Real-time Electro-tactile Biofeedback for Amputee Gait Re-Training

by

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the Degree of
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STATEMENT OF ORIGINALITY

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Date: 6th December 2012
ABSTRACT

Biofeedback is a real-time training technique that involves measuring a physiological function and conveying information back to the patient, to help them learn to adjust their performance. Biofeedback is used successfully in many areas of neuromuscular rehabilitation and sports training. Lower limb amputees particularly present a need for augmented feedback. Following amputation the proprioceptive pathways required to regulate gait are impaired. During physiotherapy patients have a limited view of their body, and the physiotherapist may not be best physically placed to witness gait changes. Outside the clinic patients often adopt poor walking patterns, such as circumduction and abduction, which can lead to lower back pain and a reduced quality of life.

This work focused on the development of a biofeedback training system to assist in the reduction of habitual circumduction and abduction gait patterns seen in trans-femoral amputees. Guided by a review of the literature, a training system was developed that uses electro-tactile sensory stimulation to provide feedback of the patient’s thigh motion whilst they walk on a treadmill.

A greater understanding of the psychophysical response to electro-tactile stimulation was required in order to present discernible information in a safe and comfortable manner. Thirteen healthy subjects were therefore recruited into a study that found thresholds of perception and discomfort to stimulation around the thigh. The study also found that subjects were able to discriminate the location of stationary stimuli and the speed and direction of moving stimuli whilst laying supine, flexing and extending the leg, and walking on a treadmill. By correctly identifying the numbered electrode locations they demonstrated an ability to perceive spatially coded information presented to the thigh using electrical stimulation.

A camera-based motion capture system was incorporated into the completed biofeedback system, and software was written to capture kinematic data in real-time. To enable the calculation of feedback stimuli, a 3-dimensional biomechanical model was constructed and the patient’s hip joint angles were compared to a joint angle reference database. Kinematic event detection made it possible to deliver the electro-tactile stimuli in relation to the users gait.

Four amputees tested the biofeedback system and reported positively on the experience. The subjects did not walk with a circumduction gait, so it was not possible to assess the therapeutic effects of the system. However they were able to perceive and understand the feedback stimuli, relate the information to their movement, and in some cases make positive changes to their gait. Sensation threshold levels and the ability to discriminate stimuli were also found in the amputee group to be comparable with the non-amputees.

This work has potential to become integrated into prosthetic components, and can be adapted for use with a broader range of patient groups with upper and lower limb movement disorders. The analysis software has potential to be further developed to provide real-time interpretation of gait patterns.
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Conference Papers and Reports

Electro-tactile sensation thresholds for an amputee gait-retraining system
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3rd Annual Conference of the International Functional Electrical Stimulation Society (UK and Ireland Chapter). University of Birmingham, UK. 2012

Helping Amputees to Walk Naturally
WEBB, G.D. EPSRC Pathways to Impact Case Study 2011

Electrotactile feedback for trans-femoral amputee gait re-education
WEBB, G. D., GHOUSSAYNI, S. & EWINS, D. J.
1st Annual Conference of the International Functional Electrical Stimulation Society (UK and Ireland Chapter). University of Salford, UK. 2010

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<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIM</td>
<td>Automatic Identification of Markers</td>
</tr>
<tr>
<td>ASIS</td>
<td>Anterior Superior Iliac Spine</td>
</tr>
<tr>
<td>BFB</td>
<td>Biofeedback</td>
</tr>
<tr>
<td>COG</td>
<td>Centre of Gravity</td>
</tr>
<tr>
<td>COP</td>
<td>Centre of Pressure</td>
</tr>
<tr>
<td>CNS</td>
<td>Central Nervous System</td>
</tr>
<tr>
<td>CPG</td>
<td>Central Pattern Generator</td>
</tr>
<tr>
<td>DM</td>
<td>Direct Method</td>
</tr>
<tr>
<td>DOF</td>
<td>Degree Of Freedom</td>
</tr>
<tr>
<td>EEG</td>
<td>Electroencephalography</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>EPP</td>
<td>Extended Physiological Proprioception</td>
</tr>
<tr>
<td>ET</td>
<td>Electro-Tactile</td>
</tr>
<tr>
<td>ETD</td>
<td>Electro-Tactile Display</td>
</tr>
<tr>
<td>FES</td>
<td>Functional Electrical Stimulation</td>
</tr>
<tr>
<td>GCS</td>
<td>Global Coordinate System</td>
</tr>
<tr>
<td>GOM</td>
<td>Global Optimisation Method</td>
</tr>
<tr>
<td>GPIO</td>
<td>General Purpose Input Output</td>
</tr>
<tr>
<td>GRF</td>
<td>Ground Reaction Force</td>
</tr>
<tr>
<td>HJC</td>
<td>Hip Joint Centre</td>
</tr>
<tr>
<td>HMD</td>
<td>Head Mounted Display</td>
</tr>
<tr>
<td>IC</td>
<td>Initial Contact</td>
</tr>
<tr>
<td>KJC</td>
<td>Knee Joint Centre</td>
</tr>
<tr>
<td>KP</td>
<td>Knowledge of Performance</td>
</tr>
<tr>
<td>KR</td>
<td>Knowledge of Results</td>
</tr>
<tr>
<td>LCS</td>
<td>Local Coordinate System</td>
</tr>
<tr>
<td>LLM</td>
<td>Limb Load Monitor</td>
</tr>
<tr>
<td>PIC</td>
<td>Peripheral Interface Controller</td>
</tr>
<tr>
<td>PSIS</td>
<td>Posterior Superior Iliac Spine</td>
</tr>
<tr>
<td>PWM</td>
<td>Pulse Width Modulation</td>
</tr>
<tr>
<td>QTM</td>
<td>Qualysis Track Manager</td>
</tr>
<tr>
<td>RT</td>
<td>Real-Time</td>
</tr>
<tr>
<td>SOM</td>
<td>Segmental Optimisation Method</td>
</tr>
<tr>
<td>TDMS</td>
<td>Technical Data Management Streaming</td>
</tr>
<tr>
<td>TO</td>
<td>Toe Off</td>
</tr>
<tr>
<td>TPTT</td>
<td>Two Point Touch Threshold</td>
</tr>
<tr>
<td>TTL</td>
<td>Transistor-Transistor Logic</td>
</tr>
<tr>
<td>VR</td>
<td>Virtual Reality</td>
</tr>
<tr>
<td>VT</td>
<td>Vibro-Tactile</td>
</tr>
</tbody>
</table>
Chapter 1

Introduction
Chapter 1: Introduction

1.1 Background

Approximately 5000 new referrals are received every year in the UK for limb amputations, as a result of pathologies such as bone cancer, diabetes and vascular diseases, or in cases of trauma and intractable pain (National Amputee Statistical Database 2009). Amputees are fitted with prosthetic limbs soon after surgery and undergo a period of intense physiotherapy as part of their rehabilitation.

Lower limb amputation not only results in reduced mobility but also a loss of the sensory neural pathways that provide a sense of limb positioning and identity. Patients also commonly experience neurological problems such as phantom limb pain for years after surgery.

Current gait re-education techniques used with amputees focus on the use of hands-on physiotherapy in a rehabilitation gym, with the aid of parallel bars, mirrors, and standard gymnasium equipment. This places a heavy demand on physiotherapist’s time. Spatially, therapists have a restricted view of the patient’s walking pattern and often lack quantitative information to guide therapy, this makes it difficult to convey information regarding kinematic alterations to the patient.

Outside the clinic patients do not have access to the expert guidance of physiotherapists and often adopt a variety of habitual and compensatory gait patterns. These can lead to lower back pain, slower walking speeds, greater energy expense and a reduced quality of life (Murdoch and Bennett Wilson 1996; Schoppen 2002). There is therefore a need to enhance the sensory feedback received by amputees throughout the gait re-training process.

This work initially focuses on a specific gait pattern known as circumduction, which is a tri-planar movement of the prosthetic leg swinging in a wider than normal lateral arc to prevent the foot striking the floor (Jaegers, Arendzen et al. 1995). This compensation strategy is used for a number of reasons, for example in people who have a limited range of motion at the knee, by those who lack confidence using their prosthesis, or those with a leg
length difference. Circumduction results in an asymmetrical movement of the pelvis and lumbar spine during walking. Excessive transverse rotation of the pelvis has been linked to an increase in lumbar pain experienced by trans-femoral amputees.

To assist in the correction of circumduction, a training system was explored which is based on a technique called biofeedback. Biofeedback (BFB) is a training technique that uses instrumentation to measure a physiological process and present information back to the patient whilst they are undergoing training. Biofeedback has been used successfully in other areas of neuromuscular rehabilitation and in gait re-training with promising results for a range of patient groups (Huang, Wolf et al. 2006). But it has not been adopted in clinical practice in amputee gait re-training. The use of biofeedback may help improve the level of awareness of limb positing for amputees, and reduce the occurrence of detrimental gait patterns such as circumduction.

1.2 Aims, Objectives and Hypothesis

The wider ambition this work falls within is to develop the field of real-time biofeedback for use with a range of patient groups during rehabilitation. This project focused on a specific aspect, the practicality of using electro-tactile feedback to assist in the reduction of circumduction and abduction gait patterns of trans-femoral amputees. The overall hypothesis was therefore:

*Real-time electro-tactile feedback is a viable method of assisting in the reduction of circumduction and abduction gait patterns in trans-femoral amputees.*

To provide an electro-tactile stimulus suitable for gait re-training, knowledge of the physiological response to electro-tactile stimulation of the thigh was required, for a range of neuromuscular states. The following additional hypotheses are also presented and are developed further in Chapter 5.
A non-painful sensation range exists around the thigh between the thresholds of perception and discomfort, during a range of neuromuscular conditions.

Subjects are able to discriminate between different electro-tactile stimulus locations around the thigh, during a range of neuromuscular conditions.

Subjects are able to discriminate different speeds of electro-tactile stimulus movement, during a range of neuromuscular conditions.

Subjects are able to discriminate the direction of electro-tactile stimulus movement, during a range of neuromuscular conditions.

To challenge the overall hypothesis the following objectives were defined, and formed a program of research for this work:

1. To review the principles and previous uses of biofeedback in neuromuscular rehabilitation, to underpin this and future research.

2. To select the most appropriate method of presenting feedback to trans-femoral amputees.

3. To design and build a biofeedback training system that can be used with trans-femoral amputees during rehabilitation. This was broken down into the following specific objectives:

   3a. Design and build an electrode array capable of delivering an electro-tactile stimulus to lower limb amputees.
   3b. Design and build an electrical stimulator capable of providing a sensory stimulus suitable for gait re-training.
   3c. Develop a physiological measurement system to provide real-time movement data to inform the correct application of the feedback stimulus.
3d. Provide a user interface to the system, and feedback about system operation and patient performance to users with a clinical background.

4. To investigate the response and practicalities of using the proposed training system with unilateral trans-femoral amputees.

1.3 Structure of the Thesis

Following from this introduction, Chapter 2 provides the knowledge underpinning this work. The clinical problem is presented in greater detail. The current topics in biofeedback are discussed through a thorough literature review, noting the limitations and shortfalls. Focus then turns to the uses of electrical stimulation as a means of presenting feedback.

Chapter 3 brings together the lessons learnt through the review and sets out the research approach taken in this work.

Chapter 4 describes the design of a stand-alone sensory electro-tactile stimulator and an electrode array for sensory stimulation. The physiological sensation thresholds produced by these devices are determined in a study of healthy subjects and described in Chapter 5.

Chapter 6 describes in detail how the electro-tactile stimulator was incorporated with a motion capture system to produce a real-time biofeedback training system. The Chapter describes some of the challenges met in handling gait data in real-time and how these were addressed. Chapter 7 then presents a pilot study investigating the practicalities of using the real-time system with a group of amputees.

Chapters 8 and 9 conclude the work by summarising how the aims were satisfied, and leading into a discussion on the limitations of this work and the potential for future research.
Chapter 2

Background and Literature Review
2.1 Introduction

This Chapter briefly introduces gait and the broader aspects of sensory loss, before presenting circumduction as the specific case example addressed in this work. Biofeedback is then presented as a technique with the potential to assist patients who experience sensory loss and adopt poor gait patterns. The key topics in biofeedback are discussed in-depth using a range of applications in rehabilitation, before turning attention to the application of electro-tactile biofeedback for amputee gait re-training. The issues and potential to use biofeedback in the correction of circumduction are then discussed. The purpose of this Chapter is therefore to provide a theoretical background and understanding of the literature in the area of research tackled in this work.

2.2 Clinical Problem

2.2.1 Normal gait

Gait is a natural method of mobility in humans and a determinant in quality of life. The upper and lower limbs and the trunk support gait and posture, but efficient gait is primarily the product of the synchronised action of the lower limbs. They provide the means of locomotion, shock absorption, efficient use of energy and stability. The body is often described in terms of segments; the pelvis segment comprises the sacrum, coccyx and hip bones which form the pelvic girdle, supports the vertebral column and provides muscle attachment points and articular surfaces for the femur. The femur, tibia and fibula form the thigh and shank segments respectively. The patella increases mechanical advantage about the knee joint. The foot segment provides a floor contact surface, shock absorption and a pivot for the progressing limb. Many muscles act about each joint and serve dual or more purposes, for example, the biceps femoris is a hip extensor and knee flexor. Lower limb muscles are innervated by branches of the lumbar and sacral plexus. Variations in anatomy can be found across a range of normal subjects.

For the purposes of conventional clinical gait analysis the hip joint is often described as a ball and socket joint, and the knee and ankle joints are described as pin or hinge joints.
This is a simplification because the knee joint is polycentric and the talocrural joint (which is formed of three articular surfaces) changes geometry under varying loads. Relative joint angles between limb segments are the net result of muscle activity, limb inertia and external forces (such as gravity and the ground reaction force). Comparison of joint angles between normal and study groups is often made in gait analysis to aid clinical decision making in rehabilitation medicine, or in the evaluation of prosthetic and orthotic component performance.

Gait is often described as a cycle, as shown in Figure 1, from one event (such as initial contact) to the subsequent event by the same limb.

<table>
<thead>
<tr>
<th>Initial Contact</th>
<th>Loading Response</th>
<th>Mid Stance</th>
<th>Terminal Stance</th>
<th>Pre Swing</th>
<th>Initial Swing</th>
<th>Mid Swing</th>
<th>Terminal Swing</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%†</td>
<td>0-10%*</td>
<td>10-30%</td>
<td>30-50%</td>
<td>50-60%</td>
<td>60-73%</td>
<td>73-87%</td>
<td>87-100%</td>
</tr>
<tr>
<td>Initial double limb stance</td>
<td>Terminal double limb stance (contra-lateral foot)</td>
<td>Double limb stance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight Acceptance</td>
<td>Single Limb Support</td>
<td>Limb Advancement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STANCE</td>
<td>SWING</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 1 Phases and events of the gait cycle, from Perry (1992) *percentages are typical values only, †Initial Contact is an event, not a gait phase

Lower limb kinematic data are typically presented graphically in three planes for the pelvis, hip, knee and ankle joints. Data are normalised to the gait cycle as a percentage and represented on the x-axis from one gait event to the subsequent event on the same foot (the initial contact event is typically used).
An example is shown in Figure 2 for the sagittal plane. The green traces in Figure 2 indicate the mean of a normative reference, whilst red and blue traces in this case indicate the mean values from a patient with and without the use of a clinical intervention. The shaded bands show ±1 standard deviation of the mean. Variation in the data is typically lowest in the sagittal plane, and increases in the coronal and transverse planes. This is due to the scale of the movement and limitations of the measurement system (discussed later in Section 3.2.2).

Figure 2 Relative joint angles in the Sagittal plane normalised to gait cycle

A normative dataset is shown in Figure 3, with a number of pertinent features in the sagittal plane highlighted. As the foot makes contact with the floor a controlled plantarflexion occurs at the ankle, providing shock absorption (1). The knee then flexes during loading response (2) as weight is transferred to the stance limb. The shank rotates over the ankle during the single limb support phase as the contralateral limb swings forward. A strong plantarflexion moment is produced about the ankle (3), providing the propulsive thrust to propel the body forwards. This is followed by a rapid dorsiflexion to prevent the foot striking the floor, as the hip and knee swing the leg forward (5) and (4). Movements in the coronal and transverse planes are less distinct and of a lower magnitude, and generally arise from the limb positioning and stabilising roles of the lower body segments.
Figure 3 Example of typical relative joint angles for the pelvis, hip, knee and ankle joints during overground walking.
2.2.2 The role of somatic sensation in gait

The somatosensory system provides a sense of limb positioning (proprioception), movement (kinesthesia) and an awareness of environmental constraints (perceived through touch, vibration, pain and heat). Somatosensation is facilitated by a range of specialist afferent nerve fibres. For example muscle spindles, Golgi tendon organs and several types of joint kinesthetic receptors make up the proprioception sense. Muscle spindles wrap around intrafusal muscle fibres and feedback information about skeletal muscle length. This is used by the stretch reflex mechanism to mediate firing of agonist/antagonist muscle pairs to prevent muscle overstretching. Golgi tendon organs encapsulate sensory nerve endings and collagen fibres within tendons. They detect and protect against excessive tension in the tendon and associated muscle. Joint kinesthetic receptors are located within synovial joint capsules and include lamellated corpuscles, which detect joint acceleration and deceleration, whilst various cutaneous mechanoreceptors and free nerve endings detect pressure, touch, pain and stretch (Tortora and Derrickson 2006; Windhorst 2007).

Somatosensory feedback is thought to regulate central pattern generators (CPGs), which are networks of spinal interneurons believed to generate the rhythmic motor neuron firing sequences required for locomotion (Dietz 2002). Nielsen (2003) summarises three areas where sensory feedback has a role in the control of human walking: 1) Direct input to motor neurons without CNS involvement. Sinkjör et al. (2000) found that when a foot with a peroneal nerve block was suddenly plantarflexed using a mechanical platform, the plantar flexion muscle activity significantly reduced following a short latency. This supports the idea of a direct role for feedback without CNS involvement. 2) Contributing to corrective reflexes following sudden perturbations. An example of this is the crossed-extensor reflex, where upon reception of a pain stimulus, flexors contract to withdraw the limb and contralateral extensors contract to support the body. 3) Providing error signals that inform the CNS of differences between the intended movement and the movement actually executed. This may be used for motor learning and refining future movements.

In a wider sense somatosensation aids the sense of embodiment, a feeling of identify a person has through the space their body occupies (Gallagher 2001).
2.2.3 Loss of somatic sensation in gait

A number of pathologies can impair the somatosensory pathways and lead to a movement disorder. These are notably the peripheral nervous system disorders and neuropathies that cause degeneration of the nervous system, either through peripheral demyelination, as in the case with Guillain-Barre syndrome; through spinal nerve degeneration seen in patients with Friedreich’s ataxia, Multiple Sclerosis and Motor Neurone Disease; or in the genetic or congenital malformation of sensory pathways as with Charcot-Marie-Tooth syndrome or spina bifida respectively. Traumatic causes of sensory loss, or parasthesia, can range from a single nerve entrapment to part or whole limb amputation. Removal of a limb clearly causes significant impairment to sensory feedback pathways.

Conditions leading to the removal or disarticulation of a limb are broadly grouped into vascular and traumatic causes. Dysvascularity accounted for 72% of amputations in the United Kingdom from 2006 to 2007, predominantly as a result of diabetes and arteriosclerosis (National Amputee Statistical Database 2009). Other common causes include trauma, infection, neoplasia, congenital limb deformities and neurological disorders. In planning the surgical procedure an important aim is to amputate as distally as possible in order to preserve the natural biomechanics and sensory pathways. This is balanced against the likelihood of progression proximally of infectious pathologies. The technical challenge of providing a functional limb is also made easier if a through-bone procedure is carried out. It can therefore be seen from Table 1 that the majority (53%) of amputations in the UK from 2006 to 2007 were trans-tibial.
Table 1 Incidence of lower limb amputations in the United Kingdom during 2006-07 by level and cause (National Amputee Statistical Database 2009)

<table>
<thead>
<tr>
<th>Level of amputation</th>
<th>Total / (percentage)</th>
<th>Cause of amputation</th>
<th>Total / (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemipelvectomy</td>
<td>14 (0.3)</td>
<td>Dysvascularity</td>
<td>3300 (72.1)</td>
</tr>
<tr>
<td>Hip disarticulation</td>
<td>26 (0.6)</td>
<td>Infection</td>
<td>356 (7.8)</td>
</tr>
<tr>
<td>Trans-femoral</td>
<td>1788 (39.1)</td>
<td>Trauma</td>
<td>337 (7.4)</td>
</tr>
<tr>
<td>Knee disarticulation</td>
<td>57 (1.2)</td>
<td>Other</td>
<td>232 (5.1)</td>
</tr>
<tr>
<td>Trans-tibial</td>
<td>2411 (52.7)</td>
<td>No data provided</td>
<td>173 (3.8)</td>
</tr>
<tr>
<td>Ankle disarticulation</td>
<td>14 (0.3)</td>
<td>Neoplasia</td>
<td>120 (2.6)</td>
</tr>
<tr>
<td>Partial foot</td>
<td>51 (1.1)</td>
<td>Neurological</td>
<td>56 (1.2)</td>
</tr>
<tr>
<td>Lower digits</td>
<td>17 (0.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral amputation</td>
<td>196 (4.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total amputations</td>
<td>4574</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

During the amputation procedure nerves are extended, transected and released to retract into the soft tissue where they serve no future purpose. In contrast to the management of peripheral neuropathies where nerve growth and the re-establishment of natural sensory pathways is encouraged, the neurological goals for amputation are more conservative and include a reduction in the incidence of pain, nerve entrapment and neuroma (Robinson 1991). As such amputees present a greater need for sensory augmentation.

2.2.4 Amputee gait

Gait abnormalities can be broadly categorised according to primary causes, secondary deviations and compensatory strategies. Primary causes may arise anatomically, from bone deformities, muscle weakness, pain, poor motor control (spasticity, hypertonicity and clonus) or from joint contractures. Poorly fitted or aligned prosthetic componentry is a major primary cause of gait deviations in amputees. Secondary deviations are subsequent limited or excessive movements. For example, a prosthesis with too much alignment stability or friction in the knee (a primary prosthetic cause) may make it difficult for the patient to bend the knee through swing. The patient may then adopt one or more compensatory strategies to accommodate the limitation (Beyaert, Grumillier et al. 2008; Grumillier, Martinet et al. 2008). In this example the patient may swing the prosthesis in a wide lateral arc to avoid floor contact during swing (a compensation known as circumduction).
Commonly recurring amputee gait deviations and their causes were identified from Berger (2002), Ham and Cotton (1991), Engstrom and Catherine (1985) and through discussions with specialist amputee physiotherapists at the Douglas Bader Rehabilitation Centre, Queen Mary’s Hospital (Roehampton). The underlying primary causes of a non-biomechanical nature (e.g. those anatomical primary causes which may be associated with a loss of sensation) are as follows (a broader list is included in Appendix A):

- **Inadequate balance** (primary) may result in lateral trunk bending, uneven arm swing and step timing (secondary). The patient may move shoulders backwards in an effort to obtain better balance (compensatory), causing excessive trunk extension (secondary)
- **Fear, insecurity and lack of confidence** with the prosthesis (primary) may result in uneven step timing (secondary). Accompanied by uneven timing leads to uneven arm swing (secondary)
- **Fear of stubbing the toe** (primary) can lead to vaulting, abducted and circumduction gait patterns (compensatory). These lead to the habitual patterns of lateral trunk bending and excessive trunk extension, to aid progression of prosthesis in swing (compensatory). Uneven arm swinging and medial or lateral whips of the heel at pre-swing may also be a habitual consequence of propelling the prosthesis in a wider lateral arc
- **More power than necessary** may be being used to force the knee into flexion (compensatory) which can lead to uneven heel rise (secondary)
- **Driving the prosthesis into the walking surface too forcefully** to assure extension of the knee and avoid a fear of the knee buckling (compensatory) may lead to foot slap (secondary) and consequently a high terminal swing impact (secondary)
- **Extending the stump too vigorously at heel strike** leading to rotation of the prosthesis on heel strike (secondary)

These clinical observations suggest that the patients limited knowledge of the prosthetic limb movement and dynamics is a common underlying cause of non-biomechanical gait deviations, e.g. limited sensory feedback required to regulate balance; a poor representation of foot position required to guide floor clearance and initial contact, and a poor awareness of the forces required to propel the limb through the gait cycle.
Chapter 2: Background and Literature Review

The scientific literature concerning the amputee population is limited compared with other patient groups. It is known that energy expenditure increases when gait kinematics deviate from that seen in a normal population (Waters 1992), but the impact of adverse walking patterns on quality of life is not well understood. The progression into and the incidence of poor gait patterns are not well documented, nor have the causes and progression of habit formation been investigated.

Discussions with specialist amputee physiotherapists at the Douglas Bader Rehabilitation Centre highlighted that whilst poor gait and posture can be identified and corrected by therapists in the short period of post-operative gait re-training, established amputees returning for three-monthly assessments have been seen to habitually revert back to poor gait patterns.

Circumduction is a one such gait deviation that habitually returns in established transfemoral amputees. Circumduction involves a wider than normal lateral arc of the prosthesis during swing to prevent the foot striking the floor. This results in an asymmetrical movement of the pelvis and lumbar spine (Jaegers, Arendzen et al. 1995; Kerrigan, Frates et al. 2000). An increase in transverse rotation of the pelvis in trans-femoral amputees is a contributing factor to lower back pain (Morgenroth, Orendurff et al. 2010), and there is a higher prevalence of lower back pain in amputees compared to the general population (Kulkarni, Gaine et al. 2005).

In a survey of 255 established amputees Ehde (2001) found that 52% reported persistent and bothersome back pain. Of those 25% described the pain as a severe interference to their social, recreational, family and work activities. Prevalence rates have been reported as high as 62 – 94% in other studies (Ephraim, Wegener et al. 2005; Smith, Comiskey et al. 2008). Smith et al.(2008) surveyed 107 established amputees and suggested that of the 47.7% who reported back pain, the cause in 52.9% of the cases was due to postural and gait abnormalities. The locus of control, particularly for trans-femoral amputees, originates from the hip and pelvis. Correcting hip-related gait abnormalities such as circumduction could therefore result in improved kinematics distally, in overall gait symmetry and in a reduction of lumbar back pain.
2.2.5 Current approaches to amputee gait re-training

Amputee rehabilitation in the UK is provided in specialist centres by multi-disciplinary teams (MDTs), involving the patient and family, Physiotherapists, Prosthetists, Occupational therapists, a Consultant in rehabilitation medicine and often Biomedical Engineers. The MDT provides continued care through the patient’s pathway, starting prior to amputation in many cases, through to post-discharge. As such the team is familiar with the issues experienced by each patient at each stage and how those affect outcomes.

From a neurological point of view gait re-training is an ongoing process of establishing neuronal connections and weightings (Halsband and Lange 2006; Wolpaw and Carp 2006), which may have important consolidation periods during sleep and other non practice times (Song 2009). As with learning any motor task it is not currently possible to define when learning begins and ends, or indeed if there is an endpoint. To consider a new gait re-training therapy it is important therefore to consider the tasks leading up to formal gait re-training sessions, in addition to training and post-training activities.

In the initial stages patient instruction begins with stump care and dressing and progresses to attachment and care of the prosthesis, to standing and balance training (Murdoch and Bennett Wilson 1996). It became widely accepted during the 1960s that inactivity through post-operative convalescence increases stump oedema, restricts patient independence and lowers motivation (Redhead 1983). The emphasis on management then changed to early mobilisation (Robinson 1991). The Pneumatic Post-Ambulation Aid (PPAM) was developed in Roehampton to provide greater independence to elderly patients (Devas 1971). It supports and cushions the stump with an air-filled sleeve placed within a crutch, and became widely used across the UK for post-operative mobilisation (Scott, Condie et al. 2000). When the stump tissue has sufficient integrity devices such as the PPAM can be used to begin physiotherapy in earnest.

Physiotherapy forms the basis for gait re-training and there are many schools of thought that provide a theoretical underpinning to the techniques used. There is ongoing debate about the relative efficacy of named physiotherapy approaches and conformance to
different schools of thought. But whilst there is a lack of sufficient evidence to guide the choice of approach used (Pollock, Baer et al. 2007; Young and Forster 2007; Mehrholz, Kugler et al. 2008), they do present complementary ideas for the ongoing use of physiotherapy in gait re-training.

A variety of techniques are often combined during amputee gait re-training, with a focus on goal-directed functional tasks. These tend to progress from sitting to standing, to walking on a level surface with the aid of parallel bars, then with a walker, two sticks or crutches, then one stick, and finally walking unaided. To prevent contractures and to maintain joint range of motion in both the stump and good leg, amputees are encouraged to perform stretching exercises. Muscle tone is improved with the use of standard gymnasium equipment such as weights, exercise balls and elastic exercise bands (as shown in Figure 4).

Standing balance can be achieved by rocking mediolaterally and anteroposteriorly between parallel bars, to gain a feeling for the limits of stability. This process can be aided with the visualisation of the ground reaction force vector measured using force plates embedded into the floor and superimposed onto a video image of the patient (Tait and Rose 1979; Rowe 1996). Staff at the Gait Laboratory at Queen Mary’s Hospital provide a feedback session to amputees and therapists, where the ground reaction force is displayed in real-time. Loading symmetry and vector progression are then discussed with the patient and therapist, an example is shown in Figure 4. This is a form of biofeedback that will be discussed in more detail later.

Figure 4 Left: Resistive stretching exercise of hip extensors and adductors using an exercise band. From (Gailey 2008). Right: Video vector use at Queen Mary’s Hospital, with a left trans-femoral amputee who is undergoing appraisal of loading. The numbers and lines shown in white indicate the force through each plate.
Single limb balance can be improved by stepping up to a stool or standing on the prosthetic limb, whilst more advanced quick stepping, jumping and ball rolling exercises can be used to improve agility (Gailey 2008).

2.2.6 Limitations in amputee gait re-training

The British Association for Chartered Physiotherapists in Amputee Rehabilitation (BACPAR) recommend the following types of goals be set with the patient according to their needs: Getting on and off of the floor, getting in and out of a car, using public transport, walking up and down stairs, kerbs, ramps, slopes and escalators, walking in a crowded environment, carrying objects whilst walking, walking over uneven terrain outdoors, changing speed and direction, picking up objects from the floor and opening and closing doors (Broomhead, Dawes et al. 2003). Many of these tasks can be taught in the controlled environment of a clinic, but not all of the situations an amputee is likely to meet in daily life can be mimicked in this safe way, for example walking on snow or ice, cycling, stepping on and off a moving platform such as an escalator or boat. Details of the BACPAR recommendations for the prosthetic rehabilitation programme can be found in Appendix B.

There is heavy demand for physiotherapy during primary amputee rehabilitation, in terms of one-to-one contact time with a therapist and access to space and equipment. Therapy is often undertaken in groups with fewer staff than patients, placing a great emphasis on the therapist to motivate patients. The therapist has to be very observant and focused to consider the safety and individual clinical needs of a number of people.

Gait deviations manifest across multiple body segments, and are described in three planes. Spatially from the therapists perspective it can be difficult to identify the principle issues and convey information to the patient to guide training. Even with the use of mirrors it can be difficult for the patient to view their own gait, assimilate the guidance and act on it in real-time. Cole (2008) questioned 48 primary amputees over a 6 month period and found benefits of force visualisation during feedback training sessions for amputees and
therapists. This however requires access to force plates which are often not found in small centres.

Established amputees often have poor functional outcomes after discharge (Greive and Lankhorst 1996; Schoppen 2002) displaying asymmetry in temporal-spatial parameters, kinetics and kinematics (Jaegers, Arendzen et al. 1995; Bateni and Olney 2002; Berger 2002). Evans found that the level of functional mobility of amputees declined after 6 months post-discharge (Evans, Buttenshaw et al. 2003). It remains unclear why amputees revert back to poor gait patterns and postures.

The focus of much amputee research has been on biomechanics and prosthetic component development, with little or no work looking at the psychological aspects of gait re-training. Little is known about the patterns of behaviour outside the clinical setting. When does learning and habituation take place and how does that impact on the timing of therapy delivery? An important distinction should be made between learning, which is an internal process of cortical re-organisation and performance which is the ability to adapt to new tasks (Schmidt 1988). Often rehabilitation intervention studies report short-term performance gains whilst clinical goals require skill retention and long-term learning. Only recently with the use of functional magnetic resonance imaging have specific brain areas been seen to show activity during motor learning tasks (Doyon, Penhune et al. 2003) and in gait re-training (Cho, Shin et al. 2007).

Ideas in the field of physiological feedback control, or biofeedback (Miller 1974) may have the potential to address some of these shortcomings in clinical practice and progress rehabilitation science. There have been positive indications in the application of biofeedback to neuromuscular rehabilitation in the past few decades and a recent resurgence of interest in biofeedback (Basmajian 1981; Schleunbaker and Mainous 1993; Teasell, Bhogal et al. 2003; Huang, Wolf et al. 2006; Wilken and Darter 2009) and the allied field of virtual rehabilitation (Kenyon, Leigh et al. 2004; Rizzo and Kim 2005).

Biofeedback draws on a wide range of technologies which can be employed in different ways. The following sections will give a detailed view of the available technologies,
approaches used and the key issues in the field. The use of electro-tactile technology is then explored as a potential means of providing biofeedback to the problem of circumduction in amputees.

2.3 Biofeedback as a Potential Solution

2.3.1 Introduction to biofeedback

Biofeedback (BFB) is a technique that uses instrumentation to guide the self-regulation of bodily processes. Self-regulation has roots in early meditation where the self-control of breathing rates and thought processes were used to foster relaxation. It was believed that autonomic functions could be controlled, to slow heart rate and decrease oxygen consumption. This is only possible due to the ability of the brain to adapt and modify its structural organisation and function. Instrumented biofeedback emerged with developments in electronics in the 1950s and has since been defined as:

“a method of training which enables a person, mostly with the help of electronic equipment, to learn to control otherwise involuntary bodily functions”

(Lang 1979)

Magill (2007) defines two types of feedback: Task-intrinsic feedback which is provided by the visual, auditory, proprioceptive and tactile senses whilst performing or practising a skill; and augmented feedback (extrinsic or external feedback) which is information from an external source complementing task-intrinsic feedback. Magill furthers the definition as:

“a type of augmented feedback that provides information about physiological processes through the use of instrumentation”

A BFB system typically comprises four major components, as shown in Figure 5. A physiological process under training, a measurement system to capture the parameters of interest, an element of data processing and a means of presenting stimuli to the user.
Application examples will now be given to provide a broad awareness of the biofeedback components, their range and uses.

**A. Physiological processes**

Physiological processes can be described in terms of measurands, parameters such as a biopotential, pressure, flow, displacement, velocity, acceleration, force, impedance, temperature or chemical concentration (Webster 1998). Many and varied physiological parameters have been used in BFB systems. For example, heart rate variability and respiratory sinus arrhythmia have been modified using ECG and respiratory frequency BFB (Lehrer, Vaschillo et al. 2000) with application in the management of asthma (Lehrer, Vaschillo et al. 2004).

Direct measurement of blood flow with infra-red plethysmography (Speckenback and Gerber 1999) and indirect measures of blood flow using skin surface temperature have been fed back to patients to successfully relieve the symptoms of peripheral vascular
disorders, notably for people with migraine headaches and Raynauld’s disease (Karavidas, Tsai et al. 2006).

**B. Measurement System**

A measurement system is required to capture the physiological parameter of interest. Parameters relevant to rehabilitation fall broadly into three categories: electrophysiological, kinematic or kinetic. Electrophysiological applications were among the first to emerge in the history of BFB development and include electroencephalographical (EEG) and electromyographical (EMG).

**EEG BFB** - encompasses the field of neurofeedback, the aim of which is to assist the patient in modifying the amplitude and relative amplitude ratios of the signals arising from central nervous activity (the alpha, beta, delta, theta rhythms) (Basmajian 1983; Sterman and Egner 2006). Applications with demonstrated success have been found in the management of anxiety, attention deficit and hyperactivity disorder (Monastra, Monastra et al. 2002; Monastra, Lynn et al. 2005), seizures (Sterman and Egner 2006), pain (Sherman 2004), hypertension, substance abuse (Sokhadze, Cannon et al. 2008) and other psychophysiological disorders that benefit from assisted relaxation techniques, such as insomnia (Lynch, Jarvis et al. 2007).

**EMG BFB** - EMG has also been used extensively, from the early investigations into the control of single motor units (Basmajian 1963) to gross motor control in current clinical applications. Cleeland (1973) presented auditory BFB to successfully train the relaxation of neck muscle spasticity. Positive findings were supported by a controlled clinical trial with 12 patients with spasmodic torticollis (Jahanshahi, Sartory et al. 1991). Cleeland was among the first to provide negative BFB, in the form of an electric shock to the finger (Carroll 1984). Applications have also been demonstrated in the management of facial palsy (Toffola, Bossi et al. 2005), temporomandibular and neck pain (Crider, Glaros et al. 2005) and shoulder pain and instability (Gibson, Growse et al. 2004). Lower limb work will be reviewed in Section 2.3.2. Whilst it is not a routine therapy, EMG BFB is a
recognised option for the treatment of urinary incontinence (Glazer and Laine 2006), particularly in women (Thüroff, Abrams et al. 2006).

**Kinematic BFB** - Kinematics is concerned with the movement of body segments (joint angles, segment positions, orientations, velocities and accelerations) without consideration for the causes of motion. Tilt sensors have been used extensively to provide angle thresholds for auditory BFB to improve control of head posture of children with cerebral palsy. A typical setup follows that of (Leiper, Miller et al. 1981). Gyroscopes are commonly integrated with head mounted displays (HMDs) to provide information about head posture for virtual reality (VR) systems. Baram et al. (2002) used a tri-axial accelerometer with a semi-transparent HMD of a virtual floor to enhance environmental visual cues. In open-loop mode the floor appears floating before the patient, irrespective of head posture. Closing the loop, the accelerometer pins the floor to the ground which is then set to move towards the wearer at a pace determined by a body-mounted accelerometer. This gait initiation aspect of the “Audio-Visual Walker” has been trialled successfully for patients with Parkinson’s disease and is being made commercially available (Medi Gait Ltd, Massachusetts USA). The team are currently testing the use of a belt-mounted accelerometer to indicate step length, as an input for an auditory BFB device for patients with Multiple Sclerosis.

Electromechanical devices such as the “T-WREX” developed at the University of California (USA) and “Armeo” developed by Hocoma (Zurich) make direct measurement of upper limb kinematics and provide visual feedback in the form of games and virtual tasks. Housman et al. (2007) found an improvement in self-rated game performance in a small group of stroke patients using the T-WREX compared to a control.

Commercial devices such as the “Wii” games console developed by Nintendo (Kyoto, Japan) were intended for the entertainment market but are now being used in upper limb motor rehabilitation under the term “wiihabilitation” (Deutsch, Borbely et al. 2008). The wii remote control uses a tri-axial accelerometer to determine the position and orientation of the device held in the user’s hand; and an optical positioning system to determine the device location in space.
Whole body position measurement using global positioning systems (GPS) are under consideration as a BFB device during community ambulation and for gait measurements (Terrier and Schutz 2005). Sánchez et al. (2007) used GPS to determine and present a desired path for users with visual impairments, the data were converted to speech and presented audibly as clock face directions.

**Kinetic BFB** – Kinetics is concerned with the forces and moments causing segment movement. Commonly used parameters in BFB applications include ground reaction forces, plantar pressures, joint torques and powers, and internal forces such as the load through prosthetic components. A number of devices are used to facilitate robot-assisted movement therapy of the upper limb (Dobkin 2003), for example: the “MIT-MANUS” (from the Latin for hand) (Krebs, Volpe et al. 2007), the “Assisted Rehabilitation and Measurement (ARM) Guide” (Kahn, Zygman et al. 2006) and the “Mirror Image Movement Enabler” (MIME) which incorporates an off-the-shelf Puma robot, are electromechanical devices which provide haptic feedback by moving the user through a pre-determined trajectory. The “Lokomat” shown in Figure 6 employs similar principles to the lower limb, whereby joint torques are directly measured, amplified and fed back haptically with varying degrees of stiffness according to the rehabilitation goals (Lunenburger, Colombo et al. 2004; Riener, Lunenburger et al. 2004; Riener, Lunenburger et al. 2005; Lunenburger, Wellner et al. 2006).

![Image of Lokomat haptic biofeedback system](Hacoma, Zurich)
Commercially available limb load monitors and alarms, such as the PedAlert (Orbital Technologies Corporation, USA) and AccuTread (Orthopaedic Technology Research USA) utilise insole force sensing transducers to measure and feedback plantar pressure information. The SmartStep (Andante Medical Devices Inc, USA) has been evaluated with 42 patients with a range of pathologies, with an audible loading target as a BFB stimulus (Isakov 2007). Instrumented walking sticks, prosthetic pylons (West 2006) and walking frames have been used to measure internal forces and present data to aid load symmetry training.

Force plates have been used extensively with auditory BFB for standing balance training and, with visual BFB of the ground reaction force, for load symmetry and temporal-spatial symmetry training. A large number of force plate BFB studies have required patients to reduce the deviation of the centre of pressure (COP) whilst following a predefined trajectory, either on a fixed or moving virtual ‘magic carpet’ platform such as the “CAREN” (Barton, Holmes et al. 2006). Santarmou et al. (2006) found a small reduction in COP corrections with auditory feedback (measured with in-sole pressure transducers) of patients tracking the motion of a tilt board to a visual stimulus. COP tracking games are now commercially available en-mass with the “Wii fit” force platform and library of computer games for aerobic, balance and strength training.

**C. Data processing (signal processing, analysis and stimulus preparation)**

Data processing has been used with varying degrees of complexity to prepare the physiological parameter for presentation as a stimulus. In addition to signal processing, conditioning and preparation for specific stimulus modalities, the level of abstraction, timing of delivery and the clinical goal should also be considered in designing a biofeedback training system (Huang, Wolf et al. 2006).

The level of abstraction must be suitable for the training task and patient, for example unprocessed joint angle data may be suitable for one task or patient but may benefit from conversion to a more cognitively accessible format, such as a visual animation for one or a
musical scale for another. Some data formats may be more comprehensible than others, for example, a virtual body model or stick figure compared to raw EMG data.

When timing feedback delivery two terms are commonly used in the psychology literature: Knowledge of Performance (KP) and Knowledge of Results (KR). KP refers to information about the subject’s performance of the task, for example: the error between actual and target COP trajectory. Whilst KR refers to goal-oriented information received after the task. For example, the number of times a centre of pressure error trajectory deviated outside predefined limits, or simply a game score. KP and KR can be presented in real-time, intermittently during the task, at pre-defined or user-requested times (Wulf 2007), or at various periods after the task.

Goals include tracking a moving parameter (or modifying an auditory pitch), maintenance of a steady state target (keeping an animated car on a road), or attaining rewards within a game (such as collecting medals or points for sporting events within a console game).

Additional features referred to in previous work, include: libraries of tasks, facility to document and analyse long-term performance, feedback to therapists, report generation, network and multi-stimulus/multi-measurement system connectivity. Xu et al. (2006) have developed a software framework that manages the “dense summary of data” present in multi-modal BFB systems.

**D. Stimulus presentation methods**

Stimulus presentation methods are as many and varied as the measurement methods and cater for the senses of sight, sound, touch and proprioception. In brief, the following modalities have found clinical application in BFB systems:

*Visual* - 2D flat screens and projections are commonly used in clinical research and can be set up at relatively little cost in movement laboratories with existing motion capture hardware.
Figure 7 shows a typical setup of a visual feedback system, one that was used during the developmental work in this project.

![Hardware setup for typical 2D visual biofeedback system](image)

A treadmill is surrounded by an optical motion capture system, capturing the movement of a subject walking on a treadmill. A standard projector is used to project kinematic data onto a wall in view of the subject. An additional projector can be added to produce a 3D image with the aid of polarized glasses. Visual presentation has been extended to VR caves, which are enclosed projection rooms with varying levels of immersion (Patton, Dawe et al. 2004) and head-mounted displays, from an occluded field of view to semi-transparent data presentations. No work was found that uses autostereoscopic displays.

Bolek (2003) presented an interesting example of BFB for children with cerebral palsy, by terminating a rewarding movie if the tibialis anterior EMG activity did not fall within defined boundaries during treadmill walking. Positive but subjective carry-over results were reported in the two cases studied. This may be more commonly recognised as an implementation of classical conditioning.

**Auditory** - Free-field speakers and headphones have recently given way to visual displays as the most commonly used means of presenting BFB data. Speaker design suited earlier
and simpler analogue electronic BFB systems. Various mappings have been used, for example: Varniet et al. (2007) mapped the error angle (desired – target angle) from a tilt platform task to the frequency of a stimulus tone, and the angular velocity to acoustic intensity and demonstrated the efficacy of this mapping in the tilt platform task. Wellner (2007) mapped the time interval between pings to the distance to virtual obstacle, and tone pitch to absolute foot height and found an increase with acoustic BFB in self-paced walking speed through a virtual-haptic environment with the Lokomat.

**Electrical stimulation (electro-tactile)** - Not explicitly functional, but often referred to as functional electrical stimulation (FES). Information is presented either through stimulation at the skin surface, or with direct nerve stimulation using implanted or percutaneous electrodes. This modality was chosen for use in this work, and is discussed in greater detail in Section 2.4 and throughout the thesis.

**Haptic** - A number of tactile methods have been employed, including examples such as: micro-mechanical vibration ‘tactors’ applied to the shoulder and trunk to feedback head tilt (Wall, Weinberg et al. 2001); torque BFB of soleus EMG applied with a pneumatic air muscle (Gordon and Ferris 2007), and tactile manipulation of the lower limb using “ARTHuR” and “PAM” electromechanical manipulators during treadmill walking (Reinkensmeyer, Wynne et al. 2002; Reinkensmeyer, Aoyagi et al. 2004; Reinkensmeyer and Housman 2007). A range of haptic actuators with potential for use in BFB applications were identified and summarised by Pasquero. They include: capacitive elements, electro- and magneto-rheological fluids, piezoelectric devices, shape memory alloys, electric motors, hydraulic and pneumatic devices, peltier elements, and those based on ultrasound and acoustic waves (Pasquero 2006).

**Multimodal** - Combinations of stimulus modalities are increasingly being used, for example the use of haptic, visual and auditory feedback with the Lokomat, and the use of audiovisual feedback with consumer games consoles. However no research was found that identified the relative benefits of different modalities or the principles of using complementary modalities.
2.3.2 Applications of biofeedback in gait re-training

293 journal papers were identified that look at lower limb BFB from 1974 to 2012. These included 28 reviews and meta-analyses, 40 randomised controlled trials (RCTs) and clinical controlled trials (CCTs) and 225 case studies, ad-hoc studies and device designs. 59 document kinematic work, 49 kinetic and 29 EMG studies. The earliest papers follow developments in EMG biofeedback, whilst kinetic and kinematic applications have grown to become the most common themes today. No patterns were found with the stimulus type except for the increasing use of the words ‘virtual reality’ in place of visual BFB. There is a large body of data on the use of force plates for sway measurement and standing balance re-training.

A range of examples now follow that demonstrate how BFB has been used in a gait re-training context. They follow the progression of the physiotherapy activities experienced during gait re-training.

Looking first at seated balance, a training system was presented by Dursan (1996) for stroke patients, which uses a mercury tilt switch strapped to the patient’s trunk. Auditory BFB was provided in the form of a buzzer, to help patients correct their posture. An experimental group (n=24) received 30 minutes of BFB training and 2.5 hours of conventional physiotherapy per day for 10 days. The number of tilt activations were compared against those in a control group (n=13), who also wore the device but received only conventional therapy. 75% of the experimental group gained independent seating balance after the 10 day trial, compared to 15% of the control group. Criteria for descriptors such as ‘good seating balance’ were not defined.

Many standing balance systems based on force plates and visual targets have been presented, such as (Chen, Cheng et al. 2002), (Rougier 1999; Rougier 2004), (Keshner, Kenyon et al. 2004). A Cochrane Review of 7 standing balance studies concluded that force platform balance trainers with auditory or visual BFB improved stance symmetry but not sway in standing (Barclay-Goddard, Stevenson et al. 2004). This conclusion was drawn in part from a standing BFB trainer by Wong et al. (1997), which incorporates two
force plates with a standing table, and a forearm suspension system to unload the upper body.

Mirelman (2007) studied the contribution of a VR cue in the goal-directed repetitive training with a Stewart platform in ankle rehabilitation (the Rutgers Ankle Rehabilitation System). The platform provides open-loop force-feedback to each ankle in planta/dorsiflexion and inversion/eversion. 18 people with hemiparesis caused as a result of stroke participated in an RCT. Experimental and control groups were required to undertake various tasks (warm-up, endurance, speed tests and warm-down) with and without virtual reality feedback. The experimental group trained with the robot-VR system, whilst the control group trained with the robot alone. Virtual tasks included manoeuvring simulated boats or aircraft towards targets presented at various locations and times. The control group received a metronome beat to progress through the tasks. KP and KR feedback was also provided verbally to both groups at subject-selected intervals. Fatigue was assessed with a Visual Analog Scale, the number of verbal commands was recorded, and instrumented gait analysis was carried out to determine walking speed and a range of hip, knee and ankle kinetic parameters pre- and post-test and at an unspecified follow-up time, with and without AFOs. Mirelman reported significant increases in kinetic parameters and average training times with VR-BFB and an increase in perceived fatigue without VR-BFB. The results supported the hypothesis that a VR stimulus has an engaging effect on repetitive task-based ankle rehabilitation.

To test the hypothesis that a rhythmic tone is more pleasing than an aperiodic tone, Baram and Miller (2007) used a belt-mounted accelerometer to trigger a ticking sound every time the wearer takes a step. 14 patients with multiple sclerosis and 10 healthy subjects were recruited in a control trial. Subjects took four 10 m walks: with no BFB, with BFB and post test no BFB. There was only a 10 minute break after BFB before the no-BFB carry-over walk test. Walking speed and stride length were reported, with 12.8% improvement in walking speed with BFB and 18.8% carry-over improvement; and 8.3% increase in stride length with BFB and 9.9% carry-over increase. In discussing the differences between auditory and visual feedback, Baram notes that auditory BFB is markedly faster making it
suited to stability mechanisms whilst the nature of video BFB allows prediction of higher level information.

Montoya (1994) used a pulley system to determine the foot position of stroke patients walking on a instrumented walkway, and employed two light bars parallel to the direction of gait progression to provide (bilateral) feedback targets. Acoustic feedback was provided in the form of a single short tone to indicate deviation from a desired step length. The programmed desired response was an equal step length calculated on a step-by-step basis according to the previous step length. Nine hemiparetic patients in an experimental group were required to traverse the 6 meter walkway at a self-selected walking speed once without BFB, then ten times with BFB based on the initial baseline step length, followed by one traverse during which post-BFB measurements were taken. A control group of 5 hemiparetic patients carried out the same walking trials with no BFB and no placebo. Each subject carried out eight sessions, with two sessions per week. Montoya showed a significant difference between BFB and control groups with an increase in paretic step length. Symmetry was not reported and data not provided to calculate symmetry. Montoya chose step length because preliminary tests showed step frequency to be harder to modify. The work provides some evidence to support the principle of applying kinematic BFB for hemiparetic patients.

A number of studies involving virtual reality are currently ongoing which use body mounted accelerometers to control a variety of parameters, for example: Koritnik (2008) uses the movement of the thigh and shank of patients carrying out stepping-in-place tasks standing in front of a projected virtual body model. Head posture of patients walking through a virtual citiescape on a treadmill with a training avatar has been used to increase immersion (Tierney, Crouch et al. 2007). Fung et al. (2006) use an instrumented self-paced treadmill to control movement through virtual scenarios, such as a street crossing, cityscape and a park.
2.3.3 Amputee specific biofeedback

Biofeedback and virtual reality has found use in phantom limb pain reduction (Brodie, Whyte et al. 2003; Murray, Patchick et al. 2006) by ‘re-embodying’ patients, most famously with the mirror box work by Ramachandran (1996). In addition to the use of mirrors (Erbahceci, Yigiter et al. 2001) and bathroom scales, research into amputee biofeedback has followed a number of distinct themes, from auditory and electrical stimulation feedback of prosthesis loading during standing and walking, treadmill work and more recently with the use of virtual reality.

The Limb Load Monitor (LLM) was perhaps the first lower limb amputee feedback device, and comprises an insole pressure sensor and audio feedback that can be presented in two modes. In ‘mode 2’ a decreasing frequency proportional to limb load is presented (KP), until silence is reached (KR) at the desired goal. In ‘mode 3’ the device is set at a calibrated load level and increasing frequency denotes increased loading (KP) (Wannstedt and Craik 1978; Wannstedt and Herman 1978). Wannstedt (1978) conducted a preliminary study of weight-bearing symmetry with 40 patients who had experienced cerebrovascular accidents, after a period of training Wannstedt found that symmetry was retained in 14 of the subjects after 1 month. Note: The presence or function of a “mode 1” was not reported.

Wannstedt (1978) then conducted a multi-centre study with 44 amputees and 37 patients with hemiplegia. Questionnaires aimed at assessing patient and therapist perceptions were distributed to 9 participating clinics in the United States. Therapists used their judgement to decide who should use the LLM and how the device should be used. The LLM was used with a mean of 4 to 7 treatment sessions per patient (stroke and amputee respectively), for 20 to 60 minutes per session. Amputees were reported to have benefitted more. 79% of completers were “judged to have improved” loading ability according to therapist comments. In 15% of the patients judged to have improved there was a reported lack of pain. 84% of amputees and 68% of stroke patients achieved their goals. Lack of success was attributed to equipment malfunctions, lack of patient cooperation and inability to understand stimulus. The authors conclude that the LLM was a useful tool in the clinical
setting and the largest group who could benefit were amputees, followed by hemiplegic and orthopaedic patients.

