb loss. This adaptability is also apparent in the results of the walking tests, as the

changes to the alignment had no statistically significant effect on the overall performance of the participants. Perhaps this is an indication that the outcome measures used in this study were not sensitive enough to capture specific changes in such a well-adapted sample. However, although not statistically significant the alignment changes did affect the times recorded in the tests. The analysis of the alignment configurations suggest that alignment change did affect the participants and induced compensatory actions in order to accommodate for the changes.

It is possible to conclude that prosthetic alignment is only one factor that can affect balance and confidence in this population and this study has shown that controlling the variables such as socket fit, suspension and componentry can allow specific examination of this important procedure. Changes to the alignment of a trans-femoral prosthesis are difficult to quantify as the prosthesis user adapts to accommodate for these changes. From the results of this study, the relationship between the range of motion at the hip of the residual limb and the angle of socket flexion has not been verified. The measurement techniques of passive and active hip movement in a lower limb absent population need further investigation. It does appear that if the stability of the prosthetic knee and foot can be achieved, through bench and dynamic alignment, and the prosthesis user has the ability to compensate for any discrepancy in socket flexion angle, it is possible to function with a less than optimal alignment. Although, the larger the difference between the angle of maximum extension in the residual limb and the angle of socket flexion, the greater effect this appears to have on the ability of the prosthesis user. The compensation movements of the individual prosthesis user to

alignment change and the long-term effects of these conditions should also be further investigated.

The objective of this pilot study was to test the methodology and determine the number of participants required for a larger study of this nature. The results of this study indicate that a future study should include 30 participants with a wider range of mobility levels. The outcome measures used in this study may be more suited to a broader range of participants, but for a specific sample such as used in this study, tests that are more sensitive may need to be considered. The test conditions should be expanded to include the 'optimum' initial set-up of the prosthesis, according to the current alignment recommendations in the literature. Protocols to improve and clarify the measurement of hip range of motion are needed, to fully verify the relationship to the initial socket flexion angle. The order of the tests should be fully randomised to reduce bias and a learning effect, and the acclimatisation time for each dynamic alignment configuration should be extended. Measurement of the pelvis and hip motions during gait would also be a useful addition and would further clarify the actual compensation mechanisms employed by individual trans-femoral prosthesis users.

Prosthetic alignment continues to challenge the skills of practitioners in clinics every day. The highly individualised nature of designing and fitting a prosthesis, which is comfortable, stable and functional, requires expertise and experience. The effect of alignment on prosthetic components and the prosthesis user is wide-ranging and long lasting and we should strive to develop our practices to provide our patients with the optimum treatment and outcomes.

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A P P E N D I C E S

APPENDIX A

Table A: Biomechanical Studies

Author	**Purpose**	**Population**	**Design**	**Method**	**Results/ Outcomes**	**Limitations**	**SIGN**
Zahedi et al, 1986 (11)	Repeatability of alignment	10 TT, 10 TF	Comparison Study	3 Prosthetists carried out multiple alignment changes on each subject. The alignments were measured using a unique axis system and alignment jig. Dynamic alignment was carried out by standard protocols.	283 fittings. Range of alignment parameters in M/L and A/P shift and tilt for TT and TF. TF more sensitive to A/P change. Established the range of acceptable alignments. Recommendations for alignment devices. Alignment of same prosthesis by same Prosthetist not repeatable.	Fit and active sample of TT and TF amputees only. Possible errors in measurement equipment.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Geil, 2002 (9)	Variability of alignment among practitioners	1 TF	Comparison Study	5 Prosthetists of varying experience dynamically aligned 1 TF subject. Kinematic and kinetic analysis carried out on each alignment when both Prosthetist and participant were satisfied that optimum alignment had been reached.	Quantifiable differences in alignment set-up between practitioners. Small changes in velocity of gait and inter-segmental angles. Alignment configurations were quantifiably different between practitioners on analysis but results of gait analysis and temporal/spatial analysis of subject did not reflect this.	Does not identify the source of differences, i.e. specific alignment difference. Levels of experience of practitioners may cause differences in alignment techniques.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Yang et al, 1991 (16)	Influence of alignment on TF gait	4 TF	Comparison Study	Gait analysis to assess 3 alignment changes at foot, knee and socket.	The angle of the prosthetic thigh was affected by changes to the socket tilt and socket and foot adjustments but not significantly affected by foot dorsi/plantar-flexion only. The GRF or knee stability was affected in different ways by changes in alignment. Dorsi/plantar-flexion of the foot affected time to maximum extension moment, flexion and extension of the socket affected the maximum value of moment and a combination of both adjustments had a significant effect on GRF. Increase of 6 degrees in socket flexion produced significant difference in GRF.	Small sample of active TF users. Effects of different types of components. Difficulty in locating hip marker positions.	1-
Koehler et al, 2012 (68)	Effect of alignment changes on TF gait	5 TF	Comparison Study	Three alignment configurations gait analysed on treadmill walking	Preliminary findings showed increases in knee flexion torque with posterior shift of knee, decreased knee flexion torque in anterior knee shift but no change in hip torques in level walking.	Small number of fit active TF subjects. No detail on measurement procedures. Preliminary findings only.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Pinzur et al, 1995 (46)	Effect of prosthetic alignment on limb loading.	14 TT	Comparison Study	Gait analysis of variety of alignments to determine loads on both limbs	Significant differences found in stance time, GRF and dynamic loading between sound limb and TT limb. No significant difference in gait parameters with changes in alignment of 10 degrees neutral, varus, valgus, flexion and extension position of socket but dynamic loading increased on TT limb in all mal-alignments with varus and extension mal-alignment producing most change.	Fit, active sample of TT users. No description of alignment measurement errors.	1-
Fridman et al, 2003 (84)	Influence of prosthetic foot alignment on TT gait.	8 TT	Comparison Study.	Gait analysis to assess speed and kinetics of various foot rotations.	Gait speed was unaffected by changes of 18 and 36 degrees to external rotation of prosthetic foot. Optimal + 36 degrees external rotation produced significant differences between sound limb and TT limb in stance time, between optimal in asymmetry, stance time, step length and swing time. Subjects adapted to changes using hip rotation rather than contra-lateral compensations.	Small fit, active sample of TT users.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Isakov et al, 1994 (12)	Effect of alignment change on standing balance	3 TT	Comparison study	Participants used their existing prostheses and 5 alignment configurations on each subject were carried out by one Prosthetist. Testing was conducted in static standing on a force plate and total body sway, asymmetry and weight-bearing imbalance measured.	A/P forces differed significantly in all alignments. Total sway and weight bearing imbalance did not differ significantly in all alignment conditions, asymmetry was significantly higher in a valgus position. Established a common standing pattern of TT amputees. GRF higher on sound side in A/P plane in standing. M/L alignment changes least stable.	Small sample size. Fit active TT amputees only.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Chow et al, 2006 (83)	Assessment of asymmetries in TT gait with alignment changes.	7 TT	Comparison study.	Kinetic and kinematic measures assessed in 7 TT subjects. 15 parameters measured with a range of A/P shift and tilt changes to alignment of each prosthesis. Level walking and slopes and stairs walking were assessed at each acceptable alignment configuration.	Range of acceptable alignments was between 6 for one subject and 16 for another subject. The most acceptable alignment for each subject was determined by the most symmetry in the parameters measured. There was no correlation between individual alignments. There were 6 gait parameters found to be consistently the most symmetrical.	Small sample size. Active non-vascular subjects. Short adjustment time to alignment changes. Alignment changes only in A/P shift and tilt not M/L. Not all acceptable alignments assessed. No unacceptable alignments assessed.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Hannah et al, 1984 (82)	Effect of alignment change on gait symmetry.	5 TT	Comparison study.	Kinematics and hip/knee angles measured in different alignments of TT prosthesis. Symmetry indices developed at each alignment configuration.	A neutral or 'optimal' alignment configuration as established by experienced clinician resulted in the most symmetrical gait pattern in hip and knee motion. Changes to the prosthetic foot alignment resulted in the most perturbations in gait. Index selected that was sensitive to changes in TT prosthetic alignment.	Small sample size. Active TT users. No detail of measurement of alignment changes.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Friberg et al, 1984 (81)	Radiological study of leg length differences in prosthetic users.	84 TT, 29 TF.	Cohort study.	Established war veteran amputees administered with a questionnaire to assess prosthetic issues and hip, knee and back pain. Standing x-rays taken of each subject. Equalizing blocks placed under shorter limb to accommodate and pelvic position re- assessed.	Only 15% of sample had an acceptable LLD within tolerances of 10mm for TF and 5mm for TT users. In 70% of the sample the prosthesis was shorter. Maximum shortening of prosthesis was 47mm and maximum difference with prosthesis longer was 40mm. Pain generally occurred in the longer limb regardless of prosthetic side. Symptoms of hip, knee and back pain correlated with lateral asymmetry caused by LLD. Clinical assessment of leg length in amputees appears to be unreliable.	Control of posture and equal weight bearing on limbs in standing position for x-ray. Errors in measurement of x-ray films.	2-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Schmalz et al, 2002 (15)	Influence of prosthetic alignment and components on energy expenditure and biomechanics.	15 TT, 12 TF	RCT	O2 consumption and biomechanics measured on TT subjects with different prosthetic feet and alignments and TF subjects with different prosthetic knee joints and alignments.	For TT subjects, A/P shift of foot position produced slight change in GRF. Angular changes plantar/dorsi-flexion produced larger change in GRF. Neither changes affected gait speed or heart rate but oxygen consumption was significantly affected by plantar/dorsi-flexion changes. Different prosthetic feet had no effect on speed or stride length but SACH foot had significant effect on oxygen consumption at faster speeds. In TF subjects, knee position change did not significantly affect speed or stride length. Posterior knee shift increased O_2 uptake at faster speeds but anterior shift increased at all speeds. O_2 uptake reduced with a MPK at slow and medium speeds compared to NMPK. TT amputees used 25% and TF 55-60% more oxygen consumption in walking. In TT subjects, changes in foot angulations lead to more compensation at the knee and result in increased O2 uptake. Alignment changes in TF subjects affect O2 uptake significantly with NMPK due to increased hip moments.	Fit, active TF and TT subjects. Sensitivity of LASAR Posture not validated.	1-

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Boonstra et al, 1994 (17)	Gait of TF amputee.	29 non-vascular TF subjects.	Observational Study	Subjects assessed using gait analysis, self- report questionnaire and energy expenditure.	Temporal measurements showed asymmetry for all subjects and hip/knee motion was asymmetrical for most subjects. Walking speed correlated with hip range of motion and was lower than for non-amputees but energy expenditure was higher. Socket design and gait speed correlated with questionnaire results. TF subjects used more energy, walked slower and had less movement at the hip and over all asymmetry in gait compared with a non- amputee population.	Non-vascular, active TF subjects only.	3

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Hoaglund et al, 1983 (6)	Evaluation of problems and needs of veteran lower limb amputees.	179 lower limb amputees.	Cross-sectional Study	Survey questionnaire and examination of lower limb amputees to assess issues and need.	179 out 251 participants in survey. 54 participants underwent assessment in clinic. Participants divided into dysvascular and non-dysvascular groups. Parameters measured- prosthetic wear, walking with/without aid, driving, ADL, recreation and pain. Non-vascular amputees wore their prosthesis longer, walked unaided further, were more independent and participated in more recreation. Both groups had issues with socket discomfort and pain, weight of the prosthesis and increased energy expenditure also suspension and alignment. Recommendations to improve fitting and maintenance of prosthesis, control of residual limb fluctuation, better facilities and improved prosthetic techniques.	Difference in time between survey and prosthetic assessments- 23 months.	3

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Rietman et al, 2002 (116)	To determine the use and function of gait analysis in prosthetics		Review of literature	Search of literature from 1990 to 2000. Use of instrumented gait analysis in the field of prosthetics investigated and papers categorized and reviewed.	34 articles reviewed in categories of: gait strategy, influence of components parts on gait, pressure measurement gait studies, weight of prosthesis on gait, energy in gait. Many studies used fit, active non-vascular amputees and cannot be generalized to the wider amputee population or individual amputee. Small sample numbers reduced power of many studies. Gait analysis provides a tool for increasing knowledge into training and development of componentry but is most appropriate for scientific research in a laboratory, clinical observation and experience is still required.	Restriction on number of papers found due to databases. Small sample numbers in papers reviewed.	3

Author	Purpose	Population	Design	Method	Results/ Outcomes	Limitations	SIGN
Lusardi, 2001 (39)	Review of literature to assess the current practices and effects on prosthetic outcomes.		Review of Literature.		Review of new technologies and components. Good advancement of prosthetic components and socket technologies, which has led to better outcomes for the prosthesis user. Importance of the team approach to rehabilitation. Emphasizes the need for sound biomechanics and good socket fit.		3

APPENDIX B

Table B: Specific Interventions

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Van der Linde, 2004 (61)	Review of literature to determine use of different prosthetic components and function of users.		Systematic review	Search of databases from 1966 to 2001. Abstracts reviewed and categorized using 13 specific criteria. Studies classified as A, B and C level according to score from grading system.	40 studies reviewed and classified in 3 groups. No clear consensus on component prescription and use for user. Gaps in knowledge of clinicians in mechanical function and effect on users. Recommendation for integrated knowledge from research, professionals and users to form a guideline for prosthetic prescription.		1+

