Creating Tactile Feedback with Intelligent Electrical Stimulation to Compensate for Sensory Impairment

By

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Abstract

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Performing daily life activities can be more challenging as a result of peripheral neuropathy in the feet and can lead to an increased risk of falls and injuries. Biofeedback, in the form of electrocutaneous stimulation, can be used as a means to transmit information about the force and pressure applied to the feet, and this can help people determine their body position in relation to the ground and the amount of sway movements. The motivation for the present work was to explore whether a wearable electrotactile feedback system (EFS) could improve life quality by supporting people with balance instability as a result of this condition. In this study a wearable EFS was designed to estimate the magnitude of pressure applied to the feet during standing and walking. The study also aimed to determine whether the EFS had an effect on posture control in standing and confidence in walking among individuals suffering from peripheral neuropathy.

A wearable EFS has been developed in this work including the hardware design for an electrocutaneous stimulation and a processing unit to compute the sensor data. The EFS uses a sensor system with piezoresitive force sensors that has been developed and tested beforehand. The proposed system considers aspects of safety and portability, as well as meeting individual parameters. The latter one was assured by implementing and testing a novel calibration method for the detection of sensory thresholds and device parameters. A software for magnitude estimation and force and pressure feedback based on the centre of pressure (COP) movement was programmed and a psychophysical transfer function involving sensory thresholds and sensor system variables was implemented. A pilot study with 11 participants was carried out to evaluate the suitability of the EFS for magnitude estimation. Magnitude estimation with the EFS showed high accuracy and sensitivity and it was found that the design proposed in this work is beneficial over other solutions. The upper leg was identified as a suitable location for electrotactile feedback. A proof of concept study was undertaken among 14 individuals suffering with peripheral neuropathy and five controls in a clinical environment, testing the effects of the EFS on balancing and walking in different scenarios. It was shown that, when used by patients with neuropathy, the EFS helped improving posture control in certain scenarios and did not hinder patients during walking. A longer learning period might be necessary so that users can fully benefit from the EFS.

The findings of the study contribute to the understanding of electrotactile feedback and are valuable for further developments of wearable EFS to compensate for sensory impairment and improve activities of daily life for people with sensation loss in their feet.

Keywords: Biofeedback, Electrocutaneous Stimulation, Electrotactile Feedback, Magnitude Estimation, Posture Control, Sensory loss

Publications resulting from this research

Proceedings & Journals

Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J. 2012. Wearable Electrocutaneous Feedback System: A Smart Device to Compensate for Sensation Loss. J. Med. Devices 6(1), 017515.

Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J. 2012. Case Study on Repeatability of a Threshold-Based Calibration Method for Electrocutaneous Feedback Systems. J. Med. Devices 6(1), 017516.

Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J., Choukri M., Swain I. 2012. Applications of Electrical Stimulation and Electrotactile Feedback in Human Spaceflight, 63rd International Astronautical Congress, Naples, Italy, IAC-12,A1,2,7.

Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J. 2011. Electrocutaneous Feedback System to Improve the Estimation of Pressure Applied to the Foot, Biodevices 2011, International Conference on Biomedical Electronics and Devices. 1(1), pp. 386-390.

Conferences & Talks

Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J. 2012. Creation of Artificial Sensation by Tactile Sensing and Intelligent Stimulation of Sensory Nerves, 3rd DEC Researchers Poster Conference.

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Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J. 2012. Multisensory Intelligent Feedback System for Sensory Substitution using Electrical Stimulation, 4th DEC Researchers Poster Conference.

Jan Walter Schroeder, Venketesh N Dubey, Tamas Hickish, Jonathan Cole, 2012. Wearable Electrocutaneous Feedback System: A Smart Device to Compensate for Sensation Loss, 5th DEC Researchers Poster Conference.

Schroeder, J. W., Dubey, V. N., Hickish, T. F., Cole, J. 2012. Electrotactile Feedback System: A Medical Device to Improve Balancing and Pressure Estimation for Patients Suffering from Loss of Sensation in their Feet, Bournemouth University's 4th Annual Postgraduate Research Conference.