Gapsis (1982) used the LLM in a study with a variety of patients undergoing physiotherapy (2 femoral and 2 hip fracture, 3 below-knee (BK) and 1 above-knee (AK) amputee, 1 hip replacement and 1 patient in chronic pain) and with 10 age and pathology matched control subjects undergoing physiotherapy alone. The device was used daily during physiotherapy. The goal was set initially to 10% of body-weight and increased daily according to clinical judgement. Time to reach load-bearing symmetry was recorded. The study group took 7 days and the control group took 14 days. The authors concluded that the LLM could shorten time to weight-bearing goals. Progression towards symmetry was determined by the number and size of increments at each session according to the therapist, so therapist involvement, patient motivation and pain suppression were confounding factors.

However when looking at postural sway, a study with 8 below-knee amputees Gauthier-Gagnon (1986) found that the LLM when used in conjunction with physiotherapy was no more beneficial than physiotherapy alone. The authors noted however that the device provides quantitative information about limb loading that was useful for the therapy team.

Pressure sensors at the heel and toe were used by Ark (1982) with audio feedback provided using tones of decreasing frequency at heel strike, and increasing frequency at toe off. A preliminary case study demonstrated the usefulness of the ‘musical’ feedback to the patient and therapist in identifying gait event timing. However there is the possibility that patients would not wish to use a device in the community that produces audible tones and thus singling them out.

Cullen (1984) developed a device that used a combination of prosthesis load and hip extension angle feedback to assist above-knee amputees gain confidence swinging their prosthesis. The device used a novel radio-goniometer developed to measure hip angle, and feedback was provided as either a simple beep when a threshold had been reached, or as a varying tone with a pitch proportional to the parameter being measured (an angle or load). Flowers et al. (1986) gave the device to five amputees to use over a four month period.
From observation and discussion with therapists after the study, Flowers described a number of technical improvements, drawing a distinction between performance evaluation and user issues. He commented that the ideal biofeedback device should be ubiquitous, wireless, employ remote sensors and provide greater control of the parameters to therapists, in order to increase the chances of clinical acceptance.

Load through the prosthesis is a common feedback parameter in amputee work and a number of instrumented pylons have been employed in various audio devices with amputees (King, Gerhardt JJ et al. 1972; Moore AJ and Byers JL 1976; West 2006), such as that shown in Figure 8. This combination of technology may have an important role to play in the protection of the residual limb, which is of particular importance for patients with osseointegrated components (Sullivan, Uden et al. 2003; Lee, Lin et al. 2007).

Chow and Cheng (2000) attached two single axis strain gauges to the longitudinal axis of the shank tube perpendicular to each other. A tone sounded when a preset loading threshold was reached. Six unilateral amputees were asked to stand and load their prosthesis and to walk with and without feedback, with an increasing loading regime for five days postoperatively. Without feedback subjects significantly exceeded the prescribed
targets for the first two days, loading fell below target when feedback was used. Variation in load bearing was also greater without feedback over the five day period.

Previous pressure and force sensing training systems, with the exception of West (2006), have used audio only feedback. This has practical justification for patients focusing on training in a clinic where the auditory stimulus does not distract the user from hazards. But there is little evidence for choosing to augment or replace a distal cutaneous sensation from an ascending pathway, with tones and beeps perceived through a central nervous system and a descending pathway. Zamarbieri (1998) describes a device that presents an information subset from plantar pressure trajectories to patients visually with a computer monitor, audibly through desktop loudspeakers and haptically from four vibrators placed on the thigh segment. Unfortunately no further details have been reported.

The devices described so far are body-worn. Dingwell and Davis (1996) demonstrated the feasibility of using an instrumented treadmill and real-time visual feedback for gait symmetry training with amputees. 6 established unilateral amputees and 6 controls were asked to walk for four minutes without feedback. The amputee group were then asked to walk for four minutes each with and without three different visual BFB presentations: A COP trajectory, and bar graphs with text showing percentage stance times and relative push off force. Subjects receiving feedback were asked to achieve symmetry. Significant differences in symmetry were noted between the normal and amputee groups in percentage stance time, single support time and push off force, which is in agreement with previous authors. Significant improvements were also seen with each of the feedback parameters. The authors note that it is not known if the amputees would maintain a decreased asymmetry without visual biofeedback, or what effects the biofeedback would have on long-term retention and learning. It is interesting to note that the choice of feedback presentation modes used by Dingwell and Davis bears little spatial relationship to the task. This is discussed further in Chapters 3 and 4 when considering the application of a BFB stimulus.

A recent research strand centres on a commercially available electro-mechanical device called the Computer Assisted Rehabilitation Environment (CAREN, Motek Medical,
Amsterdam). CAREN comprises a force sensing treadmill on a Stewart platform which permits walking and postural movements in a 6 degree-of-freedom space. The system is used in conjunction with an optical motion capture system and a projector screen, so it can be configured to allow audiovisual biofeedback of whole body kinematics, EMG or kinetic parameters.

A CAREN installed in the Walter Reed Army Medical Center (WRAMC) in Washington DC is being used with amputee service personnel. Kruger et al. (2009) reported a case of one bilateral patient (right knee disarticulation, left trans-tibial) who trained using a CAREN with audiovisual biofeedback 16.5 months after surgery. Gait analysis was conducted at 5.5 months, 18 and 23.5 months post surgery and improvements were noted in walking speed, cadence, step length, step width and support times. The patient also progressed through a number of game parameters, such as difficulty level and task speed. Virtual environments are designed using proprietary software that acquires inputs, sets game flow and drives outputs that are fed back to the patient. In one environment the user steers a boat by shifting bodyweight to avoid buoys in the water and reach targets. Another environment requires patients to reach and grasp virtual objects whilst walking through various scenic environments (such as country roads and cityscapes).

Darter and Wilken (2009) report two early case studies of amputees training with the CAREN at the WRAMC, showing improvements in energy expense and trunk posture with training. The authors comment on the need to understand the optimisation of the feedback “dose” required to achieve and sustain performance gains. Applications with the CAREN system are in their infancy, so there are currently no controlled studies that enable the effects of the CAREN to be separated from the natural maturation of the patient’s pathology. However the adaptability of the system (both hardware and software) present the CAREN as a promising device to enable a range of biofeedback training regimes. Electrical stimulation has been used as a means of delivering biofeedback. It has many advantages over other methods and potential to address some of the limitations in previous work. Before discussing those, the principle of operation and uses of electro-tactile stimulation with amputees will now be discussed.
2.4 Electrical Stimulation Feedback

2.4.1 Principles of electrical stimulation

Motor and sensory nerve fibres can be artificially stimulated by the application of an external electrical current, to produce a physiological response. In functional electrical stimulation (FES) for example, motor fibres are stimulated to cause muscle contractions that have a functional or practical use for the patient. Sensory fibres can be stimulated to disrupt or mask adverse neural activity (as in the case of pain or seizure management) or to produce a useful physiological sensation, for the presentation of biofeedback information for example.

Nerve cells typically have a resting potential of -70 mV across the cell membrane. To generate an action potential, the cell is depolarised by raising the membrane potential passed a threshold of approximately 30 mV. This can be achieved by delivering a localised electric field to the tissue, typically via two electrodes. Electrodes used in biofeedback are often surface electrodes (as shown in Figure 9), percutaneous or implanted. The resulting action potentials propagate both orthodromically and antidromically, as such the response is non-physiological.

Figure 9 Nerve fibre recruitment through the application of electrical stimulation. From Bajd (2006)

Skin is formed of a number of cell strata, which can be broadly divided into two layers. The outermost is the epidermal layer, the first 0.03 to 0.13 mm of which contains metabolically inactive and dry keratinocytes that form the high impedance stratum corneum. The deeper dermal layer contains the broad spectrum of sensory receptors as
shown in Figure 10. The dermis and subcutaneous layers are lower impedance and behave as pure resistance volume conductors (Keller 2008). As such the depth of applied current is a function of electrode spacing - the closer together the electrodes are, the more superficial the stimulation.

![Figure 10 Sensory receptors and skin layers, from (Wikibooks 2009)](image)

A number of inhomogeneous features exist at the electrode-skin interface and across the stratum corneum that can cause high localised current densities and subsequently discomfort. Higher currents exist at the edge of electrodes that can cause skin burning in high current applications such as defibrillators (Keller 2008). These edge effects are not problematic in lower current sensory stimulation applications. High current densities have been measured in anatomical features across the stratum corneum (in sweat glands, hair follicles and other appendageal pathways). These higher conductivity pathways can cause an inhomogeneous current distribution and subsequent discomfort (Chizmadzhev, Indenbom et al. 1998). These issues can be somewhat mitigated with the application of a higher impedance layer between the electrodes and the skin, hydrogel buffers are often used. The effect is to increase the impedance of all possible current pathways resulting in smaller impedance variations across the contact surface. Abrading the stratum corneum can also help to reduce impedance variations. It is important to note that variations exist in tissue thicknesses and impedances according to age, gender, body region, blood content,
skin type and smoking habits (Holbrook and Odland 1974; Sandby-Moller, Poulsen et al. 2003).

There are a wide variety of sensory receptors within the skin that respond to very specific environmental factors, as can be seen in Table 2. They reside in 0.5 mm of tissue and are superficial to the somatosensory receptors described in Section 2.2.2. Activation of combined receptor types produces the vast array of human touch percepts.

<table>
<thead>
<tr>
<th>Layer</th>
<th>Receptor Type</th>
<th>Sensory parameter</th>
<th>Adaptation rate (F)ast / (S)low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidermis</td>
<td>Thermal receptors</td>
<td>Temperature 10 – 40 degrees C (cold)</td>
<td>F</td>
</tr>
<tr>
<td>Dermis</td>
<td>Merkel cells/disks</td>
<td>Fine touch and pressure</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td>Meissner corpuscles</td>
<td>Fine touch, pressure and low f. vibration</td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>Thermal receptors</td>
<td>Temperature 32 – 48 degrees C (hot)</td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>Free nerve endings</td>
<td>Itch and tickle</td>
<td>F and S</td>
</tr>
<tr>
<td></td>
<td>Hair root plexus</td>
<td>Crude touch</td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>Ruffini corpuscles</td>
<td>Pressure, stretching of skin</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td>Superficial nociceptors, myelinated</td>
<td>Fast pain (millisecond response time) acute, sharp, pricking pain</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td>Deep nociceptors, unmyelinated</td>
<td>Slow pain (second response time) chronic, burning, aching, throbbing pain</td>
<td>S</td>
</tr>
<tr>
<td></td>
<td>Lamellated Pacinian corpuscles</td>
<td>Pressure, tickling, high frequency vibration</td>
<td>F</td>
</tr>
</tbody>
</table>

The adaptation rate refers to a neuronal response to a stimulus over time, as illustrated in Figure 11. The train of action potentials produced by fast adapting neurons, such as Meissner corpuscles, is generated when a change in the stimulus occurs. The neuron adapts to the stimulus and the train diminishes when the stimulus remains unchanged. Likewise a slowly adapting neuron changes very little or does not adapt at all to a change in stimulus.

![Figure 11 Neural adaptation](image)

This provides a mechanism to distinguish between changing and constant environmental factors, and prevents the CNS becoming overloaded with sensory information.
In the case of electrical stimuli, the presence and rate of adaptation depends on the types of receptors recruited, but also the waveform characteristics of the applied stimulus. Kaczmarek (2000) looked at the effect of adaptation to a 350 Hz biphasic electro-tactile stimulus to the surface of the abdomen of 7 healthy individuals. Participants were asked to determine their threshold of perception using an automated system every 5 - 20 seconds for 30 minutes before, in the presence of, and after the use of a conditioning stimulus. Kaczmarek reported that full adaptation occurs after 15 minutes. This was followed up by Buma et al. (2007) who determined that adaptation can be reduced by the use of intermittent stimulation with 0.3 second intervals between bursts. Buma et al. also reported that adaptation rate is reduced if stimulation is delivered at a high (80%) level of the full dynamic sensory range.

Another important concept and one that may guide the determination of biofeedback resolution is that of receptive field. The receptive field is the area of skin that a neuron responds to, as illustrated in Figure 12. The field size is inversely proportional to the density of receptors and can be determined using the two-point touch discrimination test - a pair of callipers are pressed against the skin and the subject is asked to determine if one or two points are felt. The distance between calliper legs is decreased until only one point is perceived. This distance is known as the two-point touch threshold (TPTT) and is an indication of tactile acuity.

Figure 12 Illustration of the receptive field of receptors in the hand, from Kandel (2000)
The receptive field of skin is largest at the calf (at approximately 48 mm across) where the large area of skin is served by relatively few receptors (Weinstein 1968). Conversely the TPTT of the first fingertip is 2 mm. The surface of the thigh has a TPTT of 46 mm. Other regional TPTT’s are shown in Figure 13.

When a number of receptive fields are stimulated at the same time, the firing rate of neurons that respond to receptive fields furthest from the point of contact, is diminished. This is a process called lateral inhibition and serves to sharpen tactile acuity.

Whilst the application of electrical stimulation is a wide research field, the principles of sensory adaptation and receptive field are specifically highlighted since they have a bearing on the development of electrodes for biofeedback applications.

Figure 13Two point touch discrimination thresholds for males for different areas of the body (note that female areas follow a similar pattern), from (Weinstein 1968)
2.4.2 Application of sensory electrical stimulation (SES)

Muscular stimulation has been used extensively in rehabilitation and in the gait re-education of patients with neurological impairments, such as those with cerebral palsy (Durham, Eve et al. 2004) and stroke (Burridge, Taylor et al. 1998), and has been incorporated with various sensors to time the delivery of stimuli (Ghoussayni, Stevens et al. 2004). In contrast sensory stimulation is a much less understood field. Yet there have been diverse applications.

Stimulation of sensory fibres has been used to disrupt adverse nervous system activity, for example in deep brain stimulation for the management of seizures, Parkinson’s and depression. In spinal cord stimulation, sensory fibres are stimulated to cause a change in the local neurochemistry with beneficial effects in the management of chronic pain. A major area of sensory stimulation is in rehabilitation, in the use of prosthetics and sensory substitution (Bach-y-Rita and Kercel 2003).

Electro-tactile displays (ETDs) employ transcutaneous SES in prosthetic devices to present information to wearers. Data can be presented spatially in 2 or 3-dimensional arrays of electrodes; or temporally using pairs of electrodes or arrays (Kaczmarek, Webster J.G. et al. 1991). Kajimoto et al. (2004) developed a system called “SmartTouch” which used a 4 x 4 array of 1.0 mm diameter stainless steel electrodes in a 10 mm square device. Phototransistors placed on the underside of the device detect black and white patterns drawn on a page. The user moves the device along the surface of the page with a finger and the fingertip is stimulated according to the detected pattern, allowing the user to perceive the graphical pattern. The device delivers 1.0 – 3.0 mA (100 to 300 V) for 0.2 ms. By adjusting the current level and polarity to adjacent electrodes, the device can be operated in three modes to selectively stimulate Merkel cells (which convey pressure information), Miessner corpuscles (low frequency vibration) and Pacinian corpuscles (high frequency vibration). Stimulating combinations of receptor type causes a range of different sensations. Kajimoto et al. (1999) likened this approach to mixing primary colours.
A similar spatial resolution was explored by Tang (2005) Liu and Shim (2006), who developed three 4 x 8 ETD arrays containing 75 µm, 700 µm and 1.55 mm diameter nickel-electroplated electrodes. The inter-electrode spacing ranged from 1.5 mm to 5 mm. A monophasic square waveform was used (with 3 bursts of 24 µs pulses at 200 Hz) and the sensory thresholds and spatial discrimination of lines of stimuli delivered to the lips were evaluated in 12 healthy individuals. They found the perception threshold levels significantly reduced with the increasing electrode diameters studied; and high levels (80-90%) of line discriminated with no significant difference in electrode diameter.

Whilst the work of Kajimoto and of Tang described above demonstrates the potential utility of electro-tactile stimuli to convey information, the results are limited to body region, and in these cases regions of relatively high receptor density. In the work by Buma et al. (2007) to determine the influence of current level on adaptation rates (previously described), larger electrodes were used to stimulate the medial side of the thigh above the knee. The intended application is to convey information about knee joint angle to transfemoral amputees using 2-dimensional spatial encoding. The electrodes contained a central 20 mm diameter cathode, and an outer oval anode (63 mm x 39 mm) separated by a 5 mm inter-electrode gap. Guidance on the development of suitable electrodes is sparse. As Kaczmarek notes, the dynamic range of electro-tactile stimulation is a function of electrode size, inter-electrode spacing, material and placement, as well as parameters of the stimulation waveform. All of which are poorly studied and rarely reported (Kaczmarek and Bach-y-Rita 1995).

There are many technical choices in the development of electro-tactile devices. In terms of motor learning, it is important to note that electro-tactile stimulation conveys information in a non-physiological manner. As with many of the biofeedback applications described in this Chapter, there is potential for spatial disparity between the nature of the information conveyed, and the perception pathway. For example a visual presentation of ground reaction force data, bares no spatial relationship to the movement being undertaken. This raises many fascinating questions about how to map non-physiological information to movement tasks. In practical terms a number of SES applications have been investigated with amputees, which will be examined in the next section.
2.4.3 SES feedback with amputees

The first uses of electrical stimulation to augment sensation amputees appeared in the 1960s in the development of hand prosthesis (Childress 1985), for example Beeker et al. (1967) used 5 mm diameter electrodes to stimulate the upper limb with a 4 kHz sinewave with an adjustable amplitude. This produced a pricking sensation on the skin that corresponded with pressure measured at the prosthetic thumb. Clippinger (1982) later applied sensory stimulation directly to the sciatic nerve with an implanted stimulator in 13 amputees (2 right and 3 left hip disarticulations, 5 right and 2 left above knee, and 1 bilateral below knee patient). 100 ms pulses of stimulation were delivered at 100 Hz on detection of heel contact by a piezoelectric transducer, the pulse repetition frequency then corresponded to the prosthesis bending moment measured with a strain gauge on the tibial shaft tube. Stimulation was used from 3 to 12 hours per day for an average of 8 months post fitting, although one patient continued to use the stimulation for 6 years. The immediate reported benefit was a reduction in pain, followed by a greater confidence using the prosthesis, attributed to a greater sense of the centre of gravity. A reduction in postural sway was also noticed. It is difficult in these cases to attribute changes to patient confidence to stimulation, rather than maturation. Immediate post-operative pain reduction is also difficult to separate out from maturation and history effects. Nevertheless this was an ambitious and promising piece of work that has not been replicated.

Sabolich (1994) and Ortega (1995) integrated surface stimulation electrodes into the sockets of above and below knee amputees, providing sensory stimulation to the anterior and posterior aspects of the residual limb, according to signals from anterior and posterior plantar pressure sensors. The ‘sense of feel’ device was tried initially with 12 trans-tibial and 12 trans-femoral amputees. Baseline testing followed by walking trials with BFB and post-intervention testing was conducted within the same day. Weight bearing symmetry was found to increase significantly. Stance time symmetry in the trans-femoral group increased by 2%, but not significantly. Mean stance time was greater on the sound limb throughout, as is commonly seen in amputees (Bateni and Olney 2002). Step-length symmetry increased from 69.5% to 80.3%. The authors acknowledged that outcomes may relate to performance changes rather than motor learning and that skill retention was not
addressed. Stimulation parameters and electrode placement were not discussed. It is possible to stimulate a large range of deep and superficial nerves in the lower limb which differ for trans-femoral and trans-tibial subjects. It is therefore unclear if the study takes into account the effect of stimulation to different nerve branches. Each may contain different receptor types with different functions, adaptation rates and have origins mediated by conscious and non-conscious pathways. However, in a personal communication with the author (Appendix C), Sabolich noted that some patients said they experienced sensation of their prosthetic heel compressing at heel strike and toes bending at push off. Whilst the sensory information presented does not permit this perception, this does suggests the nervous system adapted to the new sensory pathway. This re-embodiment process is not uncommon in amputees and is known as extended physiological proprioception (EPP) (Giummarra, Gibson et al. 2008).

A novel approach was taken by Lee et al. (2006) who used stochastic resonance stimulation (SRS) to provide sensory feedback to the residual limb. Stochastic resonance occurs when a weak periodic signal in a non-linear system is enhanced by an increase in system noise. The result is an increased signal to noise ratio. This counterintuitive phenomenon particularly applies to systems with a signal input threshold such as peripheral nerves, where a weak input signal is raised sufficiently to trigger an action potential. As such the technique has found use in neurophysiological applications (Mossa, Ward L.M. et al. 2004). Lee et al. applied a sub-sensory signal to the sound limb using a function generator. Two trans-tibial subjects were asked to stand quietly for as long as possible with and without sub-sensory stimulation. Lee et al. reported improvements across a range of postural sway parameters, and suggests that sub-sensory stimulation enhances somatosensation. In a parallel study Lee et al. (2006) presented foot contact data to the same two amputees walking on a treadmill. The experimental protocol is unclear, however Lee et al. report improvements in a range of temporal-spatial parameters. This work hints at the intriguing possibility of applying corrective feedback information to amputees without their conscious involvement.

A wide range of applications and principles of biofeedback were apparent in the literature. However there are equally a number of limitations that impede wider clinical acceptance,
and may diminish the potential gains from efficient application. So before looking at how biofeedback was applied in the context of this work, some of the most evident limitations are now discussed. The major issues highlighted in the literature are then pulled together at the end of this Chapter.

2.5 Limitations in Previous Biofeedback Research

2.5.1 Heterogeneity in BFB applications

The application of biofeedback to gait re-training is multi-variate. There is large variation in the choice of measurement parameter (e.g. ground reaction force, plantar pressure, COG trajectory, kinematic parameters and so on), stimulus modality (audio, visual, haptic, electrical stimulation, multi-modal feedback) and in the temporal and qualitative determinants of the feedback stimulus; which are in turn determined by the individual's goal, the motor task, the segments of interest and the nature of the pathology. There is also high heterogeneity in existing methods (Wolf 1983), in the causes and progression of pathologies and outcome measures (Woodford and Price 2007), in study designs and in the effects evaluated (Glanz, Klawansky et al. 1997).

Heterogeneity is apparent by the halting continuation of research strands. For example, despite positive preliminary results from Clippinger’s work on implanted sensory stimulation (Clippinger, Seaber et al. 1982) and Sabolich’s work in surface stimulation(Sabolich and Ortega 1994), neither have been followed up and developed into clinical applications. Simple ambulatory measurement of prosthesis loading has only recently found commercial application in BFB thirty years after the appearance of the Limb Load Monitor, with devices such as the Smart Pyramid (Orthocare Innovations, Washington DC).

It is worth considering biofeedback variability from a clinician’s point of view, when seeking to determine what barriers there are to clinical acceptance. If current BFB devices were employed on a routine basis in a lower limb rehabilitation clinic, the ‘toolbox’ would contain an impractical array of devices for patients with varying levels of mobility, for hip,
knee and ankle joints, for different pathologies and for ambulating, treadmill and wheelchair users. There are no guidelines informing the choice of BFB equipment. New rehabilitation systems such as the Lokomat (Hocoma AG, Zurich) and CAREN (Motek Medical BV, Amsterdam) attempt to address the heterogeneity issue for in-clinic use, but they are large systems currently too costly for district rehabilitation clinics.

2.5.2 Conflicting and limited evidence

Heterogeneity makes it difficult to pool and compare evidence. Despite the number and range of applications reported in scientific journals there are only published guidelines from two healthcare bodies in the UK. The Royal College of Physicians (RCP) comments on BFB for use with stroke patients, recommending that biofeedback systems should not be used on a routine basis (Intercollegiate Stroke Working Party. 2012).

The Chartered Society of Physiotherapy (CSP) reiterates the position stated by the RCP noting that:

“Biofeedback is a way of providing the patient with auditory or visual cues of muscle activity or joint position. It is usually based on electromyography (EMG). Its role in stroke has been subject to a number of systematic reviews with conflicting conclusions reflecting different study selection (Moreland and Thomson 1994), (Schleenbaker and Mainous 1993) upper limb (Moreland, Thomson et al. 1998) lower limb. It seems that biofeedback is unlikely to provide a substantive clinical benefit (Duncan 1997)”

(Forster and Young 2002)

The above guidance is based only on EMG BFB, highlighted in two meta-analyses by Moreland for the upper and lower limb (Moreland and Thomson 1994; Moreland, Thomson et al. 1998); a meta-analysis by Schleenbaker (who reported statistically significant results in favour of EMG BFB), a meta-analysis of upper and lower limb EMG work by Glanz (1995), and a review by Duncan (1997) of 7 upper and lower EMG papers.
Considering the evidence for the lower limb, Glanz compared the work of 6 studies from 1975 to 1990 using joint range of motion of a paretic limb as a pooled effect. Excluding one outlier (Hurd, Pegram et al. 1980), four of the six studies showed individual effect means favouring EMG BFB. The sixth study (Mulder, Hulstijn et al. 1986) did not include sufficient variance data, so Glanz used data from (Basmajian, Kukulka et al. 1975) and when pooled this study favoured the control. The trials were randomised and controlled with a total of 112 patients. Glanz’s concluded that EMG BFB is not efficacious, based on the combined upper and lower limb work. Glanz did note the possibility that type II errors could hide clinically significant results.

In the lower limb meta-analysis by Moreland et al. (1998), 8 studies from 1975 to 1994 were compared, including the same studies used by Glanz (1995). However two studies with statistically significant studies supported EMG BFB were excluded. The work by Mandel (1990) failed a sensitivity analysis, and there was insufficient data available in (Hurd, Pegram et al. 1980) for comparison.

Moreland compared ankle dorsiflexion strength, gait quality (based on a foot contact pattern scoring measure by Basmajian), ankle range of motion, ankle angle during gait, stride length and gait speed and found a statistically significant improvement in only ankle muscle strength. This was measured with a dynamometer by Basmajian (1975) and against the Ashworth Scale by Burnside (1982). Therapy delivery across the 8 studies ranged from 8 to 40 sessions over 4 to 8 weeks, an average of 16 training sessions over 5 weeks, and generally required the patient to reach an acoustic target.

Finally whilst discussing various therapies for motor recovery following stroke, Duncan(1997) summarised 7 lower limb EMG BFB papers from 1982 to 1990, of which 4 were included in previous meta-analyses. Duncan noted the conflict between the negative conclusion of Glanz and positive conclusion of Schleenbaker in the EMG BFB. All papers reported above were for studies of stroke patients, and were limited to the English language. None discussed the nature of the biofeedback used (the sensory modality, task or measurement).
In addition to meta-analyses, the RCP evidence also included 23 RCTs and 1 controlled clinical trial (CCT) from 1976 to 2002. 13 are EMG studies (6 of which were reported in the previous meta-analysis), 7 standing posture training studies, 1 wrist extension and 1 eye movement study. Only one study considered by the RCP looks at gait (Montoya R., Dupui P. et al. 1994), described in §2.2.2.

Not all of work identified in the literature review report the level of ability of the patient. Treadmill-based systems such as the Lokomat use body weight support for patients with severe impairments bought about through spinal cord injuries and traumatic brain injuries. No work was identified that uses biofeedback on a treadmill for less severe gait disturbances, or for ambulatory or home use, or in systems that combine feedback from the care team.

2.5.3 Additional limitations

There are many limitations in the application of different types of biofeedback with different patient groups, and in the measurement technologies, that are not addressed in this review. For example motion sickness is a recognised problem for head mounted display users (Costello 1997). As such, patients with brain injuries or balance disorders are excluded.

Commercial game devices such as the Wii (Nintendo, Kyoto Japan) and Playstation 3 (Sony, Tokyo Japan) incorporate inertia-based motion sensors and enable the user to interact with games through movement. Case studies are emerging (Sugarman and Wesisel-Eichler 2009) but no games have been written specifically to elicit therapeutic movements or aim towards clinical goals. Semantically the distinction between game and individualised therapy task could be lost, particularly with the use of game consoles in group work. Unrestricted use of game consoles could lead to unrealistic movement patterns expected by the patient and potential injury.

Sugarman and Wesisel-Eichler express caution against repetitive strain injuries that can come about through overuse of the Wii Fit. The terms wiitis, wii knee and nintendinitis are
increasingly being used to describe these injuries (Boehm and Pugh 2009). The motor patterns required to progress through commercial games have not been analysed, and there has been no work to assess any possible de-motivating effects experienced by individuals playing team games. If the game or hardware is to be adapted for clinical use, a sufficient level of programming expertise would be required to produce virtual rehabilitation scenarios.

2.5.4 Consideration of the individual in the biofeedback loop

None of the work reviewed in this Chapter comments on the psychological (or neuropsychological) state of the patient within the feedback loop. When considering gait re-training it is important to recognise that gait is not only a product of biomechanics, but also the organisation and action of neurons regulating movement. Much of the focus in gait rehabilitation has historically been on the biomechanics of gait, through research into the action of body segments and prosthetic components, gait classification, fall prevention, and through clinical management informed by the assessment of gait biomechanics. This focus on biomechanics is perhaps understandable given the complexity of the nervous system. Whilst clinicians are aware of the importance of psychological factors such, as motivation (Alfano and Finlayson 1987) the underlying neuropsychological changes are poorly understood. Consequently the optimum conditions required for neuroplasticity to take place with the greatest effect, are not known.

This lack of understanding is a limitation to the successful application of biofeedback. Biofeedback is a learning process facilitated by instrumentation, not simply an electromechanical intervention. The majority of reported evidence for biofeedback is conflicting, and this may be due to the subtle characteristics of each learning process at the neuropsychological level, the perceptual performance and the influence of the pathology in response to the various stimulus modalities that have been applied.

Therefore to implement a biofeedback training regime efficiently, it is important to understand how a training regime could potentially enhance the motor learning process. It is not currently possible to directly measure learning, because it is a re-organisation of the
central nervous system. Performance change is an outward appearance that learning has taken place, so within the field of psychology performance indicators (such as error rates or game scores) are used to quantify learning. They are often presented against trial numbers to produce performance curves (Schmidt 1988).

To inform the design and development of a biofeedback training system, the key principles in the psychology of motor learning will therefore be reviewed.

### 2.6 Psychology of Motor Learning

#### 2.6.1 Models of motor learning

There are many theories that attempt to explain the psychology of motor learning. Some are based on discrete stages, such as Fitts and Posner’s classic three stage model (Fitts and Posner 1967). Fitts and Posner suggest that learners gather information and feedback during the first *cognitive stage* and attempt to form an overall understanding of the motor skill. Movements are jerky and inconsistent. There is a high level of trial and error and low confidence. Later during the *associative stage* errors are reduced, new strategies fine tune the motor skill and the subject learns to anticipate and become aware of subtle environmental irregularities. In the final *autonomous stage* the errors are further reduced, stability is increased and the cognitive demand is lowered, allowing the learner to perform the task autonomously. Performance gains are slower to achieve as a plateau is reached.

Gentile (1972) suggests the first stage involves explicit processes in which the learner matches the body’s morphology to environmental constraints, producing the desired affordances. Later during the less conscious stage of learning, finer control is achieved by improving intrinsic processes. The memory of the skill becomes more robust to external influence in a process called consolidation.

The rules governing when consolidation occurs are not currently known. Some work points toward the value of either sleep or wake cycles for consolidating specific motor skills (Macquet, Schwartz *et al.* 2003; Walker, Brakefield *et al.* 2003).
Newell describes three interacting factors which operate when a task is being learnt: The subject (or patient), the environment, and the task. They are presented in what is known as Newell’s triangle (Shumway-Cook and Woollacott 2007).

The interaction between the patient and the environment can be described as an affordance according to Gibson’s Perception-Action theory (Gibson 1977). Affordances such as climbability, walkability, passability, catchability or graspability are relationships that emerge from the combination of geometrical properties of the environment and the patient. This is a useful concept in fields such robot navigation (Murphy 1999), where a robot may navigate through an environment with a diverse range of affordances that require different control strategies. It may be interesting to explore this further for environment classification in the case of patients walking in unstructured community environments, but perhaps not wholly beneficial to understand the gait of patients walking in controlled clinical environments.

### 2.6.2 Practice conditions and feedback delivery

The interaction between the patient and the task can be understood in terms of how the task is approached, how practice is organised and how feedback is used. This is a vast subject area, of interest to sports coaches, teachers and therapists (Schmidt 1988; Shumway-Cook and Woollacott 2007; Schmidt and Wrisberg 2008). Only key aspects will be highlighted here to gain an appreciation of the range of considerations required when developing an efficient training programme.
A number of pre-practice factors impact on the effectiveness of learning before the task is approached. Patient motivation is one that can be increased using goal setting and encouragement from the therapy team. Pre-practice instruction can convey to the patient what is required and help by establishing a frame of reference that can later be experienced and recognised when it is achieved. Instruction can be presented through modelling the task and practical demonstration, or through verbal instructions aided with graphics or text. Knowledge of the mechanical principles involved in the task may also aid the patient.

For efficient learning to take place the practice conditions must be suited to the specific motor task (Schmidt and Wrisberg 2008). Furthermore, in order to ensure transfer of gains experienced in the clinic, to practical use in the community, the practice conditions should be based on “Transfer-appropriate processes” (Morris, Bransford et al. 1977). These processes are practice conditions that promote a particular type of processing during acquisition trials, that facilitates greater transfer during transfer trials (Lee, Swanson et al. 1991). Put simply, if the practice conditions are similar to the enactment conditions, transfer will be more effective.

The need to transfer skills from the clinic to the community could be reduced or avoided with the use of emerging body-worn ambulatory gait training devices, such as the audio-visual walker biofeedback device (Baram 2009) which would enable patients to learn in the environments where the skills are required. Lee (1988) furthered the idea of transfer-appropriate processing by suggesting positive transfer also occurs when practicing cognitively similar skills even when the physical training environment is not the same as the enactment environment. This may underpin the learning processes taking place during virtual rehabilitation, where the enactment environment is simulated within the clinic.

Structuring the practice session was touched on briefly in Section 2.3.1 in terms of stimulus delivery timing, with the introduction of the concepts Knowledge of Results (KR) and Knowledge of Performance (KP). KP is ongoing instructive guidance whilst KR refers to the end result compared to a goal. One method of controlling the timing of feedback delivery is to provide KR and KP at set intervals throughout a practice session, as shown in Figure 15. The time between the subject response to a task (Rn) and the delivery of
feedback is known as the KR-delay interval, the Post KR-delay interval refers to the time between the feedback presentation and the next trial.

It is clear that this choice of feedback timing closely relates to the temporal nature of the task being undertaken, and tasks are described as either discrete, continuous or serial. A serial task is one containing a series of discrete elements that form a complete response, with the order of elements being important. Gait could be viewed in a number of ways. The cycle can be broken into functional events, making it a serial task. But it is not possible to retain dynamic stability whilst attempting to walk through discrete events, so unobstructed gait could therefore be considered a continuous task. If the environment is highly unstructured requiring greater cognitive involvement then gait may become serial or even a group of disconnected discrete tasks. No work was identified that defines gait using these concepts.

Activity carried out within either KR delay interval can have a detrimental impact on the effectiveness of learning, so there has been research into the optimum delay intervals for specific motor tasks. Short KR-delay intervals and instantaneous KR are known to have a detrimental effect on learning and retention, due to a conscious over-reliance on feedback (Swinnen, Nicholson et al. 1990). The amount of feedback delivered during the practice session can also be governed by altering the absolute and relative frequency of KR during the practice session. These are also parameters of interest in motor learning research known to affect learning and retention (Schmidt 1988; Winstein 1991). An alternative method of controlling the timing of feedback delivery is known as bandwidth feedback, whereby a stimulus is presented if a performance response deviates outside preset limits. However results are sparse and there has been no published work into feedback timing for gait re-training or amputee rehabilitation.
2.6.3 Environment and task

Finally the interaction between the environment and the task can be described in terms of the temporal-spatial consistency of the environment and the task between trials. An environment is spatially consistent if the size and location of the objects within the environment are seen to be stationary, an example of which may be the controlled space of the Action Research Arm Test, which is a test of upper limb function involving the movement of objects within a fixed workspace, where the only moving objects are those directly interacting with the subject. If the motion of a treadmill belt is unobtrusive, treadmill locomotion may also be considered spatially consistent. In contrast community ambulation takes place in a highly spatially inconsistent environment, where objects such as trees, cars and other people move and may be perceived as changing shape. An environment is temporally consistent if it is physically stationary between trials, such as experienced on a treadmill or Stewart platform (Boian, Bouzit et al. 2005). Walking within the community or clinic is considered to be carried out within a temporally inconsistent environment, where the effects of optic flow come into play (Nomura, Mulavara et al. 2005).

Gentile (1987) defines a taxonomy of 16 types of task (Figure 16), which has two dimensions: 1) The environmental context, includes consideration for the regulatory conditions and inter-trial variability, and 2) the task action, which includes consideration for body orientation and object manipulation. The simplest task is 1A and task complexity increases through the taxonomy as shown in red. This taxonomy can be used to guide how biofeedback is used with a therapy programme. Once the clinical goal has been defined and identified on the taxonomy, the therapist can structure practice and training to progress from the simpler task to the goal via changes to environmental or task conditions.
### Figure 16 Gentile’s taxonomy of motor tasks, from (Gentile 1987)

<table>
<thead>
<tr>
<th>Environmental Context</th>
<th>Body Stability</th>
<th>Body Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stationary Regulatory Conditions and No Intertrial Variability</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1A</td>
<td>1B</td>
</tr>
<tr>
<td></td>
<td>Simple</td>
<td>Body stability</td>
</tr>
<tr>
<td></td>
<td>No object</td>
<td>No object</td>
</tr>
<tr>
<td></td>
<td>Stationary regulatory conditions</td>
<td>Stationary regulatory conditions</td>
</tr>
<tr>
<td></td>
<td>No intertrial variability</td>
<td>No intertrial variability</td>
</tr>
<tr>
<td></td>
<td>Standing alone in a room</td>
<td>Practicing a basketball free-throw shot without a ball</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2A</td>
<td>2B</td>
</tr>
<tr>
<td></td>
<td>Simple</td>
<td>Body stability</td>
</tr>
<tr>
<td></td>
<td>No object</td>
<td>No object</td>
</tr>
<tr>
<td></td>
<td>Stationary regulatory conditions</td>
<td>Stationary regulatory conditions</td>
</tr>
<tr>
<td></td>
<td>No intertrial variability</td>
<td>No intertrial variability</td>
</tr>
<tr>
<td></td>
<td>Standing on different surfaces</td>
<td>Swinging a baseball bat at different ball locations without a bat or ball</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3A</td>
<td>3B</td>
</tr>
<tr>
<td></td>
<td>Simple</td>
<td>Body stability</td>
</tr>
<tr>
<td></td>
<td>No object</td>
<td>No object</td>
</tr>
<tr>
<td></td>
<td>Regulatory conditions in motion</td>
<td>Regulatory conditions in motion</td>
</tr>
<tr>
<td></td>
<td>No intertrial variability</td>
<td>No intertrial variability</td>
</tr>
<tr>
<td></td>
<td>Walking on a treadmill at a constant speed</td>
<td>Passing basketballs to a moving player running the same pattern several times, without a ball</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4A</td>
<td>4B</td>
</tr>
<tr>
<td></td>
<td>Complex</td>
<td>Body stability</td>
</tr>
<tr>
<td></td>
<td>No object</td>
<td>No object</td>
</tr>
<tr>
<td></td>
<td>Regulatory conditions in motion</td>
<td>Regulatory conditions in motion</td>
</tr>
<tr>
<td></td>
<td>Intertial variability</td>
<td>Intertial variability</td>
</tr>
<tr>
<td></td>
<td>Walking on a treadmill at different speeds</td>
<td>Passing basketballs to a moving player running the same pattern several times, without a ball</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chapter 2: Background and Literature Review

2.7 Summary and Discussion

A range of topics was introduced in the literature review and a number of important points were raised. The importance of gait was recognised as a determinant of quality of life. The regulatory input provided by the somatosensory system was described in Section 2.2.2 as providing a sense of limb positioning that enables efficient movement of the limbs, without which habitual and adverse gait patterns can develop. Limb amputation results in a loss of somatosensation. Amputees may re-learn a symmetrical gait during rehabilitation, but after discharge often develop asymmetrical use of the pelvis through vaulting, hip hiking and circumduction movements. The increased transverse rotation of the pelvis in these movements is a contributory factor in lower back pain, which is prevalent in trans-femoral amputees.

Enhancing the feedback received by amputees during gait re-training and in the community may prevent the emergence of habitual gait patterns, and lower the incidence of back pain in the amputee population. A number of issues with the gait re-training process were also discussed in Section 2.2.6. Biofeedback was presented as a technology which may prove beneficial in the reduction of adverse gait patterns, and for the clinical team during the re-training process. Focusing on pelvic-related issues may also assist in correcting more distal gait and posture asymmetries.

Biofeedback was reviewed and 293 journal articles were identified that looked at lower limb applications with a range of patient groups, from 1974 to 2012. Biofeedback is a very broad science, underpinning fields such as neurofeedback, virtual rehabilitation, sensory augmentation, motor learning and human-in-the-loop system design. In neuromuscular rehabilitation biofeedback work has predominantly incorporated the use of kinematic, kinetic and EMG measurement systems interfaced to visual, auditory and haptic means of presenting stimuli. In some cases data are fed back to the patient in raw format, in others signal processing is used to produce highly context specific guidance. Electro-tactile displays (ETDs) were presented in Section 2.4 as one potential means of presenting feedback information. ETDs have been used in a small number of biofeedback applications with promising results.
Whilst biofeedback is generally recognised as a beneficial therapy in a range of clinical areas, there is insufficient evidence to warrant organisations such as the National Institute for Health and Clinical Excellence (NIHCE) recommending use of biofeedback on a routine clinical basis. This may be in part due to the difficulties of collecting comparable data from such a highly multivariate therapy.

The majority of work reviewed documented technical aspects of developing biofeedback training devices, or the clinical application and outcome of biofeedback in case and cohort studies. Few touched on the central most important component of the biofeedback loop, the patient’s neurology. Whilst understanding the control of human locomotion is far beyond the scope of this work and may elude our best efforts for years to come, Section 2.6 set out to review the current psychological theories, to see what lessons have been learnt and what should be considered when developing a biofeedback therapy. Three important concepts were highlighted:

1. Transfer-appropriate processes are those where the practice conditions are similar to enactment conditions and allow more efficient transfer of learning to take place. This concept supports the use of both ambulatory biofeedback devices for community use and in-clinic virtual rehabilitation, as methods of transferring re-learnt movement skills into daily life.

2. Knowledge of results and knowledge of performance (and the distinction between learning and performance) were introduced in Section 2.6.3. Theses feedback delivery parameters, in relation to the temporal-spatial nature of the task, may have a role in improving the gains in gait re-training.

3. Gait can be described as a continuous or discrete series of tasks. As such it is important to consider the learning context when providing feedback.

The literature review raised many questions surrounding the efficient application of biofeedback. Some questions highlight the technical challenges of developing ambulatory devices for gait research, whilst others point at limitations in our basic understanding of the science of neuromotor control. The answers to many are beyond the reach of this work and remain of philosophical interest, whist others informed the decisions made during this
research. All will be briefly outlined now, to provide a sense of the challenges faced in approaching the work outline presented in Chapter 3.

For gait modification to be possible, biofeedback requires neuroplasticity, and scope for functional change within the constraints of the patient’s pathology. In the case of amputees this raises the question of how far can poor gait patterns be attributed to prosthesis alignment, to anatomical variation (such as in the presence of contractures, muscle strength) or to poor neurological control (through lack of motivation or impaired proprioception) or a combination? It is not currently possible to ‘separate the amputee from the prosthesis’ and examine the role of each in the gait cycle. It may be the case that some amputees walk with a poorly understood optimum kinematic solution that is better suited to their altered physiology. If that is the case, is training to bring their gait closer to a non-amputee mean possible or appropriate?

Biofeedback seeks to provide new sensory information or augment existing pathways. But it is not known which of the existing physiological feedback mechanisms plays the most significant role in different functional aspects of the gait cycle. How much redundancy is there within the feedback pathways? Which stimuli are patients in most need of, that can be sufficiently augmented to improve clinical outcomes? Whilst the basic functional anatomy is understood, the comparative significance of external stimuli in relation to gait cycle events is not, particularly in the presence of impaired pathways and cortical changes.

To follow on from that, which level of conscious involvement is required to produce the best outcomes? Is it more beneficial to deliver feedback consciously, subliminally, or through ascending or descending neural pathways? Are learning and retention gains best achieved through cognitively demanding or sub-sensory processing? If gait modification can be achieved without conscious involvement, as was raised in Section 2.4.3, what scope is there embedding biofeedback into prosthetic or orthotic devices?

Looking at the choice and provision of feedback information, a range of questions remain - which stimulus modalities (visual, auditory, vibration or electrical stimulation) are better suited to specific tasks? How can multiple stimuli, data sources and pathways be
effectively integrated? Can greater gains be made by augmenting data with reality and making transitions between virtual and real environments? For example: by altering the level of immersion dynamically during a training task with a semi-immersive head-mounted display. What stimulus specific-parameters elicit the greatest gains in learning and retention following gait re-training? Is there a role for the use of ascending and descending tones, music, key signatures, consonance and dissonance, rhythm, proportional feedback, negative feedback, use of visual imagery, colours, shapes and geometries? The list goes on.

How adaptable is the nervous system to information received from non-physiological sources, or coded in a non-physiological format? What guidance can be employed when mapping extrinsic information such as reaction forces or kinematic parameters for use by intrinsic feedback mechanisms? Is there a limit to the quantity and nature of information that can be assimilated? A link has been suggested between ‘information overload’ and depression in the general population (Klingberg 2009), which might suggest the ‘dose’ of information provided during biofeedback training requires careful consideration - a point that was raised by Darter and colleagues in relation to their work with a CAREN system (Section 2.3.3). In view of this, how can feedback information be quantified?

Looking then at how best to provide biofeedback within a rehabilitation programme - at what stage of rehabilitation is a patient most receptive to gait re-training? What environment would elicit the greatest gain in re-learning and retention when training with a biofeedback system? What activities and tasks are best suited to correcting different gait deviations? What impact do the psychological aspects of rehabilitation have on overall patient outcomes? For example: What is the impact of group therapy, goal-setting, mixed pathology training sessions or mixed age training sessions on outcomes?

Looking at the timing of feedback deliver - what are the relationships for optimum stimulus timing for gait re-training in terms of relative frequency of KR, KR-delay and post KR-delay intervals and the bandwidth of KR? How best can feedback stimuli be timed to gait cycle events? When should KP be used? There is an argument to suggest learning diminishes when subjects are presented with continuous feedback information, as a result
on over-reliance and disengagement (Schmidt and Wrisberg 2008), whilst self-paced learning may produce greater retention (Wulf 2007).

Much of the research into the psychology of motor learning has historically been carried out in the upper limb, where it is easier to control experimental design. How applicable therefore is the current understanding of motor learning to the lower limb? Particularly since gait can be defined in a number of ways.

There is clearly wide scope for multi-disciplinary research in the basic science of biofeedback, and in the application to rehabilitation. In the following Chapter some of the issues raised here are considered and help form a programme of research which is presented to test the hypothesis stated in Chapter 1.
Chapter 3

Research Approach
3.1 Introduction

This Chapter describes the choices and underlying reasoning that were considered to arrive at a programme of work to address the problem of circumduction in amputees. The hypothesis being tested is that real-time electro-tactile feedback is a viable method of assisting in the reduction of circumduction and abduction gait patterns in trans-femoral amputees, as stated in Section 1.2.

Whilst the key aim of this work was to test the hypothesis, it was important to ensure the output from the project had practical utility and relevance, given the issues and limitations of biofeedback raised in Chapter 2. These issues ranged from engineering challenges (in the particular case of electro-tactile stimulation), the clinical adoption, application and outcome in a range of pathologies, to more focused questions about the interaction of the patient within a biofeedback loop. As such, broader utilitarian goals were kept in mind when formulating this programme of research. For example, it was desirable from the outset that any methods or devices developed were: clinically relevant, in terms of adopting comparable data quality or protocols to those used in clinical practice; that they presented future potential to improve heterogeneity in the application of biofeedback, through greater clinical versatility; and that obstructions in the potential pathway for future consumer use were limited. It is important to note that accommodating these goals did not undermine the scientific approach taken to test the hypothesis.

There are currently no biofeedback devices available for use that focus on the reduction of circumduction or abduction gait patterns. Design and development of a training system was therefore required for this work before the hypothesis could be tested.

The system design choices are discussed in the next section. The physiological parameters most useful for feeding back to amputees and the most appropriate measurement system are identified. The training environment in which the system was to be used in, and the broader considerations for operation within a physiotherapy context are discussed. Finally the feedback signal processing and stimulus presentation requirements are addressed.
3.2 Decisions Leading to the Approach Taken

3.2.1 Choice of physiological parameter

The first consideration taken was whether the gait deviation or pathology of interest is a primary, secondary or compensatory mechanism. The desired gait changes, within the scope of the pathology, can then be determined. There are a wider number of options available when correcting gait deviations more distal in the kinematic chain. For example, the correction of step-length asymmetry may be achieved by focusing on the direct measurement of step-length, the dynamics of more proximal segments (the hips, knees and ankles), or the movement of the trunk and head. But in the case of circumduction, whilst there may be some benefit in focusing on foot placement for example, a more direct approach would be to feedback hip-related information. This work therefore focused on the habitual and compensatory movement of the hip which arises from sensory loss, by feeding back hip-related information.

The next consideration was the physiological parameters available to measurement with current technology, and the relevance of that information to performing the required gait change. In the case of hip movement there are many parameters open to measurement, but the activity of muscles acting around the hip and pelvis segments (outlined in Table 3) and hip segment kinematics were considered the most pertinent.

Basing feedback on the knowledge of muscle activity has two main advantages. Fine resolution can be achieved by recording from the individual motor components that combine to form gross movement patterns. A biofeedback system could then theoretically be enabled to discriminate the relative involvement and timing of individual muscles through the gait cycle. At a finer level individual motor units could be recorded with the use of fine wire electrodes, to provide further detail. This indeed was the focus of the early EMG BFB work by Basmajian and others (Basmajian 1963). The second advantage is the more immediate relationship between the patient’s volitional control and action in myography, compared to the measurement of limb movement and the subsequent dynamic effects. Basmajian demonstrated the ability to learn control of individual motor units. This
suggests the potential for more physiologically relevant and immediate forms of feedback, with the use of direct afferent nerve stimulation unhindered by the patient’s conscious interpretation of feedback data.

Table 3 Muscles contributing to movement of the thigh. Those affected by trans-femoral amputation surgery are highlighted in red. * denotes the major contributory muscle for each action. From (Standring 2005) and (Malawer and Sugarbaker 2001)

<table>
<thead>
<tr>
<th>Action</th>
<th>Compartment (group)</th>
<th>Muscle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexors</td>
<td>Deep anterior (iliapsoas)</td>
<td>Iliacus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>psoas major* and minor</td>
</tr>
<tr>
<td></td>
<td>Anterior</td>
<td>Rectus femoris</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sartorius</td>
</tr>
<tr>
<td></td>
<td>Medial</td>
<td>Pectineus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adductor longus and brevis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gracilis</td>
</tr>
<tr>
<td></td>
<td>Posterior (gluteal)</td>
<td>Tensor fasciae latae</td>
</tr>
<tr>
<td>Extensors</td>
<td>Posterior (gluteal)</td>
<td>Gluteus maximus*</td>
</tr>
<tr>
<td></td>
<td>Posterior (hamstrings)</td>
<td>Biceps femoris</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Semitendinosus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Semimembranosus</td>
</tr>
<tr>
<td>Abductors</td>
<td>Posterior (gluteal)</td>
<td>Gluteus maximus, medius* and minimus*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tensor fasciae latae</td>
</tr>
<tr>
<td></td>
<td>Anterior</td>
<td>Sartorius</td>
</tr>
<tr>
<td>Adductors</td>
<td>Anterior</td>
<td>Adductors longus*, brevis* and magnus*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pectinius</td>
</tr>
<tr>
<td></td>
<td>Medial</td>
<td>Gracilis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Obturator externus</td>
</tr>
<tr>
<td>Medial Rotators</td>
<td>Anterior (gluteal)</td>
<td>Piriformis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gemellus internus and inferior</td>
</tr>
<tr>
<td></td>
<td>Posterior</td>
<td>Obturator internus and externus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quadratus femoris</td>
</tr>
</tbody>
</table>

There are however a number of drawbacks with the use of electromyography, particularly with amputees. During amputation surgery the surrounding muscles are attached to the bone (in a myodesis) or to each other (in a myoplasty) to form a pad around the stump. Few hip muscles are unaffected by the trans-femoral procedure (Table 3). Hip muscle atrophy has been reported in 40 – 60 % of the cleaved muscles and up to 30 % of intact muscles from a study of 12 traumatic trans-femoral amputees by Jaegers et al. (1995). This reduction in muscle mass may translate into limited tissue activation. Reduced EMG amplitudes and differences in the EMG profiles of hip muscles have been reported in trans-femoral amputees’ compared to healthy individuals (Pantall, Durham et al. 2011). Any such
training device would therefore be very user specific or require complex signal processing to accommodate patient variability.

Practically it can be difficult to repeatedly place surface EMG electrodes. This is particularly the case over deep hip flexors (McGill, Juker et al. 1996) and possibly more so for patients at home. The electrodes may also cause discomfort and introduce signal reliance problems over long-term use. These issues greatly restrict the usefulness of electromyography for hip muscle biofeedback outside a research context.