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Thorn-Silver et al, 2009 (69)	Assess stability of two NMPK joints.	5 TF	Comparison study.	Gait analysis of kinetic, kinematic and temporal parameters of subjects wearing two different mechanical knee joints, 3R80 and Total 2000. Questionnaire used for subjective feedback from subject.	Velocity, cadence, step length, stride length, stance and swing time and support time were measured. Subjects had faster velocity or similar velocity with Total Knee, longer stride length and increased stance duration. Total Knee had greater overall stability than 3R80 but 3R80 showed higher stability at initial contact and Total Knee had higher stability at mid/late stance.	Small sample of fit active TF users. Use of duplicate sockets in 2 cases. Different feet for each prosthesis and time to adjust and familiarity with knees tested. Error in assumptions made for inverse dynamics and the modelling of polycentric knee to single axis knee.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Boonstra et al,1996 (70)	Comparison of mechanical swing phase control knee and pneumatic swing phase control prosthetic knee joints.	28 TF	Randomized cross-over study.	Gait analysis and gait speed assessed and 2 questionnaires administered to compare effects of 4-bar mechanical swing control knee joint and pneumatic swing control knee joint.	Higher velocities of gait were achieved with the pneumatic knee; self-selected walking speed did not differ between the two knees. Swing phase symmetry was better with pneumatic knee joint. Subjects responded to questionnaires that pneumatic control knee allowed faster walking and preferred the pneumatic knee joint to the mechanical joint overall.	Non-vascular active sample. Everyday knee was mechanical swing phase knee for all subjects.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Blumentritt, 1998 (22)	Review of gait analysis of TF prosthesis users with a hydraulic knee joint and effect of sagittal plane position of knee joint.	7 TF prosthesis users.	Preliminary report.	Gait analysis of subjects at self-selected walking speed using hydraulic 3R80 knee joint. Gait analysis repeated for each subject with knee joint shifted posterior and anterior by 1-2 cm.	Gait analysis showed significant inter-subject variation in all parameters. Within subject comparison made of knee position changes. Changing prosthetic knee position did not alter the hip extension moment in individual subjects. Hip moments were only affected by sagittal changes in knee position. The highest hip moment was into flexion and found with a posterior knee position to initiate knee flexion in a very stable condition.	Small sample of fit active non-vascular TF users.	1+
Lythgo 2010 (71)	Effect of two NMPK joints on gait, function, and balance.	5 TF	Cross over study.	Subjects assessed with their own knee joint and then fitted with 3R90 and 3R92 NMPK joints. Subjects assessed using TUG, 6MWT, FSST and PEQ and gait speed and sudden stop and turn.	TUG, FSST and 6 MWT times improved with 3R92 knee joint. Compared with subject's original knee joint PEQ was similar for original and 3R92 but lower for 3R90. Gait speed was lower for 3R92 but similar for 3R90 compared with original knee joint and gait symmetry unchanged with all knee joints.	Small sample size. Ceiling effect found in measurement of sudden stop and turn in certain conditions.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Berry et al, 2009 (38)	Comparison of perceived stability, function and satisfaction of TF users with MPK and NMPK joints.	328 TF	Comparison Study	Survey of 328 TF amputees. Subjects surveyed with existing NMPK and after 6-9 months with follow-up survey of MPK. Self-administered questionnaire assessed 6 areas of prosthetic rehabilitation.	50% responded to follow-up survey. Follow-up scores were significantly higher for all survey items. These were categorised into: Socket fit, confidence, mobility, cosmesis, adverse effect of prosthesis and safety/limiting factors were perceived to be improved with MPK joint.	Questionnaire designed specifically for this study. No details on alignment procedures. Primarily non-vascular TF sample.	3
Blumentritt, 2009 (25)	Safety evaluation of Mauch NMPK joint, 3R80 NMPK and C-Leg® MPK joint, in a number of test conditions.	3 TF	Pilot comparison study.	Gait analysis measured knee moments, knee angles and hip moments in each subject during level walking, stopping, side-stepping, stepping on an obstacle and tripping. Tests and knee joints were randomized. Comparison of results for the 3 knee joints was carried out.	C-Leg® MPK joint was found to be most stable in all conditions. The Mauch hydraulic system was most unstable when negotiating an obstacle and 3R80 knee joint least stable when subjected to tripping.	Small sample size. Active non-vascular TF users. Harness used to prevent injury in testing therefore not a “real world” situation.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Hafner et al, 2007 (118)	Evaluation of function, performance and preference between MPK and NMPK.	21 TF	Controlled reversal design (a-b-a-b)	17 subjects were tested at 2 different times with a MPK and NMPK. Function and activity was assessed using AMP, SF-36 and step monitor. Performance using stair and slope descent scores and step length. Cognitive testing was measured at self-selected walking speeds and preference by self-report.	Stair and slope descent improved with MPK. Sound side step length was more symmetrical when descending slopes. Subjects preferred the MPK reported less falls and higher satisfaction.	Non-randomized testing. Reduced period of adjustment to second NMPK test. Prosthetic components not controlled. Subjects not blinded to trials. Non-validated tests SAI and HAI.	2-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Schmalz et al, 2002 (15)	Influence of prosthetic alignment and components on energy expenditure and biomechanics.	15 TT, 12 TF	RCT	O2 consumption and biomechanics measured on TT subjects with different prosthetic feet and alignments and TF subjects with different prosthetic knee joints and alignments.	For TT subjects, A/P shift of foot position produced slight change in GRF. Angular changes plantar/dorsi-flexion produced larger change in GRF. Neither changes affected gait speed or heart rate but oxygen consumption was significantly affected by plantar/dorsi-flexion changes. Different prosthetic feet had no effect on speed or stride length but SACH foot had significant effect on oxygen consumption at faster speeds. In TF subjects, knee position change did not significantly affect speed or stride length. Posterior knee shift increased O_2 uptake at faster speeds but anterior shift increased at all speeds. O_2 uptake reduced with a MPK at slow and medium speeds compared to NMPK. TT amputees used 25% and TF 55-60% more oxygen consumption in walking. In TT subjects, changes in foot angulations lead to more compensation at the knee and result in increased O2 uptake. Alignment changes in TF subjects affect O2 uptake significantly with NMPK due to increased hip moments.	Fit, active TF and TT subjects. Sensitivity of LASAR Posture not validated.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Klute et al, 2006 (62)	Effect of prosthetic components on mobility.	12 TT, 5 TF	Cross-over Study	Effect on activity using step count and duration of rigid pylon versus shock absorbing pylon and Mauch Knee and C-Leg®.	Step count and duration of activity was not changed by the 2 different pylons in the TT users and there was no differences found in the TF group between the NMPK and MPK. Activity of TT group was shown to be highest during weekdays and both groups generally performed short bursts of activities in periods of less than 15 minutes.	All TF subjects had worn Mauch Knee and all TT subjects a rigid pylon prior to study.	1-
Segal et al, 2006 (24)	Compare gait biomechanics of TF users with MPK and NMPK.	8 TF	Comparison study.	Gait analysis comparison of swing phase, flexion angle, stance knee flexion moments, step, length symmetry, velocity and GRF were assessed with C-Leg® MPK and Mauch hydraulic NMPK.	TF users with C-Leg® showed lower peak swing phase angles than Mauch Knee and similar to control, increased stance flexion moment than Mauch Knee but less than control, shorter step length and better symmetry than Mauch Knee, higher gait speed than Mauch Knee and effect of GRF was reduced with C-Leg®.	Small sample of active TF users. Only controlled walking speed measured. Prosthetic foot type not constant.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Orendurff, 2006 (23)	Assessment of effect of NMPK and MPK on Gait Efficiency	8 TF	Randomized cross-over trial.	The oxygen consumption of subjects was measured at various walking speeds and compared with each knee joint.	Self-selected walking speed was significantly higher with C-Leg® than Mauch. There was no significant change in oxygen consumption for all speeds between the 2 knees but C-Leg® showed lower mean consumption.	Small sample of active TF users. Small differences found not statistically significant. Adjustments to C-Leg® not controlled. Prosthetic foot type not constant. Results not consistent for all subjects. Not possible to generalize prescription for whole TF population.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Meier et al, 2012 (72)	Comparison of 3 knee joints over obstacle course using heart beat measure.	12 TF	Cross over	Subjected were assessed using total heart beat index and time measurement parameters completing an obstacle course. Each subject wore 3 different knees, Mauch NMPK, C-Leg® MPK and 3R60 NMPK. The course was completed with and without a mental loading challenge.	The 3R60 NMPK had the slowest times for the overall course, and different sections produced significant differences between the 3R60 NMPK and the Mauch NMPK and the 3R60 and C-Leg® MPK. Heart rate was found to be similar for all knee joints with no mental loading challenge but significantly increased for the C-Leg® MPK with the challenge.	Small sample size. Acclimatization time to each knee joint of 4 weeks may have been inadequate. Laboratory limitations of size of obstacle course. Use of the total heart beat index rather than EMG of actual heartbeat.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Seymour et al 2007 (76)	Comparison of energy expenditure with MPK and NMPK joints during walking and an obstacle course (SWOC). Assessment of QOL.	12 TF, 1KD	Comparison study	Subjects all wore C-Leg® MPK joint and were tested for oxygen consumption during level walking at 2 different speeds and kinematics and speed recorded for completion of SWOC. Tests then repeated with different NMPK joints. QOL survey (SF-36v2) completed by each subject on use of MPK joint.	Heart rate lower than previous studies. No significant differences in heart rate between knee joints. O2 consumption with MPK joint 55% higher and NMPK 67% higher than normal. Significantly lower O2 consumption, faster SWOC times and fewer steps needed with MPK joint. High QOL score compared with general population.	Only 10 subjects completed tests. Variety of different prosthesis used, not controlled. Use of a treadmill may affect results. Results may not be generalizable to wider population. MPK joint in everyday use for all participants.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Bellman et al, 2010 (18)	Gait analysis and energy consumption in a number of test conditions for 4 MPK joints.	9 TF	Comparison study	Subjects fitted with Hybrid, Adaptive 2, Rheo and C-Leg® MPK joints. Kinematics and kinetics and energy consumption recorded in level walking at different speeds measured for each knee joint. Descending ramps and stairs and stumble scenarios were used to assess fall risk.	Walking speed and energy consumption differed only at self-selected speeds between knees. Maximum knee flexion angles differed significantly between knee joints. Significant differences were found between knees in stair descent and ramps and some of the knees in contra-lateral loading in stair descent. Stumbling tests showed the C-Leg® was least likely to result in a fall at flexion angles of less than 30 degrees.	Small sample size. Results may not be generalizable to wider population. Subjects not blinded to test knees. C-Leg® original knee joint for all participants. Stumble test anticipated by participants.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Burkett et al, 2001 (74)	Assess optimal TF alignment for running.	4 TF	Case Study	Gait analysis of effects of lowering knee joint in running prosthesis.	Kinematic measurements at hip and knee in sagittal plane, pelvic movement and ankle measurements in frontal plane were recorded. Swing, stance, step and flight time were recorded and average running velocity. Knee joint placed distally 100mm-250mm on each subject and 3 test runs preformed. Compared with standard alignment optimum lowest position of knee joint reduced asymmetry in running and increased velocity.	Small sample of active TF amputees.	1-
Burkett et al, 2004 (73)	Assess effects of asymmetry on walking and running in TF users.	4 TF	Case study	Gait analysis of kinetic, kinematic and temporal values in walking and running.	Kinematic measurements at hip and knee in sagittal plane, pelvic movement and ankle measurements in frontal plane were recorded. Swing, stance, step and flight time were recorded and average velocity. All subjects showed asymmetry in normal walking but better inter-limb symmetry in walking in kinematic, kinetic and temporal measures compared with running.	Small sample of active TF amputees.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
Wong et al, 2012 (44)	Assessment of balance and falls using 2 knees in a single TF user using ABC, TUG and BBS.	1 TF	Case study.	Comparison of balance ability, balance confidence, falls, and activity in a vascular TF user with NMPK and MPK. Subject assessed with BBS, ABC and TUG.	Subject had higher BBS and ABC scores and improved TUG times with the MPK and reported less falls and higher participation in activities than with the NMPK.	Single subject sample.	3
Kahle et al, 2008 (26)	Comparison of NMPK joint and MPK joint on stairs, descent, stumbles, falls and PEQ.	19 TF	Pre post-test (A-B) design.	9 areas investigated using NMPK (everyday knee) and after 90days MPK joint. Each subject was assessed using PEQ, stumbles and falls self-reported, self-selected and fast walking speed tests on different terrains, stair descent and knee joint preference.	PEQ improved for all subjects with MPK joint. Reported falls and stumbles decreased with MPK joint. Self-selected and fast walking speeds increased over level and rough terrain with MPK joint. Stair descent was improved and overall all subjects preferred the MPK joint.	Possible rater bias, as only one tester used and not blinded. NMPK not constant for all subjects.	1-

Author	Purpose	Population	Design	Method	Results/Outcomes	Limitations	SIGN
English et al, 1995 (111)	To establish time to consistent gait after component change in a prosthesis.	1 KD	Case study.	Gait analysis carried out immediately after fitting subject with test prosthesis with 2 NMPK joints and after 1 week for 4 weeks. Preferred knee joint further tested after 13 weeks.	Settling in period noted in results of main parameters after week 1 suggesting at least 1 week needed to adapt gait to a new knee joint. Stance phase duration increased at week 3 indicating stability adjusted with 3 weeks trial and after 21 weeks no changes had occurred. Walking speed not sensitive enough to show initial changes, prosthetic stance time better indicator of gait consistency.	Single subject sample. Test prosthesis used for study.	3
Kaufman et al, 2007 (75)	Assessment of balance and gait of TF amputees with MPK and NMPK joints.	15 TF	Cross over design.	Comparison of Gait analysis, balance tested on a force plate and Sensory organisation Test (SOT) with NMPK joint and MPK joint.	Knee extensor moment was reduced with MPK joint and a more natural gait pattern was observed with MPK joint. All subjects scored highest in SOT with the MPK joint indicating improved balance.	All subjects tested with NMPK joint first. Acclimatisation time may not have been sufficient to MPK joint. The results cannot be generalised to a wider TF population.	1-

APPENDIX C

Table C: Technical measurements and equipment

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Taylor 1979 (86)	Review of current practice		Review	Review of alignment jigs and equipment available in 1978.	A number of specifically developed jigs to enhance alignment procedures were available. Some were integrated into the prosthesis, others removed after fitting procedure. Cautionary word on the importance of socket fit.	No scientific investigation of equipment. No recommendations.	3
Staats, 1981 (87)	Design of Berkley Alignment Jig.		Technical study.		Description and design of a new alignment jig for manufacture of prostheses.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Radcliffe, 1955 (57)	Review of history of alignment mechanisms.		Historical review.		Historical background and development of alignment tools and jigs available for set-up of a TF prosthesis.	Mostly historical and out-dated equipment.	3
Boone, 2009 (88)	Introduction of computer aided alignment system.		Magazine Article.		Magazine article announcing the launch of a new computerized alignment system for prostheses.	Published research in advance of scientific research publications.	4
Stark, 2003 (19)	Comments on current alignment procedures.		Conference proceedings	Description of common alignment problems in TT and TF prosthesis.	Suggestion that modern endo-skeletal components have not improved the alignment of prostheses. Other modern components have exacerbated the problem due the position of the attachments on the socket. The importance of initial socket flexion and correct rotation in TF prosthesis is emphasized.		4

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Radcliffe, 1994 (10)	Kinematics of 4- bar knee linkage joints.		Scientific paper.	Explanation and description of biomechanical principles of alignment of TF prostheses. The influences of hip muscle force, prosthetic knee position and prosthetic foot on the overall configuration of a TF prosthesis. Comparison of different bench alignment techniques.	Detailed description of the mechanics of a 4-bar linkage prosthetic knee mechanism and the advantages of the instantaneous centre of rotation to stability for a TF user. Recommendations on alignment and gait training for TF prostheses users.	Scientific paper using biomechanical analysis no defined trials of everyday use.	3
Schuch et al, 2001 (40)	Biomechanical considerations for TF prosthetics from Atlas of Limb Prosthetics.		Book section.		Description of current prosthetic theories and practices at the time of press.		4

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Stark, 2006 (89)	Assessment of techniques and socket types for trans-femoral prostheses.		Journal of proceedings.		Description of different types of TF sockets and origins of socket design. Advantages and disadvantages of modern techniques over tradition methods. Comments on the importance of correct alignment of socket in flexion and rotation.		4

