Bournemouth University

Two-channel surface stimulation for the correction of drop foot

Earl Merson

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Abstract

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1 Functional Electrical Stimulation (FES) is used for the correction of drop foot. The clinical objective is to promote dorsiflexion to avoid tripping, and mild eversion for stability during loading. Traditional transcutaneous FES systems require the accurate positioning of surface electrodes on the skin so that the appropriate nerves are activated to give the desired muscle response. Many people find electrode positioning difficult.

2 This project examined the feasibility of using two channels of transcutaneous electrical stimulation as an adaptive system to correct drop foot. Both channels were positioned over the branches of the common peroneal nerve at the fibular head, broadly with the 'lateral' channel promoting eversion and the 'medial' channel promoting dorsiflexion. The main focus of the study was the effect on foot posture of changing the currents in each channel (the 'current balance'), and the possibility of using this in an open-loop or closed-loop control system to compensate for variation in electrode position.

3 In support of closed-loop control, a sensor consisting of switches under the heel, 1st and 5th metatarsal heads was used to assess the degree of inversion/eversion during walking. A simple controller was implemented to link the two-channel stimulation system and the foot posture sensor, with the objective of maintaining a target foot posture despite minor variation in electrode position.

4 The study found that with careful set-up the current balance could affect the inversion/eversion of the foot while also maintaining dorsiflexion. However, the range of posture control was sensitive to the electrode positions and so this approach did not significantly reduce the need to position the electrodes carefully. The signal from the in-shoe foot posture sensor was often poorly correlated with foot posture as measured by a goniometer. The control system responded appropriately to its inputs, but its overall performance was limited by the input sensor and the output range of influence. The two-channel technique may have utility as part of a leg cuff system, enabling the user to fine-tune the foot posture once the electrodes are positioned appropriately.

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List of abbreviations

AIS	Anterior intermuscular septum
AROM	Active Range Of Movement
CPN	Common peroneal nerve
CPU	Central Processing Unit
CVA	Cerebrovascular accident (stroke)
DF	Dorsiflexion
DFN	Deep fibular nerve (see DPN)
DPN	Deep peroneal nerve
EMG	Electromyography
EPSRC	Engineering and Physical Sciences Research Council
EV	Eversion
FES	Functional Electrical Stimulation
FSR	Force Sensitive Resistor
HR	Heel Rise
HS	Heel Strike
ID	Identification
IFESSUKI	International Functional Electrical Stimulation Society (United Kingdom & Ireland chapter)
IMU	Inertial Measurement Unit
MS	Multiple sclerosis
NHS	National Health Service
ODFS	Odstock Drop Foot Stimulator
OML	Odstock Medical Limited
PCB	Printed Circuit Board
PF	Plantarflexion
PIS	Posterior intermuscular septum
PROM	Passive Range Of Movement
PWM	Pulse Width Modulation
ROM	Range of movement
SCI	Spinal cord injury
SFN	Superficial fibular nerve (see SPN)
SPI	Serial Peripheral Interface
SPN	Superficial peroneal nerve
TBI	Traumatic brain injury
WFSW	Wireless Foot Switch

Preface

5 Salisbury has been a centre of research into FES since 1984, both as a department of Salisbury District Hospital and its company Odstock Medical Limited. This study is one of a series of PhD studentships sponsored by them and conducted at Salisbury hospital, in association with the universities of Bournemouth or Southampton. The findings of each of these projects, in the clinical and technical domains, are used to shape the development of the FES service and the products for sale to the wider FES community.

Dedication

6 This thesis is dedicated to our FES users, in the hope that we may continue to improve our service to them.

Acknowledgements

7 I would like to thank all those who have helped in this study. In particular, my supervisors: Paul Taylor, Ian Swain and Jon Cobb. Their guidance, experience and encouragement have been instrumental in helping me follow the research path.

8 This study was made possible through funding by Odstock Medical Limited (a company owned by Salisbury NHS Foundation Trust) and a Bournemouth University EPSRC studentship.

9 I am grateful for the assistance of the New Products Department at Odstock Medical Limited. As noted in the Author's Declaration on the next page, I developed the circuit for the stimulator based on earlier work done by Rob Batty and Rod Lane (which was part of a project funded by the National Institute for Health Research under the “New and Emerging Applications of Technology” programme). The in-shoe foot posture sensor shared the physical form and some circuitry with the OML wireless foot switch developed by Choukri Mecheraoui and Stacey Finn (electronics) and Dominic Nolan (mechanics). Stacey Finn also organised and took notes at a meeting between myself and Paul Taylor to help me plan the discussion chapter of this thesis, which helped conclude the long process of writing up.

10 I am very appreciative of the staff and patients at the National Clinical FES Centre, Salisbury, who volunteered for my experiments, without whom the entire work would have been quite speculative.

11 Finally, I am grateful for the ongoing support and encouragement of my friends, family and colleagues.

Author's declaration

12 The work presented in this thesis is my own. It builds on the work of others and these are noted in the text. In particular:

- The circuit design for the 4-channel stimulator was based on a prototype started by Robert Batty and Rod Lane. Starting with their circuit, I maintained the core architecture of the stimulator (four output stages using a high frequency pulse width modulation to adjust current) but made extensive changes to the detail to improve performance and extended the design to support this study.

- The in-shoe foot posture sensor adopted the mechanical form and parts of the circuit schematic of the OML wireless foot switch developed by Choukri Mecheraoui, Stacey Finn and Dominic Nolan.

- The idea of measuring foot posture using force sensitive resistors acting as switches under the metatarsal heads was proposed in the 'Future Work' section of Robert Batty's MSc thesis (Batty 2009). I developed this further, proposing the specific timing algorithm and implementing and testing the system.

- The volunteer information sheet in Appendix A was based on a template document in use at OML.

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Definitions

Medical terms for ankle posture

16 There are several alternative conventions in use in the medical literature to describe foot posture, with use varying with field and country. This work adopts the nomenclature proposed by the Japanese Society for Surgery of the Foot in (Doya et al. 2010). In particular, the terms dorsiflexion and eversion are used as shown in figure 1.[1]

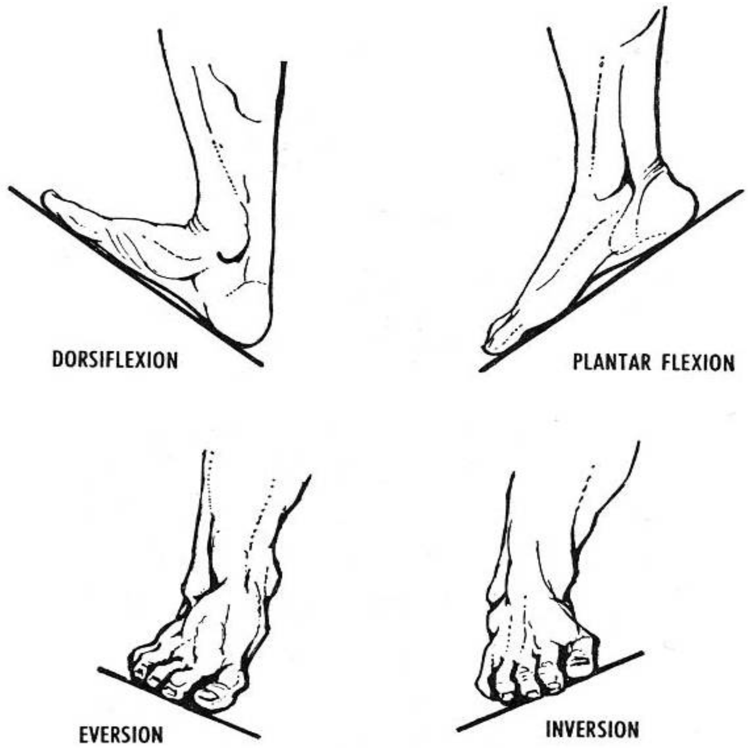

Figure 1: Anatomic terms for foot posture

17 Dorsiflexion and eversion are defined in the sagittal and coronal planes respectively. When the foot rotates out of the anatomic position in abduction or adduction, it is no longer aligned to the principle anatomic planes. For this study, dorsiflexion is measured in the plane containing the tibia and the long axis of the foot and leg (near sagittal), while eversion is measured in the plane containing the tibia and perpendicular to the dorsiflexion (near coronal).

18 The zero reference was taken as the posture during quiet standing, regardless of the orientation of the foot relative to the shoe. In the rest of this study, the orientation of the foot and shoe are used interchangeably, on the assumption that, with good support from the shoe, the offset between them is small and approximately constant.

1 Image from http://www.dartmouth.edu/~humananatomy/figures/chapter_17/17-6.HTM with permission.

1 Introduction

19 This work investigated the feasibility of a potential improvement in the use of functional electrical stimulation (FES) for the correction of drop foot. This chapter introduces drop foot and its treatment with FES, then sets out the new proposal and gives an overview of the project and explains the structure of the thesis.

1.1 Drop foot

20 'Drop foot' is a medical condition where people cannot lift one or both feet when walking, which can cause them to trip and fall. In particular, it refers to the situation where the person cannot activate the muscles of the lower leg to lift (dorsiflex) the foot.

21 Drop foot can arise from diseases affecting the central nervous system, peripheral nervous system or the muscles. FES is in general only used to treat drop foot originating from diseases of the central nervous system because it depends on a functioning peripheral nerve and healthy muscle[2]. Appropriate conditions include stroke, multiple sclerosis (MS), cerebral palsy, spinal injury or traumatic brain injury. In these cases, either the brain cannot initiate the movement or the spine is unable to carry the neural signal. The peripheral nerves and muscles are intact, but receive no stimulus from the central nervous system and so remain unresponsive. Additionally, in the absence of normal neural control, the muscles may develop elevated tone, spasticity or clonus (described later). This may frustrate the action of other muscles in the leg.

22 The prevalence of drop foot is difficult to determine accurately because of a lack of specific formal recording, but the two main conditions relevant to FES treatment are stroke and multiple sclerosis. The prevalence of stroke and multiple sclerosis in the UK is approximately 460,000 (Lee et al. 2011) and 127,000 (Mackenzie et al. 2014) respectively, though not all of these have a mobility disability. Furthermore, FES is not appropriate for all people with drop foot: either because their particular condition or co-morbidity means that FES cannot correct the drop foot, or their wider health problems prevent them from making use of it. Working from incidence and prevalence figures for stroke and multiple sclerosis, and considering the likely proportion with a

2 Direct stimulation of a muscle with a damaged peripheral nerve nerve is possible, but requires much higher energy (and commonly different equipment). This may be too uncomfortable for practical use.

mobility disability and responsive to FES, Odstock Medical estimates[3] that around 60,000 people in the UK would benefit from the use of FES.

23 Drop foot varies in its severity, from a mild reduction in muscle strength, possibly only evident after exercise, to total loss of control of the ankle joint. In people with a progressive neurological disease such as MS, the severity usually increases with time, while non-progressive conditions such as a stroke are generally stable; indeed many stroke survivors continue to recover some function long after the acute phase.

24 Lack of control of the ankle joint has two immediate effects:

- being unable to dorsiflex the foot increases the risk of catching the toes or forefoot on the ground, causing tripping and falling.
- being unable to control the inversion of the ankle presents the risk of spraining the ankle when the person puts weight on that foot.

25 This causes an immediate loss in confidence in walking. The person may adopt compensatory gait patterns to avoid catching their toes or spraining their ankle; this requires more effort that normal walking and may risk joint and skeletal problems from adverse walking posture. The increased effort of walking and fear of falling often lead to people walking less, or even ceasing to walk altogether, which in turn affects their fitness, independence, social participation and quality of life.

26 Drop foot may be accompanied by other neuro-muscular deficits, possibly affecting many muscles. Depending on the medical condition, these may include:

- rapid fatigue
- high tone – the muscle exerts force continually, whether needed or not.
- clonus – stretching the muscle provokes a contraction.
- spasticity – the muscle tone depends on the rate at which it is stretched.

27 Where joints and muscles are not exercised normally, the soft tissues can stiffen, muscles atrophy and range of movement reduce. A slow decline can set in, where walking becomes more difficult, further discouraging walking. If the person is unable to

3 Unpublished report to a local NHS Clinical Commissioning Group, 2015.

take regular exercise, there is a risk of cardiovascular and metabolic problems with serious long term effects..

28 In summary, drop foot can severely limit a persons ability to walk safely, with knock-on effects on their health and independence. Fortunately there are aids to correct drop foot, principally various ankle-foot orthoses (e.g. braces) and functional electrical stimulation (FES). Natural walking is dependent on proper coordination and control of all the joints in the leg, but where drop foot is the main impediment, an ankle-foot orthosis or FES can restore a good level of walking ability.

1.2 FES for the correction of drop foot

29 FES can be used to correct drop foot where the cause is of central nervous origin (NICE 2009), by applying an electrical stimulus to the appropriate nerves of the lower leg. This triggers an action potential to propagate along the nerve, causing the muscles to contract, lifting the foot and holding it in a safe posture for walking. It provides an immediate benefit to walking, and enables greater mobility and exercise leading to an improvement in general health and overall quality of life (Taylor et al. 2013; Street et al. 2015; Street et al. 2017).

30 The muscles recruited to correct drop foot are the tibialis anterior and toe extensors (to promote dorsiflexion) and the peroneal group (to prevent inversion). It is necessary to get the correct balance in activation of these muscles, or else the foot will not clear the ground or adopt a good, stable posture at heel strike. The stimulus is commonly applied using a pair of self-adhesive gel electrodes placed over the branches of the common peroneal nerve (near the head of the fibula) and on the bulk of the tibialis anterior (Figure 2).

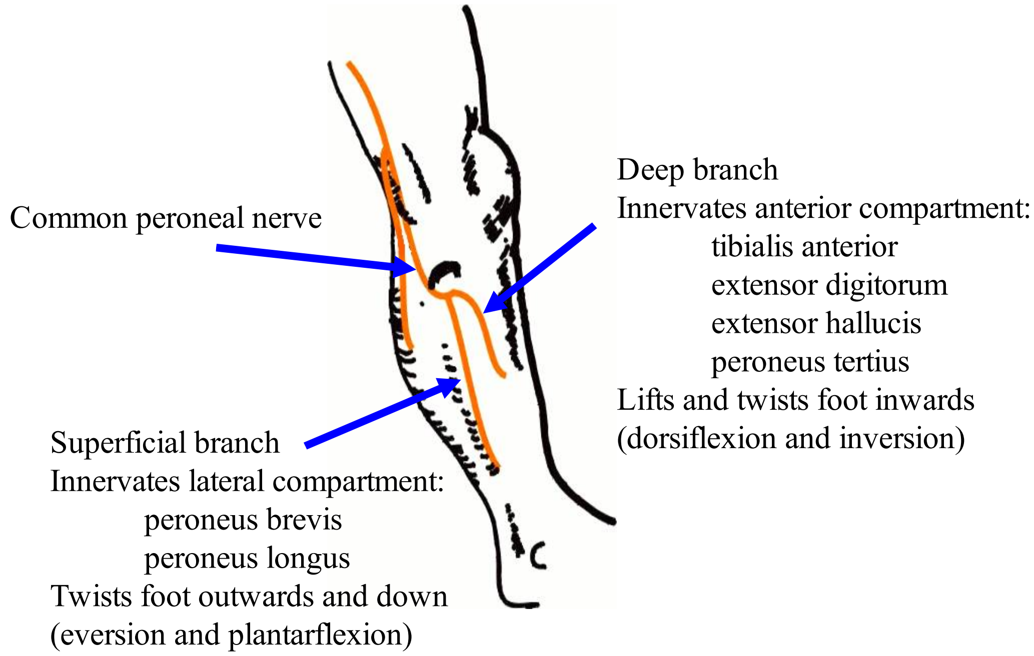

Figure 2: Branches of the peroneal nerve (adapted from ODFS Pace user guide)

31 The strength and direction of the foot response is often strongly dependent on the exact location of the electrodes: just a few millimetres can make the difference between a clinically helpful result or an ineffective or even counterproductive one. The neuromuscular response can vary with fatigue, a change in temperature or progression of the disease, making it necessary to move the electrodes a few millimetres. For this reason, permanent marking of the electrode site (e.g. tattooing) is not recommended.

32 After suitable training most FES users are able to achieve a satisfactory foot posture, although this may require several attempts at applying the electrodes. However, a notable minority have difficulty either remembering what to aim for or how to achieve it, or because their impairment affects their ability to adjust the electrodes. This is common in stroke patients, where the impairment often affects both the upper and lower limb on the same side. For some, this makes their daily set-up so time consuming or arduous that they discontinue use of the equipment (Taylor et al. 1999).

33 Various methods have been proposed to make it easier to set up the electrodes, including:

- Using a leg cuff[4] to hold the electrodes in a chosen position relative to

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4 Example leg cuff systems:
ODFS leg cuff by Odstock Medical, Salisbury, UK;
Walkaide by Innovative Neurotronics, Austin Texas, USA;
NESS L300 by Bioness, Valencia, California, USA.

anatomical landmarks. This helps with dexterity, but is bulky and may benefit from fine tuning for best effect.
- An array of electrodes[5], from which a sub-set is chosen. An automated setup routine is used, simplifying the user experience. This is an expensive and complex solution, and the construction of an electrode array practical for everyday use is as yet unresolved.

34 Effectively, all these systems attempt to place a single channel of stimulation in the optimum place for the balanced recruitment of two muscle groups (tibialis anterior and peroneal muscles).

35 Beyond single channel stimulation, some implanted systems offer multiple channels of control. For example, the STIMuSTEP implanted drop foot stimulator (Finetech Medical, UK) has two channels, connected to the deep and superficial branches of the common peroneal nerve. An implanted system has several important advantages over surface stimulation:
- Independent control of muscle group recruitment
- Excellent channel separation
- No skin irritation (as can be caused by long term contact with surface electrodes)
- Reduced sensory stimulation
- Simple daily application.

36 However, implanted systems are also expensive, invasive and difficult to repair, thus limiting their application to cases where surface stimulation cannot be used (e.g. skin irritation, extreme sensory sensitivity, or patient unable to apply electrodes).

5 For example array systems, see section 3.2

1.3 New contribution

37 This work proposes to correct drop foot using two channels of surface stimulation (one for each muscle group), adjusting the relative intensity of each channel to produce a clinically appropriate degree of eversion along with the main dorsiflexion movement. The relative intensity can be changed electrically, either under manual control or on the basis of recent foot posture (closed loop control).

38 The problem that this aims to address is that some FES users have difficulty achieving the accurate electrode placement required for effective use of traditional single-channel stimulation. Existing alternatives (reviewed further in section 3) are either complex (array electrode systems) or invasive (implanted systems). A two-channel, electrically adjustable surface stimulation system could have the following advantages:

- Accommodate minor inaccuracies in the placement of the electrodes
- Usable with standard electrodes (either plain self-adhesive or as part of a cuff)
- Provide the user with control over effect (e.g. turn a dial for more eversion). This may be used during set-up and (if needed) during the day.
- Simpler than multi-element arrays.

39 For people with limited dexterity and for whom the location of the electrodes is critical, this technique could be useful when combined with a leg cuff. The cuff eases applying the electrodes to the leg, while the two-channel stimulation provides fine control over the effect.

40 As far as the author is aware, the combination of two channels of surface stimulation for the correction of drop foot had not been reported in the literature at the start of this project. However, a conference paper by (Seel et al. 2014) presented a two-channel surface stimulation system also using iterative control to regulate the balance of inversion and eversion. Their approach is contrasted with this project in section 11.2.1, the principle difference being that Seel et al. use an inertial measurement system to measure foot posture. This has the advantage of providing continuous foot posture feedback throughout the gait cycle, but it is more complex and was not available in a practical, in-shoe format at the start of this study.

1.4 Overview of project

41 This study investigated the clinical feasibility of the two-channel surface stimulation technique, in particular its ability to provoke dorsiflexion with an electrically variable eversion in eighteen volunteers with drop foot. The interest was in the practicality of setting up the two-channel stimulation and its basic effect on foot posture.

42 The project started with a literature review of related fields and development of the equipment. Previous work by Robert Batty and Rod Lane at Salisbury Hospital had produced a prototype design for a multichannel stimulator. I built on the earlier design, improving performance and adding features to support the experiments for this project.

43 In unrelated work (Batty 2009), Robert Batty had investigated the movement of the centre of pressure under the foot while walking, and suggested that it might be possible to estimate inversion or eversion based on the timing of the ground contact of the metatarsal heads. I built an in-shoe system to do this, complete with a basic algorithm to turn the contact times into an eversion 'figure of merit'.

44 The development phase produced a body-worn ambulatory stimulator capable of providing controlled two-channel stimulation and wireless telemetry, combined with an in-shoe foot-posture sensor and ankle goniometer interface.

45 Eighteen volunteers participated in a sequence of four experiments, which carefully built up from seated to walking tests. The early experiments established that two-channel stimulation was acceptable to the volunteers and did have an effect on eversion. This was followed by an assessment the performance of the in-shoe foot posture sensor and the effect of two-channel stimulation in walking. Finally, a closed loop control system was introduced to see if it could maintain a target foot posture despite minor changes in electrode position.

46 The naturally varied conditions of daily walking were incorporated into the study: volunteers with a range of impairments walked wearing their own shoes, at their self-selected pace and, if applicable, using their own walking stick. The study demonstrated the feasibility and some limitations of the two-channel technique in a practical setting.

1.5 Aim

47 This investigation was a pilot study to determine the feasibility of using two-channel surface stimulation for the correction of drop foot. In particular, it aimed to examine whether changing the current balance between the two channels can affect the level of inversion/eversion, and whether this can be used to maintain foot posture despite variation in the position of the electrodes.

1.6 Objectives

1. Develop a programmable stimulator capable of influencing foot posture.
2. Develop a sensor system to assess inversion/eversion during everyday walking.
3. Characterise the performance of these systems and their sensitivity to setup.
4. Explore the range of control available using two channels.
5. Combine the sensor and stimulator in a closed loop control system to maintain a reference foot posture despite small changes in electrode position.

1.7 Hypotheses

48 The following hypotheses were proposed, although it should be understood that as a feasibility study with a small sample size, this work does not have the statistical power to draw strong inferences. Although the results may to some extent support or refute the hypotheses, clinical proof is likely to require a larger study. The required size of such a study would depend on the effect size, the variability of population samples and the confidence interval required. At this stage, such consideration is beyond the scope of this feasibility study.

1. Two-channel stimulation will enable a degree of control over the inversion/eversion of the foot: biasing the current to the medial electrode will promote inversion, while towards the lateral electrode will promote eversion.

2. The range of inversion and eversion available as a function of current balance will change if the electrodes are moved by 10mm, representing misalignment of a leg cuff. However, there will be some smaller common range which can be attained for each electrode position by adjusting the current balance suitably.

3. The in-shoe sensor will produce a signal correlated with measurement of eversion by an ankle goniometer.

4. The control loop will adjust the current balance between the two channels to maintain foot posture. This will compensate for minor changes in electrode position.

1.8 Structure of the thesis

49 This chapter has introduced the topic and given an overview of the project. The remainder of the thesis is structured as follows:

- Chapter 2: Background information for readers unfamiliar with FES for the correction of drop foot.
- Chapter 3: A literature review and justification for the approach used in this study.
- Chapter 4: A description of the stimulator and in-shoe sensor developed for this project.
- Chapter 5: An introduction to the experiments and their common aspects.
- Chapters 6 - 10: The method, results and discussion of each of the four experiments and some extended tests.
- Chapter 11: A general discussion of the study.
- Chapter 12: Conclusions and recommendations for future work.

2 Background

50 This section provides information on normal gait, pathological gait associated with drop foot and gait after drop foot correction with FES. Following this is a discussion of neural stimulation in general, and the specific neuroanatomy of the peroneal nerve.

2.1 Normal gait

51 Normal gait consists of the stance period where the foot is in contact with the ground and the swing period where it progresses from step to step. These periods are broken into phases as shown in figure 3 and described in (Tao et al. 2012).

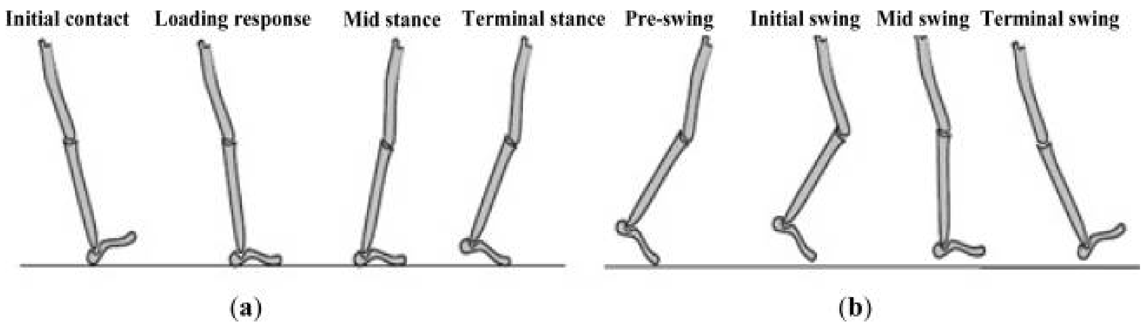


Figure 3: The phases of gait in (a) stance and (b) swing periods. (Reproduced from Tao et al. 2012 under creative commons attribution license).

52 Safe walking is dependent on having the strength and coordination to execute each of these phases. Two particularly important aspects of this are the foot posture at initial contact and ground clearance during swing.

53 The foot posture at initial contact determines the ankle stability as the foot is lowered to the ground and weight is applied to it during load response. If the foot is too inverted, the addition of the body weight will drive the ankle into over-inversion resulting in a sprain and/or fall. The degree of inversion tolerable is a complex function of joint geometry, ligament condition and neuromuscular control. In natural gait, the foot may be slightly inverted during swing, but this lessens in terminal swing.

54 Ground clearance during swing is important for efficient forward progression of the limb. Lack of ground clearance results in scuffing or tripping. The hip, knee and ankle joint all contribute to lifting the foot. Although this study is concerned with correcting drop foot to promote safe walking, deficits in hip or knee flexion (i.e. walking with a

straight leg) can also result in scuffing, tripping and falling.

The foot is positioned by the actions of the muscles of the lower leg (table 1), within the limits imposed by the ankle joint and associated ligaments. The arrangement of the muscles and the tendons connecting them to the skeleton mean that each muscle has a different contribution to dorsiflexion, plantarflexion, inversion or eversion. The muscles must work in balance to achieve a desired posture. In particular, in healthy people, the position of the foot is controlled without active thought so that the forces applied during walking do not result in high inversion or eversion moments around the ankle. This is particularly important when the body weight is applied to the foot at initial contact: the strong dorsiflexion action of the tibialis anterior controls the descent of the foot, but the position is such that there is little need for inversion or eversion forces from the muscles. Although the muscles are able to produce inversion and eversion forces, these are not strong actions; they are primarily used to precisely position the foot, not to resist high moments.

Name	Action	Nerve
Tibialis anterior	Strong dorsiflexion and inversion	Deep peroneal
Extensor digitorum longus Extensor hallucis longus	Dorsiflexion	Deep peroneal
Peroneus tertius	Weak dorsiflexion and eversion	Deep peroneal
Peroneus longus and brevis	Weak plantarflexion and strong eversion	Superficial peroneal
Gastrocnemious and soleus	Strong plantarflexion	Tibial
Tibialis posterior Flexor digitorum longus Flexor hallucis longus	Plantarflexion and inversion	Tibial

Table 1: Principle muscles of the lower leg.

2.2 Drop foot gait

56 Without proper control of the muscles, a number of gait problems can occur:

- Drop foot: lack of activation of the dorsiflexing muscles, particularly tibialis anterior, means the foot does not lift during swing, so the toes or forefoot droop and catch the ground. This results in scuffing which raises the effort of walking, and increases the risk of tripping and falling.

- Ankle instability: without the ability to position the ankle precisely during load response, the body weight may be applied off-centre from the ankle joint. This results in a bending moment driving the ankle into inversion or eversion. In acute cases, this can lead to ankle sprains, while in chronic cases the ligaments will stretch (allowing even more extreme ankle posture) and the joint capsule may be damaged.

- Without normal neural regulation, muscles may develop excess tone (where they exert force at all times), spasticity (their tone increases with rate of stretch) and clonus (repeated reflexive contractions in response to stretching). This limits the ability of the antagonist muscles to perform their role, and may put the foot into an adverse posture. In particular, these effects in gastrocnemious or soleus (both strong plantarflexors) limit the ability of tibialis anterior to dorsiflex the foot, even when using stimulation. High tone in the calf muscles can actively plantarflex the foot, exactly the opposite of what is needed for ground clearance. High tone in the inverters (tibialis anterior or posterior) results in the ankle being actively pulled into a poor (inverted) posture, increasing the risk of ankle sprains during loading.

57 These problems in the lower leg may be accompanied by similar issues affecting the muscles controlling the knee and hip. This often leads to insufficient flexion and hence walking with a 'straight' leg;

58 People often develop compensatory movements to help mobility. These include hip

hitching, circumduction (swinging the leg around to the side), vaulting (rising on the toes of the opposite foot) and a high stepping gait (lifting the knee) as well as changes in stride length and stride symmetry. All these compensations raise the effort of walking, and may place adverse loads on the skeleton, risking developing problems from joint wear and lower back pain (Gailey et al. 2008).

59 Finally, it should be noted that these lower limb problems, may (depending on the medical condition) be accompanied by wider issues such as fatigue, impaired balance and cognitive problems such as reduced spatial awareness.

2.3 Corrected gait

60 As described in subsequent sections, FES can be use to treat drop foot of central neurological origin (NICE 2009), resulting in functional gains. (Taylor et al. 2013; Street et al. 2015) However, the corrected gait is not entirely natural.

61 Current clinical stimulators do not have the subtlety of action of the normal nervous system, so the dorsiflexors are typically somewhat over-activated in order to ensure a sufficient response. Furthermore, care is needed when setting the time when stimulation turns on and off. Turning on too early limits the push-off available in late stance, while turning on too late reduces the dorsiflexion gained in swing. Turning off too soon after initial contact produces 'foot slap' as the foot makes an uncontrolled plantarflexion to the ground, but turning off too late results in more fatigue of the tibialis anterior.

62 The major difference from normal gait is that the stimulated leg does not have the accurate step-by-step positioning of the ankle needed for stability with minimum effort. Indeed, simplistic stimulation of the tibialis anterior alone (to aid ground clearance) could result in severe inversion. To avoid inversion and promote ankle stability in loading, peroneus brevis and peroneus longus are stimulated to produce a mild eversion. To the new FES user, this may feel awkward, as though the foot is hyper-everting. Excessive eversion should be avoided because of risk of damaging the ankle and knee joints and ligaments through loading while in extreme position.

63 Stimulation for drop foot may be augmented by stimulation of the quadriceps,

hamstrings and/or gluteal muscles to improve knee and hip stability during stance or movement during swing. Again, this does not result in a fully natural gait pattern, but may still be beneficial for some people.

2.4 Neural stimulation

64 Nerves at rest maintain their internal potential at about -70mV relative to the extracellular fluid, by a combination of ion pumps and ion channels that control the flow of sodium and potassium ions through the cell membrane. In the resting state, sodium ions are concentrated outside the cell and potassium ions inside the cell. The ion channels are responsive to the potential difference. If the membrane is depolarised to -55mV, the sodium channels open, allowing sodium ions to enter the cell and further reducing the potential. This positive feedback continues until all the sodium channels are open and the potential is reversed. The potential now inactivates the sodium channels and opens the potassium channels. This lets potassium ions leave the cell, restoring the negative membrane potential. Indeed, the membrane is hyper-polarised to more than -70mV until the ion pumps restore the resting ionic concentrations.

65 The above process propagates along the nerve cell and is known as an action potential. The passing of the action potential is followed by an absolute refractory period during which the action potential cannot be repeated (as the sodium channels are still inactive) and a relative refractory period during which a greater depolarisation is require to initiate another action potential (some potassium channels remain open). The absolute refractory period means that action potentials cannot return back on themselves.

66 In natural activation of a nerve, the action potential is initiated by ion channels responding to neurotransmitters (e.g. released from other neurons at a synapse). However, an action potential can also be initiated by an externally applied electric current of sufficient magnitude to depolarise the membrane. This is exploited in FES to activate the nerve; the action potential propagates to the muscle where it initiates a contraction.

67 The voltage along a neuron, and hence the transmembrane potential, can be modelled using the 'cable equation', adapted to account for the properties of myelinated segments

(Einziger et al. 2005). This considers the neuron to be similar to a lossy cable immersed in a conductive medium (as with early submarine cables). The neuron's electrical properties relative to the extracellular fluid mean that the transmembrane potential (and hence susceptibility to activation) is proportional to the second differential of the electrical potential along the nerve. However, the distribution of the electric field itself is dependent on the properties and geometry of the surrounding (often non-isotropic) tissue, complicating the process of modelling electrical neural activation. (Grill 1999)

68 Although the exact locus of nerve activation is hard to predict, the overall muscular response to stimulation is characterised by a current-force recruitment curve, for a given pulse duration, featuring a threshold current below which no motor units are recruited and a maximum current where all motor units are recruited. Maffiuletti (2010) reported a linear curve between these limits, and even a non-linear curve could be approximated by a linear fit. The recruitment curve is exploited in the present study by adjusting the stimulation currents to change the strength of response of the dorsiflexors and everters.

2.5 Anatomy of the peroneal nerve

69 Details of the anatomy of the peroneal nerve are included here to aid understanding of the strategy for positioning the stimulating electrodes later in the thesis.

70 The common peroneal nerve (CPN) is described in (Wheeless 2013) as originating from the L4, L5, S1 and S2 spinal nerves as part of the sciatic nerve. It innervates the lateral head of biceps femoris and continues to the knee. Passing over the lateral head of gastrocnemius it continues through the posterior intermuscular septum (PIS) into the lateral compartment of the lower leg. Division into the deep (DPN) and superficial (SPN) branches occurs either proximally to the PIS or under it. The superficial branch innervates the muscles of the lateral compartment (peroneus longus and peroneus brevis), while the deep branch innervates the muscles of the anterior compartment (tibialis anterior, extensor digitorum longus, extensor hallucis longus and peroneus tertius).

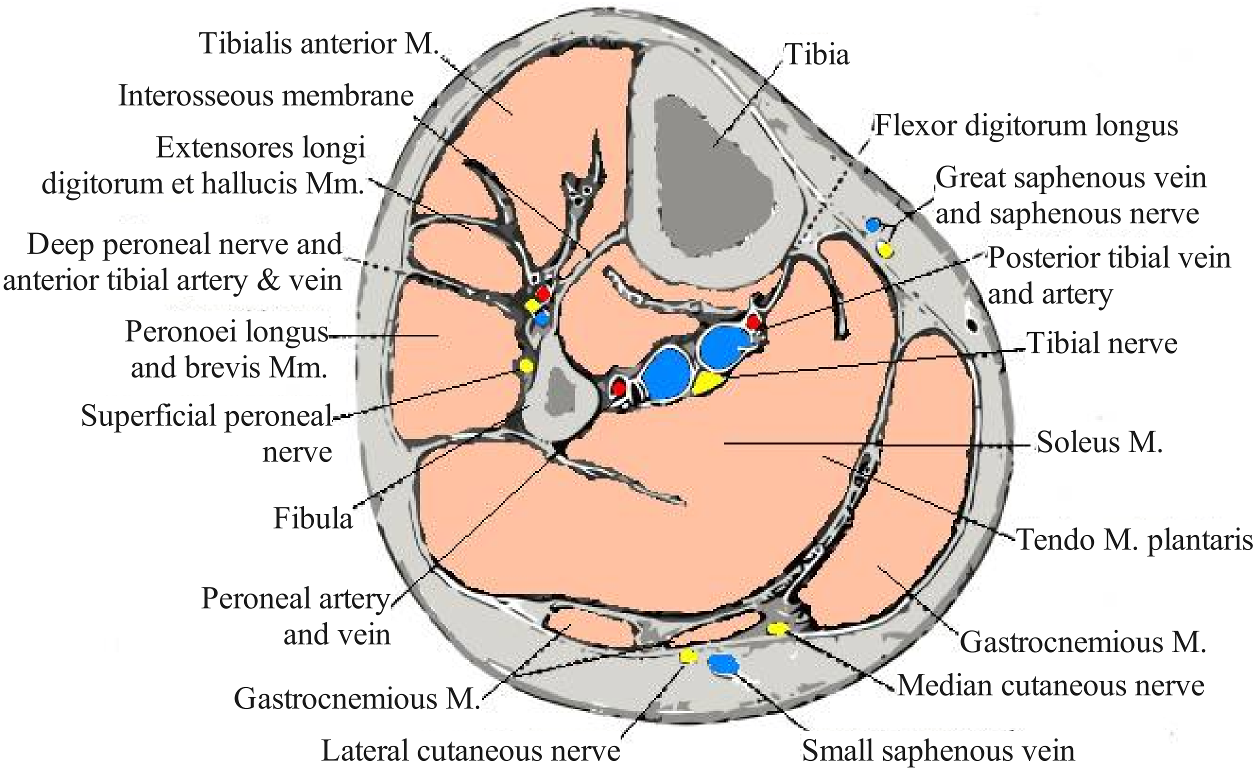


Figure 4: Cross-section of the middle of the lower leg. Image from Wikipedia based on figure 440 in (Gray & Lewis 1918)

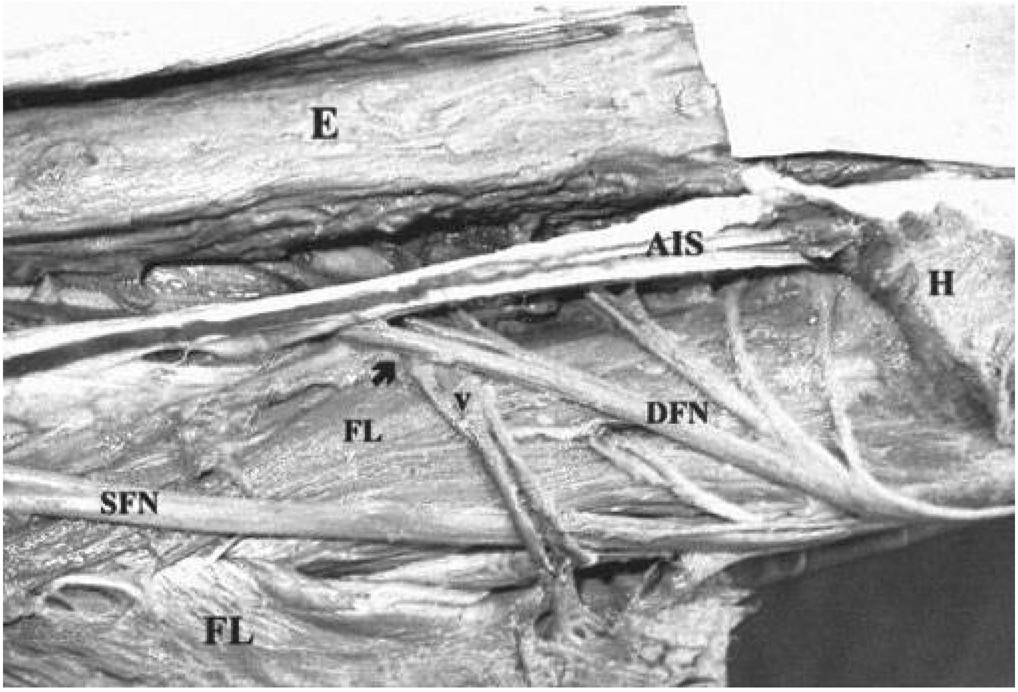
71 As shown in figure 4 (Gray & Lewis 1918), the deep and superficial are a similar depth below the skin (at least in the proximal part of the lower leg), close to the anterior/lateral aspect of the fibula and the interosseus membrane. In a study of 111 elderly legs, Aigner et al. (2004) put this depth at 5.5 mm mean (σ = 0.95 mm, range 4-10 mm) in the region of the fibular head.

72 Aigner et al. (2004) conducted a detailed examination of the peroneal nerves in the proximal lower leg, images from which are shown in figures 5 to 6. (The authors use the terms 'fibular' instead of 'peroneal'). Table 2 provides a key to the abbreviations used in the figures. These images show that the deep and superficial branches initially run adjacent to each other, before diverging. A number of sub-branches depart from the DPN (typically three) within the lateral compartment, crossing the AIS to supply parts of tibilais anterior. Aigner's study found notable variation in both the number of branches and their spatial distribution. Figures 5 to 6 illustrate some of these variations: firstly in the angle of divergence of the DPN and SPN, secondly in the number and location of the branches of the DPN.

DFN	Deep fibular nerve (DPN)	E	Extensor digitorum longus muscle
SFN	Superficial fibular nerve (SPN)	FL	Fibularis longus muscle
AIS	Anterior intermuscular septum	v	Vascular pedicle of fibularis longus
H	Fibular head	ta	Tendinous arch formed by the PIS and FL

Table 2: Key to abbreviations used in figures 5 to 7.

Distal ←



Proximal →

Figure 5: Example dissection of the lateral compartment of the lower leg (1) (Aigner et al, 2004)

73 It is the proximity of the deep and superficial branches and their sometimes slow divergence that gives rise to the positional sensitivity of FES with surface electrodes, and the difficulty of evoking separate dorsiflexion and eversion responses. The intra-subject variability also complicates efforts to position the electrodes suitably, as the individual's neuroanatomy is generally unknown. Despite this, it is hypothesised that two-channel stimulation can achieve selectivity wherever such selectivity is possible by physically moving the electrodes, whilst hopefully being easier to set up.

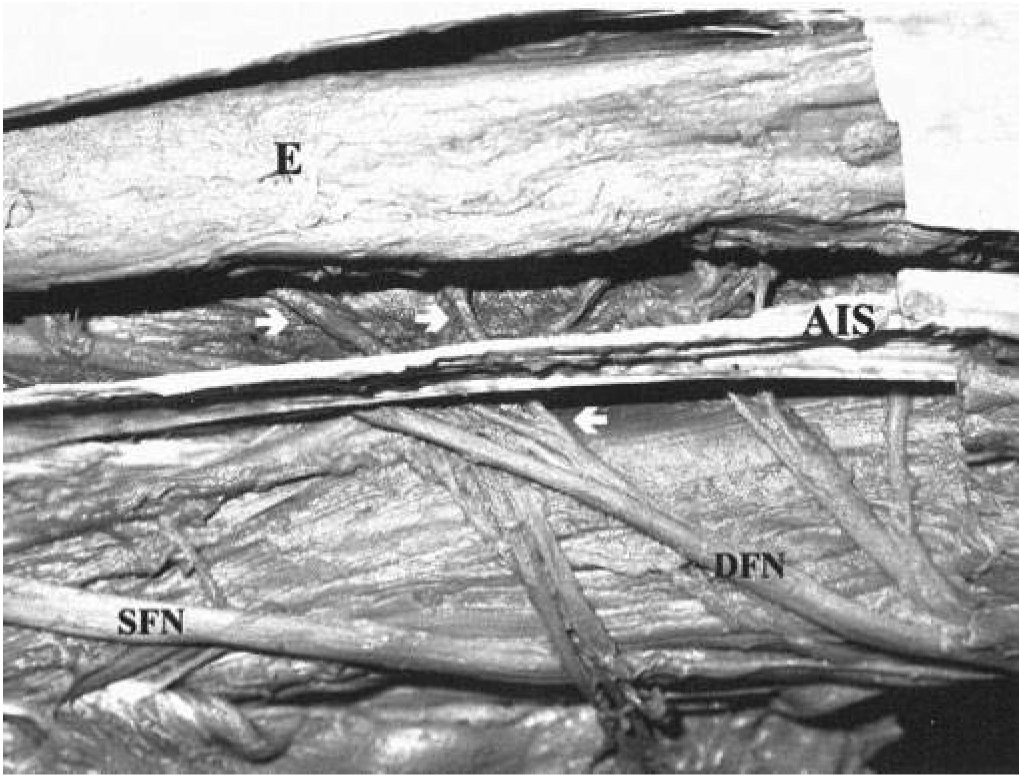


Figure 6: Example dissection of the lateral compartment of the lower leg (2) (Aigner et al, 2004)

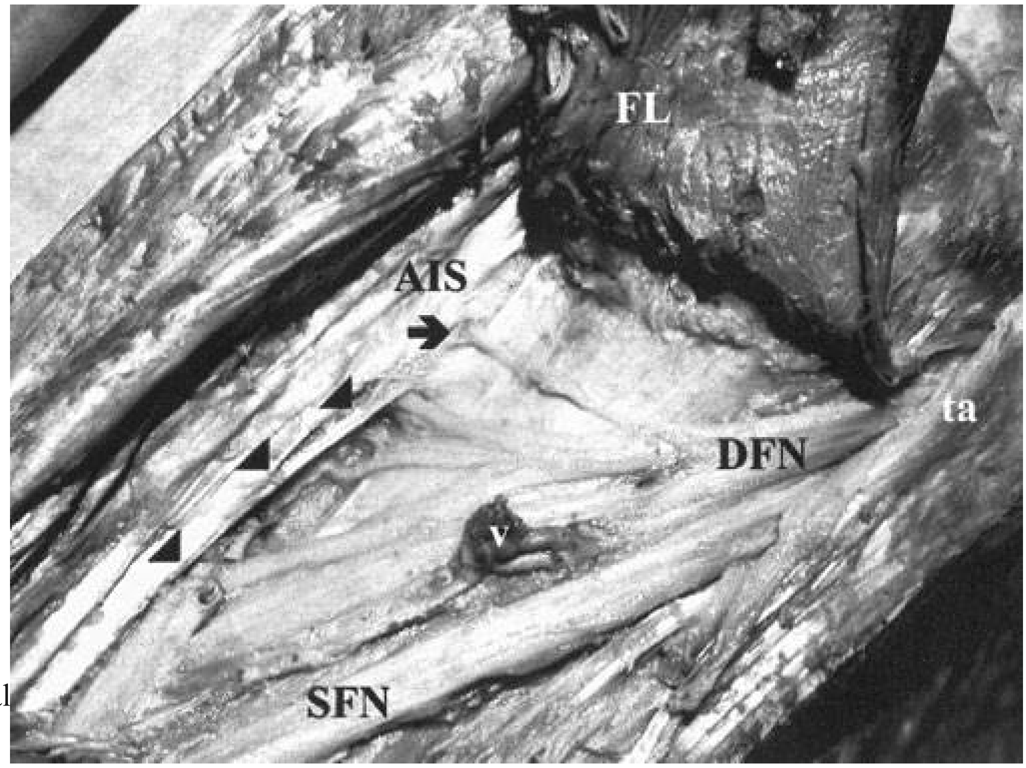


Figure 7: Example dissection of the lateral compartment of the lower leg (3) (Aigner et al, 2004)

3 Literature review

74 The first use of electrical stimulation as a functional orthotic for the correction of drop foot is credited to Liberson *et al. (1961)*. Research in this field has progressed along a number of axes, supporting both theoretical understanding and practical clinical use. These areas include:

- The physiology of stimulation, i.e. the electrochemical behaviour of nervous tissue and the influence of different fields and waveforms on nerves and muscles.

- Electrode technology: materials; geometry; surface and implanted arrangements; modelling and measurement of electric fields and current flow, to better understand how a stimulation can be applied to recruit the required muscles.

- Control of stimulation: sensors to detect posture and events (e.g. in the gait cycle), and algorithms to govern the strength and timing of stimulation (for single or multiple muscle groups) to produce a desired motion.

- The clinical application of stimulation: developing treatment protocols and demonstrating the efficacy and benefits of using FES.

- The technology of stimulation: making equipment more reliable, practical and suited to use in research tasks or daily living.

75 This is a multidisciplinary field, combining aspects of science, technology and health economics. This review focuses on the areas most relevant to the current work, bearing in mind the aim of influencing (and ultimately controlling) the posture of the foot.

3.1 Implanted electrodes

76 Stimulating the nerves directly removes the need to locate and apply surface electrodes. Such systems usually employ two or more channels, enabling the response to be tailored to give an appropriate balance of dorsiflexion and eversion. An invasive operation is needed to fit (and for any repair work) but they avoid all issues associated with placing surface electrodes and the potential for skin irritation from long term contact with electrode gel.

77 In the STIMuSTEP system from Finetech Medical (Welwyn Garden City, UK) (Holsheimer et al. 1993), cuff electrodes are fixed to the two branches of the peroneal nerve. This provides largely independent control over dorsiflexion and eversion, within the constraints of the mechanics of the joint and the action of the muscles. The system uses passive receive coils implanted subcutaneously with the electrodes.

78 The ActiGait system from Ottobock (Duderstadt, Germany) is described as:

> "… an implantable drop-foot stimulator that allows independent adjustment of stimulation output from each of 4 channels via a single nerve cuff. … The implant cuff is placed around the common peroneal nerve, just proximal to its bifurcation into the deep and superficial branches to tibialis anterior and the peronei muscles. At this point the nerve fascicles have become spatially organized within the nerve, so that each set of electrodes within the cuff is adjacent to fascicles travelling to different motor points or muscles; thus activating slightly different movements." (Burridge et al. 2007)

79 The study did not measure the selectivity provided by the four electrodes, but reported that "it was possible to achieve satisfactory ankle movement in walking" in all 13 cases.

80 Webber et al. (2005) reported a case where injectable BION stimulators were used to correct drop foot by targeting the tibialis anterior, extensor digitorum longus and peroneus longus muscles. This enabled a balanced posture to be achieved, although in the case of this subject, tibialis anterior did not produce significant inversion, and so peroneus longus did not need to be stimulated to maintain eversion. Depending on their placement, BIONs can be used to stimulate the nerve or the motor point of the muscle. This enables selectivity with a less invasive procedure than nerve cuff electrodes. However, this system does not appear to be in clinical use for treatment of drop foot.

81 The relevance of these implanted systems to the current work is that they show that a clinically useful foot posture (i.e. suitable combination of dorsiflexion and eversion) can be obtained through the application of appropriate stimulation intensity directly to the deep and superficial branches of the peroneal nerve. Surface electrodes (being much further from both nerves) will have much less specificity; the success of this study will depend on the extent to which foot posture can still be influenced.

3.2 Electrode arrays

82 Many systems have been proposed using transcutaneous (surface) electrode arrays (Elsaify 2005; Heller et al. 2010; Kuhn et al. 2009; Popović-Bijelić et al. 2005; Sha 2008; Silveira 2009; Koutsou et al. 2016). Individual or grouped elements of these arrays are used, altering the effective position of the stimulus. Various automatic setup algorithms are used to select a suitable subset of possible elements. As the number of possible combinations is vast with even a small array, the systems are commonly constrained to use contiguous regions of constant size and shape. Although the algorithms vary between studies, they typically involve brief test pulses followed by further analysis of the most promising locations. This hierarchical process enables the algorithms to narrow the search space quickly and avoid unresponsive areas.

83 These array systems all seek to enable automatic setup (to good clinical effect) without user expertise. Achieving comfortable and robust operation (including the ability to cope with events such as leg spasms or clonus) is a difficult task, as the system can only sense part of the user's response (typically foot posture or gait parameters) and not others such as comfort.

84 The “Shef Stim” (Heller et al. 2010) is a well developed example of such an automated system. It features an 8x8 element array, from which a 4x4 element sub-array is selected for the active electrode. A conventional monolithic self-adhesive gel electrode is used for the indifferent electrode. The hierarchical setup routine uses data from accelerometers mounted on the foot (for the duration of the setup). The system has achieved automatic set-up for functional walking (Heller et al. 2013; Kenney et al. 2016) but a number of difficulties remain:

- Multi-element electrode arrays are large and complex. Research is ongoing to find materials and design for an electrode array that is comfortable, durable, inexpensive and with the required electrical properties. The present design uses a high impedance gel to minimise leakage between the array elements, but the impedance drops significantly within a few hours when in contact with the skin (Cooper et al. 2011).

- Resolution is limited by the pitch of the array elements. This is typically of the order of 1cm (to obtain broad coverage with a practical number of elements.) Such displacements can have a significant effect on foot response. Higher effective resolution could perhaps be achieved by altering the current amplitude within the chosen elements – this is close to the approach chosen in this study.

- The complexity of the system has a penalty in terms of size and cost of the electronics and wiring, much of which is not used beyond setup.

- The set-up process is sensitive to disturbances, and slower than a skilled FES user, but may still find favour where the user struggles to position the electrodes.

- If the automated set-up selects an uncomfortable stimulation regime, the user can choose one of a set of alternatives presented. This is somewhat limiting compared to the fine variation available from moving an electrode or adjusting current across the electrodes.

- Set-up reflects the seated response. Changes in tone when standing mean that a set-up that works well while seated may not be as effective when standing or walking. The user cannot manually adjust their set-up to compensate.

In the 'Kneehab' physiotherapy system (Feil et al. 2011), the electrodes are not organised as an array, but can be placed over an area of interest – in this case, the branches of the peroneal nerve. The controller applies a variable current between combinations of the 16 electrodes in variable time slices. Although this system is intended for therapeutic rather than functional effect, the variable current and time slice technique could be used to change the effective location and strength of stimulation, and thus vary the muscular response.

86 The two-channel approach proposed in this study seeks to improve on the electrode array by being simpler (fewer channels and electrode elements) and providing higher effective resolution (by varying the current on the two channels). This could of course be done within an array system. Furthermore, the proposed system is amenable to either manual or automated set-up, as the main parameter (current balance between the two channels) could be adjusted manually or by a control algorithm.

87 In a wide ranging review of FES technology, (Melo et al. 2015) states that two papers (Malezic et al. 1992; Stanic et al. 1978) addressed the issue of using two channels of surface stimulation to produce dorsiflexion and correct inversion, but the 1992 paper only applied one channel to the peroneal nerve (i.e. classic single-channel correction of drop foot – the second channel targeted other muscle groups or the contra-lateral peroneal nerve). The 1978 paper was not available for this review.

88 Array systems have traditionally used a single virtual electrode (formed from one or more contiguous sub-elements of the array) with a distant common electrode. However, (Heller et al. 2003) demonstrated the ability of two sub-sections of an array to control ankle dorsiflexion and eversion (with some cross-talk). An array provides some flexibility in the size, shape and position of the electrodes at the expense of considerable complexity. In comparison, the simpler discrete electrodes used in this thesis are fixed in size and have to be placed manually, but can be positioned independently of each other. Array systems have a large potential search space (number, size, shape and location of the virtual electrodes, plus stimulation parameters), presenting challenges for automatic set-up. In subsequent work, Heller et al. tackled this by simplifying their system to one virtual electrode of fixed size and shape, resulting in the Shefstim system discussed previously.

89 More recently, the study reported in (Freeman et al. 2016) used multiple array elements targeting multiple muscles in the forearm to evoke a selection of hand gestures (pointing, pinching and hand opening). This multiple-input, multiple-output approach

goes beyond the two-input, two-output method proposed in this study, but would also be applicable to controlling foot posture.

3.3 Sensing foot posture in walking

90 Clinical gait measurement is an established field, with a large body of literature. Here we focus on systems that are suitable for daily use beyond the gait laboratory. That is, low power, unobtrusive and requiring no infrastructure.

91 Numerous studies have proposed Inertial Measurement Units (IMUs) for gait analysis and/or control of FES. The development of reliable IMUs is a field in itself and will not be reviewed here. Advances in miniaturisation have made extremely small sensors, but a full IMU implementation requires considerable signal processing to turn the raw sensor signals from accelerometers and gyroscopes into an orientation measurement. Until recently, this has required a level of power that precluded its implementation in a practical, self-contained, in-shoe system for daily use. During the course of this study, integrated circuits have become commercially available (e.g. Invensens, San Jose, USA) that combine accelerometers, gyroscopes and application specific signal processing at an unprecedented low power of a few milliwatts. This makes battery powered, in-shoe IMUs feasible, but was not an option at the start of this project.

92 In an attempt to avoid the demands of full IMU signal processing, many studies have used simple thresholds or pattern recognition on accelerometer signals alone. This may be sufficient for gait phase detection. However, this project needed a means to assess inversion/eversion during walking, during which the foot experiences both changes in orientation and accelerations often exceeding 1g. Accelerometers alone cannot provide a reliable measurement of orientation angles in the presence of unknown accelerations. The algorithmic complexity and the (then) high power requirement of a full IMU implementation led to a decision not to use this approach.

93 In (Granat et al. 1995), foot switches were used to assess inversion as an outcome measure. Inversion was calculated as the percentage difference between the contact times of the 5th and 1st metatarsal switches. This is close to the Est2 measure used in this work, the difference being that Granat et al. measured the whole metatarsal head contact

time, while in this work the measurement stops at heel rise, giving a reading slightly earlier in the gait cycle but missing out on information from late stance.

94 Sensors based on the timing of foot switches are lower power and simpler to implement than IMUs. There is also the possibility that they are more sensitive to changes in foot posture: a change in inversion/eversion about neutral may correspond to a small angular difference but a significant shift in centre of pressure and hence the activation pattern of the switches.

3.4 Adaptive stimulation

95 In the simplest drop foot stimulators, an on-off switch under the heel controls a pre-set pulse train. The amplitude profile of the pulse train does not depend on foot posture, only on whether the foot is in swing or stance. Many studies have proposed sensors and algorithms to improve the following areas:

- Gait cycle detection: measuring or estimating temporal progress through the gait cycle. In the simplest form this is for better timing of a fixed stimulation envelope; more complex systems seek to change the stimulation profile during the gait cycle according to a template.

- Foot posture control: these systems can vary their stimulation parameters (typically current amplitude or pulse duration) to change the effect of stimulation. For the purposes of this study, we divide these in to 'open-loop' or 'closed-loop' categories as follows:

    - In a closed-loop system, changes to stimulation are made automatically based on feedback from a gait or foot posture sensor.

    - In an open-loop system, stimulation does not change automatically, but the user may make manual adjustments.

96 In this categorisation, we do not consider voluntary user actions (i.e. adjusting controls)

to form a closed loop system, although strictly speaking it could be, potentially with many of the problems (e.g. phase lag and oscillation) that affect automated systems.

97 Various approaches to adaptive stimulation systems are presented here.

98 In (Breen et al. 2006), two force sensors detect heel and toe events (strike and rise) to define four gait phases. The timing of these events is compared with that of recent strides to estimate the progress through the current gait cycle. This information can be used to scale the timing of the pre-determined stimulation envelope. This method matches the stimulation profile to walking speed. It has no direct feedback of foot posture, so cannot compensate for changes in stimulation effect (e.g. due to fatigue).

99 In (Yeom & Chang 2010), filtering is used to isolate the subject's own voluntary EMG signals associated with tibialis anterior activity; these are then used to control the timing and amplitude profile of stimulation. This technique can be used to supplement voluntary efforts *where available and if appropriate.* This takes advantage of the natural sequencing of muscle activation. Unfortunately, if the user's voluntary EMG signal weakens (e.g. as for MS users) then the level of FES assistance goes down, not up. The study did not include the everters as a means to control foot posture.

100 In (Nahrstaedt et al. 2008), the electrical impedance of the front of the ankle joint (measured on the anterior surface) is used to determine dorsiflexion angle. This is then used as feedback to an iterative learning controller, which adapts the stimulation profile after each step so that dorsiflexion follows a set reference profile. The authors reported several advantages. Principally, the stimulation envelope adapts in shape and amplitude, compensating for variation in the neuromuscular system and avoiding the need to overstimulate (common in open loop systems to ensure that minimum dorsiflexion is achieved). The system monitors dorsiflexion throughout the gait cycle; the control algorithm could be developed to prioritise key regions (e.g. where toe clearance is generally most critical). One reported limitation of the given bioimpedance method is that inversion causes errors in the measurement of dorsiflexion. It is possible that multi-channel bioimpedance measurements across the joint could be used to reduce this cross-axis sensitivity.

101 Park and Durand (2008) developed a multiple-input multiple-output controller designed to accommodate the complex and variable transfer function between stimulation (with implanted electrodes) and the resulting motion. In a simulation of a human ankle joint with two degrees of freedom (dorsiflexion and eversion), they achieved good tracking of a reference trajectory despite external disturbances. In (Park & Durand 2015) they further describe *in-vivo* implementation of a dorsiflexion controller for a rabbit ankle joint, using two elements of an implanted 'flat interface nerve electrode'.

102 In (Nekoukar & Erfanian 2010) a sliding mode controller is used to control ankle dorsiflexion by regulating stimulation to dorsiflexors and plantarflexors. The advantages of this approach are its low sensitivity to the characteristics of the neuromuscular system and its convergence on the target posture in a finite time.

103 Beyond drop foot, the use of FES systems to control limb movement has been studied for many years, in applications from standing (Vette et al. 2009; Matjačić et al. 2003; Graupe 2005) to reaching (Freeman et al. 2009). Stimulation is adjusted continuously to control muscle tension and thus limb dynamics. Real-time variable control of stimulation could eventually enable limbs to follow a normal trajectory and hold desired positions. This is a fairly hard class of control problem:

- The neuromuscular response to stimulation is non-linear and varies with time, muscle length and recent stimulation history, let alone the effect of any impairment such as nerve fatigue, clonus or spasticity.

- Most joints have multiple muscles acting over them, while surface stimulation struggles to achieve recruitment specificity.

- Finally, the details of any individual's neuroanatomy and musculoskeletal properties are generally unknown and may be quite variable.

104 As a result, the transfer function from stimulus input to anatomical response is both unknown and variable. In a laboratory setting, where arbitrary sensory inputs can be used and the system can be fine tuned to the particular setup and user's condition on the

day, complex tasks such as balancing while standing can be achieved (with bracing of non-controlled joints). However, this kind of control may not perform well in the constrained environment of daily drop foot correction, where sensor data is sparse and modelling the system in the general case is difficult. There are also limits on the complexity of set-up and the practical burden of apparatus to be worn for clinical use.

105 Two-channel stimulation of antagonist muscles has been proposed to address difficulties in joint control: (Bó et al. 2016) stimulated antagonists to modulate joint stiffness and damping, while (Klauer & Schauer 2016) used the evoked EMG signal to linearise the motor response and compensate for fatigue of stimulated muscles. The benefit of improved control over recruitment must be balanced against the burden of additional electrodes for sensing the evoked EMG signal.

106 (As an aside, multichannel stimulation of sensory nerves in cochlear implants has enjoyed some success, e.g. (Koch et al. 2007). In this case, the position of the nerves around the cochlear spiral is known and we do not have the secondary complication of unknown/variable muscular response.)

107 While general control (for arbitrary limb motion) is a hard problem, the needs of drop foot correction are more relaxed. In particular, a full-range dorsiflexion response is nearly always acceptable; there is no need to gain a fine response. This means that mildly overstimulating (to ensure a firm dorsiflexion) may be acceptable if within sensory limits. That said, a degree of finesse in eversion is desirable, to avoid both inversion and excess eversion.

108 Further simplifying the control problem for drop foot is that the limb is unloaded in swing, so lower forces are needed than standing and there are few disturbances applied to the limb. Also, changes in condition (e.g. fatigue) can be expected to be gradual. The rate of change of stimulation parameters should be limited to avoid startling the user (which may affect their response further).

3.5 Recent developments in two-channel surface stimulation

109 Since the start of this project, a study has been reported by (Seel et al. 2014; Seel et al. 2016) describing their system employing two channels of stimulation to control the level of ankle eversion during swing. The discussion in section 11.2.1 compares the approach of Seel et al. with that used in this study.

110 In February 2017, Bioness, Inc. (Valencia, California, USA) announced a multi-channel drop foot stimulator:

> 111 "Multi-channel stimulation is an additional noteworthy L300 Go feature that allows clinicians to precisely control the amount of dorsiflexion and inversion/eversion the system provides. Using a new, proprietary electrode, medial and lateral stimulation can be adjusted independently."(Bioness, Inc. 2017)

112 No details of the electrode arrangement were given in the press release and the product was not mentioned on the company's website (beyond the press release) at the time this manuscript was prepared.

3.6 Relevant patent

113 International patent WO2011/068823A1 describes a system using three sensors on the sole of the foot or shoe which can be used to calculate the orientation of the foot (specifically inversion/eversion) and then adapt stimulation to control the inversion/eversion. The patent does not give a detailed description of how the signals from the sensors are used, other than to suggest (1) comparison with thresholds, or (2) comparison of medial and lateral signals to determine if 'disproportionate' force is applied to one side. This thesis gives a specific algorithm for a foot posture metric based on the timing of the ground contact at metatarsal heads, and a specific algorithm for adapting the stimulation intensity to control eversion, and then goes on to test these with FES users. As is common in patent documents, there is no indication whether the patented system has been built or its actual performance.

3.7 Summary

114 This literature review has described surface and implanted systems where the effect of stimulation can be varied in order to produce a desirable foot posture. Transcutaneous array systems do this by changing the position of a single channel (on the skin over the peroneal nerve); these systems are complex in construction and setup. Implanted systems work by changing the strength of stimulation directly to the two main branches of the nerve; they are invasive and hence expensive.

115 Real-time limb trajectory control is hard to implement in a clinically practical system. However, the established drop foot systems show that much can be achieved with a simpler, full range response. The proposed system maintains near-full range for dorsiflexion with a quasi-static level of eversion. The use of a slow (step-by-step), iterative controller (with a binary classification of under/over eversion) will help limit the effect of noise and non-linearity in the system, and ensure that any changes to stimulation are made gradually. This is important in maintaining comfort and a steady response.

116 As far as the author is aware, the use of two channels of *surface* stimulation (without an array) for the correction of drop foot was novel at the start of this project. This is probably because a single channel is generally sufficient *for people who are able to position it appropriately*. In clinical practice, multichannel systems tend to be used for additional joints rather than refining the action at one joint (e.g. quadriceps or hamstrings in addition to dorsiflexors). However, many surface stimulation systems with two or more channels could be used as suggested in this study (at least in open-loop control) if the technique is advantageous.

4 Development of equipment

117 This project required a sensor to measure foot posture and a stimulator capable of delivering two simultaneous pulses whose current amplitudes were a function of the foot posture. It was desired that this be an ambulatory system, so that it would be possible to use it on a range of terrain (not just in the laboratory) and practical enough for use by FES users at home. This chapter describes the sensor and stimulator developed for this purpose. Chapter 5 then introduces the experiments where this equipment was used to study the effect of two-channel stimulation.

4.1 Foot posture sensor

118 The purpose of the foot posture sensor is to give an assessment of the inversion/eversion of the foot, both as an outcome measure (to see if stimulation is producing the desired posture for walking) and as feedback for adaptive control of foot posture.

119 As noted in section 3.3, this project desired a solution that could be used not just outside the laboratory, but also in daily life beyond the experimental context. The desire to use the sensor for feedback in normal walking meant that it had to be suitable for everyday wearing: practical, reliable and unobtrusive. In particular, it must not require bulky equipment mounted on the leg, nor require frequent battery changes.

120 These constraints lead to the pursuit of a sensor based on force sensitive resistors (FSRs) which have been used in drop foot stimulator systems for many years (Swain & Taylor 2002). FSRs are low cost, low power and available in thin, rugged packages suitable for use in normal footwear. Typical FSRs based on conductive granules are non-linear and drift with time, temperature and wear. These limitations are addressed by comparison with an adaptive reference level to give a simple on/off indication of ground contact (Swain & Taylor 2002).

121 Traditional stimulators have just one foot switch (mounted under the heel); this project added two further switches, under the 1st and 5th metararsal heads. This was a development of an idea proposed by Robert Batty at Salisbury Hospital (Batty 2009). Batty's work looked at the movement of the centre of pressure during the stance phase

of gait, focusing particularly on the temporal characteristics of the pressure at the 1st, 3rd and 5th metatarsal heads. He observed that the timing of the peak pressure changed with inversion/eversion, and proposed that this could be used to recognise inverted and everted foot posture in walking.

122 This project proposed two algorithms (see section 8.4) to exploit the differences in ground contact time at the metatarsal heads to give a value from -1 (inverted, no medial contact) to +1 (everted, no lateral contact) at each step. The validity of this approach was tested by comparison with an electrogoniometer (see sections 8.5 for the method and 8.6 for the results).

4.1.1 Sensor hardware

123 At the start of this project, OML had just developed a wireless foot switch (WFSW) (ODFS Pace XL kit, Odstock Medical Limited, Salisbury, UK). This has the form of a 7mm thick insole containing a single FSR under the heel, a 3V coin cell and a small printed circuit board (PCB) with a processor and a radio transceiver module. The WFSW is optimised for low power operation and sends a message to the stimulator on every heel rise and heel strike while stimulation is enabled. This project adopted the same mechanical housing, but replaced the PCB with its own (figures 8 and 10) and added two FSRs on short leads, so they could be positioned under the 1st and 5th metatarsal heads. Each FSR (OML part number FSR-NVM) consists of a 25mm diameter sensing element enclosed in a 45mm diameter laminated plastic housing.

124 The circuit included an accelerometer for use when the sensors indicated the foot was flat on the ground; this could be of future use to estimate the slope of the terrain and so compensate (if necessary) for the effect of terrain slope on the inversion/eversion calculation. At this early stage, the project studied walking on level terrain only and did not make use of the accelerometer signal.

125 The circuit also included a 4Mbyte memory chip to log walking data. This could be used either for continuous sensor data sampled at 50Hz and/or summary data calculated for each step (i.e. ground contact times, estimated eversion, etc.). This could be useful in future studies measuring the foot posture that FES users attain during everyday walking

at home and in the community (where set-up may be less than ideal and the environment more complex than a gait laboratory).

126 An external two-axis electrogoniometer (Biometrics SG110/A) was interfaced to the system using a precision digital to analogue converter with a serial peripheral interface (SPI). This measured the 'true' foot posture for later validation of the in-shoe sensor.

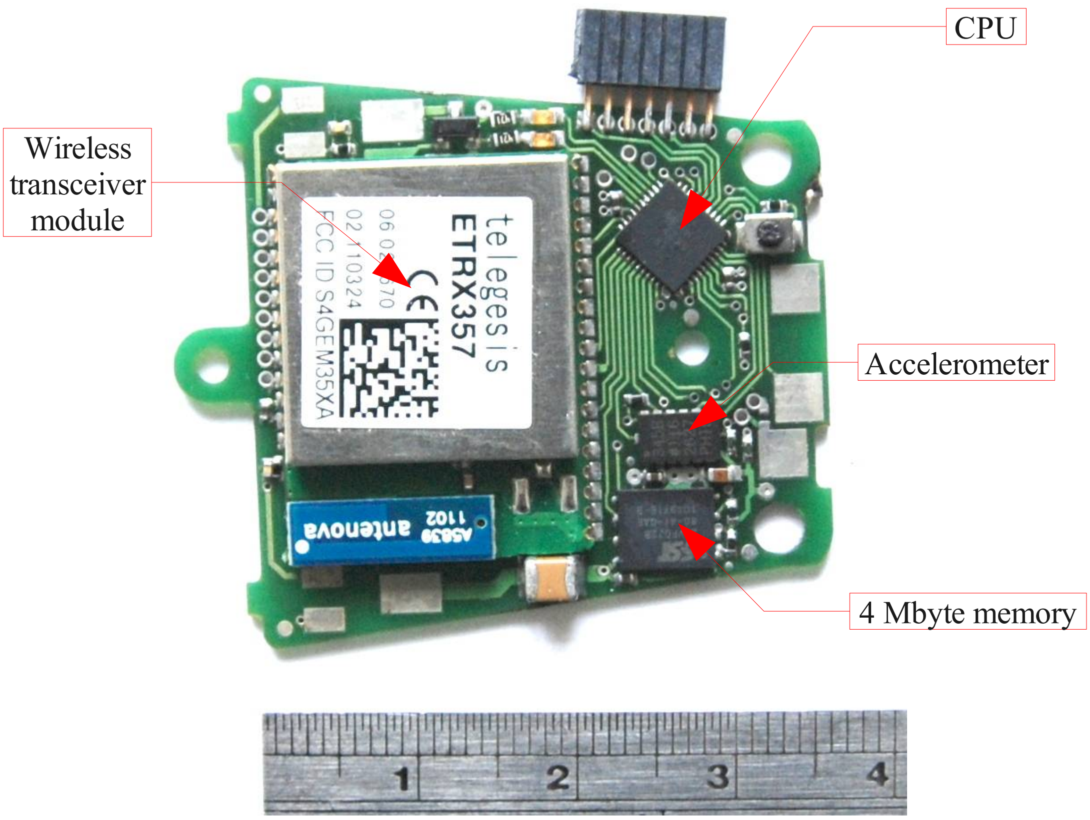


Figure 8: Circuit board for the in-shoe foot posture sensor. (Scale in centimetres)

4.1.2 Sensor Software

127 The processor was programmed to sample the FSRs at 1000Hz to provide high temporal resolution in the detection of gait events and the measurement of ground contact times. As the resistance of FSRs changes with time, temperature and usage, an adaptive threshold was used to determine if the foot was in contact with the ground. An infinite impulse response (IIR) filter was used to produce a long-term average value of the signal; the raw samples were compared with this average (±12.5% for hysteresis) to decide if the heel was in contact with the ground. OML have previously used this filter concept in other products.

128 The CPU collected samples at 50Hz from the accelerometer and the electrogoniometer. These were formed into packets with the most recent FSR samples. These 'sample packets' could be saved to the on-board memory chip, and/or transmitted wirelessly to the stimulator or a computer. The CPU matched the most recent samples from each source, ensuring that the signals were synchronous to within one sample interval. This avoided the need to combine and register separate streams for later analysis. Each packet had a sequence number and time stamp, enabling detection of any missing or out-of-order packets. Error checking and retransmission was handled by the radio module.

129 The CPU measured the contact time of the heel and metatarsal heads (from heel strike to heel rise) for use in the algorithms described in section 8.4. At each heel rise, the CPU calculated the statistics for that step, including contact times, estimated eversion and averaged goniometer readings. These were formed into 'step packets', which could also be saved to the on-board memory chip and/or transmitted to the stimulator or a computer.

4.1.3 Goniometer calibration

130 The later experiments used the electrogoniometer as a measure of the 'true' foot posture. It was therefore important that the goniometer itself produced accurate measurements. The goniometer accuracy was assessed in static conditions by reference to a clinical goniometer. The correlation was better than 0.999 and the electrogoniometer measurements were within 2 degrees of the clinical goniometer (figure 9).