Kinematics refers to segment movement, as outlined in Section 2.2.1. Whilst kinematic measures do not stand apart in ways uniquely suited to biofeedback, there is no notable loss of benefit in comparison to the advantages noted for EMG (the movement resolution and the immediacy between volitional control and action). There are however a number of practical advantages. Kinematic measures are more readily understood by clinicians, and have spatial meaning in their raw format which may be more accessible to patient understanding. There exists a wide range of instrumented systems capable of providing measures of joint angle, which include electrogoniometry, inertia-based sensors, video and stereophotogrammetry systems. All of which have the advantage of being less invasive than EMG. As with EMG, kinematic measurement systems are transferrable to other body regions, and there is equal potential to embed the devices into prosthetic components. Kinematic measures of the hip joint were chosen for this work.

3.2.2 Choice of measurement system

The relative angle between two body segments can be measured in a number of ways, the advantages and drawbacks of three of the most commonly used methods will briefly be discussed before outlining the method chosen for this work. Electrogoniometers use rigid levers connected by a potentiometer that are held against each limb segment, the joint angle can be determined directly from a voltage across the potentiometer, with an accuracy of approximately ± 2 degrees (Biometrics n.d.). They are simple to don and doff and are body-worn which permits community ambulation, yet they suffer from poor alignment against the anatomical centre of rotation.
Stereophotogrammetry motion capture tracks the movement of passive or active infra-red markers. In passive systems reflective markers are placed on anatomical landmarks to define a kinematic model, their movement is captured using an arrangement of high speed video cameras. A 3D reconstruction takes place and the relative joint angles can then be calculated. The positional accuracy depends on a number of factors, including the marker diameter and coverage quality within the capture volume (which can vary for different planes and body segments). Chiari et al.(2005) reported that absolute error in positional accuracy ranged from 0.5 to 11.6 mm from studies looking at a range of active and passive camera systems. Angular accuracy varies further, notably with kinematic modelling options and soft tissue artefacts. In a study comparing joint angles from skin-based and bone-fixated markers Cappozzo et al.(2005) reported that soft tissue artefact can account for inaccuracies in the order of 10%, 20% and 100% for knee flexion/extension, abduction/adduction and internal/external rotation range of motion respectively. However stereophotogrammetry remains the most commonly used method of capturing kinematics in clinical gait analysis, and is sometimes used as a reference standard.

Inertia-based sensors such as the MTw unit by Xsens (Enschede, The Netherlands) use a combination of solid state accelerometers, gyroscopes and magnetometers to determine body segment orientation and relative joint angles. They are typically matchbox-sized transducers which are strapped to each segment. Data are then transmitted wirelessly to a separate unit and logged. They have the advantage of being body-worn and simple to use, and the units have no line of sight or occlusion issues that are experienced by passive camera systems. Whilst relatively new and not yet adopted clinically, the devices have been validated against camera-based motion capture systems with high correlation Ferrari et al.(2010).

All systems could potentially be incorporated into a biofeedback system and enable the hypothesis to be tested. They all permit access to real-time data streams, and are all capable of providing clinically relevant data of hip joint kinematics. Placing measuring instruments across the hip and pelvis can be problematic, particularly with overweight patients, where tissue thickness can prevent clear registration with bony anatomy. This may be more problematic with electrogoniometry compared to the placement of small
markers or transducers, and more so in the case of trans-femoral amputees with high sockets.

Camera-based motion capture provides the greatest versatility of the three techniques described, because the hardware and software do not simply provide a prescriptive “off-the-shelf” solution to a particular measurement problem. Model definition and landmark selection can be focused for specific clinical issues and as such a higher degree of accuracy can potentially be achieved. The equipment is however costly, and operation requires expertise and dedicated space that could prevent wider use in rehabilitation clinics. In most circumstances their use is restricted to laboratory or clinic use. In contrast, inertia sensing and electrogoniometry have the advantage that they output joint angle data without the need for additional processing or modelling. The equipment is also relatively easy to don without the expertise required for marker placement, which could make inertia sensing and electrogoniometry more suitable for use in a physiotherapy environment.

The training environment and context in which the biofeedback system would be used was the deciding factor in the choice of measurement instrument. A camera-based motion capture system was chosen. The reasons for which will be addressed in the next section, with regard to the training environment.

3.2.3 Justification for laboratory testing and use of a treadmill

There are a number of technical challenges to using RT kinematic biofeedback in the community. A comparison is required to be made between the patient’s joint angles and a normal reference dataset in order to determine an “error” signal to drive feedback. This reference dataset would need to accommodate the many different modes of walking the patient may undertake in the community, such as turning corners, ascending and descending slopes, steps and curbs. The piecewise nature of gait in the community was highlighted by Orendurff (2008) who used a step counter to study the “gait of daily living” in 10 healthy office workers. Step length data were collected continuously over a 14 day period and a walking bout was defined as one 10-second period in which steps occurred. Orendurff reported that 40% of all walking bouts were less than 12 steps in a row. 75%
were less than 40 steps and a 2 minute walk accounted for only 1% of all walking. A biofeedback algorithm would be required to discriminate between the strategies employed for different terrains and determine if it is normal or pathological. That is a very challenging technical task. It would also be required to identify nearby slopes and objects that the patient may be trying to avoid, and predict what impact these may have on the current movement strategy being adopted by the patient.

In addition to this substantial signal processing challenge, it became clear from the review summarised in Chapter 2 that there are also a number of unknowns surrounding how biofeedback can be applied to optimise clinical gains. Issues such as the timing of delivery, the most appropriate choice of sensory modality, level of immersion and so on. These were summarised in Section 2.7. These more fundamental questions would benefit from further investigation before biofeedback can be used effectively in the community.

An alternative considered was to approach the problem in the more controlled environment of a running track. However it was considered practically advantageous to develop a biofeedback training system for initial use in a laboratory, to test the hypothesis; but ensure there is scope to migrate to a body-worn device for community use at a later stage. This enabled the benefits of using a motion capture camera system around a treadmill, within a controlled laboratory environment.

To enable the output from this work to be extended into a community application, the gait dynamics undertaken by amputees on a treadmill must be similar to that of gait enacted in the community. Given the poor understanding of community gait, from the quantification issues raised above, references are commonly adopted from straight line overground gait. This is a widely accepted limitation that is acknowledged for the practical purposes of this work.

A number of studies have compared treadmill and overground gait, reporting small and conflicting differences in joint range of motion. Riley et al. (2007) found a decrease in peak hip and knee flexion/extension with treadmill gait in healthy subjects, whilst Alton et al. (1998) and Wall and Charteris (1981) reported increases in hip range of motion. The
absolute magnitude of the differences was small however (less than 1.6 degrees) and considered to be within the range of kinematic measurement variability (Riley, Paolini et al. 2007).

Wall and Charteris looked at the habituation of 18 healthy adult male subjects to the treadmill, requiring them to walk for two 10-minute sessions per week for 12 weeks. They reported an initial rapid accommodation at the start of each session, followed by a longer and more gradual habituation. They suggested that where measurements are made of gait patterns using treadmills, subjects should be habituated in distributed practice sessions for 1 hour, and then not measured within the first 2 minutes of performance (Wall and Charteris 1981). In a later study Matsas (2000) used shorter habituation times and reported that knee kinematics and temporal-spatial gait parameters became highly correlated with overground walking after only 6 minutes of treadmill gait.

These studies looked at healthy individuals. To assess the gait pattern of amputees on the treadmill compared to overground gait, Button (2010) asked 3 male trans-tibial amputees to walk at their self-selected walking speed and at an enforced speed. They reported that maximum range for the hip and knee angles differed between conditions (by 0.2 to 3.8 degrees). The reason was unclear but they suggest research with amputees walking on a treadmill should be interpreted with caution.

In summary, there is kinematic similarity between treadmill and overground gait in healthy subjects. However it has been advised to adopt a habituation period in treadmill studies of at least 6 minutes prior to data collection, to reduce treadmill-related gait variability. Dingwell and Davis (1996) have previously demonstrated the feasibility of using an instrumented treadmill and real-time biofeedback training with amputees, as described in Section 2.3.3. Conducting biofeedback training on a treadmill is advantageous, because it enables the patient to enact a higher number of cycles than can be achieved within the community, or during overground gait in a laboratory. The use of a treadmill minimises external stimuli, allowing patients to focus safely on rehabilitation. It also enables clinical staff a better opportunity to observe and support patients. As such a treadmill was used for this work, with an optical motion capture system.
3.2.4 Choice of stimulus modality

The methods considered included: visual and virtual reality, haptic, auditory, vibration and electro–tactile stimulation. Each mode has been used in gait re-training with mixed success, as described in Chapter 2. The efficacy of each is not assessed here, because it is difficult to make a comparative assessment. The choice made was essentially a practical one, with a number of questions considered: Which modality would be the safest and easiest for a patient to use, and be transferable from treadmill to community training environments? Which method would provide scope for investigation into the timing and delivery issues raised in Section 2.7, and scope for use with other patient groups and body segments?

To narrow down the options, the first distinction made was in the neurological pathways through which the perceived information reaches the central nervous system. Visual and auditory feedback are perceived through cranial nerves (II and VIII respectively) directly into the respective cortical areas. Higher cognitive processes are engaged in interpreting the information, then forming and refining the required movement strategy. In contrast to this, vibratory, haptic and electro–tactile stimulation are perceived through the peripheral somatosensory pathways at different levels into the spinocerebellar tract of the spinal cord, before connection is made to the cerebellum where information is processed unconsciously. There has been no work comparing the role of the two pathways (descending vs. ascending) in biofeedback. Yet given the involvement of spinal cord structures in the regulation of gait, it is possible that conscious engagement with part or all of the feedback information may not be required for gait modification to take place. This is an interesting question open for future research.

On a practical level it is possible that presenting information visually or acoustically could hinder or block the patient’s ability to perceive the environment, particularly in the community. Whilst head-mounted display technology is emerging in the consumer market, with for example, the “Google Glass” project (Google Inc. California, USA), real-time visual feedback may also present a higher risk of falls in the community for patients with pre-existing mobility issues.
Chapter 3: Research Approach

Through discussion with amputees and Specialist Amputee Physiotherapists at the Douglas Bader Rehabilitation Centre (Queen Mary’s Hospital, Roehampton), it was suggested that acoustic tones and signals that are audible to the wider society, would be unwelcome to patients in daily life.

These “descending modalities” were therefore ruled out in favour of the possibility of more physiologically compatible information perception through the peripheral nervous system. In addition to being less of a hindrance to the patient, haptic, vibratory and electro-tactile stimulation elements may be more suited to being embedded in prosthetic components.

Haptic technology broadly refers to devices that physically oppose body segments to produce movement and tactile sensations. It includes vibratory and electro-tactile stimulators. Haptic technology that causes gross movement of body segments was ruled out for two pragmatic reasons: a high degree of engineering complexity would be required to move the thigh through the gait cycle. This would effectively involve the development of a body-worn exoskeleton, which could have a disproportionate cost-benefit for the clinical problem, and potentially produce a limited end-product. Haptic treadmill-based devices, such as the Lokomat described in Chapter 2 have a place in rehabilitation with high levels of impairment, but they are limited to the clinical setting. Ambulatory exoskeletons such as the “e-Legs” (from Berkeley Bionics, USA) and the “Walk Assist” (from Honda, Tokyo, Japan) are currently in development and may help patients transfer between clinical and community gait re-training environments in future.

Vibro-tactile (VT) and electro-tactile (ET) stimulation have many advantages over the modalities described so far. Unlike visual and auditory stimuli, ET and VT can spatially code the feedback information by applying localised sensations, and therefore have the potential to intuitively engage the patient with the movement task. Unambiguous feedback which is less cognitively demanding may permit patients greater freedom in normal daily living. Electrodes and vibration motors can be applied to many areas of the skin surface and the controlling software could be re-configured for a range of clinical issues, thus making vibration and electrical stimulation more versatile forms of delivering feedback.
The technology is also portable and has the potential to be less encumbering, particularly when built into prosthetic components. Both modalities presented equal merit.

Electrical stimulation is an established technology at the University of Surrey, but VT stimulation has yet to achieve the same degree of familiarity. As such two prototype VT devices were constructed and briefly investigated to gain a better understanding of VT stimulation.

**Investigation with vibro-tactile belt**

The investigation was a familiarisation exercise to experience the sensations produced by VT stimulation and determine if the technology would benefit from further development to provide feedback for the targeted population in this work.

A prototype VT belt shown in Figure 17 was developed, incorporating eight 10 mm diameter shaftless DC vibration motors (Namiki Precision Jewel Co., Ltd, Tokyo).
Current consumption of each motor was rated at 100 mA at 5 V. The motors were driven using pulse width modulation (PWM) of a TTL level digital output from a National Instruments 6008 GPIO board. The board sourced 5 mA, so eight BC549 NPN bipolar junction transistors were used as emitter followers, to provide the necessary drive currents. Each unit was secured equidistant along a 72 mm (3 inch) wide fabrifoam sleeve (Pennsylvania, US).

A software module was written using LabVIEW 2009 to deliver PWM voltage signals to each motor, and provide the operator with control over motor selection, duty cycle and frequency with a Windows based graphical user interface (shown in Appendix D1). A single motor became active when the operator placed the mouse cursor within a corresponding 45 degree arc. The operator was then able to move the cursor around the display to activate successive motors.

The belt was placed around the thighs of 4 healthy staff and student volunteers from the Centre for Biomedical Engineering (University of Surrey). The subjects wore shorts and were seated with the thigh positioned over the edge of the chair. The motors were activated individually with varying duty cycles. Subjects could not see the PC control and were asked to indicate which stimulation point was active, and then to provide feedback about the sensations experienced through discussion. This was repeated with subjects standing and walking overground through the Gait Laboratory.

The sensations were considered to be a definite presence, clearly indicating specific regions of the thigh. Subjects found the locations easy to discriminate, with all of the activations correctly located whilst sitting, standing and walking. The subjects were indifferent to the changes to the sensation with varying duty cycle. None of the sensations produced were uncomfortable. Whilst the sessions lasted only 30 minutes, subjects suggested the sensation would be acceptable on a longer-term basis.
**Investigation with vibro-tactile cuff**

To find out if these positive indications were experienced with the motors embedded into a prosthetic socket, two options were considered: To embed the motors into a prosthetic socket and gain patient feedback, or to replicate the physical arrangement in a non-prosthetic component such that non-amputees could experience the resulting sensation. Given the cost and personal value of prosthetic sockets for patients, the latter was chosen and a rigid cuff was developed to fit the Author’s thigh. The aim was to load the cuff in a similar way to that experienced by amputees and gain experience of the resulting vibrotactile sensations.

The cuff (shown in Figure 18) was developed with help from staff in the Prosthetics Department at the Douglas Bader Rehabilitation Centre (Queen Mary’s Hospital).

![Figure 18 Laminated thigh cuff containing eight DC brushless vibration motors](image)

The right thigh was cast and a positive plaster cast section was made. 11 mm diameter mild steel disks were placed equidistant around the cast at mid thigh section to create dimples in which to site the motors. The disk thickness was chosen to cause a 2 mm protrusion of the motors into the thigh. A glass reinforced plastic cuff was then produced, following the normal lamination process used in prosthetic socket production. The vibration motors were secured in place using a thermoplastic adhesive, with the motor leads fed to the outside of the cuff through holes drilled at each stimulation site.
Whilst standing with the cuff in place, the cuff was positioned onto two rigid hardwood surfaces (chair arms) placed medially and laterally, so that it was possible to unload the leg and bear all of the bodyweight through the cuff. A second experimenter activated each of the motors and varied the duty cycle. A range of bandages and sleeves were worn to replicate a socket liner, and bodyweight was subjectively shifted into and out of the cuff.

The resulting sensations were considerably diminished compared to those produced by the belt. It was not possible, under any of the conditions tried, to distinguish the location of the stimulation to one particular motor. The sensation was instead perceived in approximate quadrants (medial, lateral, anterior and posterior), as localised vibrations propagated around the cuff. An alternative arrangement was tried, using the belt inside the thigh cuff, with no notable improvement.

Both prototypes have potential to be developed for use in rehabilitation. It may be possible to mechanically de-coupled the motors from the rigid shell of the cuff, using a compliant fixing, to improve the localisation of the sensation. But this would increase the manufacturing complexity and cost. The belt could find immediate use in lower limb neurological rehabilitation, or in the upper limb as an adjunct to constraint-induced movement therapy for example. It may also be possible to incorporate a vibration belt proximal to a prosthetic socket for patients with lower sub-ischial weight bearing sockets.

There is little research in the development of prosthetic sockets generally, and no work was found in using vibration biofeedback for lower limb amputees. This may change in future if the biomechanical shortfalls in the socket are highlighted in contrast to advances in prosthetic joints. In contrast, the few workers who have developed electro-tactile stimulation biofeedback for amputees (notably Clippinger then Sabolich) have reported benefits in their patients, as discussed in Chapter 2. For this reason the decision was made to proceed with electro-tactile stimulation in this work.
3.2.5 Real-time considerations

The training system is required to provide biofeedback in real-time (RT). The Oxford English Dictionary defines real-time as:

“The actual time during which a process or event occurs, esp. one analysed by a computer, in contrast to time subsequent to it when processing may be done, a recording replayed, etc. Freq. in real time: performed or occurring in response to a process or event and virtually simultaneously with it”

The phrase emerged in the 1960s when computers were increasingly used to simulate physical processes. A simulation is considered to occur in RT when the simulation rate matches that of the physical process. The absolute definition is therefore dependent on the characteristics of the system or process under consideration. RT is also commonly described in terms of ‘hard’ or ‘soft’ deadlines. A hard RT system requires a response within a discrete timeframe, and missing a hard RT deadline has system critical implications. In contrast there is flexibility within the bounds of a soft RT deadline, and a late response diminishes the usefulness of a system over time.

In the application of real-time biofeedback there is a window within which feedback can be presented. The earliest time is limited to the physical characteristics of the instrumentation, and is an inherent latency in biofeedback. The latest time results from the reaction time of the individual, beyond which the user would perceive a time delay. For all practical purposes the real-time deadline in this work was therefore defined as user reaction time, or the speed at which biofeedback information is perceived by the patient.

Reaction times differ between sensory modalities. For example, the response to visual and auditory stimuli are 190 ms and 155 ms respectively, and approximately 150 ms for tactile stimuli (Boff and Lincoln 1988). Reaction time is dependent on a large number of factors related to the nature of the stimulus, the physiology and the test conditions, for example: a higher cognitive demand produces longer reaction times. The levels of arousal or fatigue, age, gender, handedness, prior warnings and the relevance of the stimuli to survival also
influence reaction time. It was therefore not possible to provide a definite time period, but as a design guide the shortest time of the sensory modalities was used, that of 150 ms.

As discussed in Chapter 2 the effect of varying the KR delay interval (the time between an event and reception of feedback) on motor learning is not currently known, so the criticality of a real-time requirement on learning is also not known. However a limit of 150 ms provides the greatest possible scope for future work.

Real-time processes can operate on dedicated hardware (such as the PXI platform from National Instruments, Texas, USA) which are optimised for high speed applications, and are controlled using separate hardware; or on general purpose personal computers (PCs) which incorporate application and use-interface layers. Dedicated RT hardware was discounted on the grounds of cost and the restrictions that would be placed on the end use. Those RT processes operating on PCs can either use a general purpose or a real-time operating system (GPOS/RTOS).

There is little control over task priority with GPOSs such as Microsoft Windows or Unix, where high priority tasks can be pre-empted by lower priority tasks. There is also higher and unrestricted task time variation (or system jitter) in successive program iterations within a GPOS. This arises from background user-interface and application level activity (such as peripheral interrupt handling, screen savers, disk utilities, virus scanning software and so on). This limits GPOSs to a RT loop rate of approximately 100 Hz. In contrast RTOSs limit system jitter by using a scheduler to take control over all tasks and ensure task priority is considered during execution. RTOSs are stand-alone and are capable of loop rates up to 50 kHz.

RT Targets are an alternative software option that may help, that run on general purpose operating systems but take control over low level functions for specific applications. RT operating systems and targets restrict the PC user to the specific RT application, therefore the Windows XP operating system (Microsoft, Washington, USA) was chosen for this work.
3.3 Outline of Biofeedback System

The hypothesis being tested is that real-time electro-tactile feedback is a viable method of assisting in the reduction of circumduction and abduction gait patterns in trans-femoral amputees. There are currently no devices available that can provide biofeedback to help in the correction of circumduction gait patterns, so a training system was developed for this work that could be used with healthy individuals and trans-femoral amputees. The system developed is shown in Figure 19.

![Figure 19 Overview of biofeedback training system](image)

It comprises a ProReflex optical motion capture system (Qualys Gothenburg, Sweden) to record thigh and pelvis motion whilst the subject walks on a treadmill. Real-time feedback is presented to the skin of the amputees stump using a multi-channel electro-tactile stimulator and an array of surface electrodes. A standard desktop computer running Windows XP performs data acquisition and processing, and the system operates with a real-time deadline of 150 milliseconds. The chosen options provide potential for wider research or to form part of a clinic-based gait re-training programme for a range of patient groups.
3.4 Approach and Work Outline

A number of scientific and engineering tasks were required before the patient-in-the-loop could be examined: The design and construction of an electro-tactile stimulator, an electrode array, and the development and integration of software capable of real-time motion analysis and provision of feedback.

As noted by Kaczmarek and Bach-y-Rita (1995) there are a wide range of parameters in the design of electro-tactile systems that influence the resulting sensory dynamic range. All are poorly studied and documented. In this work the electrode geometry was based on that of Buma et al. (2007), and the circuit was based on a muscle stimulator design with the assumption that the output would have sufficient range to produce the required physiological response for sensory stimulation. A bi-phasic waveform was chosen in order to limit the discomfort that can result from the net transfer of ions across the skin-electrode interface, as experienced with mono-phasic waveforms (Bajd 2006). The circuit enabled control of frequency and intensity, which required investigation.

To provide the greatest dynamic range possible within these options, a range of electrode diameters and inter-electrode spacings required investigation, from which the conductor sizes were chosen. This work is described in Chapter 4. The chosen circuit enabled adjustment of the waveform pulse width. However changing pulse width and amplitude have a similar effect, of changing power transfer to the patient, so the pulse width was fixed during development, and stimulation amplitude was investigated.

For the sensation to have practical utility as a feedback stimulus for gait re-training, the user must be able to discriminate the location of different stimulation sites on the skin surface and the movement of the stimulus around the leg. It is also very important that the sensation does not cause discomfort or harm the user, and so is required to have a wide dynamic range. The sensory thresholds (of perception and discomfort) and the discrimination ability were therefore examined for a number of movement tasks, using a range of frequencies, as described in Chapter 5.
A medical grade treadmill (Woodway, Wisconsin, USA) was in place, as was a stand-alone ProReflex optical motion capture system (Qualysis Gothenburg, Sweden).

The software used with the camera system (Qualysis Track Manager, QTM) provided the option to continuously output raw marker coordinate data on request. So software was required to read the data stream and determine where and when electro-tactile stimulation should be provided. This involved data acquisition, construction of a biomechanical model, gait event detection, comparison with a non-amputee reference data set and control of the stimulator, in real-time.

In summary the tasks required (and corresponding Chapters) included:

- Development of an electro-tactile stimulator and an electrode array (Chapter 4)
- Investigation of the sensory thresholds on the thigh (Chapter 5)
- Development of real-time acquisition and control software (Chapter 6)
- Investigation of the biofeedback system with amputees (Chapter 7)
- Evaluation of the project and a summary of further work (Chapters 8 and 9)
Chapter 4

Development of a Sensory Stimulus
4.1 Introduction

This Chapter presents the development of a feedback stimulus for use in the training system. The Chapter begins by describing the strategy that was chosen to apply the stimulus in such a way as to provide meaningful information for amputees. Designs for a surface electrode and an electro-tactile stimulator are then presented.

Electrostatic modelling of the electrode-skin interface has been used in the development of muscle stimulators and electrodes, but was not employed here. Muscle stimulation modelling has involved larger anatomical structures and tissue depths in the order of millimetres (Panescu, Webster et al. 1994). Systematic modelling errors could diminish the value of modelling when applied to the more superficial layers of interest in sensory stimulation, where receptors reside in a thinner layer with higher resistance and greater inhomogeneity.

An empirical approach was taken to narrow down the design choices, as discussed in Section 3.4. It is summarised as follows: The design of the sensory electrode was based on Buma et al. (2007), and a range of geometries were investigated to determine the most suitable conductor sizes. This work is described in Section 4.3. A commercial muscle stimulator was used (with a fixed pulse width and frequency) under the assumption that the output would provide sufficient range for the required sensory response.

The electro-tactile stimulator was based on an available muscle stimulator circuit design and expanded to include multiple channels and PC control. This work is described in Section 4.4. The stimulator was provided with control of frequency and pulse width. However to accommodate for potential sensory threshold variations around the thigh that may exist as a result of nerve distribution, the stimulator was also provided with manual adjustment of applied current for each electrode. In practice the patient would set the intensity level for each electrode, during a set-up and familiarisation process. The intensity and frequency required to produce the desired psychophysical response are investigated in Chapter 5. Note: The term electrode is used here to describe a pair of conductors. One electrode provides one localised site of stimulation.
4.2 Feedback Delivery

Looking at the electro-tactile display work described in Chapter 2, information has previously been coded spatially, such that a stimulus moves across an array of electrodes to correspond with the movement of a limb; or through graphical or textual symbols presented to a local area, such as those used in Braille. Movement of the thigh can be described by three joint angles, so the feedback error signal used was represented geometrically to correspond with limb movement, rather than presenting information using a Braille-type display.

Considering the spatial relationship between the movement of the stimulus and the limb, Buma (2007) developed electrodes which they propose could be placed on the medial side of the thigh above the knee, to present knee flexion/extension data to trans-femoral amputees. In this arrangement the stimulus movement would be spatially mismatched to that of the limb, and may be difficult for patients to understand.

During circumduction the thigh prescribes a path in the transverse plane, and is characterised by greater than normal peak excursion in abduction during swing (Kerrigan, Frates et al. 2000). It was assumed that reduction of circumduction could be achieved in the sagittal and coronal planes only. Providing feedback about rotation would also require an additional coding method that may reduce clarity in the information already presented, this was considered unnecessary. The feedback error signal was therefore coded using the coronal and sagittal hip joint angles, and thigh transverse rotation was neglected. A consequence of poor thigh rotation may be seen in foot placement, which can be observed.

The chosen coding strategy is shown in Figure 20 and the implementation is discussed in further detail in Section 6.3.8. A transverse section of a left thigh is shown with electro-tactile electrodes spaced equidistant around the leg. The leg is presented at an instance in the gait cycle, with the axes representing hip joint flexion/extension and abduction/adduction.
The cross with the square represents the mean and two standard deviations of normal sagittal and coronal hip angles at that instant in the gait cycle. The cross with the circle represents the hip posture of the patient undergoing training. The electrode which is to become active (shown in red) is selected according to the angle of the vector connecting the two crosshairs, and stimuli are delivered to that electrode when the vector magnitude exceeds user-set values for both coronal and sagittal plane vector components. The resulting sensation is that of a sensory boundary around the thigh guiding the patient towards the goals set by the clinician. The example in Figure 20 shows a patient with a slightly increased hip flexion, and an excessive hip abduction, as may be seen in an amputee circumducting through swing.

Stimulating directly over sensory nerves may lead to painful localised sensations. Looking at the anatomy of the thigh (Figure 21) there are primarily 4 superficial and 6 deep nerves...
in the area of interest. The superficial nerves are responsible for cutaneous sensation and include the lateral cutaneous nerve, the posterior femoral cutaneous nerve and the intermediate and medial femoral cutaneous nerve branches.

Figure 21 Superficial nerves of the thigh, in the sagittal plane (left) and coronal plane (right) (Biodigital Human 2011)

Deep nerves run through the thigh include the femoral, obturator, sciatic, common peroneal, saphenous and tibial nerves.

Natural bifurcation and anastomosis variations occur between the axial branches of the femoral cutaneous nerves in the normal population. Also no studies were found that identify if changes to superficial nerve distribution occur in the amputee population as a result of surgery. So it was not possible to confidently site electrodes in such a way as to avoid direct placement over sensory nerves. Control of stimulation intensity was therefore required for each electrode location, to accommodate regional and subject variations in sensory thresholds.
The level at which the electrode array was to be placed may affect the perception of the sensory boundary intended by the feedback signals. The effect may appear best at the distal tip of the limb, where the femur is prescribing an arch and ‘in contact’ with the sensory boundary. However the stump tissue is often more uneven and scarred at the distal end as a result of surgery. To ensure consistently within the amputee cohort the placement distance was fixed according to easily identifiable bony landmarks.

Following discussion with Prosthetists and Specialist Amputee Physiotherapists at Queen Mary’s Hospital (Roehampton, London), the location of the electrode array was chosen to be 2/3 the length of the stump, measured from the anterior superior iliac spine (ASIS), on a line from the ASIS to the distal-most aspect of the stump, on the lateral side. This was a practical compromise between the possibilities of poor skin contact at the distal end and reduced relevance of feedback at the proximal end.
4.3 Design and Development of Electrodes for Sensory Stimulation

4.3.1 Requirements

The surface electrodes were required to deliver a localised current flow to the superficial layers of the dermis to cause activation of sensory receptors without causing pain or skin irritation.

To minimise irritation and possible skin damage, the electrodes must not introduce non-native ions into the skin, they must not react chemically or produce an insulating layer between the electrode and skin. The conductor material must therefore not kink or introduce low resistance paths. To achieve this and provide a uniform distribution of current flow across the tissue, it was a requirement to include a low-conductive hydrogel as an electrode-skin interface. Without which current will flow through small regions of lower resistance (sweat and sebaceous glands, and small epithelial tears).

Based on the range of stimulation parameters previously reported (Chapter 2) a stimulating current range of 0 – 150 mA at 120 V would provide scope for investigating a suitable electrode for this application. The electrodes and leads must carry a proportion of the power, with a 1:40 mark-space ratio (with a frequency of 80 Hz and 300 µs pulse width).

The electrode size and inter-electrode spacing should permit an even number of equidistant stimulation sites around the thigh, so that the anterior, lateral, posterior and medial surfaces of the thigh could be stimulated, in addition to intermediate sites.

To avoid causing an encumbrance to the user, or a distraction to walking the electrodes must be relatively simple to don and doff by non-experienced users; they must not unduly press against the skin when placed inside the prosthetic socket, and the assembled electrodes, leads and connections must not be cause a vacuum loss in prosthetic suspension type, or be a trip hazard.
4.3.2 Electrode design and fabrication method

The electrodes were based on the annular design by Buma et al. (2007), as shown in Figure 22. A brief investigation was carried out with some prototype electrodes to gain familiarisation of the design, to determine what scope there was to use the electrode for this application, and to select the most appropriate sizes.

The electrodes can be described in terms of conductor surface areas, ratio of the surface areas, or the gap width and conductor diameters. Electrodes were described according to the outer diameter (D1), gap diameter (D2) and inner diameter (D3) as shown in Figure 22. Given the large combination of electrode sizes that could be generated, a representative sample was used that could be practically assessed in a short investigation. Three inner diameters and three gap widths were investigated, and each group was repeated 3 times for different outer diameters, involving investigation of 18 electrodes in total. Figure 23 and Figure 24 illustrate the effect of changing these parameters.
The choice of outer diameter was a compromise between the required resolution of the array and the minimum thigh circumference of the user population. A non-pathological adult female thigh circumference of 344 mm was used (Peebles and Norris 1998). To ensure no contact was made between adjacent electrodes around the thigh, an electrode-to-electrode space of 5 mm was considered sufficient allowance for the experimenter placing the electrodes. Placing electrodes equidistant around the thigh (including the anterior, posterior, medial and lateral-most positions) would require a minimum of 4 electrodes (requiring 81 mm of space per electrode), whilst 8, 12 and 16 electrodes would require 38, 24 and 17 mm respectively. The surface of the thigh has a TPTT of 46 mm (as discussed in Section 2.4.1), so the smaller electrodes may not present a benefit in terms of resolution. They may also experience adhesion difficulties. A resolution of 8 was therefore chosen, and the outer diameters investigated ranged from 33 to 38 mm.

The minimum inner diameter was limited to 6 mm based on Buma et al. (2007), and three diameters were selected from 6 to 12 mm. A minimum gap width of 4 mm was chosen and three gap widths were selected from 4 to 10 mm. The electrode geometries chosen for investigation are shown in Table 4.

<table>
<thead>
<tr>
<th>Table 4</th>
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<tr>
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<td>A1</td>
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<tr>
<td>Outer diameter D1 (mm)</td>
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<tr>
<td>Gap diameter D2 (mm)</td>
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<tr>
<td>Inner diameter D3 (mm)</td>
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<tr>
<td>Gap diameter (D2) mm</td>
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<td>17</td>
<td>20</td>
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<tr>
<td>Inner diameter (D3)</td>
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<tr>
<td>Gap width (mm)</td>
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Fabrication

A flexible printed circuit material was chosen to provide some flexibility and ease of construction using standard PCB production methods. The conductor material consisted of two layers of copper (35µm thick) separated by a flexible polyimide substrate (50µm thick). The material was supplied raw and non-presensitised (Figure 25), so to enable etching the material was laminated with a dry film photoresist using a standard office laminator.

Figure 25 Electrode fabrication: Raw copper/polyimide material (left), completed electrodes with hydrogel and connections - skin contact surface (middle) and outer surface (right)

A negative resist process was used. When exposed to UV light a negative resist becomes polymerised and harder to dissolve in developer. The resist remains on the surface of the substrate where it is exposed and the developer solution removes only the unexposed areas. The mask used therefore contained the photographic negative of the pattern to be transferred. The board was exposed to UV light for 20 to 30 seconds, fixing the exposed resist. A potassium carbonate developer diluted with water to 10% was used to remove the unexposed photoresist. The electrodes were then placed in a tray with ferric chloride and agitated manually for 20 minutes to remove the unexposed copper. A heated bath was not used in this case because the material lacked stiffness and would curl into the bottom of the bath. Finally the exposed photoresist was removed using a concentrated liquid developer (SENO 4006, Mega Electronics Ltd, Cambridge UK). It is common in standard PCB manufacture to apply an acrylic lacquer to protect the copper tracks. A lacquer was not applied in this case, since conduction at the surface of the copper was required. The front and back electrode pads were connected using solder via pin prick holes and soldered to insulated wires. The electrodes were pressed during the soldering process to minimise high spots at the pin prick joints.
Chapter 4: Development of a Sensory Stimulus

Based on the electrode array development work of Silveira (2009) a self-adhesive hydrogel (AG803, Amgel Technologies Inc, Fallbrook, USA) was used as an electrode–skin interface (Figure 26). Since the raw material was very soft and adhesive it was difficult to shape using scissors or shears. A sharpened punch was used against a hard surface to cut the disks and backing material. 300 disks were cut.

![Image](image1.png)

Figure 26 Hydrogel material: Supplied in a stock roll (left), punch (middle), gel and backing material (right)

![Image](image2.png)

Figure 27 Assembled electrode array (left) and a selection of electrode sizes in-situ (right)

This fabrication method enabled simple and relatively quick construction of electrodes.

4.3.3 Investigation of electrode diameter

Two asymptomatic male subjects from staff within the University of Surrey’s Centre for Biomedical Engineering volunteered to take part. Electrodes were placed one at a time on the anterior surface of thigh of the self-reported dominant leg. Stimulation was delivered using a battery-operated ODFS-II Functional Electrical Stimulator (Odstock Medical Ltd, Salisbury UK). Subjects were seated, asked to relax and could not see the stimulator controls. An asymmetrical biphasic waveform with a frequency of 40 Hz and pulse width of 100 µs was used. Amplitude was gradually increased and the subjects were asked to respond verbally when they could first perceive a sensation. The applied peak current was
measured and recorded using a current probe (Tektronix AM 503 current probe amplifier) and digital oscilloscope, and the stimulus was removed. After a brief pause, the stimulus was again increased (visually noting the point at which the first level was passed) and the subjects were asked to respond when they felt the sensation to be uncomfortable. The second value was recorded and the stimulus removed. The process was repeated for each electrode, with pauses between electrodes to examine the skin surface for reddening and reduce the chances of adaptation. The trial was repeated one week later. The results for both trials are shown below (Figure 28).

Figure 28 Peak applied current at perception (blue) and discomfort (red) levels for varying inner diameters (6, 9 and 12 mm) and outer diameters (33, 35 and 38 mm - top), and varying gap widths (4, 7 and 10 mm) and outer diameters (bottom). Values for both trials are shown for Subject 1 (left) and Subject 2 (right).
There was a distinct and perceptible difference between the perception and discomfort levels, demonstrating a potentially useful range, more so in Subject 2 than Subject 1. Less variation was seen in the perception level in both subjects compared to the discomfort level. This was expected, in part due to the subjective nature of discomfort and the subject’s repeatability in their own representation of discomfort. There are slopes in both threshold levels for each group of three electrodes, which is most notable in Subject 2 and in the 33mm outer diameter electrode. Since the electrode order was randomised during the trial this could suggest that the dynamic range is reduced with increasing gap width, increasing inner diameter and hence increased outer diameters.

The investigation was limited to only two subjects, both of whom were male and had prior familiarity with (functional) electrical stimulation. It is common practice in neurophysiological recordings (in nerve conduction measurements for example) to warm the limb in a water bath to take into account the temperature response of neural signalling, however the temperature was not controlled or monitored in this investigation. Time of day, prior physical activity and the use of stimulants (such as caffeine) were not taken into account. Future work could incorporate control measures for these factors.

The investigation was not designed to investigate the relationships between the parameters and thresholds. The aim was to gain a sense of whether there was scope to use annular electrodes, and if so to choose an electrode geometry for further detailed investigation. From these results the low variation in the sensation threshold levels and the potentially useful range between perception and discomfort levels suggested the electrodes did merit further attention. Electrode A4 (33 mm outer diameter, 7 mm inner diameter) was chosen because, from the limited results, A4 produced a separation between threshold levels and the thresholds were more consistent in both subjects.
4.4 **Design and Development of Electro-tactile Stimulator**

4.4.1 **Requirements**

The stimulator was required to deliver a sensory stimulation waveform with an output current and voltage range that would elicit the expected physiological response from perception to discomfort. Since the physiological response is also a function of electrode geometry, the required ranges were not known. So the design was based on a muscle stimulator design, with the assumption that the output would have a sufficient range for more sensitive sensory stimulation. Therefore the stimulator was required to provide a maximum current output of $\pm 120$ mA, a maximum output voltage range of $\pm 120$ V a.c., an off resistance $\geq 100$ MΩ and on resistance $\leq 10$ Ω, with no distortion to the waveform, based on Odstock Medical Ltd (2006). An adjustable pulse width was also required (ranging from 1 to 300 µs) as was an adjustable pulse repetition frequency (ranging from 1 to 300 Hz). Electrical stimulators can operate as constant current or constant voltage devices. In the presence of high impedance loads (resulting from poor electrode contact) constant current devices increase the applied voltage to maintain current density, this has potential to produce localised high current densities at the low impedance areas under the electrode, which can cause discomfort. The stimulator was therefore required to operate as a constant voltage device, in which the applied current is reduced. To limit the transfer of ions across skin-electrode interface, the device was required to use a bi-phasic waveform.

A minimum of 8 channels of stimulation were required to provide the spatially symmetrical resolution of the chosen electrode array (in practice a 16 channel device was developed to provide greater flexibility for future work). An interrupt-based emergency stop button was required for the reassurance of the user. To ensure the operator or user had physical control of the output, the stimulation amplitude was to be controlled manually via potentiometers. A PC-based user interface was required to enable control of the stimulator independent of the feedback system, for development and testing purposes. Real-time manual operator control was required to incorporate control of the active electrode selection and the ability to sweep through the electrodes, control the waveform pulse width, frequency and start/stop functions and indication of system status through lights or
PC messaging. As a failsafe measure, handshaking was required between the device and controlling PC to ensure stimulation was stopped in the event of a physical or software fault. To reduce the risk of electric shock from the device while in use, the device was required to incorporate patient isolation and be powered by a battery. The device was designed to comply with BS-EN 60601-1:2006 Medical Electrical Equipment – Part 1: General requirements for safety and BS-EN 60601-2-10:2001: Medical electrical equipment – Part 2.10: Particular requirements for the safety of nerve and muscle stimulators.

### 4.4.2 Circuit design

The pulse amplifier circuit from an FES stimulator (Odstock Medical Ltd) shown in Figure 29, was used to generate the stimulation waveform. A positive square pulse is delivered to the base of a Darlington driver, via a resistor network. The resistors provide an adjustable base bias to the driver and control the stimulus amplitude. The Darlington pair acts as a current amplifier and switches a 9 Volt supply across the transformer (TR1). TR1 steps up the voltage, providing a voltage controlled stimulus which discharges through the electrodes. A fast switching diode (D1) protects the Darlington driver when the primary field collapses.

![Figure 29 Pulse amplifier circuit](image-url)
Chapter 4: Development of a Sensory Stimulus

Assuming a purely resistive load of 1kΩ across the electrodes (Grimnes 1983), the reflected impedance \( R'_{\text{LOAD}} \) seen at the primary coil is given by:

\[
R'_{\text{LOAD}} = R_{\text{LOAD}} \cdot \left( \frac{N_p}{N_S} \right)^2
\]

\[= 1000(45/840)^2 = 3\Omega\]

Assuming no heating losses in the iron core, the voltage transformation provided by TR1 is:

\[V_S = V_P \cdot \left( \frac{N_S}{N_P} \right)\]

Where \( V_P = 9 \text{ V} \) minus one diode drop across the Darlington driver

\[= 8.4 \left( \frac{840}{45} \right) = 156.8 \text{ V}\]

The required peak collector current \( I_C \) is therefore:

\[I_C = \left( \frac{V_P}{R'_{\text{LOAD}}} \right)\]

\[= \left( \frac{8.4}{3} \right) = 2.8\text{A}\]

This is switched to the transformer primary by the Darlington driver. From the 5V regulated supply, the base current and voltage are controlled via a potentiometer across the resistor network giving:

\[V_B = V_S - 1.4\]

\[= 0 \text{ to } 3.6 \text{ V}\]

and \( I_B = 0 \text{ to } 3 \text{ mA}\)

The required 2.8 Amp collector current is produced (with \( h_{\text{FE}} = 1000 \)). The resulting waveform, shown later in Figure 36, is biphasic and asymmetrical due to first order RL characteristics of TR1.
Chapter 4: Development of a Sensory Stimulus

The current transformation across Tr1 is:

\[ I_s = I_p \left( \frac{N_p}{N_s} \right) \]

Equation 5

\[ = 2.8 \left( \frac{45}{840} \right) = 150 \text{ mA} \]

The Darlington driver has a rated peak current of 800 mA, however since the waveform is pulsed at a maximum of 300µs the device does not overheat. If a fault were to occur the Darlington would act as a fuse and prevent longer pulses being delivered to the patient.

Control was provided by a PIC16F876a microcontroller (Microchip, Arizona USA). The circuit outline is shown in Figure 30 (schematics are included in Appendix E1). The 16F876a is an 8-bit CMOS microcontroller in the mid-range family of Microchip products. It has 8 kBytes of enhanced flash program memory which enabled programming and debugging in-circuit, using a 35-word instruction set.

Figure 30 Stimulator control circuit
The stimulator was not required to store or transmit large pages of data, so the memory requirement was minimal. The 16F876a provided 256 Bytes of EEPROM for data and 368 Bytes of SRAM organised into 4 banks, it contained general purpose and special function registers. An external crystal oscillator (IQXO-22) was provided to enable the PIC to operate at 20 MHz. An instruction cycle (one fetch-execute cycle) takes 4 clock pulses, so 20 MHz provided an internal clock of 5 MHz (or 0.2 µs instructions).

The device has a 22 I/O channels arranged in 3 ports (2x8-bit and 1x6-bit port) that include a number of secondary features: 2 10-bit analog-to-digital converters, 2 timers and 2 capture/compare/PWM functions, in addition to a number of firmware and hardware interrupts. 4 pins from port B were de-multiplexed using a 74HC4514 4-to-16 line decoder, to provide the channel selection signals. These were then AND’d with a pulse generation signal (using a 74HCT08 quad 2-input AND gates) to provide the switching signals required by the Darlington drivers.

The PIC has a synchronous serial port which can be configured as a Serial Peripheral Interface or an Inter-Integrated Circuit bus, and a Universal Asynchronous Receiver Transmitter (USART). A USART was defined and connected to a line driver (MAX 233) to convert between TTL and RS232 signal levels (unlike the MAX232, the MAX233 does not require any external components). An interrupt pin (using a change on rising edge) was used as an input for a manual push button, which was used as an emergency stop. Three LEDs provided an indication of system status – red indicated a positive supply voltage, green gave an output according to the serial communication and hence indicated communication was taking place, and a blue LED was provided for development and debugging use. Remaining pins were set as outputs and connected to header pins.

Power was provided by an 8.4 Volt 1/3Ah PP9 Ni-Cd battery (RS229-059), which was regulated using a series positive voltage regulator (MC78M00). Use of a battery eliminated connection to a mains power supply. Patient isolation was also achieved by isolating the stimulator from the computer using a RS-232 optical isolator (CVT-232A-3 CommFront Communications, Singapore). The isolator was rated at 2500 Vrms for 1 minute. During
development and testing the stimulator was mains powered and isolated using a residual current device.

The circuit functions were split across two single-sided printed circuit boards: one contained the digital control functions, the other contained the analogue amplifiers. They were housed in a large instrumentation case, with the LEDs and potentiometers accessible to the operator, as shown in Figure 31. One of the output header pins emerged through the case for use as a test pin.

![Completed stimulator, front (top) and back (bottom)](image-url)

Figure 31 Completed stimulator, front (top) and back (bottom)
4.4.3 Firmware implementation

Code was developed using the MPLAB v.8.0 Integrated Development Environment (IDE) (Microchip Technology Inc. Arizona, USA) and the CCS c compiler (Custom Computer Services Inc., Wisconsin USA). Both of which are dedicated for the PIC range of microcontrollers. A PICSTART Plus Programmer was used to program the microcontroller. The organisation of programming elements and associated files is shown below (Figure 32).

![Diagram of firmware implementation]

Figure 32 Programming flow for the PIC microcontroller

On power up the stimulator outputs are held low to ensure no transient outputs are sent to the Darlington driver bases prior to operation. To ensure clarity in the code, a simple state machine was used with two states: “STIMULATING” and “STOPPED”, as shown in Figure 33. The stimulator initially enters the STOPPED state following power up and
during operation remains in either state until a new command is received by the PC, or via the emergency stop button.

Figure 33 Microcontroller code flow
Commands were received via the onboard USART port using an interrupt. Valid commands were identified as ASCII characters followed by the requested value (Table 5).

Table 5 Communications protocol: Codes sent from PC to the microcontroller

<table>
<thead>
<tr>
<th>ASCII code</th>
<th>Associated Value</th>
<th>Command</th>
</tr>
</thead>
<tbody>
<tr>
<td>“h”</td>
<td>None</td>
<td>‘Say Hello’ to PC</td>
</tr>
<tr>
<td>“s”</td>
<td>None</td>
<td>Start stimulation</td>
</tr>
<tr>
<td>“x”</td>
<td>None</td>
<td>Stop stimulation</td>
</tr>
<tr>
<td>“p”</td>
<td>0-300 (µs)</td>
<td>Change pulse width on time</td>
</tr>
<tr>
<td>“b”</td>
<td>0-999999 (µs)</td>
<td>Change pulse train off time</td>
</tr>
<tr>
<td>“e”</td>
<td>0-99</td>
<td>Change active electrode</td>
</tr>
</tbody>
</table>

The “s” command places the stimulator in the STIMULATING state, whereupon the output is pulsed if valid waveform parameters have been provided (by commands “p”, “b” and “e”). The “x” command and the emergency stop button place the stimulator back in the STOPPED state. A character is sent back to the PC when the emergency stop button is used, to inform the operator. The following ASCII characters are sent to the PC to inform the user of system operation (Table 6).

Table 6 Communications protocol: Codes sent from the microcontroller to the PC

<table>
<thead>
<tr>
<th>ASCII code</th>
<th>Associated Value</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>“A”</td>
<td>none</td>
<td>Device is in the STIMULATING state</td>
</tr>
<tr>
<td>“B”</td>
<td>none</td>
<td>Device is in the STOPPED state</td>
</tr>
<tr>
<td>“C”</td>
<td>none</td>
<td>Emergency stop button pressed</td>
</tr>
<tr>
<td>“D”</td>
<td>0-99</td>
<td>Active electrode in use*</td>
</tr>
<tr>
<td>“H”</td>
<td>none</td>
<td>The text “Hello” is sent</td>
</tr>
</tbody>
</table>

* Used only during system development, confirmation of electrode number unnecessary in normal operation

**Handshaking** - occurred between the PC and microcontroller to ensure the user had control of the stimulator. After initialization, a flag was set true each time a valid command was received by the stimulator and set false after 500 ms had expired. Between sending waveform parameter commands the PC sent “h” commands to the stimulator to ensure the timer did not expire and the microcontroller responded with “H”. If, for example, the RS232 cable was accidentally detached or a power fault occurred that prevented communication, the timer expired, the stimulator would enter the “STOPPED” state and the PC would inform the user. Stimulation would therefore only be delivered if the valid
waveform parameters had been received, the start command had been given and a valid command was received every 500 ms.

**Timing** – A baud rate of 38400 bps was chosen, which was found to be sufficiently high, permitting enough time for approximately 1000 electrode location changes per second (i.e. 38400 bps = 26 µs per bit, one electrode change command required 40 bits = 1ms, including parity and data bits).

4.4.4 Stand-alone PC code implementation

LabVIEW 2010 (National Instruments, Texas, USA) was used to develop the PC-based user interface, as shown below (Figure 34). The user had control of the pulse repetition frequency (from 1 to 100 Hz), the pulse width (from 1 to 300 µs) and selection of the active electrode. Electrode selection was either manually controlled using a dial to allow continuous transitions between electrodes; or through a pre-set routine that allowed the user to set clock-wise or anti-clockwise movement of the stimulus at user-defined speeds. Connection status was displayed, as were the commands sent to and from the stimulator (if enabled) for development.

![Stimulator graphical user interface](image)

**Figure 34 Stimulator graphical user interface**
Chapter 4: Development of a Sensory Stimulus

The software used an event-driven producer/consumer design pattern, to ensure the user interface and communication functions operated concurrently and in a controlled manner. Referring to Figure 35, after initialisation (1) an event structure responds to user interaction (buttons presses and mouse movements) by placing each event on a queue (2) thus \textit{producing} internal commands. Events are read or \textit{consumed} from the queue in parallel to this, and the appropriate communication takes place with the stimulator (3). Continuous and independent handshaking occurs throughout (4).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{diagram}
\caption{Software control of stimulator}
\end{figure}
4.5 Stimulator Testing

**Electrical testing** - Before use with subjects the circuit boards were electrically tested. To then determine the consistency of the outputs across each stimulation channel, a 1kΩ purely resistive load was applied across each channel. The stimulator was set to output a 40 Hz pulse with a width of 300 µs and the amplitude was manually set to a maximum. The output across each electrode load was captured and the pulse widths, peak amplitudes and frequency were measured. Figure 36 shows the output from each of the 16 channels. Table 7 shows the measured values for pulse width and peak amplitude. The frequency was found to be consistently 40 Hz as expected.

![Stimulator outputs](image)

Table 7 Waveform characteristics for each channel across a 1kOhm load

<table>
<thead>
<tr>
<th>Channel</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse width (µs)*</td>
<td>299</td>
<td>299</td>
<td>299</td>
<td>299</td>
<td>299</td>
<td>299</td>
<td>299</td>
<td>299</td>
</tr>
<tr>
<td>Amplitude (V)</td>
<td>121.3</td>
<td>109.2</td>
<td>109.2</td>
<td>107.7</td>
<td>107.7</td>
<td>110.7</td>
<td>107.7</td>
<td>107.7</td>
</tr>
</tbody>
</table>

The pulse width was consistently measured to be 299 µs. Measurements were made using the digital oscilloscope PC-based software Picoscope 5.21 (Pico Technology Ltd, UK). The available resolution with the cursor on screen in this case only permitted accuracy within 2 or 3 µs, and approximately 2 V (when the zoom window covered the complete signal). The amplitude ranged from 107.7 to 121.3 V, which is a difference of 13.6 Volts or 6% variation across all channels. Again given the grouping of the values around 107.7
and 109.2, it is possible this falls within the achievable precision of the measurement software. The shape of the waveforms remained consistent and as predicted. Finally to ensure no cross-talk between channels, each stimulator output was viewed whilst adjacent electrodes became active. No cross-talk was found.

**Software testing**— In addition to a firmware loop-back test, a number of software checks were carried out. The function of each operator command was checked whilst observing the pulse trains of commands sent to and from the stimulator (known as white box testing). Attempts were then made to cause software faults through robustness testing. Operator functions were rapidly and repeatedly called, and in random order. Non-valid fields were entered into all controls, for example the pulse-width values were limited to prevent the Darlington drivers overheating. To ensure the likelihood of stimulation being delivered on start-up, the start-up process was carried out under a number of different fault and false conditions. For example: without PC control. The system was found to perform as expected, and found to be robust to unplanned operation. This is in part due to the tight control of the user interface (user buttons were only made visible and active when appropriate, and all controls had pre-set limits defining their range of operation), and in part due to the combination of using a state machine in the microcontroller and an event-driven producer/consumer design pattern, both of which force a clear path through the code without the use of ambiguous `goto` commands or program branches.