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Jan Walter Schroeder, Venketesh N Dubey, Tamas Hickish, Jonathan Cole, Electrotactile feedback system for people with sensory loss (filed, but not granted due to insufficient funds)

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Dedication

I dedicate this work to two people. First to my godfather, Walter Gaier, who helped me to choose the path I have taken. May he rest in peace. And second to his father and my grandfather, Rudolf Gaier, who suffers from peripheral neuropathy in his feet caused by Diabetes and was always an inspiration for me during the time of my doctoral studies. His optimism and kindness shall never be forgotten.

Author's Declaration

This report contains the original work of the author except otherwise indicated.

Glossary

A	Area
A/D	Analogue-Digital Converter
AC	Alternating current
ADL	Activities of daily live
AP	Anterior-Posterior
BAS	Base of support
COG	Centre of gravity
COM	Centre of mass
COP	Centre of pressure
DC	Direct current
EC	Eyes closed
EEPROM	Electrically Erasable Programmable Read-Only Memory
EFS	Electrotactile Feedback System
EO	Eyes open
ES	Electrical Stimulation
ESD	Electrical Stimulation Device
f	Frequency
FES	Functional Electrical Stimulation
FM	Frequency modulation
I	Current
IP	Intellectual Property
ISA	Instruction set architecture
KB	Kilobyte
MHz	Megahertz
MIPS	Million instructions per second
ML	Medial-Lateral
OF	On foam
p	Pressure
PAM	Pulse Amplitude Modulation
PCB	Printed Circuit Board
pw	Pulse width
PWM	Pulse Width Modulation
RISC	Reduced instruction set computer

SRAM	Static random-access memory
TENS	Transcutaneous electrical nerve stimulation
TUG	Timed up and go
V	Voltage

"It is a mistake to think you can solve any major problems just with potatoes."

Douglas Adams (1982)

Chapter 1 Introduction

Impairment of the sensory system often results in limitations in performing daily life activities and increased risk of injuries. The research presented in this thesis, involved the design of a wearable electrotactile[1] feedback system (EFS) and studied the accuracy and sensitivity of force magnitude estimation, as well as its effects on balance and gait of individuals with sensory impairment caused by peripheral neuropathy[2]. Both, technical and medical, considerations were taken into account for the development of the system. A study was undertaken to test the hypothesis that such a device could potentially help people with reduced sensation to compensate for their impairment by improving estimation of magnitude, posture control and confidence in walking.

1.1. Motivation

Many individuals suffer from reduced sensory input in their feet which can lead to balance instability when standing still or walking (Kim et al. 2013; Smith and Torrance 2012; Kanade et al. 2008; Cole 1995; Lord et al. 1991). Balance is dependent on the processing of information from the vestibular[3] system, visual perception and somatosensory system[4], including mechanoception and proprioception. These are processed in the human brain enabling body positioning to be altered in order to achieve stability. Impairment of the somatosensory system is a common disorder and is a result of morbidities that damage the sensory nerves.

The elderly population is more prone to this impairment with an estimate of 8% in the age group over 55 and 2.4% among the population worldwide (Hughes 2002) Diabetes Mellitus is one of the main causes for this impairment since it can result in nerve damage, leading to a reduced sensation in the extremities, particularly in the feet (Kasthuri et al. 2000). Additional causes include the effects of chemotherapy, infection illnesses (HIV), idiopathic polyneuropathy and leprosy (Tofthagen et al. 2012; Bales and Meals 2009; Marcus et al. 2006; Hughes 2002; Cornblath and McArthur 1988).

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[1] Electrotactile means creating the sensation of touch by using electrical stimulation of the skin through electrodes.

[2] Peripheral Neuropathy is term that is used to describe reduced or no sensation in the extremities, arms or legs, and is caused by nerve damage.

[3] The vestibular in the inner ear sends information about spatial orientation to the brain which is needed to stand upright.