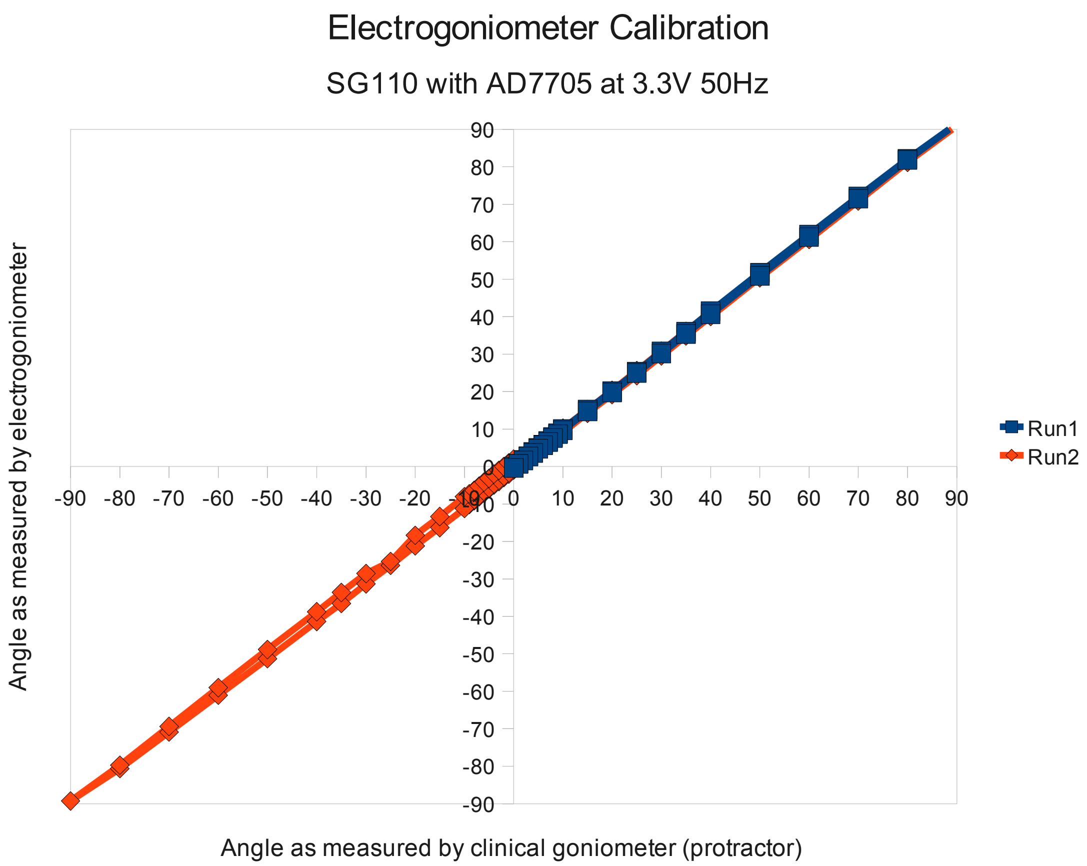


Figure 9: Calibration of the electrogoniometer

4.1.4 Change of sensor hardware

131 The sensor was installed in a prototype OML wireless foot switch insole and tested in walking. Unfortunately, the insole was unable to protect the circuitry from mechanical loading and the circuit failed after 1 hour of use. Similar problems had also been seen in the wireless foot switch. Therefore it was decided to integrate the functionality of the sensor into the stimulator. This lost the convenience of the "wireless, fully in-shoe" aspect of the sensor, and did not support long-term logging. However, neither of these limitations greatly affected this study. The stimulator was easily able to accommodate this extra task, as it featured four sockets for wired foot switches, an external Serial Peripheral Interface (SPI) for the goniometer and had adequate processing capacity. The stimulator is described in detail in the following section.

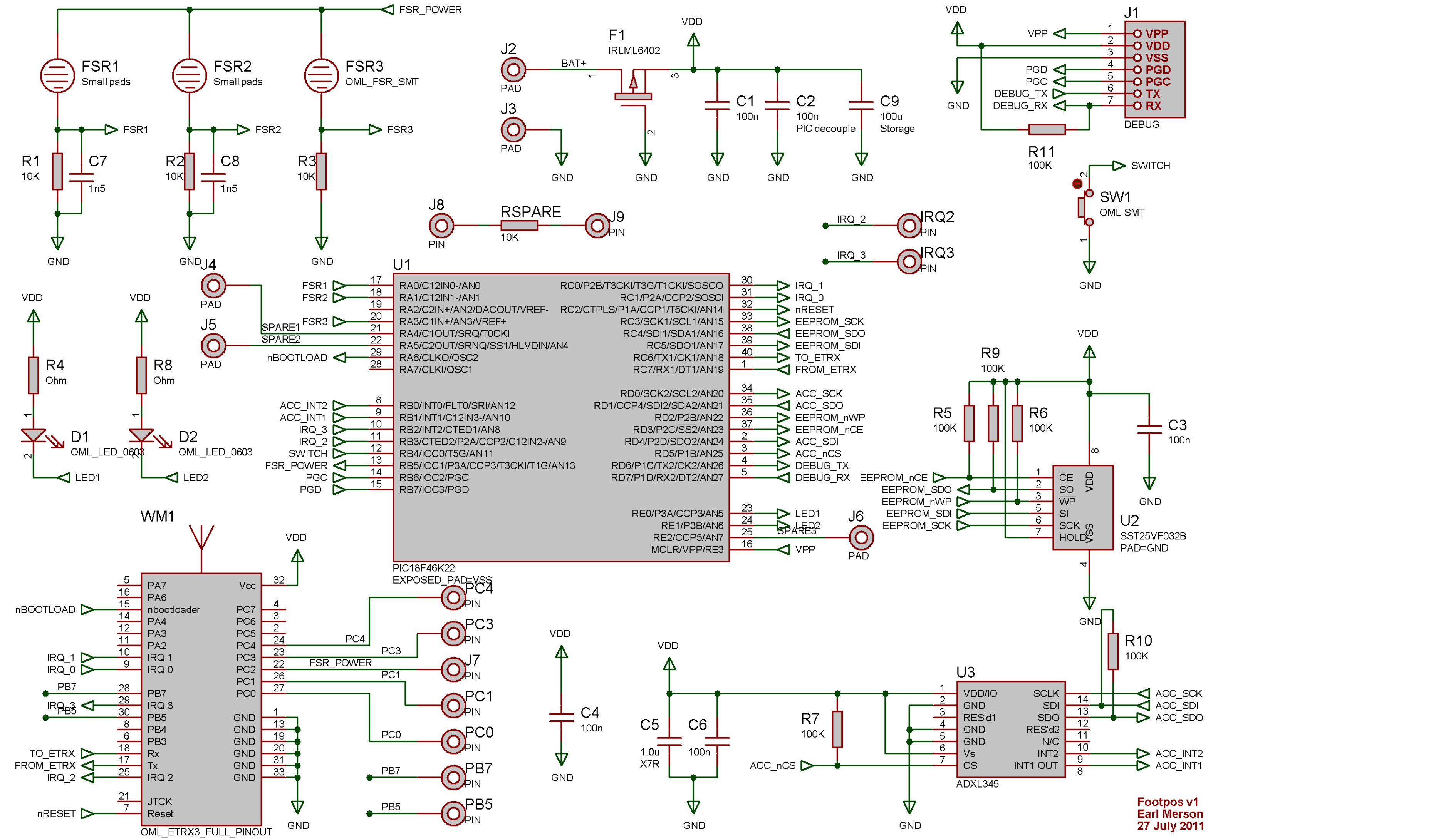


Figure 10: Circuit schematic for the in-shoe foot-posture sensor.

Acknowledgement: this circuit builds on the design of the OML wireless foot switch developed by Choukri Mecheraoui and Stacey Finn, but has a different CPU, an SST25 flash memory chip and revised connectivity.

4.2 Stimulator

132 This section describes the stimulator developed to deliver two-channel stimulation, where the current amplitude on each channel was either set manually or adjusted automatically as a function of recent foot posture.

133 The project involved both seated and walking tests. To avoid affecting the volunteers' walking during the tests, it was desirable that the system be small, lightweight and self-contained in both power and control (i.e. no cabling to computers, power supplies, etc.). This prevented the use of bench-top research stimulators.

134 A compact, portable, programmable, multichannel stimulator was under development at Odstock Medical Limited, as part of a project funded by the Department of Health's New and Emerging Applications of Technology (NEAT) programme. The prototype of that stimulator was incomplete (the hardware did not work and there was no software to control it) but the concept was well suited to use on this project. I therefore continued its development, extending the design to support this project.

135 This section of the thesis provides an overview of the stimulator. A more detailed technical description of the circuit and software can be found in appendix A.

4.2.1 Stimulator design

136 The block diagram of the stimulator hardware is shown in figure 11. Of particular interest is the output stage, designed so that each channel can deliver pulses with a different amplitude, both from channel to channel and (if desired) from pulse to pulse. To achieve this, each channel has a step-up output transformer driven by a transistor H-bridge which is in turn driven by a high speed pulse width modulated (PWM) signal from the central processor. The output circuit is presented in detail in section A.1.6.

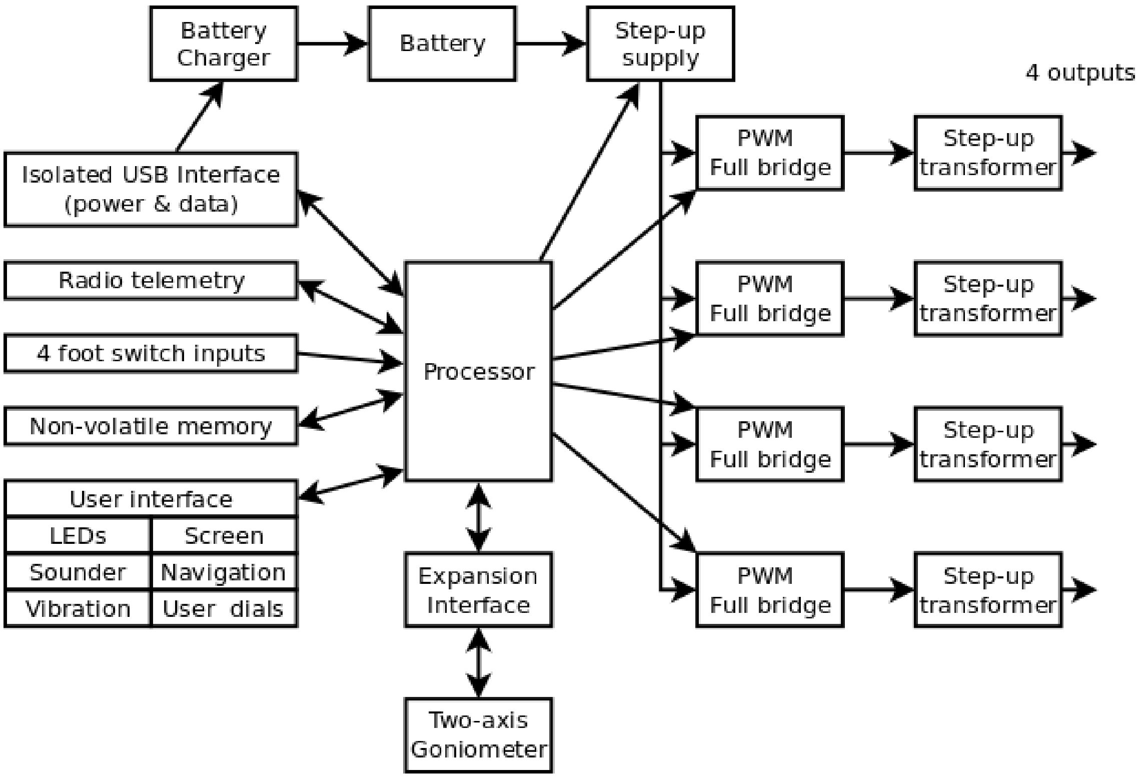


Figure 11: Block diagram of stimulator hardware

137 The PWM frequency (200kHz) is high enough that it is largely filtered by the leakage inductance of the transformer. The pulse amplitude varies linearly with the duty cycle of the PWM signal: at 100% duty it can deliver 100mA peak into a 1kΩ//100nF load, although magnetic saturation of the transformer core limits the duration of such large pulses. The PWM signal is generated by a dedicated hardware module (one for each stimulation channel) on the processor. This makes it possible to alter the stimulation current rapidly between stimulation pulses, as it does not require a change in the supply voltage. However, in these experiments the stimulation current was adjusted slowly to avoid risk of sensory discomfort or stumbling caused by a sudden change in the effect of stimulation.

4.2.2 Output pulse specification

138 The stimulator is designed to deliver charge-balanced pulses of up to 100mA peak and up to 360µs duration into a nominal 1kΩ//100nF load. A typical pulse shape at 50mA peak is given in figure 12. The pulse width of OML stimulators is specified at the drive to the H-bridge rather than the transformer output; any difference is likely to be small and of little consequence as the stimulators are always adjusted for appropriate effect rather than absolute values.

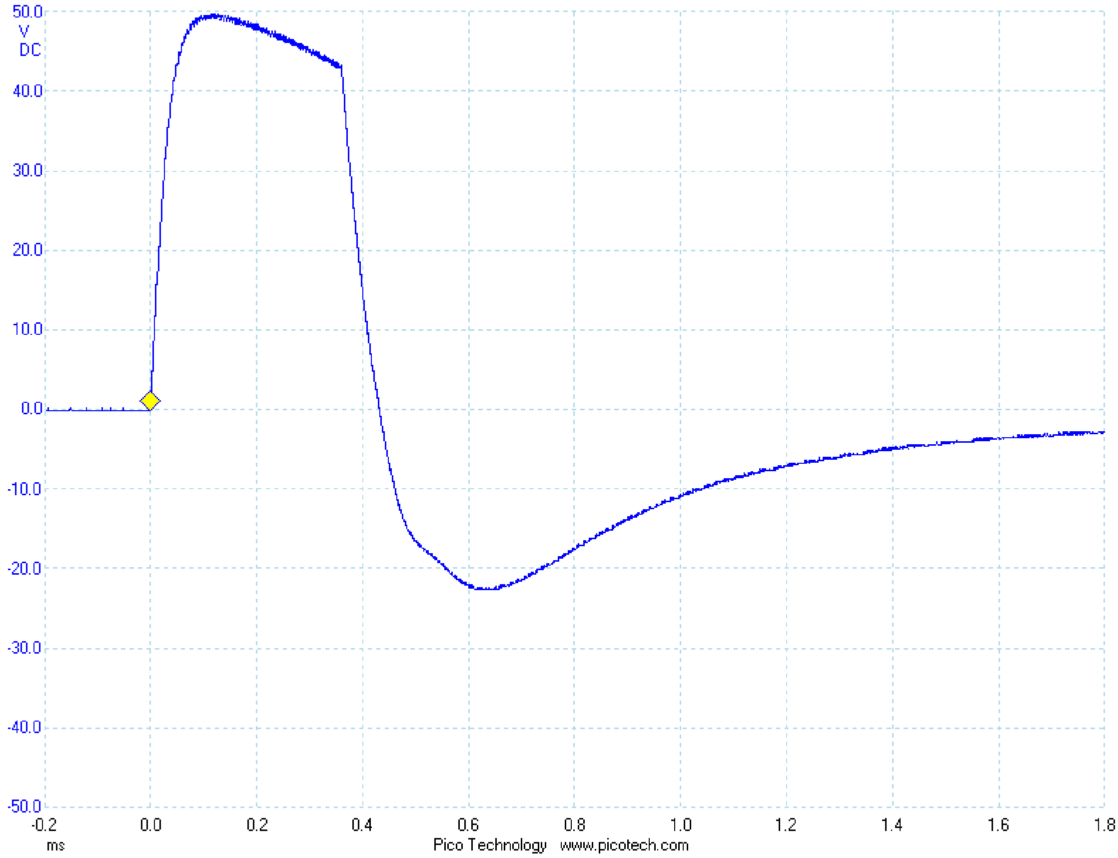


Figure 12: Typical output pulse waveform at 50mA into 1kΩ//100nF load. Axis units: abscissa: milliseconds; ordinate: Volts.

139 Pulses were delivered in trains with a trapezoidal envelope (example in figure 13). Similar pulse trains are used in all OML drop foot stimulators and are comprised of the following sections:

- A rising ramp, where pulse width increases from zero to the nominal level. This reduces the discomfort of sudden stimulation and the risk of provoking an adverse reflex response (e.g. clonus).

- A steady state, where pulse width is constant.

- A short, optional 'extension' phase, where pulse width is held constant followed by a 'falling ramp' during which pulse width is reduced to zero. This maintains the contractile force during the initial eccentric movement during the load response phase of gait, and provides a gradual release of tension to reduce the risk of 'foot slap' during walking.

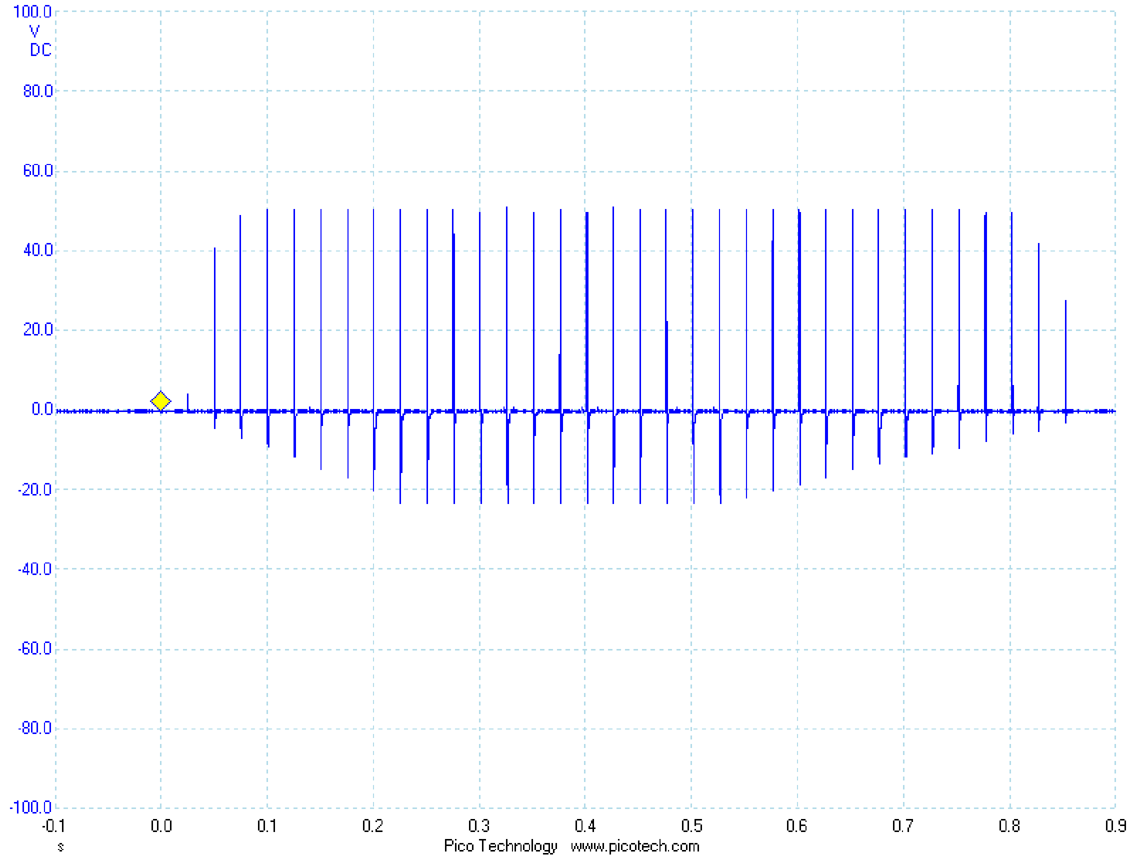


Figure 13: Example of a short pulse train envelope: charge-balanced but asymmetric pulses at 40Hz, rising ramp 200ms, 500ms timeout and 350ms falling ramp. Axis units: abscissa: seconds; ordinate: Volts. Note that during the ramp phase it is the pulse width that increases/decreases. This is not clear from this oscilloscope trace, which shows pulse amplitude. Full pulse amplitude is attained when the pulse width is at least 100µs, even if the pulse width is (as in this case) ramping to 360µs. The pulse intensity (amplitude × pulse width) is reflected in the magnitude of the negative peak.

Table 3 gives the specification of the stimulator outputs.

Parameter	Units	Min.	Max.	Default	Tolerance	Step size
Pulse amplitude into 1kΩ//100nF load (when calibrated).	mA	1	100	1	10%	0.5 (<20) 1 (20-40) 2 (>40)
Pulse width	µs	3	360	180	2%	3
Pulse frequency	Hz	20	60	40	2%	5
Rising ramp	ms	0	2000	200	2%	50
Extension	ms	0	2000	200	2%	50
Falling ramp	ms	0	2000	150	2%	50
Timeout from trigger	ms	0	6000	2500	2%	50
Inter-channel delay	µs	0	10000	0	2%	100

Table 3: Stimulator output specification, based on that of other OML stimulators.

4.2.3 User interface

The user interface consists of the following parts:

- A menu system using a liquid crystal display screen (LCD) and navigation dial, enabling the experimenter to configure the stimulation parameters. The structure of this menu is shown in figure 14.

- A hand-held remote control for the experiment volunteer, featuring:

    - A 'stop' button, which they could use at any time to stop stimulation. In practice, no-one used this during the experiment.

    - A 'test stimulation' button that started a stimulation pulse train with the presently selected settings, to test the effect of those settings.

    - Two dials for adjusting stimulation current and pulse width. The experimenter asked the volunteer to adjust these him/herself in conjunction with using the 'test stimulation' button. This helped ensure that stimulation could be set to a uniformly comfortable level despite variations in the experimental set-up.

- A diagnostic interface on a serial port, providing engineering test facilities.

- Hardware buttons to initiate delivery of stimulation and set the operating mode.

- Lamps to indicate operating mode and stimulation output activity.

- A sounder to acknowledge user actions and indicate progress through the automatic stimulation sequence.

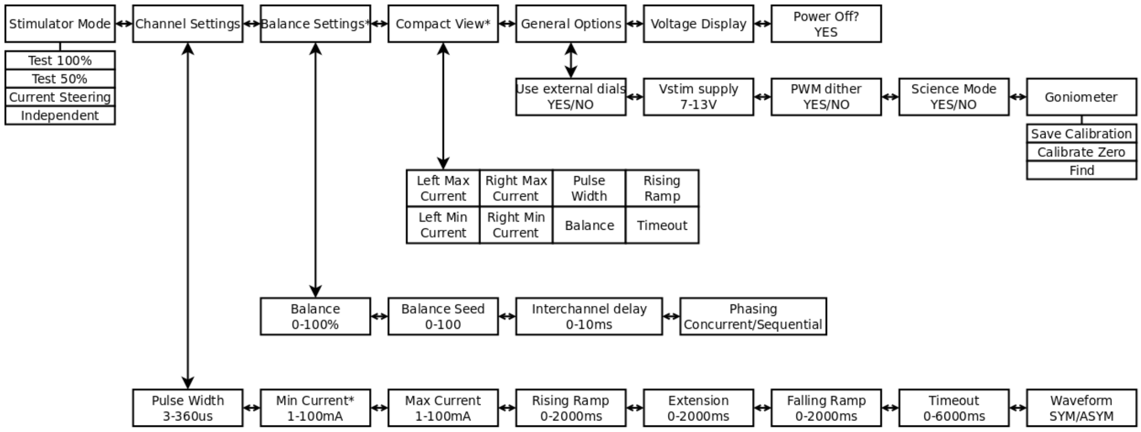


Figure 14: Structure of the stimulator's menu system.

4.2.4 Support for two-channel stimulation experiments

206 As well as providing four independent channels of stimulation, the menu system supports the conduct of the two-channel stimulation experiments presented in this thesis. In 'current steering' mode, a *balance* control enables the current of two channels to be adjusted together, linearly increasing one and decreasing the other, as described in section 7.4.3 and illustrated in figure 15.

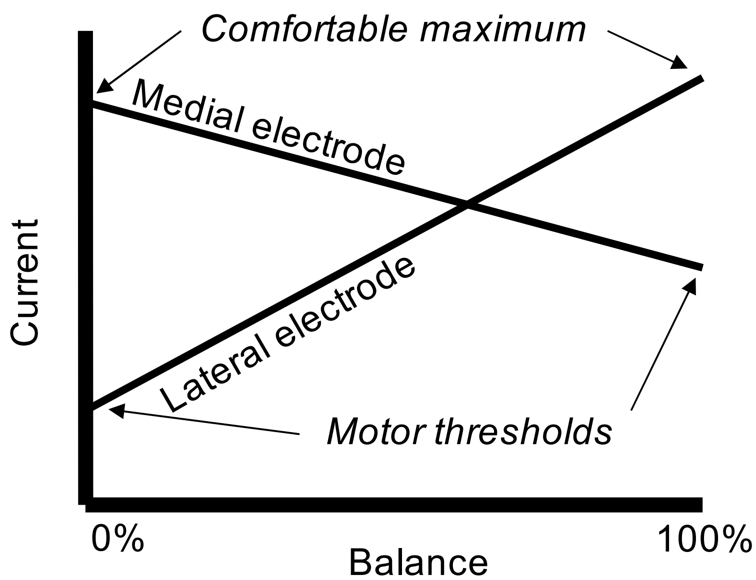


Figure 15: Example of how the current on two channels can be adjusted as a function of the balance parameter. The maximum and minimum currents for each channel are independent and set manually. The two channels can use a common reference electrode.

207 To facilitate the experimentation process, the stimulator has the ability to generate automatic stimulation sequences consisting of short (<1s) pulse trains at 3 second intervals. The stimulator can vary the current of successive pulse trains (between adjustable limits) in a linear or a pseudo-random order. To protect volunteer comfort, pressing any stimulator control cancels this automatic sequence.

4.2.5 Safety

208 It is essential that equipment used in research is safe, both for the volunteers and the experimenter. For this reason, the stimulator was developed with consideration of the medical electrical safety standard BS EN 60601 and the general requirement to avoid unacceptable risks. As an in-house tool which was not placed on the market, the stimulator did not need to be CE marked, but it was desirable that future versions of the system could be. In any case, the UK Medical Devices Regulations implementing the EU Medical Devices Directive require that all medical devices meet the requirements for basic safety. This applies to in-house devices as well as those placed on the market.

209 In addition to general product safety, the fact that the stimulator has conductive connections to the user, delivers electrical stimulation pulses and can be connected to external equipment (i.e. a controlling PC) raises the following areas for special consideration:

- The equipment must protect against electric shock (neither connecting the user to ground nor to sources of hazardous currents).

- The equipment must protect against the delivery of direct current (which can cause electrolysis leading to skin damage).

- The stimulation output must not be sufficient to cause cardiac problems.

210 Protection is provided by the hardware design, not software, as software is hard to make provably error free and has failure modes which it cannot protect against. The hardware protection measures are described in the following sections.

211 The stimulator has a hardware power switch which initiates an orderly shut down of the software, but if held down for three seconds forces the system to power off. This is protection against inappropriate stimulation caused by software malfunction.

4.2.5.1 Electrical Isolation

212 The main risk of electric shock is from faulty equipment applying mains voltages to the user, or by grounding the user and so facilitating current flow through the user from other equipment. The stimulator can be used with non-medically-certified equipment on its USB interface, so it was necessary to provide an isolation barrier to prevent this being a route for current to or from the user. High integrity parts and more than 8mm creepage distance provide two means of patient protection at 250V AC. This enables safe use of the stimulator with an ordinary (non-medical) computer.

213 As well as providing the high voltages needed for stimulation, the transformers provide AC and DC isolation between the channels. This is 'functional' rather than 'safety' isolation, as the windings and dimensions of the transformer are not sufficient to provide a means of protection at mains voltages. As a result, from a safety perspective the majority of the stimulator circuit is regarded as being connected to the patient (as a single applied part). An upgrade to the transformer could address this, enabling the channels to be considered as separate applied parts.

4.2.5.2 Charge balancing

214 The AC coupling of the transformer ensures that the output is charge balanced, even with imbalance in the H-bridge transistors. This reduces the risk of significant electrolysis and electromigration of ions in the skin, which could otherwise lead to skin irritation and harmful skin damage.

4.2.5.3 Limitation of stimulation output

215 The maximum output of the stimulator is limited by the magnetic saturation characteristic of the transformer. This transformer has been used in OML drop-foot stimulators for many years, for which it was selected as it was just able to supply the required pulses of up to 100mA peak and 360μs duration. Even at this level the core has started to saturate and the scope for larger output is very limited.

4.2.5.4 Residual risk

216 Use of electrical stimulation itself presents some risk. In this project, this inherent risk was managed by a combination of:

- Maximising effectiveness and avoid hazardous stimulation practices through training of the experimenter.

- Using volunteers who are experienced FES users and who can take a few steps unaided (in case of equipment failure during the experiment). Further details of the volunteer recruitment process are given in section 5.5.

- Documentation of the design and operation of the equipment.

4.3 Equipment summary

217 This chapter has described the foot posture sensor and stimulator developed in support of the two-channel stimulation experiments. The sensor provides an assessment of the level of inversion/eversion of the foot during gait. The stimulator enables the delivery of stimulation on two channels simultaneously, with the ability to adjust the current balance between the two channels. Furthermore, the stimulator can adjust the current balance automatically based on the signal from the foot posture sensor, or an external goniometer.

218 The following chapter presents the method by which this equipment was used to investigate the effect of two-channel stimulation when the two channels were applied to the muscles of the lower leg.

5 Introduction to the experiments

5.1 Overview

219 The primary aim of this study was to assess the feasibility of using two-channel surface stimulation to direct the foot to a good posture for safe walking. That is: dorsiflexed to reduce the risk of tripping and mildly everted to promote ankle stability during loading. A secondary aim was to assess the use of a new in-shoe sensor as a means of estimating foot posture, for potential use as an outcome measure and/or part of a system for controlling foot posture.

220 A series of four experiments were conducted to investigate the following:

1. The repeatability of response to stimulation (in support of the later experiments).
2. The effect of two-channel stimulation on foot posture (while seated).
3. The performance of the in-shoe sensor.
4. The effect of two-channel stimulation in walking, where the current balance was controlled:
    a) manually, in an open-loop system
    b) automatically, in a closed loop system using either the in-shoe sensor or an external electrogoniometer for feedback.

221 This study used 18 volunteers with various central nervous system impairments, who each participated in one or more of the experiments. The experiments involved applying various stimuli to the branches of the common peroneal nerve and measuring the resulting foot posture (while seated or walking, as appropriate for the particular experiment). In some cases this was repeated at a later date and/or with the electrodes in different positions.

222 This chapter covers topics common to the four experiments:

- Section 5.2 details the equipment used.
- Section 5.3 describes the aspects of set-up common to all the experiments.
- Section 5.4 discusses the ethical considerations of the project.
- Section 5.5 describes the volunteer recruitment process.
- Section 5.6 gives demographic details of the volunteers.

5.2 Experimental equipment

5.2.1 Electrodes

223 Self-adhesive electrodes were used (Axelgaard PALS Platinum), enabling easy repositioning and low risk of discomfort or skin irritation. The common electrode was always a Platinum Blue 5x5cm; the lateral and medial electrodes were either the same, or (in the case of smaller legs) Platinum Grey 3.3x5.5cm. To avoid cross-contamination, each volunteer used a separate set of electrodes.

5.2.2 Stimulator

224 The experiment used two channels of the 4-channel stimulator described in section 4. The stimulation parameters used are given in table 4.

Parameter	**Value**
Waveform	Asymmetric bi-phasic charge-balanced
Current	Self-selected for comfort and effect. Up to 100mA available.
Pulse width	180µs (except where self-selected to maintain comfort/effect)
Frequency	40Hz
Rising ramp	200ms
Falling Ramp	150ms

Table 4: Stimulation parameters used in all tests except where noted.

225 These values (ODFS® Pace defaults) are established clinical practice at Salisbury for the treatment of drop foot in people with stroke and MS: the frequency and pulse width balance recruitment with fatigue, while the ramps are appropriate for typical slow (<1m/s) walking.

226 The seated tests used a time-out of 700ms. Combined with the 200ms rising ramp, this value was similar to the 0.5s swing time typical for post-stroke gait (von Schroeder et al. 1995). The walking tests used a time-out of 2000ms or greater; this was sufficient that stimulation did not stop during swing.

227 In the two-channel tests, both channels stimulated concurrently (zero phase difference). This ensured that all recruited nerve fibres were only stimulated at the base frequency (not twice) and avoided the possible influence of a combination of short inter-channel delays and the nerve refractory period.

5.2.3 Goniometer

228 A twin-axis electro-goniometer (SG110/A; Biometrics, Newport, UK) was used to measure ankle dorsiflexion and eversion. This goniometer has the following specification (from the manufacturer's data sheet):

- Accuracy ±2°
- Repeatability ±1°

229 A clinical protractor was used to check that the static performance of the goniometer was within its specification. Before each experimental session, a set square was used to check the accuracy and repeatability of measurements at ±90° and zero.

230 The goniometer was interfaced to the stimulator using an Analog Devices AD7705 instrumentation amplifier and analogue to digital converter. An anti-aliasing low-pass filter (-3dB @ 16Hz) was used. The AD7705 sampled at 19.2kHz before applying a digital filter (notch at 50Hz) and generating an output data rate of 50 samples/s.

231 The measurements of dorsiflexion and eversion were processed on the stimulator to produce three data streams:

1. Raw samples at 50Hz (all experiments)
2. Average of the last four samples before the end of level stimulation (seated tests)
3. Average of all samples from heel rise to heel strike (walking tests)

5.2.4 Data collection system

232 The stimulator collected data about the stimulation parameters and goniometer readings continuously; this was transmitted wirelessly to a laptop for further processing (unit conversion), storage and real-time display.

233 The real-time display used the Kst software package (https://kst-plot.kde.org/) to display charts of the stimulation parameters and outcome measures (ankle angles) against time and against each other. Data was plotted on screen with less than one second latency from event to display.

234 This system had several beneficial features:

- Eliminated subjectivity in taking measurements.
- Eliminated transcription errors.
- Enabled confirmation during the experiment that data collection was happening.
- Enabled rapid review of results as they were gathered.
- Ensured full test coverage. For seated tests, the stimulator was set to operate automatically, such that it adjusted the stimulation parameters over the desired range and captured the resulting stimulation response automatically (with manual override).
- Enabled the volunteers to walk around the laboratory without trailing cables (which otherwise could have affected their gait).
- Recorded data in files with automatic date and time stamps. These files could be reviewed in Kst after the experiments, simplifying the identification of any unusual features.

5.3 Standard experimental set-up

235 The volunteers for each experiment were set-up in the following way.

5.3.1 Footwear

236 The volunteers wore their normal shoes, because:

- It matched their normal walking conditions;
- It provided familiar levels of safety and comfort to each volunteer;
- The shoe provided an anchor point for the goniometer, reflecting the movement of the foot as a whole, free of local skin movement artefact. The shoes were not controlled for distortion of their fabric, which was generally of a firm nature.

237 Volunteers for the walking experiments also had three foot-switches placed on a thin cork insole in their shoe. The switches were placed under the heel, 1^{st} and 5^{th} metatarsal heads. These positions were identified by observing the pressure/wear marks on the insoles.

5.3.2 Ankle instrumentation and range of movement

238 The twin-axis goniometer (section 5.2.3) was set up across the lateral malleolus to measure ankle dorsiflexion and eversion. The goniometer was secured to the volunteer's shoe using single- and double-sided self-adhesive tape. The other end of the goniometer was fixed to their leg using double-sided adhesive tape, either to their sock or an elasticated leg cuff. The cuff was used where necessary to reduce the risk that the springy measuring element of the goniometer was disturbed by passing over the lateral malleolus. The use of the cuff or sock also reduced skin movement artefact.

239 The cables were held to the leg with elasticated straps to prevent them flapping and becoming caught, annoying the volunteer or affecting their walking.

240 Figure 16 shows the goniometer in position on volunteer 24. The additional three wires passing across the ankle are from the three foot-switches for experiment 3; during the experiment, these wires were secured away from the goniometer.

Figure 16: Ankle goniometer in position

241 The goniometer was zeroed with the volunteer standing at rest, to provide a reference position. The foot inside the shoe may be at a different angle due to an insole and/or possible foot torsion/flexion.

242 The range of movement (ROM) of the ankle were recorded, in dorsiflexion, plantarflexion, inversion and eversion, for both passive movement (PROM) and active movement without stimulation (AROM). The PROM was measured in free space with manual pressure, as an indication of how far the joint could easily move under low forces (FES response is often weak). This measure of PROM can be used to illustrate how much of the readily available ROM the two-channel stimulation was able to use. It is not claimed to be representative of the PROM achievable under full body weight. Some patients achieve a greater range of movement when weight-bearing or during stimulation, as a result of the greater forces or changes in muscle tone, so it is not exceptional to see foot postures beyond the recorded passive range of movement. The zero reference for dorsiflexion and eversion was set with the volunteer standing normally in their shoes (complete with insoles if used). All volunteers wore relatively 'sensible' shoes with a low heel.

243 Additionally, for later volunteers, the limits of motion obtained by manually rolling the ankle around the neutral position (as though it had two degrees of freedom) were recorded. This shows that some foot orientations are not attainable, whether due to

pathology or normal ligament restrictions. Two-channel stimulation cannot be expected to direct the foot to unobtainable postures.

5.3.3 Electrical Stimulation

244 For single channel stimulation, setup was according to the following established clinical practice at the National Clinical FES Centre (Salisbury, UK):

- Current and electrode position were adjusted to get dorsiflexion through the full range of motion, combined with mild eversion and consistent with comfort. This reduces the risk of tripping and promotes ankle stability during loading.

- Pulse width at setup was 180µs. Subsequently, the user was able to adjust pulse width to maintain comfort when the current or electrode positions were changed.

- Pulse repetition frequency was 40Hz, as used in drop foot stimulators as a good balance between avoiding fatigue (favouring lower frequencies) and initial strength of response (favouring higher frequencies).

- Pulse trains had a trapezoidal envelope of pulse width (from 3µs to nominal level) as is used in clinical practice for drop foot walking:

    - Rising ramps were 200ms and falling ramps 150ms, except where the volunteer normally used much longer ramps (to reduce spasms or clonus) or shorter ramps (for prompt response in walking).

    - For seated tests, the duration of the pulse train at the nominal pulse width (i.e. not including ramp times) was 0.5s (identified in (von Schroeder et al. 1995) as the mean swing time of stroke patients).

    - For walking tests, the pulse train duration was not fixed: stimulation started at heel rise and finished after heel strike.

- The sequential pulse-trains in the seated tests were applied at 3 second intervals, allowing the muscle to rest between pulse trains.

245 For the tests involving two-channel stimulation, this was set up by starting from the single-channel electrode positions. All the volunteers normally used electrodes on the tibialis anterior and over the head of the fibula; the former was retained as the common electrode, while the latter was replaced with two electrodes (one for each channel). The process of determining this placement and the stimulation parameters is described in more detail in the method for experiment 2.

5.3.4 Seated and walking environments

246 The experiments were conducted indoors at the National Clinical FES Centre at Salisbury District Hospital. The rooms were quiet, well lit and uncluttered. Volunteers attended either on their own or with a companion..

247 Experiments 1 and 2 both tested the biomechanical response to stimulation while seated in a relaxed position (i.e. with a typical knee flexion estimated to be approximately 10 degrees). The volunteers sat in a comfotable high-backed seat with arm rests. A foam block was arranged to gently support the calf while alowing free movement of the ankle. This achieved an leg posture similar to that at heel strike, while being safer (no tripping) and less tiring then walking. This arrangement is not identical to walking:

- The ankle started from a relaxed position, while walking is usually associated with more tone throughout the leg.
- The level of resting plantarflexion may not be seen during normal gait.
- There was no ground reaction force on the foot at any time.

248 This limitation (poor relation to walking) was accepted, firstly to promote the safety of the volunteers and secondly as these seated tests helped build the safety case for employing two-channel stimulation in the later walking tests.

249 Experiments 3 and 4 tested the effect of changing stimulation while walking. The experiment took place in a large clinic room approximately 14x5 metres with a smooth,

hard floor surface. Volunteers were permitted to use their walking stick if they wanted to.

5.4 Ethics

250 This study was conducted according to the principles of the Declaration of Helsinki.

251 The protocol for the study was submitted to the ethical review committee at Odstock Medical Limited (OML) and approved. Volunteers were recruited from FES users registered with OML (see next section) and the experiments were conducted at the OML clinic.

252 We consulted the local NHS Research Office to see if NHS ethical approval would be required. The volunteers had originally (some years previous to this study) been referred to OML as patients by the NHS. OML is sited at Salisbury District Hospital, and the supervising staff are employed by both organisations. Any one of these of these might have indicated that NHS ethics would be required, but we were told that in fact this study was not eligible for review by the NHS Research Ethics Service, because it not an NHS study and the volunteers were OML patients not NHS patients.

253 For further independent review, an "initial ethics checklist" was submitted to the School of Design, Engineering and Computing at Bournemouth University and approved by the Deputy Dean.

254 This project posed a low risk to the volunteers:

- The volunteers were all experienced FES users (1-10 years use).
- Clear information sheets were provided (appendix B) explaining the experiment and that they were not under any pressure to take part or to continue.
- They were not offered inducement to participate; travel expenses were only paid

for any additional journeys.

- The experiment was conducted in a standard clinical environment; the volunteers were able to use their normal walking aids if they desired.

- The novel aspects of the stimulation were tried in sitting and then standing before walking. The volunteers were not asked to walk if there was any doubt of their ability to do so safely.

- The volunteers were encouraged to say if they did not want to do any part of the experiment (for example, if the stimulation was too uncomfortable or not stable enough for walking).

- I (the experimenter) had been trained in the use of FES as part of my Clinical Scientist training; my supervisors Professor Swain and Dr Taylor each have over 20 years experience in FES research and the clinical application FES.

- The stimulator design was reviewed by two senior staff at OML (both of whom are a Chartered Engineer and Clinical Scientist).

- The practical conduct of the experiment had been practised and refined with the assistance of unimpaired volunteers from the technical and clinical staff at OML.

- All staff at the OML clinic have basic life support training and there are first aiders in the building. The OML clinic is located at Salisbury District Hospital, so in the very unlikely event of an accident expert assistance is very close.

- The project was reviewed by people independent from it.

- OML's insurers agreed to cover the experiment as part of the business.

5.5 Volunteer recruitment

255 To be broadly representative of the FES user population, volunteers with central neurological impairments were recruited from FES users registered with Odstock Medical Limited (Salisbury, UK).

256 Recruitment was from a pool of 115 adult users of lower-limb FES systems who were scheduled for 6-month or 12-month FES review appointments during the experimental period. Choosing experienced FES users meant that:

- they were already screened against most of the exclusion criteria (section 5.5.1),
- they responded to stimulation,
- they were familiar with its effects,
- the risk that they would find stimulation intolerable was low.

257 To avoid unnecessarily troubling severely disabled people, potential invitees were screened by manually reviewing their case histories to exclude those who were highly unlikely to meet the selection criteria for the experiment (section 5.5.2). The specific screening criteria were:

- Not using standard electrode positions on the head of fibula and tibialis anterior.
- History of skin irritation.
- High levels of spasticity or clonus (Modified Ashworth score greater than 3).
- Other conditions recoded in their notes indicating unsuitability for participation: high levels of fatigue, cognitive impairment, balance difficulties, etc.
- For walking tests:
    - Inability to walk unstimulated.
    - People with a walking speed of less than 0.3m/s were not invited for walking experiments, on the grounds that it would be impractical to administer the tests, even if they had the stamina for the walking involved.

258 Fifty people passed the initial screening criteria and were sent written invitations to participate. The letter emphasised that participation was voluntary and would not affect their treatment. Comprehensive volunteer information sheets were included (see

appendix B). Those wishing to participate were requested to phone, email or write to book an appointment, which generally followed their next routine clinic appointment. Travel expenses were only paid if otherwise unscheduled visits were necessary, to avoid payment being a motivating factor in participation.

259 Of the 50 invitees, 22 volunteered. Two withdrew before starting because of time commitments and two were excluded because they had problems with their skin or other medical difficulties, leaving 18 who participated. Demographic information is presented in tables 5 to 11.

5.5.1 Exclusion criteria

260 The exclusion criteria consisted of the standard FES contraindications and cautions:

- Fixed contracture of the ankle joint.
- Peripheral nerve lesion or spinal damage below T12.
- Risk of autonomic dysreflexia (e.g. spinal damage above T6).
- Demand-type cardiac pacemaker.
- Pregnancy.
- Poorly controlled epilepsy.
- Cancerous tumour in region of stimulation.

261 Additionally, anyone with implanted metalwork in their lower leg was excluded, as this could have distorted or concentrated the path of the electrical currents.

5.5.2 Inclusion criteria

262 The following selection criteria were used:

- Central neurological damage causing drop foot.
- Adult FES user (at least six months experience).
- Achieves clinically appropriate dorsiflexion with FES.
- Able to give informed consent.
- Able to understand and follow trial procedures.
- No recent problems of skin irritation.

- No recent ankle injury.
- No severe clonus or spasticity of the calf muscles or leg spasms.
- Able to walk without stimulation on the popliteal fossa, quadriceps or hamstrings.
- For walking tests:
    - Using a foot switch on the same leg as the electrodes.
    - Able to achieve a clear heel strike when walking with FES.
    - Able to walk 400m using FES, with rests and walking stick if needed.
    - Not dependent on ankle-foot orthoses, as these may affect the ankle joint movement.
    - Not dependent on stimulation to promote knee flexion, as this would require different electrode positions from those used in this study.
    - Able to take at least three steps without stimulation, in case the equipment broke down during the experiment.
    - Walking speed of at least 0.3m/s, for practical administration of the tests.

5.5.3 Informed consent

263 The volunteers were encouraged to raise any concerns and have their questions answered before being asked to give consent. They were made aware of their right to withdraw from part or all of the experiments at any time and without having to give a reason.

264 None of the volunteers withdrew during or after the experiment, and none raised any concerns about their continued participation. Volunteers were only invited for a single session, but approximately one third expressed (unprompted) a willingness to return for further sessions if needed – these formed the recruitment pool for experiment 4b.

The volunteers' comfort and safety was of paramount importance at all times. The volunteers had control over the stimulation intensity (current or pulse width). They also had access to an 'emergency stop' switch, which in practice no-one used. The volunteers were not asked to put up with stimulation that was uncomfortable, nor to walk with an unsafe foot posture or beyond their endurance.

5.6 *Recruitment demographics*

5.6.1 Experiments 1 and 2 (Single- and two-channel tests)

	M	F	Total
MS	3	21	24
CVA	8	2	10
Other	5	4	9
Total	16	27	43

Table 5: Pool for expt. 1&2 (before screening)

	M	F	Total
MS	1	9	10
CVA	5	0	5
Other	2	1	3
Total	8	10	18

Table 6: Expt. 1&2 invitees (after screening)

	M	F	Total
MS	2	5	7
CVA	0	0	0
Other	2	1	3
Total	4	6	10

Table 7: Expt. 1&2 participants

5.6.2 Experiments 3 (in-shoe sensor) and 4a (open-loop control)

	M	F	Total
MS	7	21	28
CVA	17	6	23
Other	13	8	21
Total	37	35	72

Table 8: Pool (before screening)

	M	F	Total
MS	2	10	12
CVA	12	2	14
Other	3	3	6
Total	17	15	32

Table 9: Invitees (after screening)

	M	F	Total
MS	1	3	4
CVA	2	0	2
Other	1	1	2
Total	4	4	8

Table 10: Participants in experiment 3 and 4a

5.6.3 Experiment 4b (Closed-loop control)

265 Volunteers were drawn from those who had participated in the earlier sessions

	M	F	Total
MS	1	1	2
CVA	1	0	1
Other	0	1	1
Total	2	2	4

Table 11: Participants in experiment 4b

267 Details of the final 18 volunteers are given in table 12. They took part in experiments for this study during three periods (broadly May, July and September-October 2013). Each volunteer participated in several experiments, depending on their walking ability and the stage of the experiment.

Volunteer ID Notes 1 & 2	Gender	Age	Neurological Condition	Duration of FES usage (years)	Frequency of FES usage	Side
Experiments 1 and 2 (Single- and two-channel tests, seated)						
8	M	68	MS	7.5	Daily, outside	Right
9	F	56	MS	7	Daily	Left
10	F	63	MS	1	Not recorded	Left
11	M	57	SCI	5	Most days	Right
12	F	57	MS	5	Daily	Left
13a	F	55	SCI	10	2 or 3 days per week	Left
14	M	27	TBI	4	Daily	Left
15	F	63	MS	2	4 or 5 days per week	Right
16	F	58	MS	3	Daily	Right
17	M	57	MS	9	Daily	Left
Experiments 1 and 2 extended sessions						
19b	M	71	CVA	8	2 days per week	Left
24a & b	M	55	MS	4	Daily	Right
25a & b	F	52	MS	5	Daily, outside	Right
Experiments 3 (in-shoe sensor) and 4a (open-loop control)						
13b Note 3	F	55	SCI	10	2 or 3 days per week	Left
19a	M	71	CVA	8	2 days per week	Left
20	M	63	SCI	6	Daily, outside	Left
21	F	63	MS	3	Daily	Right
22 Note 4	F	54	MS	1	Daily	Right
23	M	71	CVA	3	2 or more days per week	Left
24a	M	55	MS	4	Daily	Right
25a	F	52	MS	5	Daily, outside	Right
28 Note 5	F	69	SCI	6	Daily	Left
Experiment 4a extended (open-loop control with several electrode positions)						
19b	M	71	CVA	8	2 days per week	Left
24b	M	55	MS	4	Daily	Right
25b	F	52	MS	5	Daily	Right
Experiment 4b (closed-loop control)						
13b	F	55	SCI	10	2 or 3 days per week	Left
24c	M	55	MS	4	Daily	Right

Table 12: Details of FES user volunteers

Notes to table 12:

1. In the ID column, suffixes a-c indicate repeated visits by that volunteer.
2. 1-7, 18, 26 & 27 were tests of the experiment method by unimpaired volunteers.
3. Volunteer 13 is not included in the demographic statistics for experiment 3 because she was not part of the main group doing this experiment – her charts come from her second visit primarily for experiment 4.
4. There are no walking test results for volunteer 22 because the two-channel set-up process was unable to produce any appreciable change of inversion/eversion.
5. There are no walking test results for volunteer 28 due to a failure of the goniometer recording system at a late stage in the experiment.

6 Experiment 1: Repeatability of response to single-channel stimulation while seated

6.1 Overview

268 Ankle dorsiflexion and eversion were measured in response to single-channel stimulation (while seated) at currents from the threshold of movement to comfortable maximum.

6.2 Objective

269 The primary objective of experiment 1 was to determine whether the volunteer had a stable response to (single channel) stimulation, to determine what weight to give to any changes in response that might be seen in later experiments.

270 This experiment also showed whether the volunteer's ankle normally inverted or everted significantly during stimulation. This was helpful in choosing the electrode positions for the later two-channel experiments.

6.3 Hypothesis

271 The response to stimulation is consistent, monotonic with current and time-invariant over a time-scale of minutes.

6.4 Method

272 Ten volunteers were set-up for single-channel stimulation and their range of movement measured as described in section 5.3.

273 The current required for comfortable full range response ($I_{100\%}$) and just visible response ($I_{0\%}$) was noted. This defined six equally spaced current levels: $I_{0\%}$, $I_{20\%}$, $I_{40\%}$, $I_{60\%}$, $I_{80\%}$ and $I_{100\%}$ for later use.

6.4.1 Part 1: Steadily changing stimulation current

274 One stimulation pulse-train was applied at each of 51 equally spaced current levels, from $I_{0\%}$ to $I_{100\%}$ and then from $I_{100\%}$ to $I_{0\%}$. This involved 102 pulse-trains, one every 3 seconds. The outcome was the foot posture (degree of dorsiflexion and eversion) just before the falling ramp of each pulse-train.

6.4.2 Part 2: Randomly changing stimulation current

275 Six pulse-trains at each current level: $I_{0\%}$, $I_{20\%}$, $I_{40\%}$, $I_{60\%}$, $I_{80\%}$ and $I_{100\%}$ were applied in a pseudo-random order, one pulse-train every 3. The order was unknown to the volunteer or the experimenter (having been set by a pseudo-random algorithm on the stimulator). The outcome was the foot posture (degree of dorsiflexion and eversion) just before the falling ramp of each pulse train.

6.4.3 Justification of the use of a linear test sequence

276 It was initially proposed to do the seated experiments purely with randomised current levels, as people might adapt or facilitate the response if they knew that each pulse train would be similar to the previous one. However, preliminary tests of this method with unimpaired staff at the FES clinic indicated that randomisation of current levels added notable variability to the response, and that the size of the response was in some cases affected by (positively correlated with) the preceding pulse. This would have complicated the process of determining the unbiased response to any given current level. It was also noted that (for safety) no walking system would feature sudden (step) changes in output. Although people may adapt to stimulation amplitude to some extent, it was considered valid to incorporate this into the measurement as this is how it would be used in practice. Thus the rest of the experiments use small changes in current between each measurement.

6.4.4 Data collection and processing

277 The automatic data collection system recorded the stimulation parameters used for each pulse train, and sampled the goniometer signals (dorsiflexion and eversion angles) continuously at 50Hz. For each test pulse train, the last four angle samples before the falling ramp (i.e. covering 80ms) were averaged to give the foot posture attained with

that pulse train. A longer averaging period might have reduced measurement noise, but would be more likely to cover time when the foot was not at its final posture.

6.5 Results

278 These tests show the effect of single-channel stimulation on foot posture while seated. The results are presented as charts of dorsiflexion and eversion (in degrees) against current (0% being the motor threshold and 100% being the comfortable maximum). In the charts, each data point is the dorsiflexion or eversion achieved just before the stimulation pulse train stops, i.e. at the end of a 0.5s simulation train. Reference marks show the seated and standing position of the foot, and the limits of passive range of motion. The numerical values for passive range of motion and the stimulation currents used in the experiment are presented in tables in appendices C and D respectively.

279 The data series are labelled according to the scheme in table 13.

Label	**Meaning**
DF	Dorsiflexion (stimulation current increasing and decreasing linearly)
DF-rand	Dorsiflexion (stimulation current in pseudo-random order)
DF-pmax	Dorsiflexion at upper limit of passive range of movement
DF-stand	Dorsiflexion when standing (reference for zero dorsiflexion)
DF-rest	Dorsiflexion in relaxed seated position (typically plantarflexed)
DF-pmin	Plantarflexion limit of passive range of movement
EV	Eversion (stimulation current increasing and decreasing linearly)
EV-rand	Eversion (stimulation current in pseudo-random order)
EV-pmax	Eversion limit of passive range of movement
EV-stand	Eversion when standing (reference for zero eversion)
EV-rest	Eversion in relaxed seated position (typically slightly inverted)
EV-pmin	Inversion limit of passive range of movement
P-roll	Passive range of rolling movement (foot moving with the heel at apex of a cone, toes tracing the circumference of a circular or elliptical base)
A-roll	Active range of rolling movement (where recorded)

310 *Table 13: Key to data series labelling*

311 The results are presented as a series of case studies, starting with the first impaired

volunteer, identified as number 8. His results are described in detail so the reader can become familiar with the chart format. The text accompanying the subsequent volunteers' results is more concise.

6.5.1 Volunteer 8

312 Experiment 1 showed that volunteer 8 had a stable response to stimulation (figure 17). Not only did similar consecutive pulse trains produce similar dorsiflexion and eversion, but the response was also similar when the pulse amplitude was randomised. This was not the case for all volunteers – many showed more variation, particularly with randomised stimulation.

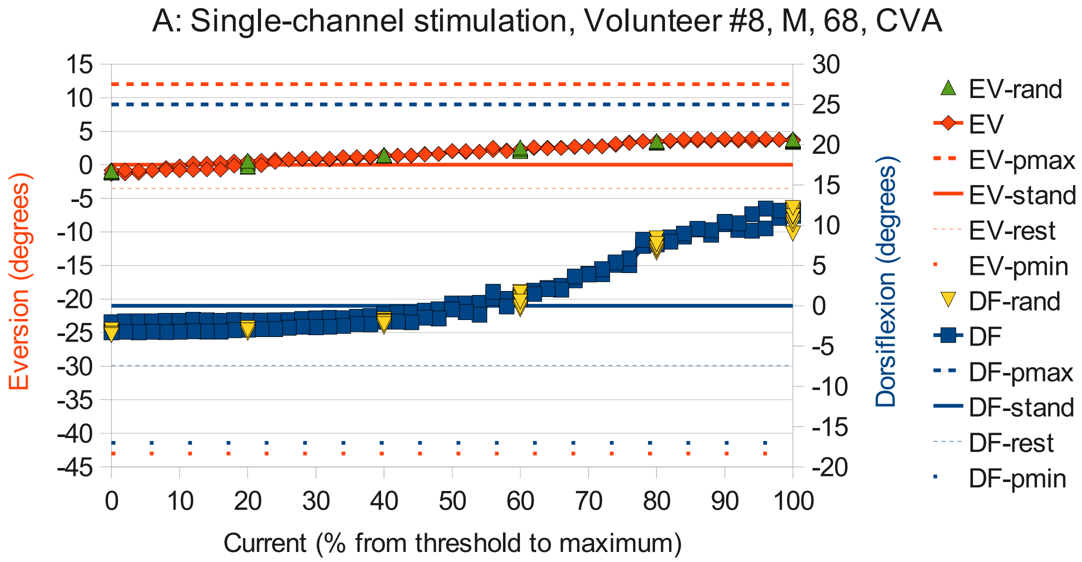


Figure 17: Single-channel result, volunteer 8: foot posture vs stimulation current.

313 The dorsiflexion data (blue in figure 17) shows a characteristic soft s-shaped curve, which is attributed to the recruitment of tibialis anterior. The dorsiflexion is initially fairly small (about 5 degrees above resting but still plantarflexed). It does not exceed neutral until about 50% current, after which it increases quickly before levelling off towards 100% current. Several others volunteers in experiment 1 also showed little increase at first – it seems the threshold current to produce a visible contraction or take up the slack in muscle/tendon is rather less than that required to produce much movement. As the focus of this study is on the resulting movement, later experiments attempted to set the 0% level closer to that needed to produce movement (i.e. operating only in the right hand side of figure 17).

314 The eversion is also stable. It does not cover much of the available range of movement (which is quite reasonable in this volunteer) but it does exceed neutral and is fully appropriate for drop-foot correction: strong dorsiflexion and mild eversion.

315 The reader may like to note the range of motion indicated by sparse dotted lines (lower limit) and thick dashed lines (upper limit), as well as the resting posture (fine dashed lines). This volunteer's resting foot is plantarflexed and inverted relative to the standing posture which is used as the zero reference and shown as solid lines. This plantarflexed and inverted resting posture was typical for most volunteers.

316 Figures 17 plots the effect of changing the current on the individual foot posture angles. To make the overall effect on the foot easier to visualise, an alternative presentation is given in figure 18. This XY chart represents the foot posture in the frontal plane. Neutral standing posture is indicated by the red dot. This locates the zero reference; dorsiflexion is positive upwards, eversion is positive to the right of the chart (regardless of whether this relates to the right or left foot). Resting foot posture, shown by the green dot, is typically plantarflexed and inverted, so in the lower left quadrant. The passive limits of dorsiflexion and plantarflexion are shown with a fine dashed box, although it is stressed that not every part of the box is a reachable posture.

317 The result shown in figure 18 is a good 'text-book' response for the correction of drop foot with FES: as the current is increased, the foot moves to a strongly dorsiflexed and mildly everted posture. The data series does not appear to start exactly at the resting posture (green dot). This may be attributed to two effects:

- Even low stimulation results in a small movement away from resting posture.
- The resting posture was measured once at the start of the experiment and may drift over time.

318 This second point bears closer consideration. The foot does not return to the same posture after every stimulation, and the volunteers often shift their position during the experiment. This means that the foot is not tracing a path from the green dot on every stimulation. All the results are affected by this possibility of drift in the resting foot posture, but it is not considered significant in investigating the trend of the stimulated foot posture, as long as drift is minimal within each data series. Some results sets do exhibit step offsets that can be seen in the original 50Hz foot posture recordings to be

associated with a shift in the resting position rather than a change in stimulation-induced lift. These are noted in the results. Where stimulation is maximal, starting foot posture has less influence on the resulting posture than when stimulation is sub-maximal.

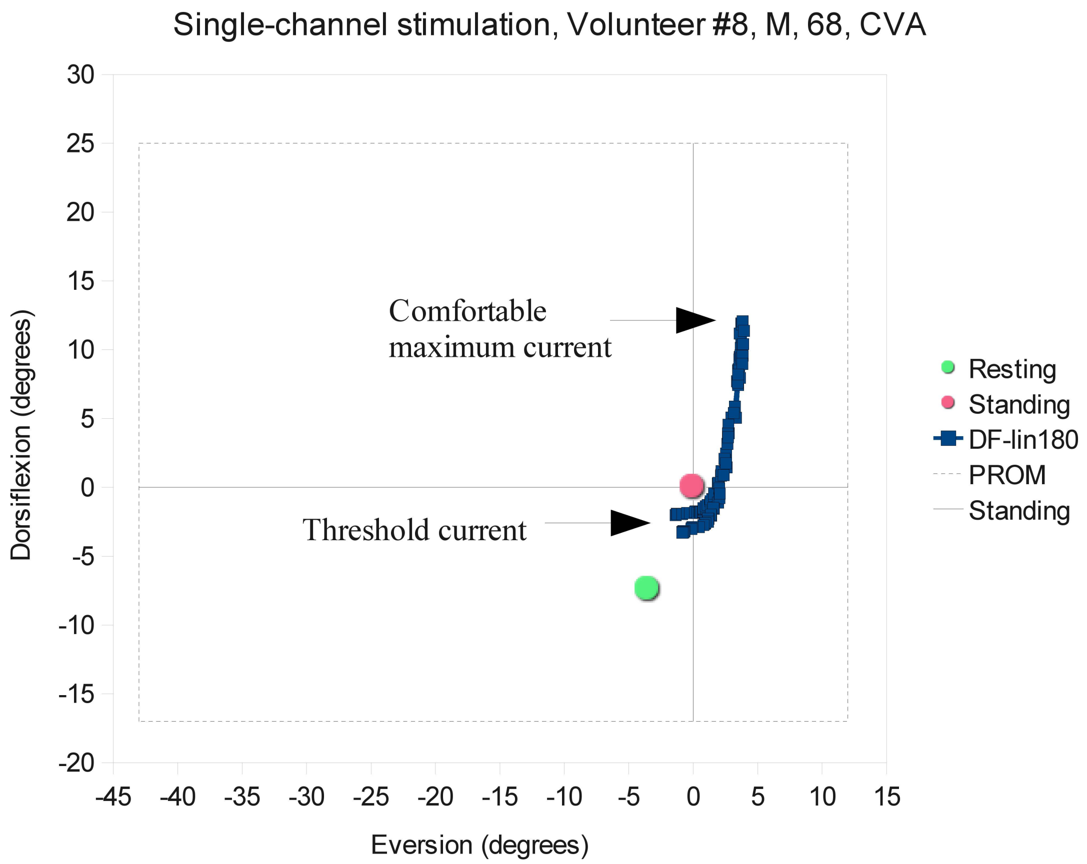


Figure 18: Single-channel result, volunteer 8.

319 For reasons of time, only the central electrode position was measured with single-channel stimulation (this being the set-up the volunteer arrived with, following his routine review in the FES clinic). Later in these results there are some volunteers who stayed for longer sessions (3 hours), which enabled data collection at four peripheral positions in addition to the central position.

6.5.2 Volunteer 9

Volunteer 9 used a reverse-polarity set-up for her normal walking. This was maintained for both single-channel and two-channel tests. Single-channel stimulation produced standard results for drop-foot correction, in that dorsiflexion increased much more than eversion, although in the seated tests neither appeared to exceed neutral. This is plotted in figures 19 and 20.

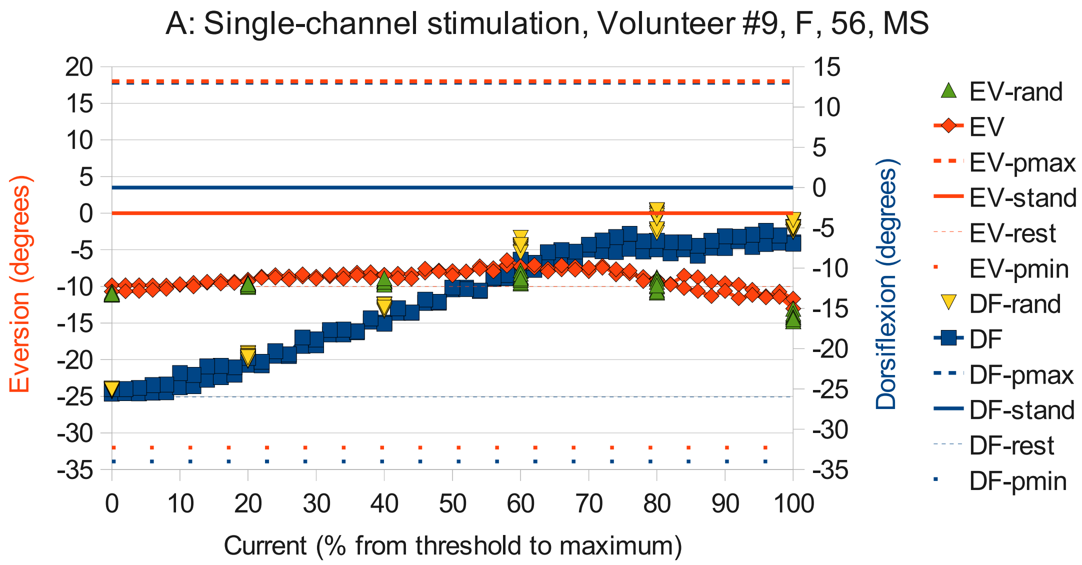


Figure 19: Single-channel result, volunteer 9: foot posture vs stimulation current.

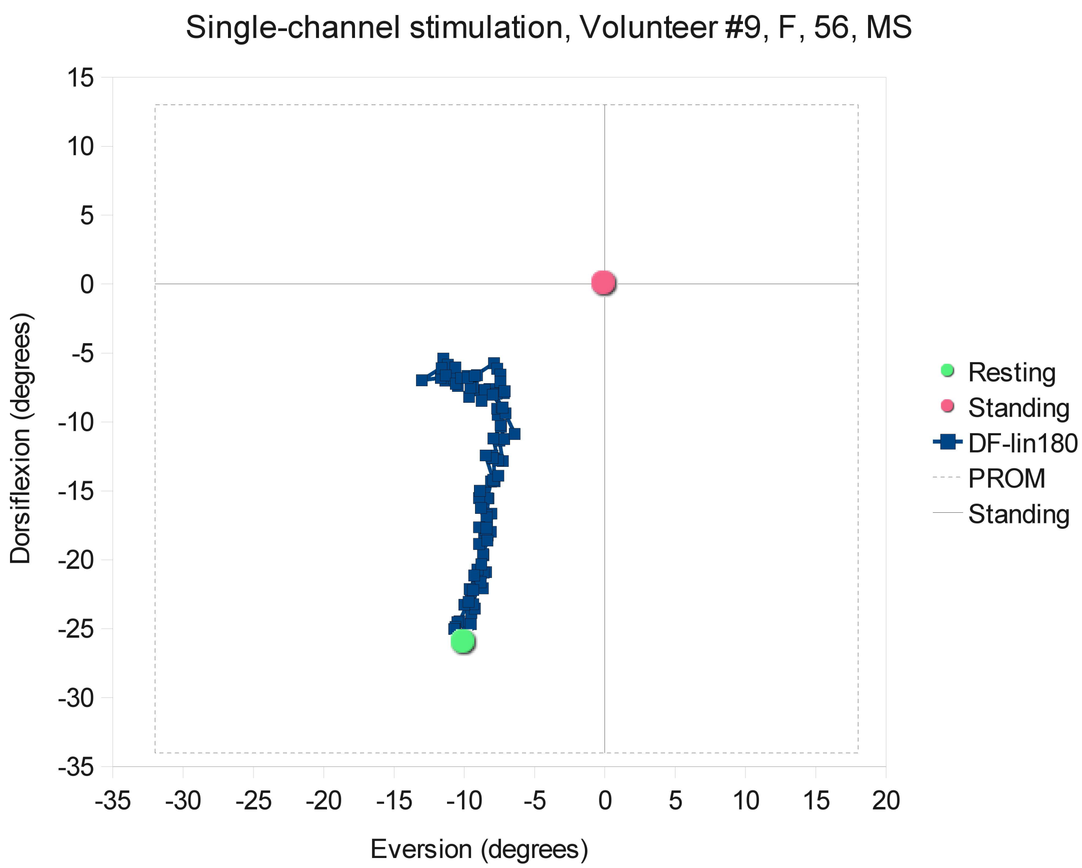


Figure 20: Single-channel result, volunteer 9.

6.5.3 Volunteer 10

With single-channel stimulation (figures 21 and 22), volunteer 10 achieved strong dorsiflexion and eversion. In this single experiment, the eversion was notably greater and more erratic when the current was increasing than at the same current levels when decreasing; this may have been caused by the volunteer pressing the electrode back into place, having noticed that it was peeling off.

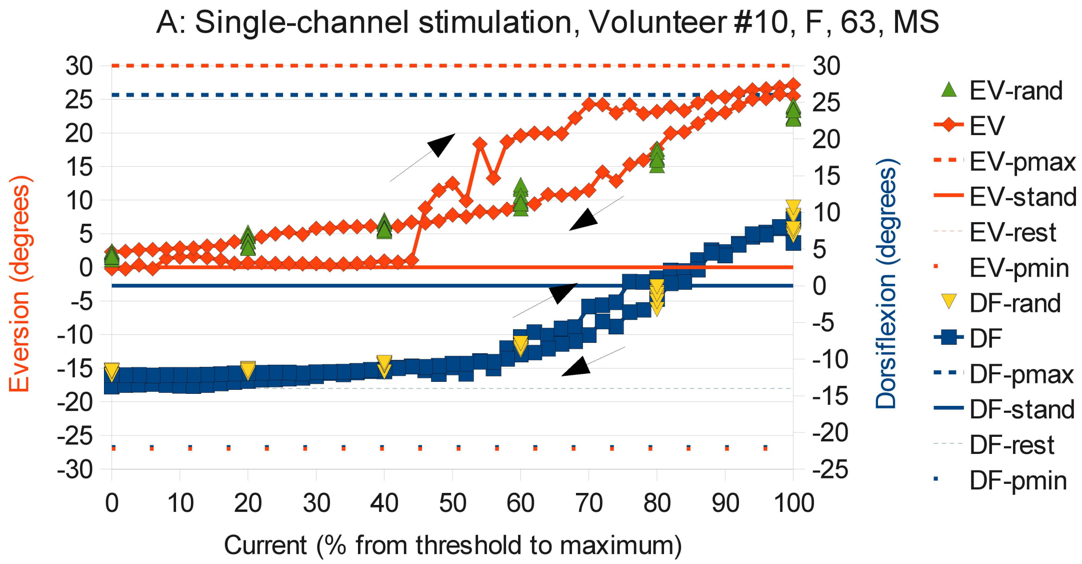


Figure 21: Single-channel result, volunteer 10: foot posture vs stimulation current.

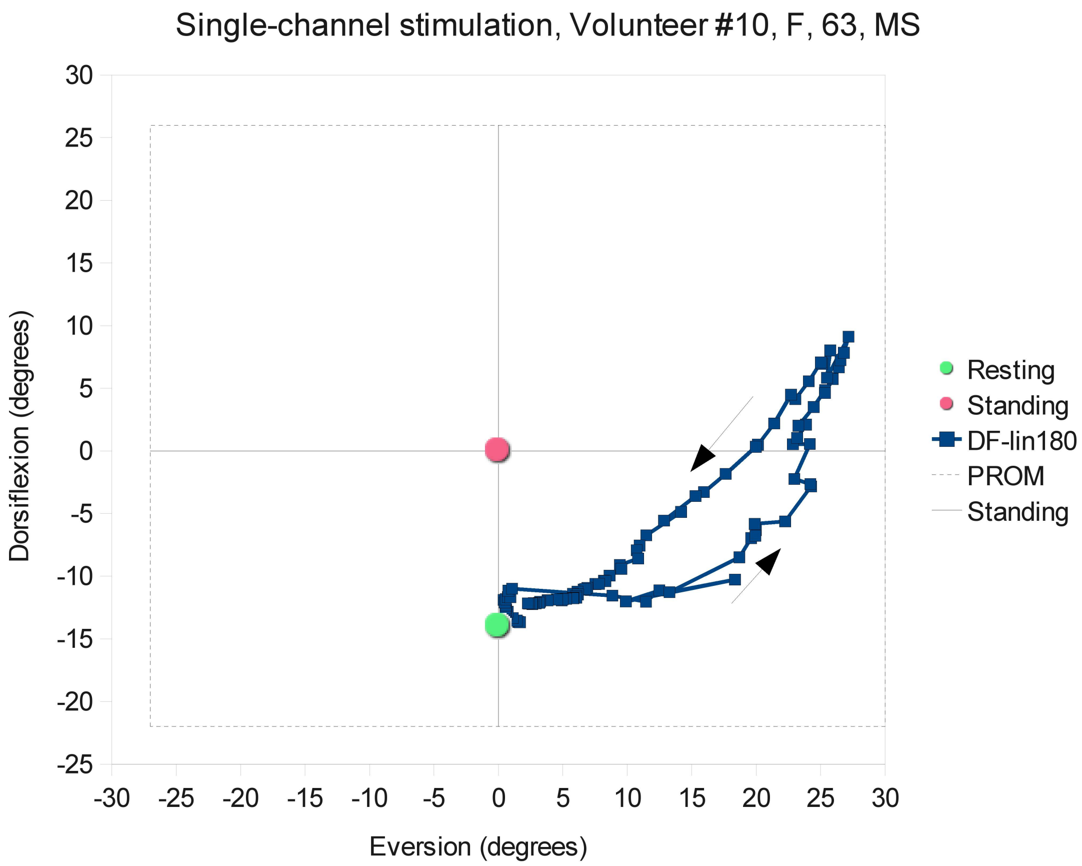


Figure 22: Single-channel result, volunteer 10.