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Nussbaumer et al, 2010 (125)	Assessment of validity and test re-test of use of manual goniometer in assessing hip patients.	30 adults	Comparison study	Passive range of hip motion measured using a manual goniometer and an electronic tracking system (ETS) in 2 different sessions. Sample of 15 healthy adults and 15 adults with femoro-acetabular impingement.	Goniometer measurements were higher for all hip ROM. Only hip abduction and internal rotation showed good concurrent validity. Both devices detected lower ROM in abduction for hip subjects compared to healthy subjects. Test re-test reliability was good for both devices. Differences attributed to methods of measurement, i.e. difficulty in assessing true range of motion at hip but goniometer suitable for longitudinal assessment of hip ROM.	Error in using electromagnetic instruments due to joint position markers and instrument errors. Inter-rater reliability not tested as all measurements conducted by 1 observer. Observer not blinded to goniometer results.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Holm et al, 2000 (134)	Assess reliability of goniometer measurement versus visual estimate of hip range of motion	25 adults	Comparison study	Hip ROM of 25 subjects with osteo-arthritis of hips, assessed by 4 teams on a single day and 1 week later. 3 teams took measures of hip ROM with a manual goniometer and 1 team took visual estimates of hip ROM.	Results were consistent for all teams between tests. Only hip abduction measurements showed significant differences between tests. Measurement of flexion showed the least variance and highest reproducibility. There was good agreement found between the visual estimates and goniometer measurements.	Margin of errors with manual goniometer measurements.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Bierma-Zeinstra et al, 1998 (133)	Assessment of goniometer and inclinometer reliability.	9 adults	Comparison study	Ten consecutive tests of active and passive ROM at the hip carried out on 9 subjects, simultaneously using a manual goniometer and an electronic inclinometer.	No difference in the reliability of goniometer and inclinometer in single observer measurements. Intra-observer reliability was similar for both instruments with inclinometer measurements lower for intra-observer validity in passive rotation. Goniometer measured higher rotational movements and inclinometer higher extension and flexion movements. Two instruments are not interchangeable due to the different methods and position of subjects when measuring. Single observer measurement most reliable.	Small sample size. Sample only contained adults affected by osteoarthritis.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Gaunaurd et al, 2011 (78)	TF users assessed for leg length, pelvic rotation, lateral trunk bend and hip extension.	47 TF	Comparison Observational cross-sectional study.	Subjects assessed at one time point. Tests carried out to assess limb length in standing, pelvic rotation, lateral trunk bending and hip extension.	Results showed leg length discrepancy in more than 50% of sample, pelvic rotation was increased by limb length discrepancy and was higher than previously reported in this sample. No relationship between hip extension and pelvic rotation was found.	Issues with the methods of measuring leg length and pelvic rotation.	3
Rabuffetti et al, 2005 (79)	Hip motion assessment of kinematics in amputee gait.	11 TF	Comparison study	11 TF users assessed, 3 subjects wore 2 different prostheses, and a total of 14 cases were tested. Gait analysis used to determine pelvic-thigh kinematics at heel strike.	Hip movements were less in extension and flexion compared with sound side. Pelvis was significantly more flexed at sound side heel strike and sound side step length was shorter in majority of cases. Hip extensions limited by socket constraints and pelvic tilt and step length differences attributed to compensation by user. Functional gait achieved but with compensation may lead to back pain.	Small sample size. Active non-vascular TF sample. Generalizability to wider population of TF reduced. Socket types not defined in detail.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Gailey, 2008 (90)	Review of literature to assess secondary conditions in young active amputees.		Literature review.	Literature search from 1970 to 2006. 34 articles reviewed and discussed under osteoarthritis, osteopenia, osteoporosis and back pain.	Musculoskeletal problems secondary to wearing a prosthesis long term can develop in prosthesis users. Good knowledge of these conditions and their pre disposing factors may improve rehabilitation and reduce the effects of long term prosthetic wear.		1-
Hagberg et al, 2005 (80)	Comparison of hip movement between osseo-integration and socket interface prosthesis.	63 TF	Comparison study.	Two groups from sample, 20 with osseo-integration sockets and 43 with standard prosthetic sockets. Active hip motion with and without prosthesis measured with a goniometer and self-reported discomfort in sitting recorded.	Hip motion in all directions especially flexion more than 90 degrees, was reduced for all subjects with standard prosthetic sockets. Almost half standard socket prosthesis users reported discomfort when sitting. Hip motion was unrestricted in osseo-integration socket users and less than 5% reported discomfort in sitting.	Lack of test re-test reliability measures for use with TF prosthesis users. Active non-vascular sample.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Tranberg et al, 2011 (77)	Assessment of hip movements pre and post osseo-integration.	19 TF, 57 non-amputees.	Comparison study	Gait analysis used to assess hip and pelvic motion in 19 TF users with standard socket prosthesis and follow-up 30 months after fitting with an osseo-integration prosthesis. 57 non- amputees were assessed in the same way as a control group.	Gait analysis showed that the range of hip extension increased significantly compared with standard socket prosthesis and pelvic tilt reduced. Values for osseo-integration gait analysis were closer to the control group measurements.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Blumentritt, 1997 (8)	Assessment of posture of 2 groups to determine difference in static standing using a new device (L.A.S.A.R. Posture).	18 TT, 20 non-amputees.	Comparison study	Standing posture of 18 TT users and 20 non-amputees measured using the L.A.S.A.R. Posture. The TT users were fitted with different prosthetic feet and static balance re-measured on the L.A.S.A.R. Posture device. The ground reaction force (GRF) measured in relation to shoulder, hip, knee and ankle points.	Differences found between the standing postures of non-amputees and TT users. A range of positions of GRF was shown at each joint for both groups and most significant was position of GRF in relation to the hip in the TT users where the amputee shifts the load line ahead of the hip joint. Using L.A.S.A.R. Posture alignment jig recommendations for static alignment but are dependent on foot type.	Small sample of TT users. No validation or repeatability of LASAR Posture alignment device.	1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Blumentritt, 2001 (85)	Effect of foot alignment on gait analysis and EMG studies.	13 TT	Comparison study.	Subjects assessed in 3 different alignment configurations, sagittal plane alignment, plantar-flexion and medio-lateral shift. Kinetics and kinematics of gait and EMG of thigh muscles were measured for each scenario. Static alignment measured using the LASAR Posture device.	Alignment change had little effect on the contra-lateral limb muscle function or joint motions. All alignment changes influenced the knee joint motions and loading on the prosthetic side in the stance phase but not in swing phase. Recommendation for static alignment of a TT prosthesis.	Small sample size. Active TT users. No validation or repeatability of LASAR Posture alignment device.	1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Willingham et al, 2004 (138)	Assessment of static alignment of C-Leg® users using L.A.S.A.R. Posture.	15 TF, 4 KD, 2 HD	Comparison study.	21 prosthesis users wearing a prosthesis with C-Leg® MPK joint were assessed for static alignment using the L.A.S.A.R. Posture device and observational gait analysis.	20 out of 21 prostheses measured were found to have the knee joint aligned posterior to the GRF by a range of 0-79mm, contrary to manufacturer's recommendations. Gait deviations were also observed in the majority of the sample.	Methodology inherently flawed as incorrect manufacturers guidelines used. No conclusions can be drawn from these results. No validation or repeatability of LASAR Posture alignment device. No detail of gait deviations and relation to alignment.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Breakey, 1998 (21)	Measurement of the zone of integrated balance using LASAR Posture device.	115 TT, 42 TF	Comparison study.	Subjects were assessed for static alignment using LASAR Posture device. The GRF or total load line was measured with both feet on force plate and the limb load line for the prosthesis determined by the prosthetic limb on the force plate and sound side on a height block. This was carried out before and after dynamic alignment and the difference in the GRF position noted for each load line.	The prosthesis was assumed to be optimally aligned when the difference between the total load line and the limb load line was 0-10mm. This appeared to produce the most symmetrical alignment and most preferable to the user. A 'zone of integrated balance' is suggested as a means of optimizing alignment using the LASAR Posture alignment device.	No validation or repeatability of LASAR Posture alignment device. Lack of detail of participants, prostheses and alignment changes.	1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Berme et al, 1978 (91)	Description of new socket alignment device.		Technical report.	An orthogonal set of co-ordinate axes obtained from previous studies of socket axis location and a device manufactured to locate the centre of a standard TT socket and standard TF socket. The device is fitted into the prosthetic socket fixed in a measuring jig.	Satisfactory results obtained to establish the socket reference axis to an accuracy of +/- 1 degree.	No description of measurement techniques.	3
Radcliffe, 1977 (14)	History of prosthetic alignment, socket design and fitting.		Lecture		Overview of history of the development in socket design and manufacture, prosthetic knee mechanism development and biomechanical set up of alignment. Recommendations for future progress and research in field of prosthetics.	Much of the equipment has been updated and further developed but biomechanical principles are still relevant.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Chow, 2006 (83)	Assessment of asymmetries in TT gait with alignment changes.	7 TT	Comparison study.	Kinetic and kinematic measures assessed in 7 TT subjects. 15 parameters measured with a range of A/P shift and tilt changes to alignment of each prosthesis. Level walking and slopes and stairs walking was assessed at each acceptable alignment configuration.	Range of acceptable alignments was between 6 for one subject and 16 for another subject. The most acceptable alignment for each subject was determined by the most symmetry in the parameters measured. There was no correlation between individual alignments. There were 6 gait parameters found to be consistently the most symmetrical.	Small sample size. Active non-vascular subjects. Short adjustment time to alignment changes. Alignment changes only in A/P shift and tilt not M/L. Not all acceptable alignments assessed. No unacceptable alignments assessed.	1-

APPENDIX D

Table D: Balance and confidence tests

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Condie et al, 2006 (58)	Review of outcomes measures for use in a lower limb absent population.		Literature Review	Review of literature from 1995-2005. 340 articles identified and 28 reviewed by panel. 25 different outcome measures found and numerous other measures used as comparisons. Studies assessed using general information, practicality, reliability, validity, scales and potential bias.	Numerous outcomes measures found with little or no consistent agreement on use. Methodological flaws found in many studies and some studies difficult to understand. Some outcome measures found to have proven reliability and validity for use with a lower limb absent population. Non-amputee specific tests of function and QOL not suitable for use with this population.	Due to lack of time and complexity unable to rigorously appraise scientific content.	1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Powell et al,1995 (48)	Comparison of FES and ABC to test consistency, reliability and validity.	60 adults.	Comparison Study.	ABC Scale developed by 15 clinicians and 12 elderly subjects. 60 subjects classified according to mobility confidence and used for psychometric testing. 21 subjects re-tested with ABC after 2 weeks and tested for postural balance.	FES and ABC Scale were internally consistent and had good test-retest reliability. Previous psychometric tests of FES confirmed. FES appropriate for less active elderly balance assessment. ABC Scale more responsive and better for various functional levels and more active elderly subjects.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Myers et al,1998 (94)	Discriminative and evaluative properties of ABC Scale.	60, 475, 63 and 27 elderly subjects	Test re-test.	Four trials carried out, the original 60 subjects from previous tests, re-tested at 1 year with ABC. 475 elderly subjects of varying levels of mobility administered ABC, TUG, and TWT. Comparison of 63 elderly subjects, half given exercise program and falls education and half only falls education and 27 subjects tested for balance confidence pre-post operation.	1 year follow up ABC scores showed only small increase. Subjects lost to follow-up generally from previous low mobility group. Balance and strength training improved the mean ABC scores in comparison to other forms of training for the elderly subjects. Baseline ABC scores similar for 2 groups of elderly home care residents, improvement in ABC scores for the education and exercise program subjects at 11 weeks and 26 weeks. ABC scores for pre-op group related to pain and gait speed, at 6 weeks post-op ABC slightly lower than baseline and at 6 months post-knee or hip replacement ABC significantly higher. ABC scores over 80 indicate high function and below 70 possible indication for intervention.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Myers et al, 1996 (49)	Psychological indicators of balance confidence and relationship between actual and perceived abilities.	60 elderly adults.	Comparison study.	FES, ABC and questions on fear of falling, perceived ability and activity avoidance. Walking speed and static posturography.	ABC score and perceived need for assistance outdoors were significantly associated with gait speed and balance. Perceived abilities related to present issues and not previous history of falls. ABC Scale good evaluative tool for moderate to high activity elderly subjects.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Miller et al, 2003 (92)	Psychometric testing of ABC Scale.	329 TT/TF	Test re-test	ABC Scale, 2 MWT and TUG test administered to 2 samples of TF and TT amputees. Test correlation between TUG, ABC and TWT. Test the discriminative ability of the ABC to different amputees.	ABC found to have good reliability and construct validity in assessing this group of amputees. ABC Scale showed better repeatability in the higher scoring subjects rather than the mid-range scoring subjects, possibly suggesting a ceiling effect. ABC did not discriminate between the different levels of amputation.	Convenience sample used. Estimation of ABC reliability may be biased. No bi-lateral amputees in study. Broad range of individuals and aetiologies within sample.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Gauthier-Gagnon et al, 1999 (32)	Survey of prosthetic use of a lower limb absent population.	396 TT/TF	Cross-sectional study.	A 5-year follow-up of participants who had undergone prosthetic training. PPA questionnaire sent to each subject to assess the amount of prosthetic wear and functional use of his or her prosthesis.	13 enabling factors for prosthetic use determined including ability to don/doff prosthesis, walking in a variety of conditions and availability of resources. Apart from accessibility to resources, enabling factors were significantly associated with wear and use of prostheses. 85% of subjects wore their prosthesis regularly and were able to perform basic walking but 50% found advanced activities difficult especially the TF subjects.	Cross sectional study, longitudinal studies of this population needed to confirm results.	3
Wong et al, 2012 (44)	Assessment of balance and falls using 2 knees in a single TF user using ABC, TUG and BBS.	1 TF	Case study.	Comparison of balance ability, balance confidence, falls, and activity in a vascular TF user with NMPK and MPK. Subject assessed with BBS, ABC and TUG.	Subject had higher BBS and ABC scores and improved TUG times with the MPK and reported less falls and higher participation in activities than with the NMPK.	Single subject sample.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Miller et al, 2004 (31)	Assessment of changes in balance and confidence in a lower limb absent population	245 lower limb amputees.	Comparison Study	245 TF and TT amputee were assessed for baseline scores using ABC, socio-demographic, general health and amputation issues and this was repeated at 2 years.	Baseline and follow-up scores on ABC Scale were consistent. Predictor of lower balance and confidence in this group were age, gender, perceived poor health, use of mobility aids, depression, concentration when walking and fear of falling.	Convenience sample. Broad range of individuals and aetiologies within sample.	3
Miller, 2011 (43)	Influence of balance and confidence on social activities of primary lower limb absent population post rehabilitation.	65 TT/TF	Comparison Study.	Primary amputees administered ABC questionnaire, L-test and FAI and followed up at 1 and 3 months post discharge.	Walking ability of amputees improved after 1 and 3 months but balance confidence scores were found to have no significant change. Balance confidence and walking ability were found to be the strongest predictors of social activity following an amputation.	Volunteer sample from a single clinic source undergoing intensive rehabilitation following amputation.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Miller et al, 2002 (37)	Assessment of balance and confidence in a lower limb population and comparison of vascular and non-vascular amputees.	435 lower limb amputees	Cross-sectional study.	Sample of TT and TF amputees assessed for demographic information, cause and level of amputation, time since amputation, gender and age, general health and psychological factors. Balance confidence rated using ABC Scale.	Significant differences between ABC scores for non-vascular and vascular amputees. Overall low scores for balance confidence, non-vascular mean score 75 and vascular amputees 54. Level of amputation was not statistically associated with balance confidence.	Not all outcome measures verified. Cross-sectional study reduces causality claims. Non-inclusion of peripheral neuropathy as a variable.	3
Stevens, 2007 (93)	Comparison of prosthetic knee joints and effects on balance and confidence.	1 TF	Case Study	TF subject using a prosthesis with mechanical prosthetic knee joint was assessed using ABC Scale 6 weeks after fitting. He was re-tested with ABC 9 days after fitting with a micro-processor knee joint and new prosthetic foot and after 6 months using the prosthesis.	The subjects' baseline ABC score with mechanical knee prosthesis increased significantly when initially tested with micro-processor knee prosthesis and was relatively unchanged at 6-month follow up.	Single TF subject. Time to adjust to prosthesis not consistent. No re-test with mechanical knee joint.	2-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Berg,1992 (96)	Validation of an instrument to measure balance.	113 Elderly 70 Stroke 31 elderly	Comparison study.	113 elderly subjects assessed regularly for 9 months using BBS, clinical assessment of balance, self-perceived balance, measured and postural sway. Stroke subjects assessed over 3 months for motor performance, functional independence and balance. 31 elderly subjects assessed for indicators for balance ability.	The BBS scores correlated with caregiver ratings, self-assessed balance, functional ability and postural sway measures. The BBS scores showed sensitivity to use of mobility aids and predicted falls in elderly subjects. BBS scores differentiated between stroke patients recovery and correlated highly with functional and motor performance in stroke subjects.		3
Tinetti, 1990 (97)	Validity of Falls Efficacy Scale.	Elderly	Comparison study.	Group of elderly subjects divided into 2 samples, fallers and non-fallers and administered with FES. Walking speed, anxiety and depression were measured.	FES found to have good test-retest reliability and validity. Walking speed, anxiety and level of depression were independent predictors of FES scores.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Berg et al, 1992 (51)	Assessment of BBS compared with postural sway, Barthel Index and TUG.	31	Cross-sectional study.	Subjects were assessed using measurements of postural sway, BBS, a balance sub-scale, Barthel Index and TUG.	The BBS showed good correlation with the postural sway results and could discriminate between subjects requiring different types of walking aids.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Muir et al, 2008 (98)	Assessment of validity of BBS to predict falls.	210	Cohort study.	Baseline geriatric survey assessment and administration of BBS. Falls information collected at 1-month intervals for 1 year.	BBS not appropriate for identifying subjects at high risk of falls. BBS had poor sensitivity for any falls and multiple falls in this sample and was best suited to predicting multiple falls.	Data on prospective falls obtained from a concurrent sample. Possible under reporting of falls due to lack of medical evidence. Lack of generalizability to general elderly population as sample of volunteers in a falls prevention study and had more males who had military background. Higher overall risk of falls in this sample than previously reported.	2-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Lajoie et al, 2004 (52)	Comparison of reaction time, ABC, BBS and postural sway in fallers and non-fallers.	125	Comparison study.	45 subjects categorized as fallers and 80 non-fallers. Administered with questionnaire to determine health status and falls history, BBS and ABC. Postural sway measured and reaction to stimulus.	The non-faller subjects had faster reaction times to stimulus, less postural sway, significantly higher ABC and BBS scores than the faller subjects. A model to assess an elderly population was proposed.		3
Lajoie et al, 2002 (95)	Comparison of BBS, reaction time and postural sway in elderly fallers and non-fallers.	80	Comparison study	40 subjects defined as non-fallers and 40 as fallers. Each administered ABC and BBS and postural sway and reaction times measured.	Non-fallers had faster reaction times, less oscillation in postural sway measurements and significantly higher BBS and ABC scores.		3