**Safety testing** – Medical devices are required to comply with the EU harmonised standard BS-EN60601. Whilst the stimulator is not a medical device, it is important to ensure comparative safety testing was carried out before the stimulator was used with human participants. In addition to the functional tests described above, a visual inspection was carried out internally and externally to identify faults. The inspection included a check of the following and no faults were found: Damage or cracks to the enclosure; cuts in the cabling, misconnections, exposed wires or incorrect colour coding, marking and labelling, integrity of the fascia, the integrity of or obstructions to the electrode connectors and emergency stop button.
Chapter 5

Study I – Electro-tactile Sensation in Healthy Subjects
5.1 Introduction

A stimulator and surface electrodes have been developed (as documented in Chapter 4) which are capable of delivering an electro-tactile sensation via the skin surface. The broad range of design parameters that govern the nature of the stimulus was narrowed down during the design process. This Chapter presents a study that examined the ability of healthy individuals to perceive electro-tactile sensation around the thigh, with three stimulation frequencies, under a range of movement patterns; and in doing so assessed the suitability of the stimulator to deliver a perceptible feedback stimulus. Results from this study informed the choice of parameters used in the biofeedback training system.

For the electro-tactile sensation to have practical utility as a feedback stimulus for gait re-training, the user must be able to discriminate the location of different stimulation sites on the skin surface and the movement of the stimulus around the leg. It is also very important that the sensation does not cause discomfort or harm the user, and so is required to have a wide dynamic range.

The waveform parameters required to produce a comfortable sensation vary according to the area of the body being stimulated, due to different impedance paths, receptive fields and receptor distribution in different regions of the body (Baker, Wederich et al. 2000). The parameters required to produce a comfortable sensation on the thigh in particular are not known.

The parameters include pulse width and amplitude, and pulse repetition frequency. Both pulse width and amplitude influence the magnitude or intensity of the sensation experienced. A pulse width of 100 us was used throughout the development and fixed, while variation in intensity was provided by manual adjustment of the amplitude.

The pulse repetition frequency influences the nature of sensation felt by the individual (sharp or dull sensations for example), and is limited to the refractory period of a neuron. The refractory period is the time taken for a neuron to repolarise, and differs for different nerve types in the region of 100 ms to 1 ms (10 Hz to 1 kHz) (Tortora and Derrickson...
Since the influence of pathology on the refractory period is not known, the frequency was limited to 100 Hz and frequencies of 40, 60 and 80 Hz were investigated.

The ability to discriminate an electro-tactile stimulus must not diminish in the presence of noise, such as the background neuromuscular activity produced during different neuromotor conditions. There may be a possibility that the level of neuromuscular activity has a masking effect on the perception of the sensation. If this were the case, there is a risk that a stimulus which is set at a perceptible and comfortable level whilst walking may produce a sensation which rises to a painful level when the wearer of the training system comes to a stand-still.

Three movement conditions were therefore considered which were representative of the range of neuromuscular activities experienced by patients during daily living: With the subject supine, during concentric knee flexion and extension tasks and finally during treadmill walking. During the supine condition the legs were unloaded and it was assumed there was no neuromuscular activity. This condition was intended to reflect situations where the subject is stationary. The treadmill walking condition was intended to reflect natural walking and the associated level of neuromuscular activity. Finally it was believed that a higher level of neuromuscular activity would be produced during active concentric contraction tasks compared to the activity during walking. As such the knee flexion/extension conditions were included for clarity. These conditions could highlight any masking effect if one exists.

5.2 Objectives and Hypotheses

This study sought to determine if the sensory stimulator developed in Chapter 4 was capable of producing a comfortable range of electro-tactile sensations on the thigh of healthy individuals, between the thresholds of perception and discomfort, and to determine if the normal neuromuscular activity generated during different lower limb movements enhances or diminishes the ability to sense and discriminate the stimuli.
The following null hypotheses are presented, encompassing the three neuromuscular conditions:

**Unloaded (supine)**
1. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location, in subjects undergoing no muscle activity
2. Subjects are not able to discriminate between different stimulus locations while exerting no muscle activity
3. Subjects are not able to discriminate different speeds of stimulus movement while exerting no muscle activity
4. Subjects are not able to discriminate different directions of stimulus movement while exerting no muscle activity

**Isometric knee flexion/extension contractions**
5. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location in subjects performing an isometric knee flexion movement
6. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location in subjects performing an isometric knee extension movement

**Walking**
7. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location in subjects walking on a treadmill
8. Subjects are not able to discriminate between different stimulus locations whilst walking on a treadmill
9. Subjects are not able to discriminate different speeds of stimulus movement whilst walking on a treadmill
10. Subjects are not able to discriminate different directions of stimulus movement whilst walking on a treadmill
5.3 Method

5.3.1 Study design

Each null hypothesis was tested individually with the correspondingly numbered tests show in Table 8. Each test is described in detail in Section 5.3.3.

<table>
<thead>
<tr>
<th>Null Hypothesis / test number (see § 5.2)</th>
<th>Condition</th>
<th>Independent variables</th>
<th>Dependent variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Supine</td>
<td>Perception thresholds</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current perception (mA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current discomfort (mA)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Supine</td>
<td>Stimulus location</td>
<td>Pass / Fail (actual / response)</td>
</tr>
<tr>
<td>3</td>
<td>Supine</td>
<td>Stimulus speed</td>
<td>Pass / Fail (actual / response)</td>
</tr>
<tr>
<td>4</td>
<td>Supine</td>
<td>Stimulus direction</td>
<td>Pass / Fail (actual / response)</td>
</tr>
<tr>
<td>5</td>
<td>Knee flexed</td>
<td>Perception thresholds</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current perception (mA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current discomfort (mA)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Knee extended</td>
<td>Perception thresholds</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current perception (mA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current discomfort (mA)</td>
<td></td>
</tr>
<tr>
<td>Session 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Walking</td>
<td>Perception thresholds</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current perception (mA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak current discomfort (mA)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Walking</td>
<td>Stimulus location</td>
<td>Pass / Fail (actual / response)</td>
</tr>
<tr>
<td>9</td>
<td>Walking</td>
<td>Stimulus speed</td>
<td>Pass / Fail (actual / response)</td>
</tr>
<tr>
<td>10</td>
<td>Walking</td>
<td>Stimulus direction</td>
<td>Pass / Fail (actual / response)</td>
</tr>
</tbody>
</table>

The study was carried out over two recording sessions. For perception threshold tests (Tests 1 and 5 to 7), the peak current applied to each electrode was a repeated measure at both threshold levels. For all other tests the user’s response was the repeated measure.

Within each test the stimulus delivery sequence was manually randomised beforehand, each condition was repeated twice and randomly included no stimulus conditions to improve the robustness against validity threats such as type I and II error responses. Delays between stimuli served to help mitigate against sensory adaptation and learning effects. No
experimenter blinding was used but precaution was made to ensure the subjects could not see the computer screen controlling stimulus delivery.

5.3.2 Participants

It was assumed that unlike vascular amputees, the remaining proximal somatosensory pathways of traumatic amputees are unchanged by the pathology and surgery, and conclusions from healthy non-amputees in this study can be extrapolated to the traumatic amputee population. Dhillon and Lawrence examined the retention of motor and sensory nerve function in patients following amputation, using percutaneous intrafascicular electrodes to record and to stimulate nerves in upper and lower limb amputees undergoing stump revision surgery. They were able to record volitional motor activity associated with the missing limb (Dhillon, Lawrence et al. 2004). They also found that distally referred sensations of touch, joint movement and position could be produced in all subjects. In a similar study of eight above-elbow traumatic amputees Dhillon found similar perception thresholds to those previously reported, and which remained relatively constant over the course of the two week study, even in one case of a patient 30 years post operative (Dhillon, Kruger et al. 2004). These studies suggest the assumption is reasonable and traumatic amputees do retain sensory nerve function which is similar to healthy individuals.

**Inclusion/exclusion criteria** - Volunteers were screened for the inclusion and exclusion criteria using the screening questionnaire in Appendix I3. Subjects sought were over the age of 18 and reported no issues that affected their gait or ability to participate in the study. So subjects with the following issues were excluded: visual, auditory or vestibular impairments, those with injury that limit movement, or require the use of mobility aids. Commonly cited contra-indicators to the use of electrical stimulation were also applied, as a conservative precaution. Subjects who experience seizures (managed or otherwise) were excluded, as were those with known cardiac arrhythmias, hyerreflexia, and implanted electrical devices. Pregnant subjects were also excluded. If subjects were unwilling to confirm pregnancy for example, for whatever reason, they were excluded.
Finally subjects were sought with healthy skin and sensory nerves, so those with dermatological conditions and nervous system pathologies (such as nerve entrapment or peripheral neuropathies) were excluded. Some individuals approached did not meet the criteria, in which case the reason for exclusion was provided.

**Sample size** - In common with similar studies (Buma, Buitenweg *et al.* 2007; Walter-Watsh, Weiss *et al.* 2009) a minimum of 12 participants were sought. A drop-out rate of 40% was taken into account, requiring 20 volunteers.

**Participant time commitment** - Due to the number of tests carried out and participant time constraints, the tests were conducted in two separate sessions. Tests 1 to 6 were carried out in Session 1, whilst the treadmill walking tests (7 to 10) were carried out in Session 2. Subjects were therefore asked to participate in two 3-hour sessions over two consecutive weeks in May and June 2011.

**Recruitment** - Participants were recruited from healthy individuals within the population of staff and students at the University of Surrey.

**Ethical consideration** - Favourable consideration was received from the University of Surrey Research Ethics Committee prior to subject recruitment. The ethical and safety issues that were considered are discussed in Appendix I6.

### 5.3.3 Intervention

The sensory stimulator developed in Chapter 4 was used to deliver a lower level sensory stimulus to the surface of the skin through each of the eight electrodes.

During each visit full instructions were given and subjects were asked to complete the health screening questionnaire (Appendix I3). Prior to seeking consent, subjects were briefed about the study and informed of the risks and benefits of taking part, and their right to leave at any time without prejudice. Informed written consent was sought and obtained in all cases (Appendix I2). The subject was given a copy of the consent form and allocated
an identifier code which was used hereinafter. The consent form and the screening questionnaire were the only identifiable documents and were handled and stored securely in accordance with the Data Protection Act 1998, the University’s annual Notification and Data Protection Principles, for the duration of this project.

**Subject Preparation** - Subjects were asked to change into shorts. With the subject laying supine on a plinth the thigh length of the dominant limb was measured from the anterior superior iliac spine (ASIS) to the ipsilateral lateral femoral epicondyle and a mark (○) was made with a non-permanent pen at 1/3 distance from the lateral femoral epicondyle (Figure 37). This marked the position which the electrode array would be used.

![Figure 37 Measurement of limb length (left) and marking anterior-most aspect (right)](image)

The most anterior aspect of the thigh (●) was identified by eye and marked level with (○). This was the position of electrode 1. Since the testing was carried out over two sessions, the distance between the two marks was recorded as a measure of electrode placement repeatability.
The circumference of the thigh was then measured using a tape measure. The surface of the limb was cleaned with an alcohol wipe and using a dividing calliper set at 1/8 of the thigh circumference. Electrodes A4 (referred to in Section 4.3.3, with a 33 mm outer diameter and 7 mm inner diameter) were placed around the thigh starting with electrode one over the anterior-most mark (●) (Figure 38).

![Figure 38 Measurement of repeatability marks (left), electrode numbering (centre) and placement of electrodes (right)](image)

A “Tubigrip” support bandage was then placed over the limb to hold the leads in place and prevent the subject inadvertently touching the electrodes. At this stage the subject was not connected to the stimulator. The operation of the stimulator stop button was demonstrated to the participants and they permitted to use it at any time. An opportunity was also provided for subjects to use the device under supervision to get an idea of what electro-tactile sensation feels like. When the subject had no further questions and was happy to proceed testing began with test 1. The test descriptions below are grouped into types for clarity, but in practice the tests were conducted in the order described in Table 8.

**Sensation threshold tests**

**Supine, relaxed (Test 1)** - Participants were asked to lay supine on a plinth with their ankles resting on the padded headrest raised to ensure the posterior surface of the thigh was not in contact with the plinth (Figure 39). This posture was assumed to minimise skin receptor activity on the posterior surface of the thigh. Participant remained in that posture for 1 minute, to allow adaptation of the area under the bandage. Participants were then
asked to respond verbally when they first perceived a sensation and again when they felt the sensation was uncomfortable. Whilst observing the subject, a stimulus was applied for approximately 2 seconds to each electrode using a pulse width of 100 µs and one of three pre-determined frequencies. The intensity was gradually increased until the first response was given. At that level the peak applied current was measured and the stimulus was removed. The ascent was then repeated and the mean of two recordings was taken. The stimulation was then removed for 5 seconds and the intensity was then increased until the subject gave the second response. The current amplitude was recorded and the stimulus removed, again this was repeated and the mean taken. The process was repeated for all eight electrodes using a pre-randomised sequence of electrode locations, and repeated for each frequency, in the order 60, 40 then 80 Hz. This test required 96 threshold levels to be taken for each subject.

**Seated, knee extended (Test 4)** - Participants were asked to sit on the edge of the plinth and respond in the same manner as Test 1. With hands away from their legs, participants were asked to maintain their leg in an extended position while the stimulus intensity was increased. When the threshold was reached the leg was relaxed (Figure 39). A pause of 5 seconds was provided between each ascent. The process was repeated for each frequency. Only electrodes placed over the anterior aspect of the thigh (electrodes 1, 2 and 8) were assessed, because contracting muscles were of interest. This assumes any neuromuscular activity in the posterior compartment of the thigh would not have an effect on the threshold levels of the anterior surface. Following the test, the participant was permitted to rest in a chair for 5 minutes before proceeding to the next test.

**Standing, knee flexed (Test 5)** - Participants were asked to stand next to the plinth. Using the plinth for support if required, participants flexed their knee to approximately 90 degrees (Figure 39). The same recording procedure used previously in Test 4 was carried out, assessing the response to stimulation, this time over the posterior aspect of the thigh (electrodes 4, 5 and 6). The subject was then permitted to rest in a chair for 5 minutes before proceeding to the next test.
Walking (Test 6) - Participants were asked to walk at a comfortable self-selected walking speed on a Woodway PPS medical treadmill (Woodway Inc, USA) facing a blank screen (Figure 39). Participants unfamiliar with walking on a treadmill were given an opportunity to gain familiarisation before the study. All subjects were attached to the emergency stop cord and shown the correct operation of the treadmill controls. The same recording procedure previously used began once a comfortable walking speed had been established. Stimuli were presented at approximately heel contact of the dominant limb (determined manually) and remained present for 5 strides. Subsequent stimuli were delivered 5 strides after the previous. The subject was permitted to rest in a chair for 5 minutes at the end of the test.

Figure 39 Postures from left to right - supine with leg raised, seated with leg relaxed, seated with leg extended, standing with leg flexed, treadmill walking

Stimulus Location Tests

Supine (Test 2) – For each electrode location the midpoint value between the threshold of perception and the threshold of discomfort (previously determined in Test 1) was calculated and each stimulation channel was set at that value. Participants were asked to remain laying supine and were given a cue card, similar to that shown in the centre of Figure 38. After a brief demonstration of the cue card numbering, participants were asked to indicate where the stimulation was felt by responding with the electrode number. Stimuli were applied to each electrode location in a pre-determined random sequence for 2 seconds, pausing for 1 second between each stimulus application. The response was recorded as correct or incorrect. This was repeated twice using different random sequences and repeated for each frequency value, in the order 40 Hz, 80 Hz then 60 Hz.
Walking (Test 7) – The stimulation channels were set at the midpoint value between the thresholds of sensation and discomfort as determined in Test 6. A cue card was placed in front of the participant, and they were asked to continue walking at their comfortable self-selected walking speed. Stimuli were applied to each electrode location, in a predetermined random sequence, at heel strike of the dominant limb and were maintained for 5 strides. Subjects responded by calling out the corresponding number as shown on the cue card. This process was repeated twice using different random sequences and repeated for each frequency value.

Stimulus Movement Tests

Supine (Test 3) - With participants remaining supine, stimulation was applied at the mid-point intensity level and move around each electrode in order, at three different speeds: “slow”, “medium” and “fast” in a clockwise and counter-clockwise direction around the array. The medium speed was set at 1.0 m/s which is an approximate normal walking speed and that which the system is expected to operate in within the completed feedback loop. Slow and fast were set at 0.5 m/s and 2.0 m/s respectively. After a demonstration of the speeds and directions, subjects were asked to indicate the speed and direction of rotation. A random sequence of 12 speeds and directions was used. Responses were recorded as correct or incorrect. The process was repeated twice for each frequency.

Walking (Test 8) - The stimulation channels were set at the mid-point value between the thresholds of perception and discomfort as determined in Test 6. Participants were asked to continue walking at their comfortable self-selected walking speed. Moving stimuli were applied in clockwise and counter-clockwise directions at three speeds, commencing at heel strike of the dominant limb and were maintained for approximately 5 strides. Subjects were asked to indicate the speed and direction of rotation. A random sequence of 12 directions and speeds was used. Responses were recorded as correct or incorrect and the process was repeated twice for each frequency.
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After all tests the electrodes were removed and the skin condition was examined. Participants were provided with alcohol wipes to clean the pen marks and given an opportunity to sit and discuss their observations with the investigator.

5.3.4 Success criteria and analysis

Null hypotheses regarding the presence or absence of a threshold range (Tests 1, 5, 6 and 7) were rejected if separation existed between the thresholds of perception and discomfort for individual electrode locations for 95% of the sample population. Null hypotheses 2, 3, 4, 8, 9 and 10 were rejected if 95% of the population achieved a pass rate greater than 80%.

For practical use it was also desirable to determine which frequency produced:

(i) The greatest separation between threshold and discomfort
(ii) The lowest variation across electrodes and tasks
(iii) The smallest difference between supine and treadmill task at discomfort level
(iv) The easiest sensation to discriminate
(v) The most favourable sensation
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5.4 Results

5.4.1 Participants

Thirteen subjects matched the selection criteria and participated in the study, all completed with no drop outs. The individual anthropometrics are shown below (Table 9). Descriptive statistics for the group are shown in Table 10.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age</th>
<th>Dominant leg</th>
<th>Height (m)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m²)</th>
<th>Femur length (mm)</th>
<th>Thigh circumference (mm)</th>
<th>Self-selected walking speed (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>25</td>
<td>R</td>
<td>1.62</td>
<td>53</td>
<td>20.2</td>
<td>430</td>
<td>458</td>
<td>1.03</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>32</td>
<td>R</td>
<td>1.76</td>
<td>73</td>
<td>23.6</td>
<td>520</td>
<td>529</td>
<td>1.04</td>
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<tr>
<td>3</td>
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<td>31</td>
<td>L</td>
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<td>95</td>
<td>27.2</td>
<td>565</td>
<td>560</td>
<td>0.84</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>31</td>
<td>R</td>
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<td>79</td>
<td>22.8</td>
<td>575</td>
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<tr>
<td>5</td>
<td>F</td>
<td>28</td>
<td>R</td>
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<td>77</td>
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<td>546</td>
<td>478</td>
<td>1.10</td>
</tr>
<tr>
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<td>F</td>
<td>22</td>
<td>R</td>
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<td>429</td>
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</tr>
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<td>R</td>
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<td>71</td>
<td>22.2</td>
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<td>473</td>
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<td>M</td>
<td>24</td>
<td>R</td>
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<td>68.5</td>
<td>22.9</td>
<td>538</td>
<td>482</td>
<td>1.20</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>24</td>
<td>R</td>
<td>1.91</td>
<td>77</td>
<td>21.2</td>
<td>574</td>
<td>505</td>
<td>1.16</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>32</td>
<td>R</td>
<td>1.59</td>
<td>52.5</td>
<td>20.8</td>
<td>481</td>
<td>393</td>
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<tr>
<td>12</td>
<td>F</td>
<td>22</td>
<td>R</td>
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<td>69</td>
<td>25.0</td>
<td>482</td>
<td>519</td>
<td>1.30</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>28</td>
<td>R</td>
<td>1.60</td>
<td>52</td>
<td>20.3</td>
<td>485</td>
<td>445</td>
<td>0.79</td>
</tr>
</tbody>
</table>

n=13 (6 male, 7 female), 12 right leg dominant, 1 left leg dominant
Table 10 Group anthropometric statistics

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Mean</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td>22</td>
<td>27</td>
<td>35</td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>27</td>
<td>35</td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
<td>24</td>
<td>32</td>
</tr>
<tr>
<td><strong>Height (m)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td>1.59</td>
<td>1.73</td>
<td>1.91</td>
</tr>
<tr>
<td>Male</td>
<td>1.73</td>
<td>1.82</td>
<td>1.91</td>
</tr>
<tr>
<td>Female</td>
<td>1.59</td>
<td>1.65</td>
<td>1.79</td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td>52.0</td>
<td>67.6</td>
<td>95.0</td>
</tr>
<tr>
<td>Male</td>
<td>68.5</td>
<td>77.3</td>
<td>95.0</td>
</tr>
<tr>
<td>Female</td>
<td>52.0</td>
<td>59.4</td>
<td>77.0</td>
</tr>
<tr>
<td><strong>Body Mass Index (kg/m^2)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Population</td>
<td>20.2</td>
<td>22.4</td>
<td>27.2</td>
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<tr>
<td>Male</td>
<td>21.2</td>
<td>23.3</td>
<td>27.2</td>
</tr>
<tr>
<td>Female</td>
<td>20.2</td>
<td>21.6</td>
<td>25.0</td>
</tr>
<tr>
<td><strong>Thigh Circumference (mm)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
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<td>479</td>
<td>560</td>
</tr>
<tr>
<td>Male</td>
<td>473</td>
<td>506</td>
<td>560</td>
</tr>
<tr>
<td>Female</td>
<td>393</td>
<td>455</td>
<td>519</td>
</tr>
<tr>
<td><strong>Femur length (mm)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td>430</td>
<td>509</td>
<td>575</td>
</tr>
<tr>
<td>Male</td>
<td>510</td>
<td>547</td>
<td>575</td>
</tr>
<tr>
<td>Female</td>
<td>430</td>
<td>476</td>
<td>546</td>
</tr>
<tr>
<td><strong>Walking speed (m/s)</strong></td>
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<td></td>
<td></td>
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<td>Population</td>
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<td>1.03</td>
<td>1.62</td>
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<tr>
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<td>0.84</td>
<td>1.16</td>
<td>1.62</td>
</tr>
<tr>
<td>Female</td>
<td>0.73</td>
<td>0.93</td>
<td>1.30</td>
</tr>
</tbody>
</table>

The mean relative error of placing the anterior electrode with respect to the thigh axis centreline (Figure 37) between recording sessions was 2.7 mm. The poorest repeatability was 9 mm, in subject 5 (Table 11).

Table 11 Repeatability measurements of electrode placement

<table>
<thead>
<tr>
<th>Subject</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurement 1 (mm)</strong></td>
<td>36</td>
<td>66</td>
<td>72</td>
<td>67</td>
<td>50</td>
<td>25</td>
<td>55</td>
<td>54</td>
<td>83</td>
<td>45</td>
<td>63</td>
<td>56</td>
<td>38</td>
</tr>
<tr>
<td><strong>Measurement 2 (mm)</strong></td>
<td>36</td>
<td>68</td>
<td>70</td>
<td>61</td>
<td>59</td>
<td>27</td>
<td>57</td>
<td>56</td>
<td>82</td>
<td>48</td>
<td>61</td>
<td>54</td>
<td>35</td>
</tr>
<tr>
<td><strong>Absolute diff. (mm)</strong></td>
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<td>2</td>
<td>2</td>
<td>6</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
5.4.2 Overall group patterns

The following plots show group mean responses for the perception and discomfort thresholds, presented for different movement tasks, electrode numbers and stimulation frequencies. Group variations and the separation between thresholds are shown in the next sections and individual subject data are included in Appendix J1.

Figure 40 Perception (bottom) and discomfort thresholds (top) for each electrode, task and frequency (with 40 Hz shown in red, 60 Hz in blue and 80 Hz in green). Note: only electrodes 4, 5, 6 and 1, 2, and 8 were assessed in the knee flexion / extension tests.
5.4.3 Separation between group mean perception and discomfort levels

The bands between the perception and discomfort levels for the supine and treadmill walking tasks are shown in Figure 41. The maximum, minimum and mean values are given, indicating the extent of overlap between bands in some cases.

Figure 41 Group mean, minimum and maximum perception (blue) and discomfort threshold (red) levels
5.4.4 Variation in group threshold levels

The variation in group mean thresholds are shown below (Figure 42) and overleaf (Figure 43). Maximum, minimum and mean values are given for each frequency.

Figure 42 Variation in discomfort (top) and perception (bottom) threshold levels for each electrode and frequency during supine, walking and knee flexion / extension tasks. 40 Hz is shown in red, 60 Hz in blue and 80 Hz in green.
5.4.5 Difference between supine and treadmill task at both threshold levels

The group mean threshold levels are shown for each task (Figure 43).

Figure 43 Mean group perception and discomfort threshold levels for 40 Hz, 60 Hz and 80 Hz and each task (The supine posture is shown in blue, knee flexed in pink, knee extended in green and treadmill walking in red)
The range and standard deviation of the upper and lower threshold levels is represented below, for each movement task and frequency (Table 12), results are averaged across the cohort and electrodes. The ratio between the threshold levels is also shown by gender in Table 13, and the mean difference between the supine and treadmill tasks for each frequency are given in Table 14.

<table>
<thead>
<tr>
<th></th>
<th>Supine</th>
<th>Knee extended</th>
<th>Knee flexed</th>
<th>Walking</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discomfort range (and SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40 Hz</td>
<td>97 (22.2)</td>
<td>79 (20.0)</td>
<td>91 (23.8)</td>
<td>88 (22.5)</td>
<td>89 (22.1)</td>
</tr>
<tr>
<td>60 Hz</td>
<td>101 (18.2)</td>
<td>92 (21.3)</td>
<td>76 (19.5)</td>
<td>91 (21.2)</td>
<td>90 (20.0)</td>
</tr>
<tr>
<td>80 Hz</td>
<td>78 (16.4)</td>
<td>77 (18.5)</td>
<td>91 (18.4)</td>
<td>87 (18.7)</td>
<td>83 (18.0)</td>
</tr>
</tbody>
</table>

| **Perception range (and SD)** |        |               |             |         |      |
| 40 Hz          | 24 (4.7) | 14 (3.9)    | 20 (5.2)    | 40 (6.8) | 25 (5.2) |
| 60 Hz          | 20 (4.6) | 33 (5.3)    | 27 (5.8)    | 34 (5.7) | 29 (5.4) |
| 80 Hz          | 27 (4.7) | 16 (3.7)    | 25 (5.9)    | 25 (18.7)| 23 (8.3) |

<table>
<thead>
<tr>
<th><strong>Difference in means</strong></th>
<th>40 Hz</th>
<th>60 Hz</th>
<th>80 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 Hz</td>
<td>32</td>
<td>32</td>
<td>40</td>
</tr>
<tr>
<td>60 Hz</td>
<td>32</td>
<td>32</td>
<td>40</td>
</tr>
<tr>
<td>80 Hz</td>
<td>32</td>
<td>32</td>
<td>40</td>
</tr>
</tbody>
</table>

Table 12 Group range and (SD) of threshold levels, and difference between group mean perception and discomfort threshold levels, across all electrodes, for each frequency and movement task.

<table>
<thead>
<tr>
<th><strong>Supine</strong></th>
<th>40 Hz</th>
<th>60 Hz</th>
<th>80 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>male</td>
<td>3.59</td>
<td>3.49</td>
<td>3.30</td>
</tr>
<tr>
<td>female</td>
<td>3.15</td>
<td>2.98</td>
<td>2.91</td>
</tr>
<tr>
<td>both</td>
<td>3.35</td>
<td>3.21</td>
<td>3.09</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Treadmill walking</strong></th>
<th>40 Hz</th>
<th>60 Hz</th>
<th>80 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>male</td>
<td>3.07</td>
<td>3.23</td>
<td>3.07</td>
</tr>
<tr>
<td>female</td>
<td>3.37</td>
<td>3.45</td>
<td>3.30</td>
</tr>
<tr>
<td>Both</td>
<td>3.23</td>
<td>3.35</td>
<td>3.19</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Knee flexed</strong></th>
<th>40 Hz</th>
<th>60 Hz</th>
<th>80 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>male</td>
<td>4.03</td>
<td>3.22</td>
<td>3.00</td>
</tr>
<tr>
<td>female</td>
<td>3.41</td>
<td>3.14</td>
<td>3.13</td>
</tr>
<tr>
<td>both</td>
<td>3.70</td>
<td>3.18</td>
<td>3.07</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Knee extended</strong></th>
<th>40 Hz</th>
<th>60 Hz</th>
<th>80 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>male</td>
<td>4.09</td>
<td>3.94</td>
<td>3.89</td>
</tr>
<tr>
<td>female</td>
<td>3.54</td>
<td>2.89</td>
<td>3.24</td>
</tr>
<tr>
<td>Both</td>
<td>3.79</td>
<td>3.38</td>
<td>3.54</td>
</tr>
</tbody>
</table>

Table 13 Ratio of discomfort to perception for each frequency and task (group mean values are shown).

Table 14 Difference between treadmill and supine group mean threshold levels

<table>
<thead>
<tr>
<th></th>
<th>Difference at discomfort threshold level (mA)</th>
<th>Difference at perception threshold level (mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 Hz</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>60 Hz</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>80 Hz</td>
<td>11</td>
<td>3</td>
</tr>
</tbody>
</table>
5.4.6 Ability to discriminate stimuli, location direction and speed

During the supine trials, the stimulus locations were correctly identified 96%, 98% and 99% of the time for 40, 60 and 80 Hz respectively (expressed as group mean percentages). The non-100% scores were attributable to 4 of the 13 participants. The stimuli direction and speed were identified 100% of the time.

5.4.7 Participant responses regarding electro-tactile sensations

All of the comments made by participants are recorded in Table 15. Eight participants commented on the sensations experienced during the supine task, and three commented on sensations experienced during the treadmill walking task.

<table>
<thead>
<tr>
<th>Frequency (Hz)</th>
<th>Comment (and task)</th>
<th>Electrode number</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>Muscle stimulation felt (supine)</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>More ‘vibration’ and definite at low intensities than 60Hz (supine)</td>
<td>All</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Tickled (supine)</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Prior sensation of pressing before vibration (supine)</td>
<td>All</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Sudden onset of discomfort approaching higher level (supine)</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Worse before initial contact (subjects slowest walking speed, treadmill)</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>60</td>
<td>Smoother than 80 Hz (supine)</td>
<td>All</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Pre-awareness of stimulation before stimulus felt (supine)</td>
<td>All</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Produces more specific sensation compared to 80 Hz (supine)</td>
<td>All</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Pins and needles in contralateral leg at same location (supine)</td>
<td>All</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Very different sensation at upper level compared to the rest (treadmill)</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>80</td>
<td>Blunter than 40 Hz (supine)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Least favourite electrode position (supine)</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Not nice (supine)</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Pin sensation felt immediately (treadmill)</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Generally an unpleasant frequency (treadmill)</td>
<td>All</td>
<td>6</td>
</tr>
</tbody>
</table>
5.4.8 Gender differences

Perception and discomfort thresholds by gender are shown below (Figure 44) for supine and treadmill walking tasks, and each electrode.

![Figure 44 Perception and discomfort thresholds by gender (male is shown in blue, female in pink), for treadmill walking and the supine posture, for each frequency and electrode](image)

5.6 Discussion

Subjects were within the normal to overweight range according to body mass index for non-amputees (McEwen 2006). Body mass index has limited use in the amputee population, due to variation in the mass of tissue removed and prosthetic component weights. As such it was not possible to assess how representative the participants are of the amputee population without the use and availability of body composition data for the amputee population. No reference anthropometric data were found for the other parameters measured using the same landmarks.
Repeatability of placing electrode one between the two sessions ranged from 0 to 9 mm with a mean difference of 3 mm. The maximum difference occurred in subject 5. There was nothing remarkable about this subject’s anthropometrics to suggest a cause for greater human error; and this error did not appear in the discrimination ability and thresholds levels of subject 5 (they were within 1 standard deviation of the group results).

Looking at the absolute perception and discomfort threshold levels, it can be seen from Figure 40 that the frequencies within tasks follow a similar pattern across the electrodes, with a dip occurring at electrode 7 during the treadmill walking task. The order of electrodes stimulated was randomised, so any familiarisation effect would not appear in Figure 40. Electrode 7 was placed medially on the thigh, which is the closest electrode location to a cutaneous nerve (the intermediate cutaneous nerve). It could be suggested that the medial surface is the most sensitive aspect of the thigh, and responsible for this dip, however this is not as clear in the supine posture.

### 5.5.1 Separation between perception and discomfort threshold levels (i)

There was a separation between the mean thresholds of perception and discomfort in all subjects, for all electrodes, tasks and frequencies as shown in Figure 41. As such the null hypothesis 1, 5, 6 and 7 were rejected:

1. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location, in subjects undergoing no muscle activity
2. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location in subjects performing an isometric knee flexion movement
3. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location in subjects performing an isometric knee extension movement
4. No range of sensation exists on the thigh of non-amputees between perception and discomfort, for each electrode location in subjects walking on a treadmill
The mean difference between the thresholds of perception and discomfort was greatest (40 mA) in the knee flexion task when 40 Hz of stimulation was applied; and lowest (24 mA) in the supine task when 80 Hz of stimulation was applied. The band between thresholds was also higher in the other tasks requiring muscle activity, compared to the no muscle (supine) condition, which could be attributable to higher discomfort thresholds in tasks requiring muscle activity. From Table 12 it can be seen that the band between perception and discomfort decreases with frequency, this is unrelated to the task, electrode location, or anthropometric factors. This is also seen in Table 13, where the ratio of discomfort to perception decreases with frequency in all tasks. The discomfort/perception ratio across all tasks and frequencies is 3.3 (or approximately 5 dB). This falls within the range quoted in previous work for other body regions, with 1.5 at the fingertip to 10 at the abdomen (Kaczmarek, Webster J.G. et al. 1991). This is a more limited dynamic range compared to other senses - audition has a dynamic range of 120 dB and the eye 70dB (Kaczmarek and Bach-y-Rita 1995).

5.5.2 Variation in threshold levels across frequencies, electrodes and tasks (ii)

From Table 12 it can be seen that the spread of threshold levels is greater at the discomfort level than at the perception level (with mean variations across tasks of 6 mA and 20 mA at perception and discomfort respectively). This was to be expected and may be due to subjective nature of defining discomfort and repeatedly reaching that definition. No discernable patterns in variation were found across tasks, electrode location, or in relation to anthropometric factors. The lowest variation in threshold levels occurred with 80 Hz at discomfort and 40 Hz at perception.

5.5.3 Difference between supine and treadmill task at discomfort level (iii)

Perception and discomfort thresholds were higher during the tasks requiring muscle activity than the supine task, notably in walking as shown in Figure 43. This could suggest muscle activity diminishes the discomfort level. However the knee extension thresholds are closer to the supine thresholds at both levels. No relationship with observed with electrode location or frequency. The smallest difference between the supine the treadmill threshold
levels occurred at 80 Hz both for perception (with a 3 mA difference) and discomfort (11 mA difference).

5.5.4 Ability to discriminate stimuli, location direction and speed (iv)

Subjects found it easy to discriminate the stimuli, as was seen in Section 5.4.6. Where mistakes were made, some subjects made corrections to their previous answers, once subsequent locations and patterns were applied. The small errors that were reported are thought to be attributable to the participant’s ability to map between the cue card and the leg, and not the physiological detection of the stimuli. Null hypotheses 2 to 4 and 8 to 10 were therefore rejected:

2. Subjects are not able to discriminate between different stimulus locations while exerting no muscle activity
3. Subjects are not able to discriminate different speeds of stimulus movement while exerting no muscle activity
4. Subjects are not able to discriminate different directions of stimulus movement while exerting no muscle activity
8. Subjects are not able to discriminate between different stimulus locations whilst walking on a treadmill
9. Subjects are not able to discriminate different speeds of stimulus movement whilst walking on a treadmill
10. Subjects are not able to discriminate different directions of stimulus movement whilst walking on a treadmill

5.5.5 Subjective experience of sensation (v)

The difficulty of describing the sensations felt and the subjective nature of the upper threshold level became apparent during data collection. Whilst the definition of discomfort was left to the discretion of the participants, subjects were asked after data collection what benchmark they had used. Participants generally responded with “would it irritate me?” When asked about their perception of levels over the course of the study, some subjects
declared a desire to “see how high they could go”, whilst others did the opposite stating they had learnt what the high range was like and settled at a “sensible definition of discomfort”. Kaczmarek notes that the subjective nature of the discomfort (or pain) thresholds is a persistent issue in sensory threshold studies (Kaczmarek and Bach-y-Rita 1995).

Referring to Table 15 the range of adjectives used to describe the sensation covered a range of receptor modalities, for example: vibration, tickle, painful, pressing, and pins and needles. This affirms the indiscriminate nature in which different receptor types (including nocioceptors) may have been activated.

Electrode location 5 was commented on most. 3 people described the location as “tickled”, “sudden onset of discomfort”, “least favourite” and “not nice”. Subjects did express that the medial and posterior surfaces were the most sensitive (electrode 5 was closest to the posterior cutaneous nerve), however any dislike of that location was not reflected in the threshold levels. All of the subjects found the sensation of a moving stimulation around the thigh amusing.

When asked about the electro-tactile sensation, subject 12 noted a pins and needles sensation on the same location of the contra-lateral leg. Whilst a physiological phenomenon is not wholly discounted, it may be the case that prompting participants for feedback could provoke a need to respond by the participant, regardless of the participant’s conviction in that response. Four of the five comments related to the 80 Hz frequency described it in unpleasant terms. No other patterns emerged through discussion with the participants regarding frequency, the task, changes to the sensation or referred sensations.

5.5.6 Gender

Referring to Figure 44 a gender difference can be seen in both threshold levels, with male subjects demonstrating higher thresholds for perception and discomfort. This is corroborated by a similar study that looked at the effect of changing temperature on electro-tactile pain thresholds (Rocha, Facini et al. 2011). Rocha and co-workers found
that female subjects had a lower pain threshold, which increased in both sexes after 15 minutes of thermotherapy. It is interesting to note that the dip at electrode 7 previously discussed is clearer when looking at thresholds by gender (Figure 44). The threshold at that location is close for male and female participants. No explanation for this is apparent.

### 5.5.7 General observations and limitations

There were a number of issues and limitations to the study that warrant consideration, particularly when formulating conclusions. Looking first at the determination of threshold levels, some subjects experienced difficulty in deciding when the lower threshold level had been crossed. This was in part due to a loss in their continued focus of attention, which could be expected within a 3-hour data collection period, but also the speed with which intensity was raised in the presence of neurological adaptation. In an attempt to maintain participant attention the experimenter spoke in a non-monotonous manner and engaged the subjects in unrelated conversation between trials, these are however subjective actions and quantitative measures of alertness could be incorporated in future (such as the psychomotor vigilance task, where the subject is asked to press a button when a visual cue appears). The stimulation intensity was controlled manually by the experimenter using a potentiometer, and an effort was made to ensure consistency in the rate of ascent. This was not ideal and could be improved with the use of computer-controlled ascent profiles, or with a completely automated data collection protocol, as used by (Kaczmarek 2000).

The difficulty in controlling for adaptation is similar to that found when testing threshold levels in other sensory modalities, in pure tone audiometry for example (Katz 2002). In those cases the protocols have been widely accepted as the best possible within the bounds of practical constraints, as was the case here.

While continuously ascending to the two threshold levels, stimulation was always present. As such neurological adaptation is uncontrolled and subjects may accommodate in–part to the sensation before reaching absolute threshold levels. Again the speed of intensity ascent may be an important factor. Adaptation may also occur in the presence of the electrodes contacting the skin surface. Kaczmerak reported full adaptation to electro-tactile stimulus...
occurred at the abdomen of 7 healthy individuals in approximately 15 minutes (Kaczmarek 2000). In this study a number of measures were in place to reduce the likelihood of adaptation; pauses were taken between stimulus applications, the threshold and discrimination trials were mixed, and within each trial randomisation and non-sequential ordering were used where possible (in terms of electrode number, task, direction of rotation and speed). Whilst the effects of adaptation should not affect the study outcomes, adaptation could be ameliorated in future with an automated protocol applying stimuli only at discrete levels.

At the upper level, the subjective nature of describing a discomfort threshold level was apparent. When asking participants to respond it was difficult to avoid asking a loaded question, for example “can you tell me when the sensation reaches an uncomfortable level?”, or “when the sensation causes discomfort or pain”. The task becomes a semantic challenge. Therefore both levels were discussed with the participants during the study briefing, to convey the intention of finding a practical mid-range sensation. This passed the semantic challenge onto each participant, requiring them to subjectively determine what they deemed appropriate. This would be the case when individual patients set up a biofeedback device. All reported discomfort (or pain) thresholds in literature have that subjective caveat. Curiously some subjects commented by saying “I’m not sure if this is painful” during the data collection process. This may indicate that prior familiarisation with electrical stimulation, or rationalisation of the sensation may also have an impact on the definition of discomfort. Again it was not possible to control for this phenomena.

The study assumed no neuromuscular activity during the supine task and neuromuscular activity during the flexion/extension and walking tasks. This was un-quantified. Subjects were also seated during the knee extension task but standing during the knee extension and walking tasks. It is also not known what role decussation plays in the somatosensory signalling between limbs. The robustness to neuromuscular artefacts could be improved using nerve blocks, but this was could place an unnecessary burden on participants taking part in two 3-hour sessions.
In terms of the anatomical relevance of the sensation thresholds, approximate n-shaped patterns were seen in the mean threshold levels in Figure 40 (and was present in individual cases). Whilst it was not possible to associate the threshold levels with participant anatomy, variation does appear which may be different between standing and supine postures. With a mean repeatability of electrode placement of 3 mm, this variation may arise from the cutaneous nerve distribution around the participant’s thigh.

An assumption has been made that the neurological pathways of traumatic amputees are unchanged by the pathology and surgery, and conclusions from this study can be extrapolated to the traumatic amputee population. This assumption was reached at through discussion with Consultants in Rehabilitation Medicine and from the studies by Dhillon and Lawrence, and was deemed reasonable from a physiological point of view. However Dhillon and Lawrence did not comment on the anatomical variation in their amputee subjects and it is possible that wider variation in threshold levels may still exist in amputees as a result of a physical movement of the nerves following surgery. For this work the sensation intensity can be manually adjusted for each channel, so any potential variation of sensations received by amputees in the final BFB implementation can be managed. This does however remain a consideration for future electro-tactile devices.

5.6 Conclusions

Despite a number of limitations which are inherent in sensation threshold testing generally, this study satisfied the aims and demonstrated that the sensory stimulator developed in Chapter 4 is capable of producing a comfortable range of electro-tactile sensations on the thigh of healthy individuals, which can be used to convey biofeedback information. The following specific points were demonstrated:

1. A comfortable range of electro-tactile sensations exists on the thigh of healthy individuals between the mean thresholds of perception and discomfort
2. The greatest range occurred with the use of 40 Hz stimulation and the range increased with muscle activity, this increase was attributable to a raised discomfort threshold
3. Greatest variation occurred at the discomfort threshold, whilst the lowest variations within the perception level occurred with 40 Hz and 80 Hz at the discomfort level.

4. Perception and discomfort thresholds were higher during tasks requiring muscle activity. The smallest difference between the supine the treadmill threshold levels occurred at 80 Hz.

5. Subjects found it easy to discriminate the location of static stimuli, and the speed and direction of moving stimuli.

6. The subjective nature of describing the sensations and defining the discomfort thresholds were noted. The sensation produced by 80 Hz of stimulation was described in unpleasant terms.

With an increase in threshold levels during muscle activity, it could be possible for an operational level set whilst walking, to cause discomfort when the patient becomes stationary. In which case, the smallest change seen in 80 Hz of stimulation would be beneficial. However 40 Hz was chosen for use in the final BFB implementation because it consistently produced a wider dynamic range in each task, it produced the lowest variation at the perception threshold, and participants did not describe the sensation produced as unpleasant. Individual cases support the conclusions here. Finally it was noted that male subjects demonstrated higher threshold levels for perception and discomfort compared to female subjects, this is in accordance with the reported literature.
Chapter 6

Design and Development of a Biofeedback Training System
6.1 Introduction

This Chapter presents the design and development of the final gait re-training system. The system incorporates the stimulator and electrodes which have been described in Chapter 4. Decisions leading to this design were also discussed in Chapter 3. As such the focus here is on the final development and integration of the system components, predominantly the software required for real-time data capture and analysis.

6.2 Training System Overview

A high-level system diagram of the training system is shown in Figure 45. The system comprises the following components:

1. Optical motion capture system (ProReflex, Qualysis Gothenburg, Sweden)
2. Desktop computer for real-time data acquisition
3. Desktop computer for real-time data processing and control of stimulator
4. Sixteen channel electro-tactile stimulator
5. Electrode array for presentation of sensory stimulus
6. Commercial medical grade treadmill (Woodway, Wisconsin USA)

![Figure 45 Overview of the biofeedback training system](image-url)
6.3 Real-time Software Development

6.3.1 Requirements and specification

In general terms the system was required to deliver a real-time electro-tactile stimulus to the patient when the hip joint angles on the prosthetic side exceed user set limits. The location of the stimulus on the thigh corresponds to the extent of deviation in the sagittal and coronal planes. The control software had the following specific requirements:

1. The software was required to communicate with the motion capture software (Qualysis Track Manager) over a standard TCP/IP network connection and acquire marker coordinate data at 120 Hz. The majority of power in kinematic data has been found to be below 6 Hz (Winter 2005), so 120 Hz is above the limit set by the Nyquist criteria.

2. Marker coordinate data quality was to be sufficient to allow analysis and clinical interpretation, therefore the signal must be appropriately conditioned, using gap filling and filtering as necessary.

3. Normalised hip joint angles were required for the sagittal and coronal planes. This required the definition of a linked-segment model of the thigh and pelvis in relation to the gait laboratory, and the detection of the gait events used for normalising joint angles to the gait cycle.

4. Normative reference hip joint angle values were required to enable a comparison with the patient’s kinematics.

5. The system was required to determine which of the electrodes around the thigh was to become active, and when feedback was to be applied.

6. System latency was to be kept to within 150 ms to enable time for the subject to perceive the stimulus in relation to the action being undertaken (this was expanded upon in Chapter 3).

7. Feedback was to be delivered via the stimulation hardware described in Chapter 4.

8. During system operation the operator requires: information from the software to assist setup and ensure data quality is maintained, indication of system status and faults, and data regarding the patient’s kinematics, gait events and feedback parameters in use.
9. The operator also requires an easy-to-use interface to control: the pre-processing functions (any interpolation and filtering), the application of stimulation (including manual control over the stimulator and the trigger threshold levels), and the selection of parameters to be saved for later analysis.

10. To aid the data collection process a participant database was required to store patient anthropometric measurements.

11. A failsafe mechanism was required to ensure no stimulation was delivered to the connected patient, in the event of a hardware or software fault. The user was to be informed if this occurred.

### 6.3.2 Design, architecture and algorithm flow

Software was developed using LabVIEW (National Instruments, Texas, USA). A number of high level programming languages were equally suited to the task (for example C++, Visual Basic or Matlab). LabVIEW was chosen due to author familiarity at the outset, for the ease of GUI design and the range of available library functions. Successive versions of LabVIEW were used over the course of development (versions 8.6 and 2009 to 2011) to exploit improvements in run-time performance, notably with the Mathscript toolbox from 2009 onwards. Development utilised the release of the first Qualysis Track Manager real-time communication protocol (version 1.0) by Qualysis (Gothenburg, Sweden). New protocol releases were incorporated as they were released but stopped at version 1.2 for expediency.

The final versions used were: LabVIEW version 2011, Qualysis Track Manager 2.6 (Build 709) and the RT communications protocol version 1.2.

The software comprised 60 user-written sub-programs and 12 libraries of proprietary functions from National Instruments (NI). Since LabVIEW is a graphical programming language it was not practical to provide complete annotated documentation here. Instead all code is provided on the attached DVD, with a stand-alone executable version. Summary flowcharts presenting the broader architecture are presented in Appendix G, as are diagrams of the major function blocks. The scientific content is described in the following
sections. The overall architecture uses an event-driven producer/consumer design pattern. This is effectively a user interrupt inside an infinite while loop to allow the user to branch back and forth into four distinct modes of operation: A file viewer, a participant database, manual control and real-time operation (Figure 46). Different design patterns were then used within each mode of operation.

1. **File viewer** (described in Section 6.3.11) enables the user to view saved data, such as joint angles and marker trajectories, in table and graphical format.

2. **Participant database** (described in Section 6.3.11) is used to store participant anthropometric measures and personal information (non-identifiable and identifiable as appropriate). On selecting a participant the database populates the relevant modelling variables.

3. **Manual control** mode allows the user to control the stimulator as a stand-alone device (i.e. in an open loop). This is based on the software described in Chapter 4 (Section 4.4.4).

4. **Real-time operation** allows the user to control feedback delivery in the biofeedback mode and hence incorporates the measurement and modelling functions.

![Figure 46 Main program branches](image-url)
The real-time mode is the principal subject of this Chapter and is described in detail in the following sections. The algorithm flow is summarised as follows:

- **Real-time data acquisition (Section 6.3.3)**
  - Read and extract parameters (the number and labels of markers placed on the subject)
  - Read and stream marker coordinate data to queue 1
  - Read queue 1, unpack data packets and match data with parameters

- **Pre-processing (Section 6.3.4)**
  - Interpolate lost frames, then place all data on queue 2
  - Read queue 2, perform linear gap filling of individual marker trajectories
  - Are coordinates within workspace volume?
  - Low pass filter
  - Are marker coordinates and anthropometric measures valid?
  - What is the participant’s direction of travel?
  - Discard first n frames (crop data)

- **Gait event detection (Section 6.3.5)**
  - Identify initial contact
  - Identify toe off

- **Biomechanical modelling (Section 6.3.6)**
  - Define pelvis and hip joint centres
  - Define thigh and knee joint centres
  - Construct linked segment model
  - Calculate relative hip joint angles
  - Normalise joint angles to the gait cycle

- **Determine and present feedback (Sections 6.3.8-10)**
  - Determine the running average of the patient’s stride frame size
  - Interpolate the reference database to match the patient’s stride frame size
  - Calculate the patient’s error vector
  - Have all conditions been met for stimulation?
  - Send appropriate command to stimulator
  - Save pre-defined data types to file

The functional blocks are shown in Figure 47.
Figure 47 System function block diagram
6.3.3 Real-time data acquisition

Two dimensional coordinates of the reflective markers were read from each camera by the proprietary software, Qualysis Track Manager (QTM), at 120 Hz. QTM then calculates the 3D coordinates. Markers placed within the capture volume are automatically labelled using an AIM model or “automated identification of markers” process which is based on pre-labelled data. On request labelled markers are transmitted continuously to a TCP/IP port. Data are then read by LabVIEW for processing. Windows background tasks can cause system jitter which, as a ‘rule-of-thumb’ limits a system loop rate on a Windows operating system to approximately 100 Hz in the worst case (Meisel 2009). Since data were captured at 120 Hz this placed a great demand on the performance of the software. To put this into context Visual3D (C-Motion, Rockville, USA) displays real-time kinematics, but samples the data in order to enable the required calculations. Wrigley et al. (2009) developed similar software using Matlab for the Vicon motion capture system and experienced several frames being dropped between processed frames.

A requirement in this work was for clinical gait quality data, as such all data packets were required at 120 Hz. In addition to these challenges, no handshaking was employed in the QTM RT protocol. To ensure no data packets were lost a producer-consumer architecture was chosen (see Figure 47). The TCP/IP read function operates in a producer loop with a higher priority than the Windows operating system. Data were read and immediately placed on a queue. This provides the highest possible level of assurance of data capture for a soft real-time application. The consumer loops run in parallel, reading the data from the queues and performing the required calculations. If processor utilisation increases as a result of processes in the consumer loops, the data are stored on the producer queue. When the processor load returns to normal, data on the queue are rapidly processed in succession. In order to ensure the attached patient does not perceive a shock-wave effect, the queue sizes were limited to 50 frames (approximately 0.4 seconds) after data on the queues are removed. 50 frames was chosen as a compromise between losing data and producing a perceptible effect. The second consumer loop is in place to compartmentalise the data processing further and provide further flexibility in the loop.
Parameter data were sent once on request at start-up, and contain information about the requested data components.

Parameters can include: the capture frequency, the number of markers, the marker labels, the number, size and calibration matrices of force plates (if force data components were requested). 3D kinematic parameters were requested and the QTM RT server responds with a string in XML format containing labels of all the identified markers. The proprietary XML read functions in LabVIEW were incompatible with the format used by QTM, so an XML parser was written to extract and save the marker labels.

After receiving the parameters, a continuous data stream was requested and the server responded by sending packets of data at the requested rate. A number of data components can be requested, including: 3D marker coordinates, 6D body coordinates, 6D body Euler angles, analog and force plate data. A single packet contains one frame of each data component requested. 3D kinematic data were requested. After reading and buffering data, marker coordinates were paired to the corresponding label. The data packets vary in length according to the presence or absence of labelled markers within the workspace, so the acquisition is very sensitive to correctly identifying the packet length header byte.
6.3.4 Pre-processing

There was the possibility that two types of data transmission error could occur: The loss of a complete packet (one or more frames), or the loss of individual markers within a packet. Packet losses may result from network load changes or system jitter that causes the hardware polling to miss the transmission. The lack of handshaking increases the likelihood of this happening. A marker loss results when a marker is occluded in the capture volume. Both errors are shown in Figure 48.