6.5.4 Volunteer 11

321 Volunteer 11's ankle suffered from stiffness, limited range of movement and flexor tone. This explains why the PROM measured by hand does not include the standing posture (where the joint is load bearing and can achieve greater eversion as the ankle rolls inwards). This may also be responsible for the fact that the single-channel stimulation did not achieve neutral dorsiflexion or eversion (figures 23 and 24).

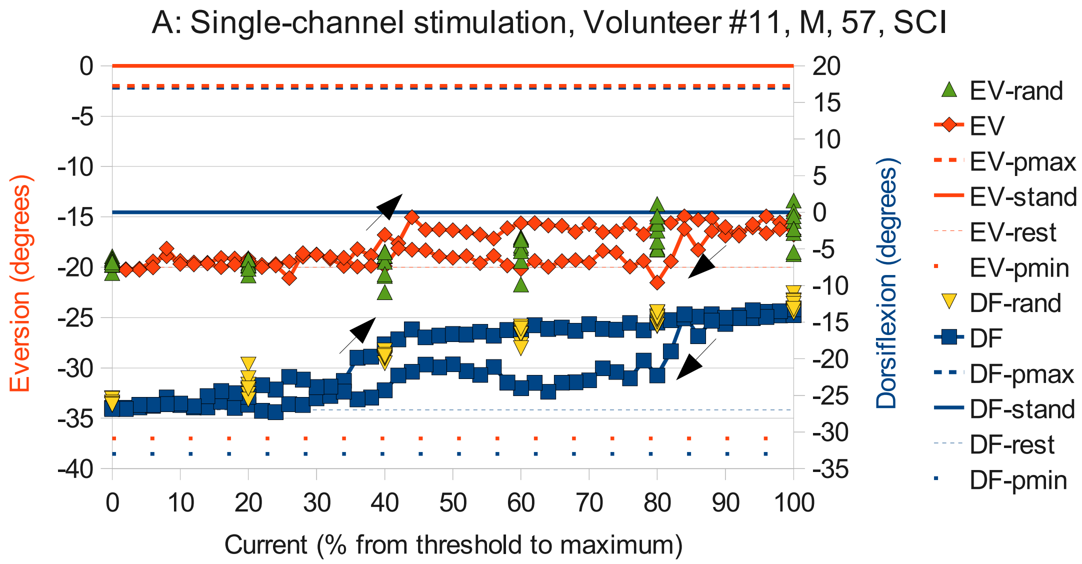


Figure 23: Single-channel result, volunteer 11: foot posture vs stimulation current.

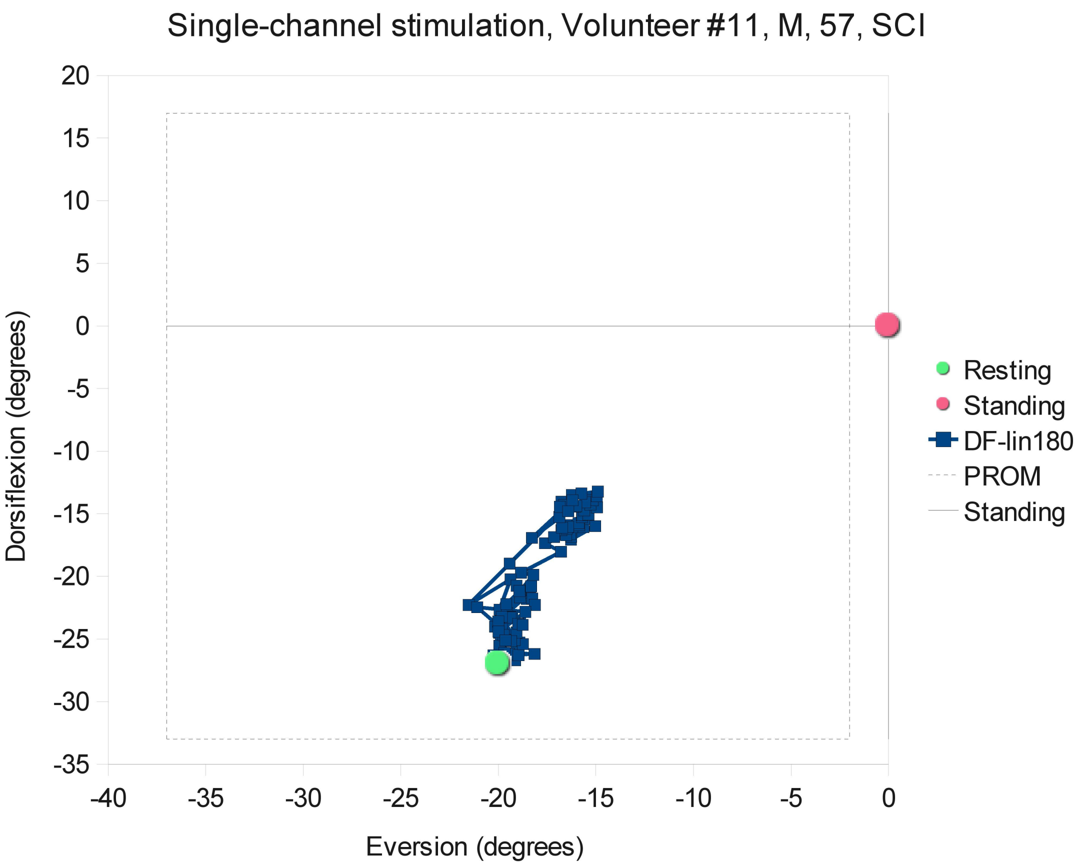


Figure 24: Single-channel result, volunteer 11.

6.5.5 Volunteer 12

322 The single-channel results for volunteer 12 (figures 25 and 26) show strong dorsiflexion and eversion, beyond neutral, making a good correction for drop foot (stable and able to clear the ground).

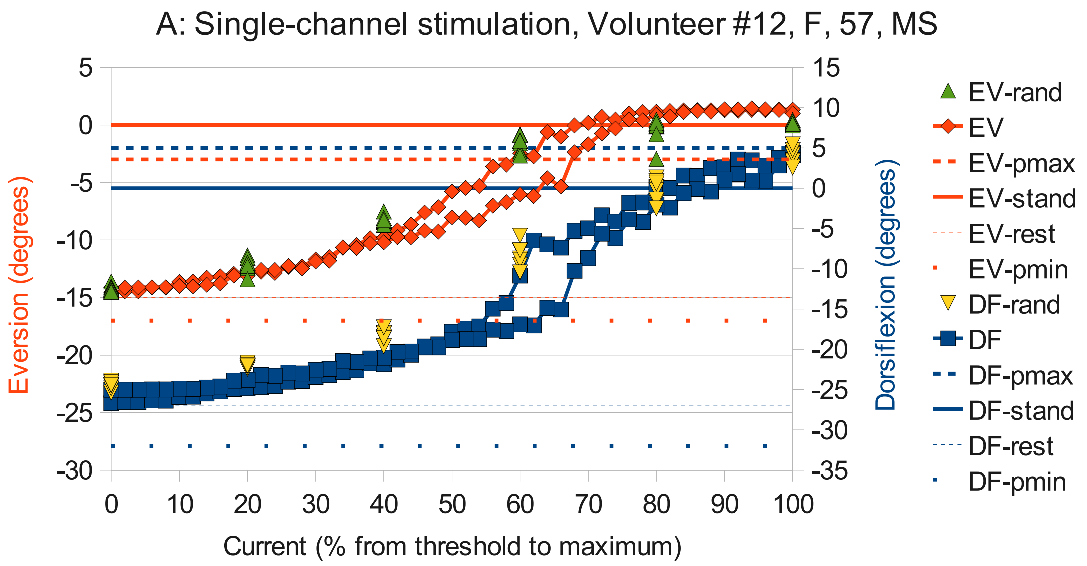


Figure 25: Single-channel result, volunteer 12: foot posture vs stimulation current.

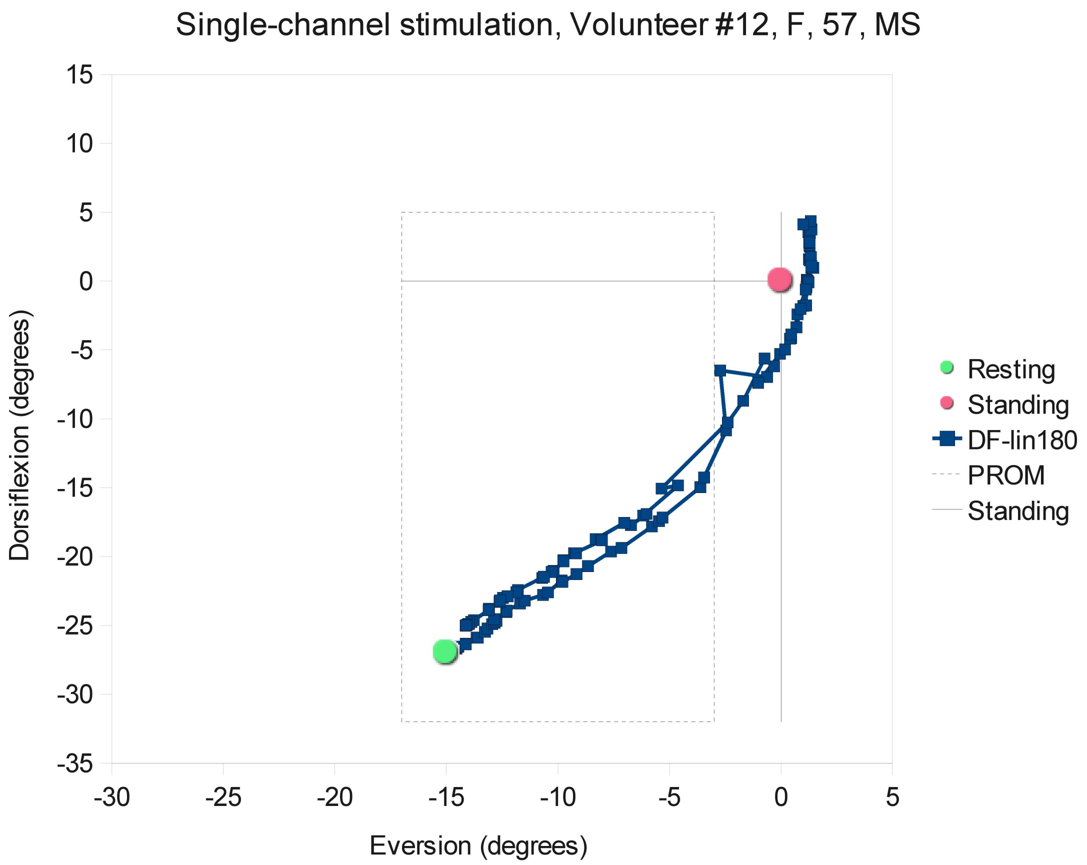


Figure 26: Single-channel result, volunteer 12.

6.5.6 Volunteer 13

323 Volunteer 13's single-channel response (figures 27 and 28) produced a typical dorsiflexion almost to neutral and a clear eversion.

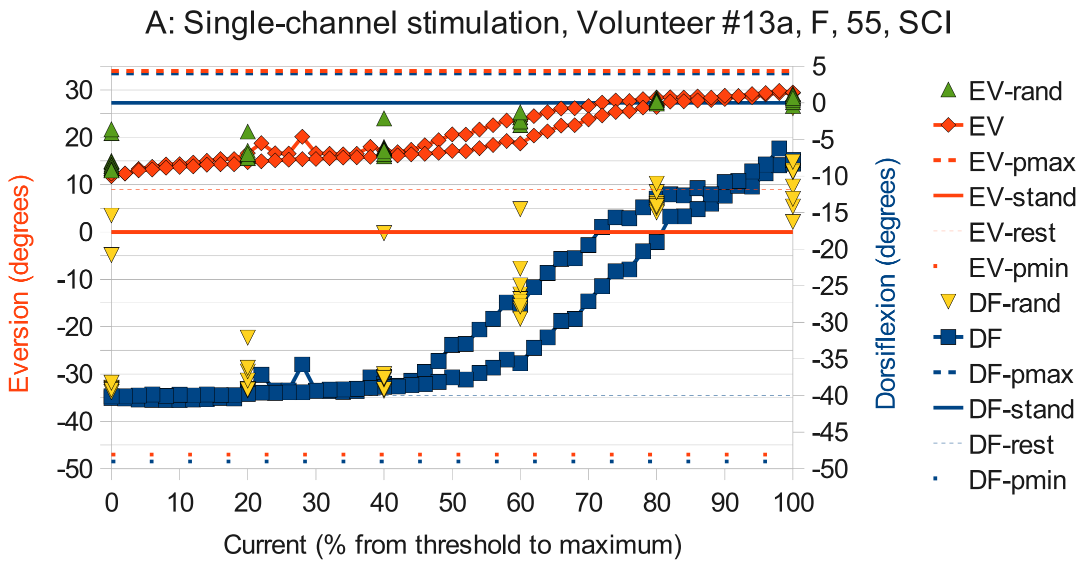


Figure 27: Single-channel result, volunteer 13: foot posture vs stimulation current.

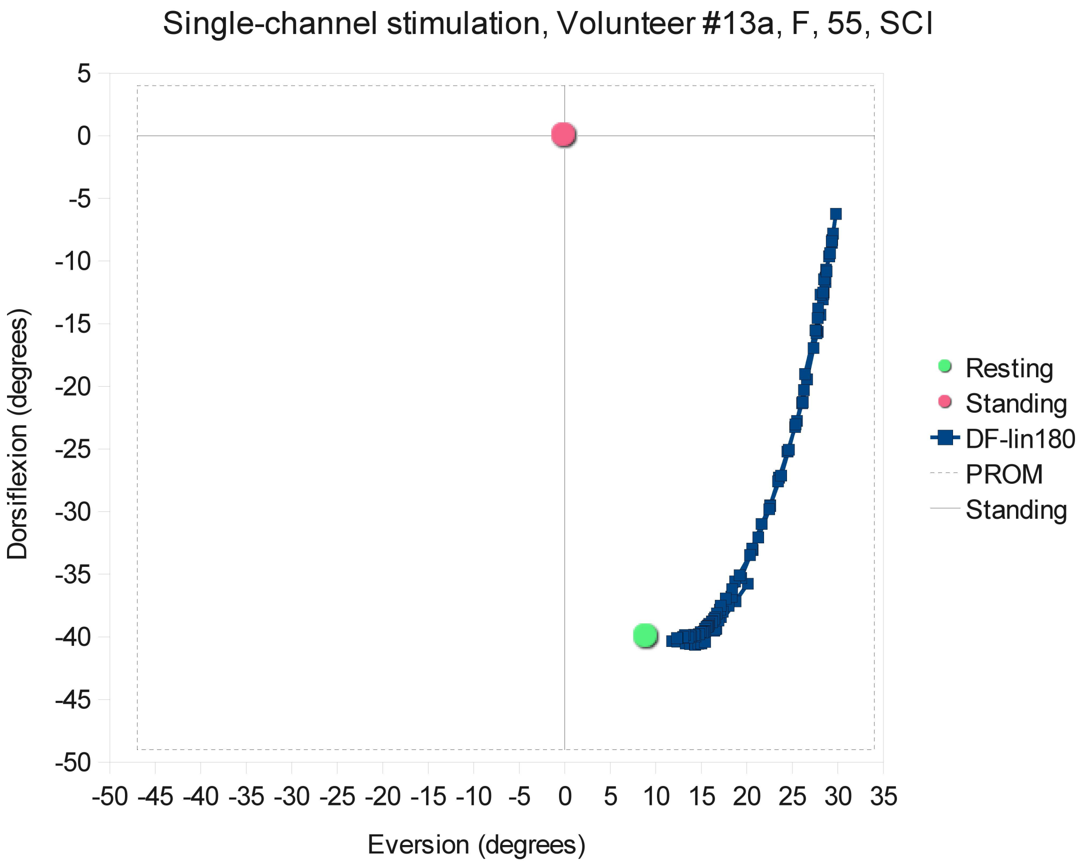


Figure 28: A typical single-channel stimulation response for volunteer 13.

6.5.7 Volunteer 14

324 The single-channel results (figures 29 and 30) were affected by a shift in resting posture during experiment. Although figure 29 shows eversion decreasing above 55% current, this does not reflect the fact that the resting foot posture also became more inverted. This experiment would have benefited from further repetition, but time was limited.

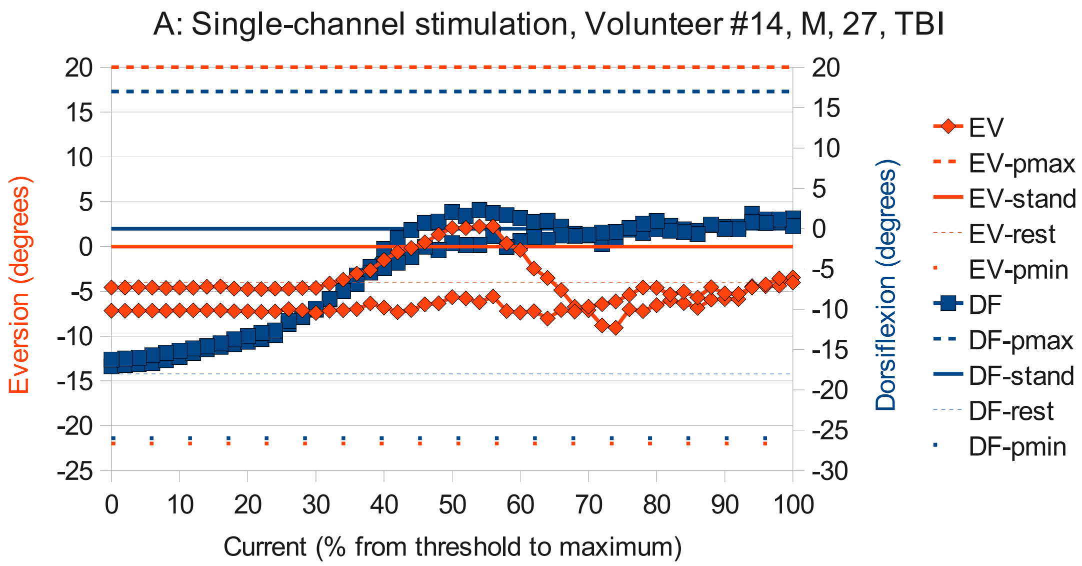


Figure 29: Single-channel result, volunteer 14: foot posture vs stimulation current.

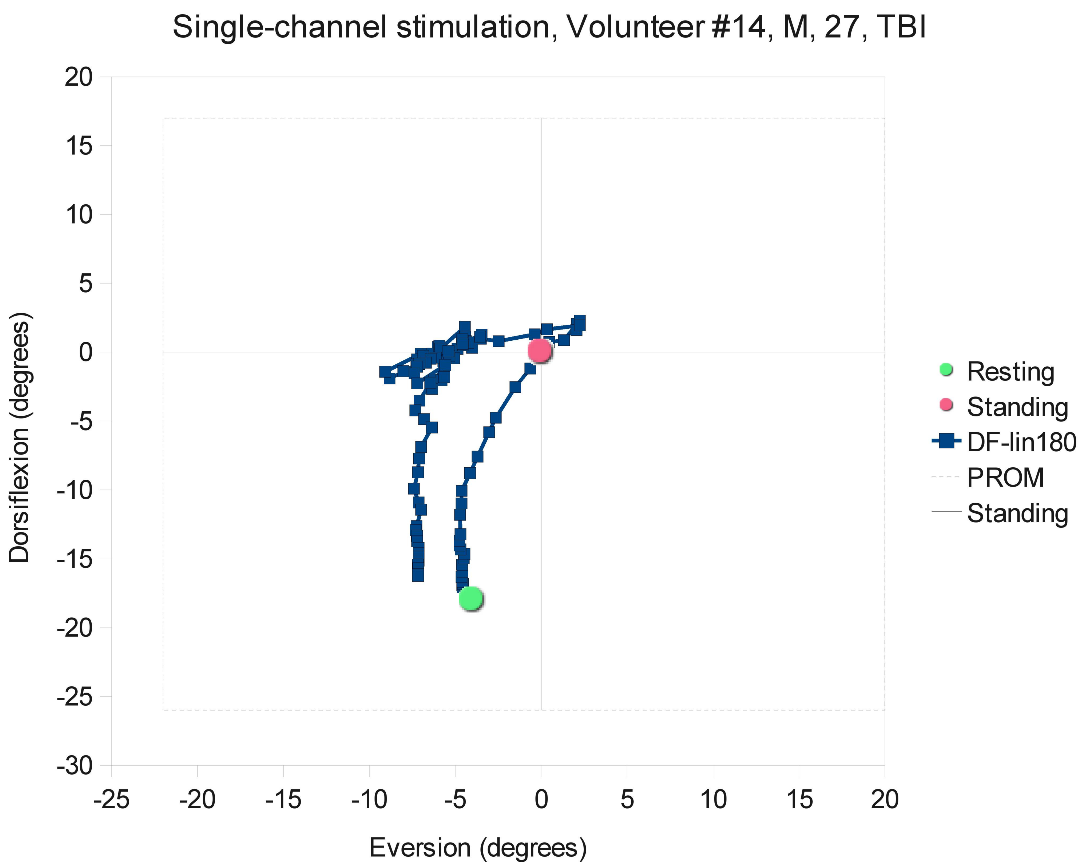


Figure 30: Single-channel stimulation, volunteer 14.

6.5.8 Volunteer 15

In the single-channel tests (figures 31 and 32), volunteer 15 showed increasing dorsiflexion and eversion with stimulation current, but interestingly there were two or three small steps in effect and a visible hysteresis loop. These were less evident in the randomised stimulation.

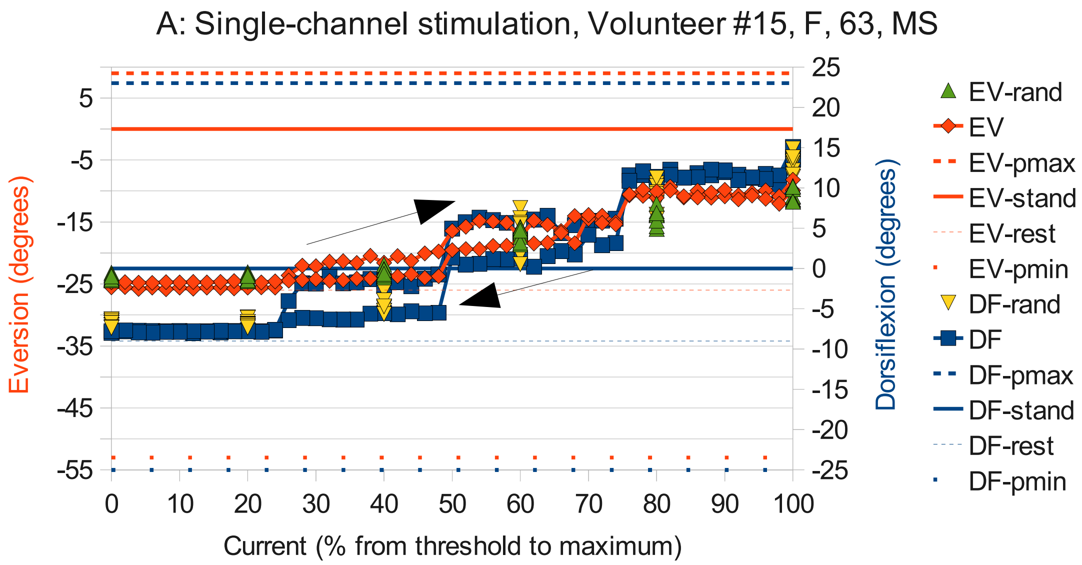


Figure 31: Single-channel result, volunteer 15: foot posture vs stimulation current.

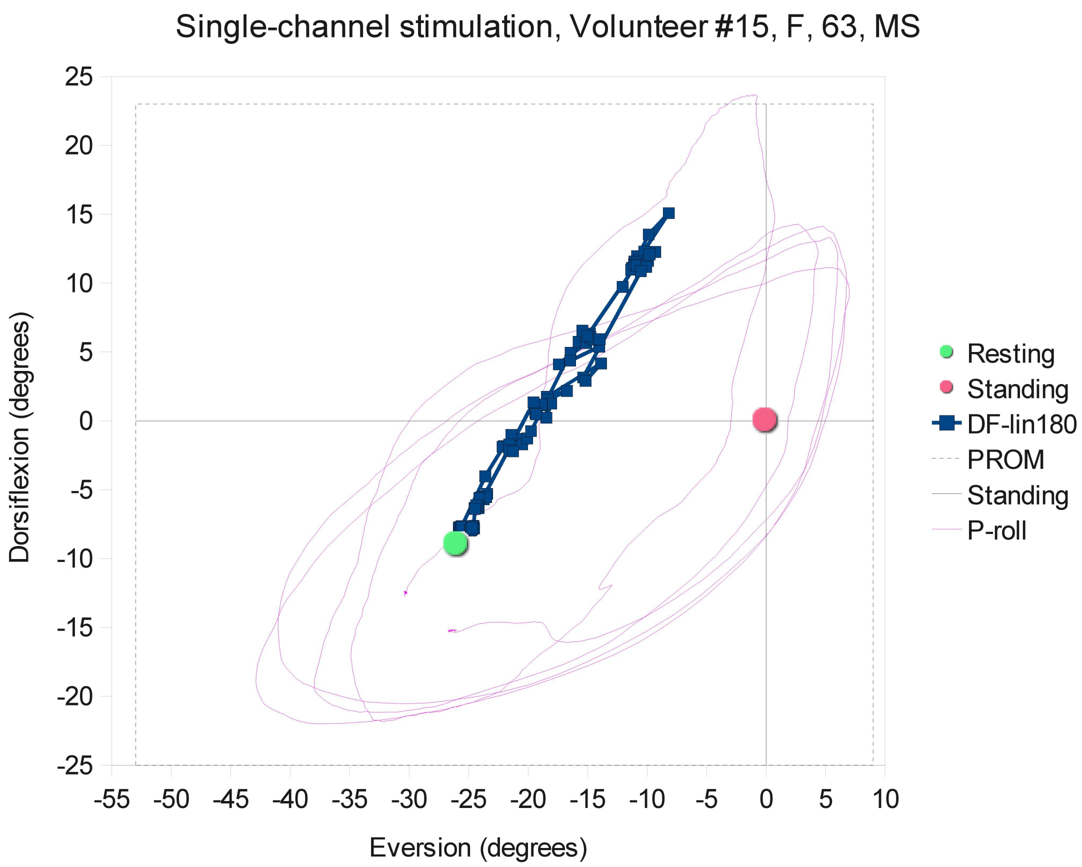


Figure 32: Single-channel stimulation, volunteer 15.

6.5.9 Volunteer 16

326 The single-channel results for volunteer 16 (figures 33 and 34) were entirely standard: dorsiflexion and eversion increase with stimulation current.

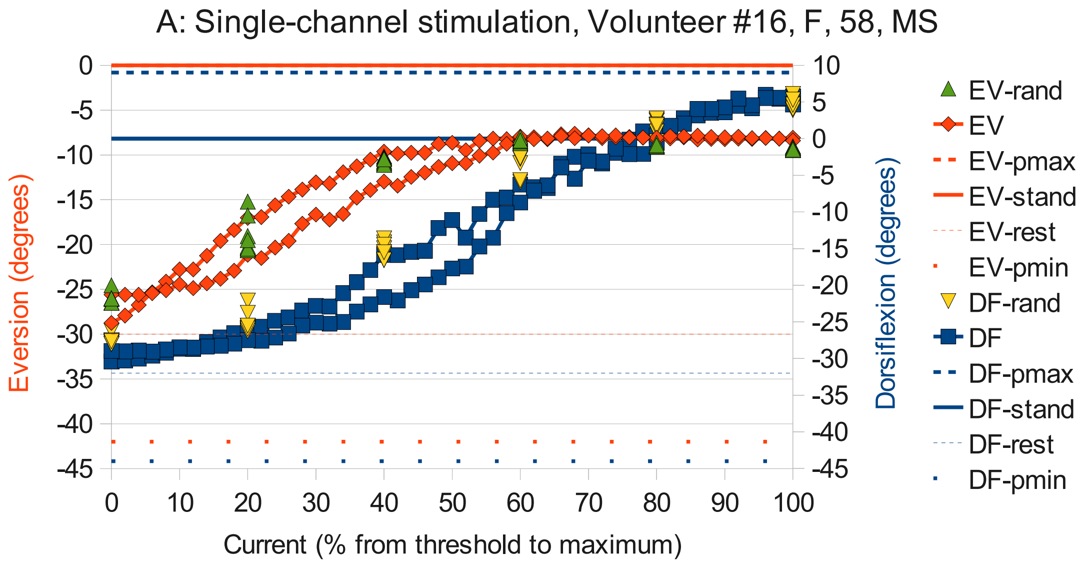


Figure 33: Single-channel result, volunteer 16: foot posture vs stimulation current.

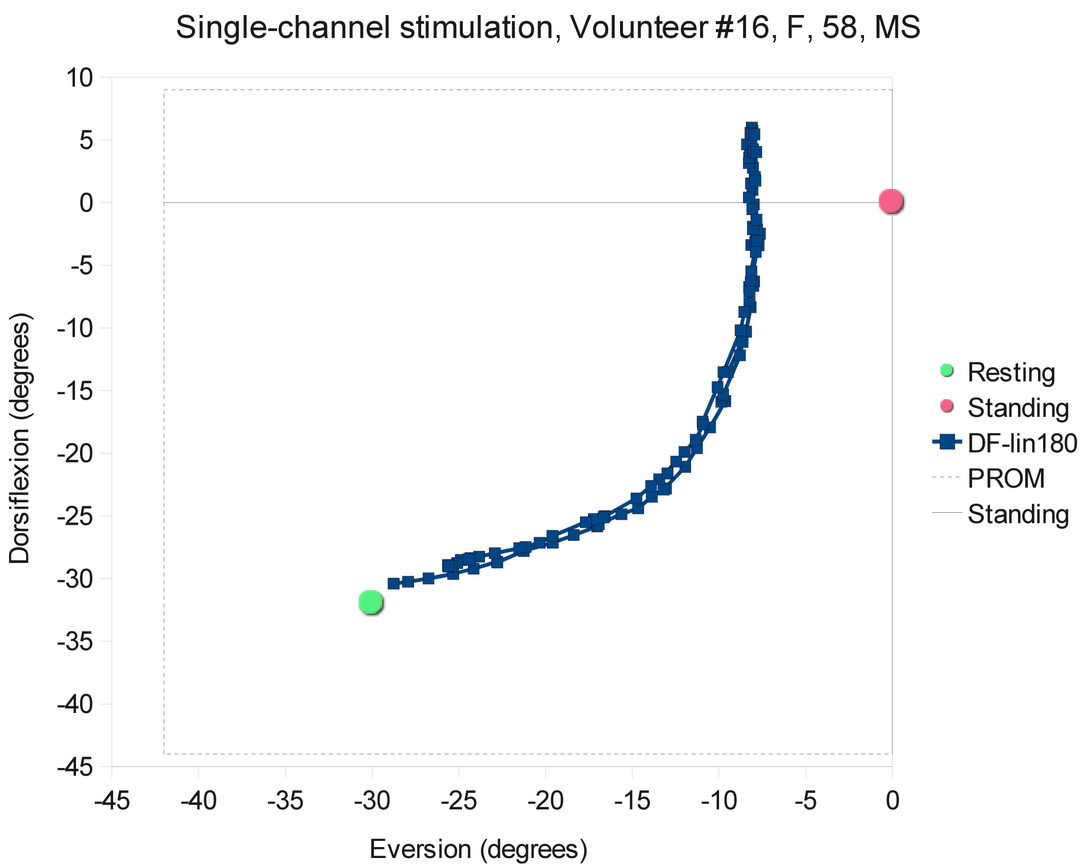


Figure 34: Single-channel stimulation, volunteer 16.

6.5.10 Volunteer 17

327 Volunteer 17's single-channel results were also entirely standard (figures 35 and 36): increasing stimulation current produced increasing dorsiflexion and eversion.

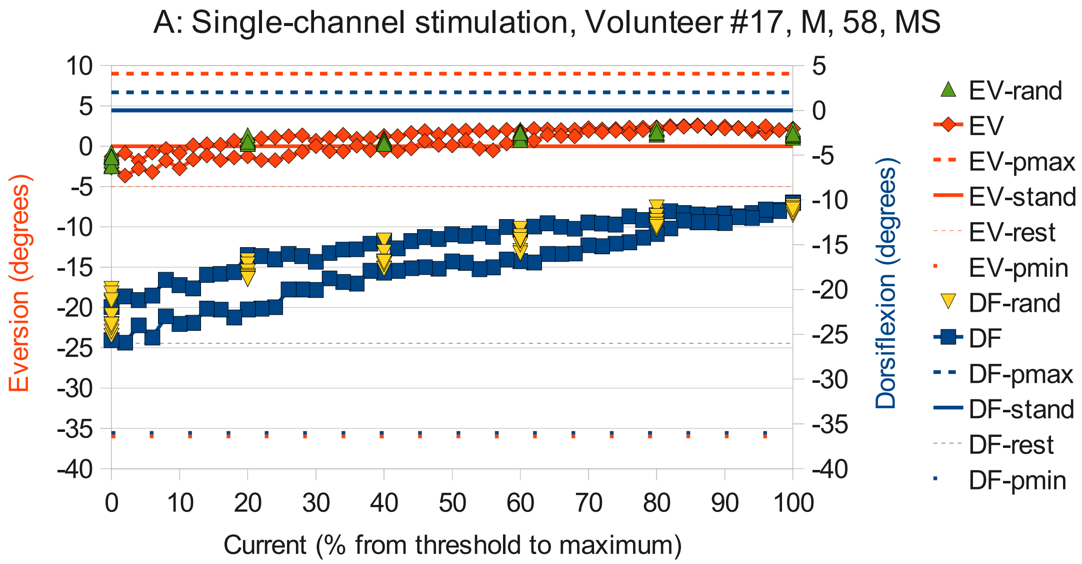


Figure 35: Single-channel result, volunteer 17: foot posture vs stimulation current.

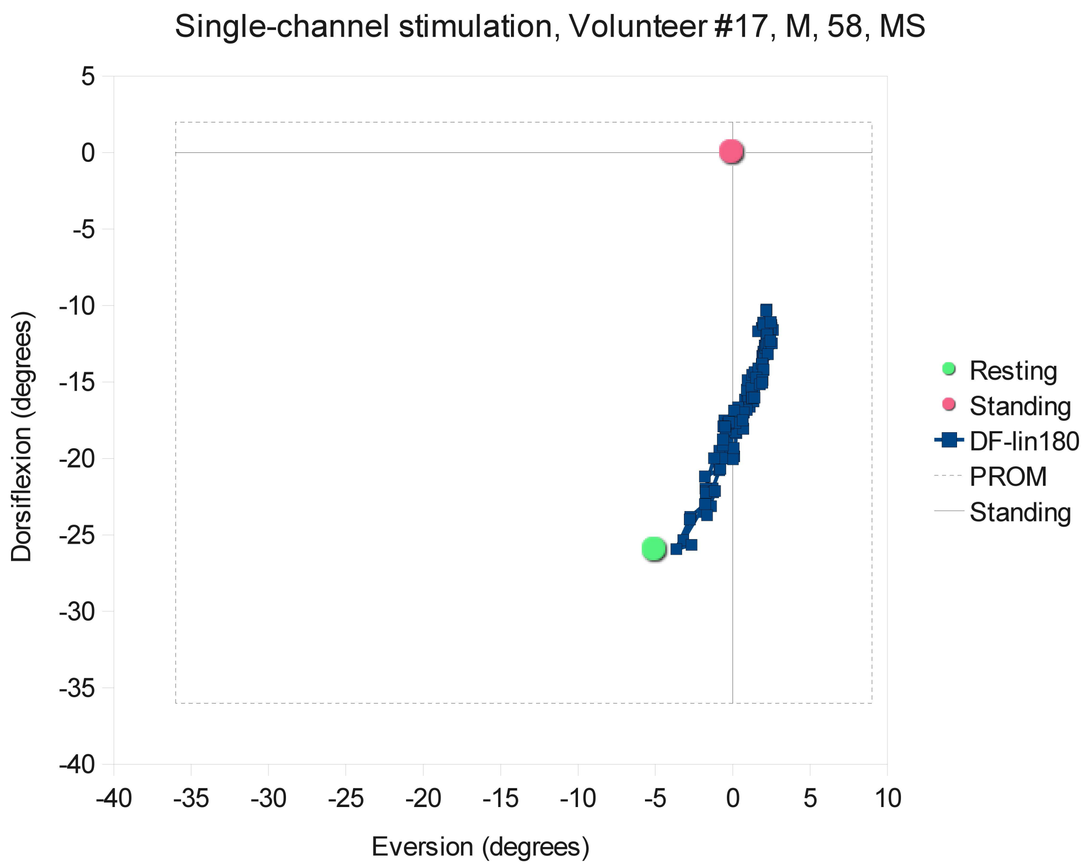


Figure 36: Single-channel stimulation, volunteer 17.

6.5.11 Summary of single-channel results

328 Figure 37 plots the single channel result for each of the ten volunteers on a single chart. The chart origin represents the foot posture in quiet standing.

329 If attempting to compare the volunteers, it should be recognised that their different pathologies limits the usefulness of such a comparison. That said, they all show a general trend of increasing dorsiflexion and eversion with current.

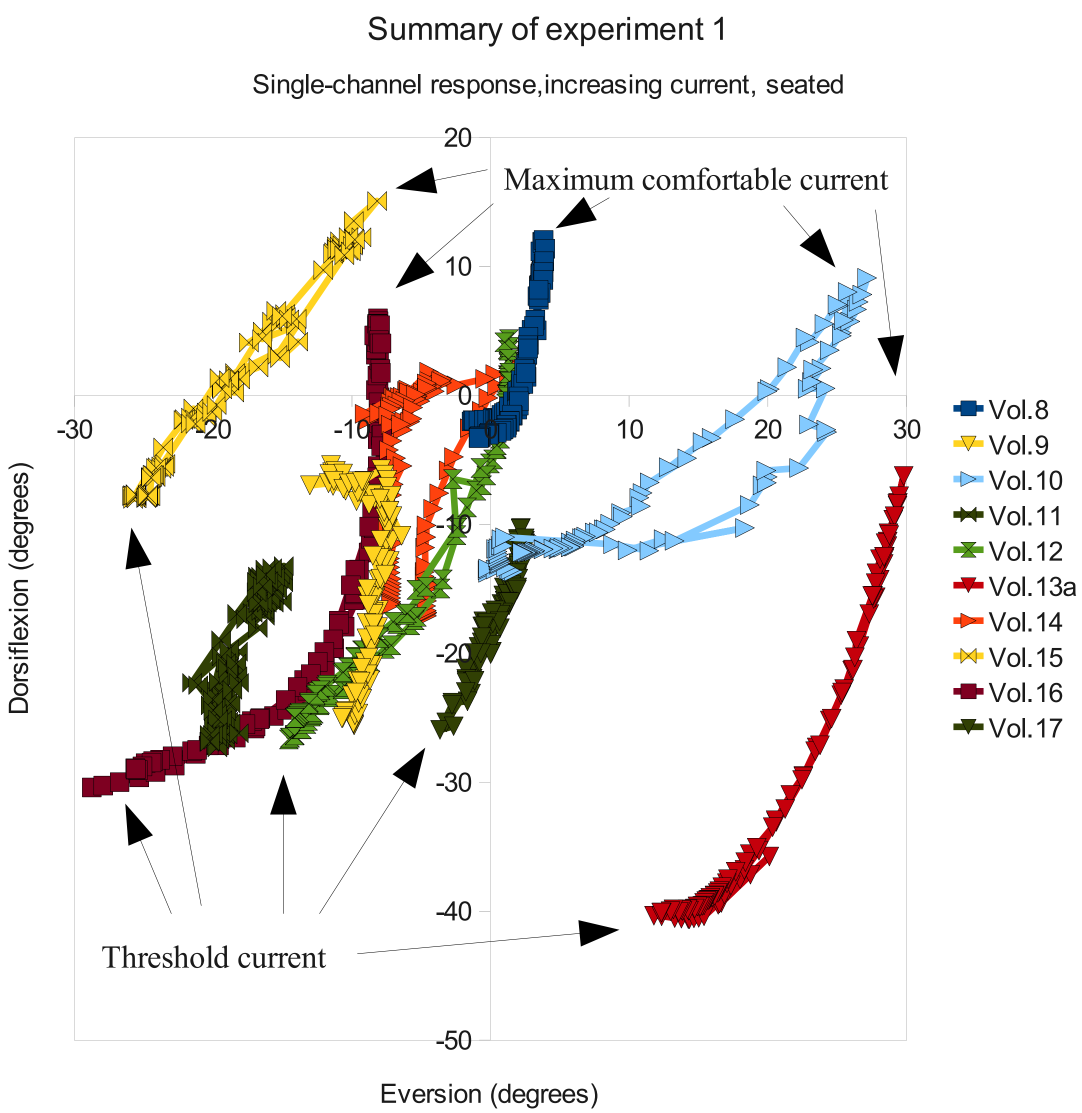


Figure 37: Combined plot of all single-channel results for experiment 1.

6.6 Discussion

330 This section discuses the extent to which the results support the hypothesis for experiment 1, which was as follows:

- The response to stimulation is consistent, monotonic with current and time-invariant over a time-scale of minutes.

6.6.1 Observations

331 The results showed that most volunteers responded with a steady increase in eversion and dorsiflexion with increasing current. There were cases where the response differed:

- The level of eversion sometimes declined as maximum dorsiflexion was reached. This may be a result of the mechanics of the joint as the Achilles tendon tightens.

- Some responses featured a hysteresis loop, although the direction of this was not consistent. Many factors could have contributed to this, such as a reduction in antagonist tone from reciprocal inhibition; fatigue or partial habituation to the stimulus and interaction with the volunteer's reflexes.

332 The tests with randomised currents showed greater variability in response than the linear current ramps. As with the hysteresis effect, recent stimulation history can affect the response to stimulation. Randomisation is often used to eliminate such effects which might be seen as a source of bias. However, in its clinical application, any adaptation to stimulation (tone changes, reflex excitability, etc.) by the FES user is a genuine part of their response to stimulation. As this study seeks to measure the response most relevant to the clinical use for treating drop foot, and in practice randomised stimulation is not used, it was decided not to continue randomisation to the other experiments.

333 Limits on the available time and volunteers' endurance meant that the volunteers for experiment 1 were only asked to perform one cycle of the single channel test, prior to

their participation in experiment 2. The linear current ramp test took 5 minutes (100 pulses at 3 second intervals) and, given the varying current, provides no real observation of the temporal stability of the response to stimulation. However, it demonstrated that the volunteers were able to complete this kind of test and so were suitable to continue to experiment 2.

6.6.2 Interpretation

334 The results from experiment 1 partially supported the hypothesis: response to stimulation is broadly consistent, but there are a number of factors that can cause the response to vary (e.g. adaptation to stimulation and fatigue) or limit the response (e.g. joint stiffness and range of movement). While these could be significant if we were trying to measure the precise response sizes, the broad trend of dorsiflexion and eversion to increase with current is not masked by an occasional erratic response.

6.6.3 Critical review

6.6.3.1 Seated testing

335 The relevance of seated testing could be questioned given that the overall objective of the project is to direct the foot while walking. When walking, the foot is constrained by periodic contact with the floor and usually adopts a posture conforming to the surface of the ground during stance. Also, the general muscle tone is higher in walking than when seated. The differences between the seated and walking cases mean that the results of experiments 1 and 2 could not be used to reliably predict the response in walking. However, a key finding of this part of the study was that two-channel stimulation was tolerable, and some degree of consistent response could be seen in most cases. Therefore experiments 1 and 2 were successful in their main goal of establishing, in a safe environment, that it was reasonable to proceed to the walking tests.

6.6.3.2 Use of an unconstrained foot

336 In many studies of the effect of motor nerve stimulation, the limb is held firmly and the evoked muscular force is measured isometrically. This experiment chose to allow the foot to move and measure the resulting postural angles because this movement was felt to resemble the reality of the swing phase of gait. The results from an isometric

technique could be expected to be purely due to the effects of simulation on recruitment, enabling one to study the effect of stimulation on nerve recruitment. Allowing free movement introduces several possible complications from the joint biomechanics, surface movement artefacts and dynamic characteristics of the muscle. For example:

- As the joint moves, the line of action of the force may pass closer to or further from the centre of rotation, changing the moment even if the force is constant.

- A moving joint may enter a range of higher or lower stiffness.

- Changes in muscle length may provoke stretch reflexes.

- Identical stimulation produces different forces depending on the force-length characteristic of the muscle.

- Movement of the skin associated with joint movement or muscle contraction may move the electrode over the nerve, potentially altering the level of recruitment.

337 Any of these could alter the apparent response. However, these effects occur in clinical practice and so were considered valid to include in this study. More detailed studies of the recruitment patterns of two-channel stimulation could use isometric measurements to reduce the variability associated with joint movement.

6.6.3.3 Foot posture measurement technique

338 Comparison with a clinical goniometer showed that the instrumentation (electogoniometer and sampling system) was appropriate for pseudo-static measurement of angles, but the use of this angle as a measure of response to stimulation is not without problems, both in principle and in this particular implementation:

- The resting foot posture was assumed to be constant, or at least that any variation could be neglected, although it was sometimes seen that the volunteer had shifted their position. The change in starting posture could have an unknown effect on the response to stimulation, either through variation in surface artefacts such as electrode movement over the nerves and/or due to changes in the trajectory of the joint given different starting orientations when the muscles contract.

- The experiment made no measurement of internal/external rotation of the foot/lower leg, which is often a notable part of the response and can contribute to both stability in stance and ground clearance in swing.

339 The repeatability of the study may be improved by controlling the starting foot posture. Future studies should consider measuring rotation in addition to dorsiflexion and eversion.

6.6.3.4 Variability in set-up

340 The set-up procedure followed the common clinical practice of using an iterative/adaptive process for positioning the surface electrodes and setting currents to achieve the desired response. The electrodes for the two-channel tests were selected on the basis of leg size (smaller electrodes on small legs) and comfort (the larger electrodes sometimes being more comfortable). All these factors contributed to each volunteer being set up slightly differently, both inter-subject and inter-test (for those volunteers who repeated some tests). This variability could be expected to contribute to variability in the results. This is a realistic aspect of surface stimulation, but not helpful in trying to understand the effect of any particular stimulation pattern.

341 This variation in set-up is compounded by the unknown variation between the neural anatomy of the volunteers. The effect of this is that we do not know the exact nerves that were recruited for each test. A more thorough examination could use evoked EMG to determine the recruitment patterns (monitoring the compound muscle action potentials of tibialis anterior and the peroneal muscles in response to stimulation), as a check that the set-up was repeatable. This might also help understand the mechanism for the effects of two-channel stimulation in experiments 2 and 4.

6.6.3.5 Low response to stimulation

342 The levels of dorsiflexion and eversion seen in the results were often less than might be expected for safe walking, frequently not achieving positive dorsiflexion or eversion. This was seen particularly in the seated tests (experiments 1 and 2). There are at least three possible contributing factors:

- Sub-optimal electrode placement. Time constraints limited the number of combinations of placement and current that could be tested. Except where noted, the volunteers usually arrived for their first experimental session direct from a clinical review appointment, so should be set-up well. At repeat visits they had their own set-up, which may be different.

- Physiological properties affecting sensitivity and movement, e.g. stiffness, spasticity, or tone. These might be different when seated than when standing, and when resting than in walking. Some of these effects may also vary in response to repeated stimulation.

- Possible low current intensity. Volunteers were asked to set the current to their 'normal level' of comfort and effectiveness while seated. The current chosen was not compared to their normal walking stimulator setting. Some volunteers lacked full sensory ability, or may have chosen levels that were comfortable for sitting rather than effective for walking. In tests with different electrode positions, many volunteers did not feel the need to adjust the pulse width from one position to the next to compensate for change in effectiveness or comfort. Again, this could be due to low sensory awareness or only partially considering the need to maintain a strong response.

343 As well as generating a small response, low stimulation levels may also increase the variability of the response, as the joint may not be driven to its end of range. In the region where the nerve bundle is partially recruited, small surface movements may have a more significant effect than if the current is sufficient for full recruitment. Furthermore, if two muscle groups are promoting opposite movements, such as inversion and eversion, these variations in neuromuscular response may result in a wide

variation in foot posture.

344 An improvement to the method would have been to use the same current as their normal walking stimulator. No two stimulators are identical, so this normal current would have had to be measured. In these tests, the volunteer's own stimulator was not used, to avoid the risks of adjusting its settings and to facilitate integration between the stimulating and data logging parts of the equipment.

345 Despite the fact that the response magnitude was often lower than ideal for walking, the value of the results lies in the trend as the two-channel stimulation shifts from medial to lateral electrode. The later experiments enable examination of whether this trend is maintained in walking, where stimulation levels were adjusted until the response was appropriate for walking, although sometimes this was still more inverted than ideal.

6.6.3.6 Role of electrodes

346 This study used self-adhesive gel electrodes as per normal clinical use. However, these can suffer from a tendency to peel off the skin and this was not well controlled in these tests, leading to further variability in the effectiveness of stimulation and hence the response. A simple solution is to apply an elastic bandage (e.g. Tubigrip) to hold the electrodes in contact with the skin.

6.6.3.7 Volunteer selection

347 The sample size of ten volunteers was a considered appropriate for a feasibility study at this stage of development. A larger sample size would have improved the statistical robustness of the tests, but that must be weighed against the need to avoid troubling volunteers unnecessarily and to complete the work in the available time.

348 Section 11.1.1 provides an analysis of the volunteers, showing that their walking abilities appear to be representative of the wider FES user population.

7 Experiment 2: The effect of two-channel stimulation on foot posture while seated

7.1 Overview

349 Ankle dorsiflexion and eversion were measured in response to two-channel stimulation (while seated) while the current balance was shifted from medial to lateral electrode and back. This was repeated after translating the electrodes by 10mm laterally, medial proximally and distally.

7.2 Objective

350 The primary objective of experiment 2 was to see the effect on foot posture (dorsiflexion and eversion) of changing the current balance between the medial and lateral electrodes. The electrode placement was set up such that this range included, as far as possible, a posture suitable for walking, i.e. dorsiflexed and everted. The secondary objective was to see whether, once the electrodes had been moved by 10mm, it was possible to maintain this good posture by changing the current balance between the medial and lateral electrodes.

7.3 Hypotheses

351 The degree of eversion accompanying a clinically beneficial dorsiflexion can be influenced by varying the balance of currents stimulating the tibialis anterior and peroneal muscles through medial and lateral electrodes.

352 Clinically acceptable foot posture can be maintained in the face of small changes in electrode position by altering the current balance.

7.4 Method

353 Following their participation in experiment 1, the ten volunteers were seated with leg extended and a goniometer fixed to the lateral maleolus at the ankle, as described in section 5.3. Electrodes and currents for two-channel stimulation were set up as follows:

7.4.1 Electrode positioning procedure

1. A common indifferent electrode was positioned on (or slightly proximal to) the bulk of the tibilais anterior. This was the same position as the indifferent electrode for single channel stimulation.

2. The active electrode of the first channel (designated 'medial') was placed anterio-medial to the head of the fibula, targeting the deep branch of the peroneal nerve (for tibialis anterior recruitment giving dorsiflexion but possibly also inversion).

3. The active electrode of the second channel (designated 'lateral') was placed on or posterior to the head of the fibula, targeting the superficial branch of the peroneal nerve (for peroneus group recruitment giving eversion).

4. Variability between individual's neuroanatomy means that some repositioning was necessary to find suitable locations, defined as follows:

(a) For the medial (dorsiflexing/inverting) channel, stimulation should produce strong dorsiflexion. Mild inversion was acceptable at this stage.

(b) For the lateral (everting channel), the position should produce eversion without plantarflexion. Some dorsiflexion was desirable but not essential.

(c) As the overall objective was to produce dorsiflexion with a net mild eversion, positions producing strongly unbalanced responses were avoided. (Rationale: the peronei muscles were unlikely to be strong enough to overcome severe inversion caused by the tibialis anterior muscle, plus strong co-contractions would be uncomfortable).

5. The electrode positions were photographed to record their location. Example arrangements are shown in figures 38 and 39.

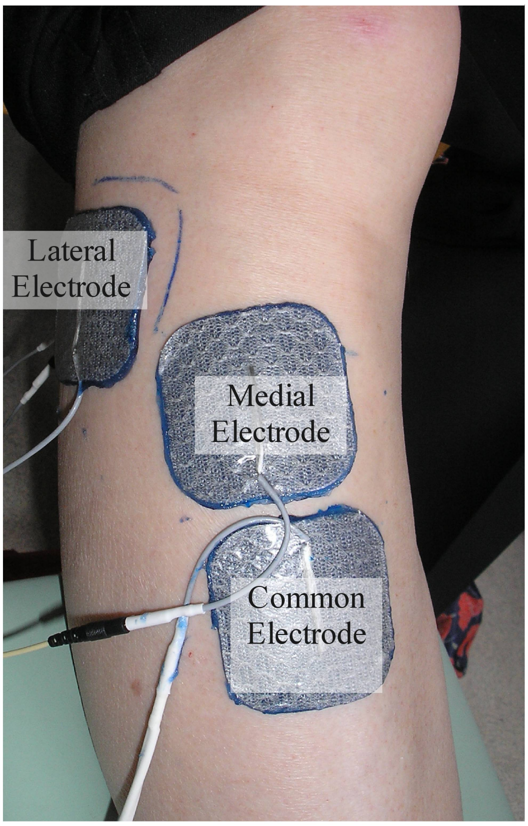


Figure 38: Example electrode placement (with 5x5cm electrodes)

354 In figure 39, small electrodes were used as this volunteer was particularly sensitive to the placement position. Moving either electrode off the head of fibula produced little movement at all, so the small electrodes enabled the current to be concentrated over the area where stimulation was effective.

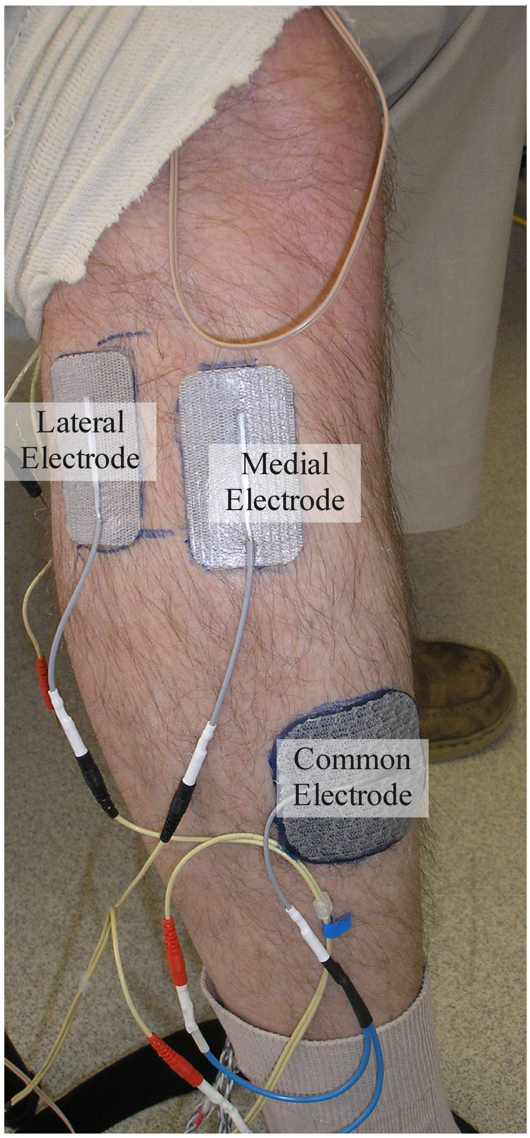


Figure 39: Example electrode placement (with 5x5 and 3.3x5.5 cm electrodes)

7.4.2 Stimulation currents

355 The maximum and minimum currents on each channel were set by the following procedure:

1. The stimulation frequency was set to 40Hz and the pulse width to 180μs.

2. A series of 3 second pulse trains were applied to each channel <u>separately</u> while the current was increased from zero and the resulting foot posture observed:

(a) The current on the medial channel was increased to produce dorsiflexion through the available range of movement (ROM) while remaining comfortable and without gross inversion. This defined the maximum current applied to this channel for this volunteer. The current was reduced to the minimum needed to produce a visible movement; this defined the minimum current.

(b) The current on the lateral channel was increased to produce some dorsiflexion and eversion through the available range of movement while remaining comfortable. The current was then reduced to the minimum level needed to produce visible movement.

(c) If necessary, steps (a) and (b) were repeated with small changes in electrode position until each channel could give its desired response individually.

3. The pulse width was temporarily reduced to 36μs to ensure comfort when both channels were enabled together. Both channels were enabled, and the pulse width increased to a level that produced a strong foot response without being uncomfortable. The effect of varying the balance of current between the two channels was observed, and minor adjustments to current were made as follows:

(a) If the foot tended to evert regardless of current ratio, then the lateral minimum was reduced or the medial maximum increased.

(b) If the foot tended to invert regardless of current ratio, then the medial minimum was reduced or the lateral maximum increased.

(c) In both cases care was taken to ensure that stimulation remained comfortable and that the foot response approximated that for safe walking with both channels mid-way between their minima and maxima.

4. If these electrode positions and current settings did not produce a usable range of foot responses, one or more of the electrodes were moved (medially to increase

dorsiflexion/inversion or laterally to increase eversion) and the currents re-established from zero.

7.4.3 Current balance

356 From this point on, the current delivered to the lateral (everting) channel (I_{lat}) and medial (dorsiflexing) channel (I_{med}) was a function of the *balance* parameter in the range 0 to 100%:

$$I_{lat} = I_{lat,min} + \frac{balance}{100}(I_{lat,max} - I_{lat,min}) \quad (1)$$

$$I_{med} = I_{med,min} + (1 - \frac{balance}{100})(I_{med,max} - I_{med,min}) \quad (2)$$

357 Thus *balance=0%* implies maximum on the medial channel and minimum on the lateral channel, while *balance*=100% implies maximum on lateral and minimum on medial channels. The term *balance* is used in this document, although it should be noted that at 50% the currents were not necessarily equal, just both mid-way between their minima and maxima.

7.4.4 Two-channel stimulation measurement procedure

358 A sequence of 102 pulse trains were applied with 3 second intervals. Each pulse train had the same envelope (200ms rising ramp, 500ms steady, 150ms falling ramp) as for experiment 1, but the balance was automatically changed from 0% (maximum on the medial channel) to 100% (maximum on the lateral channel) in 2% steps. This meant that every pulse train delivered a strong net stimulation current; this contrasts with experiment 1 where the stimulation current increased from minimum to maximum and back; this was intentional: experiment 1 investigates response with changing current, while experiment 2 focuses on the effect of changing the balance.

359 As before, the data collection system used the goniometer to measure the dorsiflexion and eversion just before the falling ramp. The Kst software plotted a chart of dorsiflexion and everison vs. balance as the experiment progressed.

7.4.5 Sensitivity to electrode position

360 To study sensitivity to electrode position, the whole set of electrodes was displaced by ±10mm distally and circumferentially around the leg, representing a variety of possible repositioning errors.

361 These four extra locations were known as the lateral, medial, proximal and distal positions, in their relation to the original. At each new location:

- The balance was set to 50% and the pulse width reduced to 36μs, before being ramped up to the value required for a comfortable full range response (nominally 180μs). This was necessary as the new position may have had greater sensory sensitivity and/or different effectiveness in producing movement of the joint.

- The balance was manually adjusted and test pulse trains delivered throughout the range from 0 to 100%. This checked that stimulation was tolerable at all balance settings in the new position. Pulse width was adjusted where necessary, accepting lower response if needed. If the new position was too uncomfortable at any effective level of stimulation, this was recorded and the position abandoned.

- If stimulation at the new position was found to be tolerable, the two-channel stimulation measurements described in the previous section (7.4.4) were repeated.

7.4.6 Extended tests – single-channel sensitivity to position

362 The above experiments studied the effect of moving the two-channel electrodes and the ability of the current balance to compensate for that change. Testing each electrode position typically took 7-10 minutes and involved over 100 stimulation trains. Time limitations meant that most volunteers were not asked to repeat the experiment nor to be tested with multiple single-channel electrode positions, as single-channel sensitivity to position was not the main focus of this research. However, three participants volunteered for extended sessions (a further 3 hours) which enabled us to perform the single-channel tests at five electrode positions. Limited comparisons can also be made

between their first and second visits.

7.4.7 Data collection and processing

363 As for experiment 1, the automatic data collection system recorded the stimulation parameters used for each pulse train, and sampled the goniometer signals (dorsiflexion and eversion angles) continuously at 50Hz. For each test pulse train, the last four angle samples before the falling ramp (i.e. covering 80ms) were averaged to give the foot posture attained with that pulse train.

7.5 Results

364 These tests show the effect of two-channel stimulation on foot posture while seated. The results are presented as charts of dorsiflexion and eversion against the current balance setting. Section 7.6 contains the results of the extended tests which included comparison with moving the single channel electrodes.

7.5.1 Structure of the results charts for experiment 2

365 In the charts, each data point is the dorsiflexion or eversion achieved just before the stimulation pulse train stops, i.e. at the end of a 0.5s simulation train. Reference marks show the seated and standing position of the foot, and the limits of passive range of motion. Each data series represents measurements from test pulses at various balance setting in one electrode location. Most charts plot data from multiple electrode positions, with the series colour coded as follows:

- Blue: electrodes at nominal location
- Red: electrodes all 10mm lateral
- Yellow: electrodes all 10mm medial
- Green: electrodes all 10mm proximal
- Brown: electrodes all 10mm distal

366 This is also reflected in the series names including *lin, lat, med, prox* or *dist* respectively. A numeric suffix indicates a pulse with other than the default of 180µs (chosen by the volunteer to maintain comfort and effectiveness at producing foot lift).

367 Charts of eversion and dorsiflexion are plotted in degrees, with the scale span covering at least the whole passive range of movement (PROM, determined manually at the start of each session). The PROM limits are indicated by dotted lines on the charts, but the rectangular boxes on the XY charts should not be taken as implying that the foot can move over the entire range within the box. Indeed, some volunteers also have their 'circular' range of foot movement plotted to illustrate their passively-available foot postures.

368 As with experiment 1, the results are presented as a series of case studies, starting with the first impaired volunteer, identified as number 8. His results are described in detail so the reader can become familiar with the chart format. The text accompanying the subsequent volunteers' results is more concise.

7.5.2 Volunteer 8

369 Figure 40 shows the two-channel electrode arrangement used for volunteer 8; the corresponding results are plotted in figures 41 to 43. In this experiment, the distribution of the current shifts from medial to lateral electrode, although each electrode maintains at least a minimum 'threshold' current. Thus each pulse train produces a significant movement (not just a threshold twitch); the purpose of this experiment was to see if the eversion could be affected by the change in current distribution while maintaining dorsiflexion.

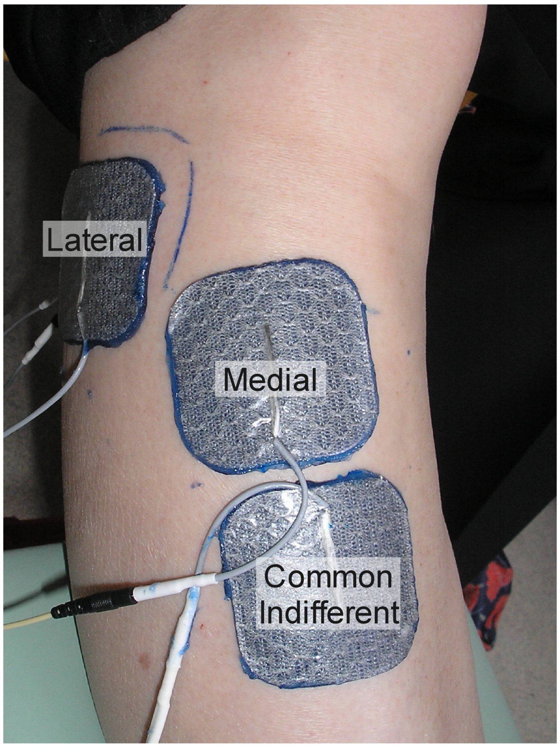


Figure 40: Volunteer 8 electrode placement for two-channel stimulation

370 Figure 41 shows that dorsiflexion is indeed well maintained (with a slight reduction when the current is biased towards the lateral electrode). The response is strong and consistent (the spike in the medial trace near 80% is an artefact caused by the volunteer moving unrelated to stimulation). The five electrode positions are broadly comparable, with a slightly stronger response in the medial position and slightly weaker in the lateral position.

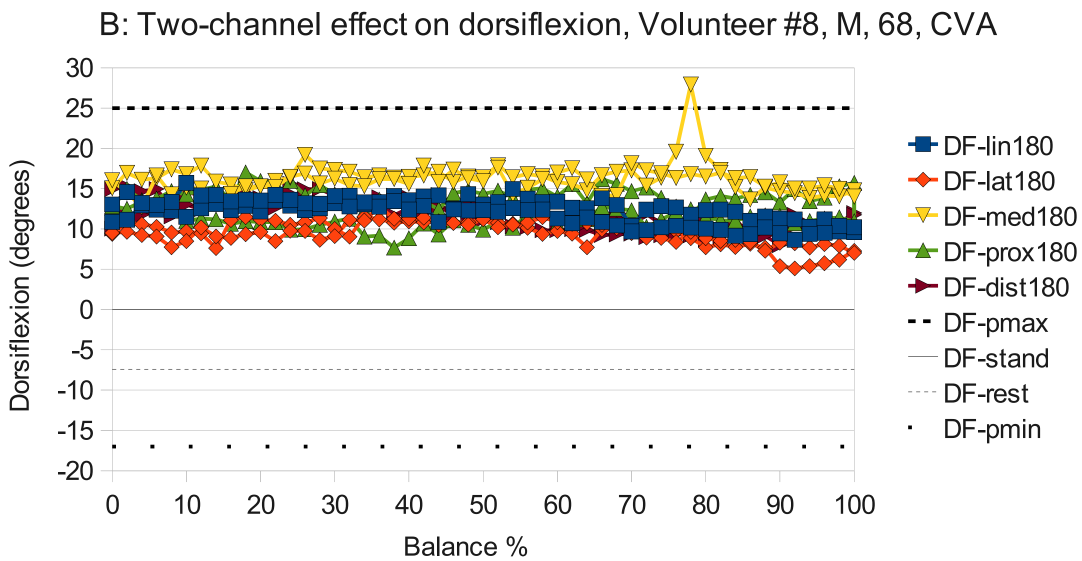


Figure 41: Two-channel stimulation effect on dorsiflexion, volunteer 8.

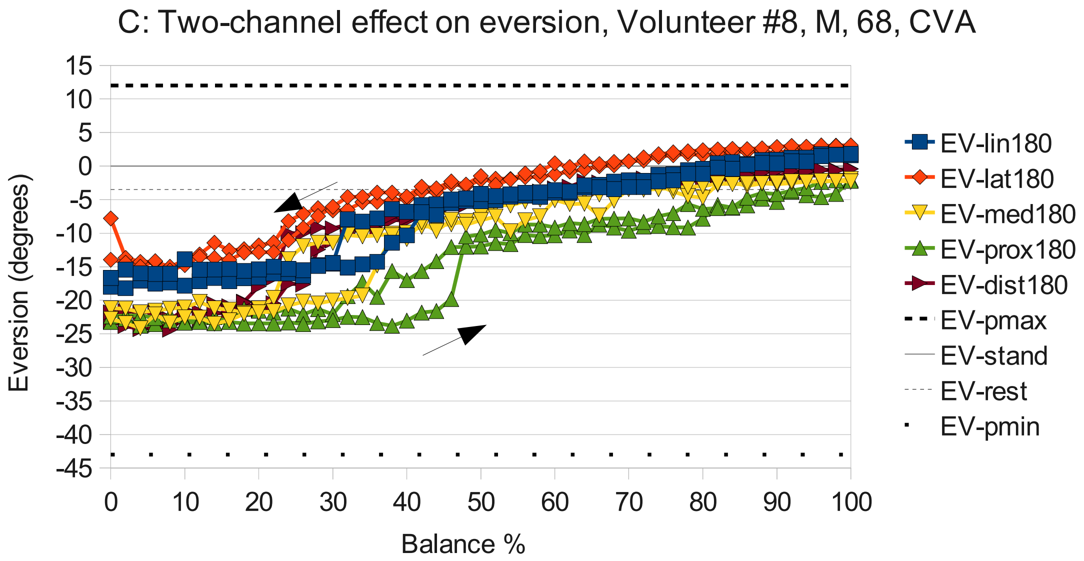


Figure 42: Two-channel stimulation effect on eversion, volunteer 8.

371 The eversion results in figure 42 show several interesting features:

1. Eversion does increase as the bias shifts to the lateral electrode.

2. There is a notable step increase in eversion in the 20-45% region, across all electrode positions. This step features a hysteresis loop. The loop direction implies that the stimulation response remains similar to recent responses until sufficient change in the input has occurred. Some other volunteers also exhibited this loop, usually less clearly, and not always in the same direction.

3. The response is consistent amongst adjacent data points, though stronger at some electrode positions than others. As would be expected, the lateral electrode position produces greater eversion than the medial position.

4. The eversion barely exceeds neutral, and is often (much) more inverted than for normal single-channel stimulation. This would not be appropriate for drop-foot correction. The degree of inversion may be a result of two factors: firstly, it was often difficult to provoke strong eversion (although visually external rotation/abduction could become very strong); secondly, for the seated experiments, a setup producing notable inversion was quite acceptable for the purpose of showing that a range of foot postures could be achieved.

372 Figure 43 shows the same dorsiflexion and eversion data in an XY chart. (This format was as introduced in section 6.5.1; later volunteers also have their reachable passive range illustrated in a pink solid line). Figure 43 contains the results for two-channel stimulation at each of five electrode positions. This illustrates that dorsiflexion is approximately constant while the degree of eversion can be adjusted through a wider range (in practice, mainly inversion). Note again the single outlier in the medial data series, and the generally stronger, more inverted result of the medial data series.

373 The format of figure 43 provides a clear visual representation of whether and how much seated (unloaded) foot posture can be influenced by two-channel stimulation. This chart is the main result for the seated two-channel experiment with each volunteer.

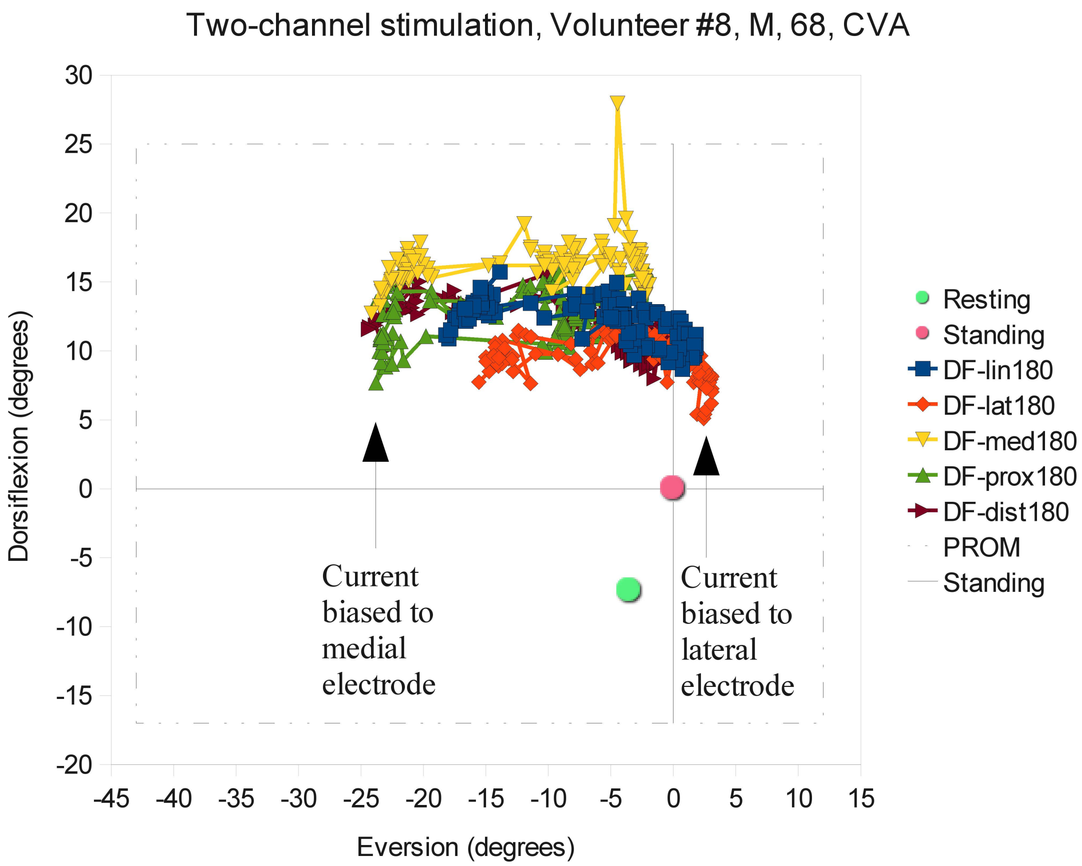


Figure 43: Two-channel stimulation result, volunteer 8.

7.5.3 Volunteer 9

374 Volunteer 9 used a reverse-polarity set-up for her normal walking. This was maintained for both single-channel and two-channel tests. Small electrodes were used in the two-channel tests to fit in the available area (figure 44).

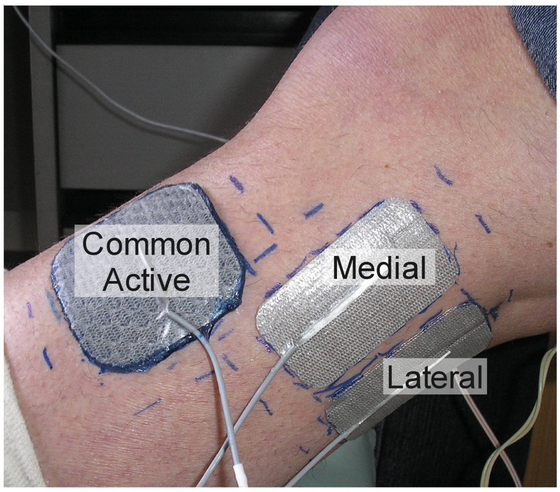


Figure 44: Volunteer 9 electrode placement for two-channel stimulation.