APPENDIX E

Table E: Functional and walking tests

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
WHO, 2001 (99)	International classification of functioning, disability and health.	A limb absent population.			Classification divided into 2 parts, functioning and disability and subdivided into body functions and structures, and activities and participation.		4
Deathe et al, 2009 (59)	Evaluate outcome measure with ICF.		Systematic review.	Comparison of current outcome measures with ICF.	Seventeen instruments identified from the literature and classified as walk tests, mobility grades and generic and amputee specific indices. Lack of sound evidence for most instruments and further research required, although all have potential for use on with a lower limb absent population.		1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Xu et al, 2011 (101)	Review of literature to compare ICF and establish core sets.		Systematic review.	Review of current literature and outcome measures used for a lower limb absent population assessed for links to ICF categories.	There were 113 different outcome measures identified in the literature with 2210 functional concepts almost 90% could be linked to the 4 ICF sub-categories. Majority of concepts used in current literature related to ICF could be used to develop core sets for use with a lower limb absent population.	Studies reviewed only in English. Search limited to previous 15 years only.	1-
Kohler et al, 2011 (102)	Evaluation of ICF checklist to detect changes in function and QOL.	14 TT, 5 TF, 1 HD	Time series study.	Subjects assessed at 4 time points, pre-admission, 1-week post-surgery, at discharge and 3 months post-surgery.	17 subjects completed testing. Significant deterioration of function found at initial test after surgery and an improvement over the 3-month period after surgery.	Small sample size. Pre amputation and follow up scores conducted by telephone interview.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Burger et al, 2011 (103)	Use of ICF in clinic situation.	100 adults.	Prospective study	Short list of ICF codes used to assess out-patients in a prosthetic/orthotic clinic over 1 month. Average of 14 categories used from the 4 components of ICF.	Most frequently used categories were activities and participation and body functions. With activity and participation defining prosthetic and orthotic use. Qualifiers may not improve information and an additional outcome measure may be required to assess more detail.	Short list of codes used chosen by single clinician. Study of one clinic and clinician only.	3
Rommers et al, 2001 (60)	Review of measures of mobility and their effectiveness.		Systematic review	Review of the literature from 1978-1998 to identify the use of mobility scales and range of measurements in a lower limb absent population.	Search identified 35 studies containing numerous mobility scales and questionnaires. None had a continuous measure of mobility; there were limitations in ordinal mobility measurement scales and no consensus in the literature on measurement of mobility in a lower limb absent population.		1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Datta et al,1996 (104)	To assess the 10m walk test as a measure of functional outcome in a lower limb absent population.	26 TT, 27 TF	Comparison study.	Subjects tested with 10m walk test and turn, Barthels Index of ADL, FAI and Volpicelli Mobility Grading system.	Correlation between the 10 m walk test and all three measurements were significant but clinically weak. The TWT was found to be a useful indicator of walking ability and a guide for further intervention but not suitable as an outcome measure in isolation.	Mostly elderly vascular sample.	3
Brooks et al, 2001 (105)	Determine the responsiveness and construct validity of 2-minute walk test as a functional measurement in lower limb absent population.	290 Lower limb amputees.	Comparison study	Subjects classified as TT, TF and bilateral LLA. 2 MWT administered at initial fitting and Houghton scale and SF-36 function sub-scale administered after 48 hours and at 3 month follow up.	The 2 MWT was responsive to changes in function after rehabilitation with a significant change from baseline times in all groups. Weak correlation was found with the SF-36 function sub-scale and moderate correlation with the Houghton Scale. Age and gender within groups showed significant differences in 2 MWT before and after rehabilitation.	Specific population of LLA who had undergone rehabilitation results not generalizable. All tests used not fully reliable and valid in this population. Variables within study not controlled.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Raya et al, 2010 (106)	Determine prediction of performance in 6 MWT using impairment measures, personal factors and amputee specific variables.	44 TT, 28 TF	Cross-sectional study.	Each subject administered 6 MWT, AMP and muscle strength testing. Medical and social history obtained.	Age, balance, time since surgery, reason for surgery and level of amputation were all predictive of variations in 6 MWT with muscle strength the strongest predictor.	Use of alternative hip strength test and plantar flexor power tests not psychometrically tested. Large number of variables in model may limit use in other populations.	3
Podsiadlo et al, 1991 (107)	Evaluation of TUG with BBS, gait speed, Barthel Index	60 elderly.	Observational study.	Sixty geriatric subjects administered the BBS, Barthel Index, gait speed measured and a modified version of the Get Up and Go Test (TUG).	Results showed the TUG test to be valid and reliable in quantifying mobility in this population and it may be sensitive to changes over time. TUG correlated with BBS and appeared to predict outdoor mobility in this group.		3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Schoppen et al, 1999 (108)	Validity of TUG test in elderly vascular amputees.	32 TT, TF	Comparison Study.	Inter-rater reliability tested by 2 observers on sample at different times and in random order. Intra-rater reliability tested on sample by 1 observer with 2 weeks between tests. Validity of TUG tested by comparing results with SIP68 and GARS.	TUG showed good inter and intra rater reliability and showed moderate correlation with GARS and good correlation with physical sub scales of SIP68. TUG was found to be a reliable instrument with reasonable concurrent validity for use in this population.	Lack of gold standard for testing concurrent validity. Elderly vascular limb absent sample used.	3
Condie et al, 2006 (58)	Review of outcomes measures for use in a lower limb absent population.		Literature Review	Review of literature from 1995-2005. 340 articles identified and 28 reviewed by panel. 25 different outcome measures found and numerous other measures used as comparisons. Studies assessed using general information, practicality, reliability, validity, scales and potential bias.	Numerous outcomes measures found with little or no consistent agreement on use. Methodological flaws found in many studies and some studies difficult to understand. Some outcome measures found to have proven reliability and validity for use with a lower limb absent population. Non-amputee specific tests of function and QOL not suitable for use with this population.	Due to lack of time and complexity unable to rigorously appraise scientific content.	1-

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Deathe et al, 2005 (100)	Reliability and validity of L-test of functional mobility.	93 TT, TF	Comparison study.	Subjects performed L-test, TUG, 10 MWT and 2 MWT then the ABC, FAI and PEQ were administered. Repeated to 27 of the sample 2 weeks later. Demographics and history used to assess discriminant validity.	L-test had excellent inter and intra-rater reliability and good discriminant validity between amputation levels. L-test shown to have lower ceiling effect than TUG for active amputees.	Test order was not randomized. Convenience sample used. Third test sample may not have been representative of whole sample. Generalizability limited by higher activity and prosthetic use of sample.	3
Dite et al, 2002 (110)	Establish the reliability and validity of clinical test of balance- Four Square Step Test.	81 elderly adults.	Comparison study.	Sample divided into 3 groups, multiple fallers, non-multiple fallers and healthy group. 3 validated tests TUG, Step Test and FRT used to compare to FSST.	Inter-rater and retest reliability was high. Validity confirmed by correlation with TUG and Step test with healthy group performing better. Assessment of sensitivity and specificity showed FSST to be better than comparison tests.	Relatively active sample.	3

Author	Purpose	Population	Design	Methods	Results/Outcomes	Limitations	SIGN
Dite et al, 2007 (109)	Assessment of tests to discriminate between fallers and non-fallers among TT prosthesis users.	47 TT prosthesis users.	Comparison study.	Subjects tested with FSST, TUG, LCI and 180' turn at discharge following amputation and re-tested at 6 months post discharge. Background and history collected and repeated at 6 months along with falls history, which was used to divide sample into 2 groups.	Significant differences found between Non-faller and faller groups in FSST, TUG and 180 turn times and LCI scores between discharge and 6 month follow up. FSST had highest sensitivity, specificity and predictive values for discriminating between groups, TUG and 180 turn had good values and the LCI score was less sensitive to predicting fallers from non-fallers.	Small sample size. Convenience sample. Retrospective collection of falls history. Self-reporting on daily activity and LCI score based on one point in time only.	3
Lythgo et al, 2010 (71)	Effect of two NMPK joints on gait and function and balance.	5 TF prosthesis users.	Cross over study.	Subjects assessed with their own knee joint and then fitted with 3R90 and 3R92 NMPK joints. Subjects assessed using TUG, 6MWT, FSST and PEQ and gait speed and sudden stop and turn.	TUG, FSST and 6 MWT times improved with 3R92 knee joint. Compared with subject's original knee joint PEQ was similar for original and 3R92 but lower for 3R90. Gait speed was lower for 3R92 but similar for 3R90 compared with original knee joint and gait symmetry unchanged with all knee joints.	Ceiling effect found in measurement of sudden stop and turn in certain conditions.	1-

APPENDIX F

THE MOBIS® SYSTEM*

The Otto Bock Mobility System	
	MOBIS®– **starts with four Mobility Grades*:** the Indoor Walker, the Restricted Outdoor Walker, the Unrestricted Outdoor Walker, and the Unrestricted Outdoor Walker with Especially Rigorous Demands. * This classification corresponds to the profiling questionnaires of the German Association of Medical Services for the National Health Insurance Companies (MDS).
	MOBIS®– **includes four weight classes:** patient weight below 75 kg/165 lbs, below 100 kg/220 lbs, below 125 kg/275 lbs and above 125 kg/275 lbs. We combine all the information you need for selecting prosthetic components in one simple symbol.

MOBIS®– **is easy to use.**

The colored-in segments in the upper half of the symbol show that the 3R60 knee joint is recommended for patients with Mobility Grades 2 or 3. In the lower half, the segments <75 kg/165 lbs and <100 kg/220 lbs are colored to show that the 3R60 is approved for patients with a weight of up to 100 kg/220 pounds.

- Extract from www.ottobock.com

APPENDIX G

PARTICIPANT COVER LETTER

Date

Participant Name

Participant Address

Dear Sir/Madam,

As part of my post-graduate studies with the University of Strathclyde in Glasgow Scotland, I am conducting a study in Cappagh National Orthopaedic Hospital on the effect of prosthetic alignment.

In order to carry out this study it is necessary to conduct an investigation with a number of participants who wear a prosthesis.

I have enclosed a Participant Information Form, which describes the procedures in more detail. I would be most grateful if you would consider reading this information with a view to taking part in this investigation. Should you wish to participate please return the consent form in the stamped addressed envelope enclosed by the 26th April, 2013.

Thank you for taking the time to read this letter and should you have any further questions please contact the department.

Yours sincerely,

Donna Fisher B.Sc. (Hons) P&O

APPENDIX H

PARTICIPANT INFORMATION SHEET

Name of department: Orthotic and Prosthetic Department, Cappagh National Orthopaedic Hospital, Dublin.

Title of the study: The effect of alignment on the balance and confidence of trans-femoral prosthetic users.

Introduction

My name is Donna Fisher; I am a Clinical Specialist in Prosthetics and Orthotics in Otto Bock IDS, Cappagh National Orthopaedic Hospital, Dublin. I am currently undertaking a Masters of Philosophy (M.Phil.) in University of Strathclyde, Glasgow. From the local database, you have been identified as a client of the Orthotic and Prosthetic Department in Cappagh Hospital and have been randomly selected to take part in this study, should you wish to do so.

What is the purpose of this investigation?

This investigation involves a number of trans-femoral (above knee) amputees attending the Prosthetic Department in Cappagh Hospital. The aim of the study is to assess the effect the alignment of a prosthesis has on the balance and confidence of the user.

Do you have to take part?

Participation in this project is voluntary and there is no obligation for you to take part. A random selection of suitable candidates has been chosen and a further selection will be made on receipt of consent to participate, therefore your agreement at this time may not lead to your participation in the final study.

Should you agree to take part and wish to discontinue at any time this is your right and your decision will be fully respected.

What will you do in the project?

You will be sent an appointment to attend the clinic and your current prosthesis will be assessed for the current alignment configuration, this is the same procedure as is normally carried out at most fitting appointments. You will be given a questionnaire to complete consisting of 16 questions, which will take about 15 minutes to complete. An examination of the movements at your hip and residual limb will be carried out and you will then be asked to complete a 20-meter walking test in the clinic room which will be timed and a stepping test which will also be timed. These tests will be fully explained and demonstrated at this appointment.

Your prosthesis will be assessed in the workshop on the alignment jig and the prosthesis will be re-aligned. The prosthesis will be re-fitted, this is your own prosthesis with the same socket and components only the alignment will be different. The process of walking and adjustment of the prosthesis will be carried out in the usual way when fitting your prosthesis and you will be familiar with all of the

procedures. When the alignment procedure is complete the 20m walking test and the Stepping Test will then be performed again and timed.

This process will be carried out in two alignment configurations. The tests will be carried out at a single visit to the clinic and will take approximately 3-4 hours. At the end of the visit your prosthesis will be returned to the original condition and no permanent changes will be made.

Why have you been invited to take part?

You have been invited to take part in this study as you have been identified as a trans-femoral amputee currently using a prosthesis. You are an adult aged between 18 and 65 years who is independently mobile and you have no history of vascular problems.

What are the potential risks to you in taking part?

There are no potential risks in taking part in this project as the procedures which will be followed are standard procedures used when fitting any prosthesis. You will be familiar with all of these and on completion of the tests your prosthesis will be re-instated to its original state.

What happens to the information in the project?

The information gathered from this study will collected by myself and will be stored securely and confidentially. I will be unaware of who has been invited to participate until you are appointed for the first trial.

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.

What happens next:

If you would like to be considered for involvement in this project, please sign the consent form to confirm this and return in the stamped addressed envelope.

If you do not wish to take part, there is no need to take any action and I very much appreciate your time in reading this letter.

Researcher Contact Details:

Pauline Wilkins

IDS Ltd., Cappagh National Orthopaedic Hospital, Finglas, Dublin 11.

Tel: 01 8348970

E mail: Pauline.Wilkins@idsltd.ie

Chief Investigator Details:

Donna Fisher

IDS Ltd., Cappagh National Orthopaedic Hospital, Finglas, Dublin 11.

Tel: 01 8348970

E mail: Donna.Fisher@idsltd.ie

Co-Investigators:

Prof. Damian McCormack

Cappagh National Orthopaedic Hospital, Finglas, Dublin 11.

Tel: 01-8140400

Dr Anthony McGarry

N.C.P.O, University of Strathclyde, 131 St. James Road, Glasgow, Scotland.

Tel: +44 (29) 1415485868
E-mail: anthony.mcgarry@strath.ac.uk

This investigation was granted ethical approval by Cappagh National Orthopaedic Hospital Ethics Committee and the University of Strathclyde Ethics Committee.

If you have any questions/concerns, during or after the investigation and wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Ailsing Tunstead,

P.A. to C.E.O.

Cappagh National Orthopaedic Hospital,

Finglas

Dublin 11.

Tel: 353-01-8140461

email: aisling.tunstead@cappagh.ie

A P P E N D I X I

CONSENT FORM

Name of department:

National Centre for Prosthetics and Orthotics, Department of Biomedical Engineering

Title of the study:

The effect of alignment on the balance and confidence of trans-femoral prosthesis users.

- I confirm that I have read and understood the information sheet for the above project and 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

(PRINT NAME)	I hereby agree to take part in the above project
Signature of Participant:	Date
Signature of Researcher	Date

APPENDIX J

ETHICAL APPLICATIONS TO CAPPAGH NATIONAL ORTHOPAEDIC HOSPITAL AND UNIVERSITY OF STRATHCLYDE.

Cappagh National Orthopaedic Hospital
Ethics (Medical Research) Committee

Applicant's Checklist
Applicant's Reference: Version 1

Please do not submit any application without first making contact with the committee administrator.

Please complete the checklist and application form, and send with enclosures to:
Ailsing Tunstead, P.A. to C.E.O. Cappagh National Orthopaedic Hospital, Finglas Dublin 11.
(tel: 353-01-8140461, email: aisling.tunstead@cappagh.ie
Please DELETE "Yes; No; N/A" as appropriate

10 Applications– **collated** to include: -		**Document Version / Date**		
Covering letter to the committee x 10	Yes			
Application Checklist x 10	Yes			
Ethics application x10 (original application signed and dated by Chief Investigator with original signature)	Yes			
Consent Form (s) x 10	Yes			
Information Leaflet / Sheet (s) x 10	Yes			
Letter to Family Doctor x 10			No	N/A
Recruitment material/advertisement x 10			No	N/A
Questionnaire x 10	Yes			
Genetic Consent Forms x 10			No	N/A
Consent Form for Tissue or Organ Retention x 10			No	N/A
Protocols (i.e. research proposals or study summaries) x 10			No	
Proof of Insurance for investigators who are not covered by the Clinical Indemnity Scheme x 10	Yes			
CV of Chief Investigator, signed and dated x10			No	
Other Documents: please list				

Additional documents for clinical trials, not collated: -		**Document Version / Date**	
Clinical Trial Protocol x10			No
Investigators' Brochure (or SmPC – Summary of Product Characteristics) x10			No
Standard Indemnity Form x10			No
Draft Clinical Trial Agreement, Sponsor & trial site x10			No
Certificate of Insurance for Sponsor Company x10			No
10 CV- of Principal Investigator at each site – 2 page summary document, signed and dated.			No
Application fee - €1000 + €150 per site			No
Site Specific Assessment Form (for each site) x 10, signed by site Principal Investigator, (and if possible, signed by site CEO also.)			No
Irish Medicines Board approval or proof of application to the IMB x 10			No
Other Documents: please list:			
Additional documents for clinical investigations of medical devices:			
Clinical Investigational Plan x10			No
Medical Device Brochure x10			No
CE Mark information x10			No
Draft Indemnity Form (for Cappagh National Orthopaedic Hospital) x10			No
Draft Indemnity Form (for RCSI) x10			No
Draft Agreement, Sponsor & trial site x10			No
Certificate of Insurance for Sponsor Company x10			No
Application fee - €1000			No
Site Specific Assessment Form (for Cappagh National Orthopaedic Hospital) x 10			No
Letter from Irish Medicines Board (where applicable) x 10			No
Other Documents: please list:			

Appendix 9.2

Cappagh National Orthopaedic Hospital
Ethics (Medical Research) Committee

APPLICATION FORM

1. Title of the Research Project:

The effect of alignment on the balance and confidence of trans-femoral prosthesis users.