[4] The somatosensory system is an umbrella term for nerve cells in the human body that detect tactile stimulation, like touch and pressure (mechanoception) but also the position of body parts to each other (proprioception). For balance the pressure distribution on the feet and position of the ankles are mainly contributing as a source of information.

The reduced or non-existing sensation in the feet can lead to balance instability and consequently, increase falls risk and injuries of affected individuals (Cimbiz and Cakir 2005; Riskowski et al. 2012; Gulbandilar et al. 2008; Kanade et al. 2008; Spirduso et al. 2005). It was found that accidental falls are the fifth leading cause of death amongst the elderly (Ochs et al. 1985) and they are a result of a combination of factors, some of which are of both a psychological and muscoskeletal nature (Rubenstein 2006). Additionally individuals with neuropathy have a lack of an awareness of tissue damage putting them at higher risk of developing ulcers. There are also associated limitations in the performance of useful motor tasks due to the lack of somatosensory feedback (Cole 1995) and simple activities such as driving a car can become impossible.

Therefore, the motivation behind this research is to help individuals with sensory impairment by improving their ability to estimate the pressure[5] that is applied to their feet. As a result this might have remarkable impact on one's ability to carry out basic tasks such as walking, standing and driving and other activities of daily life (ADL). A suitable biofeedback system could give feedback about the pressure applied to the non sensing feet and allow its user to estimate the magnitude of the pressure. Electrotactile feedback is a form of biofeedback which can potentially help to compensate for reduced sensation in the feet. In the form of a wearable device it would inform the wearer of the pressure applied to their feet by redirecting it to other parts of the body via electrocutaneous stimulation[6] of the skin. The pressure is detected via a sensory system and the information is processed. Electrodes that are placed on a location with sensing skin transmit a tickling tactile[7] sensation depending on the pressure information. This feedback can be used to transmit information by changing the magnitude of the pulse so that the wearer can feel the feedback and be conscious about the pressure applied to the feet and react accordingly. In the case of balance disorder, the additional tactile information about the displacement of the centre of pressure as an indicator for balance, might lead to a correction in body position and thus resulting in an improvement in stability. Additionally the feedback given by the EFS could potentially heighten an individual's senses and awareness of the movement and direction of their feet by raising the awareness when the foot touches the ground, which consequently could reduce falls and injury risk[8].

Summarising these points, the motivation for the research was to help people with impairment of their sensory system through using a wearable EFS improving their living conditions and ability to live a normal live.

1.2. Objectives

The main aim of this study was to design and develop a wearable electrotactile feedback system to assist people with limited sensation in their feet to improve

[5] Force and pressure are proportional to each other, as pressure is the force applied over a certain area. Therefore the two terminologies are used likewise when explaining the device functionality.

[6] Electrocutaneous stimulation means electrical stimulation of the skin via surface electrodes, while the current of the stimulation flows from one electrode to the other through the skin.

[7] Tactile describes something that is related to touch.

[8] Individuals with neuropathy are often not aware that their feet are opposed to pressure, thus resulting in unstable walking and tissue damage.

magnitude estimation, balancing and walking. In order to achieve this, the following primary objectives were set:

(i) Development of hardware and embedded[9] software for a wearable EFS

(ii) Evaluation of accuracy and sensitivity for magnitude estimation using the developed biofeedback system.

(iii) Proof of concept of the system functionality for improving balance and walking in a clinical study with patients suffering from neuropathy

The secondary objectives of the study included the following points:

(iv) Identification of an appropriate force sensing technology and parameters for optimised electrotactile feedback

(v) Development of a measurement system for analysing balance behaviour

The design of a wearable EFS should meet several requirements to ensure optimal functionality. The following design criteria need to be considered including: Safety to the user, individual physiological requirements, user preferences regarding device parameters, technical aspects and limitation of the hardware and software, practicability in relation to portability, user friendliness, low-cost approach and use of off-the-shelf components.