375 Figures 45 to 47 present the results for volunteer 9.

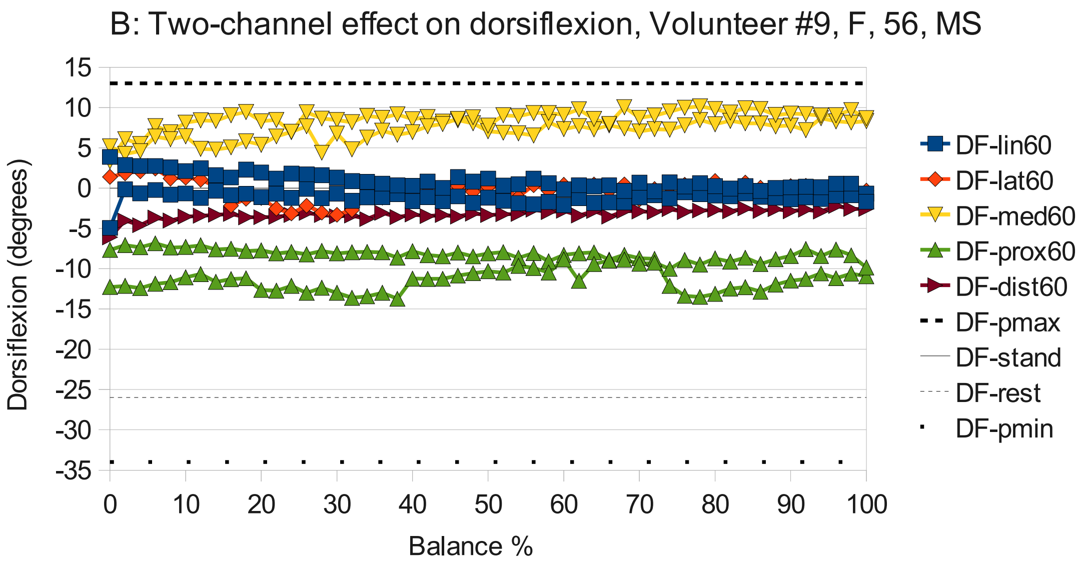


Figure 45: Two-channel effect on dorsiflexion, volunteer 9: changing the current balance had little effect on foot posture.

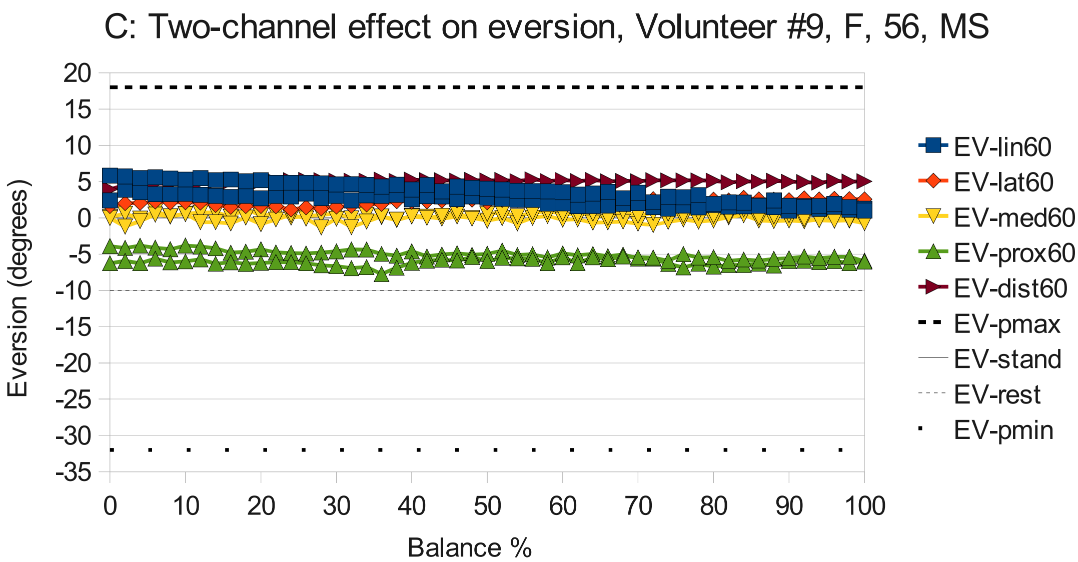


Figure 46: Two-channel effect on eversion, volunteer 9: changing the current balance had little effect on foot posture.

376 Two-channel stimulation produced generally more dorsiflexion and eversion than in her single-channel tests, which may simply be a result of the higher currents used (although pulse width was quite low, at 60µs). However, adjusting the balance between medial and lateral electrodes had no appreciable effect. This may be a result of the location, close proximity and small size of the electrodes used, but other volunteers showed stronger changes in eversion with similar electrode arrangements. Another possibility is the use of reverse-polarity stimulation in this case, meaning that most change in current occurred at the indifferent electrodes.

377 Volunteer 9 noted that the two-channel stimulation in the distal position was less comfortable than the other positions. The slightly elevated dorsiflexion in the middle (40-70%) of the proximal trace (green) was observed as a movement artefact during the experiment.

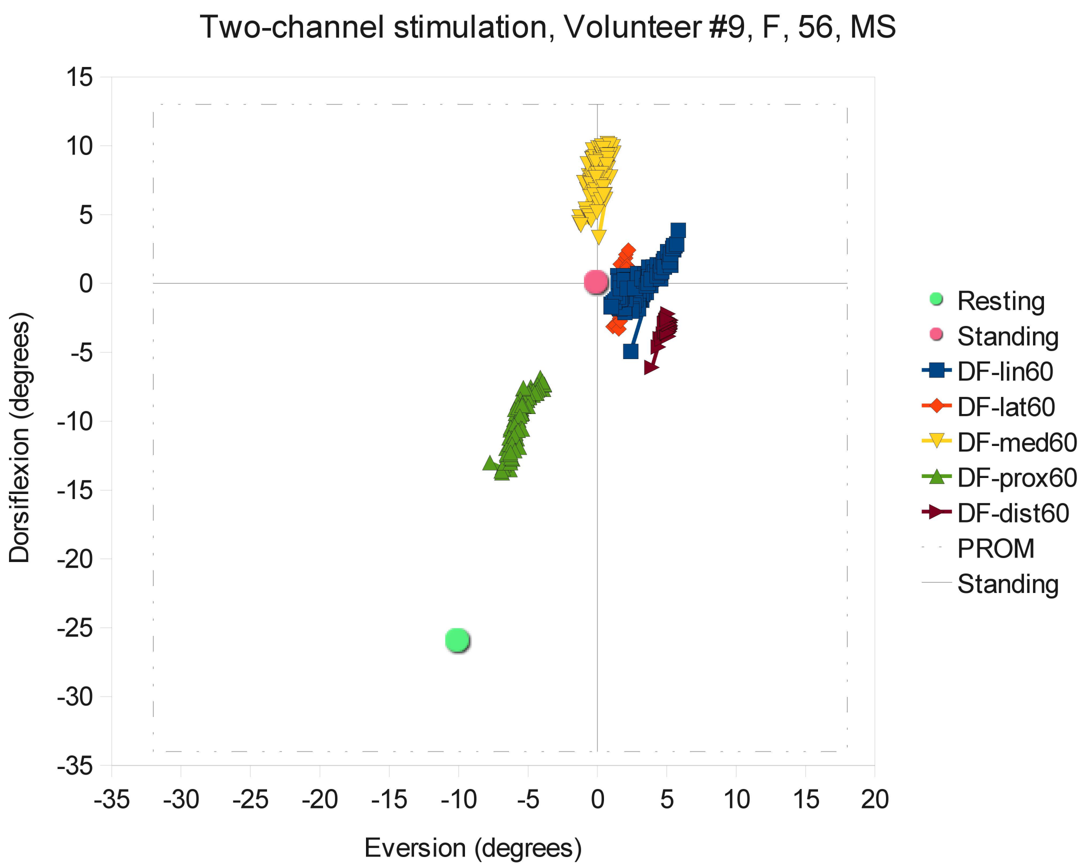


Figure 47: Two-channel stimulation result, volunteer 9. Changing the current balance had little effect on foot posture.

7.5.4 Volunteer 10

378 Volunteer 10 experienced leg spasms during the set-up of two-channel stimulation. This was at least partially resolved by a short break to walk around the room.

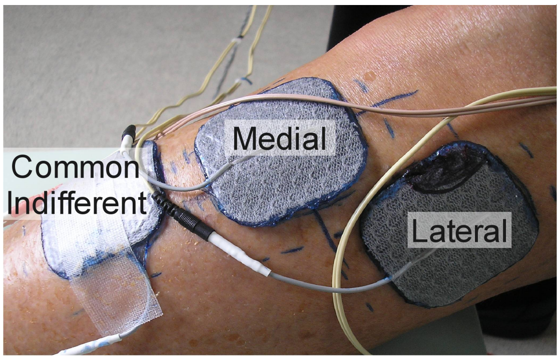


Figure 48: Volunteer 10 electrode placement for two-channel stimulation

379 The two-channel response (figures 49, 50 and 51) shows a very large steering effect (from inversion to eversion) as the balance shifts from the medial to lateral electrode, but only with the electrodes in the central, medial and distal positions. The lateral position had a reduced steering effect, and the proximal position negligible steering.

380 There was some drop in dorsiflexion at intermediate balance values. In the case of the distal trace, this was exacerbated by the electrode peeling off during part of this test.

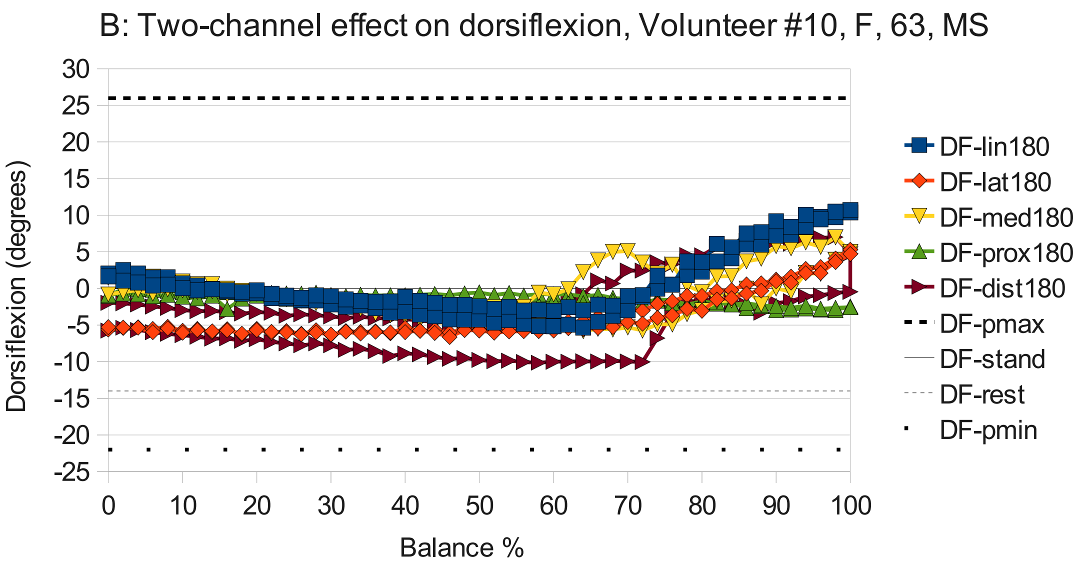


Figure 49: Two-channel effect on dorsiflexion, volunteer 10.

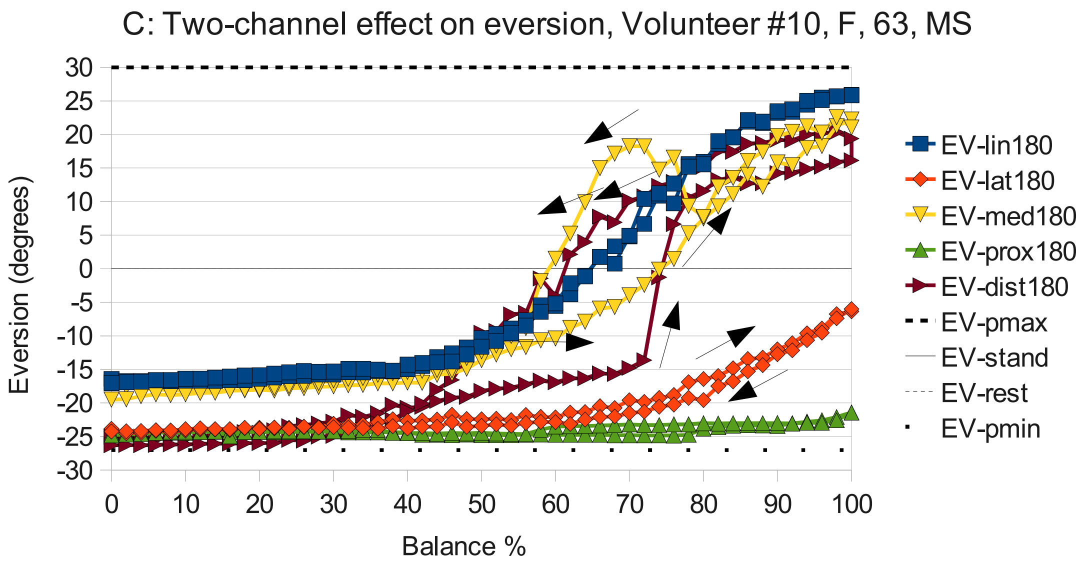


Figure 50: Two-channel effect on eversion, volunteer 10.

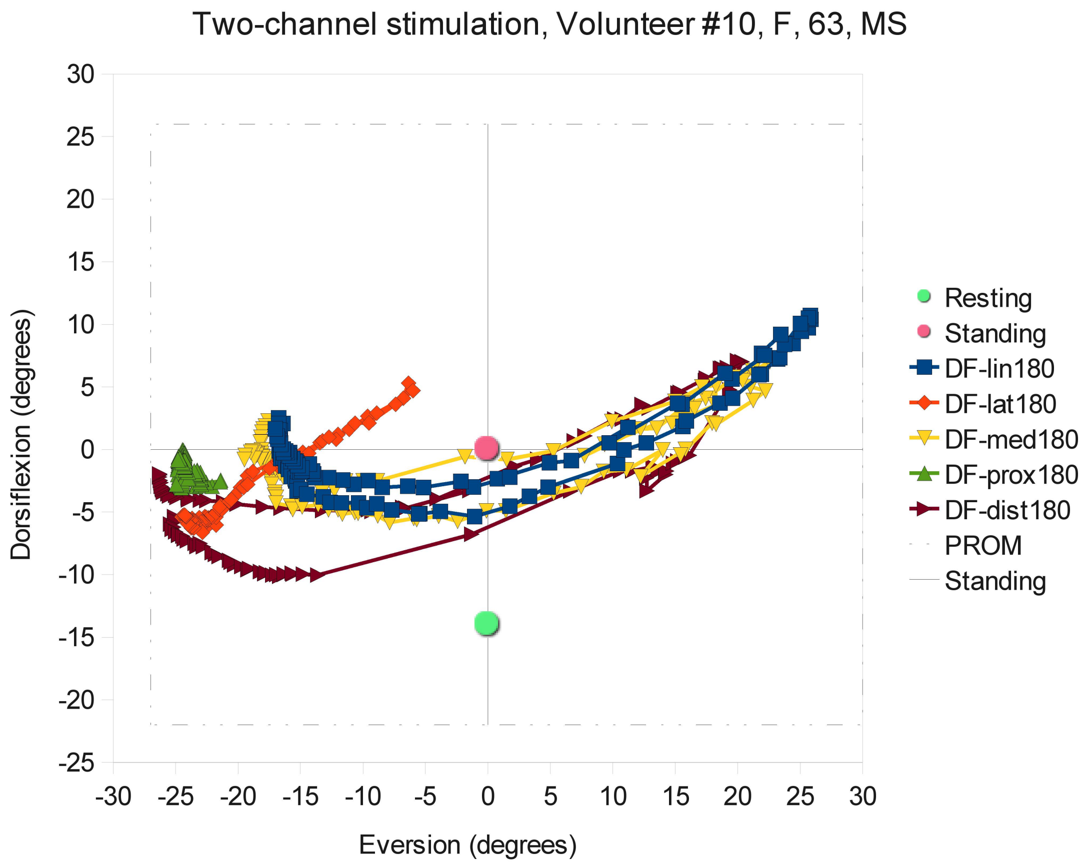


Figure 51: Two-channel stimulation result, volunteer 10, showing wide range of influence over eversion in central, medial and proximal electrode positions.

7.5.5 Volunteer 11

381 The two-channel stimulation results for volunteer 11 (figures 53 to 55) have two notable features: firstly there is notable (5-10 degree) step-to-step variation in both eversion and dorsiflexion at all electrode positions. Secondly, the dorsiflexion and eversion were strongly correlated; this can be seen as the points in figure 55 lie along a common diagonal trend. This trend line may be the result of

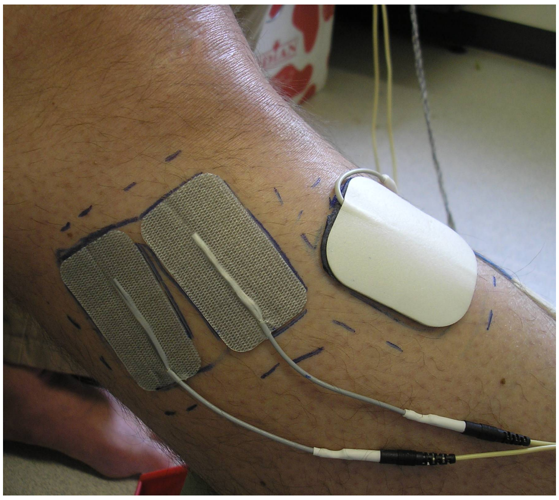


Figure 52: Volunteer 11 electrode placement for two-channel stimulation

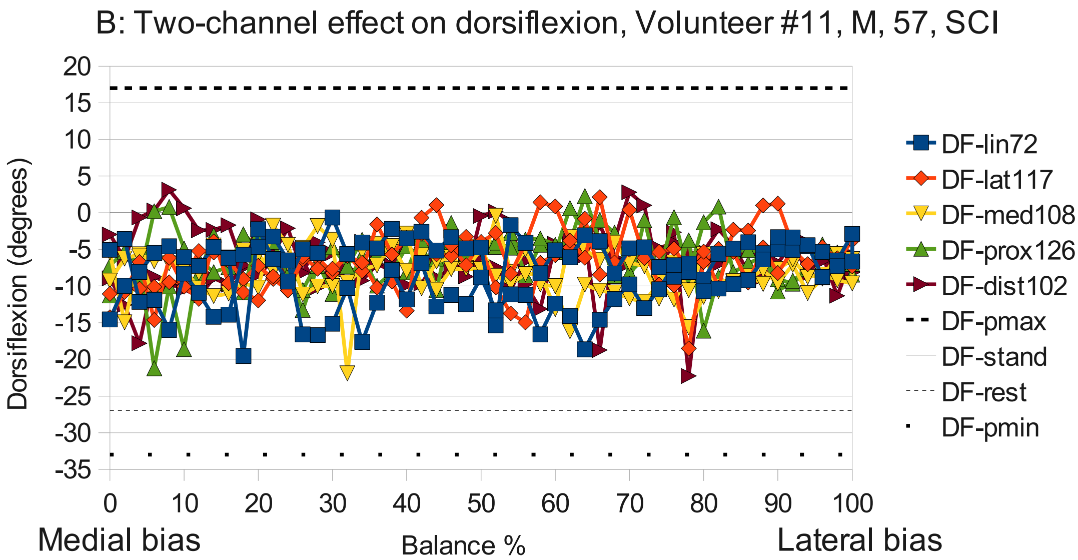


Figure 53: Two-channel effect on dorsiflexion, volunteer 11.

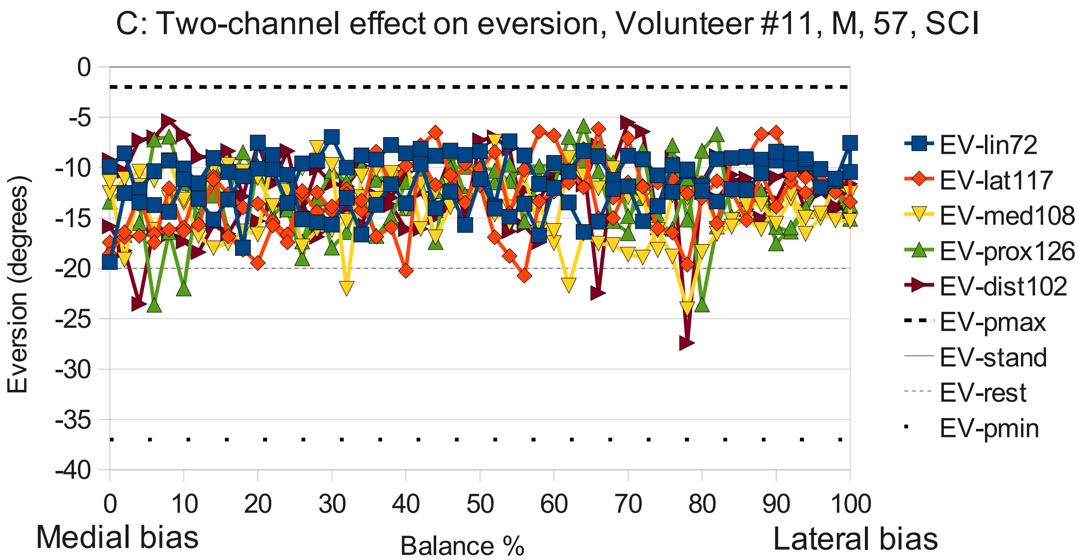


Figure 54: Two-channel effect on eversion, volunteer 11.

a biomechanical limitation of the joint (e.g. from muscle contracture or ligament/capsule limits).

382 The current balance did not appear to have a significant effect on either dorsiflexion or eversion. The electrode position had a small effect on the strength of the response, but did not affect the diagonal trend much.

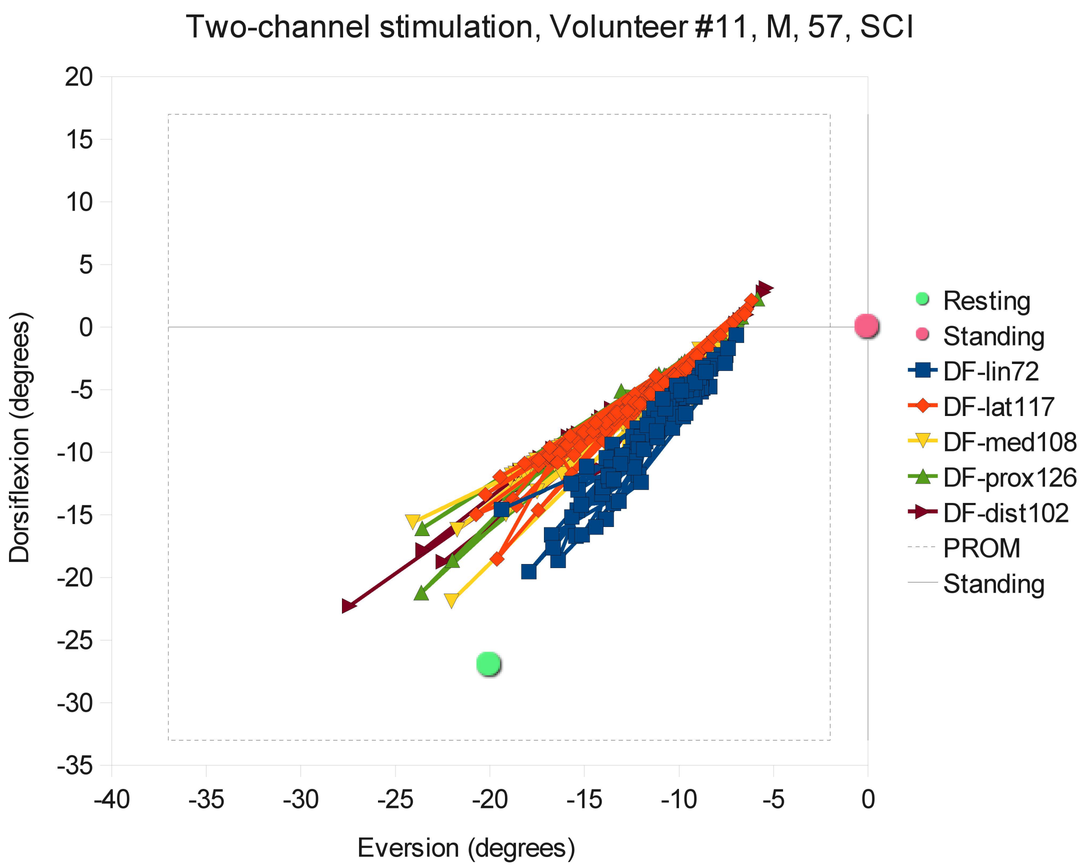


Figure 55: Two-channel stimulation result, volunteer 11. Movement of the foot was along a common linear trend, regardless of the electrode position or current balance.

7.5.6 Volunteer 12

383 The two-channel results for volunteer 12 (figures 57, 58 and 59) show an interesting variation with electrode position:

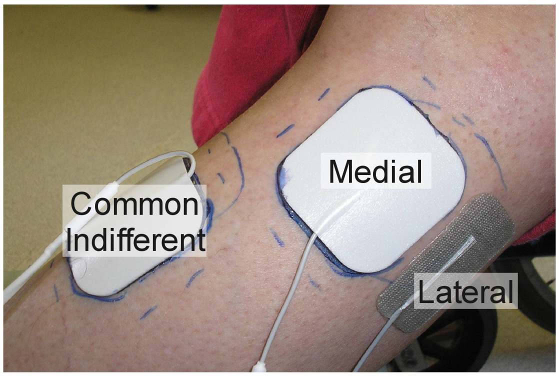


Figure 56: Volunteer 12 electrode placement for two-channel stimulation

- In the distal position, the response was largely independent of current balance.
- In central and proximal positions, there was a slight reduction in response at medium current balance values.
- In the lateral and medial positions, the responses were opposite to each other: the medial position showed an *increase* in dorsiflexion and eversion as the current balance shifted from the medial to lateral electrode, but with the electrodes in the lateral position this shows a *decrease*. With both dorsiflexion and eversion affected similarly, it is possible that this volunteer's locus for effective stimulation is very small: perhaps in the medial position only the lateral electrode was effective, while in the lateral position only the medial electrode was effective. In either case, moving the current bias to the other electrode resulted in significant loss of motor recruitment.

384 Despite the different circumstances in which stimulation caused a neuromuscular response, the resulting foot postures were along a common trend line, possibly the result of joint restrictions (i.e. like volunteer 11).

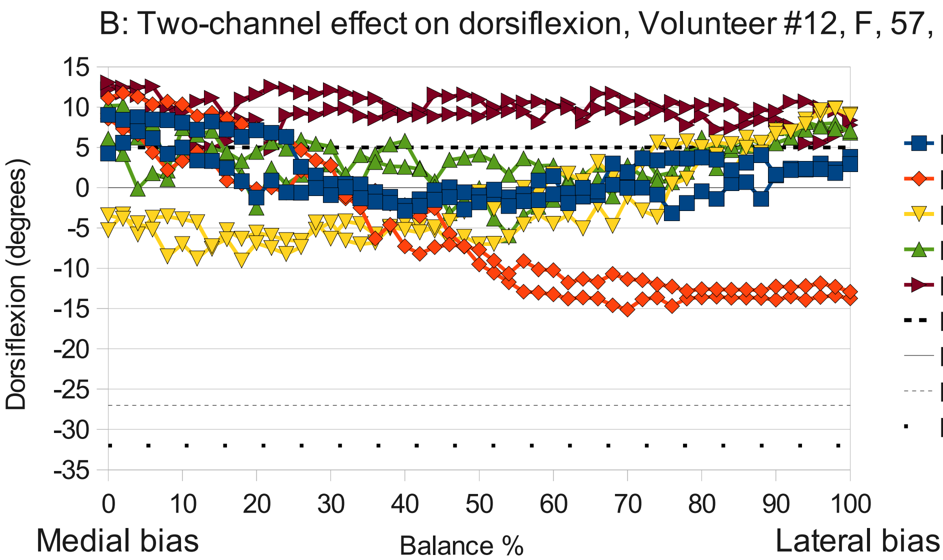


Figure 57: Two-channel effect on dorsiflexion, volunteer 12.

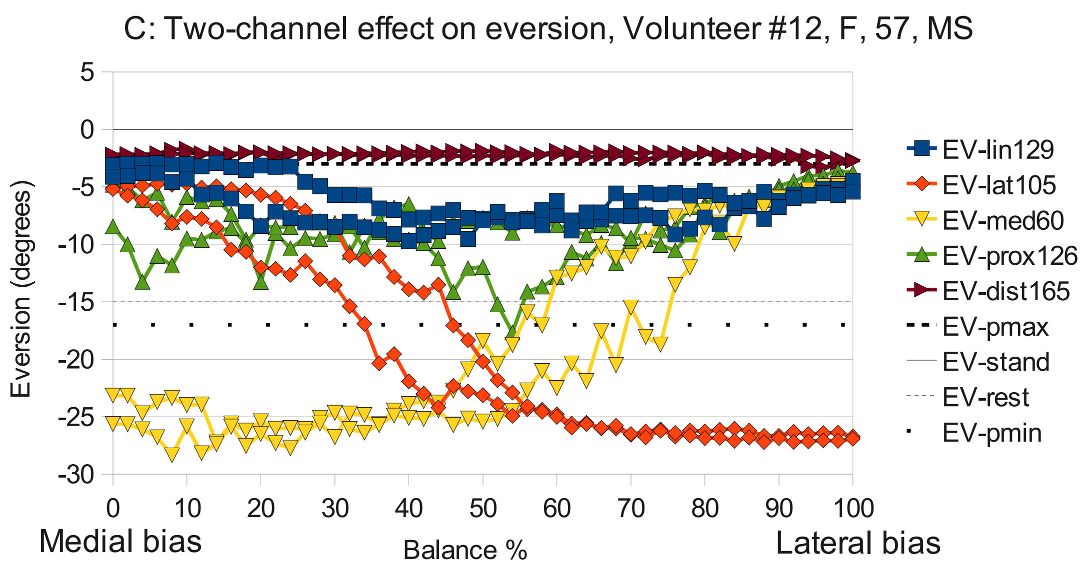


Figure 58: Two-channel effect on eversion, volunteer 12; note that lateral and medial positions produced opposite effect on foot posture with respect to current balance.

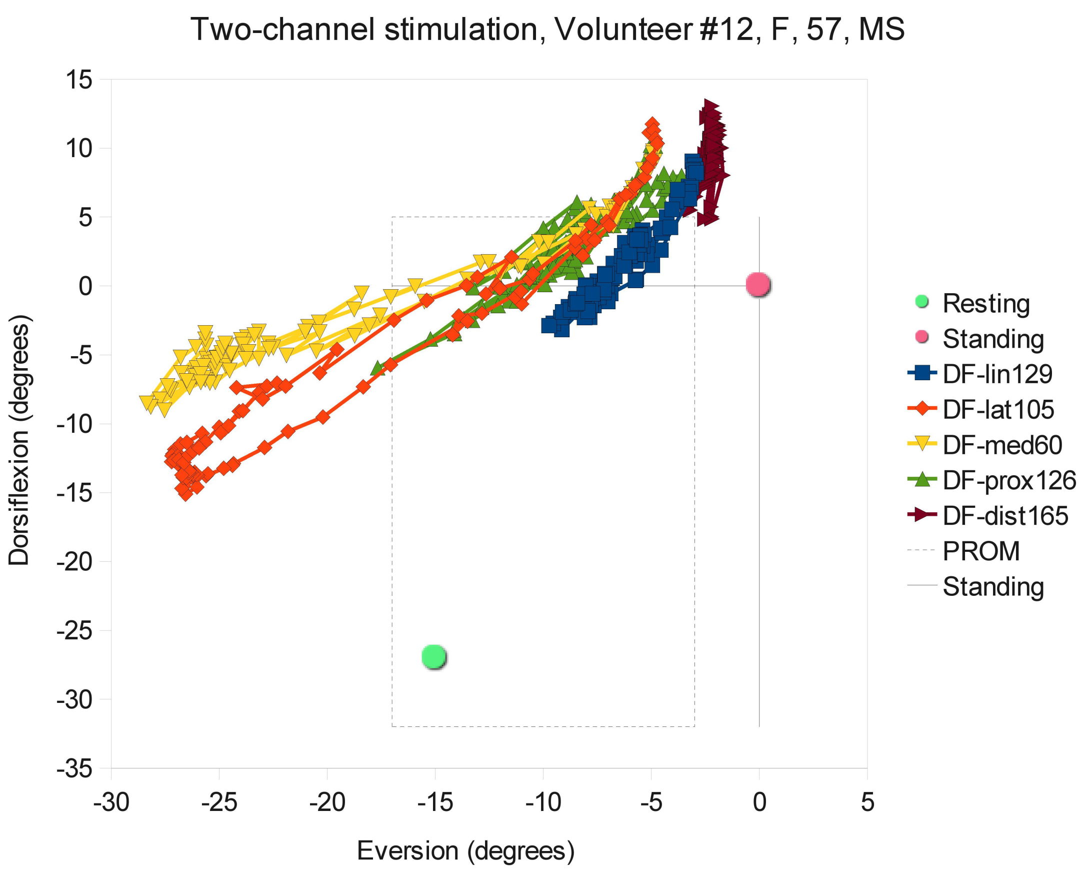


Figure 59: Two-channel stimulation result, volunteer 12.

7.5.7 Volunteer 13

385 Volunteer 13's two-channel dorsiflexion response (figures 61) was in general weaker than the single-channel response; this may be attributable to the lower stimulation levels that were tolerable with two electrodes in most positions.

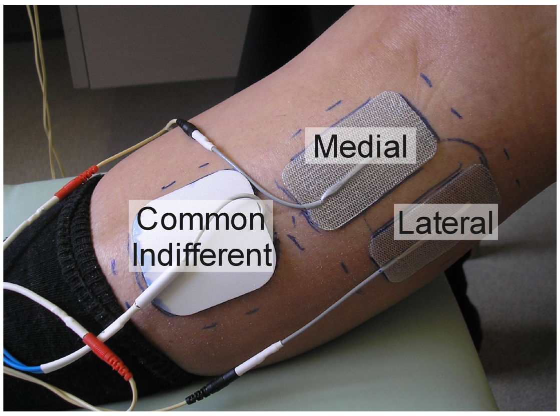


Figure 60: Volunteer 13 electrode placement for two-channel stimulation

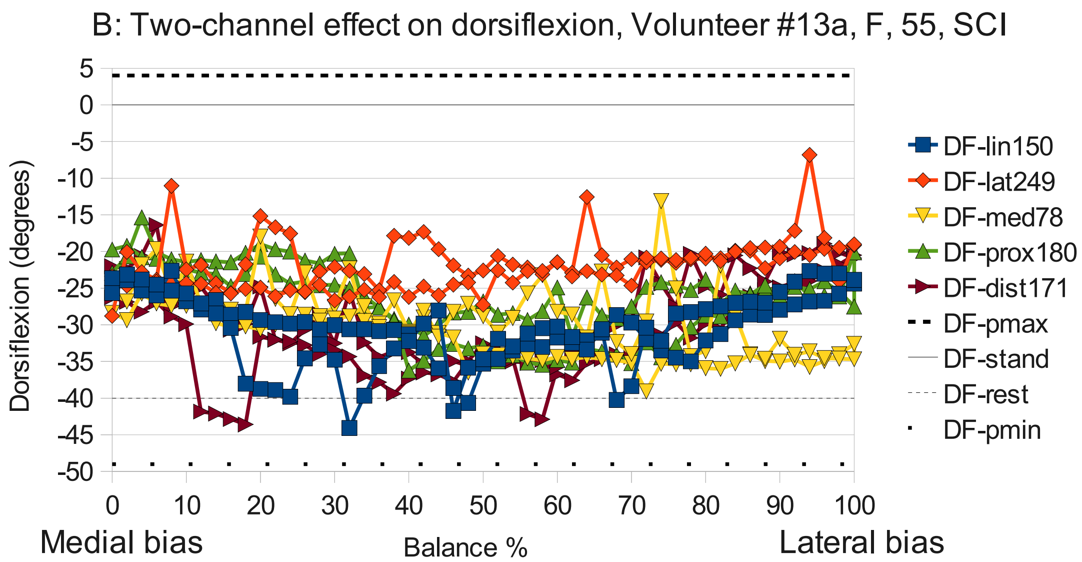


Figure 61: Two-channel effect on dorsiflexion, volunteer 13.

386 Despite the generally lower dorsiflexion, there was a wide range (up to 40°) of inversion/eversion as a function of current balance (figures 62 and 63). Although slightly different in each electrode position, the ranges overlapped, indicating that a moderate level of eversion could be reached in all electrode positions.

387 The large step changes on dorsiflexion seen in the two-channel results at the lateral, distal and proximal positions are artefacts of the electrodes peeling off during the experiment. Some increase in response excitability may be attributable to having been seated for an extended period of time.

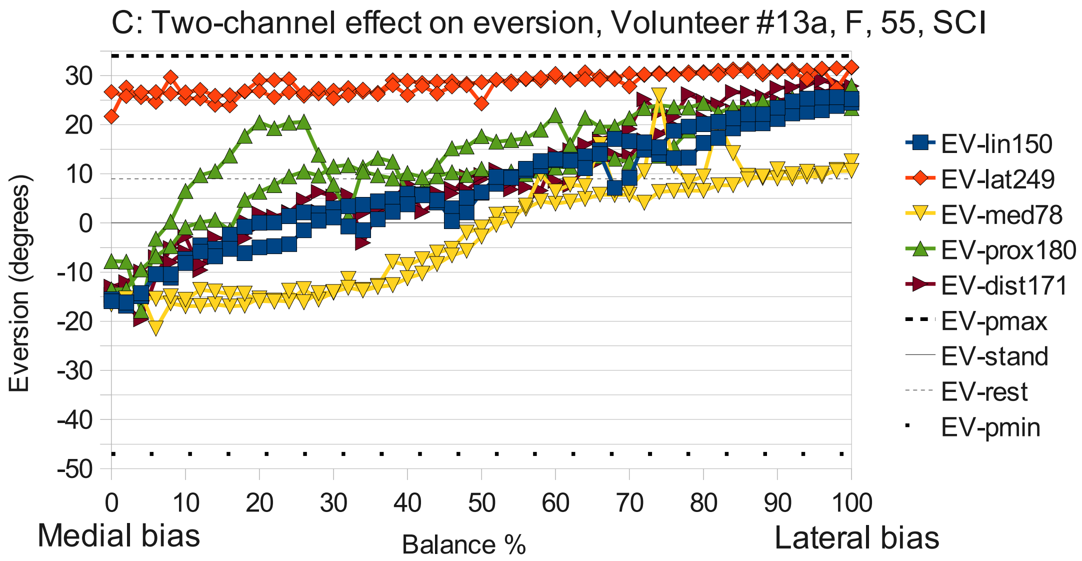


Figure 62: Two-channel effect on eversion, volunteer 13.

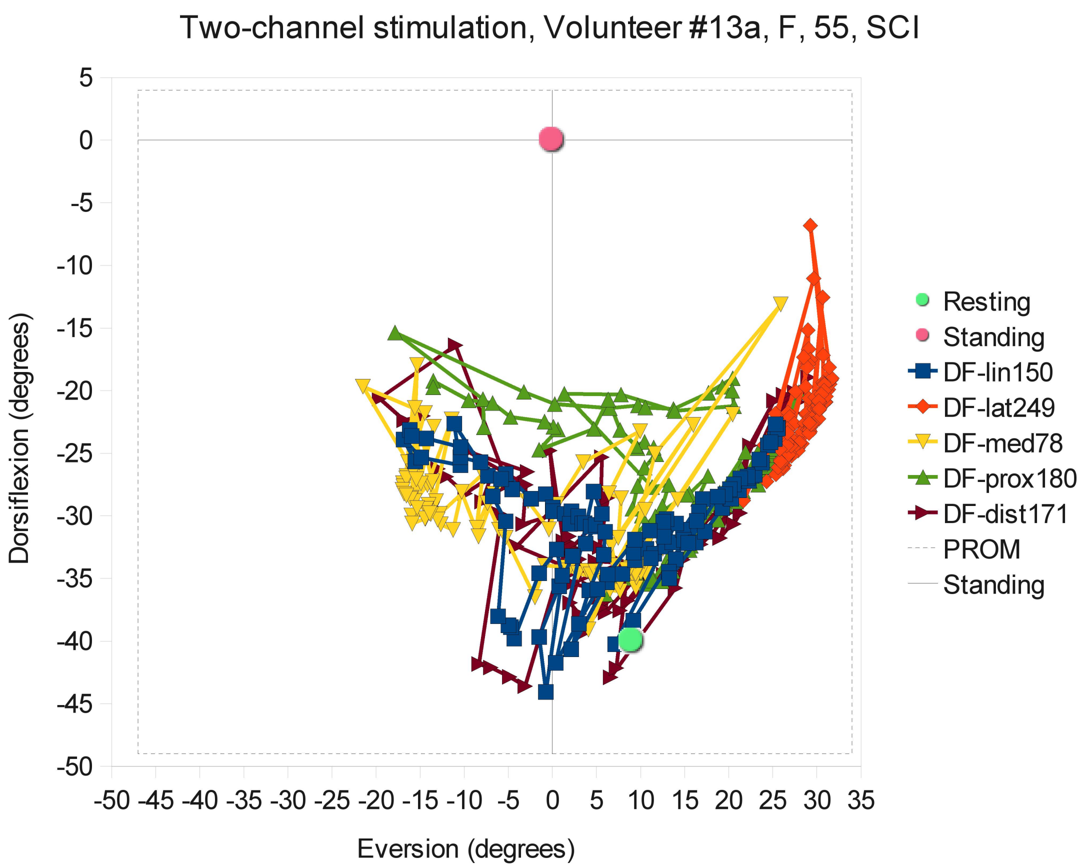


Figure 63: Two-channel stimulation, volunteer 13. Despite generally low dorsiflexion, there was a large range of inversion/eversion at most electrode positions.

7.5.8 Volunteer 14

388 [No electrodes photos were taken for volunteer 14.]

389 Volunteer 14 did not have time to participate in the full experiment due to prior commitments. He completed the two-channel test at only one electrode position.

390 The two-channel results in figures 64 to 66 showed that both eversion and dorsiflexion were weakest at intermediate balance values (40-70%) although there was more variation in the eversion. It could be that at these intermediate balance values, simulation was simply less effective; however, dorsiflexion was maintained almost entirely above neutral, with a range of inversion. Although these seated foot postures were not appropriate for walking, the test did show some ability to bias foot posture on the inversion-eversion scale.

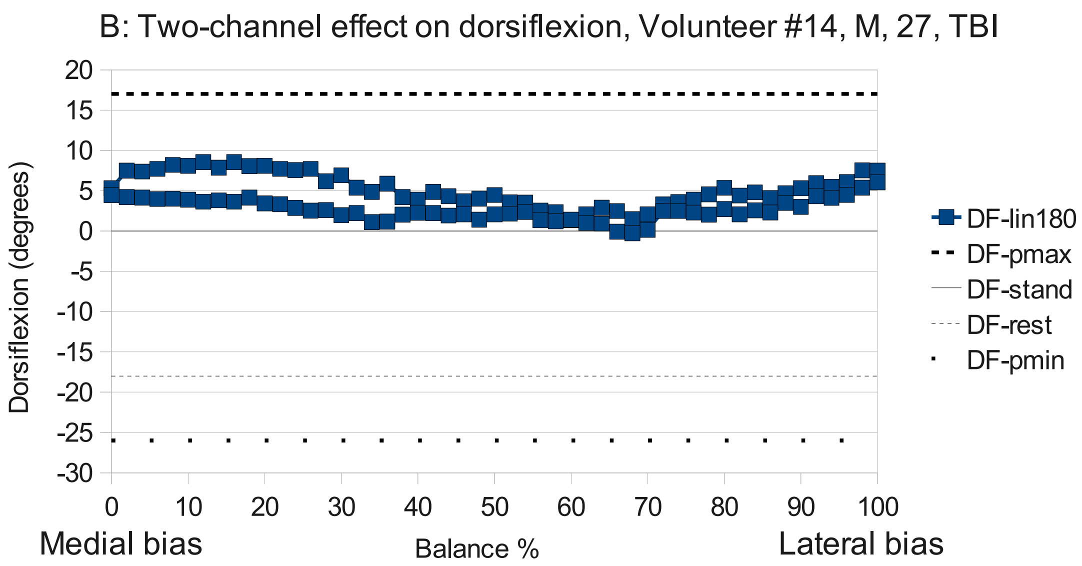


Figure 64: Two-channel effect on dorsiflexion, volunteer 14.

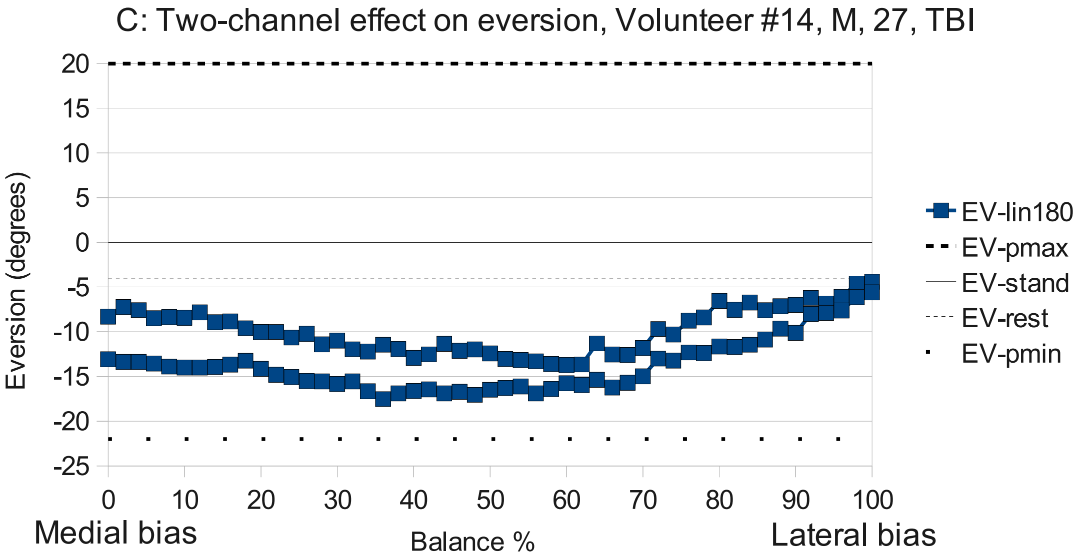


Figure 65: Two-channel effect on eversion, volunteer 14.

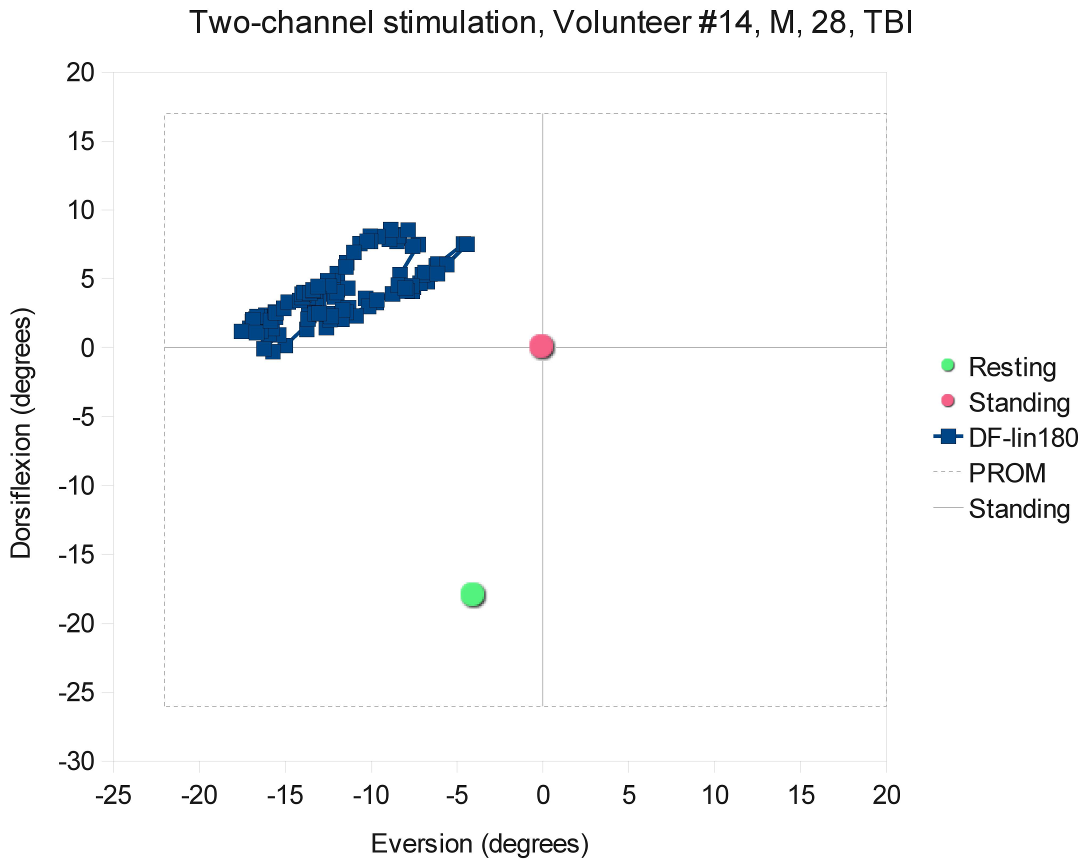


Figure 66: Two-channel stimulation, volunteer 14.

7.5.9 Volunteer 15

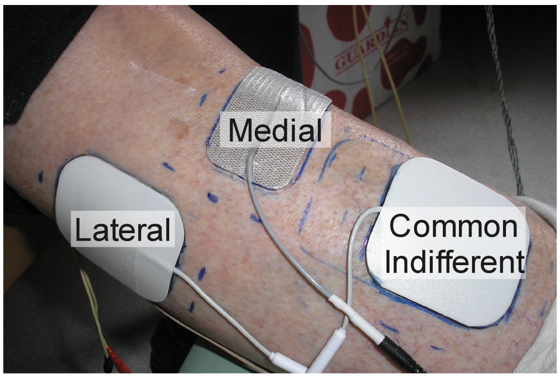


Figure 67: Volunteer 15 electrode placement for two-channel stimulation

391 The two-channel tests (figures 68 to 70) started with some heightened responses (from 0-50% balance on the DF-lin180 and EV-lin180 series) before settling down. Both dorsiflexion and eversion increased with the balance parameter; this may mean that the lateral electrode position was simply more effective for stimulation than the medial one, which is unsurprising given the highly medial position of the medial electrode. (The volunteer also reported having had previous issues with her Achilles tendon).

392 The relevance of the limit of the passive range of movement is illustrated in figure 70 by its broad coincidence with the diagonal trend in stimulation response.

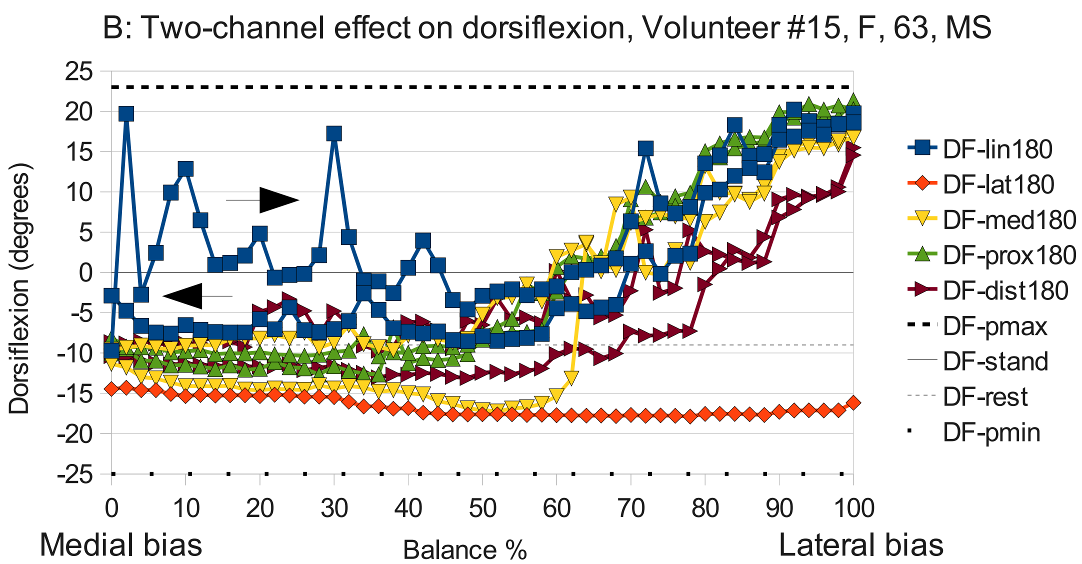


Figure 68: Two-channel effect on dorsiflexion, volunteer 15.

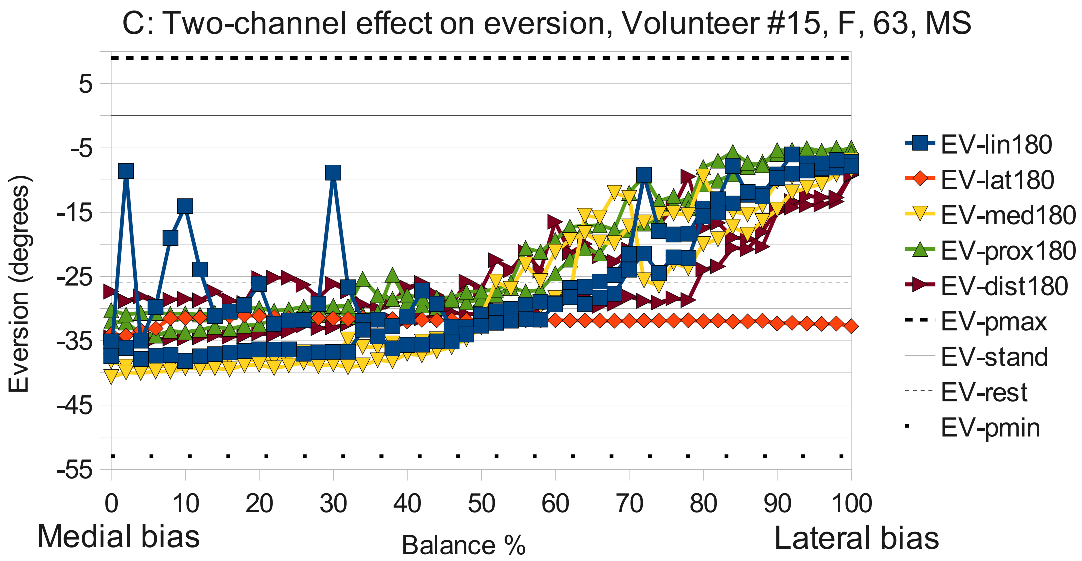


Figure 69: Two-channel effect on eversion, volunteer 15.

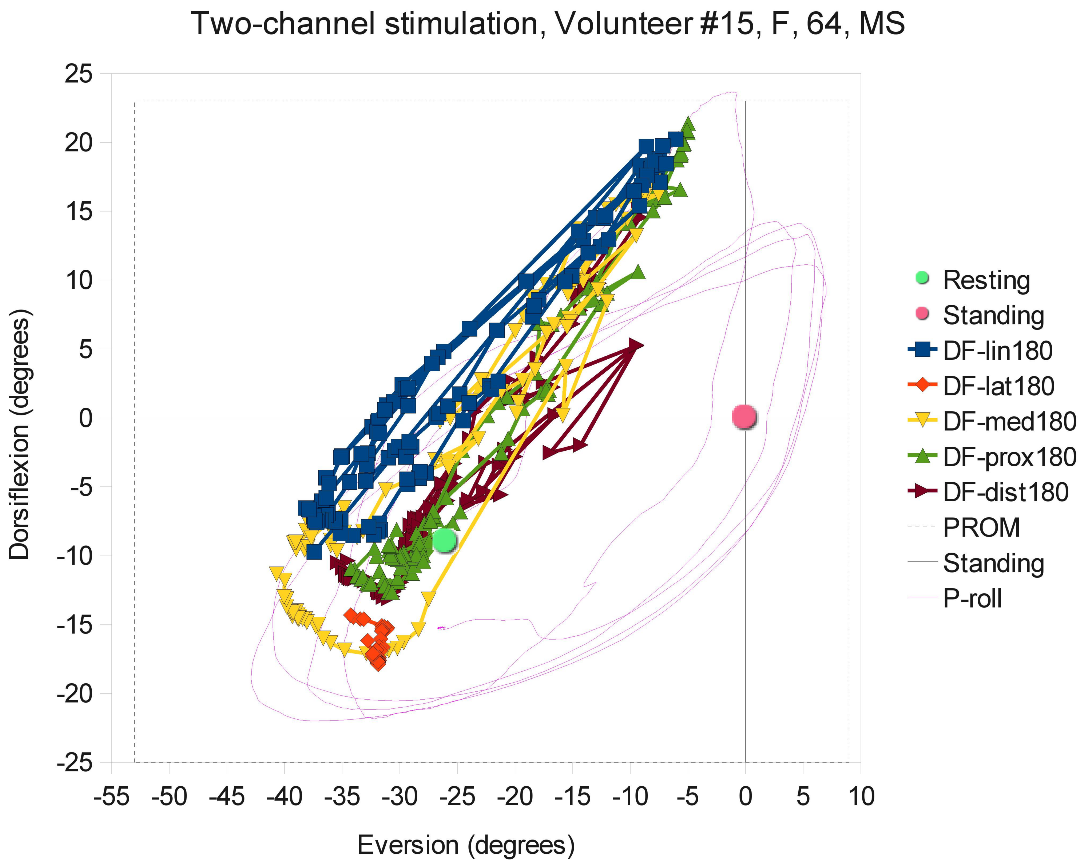


Figure 70: Two-channel stimulation, volunteer 15.

7.5.10 Volunteer 16

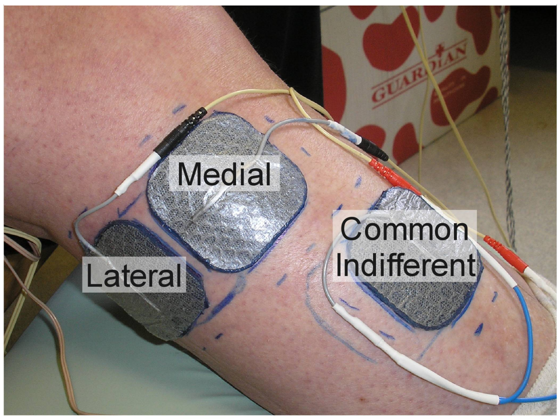


Figure 71: Volunteer 16 electrode placement for two-channel stimulation

393 The two-channel results (figures 72 to 74) showed that the balance parameter had almost no effect with the electrodes in the proximal and medial positions, and a small effect in the distal position. However, in the central and lateral positions (labelled 'lin81' and 'lat180' respectively), increasing the balance parameter had opposite effects. That is, in the central position, biasing the current to the lateral electrode became more effective at generating dorsiflexion and eversion, while in the lateral position, further lateral bias decreased the effect of stimulation. Note also that the central position only required 81µs pulses compared to the 180µs pulses in the lateral position. This indicates that the 10mm movement to the lateral position was enough to render the lateral electrode largely ineffective, rather than evoking a more everted response.

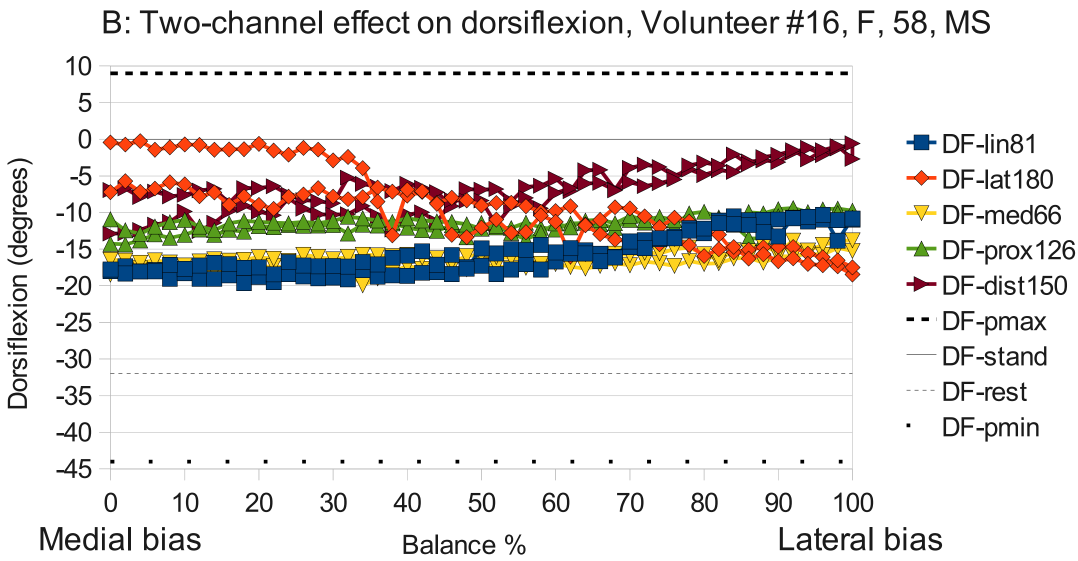


Figure 72: Two-channel effect on dorsiflexion, volunteer 16.

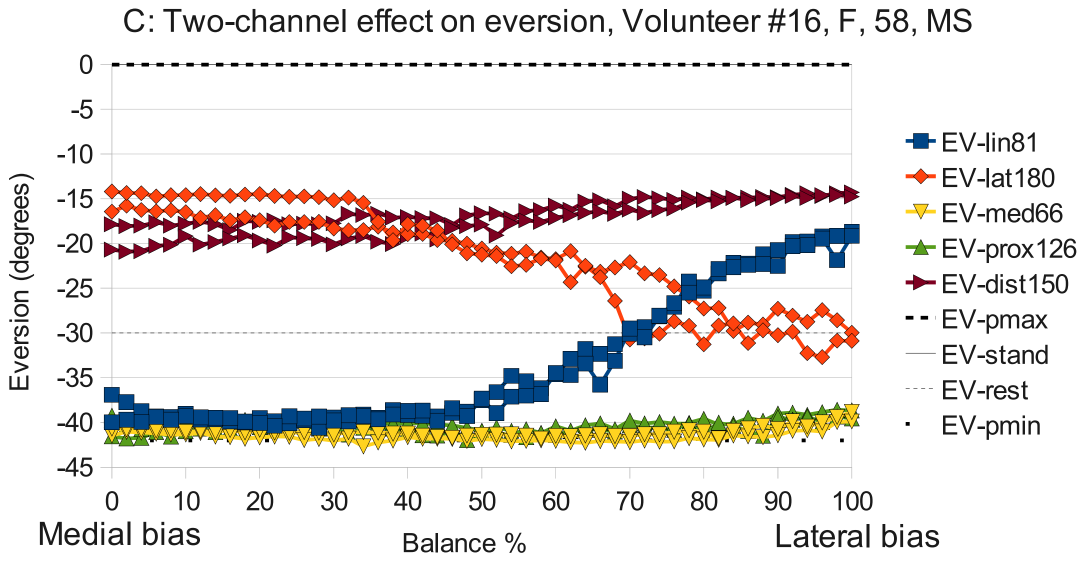


Figure 73: Two-channel effect on eversion, volunteer 16.

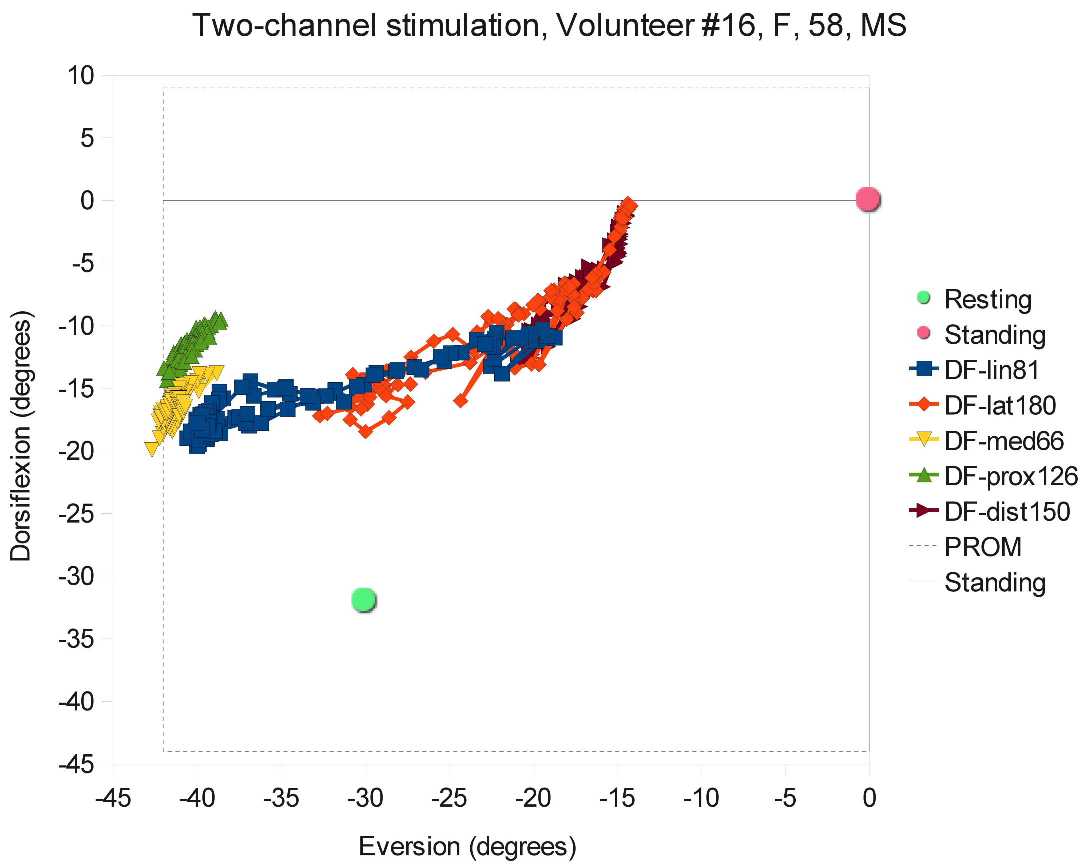


Figure 74: Two-channel stimulation, volunteer 16.

7.5.11 Volunteer 17

394 The two-channel results (figures 76 to 78) indicate that the current levels on each channel had not been set well. Dorsiflexion is not maintained at intermediate balance values (being higher at balance=0% and balance=100%), which may be because the minimum on each channel had been set too low. This is supported for the lateral channel by the general lack of change in eversion until the balance is greater than 70%. Despite this, there was a change in eversion of over 20 degrees at all electrode positions except the distal position. While this was almost entirely in the inversion region and not usefully dorsiflexed, it is an illustration of the ability of the changing current balance to affect foot posture.

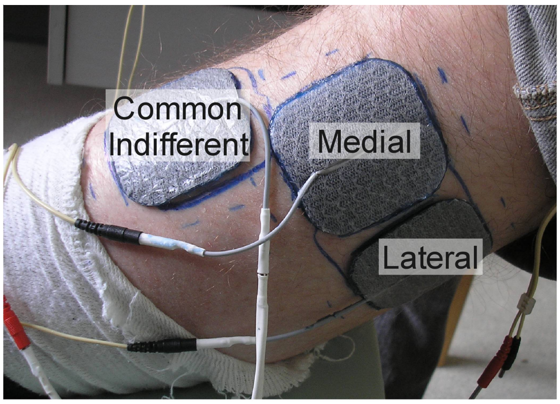


Figure 75: Volunteer 17 electrode placement for two-channel stimulation

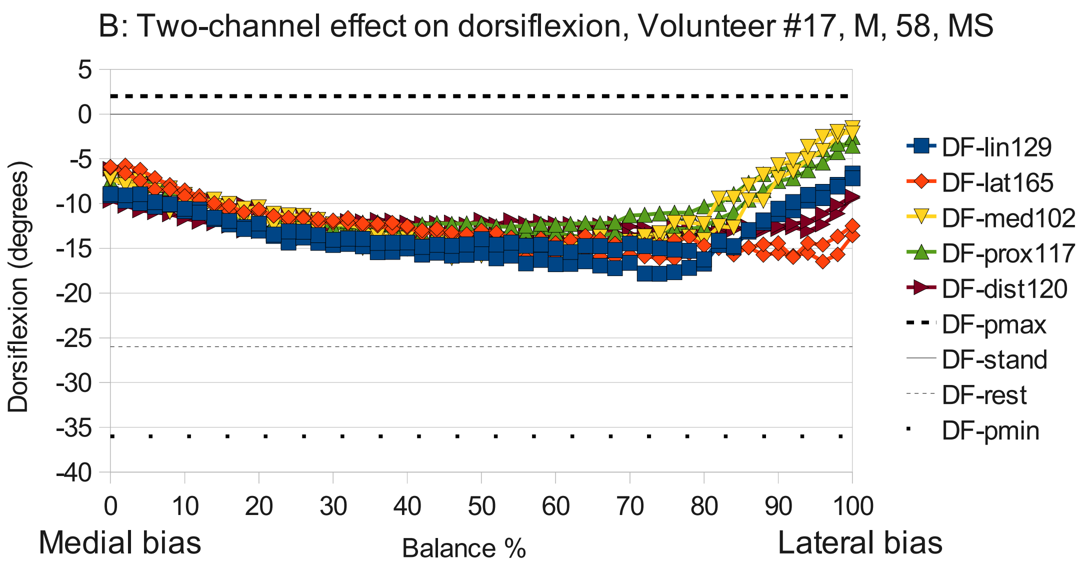


Figure 76: Two-channel effect on dorsiflexion, volunteer 17.

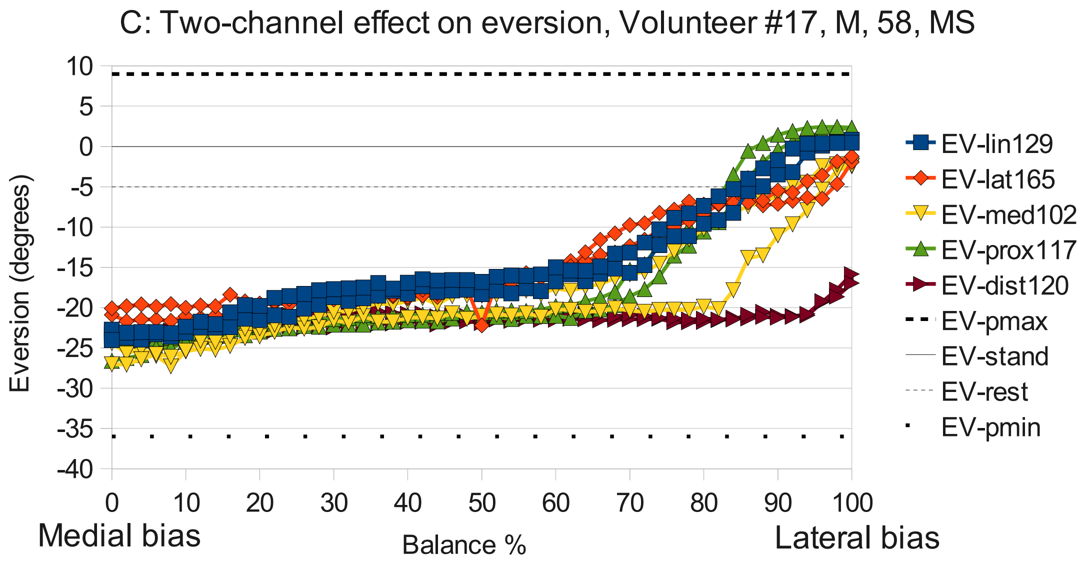


Figure 77: Two-channel effect on eversion, volunteer 17.

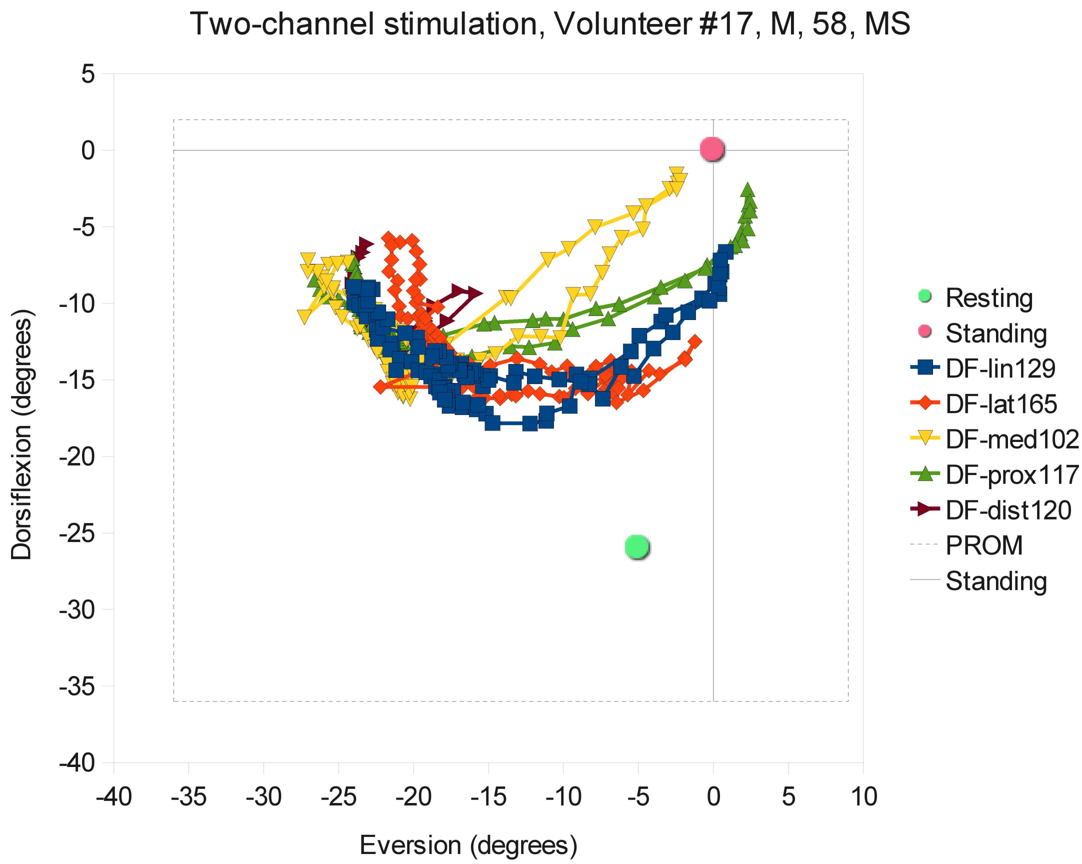


Figure 78: Two-channel stimulation, volunteer 17.