Is this study a clinical trial of a medicine or a clinical investigation of a medical device? No

If No, please delete Box A and move to Box B. If yes, and your trial relates to medicinal products for human use, please do not use this application form. Please fill in the standard Department of Health and Children Application Form:

http://www.dohc.ie/issues/clinical_trials_2004/forms.doc

Box B:

Is Cappagh National Orthopaedic Hospital the only site in which it is proposed that this research will take place? Yes

Is this a multi-centre study? No

If so, give a listing of all proposed sites in Ireland and the proposed Principal Investigators?

	Principal Investigator at each site:	**Site:**
1		
2		
3		
4		

2. Principal Investigator: The person who takes primary responsibility for the conduct of the research.
For research involving patients, it is essential that a Cappagh National Orthopaedic Hospital Consultant be named as a co-investigator.

Name:	**Present Appointment:**	**Title: (Dr. / Mr. / Ms)**	**Qualifications**
Damian McCormack	Consultant Orthopaedic Surgeon	Professor	F.R.C.S.I.
Address:	**Direct Telephone No.**	**Mobile**	**E-Mail**
Cappagh Hospital, Dublin 11	01 8140400		

Other Investigators (details of each Co-Investigator)

Name:	**Present Appointment:**	**Title: (Dr. / Mr. / Ms)**	**Qualifications**
Donna Fisher	Clinical Specialist in Prosthetics and Orthotics	Ms.	B.Sc.(hons) Prosthetics and Orthotics
Address:	**Direct Telephone No.**	**Mobile**	**E-Mail**
Orthotic Department, Cappagh Hospital, Dublin 11	01 8348970	0868435492	Donna.Fisher@idsltd.ie

Other Investigators (details of each Co-Investigator)

Name:	**Present Appointment:**	**Title: (Dr. / Mr. / Ms)**	**Qualifications**
Anthony McGarry	Teaching Fellow	Dr.	B.Sc (hons) Prosthetics and Orthotics, PhD.
Address:	**Direct Telephone No.**	**Mobile**	**E-Mail**
N.C.P.O., Department of Biomedical Engineering, University of Strathclyde, Glasgow, Scotland	+44 (0) 1415485868		anthony.mcgarry@strath.ac.uk

Other Investigators (details of each Co-Investigator)

Name:	**Present Appointment:**	**Title: (Dr. / Mr. / Ms)**	**Qualifications**
Louise Ballantyne	Prosthetist/Orthotist	Ms	B.Sc. (hons) P&O
Address:	**Direct Telephone No.**	**Mobile**	**E-Mail**
Orthotic Department Cappagh Hospital Dublin 11	01 8348970		Louise.Ballantyne@idsltd.ie

Other Investigators (details of each Co-Investigator)

Name:	**Present Appointment:**	**Title: (Dr. / Mr. / Ms)**	**Qualifications**
Angus MacFadyen	Statistical Consultant	Dr	BA, MA, Ph.D
Address:	**Direct Telephone No.**	**Mobile**	**E-Mail**
The National Centre for Prosthetics and Orthotics, Department of Biomedical Engineering, University of Strathclyde, Glasgow, Scotland	0044141 5303829		akm@akm-stats.com

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3. Please indicate whether any payments, monetary or otherwise, are to be made to a person for conducting this research project or any part of the project.
Give details of the value of the funding obtained or sought and the source of that funding.

Travel expenses will be re-imbursed.

Do not leave any question unanswered. As far as possible, type an answer to each question and do not use 'non-applicable' or 'as above.'

It is important that the language used in this application is clear and understandable to lay members. Do not use acronyms.

DETAILS OF THE RESEARCH PROJECT

4. Has this or a similar application been previously submitted for review to this or any other Ethics Committee in Ireland or the EU and, if so, what was the outcome? No

Has similar research on this topic been done before in this country or elsewhere? No

If Yes, please elaborate and justify this proposed research.

5.

Proposed Commencement Date:	**30.4.2013**	
Proposed Duration:	**Years**	**5 Months**
Proposed Completion Date:	**30.9.2013**	

6(a) What is the principal research objective of the proposed study?
The purpose of this investigation is to pilot the effect of alignment changes to a trans-femoral prosthesis on the balance and confidence of a lower limb absent population.

6(b) What are the secondary research objectives? To ascertain the efficacy of the methodology and the number of participants required for a fully powered study.

6 (c) What is the scientific justification for this research?

The prosthetic management and rehabilitation following an amputation involves a complex series of procedures. To ensure successful rehabilitation the socket fitting, method of suspension, alignment of components and education of the patient must be considered. These areas cannot be considered in isolation as each will affect the overall outcome of such a fitting procedure.

Arguably, the most important part of any prosthesis is the interface between the user's residual limb and the prosthesis known as the prosthetic socket. This is designed specifically to fit the user and to allow comfortable use of the prosthesis. Optimal socket fit is essential and much time is spent refining and adjusting this until the user is satisfied. The quality of the method by which the socket suspends will influence the comfort and fit of the socket and the ability of the user to control their prosthesis.

Prosthetic alignment is an inherent part of the procedure and is individually configured for each user. Alignment is crucial in facilitating optimal gait; socket fit and ensuring correct function of limb components. (10) The higher the level of amputation the more influence alignment has on the user and their ability to control the prosthesis and function. (11) Historically alignment has been approached in a subjective way by practitioners using clinical experience, manufacturer's guidelines and feedback from the prosthetic user. The desire to find a universal procedure to solve what is essentially a biomechanical problem has been approached in a number of different ways in the literature. However, it has proved difficult to gain consensus due to a number of influencing variables which make alignment so much more than a simple biomechanical problem. (9)
The alignment of a trans-femoral prosthesis is based on the anatomical position and condition of the residual limb, the anatomy of the sound side and the type of prosthetic components. There are three stages of alignment:-

1. Bench alignment – The initial set-up of the prosthesis to configure the components and socket before fitting to the user.
2. Static alignment – The initial assessment of the position and heights of the components and socket fit in a weight-bearing situation.
3. Dynamic alignment – The process of aligning the prosthesis during walking, by altering the configuration of socket, knee and foot to achieve a safe and comfortable gait pattern for the user.

Safety is of inherent importance to the trans-femoral prosthesis user, a feeling of instability and essentially a fear of falling leads to a lack of

confidence in using the prosthesis and reluctance to weight bear fully on the device. (14) This is especially difficult for trans-femoral or higher level amputees due to the loss of active muscle control over multiple joints and the reduced proprioception in an artificial limb. This results in increased load and pressure on the sound or contra-lateral side and can increase energy expenditure. (47)

Balance confidence has been assessed in the elderly population and the effect of low balance confidence, reported falls and fear of falling has been shown to be detrimental to mobility, independence and social participation. (28, 49) In a limb absent population and particularly a trans-femoral population the effects of low balance and confidence has been shown to have similar results. (30, 43)

7. Give a full summary of the purpose, design and methodology of the planned research, including explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the participant, how many times and in what order.

This investigation is a pilot study to assess the feasibility of the methodology to measure changes in prosthetic alignment and the number of subjects required to engage in a larger investigation.

This pilot study will assess the effect of alignment change on the balance and confidence of a group of trans-femoral prosthesis users. The participants will be asked to complete a questionnaire to establish their baseline balance and confidence and will complete a timed walking test and a timed stepping test to assess their mobility and balance with their current prosthesis. An assessment of the range of motion at the hip on the affected side will be carried out.

The current alignment of the prosthesis will be assessed using an alignment jig and the prosthesis will be set up in two different configurations of socket flexion. Each configuration will be fitted to the participant and the standard process of alignment carried out. The participant will then repeat the walking test and stepping test. The results of the timed tests for each configuration will be compared to determine the effect of the alignment changes on each participant.

There are two functional walking tests, a physical assessment and a questionnaire which will be used in assessing the balance and confidence of the participants. The Activity-specific Balance and Confidence Questionnaire (ABC) [48], the L-Test [100], a modified version of the Timed Up and Go Test (TUG) [107], and the Four Square Step Test [110]. The Thomas Test [124] will be used to assess the range of motion at the hip joint for each participant.

ABC Questionnaire

The participants will be asked to complete the ABC questionnaire before any intervention (Appendix B). This questionnaire was developed by Powell and Myers [48] to assess balance and confidence in the elderly population. It has also been found to be useful in assessing the balance and confidence in a lower limb absent population and there is evidence to support the reliability and validity of this questionnaire. [92]

The ABC Scale is a 16 item self-assessment questionnaire which assesses the level of confidence of an individual in performing a task without becoming unstable or losing their balance. It is rated on a scale of 0 (no confidence) - 100 (full confidence). The mean score is calculated with a score of less than 80 indicating low balance and confidence and a need for intervention. [94]

L-Test

The L-Test is a version of the Timed up and Go Test (TUG) [107] to measure physical mobility. The participant is required to stand up from a standard height chair, walk three meters, make a 90-degree turn, walk seven meters and then turn around and retrace their path. The time it takes in seconds to complete the 20 meter circuit from the time the individual starts to stand to the point that they sit down again is recorded. This test has been shown to have excellent reliability and validity when testing a lower limb absent population. [100, 108, 109]

Four Square Step Test [FSST]

The Four Square Step Test is a clinical test which has been shown to have reliability and validity in testing physical mobility [110, 151] . It has been used to assess an amputee population [71, 109] and differs from many of the other tests

of mobility in that it involves stepping in different directions over a low obstacle and recording the time taken to complete the test.

It is a simple test to set up and administer, the participant will be given instructions and allowed to do a trial test before being timed. A square is formed on a level surface using four walking sticks. The squares are numbered from 1 to 4 and the participant is instructed to move from square 1 to 4 and back again as quickly as possible without disturbing the sticks. The most efficient way is to face in the same direction, side step and step back and forward over the obstacles but as long as both feet make contact with each square the participant is free to use their preferred method to negotiate the test.
These types of movement are present in everyday activities but can be challenging for a trans-femoral prosthesis user. The score is recorded as the time taken to complete the sequence. The stopwatch starts when the first foot contacts the floor in square 2 and finishes when the last foot contacts the floor in square 1. Two FSST are completed with the best time taken as the score.

Thomas Test

The Thomas Test [124] is described as a clinical examination of the hip to determine if there is a flexion contracture of the iliopsoas muscle. This test is widely used by clinicians in many disciplines to assess hip range of motion and is the most commonly used test among clinicians to assess for a hip flexion contracture in the residual limb.[80]

The Thomas Test is carried out with the participant lying in a supine position on a plinth, the subject's pelvis should be secured with a stabilizing strap to limit pelvic rotation. The examiner places their hand under the lumbar spine and flexes the sound side hip and knee until the lumbar lordosis becomes flattened. The angle of the midline of the residual limb and the trunk is measured as the angle of hip flexion.

There have been a number of studies carried out to assess the reliability and repeatability of the Thomas Test. None of these studies relate directly to the measurement of residual limbs in amputees and there appears to be no consensus in the literature regarding the reliability of this test for non-amputees. [132]

Procedures

On arrival at the clinic each participant will be asked to complete the ABC questionnaire. This will provide a baseline balance confidence score.

The participant will then perform the L-Test and Four Step Square Test (FSST) wearing their everyday prosthesis and usual footwear. These times will be recorded in seconds as L-Test A and F-Test A, respectively.

The participant will then be asked to remove their prosthesis and lie supine on the plinth. The Thomas Test will be carried out by the primary investigator and a qualified assistant. This test will be repeated by the same team before each intervention to ensure consistency. This will be recorded as Thomas Test A.

The participant's prosthesis will then be assessed for the present alignment situation. If the participant reports any issues with their prosthesis at this stage such as socket discomfort will be corrected before commencing with the tests. Any major issues which involve time consuming adjustments or which may inhibit the participant in completing the tests will be resolved through the usual procedures in the clinic and the participant will be excused from the study. The prosthesis will be placed in the bench alignment apparatus. This apparatus is routinely used in the clinic to set up or bench align the prosthesis before fitting to the patient. This is a crucial part of the manufacture and fitting of a prosthesis and is achieved by following the alignment recommendations from the manufacturer of the specific components and the position of the socket according to the position of the residual limb.

The sagittal alignment will then be recorded with the laser line, using the reference line of the socket, knee centre of the prosthetic knee joint and the reference line on the bench alignment apparatus for the foot. This will be documented as Dynamic Alignment A. This is the original dynamic alignment of the prosthesis, the original bench alignment cannot be recorded as this was established during the fitting of this prosthesis and subsequently changed during the alignment procedure. The height and configuration of the prosthesis will be preserved in the adapters, to ensure the prosthesis will be returned to the participant in the original configuration after the completion of the tests.

The prosthesis will then be re-set in the alignment apparatus. The prosthesis will be bench aligned according to the manufacturers guidelines for the components.

In order to assess the effect of changing the initial angle of flexion of the socket this process will be carried out by setting the socket in 20 and 30 degrees of flexion. The order in which the socket angle will be set up will be randomised by the flip of a coin, for each participant to avoid the effect of learning during the functional walking tests. This will be documented as Bench Alignment B and C.

The prosthesis will be re-fitted to the patient and statically aligned using the LASAR Posture apparatus. The patient will then be asked to walk with the prosthesis at the adjusted angle of flexion of the socket. The static alignment of each configuration will be noted using the LASAR Posture device. This is a standard procedure for the fitting of all prosthetic limbs and the process can take a number of hours.

This study does not propose to make any changes to the socket or componentry of the subject's current prosthesis but to assess the effect of changes in alignment of the prosthesis. This is part of standard clinical practice during dynamic alignment, where clinical observations and prosthesis user feedback initiate any changes made to the alignment or socket fit, in order to reach an agreed 'optimum' fitting. This generally takes a number of hours, therefore each participant will have a minimum of one hour to adapt to the new alignment configuration. It is general practice to allow the user to become familiar with their new limb or component in their own environment and for a longer period before finalising a decision or completing the prosthesis, therefore the participants will have no permanent changes made to their prosthesis during this study.

This process will be repeated for each participant in each of the increments of flexion. Two angles will be assessed in one visit and the necessary time to rest between tests will be consistent for each participant. The participant will be asked to repeat the L-test and FSST with the new alignment configurations and these will be documented as L-Test B and C and F-Test B and C.

The results of each of the L-tests and F-Tests will be compared to ascertain if changing the initial angle of flexion and its resulting effect on the prosthetic alignment has any influence on the dynamic balance and confidence of an active sample of trans-femoral prosthesis users.

The prosthesis will be returned to the participant following the tests in the original configuration. Should the participant or clinician feel they may benefit from a review of the alignment due to the findings in the tests this will be carried out after the completion of the tests.

8(a) Does the design of the study allow a statistically significant conclusion to be reached?

No

8(b) What method(s) of analysis will be used?

Descriptive statistical analysis will be performed to compare results. The mean, range and standard deviations for each result measured will be examined and used to determine the appropriate sample sizes required to design a fully powered future study.

---

10. Please name the medical device that it is proposed to investigate in the course of the study? (ONLY RESPOND TO THIS QUESTION IF YOU RESPONDED TO BOX A, Question 1)

10(a) **State all possible risks to be incurred by PARTICIPANTS in the proposed clinical trial or research study? (Indicate the nature, probability and magnitude of risk, whether physical, psychological, psychosocial or other)**

Nature of Risk:	**Probability of Risk:**	**Magnitude of Risk:**	**Physical / Psychological/Psychosocial or other**
(e.g bruising due to blood sample)	*(e.g. Very High Risk)*	*(e.g. not serious)*	*(e.g. physical)*
Falling	Very low	Not serious	Physical

10(b) **State all possible risks to be incurred by CONTROLS in the proposed clinical trial or research study?** NA

(Indicate the nature, probability and magnitude of risk, whether physical, psychological, psychosocial or other)

Nature of Risk:	**Probability of Risk:**	**Magnitude of Risk:**	**Physical / Psychological/Psychosocial or other**
(e.g bruising due to blood sample)	*(e.g. Very High Risk)*	*(e.g. not serious)*	*(e.g. physical)*

11(a) Please list those procedures in the study to which SUBJECTS will be exposed indicating those which will be part of Normal care and those that will be <u>Additional</u>. (If your participants are staff members, normal is the normal working day, additional is your research i.e. questionnaires, interviews and focus groups.)

Normal Care:	**Additional Care:**
Measurement of hip flexion	Timed walking tests
Alignment of prosthesis	Filling out questionnaire

11(b) Please list those procedures in the study to which CONTROLS will be exposed indicating those which will be part of Normal care and those that will be <u>Additional</u>. NA

Normal Care:	**Additional Care:**
NA	NA

12. Please indicate if any treatment is withheld as a result of taking part in the study.

No treatment is being withheld as a result of taking part in this study.