<table>
<thead>
<tr>
<th>Frame number</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 48 Packet and marker losses. “1” indicates successful transmission, “0” indicates lost data. A complete packet is lost at frame 2 and marker frames are lost for marker B from frames 4 to 6 and for marker C from frames 6 to 8.

In earlier versions of the QTM RT communication protocol, packets were not sent when marker drop-outs occurred. This was originally handled by interpolating the complete packet. However in later versions of the RT protocol, QTM outputted a “NaN” character inside the packet when a marker loss occurred. In that case if packets were interpolated, successive marker losses (in Figure 48 for example) appeared as a packet gap from frames 4 to 8, and there was potential for overlapping marker drop-outs to cause much larger gaps.

Two methods were therefore required to handle the errors separately.
Packet losses were identified by a gap in the frame numbering, and were handled by interpolating the individual data components within the packet (e.g. the x, y and z coordinates of each marker trajectory).

Figure 49 shows 10 example data points (in blue) with point 4 missing. Four different interpolation methods are shown (linear, rational, cubic-spline and polynomial algorithms), with 10 of the interpolated values shown between the known data points (orange).

The cubic-spline method was chosen because it provides a smoother and closer fitting curve than the other methods. The function was implemented using a NI library function, which derives a third-order polynomial for each interval between two adjacent points. Following interpolation of complete frames, all data were placed onto queue 2.

Packet losses could only be identified after the event, so there was potential for a gap to occur and introduce a latency in the system. A maximum allowable gap width of 50 frames was therefore used (this could be adjusted by the operator).
Individual marker drop-outs however were identified in the current frame by the presence of an NaN character. These were filled in real-time using a linear extrapolation. The previous two values of the marker trajectory were used to form the straight line prediction.

A check was then made to ensure all data subsequently processed were in the workspace volume. A 2 m cube was defined and centred on the treadmill for this purpose.

A low pass filter was then used to reduce noise in the data. A 2nd order low pass Butterworth filter was chosen because it has a flat unity response in the pass band and zero in the stop band. Data were sampled at 200 Hz and a cut-off frequency of 10 Hz was used which has been shown to maintain at least 95% of the power in gait signals (Ghoussayni S. 2004) and is consistent with gait-related research. It is not possible to use double-pass or zero-phase filtering in real-time, so there is potential for lag. Cascaded IIR filters were therefore used because they require fewer coefficients than other types of digital filters, and can provide faster filtering. They were implemented using a NI Library point-by-point function. A transient response from the filter occurred in the first few frames, but since individuals walking on a treadmill generate data prior to steady gait, the transient data were discarded. An alternative method to minimise the transient is to ‘pre-charge’ the filter before use, by inserting values similar to those expected in operation into the filter.

Before the data were used in event detection and modelling calculations, they were checked to ensure they were numerical and within expected ranges. The direction of travel was also calculated. In overground gait the rate of change in the axis of progression, of one marker (such as the sacrum) provides the direction of travel. But this is not possible during treadmill gait. In this case the orientation of three pelvis markers was used.

### 6.3.5 Gait event detection

Gait events were required in order to partition the marker trajectory signals into defined gait cycles, and permit comparison of the patient’s data with the reference dataset. Events could include heel contact, heel rise, toe contact or toe-off. Initial contact and toe off were
used in this work, because they are more distinct than heel rise for example, and potentially more suitable for use with patient’s with prosthetic feet.

A number of methods can be used to give an estimation of when gait events occur. Visual inspection can be carried out of the kinematic data, this can be repeatable with experience but time-consuming. Algorithms based on the position or the velocity of reflective markers can be used to automatically detect events. These are quick and have been found to have comparable accuracy with other visual inspection. However there is the risk that artefacts or noise in the data can cause false positive detections. The ‘gold standard’ method of event detection is the use of ground reaction force data. An event is defined when the magnitude of the force rises above a pre-set threshold (Ghoussayni, Stevens et al. 2004; Zeni, Richards et al. 2008).

For real-time analysis without an instrumented treadmill, a position-based marker algorithm was used. Initial contact was defined as the maximum 3-dimensional distance between the sacrum marker and each heel marker (Equation 6). Toe-off was defined as the minimum distance (Equation 7).

\[ IC = \sqrt{(heel_{x_{\text{max}}} - sacrum_{x_{\text{max}}})^2 + (heel_{y_{\text{max}}} - sacrum_{y_{\text{max}}})^2 + (heel_{z_{\text{max}}} - sacrum_{z_{\text{max}}})^2} \quad \text{Equation 6} \]

\[ TO = \sqrt{(heel_{x_{\text{min}}} - sacrum_{x_{\text{min}}})^2 + (heel_{y_{\text{min}}} - sacrum_{y_{\text{min}}})^2 + (heel_{z_{\text{min}}} - sacrum_{z_{\text{min}}})^2} \quad \text{Equation 7} \]

The difference between sacrum and heel markers provides an approximate sinusoid waveform. The events were therefore calculated by using a peak detector to find the peaks (for IC) and troughs (for TO). The NI Library point-by-point peak detector function was used. This maintains running maxima and minima values within a predefined width and above a threshold. Since there were no secondary peaks or troughs in the data, the events were easily found with a threshold of 0 and width of 10 frames. Algorithm testing is discussed in Section 6.4.2.
6.3.6 Biomechanical modelling

Introduction

The relative joint angles were required between each thigh and the pelvis. For this purpose a linked-segment kinematic model was used. Whilst stereophotogrammetry is sometimes referred to as a reference standard, there is no ‘gold standard’ method for determining 3-dimensional joint angles from marker data. Differing approaches use different marker sets, anatomical models, local frame definitions and sequences of rotations based on the biomechanical requirements.

Coordinates from a minimum of three non-coplanar points, on each body segment of interest are required to enable descriptions of rotation and translation in three dimensions, thus permitting a maximum of six degrees-of-freedom to be assessed per segment. The three points can be provided using clusters of physical markers placed on a rigid backing, such as the Cleveland Clinic set described by Cambell, from Sutherland (2002). The clusters are then strapped to each body segment. Cluster-based 6 degree-of-freedom (6DOF) sets have the advantage of reducing skin motion artefact, but were found to be problematic in small children (Sutherland 2002). To minimise the number of markers used, a compromise can be reached by sharing markers across body segments. For example, the Helen Hayes marker set, which has become the basis for many modern sets, uses a lateral knee marker in the definition of the shank and the thigh segments (Kabada, Ramakrishnan et al. 1990; Davis RB., Ounpuu S. et al. 1991). A resulting drawback is to prevent the independent assessment of translation. These sets are therefore described as constrained or 3 degree-of-freedom (3DOF) sets. A further simplification can be made by limiting the model to 2-dimensions.

From a survey looking at the kinematic modelling options used in amputee studies, 25 of the 51 studies reviewed involved trans-femoral amputees (Kent and Franklyn-Miller 2011). The majority (64%) of those trans-femoral amputee studies used 3DOF models, 20% used 6DOF models and 16% used linear segment (or 2D planar) representations. The reason for
the use of 3DOF models with amputees may be due to the general familiarity with 3DOF models in clinical practice, and the presence of historical data built up using 3DOF models. Collins compared a cluster set with a modified Helen Hayes marker set, using ten healthy young subjects walking on a treadmill (Collins, Ghoussayni et al. 2009). Looking specifically at the hip joint, Collins reported moderate to poor correlation between the two models in the coronal plane (at peak adduction in stance and peak abduction in swing). This may be due to difficulties with marker placement on the pelvis and the reduced range of movement. Good correlation was reported in the Sagittal plane (in flexion at initial contact and peak extension in stance) as may be expected.

There is a requirement to register the location of physical (technical) markers against anatomical markers at bony landmarks on the patient’s skeletal system. This is performed during a calibration routine and is always a requirement with 6DOF clusters. In 3DOF marker sets anatomical registration methods can vary on a joint-by-joint basis. In the Helen Hayes (HH) marker set the technical and anatomical markers are congruent, and the calibration procedure can be made redundant with the use of anthropometric measures and anatomical relationships. A 3DOF modified Helen Hayes marker set was therefore used. This reduced the need for patients to perform a standing calibration trial and also permitted data compatibility with clinical collaborators.

The resulting choices enabled the use of a minimal marker set to define a clinically relevant 3DOF model of the pelvis and thighs. There was also no need for patients to perform functional axis movements or standing trials. The distal markers in the modified HH set that define shank and foot segments were included in software for completeness.

**Body segments and landmarks**

The segments of interest were the left and right thighs and the pelvis. Each segment was assumed to be rigid and assigned a local coordinate system (LCS). The anatomical landmarks shown in Figure 50 were located with reflective markers. Virtual markers were used for model definition and were calculated in real-time from anthropometric measures.
**PELVIS**

**Anatomical landmarks**

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LASIS &amp; RASIS</td>
<td>Placed over the prominent aspect of the Anterior Superior Iliac Spine</td>
</tr>
<tr>
<td>SACRUM</td>
<td>Placed mid-way between the left and right posterior iliac spine</td>
</tr>
</tbody>
</table>

**THIGHTS**

**Anatomical landmarks**

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTHIGH &amp; RTHIGH</td>
<td>On a line formed between the greater trochanter and the knee marker, below the level of the swinging hand</td>
</tr>
<tr>
<td>LKNEE &amp; RKNEE</td>
<td>Placed over the lateral femoral epicondyle, at half the knee width in the coronal plane (excluding the patella)</td>
</tr>
</tbody>
</table>

**Virtual landmarks**

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LHJC &amp; RHJC</td>
<td>Hip joint centres with respect to the pelvis segment frame origin</td>
</tr>
<tr>
<td>LKJC &amp; RKJC</td>
<td>Knee joint centres, approximated to be at half the knee width at the KNEE marker</td>
</tr>
</tbody>
</table>

**SHANKS (included for completeness)**

**Anatomical landmarks**

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LSHANK &amp; RSHANK</td>
<td>Placed on a line formed by the KNEE and ANKLE markers</td>
</tr>
<tr>
<td>LANKLE &amp; RANKLE</td>
<td>Placed on the most prominent aspect of the lateral malleolus</td>
</tr>
</tbody>
</table>

**Virtual landmarks**

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAJC &amp; RAJC</td>
<td>Ankle joint centres with respect to the pelvis origin</td>
</tr>
<tr>
<td>RAJC</td>
<td>Right hip joint centre with respect to the pelvis origin</td>
</tr>
</tbody>
</table>

**FEET (used for event detection)**

**Anatomical landmarks**

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LHEEL &amp; RHEEL</td>
<td>On the mid line of the calcaneus, at the height of the foot measured from the metatarsals</td>
</tr>
<tr>
<td>LTOE &amp; RTOE</td>
<td>Placed over the skin between the second and third metatarsal heads</td>
</tr>
</tbody>
</table>

---

Figure 50 Segment landmarks identified by reflective markers (blue) and virtual markers (red)
**Hip Joint Centre definitions**

Two methods are commonly used to determine joint centre locations: 1. Anatomical models are based on known relationship between anatomical proportions and the joint centre locations for a given population. 2. Functional models that require the patient to undertake a wide and varying movement pattern, from which a geometrical approximation can be made from the tracked markers. For the hip joint Piazza *et al.* (2004) compared a least-squares functional approach to an anatomical model in 22 healthy subjects whilst walking, and conducting sit-to-stand, stair climbing and limited range-of-motion walks using a static *varied hip motion* trial as a reference. Piazza reported a worst-case joint centre location error of 26 mm when restricted movements were made, and 36 to 52 mm errors in the stair ascent task. Whilst the study did not use a reference joint centre location method, such as x-ray, it does suggest the functional approach produces wider variation in normal activities.

A disadvantage of functional methods, particularly in pathological subject’s, is the requirement for patients to stand on one leg and perform a pre-set movement pattern to generate the required data. This was thought to be unacceptable for amputees, so for this reason an anatomical hip joint definition was used. Visual3D uses anatomical relationships developed by Davis *et al.* (1991) which are based on regression equations from x-ray data. Davis’ relationships require knowledge of the leg length. In amputees this would impose an assumption of leg–length symmetry. The alternative chosen was to use approximations developed by Bell (1990). These use the following regression equations from x-ray data of the normal pelvis only:

\[
\begin{align*}
X_{hip} &= -0.19 \text{ PW} \\
Y_{hip} &= 0.36 \text{ PW} \\
Z_{hip} &= -0.30 \text{ PW}
\end{align*}
\]

Where PW is the pelvis width or inter-ASIS distance

Leardini *et al.* (1999) have shown that Bell’s method is a closer approximation to an x-ray reference than Davis’.
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Knee Joint Centre definitions

Definition of the knee joint centre (kjc) is problematic in all cases because the joint is polycentric. No methods of anatomical registration currently take into account the joint polycentricity. The kjc is often assumed to lie midway between the lateral and medial femoral epicondyles. Markers placed on the medial epicondyle can get knocked off during walking, also placing a limitation on tracking the knee. Four methods were reviewed for use in this work. Mechanical devices (such as the knee alignment device from Vicon, UK) or a digitising (or Davis) pointer can be used to indicate the location of the landmarks during a static calibration routine. A single marker is then used with thigh or shank markers for tracking. Alternatively a medial marker is used in the role of a Davis pointer during a static calibration with a lateral marker. These methods require a static calibration stage.

A trigonometric method was chosen, which uses one tracking marker placed over the lateral femoral epicondyle. A number of assumptions were made. Referring to Figure 51, the hjc, thigh and knee markers were assumed to lie on a plane, with a right angle formed between the principal axis p and the knee joint axis. The knee is assumed to be a hinge joint with a functional centre mid-way between the medial and lateral epicondyles. This method was chosen to obviate the need for a static trial.

![Figure 51 Knee joint centre definition](image)

\[ \begin{align*}
\text{hjc} &= \text{position vector of HJC wrt GCS} \\
\text{kjc} &= \text{position vector of KJC wrt GCS} \\
\text{thigh} &= \text{position vector of THIGH wrt GCS} \\
\text{knee} &= \text{position vector of KNEE wrt GCS} \\
|d| &= \frac{1}{2} \text{knee width} \\
a &= \text{THIGH vector wrt to HJC} \\
b &= \text{KNEE vector wrt to HJC} \\
p &= \text{KJC vector wrt to HJC (principal axis of the femur)}
\end{align*} \]
The vector \( \mathbf{k}_{jc} \) was found by determining the vector \( \mathbf{p} \) (the principal axis of the femur) in the GCS, since:

\[
\mathbf{k}_{jc} = \mathbf{h}_{jc} + \mathbf{p}
\]  
Equation 11

An orthogonal coordinate frame (green) was placed at the HJC and aligned with \( \mathbf{a} \). If \( \mathbf{p} \) has components \( \mathbf{a} \) and \( \mathbf{b} \) with proportions \( \alpha \) and \( \beta \) respectively then:

\[
\mathbf{p} = \alpha \mathbf{a} + \beta \mathbf{b}
\]  
Equation 12

Where \( \mathbf{a} = \text{thigh} - \mathbf{h}_{jc} \)  
Equation 13

and \( \mathbf{b} = \text{knee} - \mathbf{h}_{jc} \)  
Equation 14

In terms of unit vectors \( \mathbf{i} \) and \( \mathbf{j} \) equation 12 becomes:

\[
\mathbf{p} = |\mathbf{p}| \cos(\theta + \phi) \mathbf{i} + |\mathbf{p}| \sin(\theta + \phi) \mathbf{j}
\]  
Equation 15

Where \( \mathbf{i} = \frac{\mathbf{a}}{a} \)  
Equation 16

And \( \mathbf{i} \) is orthogonal, so \( \mathbf{j} = \frac{\mathbf{a} \times \mathbf{b} \times \mathbf{a}}{|\mathbf{a} \times \mathbf{b} \times \mathbf{a}|} \)

Which simplifies to \( \frac{ab - b \cos(\theta)\mathbf{a}}{ab \sin(\theta)} \)  
Equation 17

Substituting equations 16 and 17 into equation 15 gives:

\[
\mathbf{p} = |\mathbf{p}| \cos(\theta + \phi) \frac{\mathbf{a}}{a} + |\mathbf{p}| \sin(\theta + \phi) \frac{ab - b \cos(\theta)\mathbf{a}}{ab \sin(\theta)}
\]  
Equation 18

Which simplifies to:

\[
\mathbf{p} = -\frac{|\mathbf{p}| \sin(\phi)}{a \sin(\theta)} \mathbf{a} + \frac{p \sin(\theta + \phi)}{b \sin(\theta)} \mathbf{b}
\]  
Equation 19

So \( \alpha = -\frac{|\mathbf{p}| \sin(\phi)}{a \sin(\theta)} \)  
Equation 20
and \[ \beta = \frac{p \sin(\theta + \phi)}{b \sin(\theta)} \] Equation 21

Combining equations 11, 12, 13, 14, 20 and 21 gives the knee joint centre relative to the GCS:

\[ k_{jc} = h_{jc} + \frac{|p| \sin(\phi)}{a \sin(\theta)} (\text{thigh} - h_{jc}) + \frac{p \sin(\theta + \phi)}{b \sin(\theta)} (\text{knee} - h_{jc}) \] Equation 22

Values for $|p|$, $a$, $\phi$ and $\theta$ were found using Pythagoras theorem and trigonometric ratios.

Coordinate Frame definitions

A global coordinate system (GCS) was defined and fixed in the capture volume. In common with biomechanics work (Cole GK, Nigg BM et al. 1993; Capozzo 1995) a right-handed coordinate system was used (Figure 52). QTM provided Cartesian coordinates of the reflective markers with respect to the GCS origin.

Global Coordinate System

- **Origin** is at the bottom right corner of the treadmill belt on the belt surface such that all data are positive
- $X_{\text{GCS}}$ is the axis of progression and aligned with the right side of the treadmill belt, pointing towards the front of the treadmill
- $Y_{\text{GCS}}$ is orthogonal to $X_{\text{GCS}}$ and points to the left to form the medial-lateral axis
- $Z_{\text{GCS}}$ is orthogonal to $X_{\text{GCS}}$ and $Y_{\text{GCS}}$ and points upwards to form an inferior-superior axis

Figure 52 Global coordinate system in relation to treadmill
Segment Coordinate Frames

The segments were assumed to be anatomically symmetrical to enable the construction of orthogonal coordinate frames. In reality anatomical asymmetry would introduce differences in alignment between the frames and the anatomy. For example the line from the sacrum to the inter-ASIS mid-line would not intersect at the mid-point in the presence of asymmetry. Floating axes (Xf<sub>P</sub> and Yf<sub>T</sub>) were therefore used during the construction of the coordinate frames to ensure the vectors within the frames were orthogonal. To minimise the error the floating axes were assigned to minor anatomical axis in each case.

Pelvis frame

**Origin**  Centred on the mid-point between the left and right ASIS

**Y<sub>P</sub>**  Pelvis y-axis points medially towards the left ASIS from the origin

**Xf<sub>P</sub>**  Pelvis floating x-axis, is a temporary axis pointing in the direction of x from the sacrum marker

**Z<sub>P</sub>**  Pelvis z-axis is orthogonal to Y<sub>P</sub> and Xf<sub>P</sub> and points up

**X<sub>P</sub>**  Pelvis x-axis is orthogonal to Z<sub>P</sub> and Y<sub>P</sub> and points in the direction of gait progression

Thigh frames

**Origin**  Centred on the knee joint centre

**Z<sub>T</sub>**  Thigh z-axis, principal axis from the knee joint centre to the hip joint centre, points up

**Yf<sub>T</sub>**  Thigh floating y-axis is a temporary floating axis from the knee marker to the knee joint centre

**X<sub>T</sub>**  Thigh x-axis is orthogonal to Yf<sub>T</sub> and Z<sub>T</sub>

**Y<sub>T</sub>**  Thigh y-axis is orthogonal to Z<sub>T</sub> and X<sub>T</sub>

Figure 53 Local Coordinate System definitions (for clarity only the right thigh is shown)
### Relative Joint Angle calculation

The hip joint centres were translated to the pelvis origin. The pelvis frame was then rotated and translated to the global frame, such that both thighs were centred about the global frame. To determine the hip joint angles relative to the pelvis a Cardan (or three angle) sequence of rotations was performed. It is standard practice in gait research to use successive rotations from the most influential plane to the least influential. The order Y-X-Z was therefore used.

Where Y is a flexion/extension rotation ($\beta$) in the sagittal plane:

\[
y = \begin{bmatrix}
\cos(\beta) & 0 & -\sin(\beta) \\
0 & 1 & 0 \\
\sin(\beta) & 0 & \cos(\beta)
\end{bmatrix}
\]

Equation 23

X is an abduction/adduction rotation ($\alpha$) in the coronal plane:

\[
x = \begin{bmatrix}
1 & 0 & 0 \\
0 & \cos(\alpha) & \sin(\alpha) \\
0 & -\sin(\alpha) & \cos(\alpha)
\end{bmatrix}
\]

Equation 24

And Z is an internal/external rotation ($\theta$) in the transverse plane:

\[
z = \begin{bmatrix}
\cos(\theta) & \sin(\theta) & 0 \\
-\sin(\theta) & \cos(\theta) & 0 \\
0 & 0 & 1
\end{bmatrix}
\]

Equation 25

Pre-multiplication of the sequence Y-X-Z produced the following transformation matrix ($R_{YXZ}$):

\[
R_{YXZ} = \begin{bmatrix}
\cos(\theta) \cos(\beta) + \sin(\theta) \sin(\beta) \sin(\alpha) & \sin(\theta) \cos(\alpha) & -\cos(\theta) \sin(\beta) + \sin(\theta) \cos(\beta) \sin(\alpha) \\
-\sin(\theta) \cos(\beta) + \cos(\theta) \sin(\beta) \sin(\alpha) & \cos(\theta) \cos(\alpha) & \sin(\theta) \sin(\beta) + \cos(\theta) \sin(\alpha) \cos(\beta) \\
\sin(\beta) \cos(\alpha) & \sin(\alpha) & \cos(\beta) \cos(\alpha)
\end{bmatrix}
\]
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$R_{YXZ}$ was equated to the thigh and pelvis frames since:

$$R_{yxz} = (\text{distalsegmentLCS}).(\text{proximalsegmentLCS})^T$$ \hspace{1cm} \text{Equation 26}

$$R_{yxz} = (\text{thigh}^A_{toG}).(\text{pelvis}^A_{toG})^T$$ \hspace{1cm} \text{Equation 27}

The local coordinate frames $\text{thigh}^A_{toG}$ and $\text{pelvis}^A_{toG}$ are both orthonormal, so a numerical check was made with sample data to ensure they were correct, since for orthonormality:

$$A^T = A^{-1} \quad \text{and} \quad A^T A = AA^{-1} = I$$ \hspace{1cm} \text{Equation 28}

Joint angles were then determined from the matrix elements of $R_{YXZ}$, accordingly:

- **Flexion/extension**
  $$\beta = \sin^{-1}\left(\frac{-R_{31}}{\cos \alpha}\right)$$ \hspace{1cm} \text{Equation 29}

- **Abduction/Adduction**
  $$\alpha = -\sin^{-1}(R_{32})$$ \hspace{1cm} \text{Equation 30}

- **Internal/External rotation**
  $$\theta = -\sin^{-1}\left(\frac{R_{12}}{\cos \alpha}\right)$$ \hspace{1cm} \text{Equation 31}

Finally conditions were imposed on the resulting values to avoid asymptotic solutions. All matrix calculations were performed using LabVIEW Mathscript.

### 6.3.7 Normative reference data

A normal joint angle dataset was required to provide a reference for comparison with the participants. The dataset required hip angles in the coronal and sagittal planes normalised to the gait cycle, from non-amputees during treadmill walking. Data previously collected by Collins (2007) was available and used for this work. Collins selected subjects to ensure the best likelihood of a consistent gait pattern.
Selection criteria included the following:

- In the age range of 18 to 50 years
- Body mass index in the normal and overweight range 18.5 – 29.9 kg/m²
- Leg length discrepancy of less than 15mm
- No musculoskeletal injuries or disorders that affect walking ability

Collins used a modified Helen Hayes marker set (containing the markers of interest for this work) and a six degree of freedom set. Participants attended twice and walked for 15 seconds on a treadmill, enabling a minimum of 24 strides per person. Data were captured at the Centre for Biomedical Engineering using the same ProReflex motion capture system used in this work, with a sampling frequency of 120 Hz. Marker data were processed using the code described in this Chapter. Mean values for 144 strides are shown in each case for the left and right leg (Figure 54). The joint angles follow the known kinematic profiles of the hip. A comparison with published algorithms is discussed in Section 6.4.1.

Figure 54 Normal reference joint angles – group mean and 2 standard deviation bands are shown
6.3.8 Determination of feedback

Sensation feedback is applied when the patient deviates outside a kinematic boundary defined by the variation seen in a normal population. The boundary moves in real-time with the patient to indicate they have moved excessively in a particular direction. It is therefore to be avoided. The clinician can change the boundary, setting it closer to the population mean (which increases the sensitivity or difficulty for the patient) or further away (creating a wider band for error). For example excessive abduction in the right leg will cause a stimulus to be delivered on the lateral surface of the thigh. Excessive flexion will present a stimulus to the anterior surface.

To illustrate how this is implemented, an example is shown in Figure 55 of a right leg with a slight hip abduction and extension throughout the gait cycle. The deviation is small and within the variation seen in the normal population, but this is not of concern for the purposes of illustration.

![Figure 55 Sagittal and coronal hip joint angles of an example patient (blue) and the normal reference dataset (red), shown with ± 2 SD bands (dashed)](image)

Figure 55 Sagittal and coronal hip joint angles of an example patient (blue) and the normal reference dataset (red), shown with ± 2 SD bands (dashed)
Plotting the hip joint angles against each other produces the angle-angle graph (Figure 56) which shows the combined effect of the gait deviations. Initial contact occurs at point 1 and gait progresses clockwise. At point A (one instance in the gait cycle) a transverse section of the leg is shown as a pink circle with a number of electrodes. The error signal is defined as the difference between the patient and the reference at a point in time. This is represented as a vector (green) pointing towards the electrode that is to become active. The angle of the vector (the error angle) determines the electrode selection.

Figure 56 Angle-angle graph of hip joint angles (left) for an example patient (blue) and the normal reference data (red). Also shown are the error vector (green) and transverse section of the right thigh (pink) with electrodes. The electrode numbering is also shown (right). The vector angle is divided into the eight numbered arcs. In this case data for the right leg are shown. For the left leg the sagittal component of the vector remains the same but the coronal component would be mirrored about the vertical.

To enable the feedback to be focused on a specific rehabilitation issue, the magnitude of the vector (the error magnitude) is compared against a user-defined threshold to determine if the selected electrode is to become active or not. A temporal window can be set to confine stimulation to a particular range within the gait cycle. The coronal and sagittal components were also weighted to enable the clinician to adjust the extent to which they influence the electrode selection. An example of this is shown in the software screenshot in Figure 57. Data are shown for a patient abducted throughout the gait cycle (notably in early stance and swing) and slightly flexed in late stance/early swing. In this case the clinician
may wish to focus attention on the patient’s abduction in swing (as may be the case with an amputee walking with a circumduction gait pattern). The weighting is set to use 100% of the coronal data (i.e. the anterior/posterior electrodes are not in operation). There are two peaks in the error vector magnitude which correspond to the two major abduction gait deviations. To ensure stimulation is only delivered in swing the activation window cursors have been positioned to bound the second peak. Stimulation will therefore only occur if the error signal enters the blue shaded region.

Figure 57 Screenshot of real-time kinematics display. Hip joint angles normalised to the gait cycle are shown (top left) and the error magnitude (bottom left). Continuous values are shown as a function of time (top right) and as an angle-angle graph (bottom right). Data are shown for a patient (white) and the normal reference (red). The activation window cursors are shown (yellow) on the left.

This implementation provides flexibility to set feedback at specific instances in the gait cycle and when a threshold has been crossed. However this approach is limited. By using weightings to gain greater control of the error vector, the number of potential electrode sites was reduced. In this example where only coronal data were taken into account, only the lateral and medial electrodes are being used.
6.3.9 Timing strategy for feedback delivery

The previous section dealt with *where* stimulation should be applied and creating conditions for electrode selection. Attention will now turn to *when* the application of feedback occurs.

It is not currently possible to provide informed feedback of gait kinematics in real-time. To do so would require instantaneous determination of the error signal. The error signal is derived from the patient’s current frame of angle data and the corresponding reference frame from a normal database. Since gait is defined as a cycle, the timing information required to synchronise the two signals only becomes available after the cycle is complete. One solution would be to instantaneously detect where the patient is in the gait cycle. This is an interesting challenge that would require a gait detection algorithm to be robust in the presence of pathological gait patterns. However, this was not available and no previous work into instantaneous gait detection was identified. A compromise used was therefore based on past knowledge of the gait signals.

A running average of the stride frame size was calculated from the three previous strides, to provide a value to index into the normal reference database. The reference angles were then compared with the patient’s current angles to produce the error signal. It would equally have been possible to use timing values from the previous stride but this may introduce the possibility of ringing (or hunting) as seen in control systems, whereby the patient overcompensates based on previous values causing the next value to require an underestimation, making it difficult to reach the target. A mean using a larger number of strides would smooth the data and potentially reduce the relevance of the error signal to the patient’s current action. Three strides were used as a compromise. This approach requires low variability in the stride timing, to avoid erratic behaviour around the loop. The patient walks on a treadmill with a set speed, so this is a reasonable assumption. Stride timing variability would then be limited to changes in step length. During operation patients were required to walk at their chosen walking speed for a period of time before feedback is applied, this would help to reduce step length variations. Returning to Figure 57, the error signal shown is therefore the mean error in the coronal plane of the three previous strides.
6.3.10 Control of stimulator

Two methods were required to control the stimulator hardware within the real-time loop: manual control and automatic control. The operator can switch between the two. These modes are in addition to the software used to control the stimulator as a stand-alone device, as described in Chapter 4 (§4.3.4), and are distinguished by the suffix “RT”.

The Manual_RT software replicates the stand-alone version but required a different implementation because it sits inside the real-time acquisition and control loop. The stand-alone version was based on user event interrupts. In contrast the Manual_RT version operates by polling for a response from the user during each loop iteration. Automatic_RT control is an addition which automatically passes electrode selection commands to the Manual_RT code section, based on the requirement for feedback (previously described). Handshaking commands were required less frequently in Automatic_RT mode since the electrode change commands, which were sent on a more frequent basis, serve the same purpose.

During operation the operator enables the stimulator, which initialises communication with the stimulator and starts transmitting the handshaking commands. The stimulator is in the default “STOPPED” state and no stimulation commands are sent. The operator can then either take manual control of the stimulator or toggle a “send to stim” button which starts transmission of a stream of the appropriate electrode selection commands. As described in Chapter 4, the baud rate was set at 38400 bps which permits enough time for approximately 770 electrodes location changes per second. Additional handshaking commands are inserted into the loop when there has been no user interaction or electrode selection commands sent for over 40 ms. At this stage the stimulator is still not stimulating, but the selected electrodes are displayed to the operator. Stimulation can then be started and stopped by the operator. It was important that start and stop functions remain in the control of the operator throughout. The stimulator responds in the same way as described in Chapter 4. The user interface displaying these functions is described in the next section.
6.3.11 User interface and ancillary functions

The user interface (as shown in Figure 58) is divided into two sections: The top bar (highlighted in red) is accessible at all times and shows functions that are applicable to all modes of operation: the system status, the file saving and viewing controls and the main controls that cause the program to branch into different modes (described in §6.3.2). Function specific information is provided in separate pages in the main workspace (purple).

To ensure no invalid sequence of operations occur, user controls are hidden and revealed when required. The main workspace is broken down into nine separate pages, which contain features to improve the expediency of data collection and analysis.

Figure 58 Main graphical user interface
A screenshot of each page is provided in Appendix G3. They include:

- **Participant database** – Microsoft Excel was used to store anthropometric and subject data. The Biofeedback software takes control of Excel to transfer data between the database and specific variables within the software.

- **Model display** (seen in Figure 58) – Marker coordinates and the calculated anatomical landmarks were plotted in three 2-dimensional displays, showing a stick figure of the biomechanical model. This was useful for the operator to check the markers have been captured and labelled correctly.

- **Marker coordinates** – Marker coordinates were displayed graphically against time as continuous real-time variables. Options are provided to enable the gap filling interpolation and adjust filtering parameters.

- **Joint angles** – The calculated joint angles of the hip and pelvis are displayed graphically against time as continuous real-time variables.

- **Normalised joint angles** – After two successive events have been detected, the joint angles are normalised to the gait cycle and displayed at each subsequent event. Since the timing required for normalisation is based on the assumption of low variability in mean stride frame sizes, the frame size value is also graphed to enable to operator to monitor that assumption.

- **RT control** – The synchronised patient and reference joint angles are displayed (as shown in Figure 57) as continuous and normalised variables, and as an angle-angle graph. The error vector and activation window are also shown. Controls are provided to set the activation window and take control of the stimulator in manual_RT or automatic_RT modes.

- **Manual control** – Shows the controls that enable the operator to use the stimulator as a stand-alone device.

- **Settings** – Allow the operator to change the QTM capture settings (IP connection, and capture frequency), the serial port hardware settings and the graphical refresh rate. An option is provided to enable the operator to assign physical electrode channels to different software channels. The user can also select which data variables are saved.
The National Instruments Technical Data Management Streaming (TDMS) file format was chosen and implemented for saving and viewing real-time data. TDMS is a NI format which is optimised for high-speed data transfer to disk, it is capable of transfer speeds of up to 400 MB/s. Data are structured in three levels of hierarchy: files, groups and channels, including a binary attribute header file. The Biofeedback software allows the operator to choose to save the following variables: All marker coordinates, left and right hip joint angles and pelvic angles, frame numbers, left and right IC and TO events, left and right hip and knee joint centres, selected active electrodes. The software was written to allow the operator to automatically redirect the saved data stream to new files, without interrupting the RT loop with dialogue boxes, or losing a frame. After capture, data can be viewed in a separate LabVIEW programme in table or graphical format, or imported directly into Excel using a TDMS Excel plug-in (provided on the accompanying DVD).

6.4 Software Testing

6.4.1 Validation of biomechanical model

The aim of validation was to determine the accuracy of the calculated joint angles and ensure the sign conventions used clinically were adhered to. As discussed in Chapter 3, there is no ‘gold standard’ method for determining 3-dimensional joint angles from marker coordinate data. The approach taken was to therefore to compare the angles calculated from the algorithms developed for this work (the “LabVIEW angles”) with those produced by proprietary biomechanics software that is used clinically (“Visual3D” angles). Visual3D was not treated as an absolute reference, but it was hoped that a comparison would help enable a better understanding of the validity of the LabVIEW angles. A spot check of angles and signs was also made using a mechanical rig.

**Spot check**

The mechanical rig shown in Figure 59 is a representation of a left leg, which comprises a number of rigid (tubular aluminium) segments with slight adjustment of segment lengths and rotations. The leg is passive and suspended, allowing manual movement. Using
locking rings there is some ability to hold the leg in a fixed flexion or extension (only). Stalks and flat circular disks allow the placement and alignment of reflective markers.

![Mechanical rig (left leg). Detail of thigh is shown (right)](image)

The reflective markers required for the LabVIEW calculations were applied. Using Equations 8, 9, and 10 the location of the hip joint centre was calculated in order to manually position the hip joint. The rig did not permit physical adjustment of the joint in the z or x-axis, but since it was possible to move the ASIS markers in the z and y direction adjustments were made to the pelvis proportions and leg length to satisfy the calculations. Placement of the other markers did not alter the ‘anatomical’ definition.

Using a goniometer the leg was then positioned and held manually in a number of fixed rotations about a single axis. For example: A fixed flexion of 20 degrees, a fixed 45 degree internal rotation and so on. Each angle of rotation was in part determined by the constraints of the mechanical rig, but where possible whole integer values were used to minimise error in the comparison. 60 seconds of data were captured and processed using LabVIEW, mean angle values were calculated (as shown in Table 16). The leg was then moved bi-axially and the calculated angles were monitored in real-time via the PC screen. It was not possible to accurately align the leg in two axes using goniometers manually, so this was only used a visual check of crosstalk in the calculations.
Table 16 Hip joint angles (all values are given in degrees)

<table>
<thead>
<tr>
<th></th>
<th>Goniometer</th>
<th>LabVIEW</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left abduction</td>
<td>-30</td>
<td>-29.5</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>-20</td>
<td>-19.9</td>
<td>0.1</td>
</tr>
<tr>
<td>Left adduction</td>
<td>20</td>
<td>19.1</td>
<td>0.9</td>
</tr>
<tr>
<td>Left flexion</td>
<td>20</td>
<td>20.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Left extension</td>
<td>-20</td>
<td>-19.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Internal rotation</td>
<td>45</td>
<td>46.5</td>
<td>1.5</td>
</tr>
<tr>
<td>External rotation</td>
<td>-45</td>
<td>-44.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

From Table 16 it can be seen that the sign convention is correct and in accordance with Kabada et al. (1990). The calculated values are within a maximum of 1.5 degrees of those measured manually and as low as 0.1 degrees in the case of the -20 degree abduction. Goniometer precision is typically around 1 degree, so these values fall within what could be achieved. The mechanical setup introduced potential for a large parallax/perspective error particularly in the sagittal plane. Whilst the use of a goniometer was not an ideal reference the test provided an adequate indication that the calculations produced sensible values. The reference measurement accuracy could be improved by using shaft encoders fitted into the mechanical rig and validated against a mechanical frame machined to known angles.
Comparison with Biomechanics Software “Visual3D”

Data were captured from a healthy individual wearing a Helen Hayes marker set (including the markers required for this work), walking normally through the capture volume. 15 seconds of data were recorded which included 2 complete strides. The data were processed using the LabVIEW code and separately using the proprietary biomechanics software Visual3D (C-Motion Inc. Maryland USA). The same anthropometric parameters were used in each case and the gait events that were automatically detected by the LabVIEW code were used in Visual3D. In each case the data were gap filled (to a maximum of 40 frames) and filtered using a 2nd order low pass Butterworth filter with a 10 Hz cut-off frequency. The body segments were defined in the same way and the relative joint angles were calculated and compared. The joint centres were also compared.

Joint Angles

The mean angles in the sagittal plane for the Visual3D and LabVIEW methods are shown in Figure 60, along with the differences.

Figure 60 Mean hip flexion/extension calculated using Visual3D and LabVIEW (top), absolute difference between methods (below)
Referring to Figure 60 a close similarity can be seen between the two calculation methods throughout the gait cycle. A maximum difference of 1.5 degrees occurs in late swing on the left and 3.5 degrees in mid-stance on the right. There is a slight shift to the right in the Visual3D data. The peak difference in range between the two methods is 1 degree on the left and 3 degrees on the right.

The coronal data are shown in Figure 61, from which marked differences can be seen in mid-stance and late to terminal swing. A maximum of 5 degrees difference occurs in mid-swing on the left, with a second peak of 3 degrees at mid-stance. On the right there is a difference of 10.5 degrees from initial contact and 10 degrees in terminal stance. There is a slight shift to the left of the Visual3D data on the left leg and a shift to the right on the right sides. The peak difference in range is 4 degrees on the left and 5 degrees on the right.

Two factors may contribute to the differences seen: the definitions used for the hip and knee joint centres and the use of optimisation.
**Hip Joint Centres**

As described in Section 6.3.6, the hip joint centre definitions used were based on relationships developed by Bell et al. (1990) to avert the reliance on leg length measurements with amputees. The definitions used within Visual3D differ. They are based on relationships developed by Davis et al. (1991) which also uses regression equations from x-ray data but require known leg lengths. The differences in hip joint centre coordinates calculated by LabVIEW and Visual3D were compared for 200 frames of walking data. There are constant offsets in each axis throughout the gait cycle, as shown in the summary Table 17. Graphical data are included in Appendix H.

<table>
<thead>
<tr>
<th>Axis</th>
<th>Left hip</th>
<th>Right hip</th>
</tr>
</thead>
<tbody>
<tr>
<td>X (anterior/posterior)</td>
<td>10.8 mm more posterior</td>
<td>12.9 mm more posterior</td>
</tr>
<tr>
<td>Y (mediolateral)</td>
<td>6.0 mm more medial</td>
<td>4.5 mm more medial</td>
</tr>
<tr>
<td>Z (inferior/superior)</td>
<td>2.5 mm more superior</td>
<td>2.4 mm more superior</td>
</tr>
</tbody>
</table>

Leardini et al. (1999) compared the methods of Bell and Davis (and a functional method) against an x-ray reference dataset. Leardini’s data show that Bell’s method produced hip joints centre locations that were more posterior, medial and superior compared to Davis’s method, in the order of 4 mm, 11 mm and 27 mm respectively. They also reported that Bell was closer to the reference method compared to Davis. Whilst the differences are not numerically similar with this comparison, the direction of the bias is comparable.

**Knee Joint Centres**

Looking at the knee joint centres, again the differences in joint centre coordinates calculated by LabVIEW and Visual3D are shown graphically in Appendix H, for 200 frames of walking data. They also show constant offsets in each axis throughout the gait cycle. The mean offsets are shown in Table 18.

<table>
<thead>
<tr>
<th>Axis</th>
<th>Left knee</th>
<th>Right knee</th>
</tr>
</thead>
<tbody>
<tr>
<td>X (anterior/posterior)</td>
<td>12.8 mm more anterior</td>
<td>15.1 mm more anterior</td>
</tr>
<tr>
<td>Y (mediolateral)</td>
<td>8.9 mm more medial</td>
<td>8.4 mm more medial</td>
</tr>
<tr>
<td>Z (inferior/superior)</td>
<td>10.6 mm more superior</td>
<td>10.7 mm more superior</td>
</tr>
</tbody>
</table>
Optimisation

This work uses a non-optimal or direct trigonometric solution to approximate the medial knee location, and hence determine the knee joint centre location. Visual3D uses a similar vector approach to define a virtual medial knee landmark, which is used during a calibration process. However during tracking Visual3D then uses an optimal pose estimation method by (Spoor and Veldpaus 1980). This is a segment optimisation method which is used to minimise the effect of measurement error and soft tissue artefacts. It is also referred to as a 6DOF method, because each segment is considered to have 6 variables that describe its pose (3 variables describe the position of the origin and 3 describe rotation about the principal axes of the segment). Given 3 markers on each rigid segment a least squares calculation is used to determine the optimal pose using the complete set of data.

Since the method is used to reduce motion and soft tissue artefacts, the magnitude of the distance between markers on the pelvis and thigh segments were examined, to find the extent of marker wobble and possible effects in the LabVIEW calculations. Figure 62 shows the magnitude in 3-dimensions of the displacement between the thigh marker and knee marker, normalised to the gait cycle and plotted alongside the coronal joint angles.

There is an excursion of marker displacement at swing, of 28 mm on the left and 26 mm on right, which is comparable to the potential 30 mm artefact seen in stereophotogrammetry (Cappozzo, Catani et al. 1996). However the peaks do not correspond to differences in the joint angle calculations. Some movement was expected since the thigh markers were
placed on wands and more susceptible to movement artefacts, which may become more pronounced during the limb acceleration. Similar peaks were seen in other marker combinations containing wand markers (the left and right shank-to-ankle markers for example), but not in any surface marker combinations. It would be beneficial to repeat the test using a rigid mechanical rig to remove marker wobble from the comparison of joint angle output.

In conclusion, there are two notable differences in the chain of calculations that could influence the differences seen in the angles in the sagittal plane (Figure 60), and more markedly in the coronal plane (Figure 61). Firstly in the definition of joint angles: The hip joint centres are positioned more posteriorly, medially and superiorly in this work compared to those calculated using Visual3D. This shift will be subject to an error propagation effect when the local coordinate frames (which are centred on the hips) undergo the successive sequence of Euler rotations. The shift in hip centres is also asymmetrical between the left and right leg (notably in X and Y), which may influence the asymmetrical differences seen in the angles. The knee joint centres are also positioned more anteriorly, medially and superiorly in this work compared to those calculated in Visual3D. They also have an asymmetrical difference in X. A position shift in the knee joint centres will cause a rotation in the thigh local coordinate frames, which again will be subject to error propagation when the frames undergo Euler rotations.

Visual3D then uses the least squares segment optimisation method by Spoor and Veldpaus which minimises the effects of motion artefact and joint dislocation. Figure 62 shows that there is up to 28 mm of artefact in the data, which could be attributable to motion artefact or dislocation. The extent of the influence is difficult to evaluate quantitatively without replicating and interrogating the optimisation calculations. Lu and O’Connor (1999)did this by comparing three calculation methods: a Direct Method (DM, as used here), a segmental Optimisation Method (SOM, as used by Visual3D) and their own Global Optimisation Method (GOM), against a set of 20 simulated walking trials. The simulated data included a soft-tissue noise model of Cheze et al. (1995). From their results of the hip joint (shown in Figure 63) a marked difference can be seen in the coronal plane between the DM and the other three methods throughout the gait cycle, but most notably in terminal
swing. These differences are similar or greater in magnitude to those seen in Figure 60 and Figure 61. This was reportedly due to a 38 mm dislocation at the hip joint.

![Figure 63](image) Results of a typical trial. Joint angles in degrees at the hip (a-c) were each calculated using the tested methods (True values: thick solid lines; DM: dotted lines; SOM: dashed lines; GOM: thin solid lines). Horizontal axes are data frame numbers. Taken from (Lu and O'Connor 1999).

The authors of Visual3D note that is it impossible to determine how close the methods are and which is correct, because they will vary tremendously due to difference in the quality of the data, the type of movement, the amount and type of soft-tissue movement and the validity of the constraints assumed at the joints (C-Motion 2012).

There were a large range of modelling options and many differences in the published calculation methods. The methods used by Visual3D were not known until the late stages of this work. It was decided that the calculation method used here would be sufficient for the purposes of this work if the normal reference database used to produce the feedback signal was produced using the same calculation method.
6.4.2 Validation of event detection algorithm

The aim of validation was to quantify the accuracy and repeatability of the gait event detection algorithms described in Section 6.3.5.

Data were captured from a healthy individual with a sacrum and heel markers, walking normally through the capture volume wearing everyday shoes. 5 seconds of kinematic data were captured at 120 Hz using the ProReflex motion capture system. Ground reaction force (GRF) data were also captured at 500 Hz using two AMTI force plates, measuring 400 x 600 mm (Advanced Mechanical Technology Inc, USA), with a threshold of 10 N.

Kinematic data were processed using the LabVIEW programme. Trajectories were gap filled (to a maximum of 40 frames) and filtered using a 2\(^{nd}\) order low pass Butterworth filter with a 10 Hz cut-off frequency. Events were detected using the LabVIEW kinematic algorithm. GRF data were filtered at 25 Hz and events were manually identified from the force data within Qualysis Track Manager (QTM).

Eight traverses were made through the capture volume, with approximately 5 strides per traverse. 90 events were detected in total by the LabVIEW algorithm (47 initial contact and 43 toe off events), of which 27 occurred over the force plates (13 initial contact and 14 toe off events). The event frame numbers were recorded and the differences between the algorithm and force plates were calculated, as shown in Table 19. All numerical data are included in Appendix H.

<table>
<thead>
<tr>
<th></th>
<th>Initial contact</th>
<th>Toe off</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean difference (frames)</td>
<td>Mean difference (ms)</td>
<td>Standard Deviation</td>
<td>Mean difference (frames)</td>
<td>Mean difference (ms)</td>
<td>Standard Deviation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>-0.14</td>
<td>-1.2</td>
<td>1.1</td>
<td>4.6</td>
<td>38.1</td>
<td>0.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>0.83</td>
<td>6.9</td>
<td>0.8</td>
<td>6.0</td>
<td>50.0</td>
<td>0.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td>0.31</td>
<td>2.6</td>
<td>1.0</td>
<td>5.3</td>
<td>44.1</td>
<td>0.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The agreement between the two methods is clearly shown in Figure 64.

![Figure 64 Linear regression plots of the differences between gait events determined by force plates and algorithm, an identity line is shown in red.](image)

Amore comprehensive study of event detection methods was carried out by Ghoussayni et al. (2004). They compared heel contact, heel rise, toe contact and toe off events from data collected from 12 subjects walking barefoot and shod. Three detection methods were compared: Visual inspection, force plates and a velocity-based algorithm. They found no statistically significant differences between the visual and algorithm methods. The floor contact events were within 1.5 frames of each other. The heel rise events (visual and algorithm) were within 0 to 4 frames of the force plates, and the toe off events (visual and algorithm) were between 6 and 7 frames different for shod and 9 to 10 frames for barefoot walking compared to force plates.

The results of this work are comparable to Ghoussayni and show slightly lower latencies in detection. Whilst validation did not take into account pathological subjects, the event detection algorithms used were within 1 frame for IC (and 6 frames for TO) and considered acceptable.
6.4.3 System timing, latency and recovery

As discussed in Section 6.3.1, the system is required to operate with a total system latency of less than 150 ms. This section describes the testing that was carried out to quantify latency. Figure 65 shows the major information processing components in the feedback system. Total system latency ($t_{total}$) refers to the total time taken from a physical movement to the reception of an electrical stimulus. The principal aim of testing was to experimentally determine $t_{total}$. Two components were also investigated, both of which were thought to be the more time-consuming elements of the system. Inclusion of the network (time $t_B$) and inclusion of the computations required to output joint angles (time $t_D$). Individual component latencies are discussed later.

![Figure 65 Information flow though Biofeedback Software](image)

The system latency was measured with the calculations included (calc) and without the calculations (nocalc), under two conditions: with inclusion of the hardware network (net) and with all software operating on a standalone PC (nonet). The time $t_{total}$ is the latency with conditions calc and net, and $t_D$ is the time difference between calc and nocalc.
Method - The hardware setup shown in Figure 66 was used. The mechanical rig (previously described in Section 6.4.1) was positioned in the capture volume and reflective markers were placed to define the pelvis and thigh segments. Adjustments were made to the leg to prevent coronal and transverse plane movements. A micro switch was held in a clamp and placed in line with the leg, such that a flat surface on the distal end of the thigh could be brought into contact with the switch. The clamp was held rigidly by a tripod, which was weighted to minimise movement. The switch was connected to a 9 V PP3 battery and the voltage across the switch was measured using a digital oscilloscope (ADC-220 Piscoscope from Pico Technology Ltd, UK). This arrangement and switch signal represented the physical movement within the workspace.

![Figure 66 Experimental setup for testing system latency](image)

To measure the output to the patient, a test pin on the stimulator circuit was set to toggle a logical output when the stimulator changed between the STOPPED and STIMULATING states. This signal was measured using the same oscilloscope. Latency was assessed as the time difference between the micro switch and the stimulator signals.

Protocol - During the calc condition the stimulator was set to become active when the leg reached a predefined hip extension angle. This condition incorporated all of the
computations that were required for normal system operation (interpolation, filtering and modelling). During the nocalc condition, the stimulator was set to become active when the leg reached a preset x coordinate value for the knee marker. This was unprocessed coordinate data and all other algorithms within the code were disabled. For the net condition, the system operated across two networked PCs as described in Section 6.2 and during the nonet condition QTM and LabVIEW both operated on a single PC. LabVIEW then read the marker coordinate data directly from the localhost.

To define the target angle and knee coordinate values the leg was repeatedly moved to make contact with the switch, whilst the movement was captured and the hip extension angle and knee marker x coordinate were plotted on the PC screen. Alongside which the switch oscilloscope trace was shown. The switch and clamp were iteratively positioned such that the switch closed at the nearest whole number integer (33 degrees of hip extension and 270 mm for the knee marker in the x direction). To minimise error the switch was positioned inside the clamp such that leg made contact with the clamp at the same time as switching. With the leg positioned at the point of switch contact, the target values varied in the order of ± 0.2 degrees and ± 0.1 mm. The target values were then used to active the stimulator, and the leg was moved against the switch for each condition for 12 trials.

**Results** - The total latency ranged from 38 ms to 135 ms (with a mean of 80 ms) this is shown as the dashed blue line in Figure 67 and is within the requirements for the software.

![Figure 67 Latency within the biofeedback system](image)
The latency increased with inclusion of the network and with inclusion of the computations, as expected. The mean difference between the net and nonet conditions (the time attributed to inclusion of the network $t_B$) was 27 ms when performing calculations and reduced to 6 ms without performing calculations. The mean time difference between the calc and noncalc conditions (the calculation time $t_D$) was 48 ms when the system operated across the network and 21 ms without the network.

**Discussion** – The calculations performed more quickly when the software operated on a standalone computer, which would suggest it would be beneficial to eliminate the network connection. However during testing it was noted that the consumer queues quickly built up on the standalone PC when the software was left to run capturing data for a longer period. This did not affect the short test but would affect a longer clinical data capture session. To examine this further the software was run on 3 different standalone computers and the CPU usage was monitored as increasing functions in the software were enabled. Table 20 shows that the software demands a high level of CPU usage. When the load reached 100% data were placed on the queues.