7.5.12 Summary of seated two-channel tests

395 In two-channel stimulation, moving the current balance to the lateral electrode generally increased eversion; the effect on dorsiflexion (if any) varied between volunteers. Figures 79 and 80 and table 14 provide a summary of the response of each volunteer.

396 These results show that it is often feasible to affect the level of eversion by changing the current balance with two-channel stimulation, at least while seated. In some cases the seated response (of the relaxed, unconstrained limb) was quite variable, but this may not occur in walking (where muscle tone is higher and the limb has periodic contact with the ground). The effect in walking was studied in experiments 4a and 4b.

397 In setting up two-channel stimulation, care was required to avoid one channel dominating the response (preventing any significant steering effect). One could not simply apply the electrodes arbitrarily then adjust the currents to give the desired dorsiflexion and mild eversion – some repositioning and rebalancing of currents was often required. This meant that the complexity of set-up was comparable to single channel stimulation (or greater, if a wide range of posture control was desired).

398 This study did not investigate whether the two-channel stimulation was working as two separate channels or whether their superposition led to a single effective channel where the locus of maximum stimulation could be shifted across the nerves by altering the current bias. In terms of effect, in some cases it seemed that one channel produced the main dorsiflexion, while the other modulated the amount of inversion/eversion. In other cases both contributed to dorsiflexion. Without detailed knowledge of the subjects' neuroanatomy and EMG studies it was not possible to comment further on the mechanism.

399 There were no significant problems in administering the two-channel stimulation. As with any functional stimulation system, some electrode positions were ineffective and/or uncomfortable, but these were easily addressed by changing the set-up in line with standard clinical practice. With appropriate set-up, the two channel system was capable of producing foot postures suitable for safe walking, as so it was felt that with care (specifically, not making rapid changes to stimulation while walking at speed) the

system could proceed to the walking tests.

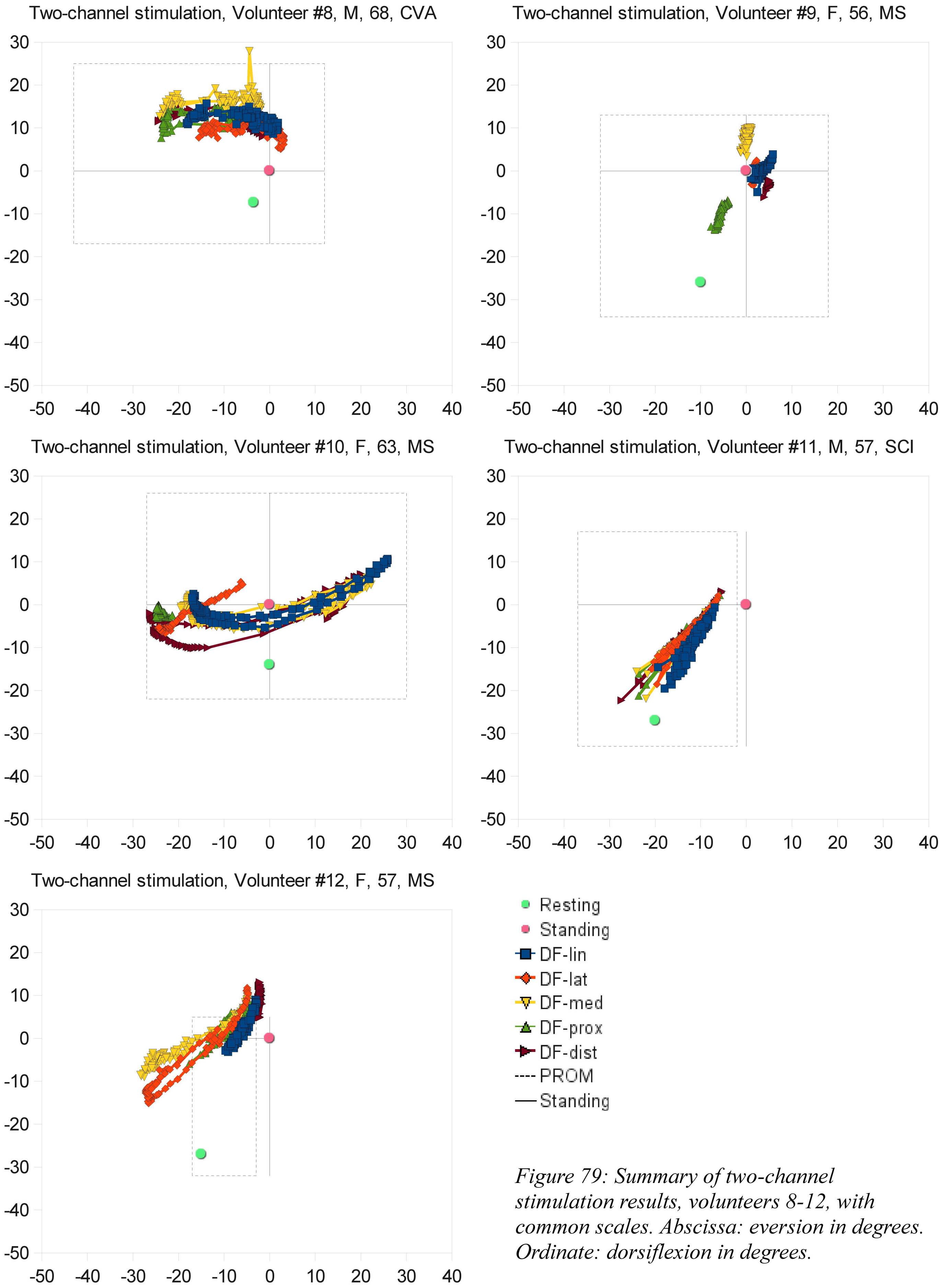


Figure 79: Summary of two-channel stimulation results, volunteers 8-12, with common scales. Abscissa: eversion in degrees. Ordinate: dorsiflexion in degrees.

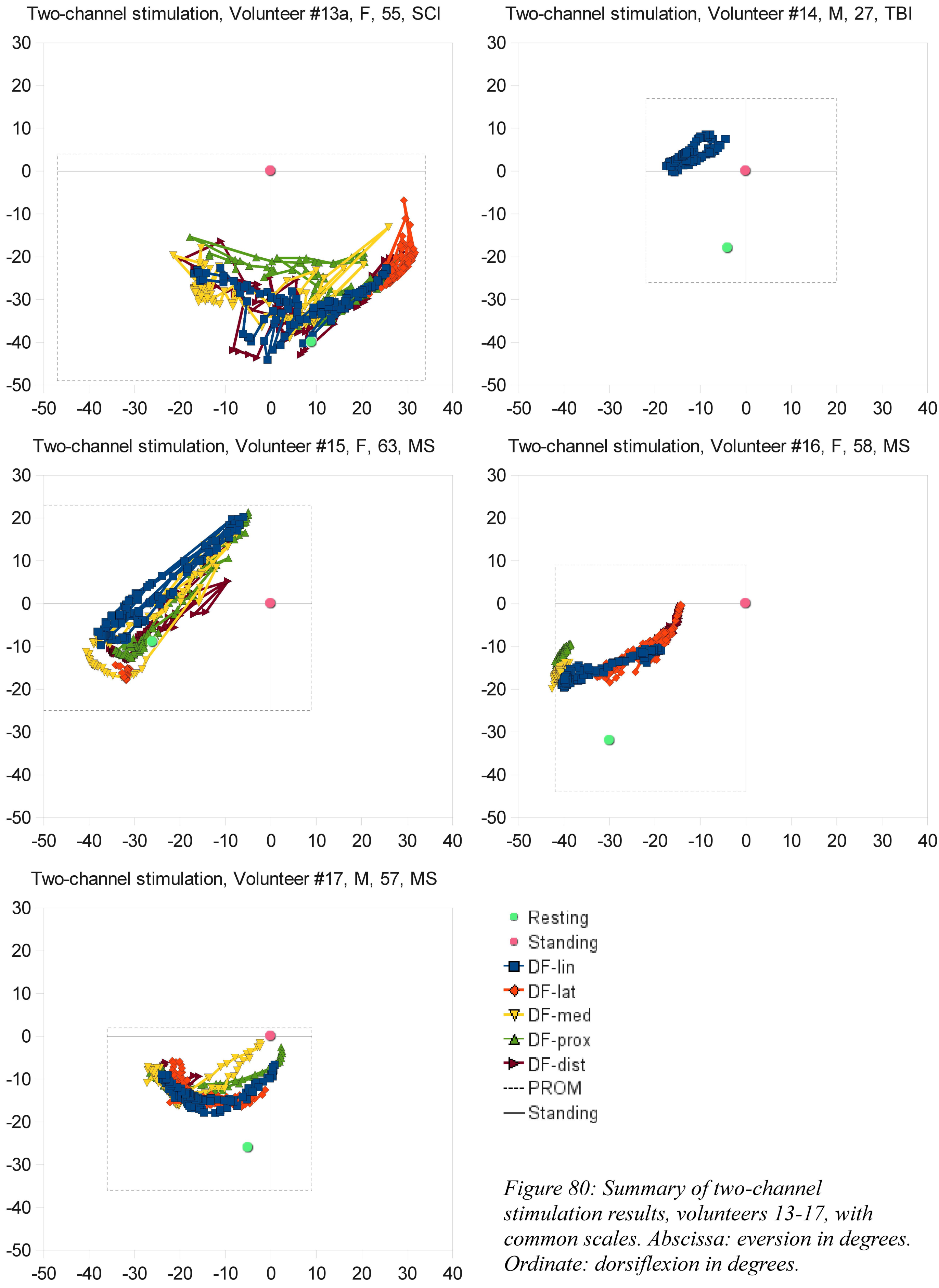


Figure 80: Summary of two-channel stimulation results, volunteers 13-17, with common scales. Abscissa: eversion in degrees. Ordinate: dorsiflexion in degrees.

ID	Single channel stimulation (Change in foot posture when increasing current from threshold to comfortable maximum)	Two channel stimulation (Change in foot posture when altering current balance from medial to lateral)	Two channel (Effect of changing electrode position)
8	15° dorsiflexion and 5° eversion.	Dorsiflexion approximately constant, eversion increases by about 20°.	In all positions, inversion/eversion could be affected by about 20 degrees; ranges overlap.
9	Dorsiflexion increases 20° without much change in eversion.	Current balance had almost no effect.	Some electrode positions produced a stronger response, but none featured significant 'steering'.
10	20° increase in dorsiflexion and 25° increase in eversion	Eversion changes by over 40° in some positions. Dorsiflexion around neutral, less affected than eversion.	Almost no steering in the proximal position, 20° in lateral and 40° in other positions.
11	15° increase in dorsiflexion, 5° in eversion.	Current balance had no visible effect; foot posture dominated by joint constraints.	Electrode position may have small effect on response, but still dominated by joint limits.
12	>30° increase in dorsiflexion, >15° in eversion.	Effect of current balance depended on electrode position: minimal, small, positive or negative effect on eversion and dorsiflexion.	Indicated that some electrode positions were ineffective at motor nerve recruitment.
13	35° increase in dorsiflexion, 20° in eversion	Up to 40° change in eversion at most electrode positions.	Wide range of steering at all electrode positions, ranges overlapping.
14	15° increase in dorsiflexion, eversion uncertain.	Eversion changes but not uniformly.	No time to test at different electrode positions.
15	20° increase in dorsiflexion, 15° in eversion.	Eversion and eversion change together indicating effectiveness of lateral electrode.	All positions were similar except the lateral position which appeared ineffective.
16	35° increase in dorsiflexion, >20° in eversion.	>20° change in eversion, <10° in dorsiflexion.	No steering in medial or proximal positions.
17	15° increase in dorsiflexion, <10° in eversion.	Up to 20° change in eversion, but dorsiflexion not maintained at medium balance values.	Wide steering in most postitions.

Table 14: Summary of response to stimulation while seated. 'Steering' is used as a term to describe ability to alter the inversion/eversion of the foot.

7.6 Moving a single-channel vs. two-channel electrode group

400 The limited time available with most volunteers (90 minutes) meant that the results so far concentrate on the two-channel performance and the effect of moving these electrodes. It was desirable to compare this with single-channel stimulation: in particular, how does the range of foot postures resulting from moving a single channel of stimulation, which cannot compensate for movement, compare with the range of postures achieved with two-channel simulation, which may be able to compensate by changing the current balance?

401 Three volunteers returned for extended sessions of up to 3 hours. This enabled us to repeat experiment 1 (seated single-channel effect) at additional positions, 10mm lateral, medial, proximal and distal of the starting point, as well as the five positions for experiment 2 (seated two-channel effect). These results are presented here. During the extended session, these volunteers also completed experiment 4a (open-loop walking with two-channel stimulation) five times, with the electrodes in the same five positions as experiment 2. Results from the walking tests are presented in section 9.5.

402 It should be noted that, the volunteers for these extended tests were selected on the basis of having a good walking ability and showing a clear response to two-channel stimulation at their initial visit. Together with the small sample size, this suggests caution is needed in interpreting the result of these extended tests.

7.6.1 Extended seated tests – volunteer 19b

ID	Gender	Age	Neurological Condition	Duration of FES usage	Frequency of FES usage	Side
19	M	71	CVA	8 years	2 days per week	Left

Currents used (mA)			
Balance setting		**At 0%**	**At 100%**
Single channel		36	54
2-channel	**Medial**	50	35
	Lateral	36	54

Passive range of movement	Dorsiflexion (degrees)	Eversion (degrees)
Maximum	17	16
Minimum	-25	-22

(negative indicates plantarflexion/inversion)

403 Figure 81 shows the single-channel results: as the current increased, strong dorsiflexion occurred together with a range of eversion: more inversion with medial stimulation, more eversion with lateral stimulation. In the central and lateral positions, the posture at maximum current was stable and everted. At the other electrode positions, when the maximum dorsiflexion was reached then further increase in current caused the degree of inversion to increase by 5 to 10 degrees.

404 Figure 82 shows the two-channel results. At each electrode position, dorsiflexion was maintained and the current balance could provoke a change of 5 to 10 degrees in eversion. The ranges obtained at the lateral, proximal and distal positions overlap with the central range; enabling the current balance to compensate at least partially for moving the electrodes. The medial position produced a range that was notably more inverted and did not overlap the original range: adjusting the current balance could not compensate for the this change in electrode position.

405 The foot postures achieved in the two-channel experiment were similar to that with single-channel stimulation. However, the two-channel system was able to make 5-10 degrees of adjustment to eversion with the electrodes in place, which is not possible with single-channel stimulation.

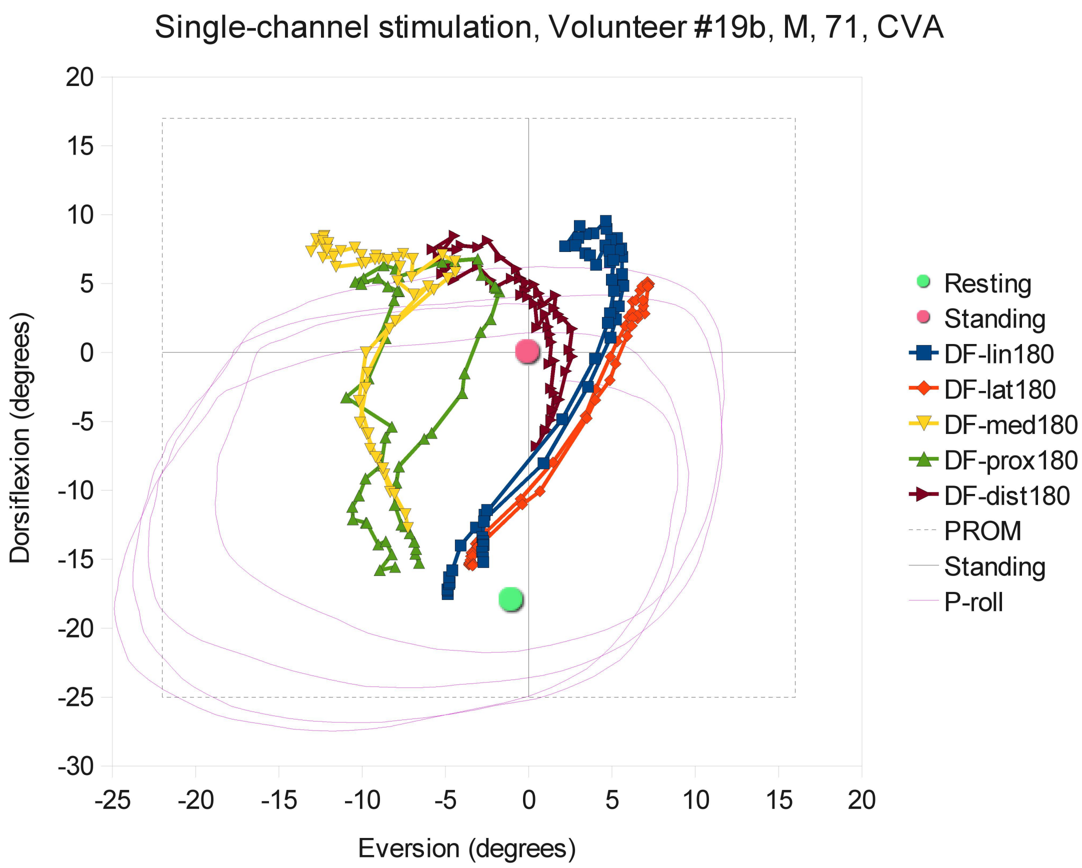


Figure 81: Single-channel stimulation - foot posture with current from $I_{0\%}$ to $I_{100\%}$ at five electrode positions, volunteer 19b.

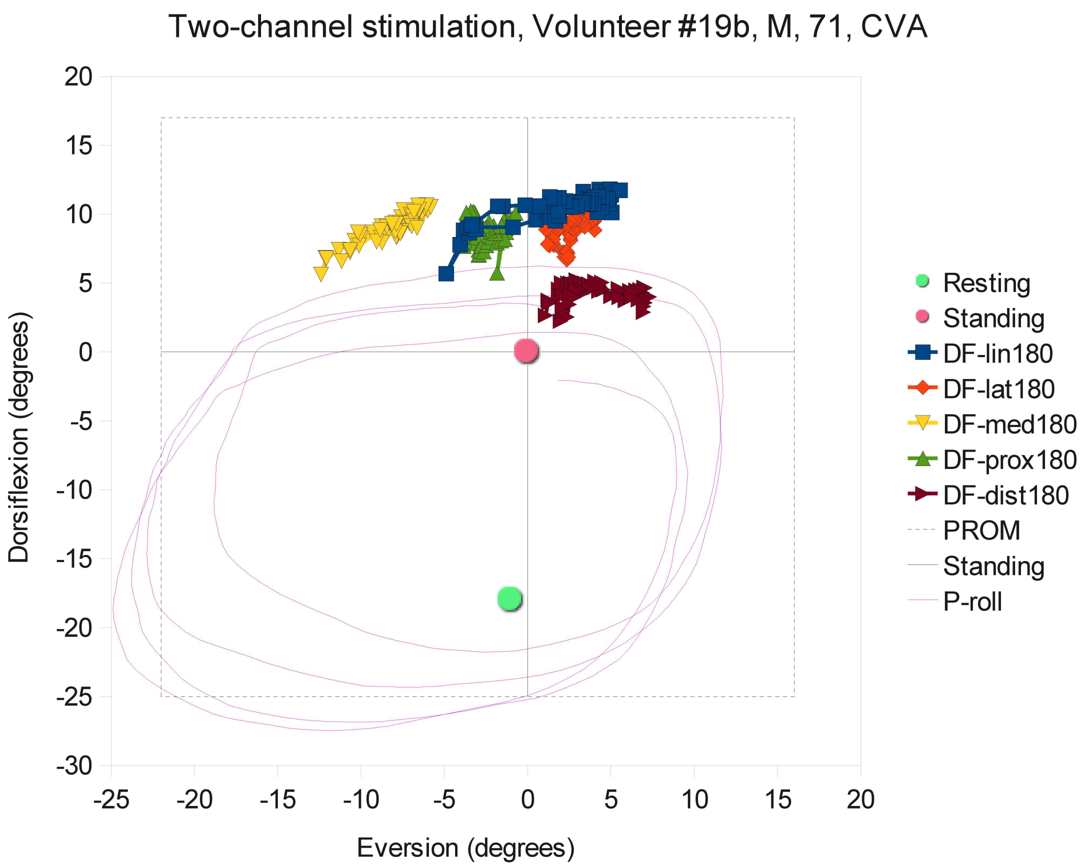


Figure 82: Two-channel stimulation - foot posture with current balance from 0% to 100% at five electrode positions, volunteer 19b.

7.6.2 Extended seated tests – volunteer 24

ID	Gender	Age	Neurological Condition	Duration of FES usage	Frequency of FES usage	Side
24	M	55	MS	4 years	Daily	Right

406 Volunteer 24 returned for two extended sessions. On both occasions he was set up following the protocol for experiments 1 and 2, with five electrode positions for each experiment.

407 The set-up process resulted in different currents on each day; this may be due to differences in electrode position and/or daily variation in his MS. The differences in Passive Range of Movement may be due to differences in the force used when manipulating the foot, changes in muscle tone and measurement inaccuracy.

408 When this volunteer stood while the goniometer was zeroed, his ankle everted under the static. This has caused all measurements for this volunteer to appear more more inverted than would be expected, but the offset is constant within each session.

409 Details for volunteer 24 (first visit, 24a, figures 83 and 84):

Currents used (mA)			
Balance setting		**At 0%**	**At 100%**
Single channel		36	46
2-channel	**Medial**	54	34
	Lateral	27	35

Passive range of movement	Dorsiflexion (degrees)	Eversion (degrees)
Maximum	7	7
Minimum	-35	-35

(negative indicates plantarflexion/inversion)
In this case, both ranges were the same.

410 Details for volunteer 24 (second visit, 24b, figures 85 and 86):

Currents used (mA)			
Balance setting		**At 0%**	**At 100%**
Single channel		29	37
2-channel	**Medial**	62	38
	Lateral	30	40

Passive range of movement	Dorsiflexion (degrees)	Eversion (degrees)
Maximum	9	14
Minimum	-43	-39

(negative indicates plantarflexion/inversion)

411 Figures 83 and 85 show the foot posture response to increasing single-channel current:

the foot dorsiflexes strongly, while lateral positions favour eversion and medial positions favour inversion. The five electrode positions differ from each other in their eversion by as much as 20 degrees.

412 Figures 84 and 86 show the foot posture response to changing current balance with two-channel stimulation. Dorsiflexion is largely maintained; while inversion/eversion shifts with the current balance (0% favouring inversion, 100% favouring eversion) in all positions except the following:

- For 24a, in distal and lateral positions there was very little change in eversion.

- For 24b, the lateral position had very little change in eversion.

413 For the majority of electrode positions, current balance could affect eversion by approximately 10 to 20 degrees. In most positions, there is a degree of overlap with the central range, and for some electrode positions this was enough that the current balance could compensate for the change in electrode position.

414 The foot postures produced with two-channel stimulation were again similar to those with single-channel stimulation, with the two-channel system having the advantage that the current balance enabled some adjustment of foot posture.

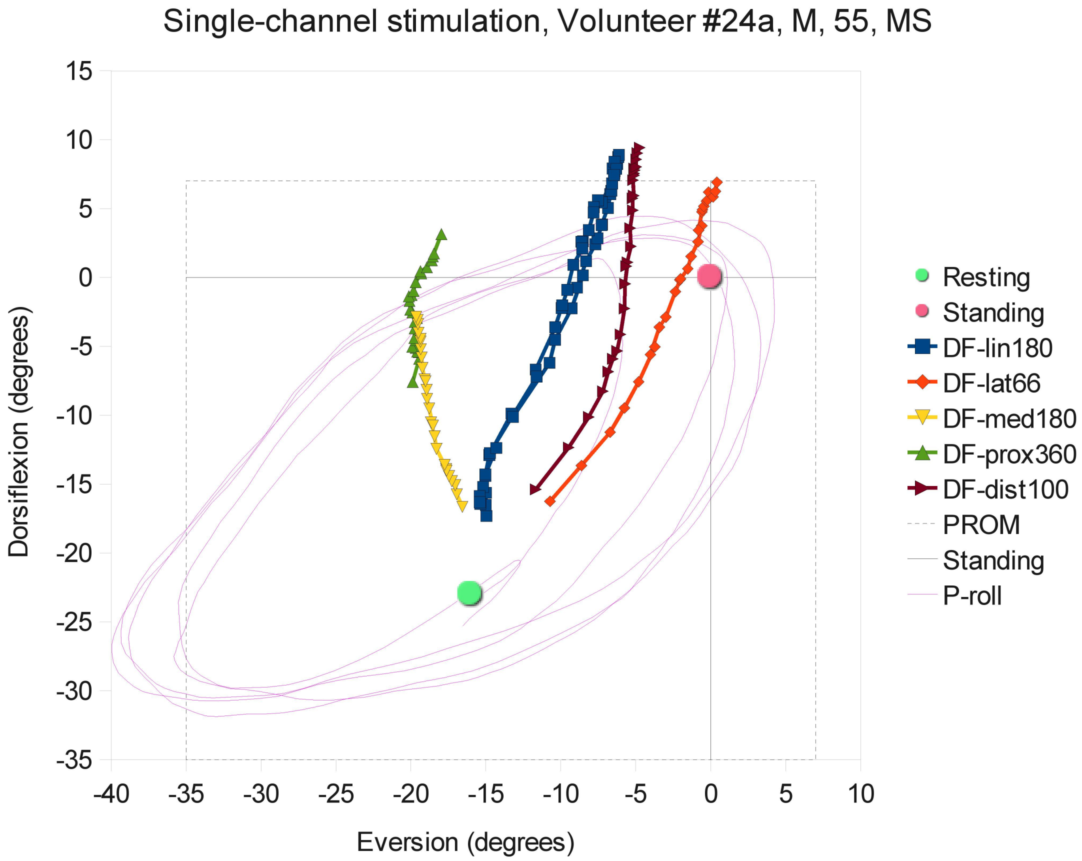


Figure 83: Single-channel stimulation - foot posture with current from $I_{0\%}$ to $I_{100\%}$ at five electrode positions, volunteer 24a.

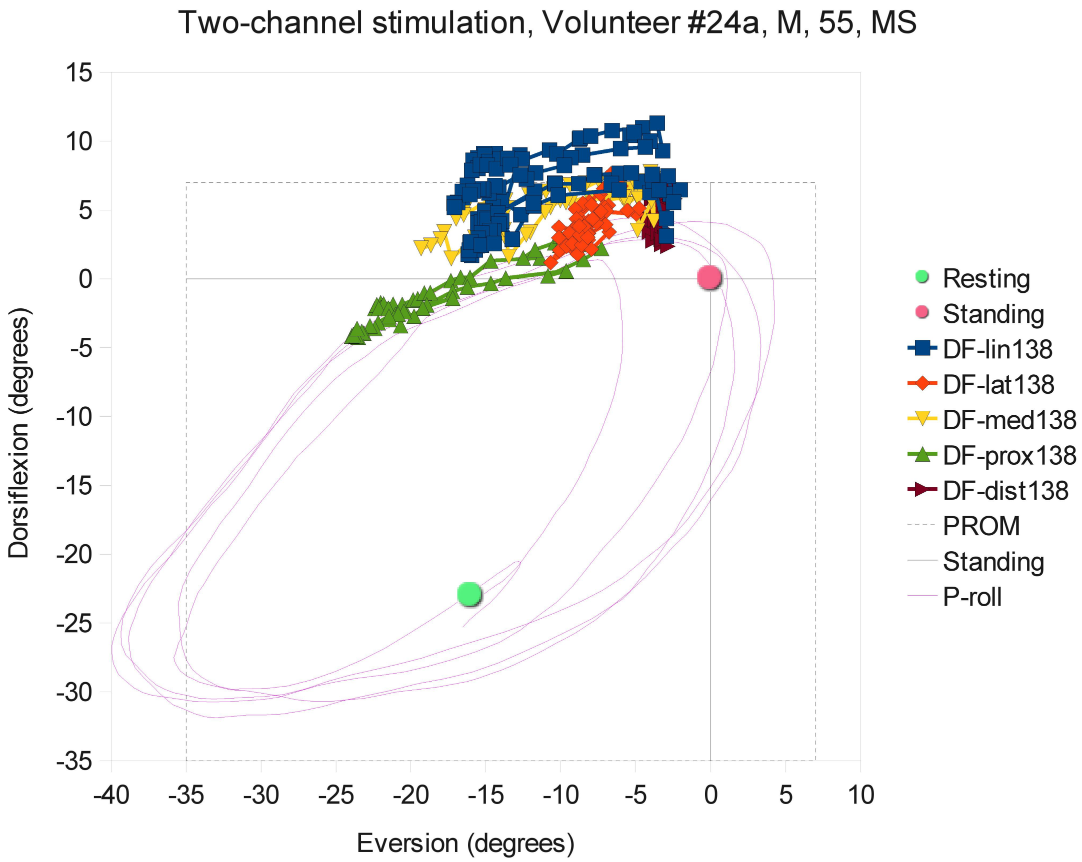


Figure 84: Two-channel stimulation - foot posture with current balance from 0% to 100% at five electrode positions, volunteer 24a.

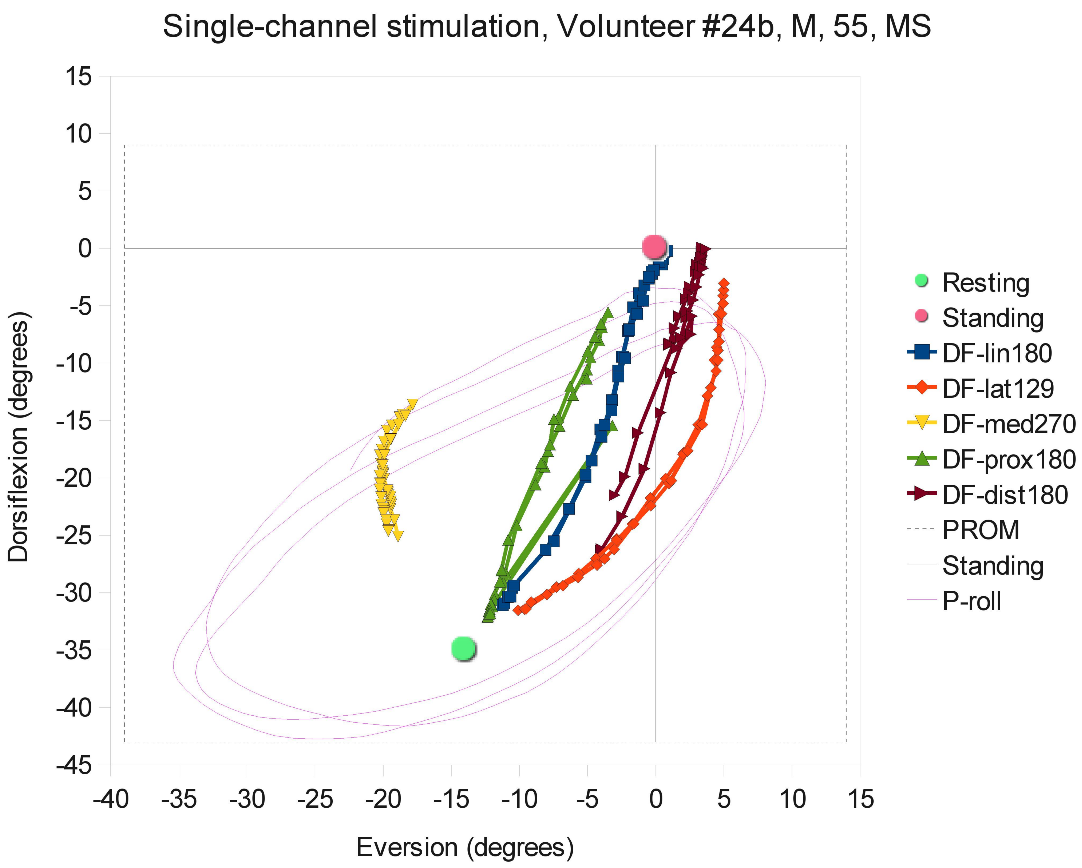


Figure 85: Single-channel stimulation - foot posture with current from $I_{0\%}$ to $I_{100\%}$ at five electrode positions, volunteer 24b.

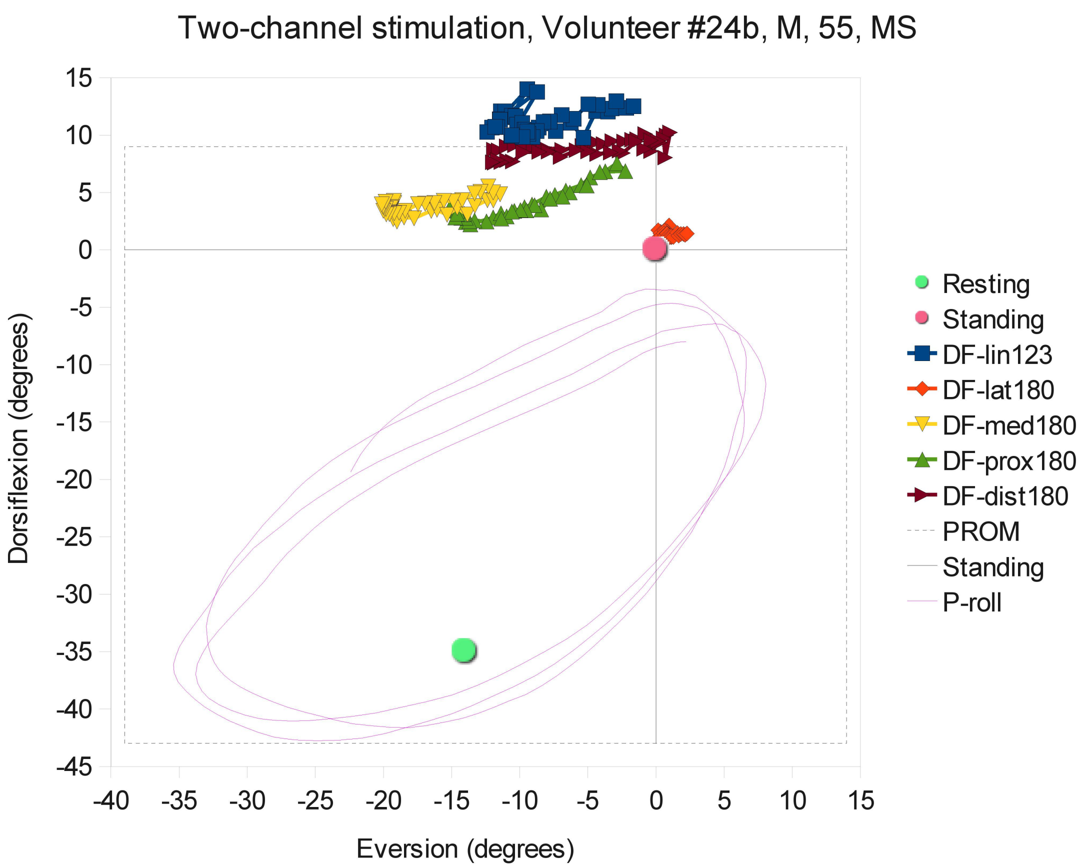


Figure 86: Two-channel stimulation - foot posture with current balance from 0% to 100% at five electrode positions, volunteer 24b.

7.6.3 Extended seated tests – volunteer 25

ID	Gender	Age	Neurological Condition	Duration of FES usage	Frequency of FES usage	Side
25	F	52	MS	5 year	Daily	Right

415 Volunteer 25 also returned for two extended sessions. On both occasions she was set up following the protocol for experiments 1 and 2, with additional electrode positions for experiment 1.

416 These results may have been affected by changes in medication:

- On the first session, her leg responded increasingly erratically to the stimulation, which she attributed to being sat down for an extended period of time. I stopped the experiment after the first of the two-channel tests as we were unable to make sensible measurements (as her foot would stay dorsiflexed even between the stimulation pulse trains).
- On the second session she took her medication (details not recorded) at the start of the experiment. This session gave a more stable response.

417 Details for volunteer 25 (first visit, 25a, figures 87 and 88):

Currents used (mA)			
Balance setting		**At 0%**	**At 100%**
Single channel		42	52
2-channel	**Medial**	48	11
	Lateral	7.5	40

Passive range of movement	Dorsiflexion (degrees)	Eversion (degrees)
Maximum	5	21
Minimum	-48	-36

(negative indicates plantarflexion/inversion)

418 Details for volunteer 25 (second visit, 25b, figures 89 and 90):

Currents used (mA)			
Balance setting		**At 0%**	**At 100%**
Single channel		32	48
2-channel	**Medial**	48	24
	Lateral	27	44

Passive range of movement	**Dorsiflexion (degrees)**	**Eversion (degrees)**
Maximum	11	19
Minimum	-38	-42

(negative indicates plantarflexion/inversion)

419 Figures 87 to 90 show notable difference between the visits; the data from the first visit is essentially unusable because of the erratic response, but the second is more consistent. The fact that the response variability was seen with both single- and two-channel stimulation suggestes it was not caused by the novelty of the two-channel stimulation.

420 At the second visit, it was difficult to set stimulation levels that produced strong dorsiflexion without being either uncomfortable or triggering an erratic response. This resulted in dorsiflexion levels were generally lower than would be used for walking, but were acceptable for seated tests. Similarly, the use of quite inverted postures is acceptable for seated tests, and illustrates the ability to evoke a range of angles, but would not be suitable for walking.

421 The two-channel results from the second visit (figure 90) show an particularly wide range of eversion, albeit at a low level of dorsiflexion. The first few pulse trains at each position evoked a greater response, which can be seen as widely spaced points with a diagonal trend. It was also clear that the two-channel postural ranges were more inverted than with single-channel stimulation; this may be due to fact that the single channel response followed the everted end of a very wide available range of movement, and that her ankles were very flexible with low tone in the associated muscle.

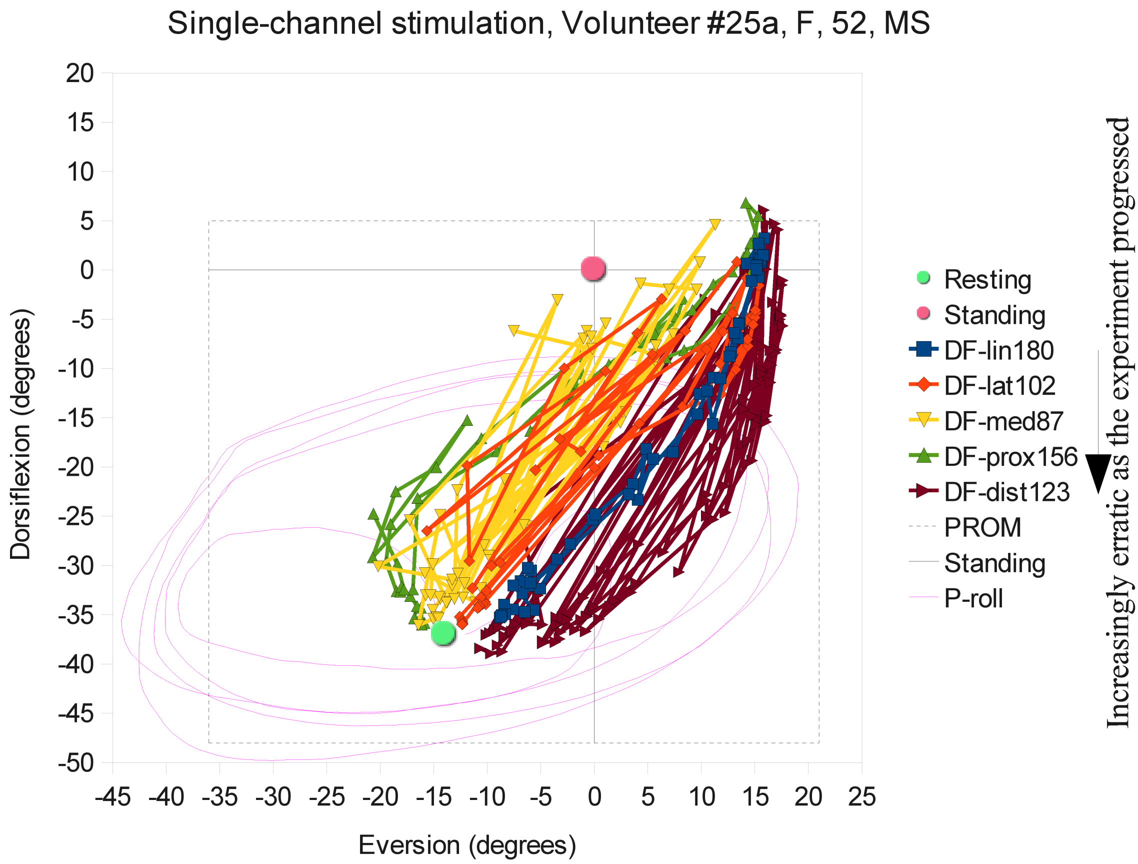


Figure 87: Single-channel stimulation - foot posture with current from $I_{0\%}$ to $I_{100\%}$ at five electrode positions, volunteer 25a. The foot response became increasingly erratic.

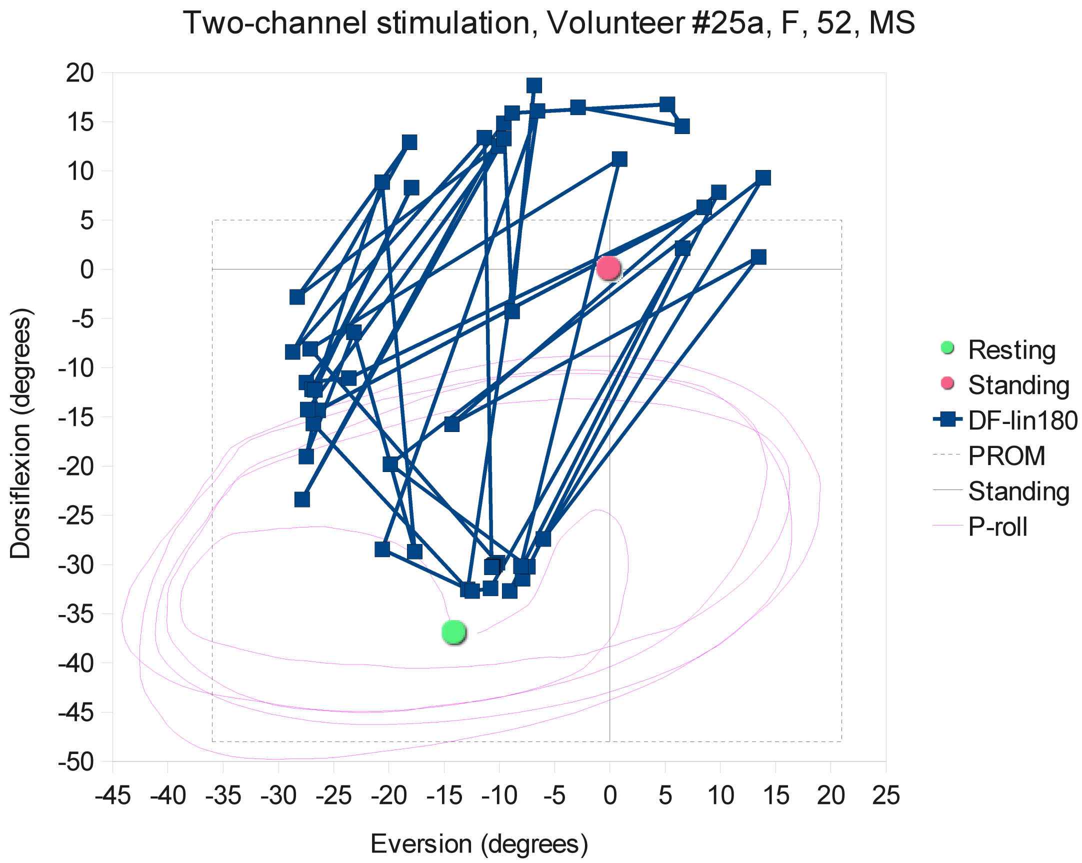


Figure 88: Two-channel stimulation, volunteer 25a – the response became extremely erratic from being seated for so long. This part of the experiment was abandoned.

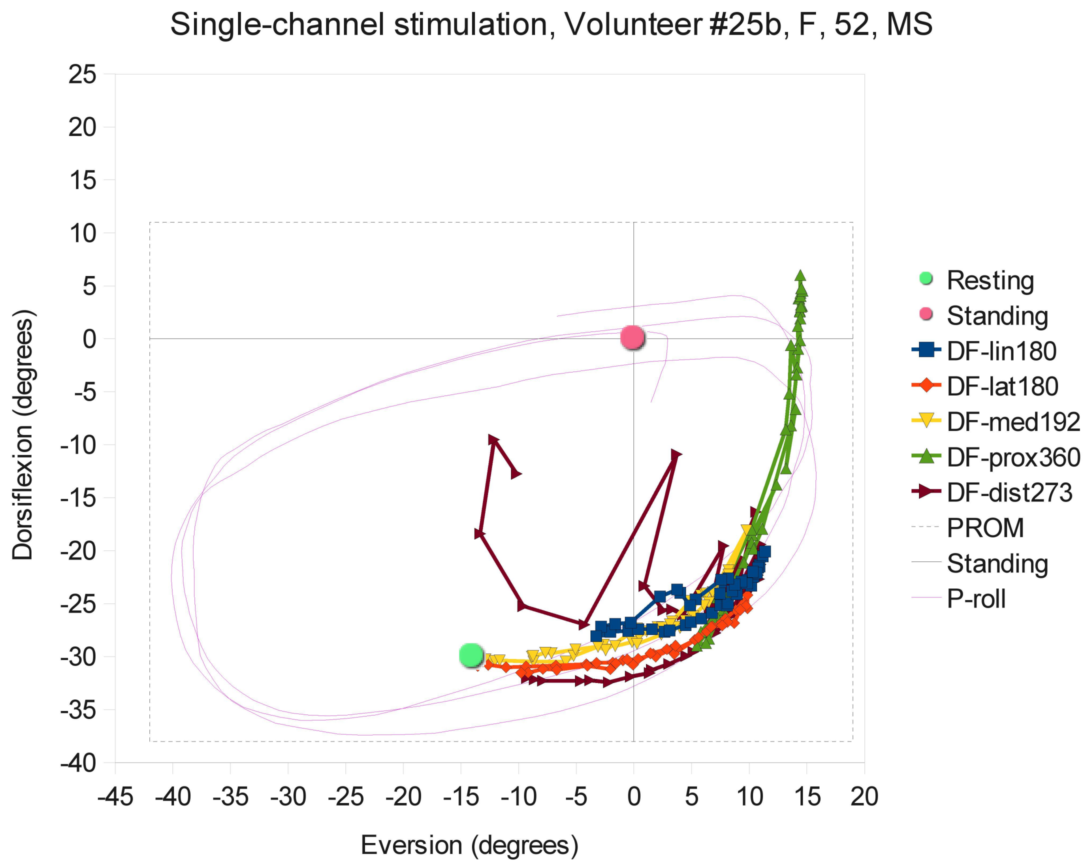


Figure 89: Single-channel stimulation - foot posture with current from $I_{0\%}$ to $I_{100\%}$ at five electrode positions, volunteer 25b.

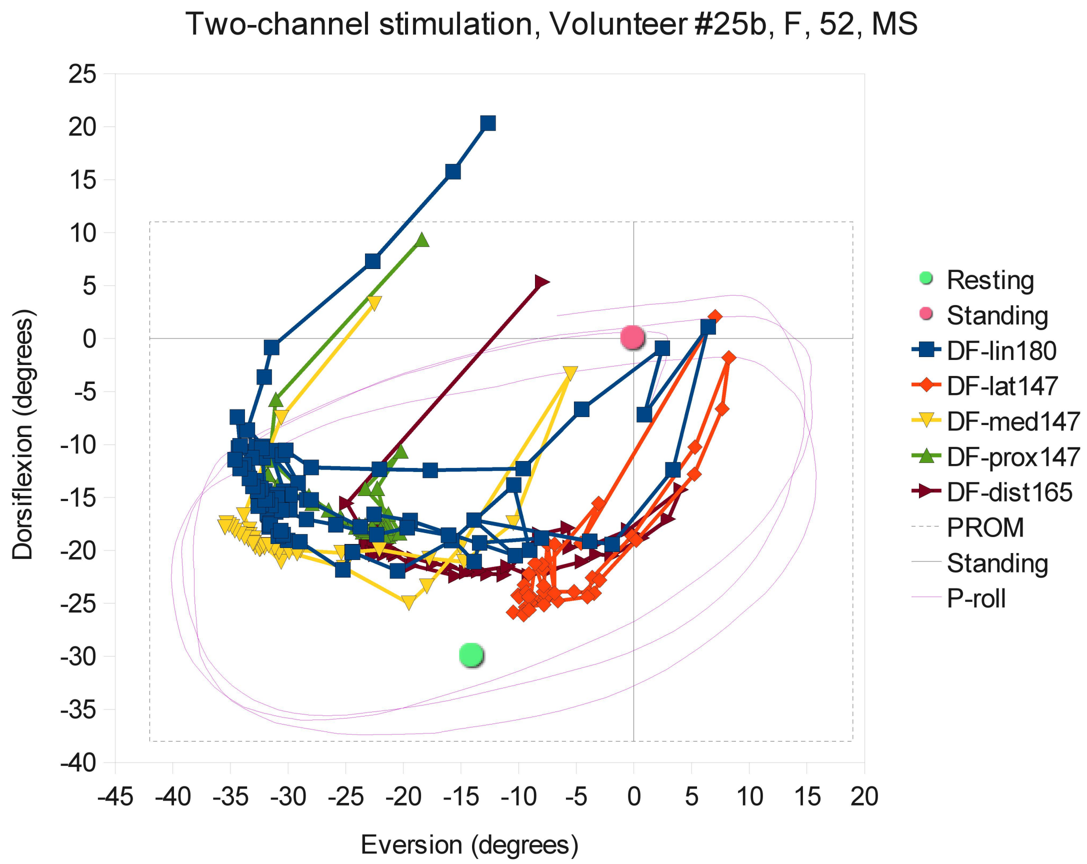


Figure 90: Two-channel stimulation - foot posture with current balance from 0% to 100% at five electrode positions, volunteer 25b.

7.6.4 Summary of extended seated tests

422 The extended seated tests examined the foot postures resulting from single-channel and two-channel stimulation, each at five electrode positions. The results showed that:

- Generally (but not always) a more lateral stimulation position leads to a more everted response. The exceptions to this might be due to the point of stimulation having been moved so far from the nerve that the response as a whole is now smaller.

- In two of the three cases, two-channel stimulation produced foot postures that were similar to the single-channel system with the same electrode offset, but with the ability, at most electrode positions, to adjust the eversion by 5-10 degrees while broadly maintaining eversion. The third case demonstrated a remarkably wide range of eversion, although we were unable to gain strong dorsiflexion in her seated tests without provoking erratic, reflex-driven responses.

423 Although the results from these volunteers showed a good and often consistent ability of the current balance to affect eversion, the small sample size and positive selection of more able volunteers who responded well at their initial visit means that caution is needed in extrapolating these results to the general FES user population.

7.7 Discussion

424 As a reminder, the hypotheses for experiment 2 were:

1. The degree of eversion accompanying a clinically beneficial dorsiflexion can be influenced by varying the balance of currents stimulating the tibialis anterior and peroneal muscles through medial and lateral electrodes.

2. Clinically acceptable foot posture can be maintained in the face of small changes in electrode position by altering the current balance.

7.7.1 Observations

425 With suitable positioning of the electrodes and appropriate choice of currents, approximately half the volunteers exhibited the ability of the current balance to affect the level of eversion. In some cases this was maintained, to a greater or lesser degree, at other electrode positions. In many cases the tests were conducted with more inversion and less dorsiflexion than normal. Dorsiflexion was less affected by the current balance than eversion, although in some cases the available range of movement acted to reduce dorsiflexion as the foot posture became more inverted.

7.7.2 Interpretation

426 The results support the hypothesis that current balance can affect the level of eversion in some cases. However, the set-up process was sensitive to both the location of the electrodes and the current levels used: poor set-up could easily lead to a lack of 'steering' of the foot posture. The experiment did not study the reasons for this lack of steering in any given position, but the following could be contributing factors:

- Limited, or no recruitment of muscles with different inverting/everting action, i.e. lateral and medial channels both producing eversion, or both inversion.

- Imbalance in the strength or impairment of the inverting/everting muscles.

- The biomechanical constraints of the joint, particularly the limits of available range of movement, limiting the range of achievable foot posture and thus the ability to change the foot posture.

427 It is possible that had there been time for trying other electrode arrangements and current settings, some of the non-responders could have attained a degree of foot posture steering. This may have included the use of smaller or differently shaped electrodes. Such further experimentation was beyond the scope of this study.

428 The common loss, degradation or alteration of steering effect with only a 10mm shift in electrode position showed that hypothesis 2 could not be supported in the general case with the present experimental arrangement. Even where some steering was maintained, the ranges often did not overlap, let alone include a clinically desirable foot posture.

429 The fact that the steering effect was so sensitive to the set-up was a major outcome of this study, indicating that one could not reliably compensate for a poor electrode set-up by a simple adjustment of the current balance. However, even a limited steering capacity may still be useful, for example as a means to fine-tune the response when wearing a leg cuff. In this situation, the cuff holds the electrodes close to the preferred location, where the current balance is able to moderate the level of inversion/eversion. This is particularly useful as a leg cuff makes it difficult to adjust electrodes individually, as is often done when optimising the response to surface stimulation.

7.7.3 Critical review

430 As a seated experiment, experiment 2 suffered from many of the difficulties highlighted in the discussion of experiment 1. In particular, again the seated test is not directly equivalent to walking. The discussion of the results of experiment 1 in section 6.6.3 noted the variability in response to stimulation; this was seen in many of the tests in experiment 2. This could be explained by the fact that at intermediate balance settings, the moments from the everting and inverting muscle groups are finely balanced, so that changes in current balance can affect foot posture. Small perturbations in the electrodes (e.g. surface movement artefacts) or changes to the current levels can result in variation in recruitment, and hence muscular force and ultimately foot posture. Such variability

could be expected to be less evident in normal drop foot stimulation, where each stimulation train drives the foot if not to its limit of movement then quite firmly, without much attempt to finely balance two opposing muscle groups. A degree of clear, but gentle over-eversion is accepted in the clinical treatment of drop foot, and this provides a margin against small changes in stimulation affecting the foot posture.

431 The mechanics of the ankle joint are such that under strong dorsiflexion the tightening of the Achilles tendon tends to cause the foot to either evert or invert; this may limit the ability to see both wide and stable changes in eversion with strong dorsiflexion. Indeed, the decision for the set-up of this experiment to aim for a wide change in posture, from inversion to eversion, regardless of whether this was compatible with the clinically important strong dorsiflexion, may have lead to the postures that are likely to be inversion-eversion unstable. This can be seen in the often weak or negative dorsiflexion and inversion range of many of the results.

432 As well as demonstrating the effect of changing the current balance, the seated tests of experiment 2 were designed to establish that two-channel stimulation was safe for use in the walking experiments. This meant that the unpredictability of the response to a changing current balance was a cause for concern. However, as discussed in relation to experiment 1, it was thought that the variability would probably reduce in walking as a result of generally higher muscle tone and periodic contact with the ground. It was on this basis that experiment 4 proceeded carefully, i.e. walking with two-channel stimulation.

7.7.3.1 Uncertainty of precise mechanisms

433 The detailed neuroanatomy and impairment of each volunteer was unknown, making it hard to be sure which nerves were being recruited and whether the effect was closer to a moving a single channel of stimulation or balancing two channels. A more detailed study could include EMG measurements to clarify this point. Care would be needed to prevent the stimulation pulses damaging the EMG equipment or contaminating the EMG signal. Understanding the mechanism may enable better choices of electrode placement and stimulation parameters, particularly the mapping of balance setting to the current for each channel.

7.7.3.2 Choice of experimental parameters

434 The 10mm offset for electrode position was an arbitrary value and possibly not representative of clinical practice. It would be beneficial to study the repeatability with which patients and leg cuffs, together and/or individually, can reposition a group of electrodes. Loss of steering may occur less if the electrodes can be maintained closer to their optimal position.

7.7.3.3 Repeatability of set-up

435 The electrode arrangements were not recorded with any precision, for two reasons. Firstly, in clinical use, reproducing the exact electrode position is considered less important than following the procedure to attain an acceptable foot posture. This compensates for variation in the neurological condition and the properties of the electrodes. Secondly, it was not originally intended to re-test the volunteers during this study. However, the lack of detailed records makes it difficult to compare the results of the repeat visits which three of the volunteers made: were the changes a result of differences in the set-up, or in the volunteer?

436 In clinical practice is common to follow an iterative set-up process rather than expect placement of the electrodes in the same position to produce the same response. In practice it seems that this also applies, to some degree, to two-channel stimulation.

8 Experiment 3: The performance of the in-shoe sensor

8.1 Overview

437 This experiment aimed to assess whether the in-shoe foot posture sensor was able to gauge inversion and eversion during walking. Three force sensitive resistors (FSRs), acting as pressure switches, were used to measure the time that the heel, 1st and 5th metatarsal heads contacted the ground. From these timings, two estimates of ankle eversion were calculated, on the premise that greater eversion would lead to the 1st metatarsal head contacting the ground more than the 5th metatarsal head. Eight volunteer FES users walked with the sensor in their shoe while FES was used cause to their ankle to adopt a range of postures from inverted to everted (within safe limits). The eversion estimates from the sensor were compared with measurements taken by a goniometer on the ankle.

8.2 Clinical objective

438 It is desirable to have a good measure of foot posture during walking (particularly inversion/eversion during loading) without needing the apparatus of a gait laboratory. This could be useful as a treatment outcome measure, or as feedback in a closed-loop control system.

8.3 Hypothesis

439 The in-shoe sensor can detect clinically relevant levels of inversion and eversion based on the timing of ground contact of foot switches placed under the heel, 1st and 5th metatarsal heads (figure 91).

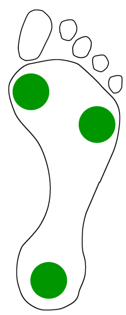


Figure 91: Location of FSRs

8.4 Theoretical basis

440 Although the foot tends to conform to the ground during loading, walking with eversion or inversion causes the 1st or 5th metatarsal heads respectively to contact the ground for longer between heel strike and heel rise (assuming the person is able to walk with the normal heel strike → toes down → heel rise → toe-off sequence). This timing can be

used to produce a figure of merit as a proxy for stability or degree of inversion or eversion. For each step, we define t_h as the duration of heel contact, and t_1 and t_5 as the duration of contact of the 1st and 5th metatarsal heads respectively, occurring after heel strike and before heel rise. (The algorithm was chosen to provide an estimate of eversion at heel rise so that it would be immediately available for use in setting stimulation parameters, rather than waiting for toe-off.)

441 Two stability estimates were defined:

442 $$Est_1 = \frac{t_1 - t_5}{t_h}$$ 443 (3)

444 $$Est_2 = \frac{t_1 - t_5}{t_1 + t_5}$$ 445 (4)

446 These attempt to normalise for walking speed. A value of +1 corresponds to fully everted, while -1 is fully inverted. Est_2 is more sensitive than Est_1 (to the relative contact duration of the metatarsal heads), but saturates at ± 1 if only one of the metatarsal head FSRs contacts the ground. Factors such as sensor placement and gait style mean that a neutral posture does not necessarily yield an estimate of 0. No estimate is produced unless a heel strike occurs.

8.4.1 Justification for using Est1 and Est2

447 In this study it is assumed that Est1 and Est2 relate to the posture of the foot during the loading phase of stance; in this experiment they are compared with the average eversion measured by a goniometer from heel rise to heel strike. They do not measure the same parameter nor at the same time, but both are taken to be proxies for the real subject of interest: stability in loading.

448 Stability is a function of many factors internal and external to the ankle, its muscles and ligaments; these include muscle strength, ligament condition, joint stiffness and geometry, the moments of the forces about the ankle and its dynamic response to these. Crudely assimilating all these, in clinical practice it is taken that an ankle is more stable if inversion is avoided, and so one of the objectives of clinical FES is to promote stability during loading by evoking a mildly everted foot posture. Gauging the

effectiveness of this requires the ability to measure eversion. It is not practical for FES users to wear ankle goniometers in daily life, but additional FSRs would be feasible; thus the motivation to see if Est1 or Est2 are correlated with the goniometer readings of eversion.

449 It may even be that Est1 and Est2 are more sensitive than goniometers in assessing stability: as the centre of pressure moves from medial to lateral side of the foot, the majority of contact time with the ground may switch from the medial to lateral aspect of the foot quite dramatically, with only a small change in ankle angle.

8.5 Method

450 Eight volunteer FES users participated, walking on a smooth floor in a large, uncluttered clinic room while two-channel stimulation was used to cause a range of inverted/everted foot postures, which were measured by both the goniometer and the in-shoe foot posture sensor. Thus each walk contributed both to experiment 4a (effect of two-channel stimulation on foot posture) and 3 (comparing in-shoe sensor to the goniometer).

451 This experiment could perhaps have been done by unimpaired volunteers as it only requires people to walk with a variety of foot postures. Indeed, the source of the variety could be deliberate action on the part of the volunteer. However, two factors contributed to the decision to use FES users:

452 The data for this experiment could be collected at the same time as experiment 4a (which is only valid with FES users), so there was no additional exposure for the FES users.

453 The type and range of foot postures arising with unimpaired volunteers is not necessarily representative of that of genuine FES users: ankles mobility may be different, and the unimpaired individual may be able to deliberately & safely exercise (or compensate for) a wider range of foot posture, either voluntarily or via FES. Showing that the sensor could work with unimpaired people would not greatly inform its utility with FES users.

8.5.1 Set-up for in-shoe sensor testing

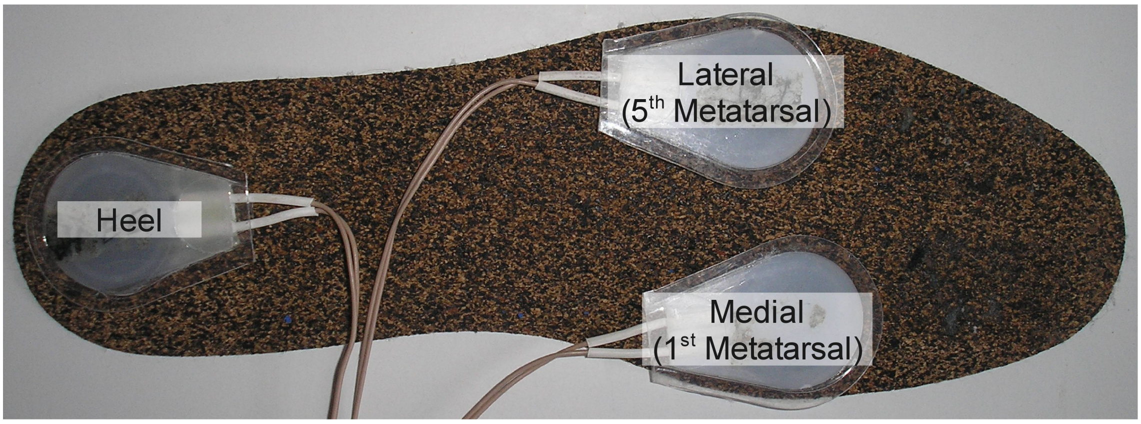


Figure 92: The FSRs of the in-shoe foot posture sensor (underside of a right-side sensor).

454

455 The equipment was set up as follows:

456 Three FSRs were fitted under an insole in the volunteer's shoe, positioned under the heel and 1st and 5th metatarsal heads (figures 91 and 92). The volunteer's normal insole acted as a guide for the size required (ensuring a secure fit), and by visible wear as an indication of the location of the metatarsal loading areas. The FSR outputs were checked for activation and the position adjusted if needed to ensure that the lateral and medial signals varied with inversion/eversion.

457 The electro-goniometer was fitted to measure inversion/eversion at the lateral malleolus.

458 Two-channel FES was set up as for experiment 2, so that stimulation was capable of giving a range of foot postures while seated.

459 Prior to the walking tests, the volunteer stood up and the response to stimulation from 0 and 100% balance was observed informally, to check that the foot postures were suitable for safe walking. The balance was set to 50% and the volunteer practised walking for a few steps to ensure they were happy with the arrangement; they could also adjust the pulse width to ensure they had sufficient dorsiflexion for walking.

8.5.2 Procedure

460 Each volunteer walked for between 64 and 318 steps (typically about 100) on the smooth vinyl floor of a large clinic room. The two channel stimulation was used to provoke a range of foot postures from inverted to everted by altering the balance between medial and lateral stimulation channels. Volunteers walked in their normal shoes at a self-selected pace. If the volunteer normally used a walking stick, they continued to use it for the experiment; the effect, if any, that this has on their foot posture is a valid part of their normal gait.

461 For experiment 3, the exact range of foot posture attained was not critical, as this experiment sought only to measure the correlation between the eversion estimates and the goniometer. Despite this, the intention to use this sensor as part of a feedback system meant that it was beneficial that the sensor was tested over the range of foot postures that could be provoked by the two-channel stimulation – the sensor would be of little use if it could only gauge foot posture over some sub-range of possible foot postures. In practice, both inverted and everted foot postures were seen; at the extremes, these were rather inappropriate for normal walking, but it was useful to test the performance of the sensor under these conditions in case they arose. The range of foot postures attained was limited by either the ability of the stimulation to change the foot posture, or by reaching postures that were at the limit of what was safe or comfortable. No statement is made as to whether this represented the full range with which the volunteer was capable of walking.

462 In early walks the balance was adjusted in large (e.g. 25%) steps when the volunteer reached the end of the room (to avoid the safety risks of adopting an unexpectedly different foot posture while walking). In later walks the balance was adjusted in much smaller (4%) steps while walking, to be more representative of the gradual shift in current balance that could be driven by a control system trying to control foot posture.

463 The stimulator calculated Est1 and Est2 at heel rise, sampled the goniometer signals continuously at 50Hz and calculated the average eversion between heel rise and heel strike (i.e. late stance plus the whole of swing phase). This was all transmitted wirelessly to a computer for real-time plotting and recording.

8.5.3 Data processing

464 The collected data was trimmed manually to discard any shuffling steps before and after the normal walking.

465 Each data set contained some steps recorded while the user paused or turned at the end of the room. The duration of the stance and swing phases of these steps were generally much shorter or longer than the steady walking pace. An empirical filter was set up to reject any step where the swing phase duration or heel contact time was less than half or more than twice their respective medians.

466 Est1 and Est2 for the remaining steps were plotted against the average eversion during swing. There was a notable step-to-step variation in the estimates and goniometer signals (the goniometer variability is investigated in appendix E). A 6-point moving average filter was implemented to reduce the noise, accepting that it would blur the edges of the step changes in balance and eversion.

467 The Pearson product-moment correlation coefficient was calculated for each plot as a measure of how well the estimates followed the goniometer.

The results are shown in section 8.6. as plots of Est1 and Est2 against the goniometer measurement of eversion. This is followed by a table that summarises the correlation coefficients.

8.6 Results

468 This experiment compared the in-shoe foot posture sensor to the goniometer, as a means of estimating the degree of eversion of the foot. The volunteers walked with a range of foot postures (caused by varying stimulation); while the exact range was unimportant, it is at least indicative of postures that occur during walking.

469 The results are presented as plots of the two estimates (Est1 and Est2) calculated at heel rise against the average goniometer reading of eversion during the preceding swing phase. Section 8.7.3.1 discusses the assumed equivalence of these two measures.

470 In each chart, steps where the heel contact time or swing phase time are more than twice or less than half their respective median values are considered outliers; these points are marked with white squares/diamonds and do not contribute to the statistics for that chart.

471 As discussed in appendix E, the goniometer signal had greater step-to-step variation than might be expected. A six-point moving average filter was used to smooth the results (six being a compromise between noise reduction and the risk of loosing real changes.

472 Each data series has a linear regression line fitted. The correlation coefficient is used as a measure of how well the in-shoe sensor functions as a measure of eversion. These statistics are summarised in table 15.

473 Volunteer 22 did not participate in experiment 3 because the two-channel set-up process was unable to produce any appreciable change of inversion/eversion, meaning that the in-shoe sensor could not be tested over a range of postures.

474 Volunteer 28 is missing from this experiment because of a failure of the goniometer sub-system.

475 Figure 93 shows the in-shoe sensor results for volunteer 13. Although there is much step-to-step variation in both the goniometer readings and estimates, a mild correlation can be seen between the two. This improved from 0.45 to 0.78 with the addition of the moving average filter, suggesting that in this case the sensor appeared to work reasonably well.

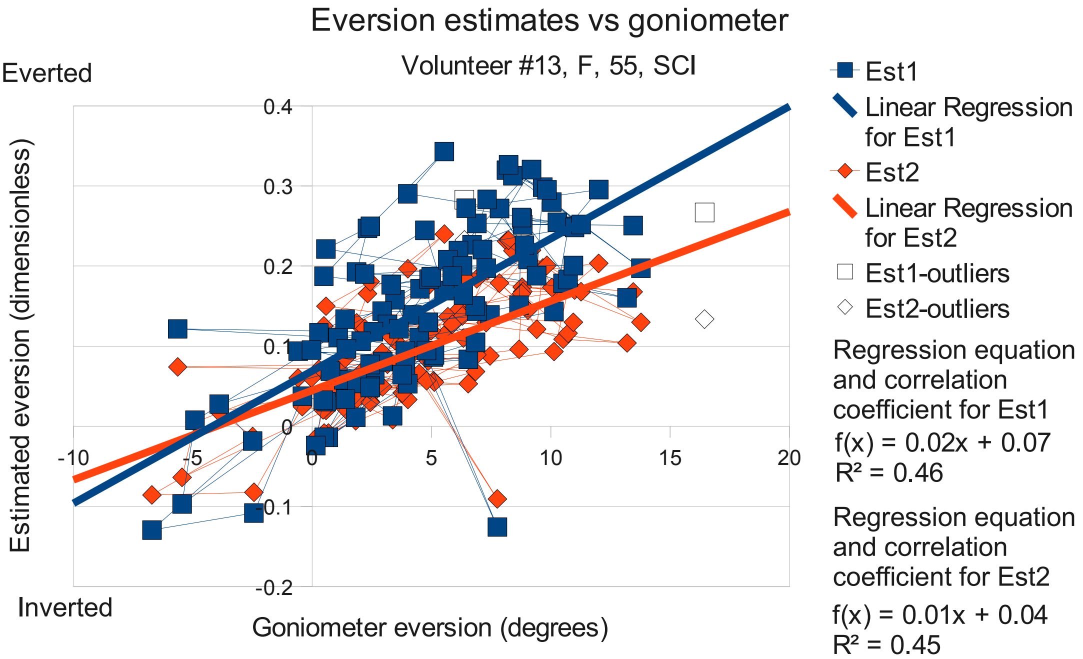


Figure 93: Eversion estimates vs goniometer measurements, volunteer 13.

476 Figure 94 presents the results for volunteer 19. Notable features:

- The foot did not press the lateral foot switch at all, so estimate 2 shows 'fully everted' for all steps.
- The correlation between the goniometer and Estimate1 was very weak.
- Both the goniometer and estimate showed some step-to-step variation.

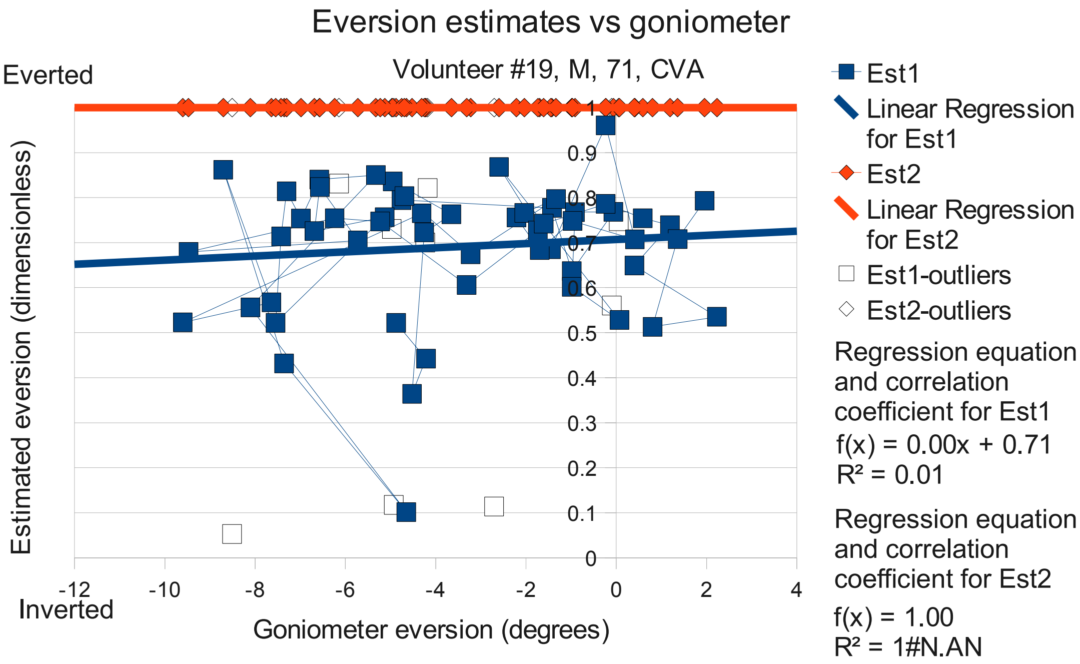


Figure 94: Eversion estimates vs goniometer measurements, volunteer 19.