13(a) What is the potential for pain, discomfort, distress, inconvenience or change to lifestyle for RESEARCH PARTICIPANTS?

Pain (e.g. skin biopsy, lumbar puncture):	Discomfort (e.g. while giving a blood sample):	Inconvenience (e.g. attending a clinic/filling in a questionnaire):	Change to lifestyle (e.g. results of genetic testing / risk of surgery impacting on participant lifestyle etc):
None	None	Attendance at clinic	None
		Completion of tests and questionnaire	

13(b) What is the potential for pain, discomfort, distress, inconvenience or change to lifestyle for CONTROLS?

Pain (e.g. skin biopsy, lumbar puncture):	Discomfort (e.g. while giving a blood sample):	Inconvenience (e.g. attending a clinic/filling in a questionnaire):	Change to lifestyle (e.g. results of genetic testing / risk of surgery impacting on participant lifestyle etc):
NA	NA	NA	NA

14. (a) What is the potential for benefit for RESEARCH PARTICIPANTS who agree to take part in this research, if any?
They will possibly benefit from an improved prosthetic alignment and from improved techniques in the future.

14 (b) What is the potential for benefit for CONTROLS who agree to take part in this research, if any? NA

---

15 (a) How will the health of the participants be monitored both *during* and *after* the study? There is no necessity to monitor health outside of normal procedures.

15 (b) What criteria exist for withdrawing individual participants prematurely?
The participants are free to withdraw from the study at any time. The tests will be carried out in one visit to the clinic therefore should a participant withdraw before their attendance a replacement can be appointed using the selection criteria.

15 (c) What steps will be followed if participants decide to withdraw during the course of the study? (Participants who withdraw have the right to expect the destruction of identifiable data and samples, and that their data/samples/results will not be used in the final research)

Should a participant wish to withdraw during the study all recorded results will be destroyed.

16. What criteria exist for stopping or prematurely ending the research study?

All participants will be informed in writing of the premature ending or stopping of the research, they will be thanked for their participation.

15. (a) What arrangements are in place for monitoring, recording and reporting and evaluating adverse enents? Please state who has overall responsibility in this area and what protocols are in place to monitor any unforeseen events. (Please name the person with overall responsibility.)

Donna Fisher will have responsibility for monitoring, reporting and evaluating adverse events. Any adverse events occurring during this study will be reported in writing to the Ethics (Medical Research) Committee.

17. (b) Will a data monitoring committee be convened?
No

If Yes, please give details.

18. Does the Principal Investigator or any of the key investigators have any direct or indirect involvement in the outcome of the study that could in any way be regarded as a conflict of interest?
No

Detail of Participants /

19. How many Subjects and Controls are expected to participate at each named site?

Principal Investigator:	Site:	Number of Subjects:	Number of Controls:
Donna Fisher	Cappagh National Orthopaedic Hospital	5-10	0
		Total: 5-10	Total: 0

20. (a) How will Subjects be identified, approached, recruited and selected? (Please be clear on whether you are approaching subjects in person in a clinic / on a ward, or in writing via letter at home, and how you are identifying patients e.g. from clinic lists etc. Also, be clear on how you are recruiting e.g. by poster, by website advertisement.)

Identified	Approached	Selected	Recruited
Database of prosthetic clients attending the Orthotic and Prosthetic Department, Cappagh National Orthopaedic Hospital.	In writing via letter to home to explain and invite to participate.	Randomly from received agreement to proceed forms.	No recruitment by advertising.

20 (b) How will Controls be identified, approached, and recruited and selected? (Please be clear on whether you are approaching controls in person in a clinic / on a ward, or in writing via letter at home, and how your are identifying patients e.g. from clinic lists etc. Also, be clear on how you are recruiting e.g. by poster, by website advertisement.) NA

Identified	Approached	Selected	Recruited
NA	**NA**	**NA**	**NA**

21. What are the principal inclusion criteria? (Please be careful not to contradict your replies to Question 29)

1	Non-vascular trans femoral amputees	
2	18-65 years	
3	Uni-lateral trans femoral amputee	
4	Independently ambulant	
5	Current user	
6	1 year post surgery	
7		
8		

22. **What are the principal exclusion criteria? (Please be careful not to contradict your replies to Question 29**)

1	Vascular amputee
2	Over 65 years
3	Bilateral amputee
4	Less than 1 year post surgery
5	Not currently using a prosthesis
6	
7	
8	

23. Will any of the participants be simultaneously involved in any other research investigation? No

24. Will participants receive reimbursement of expenses (travel costs, loss of earnings) or any other incentive or benefits for taking part in this research? Yes

If so please provide details. Travel to and from clinic will be re-imbursed.

25 (a) Will the participant's family Doctor be notified of the proposed study?[1] No

25 (b) Does the Information Leaflet inform the participant that their GP will be contacted? No

25 (c) Have you included a copy of the letter to the General Practitioner for review? No

---

[1] If you replied 'yes' to Question 25 (a), please enclose the letter of notification to the GP for review.

PATIENT INFORMED CONSENT

26 (a) Will written informed consent be obtained?
Yes
26 (b) Have you enclosed a copy of the Consent Form for Review?
Yes
26 (c) Which named person(s) will be responsible for obtaining consent? (qualifications and experience)

	Name:	*Qualification*	*Experience*
1	Donna Fisher	B.Sc. (Hons) Prosthetics and Orthotics	20 years of clinical experience
2	Louise Ballantyne	B.Sc. (Hons) Prosthetics and Orthotics	2.5 years of clinical experience
3			
4			

26 (c) Give details of how this will be done. (Be careful to ensure your replies are consistent with Questions 20 (a) and 20 (b))

Selection Procedure

A search will be conducted of the clinical database in the Orthotic Department of people registered who have amputation above the knee. Figure 2 outlines the selection process. In accordance with the inclusion criteria, the database will be filtered by age, level of amputation and reason for amputation.

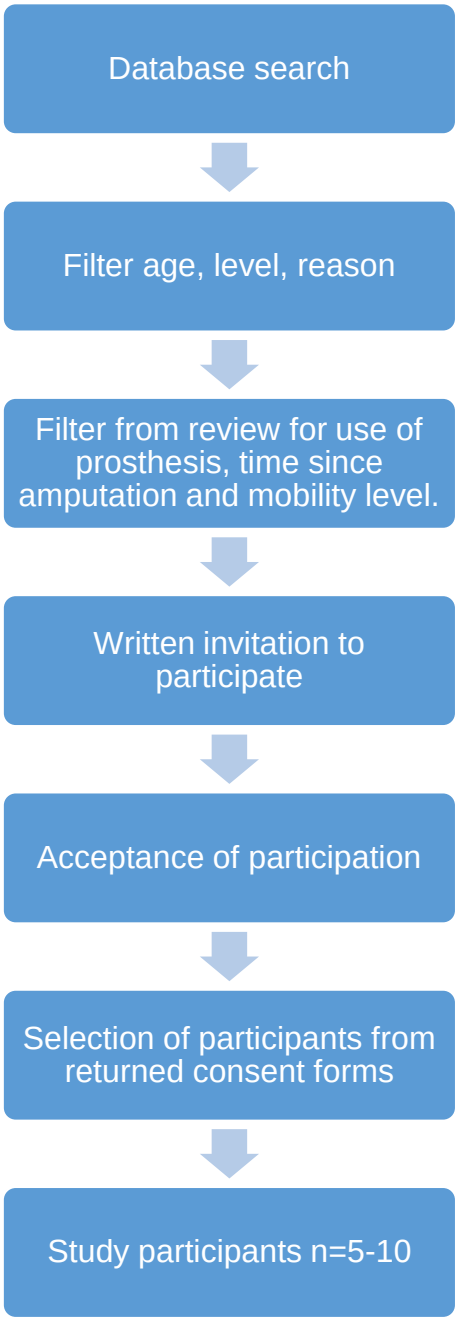


Figure 2 Selection criteria

Due to the limited information stored in the database it is not possible to filter for all of the inclusion criteria, therefore from this group a random selection (random number generation) will be made. The prosthetic records of this group will be independently screened by a certified clinician for the remaining inclusion criteria- current use of a prosthesis, mobility level and the time since they had surgery. The resulting group will then receive a written invitation to participate in the study. (Appendix A) The procedure to be undertaken will be explained fully and they will be requested to accept participation by returning the enclosed form. (Appendix A) From the returned consent forms a selection of 5 participants will be randomly selected (random number generation) to take part in the study and will be sent notification to attend the facility.

27 (a) Will the participants be provided with an Information Sheet and Consent Form?
Yes

27 (b) Will the controls be provided with an Information Sheet and Consent Form?
NA

28. Will the participant be given as much time as they require in which to make a decision regarding participation in this research study?Yes

29 (a) Are any of the following groups included:

Pregnant Women		No
Women of Child bearing potential	Yes	
Children or Minors (≤16 years)[2]		No
Cognitively impaired persons[3]		No
Comatose patients		No
Elderly/aged persons (> 65 years)		No
Hospital Employees[4]		No
Students in the Hospital e.g. NCHD students[5]		No

[2] Parts 4 and 5 of Schedule 1of the *European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004* clearly outlines conditions and principles which apply in relation to treatment of Minors who are participants in medical research.

[3] Parts 4 and 5 of Schedule 1of the *European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004* clearly outlines conditions and principles which apply in relation to treatment of Incapacitated Adults who are participants in medical research.

[4] Hospital staff are excluded from participating in Cappagh National Orthopaedic Hospital studies, where a supervisory or dependent relationship exists with the Principal Investigator or any of the co-investigators listed in response to Question 2.

[5] Medical Students and NCHDs are excluded on ethical grounds from participating in Cappagh National Orthopaedic Hospital studies.

29 (b) If so, please justify outlining how the study is expected to benefit the individual who participates.

Risk Group to be included in the study:	Benefit to individuals in that risk group:
NA	**NA**

29 (c) State the manner in which consent will be obtained paying particular attention to the role of parents, legal representatives, witness etc

Minors & the role of parents /guardians:	Adults without capacity and the role of legal representatives:	Will the consent form include a witness signature?
NA	**NA**	**NA**

30(a) Does the Research involve the COLLECTION of human biological material?
No

If yes, please specify what material:

DNA		NO
Blood		NO
Bone		NO
Connective Tissue		NO
Skin		NO
Muscle		NO
Organs e.g. heart, liver, kidney etc.		NO
Gametes e.g. sperm, ova		NO
Embryos		NO
Foetal Tissue		NO
Waste e.g. hair, nail clippings, urine, faeces, sweat		NO

30(b) Does the Research involve the RETENTION of human biological material? No

If yes, please specify what material:

DNA		No
Blood		No
Bone		No
Connective Tissue		No
Skin		No
Muscle		No
Organs e.g. heart, liver, kidney etc.		No
Gametes e.g. sperm, ova		No
Embryos		No
Foetal Tissue		No
Waste e.g. hair, nail clippings, urine, faeces, sweat		No

30(c) Who is the custodian of this human biological material? NA

30 (d) Does a recognised protocol exist for the collection, storage, care and disposal of this material? NA

30 (d) Have you enclosed a separate Consent Form for the Retention of Human Tissue for review? NA

30 (e) Does your research involve GENETIC TESTING? No

30 (f) Have you enclosed a separate Consent Form for Genetic Testing for review? NA

30 (g) Are arrangements in place for destroying identifiable samples to prevent further analysis should consent be withdrawn at a later time? NA

30 (h) Are samples sent outside of Cappagh National Orthopaedic Hospital? NA

If yes, are participants informed of this in the Information Leaflet NA

31. What arrangements exist to ensure participants are informed of any new information that becomes available during the course of the study? (Particularly information that could impact on their initial consent.)

Any information which may affect participation in this study will be immediately imparted to the participants in writing.

32 (a) How will the results of this study be reported and disseminated?

On successful completion, results will be published in a peer reviewed journal and presentation of the results at a clinical conference.

32 (b) Will results be made available to research participants?

Yes

If so, how will this be done?

Participants will be informed of the overall results of the study on request. This will be done in a clinical appointment or in writing. The results and possible impact of the study will be explained to the interested participants. The results of the study will be displayed in the department following successful completion of the study.

INDEMNITY

33. What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for negligent harm?[6] *(Employees of Cappagh National Orthopaedic Hospital Board are covered by the Clinical Indemnity Scheme. Non-hospital employees will need to provide proof of indemnity.)*

Indemnity form attached and letter stating insurance cover through Strathclyde University.

34. What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for non-negligent harm?[7] *(Employees of Cappagh National Orthopaedic Hospital Board are covered by the Clinical Indemnity Scheme. Non-hospital employees will need to provide proof of indemnity.)*

Indemnity form attached and letter stating insurance cover through Strathclyde University.

35 (a) Have all medical practitioners involved in this study current medical malpractice insurance? Yes

35 (b) Is each member of the investigative team insured? Yes

[6] **NB** *Sponsors must comply with the Association of British Pharmaceuticals Industry (ABPI) compensation guidelines and Irish law*

[7] **NB** *Sponsors must comply with the Association of British Pharmaceuticals Industry (ABPI) compensation guidelines and Irish law*

.

CONFIDENTIALITY[8]

36. (a) Who is the custodian of the data generated? **(This may be the same custodian as for the human biological material – see Question 30 (c), or may be a different custodian)**

Donna Fisher.

36 (b) Who has access to this data?

		Hospital Employee?	
1	Donna Fisher		No
2		Yes	No
3		Yes	No
4		Yes	No
5		Yes	No
6		Yes	No
7		Yes	No
8		Yes	No
9		Yes	No

[8] **NB.** ***Investigators should be aware of the provisions of the data Protection Acts 1988 and 2003 and their obligations as set out in those Acts.***

36 (c) Does the Information Leaflet inform participants who is going to have access to their data?

Yes

36 (d) How is security of data maintained?

Data collected during this study will be confidential. No participant will be named and all results will be given a code referring to the participant. The information collected will be stored in a password protected file on the main frame computer of the department. No-one other than the investigators will have access to this.

---

37 (a) How will the data be stored AND for how long? On completion of the study all data relating to the participants will be destroyed. The information collected will be stored in a password protected file on the main frame computer of the department. No-one other than investigators will have access to this. Data will be stored until the study is completed.**37 (b) How will the data be disposed of?**

File on computer will be deleted. Any hard copies will be shredded.

37 (c) Does the Information Leaflet inform participants how long data will be stored for, and how data will be destroyed: Yes

38 (a) What action will be taken to ensure that the identity of each participant remains confidential?

Data collected during this study will be confidential. No participant will be named and all results will be given a code referring to the participant.

---

38 (b) Would you class the data as anonymous, identifiable or coded? (Be careful: data is only anonymous if you have no idea who the data belongs to and have no way of finding out who it belongs to. Most data in research is coded, and the code can be broken by the custodian of the data, so that the identity of the participant is known.)
Coded

39 (a) Will the participant's medical records be examined?

No

39 (b) Will any medical records be examined by research workers

No

If Yes, please justify.

39 (c) Does the Participant Information Leaflet inform participants that their medical records will be examined, and by whom?

NA

ETHICAL CONSIDERATIONS:

40. Does the Chief Investigator consider that there are any specific ethical issues that this study might present and how would these be dealt with? Please identify and evaluate.

All information recorded during this investigation will be made anonymous. The investigator will only store a list of contact details for necessary appointments at a secure location. All personal information will be regarded as confidential. No information that identifies a distinct participant will be made publicly available.
Changing the prosthetic alignment of a trans femoral prosthesis may increase or decrease the stability of the prosthesis and could result in a higher risk of falling or higher energy expenditure in walking. This will be dealt with by using the walking bars and carrying out the changes in a safe and controlled environment. No outdoor unsupervised walking trials will be carried out.

Title of the Research Project:

The effect of alignment on the balance and confidence of trans-femoral prosthesis users.

PLEASE ENSURE THAT YOU COMPLETE THE CHECKLIST ON THE FRONT COVER OF THE APPLICATION FORM AND ENCLOSE ALL RELEVANT ADDITIONAL DOCUMENTS.

DECLARATION:

- **I certify the information in this form is accurate to the best of my knowledge and belief and I understand my ethical and legal responsibilities as Chief Investigator of this study.**
- **I confirm that the protocol and research will comply with all relevant Irish legislative requirements and will be conducted in accordance with European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 and will abide by the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice.**
- **If the study receives a *favourable opinion* I agree to supply Annual Progress Reports, a Final report, and to seek prior approval from the Ethics Committee of any proposed changes/amendments to this protocol.**
- **All relevant information about serious adverse reactions and new events likely to affect the safety of the subjects will be reported to the Ethics (Medical Research) Committee in accordance with the obligations outlined in the Commissions guideline document.**

Name of Chief Investigator: _____

Signature of Chief Investigator: _____

Date: _____

The Chief Investigator who signs the Ethics Committee Application takes responsibility for the standard and quality of this application. Substandard application forms, and substandard accompanying documentation will not be accepted for review by the committee.