<table>
<thead>
<tr>
<th></th>
<th>Laptop</th>
<th>Desktop 1</th>
<th>Desktop 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resting</strong></td>
<td>52 – 54</td>
<td>54 – 65</td>
<td>9 – 10</td>
</tr>
<tr>
<td><strong>VI running</strong></td>
<td>72 spike, 54</td>
<td>66</td>
<td>9 – 10</td>
</tr>
<tr>
<td><strong>Collecting data</strong></td>
<td>75 – 79</td>
<td>88 - 100</td>
<td>14 – 17</td>
</tr>
<tr>
<td><strong>Filtering</strong></td>
<td>87 – 89</td>
<td>78 – 100*</td>
<td>16 - 17</td>
</tr>
<tr>
<td><strong>Calculating angles</strong></td>
<td>73 – 93</td>
<td>78 – 100*</td>
<td>16 – 19</td>
</tr>
<tr>
<td><strong>Normalising</strong></td>
<td>98 – 100</td>
<td>78 – 100*</td>
<td>19</td>
</tr>
<tr>
<td><strong>Calculating FB</strong></td>
<td>100</td>
<td>78 – 100*</td>
<td>22</td>
</tr>
</tbody>
</table>

* QTM running, LabVIEW open but VI not running. * Fluctuating between 78 – 100 irrespective of action

This quick test was repeated over the networked PCs and the CPU usage remained within approximately 40% throughout operation. It was therefore necessary to split the processing tasks over two networked computers. It was not possible to assess the speed of packet reception by LabVIEW ($t_C$) across the network. However an open source network analyser (Wireshark) was used to interrogate the network transmission, no errors were found. The
LabVIEW code was also tested by National Instruments UK Ltd and examined by Qualysis and no faults were identified in the data capture or software.

Looking at the other components in the system, there are no reported data on the latency of the Qualysis ProReflex camera system \((t_A)\). However as a guide, a test carried out by Wolf (2009) found a 6 to 7 ms systemic latency in the newer Qualysis Qqus camera system. The latency in writing the data stream to disk drive \((t_E)\) was not assessed, nor was the serial data transmission or microcontroller operation. These were assumed to be in the order of microseconds.

A number of errors were present in the latency test, for example, a difference existed between the position of the physical movement measured using the motion capture system, and the position limit defined by the action of the micro switch. This was minimised by ensuring the clamp acted to stop the leg in a definite position when the switch closed. However this could be improved by using the metal clamp and leg as switch contacts in place of the micro switch. The operating system processes in each case were not controlled. A number of background tasks were disabled, but it was possible that fluctuating system level tasks changed the latency measurements.

The sum of the component latencies did however approximate the mean latency, which was within the requirement for the software.

### 6.5 Closed-Loop System Testing

Finally testing was carried out with two healthy individuals to ensure the system components worked effectively together.

**Static check**

Four static angle limits were coded into the software such that stimulation was applied according to the corresponding movement. For example the anterior-most electrode became active when the subject flexed the thigh beyond an operator set hip flexion angle. Hip adduction, abduction and extension limits were also coded. Two subjects wearing
Chapter 6: Design and Development of a Biofeedback Training System

Reflective markers were asked to stand in the capture volume and move their thigh through the four individual limits, then in an arc pattern to trigger the appropriate electrodes.

The static trial enabled a number of visual checks – the reliability of the AIM model (described in Section 6.3.3) was demonstrated. Markers were correctly identified by QTM and coordinate data were transmitted and correctly labelled within LabVIEW. The robustness of the gap filling was found to be adequate for the movements made. The calculation and orientation of the joint angles was correct, as was the selection and real-time application of stimulation. The stimulator controls were also tested (including use of the emergency stop buttons).

**Walking check**

The subjects were then asked to walk normally at a range of speeds. In addition to repeating the visual checks previously described, the reliability of the real-time event detection was observed. Finally one subject was asked to mimic a range of pathological gait patterns and stimulation was applied as it would be during normal system operation.

A number of issues were identified. The previous latency testing assumed that streaming data to disk would not introduce a delay. This was not the case. It was found that the consumer queues built up when data was being displayed to the user and streamed to disk. To prevent this high CPU usage, a minimal dataset was saved to minimise disk writing, and a low (20 Hz) graphical user interface refresh was coded. The minimal dataset included the marker coordinates (so that all calculations could be reproduced at a later stage if required), the joint angles, and the feedback magnitude and error vector (from which the selected electrodes could be calculated).

It is important to note the quantity of data flowing around the software - 32 kBytes of coordinate data were captured per second when 11 reflective markers were tracked at 120 Hz. This was found to be an issue not only when streaming to file, but when normalised joint angle graphs were refreshed (because all data were redrawn at successive initial contact events), and during memory allocation. In future the graphical update could be more selective, and array initialisation should take into account the expected data capture
time period to prevent large quantities of data being re-allocated by the operating system during the recording session.

To improve memory management National Instruments Ltd recommended using larger cluster sizes when originally formatting the hard drive, in addition to using write caching and ensuring that Windows operating system functions such as system restore and the recycle bin are disabled.

As described in Section 6.3.8, stimulation is applied when patient hip joint angles exceed user set limits in the coronal and sagittal planes. Standard deviations were applied to each plane, and the influence of deviations in each plane was weighted. In practice however the combined effect (the error vector magnitude) did not produce a smooth coupling of the two planes of stimulation. In other words if the subject moves the limb in a bi-planar arc at the trigger thresholds for both planes, the stimulation boundary was expected to follow a continuous arc that can be deformed using the weightings. However this did not take into account the relative difference of the gait deviations in each plane, as such deformation of the stimulation boundary was not proportionally adjustable. The effect was suitable for minor deviations, but the rules governing the stimulation boundary will require further work.

Finally the system was found to be heavily dependent on correct event detection. It was found that during some strides a marker drop out occurred that caused the miscalculation of gait events. This subsequently caused incorrect normalisation and calculation of feedback. In this case the errors were due to poor capture of a heel marker. A real-time validation check of the calculated events was not written into software, given the complexity of the tasks (particularly for pathological gaits). But the numerical range of the marker coordinate and joint angle data were checked to prevent unplanned stimulation in the event of a marker drop-out.
Chapter 7

Study II – Evaluation of the Closed-Loop Training System with Amputees
7.1 Introduction

A biofeedback training system was developed as part of this research. This Chapter describes an exploratory study that was carried out to satisfy the final aim stated in Chapter 1, of investigating use of the training system with trans-femoral amputees. Three aspects were considered:

1. Electro-tactile threshold levels and discrimination in amputees
2. Practicality and user acceptance of the biofeedback system
3. Therapeutic effects of the biofeedback system

The training system was designed to address circumduction in unilateral trans-femoral amputees. As such, an essential inclusion criterion was the need for study participants who displayed a circumduction pattern. In practice that criterion was not adequately assessed by the collaborating hospital when study participants were identified. This issue became apparent during data collection with the first participant. As such a brief gait assessment was added to the start of subsequent sessions, to determine if it was appropriate to assess the therapeutic effect of the training system with those individuals. None of the participants presented with a circumduction issue at the time of the study. So it was not possible to assess the therapeutic effect as planned.

This Chapter presents the exploratory study, detailing investigation of sensation levels, and the practicalities and amputee perspectives of the training system. The method outlined to examine the therapeutic effects is included for reference and referred to in Chapter 8.
7.2 Aims and Objectives

The study had the following aims:

1. To examine the electro-tactile sensory threshold levels of unilateral trans-femoral amputees. To specifically determine:
   
   1a. If the range of sensation between perception and discomfort that was seen in non-amputees exists in amputees.
   
   1b. If the ability to discriminate stimuli locations, speeds or directions that was seen in non-amputees exists in amputees.
   
   1c. If the sensation threshold levels diminish when muscle activity reduces.

2. To determine if the biofeedback training system is a practical and acceptable method of providing gait re-training for trans-femoral amputees.

3. To examine the therapeutic effects electro-tactile biofeedback has on gait.
7.3 Method

7.3.1 Study rationale and outcomes

The three study components are summarised in Table 21 with the associated outcomes that were used. Each are described in further detail below.

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Aspect</th>
<th>Outcome measures (and tools)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Electro-tactile sensation</td>
<td>Perception and discomfort threshold levels</td>
<td>Peak current (measured in mA)</td>
</tr>
<tr>
<td></td>
<td>Discrimination of stimulus location, speeds and direction</td>
<td>Pass / Fail (cue cards, questioned)</td>
</tr>
<tr>
<td></td>
<td>Change in sensation from walking to standing</td>
<td>Participant perspectives (questioned)</td>
</tr>
<tr>
<td>2. System viability</td>
<td>Practicality</td>
<td>Qualitative analysis (observation, participant questionnaires and discussion)</td>
</tr>
<tr>
<td></td>
<td>User acceptance</td>
<td></td>
</tr>
<tr>
<td>3. Therapeutic effects</td>
<td>Gait changes</td>
<td>Gait analysis (observation and kinematics)</td>
</tr>
</tbody>
</table>

1. Electro-tactile sensation - An assumption was made in the development of the stimulator and electrodes that traumatic amputees have comparable electro-tactile sensory threshold levels to non-amputees. That assumption was challenged here and formed the first part of this study.

Tasks included in the non-amputee study involved laying supine, flexing and extending the knee, and then walking. The purpose of the different tasks was primarily to determine if the threshold levels fall when muscle activity reduces, in view of the possibility that a sensation level required for walking may cause discomfort when the subject comes to a rest. It was shown in Chapter 5 with non-amputees that threshold levels are lower when there is reduced activity, but the mean threshold levels (of perception and discomfort) do not overlap. To assess the possibility of discomfort arising from threshold levels changing with muscle activity in amputees, participant feedback was sought during the system evaluation.
The most suitable stimulation frequency was required, from those chosen and discussed in Section 4.1. This was defined as one which produced the greatest separation between perception and discomfort threshold levels, the lowest variation in thresholds across electrodes, one that produced the easiest sensation to discriminate and the most favourable sensation. The three frequencies used in the non-amputee study and used here were 40, 60 and 80 Hz.

To evaluate these sensation aspects, the methods used in the non-amputee study were adopted here. Again, the stimulus delivery sequence was manually randomised beforehand within each test, the test was repeated twice and randomly included no stimulus conditions to improve the robustness against validity threats such as type I and II error responses. Delays between stimuli served to mitigate against adaptation and learning effects. No experimenter blinding was used but precaution was made to ensure the subjects could not see the computer screen controlling stimulus delivery.

The primary outcome measures were the peak currents (in mA) for the threshold levels, a pass / fail rate for the discrimination tests and participant feedback regarding the stimulus sensation when coming to a standstill on the treadmill.

2. System Viability (practicality and user acceptance) - Practicality was examined by observation from a technical perspective. The following are important for the correct operation of the system with amputees, and were considered in this study: The donning and doffing of electrodes and markers; the socket fit, the skin-surface contact of the electrodes and the equipment robustness. Any issues with the capture, processing and use of real-time kinematic measures from the camera system and the delivery of electro-tactile stimulation were also observed.

User acceptance was examined from the amputee’s perspective. The comfort of the electrodes within the socket and any encumbrance or distraction to walking were considered; as were the evenness and comfort of the sensations, and the potential for discomfort when transitioning from walking to standing. The ability to understand feedback and associate the stimulation with the participants walking pattern were
questioned. The participant’s focus of attention was also examined to better understand how prominent different components of the experience were during the walking trials. The participant’s views of the stimulation alone and of the training system were also sought.

These practical and user acceptance issues were assessed qualitatively through observation, discussion with the participants and the use of a questionnaire repeated after each walking trial (as described in Section 7.3.3). The questionnaire was part of the experimenters recording sheet and is included in Appendix I8.

3. **Therapeutic effects** - The purpose of the training system was to reduce circumduction gait patterns. There is a possibility that modifying the extent of circumduction alone may not result in an overall improvement in gait. For example the biofeedback stimulus may elicit unrealistic and temporary movement patterns, or the circumduction may be replaced by a more detrimental compensatory mechanism. As such this study initially sought to assess changes to participant gait as a whole with the use of video and kinematic analysis.

The magnitude of the circumduction deviation was described in Section 6.3.8 as the magnitude of the vector representing the difference between the actual hip joint angles (in the sagittal and coronal planes, plotted against each other) and the desired angles determined from a local population normal data set. The primary outcome measure was therefore the change in the vector magnitude over time.

It was not possible to blind the participants because the feedback stimuli needed to be perceived and understood by the subjects. It was not practical to blind the experimenter. A one way repeated measures design was chosen, with time as the independent variable and the error vector magnitude on the prosthetic side as the dependant variable. In the absence of a control or blinding, the one way repeated measures design was chosen as the most robust design. It is however susceptible to changes to stump shape, pain, socket fit and familiarisation with the treadmill. Changing motivation through participation and selection interaction effects such as competition within the subject group may also be detrimental to this type of design. However study subjects did not interact with each other. The dependant variable could also be measured continuously throughout the walking trials.
7.3.2 Participants

**Inclusion criteria** – Unilateral trans-femoral amputees over the age of 18 were sought, who had undergone an amputation as a result of trauma. As stated in Section 5.3.2 it was assumed that unlike vascular amputees, the remaining proximal somatosensory pathways of traumatic amputees are unchanged by the pathology and surgery. Established amputees were required, i.e. those who had received prosthetic provision no less than 12 months prior to the start of the study, under the assumption that their gait pattern and any deviations are habitual and not linked to post-operative issues or an ongoing gait rehabilitation programme.

Individuals were required to have good mobility (scored as level E or above using the SIGAM tool: "walks 50 metres or more without walking aids except to improve confidence in adverse terrain or weather", or equivalent K-codes A3 and A4), to walk without the use of crutches or sticks and to have been identified displaying a circumduction / abduction gait pattern. Subjects were required to have had a review with their prosthetist within two months prior to the study, to ensure there were no outstanding issues with the prosthesis fit or stump.

**Exclusion criteria** - The exclusion criteria were as follows: those with visual, auditory or vestibular impairments that affected walking or balance. Those with injury that affected mobility, or required the use of mobility aids (other than the use of a prosthesis). Subjects who used donning socks - a method of fitting the socket which may cause the electrodes to pull away from the skin. As in the non-amputee study, commonly cited contra-indicators to the use of electrical stimulation were applied as a conservative precaution. Subjects who experienced seizures (managed or otherwise) were excluded, as were those with known cardiac arrhythmias, hyperreflexia, and implanted electrical devices. Pregnant subjects were also excluded. If subjects were unwilling to confirm pregnancy for whatever reason, they were excluded.

Subjects were sought with healthy skin and stump tissue, so those with dermatological conditions or oedema were excluded. Subjects were required to have no conditions
affecting the nervous system or sensory nerves, other than amputation (for example: stroke, multiple sclerosis, cerebral palsy, nerve entrapment or peripheral neuropathies). Finally, individuals were excluded if they were recently or concurrently involved in another research project, as this may introduce unknown confounding factors and possibly indicate over-enthusiasm to perform.

**Sample size** - A convenience sample of 8 subjects was chosen, in common with other studies in the field of gait rehabilitation. A drop-out rate of 40% was taken into account, requiring 11 volunteers. Results from this pilot study could inform a power analysis calculation for future work.

**Recruitment** - Subjects were recruited from the population of patients under the care of Mr Thomas Wickerson, Lead Prosthetist at the Douglas Bader Rehabilitation Centre, Queen Mary’s Hospital. Discussion took place between Professor David Ewins (Queen Mary’s Hospital) and Mr Wickerson to identify potential participants. Invitation letters (Appendix I4) were sent to potential participants, with copies of the information sheet, consent form and screening questionnaire. Potential participants expressed an interest to Professor Ewins, who discussed the study and answered any questions raised. Appointments were arranged by the Author, and participants received a telephone call prior to the appointment to confirm the date, time and any special travel requirements.

**Participant time commitment** – Subjects attended one session which lasted approximately 3 hours, between June and August 2012 at the Centre for Biomedical Engineering, University of Surrey. This allowed time for travel, preparations and all testing to be carried out. No follow-up sessions were required.

**Ethical consideration** - Favourable consideration of this study was given by the NHS Research Ethics Service (London-Surrey Borders Research Ethics Committee), and locally by the University of Surrey Research Ethics Committee, prior to subject recruitment (see Appendix I7).
7.3.3 Study Protocol

Prior to attendance subjects had received a participant information sheet, health screening questionnaire and a consent form, and were given a minimum of three weeks to read and discuss the information with the experimenters, as required by the NHS Research Ethics Committee.

1. **Introduction and administration (approximate time 15 minutes)**

Subjects attended individually and were welcomed to the Centre. The study and process were explained. An additional copy of the screening questionnaire was provided for completion and subjects not eligible would leave the study. If the criteria were met an opportunity was provided to re-read the information sheet away from the experimenters. If the subject understood and agreed to participate a consent form was provided for their signature. Following receipt of informed consent, subjects were asked to change into close fitting shorts (either their own, or Lycra shorts provided), for the purposes of examination and motion capture.

2. **Treadmill familiarisation and gait assessment (approximate time 20 minutes)**

Subjects were asked about their level of experience using a treadmill. Prosthetic component types being worn and any current issues with them were noted. Subject were then instructed in the operation of treadmill controls and allowed time to become familiar with walking on the treadmill. If subjects were not confident, they would leave the study. Subjects were then asked to rest for 30 seconds, followed by a 30 second walk at their self-selected comfortable walking speed. Video was captured in the sagittal and coronal planes and walking speed was noted. Subject rested in a chair, while an observational gait assessment was carried out based on the captured video. Particular note was made of pelvic-related deviations, and a decision was made on an individual basis if and how the subject may benefit from use of the biofeedback training system.
3. **Sensation Trials** *(approximate time 1 hour)*

**Preparation**

Subject height was recorded (with prosthesis and shoes), then subjects were asked to remove their prosthesis and sit on an examination table. The stump skin condition was visually checked for the presence of pain, ulcerations or other skin conditions. Comparison was made with the good leg. With the subject laying supine the good leg length was measured from the anterior-supior iliac spine (ASIS) to the medial malleolus using a tape measure (this was required for biomechanical modelling). The stump length was also measured from the greater trochanter to the distal tip of the stump (determined visually). The stump circumference was measured 2/3 distally from greater trochanter and eight electrodes were placed equidistant around the surface of the thigh using the self-adhesive pads at that height. A ‘Tubigrip’ sleeve was placed over the electrodes to protect the socket liner and hold the leads in place. Subjects were then asked to fit their prosthesis (with socket liners or socks) and ensure there was no encumbrance or discomfort from the electrode leads. Subjects were then shown the user controls of the electrical stimulator and asked to apply a low level stimulation in order to become familiar with the sensation.

**Threshold test**

The process followed was similar to that outlined in the non-amputee study (Section 5.3.3). Subjects were asked to lay supine on a plinth and remain in that posture for 1 minute to allow adaptation within the socket. Participants were then asked to respond verbally when they first perceived a sensation and again when they felt the sensation was uncomfortable. Whilst observing the subject, a stimulus was applied for approximately 2 seconds to each electrode using a pulse width of 100 µs at one of the three frequencies. The intensity was gradually increased until the first response was given. At that level the peak applied current was measured and the stimulus was removed. The ascent was then repeated and the mean of two recordings was taken. The stimulation was then removed for 5 seconds and the intensity was then increased until the subject gave the second response. The current amplitude was recorded and the stimulus removed, again this was repeated and the mean taken. The process was repeated for all eight electrodes using a pre-randomised sequence of electrode locations, and repeated for each frequency in the same random order (60, 40 then 80 Hz).
Discrimination tests (location, direction and speed)
Each channel was set at the midpoint between the thresholds of perception and discomfort previously determined. Subjects were asked to remain supine and were given a cue card. After a brief demonstration of the cue card numbering, participants were asked to indicate where the stimulation was felt by responding with the electrode number. Stimuli were applied to each electrode location in a pre-determined random sequence for 2 seconds, pausing for 1 second between each stimulus application. The response was recorded as correct or incorrect. This was repeated twice using different random sequences and repeated for each frequency value, in the order 40 Hz, 80 Hz then 60 Hz. Stimulation was then applied at the mid-point intensity level and moved around each electrode in order, at three different speeds: “slow”, “medium” and “fast” (as defined in Section 5.3.3) in a clockwise and counter-clockwise direction. After a demonstration of the speeds and directions, subjects were asked to indicate the speed and direction of rotation. A random sequence of 12 speeds and directions was used. Responses were recorded as correct or incorrect. The process was repeated twice for each frequency. Subjects were then permitted to rest in a chair if required.

4. Treadmill walking trials (approximate time 1 hour)

Preparation
Reflective surface markers were placed on the sacrum, left and right ASIS, lateral femoral epicondyles, lateral malleoli, heels and toes (mid 2nd and 3rd metatarsal heads). The prosthetic knee joint centre could be visually determined with manipulation of the joint, and markers placed accordingly. The cosmetic feet had palpable landmarks for marker placement. However consideration was also given to marker placement symmetry with the good leg. Markers on wands were placed on the left and right thighs and shanks, making contact on the socket and the body of the knee housing on the prosthetic side. Sagittal and coronal photographs were taken for record if consent was given. Subjects were then asked to adjust stimulation levels whilst standing, to gain an even intensity sensation around the circumference of the thigh (these are presented in Section 7.5.1).
Walking trials

The pattern of the walking trials is shown in Figure 68. During the baseline walk subjects were asked to walk at their self-selected comfortable walking speed for 1 minute. Kinematics and video in the sagittal and coronal planes were captured throughout the trials. A 5 minute training phase then followed where subject were instructed how to respond to the feedback stimulus. They were given the opportunity to walk with feedback and request stimulation at particular electrodes in order to understand what was required. Subjects were also able to request changes to the intensity level (as reported in Section 7.5.1).

<table>
<thead>
<tr>
<th>Pre-test questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 minute baseline walk no stimulation</td>
</tr>
<tr>
<td>5 minute walk with biofeedback – training phase</td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
</tr>
<tr>
<td>1 minute walk with biofeedback</td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
</tr>
<tr>
<td>1 minute walk with biofeedback</td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
</tr>
<tr>
<td>1 minute walk with biofeedback</td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
</tr>
<tr>
<td>1 minute walk, post-test no stimulation</td>
</tr>
<tr>
<td>Post-test questionnaire</td>
</tr>
</tbody>
</table>

Figure 68 Pattern of walking trials, training phase (light green), walking with biofeedback (light red) and questionnaire data collection periods (light blue)

During the feedback trials subjects were asked to walk in a manner that avoided any sensations felt. No response was required when no sensation was felt. For example: if a sensation was felt on the anterior aspect of the thigh, subjects were expected to reduce their hip flexion. If a sensation was felt on the posterior aspect subjects were expected to reduce hip extension. Likewise with abduction and adduction movements and combinations of both planes as discussed in Section 6.3.8. The feedback delivery varied for each subject according to the 30 second familiarisation gait assessment. Decision making was made on an individual basis, so details of the feedback used and the number of walking trials undertaken are presented on a subject by subject basis in Section 7.6.

After each walking trial and at various stages of the session participants were asked a series of questions. The questions (shown in Figure 69) included a mix of positively and negatively phrased questions, which explored the comfort of the system, the electro-tactile
sensation and the association with the participant’s movement, the participant’s focus of attention, and finally the usability of the training system. Each question was scored using a five item Likert scale from strongly disagree, disagree, neutral, agree and strongly agree.

<table>
<thead>
<tr>
<th>Pre-test questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comfort</strong></td>
</tr>
<tr>
<td>The electrode wires are comfortable</td>
</tr>
<tr>
<td>The prosthesis is comfortable</td>
</tr>
<tr>
<td>The prosthesis and liner are fitting well</td>
</tr>
<tr>
<td>The electrodes are comfortable</td>
</tr>
<tr>
<td>The kit feels cumbersome</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mid-test questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensation</strong></td>
</tr>
<tr>
<td>The sensation felt even around my thigh</td>
</tr>
<tr>
<td>There were moments when the sensation was unpleasant</td>
</tr>
<tr>
<td>There were unexpected sensations under the electrodes</td>
</tr>
<tr>
<td>There were unexpected sensations from other parts of my body</td>
</tr>
<tr>
<td><strong>Association with movement</strong></td>
</tr>
<tr>
<td>It was easy to associate the sensation with my movement</td>
</tr>
<tr>
<td>It was easy to correct my movement to avoid the stimulus</td>
</tr>
<tr>
<td>I found the experience frustrating</td>
</tr>
<tr>
<td><strong>Focus of attention</strong></td>
</tr>
<tr>
<td>Walking</td>
</tr>
<tr>
<td>The stimulus</td>
</tr>
<tr>
<td>My balance</td>
</tr>
<tr>
<td>The prosthesis</td>
</tr>
<tr>
<td>The equipment (leads and markers)</td>
</tr>
<tr>
<td>Pain and discomfort</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-test questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usability</strong></td>
</tr>
<tr>
<td>The electrodes remained in place for the duration of testing</td>
</tr>
<tr>
<td>I would have been happy to wear the system during my rehabilitation</td>
</tr>
<tr>
<td>I would be happy to wear the system on a longer term basis</td>
</tr>
</tbody>
</table>

Figure 69 User acceptance questions

Pre-test questions were asked once after the subject preparation and sensation threshold testing had been carried out. The mid-test questions were asked after each walking trial, in addition to the set of pre-test questions. The post-test questions were asked after the final walking trial. On completion of the trials the markers and electrodes were removed and the skin checked under the electrode surfaces for any irritation. An opportunity was provided to discuss the study with the experimenters and see any images and data. Subjects could then leave the study.
Chapter 7: Study II – Evaluation of the Closed-Loop Training System with Amputees

7.4 Results - Participants

20 potential test subjects were identified and contacted. 6 people expressed an interest in participating, of which 5 were available and attended the study session. 2 subjects used a donning sock to fit the prosthesis, contrary to the exclusion criteria. These pulled the electrodes away from the skin. Suction was not maintained in one case, and after repeated attempts it was not possible to adequately secure the limb with the electrodes in place. He therefore withdrew from the study. 4 subjects completed and are included in the final analysis, giving a 20% recruitment rate. None of the subjects walked with a circumduction gait pattern, contrary to the inclusion criteria. The individual anthropometrics and group descriptive statistics are shown in Table 22. All items are presented for discussion in Section 7.7. Items 7 to 11 were collected for modelling and electrode placement. Non-amputee subject anthropometrics are included for reference.

Table 22 Individual subject anthropometrics and group statistics

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject S1</th>
<th>Subject S2</th>
<th>Subject S3</th>
<th>Subject S4</th>
<th>Amputee group mean values</th>
<th>Non-amputee group mean values⁶</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<tr>
<td>3</td>
<td>Height (m)</td>
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<td>1.87</td>
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<td>Weight (kg)</td>
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<td>85</td>
<td>87</td>
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<td>5</td>
<td>BMI (kg/m²)</td>
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<tr>
<td>6</td>
<td>Thigh circumference (mm)¹</td>
<td>460</td>
<td>390</td>
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<tr>
<td>7</td>
<td>Non-prosthetic knee width² (mm)</td>
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<td>8</td>
<td>Non-prosthetic leg length³ (mm)</td>
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<td>951</td>
<td>880</td>
<td>920</td>
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<td>Prosthetic leg length⁴ (mm)</td>
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<td>878</td>
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<td>Leg length discrepancy (mm)</td>
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<td>11</td>
<td>Stump length⁵ (mm)</td>
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<td>540</td>
<td>390</td>
<td>400</td>
<td>428</td>
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</tr>
</tbody>
</table>

¹At 2/3 the distance from the ipsilateral ASIS
²Distal to the medial and lateral epicondyles
³From ipsilateral ASIS to medial malleolus
⁴From ipsilateral ASIS to approximated ankle joint centre
⁵From ipsilateral ASIS to the distal-most end point
⁶Only male subjects are included (n=6)
7.5 Results I - Amputee Sensation Thresholds

7.5.1 Overall patterns

The following plots (Figure 70) show the group mean responses for the perception and discomfort thresholds for the amputees and non-amputees in the supine task. Data are presented for each electrode location and the three stimulation frequencies used. Individual subject data are included in Appendix J1.

Figure 70 Perception (bottom) and discomfort thresholds (top) for each electrode and frequency (with 40 Hz shown in red, 60 Hz in blue and 80 Hz in green) for the supine task with (n=4) amputees (left) and (n=13) non-amputees (right)
The absolute difference between the amputee and non-amputee threshold levels are shown below (Figure 71) by electrode and for each frequency. Data are averaged across subjects.

![Figure 71](image-url)

Figure 71 Absolute difference between amputee and non-amputee threshold levels, positive values indicate non-amputee threshold > amputee threshold

The participant-selected stimulation levels are shown in Figure 72. Data shown include the mean perception and discomfort levels found with the amputee participants adopting a supine posture, the mid-point levels used for presentation of biofeedback selected prior to treadmill walking, and the adjusted levels after five minutes of training. The absolute difference in self-selected feedback level is shown in Figure 73.

![Figure 72](image-url)

Figure 72 Mean stimulation levels for perception (blue) and discomfort (red) during supine posture, and chosen biofeedback level before (green) and after (purple) five minutes of training

![Figure 73](image-url)

Figure 73 Absolute change in mid-point stimulation level for each subject after five minutes of familiarisation training
7.5.2 Separation between threshold levels and data variation (amputee and non-amputee groups)

The bands between the perception and discomfort levels during the supine tasks for the amputee group are shown below alongside the non-amputee group data (Figure 41). The group maximum, minimum and mean values are given, indicating the extent of overlap between bands in some cases.

Figure 74 Group mean, minimum and maximum perception (blue) and discomfort (red) threshold levels
7.5.3 Amputee ability to discriminate stimuli, location, direction and speed

The stimulus locations were correctly identified 100%, 98% and 100% of the time for 40, 60 and 80 Hz respectively (expressed as group mean percentages). The non-100% score was attributed to one incorrect answer from one participant. The stimuli direction and speed were identified 100% of the time in all cases.

7.5.4 Amputee experience of electro-tactile sensations

Two participants commented on the sensations experienced during the study. When prompted the remaining two said they were indifferent about the sensations. One subject described the sensation as producing a “nice deep massaging sensation”, although no muscle twitches were felt, giving “a positive feeling of the stump for the first time in many years”. He requested a stand-alone stimulator for exercise use. A second subject commented that the sensations “tickled” and “felt funny”.
7.6 Results II - Use of Biofeedback System

7.6.1 Data quantity, analysis and presentation

A large quantity of data was collected during the treadmill walking trials, which required consideration in terms of post-processing, presentation for interpretation and presentation within this thesis. The limitations of this are discussed in Chapter 8 but it is important to note the following points before the results are presented.

Subjects walking in a gait laboratory typically produce approximately 6 strides per walk. However, in this study data were collected throughout 1 minute walks, with the intention of capturing a change in error vector over time. 998 strides were collected in total. 12 parameters were of interest (the left and right pelvic and hip angles in three planes), resulting in approximately 12000 series of data being saved. Post-processing required normalising these data to the gait cycle, the calculation of means and standard deviation bands and the production of graphs. 4 subjects undertook a total of 22 walking trials, which would require 264 graphs in order to present the left and right pelvic and hip angles in three planes. Practically, the data quantity exceeded the number of permissible columns in Microsoft Excel, and a number of limitations were found within the report generation toolkit in LabVIEW that prevented programmatic output of graphs into a suitable format. To tackle these issues a separate program was written using LabVIEW to carry out the following post-processing: data were read from the TDMS files, normalised to the gait cycle and groups of strides were displayed onscreen for each walking trial. Artefacts were then manually removed and the mean and standard deviation bands were calculated. The data were then saved and written to Microsoft Excel. A series of macros were then used within Excel to help with the production of graphs.

This process was not an issue when viewing data in real-time or during the capture sessions, but it became problematic during manual data interpretation. Given the large number of graphs that could be presented displaying different trial conditions, a number of set graphical formats were chosen from the outset. For example, Figure 75 is one format chosen which shows all of the walking trials undertaken by subject 4, including the 1
minute baseline trial without biofeedback (blue), two walking trials with biofeedback (BFB1 and BFB2, purple and red respectively), the 1 minute post-test walk without biofeedback (orange) and the normal reference data (green). The thick line indicates the mean, and 2 standard deviations from the mean are shown by the error bands.

![Figure 75 Left hip joint angles normalised to the gait cycle for Subject 4, including the baseline condition (blue), BFB1 condition (purple), BFB 2 condition (red), post BFB (orange) and normative reference (green). The thick line indicates the mean and ±2SDs are shown by error bands](image)

Other formats chosen show specific groups of trials, to improve clarity. All the data are included in Appendix J2 and only subsets are included in this section.

The interpretations provided in the following Results section include descriptive assessment of the data, including brief comments on possible causes and effects. This is to aid presentation of the data. Broader comments and observations regarding individual results and across the group are included in the Discussion section. Photographs are included where consent was given.
7.6.2 Subject 1

Subject 1 (S1) is a 56 year old male, who underwent a right trans-femoral amputation as a result of cancer at an early age. He used a suction socket with a sock, a sensor hydraulic knee (Ortho Europe), a TT Pro shock absorbing ankle (Blatchford Ltd, UK) and a carbon flex foot. He reported no problems with the prescription. On inspection there was good skin condition, with no scarring, pain or ulcerations. Electrodes were placed equidistance around his right thigh with a spacing of 58 mm, at 253 mm from his right ASIS. S1 requested that the treadmill be inclined (2 degrees) because on the level he had a feeling of walking downhill.

During the treadmill familiarisation period prior to the trials S1 selected a walking speed of 0.50 ms\(^{-1}\). The following trials were then carried out (Table 23) with questionnaires completed after each walk. Video was recorded throughout in the sagittal and coronal planes.

### Table 23 Walking trials for Subject 1

<table>
<thead>
<tr>
<th>Walk</th>
<th>Condition</th>
<th>Strides</th>
<th>Data capture period* seconds (&amp; frames)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 minute baseline walk (no BFB)</td>
<td>90</td>
<td>123 (14713)</td>
</tr>
<tr>
<td>3</td>
<td>5 minute walk with stimulation – training phase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1 minute walk with biofeedback (BFB1)</td>
<td>95</td>
<td>135 (16319)</td>
</tr>
<tr>
<td>6</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>2 minute walk with biofeedback (BFB2)</td>
<td>46</td>
<td>60 (7227)</td>
</tr>
<tr>
<td>8</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>1 minute walk with biofeedback (BFB3)</td>
<td>73</td>
<td>97 (11624)</td>
</tr>
<tr>
<td>10</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>1 minute walk with biofeedback (BFB4)</td>
<td>58</td>
<td>79 (9463)</td>
</tr>
<tr>
<td>12</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>1 minute walk, post-test no stimulation (no BFB)</td>
<td>46</td>
<td>62 (7430)</td>
</tr>
<tr>
<td>14</td>
<td>Post-test questionnaire</td>
<td></td>
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</tr>
</tbody>
</table>

*The data capture period indicates the total time during which data was collected. Times were greater than planned with the first subject because this was the first exploratory session.

S1’s confidence with walking on the treadmill increased from 7 out of 10 (where 10 is the most confident) during the baseline recording, to 9 out of 10 for the rest of the session.
Chapter 7: Study II – Evaluation of the Closed-Loop Training System with Amputees

**Baseline kinematics**

The following results show the kinematics for the pre-biofeedback condition against the normative reference for the pelvis and both hips. The contralateral pelvis is not shown here and in subsequent subjects because it is symmetrical, however the data are included in Appendix J2.

Figure 76 Pelvic and hip joint angles for Subject 1 for the baseline condition (blue) and the normal reference database (green). Data are normalised to the gait cycle and are indicated by mean values (thick line) and ±2SD error bands.
Interpretation of baseline kinematics

S1’s pelvis was anteriorly tilted throughout the gait cycle on the right side in relation to the normal reference, and showing a relative increase in posterior tilt during swing. This corresponds with a noticeable right superior obliquity in swing (right side up). There was a greater range of motion in the sagittal and coronal planes compared to the normal reference, notably so in the coronal plane.

Hip motion was within the normal range from late swing into initial contact, but reduced in both hips throughout the rest of the gait cycle, more so on the left side. The data suggest the right side of the hip was adducted during swing and the left abducted during stance. There was an external rotation on the right during mid-stance, and throughout swing on the left side.

The difference in anterior pelvic tilt from the normal may result from poor placement of the sacrum marker. The right pelvic positive tilt and obliquity during swing indicate a prominent hip hiking motion to clear the prosthesis through swing. Hip hiking would account for the appearance of adduction on the right and abducted on the left hip in relation to the pelvis. These features were evident during observation and were supported by video.

Despite reporting a confidence of 7 out of 10 walking on a treadmill, S1 walked at 0.5 ms⁻¹, which is half the self-selected comfortable speed previously reported for above-knee amputees (Perry 1992). He also had a forward trunk lean, which with the anterior tilt, would result in the apparent hip flexion seen in the kinematic data. The transverse plane calculations were not validated during system development and typically have greater variation compared to the sagittal and coronal planes, so these are interpreted with caution. Rotation on the prosthetic side may result from poor marker alignment, or relative movement of the socket around the stump. Biomechanical causes of the rotation patterns in this case were not clear.
Feedback delivered

Following the observational assessment, feedback was initially set to focus on the correction of the hip adduction seen during swing (Figure 76). Figure 77 shows a screenshot of real-time data during walk 1, indicating S1’s gait deviation in the sagittal and coronal planes, and their combination that forms a bimodal pattern in the error vector. The feedback delivery window was set to bound the swing phase peak, and the threshold was arbitrarily set to encompass as much of the peak as possible without artefacts, after observing a number of strides. The feedback delivery thresholds for all of the walking trials are shown in Table 24. In this case stimulation became active between 46% and 96% of the gait cycle, when the error vector exceeded 6.5 degrees. Only deviations in the coronal plane contributed to the error vector and feedback delivery.

![Figure 77 Feedback delivery during walk 1. S1’s hip flexion/extension (white) is shown (top left) against the normal reference (red), and the adduction/abduction is shown (top right). The error vector is shown below, windowed in yellow.](image)

<table>
<thead>
<tr>
<th>Walk</th>
<th>Contribution from each plane</th>
<th>Lower %</th>
<th>Upper %</th>
<th>Band %</th>
<th>Threshold (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>100% coronal</td>
<td>47.2</td>
<td>97.2</td>
<td>50</td>
<td>6.5</td>
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<tr>
<td>3</td>
<td>100% coronal</td>
<td>47.2</td>
<td>97.2</td>
<td>50</td>
<td>6.5</td>
</tr>
<tr>
<td>4</td>
<td>100% sagittal</td>
<td>38.7</td>
<td>98.7</td>
<td>60</td>
<td>15.3</td>
</tr>
<tr>
<td>5</td>
<td>100% sagittal</td>
<td>38.7</td>
<td>98.7</td>
<td>60</td>
<td>15.3</td>
</tr>
</tbody>
</table>
Walk 3 was a repetition of Walk 2. Walks 4 and 5 attempted to modify the hip flexion deviation seen in Figure 76, by providing feedback in the sagittal plan. Mixing the contributions from each plane was not tried at this stage, because the response to biofeedback in individual planes was not known. The effect of walks 2 and 3 are therefore viewed combined and the intervention is described as “coronal BFB”. Likewise walks 4 and 5 are combined and termed “sagittal BFB”.

**Response to biofeedback in the coronal plane**

For clarity only the mean values of the last 10 strides of walk 3 (out of 141) are shown in Figure 78 and Figure 79. All data are presented in Appendix J2. Generally only slight differences were seen in response to the feedback stimuli. The pelvis became more anteriorly tilted and rotated further away from normal. Movement in the coronal plane remained the same. There was no noticeable change in hip flexion/extension. The left thigh followed a similar pattern to the baseline condition and the right became slightly more adducted following response to feedback. Both left and right thighs became more externally rotated away from normal.

![Figure 78 Pelvic angles for S1 for the baseline condition (blue), post-coronal BFB conditions (purple) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented](image-url)
Figure 79 Left and right hip joint angles for Subject 1 for the baseline condition (blue), post-coronal BFB conditions (purple) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented.
Response to biofeedback in the sagittal plane

Figure 80 shows the pelvic and hip kinematics following application of biofeedback in the sagittal plane. Again only the mean values of the last 10 strides of walk 5 are shown (out of 176 strides).

<table>
<thead>
<tr>
<th>Right pelvic tilt (+ve up)</th>
<th>Right pelvic obliquity (+ve up)</th>
<th>Right pelvic rotation (+ve ext)</th>
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<tr>
<td>Degrees</td>
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<td>Degrees</td>
</tr>
<tr>
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<td>% Gait cycle</td>
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<thead>
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<th>Left hip rotation (+ve int)</th>
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<tbody>
<tr>
<td>Degrees</td>
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<td>% Gait cycle</td>
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<table>
<thead>
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<th>Right hip (+ve adduction)</th>
<th>Right hip rotation (+ve int)</th>
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<td>Degrees</td>
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</table>

Figure 80 Pelvic and right hip joint angles for Subject 1 for the baseline condition (blue), post-sagittal BFB condition (red) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented.
Referring to Figure 80 there was greater anterior pelvic tilt during stance, with a slight reduction in range of motion. Pelvic motion in the coronal plane remained similar to the baseline and the coronal-BFB conditions. The range of rotation was closer to normal, but there was still a large difference compared to the reference data during swing.

At the hips, the right side was more flexed in stance (when feedback was not being received), whilst the left was slightly more flexed throughout the gait cycle. The right hip was more adducted throughout stance and into swing. But there was little change to the mean left hip abduction/adduction. Both thighs were more externally rotated away from normal, but remained within the variation in the data.

**Post-biofeedback kinematics**

Referring to Figure 81 the pelvis was seen to be more anteriorly tilted from early stance to mid swing, following biofeedback. However the excessive range of motion reduced. There was still a hip hike on the right side, but this reduced. The left hip range of motion in the sagittal plane was closer to the normal reference, and there was a slight delayed flexion on the right side. This may be due to the greater rotation of the pelvis (from external rotation at IC, internal into swing and returning to external rotation at IC). Following biofeedback the right hip add / abduction moved closer to the reference, but remained adducted throughout.

In both sets of biofeedback walks, limited changes were seen in response to biofeedback, with some deviation away from the normal reference kinematics. There is no clear distinction between the extent of gait deviations during the periods where feedback was delivered or when it was not. From observation S1 was leaning forwards in each of the walks, and reported that he was concentrating on this gait throughout. This may explain for the presence of hip flexion seen in the data. The compensatory hip hiking movement remained evident in all of the walks, and walking speed remained at a slower than normal 0.50 ms⁻¹.
After the final walking trial, stimulation was applied to each channel at the levels indicated in Figure 73, whilst S1 stood quietly on the treadmill. S1 reported no difference in the sensations felt compared to the walking trial, but noted the levels were “slightly softer”.

Figure 81 Pelvic and right hip joint angles for Subject 1 for the baseline condition (blue), post-biofeedback condition (orange) and the normal reference database (green)
7.6.3 Subject 2

Subject 2 (S2) is a 25 year old male, who underwent a right below-knee amputation in 1987, followed by a right through-knee amputation in 2002 as a result of a surgical accident. He walked with a p-lite lining and stump socks within a supra-condylar suspension, a KX06 knee and an Echelon foot (both from Blatchford Ltd, UK). No problems were reported with the prescription. On inspection there was good skin condition with no scaring, pain or ulcerations. Electrodes were placed at 360 mm from his right ASIS with 49 mm spacing, as shown below (Figure 82).

![Figure 82 Subject 2, showing placement of electrodes (far left) and reflective markers](image)

During the treadmill familiarisation period S2 walked at a speed of 0.74 ms\(^{-1}\) and remained at this speed throughout the session. Four walking trials were carried out (as indicated in Table 25) with questionnaires completed after each walk. Video was recorded throughout in the sagittal and coronal planes. Sagittal and coronal photographs were taken without the prosthesis (detailing electrode placement) and whilst walking.

<table>
<thead>
<tr>
<th>Walk</th>
<th>Condition</th>
<th>Strides</th>
<th>Data capture period seconds (&amp; frames)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 minute baseline walk (no BFB)</td>
<td>42</td>
<td>60 (7316)</td>
</tr>
<tr>
<td>3</td>
<td>5 minute walk with stimulation – training phase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 minute walk with biofeedback (BFB1)</td>
<td>45</td>
<td>60 (7193)</td>
</tr>
<tr>
<td>3</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 minute walk with biofeedback (BFB2)</td>
<td>66</td>
<td>86 (10384)</td>
</tr>
<tr>
<td>4</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 minute walk, post-test no stimulation (no BFB)</td>
<td>46</td>
<td>62 (7408)</td>
</tr>
<tr>
<td></td>
<td>Post-test questionnaire</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The treadmill remained level throughout, and S2 indicated a treadmill walking confidence level of 10 (out of 10) in each trial.

**Baseline kinematics**

The following results show the mean pelvic and hip joint angles of the last 10 strides of walk 1 (the baseline trial in blue) and the normal reference data set (green). Again all data are included in Appendix J2.

![Diagram of pelvic and hip joint angles](image)

**Figure 83** Pelvic and hip joint angles for Subject 2 for the baseline condition (blue) and the normal reference database (green). Data are normalised to the gait cycle and are indicated by mean values (thick line) and ±2SD error bands.
Interpretation of baseline kinematics

S2 walked with an apparent anterior pelvic tilt throughout the gait cycle. One cause of this may be poor placement of the sacrum marker. The pelvis had a superior obliquity (with the prosthesis side up) which was more evident during swing. The pelvis followed a similar rotation pattern to normal but does show an external rotation offset throughout the cycle.

Both hips had limited extension in late stance, more so on the right side, and showed excessive flexion throughout the gait cycle. The left side was abducted in stance, tending to normal in swing, and externally rotated in stance. Conversely the right hip was abducted greater than normal in stance and adducted in swing. There was also an internal rotation throughout.

The pelvic tilt and exaggerated obliquity during swing indicate a hip hiking motion, which is also apparent in the right adduction and left abduction of the hips in relation to the pelvis. These features were evident during observation. Like S1, S2 displayed a hip hiking compensation to clear the prosthesis through swing. S2 also commented that he had been recently taking shorter steps than he normally would, out of personal preference. This may account for the reduced hip extension seen in the data.
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**Feedback delivered**

After observation of the error vectors during the baseline walking trial (shown in Figure 84), and video assessment of S2’s gait, the delivery of feedback was set to focus on the two planes of hip joint motion individually. The first biofeedback session (walk 2) focused on reducing the hip abduction seen in swing (in the left-hand image of Figure 84). The second session sought to bring the range of hip flexion/extension closer to that seen in the normal data set (as indicated on the right-hand image of Figure 84).

![Feedback delivery windows during walk 2 (left) and walk 3 (right). S2’s hip joint angles are shown against the normal reference (top) and the error vector is shown (below) windowed in yellow.](image)

During walk 2 the feedback delivery window was therefore set around the peak coronal plane error in swing. Whilst in walk 3 the feedback was delivered during the greatest range of error in the sagittal plane only. The thresholds (Table 26) were chosen to minimise the influence of secondary peaks in the error signal, after observing the variation in 4 strides.

<table>
<thead>
<tr>
<th>Walk</th>
<th>Contribution from each plane</th>
<th>Lower %</th>
<th>Upper %</th>
<th>Band %</th>
<th>Threshold (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>100% coronal</td>
<td>51.8</td>
<td>87.5</td>
<td>35.7</td>
<td>3.7</td>
</tr>
<tr>
<td>3</td>
<td>100% sagittal</td>
<td>17.7</td>
<td>75.6</td>
<td>57.9</td>
<td>9.8</td>
</tr>
</tbody>
</table>

Table 26 Feedback window settings used during walking trials for Subject 2
Chapter 7: Study II – Evaluation of the Closed-Loop Training System with Amputees

**Response to biofeedback in the coronal plane**

The mean pelvic and hip joint angles for the last 10 strides of walk 2 are shown below (Figure 85), showing also when in the gait cycle feedback was provided.

![Figure 85 Pelvic and right hip joint angles for Subject 2 for the baseline condition (blue), post-coronal BFB condition (purple) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented.](image-url)
The anterior tilt previously seen in the baseline reduced following the biofeedback trial, but there was a greater range of pelvic sagittal plane motion in swing. There was also a reduction in pelvic obliquity in swing which is closer to normal, and a reduction in external rotation which is closer to normal. Generally there is an improvement in S2’s pelvic motion pattern following the biofeedback.

The left hip motion became closer to the normal reference from swing through to loading response. However there was little change in the coronal and transverse planes.

The right (prosthetic) side appeared flexed earlier than normal in swing. The excessive internal rotation seen during the baseline reduced and there was greater abduction in swing, which is closer to the reference data. This may result from the improvement in pelvic obliquity.

There was greater variability during the feedback trials compared to the baseline walk. This was noted during observation, where S2 tried different strategies to reduce instances of stimulation. The data show the greatest mean change was in pelvic tilt and rotation, which may indicate his focus of control. As with S1 it is not clear what extent gait changes occurred in relation to the timing of feedback delivery.

**Response to biofeedback in the sagittal plane**

From the kinematic data (Figure 86) and observation, S2’s gait changed little from the baseline walk following biofeedback in the sagittal plane. No notable changes were seen in the pelvis, other than a slight reduction in pelvic obliquity on the right side throughout. There was much greater variation in the pelvic rotation data. It is not clear why this may be the case. In the hips S2 walked with an increased range of motion on the right side and greater extension towards the reference data. The right hip was also more abducted and externally rotated. There were no notable changes on the left.
Figure 86 Pelvic and right hip joint angles for Subject 2 for the baseline condition (blue), post-sagittal BFB condition (red) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented.

**Post-biofeedback kinematics**

Following biofeedback S2’s pelvic motion became closer to the normal reference in all three planes. The left and right hips were more extended throughout the gait cycle, and closer to the reference. The left hip appears to be more abducted throughout the gait cycle.
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The right hip was more abducted in stance (away from normal) and less adducted in swing (closer to normal), however these changes may be due to pelvic motion. As with S1, the variation seen in the joint angle data during the non-biofeedback trials was lower than the biofeedback trials and more consistent through the gait cycle.

![Graphs showing joint angles for different conditions](image)

Figure 87 Pelvic and right hip joint angles for Subject 2 for the baseline condition (blue), post-biofeedback condition (orange) and the normal reference database (green)

After the final walking trial, stimulation was applied at the levels indicated in Figure 73, whilst S2 stood quietly on the treadmill. S2 reported no difference in the stimulation levels or sensations produced compared to the walking trial.
7.6.4 Subject 3

Subject 3 (S3) is a 42 year old male weight lifter and right trans-femoral amputee since 2005 (Figure 88). His left patella has also been removed as a result of osteomyelitis, following a mechanical accident during military service. S3 walked with an “Icecross 5” seal-in liner and suction socket, an 3R80 knee (Otto Bock, Germany) and a carbon flex foot. No problems with the prescription were reported. There was good skin condition with no scaring, pain or ulcerations. Electrodes were placed at 260 mm from his right ASIS with a spacing of 56 mm spacing.

![Figure 88 Subject 3 on treadmill, showing placement of reflective markers](image)

During the treadmill familiarisation S3 walked at a speed of 0.98 m s\(^{-1}\) and made changes to his walking speed as noted below (Table 27).

<table>
<thead>
<tr>
<th>Walk</th>
<th>Condition</th>
<th>Walking speed (m s(^{-1}))</th>
<th>Strides</th>
<th>Data capture period seconds (&amp;frames)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 minute baseline walk (no BFB)</td>
<td>0.98</td>
<td>74</td>
<td>89 (10630)</td>
</tr>
<tr>
<td>3</td>
<td>5 minute walk with stimulation – training phase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1 minute walk with biofeedback (BFB1)</td>
<td>0.89</td>
<td>52</td>
<td>88 (10506)</td>
</tr>
<tr>
<td>6</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>1 minute walk with biofeedback (BFB2)</td>
<td>0.90</td>
<td>32</td>
<td>60 (7177)</td>
</tr>
<tr>
<td>8</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>1 minute walk with biofeedback (BFB3)</td>
<td>1.00</td>
<td>11</td>
<td>16 (1908)</td>
</tr>
<tr>
<td>10</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>1 minute walk with biofeedback (BFB4)</td>
<td>1.00</td>
<td>44</td>
<td>65 (7860)</td>
</tr>
<tr>
<td>12</td>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>1 minute walk, post-test no stimulation (no BFB)</td>
<td>1.00</td>
<td>19</td>
<td>30 (3511)</td>
</tr>
<tr>
<td>14</td>
<td>Post-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Six walking trials were carried out (Table 29), with questionnaires completed after each walk. Video was recorded throughout in the sagittal and coronal planes. Sagittal and coronal photographs were also taken. The treadmill remained level, and S3 indicated a treadmill walking confidence level of 10 (out of 10) throughout.

**Baseline kinematics**

Figure 89 shows the mean pelvic and hip joint angles of the last 10 strides of the baseline trial and the normal reference data set.

Figure 89 Pelvic and hip joint angles for Subject 3 for the baseline condition (blue) and the normal reference database (green). Data are normalised to the gait cycle and are indicated by mean values (thick line) and ±2SD error bands.
Interpretation of baseline kinematics

S3 generally walked with a good gait pattern and normal walking speed. There was a greater pelvic anterior tilt compared to normal throughout the gait cycle, and a greater range of excursion in tilt. Also the left and right hips appeared to have a 20 degree flexion offset throughout the gait cycle, however the range of motion and pattern was similar to the normal reference. Both of these features could be expected when the sacrum marker is placed higher than the sacral landmark.

Other features in S3’s walking were minor. There was some pelvic obliquity (with the right side down) in late stance / early swing and the right side moved up from mid-swing to stance. The pelvic rotation pattern was close to the normal range but was excessively externally rotated from mid-swing through to stance. The left hip motion was normal in the coronal plane, with some external rotation seen in late stance into swing, whilst the right hip was adducted early in stance and again in swing. The right hip was also externally rotated throughout stance and into swing.