477 Figure 95 shows the in-shoe sensor results for volunteer 20. The correlation of both estimates with the goniometer is very weak, despite the goniometer recording over 15 degrees range of eversion.

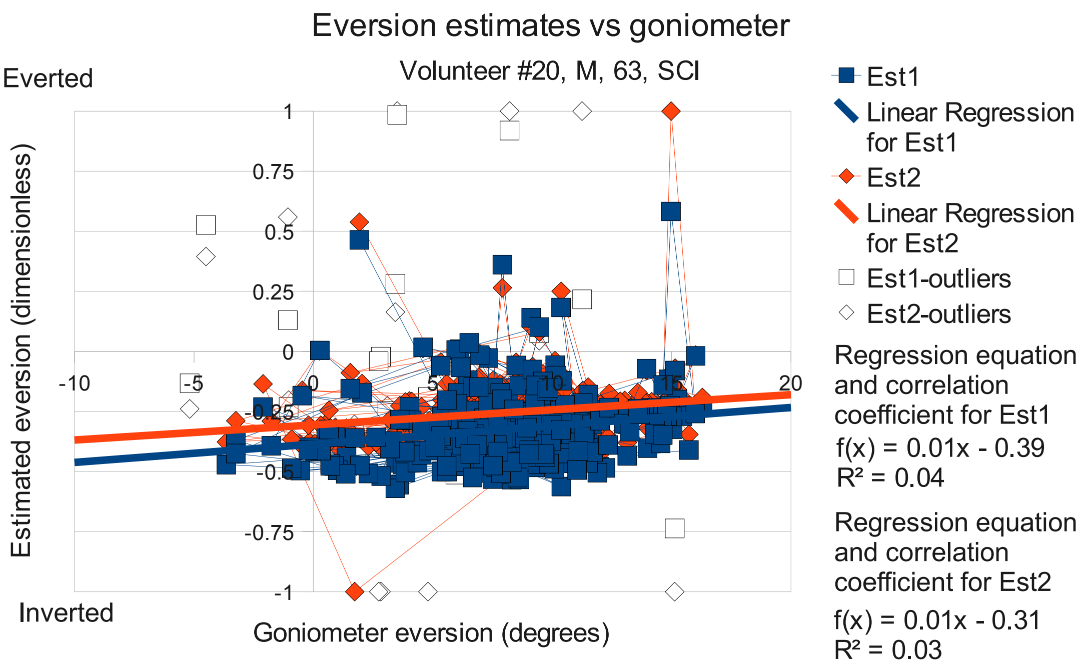


Figure 95: Eversion estimates vs goniometer measurements, volunteer 20.

478 Figure 96 shows the in-shoe sensor results for volunteer 21. The outlier points are clustered at the more everted regions, resulting from pausing after an initial test at a balance value of 100% The small number of non-outliers in this region occurred when the volunteer turned around at the end of the clinic room.

479 The data in this chart may contain two regions, or indicate a non-linear relationship between goniometer reading and eversion estimates. A linear fit gives modest correlations of 0.49 and 0.45. Applying the moving average filter improved both correlation coefficients to 0.6.

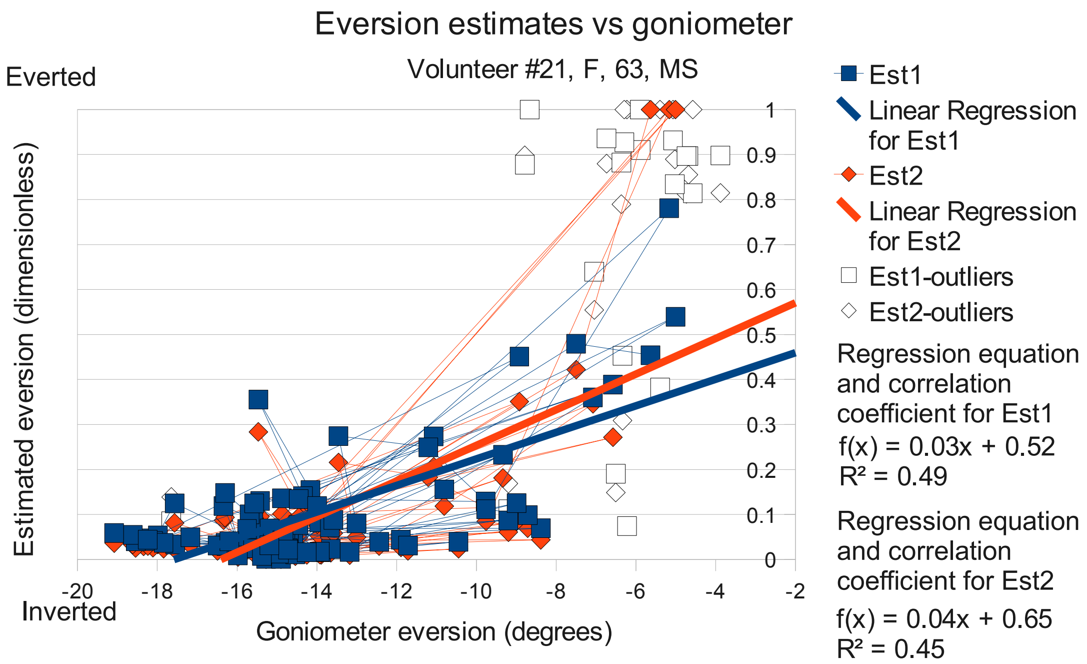


Figure 96: Eversion estimates vs goniometer measurements, volunteer 21.

480 Figure 97 shows the in-shore results for volunteer 23. Correlation was very weak, and did not improve much with the moving average filter. Most of the points fell within a small span of inversion, so this may not be a thorough test of the in-shoe sensor.

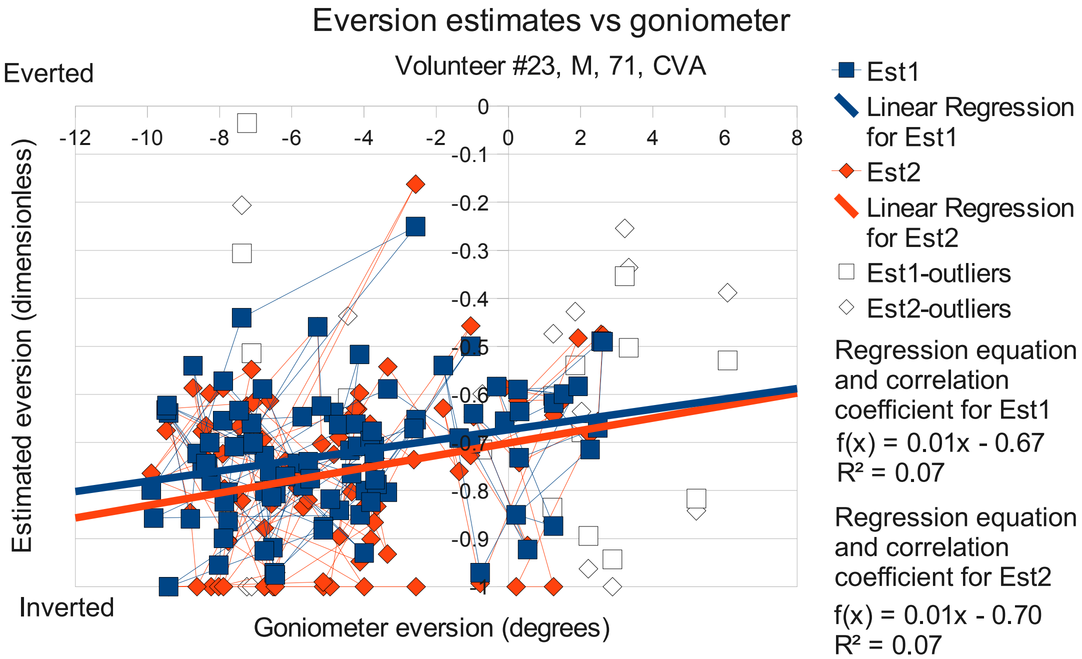


Figure 97: Eversion estimates vs goniometer measurements, volunteer 23.

481 Figure 98 shows the in-shoe results for volunteer 24. The correlation was very weak (R^2=0.13), increasing to 0.18 with the moving average filter.

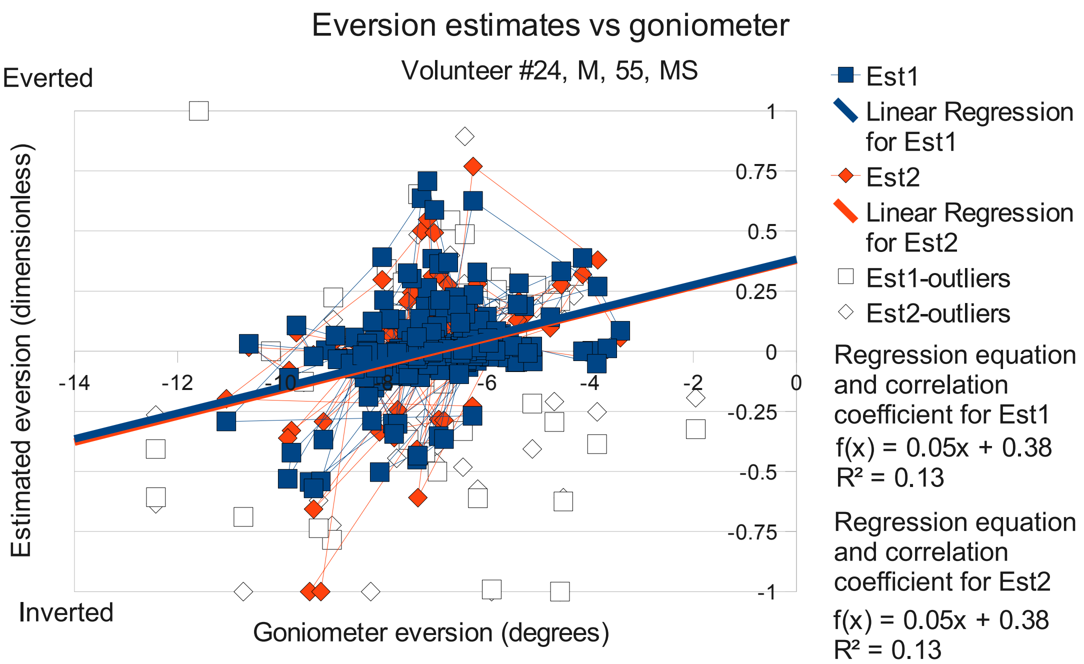


Figure 98: Eversion estimates vs goniometer measurements, volunteer 24.

482 Figure 99 shows the in-shoe results for volunteer 25. There is no correlation between the estimates and the goniometer readings, despite the latter covering a wide range of angles (over 20 degrees).

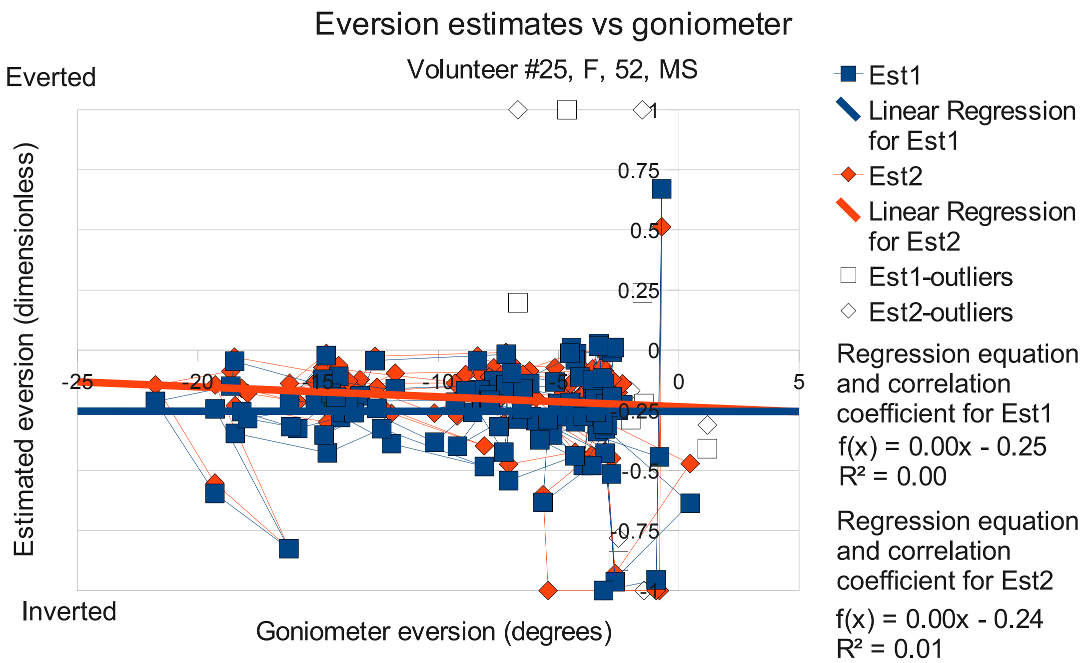


Figure 99: Eversion estimates vs goniometer measurements, volunteer 25.

8.6.1 Summary of in-shoe sensor results

483 Figure 100 presents an overview of the sensor results plotted side by side-by-side at common scale to illustrate the variation in sensor performance in each case.

484 Table 15 summarises the correlation between the average goniometer measurement of eversion during swing and the two estimates of foot posture derived from the timing of the in-shoe foot-switches. A fairly clear distinction can be made between cases where there is some correlation (volunteers 13 and 21), and those where there is virtually no correlation (all other volunteers). The results are therefore classified into 'effective' or 'ineffective', on the basis of the strength of the correlation (arbitrarily set at r^2>0.4 for effective).

485 It is suggested that the placement of the sensors under the metatarsal heads is critical for effective performance of the sensor. It is difficult to asses this aspect of the set-up in practice, and so the 'ineffective' outcomes may be an indicator of poor experimental set-up rather than a flaw in the principle of the sensor. However, significant gait deformities could nullify the assumption that inversion/eversion affects the relative loading of the lateral/medial aspects of the foot. These results are discussed further in section 8.7.

Volunteer ID	Linear correlation coefficients (r^2) with goniometer reading				Categorisation
	Without filter		With 6-point moving average filter		
	Est1	Est2	Est1	Est2	
13	0.46	0.45	0.79	0.78	Effective
19	0.01	0	0.05	0	Ineffective
20	0.04	0.03	0.03	0.01	Ineffective
21	0.49	0.45	0.61	0.58	Effective
23	0.07	0.07	0.08	0.12	Ineffective
24	0.13	0.13	0.18	0.19	Ineffective
25	0	0.1	0	0.04	Ineffective

Table 15: Summary of in-shoe sensor results

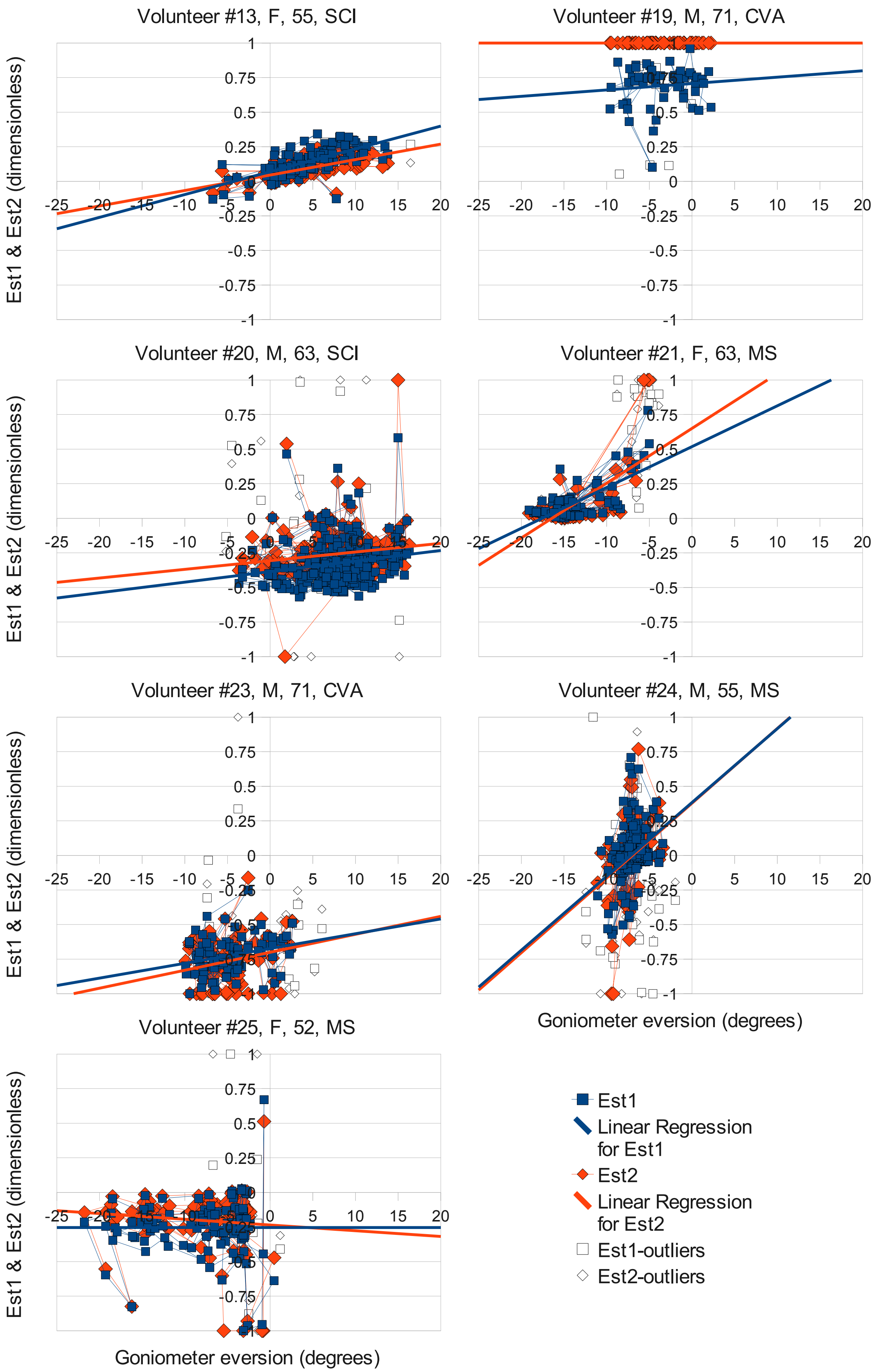


Figure 100: Overview of the performance of the in-shoe sensor: Est1 and Est2 vs goniometer measurement of eversion for each volunteer.

8.7 Discussion

486 The hypothesis for experiment 3 was:

- The in-shoe sensor can detect clinically relevant levels of inversion and eversion based on the timing of ground contact of foot switches placed under the heel, 1st and 5th metatarsal heads

8.7.1 Observations

487 The results in section 8.6 showed that the in-shoe sensor was often very poorly correlated with the goniometer. The seven tests consisted of two where the sensor was considered effective (with $r^2>0.6$) and five where it was ineffective (with $r^2<0.2$).

488 There was some notable (but uncorrelated) step-to-step variation in both the goniometer measured foot posture and the sensor estimated foot posture. It was unclear whether this was a genuine variation in foot posture or a measurement artefact. The performance of the goniometer is examined in appendix E.

8.7.2 Interpretation

489 The sensor did not appear to be suitable, in its current form, for clinical use assessing the degree of inversion/eversion. The experiment did not provide reasons for the sensor's often poor performance, although a plausible explanation is that the FSRs may not have been positioned appropriately to be sensitive to changes in foot posture. It was very difficult to verify the placement of the FSRs relative to the metatarsal heads once the foot and sensor were inside the shoe. Suggested improvements to the method and sensor are presented in the critical review and future research sections.

8.7.3 Critical review

8.7.3.1 Assumed equivalence of goniometer and in-shoe sensor

490 The goniometer signal was used to measure the average foot posture from heel rise to heel strike. This was then compared with the estimated foot posture calculated on the

duration of metatarsal head contact between heel strike and heel rise. Clearly these are separate parameters and might not be correlated. However, the experiment implicitly assumes these parameters should be correlated in using the apparent correlation as a measure of the sensor's effectiveness. They differ in the quantities measured and the phases of the gait cycle that they cover. Further study would be needed to verify whether a correlation should actually be expected. Eversion varies throughout the gait cycle, but the relationship between eversion at earlier points during swing and ankle stability during loading might not be straightforward. The experiment was in effect testing both the principle that the two signals were correlated and the implementation with discrete FSRs. When little correlation was found, it could not distinguish the cause.

8.7.3.2 Relevance of parameters to drop foot walking

491 The period averaged for the goniometer measurement of foot posture (heel rise to heel strike) included late stance, where foot posture is expected to be strongly affected by contact with the ground. This may reduce its sensitivity to posture during swing. A better approach, that would have been only a minor engineering change, would have been to use the period from toe-off to heel strike. Unfortunately the initial design of the system was based around calculating gait statistics at heel rise and strike and the potential improvement of including toe events was not realised until part-way through the experiment. The method was not changed at this point so that results from different volunteers remained comparable.

492 The foot posture averaging process ignores the different foot postures that are expected in different phases of the gait cycle, but this was accepted as the system was unable to distinguish between the early, mid or late swing phases. Maintaining a sufficiently everted foot posture during loading is safety-critical in avoiding the ankle inverting and consequently spraining the ankle and/or the user falling. Further study could show whether it would be beneficial to use the average of the last few samples before heel strike, rather than the average over swing, as a measure of foot posture. Such a metric might be more sensitive to the foot posture at the critical moment, but also more noisy as it involves fewer samples.

493 The range of foot postures used to test the in-shoe sensor were those that could be

obtained with the volunteers using the two-channel stimulation. As was the case for experiment 2, this was often more inverted than ideal for walking. The justification for this that a practical sensor has to be able to work at, and beyond, the limits of normal walking. However, the experiment did not clearly define the range of 'clinically relevant foot posture' to confirm that it had tested the sensor in that range.

8.7.3.3 Goniometer limitations

494 The experiment used a two-axis ankle electrogoniometer as a 'gold standard' measure of foot posture. This was found to have some technical problems (noise or cross-axis sensitivity) in dynamic applications (i.e. walking), but these did not prevent its use. A greater issue might be the neglect of the internal/external rotation of the foot. External rotation of the foot is often a significant component of stimulated gait, also affecting both toe clearance in early swing and reducing the risk of hyper-inversion during loading. Of course, none of these parameters directly measures ground clearance or ankle stability.

8.7.3.4 Effect of turning at the end of the gait laboratory

495 Anomalies caused by slowing and turning at the end of the gait laboratory may have affected the results by differently affecting the goniometer and in-shoe sensor. A better course would be either a single long straight or a large figure of eight, such that turn effects could be minimised. This would require a larger room to conduct the experiment.

8.7.3.5 Effect of gait pathologies

496 The experiment did not consider whether gait pathologies such as toe clawing or compensatory movements such as vaulting might have affected the way the volunteer's feet contacted the ground. This is another source of intra-subject variability in the apparent effectiveness of the sensor. Of the four experiments, this is the one which could have most easily used unimpaired volunteers, as it does not require a neurological impairment, just a range of foot postures to assess. However, using unimpaired volunteers might have lead to testing over a different range of inversion/eversion and given a misleading impression of the consistency of the sensor's performance, if unimpaired volunteers are assumed to walk with a more 'standard' gait pattern. Thus the

presence of a range of common pathologies was considered an advantage for the clinical relevance of this experiment.

8.7.3.6 Comparison with inertial sensors

During the course of this project, compact, low power inertial measurement systems with integrated signal processing have become available (e.g. MPU6500 from Invensens, San Jose, USA). These sensors make in-shoe real-time foot posture measurement entirely practical. However, foot posture is not necessarily the most sensitive indicator of ankle stability, so there remains room for a pressure (force) based sensor. Even quite significant changes in centre of pressure (e.g. from medial to lateral) and hence stability may not be accompanied by much change in foot posture angle when the foot conforms to the ground, at least until the ankle becomes unstable.

9 Experiment 4a: Open-loop control of walking foot posture

497 This experiment investigated the effect of two-channel stimulation on foot posture (dorsiflexion and eversion) while walking. Experiment 2 had studied the effect while seated (with the foot unloaded and unconstrained). This experiment looked at the effect in walking (where the foot is affected by contact with the ground and altered tone in the skeletal muscles).

9.1 Clinical objective

498 For safe walking despite sub-optimal electrode set-up, it is desirable to be able to adapt the effect of stimulation so that mild eversion can be evoked, even if the electrodes are not initially placed in quite the best position. Furthermore, it is advantageous if a stimulation system can cope with day-to-day variations in electrode placement.

9.2 Hypotheses

1. Altering the current balance between the lateral and medial electrodes will affect the level of eversion in walking. Specifically, that greater lateral bias will increase eversion, while the level of dorsiflexion will be much less affected.

2. When the electrodes are moved as a group by a small distance (10mm) from the initial set up position, the range of eversion evoked by two-stimulation (over the full range of current balance) will substantially overlap the original, making it feasible to compensate for small variations in electrode position by altering the current balance.

9.3 Method

499 This experiment was conducted simultaneously with experiment 3: while experiment 3 looked at the correlation between the goniometer and in-shoe sensors, experiment 4a looked at the influence of the balance setting on the foot posture (as measured by the goniometer). The set-up and procedure were described for experiment 3 in section 8.5. In summary:

- Eight volunteer FES users walked on a smooth floor with two-channel stimulation.

- The current balance was altered between medial and lateral bias as they walked.

- An electrogoniometer was used to measure ankle dorsiflexion and eversion (averaged from heel rise to heel strike).

- The data logging system recorded current balance, eversion and dorsiflexion for each step.

500 The results are presented in section 9.4, as charts of walking foot posture against current balance.

501 In an extension to this experiment, three volunteers returned for longer sessions, enabling this procedure to be repeated at five different electrode positions: a central reference position and 10mm laterally, medially, proximally and distally.

The results of the extended experiment are presented in section 9.5.

9.4 Results

9.4.1 Introduction

502 This experiment measured the average foot posture in swing (dorsiflexion and eversion) while the current balance was adjusted over its full range (or just the safe range, where excessive inversion or eversion occurred).

503 The results for each volunteer are presented as a chart of dorsiflexion and eversion against current balance, together with an explanation of the features of interest.

504 In these charts, each data point represents measurements transmitted at heel strike: the dorsiflexion and eversion angles cover the preceding swing phase, and the balance value is that in force at the time.

505 Steps where the heel contact time or swing duration were more than twice or less than half the median values (typically occurring while turning at the end of the room) were rejected as outliers; these are shown as empty squares/diamonds on the charts.

506 A linear best-fit line has been added to show the trend for each data series. This is a first-order approximation, and it is quite possible that a more detailed study could find a higher-order curve a better fit. Unfortunately the charting software has extrapolated the line beyond the tested range, and quite possibly beyond it region of validity.

507 Appendix E discusses the possibility that these results are contaminated by angle measurement noise; this may be seen most obviously in some wide step-by-step variations in foot posture. It is not clear whether successive steps while walking were actually as different as these measurements suggest, although pivoting while changing direction of walking may have contributed in some cases. The lines between each point give an indication of the measured step-by-step variation. As none of the volunteers walked with a visibly erratic gait pattern, this may indicate cases of high levels of goniometer noise.

508 The reader is reminded that the angles are measured on the volunteers' shoes and in

relation to quiet standing. Thus they will be somewhat offset from true anatomic angles. For the purposes of this study, the changes in angle *with current balance* are more important than the absolute values or step-by-step variations.

509 The results charts are followed by a summary of the average change in angles over the 0-100% range of balance settings.

9.4.2 Open-loop results

510 Figure 101 shows the open-loop results for volunteer 13. Dorsiflexion and eversion were both affected by the change in current balance: the linear regression lines both show a change of eight degrees over the balance range from 0 to 100%. However, an eight degree change in eversion could be clinically significant in terms of ankle stability during loading, while (as long as the foot clears the ground) a similar change in dorsiflexion is less important. This result may be summarised as giving a wide range of control over eversion, although care may be needed to ensure sufficient dorsiflexion is maintained.

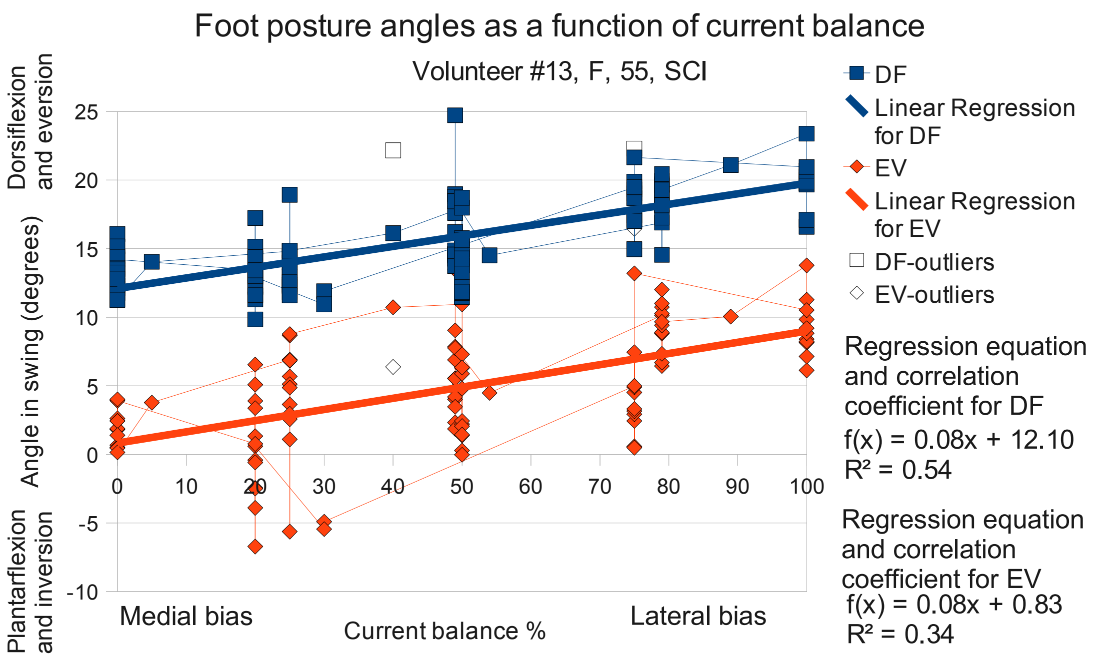


Figure 101: Open-loop results for volunteer 13.

511 Figure 102 shows the open-loop results for volunteer 19. The change in dorsiflexion (2 degrees) is clinically negligible, while the range of eversion angles is again about 8

degrees.

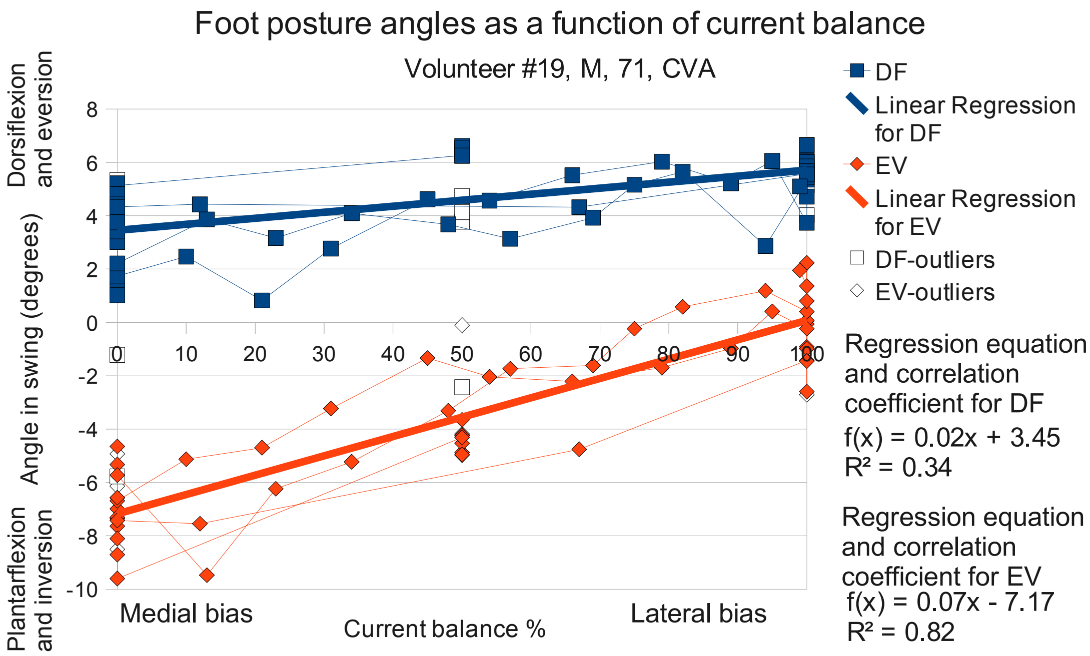


Figure 102: Open-loop results for volunteer 19.

512 Figure 103 shows the open-loop results for volunteer 20. Similarly to volunteer 13, both dorsiflexion and eversion were affected – by approximately 7 and 9 degrees, although this change occurred in just half the balance range (0-50%). In fact, the eversion became so great that current balances greater than 50% were not tested for this volunteer.

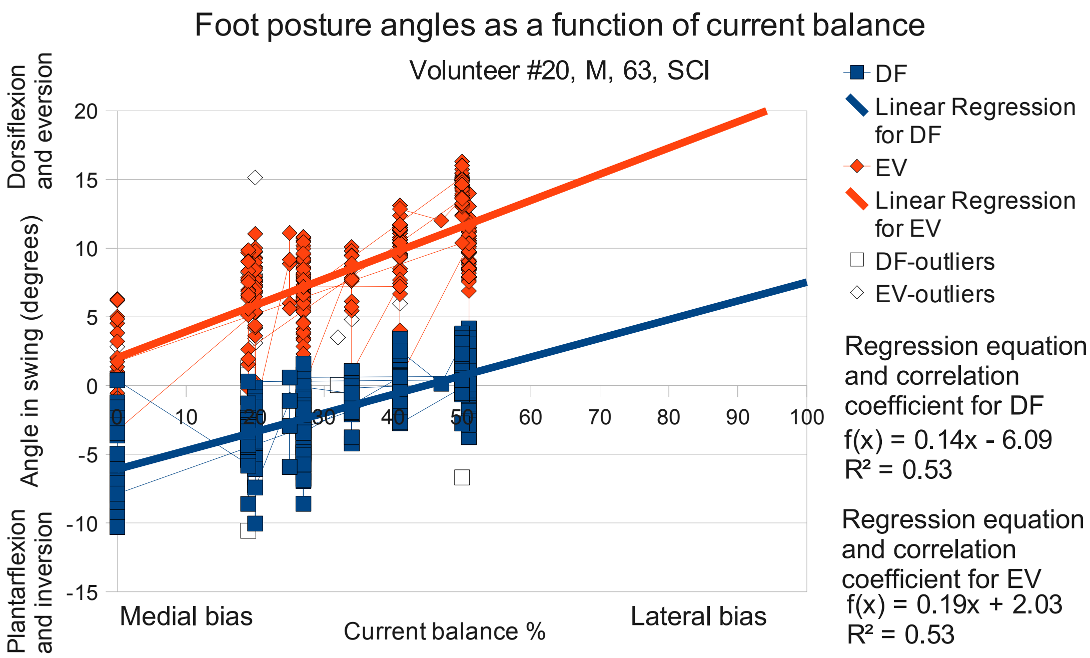


Figure 103: Open-loop results for volunteer 20.

513 Figure 104 shows the open-loop results for volunteer 21. Dorsiflexion was largely unaffected by current balance, while eversion responded positively. Current balances less than 55% were not tested in walking as the inverted foot posture became too uncomfortable for walking. These results contain an experimental artefact caused by the volunteer stopping to turn at the end of the clinic room. These steps are all much more everted (by approximately 10 degrees) than the other steps measured at the same balance setting.

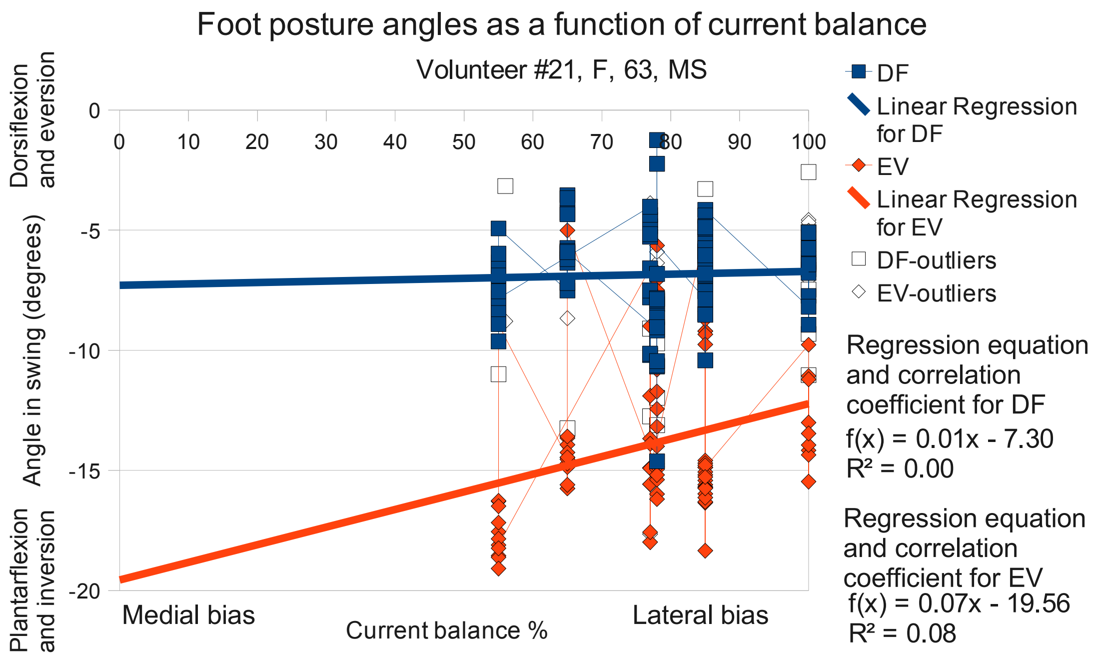


Figure 104: Open-loop results for volunteer 21.

514 Figure 105 shows the open-loop results for volunteer 23. There is a clear trend for eversion to increase with greater bias towards the lateral electrode. Dorsiflexion was also affected but to a lesser degree. The balance setting could not be safely tested below 35% because of excessive inversion.

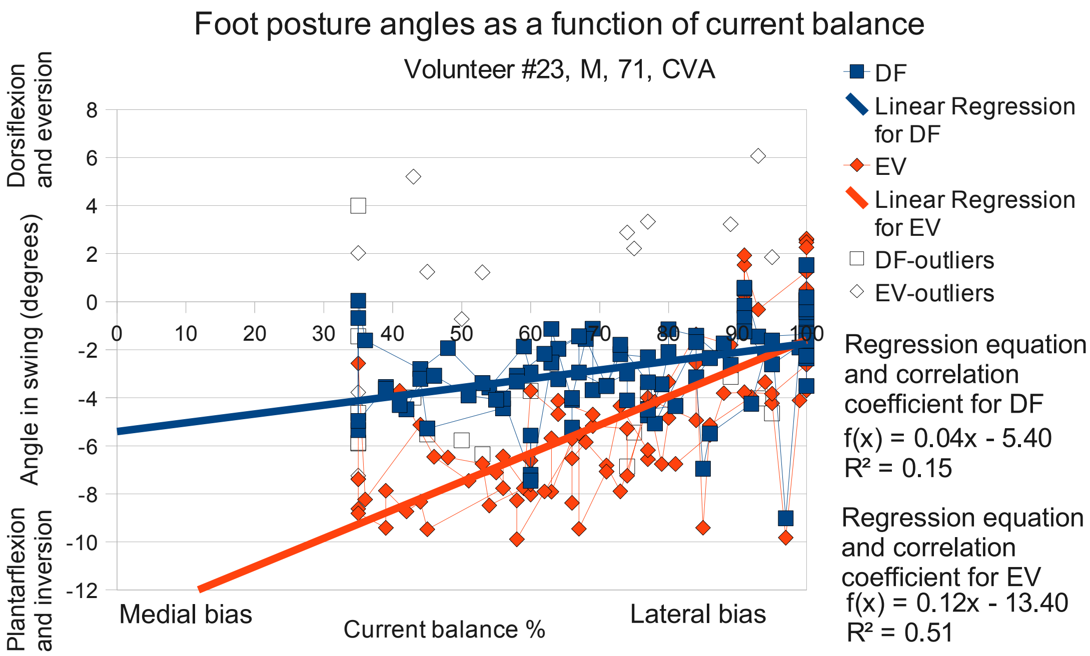


Figure 105: Open-loop results for volunteer 23.

Figure 106 shows the open-loop results for volunteer 24. There was no change in dorsiflexion and little change in eversion with change in current balance. Balance values less than 48 were not tested in walking because the volunteer found them uncomfortable to walk with (despite the level of inversion being similar across the range).

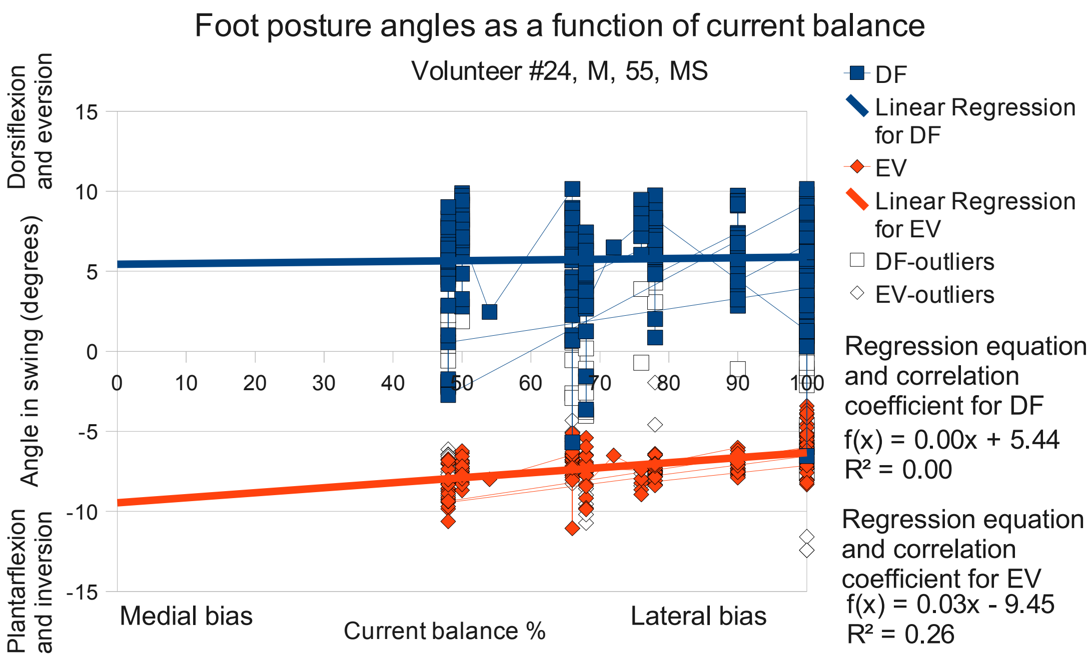


Figure 106: Open-loop results for volunteer 24.

516 Figure 107 shows the open loop results for volunteer 25. Eversion was strongly affected by the current balance. The effect was so strong that we could test only 25% of the balance range before inversion became excessive and unsafe for walking. Dorsiflexion was also affected notably, but to a lesser degree than the inversion.

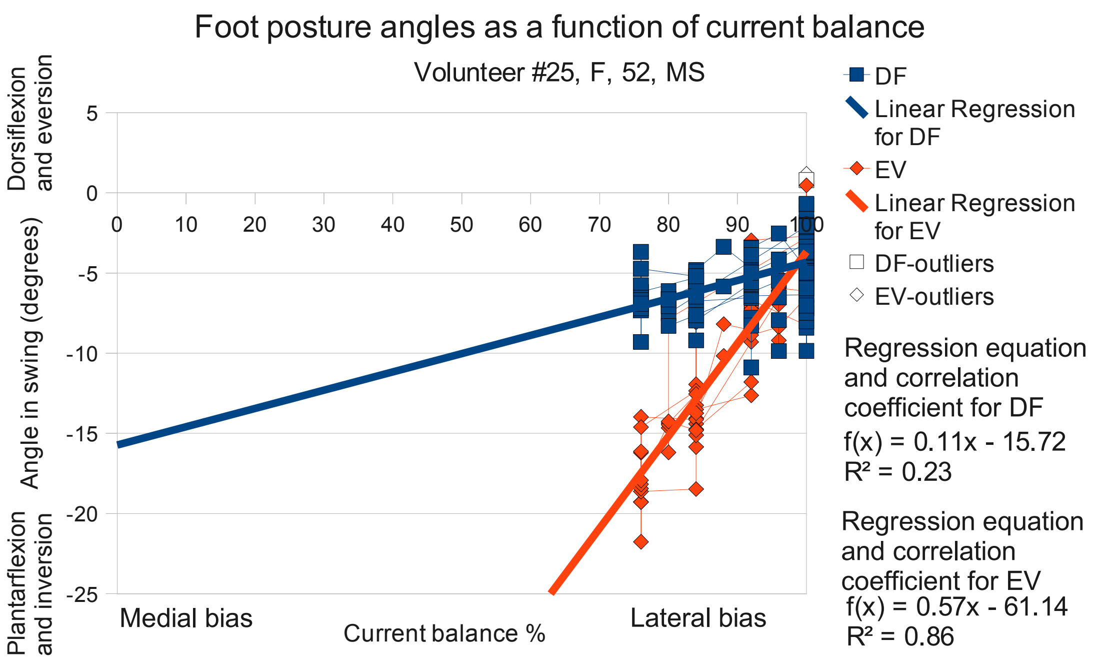


Figure 107: Open-loop results for volunteer 25.

9.4.3 Summary of open-loop results

517 The following table summarises the sensitivity of foot posture to current balance for each of the volunteers, based on a linear regression of the dorsiflexion and eversion data with respect to current balance. Sensitivity is defined as the number of degrees change in angle over the 0-100% change in current balance from the linear regression.

		Dorsiflexion			**Eversion**		
ID	**Balance range tested**	**Sensitivity (deg. per full scale)**	**Correlation coefficient r^2**	**Range in test (deg.)**	**Sensitivity (deg. per full scale)**	**Correlation coefficient r^2**	**Range in test (deg)**
13	0-100%	8	0.54	8	8	0.34	8
19	0-100%	2	0.34	2	7	0.82	7
20	0-50%	14	0.53	7	19	0.53	9
21	55-100%	1	0.00	0.5	7	0.08	3
23	35-100%	4	0.15	3	12	0.51	8
24	50-100%	0	0.00	0	3	0.26	1.5
25	75-100%	11	0.23	3	57	0.86	14
	Average	**5.7**	**0.26**	**3.4**	**16.1**	**0.49**	**7.2**
	Std. dev.	**5.4**	**0.23**	**3.1**	**18.7**	**0.29**	**4.1**

Table 16: Statistics for open-loop tests: sensitivity of foot posture to current balance.

518 As noted earlier and explored in appendix E, there was more step-to-step variation in the angle measurement than might be expected. To reduce the effect of noise in the goniometer reading, a six point moving average filter was used to smooth the data in the preceding charts and the statistics above recalculated (table 17). Six points were a compromise: long filters reduce noise, but also risk mixing results from different balance settings. The filter has little effect on the sensitivity, but increases the average correlation coefficient for eversion as a function of current balance from 0.49 to 0.60.

		Dorsiflexion			Eversion		
ID	**Balance range tested**	**Sensitivity (deg. per full scale)**	**Correlation coefficient r^2**	**Range in test (deg.)**	**Sensitivity (deg. per full scale)**	**Correlation coefficient r^2**	**Range in test (deg)**
13	0-100%	8	0.77	8	8	0.49	8
19	0-100%	2	0.38	2	7	0.89	7
20	0-50%	13	0.71	6.5	19	0.65	9
21	55-100%	1	0.01	0.5	7	0.21	3
23	35-100%	3	0.24	2	12	0.66	8
24	50-100%	0	0.00	0	3	0.35	1.5
25	75-100%	12	0.37	3	60	0.96	15
	Average	**5.6**	**0.35**	**3.1**	**16.6**	**0.60**	**7.4**
	Std. dev.	**5.4**	**0.30**	**3.0**	**19.8**	**0.27**	**4.4**

Table 17: Statistics for open-loop tests after using a six-point moving average filter.

519 Figure 108 is an overview of the responses to open-loop two-channel stimulation while walking, in which each small chart contains the same data as presented in this section, but plotted side-by-side and with common scales. This shows the general variety of response, although also consider that the volunteers' pathologies are different.

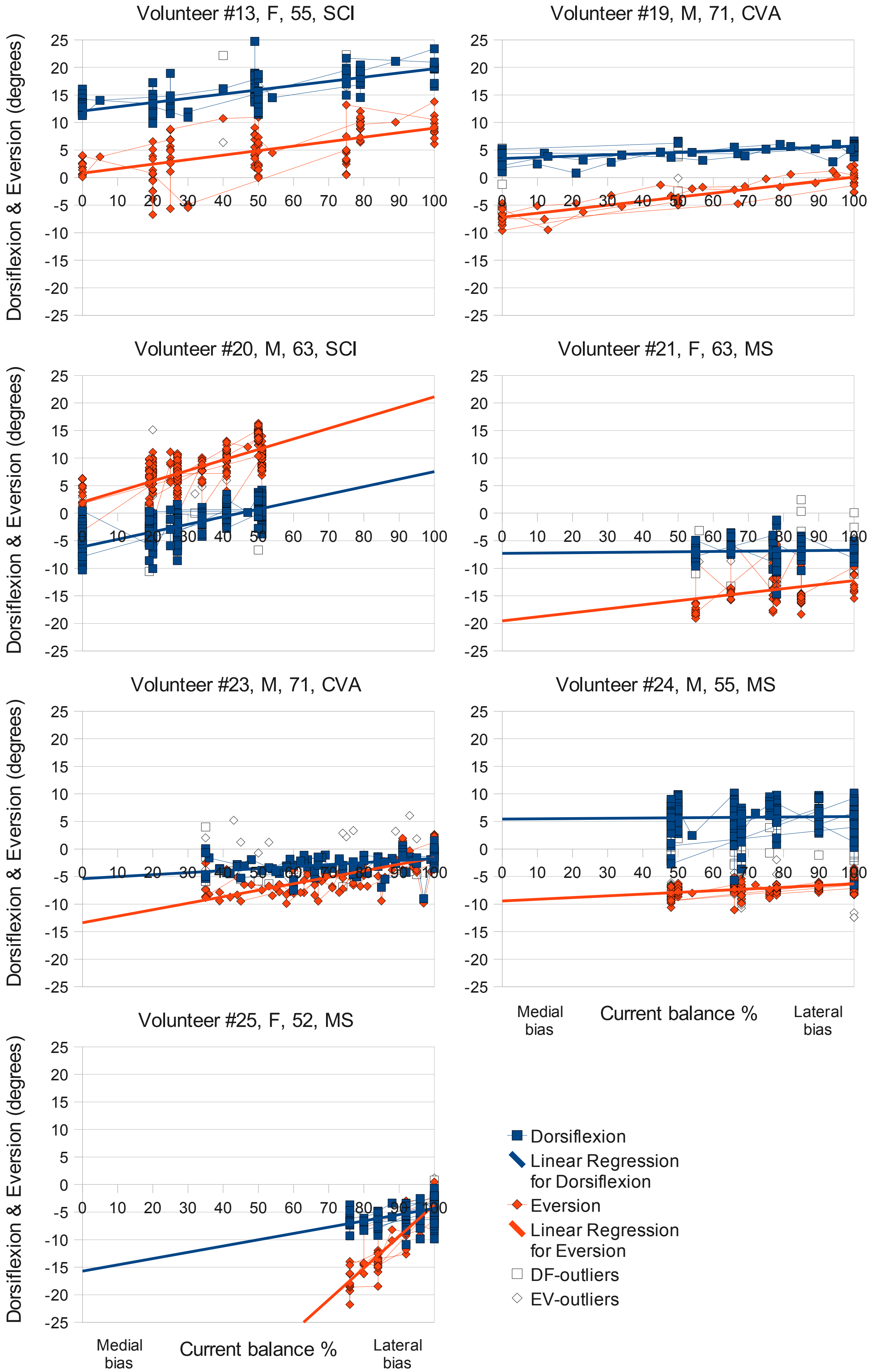


Figure 108: Overview of open-loop responses to two-channel stimulation while walking.

9.5 Experiment 4a extended: Open loop control with more electrode positions

520 The open loop tests presented in section 9.4 only tested the effect of two-channel stimulation while walking with the electrodes in one position (because volunteers' time was limited and each session started with a characterisation of their seated response). Three volunteers returned for a second session (3 hours each), at which response to two-channel stimulation in five positions (initial and 10mm laterally, proximally and distally) was recorded. The response was measured both while seated and while walking. The seated results were presented in section 7.6; the walking test results are presented in this section.

521 Each of the three volunteers has two charts (listed in table 19): one showing dorsiflexion and one showing eversion, both as a function of the current balance, which was varied over the full range as they walked. Each chart has six series, as follows:

Series marker	Electrode position
Blue dotted hourglass	Session 'a': central (from section 9.4 for reference)
Blue square	Session 'b': central
Red diamond	Session 'b': 10mm lateral
Yellow triangle (point down)	Session 'b': 10mm medial
Green triangle (point up)	Session 'b': 10mm proximal
Brown triangle (point right)	Session 'b': 10mm distal

Table 18: Descriptions of the series in the charts

522 The legend for each chart names each series with the volunteer ID (V19, V24 or V25), session (a or b) electrode position (lin=central, lat, med, prox, dist) and the pulse width chosen by the volunteer when adjusting for comfort and effect at each position.

523 As in section 9.4, outlier points were identified as those with less than half or more than twice the medial heel contact time or swing phase time. For clarity, outlier points are not shown in these charts, but were a small proportion of the total.

Volunteer	Measurement	Figure number	Observations
19 (page 182)	Dorsiflexion	109	Largely unaffected by current balance.
	Eversion	111	Moderate to good correlation. Eversion altered by an average of over 6 degrees.
24 (page 183)	Dorsiflexion	112	Very weak positive correlation with current balance at session B, none at session A.
	Eversion	113	Weak correlation at session A, moderate to good correlation at session B. Eversion altered by over 7 degrees on average at session B.
25 (page 184)	Dorsiflexion	114	Weak correlation with current balance; sign differed at each session.
	Eversion	115	Very strong positive correlation at session A, moderate positive correlation at session B.

Table 19: Figures giving the results of the extended open-loop walking tests.

524 A linear regression line was fitted to each series. The slope of this line and the correlation coefficient (r^2 value) are taken as a measure of the effect of current balance on foot posture in each position. These results are summarised in table 20.

525 As an overall observation, eversion was much more strongly correlated with current balance than dorsiflexion. Within each volunteer's results:

- Most electrode positions showed similar sensitivities, but some were much less effective.

- As might be expected, lateral electrode positions produced more eversion than medial.

- The eversion angles ranges accessible at each electrode position did include a range of overlap, but this may not have included the clinically desirable posture.

Dorsiflexion	Sensitivity (degrees change over full 0-100% range of current balance)			Pearson correlation coefficient R^2		
Position	**Vol. 19**	**Vol. 24**	**Vol. 25**	**Vol. 19**	**Vol. 24**	**Vol. 25**
'a' central	2	0	11	0.34	0	0.23
'b' central	0	4	-1	0	0.13	0.01
'b' lateral	1	3	-4	0.05	0.13	0.26
'b' medial	2	6	-3	0.04	0.53	0.33
'b' proximal	0	6	-3	0	0.4	0.25
'b' distal	1	5	-6	0.02	0.32	0.3
Average for session 'b'	0.8	4.8	-3.4	0.02	0.30	0.23

Eversion	Sensitivity (degrees change over full 0-100% range of current balance)			Pearson correlation coefficient R^2		
Position	**Vol. 19**	**Vol. 24**	**Vol. 25**	**Vol. 19**	**Vol. 24**	**Vol. 25**
'a' central	7	3	57	0.82	0.26	0.86
'b' central	7	6	4	0.44	0.79	0.24
'b' lateral	6	2	3	0.69	0.18	0.32
'b' medial	5	13	8	0.52	0.86	0.65
'b' proximal	7	7	6	0.75	0.69	0.54
'b' distal	7	8	6	0.81	0.72	0.38
Average for session 'b'	6.4	7.2	5.4	0.64	0.65	0.43

Table 20: Summary statistics for the extended open-loop walking tests.

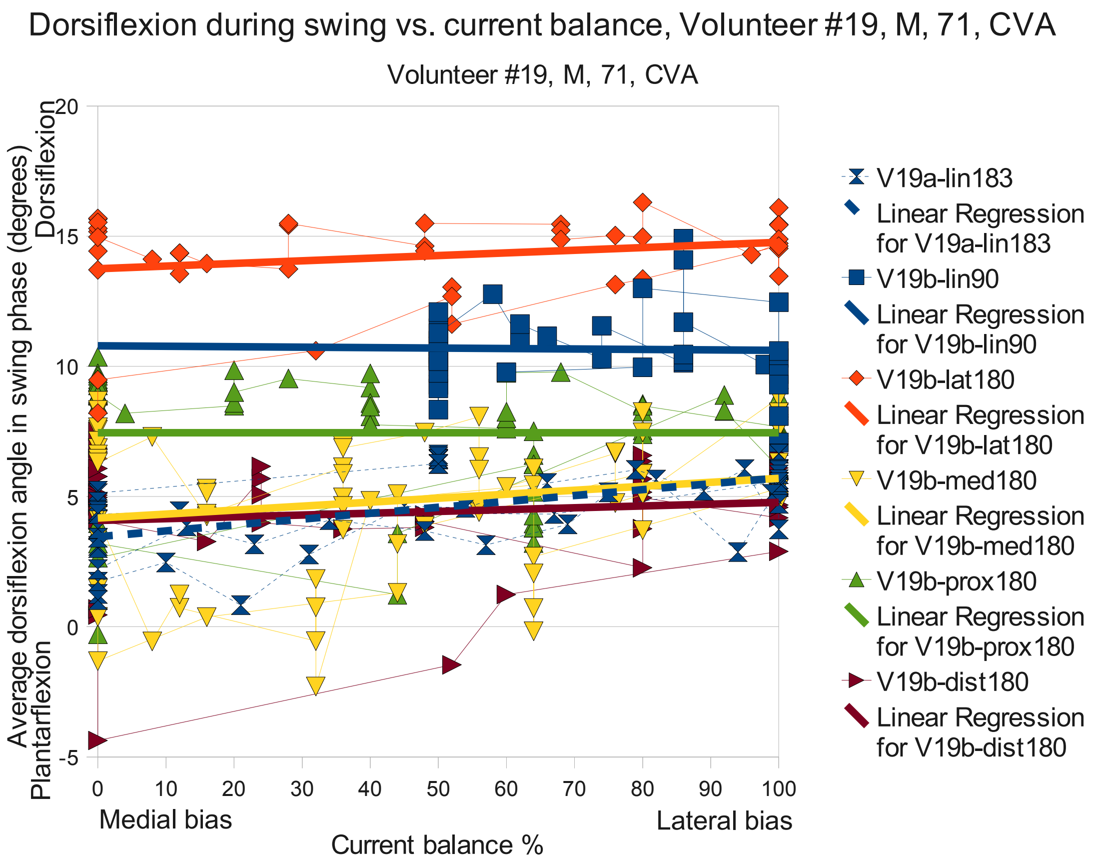


Figure 109: Effect of balance on dorsiflexion, various electrode positions, volunteer 19.

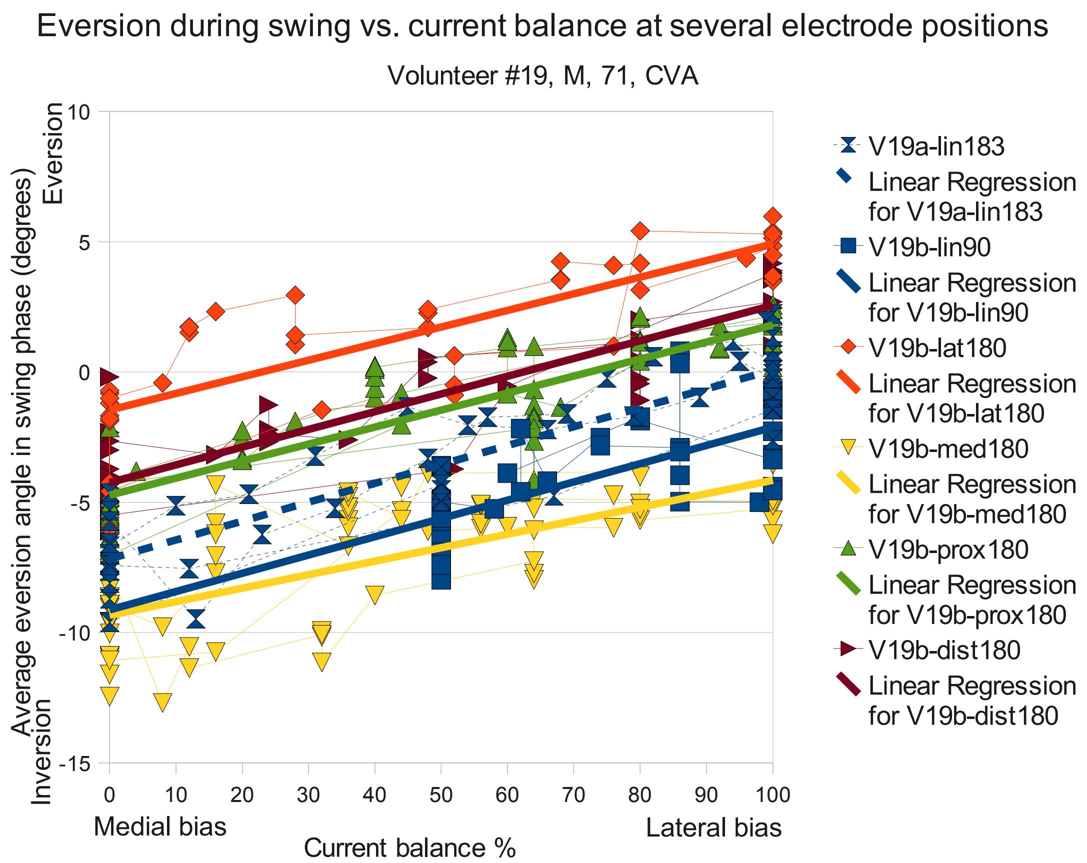


Figure 110: Effect of balance on eversion, various electrode positions, volunteer 19.

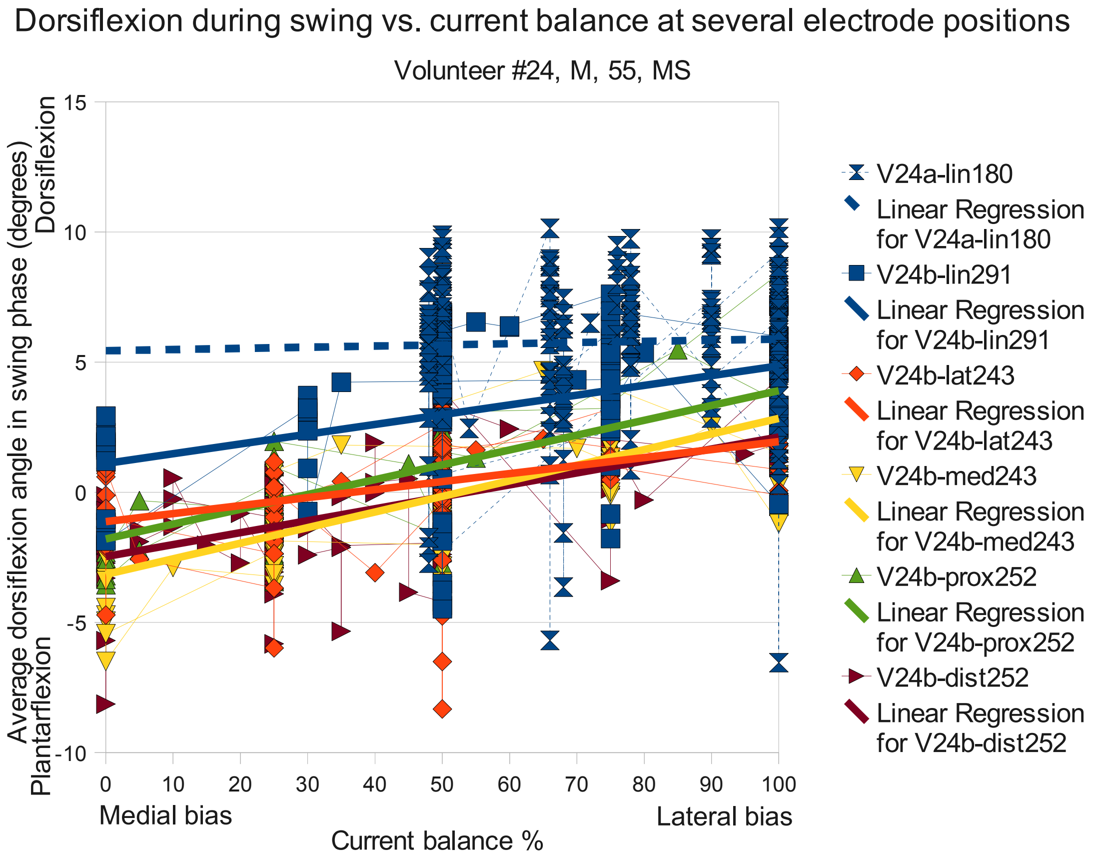


Figure 111: Effect of balance on dorsiflexion, various electrode positions, volunteer 24.

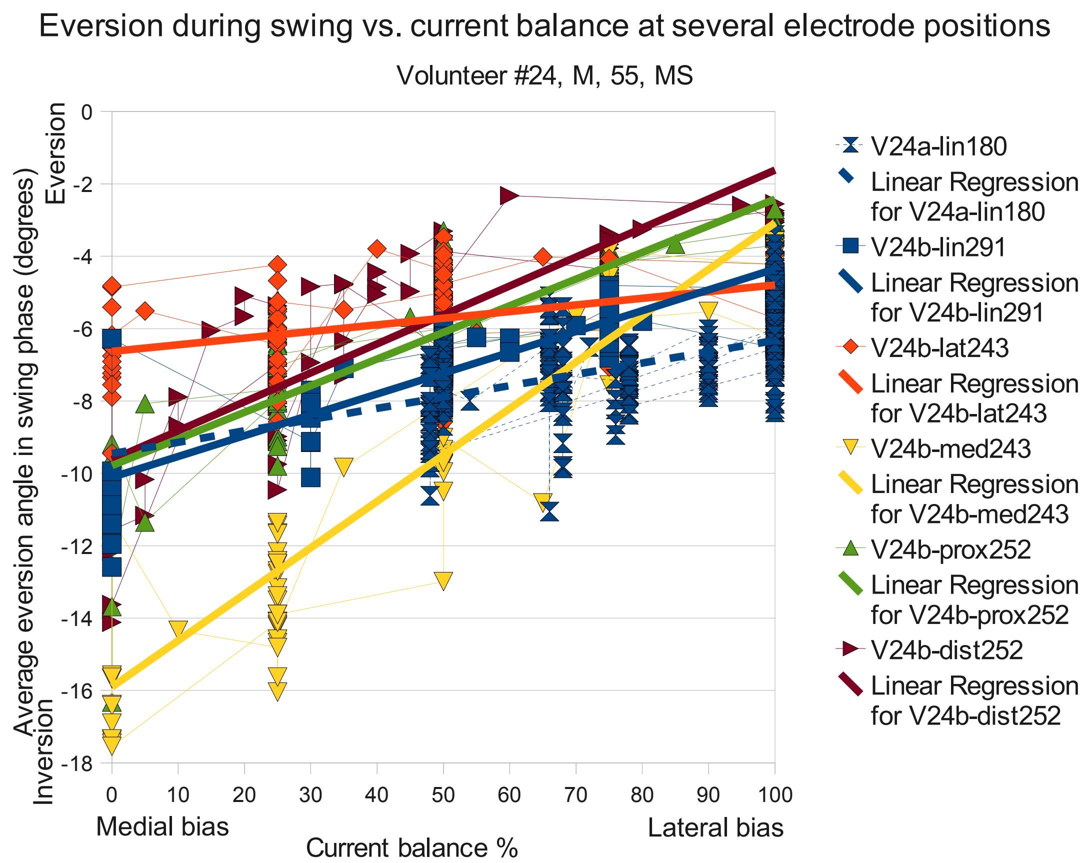


Figure 112: Effect of balance on eversion, various electrode positions, volunteer 24.

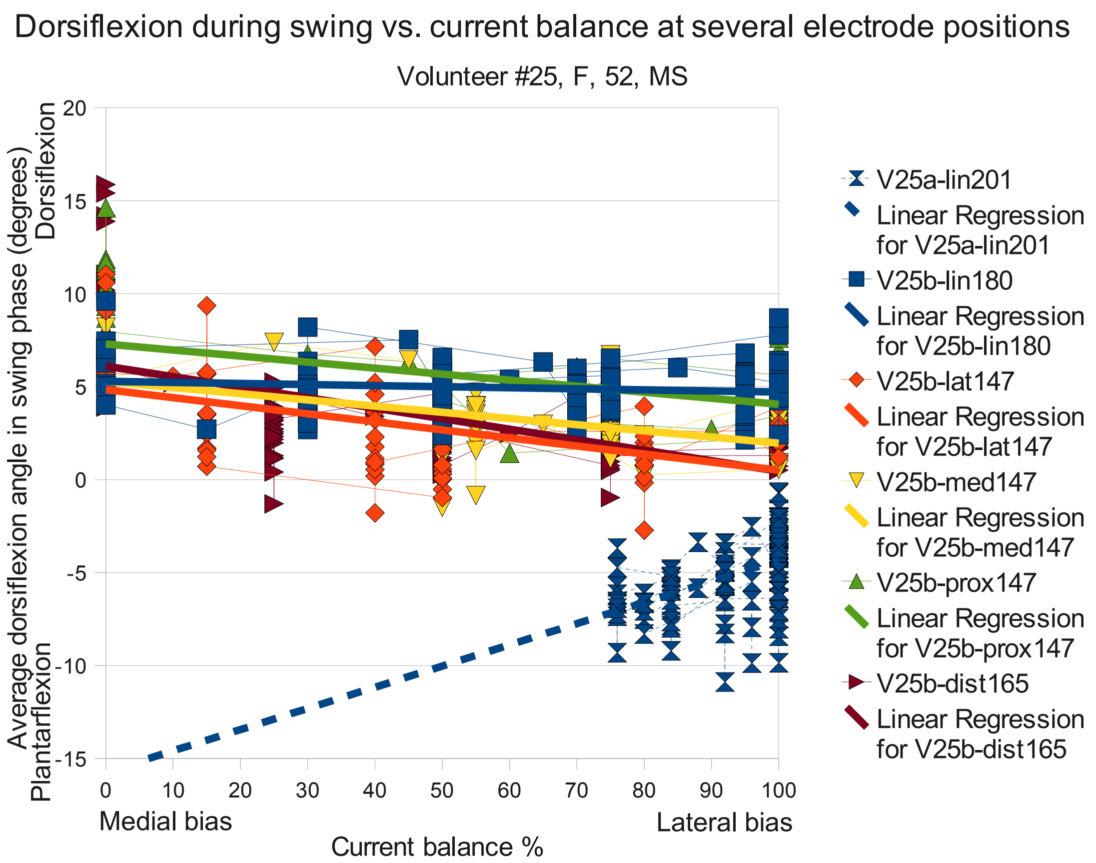


Figure 113: Effect of balance on dorsiflexion, various electrode positions, volunteer 25.

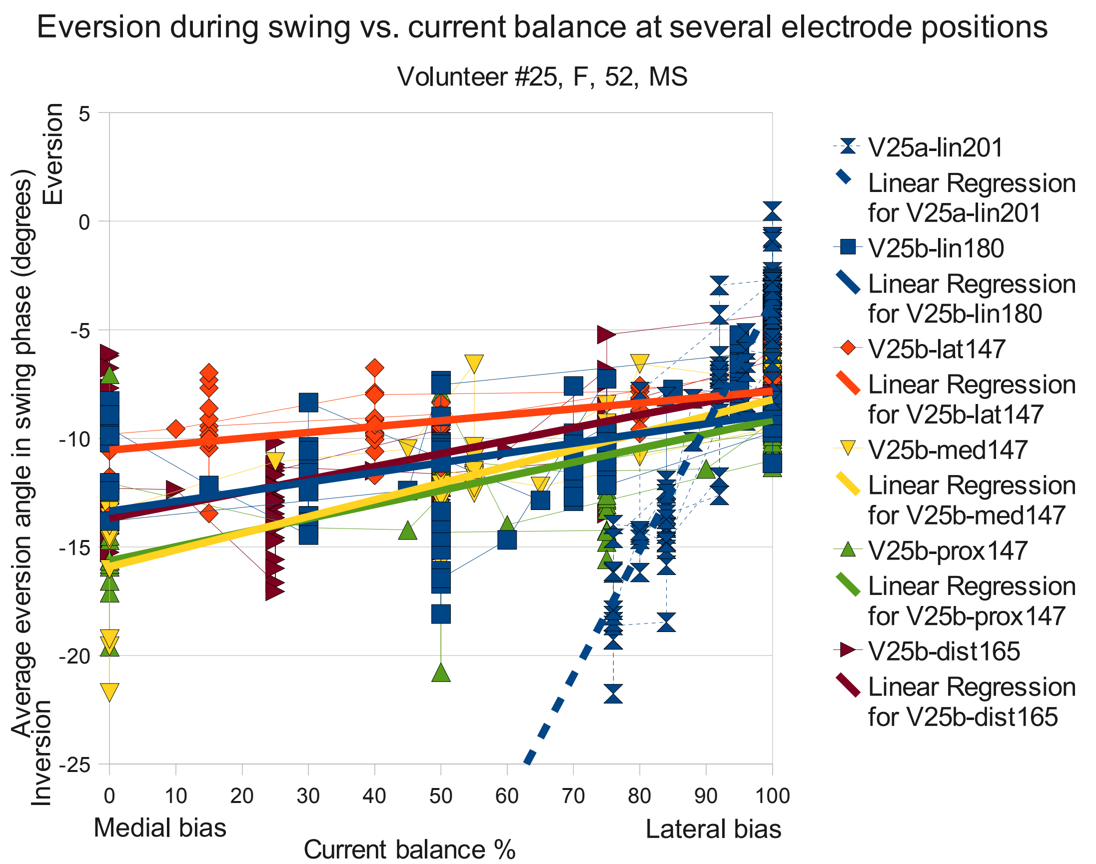


Figure 114: Effect of balance on eversion, various electrode positions, volunteer 25.