APPENDIX K

ETHICAL APPROVAL FROM CAPPAGH NATIONAL ORTHOPAEDIC HOSPITAL AND UNIVERSITY OF STRATHCLYDE ETHICS COMMITTEE.

Ethical Approval
The effect of alignment on the balance and confidence of trans-femoral prosthetic users (UEC 13/17)
Sponsor: Cappagh Hospital, ROI

I can confirm that the University Ethics Committee has approved this protocol and appropriate insurance cover has also been confirmed.

I would remind you that the Committee must be informed of any changes that are made to the research project, so that they have the opportunity to consider them. The Committee would also expect you to report back on the progress and outcome of your project, with an account of anything which may prompt ethical questions for any similar future project and with anything else that you feel the Committee should know.

University ethical approval remains in place subject to the following conditions:

1. That the project obtains/has and continues to have Cappagh Hospital Ethics Committee approval.

2. That the project is carried out according to the project protocol.

3. That the project continues to be covered by the University's insurance cover.

4. That the Director of Research and Knowledge Exchange Services is immediately notified of any change to the project protocol or circumstances which may affect the University's risk assessment of the project.

5. That the project starts within 12 months of the date of this letter.

On behalf of the Committee, I wish you success with this project.

Kind regards

Helen Baigrie
Contracts Manager
Research & Knowledge Exchange Services
University of Strathclyde
Graham Hills Building
50 George Street
Glasgow
G1 1QE

CAPPAGH
NATIONAL
ORTHOPAEDIC
HOSPITAL

FOUNDED 1908
THE SISTERS OF CHARITY

FINGLAS, DUBLIN 11, IRELAND.
TEL:8140 400 FAX:8140 327

2nd April 2013

Ms. Donna Fisher,
C/o Independent Disablement Services
Cappagh National Orthopaedic Hospital
Finglas
Dublin 11

Our Ref: **DF.4.2013.**
Re: **Cappagh National Orthopaedic Hospital Research Ethics Committee**

Dear Donna,

The Research Ethics Committee of Cappagh National Orthopaedic Hospital reviewed your recent application. It was the decision of the committee to fully approve your application of research.

The Research Ethics Committee requests that the committee be formally notified of the date of finalisation of the study and provided with a formal report as to the outcome and success of this trial.

Should you require any further information please do not hesitate to contact me.

Yours sincerely,

Aisling Tunstead
Chief Executive's Office
Ph: 01 8140461
Email: aisling.tunstead@cappagh.ie

8 APR 2013

ADMISSIONS Tel: 8140 452 | AUTOTRANSFUSION Tel: 8140 479 | BONE BANK Tel: 8140 337 | MEDICAL RECORDS Tel: 8140 447 | OPD APPOINTMENTS Tel: 8140 408

APPENDIX L

THE ACTIVITIES-SPECIFIC BALANCE CONFIDENCE (ABC) SCALE*

Instructions to Participants:

For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale form 0% to 100%. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports. If you have any questions about answering any of these items, please ask the administrator.

The Activities-specific Balance Confidence (ABC) Scale*

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0 10 20 30 40 50 60 70 80 90 100	%

0%- no confidence

100%- completely confident

"How confident are you that you will not lose your balance or become unsteady when you…

1. …walk around the house? ____%
2. …walk up or down stairs? ____%
3. …bend over and pick up a slipper from the front of a closet floor ____%
4. …reach for a small can off a shelf at eye level? ____%
5. …stand on your tiptoes and reach for something above your head? ____%
6. …stand on a chair and reach for something? ____%
7. …sweep the floor? ____%
8. …walk outside the house to a car parked in the driveway? ____%
9. …get into or out of a car? ____%
10. …walk across a parking lot to the mall? ____%
11. …walk up or down a ramp? ____%
12. …walk in a crowded mall where people rapidly walk past you? ____%

13. …are bumped into by people as you walk through the mall? ____%

14. … Step onto or off an escalator while you are holding onto a railing? ____%

15. … Step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%

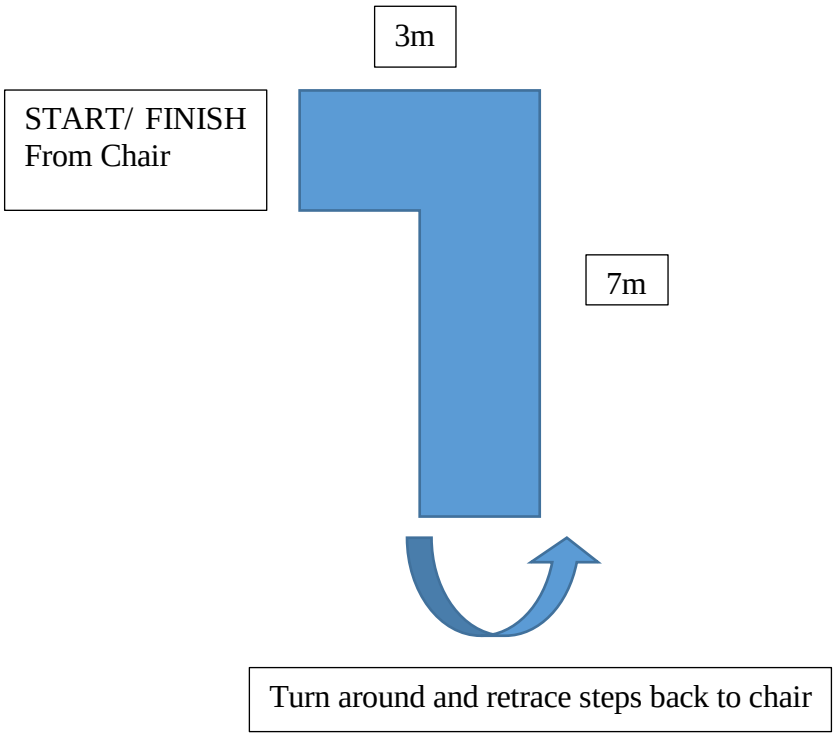
16. …walk outside on icy sidewalks? ____%

*Powell, LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. *J Gerontol Med Sci* 1995; 50(1): M28-34

APPENDIX M

INSTRUCTIONS FOR L-TEST

The L-Test is a version of the Timed up and Go Test (TUG) to measure physical mobility. The participant is required to stand up from a standard height chair, walk three meters, make a 90-degree turn, walk seven meters and then turn around and retrace their path. The time it takes in seconds to complete the 20 meter circuit from the time the individual starts to stand to the point that they sit down again is recorded.



APPENDIX N

INSTRUCTIONS FOR THE FOUR SQUARE STEP TEST

Derived from www.rehabmeasures.org Test instructions provided courtesy of Wayne Dite (110)

General Information:

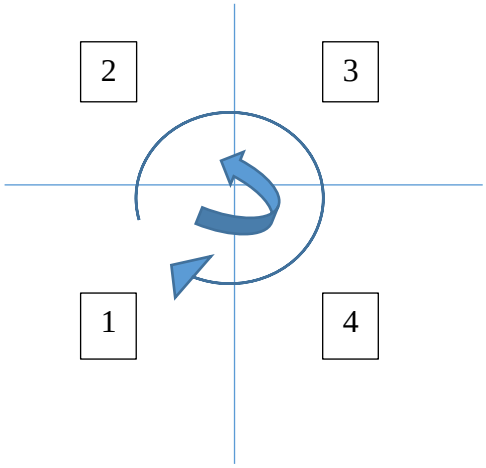
A cross is formed on a level surface using four sticks. The squares are numbered from 1 to 4 and the participant should move from square 1 to 4 and back again as quickly as possible without disturbing the sticks. The most efficient way is to face in the same direction, side step and step back and forward over the obstacles but as long as both feet make contact with each square the participant is free to use their preferred method to negotiate the test.

The Test:

The participant should stand in square 1 facing square number 2. The participant is required to step as fast as possible into each square in the following sequence: 2, 3, 4, 1, 4, 3, 2, and 1.

This requires the participant to step forward, backward, and sideway to the right and left, the test is timed from the foot contact in square 2 to the return and foot contact in square 1.

Two FSST will be completed with the best time taken as the score. A score is still provided if the participant is unable to face forward during the entire sequence.



APPENDIX O

PARTICIPANT INFORMATION PACK AND FORMS

Welcome and thank you for agreeing to participate in this study.

Below is a brief outline of the procedures which will be carried out today, should you have any concerns or questions at any time please do not hesitate to ask myself or my colleagues.

1. If there is a cosmetic cover on your prosthesis this will be removed before the tests begin. The lateral top trim of the socket will be marked to determine the measurement for the marker of the hip joint.
2. The current alignment of your prosthesis will be checked on the LASAR posture device.
3. Walking Test 1 (L-Test) will be demonstrated and completed twice.
4. Walking Test 2 will be demonstrated and completed twice.
5. Your prosthesis will be removed and a measurement of your hip joint motion taken lying on a plinth. (Thomas Test)
6. The prosthesis will then be taken to the workshop for the alignment adjustments. This may take some time and you will be asked to fill in a short questionnaire while you are waiting. (ABC)

7. You will then be re-fitted with your prosthesis and after some adjustments and acclimatisation Walking Test 1 and 2 will be repeated.
8. The prosthesis will then be taken to the workshop for the second alignment adjustments, again this may take some time.
9. You will then be re-fitted with your prosthesis and after some adjustments and acclimatisation Walking Test 1 and 2 will be repeated.
10. The prosthesis will then be taken back to the workshop and re-set to the original configuration

APPENDIX P

ALIGNMENT OF MODULAR LEG PROSTHESES (L.A.S.A.R. POSTURE)*

The L.A.S.A.R. Posture (743L100) is used to optimize the static alignment of modular limb prosthesis during trial fitting. The L.A.S.A.R. Posture is used to visualize the position of the body´s center of gravity line, or load line while standing.

To measure the load line, the amputee user steps onto the force sensor platform and places his/her contralateral leg on the levelling step plate.

A laser projects the measured GRF as the body´s center of gravity line/load line on the body. Classification of the body posture in the sagittal plane is visualized by comparing the distances between the GRF and joint points or body points. The alignment of the prosthesis can then be optimized based on this load line. Since the adjustment of the trans-tibial prosthesis is controlled by force, the L.A.S.A.R. Posture enables an objective adjustment of the physiological load on the knee, which is the biomechanical goal.

The trans-femoral prosthesis is adjusted in relation to the knee. When force is transferred correctly between the socket and the residual limb, particularly in the proximal region, the distance between the knee and the load line is adjusted through appropriate plantar-flexion only. Finally, dynamic optimization can take place between parallel bars.

APPENDIX Q

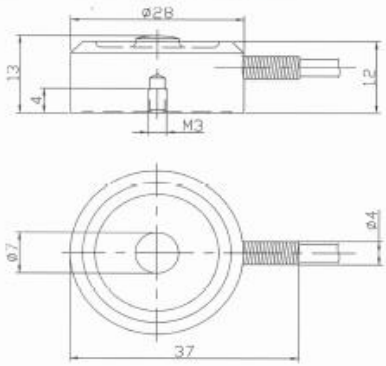
FORCE PLATE DATA*

Miniatur-Kraftaufnehmer
Serie KMM 50A

inelta Sensorsysteme

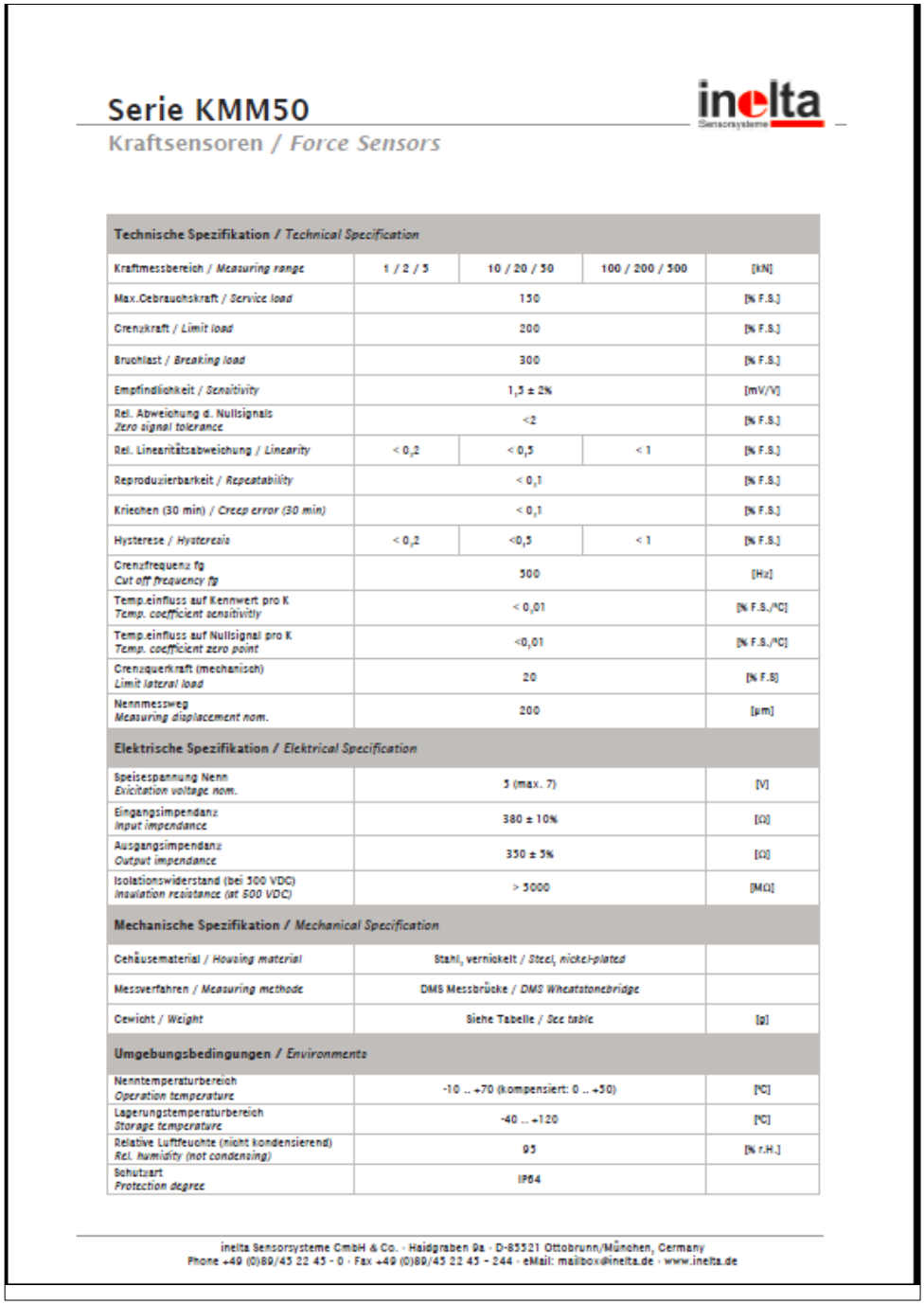
- Messbereich: 0,6kN
- Druckmessung
- robuster Aufbau bei kleinen Abmessungen
- Ausgang normiert
- für elektronische Waagen geeignet

Maßzeichnung



Anschlußbelegung Kabel	
+ Versorgung	weiß
- Versorgung	braun
+ Signal	gelb
- Signal	grün
Schirm	Gehäuse

Inelta Sensorsysteme GmbH & Co. - Hermann-Oberth-Strasse 7 - 85640 Putzbrunn
Tel. 089/46094-100 - Fax 089/46094-244 - e-Mail: info@inelta.de