Feedback delivered

S3 walked with a relatively good gait and reported no issues with his walking. Four walking sessions were carried out using biofeedback to improve the coronal plane motion on the right side. During the first two walks application of biofeedback focused on coronal plane movement only. This was extended in walks 4 and 5 to include contribution from the sagittal plane gait deviation in the presentation of feedback delivery as outlined in Table 28. The error vector seen during the trial is shown in Figure 90.

<table>
<thead>
<tr>
<th>Walk</th>
<th>Contribution from each plane</th>
<th>Lower %</th>
<th>Upper %</th>
<th>Band %</th>
<th>Threshold (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>100% coronal</td>
<td>57.9</td>
<td>87.9</td>
<td>30</td>
<td>6.3</td>
</tr>
<tr>
<td>3</td>
<td>100% coronal</td>
<td>61.0</td>
<td>90.9</td>
<td>30</td>
<td>5.6</td>
</tr>
<tr>
<td>4</td>
<td>50:50 both planes</td>
<td>55.9</td>
<td>95.9</td>
<td>50</td>
<td>12.6</td>
</tr>
<tr>
<td>5</td>
<td>50:50 both planes</td>
<td>55.9</td>
<td>95.9</td>
<td>50</td>
<td>12.6</td>
</tr>
</tbody>
</table>
Response to biofeedback in the coronal plane

Referring to Figure 91, little change can be seen to the pelvic kinematics following the application of coronal plane biofeedback in walk 3. There is an increase in mean pelvic tilt can be seen throughout the gait cycle. But there is no change to obliquity and only a slight reduction in external rotation. As with other subjects, greater variation can be seen in the data from the biofeedback trials.

The left hip shows a slight increase in extension, but it is still within 2SD of the baseline mean. There were no notable changes in the coronal and transverse planes for the left hip. The right hip flexion/extension range and pattern remained the same as the baseline, but there was a marked improvement in the right hip in the coronal plane throughout the gait cycle. The pattern was bought within the normal range through the majority of the cycle. A marked improvement can also be seen in right hip rotation.
Figure 91 shows S3’s pelvic and hip joint kinematics following application of biofeedback in the coronal plane only. The mean and ±2SD of the last 10 strides of walk 3 are shown.

Figure 91: Pelvic and right hip joint angles for Subject 3 for the baseline condition (blue), post-coronal BFB condition (purple) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented.
Response to biofeedback in both planes

The application of biofeedback in this case continued from the first two walks and used stimulation in all electrode locations. S3’s gait was generally similar to the previous walks presented in Figure 91, so the data are not shown here. All data are included in Appendix J2. The most prominent difference was seen in the right hip as shown below (Figure 92). The hip pattern following walk 5 (shown in red) is further abducted throughout the gait cycle, compared to walks 2 and 3 (shown in purple).

![Figure 92](image)

*Figure 92 The right hip abduction pattern for Subject 3 for the baseline condition (blue), the post-coronal BFB condition (purple), the post-50:50 BFB condition (red), the post-trial condition (orange) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented during walk 5.*

Post-biofeedback kinematics

Following from the biofeedback walking trials, S3 showed a greater anterior tilt of the pelvis throughout the gait cycle (Figure 95). There was little change in obliquity, and the rotation pattern was closer to the normal reference. The left and right hips retained a 20 degree flexion offset throughout the gait cycle, which may be caused by poor marker placement. The range of motion and pattern was similar to the normal reference.

Improvements were seen in the coronal plane. The left hip was closer to normal, and there was a notable improvement in the right hip range of motion and pattern. S3 was confident walking on the treadmill. He walked with a good gait pattern and maintained a normal
walking speed throughout the trials. He noted that the feedback stimuli became easier to understand and respond to during the course of the walking trials. From observation S3 was seen to adopt a more upright posture towards the end of the session.

![Figure 93 Pelvic and right hip joint angles for Subject 3 for the baseline condition (blue), post-biofeedback condition (orange) and the normal reference database (green)](image)

After the final walking trial, stimulation was applied to each channel with S3 standing quietly. S3 also reported no difference in the levels felt compared to the walking trials. Participants views on the biofeedback training are included in Section 7.6.6, and discussed more broadly in Section 7.7.
7.6.5 Subject 4

Subject 4 (S4) is a 48 year old male, who had a right below-knee amputation as a result of a mechanical accident during military service. He used a donning sock to fit a suction socket, and walked with a Mauch hydraulic knee (Ossur, Iceland) and a carbon flex foot. He reported no problems with the prescription. On inspection there was good skin condition with no scaring, pain or ulcerations. Following anthropometric measurements, electrodes were placed at 266 mm from his right ASIS with a spacing of 61 mm.

As a result of using a donning sock, problems were experienced maintaining electrode placement during donning, and then maintaining suction during the latter walking trials. As a result only four walking trials were carried out (Table 29). Video was recorded throughout. The treadmill remained level, and S4 reported a confidence of 10 walking on the treadmill. Walking speed remained at 0.84 ms$^{-1}$ throughout the session.

<table>
<thead>
<tr>
<th>Walk</th>
<th>Condition</th>
<th>Strides</th>
<th>Data capture period seconds (&amp; frames)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 minute baseline walk (no BFB)</td>
<td>40</td>
<td>60 (7224)</td>
</tr>
<tr>
<td>5 minute walk with stimulation – training phase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 minute walk with biofeedback (BFB1)</td>
<td>46</td>
<td>59 (7098)</td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 minute walk with biofeedback (BFB2)</td>
<td>43</td>
<td>59 (7131)</td>
</tr>
<tr>
<td>30 second rest, mid-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1 minute walk, post-test no stimulation (no BFB)</td>
<td>18</td>
<td>28 (3414)</td>
</tr>
<tr>
<td>Post-test questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Kinematics**

Figure 94 shows the mean and ± 2SD of the pelvic and hip joint angles of the last 10 strides of the baseline trial and the normal reference data set for S4.

Figure 94 Pelvic and hip joint angles for Subject 4 for the baseline condition (blue), the post-biofeedback condition (orange) and the normal reference database (green). Data are normalised to the gait cycle and are indicated by mean values (thick line) and ±2SD error bands.
S4 displayed a marked hip hike in his gait, which was apparent through observation and in the kinematic data (Figure 94). The pelvis is posteriorly tilted in swing and also has a superior obliquity with the right (prosthesis) side up during swing. Consequently the right hip appears to be adducted in swing, (in relation to the pelvis) and the left is abducted in stance, again in relation to the pelvis. The range of hip motion in the sagittal plane is close to the normal reference, however an early flexion was seen in the left hip.

**Feedback delivered**

As with previous subjects the focus of feedback delivery was based on the error vector information and brief observational gait assessment made during the 1 minute baseline walk. The underlying hip hike was not distinguished from a circumduction pattern during the baseline walk, so feedback focused on the reduction of the hip adduction pattern seen in the right leg, during walks 2 and 3. The trials stopped due to problems with poor socket suction. The appropriateness of the subjects and intervention is discussed in detail in Section 7.7. The following feedback parameters were used during trials with S4 (Table 30).

<table>
<thead>
<tr>
<th>Walk</th>
<th>Contribution from each plane</th>
<th>Lower %</th>
<th>Upper %</th>
<th>Band %</th>
<th>Threshold (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>100% coronal</td>
<td>48.6</td>
<td>77.6</td>
<td>29</td>
<td>6.6</td>
</tr>
<tr>
<td>3</td>
<td>100% coronal</td>
<td>48.6</td>
<td>77.6</td>
<td>29</td>
<td>6.6</td>
</tr>
</tbody>
</table>

**Response to biofeedback in the coronal plane**

The mean pelvic and hip joint angles for the last 10 strides of walk 3 are shown below (Figure 95), showing also when in the gait cycle feedback was provided. The kinematic data show that the hip hiking pattern was still present. There was a reduction in pelvic tilt across the gait cycle, however the range of motion in pelvic tilt remained greater than that of the reference data. An improvement was seen in the pattern of sagittal plane motion in both hips. The left side followed a similar coronal plane motion compared to the baseline condition (retaining the excessive abduction during stance). The right hip changed from being adducted in early stance and late swing to becoming abducted. As with the other
subjects, there was greater variability in the data during the feedback trials, notably so in the pelvis and hip coronal plane motion. No relationships between periods of feedback delivery and gait changes were visually identified.

Figure 95 Pelvic and right hip joint angles for Subject 4 for the baseline condition (blue), post-coronal BFB condition (red) and the normal reference database (green). The orange shaded region indicates the period during which feedback was presented.

**Post-biofeedback kinematics**

The pelvis was still posteriorly tilted in swing and had a superior obliquity with the right (prosthesis) side up during swing. However these features reduced following the use of
biofeedback and became closer to normal. Both hips displayed a pattern closer to the normal reference in the sagittal plane, with a reduction in the early flexion seen on the right, and an improved range of motion on the left. The right hip moved from being adducted in swing in relation to the pelvis, to being abducted and closer to the normal reference after the use of biofeedback. The left hip became more adducted in stance (towards the normal) and in swing (away from normal).

Figure 96 Pelvic and right hip joint angles for Subject 4 for the baseline condition (blue), post-biofeedback condition (orange) and the normal reference database (green)

S4 reported no difference to the stimulation levels felt whilst standing, compared to walking.
7.6.6 Participant views and practical observations

The participant questionnaire responses are shown below and overleaf (Figure 97). The number of times the questions were asked varied for each subject, and is indicated in brackets for each subject. The mean of the group response is also shown in red.

Comfort

1. The electrodes are comfortable
2. The electrode wires are comfortable
3. The kit feels cumbersome
4. The prosthesis and liner are fitting
5. The kit feels cumbersome

Sensation

6. There were moments when the sensation was unpleasant
7. The sensation felt even around my thigh
8. There were unexpected sensations under the electrodes
9. There were unexpected sensations from other parts of my body

Figure 97 Participant questionnaire responses
**Association with movement**

10. It was easy to associate the sensation with my movement
11. It was easy to correct my movement to avoid the stimulus
12. I found the experience frustrating

**Focus of attention**

13. Walking
14. My balance
15. The stimulus
16. The prosthesis
17. The equipment (leads and markers)
18. Pain and discomfort

**Usability**

19. The electrodes remained in place for the duration of testing
20. I would have been happy to wear the system during my rehabilitation
21. I would be happy to wear the system on a longer term basis

Figure 97 cont. Participant questionnaire responses
In addition to these user perspectives, the following practical observations were made during the course of the study.

Donning and doffing of electrodes presented no problems with the first three subjects. However, as highlighted in Section 7.4, S4 used a donning sock to fit the prosthesis. The sock pulled the electrodes away from the skin as expected and required repeated attempts and the use of talcum powder to fit the socket without electrode movement. It was not possible to visually check the location of the electrodes with the prosthesis on, however each subject was able to give an indication prior to stimulation if they felt movement had occurred. Only S4 reported problems.

Towards the end of Walk 3 S4 reported suction problems as a result of the electrode leads emerging through the top of the socket. After repeated attempts to improve the fit, a decision was made to end the biofeedback walking trials in his case. However good socket fit was maintained in the first three subjects.

The skin condition under the electrodes did not deteriorate or show signs of redness after walking trials in all subjects. The study involved approximately 2 hours with the electrodes in place. Placement of markers did not present any problems and there were no other issues in terms of equipment use, robustness or comfort. Marker dropouts were present as a result of occlusion from arm swinging and loose clothing; however these were indicated in software and handled as described in Section 6.3.4. Data capture from the camera system and real-time processing took place without any problems. Finally no problems were experienced with operation of the electrical stimulator by the experimenter or participants.
7.7 Discussion

7.7.1 Participants

A low recruitment rate resulted in half of the planned sample participating. The study coincided with the London 2012 Olympics with local traffic changes making it difficult for some potential participants who expressed an interest to attend.

Individuals who were referred to this study and did participate did not display a circumduction gait pattern as required in the inclusion criteria. It was therefore not possible to investigate the therapeutic effects of the biofeedback training system. This did not become apparent until the participants were involved in the study. The final element of the study was therefore modified to examine general user interaction within the biofeedback loop on a case-by-case basis. The nature of each individual's gait pattern was therefore a significant limitation to the final part of this work, because the system was designed specifically to modify circumduction patterns.

Comparison is made here between the amputee participants and the non-amputees tested in Chapter 5, but this is only indicative because the groups varied in sample size and were not matched in terms of age or anthropometric factors. In general the amputee subjects were older, shorter, had a higher body mass index and thinner thighs (Table 22). The latter was expected as a result of muscle disuse following amputation. The small and uneven sample sizes did not warrant statistical comparison of anthropometrics.

7.7.1 Sensation thresholds (I)

Looking at Figure 40 the amputee participants demonstrated broadly comparable sensory thresholds to electro-tactile stimulation on the thigh to the non-amputees.

Amputees reported 5 mA lower thresholds on average compared to the non-amputees. From Figure 71 the greatest difference between the groups was consistently seen in electrodes 3 and 4, in all levels and stimulation frequencies. Electrode 3 was placed on the
lateral surface of the thigh, which is closer to the lateral femoral cutaneous nerve than the other electrode locations. The difference in sensory thresholds at 3 and 4 may therefore result from lower sensitivity following amputation. The Semmes Weinstein monofilament test is used to assess the cutaneous sensitivity of amputees post-operatively. However its use is non-routine and no published data on cutaneous sensitivity changes following amputation were identified.

Again from Figure 40, a stimulation frequency of 80 Hz was perceived first and produced discomfort first, followed by 60 Hz and then 40 Hz. This pattern was also seen in the non-amputees. No clear explanation is apparent.

Prior to treadmill walking participants were instructed to set the intensity levels mid-way between perception and discomfort for use as a biofeedback stimulus. The user-selected levels are shown in Figure 72 and indicate how well this was achieved. The data indicate a high level of threshold discrimination ability, given that the adjustment period only lasted a few minutes to adjust all channels (this was untimed). The changes made to the stimulation levels following the 5 minute training phase are also shown in Figure 72, and the absolute change per subject are shown in Figure 73. The group mean level raised consistently after stimulation by 4 mA (17% of the final value). 3 of the 4 subjects raised the intensity level, with a greatest increase of 10 mA. Subject 2 used the original intensity levels, and only one channel intensity reduced in one subject (electrode 7 in Subject 4 reduced by 1 mA). The measurement error was approximately ±0.2 mA, due to noise in the signal and the screen resolution of the digital oscilloscope used.

Figure 41 and Figure 74 Group mean, minimum and maximum perception (blue) and discomfort (red) threshold levels show that greater variation existed in the discomfort level, as was previously seen in the non-amputee group. The possible causes for this were discussed in Chapter 5 (Section 5.6) and there is no reason to suspect they change with amputees. The variation in perception and discomfort is lower in amputees and the only overlap between the maximum perception and the minimum discomfort levels occurred in one electrode for one amputee subject, whereas greater overlap was seen in the non-
amputee group. The group sizes did vary (amputee n=4, non-amputee n=13) so greater variation and overlap between thresholds may be experienced with more participants.

The ability to discriminate the location of static stimuli and the direction and speed of moving stimuli was high in the amputee participants, and is comparable to non-amputees. Finally no negative comments or opinions were reported regarding the sensation of the stimulus.

Movement patterns experienced in daily living involve a combination of eccentric, concentric and isometric muscle contractions. Trans-femoral amputees have limited eccentric / concentric control of the residual muscles of the thigh. It is likely they predominately perform isometric contractions against the myodesis or myoplasty. Whilst determining sensory thresholds in a supine posture it was assumed there was no muscle activity. It would be interesting to found out what impact contraction type has on sensory threshold levels. In future work subjects could be asked to perform different contraction types whilst undergoing the sensory threshold tests, using dynamometry to quantify the contraction.

7.7.2 Practicability and user acceptance (II)

There was generally a positive response towards the training method from participants, according to the questionnaire responses in Figure 97. On average participants strongly agreed that the electrodes and prosthesis were comfortable and the prosthesis and liner fitted well. Subject 4 (S4) disagreed due to the problems experienced with the donning sock. The first three subjects, with the exception of S4, disagreed that the equipment felt cumbersome.

In terms of the quality of sensation experienced whilst walking the group disagreed that the sensation was unpleasant, or that it produced unexpected sensations under the electrodes or in other parts of the body. This positive response could be expected since the stimulation levels were set below the measured discomfort threshold. On average the group strongly
agreed that the sensation felt even around the thigh. Again this could be expected because each participant adjusted the levels to produce the desired evenness.

Interestingly all of the subjects agreed that it was easy to associate the biofeedback sensation with their movement and that it was easy to correct their movement to avoid the stimulus. A neutral or more negative response was expected, because it is a complex task (involving spatial awareness of the stimulus in relation to movement patterns produced on a treadmill) that participants may not have considered before. A positive response given here in view of the kinematic changes experienced, may indicate a false positive arising from a willingness to help the experimenter.

The group indicated strong agreement that they focused on their walking and the stimulus, as may be expected in this learning task. On average they expressed a neutral response in terms of focusing on the prosthesis, balance and equipment. This included S4 who experienced problems with socket fit, so again this may indicate a bias towards positive responses. The group disagreed that they focused on pain or discomfort, which suggests a comfortable experience from the sensation and wider aspects of the study.

Finally in terms of usability participants agreed that the electrodes remained in place throughout the duration of the study. S4 was the only subject to strongly agree, but was also the only subject who experienced problems with electrode placement during the setup. All subjects agreed they would have been happy to wear the system during rehabilitation and on a longer term.

A number of responses indicate the presence of false positives in the data. This may have been exacerbated by the experimenter asking the questions directly and the subjects being aware of the personal input the experimenter had in developing the system. A more robust approach would be to disassociate the experimenter from the experiment in the minds of the participants and from the collection of questionnaire responses. This could be achieved with a more neutral introduction to the study or blinded experimenters, and the use of an electronic questionnaire.
7.7.3 Kinematic response to biofeedback (III)

All four subjects presented with varying levels of a hip hiking pattern, which is characterised by excessive pelvic range of motion (notably higher than normal obliquity in swing). The system was designed to provide biofeedback based on thigh motion, not pelvic motion. However feedback was delivered based on the thigh kinematic data available and a number of observations can be made from the results outlined in Section 7.6.

It was not possible to assess the biofeedback system with individuals walking with a normal gait since it required a pathological deviation to elicit an error signal. A normal walker may have been able to produce an error by mimicking a pathological gait but any subsequent gait modification would be artificial and of limited use in this study. Subject 1 therefore presented the first opportunity to trial the system. In the session and with subsequent participants, pathological gait deviations were identified in real-time and presented to the experimenter who was able to direct the focus of stimulation.

The stimulation was presented to each subject in the desired location around the thigh and for the desired period of the gait cycle. This produced the intended effect described in Chapter 6 (Section 6.3.8) of a ‘sensory boundary’ around the thigh to improve awareness to the participant. Each subject attempted to respond to the biofeedback by changing their gait and S2 and S3 were able to do this with positive effect. S1 but was unable to respond as required because a movement correction of the pelvis was required to reduce a pelvic hike, instead of correction of his adducted thigh. Consequently the feedback information being received was not the most pertinent for him, and he was unable to find a kinematic strategy to reduce the feedback signal. Whilst all of the subjects presented with similar gait issues, S2 and S3 were able to make positive corrections because they appeared to be more experimental in trying out different gait strategies. This was evident through observation and discussion, and also through the variation seen in the kinematic data for each subject.

Feedback was limited to individual planes of thigh motion in three of the four cases to suite the clarity and ease with which subject reported they were able to respond to the stimuli. Subject 3 walked with a good gait and during the training phase demonstrating greater
ability to respond to the stimulus, as such the error vector in his case included a mixed contribution of both planes of motion. During the biofeedback trials, he was able to interpret the biofeedback signal, and from Figure 91 made positive changes to his thigh kinematics in both planes, without detriment to walking speed or other aspects of his gait.

The extent of control an amputee has at different stages of the gait cycle and how to time feedback to those stages is an area for further investigation. For example S1 reported that after initial contact he had limited ability to change his thigh motion through to stance. The main action he and others could make a difference in was in pre-swing and by choosing the trajectory with which to propel the limb through swing.

The study did not seek to identify how the gait changes were related to the timing of feedback delivery. But from the positive indications shown here, it would be beneficial for future work to investigate this in the context of KR and KP timing (as introduced in Section 2.6.3).

None of the subjects reported that the intensity level of the stimulation caused discomfort when they transitioned from walking to standing. This is contrary to the change in stimulation levels seen in Figure 73, where individuals raised intensities to suite the walking perceptual condition. This acceptance of a higher level may be due to adaptation after the walking trials involving electro-tactile stimulation, which was up to 10 minutes in the case of S1 and S3. Further work would be required to assess the presence and effect of adaptation if the system is to be used on a longer term basis.

In addition to the selection criteria issues already highlighted, fatigue may be a confounding factor effecting results in this study. Focus of attention was questioned, however it would be beneficial in future to incorporate a psychomotor vigilance task (as described in Section 5.5.7) into the walking trials and the sensory threshold tests.

There is also potential for pareidolia to produce Type I and type II errors when associating the stimulus with movement. Pareidolia is a psychological phenomenon whereby an unclear perception is understood to have significance (such as identifying non-existent...
shapes in noisy images). Subjects noted that they focused on the stimulus, which may produce a heightened response to pareidolia. Future work could consider the use of dual tasking and sub-threshold stimulation to help control against this phenomena, but also to investigate the role of different sensory pathways and questions summarised in Section 2.7.

It is unclear in this study when and how biofeedback information was interpreted. This could be quantified with a more structured conditioning to different feedback stimuli. Participants could be asked to respond to discrete events at the appearance of visual stimuli and then transferring to electro-tactile stimuli, such that reaction times could be measured and compared. A beneficial extension to this investigation would be to quantify if and how variation in their training data indicates the adoption of different walking strategies.

The system generated a lot of data, and there is also scope for presenting more information to the operator but with the potential to impede the system latency. This is discussed further in Chapter 8.

7.8 Conclusions

The work described within this Chapter sought to investigate the electro-tactile sensory threshold levels of unilateral trans-femoral amputees.

It was found that the range of sensation between perception and discomfort that was seen in non-amputees does exist in all of the amputee participants. The amputee group also demonstrated the ability to discriminate the location of static stimuli, and the speed and direction of stimuli moving around the thigh, as was seen in non-amputees. The assumption was challenged that traumatic amputees have comparable electro-tactile sensory threshold levels to non-amputees, and found to be a fair assumption. The sensation intensity levels were increased after a period of treadmill walking, but the increased levels did not cause discomfort when amputee subjects came to rest after treadmill walking. These aspects indicate that the stimulator and electrodes developed in Chapter 4 are suitable for presenting electro-tactile stimuli to trans-femoral amputees.
The study sought to determine if the biofeedback training system is a practical and acceptable method of providing gait re-training for trans-femoral amputees. By observing the practical aspects of system use and in discussion with the participants, the system was found to be practical and acceptable if used with the correct suspension types. The only practical issue experienced was from one subject who used a method of donning the prosthesis that would have otherwise been excluded from the study. The data capture software and integrated system components performed as expected, demonstrating that real-time electro-tactile biofeedback could be delivered to amputees walking on a treadmill.

The final element of the study sought to examine therapeutic effect of training. This was not possible as a result of poor recruitment, however a number of features were identified that suggest the system has potential to produce a positive effect on gait. Subjects were able to perceive and interpret the biofeedback stimuli whilst walking, and make changes demonstrating a positive effect on their gait. The magnitude and duration of the effect was not assessed, however the discussion raised a number of areas that could benefit from future work.
Chapter 8

Summary and Conclusions
This work sought to develop the field of biofeedback for clinical rehabilitation, and focused specifically on the viability of using electro-tactile feedback to assist in the reduction of circumduction and abduction gait patterns seen in trans-femoral amputees.

The hypothesis challenged was that *real-time electro-tactile feedback is a viable method of assisting in the reduction of circumduction and abduction gait patterns in trans-femoral amputees.*

It was not possible to investigate the therapeutic effects of electro-tactile feedback, but from the practical and user perspectives gained from amputees, it is the view of the author that real-time electro-tactile feedback is a viable method of assisting in the reduction of circumduction and abduction gait patterns in trans-femoral amputees. To reach that conclusion the following objectives, which were defined in Chapter 1, formed the programme of research undertaken:

1. To review the principles and previous uses of biofeedback in neuromuscular rehabilitation, to underpin this and future research

2. To select the most appropriate method of presenting feedback to trans-femoral amputees

3. To design and build a biofeedback training system that can be used with trans-femoral amputees during rehabilitation. This was broken down into the following specific objectives:

   3a. Design and build an electrode array capable of delivering an electro-tactile stimulus to lower limb amputees
   3b. Design and build an electrical stimulator capable of providing a sensory stimulus suitable for gait re-training
   3c. Develop a physiological measurement system to provide real-time movement data to inform the correct application of the feedback stimulus
3d. Provide a user interface to the system, and feedback about system operation and patient performance to users with a clinical background

4. To investigate the response and practicalities of using the proposed training system with unilateral trans-femoral amputees

The work carried out and results for each objective are summarised below.

1. **To review the principles and previous uses of biofeedback in neuromuscular rehabilitation, to underpin this and future research.**

A review of 293 published papers in lower limb biofeedback was carried out (as summarised in Chapter 2). It found that biofeedback is a wide multidisciplinary field which encompasses biofeedback measurement and presentation technology, and draws on current research themes such as body-worn and wireless motion capture technology, virtual rehabilitation, telemedicine and neuroprosthetics. Applications were found predominantly in rehabilitation medicine and sports performance coaching. Examples were also found more widely in ergonomics, occupational therapy, guided surgery and consumer video gaming.

The user is central to the biofeedback loop, and research was also found in understanding the psychology of individuals undergoing training. However that work predominantly describes upper limb motor learning studies. Limited research was found for lower limb motor learning and no studies were found that apply motor learning theory within clinical lower limb biofeedback applications. Despite being a multidisciplinary subject area, the research review suggests there is greater scope for crossover between fields.

In lower limb rehabilitation biofeedback provides information to patients and therapists, which can be a motivating influence in individual and group therapy environments. High variation and heterogeneity was found within the published intervention studies, with clinical evidence limited to case and cohort studies. However positive results were found in a range of gait and posture outcomes, that suggest biofeedback has a greater role to play in
gait re-education. Some adverse effects were also found. Physiotherapists report some patients can become de-motivated when a competitive gaming element is introduced into group therapy. Cases were also found of repetitive strain injuries in patients engrossed in biofeedback training with poorly structured movement tasks. However the literature suggests these issues can be avoided with the appropriate selection of technology and approach for the patient, careful task planning, and greater use of feedback to the clinical team.

2. **To select the most appropriate method of presenting feedback to trans-femoral amputees.**

Based on the literature review, visual, auditory, vibro-tactile, electro-tactile, and haptic forms of feedback presentation were considered, and two vibro-tactile prototype devices were developed (Section 3.2.4). In a short test a vibro-tactile belt was found to produce sensations that were easy to discriminate whilst sitting, standing and walking. The vibro-tactile motors were then embedded into a laminated cuff, but the rigidity of the assembly prevented clear sensory discrimination of the vibration at distinct regions around the thigh, and the prototype was rejected. The vibro-tactile elements in the belt do however have potential to be developed for use with upper and lower limb neurological patients for example, where no mechanical constraining device is worn. Based on the literature review and previous expertise within the University of Surrey, electro-tactile feedback was chosen, investigated and adopted as the presentation modality in the final design.

A research approach was formulated to develop a training system that could be used to investigate the basic science of biofeedback, initially for the problem of circumduction in trans-femoral amputees, whilst ensuring a pathway for future development for use in the community and with a broader range of patient groups. This approach was described in Chapter 3.
3. **To design and build a biofeedback training system that can be used with transfemoral amputees during rehabilitation.**

A real-time training system has been developed that is capable of conveying meaningful feedback regarding thigh kinematics using electro-tactile stimulation to amputees walking on a treadmill. The development work, documented in Chapters 4 and 6 followed and met the following objectives:

3a. **To design and build an electrode array capable of delivering an electro-tactile stimulus to lower limb amputees**

and

3b. **To design and build an electrical stimulator capable of providing a sensory stimulus suitable for gait re-training**

An annular electrode design was chosen based on the work of Buma *et al.* (2007) and an investigation was carried out with two subjects to gain familiarisation of a range of electrodes with varying geometric properties (varying active conductor diameters and varying inter-conductor spacing). A commercial stimulator was used (ODFS-II Functional Electrical Stimulator from Odstock Medical Ltd, Salisbury UK) to provide a varying amplitude stimulation at a fixed frequency and pulse width. Sensory threshold ranges were identified that demonstrated that the electrodes warranted further investigate for use in a training system. From the investigation the electrode geometry was chosen.

A 16-channel electrical stimulator was then constructed that is capable of delivering asymmetrical biphasic waveforms to the stimulation electrodes. The device has PC control of pulse width (ranging from 1 to 300 µs) and pulse repetition frequency (ranging from 1 to 300 Hz), and manual control of amplitude (up to 120 mA applied current at 120 V).

To determine the most appropriate pulse repetition frequency and intensity levels for presenting discernible information in a safe and comfortable manner, a study involving 13
non-pathological subjects was carried out using the stimulator and the chosen electrode design. The study investigated the parameters in four different neuromuscular states that were expected of the end user. The study is described in Chapter 5 and the following hypotheses were posed:

- A non-painful sensation range exists around the thigh between the thresholds of perception and discomfort, during a range of neuromuscular conditions
- Subjects are able to discriminate between different electro-tactile stimulus locations around the thigh, during a range of neuromuscular conditions
- Subjects are able to discriminate different speeds of electro-tactile stimulus movement, during a range of neuromuscular conditions
- Subjects are able to discriminate the direction of electro-tactile stimulus movement, during a range of neuromuscular conditions

The thresholds of perception and discomfort to stimulation around the thigh were measured, and the study found that a non-painful range does exist between the two thresholds in each neuromuscular state. A pulse repetition frequency of 40 Hz was chosen for the final design because it produced a wider dynamic range.

The study demonstrated that subjects could discriminate the location of stationary stimuli, and the speed and direction of stimuli moving around the thigh, and were thus able to perceive spatially coded information presented electro-tactilely.

Male subjects were observed to have higher threshold levels for perception and discomfort compared to female subjects, which is supported by published literature.
3c. To develop a physiological measurement system to provide real-time movement data to inform the correct application of the feedback stimulus.

and

3d. Provide a user interface to the system, and feedback about system operation and patient performance to users with a clinical background.

Hip muscle EMG and kinematic measures were initially considered as feedback parameters for the training system (Chapter 3). EMG was rejected on practical grounds and a camera-based motion capture system was chosen. The completed system development is described in Chapter 6. The software developed captures the marker coordinate data, filters and then gap fills the trajectories (using a combination of cubic-spline interpolation and linear extrapolation to handle different errors) in real-time. The data capture code was provided to Qualysis (Gothenburg, Sweden) and used in a commercially available plug-in.

A 3-degree-of-freedom linked-segment model was constructed based on the Helen Hayes marker set, such that patient hip and pelvic joint angles could be calculated. A normal reference database of joint angles was also constructed using treadmill walking data collected previously from 6 subjects at the University of Surrey.

To calculate a feedback error signal the algorithm needs to know where the patient is in the gait cycle. That knowledge is not available until the subsequent initial contact event (that defines the cycle). It therefore became apparent that it is not possible to provide direct feedback during gait, in relation to a normal reference database. This issue was not identified in the previous literature. To resolve this, the running mean stride time from n previous strides was used, and the reference database was re-sampled after each initial contact event. The database was then indexed according to the patients current frame and the error signal could be calculated. A kinematic gait event detection algorithm was used to find the gait cycle events for the comparison to take place.
The joint angle calculations were validated against a commonly used commercial software package (Section 6.4.1), and found to be suitable for the purposes of this work. The event detection algorithm was validated against 90 strides of force plate data collected from a single individual walking in the laboratory. The two methods were found to be within 2.6 ms of each other, which was acceptable and comparable to published work (Section 6.4.2).

The electrical stimulator was integrated into the system and a strategy for delivering feedback was devised (Section 6.3.8). The chosen method results in individual electrodes being selected based on the difference between the patient and reference joint angles, in weighted contributions from coronal and sagittal planes. The selected electrode then became active when the combined error exceeded a user-set threshold. A window was also incorporated so that feedback could be targeted to specific periods within the gait cycle.

The system was required to operate in real-time. This was defined in Section 3.2.5 as the time between an event occurring and the perception of that event by the patient. This is a context-based concept so the system latency was therefore limited to 150 ms based on published tactile reaction times. The completed system latency was experimentally tested and found to be acceptable, within 38 ms to 135 ms (with a mean of 80 ms).

Finally a software user interface was developed to provide the experimenter access to system status and operational parameters, and the following graphical information: displays of marker coordinate signals and 2D ‘stick figures’ for each plane (filtered or unfiltered); graphical displays of continuous and normalised pelvic and hip joint angles. The error signal, feedback delivery window and stimulator controls also displayed data to the user in real-time.

In addition to providing ability to control the training system, the following features were also included to assist the user: A patient database was provided to input, store and retrieve anthropometric data; a real-time data storage facility enabled the user to save a range of marker, angular, feedback and system data, and change file types in real-time without causing disruption to the feedback delivery timing. A stand-alone file viewer enabled the
user to selectively view signals. A stop watch and automatic file indexer were also included to assist the user during patient trials.

4. To investigate the response and practicalities of using the proposed training system with unilateral trans-femoral amputees

Four trans-femoral amputees were recruited into a study that sought to test the completed biofeedback system, and provide user perspectives. This work is described in Chapter 7.

The sensation thresholds of each subject were examined, to challenge the assumption previously made that non-amputees have comparable electro-tactile sensation to traumatic lower limb amputees. On average the group thresholds were 5 mA lower in the amputee subjects, but the mean remained within the variation. Participants also demonstrated comparable ability to discriminate the location, direction and speed of locally applied stimuli, as was found in the non-amputees. Both results suggest the assumption is fair, that traumatic amputees do retain a comparable cutaneous sensation on the thigh to non-amputees. Moreover the work demonstrated that electro-tactile stimulus could be used to convey meaningful information to lower limb amputees during sitting, standing and treadmill walking.

Following walking trials using biofeedback the participants reported positively on the experience. They were able to perceive and understand the feedback stimuli, relate the information to their movement, and in some cases make positive changes to their gait.

There are a number of limitations of this work which will be addressed in Chapter 9, along with recommendations for further work.
Chapter 9

Limitations and Further Work
9.1 Limitations

The work has a number of limitations. The following are of particular note:

- The discomfort threshold level for electro-tactile stimulation is subjective. Whilst a band was found to exist between the perception and discomfort levels, greater variation was seen in the discomfort level that may restrict the selection of biofeedback stimulus for some individuals.
- It was not possible to study the therapeutic effects with patients, due to issues with patient recruitment and suitability. The amputee study was also limited by the low sample size and socket donning method used by one of the participants.
- Donning and doffing of the electrodes was time-consuming and alignment to the direction of gait progression was un-quantified.
- The event detection algorithm used to identify initial contact in the kinematic data was not validated with pathological subjects.
- The joint angle reference database was based on non-amputee subjects. It is common to use non-pathological subjects in clinical reference databases, but this assumes non-amputee gait is the most beneficial outcome for individual lower limb amputees, regardless of amputation level.

9.2 Further Work

The following sections summarise how these limitations may be addressed and recommends areas for future work.

9.2.1 Hardware and software development

The stimulator developed is a desktop device connected to the patient electrodes via a long cable. The circuit would benefit from miniaturisation so that it could be body-worn, and potentially embedded into a prosthetic component. The channels are duplicates of each other, so a smaller circuit footprint could be achieved by using a single pulse generator and
solid state relays to divert the signal to each electrode. Alternatively a strowger switch could be used in place of relays to reduce cost. To improve electrode placement and alignment problems a single piece electrode array could be used, and potentially designed into an elaticated band. It would be beneficial to investigate the use of electrically conductive textiles, and non-sticky skin-surface media, to make it easier to change alignment. Inertia-based motion capture systems are entering clinical use, such as those produced by Xsens (Enschede, Netherlands) that could replace the camera-based motion capture system. However anatomical registration of pelvic landmarks remains an issue. Using body-worn technology would allow transition of training goals and tasks from a gait laboratory setting to a rehabilitation gym, or into home and community use. This could benefit the patient by continuing their engagement and motivation in their rehabilitation.

To track the progress of patients using the system, the error vector could be viewed for consecutive strides over a period of time. To illustrates how this could be possible a typical error vector is plotted in Figure 98 and duplicated for subsequent strides towards an ideal outcome. Whilst this example is idealised, the method provides a relatively simple graphical view of progress that could be presented to patients or physiotherapists in clinic as a form of visual feedback.

![Figure 98 Illustrative data representing the change in hip joint error (in the coronal and sagittal planes) normalised to the gait cycle, shown for a number of strides](image)

Figure 98 Illustrative data representing the change in hip joint error (in the coronal and sagittal planes) normalised to the gait cycle, shown for a number of strides
Chapter 9: Further Work

9.2.2 Alternative coding strategies

An extension to the coding strategy could be to place electrodes around the entire surface of the stump, in a similar manner to the 10:20 electrode placement system used in EEG recording. This would enable the circumferential stimulation of the stump that was used in this work, with an additional axis (axially along the length of the femur, making 2-dimensions available). This could be used to present other gait parameters, for example: force through the prosthesis during stance could be presented linearly along the axis alone, or movement of the force could be mapped around the 2-dimensional array. In this work the stimulation amplitude was investigated and set at a fixed level during feedback trials. However facility was provided to control the pulse width in software. This could enable proportional or logarithmic feedback to be added to the existing scheme, such that the intensity increases as the patient deviates further from the target.

9.2.3 Real-time kinematic analysis

The software developed for this work demonstrates a proof of principle for using kinematic data from a marker-based motion capture system in a real-time gait application. The biomechanical model can be extended to the full lower limb and optimisation can be incorporated and validated to produce data quality that is comparable to that used in clinical gait analysis. The Qualysis Track Manager software also outputs analog data (such as force plate and EMG data), so there is potential to conduct real-time kinetic and EMG analysis. The GRAIL (Motek Medical, Amsterdam) was launched at the end of 2012 and permits similar functionality, but it is unclear if or how real-time event detection is achieved.

Beyond the ability to access clinical quality data there is also scope for the development of expert-based gait analysis software within the feedback loop. This potential is outlined in Figure 99. The decision making element use in this work was focused toward patients with circumduction patterns identified by a clinician or operator. This proved problematic in the cases studies presented, due to the presence of additional hip hiking. It would therefore be beneficial to extend the decision making algorithm to identify the influence of pelvic
motion in these cases. For example, if an excessive add/abduction is recorded, the extent of pelvic tilt may differentiate between a hip hiking or circumduction pattern, and feedback can be directed accordingly. This piecewise development is a simple example of how biomechanical and clinical knowledge could be coded into a rule-based expert system. With the ability to automatically identify gait deviations and guide delivery of biofeedback (or other interventions) the system has potential for use with a broad range of patient groups, and expand comparative studies of pathological gait.

As highlighted in Section 9.1, knowledge of the patient’s position at an instance in the gait cycle is required for direct comparisons with a reference to be made. No work has been identified in ‘instantaneous gait detection’, and this is also a fascinating area that extends the development of event detection algorithms.
9.2.4 Laboratory-based studies

A number of studies into the physiological response to different electrode geometries and simulation waveforms would be beneficial, to find a greater physiological bandwidth. The threshold studies were time-consuming and could be speeded up with the use of an automated measurement system, printable electrode arrays and non-sticky skin-interface layers. As with other sensory threshold tests, the subjectively of defining discomfort thresholds remains problematic.

A wide range of scientific questions arose from the literature review which were summarised in Section 2.7 and merit further investigation. Longitudinal studies would be beneficial for investigating the clinical relevance of biofeedback, at different stages of rehabilitation and in different training environments. Using the system developed in this work, it would be particularly interesting to compare learning rates when training with electro-tactile biofeedback and with visual biofeedback, whilst dual tasking. This may shed some light on the different roles of the sensory pathways during gait. Studies of this nature may also provide more information about the sensory requirements during different stage of the gait cycle. This has implications for targeting gait re-education for a range of patient groups, guiding nerve transfer surgery, or developing assistive devices. Finally this work could lead into investigation of sub-threshold stimulation, to determine if gait modification can be directed without conscious awareness.

9.2.5 Wider Application

The wider application of electro-tactile feedback was considered during the system design. The electrodes can be applied to the upper and lower limb and trunk without any changes. Specific feedback delivery regimes can then be written to suite the requirements of training. This work therefore has potential application in the areas of movement science identified in the literature review: in sports and performance coaching, ergonomics, occupational therapy, guided surgery and consumer video gaming; in standing, seated or ambulatory applications where there is a requirement to inform the user where their body is in space.


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Appendix A  Gait deviations in amputees

The following are gait deviations seen by amputees during clinical assessment.

- **Lateral bending** of the trunk is characterised by excessive bending laterally from the midline, generally to the prosthetic side.
  - Prosthetic causes:
    - Prosthesis may be too short.
    - An improperly shaped lateral wall may fail to provide adequate support for the femur.
    - A high medial wall may cause the amputee to lean away to minimise discomfort.
    - A prosthesis aligned in abduction may cause a wide-based gait, resulting in this defect.
  - Amputee causes:
    - Amputee may not have adequate balance.
    - Amputee may have abduction contracture.
    - The stump might be over-sensitive and painful.
    - The stump may fail to provide a sufficient lever arm for the pelvis.
    - Defect may be due to habit pattern.

- **Abducted gait** is characterised by a very wide base with the prosthesis held away from the midline at all times.
  - Prosthetic causes:
    - Prosthesis may be too long.
    - Too much abduction may have been built in to the prosthesis.
    - A high medial wall may cause amputee to hold prosthesis away to avoid ramus pressure.
    - An improperly shaped lateral wall can fail to provide adequate support for the femur.
    - Pelvic band may be positioned too far away from the patient’s body.
  - Amputee causes:
    - Patient may have an abduction contracture.
    - Defect may be due to habit pattern.

- **Circumduction** is swinging of the prosthesis laterally in a wide arc during swing phase.
  - Prosthetic causes:
    - Prosthesis may be too long.
    - Prosthesis may have too much alignment stability or friction in the knee, making it difficult to bend the knee through swing.
  - Amputee causes:
    - Amputee may have an abduction contracture of the stump.
    - Patient may lack confidence for flexing the prothetic.
    - Defect may be the result of habit pattern.
• **Vaulting** is characterised by a rising on the toe of the normal foot permitting the amputee to swing the prosthesis through with little knee flexion.
  
  o **Prosthetic causes:**
    - Prosthesis may be too long.
    - There may be inadequate socket suspension.
    - Excessive stability in the alignment or some limitation of knee flexion such as a knee lock or a strong extension aid may cause this defect.
  
  o **Amputee causes:**
    - Vaulting is a fairly frequent habit pattern.
    - Feat of stubbing the toe may cause this defect.
    - Stump discomfort may be a factor.

• **Rotation of the prosthetic foot** on heel strike.
  
  o **Prosthetic causes:**
    - This defect may be caused by too much resistance to plantar flexing by the plantar flexion bumper or heel wedge.
    - Too much toe-out may have been built into the prosthesis.
    - Socket may fit too loosely.
    - Gluteus maximus too tight in the socket.
  
  o **Amputee causes:**
    - Patient may extend the stump too vigorously at heel strike.
    - Amputee may have poor muscle control of the stump.

• **Uneven arm swing** is characterised by the arm of the prosthetic side held close to the body during locomotion.
  
  o **Amputee causes:**
    - Amputee may not have developed good balance.
    - Fear and insecurity accompanied by uneven timing will also contribute to this defect.
    - Defect may be due to habit pattern.

• **Uneven timing** is characterised by steps of unequal duration, usually by a very short stance phase on the prosthetic side.
  
  o **Prosthetic causes:**
    - Improperly fitting socket may cause pain and a desire to shorten the stance phase on the prosthetic side.
    - A weak extension aid or insufficient friction in the prosthetic knee can cause excessive heel rise and thus result in uneven timing.
  
  o **Amputee causes:**
    - Amputee may have a weak stump.
    - Patient may not have developed good balance.
    - Fear and insecurity may contribute to this defect.

• **Uneven heel rise** is characterised by the prosthetic heel rising quite markedly and rapidly when the knee is flexed at the beginning of swing phase.
  
  o **Prosthetic causes:**
    - Knee joint may have insufficient friction.
- There may be an inadequate extension aid.
  o Amputee causes:
    - Amputee may be using more power than necessary to force the knee into flexion.

- **Terminal swing impact** is characterised by rapid forward movement of the shin allowing the knee to reach maximum extension with too much force before heel strike.
  o Prosthetic causes:
    - Insufficient knee friction may be a factor.
    - Knee extension aid may be too strong.
  o Amputee causes:
    - Amputees may try to assure themselves that the knee is in full extension by deliberately and forcefully extending the stump.

- **Instability of the prosthetic knee** creates a danger of falling.
  o Prosthetic causes:
    - Knee joint may be too far ahead.
    - Insufficient initial flexion may have been built into the socket.
    - Plantar flexion resistance may be too great causing the knee to buckle at heel strike.
    - Failure to limit dorsiflexion can lead to incomplete knee control.
  o Amputee causes:
    - Patient may have hip extensor weakness.
    - Severe hip flexion contracture may cause instability.

- **Medial or lateral whips** are observed best when the patient walks away from the observer. A medial whip is present when the heel travels medially on initial flexion at the beginning of swing phase; a lateral whip exists when the heel moves laterally.
  o Prosthetic causes:
    - Lateral whips may result from excessive internal rotation of the prosthetic knee.
    - A medical whip may result from excessive external rotation of the knee.
    - Socket may fit too tightly thus reflecting stump rotation.
    - Excessive valgus or “knock” in the prosthetic knee may contribute to this defect.
    - A badly aligned toe-break in a conventional foot may cause twisting on toe-off.
  o Amputee causes:
    - Faulty walking habits may result in whips.

- **Foot slap** is too rapid a descent of the anterior portion of the prosthetic foot.
  o Prosthetic causes:
    - Plantarflexion resistance is usually too soft.
  o Amputee causes:
    - Amputee may be driving prosthesis into the walking surface too forcefully to assure extension of the knee

- **Drop-off** at the end of stance phase is characterised by a downward movement of the trunk as the body moves forward over the prosthesis.
  o Prosthetic causes:
    - There may be inadequate limitation of dorsiflexion of the prosthetic foot.
- The keel of a SACH-type foot may be too short, or the toe break of a conventional foot may be too far posterior.
  - Amputee causes:
    - There are no specific medical causes of this defect.

- **Long prosthetic step** is seen when the amputee takes a longer step with the prosthesis than the normal leg.
  - Prosthetic causes:
    - Insufficient initial flexion in the socket can cause this defect, when an irreducible stump flexion contracture is present.
  - Amputee causes:
    - Amputee may have flexion contracture which cannot be accommodated prosthetically.

- Excessive trunk extension during stance phase in which the amputee creates an active lumbar lordosis.
  - Prosthetic causes:
    - Improperly shaped posterior wall may cause forward rotation of the pelvis to avoid full weight-bearing on the ischium.
    - Insufficient initial flexion may have been built into the socket.
  - Amputee causes:
    - Amputee may have hip flexor tightness.
    - Amputee may have weak hip extensors and may be substituting lumbar erector spine.
    - Weak abdominal muscles may contribute to this defect.
    - Deviation may be due to habit pattern.
    - Patient may be moving shoulders backwards in an effort to obtain better balance.
Appendix B  BACPAR Recommendations concerning the rehabilitation programme

- Prosthetic rehabilitation should aim to establish an energy efficient gait based on normal physiological walking patterns
- The physiotherapist should be aware that level of amputation, pre-existing medical conditions and social environment will affect rehabilitation
- During rehabilitation the physiotherapist should take into account that prosthetic gait demands higher energy expenditure
- The physiotherapist should teach efficient control of the prosthesis through postural control, weight transference, use of proprioception and specific muscle strengthening and stretching exercises to prevent and correct gait deviations
- Prosthetic rehabilitation should begin within a maximum of 5 working days after receipt of the prosthesis
- During prosthetic rehabilitation patients should receive physiotherapy as often as their needs and circumstances dictate
- The prosthesis should be worn for short periods of time initially, increasing in use as exercise and skin tolerance allow
- Gait re-education should commence within parallel bars
- Gait re-education should progress through walking within the hospital environment to walking within the home environment
- Walking aids should be provided to ensure that prosthetic users, where possible, progress to being fully weight bearing through their prosthesis
- Functional skills progressing in complexity should be taught within the patient’s limits
- Rehabilitation should be functional and integrated with activities of daily living
- The physiotherapist should instruct the patient in a range of functional tasks relevant to the goals set with that individual. These may include:
  - Getting on and off the floor
  - Getting in and out of a car, and the use of public transport
  - Going up and down stairs, kerbs, ramps and slopes, and to use escalators
  - Walking in a crowded environment
  - Carrying an object whilst walking
  - Walking over uneven ground outdoors
  - Changing speed and direction
  - Picking up objects from the floor
  - Opening and closing doors

Appendix C  Email correspondence

The following is a personal email from John Sabolich referring to his experience with the ‘Sense of Feel’ device when used with amputee test subjects. Commercially sensitive sections have been redacted and do not relate to this project.

-----Original Message-----
From: jsab@aol.com
To: deborah@scottsabolich.com; giovaniortega@comcast.net
Sent: Fri, 24 Apr 2009 1:43 am
Subject: Re: FAO John Sabolich

Hello Graham,

I always thought from actual patient experience that the system not only gave the patient proportional feed back from the floor, but noticed that they even experienced a substantial reduction in phantom pain. Also it allowed them to begin to feel there foot again in a more natural way when the brain started to fill in the blanks, which of course led to a more symmetrical and natural gait. Some said that they could even feel there heel compressing at heel strike and toes bending at push off. Some of the patients refused to give up on the prototypes and we had to keep making prototypes and installing them in there prosthesis way after the study ended. There is no doubt in my mind that some one will find a way to make this kind of system commercially feasible. It just makes since that this should be logical extension of prosthetic progress in the future.