9.5.1 Time series examination of selected data sets

526 The following charts present selected datasets for later discussion of possible weaknesses in the method.

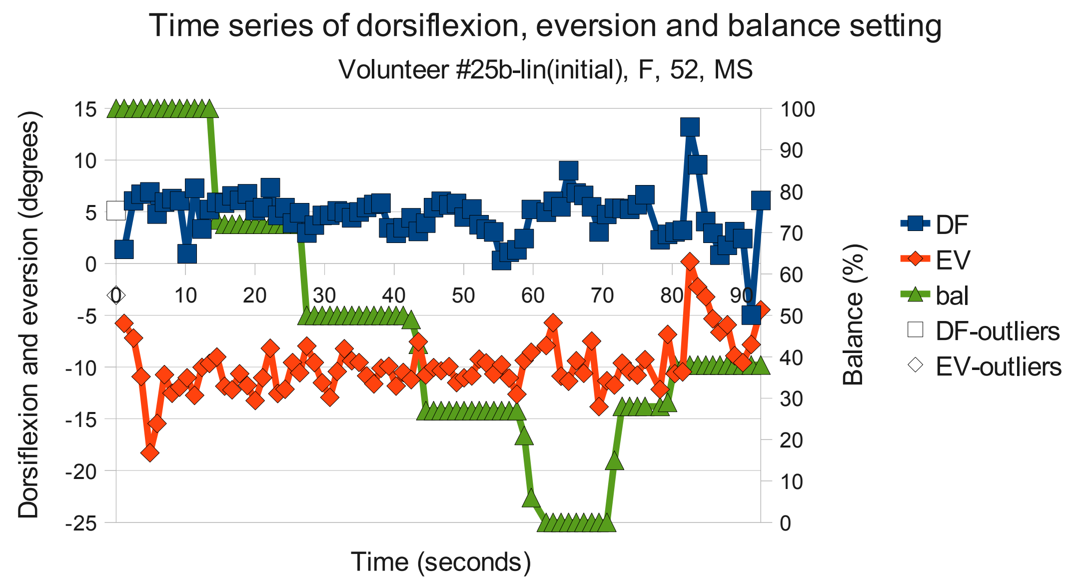


Figure 115: Time series recorded during set-up for open-loop walking.

527 Figure 115 shows measurements from a practice walk during set-up of volunteer 25 for her extended experiment 4a. Eversion was not much affected by the balance setting: showing a very slight increase with time, regardless of whether the balance control was decreased towards zero (first 60 seconds) or increased back to mid levels (last 20 seconds). The change in foot posture could be due to the volunteer getting into her stride – it is possible the change in stimulation setting was not having any effect. After slight adjustment of the electrode positions (with the same stimulation parameters), eversion was more strongly correlated with the balance setting (figure 116).

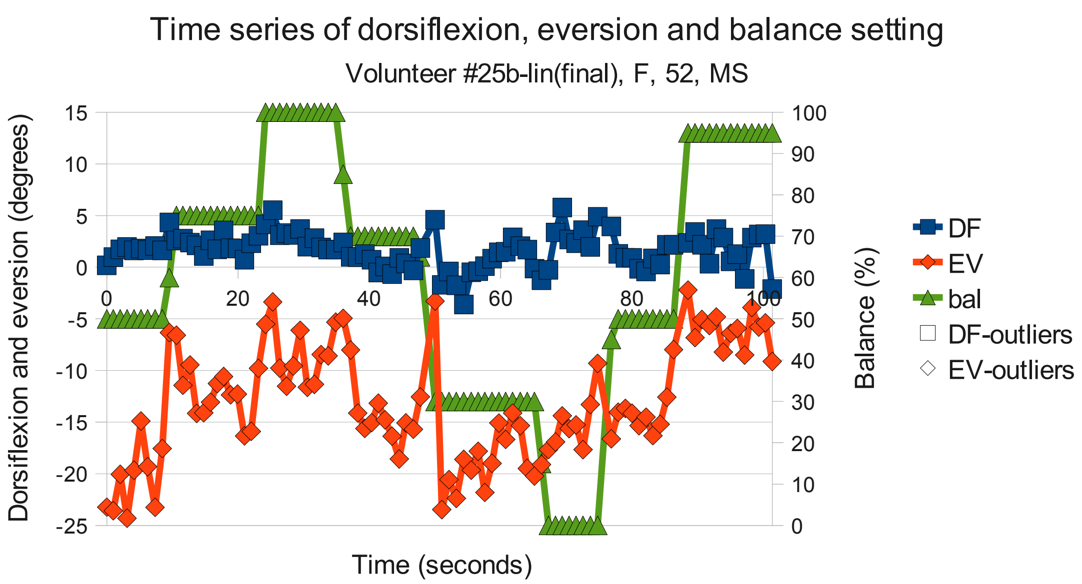


Figure 116: Time series recorded after adjustment of the electrode positions.

528 Another feature visible in figure 116 is that when the balance changed (particularly at the 10 and 50 second mark) the data shows briefly increased eversion. This may be due to the step change, or (as such step changes were generally implemented when the volunteer turned at the end of the room) could be artefacts of turning. The data system ran continuously and although it screened for outliers (on the basis of swing time and heel contact time being between half and double the medial) did not reject these steps, despite them likely being not truly representative of regular walking with these settings.

9.5.2 Summary of extended open-loop control results

529 These tests repeated the open-loop walking test with the electrodes offset by 10mm laterally, medially, distally and proximally. Three volunteers participated in these extended tests, the duration of which may have lead to a degree of selection bias towards more able walkers; these volunteers appeared to exhibit a slightly stronger and more consistent response to the effect of current balance than the initial group of volunteers.

530 The current balance had a larger and more highly correlated effect on eversion than dorsiflexion. The range of eversion at different electrode positions generally overlapped, however the experiment did not assess whether this included a clinically desirable foot posture.

531 Examination of the time series data shows some likely potential artefacts (possibly from step changes in stimulation or turning at the end of the room, etc.) were not rejected by the automatic screening process employed in these experiments.

9.6 Discussion

532 The hypotheses for experiment 4a were:

1. Altering the current balance between the lateral and medial electrodes will affect the level of eversion in walking. Specifically, that greater lateral bias will increase eversion, while the level of dorsiflexion will be much less affected.

2. When the electrodes are moved as a group by a small distance (10mm) from the initial set up position, the range of eversion evoked by two-stimulation over the full range of current balance will substantially overlap the original, making it feasible to compensate for small variations in electrode position by altering the current balance.

9.6.1 Observations

533 Changing the medial-lateral current bias altered eversion by 7 degrees on average over the range that could be tested. The strength of the effect varied between individuals, from almost nothing to double this. Dorsiflexion was also affected but generally at a much smaller level.

534 When the tests were repeated at multiple electrode positions, the results showed less variation between positions than in the seated tests. However, there were only three volunteers for this part of the experiment and they had visibly better-than-average walking ability and responsiveness to two-channel stimulation.

9.6.2 Interpretation

535 The results strongly support the first hypothesis: the current balance can be used to change the level of eversion. The fact that eversion was generally affected more than dorsiflexion is clinically important as dorsiflexion must be maintained for good ground clearance, even when eversion is adjusted for a stable foot posture for loading at initial contact.

536 The second hypothesis is only partially supported: while some influence over eversion is often maintained when the electrodes are moved, the ranges of eversion available may not overlap. This means the system may not be able to compensate for changes in electrode position, at least for the 10mm displacements tested and the stimulation parameters used.

9.6.3 Critical review

9.6.3.1 Linking to clinically desirable foot posture

537 The experiment did not identify the clinically desirable foot posture for each volunteer (i.e. a posture giving ground clearance and stability in loading). Thus although the experiment shows that eversion can be affected over a particular range, and in some cases can even be maintained in the face of electrode movement, the experiment does not show whether this included a clinically desirable posture. The use of a non-standard postural reference, i.e. each volunteer's standing posture taken as zero, without recording the anatomic angles, makes it impossible to compare this experiment's data with normal measures of foot posture in the gait analysis literature.

9.6.3.2 Changes to the current balance during the test

538 During the experiment the current balance was adjusted manually, either in small increments (~4%) while walking or in larger increments(~25%) when the volunteer turned at the end of the room. The small increments allowed continuous, gradual change without startling the user, but the larger increments meant that most of the steps could be tested with a constant balance setting. Neither is exactly like the likely clinical use, where a mainly constant level would be occasionally adjusted in small increments. However, the desire to test a wide range of current balance within a short test required significant balance changes during the test. The choice of many small or a few large changes was made arbitrarily by the researcher and the experiment did not examine whether this affected the results. The limited endurance of the volunteers precluded examination of this possibility.

9.6.3.3 Small sample size

539 The use of very small sample sizes – as few as three volunteers – means the experiment

could have been be strongly affected by the characteristics of individual volunteers or the their particular set-up. Further study would be needed to draw conclusions about the effects in the general FES user population.

9.6.3.4 Fatigue during the test

Several of the volunteers grew tired during the tests. This may have affected the results, particularly if their level of fatigue was accidentally correlated with changes in the balance setting. It could not be determined if the changes in foot posture were due to increasing fatigue or changes in the balance setting. A possible mitigation would be to repeat the test after a rest, with the balance control adjusted in the opposite sense. However, this involves yet more walking. Fatigue was a particular issue in the extended tests as they involved multiple walks with the electrodes in various positions. Although fatigue complicates the experimental analysis, it can also be a problem in maintaining a good foot posture for safe walking in daily life, and thus something that a foot posture control system would need to be able to accommodate.

10 Experiment 4b: Closed-loop control of walking foot posture

541 This experiment built on the others by combining the ability of two-channel stimulation to affect foot posture, with the (rather limited) ability of the in-shoe sensor to measure it. The experiment sought to demonstrate that by placing these two parts in a closed loop control system, deviations form the initial foot response could be detected and corrected.

10.1 Clinical objective

542 To maintain an established foot posture despite minor variations in the set-up. Variations could be caused by changes in electrode position, electrode condition (e.g. drying out), user fatigue or changes in tone, etc.

10.2 Hypotheses

1. If the sensor detects inversion, the system will move the current balance to the lateral electrode in order to promote eversion, until the original foot posture is restored, and vice-versa with eversion and the medial electrode.

2. If an electrode is moved slightly, simulating an imperfect repeat set-up, the current balance will shift to restore the original foot posture.

10.3 Method

543 A simple iterative controller was implemented on the stimulator. Either the in-shoe sensor (Est1) or goniometer could be selected for foot posture feedback. The median of the last five steps' inversion/eversion levels was used to decide if the foot was more or less everted than a reference position. At each heel rise, if the median foot posture was more everted, the current balance was reduce by 1% of full scale; if it was less everted, the balance was increased by 1% of full scale. This ensured that:

- Changes were slow, reducing the risks (to safety and comfort) of sudden changes in stimulation.

- Even small offsets in foot posture would (if maintained) eventually produce significant changes in current balance.

- Momentary errors or outlier foot postures (e.g. while turning) would not affect the current balance much, if at all.

544 For the purposes of the control loop, when the goniometer was used for feedback, the eversion angle for each step was the average of the last four samples (at 50Hz) before heel strike, rather than the average between heel rise and heel strike (as used in the previous experiments). This change was made to reduce the influence of the foot's contact with the ground during late stance. It was accepted that the smaller number of samples being averaged (four rather than 20-30 as was common) could increase the noise in the angle measurement, but it was felt that using the 5-step median and the slow adaptation of the current balance would provide robustness to random noise in the measurement. Sampling just before heel strike would also increase the influence of the tightening of the hamstrings that occurs in late swing, and so foot posture values derived from the end of swing may not be directly equivalent to the average from heel rise to heel strike. However, the control system did not act on the absolute value of foot posture, and depended only on changes in foot posture (with respect to the reference) being monotonic.

545 Two volunteer FES users were set up with two-channel stimulation to produce a normal corrected foot-drop posture (dorsiflexion with mild eversion) at a current balance of approximately 50%. Their seated response was measured according to the method of experiment 2.

546 The volunteers then walked and adjusted the stimulation pulse width and current balance until they were happy with the effect for walking. At this point, the median foot posture was set as the reference (target) and the control loop enabled.

547 The volunteer continued to walk with the control loop active. This enabled study of the

reaction of the control system (increasing of decreasing the current balance) in response to the foot postures which arose.

548 The control system was then paused so that no change was made to the current balance, while the medial electrode was moved 10mm more medially. This represented a slight mis-application of the system at a later session. The volunteer resumed walking with this set-up, which could be expected to give a more inverted posture. The sensors recorded the foot posture but the control loop was not allowed to change the balance at this point.

549 The control loop was then re-enabled; it then proceeded to try to restore the target foot posture by adjusting the current balance.

550 At every step throughout this process, the data logging system recorded the stimulation pulse width, current balance, median foot posture, target foot posture and the operating mode of the control system (i.e. paused or not).

551 Three walks were conducted: two using the in-shoe sensor for feedback and one using the goniometer. The results are presented in section 10.4. Lack of time and concerns about potential noise in the goniometer signal meant that this experiment was not taken further. See Appendix E for details of an investigation into the goniometer noise.

10.4 Results

552 This experiment studied the ability of the control system to maintain a fixed level of eversion while walking, despite perturbation of the system caused by moving one of the electrodes by 10mm.

553 Two volunteers participated in this experiment. They were set-up for two-channel stimulation and their seated response was measured according to the method of experiment 2 (at a single electrode position). This checked that the current balance had some influence over the level of eversion.

554 Following the seated tests the volunteer walked with stimulation (but without the control system active) while the pulse width and current balance were adjusted manually until the volunteer was happy with the effect and sensation. At this point the instantaneous posture was captured as a target to maintain, and the control loop was enabled. The control loop was allowed to adjust the current balance by 1% of full scale at each step, moving the current balance towards the lateral electrode to promote eversion or towards the medial electrode to promote inversion.

555 After a period of walking with the control loop, the loop was paused (so the current balance did not change at all) and the medial electrode was moved more medially. This induced a more inverted foot posture, which was recorded by walking for a short period with the control loop still paused at the last balance setting.

556 The control loop was then re-enabled. It then attempted to correct the excessive inversion by altering the current balance (moving the current balance towards to the lateral electrode when the posture was too inverted, and to the medial electrode when too everted).

557 The in-shoe sensor (Est1) was used as the feedback source for one walk with each volunteer; additionally, volunteer 24 also did a walk with the goniometer eversion angle as a feedback source.

10.4.1 Limited extent of experiment 4b

558 This part of the experiment was limited to three case studies, because it became apparent (from experiment 3) that the in-shoe sensor was hard to set up reliably, and (from experiment 4a) that there was often an unexpectedly high level of noise on the goniometer readings. Without a reliable source of foot posture feedback, and given the limited time and endurance of the volunteers, it was not considered appropriate to ask them to perform further walks. Instead, effort was put into characterising the goniometer noise (see appendix E).

10.4.2 Presentation of results

559 The results are presented as annotated charts showing (step by step) the level of eversion, the status of the control system and the value of the current balance setting which the control system used in attempting to maintain the target foot posture.

560 Note: the pulse width is plotted as a percentage of the stimulator maximum of 360µs.

10.4.2.1 Note on the control mode variable

561 In these charts, the “control mode” variable is a number 0 to 15 which represents the operating mode of the control algorithm. This was transmitted with the sensor data and stimulation parameters to facilitate interpretation of the results. As a result of the method described above, the values appearing in charts for this experiment are as listed in table 21. The charts are annotated so the reader does not need to remember these figures.

Stage of experiment 4b	Using the in-shoe sensor for feedback	Using the goniometer for feedback
During manual set-up (no target yet)	3	1
Control loop active	7	5
Control loop paused	14	12

Table 21: Values of the 'control mode' variable during experiment 4b.

10.4.3 Closed-loop results – volunteer 13

565 Volunteer 13 had a variable response to two-channel stimulation at her first session (see section 7.5.7). At this return visit, her foot also responded erratically during the seated tests – a single 0.7s stimulation train could evoke a sustained contraction of variable amplitude lasting for several seconds, sometimes overlapping with the next stimulation pulse train. This makes the sampled angles (one point per test train) in figure 117 hardly representative of the actual motion, although it was clear that changing the current balance value dis have some effect on eversion. We proceeded to the walking test as it was possible that the general increase in tone that occurs during walking would dampen the erratic response.

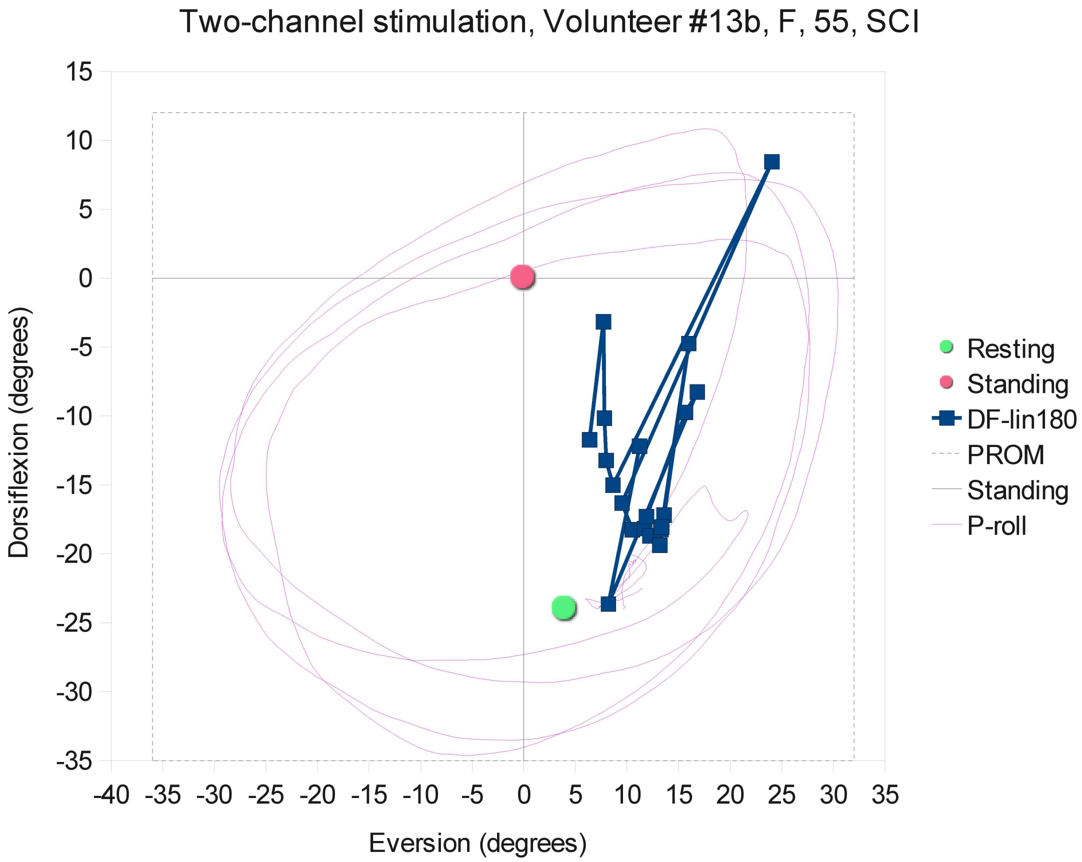


Figure 117: Seated characterisation of two-channel stimulation response, volunteer 13b.

566 Figure 118 shows the result of the closed loop walking tests for volunteer 13. In the first 300 seconds, the control loop was not active. The pulse width (yellow triangles) and current balance (green triangles) were adjusted manually until the volunteer was happy with the strength of response and the level of eversion. The volunteer chose a slightly stronger pulse width and more medial bias than as initially set-up, and it can be seen that this produced a less everted foot posture by 230-300 seconds compared to the first 100 seconds.

567 At 315 seconds, the control loop was activated, capturing the instantaneous level of eversion (Est1=0.18) as a target posture to maintain. The control system then changed the balance setting by 1% of full scale at each step, moving the bias laterally when more eversion was needed and medially when more inversion was needed. The control system is clearly acting consistently with the feedback signal, and there is some correlation between the balance setting and the median foot posture. Endurance limits meant that we could not continue the test for a long time, so it is difficult to say whether

the control loop had reached (or would reach) an equilibrium. The median foot posture oscillated about the target several times. This is consistent with other peaks in the median posture (occurring even when the balance was not changing) that may be related to turning at the end of the room. However, other possibilities exist, such as a low frequency oscillation in foot posture caused by a slow or delayed neuromuscular adaptation to the changing stimulation levels.

568 At 425 seconds, the control loop was paused, so that the balance was no longer changed by the foot posture. The medial electrode was moved 10mm more medially, which naturally caused a more inverted gait, as can be seen by about 500 seconds. (The delay between the resumption of walking and the shift towards inversion around 500 seconds is unexplained, but may be a result of stopping while the electrode position was adjusted.)

569 At 533 seconds, the control loop was re-enabled. The posture (around 0.1) was more inverted than the target (0.18) and so the control system moved the balance towards the lateral electrode. Although the foot posture did briefly reach the target twice, the system appeared to have lost the ability to keep the foot at this level of eversion. Eventually, the balance setting saturated at 100% (i.e. fully biased to the lateral electrode).

570 The limits on how much time and walking it was reasonable to ask of each volunteer precluded further investigation.

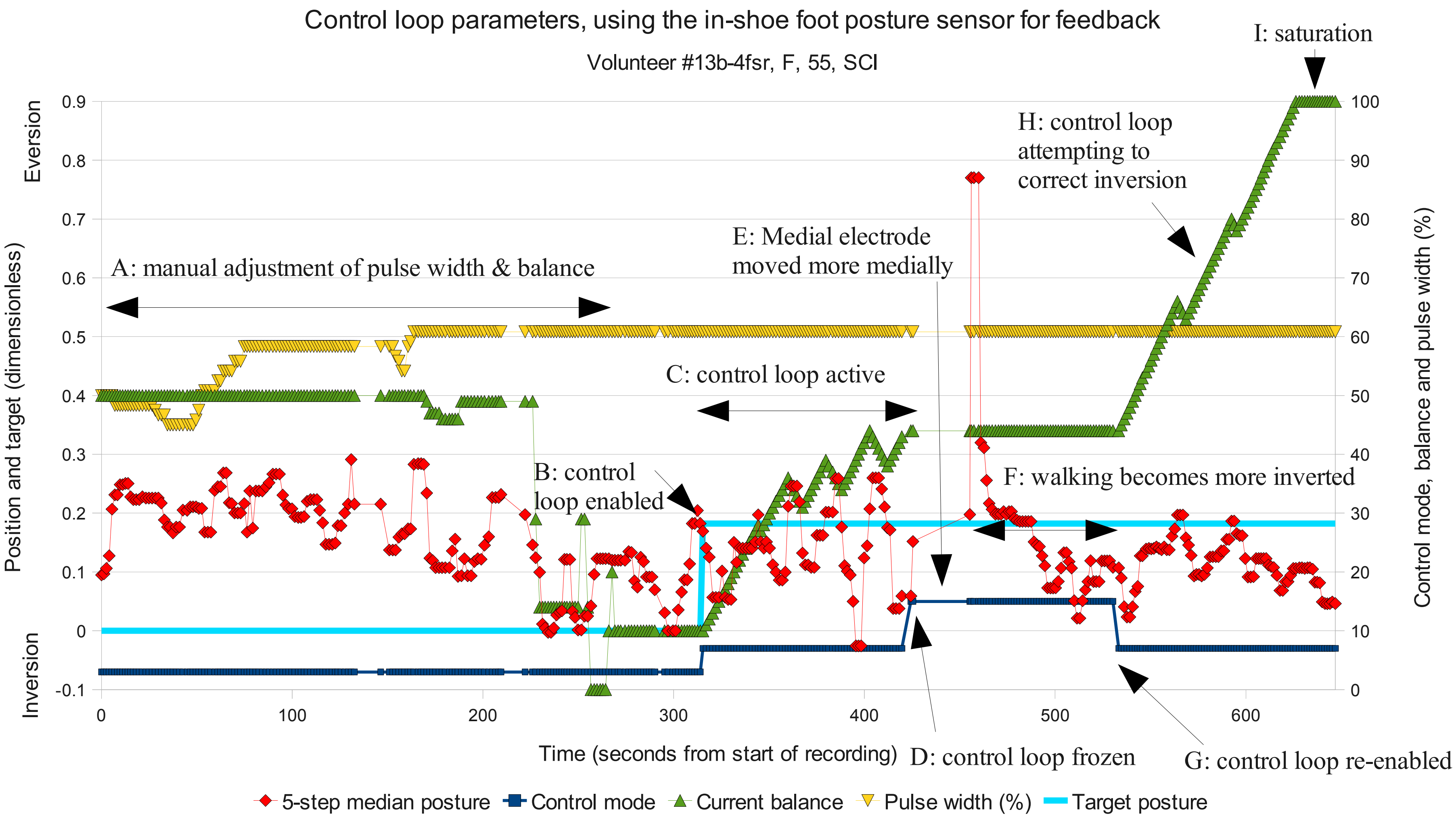


Figure 118: Closed loop control using the in-shoe foot posture sensor for feedback, volunteer 13.

10.4.4 Closed-loop results – volunteer 24

571 Volunteer 24 had a very strong and steady response to two-channel stimulation, as shown in the seated characterisation recorded in figure 119: dorsiflexion is maintained, and inversion/eversion varies smoothly as the current balance shifts between the medial and lateral electrodes. Figure 119 also shows both the passive and active range of movement achieved when asked to move his foot in a circular pattern about the resting position.

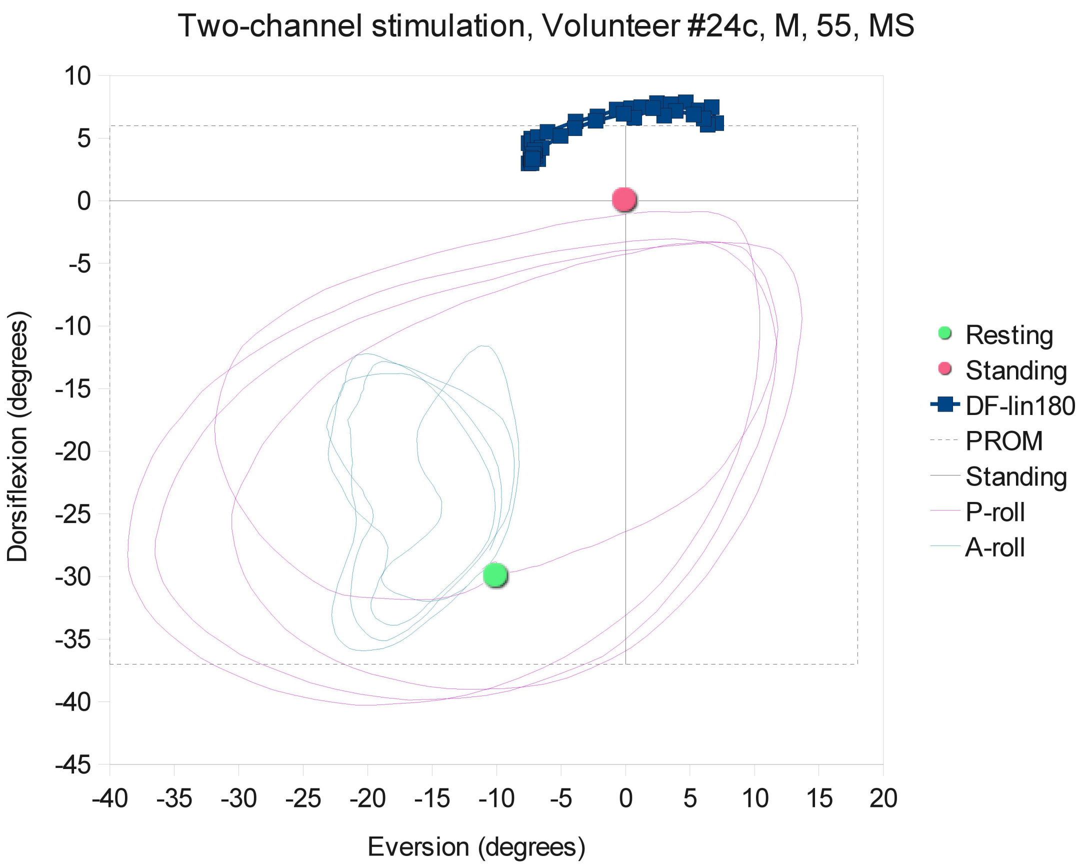


Figure 119: Seated characterisation of two-channel stimulation response, volunteer 24c.

572 Volunteer 24 performed two walks for experiment 4b: first using the in-shoe sensor for foot posture feedback (figure 120) then using the goniometer for feedback (figure 121).

10.4.4.1 Closed loop control using the in-shoe sensor for feedback

573 Considering figure 120, the first 200 seconds are used to set up the balance and pulse width for comfortable walking. At 218 seconds the control loop was engaged, capturing a target foot posture of 0.12. This is quickly attained and for the next 100 seconds foot posture is rather less variable than previously.

574 At 322 seconds, the control loop was paused and the medial electrode moved 10mm more medially. Unfortunately, during this process the power switch for part of the system was knocked off, necessitating a restart of the data logging and the resulting long gap. When walking resumed at 785 seconds it was more inverted (less everted), and when the control system was re-enabled at 935 seconds it acted appropriately, moving the bias towards the lateral electrode in an attempt to increase eversion. This appears to have been only partly successful, with the balance again saturating at 100%.

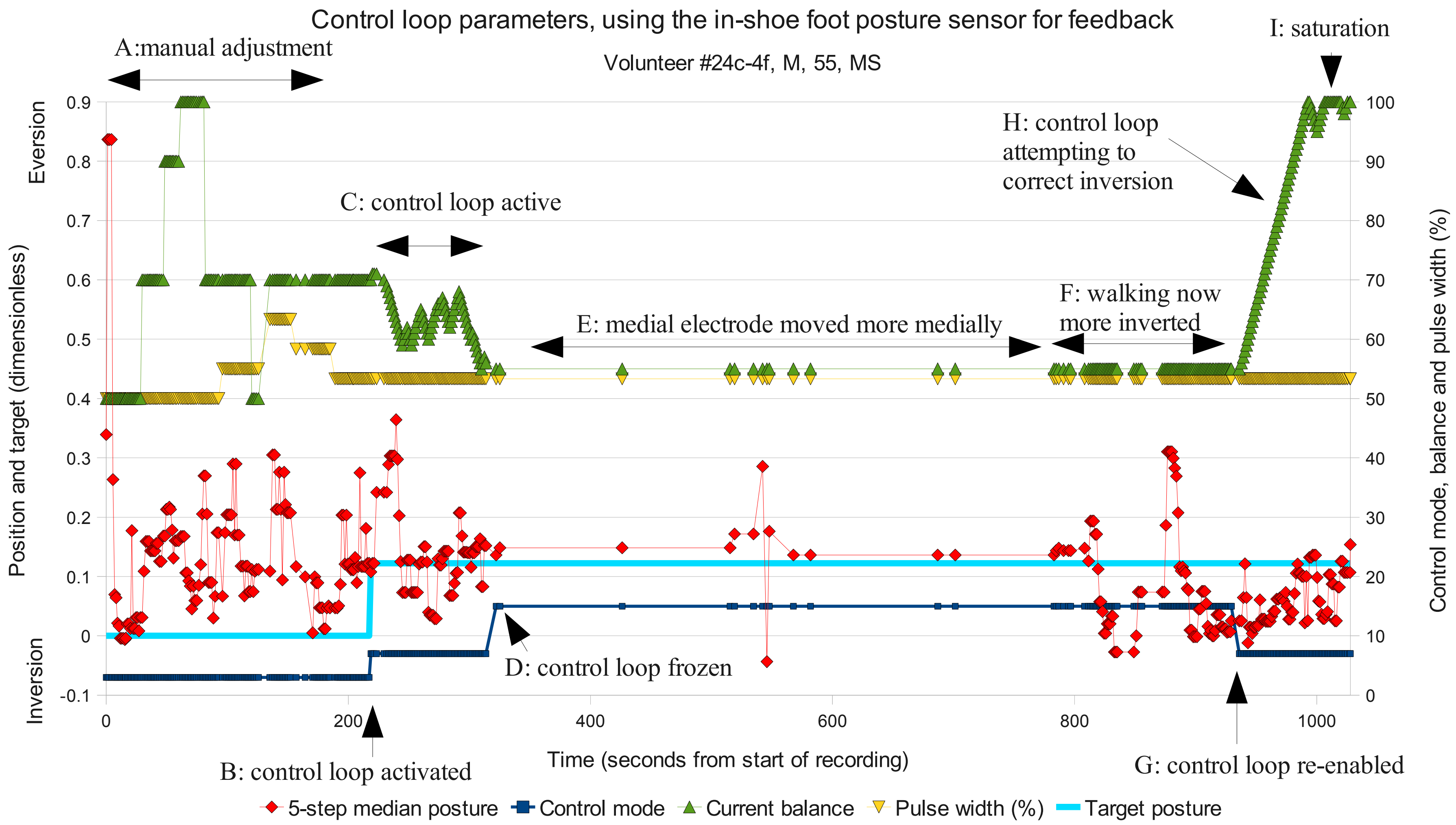


Figure 120: Closed loop control using the in-shoe foot posture sensor for feedback, volunteer 24.

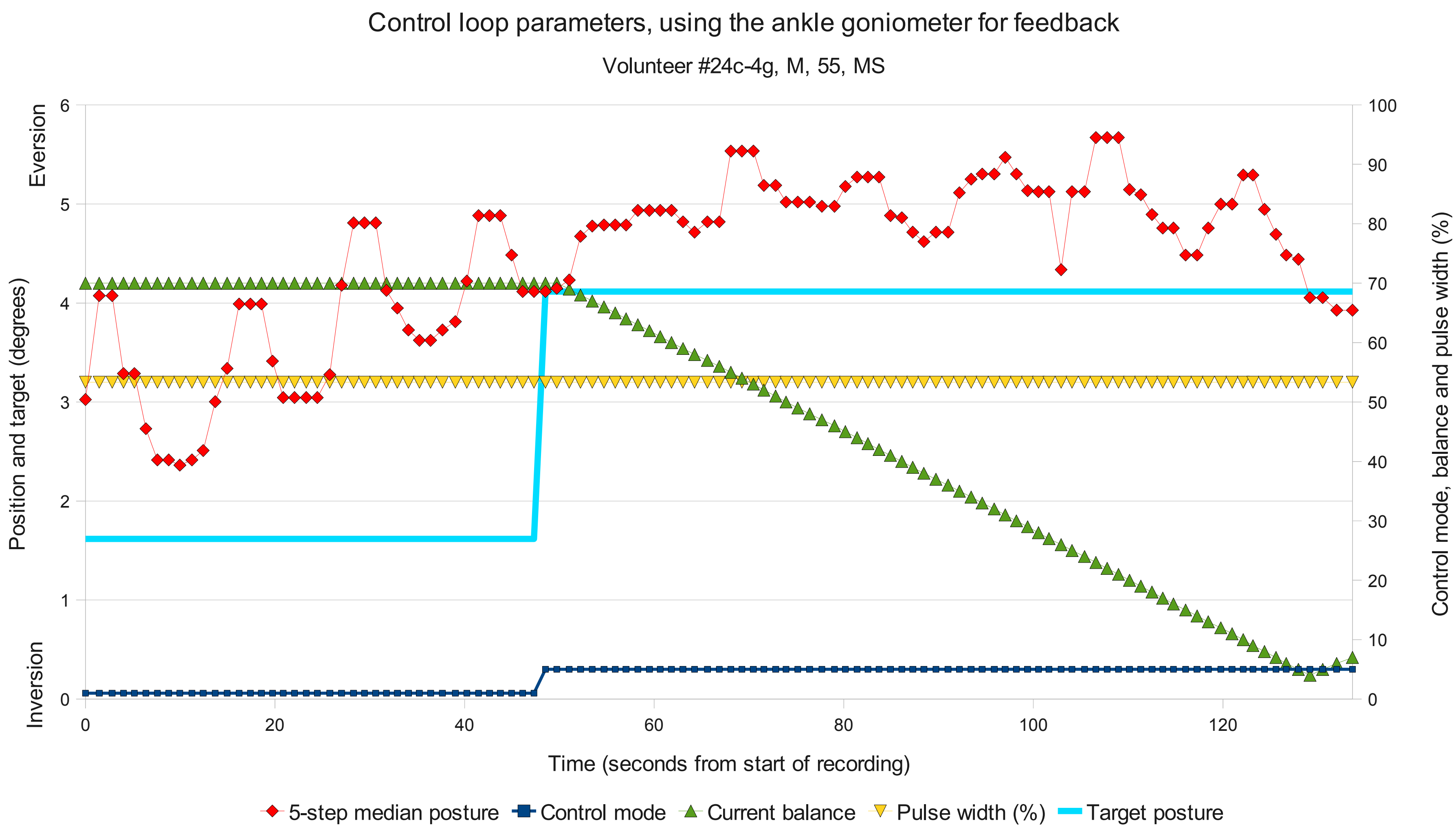


Figure 121: Closed loop control using the goniometer for eversion feedback, volunteer 24.

10.4.4.2 Closed loop control using the goniometer for feedback

575 Figure 121 shows the closed loop test with goniometer feedback. The balance and pulse width had already been adjusted to comfortable levels, and so the first 48 seconds were used make a baseline measurement of walking foot posture. There is a clear cyclical pattern, with the peaks corresponding to increased eversion as the volunteer turned (leaning in to his affected side) at each end of the room. There is also a trend of steadily increasing eversion with time. This could be a result of changes in muscle tone, spasticity or joint stiffness as he got into his stride.

576 At 48 seconds the control loop was enabled with a target posture of 4.1 degrees eversion. The foot posture remained more everted than this for the next 80 seconds, while the control system moved the current balance towards the medial electrode to reduce the eversion. Although the eversion did eventually reduce to the target level, it is difficult to say whether this was due the large change in balance (from 70% to 5%) or a random variation independent of the balance.

10.4.5 Summary of closed loop control results

577 The closed loop results showed that the control system acted appropriately, shifting the current balance medially or laterally to promote inversion or eversion as needed. However, the effectiveness of this process is dependent on both:

- A valid foot posture feedback signal, and
- The ability of the two-channel stimulation to move the foot to the desired posture.

578 The former is not always available from the in-shoe sensor (being strongly dependent on correct set up), and the latter (assuming it is present at the start) is easily disrupted by movement of the electrodes.

10.5 Discussion

579 The hypotheses of experiment 4b were:

- If the sensor detects inversion, the system will move the current balance to the lateral electrode in order to promote eversion, until the original foot posture is restored, and vice-versa with eversion and the medial electrode.

- If an electrode is moved slightly, simulating an imperfect repeat set-up, the current balance will shift to restore the original foot posture.

10.5.1 Observations

580 The control system acted appropriately: when it detected excess eversion it reduced the balance (i.e. biased more medially), when it detected excess inversion it increased the balance (i.e. biased more laterally). However, overall performance was limited by the amount of correction that a change in stimulation could provide. The in-shoe sensor was not a reliable source of feedback for the control system.

10.5.2 Interpretation

581 The results partially support the hypotheses: the control system acts as it should, but it may not be able to restore the target foot posture against a perturbation.

10.5.3 Critical Review

10.5.3.1 Case study nature

582 The small sample size (three cases) and the variation in the conduct of each test limits the conclusions one can make from this feasibility study.

10.5.3.2 Control loop parameters

583 The control loop was intentionally set up so that it could only change stimulation very slowly (1% of full scale per step) to avoid an uncomfortable or disconcertingly sudden

change that could cause tripping. However, it is likely that the system was over damped. The slow response meant that the experiment required many steps to test the control system's response, during which time the volunteer could fatigue. There are a variety of adaptive control strategies that could be used to speed up the responsiveness but these would have to balance the desire for a rapid response with the need for stability and a comfortable output.

584 The small, fixed increments in which the balance control is adjusted make the control system robust to quite high levels of noise on the foot posture signal: the balance will chatter around the average value but one or two percent changes are unlikely to have a significant effect. In particular there is no risk of the system causing significant high frequency foot posture oscillations. However, low frequency oscillations may be possible, particularly if stimulation has the effect of modulating biomechanical properties such as muscle tone or if the user's voluntary effort adapts to the changes in stimulation.

10.5.3.3 Choice of perturbation

585 For simplicity, the experiment used a 10mm offset in just one electrode to perturb the system. Other possible perturbations were not explored, but might be more relevant to drop foot walking. These include:

- Change in terrain slope, either in the direction of travel or across it.

- Change in the volunteer's neuromuscular characteristics: (antagonist) muscle tone, agonist fatigue, etc. Although these changes would provide a challenge to a control system, they cannot be expected to change on demand for the purposes of an experiment. Therefore they would require emulation, for example applying a lightly restrictive orthotic sleeve to reduce the effective strength of the muscle, or low-level stimulation of antagonist muscle groups to emulate elevated tone.

- Change in all electrodes: position, spacing and impedance.

586 The use of a single perturbation was not a thorough test of the control system, particularly when combined with a rather limited ability to measure the response.

10.5.3.4 Clinical relevance

587 The closed-loop control system in its present form appears to be unsuitable for maintenance of foot posture in the face of a single 10mm electrode offset. The simple reason is that moving the electrodes creates a new system with a new control law, and the reachable foot postures may not include the desired foot posture. The lack of a reliable in-shoe sensor to provide feedback is also a barrier to clinical use.

588 Even where electrodes can be repositioned accurately (e.g. using leg markings or possibly a leg cuff), a practical system still has to compensate for fatigue and changes in muscle tone without adjusting to a level that is uncomfortable. The closed loop system is heavily constrained and unlikely to be able to achieve this. However, an open-loop system, adjusted manually by the user, could have more success. The disadvantage of manual adjustment is that the user must be aware of the desired foot posture and be able to operate the controls. The advantages of manual control include an ability to use the full comfortable range of stimulation current and to ignore any irrelevant foot posture disturbances.

589 Given the limited range of control seen, it seems that the current balance could best be used to 'fine tune' the response for drop foot correction, provided the electrodes are in the correct location, for example using a leg cuff. The principle of altering current bias could also be applied to balancing other sets of muscles.

11 General discussion

590 The experiments were discussed individually in each of the preceding five chapters. This chapter addresses points that are common to all the experiments, draws comparisons with other published studies, and makes recommendations for future research.

11.1 Issues common to all the experiments

591 The approach of this study was to use techniques that could be readily applied in a clinical setting and to test their feasibility with actual FES users. While this provides a useful test of real-world application, there were a number of factors that could not be readily controlled.

592 Firstly, each FES users' impairment, affecting voluntary control, passive and active range of movement, tone, spasticity, etc., could have affected their contribution to the results. The study did not have the resources to conduct a detailed analysis of each volunteer, nor was it appropriate at this stage to ask for large numbers of volunteers. Selecting only FES users with flaccid foot drop and a full range of motion might improve the apparent success and consistency of the technique, but would also make the findings less applicable to the wider FES user population.

593 Beyond the unknown variability between the volunteers, their limited time and endurance meant that only a small amount of testing could be done with each person. This makes it hard to be clear whether apparent differences in the results for each volunteer are due to genuine differences between the volunteers, random noise or confounding factors such as peculiarities of their set-up or the conduct of their particular test (e.g. a chance interruption or a temporary gait disturbance).

594 The project adopted standard gel electrodes and an empirically derived set-up procedure, which helped focus the lines of enquiry, but also limits the scope of the conclusions we can draw to this arrangement. There is clearly the possibility that with a different electrodes or a different process for setting them up, an otherwise similar experimental method might produced different results. There are many interesting

questions about two-channel stimulation that are beyond this study. Some of these are discussed in the suggestions for future research in section 11.4.

595 The study shows more eversion is produced with a greater lateral current bias, but in none of the experiments do we know exactly which nerves and muscles were recruited. The experiment does not tell us the mechanism: were the two channels effectively super-posed to form one channel, the location of which moves between the deep and superficial branches of the peroneal nerve, or were they acting as two separate channels? Without a known mechanism, the steps required to improve the technique are unclear.

596 In general it was felt that the experimental equipment performed well, although the limitations of the ankle goniometer in measuring dynamic angles are acknowledged. However, some of the choices in its use limit the comparability of this study with others. The zero reference for dorsiflexion/plantarflexion and eversion/inversion was taken as the foot posture in quiet standing. This is generally not the same as the common anatomical references in relation to the lower leg. Several volunteers stood with some level of ankle eversion or inversion as a result of their pathology, in addition to natural standing not being at zero dorsiflexion or eversion. The zero references in this study are therefore at a volunteer-specific offset from common usage. This has no effect on the main result, that is is possible to change the degree of eversion with current balance, but stops direct comparison of the absolute angles.

11.1.1 Possibility of selection bias

597 Three sources of potential selection bias were identified: the recruitment pool, the initial screening process, and volunteer self-selection.

598 Volunteers were recruited from experienced FES users registered with Odstock Medical Limited (Salisbury, UK). This ensured that they responded to stimulation, were familiar with its effects and reduced the risk that they would find stimulation intolerable. However, this group may have different characteristics from novice or non-FES users. In particular, their ankle joint range of movement could be affected by a combination of long-term raised/lowered muscle tone and long-term use of FES. People with less

'established' movement patterns might have responded more strongly to the change in stimulation.

599 This study only included current FES users. People who discontinue FES do so for a number of reasons (Taylor et al. 2013), including difficulty of set-up. Difficulty of set-up might in some cases be related to an individual's neuroanatomy that increases their sensitivity to electrode position. This could also affect the presence or reliability of any steering effect. Although they might stand to gain the most from a tunable FES system, this study did not target this population. The case, ethically and practically, for recruiting people who had discontinued FES was not strong, given that it was not certain any steering effect would be seen in anyone.

600 To avoid troubling people unnecessarily, the screening process avoided inviting people whose case history indicated that they were highly unlikely to be suitable for the experiment. (Screening criteria were given in section 5.5.1.) There is a risk that this process could have biased the sample in favour of better walkers than the general FES user population. Furthermore, it is possible that only the better-able invitees volunteered for the experiment, particularly as experiments 3 and 4 involved considerable walking. To tests for this possibility, the volunteers were compared to average long term FES users, using measurements of 10 metre walking speeds and subjective walking effort ratings from the clinic database. These figures, presented in table 22, showed little difference between the volunteers and the average experienced FES user.

Group	Number	Walking speed, m/s (average over 10m)		BORG rating of perceived effort		Age	Years using FES
		No-stim mean (s.d.)	Stim. mean (s.d.)	No-stim mean (s.d.)	Stim. mean (s.d.)	Mean (s.d.)	Mean (s.d)
All experienced FES users (i.e. with 6 or 12 month appointments in 2012) for whom valid data was available	391 walking 379 BORG	0.64 (0.33)	0.73 (0.34)	4.1 (1.9)	2.5 (1.1)	59.5 (15.0)	5.9 (3.9)
Experienced FES users (MS only)	154 walking 150 BORG	0.63 (0.32)	0.72 (0.32)	4.5 (2.0)	2.7 (1.1)	61.2 (10.6)	5.2 (3.4)
Experienced FES users (CVA only)	156 walking 151 BORG	0.61 (0.34)	0.69 (0.34)	3.9 (1.8)	2.4 (1.1)	62.7 (14.3)	6.3 (4.0)
This study, seated tests. (Clinic data available for 7 out of 10 volunteers)	7 walking 7 BORG	0.60 (0.31)	0.71 (0.22)	4.7 (2.7)	2.4 (1.0)	56.1 (11.1)	5.4 (3.4)
This study, walking tests. (Clinic data available for 6 out of 8 volunteers)	6 walking 6 BORG	0.63 (0.18)	0.73 (0.22)	4.8 (1.8)	2.3 (1.3)	62.3 (7.8)	4.6 (2.2)

Table 22: Comparing the general population of experienced FES users with the volunteers for this study.

601 Selection bias does not prevent us from testing the hypotheses – but would mean that the results may not apply equally to the general FES user population or to other sub-groups.

11.1.2 Reproducibility

602 This study only used one researcher and most of the volunteers participated in the tests only once. Obviously this tells us little about the reproducibility of the results: would another experimenter – or the same one on a different day – have found the same variability? How critical is the skill of the experimenter in setting up FES systems?

11.2 Comparison with other adaptive stimulation systems

603 This study was not designed to compare the two-channel method with other systems, but some observations can be made on the methods. The performance is difficult to compare because many studies use different outcome metrics, e.g. walking speed rather than foot posture, as well as very small sample sizes.

11.2.1 Two-channel surface stimulation by Seel et al.

604 The literature review in section 3.5 noted the papers by (Seel et al. 2014; Seel et al. 2016) describing their system which uses two channels of stimulation to control the level of ankle eversion during swing. In some respects their approach is similar to this study:

- The two channels target the deep and superficial branches of the common peroneal nerve (for dorsiflexion with inversion and dorsiflexion with eversion, respectively).

- The current intensity to each channel is adapted based on a filtered error signal (the difference between the measured and desired ankle eversion trajectory).

605 Both projects vary the stimulation current as a linear function of eversion error, but Seel et al. keep the total current fixed, while this work adjusted each channel between its threshold and maximum regardless of the total current (as slope of the force-vs-current recruitment curves of the two muscle groups are likely to be different). Seel's constant total current may be best suited to situations where both channels are equally able to generate dorsiflexion. The more general approach used in this project caters for cases where, to maintain dorsiflexion while altering eversion, one channel needs a relatively small adjustment while the other a much larger change. Typically this would be maintaining the current for tibialis anterior with a proportionally larger change in the current for the superficial peroneal current.

606 Both this study and Seel et al used a trapezoidal intensity envelope through the swing phase of the gait cycle, although Seel references earlier work by the same researchers

where they used an adaptive, non-trapezoidal envelope to follow a natural dorsifelxion trajectory. However, a major difference between the two projects is that Seel's iterative learning controller attempted to match eversion to a desired, neutral trajectory throughout stimulation by adapting a *sequence* of current ratios for use throughout the gait cycle, while this project takes a simpler approach, similar to Seel's 'run-to-run' controller, where one current ratio is used for the whole gait cycle. Seel's iterative controller can accommodate differences in the need and ability to evert more or less at different points in the gait cycle, but this adds complexity and requires a source of continuous eversion feedback throughout swing. Seel obtains this from a shoe-mounted inertial measurement unit. Although such sensors have been available in the laboratory for some years, they have only very recently reached the levels of miniaturisation necessary for daily wearing in shoes. For practicality, this project targeted a simpler footswitch-based sensor which only provides one summary measurement of eversion per gait cycle; thus we are limited to one update per gait cycle, as with Seel's run-to-run controller. The goniometer also used in this study does provide continuous measurements, but is not practical for daily use outside the laboratory.

607 Seel reports results from one patient. In contrast, this study used multiple volunteers and often multiple electrode positions in an attempt to illustrate the level of variability that may be seen. This is important as it is well known that neuroanatomy varies between individuals and that the effect of stimulation is often strongly dependent on electrode position.

608 Seel's iterative learning controller is reported to converge rapidly, producing corrected foot posture within two gait cycles. In contrast, the highly damped algorithm used in this study can take dozens of steps to reach the required posture. However, one should also consider the ability of a system to handle perturbations and changes in the input (sensor) or output (neuromuscular) system. Neither study explored this in detail.

11.2.2 Array systems

609 As reviewed in section 3.2, systems with electrode arrays generally use some sub-section of the array to deliver a single channel of stimulation. The spatial resolution is limited by the pitch of the array elements, which in turn limits how close to the ideal

location stimulation can be applied. Higher effective resolution might be possible by dithering between two or more elements on successive stimulation pulses. A similar approach was explored in (Salchow et al. 2016) where interpolation of asynchronous pulses was used to deliver current to a single spatial region. However, that work did not consider the possibility of using the array to target two separate regions both contributing towards a desired motion. This could be useful in finding and balancing the effect of each branch of the common peroneal nerve when correcting drop foot.

Two channels of stimulation could be applied using an array system, with either adjacent or non-adjacent sub-sections of the array. This would be consistent with the need to get the electrodes in approximately the right location using the array, then using the current balance to fine tune the response. The current balance between the elements could be controlled using either the method of this study, that of Seel et al. or other suitable algorithms.

11.3 Comparison of the in-shoe foot posture sensor with other systems

611 Several researchers in the field of gait analysis have used FSRs as simple, low cost sensors for gait analysis, but the majority use them in one of two ways:

- to measure ground reaction force, for itself or in support of analysis of further kinetic analysis (moments, power, etc.).

- as a means of detecting the phases of the gait cycle.

612 In measuring a gait parameter directly, these works are not comparable to the current in-shoe sensor, which aims to derive an estimate of a *different* gait parameter (i.e. inversion/eversion, itself taken in this study as a proxy for ankle stability). The literature review found one directly equivalent study (Granat et al. 1995). That study assessed inversion/eversion using a calculation almost identical to Est2 in experiment 3, although they used duration until to toe-off whereas this study stopped at heel-off.

613 While the sensor of Granat et al. was of the same basic design to this study, the performance analysis was not. In this study the signal from the in-shoe sensor was compared to a goniometer. The paper by Granat et al.did not compare their sensor with any other gait measurement system. While is likely that their sensor did measure some gait characteristics, sensitivity, specificity and repeatability were not assessed. The authors took FSR-based measurements using one post-stroke volunteer over a period of twelve weeks and stated that this showed changes (or not) in several gait parameters, without apparent verification that such changes had indeed occurred (rather than being artefacts of the method).

614 The sensor of Granat el al. was so similar in concept and implementation to this one that it is reasonable to suppose they they would function similarly in practice. The in-shoe sensor in this thesis appeared inconsistent (perhaps as a result of sensitivity to positioning of the FSRs within the shoe), but this important aspect was not explored in the single case reported by Granat et al. This makes comparison of the two systems difficult.

11.4 Recommendations for future research

615 This study has shown that it is possible to influence foot posture using two channels of stimulation, but many questions remain regarding how the technique can be improved and applied in clinical practice.

616 The seated tests showed that two-channel stimulation was tolerable and generally had an effect on foot posture. However, given the variability of the response of the unconstrained foot and its difference from walking, it is suggested that further seated tests of this nature are not required. Different research questions may be best served by different methods. For example, tests of isometric force or EMG activity for studies of muscle recruitment, and walking tests for measuring the performance of control algorithms and overall clinical benefit to walking. Sometimes it is appropriate to isolate a single issue for study, whereas in other cases one is interested in the overall effect in a wider context.

617 Isometric force measurements would not take into account movement-related symptoms such as a tight Achilles tendon or calf spasticity. Any practical system would eventually need to be tested in walking with a range of pathologies, symptoms and compensations as are common in paretic gait.

618 The remainder of this section presents a selection of topics that were beyond the scope of this study and which provide potential directions for future research.

11.4.1 Extent of separation of the two channels

619 This seeks to understand whether the stimulation is produced by two independent channels or whether they are superposed to form one movable channel. The question is relevant because it is likely to affect the optimum size and spacing of the electrodes.

620 Where the electrodes are close there is scope for their electric fields to overlap leading to a superposition effect which would only be maintained if the two channels stimulate concurrently. The existence of a threshold current (rheobase), below which an action potential will not be initiated, means that firing the two channels together, where the

currents sum, may be able to stimulate some nerves that would not respond to either channel in isolation. This is most likely to be the case for nerves positioned between the two electrodes. However, if the channels are truly separate, it would make no difference whether the channels stimulated concurrently.

621 The stimulator presented in this study has the ability to insert an delay between the pulses on each channel. Measuring the response, with EMG, foot posture or isometric force, both with and without an inter-channel delay would show whether a superposition effect existed. In choosing the inter-channel delay, it may be advantageous to apply the second pulse in the absolute refractory period following the first, to avoid stimulating some nerves twice.

11.4.2 Choice of electrode arrangements

622 The first question is likely to be what is the appropriate size and spacing for electrodes for comfortable control of foot posture.

623 If two, separate, widely spaced electrodes are used then conventional monolithic electrodes are likely to be preferred. However, if current superposition is desired, or where very fine control over the effective position of stimulation is required then the size of common monolithic electrodes (e.g. 3 to 5cm square) may be a problem: the size is needed for comfortable current density at the surface, but their geometric centres will always be at least that distance apart. Finer effective resolution might be obtained with interdigitated electrodes as shown in figure 122. The two channels are connected to parts A and B, with a common or separate, distant reference electrode (not shown). This arrangement would be more difficult to manufacture than conventional electrodes, but could allow extremely fine shifting of the effective location of stimulation.

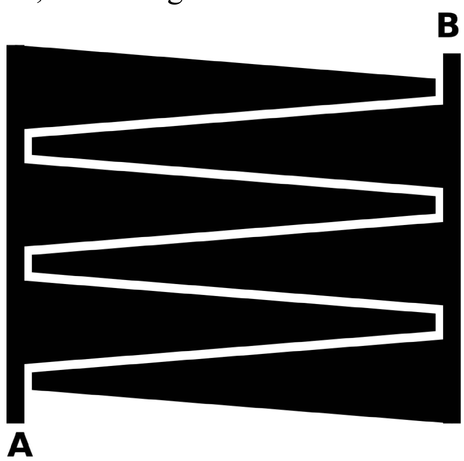


Figure 122: Interdigitated electrodes for two-channel stimulation.

11.4.3 Preferred mapping from balance control to channel current

624 In this study, the justification for a linear mapping from balance control (0 to 100%) to channel current (threshold to comfortable maximum) was an assumption that the recruitment curve (force vs. current) could be approximated by a linear relationship between current and force over this range of currents. However, this assumption may be an oversimplification. Further exploration of the steering effect in cases where dorsiflexion reduces at medium balance values, indicating under-simulation of one or both channels, may indicate that other current mappings are desirable. An example of a possible non-linear mapping is given in figure 123. This applies more current at middle balance settings to avoid under-stimulation.

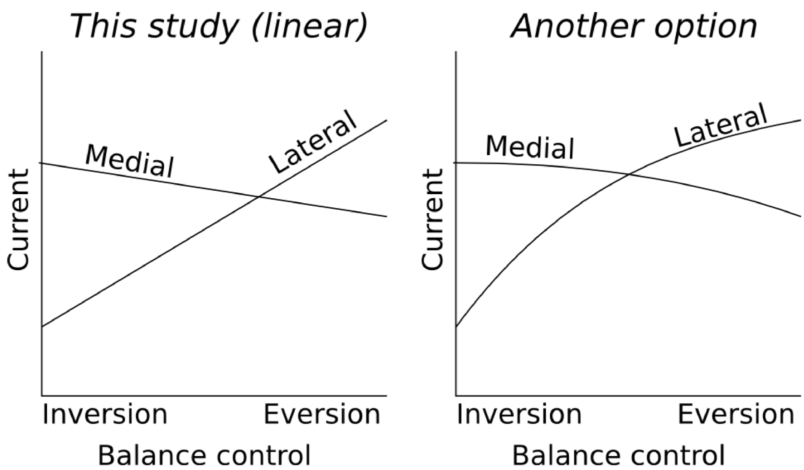


Figure 123: Example mappings from balance to current.

11.4.4 Effect of changing the pulse width on foot posture

625 Where current balance is used to control the inversion/eversion aspect of foot posture, it would be convenient if pulse width could then be used as a simple means to scale the magnitude of the dorsiflexion. However, potential differences in the excitability of the various motor neurons involved mean that this might not work in practice. (This is quite apart from joint limits and tendon/ligament constraints). A more complex two-dimensional function might be needed to map the desired inversion/eversion balance and dorsiflexion strength to the necessary currents and pulse widths to use in the two channels.

626 A starting point for this research could be to measure the foot posture as a function of the balance, but then repeat the experiment with somewhat greater or less pulse width. This would show whether the steering effect is maintained at higher and lower levels of stimulation. This is relevant to clinical use of the technique as users will often need to

adjust the strength of their stimulation as they fatigue; any significant change in inversion/eversion with pulse width would complicate this process.

11.4.5 Practical, real-time measurement of foot posture

627 The in-shoe sensor was not sufficiently reliable in its present form, probably because it depended on the FSRs being just on the margin of the metatarsal heads for changes in posture to affect the measured duration of ground contact. An alternative approach would be to use a larger sensor (e.g. covering the medial and lateral quadrants of the insole) which the metatarsal heads are sure to bear upon. Additionally, rather than using just the duration of ground contact, one could perhaps compare the medial and lateral values of other metrics such as the relative timing of peak force or the ratio of peak to average force during stance. The metrics should avoid dependency on the absolute signal from the FSRs because of their tendency to drift with wear.

628 Beyond FSR-based sensors, low cost integrated circuits for inertial measurement have now reached the stage where they could be used for real-time in-shoe foot posture measurements. These have the advantage of providing readings throughout the gait cycle, presenting the possibility of changing stimulation to produce different foot postures at different points in the gait cycle, as (Seel et al. 2014) did.

11.4.6 Preferred gait quality metric and measurement techniques for use in daily walking

629 The literature contains detailed gait analyses of both normal and pathological gait. Given the limitations of surface stimulation and the common presence of multiple gait weaknesses, it is extremely unlikely that perfectly normal gait can be restored. This leads to the questions of which aspects are important, how can they be measured simply and reliably, as well as how can stimulation be adjusted to promote better gait.

630 This study focused on foot posture as it was considered potentially tractable to measure and important to both stability during loading and ground clearance in swing. However, it did not actually measure either of these directly. Ground clearance is difficult to measure if one accepts the constraints of daily practicality: sensors must work on all

surfaces, be discrete and be robust against dirt, moisture and electromagnetic interference. Linking inertial sensors in both shoes is a possibility for situations where the ground is uniform: the stance foot provides a reference against which the clearance of the swing foot can be estimated (if the extent of the shoe is known). However, the signal processing required to calculate this is onerous, and the technique does not help when the ground is not uniform.

631 Future systems might seek to combine data from multiple sensors: just as both stability and ground clearance are important to good gait, advanced adaptive stimulation systems would be likely to benefit from sensing both centre of pressure and ground clearance if possible.

11.4.7 Response time of adaptive stimulation

632 This study deliberately chose an algorithm with a slow response, with the justification that this would reduce the risk of a sudden change in stimulation distracting the user which might lead to tripping, and that a slow response makes it tolerant of high frequency step-to-step noise in the feedback signal. The study did not attempt to optimise the response time of the system. This would be worthy of study, taking into account the psychological, neurological, biomechanical and engineering factors that might indicate different response times.

11.4.8 Applications beyond drop foot correction

633 Two-channel stimulation might be useful in stimulating other antagonist muscle pairs, for example in transitioning smoothly from flexion to extension of a joint, including maintaining some tone for stability through the neutral position. However, the results of this study indicate that if the joint is unconstrained the results of this may well be erratic. Even with some damping or constraint there are likely to be problems balancing the requirement for a wide range of control with a comfortable and stable stimulation regime.

634 Alternating/dithering the pulses between two channels of stimulation might also be able to reduce fatigue in large muscles by stimulating different motor units in the same

muscle. This could be useful in applications such as FES rowing and cycling, where it is desirable to be able to spread the load across the many motor units in the quadriceps muscle and avoid relying on, and fatiguing, just a subset of them.

12 Conclusions

635 This thesis proposed the use of two channels of surface stimulation to control the balance of inversion/eversion during walking. The hope was that this would simplify the process of setting up FES for the correction of drop foot by reducing the importance of precise electrode placement, as minor inaccuracies could be compensated for by changing the current balance between the two channels.

636 The technique was tested in a series of four experiments, building up from the basic effect while seated to its use in a simple foot posture control loop while walking. The method was able to alter average inversion/eversion in walking by several degrees in most cases, but this was often lost if the electrodes were moved by 10mm. Thus electrode placement remained important.

637 The study also investigated the performance of an in-shoe foot posture sensor based on the duration of ground contact of the 1st and 5th metatarsal heads between heel strike and heel rise. The sensor was tested by comparison with a two-axis electrogoniometer measuring average ankle angles during swing. Although in some cases there was a reasonable correlation between the two signals, in other cases the performance was extremely poor. It was suspected that this was due to a sensitivity to the location of the sensing element under the edge of the metatarsal heads.

638 A simple closed-loop control system was developed to control foot posture in walking using the two-channel stimulation. The system responded appropriately to perturbations but suffered from a limited ability to restore the target foot posture. Concerns over stability and comfort make reliable, automatic control systems extremely difficult to implement. This is particularly the case in practical clinical applications where the biological system is uncharacterised and tends to change with time and each set-up is effectively a different system.

639 The technique is most likely to be of use in fine tuning the response to stimulation where the electrodes can be positioned and repositioned relatively accurately, perhaps as part of a leg cuff system. However, this is dependent on achieving greater reliability of effect and the benefits of tuning being worth the complexity of setting up an additional

electrode.

12.1 Contribution to knowledge

At the start of this study, the use of two-channels of surface stimulation for balancing inversion/eversion during the treatment of drop foot was novel. This study has made the following contributions to knowledge:

- Proposal and demonstration of the ability of two-channel surface stimulation to influence foot posture.

- Demonstration of the effect in multiple FES users, both seated and walking, and the sensitivity of the effect to electrode position. Limited demonstration of its use in a closed-loop control system to maintain a target foot posture.

- Implementation of a specific algorithm for a simple in-shoe foot posture sensor based on timing of ground contact of the 1^{st} and 5^{th} metatarsal heads, and demonstration of its unreliable performance in a simple practical implementation. A very similar algorithm was proposed in (Granat et al. 1995) but that work did not compare their system against an independent measure of giat performance.

- Improvement and successful implementation of a previously proposed stimulation output circuit, using pulse width modulation of a fixed supply into a step-up transformer to generate pulses of adjustable amplitude.

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Appendix A: Stimulator technical details

641 The detailed implementation of the stimulator hardware and software are not central to the thesis. They were simply a means to generate the two channels of stimulation needed for the experiment and other stimulators could have been used instead. However, the implementation is of technical interest and so this appendix provides a more detailed description to complement the overview in section 4.2.

A.1 Circuit schematic

642 The circuit for the stimulator was a continuation of an earlier prototype developed by Rob Batty at OML. The circuit was changed to add functionality and resolve a number of problems with the original. This section describes the schematic, except the CPU, memory and some peripheral circuits which have fewer features of note.

A.1.1 Battery charger

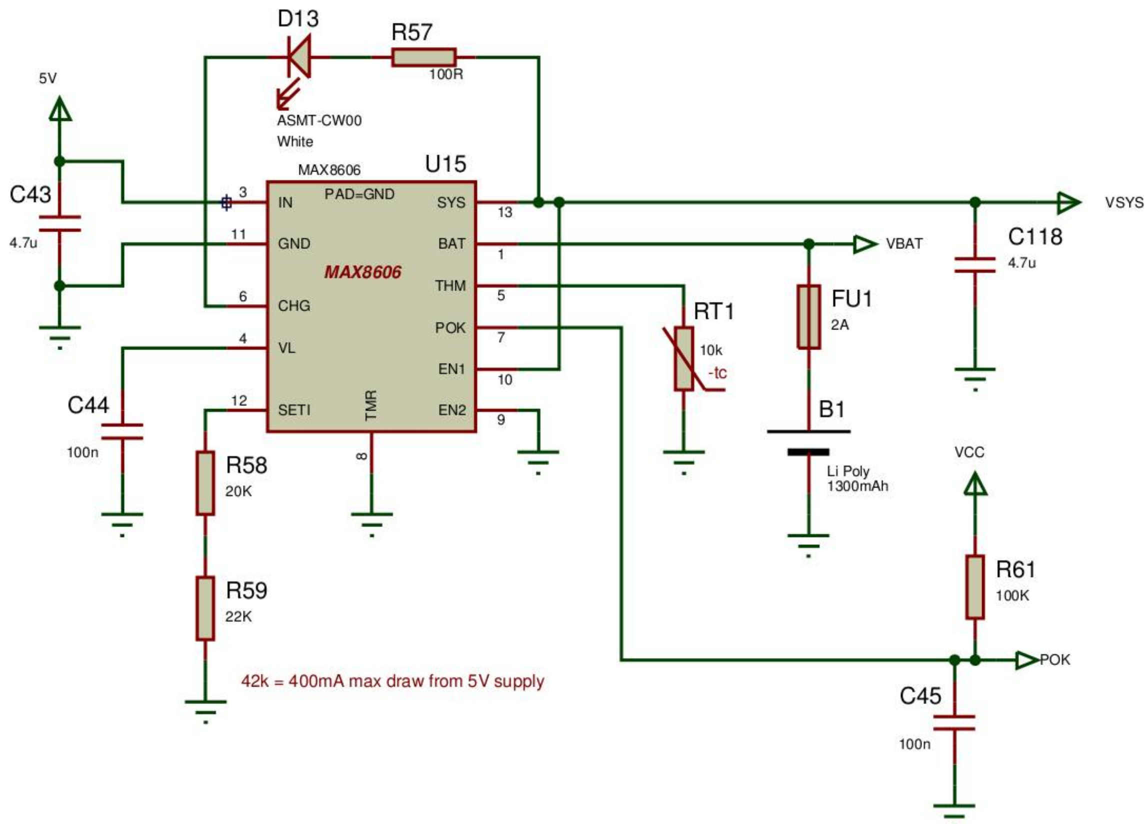

Figure 124: Battery charger

643 The stimulator has an internal 1.3Ah lithium ion battery. The charger (figure 124) was adopted largely unmodified from the original OML design. The MAX8606 charges the

battery to 4.2V using the 5V supply from the isolated USB interface; however, it prioritises current to the system load over charging the battery.

A.1.2 3.3V regulated supply

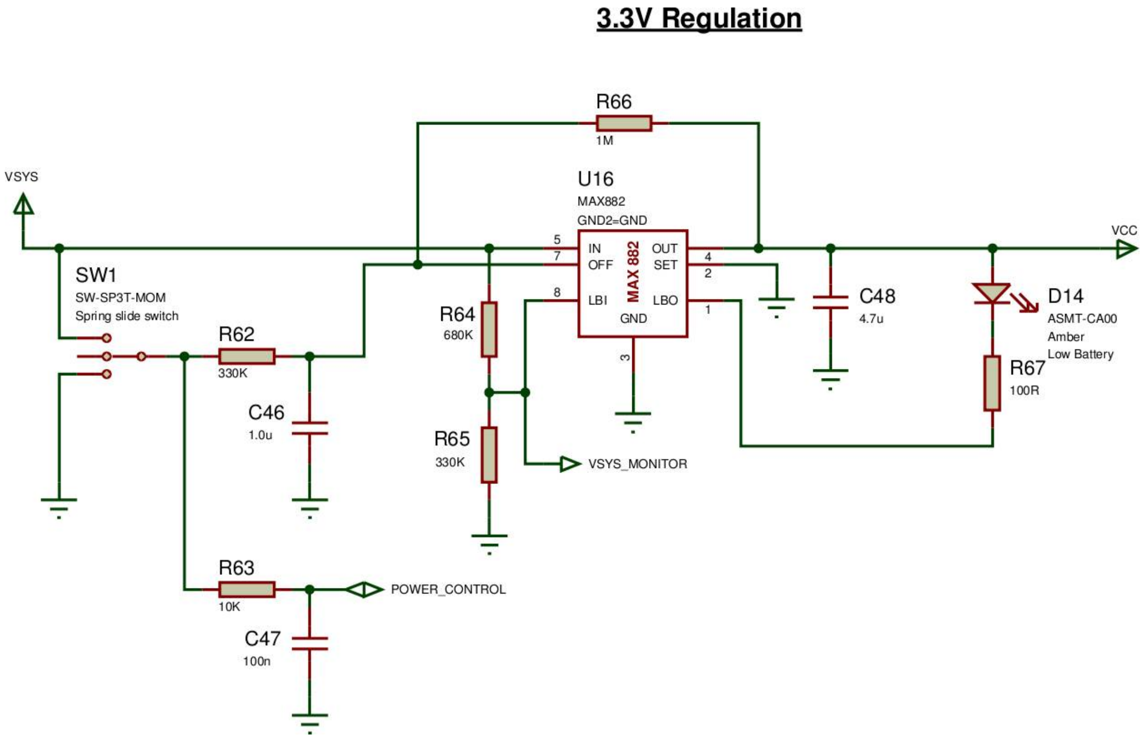

Figure 125: 3.3V regulator

644 The stimulator logic circuits run from a 3.3V supply (figure 125). This features a momentary action slide-switch that can be used to turn the system on or off. Positive feedback ensures that the regulator stays on unless commanded off. In normal use, the POWER_CONTROL signal is an input to the CPU, informing it when the user wishes to turn the system off (enabling the software to shut down in a controlled way), but it can also be an output, enabling the CPU to turn the system off (e.g. after a prolonged idle period).