Serie KMM50

inelta Sensorsysteme

Kraftsensoren / *Force Sensors*

Technische Spezifikation / *Technical Specification*				
Kraftmessbereich / *Measuring range*	1 / 2 / 5	10 / 20 / 50	100 / 200 / 500	[kN]
Max.Gebrauchskraft / *Service load*	150			[% F.S.]
Grenzkraft / *Limit load*	200			[% F.S.]
Bruchlast / *Breaking load*	300			[% F.S.]
Empfindlichkeit / *Sensitivity*	1,5 ± 2%			[mV/V]
Rel. Abweichung d. Nullsignals *Zero signal tolerance*	<2			[% F.S.]
Rel. Linearitätsabweichung / *Linearity*	< 0,2	< 0,5	< 1	[% F.S.]
Reproduzierbarkeit / *Repeatability*	< 0,1			[% F.S.]
Kriechen (30 min) / *Creep error (30 min)*	< 0,1			[% F.S.]
Hysterese / *Hysteresis*	< 0,2	<0,5	< 1	[% F.S.]
Grenzfrequenz fg *Cut off frequency fg*	500			[Hz]
Temp.einfluss auf Kennwert pro K *Temp. coefficient sensitivity*	< 0,01			[% F.S./°C]
Temp.einfluss auf Nullsignal pro K *Temp. coefficient zero point*	<0,01			[% F.S./°C]
Grenzquerkraft (mechanisch) *Limit lateral load*	20			[% F.S]
Nennmessweg *Measuring displacement nom.*	200			[µm]
Elektrische Spezifikation / *Elektrical Specification*				
Speisespannung Nenn *Excitation voltage nom.*	5 (max. 7)			[V]
Eingangsimpendanz *Input impendance*	380 ± 10%			[Ω]
Ausgangsimpendanz *Output impendance*	350 ± 5%			[Ω]
Isolationswiderstand (bei 500 VDC) *Insulation resistance (at 500 VDC)*	> 5000			[MΩ]
Mechanische Spezifikation / *Mechanical Specification*				
Gehäusematerial / *Housing material*	Stahl, vernickelt / *Steel, nickel-plated*			
Messverfahren / *Measuring methode*	DMS Messbrücke / *DMS Wheatstonebridge*			
Gewicht / *Weight*	Siehe Tabelle / *See table*			[g]
Umgebungsbedingungen / *Environments*				
Nenntemperaturbereich *Operation temperature*	-10 .. +70 (kompensiert: 0 .. +50)			[°C]
Lagerungstemperaturbereich *Storage temperature*	-40 .. +120			[°C]
Relative Luftfeuchte (nicht kondensierend) *Rel. humidity (not condensing)*	95			[% r.H.]
Schutzart *Protection degree*	IP64			

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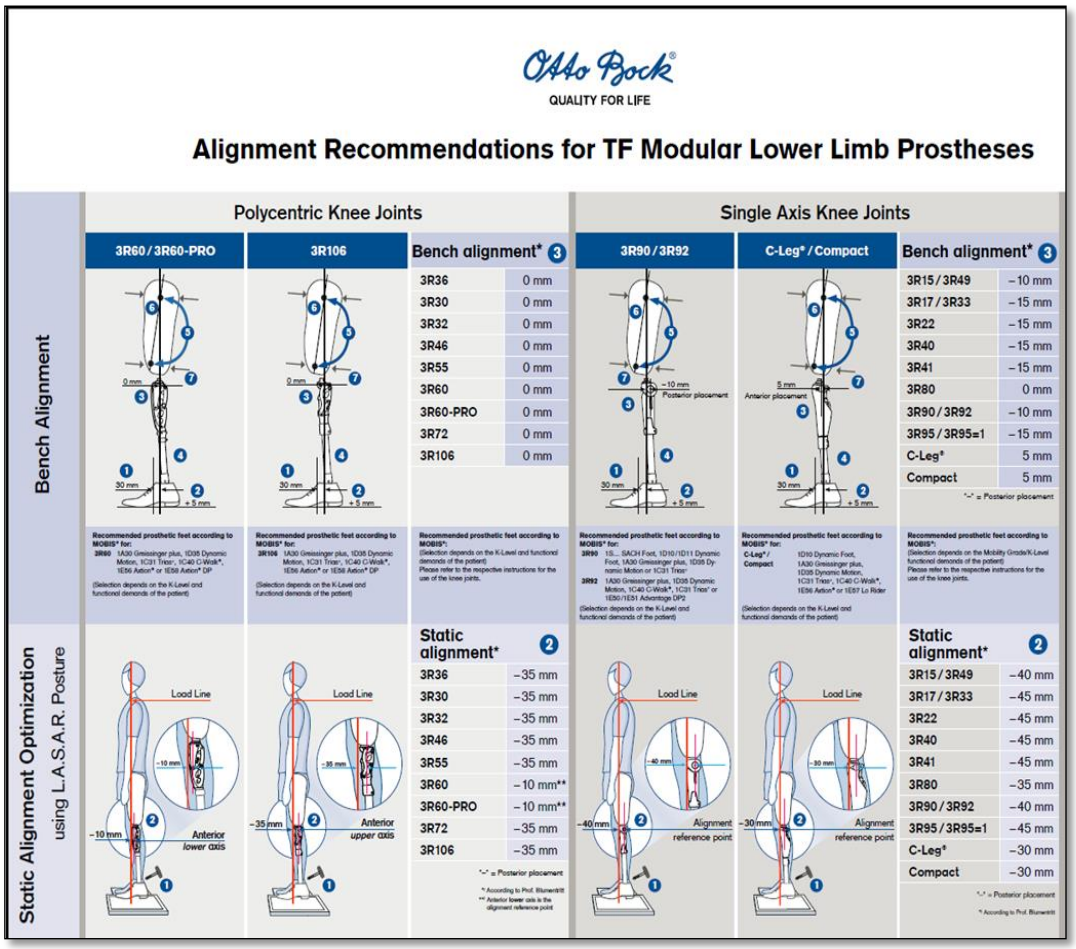
*Technical Information derived from manufacturer (www.inelta.de)

APPENDIX R

ALIGNMENT RECOMMENDATIONS FOR TF MODULAR LOWER LIMB PROSTHESES



Otto Bock
QUALITY FOR LIFE

Alignment Recommendations for TF Modular Lower Limb Prostheses

Bench Alignment

Polycentric Knee Joints

3R60 / 3R60-PRO	3R106	Bench alignment* 3	
		3R36	0 mm
		3R30	0 mm
		3R32	0 mm
		3R46	0 mm
		3R55	0 mm
		3R60	0 mm
		3R60-PRO	0 mm
		3R72	0 mm
		3R106	0 mm

Single Axis Knee Joints

3R90 / 3R92	C-Leg* / Compact	Bench alignment* 3	
		3R15 / 3R49	–10 mm
		3R17 / 3R33	–15 mm
		3R22	–15 mm
		3R40	–15 mm
		3R41	–15 mm
		3R80	0 mm
		3R90 / 3R92	–10 mm
		3R95 / 3R95=1	–15 mm
		C-Leg*	5 mm
		Compact	5 mm

Static Alignment Optimization using L.A.S.A.R. Posture

Static alignment* 2	
3R36	–35 mm
3R30	–35 mm
3R32	–35 mm
3R46	–35 mm
3R55	–35 mm
3R60	–10 mm**
3R60-PRO	–10 mm**
3R72	–35 mm
3R106	–35 mm

Static alignment* 2	
3R15 / 3R49	–40 mm
3R17 / 3R33	–45 mm
3R22	–45 mm
3R40	–45 mm
3R41	–45 mm
3R80	–35 mm
3R90 / 3R92	–40 mm
3R95 / 3R95=1	–45 mm
C-Leg*	–30 mm
Compact	–30 mm

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APPENDIX S

ALIGNMENT OF MODULAR LEG PROSTHESES (BENCH ALIGNMENT APPARATUS)*

Alignment Instructions

The prosthetic alignment of a lower limb prosthesis has considerable influence on the functional qualities of the prosthesis and thus on the quality of the fitting.

Optimal prosthetic alignment is achieved in three steps:

1. Bench alignment or plumb line alignment

2. Static alignment optimization

3. Dynamic alignment optimization

The Otto Bock L.A.S.A.R. Assembly and L.A.S.A.R. Posture alignment units are used to facilitate working techniques, document prosthesis alignment, observe alignment instructions and to ensure reproducible fitting quality.

The L.A.S.A.R. Assembly is designed for bench alignment of modular lower limb prostheses. It is available as a Floor model 743L200/250 and as a Bench Top model 743L300/350. In sagittal and frontal views, three laser lines are projected medially, laterally and anteriorly on the prosthesis or orthosis as alignment reference lines.

For the three-dimensional alignment of a modular lower limb prosthesis, the knee joint is fixed in the apparatus, while the prosthetic foot, other prosthetic components and socket are mounted in accordance with the alignment recommendations.

When aligning a trans-femoral prosthesis according to the Otto Bock alignment recommendations, the knee joint is used as the basis in the L.A.S.A.R. Assembly. The knee joint is fixed with joint-specific brackets (adapter inserts) at the alignment reference point (single axis joints = rotation axis; polycentric joints = anterior upper axis).

The recommended position of the alignment reference point is 20 mm above the medial tibial plateau. The socket is positioned so that its sagittal proximal centre coincides with the alignment reference line. The socket flexion should be set to a 3-5 degree angle, though it may vary in different situations (e.g. in the case of hip joint contractures). The centre of the foot is normally placed 30 mm in front of the

alignment reference line and mounted with plantar-flexion. Add 5 mm to the effective heel height (see illustration for 3R90). The outer position of the foot can be adjusted freely. The frontal alignment is based on the anterior projection of the laser beam.

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APPENDIX T

DESCRIPTION OF COMPONENTS*:

Prosthetic Feet

1C30-Trias®

The main features of the 1C30 Trias carbon fibre foot are the lightweight construction and unique interconnected functional elements which permit amputees with MG 2 or 3 the ability to walk effortlessly in everyday life situations.

The combination of the spring elements offers the following functional advantages:

• Comfortable heel strike with noticeable plantar flexion

• Progressive movement of the ankle in the mid-stance phase for the natural rollover of the foot

• Dynamic transition from the stance to swing phase

• Smooth dynamic forefoot response

• Compensation for uneven terrain

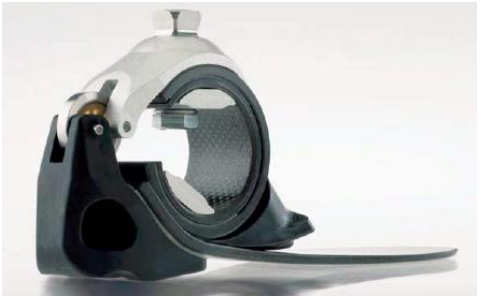
1D35 Dynamic Motion Foot

The Dynamic Motion mainly distinguishes itself through a progressive ankle moment in mid-stance creating a smoother, more natural rollover and makes walking easier.

- Progressive ankle moment
- Comfortable heel strike with noticeable plantar flexion
- Physiological rollover
- Optimized anterior/posterior and medial/lateral mobility
- High energy return
- Dynamic transition from stance to swing phase
- Suitable for Mobility Grades 2 and 3

Due to the special characteristics of the plastic spring combined with the functional foam and the integrated 3D liner, the Dynamic Motion returns stored energy. Therefore, it enables a dynamic transition from stance through swing phase. Torsion movements are compensated. The contralateral side is relieved efficiently. The result is a smooth and physiological rollover. Uneven surfaces can also be compensated for because the shape and flexibility of the spring make sideways movements possible.

1C40 – C Walk®



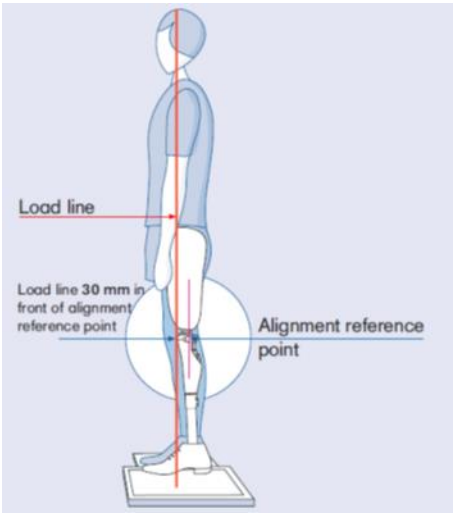
The unique design of the C-Walk® helps achieve an improved gait. The basic principle is the dynamic interlinking of the C-shaped carbon fibre spring and the base spring. These two elements are linked by a titanium control ring.

The C-Walk® acts like a virtual joint, which is positioned close to the physiological ankle. Because of this the ankle moments and the ground reaction forces are almost identical to the sound side limb. The progressive characteristic of the C-Walk® spring system provides just the right amount of movement and energy return required for each phase of rollover. Shock absorption is provided through the transfer of forces into the C-shaped spring. The spring is compressed and closes to a certain degree. The lever-effect between heel and ankle section results in an articulated plantarflexion, providing a fast ground contact of the base spring.

The relatively soft two-layer C-spring allows for controlled multiaxial movement and enables a secure mid-stance – also on uneven terrain. During rollover the C-shaped spring opens up. The energy which has been stored by compression at heel strike is discharged as the C-Walk® rolls over.

Prosthetic Knee Joints

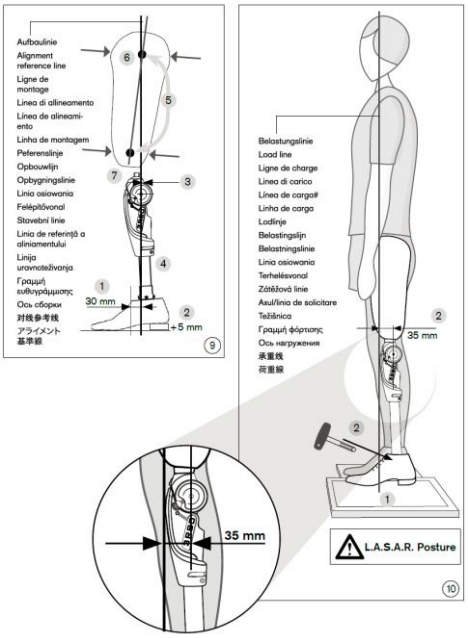
C-Leg®



The C-Leg® takes advantage of microprocessor-controlled hydraulics, which adapt dynamically to all walking speeds, in real time. In addition, the microprocessor makes it possible to reliably secure the stance phase in the C-Leg®. This is made possible through the use of a sensor system. Fifty times a second an ankle moment sensor measures stress while a knee angle sensor reports angle and angular velocity at the knee.

The result is a system that recognises which phase of gait the amputee is in and reacts accordingly. The prosthesis system is stabilized with a high level of resistance in stance phase, and will only switch to swing phase when certain criteria are met-helping to prevent stumbles and falls. C-Leg® technology offers users many advantages, including permanent stance phase control, the ability to weight the prosthesis during flexion, dynamic alignment, lower energy expenditure while walking, and relief for the sound side and the rest of the body.

3R80

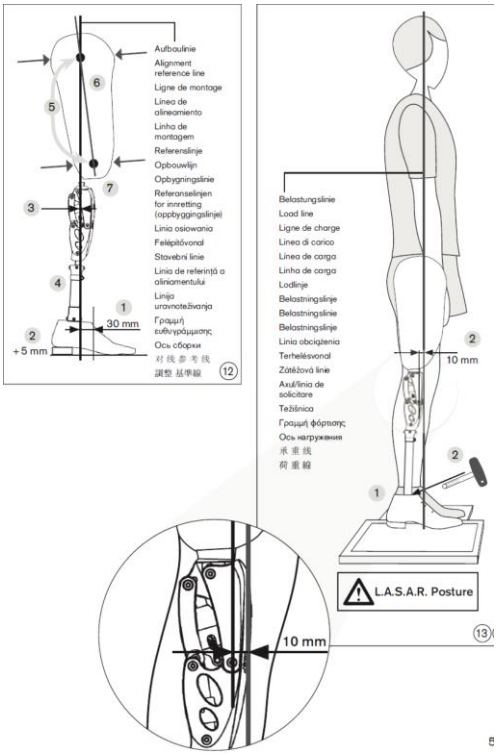


A patented rotary hydraulic design for stance phase stability and swing phase control distinguishes this modular knee joint from other hydraulic knee joints.

Stance phase damping is activated when bearing weight on the prosthesis. It provides for a secure heel strike and adjustable knee flexion under load (stance phase flexion up to 4° while bouncing and more than 4° while yielding). This special kind of stance phase control allows the user to walk down inclines or stairs step over-step.

The rotation principle also offers decisive advantages for swing phase control. Adjustable extension and flexion damping allows comfortable walking over a broad range of gait speeds. An integrated extension assist spring creates an extension moment, which allows comfortable full extension in combination with the harmonious terminal damping.

3R60



The 3R60 EBS knee joint provides knee flexion up to 15° during heel impact. Stance phase flexion of the knee joint can be customised to any walking pattern. This relieves the residual limb, hips, and spine of the prosthesis wearer and results in additional stability.

An innovative hydraulic system controls the behaviour of the knee joint during the swing phase. The 3R60 allows easily initiated swing phase and can adapt to a wide range of walking speeds. Flexion and extension dampening can be separately and individually adjusted to the requirements of the prosthesis wearer.
The special polycentric structure makes it possible to sit down easily without targeted load relief, and also offers more ground clearance during swing-through. This contributes to enhanced safety and comfort.

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APPENDIX U

RESIDUAL PLOTS FOR L-TEST AND FSST