Hope this helps, John Sabolich.  cc copy
Appendix D  Vibration Belt Design

D1. Graphical user interface
D2. High level code (LabVIEW)

1. Setup DAQmx hardware

2. Find cursor coordinates

3. Calculate angle

4. Determine which motor to use

5. Switch motor on

5. Switch motor off
Appendix E  Stimulator Design

E1.  Circuit schematics

Figure E1.1 Microprocessor board
Figure E1.2 Electrodes 1 to 6
Figure E1.3 Electrodes 7 to 12
Figure E1.4 Electrodes 12 to 16
Figure E1.5  Signal connectors
Figure E1.6 Power connectors
Figure E2.1 Microcontroller board top and bottom copper (left and right respectively)
Figure E2.2 Transformer board, top and bottom copper (left and right respectively)
E3. Microcontroller code (Ansi C)

#include <C:\Program files\PICC\devices\16f876a.H>
#include <C:\Program files\PICC\drivers\stdio.h>
#fuses HS,WDT,NOPROTECT,NOLVP, NOBROWNOUT

#use delay(clock=20000000)
#use RS232[Baud=38400,XMIT=PIN_C6,RCV=PIN_C7)

/*****************************************************************
FUNCTION PROTOTYPES
******************************************************************/
void initialise_pic(void);
void get_pc_command(void);
int decimal_adjust_int(void);
long decimal_adjust_int16(void);
long decimal_adjust_int32(void);
int adjust_int(void);
SKIP 

DECLARATIONS
******************************************************************/
#define STOP_BUTTON PIN_A0 //pin A0 = inp stop button
#define BLUE PIN_C0 //pin C0 = out blue LED
#define GREEN PIN_C1 //pin C1 = out green LED
#define YELLOW PIN_C2 //pin C2 = out yellow LED
#define STIMON PIN_C3 //pin C3 = device is stimulating
#define TX PIN_C6 //pin C6 = out RS232 Tx
#define RX PIN_C7 //pin C7 = inp RS232 Rx
#define ENABLE PIN_B0 //pin B0 = out demux enable
#define LATCH PIN_B3 //pin B3 = out demux latch enable
#define PULSE PIN_B6 //pin B6 = out pulse waveform
#define PORTA_DIRECTION 0b00000001
#define PORTB_DIRECTION 0b00000000
#define PORTC_DIRECTION 0b00000001

SET_TRIS_A(PORTA_DIRECTION);
SET_TRIS_B(PORTB_DIRECTION);
SET_TRIS_C(PORTC_DIRECTION);

char command_string[8];
char expected[8];
int result;
byte status = 0;
#define COMMAND_STATUS = status.0

int current_state;
#define STIMULATING 0
#define STOPPED 1
#define ILLEGAL_COMMAND 3
#define NEW_COMMAND 1
#define NO_COMMAND 0
#define ON 1
#define OFF 0
#define OFFLINE 0
#define ONLINE 1

int electrode; //e
int pulse_width; //p
long off_time; //b
long i, n;
int comms_status, value;
/*******************************************************************
FUNCTION main
*******************************************************************/
void main()
{
pulse_width = 40; // Initial on width
off_time = 6000; // Initial off time
command_status = NO_COMMAND; // no new commands have been received
current_state = STOPPED; // Stimulator is in "stop" state
comms_status = OFFLINE; // No comms. with PC (not established, or lost)
output_low(PULSE); // No stimulation output
output_low(YELLOW); // No stimulation output
output_low(STIMON); // No stimulation output

ENABLE_INTERRUPTS(INT_RDA); // setup complete, set RDA interrupt
ENABLE_INTERRUPTS(GLOBAL); // then enable interrupts

while (true) // do while WDT not timed out
{
    if(command_status) // new command received?
    {
        get_pc_command(); // yes, get it
        command_status = NO_COMMAND; // reset flag
    }

    switch(current_state) // current state?
    {
        case STIMULATING:
            if (comms_status == OFFLINE)// comms. established?
            {
                setup_wdt(WDT_576MS);
                comms_status = ONLINE; // comms. established flag set
            }
            output_high(YELLOW); // output to stim.
            output_high(STIMON);
            output_high(PULSE);
            for(i=0;i<pulse_width;++i)
            {
                delay_us(1);
            }
            output_low(PULSE);
            for(n=0;n<off_time;++n)
            {
                delay_us(1);
            }
            break;
        case STOPPED: // stimulator in stopped state
            output_low(PULSE);
            output_low(YELLOW);
            output_low(STIMON);
            break;
        case ILLEGAL_COMMAND:
            break;
    }
}
}
/********************************************************************************
FUNCTION : Interrupt Service Routines
Purpose : handles interrupts
***********************************************************************************/

#define RDA

RS232_receive()
{
    output_low(PULSE);
    output_high(GREEN);
    gets(command_string);
    output_low(GREEN);
    command_status = NEW_COMMAND;
    if (comms_status == ONLINE)
    {
        restart_wdt();
    }
}

/********************************************************************************
FUNCTION : get_pc_command
Arguments : start s
            stop x
            pulse width pxxxxx long
            electrode exxxxx long
            off time bxxxxxx long long?
***********************************************************************************/

void get_pc_command(void)
{
    switch(command_string[0])
    {
        case 's':
            current_state = STIMULATING;
            printf("A"); // printf("Stimulator: stimulating");
            COMMAND_STATUS = NO_COMMAND;
            break;
        case 'x':
            current_state = STOPPED;
            printf("B");
            COMMAND_STATUS = NO_COMMAND;
            break;
        case 'h':
            value = input(STOP_BUTTON);
            if (value == 1)
            {
                output_high(BLUE);
                printf("H"); // Stopped by user
                current_state = STOPPED;
            }
            if (value == 0)
            {
                printf("C"); //Still ok
                COMMAND_STATUS = NO_COMMAND;
                output_low(BLUE);
            }
            break;
        case 'e':
            electrode = decimal_adjust_int();
            output_b(0x00);
            output_low(ENABLE);
            output_low(LATCH);
            if(electrode == 21)
            {
                printf("D01");
            }
    }
}
else if (electrode == 23)
{
    printf("D02");
    output_high(PIN_B1);
    output_high(PIN_B5);
    output_high(PIN_B4);
    output_high(LATCH);
}

else if (electrode == 20)
{
    printf("D03");
    output_high(PIN_B1);
    output_high(PIN_B4);
    output_high(LATCH);
}

else if (electrode == 15)
{
    printf("D04");
    output_high(PIN_B2);
    output_high(PIN_B5);
    output_high(PIN_B4);
    output_high(LATCH);
}

else if (electrode == 13)
{
    printf("D05");
    output_high(PIN_B2);
    output_high(PIN_B5);
    output_high(LATCH);
}

else if (electrode == 14)
{
    printf("D06");
    output_high(PIN_B2);
    output_high(PIN_B4);
    output_high(LATCH);
}

else if (electrode == 12)
{
    printf("D07");
    output_high(PIN_B2);
    output_high(LATCH);
}

else if (electrode == 7)
{
    printf("D08");
    output_high(PIN_B5);
    output_high(PIN_B4);
    output_high(LATCH);
}

else if (electrode == 6)
{
    printf("D09");
    output_high(PIN_B4);
    output_high(LATCH);
}

else if (electrode == 5)
{
    printf("D10");
    output_high(PIN_B5);
if (electrode == 4)
{
  printf("D11");
  output_b(0x00);
  output_high(LATCH);
}
else if (electrode == 30)
{
  printf("D12");
  output_high(PIN_B1);
  output_high(PIN_B2);
  output_high(PIN_B4);
  output_high(LATCH);
}
else if (electrode == 28)
{
  printf("D13");
  output_high(PIN_B1);
  output_high(PIN_B2);
  output_high(LATCH);
}
else if (electrode == 31)
{
  printf("D14");
  output_high(PIN_B1);
  output_high(PIN_B2);
  output_high(PIN_B5);
  output_high(PIN_B4);
  output_high(LATCH);
}
else if (electrode == 25)
{
  printf("D15");
  output_high(PIN_B1);
  output_high(PIN_B2);
  output_high(PIN_B5);
  output_high(LATCH);
}
else if (electrode == 18)
{
  printf("D16");
  output_high(PIN_B1);
  output_high(PIN_B4);
  output_high(LATCH);
}
else
{
  output_b(0x00);
  output_high(LATCH);
}
COMMAND_STATUS = NO_COMMAND;
break;
case 'p':
pulse_width = adjust_int();
printf("E");
COMMAND_STATUS = NO_COMMAND;
break;
case 'b':
onf_time = decimal_adjust_int32();
printf("F");
COMMAND_STATUS = NO_COMMAND;
break;
```c
break;
default:
    current_state = ILLEGAL_COMMAND;
    COMMAND_STATUS = NO_COMMAND;
break;
}
}/**
* FUNCTION :  decimal_adjust_int
* Arguments :  3 chars
* Return Value :  int8
*
* int decimal_adjust_int(void)
* {
*     return ((command_string[1] - 0x30) * 100) +
*             ((command_string[2] - 0x30) * 10) +
*             (command_string[3] - 0x30);
* }
*/

FUNCTION :  adjust_int
Arguments :  2 chars
Return Value:  int8

int adjust_int(void)
{
    return ((command_string[1] - 0x30) * 10) +
            (command_string[2] - 0x30);
}

FUNCTION :  decimal_adjust_int16
Arguments :  5 chars
Return Value :  int16

long decimal_adjust_int16(void)
{
    long temp;
    long temp2 = 0;

    temp = command_string[1] - 0x30;
    temp2 += temp * 10000;
    temp = command_string[2] - 0x30;
    temp2 += temp * 1000;
    temp = command_string[3] - 0x30;
    temp2 += temp * 100;
    temp = command_string[4] - 0x30;
    temp2 += temp * 10;
    temp = command_string[5] - 0x30;
    temp2 += temp;
    return(temp2);
}

FUNCTION :  decimal_adjust_int32
Arguments :  6 chars
Return Value :  int32

long decimal_adjust_int32(void)
{
    long temp3;
    long temp4 = 0;
    temp3 = command_string[1] - 0x30;
    temp4 += temp3 * 100000;
    temp3 = command_string[2] - 0x30;
    temp4 += temp3 * 10000;
    temp3 = command_string[3] - 0x30;
    temp4 += temp3 * 10000;
    temp3 = command_string[4] - 0x30;
    temp4 += temp3 * 1000;
    temp3 = command_string[5] - 0x30;
    temp4 += temp3 * 100;
    temp3 = command_string[6] - 0x30;
    temp4 += temp3;
    return(temp4);
}
*/
temp3 = command_string[3] - 0x30;
temp4 += temp3 * 1000;
temp3 = command_string[4] - 0x30;
temp4 += temp3 * 100;
temp3 = command_string[5] - 0x30;
temp4 += temp3 * 10;
temp3 = command_string[6] - 0x30;
temp4 += temp3;
return(temp4);
Figure F1 Electrode geometries used during prototyping, skin contact side (left) and connection side (right)
Figure F2 Chosen electrode geometry, skin contact side (left) and connection side (right)
Appendix G  Software Design

G1.  Detailed flowcharts

Figure G1.1 Main program flow for Biofeedback Software.
3. Manual stimulator control

Connect to stimulator / initialise

Start button pressed?

Timing parameter change?

Electrode change?

NO

Connect to stimulator / initialise

sent start command

Correct response from stimulator?

Increment error counter

Error count = 2

YES

Start timer

Reset timer

Send new on_time / off_time

Correct response from stimulator?

Increment error counter

Error count = 2

YES

Start timer

Reset timer

Send new electrode selection

Correct response from stimulator?

Increment error counter

Error count = 2

YES

Start timer

Figure G1.2 Program branch describing manual control of stimulator, 1 of 3
Figure G1.3 Program branch describing manual control of stimulator, 2 of 3
Figure G1.4 Program branch describing manual control of stimulator, 3 of 3
4. Real-time routines

- Initialise variables and display
- Connect to QTM
- Request h/w parameters
- Read h/w parameters
- Create queue and pre-allocate memory
- Request RT data stream

Producer loop

- Read data from TCP/IP port
- Place valid packets on Queue 1
- USER: Stop button pressed?
- Inform user
- Tell QTM to stop data stream
- Flush queues
- EXIT

Consumer loop 1

- Read Queue 1
- Parse XML data to find parameters
- Extract valid data types
- Associate data with h/w parameters (numbers with labels)
- Interpolate missing frames
- Place complete frames on Queue 2
- Queue 2
- USER: Stop button pressed?
- YES
- Flush queues
- EXIT
- NO

Consumer loop 2

- 4a

Note: the producer and consumer loops 1 and 2 operate in parallel

Figure G1.5 Program branch describing real-time subroutine, 1 of 4
Consumer loop 2

4a

Read Queue 2

Gap fill trajectories

filter trajectories

Within measurement volume?

Inform user

Are data valid?

Informe user

YES

USER: Events required?

Detect heel contact and toe off frames

Calculate stride timing

4b

4c

Figure G1.6 Program branch describing real-time subroutine, 2 of 4
Figure G1.7 Program branch describing real-time subroutine, 3 of 4
Figure G1.8 Program branch describing real-time subroutine, 4 of 4
G2. Biomechanical model (Mathscript code)

%DEFINE PELVIS
rasis = RASIS';
lasis = LASIS';
sacrum = SACRUM';

pelvis_origin=0.5*(rasis+lasis);
tempx= pelvis_origin-sacrum;
y=lasis-pelvis_origin;
z=cross(tempx, y);
x=cross(y,z);

x_unity=x/sqrt((x(1,1)^2)+(x(2,1)^2)+(x(3,1)^2));
y_unity=y/sqrt((y(1,1)^2)+(y(2,1)^2)+(y(3,1)^2));
z_unity=z/sqrt((z(1,1)^2)+(z(2,1)^2)+(z(3,1)^2));

pelvisatog=[x_unity y_unity z_unity]; %pelvis anatomical to global frame

%Define hip joint centres
pelvis_width=sqrt((rasis(1,1)-lasis(1,1))^2+(rasis(2,1)-lasis(2,1))^2+(rasis(3,1)-lasis(3,1))^2);

if (method == 0)
    %two methods to find hip joint centres
    %Determine hip joint centres based on relationships used by Bell(1990): leg lengths not known
    lhjc(1,1)=-0.19*pelvis_width;
    lhjc(2,1)=0.36*pelvis_width;
    lhjc(3,1)=-0.3*pelvis_width;
    rhjc(1,1)=-0.19*pelvis_width;
    rhjc(2,1)=-0.36*pelvis_width;
    rhjc(3,1)=-0.3*pelvis_width;
    else (method == 1);
    %Determine hip joint centres based on relationships used by Davis(1991) - leg lengths known
    markerradius = markerradius/1000;
    leftleglength = leftleglength/1000;
    rightleglength = rightleglength/1000;
    c_left=0.115*leftleglength - 0.0153;
    c_right=0.115*rightleglength - 0.0153;
    theta=28.4*pi/180;
    beta=18.0*pi/180;
    distASIS=pelvis_width/1000;
    Xdis_left=0.1288*leftleglength-0.04856;
    Xdis_right=0.1288*rightleglength-0.04856;
    lhjc(1,1)=(-Xdis_left-markerradius)*cos(beta)+c_left*cos(theta)*sin(beta)*1000;
    lhjc(2,1)=(-c_left*sin(theta)-0.5*distASIS))*1000;
    lhjc(3,1)=(-Xdis_left-markerradius)*sin(beta)-c_left*cos(theta)*cos(beta)*1000;
    rhjc(1,1)=(-Xdis_right-markerradius)*cos(beta)+c_right*cos(theta)*sin(beta)*1000;
    rhjc(2,1)=(c_right*sin(theta)-0.5*distASIS))*1000;
    rhjc(3,1)=(-Xdis_right-markerradius)*sin(beta)-c_right*cos(theta)*cos(beta)*1000;
end;

if(legtype == 0);
    %mechanical rig
    lhjc=[-46;50;-87];
end;
%Rotate and translate hip joint centres to pelvis frames
rhjc_wrt_g=pelvisatog*rhjc+pelvis_origin;
lhjc_wrt_g=pelvisatog*lhjc+pelvis_origin;

%calculate pelvic orientation angles wrt global using yxz sequence
alpha_yxz=-asin(pelvisatog(3,2));
beta_yxz=asin(pelvisatog(3,1)/cos(alpha_yxz));
gamma_yxz=asin(pelvisatog(1,2)/cos(alpha_yxz));
pelvic_obliquity=alpha_yxz*180/pi;
pelvic_tilt=beta_yxz*180/pi;
pelvic_rotation=gamma_yxz*180/pi;

%DEFINE LEFT AND RIGHT THIGHS
llfe=LLFE';
lthigh=LTHIGH';
llhc=LHJC';
a=lthigh-lhjc
mag_a=sqrt((a(1,1)^2)+(a(2,1)^2)+(a(3,1)^2))
b=llfe-lhjc
mag_b=sqrt((b(1,1)^2)+(b(2,1)^2)+(b(3,1)^2))
mag_p = sqrt(((mag_b^2)-(((left_knee_width/2)+markerradius)^2))
theta=acos(dot(a,b)/(mag_a*mag_b))
phi = asin(((left_knee_width/2)+markerradius)/mag_b)
alpha = -(mag_p/mag_a)*(sin(phi)/sin(theta))
beta = (mag_p/mag_b)*(sin(phi+theta)/sin(theta))
p=(alpha*a) + (beta*b)
lkjc=lhjc+p
%

lkjc wrt global

%Unity vector tempz origin at kjc, pointing towards hjc
lz=(lhjc-lkjc)
z_lthigh=lz/sqrt((lz(1,1)^2)+(lz(2,1)^2)+(lz(3,1)^2))
%

%Unity vector x_lthigh orthogonal to tempz
lx=cross(ltempy, lz)
x_lthigh=lx/sqrt((lx(1,1)^2)+(lx(2,1)^2)+(lx(3,1)^2))
%

%Unity vector y_lthigh orthogonal to x_lthigh and z_lthigh
ly=cross(lz, lx)
y_lthigh=ly/sqrt((ly(1,1)^2)+(ly(2,1)^2)+(ly(3,1)^2));
lthighatog=[x_lthigh y_lthigh z_lthigh];
%

%left thigh frame anatomical to global

rlfe=RLFE';
rlthigh=RTHIGH';
rlhjc=RHJC';
a=rlthigh-rlhjc
mag_a=sqrt((a(1,1)^2)+(a(2,1)^2)+(a(3,1)^2))
b=rlfe-rlhjc
mag_b=sqrt((b(1,1)^2)+(b(2,1)^2)+(b(3,1)^2))
mag_p = sqrt(((mag_b^2)-(((right_knee_width/2)+markerradius)^2))
theta=acos(dot(a,b)/(mag_a*mag_b))
phi = asin(((right_knee_width/2)+markerradius)/mag_b)
alpha = -(mag_p/mag_a)*(sin(phi)/sin(theta))
beta = (mag_p/mag_b)*(sin(phi+theta)/sin(theta))
p=(alpha*a) + (beta*b)
rkjc=rlhjc+p
%

rkjc wrt global

%Unity vector tempz origin at kjc, pointing towards hjc
rz=(rlhjc-rkcj)

z_rthigh=rz/sqrt((rz(1,1)^2)+(rz(2,1)^2)+(rz(3,1)^2))
%Unity vector x_rthigh orthogonal to tempz
rtempy=rfe-rkjc
rx=cross(rtempy, rz)
x_rthigh=rx/sqrt((rx(1,1)^2)+(rx(2,1)^2)+(rx(3,1)^2))
%Unity vector y_rthigh orthogonal to x_rthigh and z_rthigh
ry=cross(rz, rx)
y_rthigh=ry/sqrt((ry(1,1)^2)+(ry(2,1)^2)+(ry(3,1)^2));
rthighatog=[x_rthigh y_rthigh z_rthigh]; %right thigh frame anatomical to global

%Calculate right hip orientation angles wrt pelvis
RRm=(pelvisatog'*(rthighatog);
alpha=-asin(Rm(3,2))
beta=acos(Rm(3,3)/cos(alpha))
theta=acos(Rm(2,2)/cos(alpha))
right_hip_abdadd=alpha*180/pi
right_hip_flexext=beta*180/pi
right_hip_rotation=theta*180/pi

%Calculate left hip orientation angles wrt pelvis
LRm=(pelvisatog'*(lthighatog);
alpha=-asin(Lm(3,2))
beta=acos(Lm(3,3)/cos(alpha))
theta=acos(Lm(2,2)/cos(alpha))
left_hip_abdadd=alpha*180/pi
left_hip_flexext=beta*180/pi
left_hip_rotation=theta*180/pi
G3. **Graphical user interface for biofeedback training system**

**Figure G2.1 Main graphical user interface**

**Figure G2.2 Participant database**
2D plots of marker coordinates (red = right leg, green = left leg), joint centres (pale blue) and segment principle axis (red lines)

Figure G2.3 Visualisation of biomechanical model

Marker coordinate plots

Figure G2.4 Marker coordinate plots
Figure G2.5 Relative joint angles (continuous)

Figure G2.6 Joint angles normalised to gait cycle
Figure G2.7 User interface for RT Control of the stimulator

Electrode selection controls. In RT mode they act as displays.

Automatic / Manual control selection

Manual control

Connection status indicator

Automatic control enable

Activation window cursor (left) and static test (right)

Chosen parameters are defined and saved hierarchically

Right knee joint centre y-axis is shown

Figure G2.8 File viewer and example of saved data
Appendix H  Model Validation Results

The following are plots of the hip and knee joint centres for both legs against frame number, taken from a walking trial with one normal subject. They were calculated using LabVIEW and Visual 3D and used for validating the biomechanical model, as described in Section 6.4.1.

Figure H1 Left and right hip joint centres in the x-axes against frame number (top) calculated using LabVIEW (green) and Visual3D (dashed blue). The differences are shown in red (below)

Figure H2 Left and right hip joint centres in the y-axes against frame number (top) calculated using LabVIEW (green) and Visual3D (dashed blue). The differences are shown in red (below)
Figure H3 Left and right hip joint centres in the z-axes against frame number (top) calculated using LabVIEW (green) and Visual3D (dashed blue). The differences are shown in red (below).

Figure H4 Left and right knee joint centres in the x-axes against frame number (top) calculated using LabVIEW (green) and Visual3D (dashed blue). The differences are shown in red (below).
Figure H5 Left and right knee joint centres in the y-axes against frame number (top) calculated using LabVIEW (green) and Visual3D (dashed blue). The differences are shown in red (below).

Figure H6 Left and right knee joint centres in the z-axes against frame number (top) calculated using LabVIEW (green) and Visual3D (dashed blue). The differences are shown in red (below).
Table H1 Frame numbers for left and right initial contact and toe off events, calculated using the LabVIEW algorithm and found directly from force data, bold values indicate data used for validation of the algorithm

<table>
<thead>
<tr>
<th>Walk 0002</th>
<th>LabVIEW Algorithm</th>
<th>Force plate</th>
<th>Frame error</th>
</tr>
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<tbody>
<tr>
<td>RIC</td>
<td>95</td>
<td>400</td>
<td>196</td>
</tr>
<tr>
<td>LTO</td>
<td>100 121 212 315</td>
<td>415 207</td>
<td>-5</td>
</tr>
<tr>
<td>LIC</td>
<td>146 249 351 438</td>
<td>249 0</td>
<td></td>
</tr>
<tr>
<td>RTO</td>
<td>162 264 364 258</td>
<td></td>
<td>-6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walk 0003</th>
<th>RIC</th>
<th>131 232 485 130</th>
<th>-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO</td>
<td>147 247</td>
<td>143</td>
<td>-4</td>
</tr>
<tr>
<td>LIC</td>
<td>183 281</td>
<td>182</td>
<td>-1</td>
</tr>
<tr>
<td>RTO</td>
<td>95 196 295</td>
<td>190</td>
<td>-6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walk 0004</th>
<th>RIC</th>
<th>127 226 326 426 225</th>
<th>-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO</td>
<td>152 241 341 440 237</td>
<td>-4</td>
<td></td>
</tr>
<tr>
<td>LIC</td>
<td>177 276 377 461 278</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>RTO</td>
<td>192 291 391 285 285</td>
<td>-6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walk 0005</th>
<th>RIC</th>
<th>51 151 250 335 151</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO</td>
<td>166 264 362 161</td>
<td>-5</td>
<td></td>
</tr>
<tr>
<td>LIC</td>
<td>103 202 299 384 201</td>
<td>-1</td>
<td></td>
</tr>
<tr>
<td>RTO</td>
<td>115 214 313 207</td>
<td>-7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walk 0006</th>
<th>RIC</th>
<th>152 253 351 151</th>
<th>-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO</td>
<td>167 268 368 163</td>
<td>-4</td>
<td></td>
</tr>
<tr>
<td>LIC</td>
<td>102 203 303 393 204</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>RTO</td>
<td>116 218 318 212</td>
<td>-6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walk 0007</th>
<th>RIC</th>
<th>91 189 291 89</th>
<th>-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO</td>
<td>105 204 307 100</td>
<td>-5</td>
<td></td>
</tr>
<tr>
<td>LIC</td>
<td>141 241 329 141</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>RTO</td>
<td>155 256 149</td>
<td>-6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walk 0008</th>
<th>RIC</th>
<th>150 252 351 150</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO</td>
<td>166 267 368 161</td>
<td>-5</td>
<td></td>
</tr>
<tr>
<td>LIC</td>
<td>100 202 303 392 202</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>RTO</td>
<td>116 216 318 211</td>
<td>-5</td>
<td></td>
</tr>
</tbody>
</table>
Appendix I  Study Documents

II.  Participant information sheet

[INFORMATION SHEET

Biofeedback study

You are being invited to take part in a research study being conducted at the Centre for Biomedical Engineering at the University of Surrey. Before you make a decision it is important for you to read and understand why the research is being carried out and what it will involve. Please take time to read the following information carefully. Please ask if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
We are developing a new device to fit into the socket of a prosthesis which will provide sensations that may help improve the sense of limb position for amputees whilst undergoing rehabilitation. The sensation will be generated by an electrical stimulator (similar to a TENS machine). In order to develop the technology we need to know how amputees respond to the sensation whilst walking. We would particularly like to know if the device changes your walking pattern. The study will form part of my PhD research.

Can I take part?
You will be asked to complete the screening questionnaire provided, to find out if you can participate. Please read through it carefully. We wish to study a group of above-knee amputees over the age of 18 who have none of the following conditions:

- Uncorrected visual, auditory, vestibular or sensory impairments that affect your balance or walking
- Conditions affecting the nervous system, such as seizures or nerve entrapment
- Pregnancy
- Sensitive skin or dermatological problems
- Implanted electrical devices such as pacemakers
- Need to use a wheelchair
- Heart problems

If you have any concerns or queries please ask.

Do I have to take part?
No, you do not have to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Participants will be free to withdraw at any time without giving a reason and with no adverse consequences for education or employment.

What does the study involve?
You will be asked to attend the University Gait Laboratory once, bringing a pair of shorts with you (for motion capture), a hand towel to dry your stump (if required) and a pair of crutches (if you need assistance to move briefly without a prosthesis).

All of the procedures and measurements will take approximately 3 hours to complete. During the visit we will talk you through the process and answer any questions you have. You will then

Centre for Biomedical Engineering, University of Surrey, Guildford, GU27E - Information Sheet Revised 01/2012 Version 1.0
be asked to change into shorts and we will measure the length and circumference of your stump, the range of movement of your leg and we will check the skin condition.

We will then stick 8 self-adhesive electrodes around your thigh, each the size of a ten pence piece. The electrodes are worn inside the socket, in contact with the skin. Wires from the electrodes connect to the electrical stimulator. The electrodes should not affect the socks and liners you normally wear, but you may need to make adjustments for comfort.

When everything is in place, you will have the opportunity to sit down and try the stimulator yourself to get an idea of what the sensation feels like. The stimulator will provide a sensation that moves around the thigh as you walk, depending on your walking pattern. The sensation is similar to running a finger over the surface of the skin.

We will also stick 15 small plastic balls to your legs (using double sided tape) which are used for motion capture. We will then take digital photographs for our reference. You can decide how these images are used.

When you are happy to continue, you will be asked to walk on a treadmill for short periods of time (whilst wearing your prosthesis) with the stimulator turned on. Over the 3 hour visit you will be asked to walk for about 1 hour, with breaks every few minutes. During that time we will monitor how you walk and how you respond to the stimulation. If you are unfamiliar with walking on a treadmill, or don’t feel so confident there will be time to try it out first. We appreciate this can be difficult for some people.

At the end of the session we will remove the markers and electrodes and give you time to change, clean and make any adjustments. We would then like to sit down with you and hear your views about the experience.

Travel expenses up to £30 can be reimbursed from the University, so it is advisable to keep bus or train ticket receipts if appropriate.

What are the possible disadvantages and risks of taking part?
Electrical stimulation is used regularly in many clinical areas, however with prolonged use the sticky electrodes can sometimes cause skin irritation. In those situations reactions do clear up within a few hours. Throughout the study you will have access to a stop button which will switch off the stimulator and stop the sensation. This is provided for your piece of mind and you are free to use it at any time.

We would like you to walk on a treadmill. If you are haven’t tried this before or don’t feel confident walking on a treadmill, there will be time to try it out and see if you feel ok to continue. There is no rush and no obligation to continue if you don’t wish to. The treadmill does have handrails for support.

What are the possible benefits of taking part?
It is unlikely you will have any direct benefit for taking part in the study. However, we hope that the work will help in the design of a device for enhancing the sensation amputees receive from their artificial legs. We believe that this work will help to develop the device.
How will your data be used?
We may use your photographs for teaching and presenting the research. There is a section on
the consent form for you to give permission for this or not if you wish. If you do consent we can
cover your face in any photographs so that you remain anonymous. All information that is
collected about you during the course of this research will be kept strictly confidential and any
information about you that leaves the University will have your name removed so that you
cannot be recognised from it. You GP will be contacted with your agreement. You may wish to
discuss this with your GP.

Who is organising and funding the research?
This research is funded by the Engineering and Physical Science Research Council. No
payment is being made to the investigators for running this study.
Dr David Ewins is a Consultant Clinical Scientist at the Douglas Bader Rehabilitation Centre,
Queen Mary’s Hospital. He has more than 25 years experience in rehabilitation science and has
been involved in the development of electrical stimulation. David runs a clinic at the hospital,
using electrical stimulation for patients with neurological impairments.

Graham Webb is a PhD researcher at the University of Surrey, under the supervision of Dr
Ewins. He has trained in the NHS (including the Douglas Bader Centre) and has 5 years
experience in medical engineering. He has undergone training in the uses of electrical
stimulation.

What will happen to the results of this research study?
The data will be collected by Graham Webb and analysed by researchers from the University of
Surrey, who have received appropriate training. The results of the work may be submitted for
publication in a peer-reviewed journal. Should this happen, you will be identified only by a code,
the key to which will be held in a secure location by the research team. Other use of identifiable
data will conform to your wishes as given in the consent form.

What if something goes wrong?
You are expected to comply with instructions given to you during the study and to co-operate
fully with the investigators. You should inform us immediately if you suffer any deterioration
of any kind in your health and well being, or experience any unexpected or unusual symptoms.
However, you will be free to withdraw from the study at any time without needing to justify your
decision and without prejudice.

Advanced first aid facilities are available if required in the event of an emergency (such as
cardiac arrest). A medical emergency is unlikely to occur as a result of this study.

The University of Surrey holds two types of insurance to cover claims arising from its
involvement in clinical trials, liability and no-fault. The liability policies cover the University
against liability claims (where the University is at fault). The no-fault policy is intended to
provide compensation to subjects, regardless of liability, in the event of their suffering a
significant and enduring injury (including illness and disease) which, on the balance of
probabilities, is directly attributable to their involvement in the trial.

In the event of you suffering a significant and enduring injury (including illness or disease) as a
direct result of participation in the study, compensation may be paid by the University subject
to certain provisos and limitations. The amount of compensation will be appropriate to the nature,
severity and persistence of the injury and will, in general terms, be consistent with the amount of
damages commonly awarded for similar injury by an English court in cases where the liability has been admitted.

Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study please contact Dr David Ewins. The normal University of Surrey complaints mechanisms may be available to you.

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Duke of Kent Building
University of Surrey
Guildford
SURREY
GU27 TE

Dr David Ewins
Tel: 0208 487 5014
d.ewins@surrey.ac.uk

Graham Webb
01483 689350
a.d.webb@surrey.ac.uk

Should you have any questions regarding this study please contact either of the investigators.

The study has been reviewed and received a favourable ethical opinion from the National Research Ethics Service and the University of Surrey Ethics Committee.
I3. Screening Questionnaire

SCREENING QUESTIONNAIRE for BIOFEEDBACK STUDY

The following questions will help us determine your suitability to take part in this study. All information will be kept strictly confidential.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have visual, auditory or vestibular problems that affect your balance or walking?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Are you pregnant?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Do you have sensitive skin or dermatological problems?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Do you have any condition affecting your nervous system?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Do you have seizures (epilepsy)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Do you have heart problems?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Do you have an implanted electrical device, such as a pacemaker?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Have you had an injury that limits your movement other than the amputation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Do you use or need to use mobility aids, other than a prosthesis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Do you experience problems with high or low blood pressure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Do you have other problems that affect your balance or walking, other than your amputation? (please comment below):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Are you confident to walk on a treadmill, or try to walk on a treadmill (if you have never done so)?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Completed by:
(signature) ---------------------------------------------------------------
(print name) ---------------------------------------------------------------

Reviewed by:
I4. Participation invitation letter

Dear

We are carrying out research with the University of Surrey into a new technique which may help improve the rehabilitation of above-knee amputees. The research involves using electrical stimulation to provide a sensation around the stump as patients walk. It is hoped that this sensation will provide a greater level of feedback and improve the awareness of walking patterns.

We would like to find out how practical this method is, which is why I am writing to you, to ask if you would be interested in taking part in a small pilot study.

The study will take place at the University of Surrey, in Guildford during July and August 2012 and take approximately 3 hours to complete.

I have enclosed further information describing what is involved. Please also read the screening questionnaire to determine if you are eligible to take part.

If you are interested in taking part and meet the criteria, please complete and post the reply slip enclosed using the stamp addressed envelope provided. Graham Webb, my PhD researcher at the University, or I will then contact you to discuss the project in more detail and answer any questions you may have. If appropriate we will then arrange a convenient time for you to participate in the study.

If I do not hear from you within 14 days, I will assume that you do not wish to participate in this study at this time. Please be assured that this decision will have no impact on the future care provided for you by the Hospital.

Thank you for reading this letter.

Yours sincerely

Professor David Ewins
Consultant Clinical Scientist

The Gait Laboratory is associated with the Centre for Biomedical Engineering, University of Surrey, Version 1.1
## I5. Risk Assessment

### Description of the activity:
Investigating an electro-cutaneous feedback device with trans-femoral amputees

### Person(s) undertaking activity:
Graham Webb, Dr David Ewins and volunteer test subjects

### Person carrying out the assessment:
Graham Webb (PhD student, Centre for Biomedical Engineering) Extension: 9350

### Signature:  Date of assessment: 05th May 2011

<table>
<thead>
<tr>
<th>Risk/Hazard</th>
<th>Persons at Risk</th>
<th>Control Measures</th>
<th>Severity (see Table II)</th>
<th>Likelihood (see Table )</th>
<th>Risk rating (see Table 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inappropriate electrode use. For example: Removal of electrodes whilst stimulator is on, incorrect placement of electrodes</td>
<td>Test subjects and experimenter</td>
<td>Experimenters are trained in the correct operation of electrical stimulation and will apply the electrodes to the test subjects according to pre-defined position marks.</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2. Skin irritation caused by reaction to electrodes</td>
<td>Test subjects</td>
<td>The study duration will be short. The stimulator is designed to use biphasic waveforms. Electrodes incorporate a hydrogel layer to minimise high current densities.</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3. Falling due to trailing wires</td>
<td>Test subjects</td>
<td>All wires will be attached to the patient by a waistband prior to any walking.</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4. Temporary localised pain at skin surface due to application of high current</td>
<td>Test subjects</td>
<td>Hardware stop button provided for the test subjects. Software emergency stop button provided for the experimenter. Maximum current provision limited to 100mA.</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5. High pressure points around socket due to stimulation arrays</td>
<td>Test subjects</td>
<td>Some pressure will be absorbed by the socket liner silicone.</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>
In addition to the Faculty of Engineering and Physical Sciences risk management guidance, the Wandsworth Primary Care Trust Risk Management Strategy was used to evaluate the scale of risk. Because the strategy uses a risk severity rating developed by the National Patient Safety Agency which is suited to evaluating studies of this nature. The strategy classifies risks as either Acceptable or Unacceptable. An acceptable risk is “one which has been accepted after proper evaluation and is one where appropriate controls have been implemented. The risk must not only be identified, but also quantified to the maximum practicable, analysed and communicated to the appropriate level of management” (Caulfeild-Stoker 2002). Action should be taken to reduce any unacceptable risks to an acceptable level. All acceptable risks are measured according to their likelihood (or frequency) and severity (or consequences) and entered into a risk matrix (Table 31). The acceptance of a risk should therefore represent an informed decision to accept the consequences and likelihood of that risk. Table shows the risk severity descriptors and Table shows the descriptors used to quantify risk likelihood.

**Table 31 Risk Matrix**

<table>
<thead>
<tr>
<th>Likelihood (frequency)</th>
<th>Severity (consequences)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (Insignificant)</td>
</tr>
<tr>
<td>5 Certain</td>
<td>5 Y</td>
</tr>
<tr>
<td>4 Likely</td>
<td>4 G</td>
</tr>
<tr>
<td>3 Possible</td>
<td>3 G</td>
</tr>
<tr>
<td>2 Unlikely</td>
<td>2 G</td>
</tr>
<tr>
<td>1 Rare</td>
<td>1 G</td>
</tr>
</tbody>
</table>

- Green risks are regarded as low/acceptable, to be investigated by local managers
- Yellow risks are regarded as medium to be investigated by a Senior Manager/Head of Services or equivalent and acted upon where appropriate, including producing an action plan
- Red risks are regarded as high or significant and must be reported at Associate Director level for an action plan to be agreed and implemented, as quickly as possible

**Evaluation of Risk:** All risks in this activity are deemed low/acceptable
### Table I1: Risk severity levels identified by the National Patient Safety Agency

<table>
<thead>
<tr>
<th>Description</th>
<th>Impact on individual</th>
<th>Impact on organisation</th>
<th>Person affected at any one time</th>
<th>Financial Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Insignificant</td>
<td>No injury</td>
<td>No risk</td>
<td>None</td>
<td>Theft/loss up to £1k</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No impact on service</td>
<td></td>
<td>Complaint unlikely</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No impact on environment</td>
<td></td>
<td>Litigation risk remote</td>
</tr>
</tbody>
</table>
| 2 Minor | First Aid  
Minor Injury or Minor illness up to 1 month | Minimal risk  
Slight impact on service  
Slight impact on environment | Very few  
1-2 | Theft/loss between £1k - £5K |
|  |  |  |  | Complaint possible |
|  |  |  |  | Litigation <£50K |
| 3 Moderate | Temporary incapacity. Short term monitoring.  
Additional Medical treatment required up to 1 year | Some service disruption.  
Potential for adverse publicity  
Moderate impact on environment | Small numbers  
3 - 15 | Theft/loss £5k - £25k |
|  |  |  |  | Complaint expected |
|  |  |  |  | Litigation possible >£50k - £500k |
| 4 Major | Major Injury (reportable) major clinical intervention  
Permanent incapacity | Service restriction  
Adverse publicity  
Loss of reputation  
Major impact on environment | 16 – 50 | Theft/loss £25k – £200k |
|  |  |  |  | Litigation >£500 - £1m expected |
| 5 Catastrophic | Death | National Media Interest. Severe loss of confidence | 50+ | Theft/loss over £200k |
|  |  |  |  | Litigation >£1m |

### Table I2: Likelihood (frequency or probability) or risk occurring or repeating.

<table>
<thead>
<tr>
<th>SCORE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RARE</td>
</tr>
<tr>
<td>2</td>
<td>UNLIKELY</td>
</tr>
<tr>
<td>3</td>
<td>POSSIBLE</td>
</tr>
<tr>
<td>4</td>
<td>LIKELY</td>
</tr>
<tr>
<td>5</td>
<td>ALMOST CERTAIN</td>
</tr>
</tbody>
</table>
I6. Ethical and Safety Considerations

**Sensation Study**

No additional ethical issues were identified in relation to the study beyond those normally considered in studies involving healthy adults capable of providing consent. However, electro-tactile stimulation is an uncommon sensation. It is the experience of the author that some patients who receive the higher intensity function electrical stimulation (FES) can be apprehensive about the experience. This is particularly the case when the individual does not have personal control of the stimulator. As such a number of risk mitigation measures were in place which went above and beyond those utilised routinely by FES practitioners in clinical practice. A formal risk assessment was carried out and additional risk mitigation measures are detailed in Appendix H5.

The stimulator was voltage-controlled to ensure changes in skin impedance did not induce high localised currents. Current amplitude was manually controlled using potentiometers. The stimulator was battery-powered and connected to a desktop computer via a USB-based optical isolator. The communications protocol between the computer and stimulator hardware employed a handshaking failsafe routine, whereby both devices confirm their presence every 10 ms. If the connection was broken the stimulation would immediately stop and the user would have been informed. A hand-held stop button was provided for the subject, which would immediately stop the delivery of current from the stimulator and inform the experimenter on-screen. The order of events in the data collection protocol ensured that neither subject nor experimenter could make accidental contact with conducting elements during stimulation.

Prior to the study the stimulator was tested for electrical safety according to BS-EN60601-1 and BS-EN60601-2-10:2001. BS EN60601-1 is the base standard adopted by the UK to conform to the Medical Devices Directive 93/42/EEC. BS-EN60601-2-10:2001 is a particular standard for the requirements of the safety of nerve and muscle stimulators.

The investigation of discomfort required careful consideration. The definition of discomfort was ultimately left to the participant, to ensure that no undue pressure was felt
to be placed on the participant to reach a pre-defined level. It was accepted that this may cause greater variation in the discomfort threshold levels recorded. But it was believed that the participant’s subjective judgment of discomfort would be similar to their judgement in the suitability of a final design. Participants were given the opportunity to control the stimulator and experience the sensation prior to data collection.

The risk assessment also identified the potential for personal injury through the use of a treadmill. Participants were instructed in the use of the treadmill and given an opportunity to gain familiarisation. An emergency stop cord was used. The surrounding area was made clear. Participants were in control of the treadmill and were in clear communication with the investigator throughout the study.

Favourable consideration was received from the University of Surrey Research Ethics Committee (see Appendix H7) prior to subject recruitment.

**Biofeedback Study**

The study employed the use an electro-tactile stimulator to deliver low levels of current to the surface of the skin via adhesive electrodes. The design of the stimulator was based on higher current muscle stimulators which are routinely used for the management of neuromotor dysfunction, such as dropped foot in stroke patients. Patients receiving muscle stimulation are given devices to take home and use themselves. The sensory stimulator used in this study did not aim to produce a muscle contraction, but simply a tingling sensation on the skin surface. As such the device used a lower current than those routinely used for muscle stimulation. Based on this and the clinical experience of the research team, the intervention was considered to present a low risk for participants. Despite this, the use of electrical stimulation can be a new experience for some patients. A number of measures were therefore in place for participant reassurance. The intensity was manually controlled, participants had the opportunity to adjust the intensity themselves to get an idea of what the sensation felt like before the study. A stop button was added which the participants could hold and use throughout the study. The button stops the stimulation immediately and tells the experimenter what has happened. The array of electrodes was connected via one simple mechanical connector, which was shown to the participants. If for any reason the
participant wished to leave, they could disconnect the array themselves. Additional safety features were included in the stimulator design which comply with current EU/UK regulation for the design of electrical stimulators.

Participants were asked to walk on a treadmill for a total of one hour with breaks, during the three hour session. Before doing so they had the opportunity to familiarise themselves with the treadmill. The treadmill controls were demonstrated, including the operation of the stop buttons and the emergency stop cord. The research team were mindful that some amputees are apprehensive of using a treadmill. The participants were established amputees (post one year surgery) and their requirements took precedence over the requirements of the study. The treadmill has a handrail and a chair was made available throughout.

The researchers are aware of and operated under the Caldicott Principles and the regulatory requirements of the Health Professions Council. Data required for processing was entered manually onto an anonymised recording sheet at the time of collection and then entered into a software database for processing for the study. No identifiable data was held on the database or the recording sheet. The recording sheets provided a backup requiring no further contact with the participant.

No serious risk occurred that required a break of confidentiality. The researchers are aware of and will acted within the requirements of the “NHS Confidentiality Code of Practice”.

Participants were made aware that the study is part of a longer term aim, and as such any benefits may not become apparent to them, and any intervention was not available after the study. At the end of the study results were fed back to participants. There are no conflicts of interest.
17. Ethics Committee Responses (Biofeedback study)

Date: 13th February 2012

Mr Graham Webb, PhD researcher
University of Surrey
Centre for Biomedical Engineering
University of Surrey
Guildford, GU2 7XH

Dear Mr Webb

Study title: An investigation of real-time electro-tactile feedback for trans-femoral amputees undergoing gait re-training

REC reference: 12/LO/0032

Protocol number: N/A

Thank you for your letter of the 2nd February 2012, responding to the Committee’s request for further information on the above research and for submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.
Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rctforum.nhs.uk

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering Letter</td>
<td></td>
<td>15th November 2011</td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>2nd February 2012</td>
</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>8th July 2011</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>9th November 2011</td>
</tr>
<tr>
<td>Letter of invitation to participant</td>
<td>1</td>
<td>9th December 2011</td>
</tr>
<tr>
<td>Other: Dr Srdjan Cricovic - Academic Supervisor</td>
<td></td>
<td>9th December 2011</td>
</tr>
<tr>
<td>Other: Dr David Ewins - Academic Supervisor</td>
<td></td>
<td>9th December 2011</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>1</td>
<td>15th November 2011</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>2.0</td>
<td>2nd February 2012</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>1</td>
<td>15th November 2011</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>1.0</td>
<td>1st February 2012</td>
</tr>
<tr>
<td>Protocol</td>
<td>1141111</td>
<td>12th December 2011</td>
</tr>
<tr>
<td>Questionnaire. Screening</td>
<td>1</td>
<td>13th November 2011</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>1.0</td>
<td>1st February 2012</td>
</tr>
<tr>
<td>REC application</td>
<td>IRAS 3.4</td>
<td>9th December 2011</td>
</tr>
<tr>
<td>Response to: Request for Further Information</td>
<td></td>
<td>2nd February 2012</td>
</tr>
</tbody>
</table>

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:
• Notifying substantial amendments
• Adding new sites and investigators
• Notification of serious breaches of the protocol
• Progress and safety reports
• Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/0032 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely

[Signature]

Dr Hervey Wilcox
Chair

Email: joan.baley@imperial.nhs.uk

Enclosures:

List of names and professions of members who were present at the meeting.

“After ethical review – guidance for researchers”

Copy to:

Dr Serge Cirovic
Centre for Biomedical Engineering
University of Surrey
Guildford, GU2 7XH

Mr Glenn Moulton
Senate House
University of Surrey
Guildford, GU2 7XH
A Pilot Study of Biofeedback training in transfemoral amputees EC/2012/22/FEPS Fast-Track

On behalf of the Ethics Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the submitted protocol and supporting documentation.

Date of confirmation of ethical opinion: 1 March 2012.

The final list of documents reviewed by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of the project</td>
</tr>
<tr>
<td>Detailed protocol for the project</td>
</tr>
<tr>
<td>Information sheet for participants</td>
</tr>
<tr>
<td>Consent form</td>
</tr>
<tr>
<td>Screening Questionnaire for Biofeedback Study</td>
</tr>
<tr>
<td>Invitation to Participate</td>
</tr>
<tr>
<td>Risk assessment</td>
</tr>
<tr>
<td>Protocol Submission Proforma: Insurance</td>
</tr>
<tr>
<td>NRES Committee London – Surrey Borders Confirmation of a favourable ethical opinion</td>
</tr>
</tbody>
</table>

This opinion is given on the understanding that you will comply with the University’s Ethical Guidelines for Teaching and Research. If the project includes distribution of a survey or questionnaire to members of the University community, researchers are asked to include a statement advising that the project has been reviewed by the University’s Ethics Committee.

The Committee should be notified of any amendments to the protocol, any adverse reactions suffered by research participants, and if the study is terminated earlier than expected with reasons. Please be advised that the Ethics Committee is able to audit research to ensure that researchers are abiding by the University requirements and guidelines.

You are asked to note that a further submission to the Ethics Committee will be required in the event that the study is not completed within five years of the above date.

Please inform me when the research has been completed.

Yours sincerely,

Glenn Moultin
Secretary, University Ethics Committee
Academic Registry

CC: Professor S Williamson, Chairman, Ethics Committee
## I8. Recording Sheet (Biofeedback study)

<table>
<thead>
<tr>
<th>Subject ID:</th>
<th>Date of visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimenter:</td>
<td>Experimenter Signature:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information sheet given</th>
<th>Prosthetic Side (L or R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening questionnaire given</td>
<td>Treadmill confidence (1 low 10 high)</td>
</tr>
<tr>
<td>Consent form given</td>
<td>Comfortable walking speed (m/s)</td>
</tr>
</tbody>
</table>

### Prescription
- Lining
- Suspension type
- Knee
- Ankle
- Foot

<table>
<thead>
<tr>
<th>Height (m)</th>
<th>Weight (kg)</th>
<th>BMI</th>
</tr>
</thead>
</table>

### Static Examination
- **Skin condition** (pain, ulcerations, rashes or other skin conditions)
- **Leg length (mm)**
  - ASIS to medial malleolus
- **Stump length (mm)**
  - ASIS to most distal point
- **2/3 Stump length (mm)**
- **Thigh circumference (mm) at 2/3 from ASIS**
- **1/8 thigh circumference (electrode spacing)**
- **Knee width (mm)**

### Self-selected stimulation intensity: \( PW = 100\,\text{us}, \; f = 40\,\text{Hz} \)

<table>
<thead>
<tr>
<th>Electrode</th>
<th>User set level (mV)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Walking Files**

<table>
<thead>
<tr>
<th>Walk no.</th>
<th>File name</th>
<th>Start time</th>
<th>End time</th>
<th>Technical issues</th>
</tr>
</thead>
</table>

**Pre-Test Questions**

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The electrodes are comfortable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The electrode wires are comfortable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The prosthesis is comfortable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The prosthesis and liner are fitting well</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The kit feels cumbersome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject ID:</td>
<td>Walk no:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>---------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Mid-Test Questions

<table>
<thead>
<tr>
<th>Comfort</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The electrodes are comfortable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The electrode wires are comfortable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The prosthesis is comfortable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The prosthesis and liner are fitting well</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The kit feels cumbersome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sensation</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>There were moments when the sensation was unpleasant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The sensation felt even around my thigh</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There were unexpected sensations under the electrodes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There were unexpected sensations from other parts of my body</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Association with movement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>It was easy to associate the sensation with my movement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>It was easy to correct my movement to avoid the stimulus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I found the experience frustrating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Focus of attention - I was concentrating on:</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My balance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The stimulus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The prosthesis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The equipment (leads and markers)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain and discomfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treadmill confidence (1 low to 10)</th>
<th>Change to walking speed?</th>
<th></th>
</tr>
</thead>
</table>

How did you feel your walking went? Any other comments
<table>
<thead>
<tr>
<th>Post-Test Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usability</td>
</tr>
<tr>
<td>The electrodes remained in place for the duration of testing</td>
</tr>
<tr>
<td>I would have been happy to wear the system during my rehabilitation</td>
</tr>
<tr>
<td>I would be happy to wear the system on a longer term basis</td>
</tr>
</tbody>
</table>

How did you feel your walking went? Any other comments
Appendix J  Study Results

J1.  Sensation Study Results

[Graphs showing absolute difference (mA) vs. electrode number for supine, treadmill walking, and knee flexed/extended positions at 40 Hz, 60 Hz, and 80 Hz.]
Figure 100 Subject 1 left and right pelvic and thigh relative joint angles normalised to gait cycle: Baseline (blue), post coronal feedback trial (purple), post sagittal feedback trial (red), post session no feedback (orange) and normative reference (green)
Figure 101 Subject 1 left and right pelvic and thigh relative joint angles normalised to gait cycle: Baseline (blue) and normative reference (green)
Figure 102 Subject 1 left and right pelvic and thigh relative joint angles normalised to gait cycle: Baseline (blue), post coronal feedback trial (purple) and normative reference (green)
Figure 103 Subject 1 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post sagittal feedback trial (red) and normative reference (green)
Figure 104 Subject 1 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post session no feedback (orange) and normative reference (green)
Figure 105 Subject 2 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post coronal feedback trial (purple), post sagittal feedback trial (red), post session no feedback (orange) and normative reference (green)
Figure 106 Subject 2 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue) and normative reference (green)
Figure 107 Subject 2 left and right pelvic and thigh relative joint angles normalised to gait cycle: Baseline (blue), post coronal feedback trial (purple) and normative reference (green)
Figure 108 Subject 2 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post sagittal feedback trial (red) and normative reference (green)
Figure 109 Subject 2: Left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post session no feedback (orange) and normative reference (green)
Figure 110 Subject 3left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post coronal feedback trial (purple), post 50:50 feedback trial (red), post session no feedback (orange) and normative reference (green)
Figure 111 Subject 3left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue) and normative reference (green)
Figure 112 Subject 3left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post-coronal feedback (purple) and normative reference (green)
Figure 113 Subject 3 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post 50:50 feedback trial (red) and normative reference (green)
Figure 114 Subject 3 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post session no feedback (orange) and normative reference (green)
Figure 115 Subject 4left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post feedback trial walk 2 (purple), post feedback trial walk 3 (red), post session no feedback (orange) and normative reference (green)
Figure 116 Subject 4 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue) and normative reference (green)
Figure 117 Subject 4 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post coronal feedback trial walk 2 (purple) and normative reference (green)
Figure 118 Subject 4 left and right pelvis and thigh relative joint angles normalised to gait cycle: Baseline (blue), post session no feedback (orange) and normative reference (green)
Appendices

Appendix K  Contents of accompanying DVD

The folder “Ch 4 Stimulator and electrode design” contains:

- Component datasheets in .pdf format.
- Schematics and PCB layouts, viewable using Proteus VSM (ISIS and ARES).
- Fascia artwork in Microsoft Word format.
- stimulator controller 050810b.txt contains the PIC firmware written in c.
- stimulator controller 250610.vi is the PC software for the stimulator as a standalone device, written using LabVIEW.
- stimulator controller 250610.exe is an executable version. Note: the software requires the stimulator to be connected.
- Electrode artwork is contained as .png images and scalable vector graphics files which can be viewed using an open source .svg editor such as “Inkscape” (www.inkscape.org).
- ag803.pdf contains the hydrogel technical specification.

The folder “Ch 5 Sensation study data” contains:

- sensation study data non-amputee.xls is a Microsoft Excel 2007 spreadsheet containing the data collected during the electro-tactile sensation study described in Chapter 5.

The folder “Ch6 System software” contains:

- *.vi files contain the high level code for the Biofeedback training system software and the Data analysis software. Biofeedback System 090812.vi and data analysis 090812.vi are the top level vi’s in each case.

- Biofeedback System 090812.exe and data analysis 090812.exe are executable versions, compiled for the Windows operating system.

Viewing the *.vi files requires LabVIEW 2011 or greater. A 7 day evaluation copy can also be used and is free to download (www.ni.com/trylabview). The Evaluation copy is time limited from the time of download so it cannot be included on the DVD. In the absence of LabVIEW a run-time engine is also required, which is available here: http://joule.ni.com/nidu/cds/view/p/id/2534/lang/en

- LabVIEW generated screenshots of the code are provided if neither of these viewing methods are practical. These are viewable using the included .html files.
The folder “Ch 7 – Biofeedback study data” contains:

- **normal database.xls** contains the normative joint angle data used for comparison with user data.

- **questionnaire responses.xls** contains the individual amputee and group responses to questions regarding training system use, received from participants in the study in Chapter 7.

- **sensation data amputee.xls** contains the threshold and discrimination data collected during the amputee study in Chapter 7.

“Original” data folders contain:

- *.TDMS files** contain the raw data captured and generated by LabVIEW. Data types include: Marker coordinates, joint angles, event frame numbers, feedback presented, frame number.

- **tdm_excel_add-in_2012.exe** is a plug-in to enable the TDMS files to be viewed with Microsoft Excel. Note: the *TDMS index* files are required by the TDMS viewer.

- ***.TSV files** contain the raw marker coordinate data formatted as tab separated variable format which can be read using Qualysis Track Manager. The data were then saved as *.QTM files.

All .TDMS, .tsv and .qtm files contain continuous data (i.e. not normalised to the gait cycle).

“Processed” data folders contain:

- The Microsoft Excel files contain the joint angle data that has been normalised to each stride using the data analysis software. The files are named with the following format: S[subject ID]_[date of trial]_[walk number].xls eg. S1_060812_3.xls

- Microsoft Word files contain the normalised joint angle graphs for groups of walking trials for different test conditions.