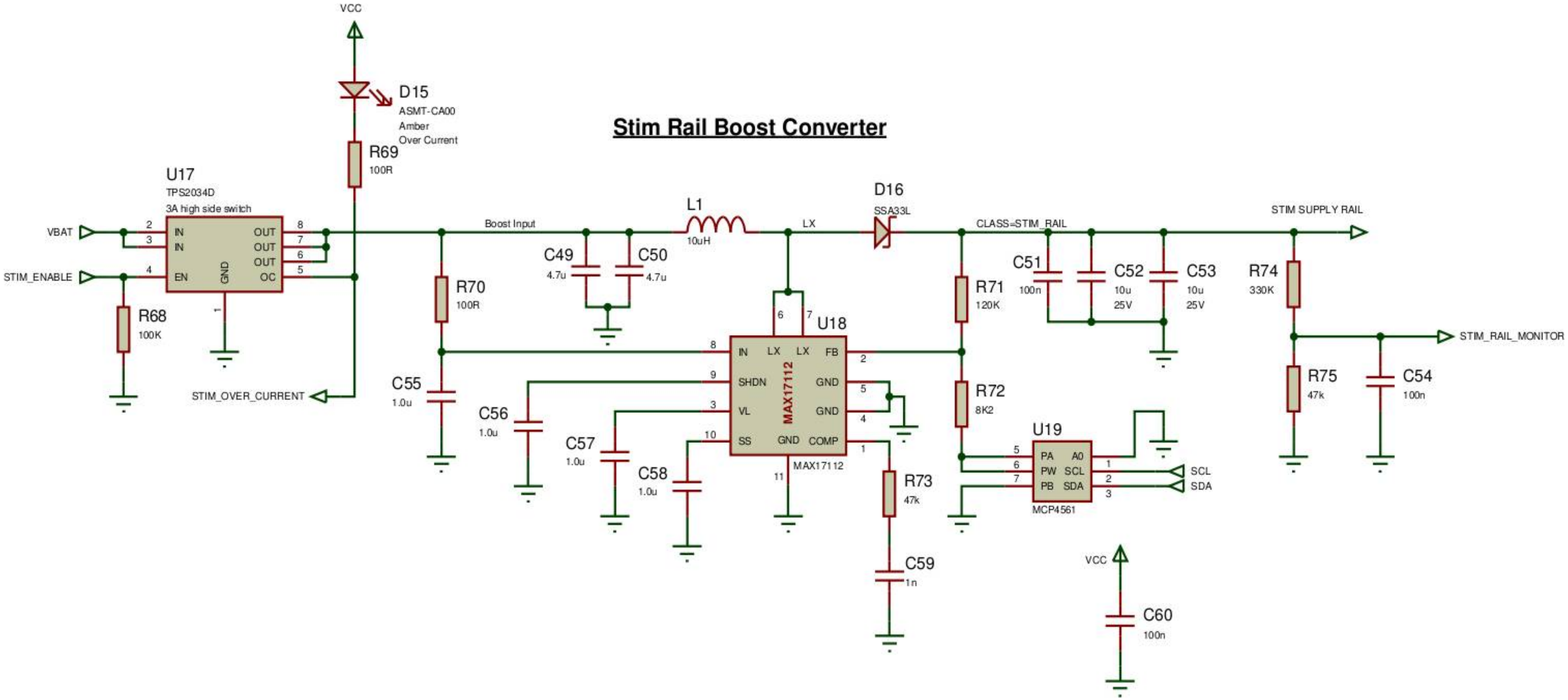

Figure 126: Boost converter supplying the stimulation output stages.

A.1.3 Boost converter

645 The boost converter (figure 126) provides a stable supply to drive the stimulation output stages. The voltage is adjustable under the control of the CPU; in practice 8.7V was sufficient to produce a 100mA peak pulse from the output transformers. The original OML design suffered a number of performance problems which were rectified for this project:

- Losses were reduced by using a Schottky diode instead of an ordinary silicon diode.

- Power handling ability was improved by using an inductor with higher saturation current rating.

- Output stability was achieved by revising the values of the compensation components C59 and R73.

- The PCB layout was revised to significantly reduce the impedance of the high frequency/high current loops around the switching node and improve thermal dissipation from the regulator.

646 As a worst case test, the circuit was tested with all channels at maximum output. Under these conditions the circuit draws 1.5A from the battery (4.2A peak). The battery is not suited to such high power demands, and a vicious cycle of declining terminal voltage and increasing current demand sets in. The battery is quite able to sustain the lighter loads of normal drop foot walking (less than 150mA from the battery), but for applications requiring maximum output (e.g. FES rowing) it would be advisable to use an external supply.

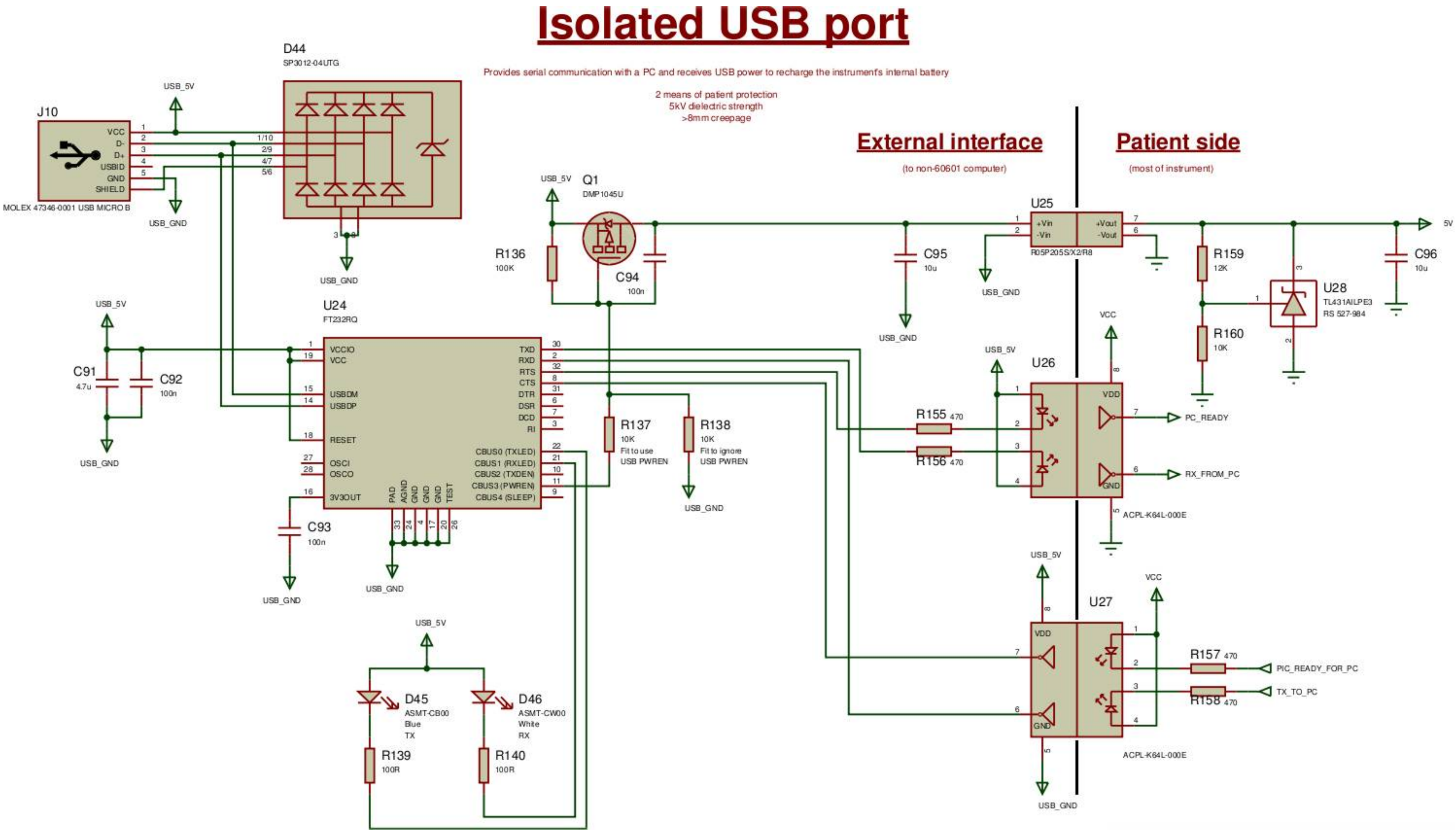

Figure 127: Isolated USB port providing communications and power across two means of patient protection at 250V AC.

A.1.4 Isolated USB port

647 The isolated USB port (figure 127) provides power to recharge the internal battery and communications for system development and operation with a computer during the conduct of the trial.

648 It is expected that the stimulator will be used with non medical-grade computers. These often exceed the permissible leakage current for equipment accessible to the patient. To reduce the risks at these currents could flow to/from the patient, this project included an isolated interface providing two means of patient protection at 250V AC. This involved the use of high integrity components and creepage and clearance distances greater than 8mm.

A.1.5 Non-isolated expansion port

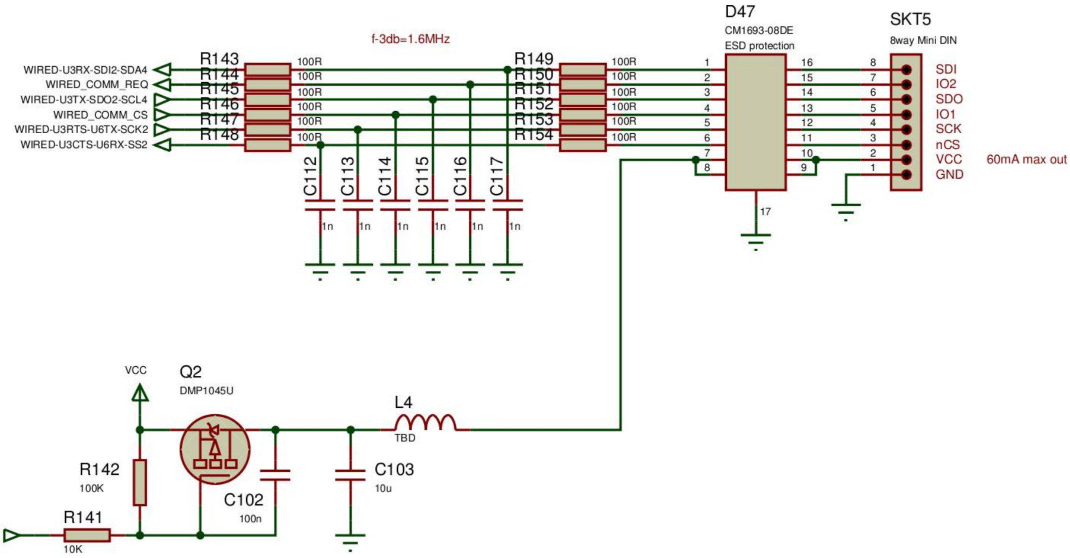

Figure 128: Non-isolated expansion port.

649 The non-isolated expansion port (figure 128) was used to connect the electrogoniometer interface. The interface includes a low-pass filter to reduce the risk of electromagnetic comparability (EMC) problems caused by emission of (or susceptibility to) radio frequency signals. These were considered a risk as the SPI bus has high speed clock edges and the external cable could act as an antenna. The circuit also includes an array of diodes close to the connector to protect against damage from electrostatic discharge (ESD). The goniometer interface itself was an Analog Devices AD7705 instrumentation analogue-to-digital converter in an external box with an analogue anti-aliasing filter.

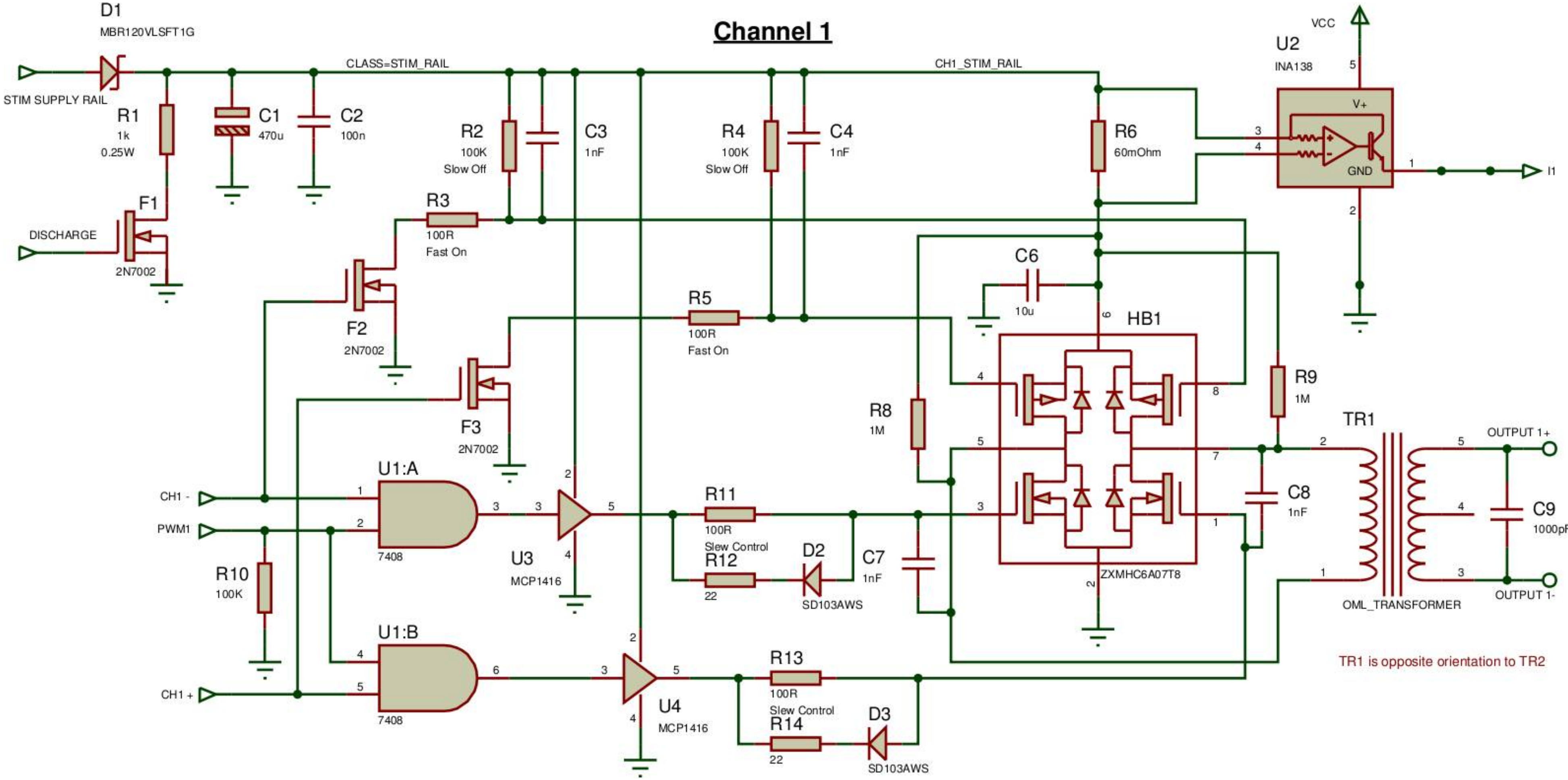

Figure 129: Stimulation output stage. There are four of these per stimulator.

A.1.6 Stimulation output stage

OML had proposed the idea of using pulse width modulation to enable rapid changes in current (and different current per channel) for their NEAT project, and produced a prototype design using Zetez ZXMHC6A07T8 MOSFET H-bridges. The output stage for this project (figure 129), retained the same H-bridge and PWM concept, but had the following changes:

- The original circuit driving the H-bridge could not provide enough current to switch the MOSFETS at the desired 200kHz. This project used MCP1416 transistor drivers on the low-side of the bridge, enabling operation in excess of 200kHz.

- The slew rate of the output stage is deliberately limited by the introduction of negative feedback to the MOPSFET bridge (C7 and C8 working with R11-R14 in figure 129). This slows the on/off transitions from tens to hundreds of nanoseconds, reducing electromagnetic emissions.

- The 470µF capacitors (C1 in figure 129) store the energy needed for a stimulation pulse. These capacitors were changed to low impedance types and connected to the H-bridge with short, broad tracks. This reduced the voltage drop at the H-bridge during pulse delivery, increasing the circuit's efficiency and ouput capability.

- The PCB was redesigned to use copper planes for the power supplies, eliminating interference between the power and logic sections of the circuit.

A.1.7 Foot switch inputs

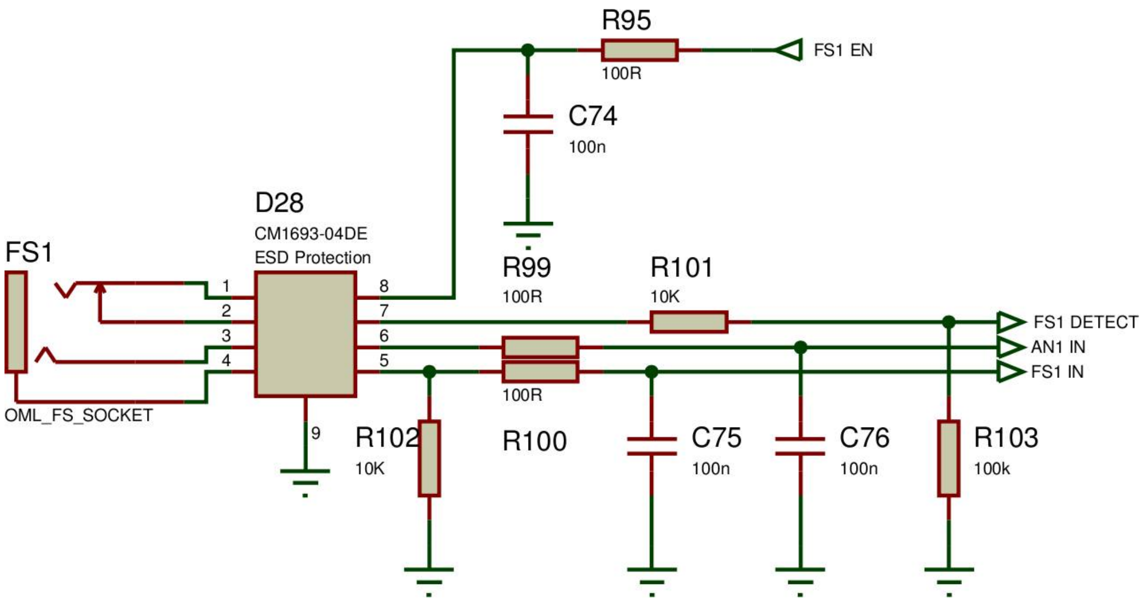

Figure 130: Foot switch input circuit. There are four of these per stimulator.

651 The stimulator includes four foot switch inputs, based on a previous OML design with the addition of ESD protection diodes. Low-pass filtering reduces the risk of radio frequency pick-up on the (unshielded) leads to the foot switch. The socket also provides an uncommitted analogue input for future expansion.

A.2 Equipment photographs

652 The main stimulator circuit was made on a 6-layer PCB (figures 131 and 132), populated by hand and assembled into a case 120x70x35mm. The case also contained a double-sided auxiliary PCB to hold the screen, navigation dial and an input/output expander for the remote control.

653 Figure 133 shows the final equipment used for both seated and walking tests. During the walking tests, the boxes were mounted on an equipment belt worn around the waist. The cables were held loosely to the leg with elasticated straps to avoid them flapping and the risk of tripping or distracting the user. The users did not report any problems walking with the equipment, although there is a risk that the quantity of wiring could have had some effect on gait.

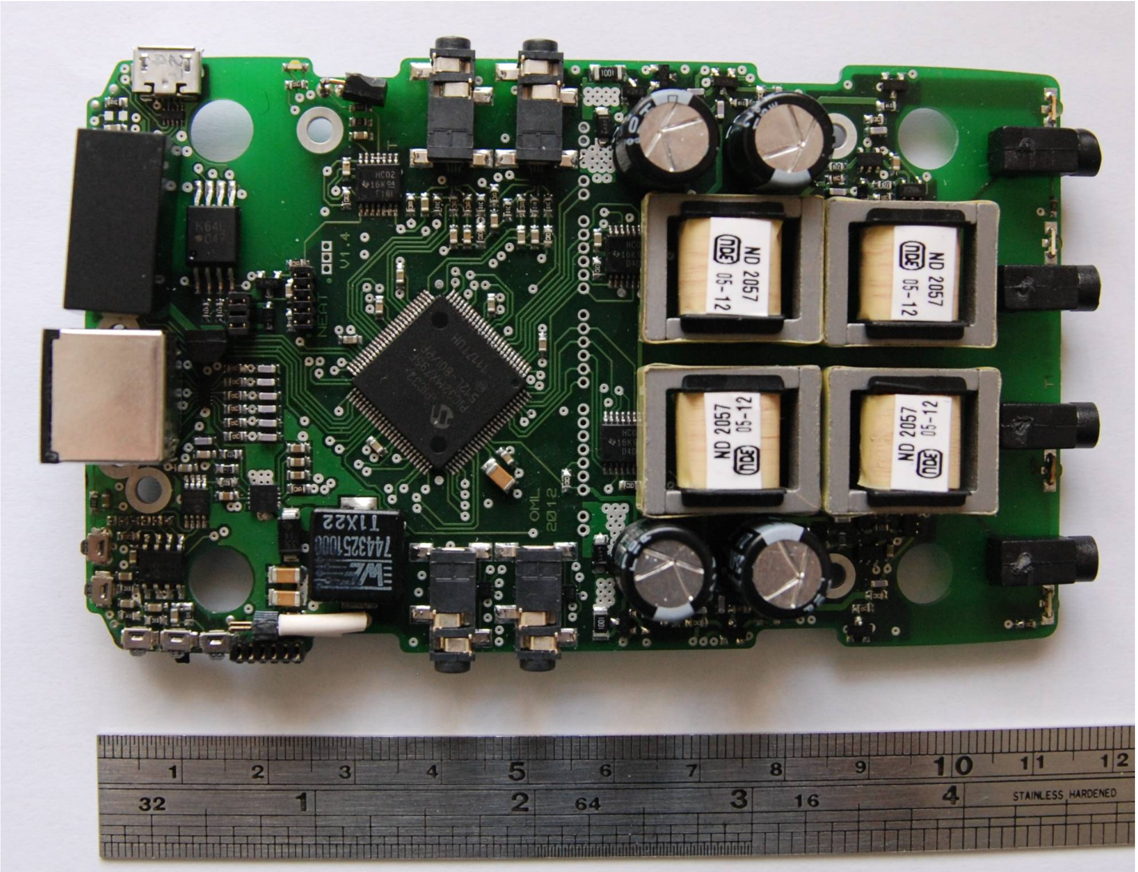

Figure 131: Stimulator main PCB, top side.

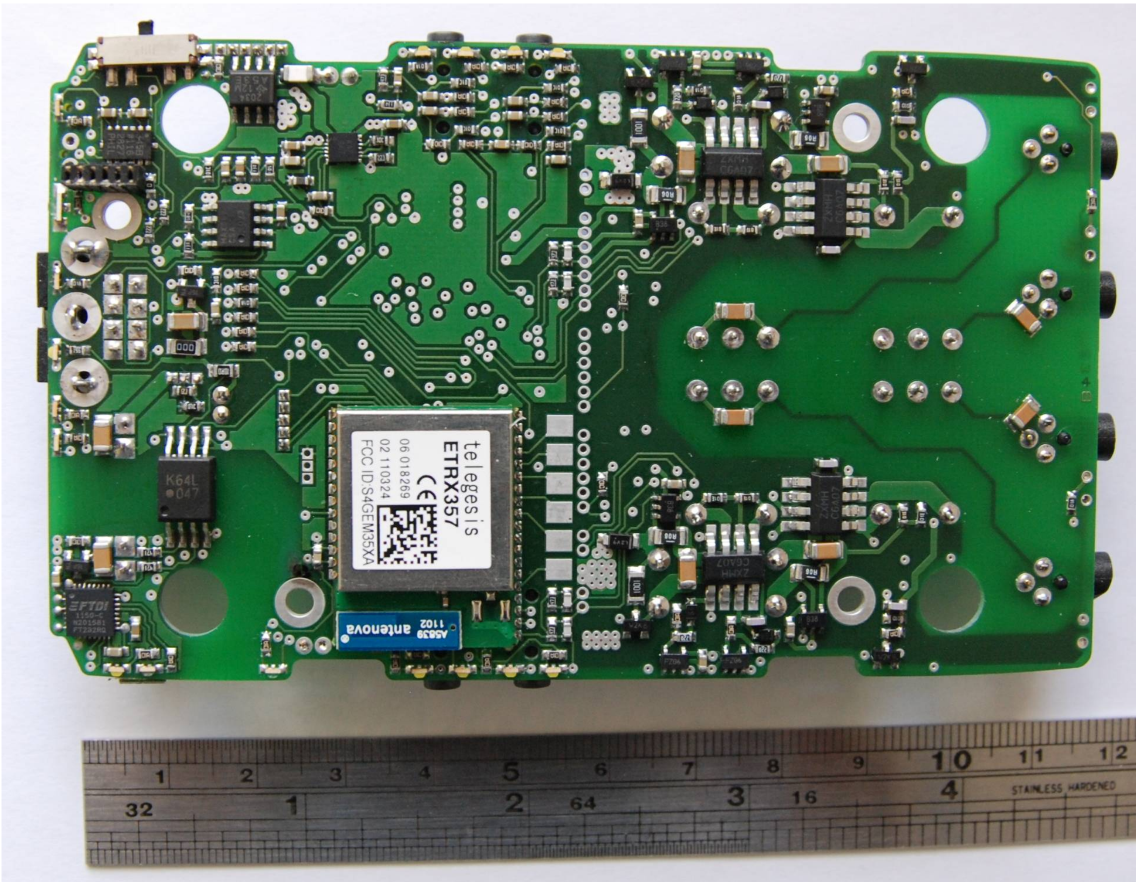

Figure 132: Stimulator main PCB, bottom side.

Figure 133: Experimental equipment: (left to right) Remote control, stimulator, goniometer interface, goniometer. The ruler above is 15cm long.

A.3 Stimulator Software

654 The stimulator software performs the following tasks:

- Deliver stimulation according to the set parameters, including single pulse trains and sequences with automatically varying pulse parameters.

- Provide a menu to display and edit the stimulation parameters.

- Provide an engineering interface to test and debug the system.

- Sample the goniometers and FSRs, sending the raw samples to a computer, and processing the samples on the stimulator:

    - To produce summary step data at every heel event, including ground contact times and estimated inversion/eversion.

    - To run the algorithm to adapt stimulation in response to measured inversion/eversion.

655 The stimulator source code is divided into 29 modules, each contributing a defined aspect of this functionality. The modules are arranged in layers as shown in figure 134. The lower layers deal with the hardware, while the upper layers co-ordinate the activities to implement the instrument's desired behaviour. Each module consists of a 'header' file, which declares the functions that the module provides, and a 'c' file which implements the functionality. Dividing the 11557 lines of source code in this way makes the software easier to understand and maintain.

656 The rest of this section describes some important features of the software.

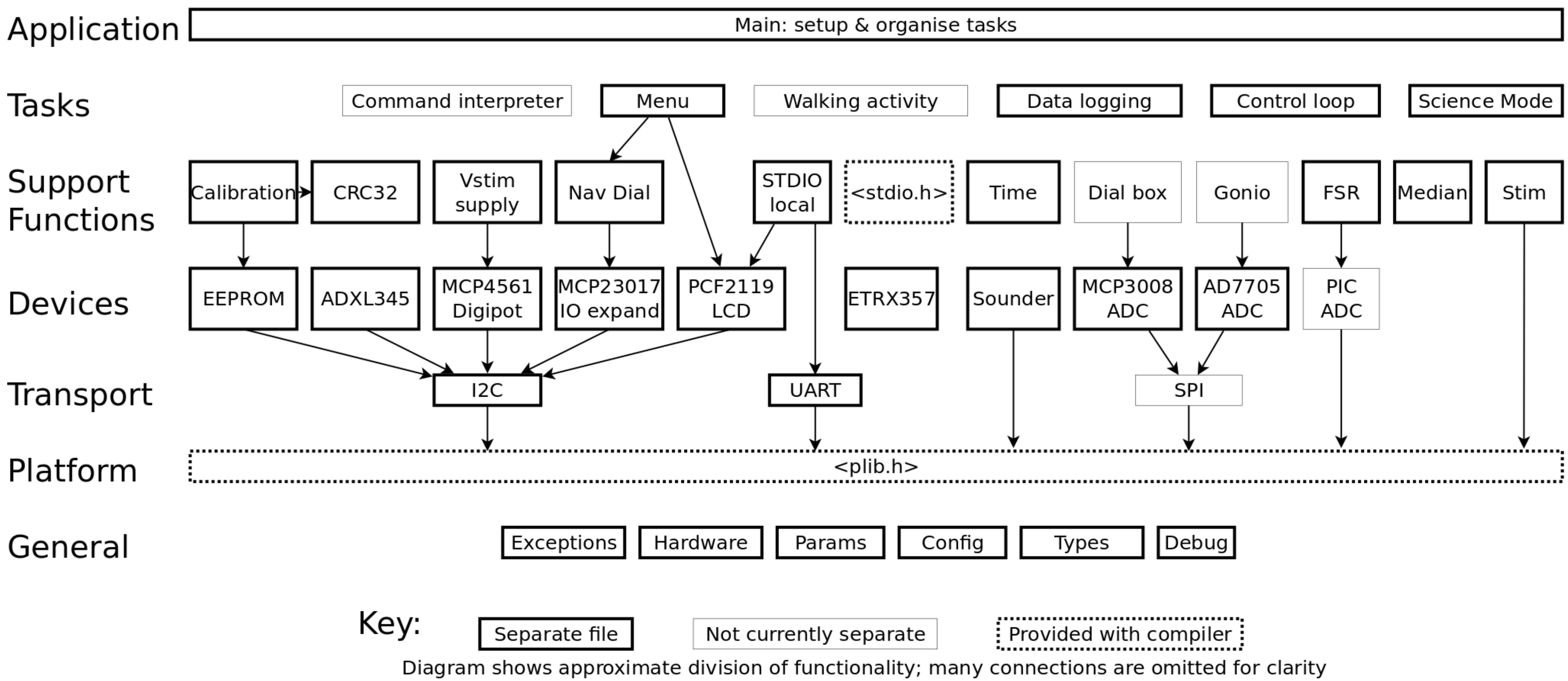

Figure 134: Structure of the stimulator software

Terms used in figure 134: CRC32: Cyclic redundancy check, using the polynomial from the PNG image format and example code from rosettacode.org.

STDIO: functions to print formatted text to the screen or debug terminal.

ADXL345: 3-axis accelerometer. MCP4581: digital potentiometer to adjust the stimulation supply voltage. ETRX357: Zigbee wireless modem.

Params: adjustable parameters such a s buffer lengths. Config: Microprocessor configuration fuse settings

A.3.1 Delivering stimulation

657 For comfort and effectiveness, it is important that the stimulation parameters are correct. The stimulator checks that the values are within the permitted range in two separate sections of code: when receiving them from the controls and when delivering the stimulation. The pulse duration is a critical parameter; to avoid variation in the pulse duration, all interrupts are disabled for the duration of the pulse, and the pulse is automatically terminated if the processor resets.

A.3.2 Concurrent operations

658 Many functions are time critical. In particular, data samples must be gathered, processed and transmitted at the rate they are generated, and the user interface must be responsive to remain usable. The software was profiled to ensure that it could complete its tasks quickly enough.

A.3.3 Communications reliability

659 A system of hardware and software buffers is used, linked by software interrupts, to reduce the risk that communication data is not lost. Hardware handshaking is used between the CPU and the radio modem and between the CPU and the USB serial port to avoid lost data bytes. Finally, packet counters and checksums are used to detect data loss or corruption.

A.3.4 Gait event detection and FSR signal processing

660 The stimulator implements the FSR signal processing described in section 4.1, following the failure of the in-shoe circuit. This enables detection of heel rise and heel strike, and an assessment of foot inversion/eversion for each step. This can then be used to adapt the stimulation in an attempt to maintain a set foot posture. The specific algorithms for foot posture calculation and two-channel stimulation adjustment are given in the methods for experiments 1 and 2 (see sections 6.4 and 7.4); these run on the stimulator in real time.

A.3.5 Algorithms and data structures

661 The majority of the software consists of a large number of relatively simple procedural functions. There are a few modules that include optimisations to enhance their scalability or suitability for implementation on a micro-controller.

662 An example of this is the calculation of the median foot posture, used in the closed loop control. Calculating the median involves keeping the last *n* values, and at each step adding the new sample, discarding the oldest, and determining the middle value. In Although the present implementation only uses the five most recent steps, it was desirable to be able to scale to an arbitrary number of steps. In particular, it was preferable that the processor did not need to re-sort a large list of samples at every step. The algorithm that was used exploited the fact that once sorted, adding and removing samples does not change the order of the rest of them. Each sample was stored in a structure together with pointers to the next bigger and next smaller sample. The structures were arranged in a circular buffer, with the oldest and newest identified by index variables. The pointers formed a doubly-linked list of sorted values. The indexes were used to easily discard the oldest sample and add a new sample, while the liked list avoided having to resort the entire list when a single value changed.

663 Structures were used extensively in the code for the menu displayed on the LCD. The menu had to be able to display and adjust multiple parameters for each of four channels, as well as various controls for the overall operation of the stimulator. Each logical menu screen was represented in a structure that associated the caption text with a parameter, and a function for each of the up, down, left, right and select buttons. These structures were held in an array with pointers linking the logical screens to provide a navigable menu system. Each screen structure included functions that determined whether the user was able to navigate to or from it. Separate structures held the details on the step size and limits of adjustment for each parameter. This meant that the controls operated consistently and it was simple to add additional screens to the menu as the need arose.

Appendix B: Volunteer information sheet

664 The volunteer information sheet for this experiment was developed from a template document in use at Odstock Medical. It was sent with a covering letter inviting FES users to volunteer for the experiment.

Odstock Medical Limited
National Clinical FES Centre
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ

Telephone (01722) 439566
Fax (01722) 425263
E-mail earl.merson@odstockmedical.com
Web www.odstockmedical.com

VOLUNTEER INFORMATION SHEET
June 2013

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Project title: Two-channel stimulation for the correction of drop foot.

What is the purpose of the project?

The purpose of the study is to find out if we can make it easier to control the movement of the foot using two channels of stimulation. When setting up a normal drop foot FES system, some people find that their foot twists outwards or inwards too much. They have to position the electrodes (pads) very carefully to get the correct movement, and some people find this quite awkward. This project will test a new method, using an extra electrode, where the exact position of the electrodes might not matter so much.

Our preliminary tests with non-impaired people showed that this method could 'steer' the direction of the foot without moving the electrodes. We would like to see if this will work with people who have a dropped foot, and whether it is good for walking.

Why have I been asked?

You have been asked because you are a regular user of FES for walking and have greater than 6 months experience of doing so. If you choose to take part you will need to stay for up to 90 minutes following your regular review appointment or come for a separate appointment.

Volunteer requirements

We have to check that you are suitable to take part, for your safety and to ensure that the tests produce clear answers. To be suitable for the study, you must meet the following requirements:

- Adult FES user with at least six months experience of FES.
- Able to understand and follow assessment procedures.
- Able to give informed consent.
- No recent skin irritation.
- No recent ankle injury.
- No implanted metalwork in the knee or lower leg e.g. pins.
- No severe leg spasms when using FES.

The walking tests have additional requirements:

- Using a foot switch on the same leg as the electrodes.
- Can walk without using FES on your thigh.
- Able to walk with a clear heel strike when using FES.
- Able to walk at least 200m (220 yards) using FES (with rests).
- Able to walk without an AFO, splint or brace when using FES.
- Able to take at least a few steps without FES.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. During the project, you are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from Odstock Medical Ltd (OML).

How long will I be involved with the project if I take part?

You will be asked to participate in one one session approximately 90 minutes long. If you want to be more involved, you could return for a different session later in the study, as we are conducting different tests over a period of six months.

What will happen to me if I take part?

Following your review appointment, or at a separate appointment, you will be asked to come next door to the consulting room. You may bring a companion with you if you wish. We will talk you though what is involved, you will have the opportunity to ask questions, and if you still wish to participate then we will ask you to sign a consent form.

The experiment has some seated tests and some walking tests, which are described below. We will agree with you how much to do based on your walking ability. You can opt out of any part.

Seated tests
You will sit in a chair with your leg nearly straight but relaxed, with an angle measuring device on your ankle. We will ask you to set a comfortable maximum for your stimulator, and also find the minimum needed to get any movement. We will then apply various test stimulations to your leg and record the angle of your foot each time. The burst of stimulation (less than one second long) will be repeated every 3 seconds. The strength of the pulses will vary from quite weak to about as strong as your usual FES. There will be about 50 test stimulations after setup, but you can have a rest or stop if it is too tiring.

Then we will add a third electrode, in a similar way to the arrangement shown in the photo (figure 1), to see if it can 'steer' which way your foot points. The exact size, shape and type of electrodes may be different. With this new arrangement, we can stimulate the muscles on the side of your leg and the muscles on the front of your leg. The aim is to be able to steer your foot to a good position for walking. We will adjust the settings carefully, to try to get a controlled response and avoid it being uncomfortable. We will take a photograph of the electrodes on your leg.

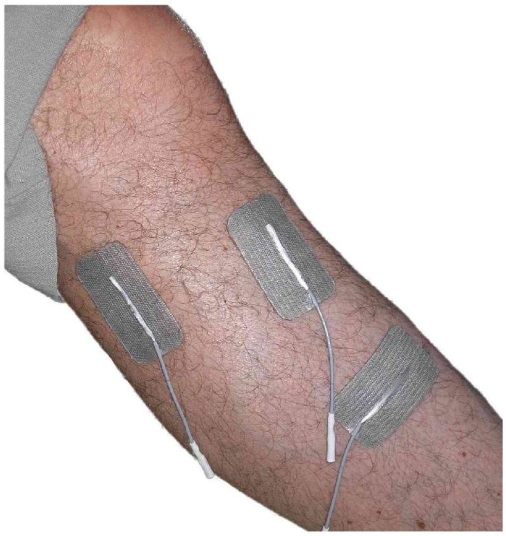

Figure 1: Example two-channel electrode arrangement

Once the electrodes are in place and the simulator set up, we will apply short test pulses with different settings, and measure your foot movement each time. In total, there could be about 250 stimulations. Again, you can have a rest or stop if this is too tiring.

Walking tests
This part is only suitable for people who can walk up and down the length of the corridor in the FES centre (about 20 metres each way). You can have a rest or stop at any time if it is tiring or uncomfortable.

We will set up the three electrodes as described earlier and put three foot switches in your shoe (one under your heel and two at the front of your foot). You will be given two controls: one for stimulation strength, and one for foot direction. Together, we will adjust the controls until you are happy with the movement of your foot, then walk around the room or corridor in the FES centre. You can use a walking stick or other aid if you would like to. While you are walking, you can pause to adjust the stimulation if you need to. You will be asked to repeat this walk a few times with different FES settings.

If I am a suitable candidate and decide to be involved, what happens next?

You will attend your FES appointment as normal at the National Clinical FES Centre in Salisbury District Hospital and after you are finished we will collect you from the waiting area by the FES reception. Alternatively we can arrange a separate appointment for the study. If we ask you to make a separate appointment, we will pay your travel expenses for a journey of up to 50 miles.

What shall I bring to the appointment?

For the appointment please wear your normal stimulator. We will not change it for this experiment, but we would like to record how well it lifts your foot for comparison with the new method.

Please wear loose clothing so we can easily fit and move the electrodes around your knee. Trousers are acceptable if they can be rolled up above the knee.

What facilities does your department have?

There are disabled parking facilities outside the department. Within the department there is a toilet suitable for wheelchair users and we have facilities to enable privacy when changing, placing electrodes or measuring equipment.

What are the possible disadvantages and risks of taking part?

As with any FES system, if the level is set too high it may be uncomfortable. This is also true when using two channels at once, because more nerves could be stimulated. You will be able to control the stimulation level, so we hope you will not be too uncomfortable.

It is possible that the stimulation will not work in lifting your foot. This is why we ask that (for the walking tests) you are able to take a few steps without stimulation. We do not want you to fall if the stimulation is ineffective. You can use a walking stick or frame if you would like to.

No changes will be made to your existing stimulator and hence the benefit you receive from this will not be influenced by participating in this study.

Your leg may feel more exercised immediately after this study, but there should be no lasting effect. You will be given rests and will not be asked to walk for longer than you are comfortable, but you may feel a little tired afterwards, as you would after a short walk.

What are the possible benefits of taking part?

There is no intended direct clinical benefit from taking part from this study.

The results will improve our understanding of FES systems, which may lead to improvements in FES. In the future, this could benefit all FES users.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this project, then please contact Professor Ian Swain, OML Clinical Director.

Will my taking part in this project be kept confidential?

All information collected about you during the course of the research will be kept confidential. Each volunteer on the project will be given a unique code that does not contain any personal details. All data collected will be anonymised and confidentiality will be maintained at all times.

In the consent form, we will ask for your permission to take photos of the electrode positions. These will be used anonymously in our reports and for conference presentations.

What will happen to the results of the research project?

The results may be published in scientific and medical journals, and presented at conferences and at training days for clinicians. Confidentiality and patient anonymity will always be maintained. If you are interested, we would be pleased to discuss the results and conclusions from the project with you.

Who is organising and funding the research?

The experiments are organised and funded by OML. The PhD researcher is funded by OML and a Bournemouth University studentship.

Who has reviewed the project?

The research has been reviewed and approved by:

- OML Research Ethics Committee.
- Research Ethics Committee of the School of Design, Engineering & Computing at Bournemouth University.

Travel expenses

If you attend an extra appointment to take part in this study you may claim travel expenses up to a car journey of 100 miles (round trip) or public transport equivalent.

Further information

If you need further information about the project, please contact any of:
Earl Merson – PhD student and pre-registration clinical scientist
Prof. Ian Swain – Consultant Clinical Scientist
Dr. Paul Taylor – Consultant Clinical Scientist

All three are staff at Odstock Medical Limited, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ. Telephone. 01722 429065.

How to volunteer

If you would like to take part, please contact Earl Merson:

- by phone on 01722 439566
- or by email earl.merson@odstockmedical.com
- or fill in the reply slip and return in the enclosed prepaid envelope.

Thank you for reading this information sheet.

Leading Rehabilitation
Through Technology

CONSENT FORM

Title of Project: Two-channel stimulation for the correction of drop foot.

Please initial each box if you agree.

1. I confirm that I have read and understand the information sheet dated June 2013 for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that at the end of the study data collected from me will be stored at the National Clinical FES Centre, Salisbury District Hospital in line with the institutional guidelines for good clinical practice in research and in line with the policies for postgraduate research.
4. I am/am not participating in another study at this time (delete as appropriate)
5. I agree that my leg will be photographed to record the position of the electrodes and the effect of the stimulation.
6. I agree for the photos to be used for publications, teaching or scientific conferences.
7. I agree to take part in the above study.

____________________ ____________________ ____________________

Name of Participant Date Signature

____________________ ____________________ ____________________

Researcher Date Signature

One copy for participant, one for OML FES notes and one for the Research Team

Appendix C: Volunteer's passive range of movement.

The passive range of movement (under light manual pressure) was measured as part of the seated tests, for comparison with the movement made when stimulated. The numerical values are provided in table 23. The zero reference is the position when standing quietly wearing the volunteer's normal shoes.

Volunteer ID	Dorsiflexion (degrees)		Eversion (degrees)	
	Minimum	Maximum	Minimum	Maximum
8	-17	25	-43	12
9	-34	13	-32	18
10	-22	26	-27	30
11	-33	17	-37	-2
12	-32	5	-17	-3
13	-49	4	-47	34
14	-26	17	-22	20
15	-25	23	-53	9
16	-44	9	-42	0
17	-36	2	-36	9

Table 23: Volunteer's passive range of movement.

Appendix D: Stimulation currents used in seated tests

711 In this study, the stimulation currents uses were adjusted to suit each volunteer, and then referred to in terms of a 0-100% scale where:

- In experiment 1 (single-channel stimulation) 0% is the motor threshold and 100% is the maximum comfortable stimulation.

- In experiment 2 (two-channel stimulation), the the currents to the medial and lateral electrode were a linear function of the 0-100% balance parameter.

712 Table 24 gives the actual currents corresponding to the 0% and 100% points of these scales as used in experiments 1 and 2.

Volunteer ID	Experiment 1		Experiment 2			
	Single channel current (mA)		Medial current (mA)		Lateral current (mA)	
	0% (threshold)	100% (max. comfort)	Balance 0%	Balance 100%	Balance 0%	Balance 100%
8	27	36	42	30	25	36
9	29	40	52	39	35	44
10	30	46	35	17.5	31	44
11	33	42	48	40	40	52
12	21	33	38	25	36	58
13	21	40	36	23	18.5	36
14	27	54	54	27	16.5	29
15	17.5	19.5	26	10.5	18	23
16	42	62	56	29	52	70
17	52	60	66	24	26	64

Table 24: Stimulation currents used in experiments 1 and 2

Appendix E: An investigation into goniometer noise

794 During the walking experiments it became clear that the goniometer signal often had notable step-to-step variation. For example, figure 135 shows the time series of step data from volunteer 13b walking for experiments 3 and 4a. There are several points where the average eversion angle appears to be more than 5 degrees different in successive steps. There was no obvious cause for this variation (apart from a few steps when turning at the end of the room). However, the data shows several steps with alternating higher and lower angles. This raises the question of whether the steps truly were different, or whether this was an artefact of the conduct of the experiment or the measurement system.

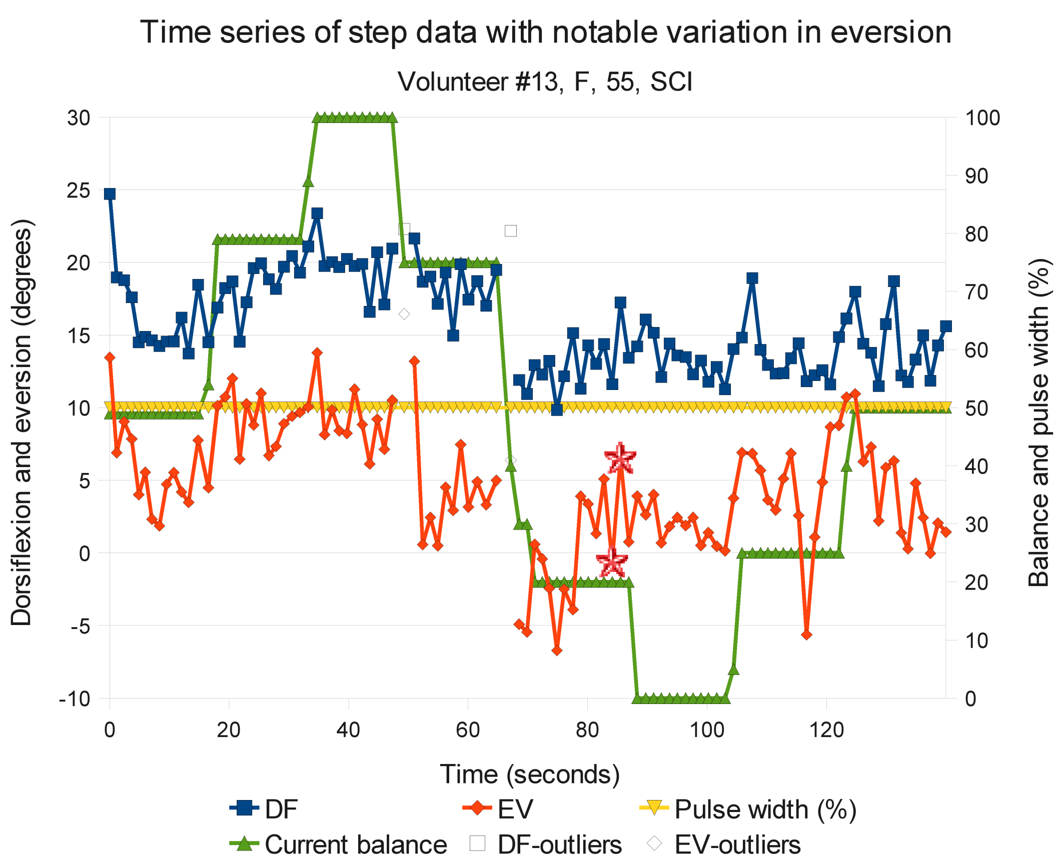

Figure 135: Time series of step data from volunteer 13 walking for experiments 3 & 4a. Detailed goniometer data for the two steps marked with stars is presented in figure 136.

795 The angle data for each step is the average recorded by the stimulator in the period heel rise to heel strike. The stimulator also transmitted the full goniometer data at 50Hz. Comparing the timestamps on the goniometer samples with the heel rise data enables examination of any step in some detail. For example, figure 136 shows the goniometer

data for the two steps marked with stars in figure 135. Please note that unlike formal gait analysis plots, the zero angle reference is relative to standing (not necessarily anatomical zero), and that heel rise (HR) and heel strike (HS) events were determined from the foot-switch signal. Figure 136 shows two steps, where during flat-foot there is approximately 16° eversion relative to standing, rolling into inversion after heel rise and before toe off. The average eversion from heel rise to heel strike (used throughout this study as a measure of the effect of stimulation) is closely matched to the eversion plateau visible after toe off and before heel strike. The use of this metric is discussed further in section 8.7.3.1, but in this case it appears to represent the step reasonably well. That is, the step-to-step variation did not seem to be entirely the result of averaging over an inappropriate portion of the gait cycle. It is possible that these two steps really were as different as recorded, although we cannot be sure without a further independent measurement (such as from an optical marker system).

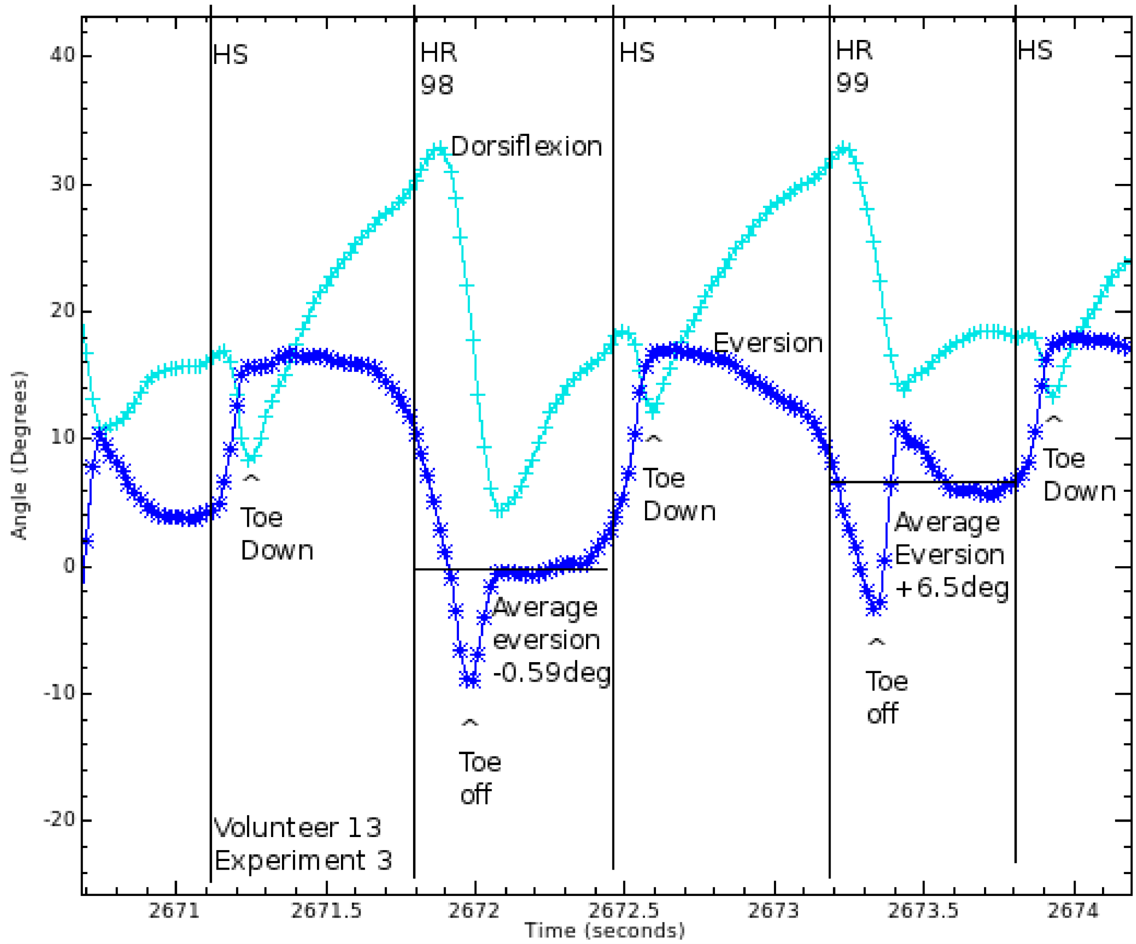

Figure 136: Goniometer data from consecutive steps, volunteer 13 walking with two-channel FES. This chart illustrates two steps with notable inter-step differences in average eversion.

796 Considering other potential sources of variability, static tests in single planes on the laboratory bench had shown that the goniometer and associated signal processing

produced accurate (<2 degrees) and repeatable (<1 degree) measurements in static conditions. However, the unexplained variation in step-by-step values gave cause for doubt about the measurement system's dynamic response. There were several potential sources of error to consider:

- Electromagnetic or microphonic interference on the cables, or poor/intermittent connections.

- Artefacts from limitations in the goniometer's ability to measure dynamic angles and/or compound curves as the sensing element moves over the lateral malleolus.

- Artefacts from the mounting of the sensor on the ankle joint (skin artefact).

797 To eliminate electronic effects, the goniometer was immobilised by fixing it to a small rigid board, which was secured to the ankle of an unimpaired volunteer and the goniometer signal recorded while walking. This exposed the system (including cables) to the normal motions. Nine walks were recorded using two sets of cables and four walking speeds (normal, fast, slow and very slow). In all cases the signal from the goniometer was very small, with just a little signal at the step frequency and its harmonics present. Table 25 summarises the values recorded from nine walks at different speeds and with different cables. The negligible signal in these conditions essentially eliminated non-sensor effects as a significant source of error.

9 walks measuring a fixed zero angle at 50Hz	**Dorsiflexion**	**Eversion**
Average zero offset	0.4 degrees	0.0 degrees
Worst zero offset	0.5 degrees	0.1 degrees
Average standard deviation	0.3 degrees	0.3 degrees
Worst standard deviation	0.5 degrees	0.5 degrees

Table 25: Error when measuring a fixed zero angle while walking.

813 Having ruled out electronic sources of noise, this left problems with the dynamic performance of the sensor itself, or its mounting to the body. Assessing the former

would have required a complex moving test jig with a known motion, which was beyond the scope of this project. Assessing the later would require knowledge of the true motion of the joint, which would have required an accurate source of kinematic data (e.g. simultaneous capture from a high resolution optical marker system) which was also not available.

814 Accepting that the goniometer signal may be distorted in dynamic situations (either inherently, or by its mounting) it is desirable to be able to estimate the maximum size of this effect, and whether it would affect the validity of the results.

815 A typical step might be expected to be similar to its predecessor, as most steps did not have a large change in current balance and were not during turning. Indeed, to visual observation, the volunteers' walking did not appear to have large step to step variation. Despite this, the average absolute difference between consecutive steps (across all walks by the volunteers) was 1.7 degrees for both dorsiflexion and eversion. This includes:

- occasional large changes from outliers which it was impractical to screen for this statistic (including artefacts when some volunteers turned at the end of the room).
- actual changes caused by the current balance (but the current balance did not change at all on most steps)
- mounting artefacts
- noise from the goniometer's imperfections (i.e. distorted dynamic response)

816 Although random noise can make it harder to see small changes, the problem is reduced by averaging over many steps. Random noise would be more significant if one were trying to measure effect size without asking the volunteers to walk for too long. More problematic would be systematic distortion (e.g. non-linearity or cross-axis sensitivity) which if present could mask some outcome effects.

817 In summary, it appears that although the goniometer signal has some noise (probably less than 1.7 degrees) when measuring dynamic angles on the ankle, this is smaller than the angular change caused by altering the current balance observed in these experiments (which averaged 7 degrees for eversion in the open-loop walking tests).

818 Future studies aiming to gauge the effect of two-channel stimulation more accurately, may seek to ameliorate the imperfections of the goniometer system, either by replacing it or by using a jig to ensure that the goniometer spring is not subjected to complex curvature.

Appendix F: Posters and conference presentations

819 During this project, several posters and presentations were made, both for internal conferences at Bournemouth University, and at the annual FES conferences organised by the UK & Ireland chapter of the International Functional Electrical Stimulation Society (IFESSUKI). This appendix contains a selection of these posters and abstracts of the main presentations.

820 The following are included:

- Poster: In-shoe assessment of ankle stability for drop foot FES.
  IFESSUKI 2012, Birmingham, UK, 27-29 April 2012.

- Abstract: Point accelerometery alone is not an accurate measure of limb tilt when walking.
  IFESSUKI 2013, Southampton, UK, 12th April 2013

- Poster: Two-channel functional electrical stimulation for the correction of drop foot.
  Bournemouth University Post-Graduate Conference, 23rd January 2014

- Abstract: Two-channel stimulation for the correction of drop foot.
  IFESSUKI 2015, Sheffield, UK, 8-9th May 2015. (Merson et al. 2015)

Bournemouth University

In-shoe assessment of ankle stability for drop-foot FES

Salisbury NHS Foundation Trust

Earl Merson[1,2] emerson@bournemouth.ac.uk Supervisors: Ian Swain[1,2], Jon Cobb[1], Paul Taylor[2,3]

1: The School of Design, Engineering and Computing, Bournemouth University

2: The National Clinical FES Centre, Salisbury District Hospital, Salisbury

3: University of Southampton

Introduction

- Good foot posture at initial contact is important in ensuring ankle stability during the loading phase of walking.
- Functional Electrical Stimulation (FES) for drop foot is usually arranged to give a mild eversion at the ankle.
- Some FES users do not achieve a good setup, because either they are unaware of the desirable foot posture or they find it difficult to make appropriate adjustments to their equipment.
- We present a newly developed in-shoe sensor which can assess ankle stability during loading.
- This is potentially useful both as a clinical outcome measure and as feedback for closed-loop control of foot posture.

Aim

To develop a convenient, unobtrusive sensor to assess ankle stability during loading.

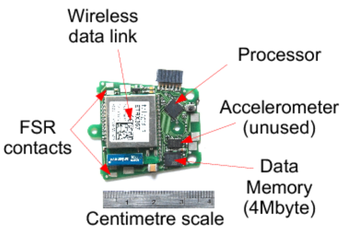

Figure 1: In-shoe signal processing board (approximately actual size)

Method

- Three Force Sensitive Resistors (FSRs) are mounted on an insole (under the heel and the 1st and 5th metatarsal heads).
- The insole contains a thin battery and a signal processing circuit (figure 1), providing data storage and wireless communication.
- Data from the FSRs can be used to assess ankle stability (a function of centre of foot pressure), on the basis that inversion and eversion alter the way the metatarsal heads contact the ground.

In the initial implementation, the algorithms are based on the following time measurements:

t_h: duration of heel contact.

t_1: 1st met head contact duration before heel rise

t_5: 5th met head contact duration before heel rise

Two estimates of stability are produced:

$Est1=(t_1-t_5)/t_h$ $\quad$ $Est2=(t_1-t_5)/(t_1+t_5)$

- Estimate 2 is more sensitive to small changes, but saturates if one of the met-head sensors does not touch the ground at all.
- Factors such as sensor placement and gait style mean that a neutral posture does not necessarily yield an estimate of 0.

To assist validation, an electro-goniometer measured foot eversion at the lateral malleolus. FES was set up on an unimpaired subject, to give inverted or everted gait. Data was recorded as the subject walked an indoor course three times, with respectively inverted, neutral (FES off) and everted gait.

Results

Figure 2 plots the FSR-derived estimate of ankle stability against the average foot eversion angle during the preceding swing phase.

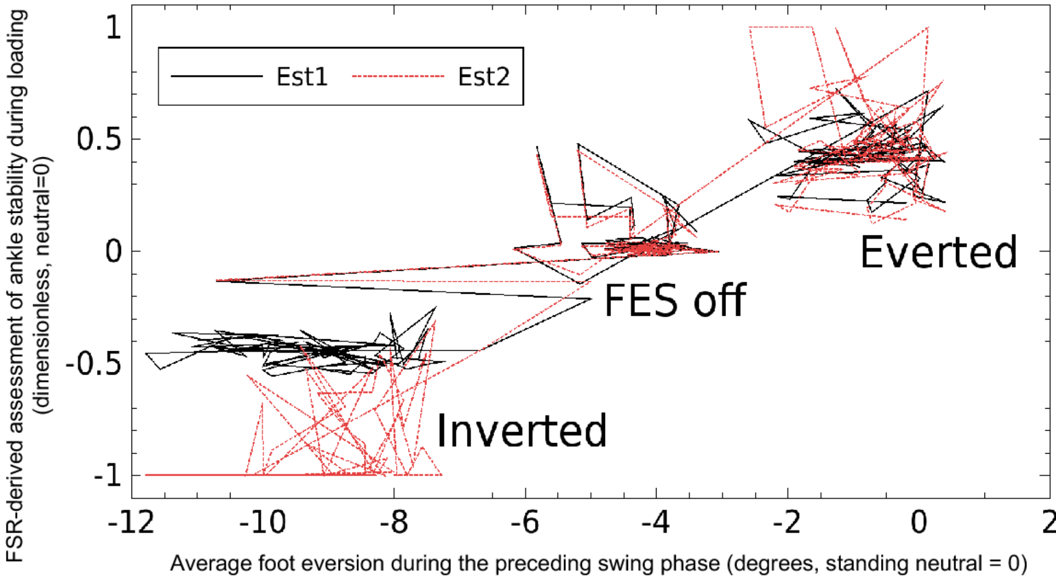

Figure 2: Stability estimate vs. foot eversion for 212 steps by an unimpaired subject

Discussion

- The data is clearly noisy and there appears to be an angular offset in this case.
- There is a correlation between the angles and the stability estimates: in this dataset, both estimates have $R^2=0.86$ for a linear fit.
- Full consideration of stability would take into account the perturbation required to cause the ankle to twist; neither ankle angle nor the FSR timings give this information completely.

Distinct (but as yet unqualified) variations have been seen between successive runs of this experiment. Further work is required to validate the technique, particularly its inter- and intra- subject reliability and the effects of FSR positioning and uneven ground.

Conclusions

- A low-power, unobtrusive system enables the collection of gait data outside the gait lab.
- If validated, this system could enable the measurement (and possible optimisation) of FES performance in the patient's daily life.

Acknowledgements

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Point accelerometery alone is not an accurate measure of limb tilt when walking

E. Merson[1,2] **Supervisors: I. Swain**[1,2]**, J. Cobb**[1]**, P. Taylor**[2]

[1]**Bournemouth University, Bournemouth, UK.** [2]**Salisbury District Hospital, Salisbury, UK.**
Contact emerson@bournemouth.ac.uk

Introduction

In situations where there is no horizontal acceleration, accelerometers can be used to measure orientation by sensing gravity. However, accelerometers cannot distinguish the effect of gravity in the presence of an arbitrary unknown acceleration, resulting in errors in tilt calculations.

Aim

To illustrate the errors in the estimates of shank angle and knee flexion derived solely from single-point accelerometers.

Method

A Vicon 3D motion capture system recorded an unimpaired man walking on a level floor at a self-selected pace with Plug-in Gait markers on his legs. The system calculated the accelerations and angles of the thigh and shank segments in the saggital plane at 50Hz for one gait cycle.

A spreadsheet model was constructed, featuring one pair of ideal orthogonal accelerometers mounted on the thigh and another pair on the shank, both in the saggital plane. Each pair had one axis (a_{par}) parallel to the limb and one axis (a_{perp}) perpendicular.

The accelerometer output signals were calculated using the limb accelerations and orientations from the motion capture data and taking the gravitational force as equivalent to an acceleration of 9.81ms^{-2}.

Estimates of the angles of the thigh and shank segments to horizontal were calculated from the accelerometer outputs for each frame, using $\theta_{estimate}=\tan^{-1}(a_{par}/a_{perp})$. Knee flexion was estimated as $\theta_{knee\ flexion} = \theta_{thigh} - \theta_{shank}$. These estimates were then compared with the original measured values.

Results

The errors for one gait cycle are shown in table 1.

Table 1: Errors in estimated angles over 1 cycle.

Right (Left) leg	Thigh angle error in degrees	Shank angle error in degrees	Knee flexion error in degrees
Max. absolute err.	69 (79)	101 (146)	128 (167)
Average absolute err. over gait cycle	30 (32)	33 (37)	34 (38)

Figure 1 shows the angles for one gait cycle.

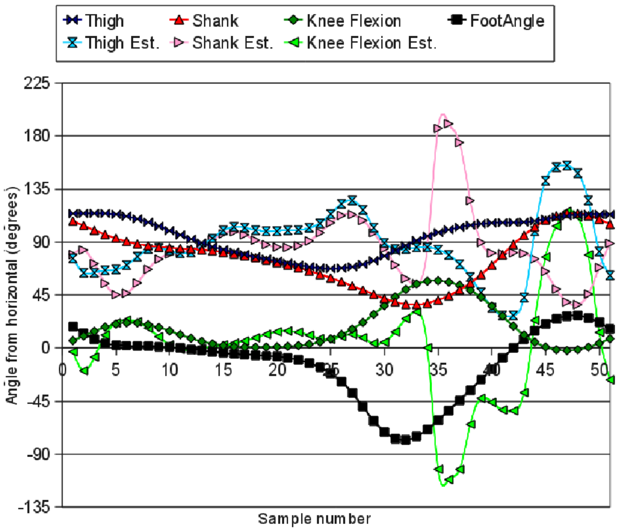

Figure 1: True and estimated angles through the gait cycle (left leg) The true foot angle is included to aid interpretation, but was not part of this study.

Discussion

The errors in the estimated angles were both large and highly variable. Rapid (and erroneous) changes in estimated shank angle occurred during early swing, when the shank is close to free-fall. At this point, small changes in the net acceleration vector can have a large impact on the estimated orientation (apparent changes of over 90 degrees between adjacent frames were seen in this study). Large errors in estimated knee flexion occurred in late swing when the thigh and shank accelerations were in opposite directions with notable horizontal components.

These effects are expected to be reduced when walking more slowly, as the limb accelerations become less significant compared to gravity.

For accurate determination of tilt in the presence of arbitrary accelerations, one must be able to sense and track rotation distinct from linear motion. This requires integrating the signal from a gyroscope (or non-coincidental accelerometers with a known spatial relationship, e.g. fixed to a rod, which can be used as a gyroscope).

Acknowledgements

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Two-channel functional electrical stimulation for the correction of drop foot

Bournemouth University

OML Leading Rehabilitation Through Technology

Earl Merson[1,2] emerson@bournemouth.ac.uk Supervisors: Jon Cobb[1], Ian Swain[1,2], Paul Taylor[2,3]
1: The School of Design, Engineering and Computing, Bournemouth University, UK
2: The National Clinical FES Centre, Salisbury District Hospital, Salisbury, UK
3: University of Southampton, UK

Background

'Drop foot' is a medical condition where people cannot lift their feet when walking. It is often caused by central nervous system damage, due to a stroke, multiple sclerosis, or injury to the brain or spine.

Functional electrical stimulation (FES) is a treatment for drop foot. Two electrodes are placed on the lower leg to stimulate the nerves which activate the muscles that lift and stabilise the foot. The effectiveness of this is sensitive to electrode position, and people often struggle to position the electrodes appropriately.

Aim

This study investigated the use of three electrodes, aiming to balance the action of the various leg muscles to attain a safe foot posture for walking and compensate for small changes in electrode position.

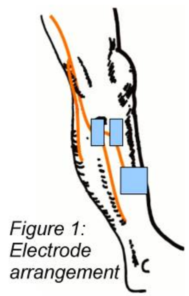

Figure 1: Electrode arrangement

Method

Two electrodes were placed by the knee to target the deep and superficial branches of the common peroneal nerve, for foot lift [dorsiflexion] and stabilisation of the ankle [eversion] respectively. A common return electrode was placed on the tibialis anterior muscle near the shin.

18 volunteers with neurological conditions (11 MS, 2 stroke, 4 spinal injury and 1 brain injury) took part in seated and/or walking tests where the balance of current between the two electrodes was varied between 0% (biased to the inner [medial] electrode for foot lift) and 100% (biased to the outer [lateral] electrode for ankle stability). The outcome foot posture (ankle dorsiflexion and eversion) was measured with an electrogoniometer.

The seated tests involved 0.5s bursts of stimulation and were conducted with the leg supported in a relaxed, extended position. The walking tests took place indoors on a smooth, level floor at a self-selected pace.

Results: seated tests

Each volunteer responded differently, both in how critical the electrode positions were and in the range of foot postures achieved.

Chart 1 shows an example of how the foot posture was affected by both the current balance and the position of the group of electrodes. Each colour represents a position 10mm from the starting position. Each point is a different current balance, from biased medially to biased laterally. The pink lines show the passive range of movement of the ankle when rolled around a relaxed posture.

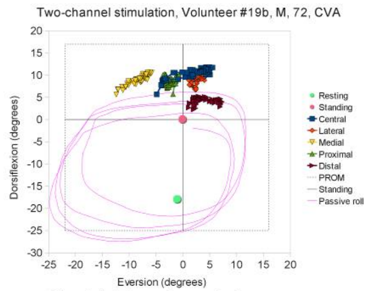

Chart 1: Example seated response

Chart 2 (different volunteer) shows a wider range of eversion, with generally less foot lift. There is also notable variability during the first few bursts of stimulation at each position.

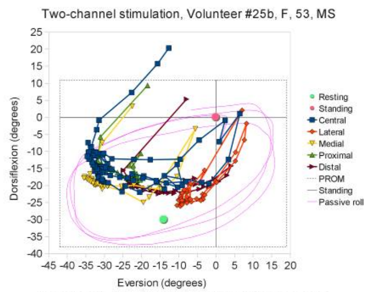

Chart 2: Another seated response

Results: walking tests

Chart 3 shows a particularly strong response (red) to changes in stimulation (green) when walking (r^2>0.9). A lateral current bias produces eversion, but the effect was often small and sometimes masked by step-to-step variation and/or noise in the measurement system.

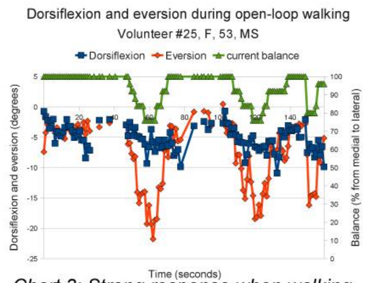

Chart 3: Strong response when walking

Chart 4 shows the response of an unimpaired volunteer to closed loop stimulation. The system compensates for a small change in the position of one electrode by changing the current balance to bring the foot back towards the target posture. Experiments with neurologically impaired volunteers were more difficult to conduct due to their reduced stamina, less safe walking and individual response. Their results were less distinct, and the control system was not always able to maintain the target foot posture.

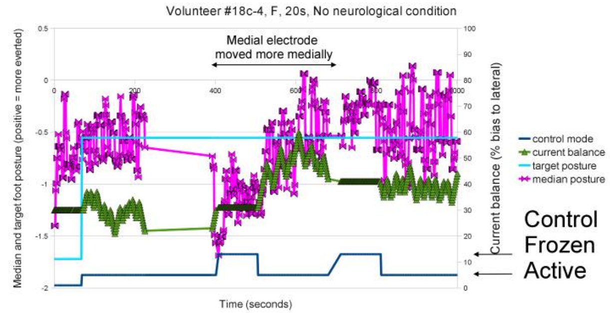

Chart 4: Example unimpaired closed-loop response

Discussion

Part of the aim was to investigate the possibility of reducing the need to accurately position the electrodes. However, it was found that the range of control was strongly dependent on electrode position as well as the currents used. Although some degree of control was possible most cases, in general the difficulty of setup was comparable to traditional stimulation.

Conclusions

- Influencing foot posture is possible.
- Strongly dependent on electrode position.
- Effect varies between and within people.
- Control system has limited correcting action.
- Further study needed to determine effect size and applicability.

Acknowledgements

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Two-channel stimulation for the correction of drop foot

Merson, E[1,2], Swain, ID[1,2], Taylor, PN[2], Cobb, JE[1]

[1]Bournemouth University, Bournemouth, UK

[2]Odstock Medical, Salisbury, UK

emerson@bournemouth.ac.uk

Introduction

Functional Electrical Stimulation (FES) is used for the correction of drop foot. The ability to gain a functional and safe foot posture (i.e. dorsiflexed and mildly everted) is dependent on recruiting the deep and superficial branches of the common peroneal nerve in suitable proportion. Implanted stimulators require an invasive operation, while traditional single-channel surface stimulation systems require careful manual placement of surface electrodes (which may be difficult for FES users). Cuff systems are simple to apply but are bulky and may suffer from slight misalignments. Electrode arrays may be able to adapt for changes in response, but are complex to manufacture. The approach presented here uses two channels of stimulation (lateral and medial), altering the inter-channel bias to influence the degree of eversion and dorsiflexion. The hypothesis was that inaccuracy in the positioning of the electrodes could be accommodated by adjusting the bias point to maintain a safe and functional foot posture.

Method

Volunteer FES users were set up with two channels of stimulation. The lateral electrode (3x5 or 5x5cm, depending on leg size) was on or slightly posterior to the head of fibula, and the medial electrode was slightly anterior; the common indifferent electrode (5x5cm) was on the tibialis anterior. Placement and current levels were adjusted by trial and error to provoke a range of eversion with dorsiflexion. The response to stimulation pulse trains (ankle dorsiflexion and eversion) was recorded both in sitting and while walking on smooth level ground, while the current bias was shifted between the channels. This was repeated after all electrodes were translated 10mm laterally, medially, proximally and distally.

Results

Careful electrode positioning was required to avoid either inversion or eversion dominating. In nearly all cases the level of eversion increased as the current was biased to the lateral electrode. The effect varied notably between individuals. Moving the electrodes by 10mm often produced a markedly different response, which could only be partially compensated for by changing the current bias.

Conclusion

This approach did not avoid the need to position the electrodes accurately. However, in most cases there was some influence over eversion. The technique may have utility as part of a cuff system, to fine-tune the response once the electrodes are positioned appropriately.