With regard to safety it is necessary to ensure that the wearer is not at risk of harm. This mainly concerns the use of electrical stimulation. A wrong placement of the electrodes or inappropriate pulse parameters might lead to an uncomfortable feedback and needs to be avoided. It is also necessary to consider each individual's preferences when developing an EFS, because each person has different psychophysical requirements (Fechner 1860) and stimulation thresholds for sensation and discomfort. This can influence on how effective the electrotactile feedback is, therefore the device needs to be calibrated with each participant.

Technical aspects which have to be considered are the requirements of the software used to operate the device and the correct implementation of hardware components which are integrated on the device's Printed Circuit Board (PCB)[10]. Another factor is the practicability and the design considerations for a wearable device. As there is no product commercially available which delivers the combined functionalities listed above, the costs of the components should be also taken into consideration preferring off-the-shelf components for the design.

Another objective includes testing the accuracy and sensitivity of electrocutaneous stimulation for magnitude estimation and determining whether the developed device improves posture control in balancing and walking. Secondary objectives are the identification of a sensor system that allows detection of pressure applied to the feet as well as the development of a measurement system for the analysis of posture control.

[9] Embedded software is the programming code on a microcontroller.

[10] A Printed Circuit Board (PCB) is the electronic hardware part of an electronic device with all its components.

1.3. Methodology and Contributions

The main contributions are summarised below:

- Hardware development of a novel wearable electrotactile feedback system (EFS)
- Development of a shoe insole based sensor unit for balance detection
- Programming of intelligent agent based embedded device software
- Newly developed training routines allow individualisation of the EFS
- An investigation of magnitude estimation with the EFS with 11 study participants
- Accuracy and sensitivity of PWM were found better than comparable methods
- Development of a measurement system for balance analysis and visualisation
- Design of a clinical trial with 14 patients with neuropathy and 5 control subjects
- Studying the effects of the EFS on posture control in various balance scenarios
- Improvement of balance was shown when study participants had their eyes open

Based on pre-tests with commercial electrical stimulators and literature research a novel wearable EFS was designed and assembled. A practical approach towards a portable device was taken and innovative design ideas were used with low-cost components. Piezoresistive[11] force sensors were identified to be suitable for the present approach due to their costs and established application experiences in the field of force and pressure measurement. The device that has been developed contained a sensor unit with four force sensors which were integrated into a shoe insole. Four pairs of electrodes as well as a unit to process sensor information and create electrotactile feedback in the form of electrocutaneous pulses were also integrated to create a tactile sensation.

An algorithm using an intelligent agent has been developed and implemented on the EFS. The agent concept implies a training routine to detect individual and device specific parameters. The information is later used to dynamically generate an electrotactile feedback based on the centre of pressure (COP) movement at the feet. During the training routine the user's thresholds of sensation and discomfort for electrotactile feedback are detected. The routine was tested in a preliminary test showing that thresholds could accurately be detected. In the training routine the EFS also detects the wearer's centre of pressure[12]. The developed algorithm uses the information of the COP and the threshold to automatically create a transfer function to transform information from the sensor unit of the EFS into electrocutaneous stimulation when the device is used for balancing and walking.

[11] Piezo-resistive force sensors are a made of a material which changes its resistance when load is applied to the sensor area. By measuring the change of resistance with an appropriate circuit the original force can be measured.

[12] The centre of pressure (COP) is a term to describe the vector that represents all forces that are acting on a surface. In balance analysis it is used as a indirect measure for postural sway.

In a pilot study with 11 test participants magnitude estimation was tested with electrocutaneous stimulation. The psychophysical power function [13] for all test participants was derived and compared with the work of others. It was shown that the upper leg was an appropriate area for force feedback allowing high accuracy and sensitivity. The aim of the study was also to identify if pulse width modulation (PWM)[14] has any drawback compared to pulse amplitude modulation (PAM) and frequency modulation (FM) for force magnitude estimation. The study revealed that PWM is beneficial over PAM and FM in certain scenarios and should be considered in future device designs.

A balance measurement system has been developed using the COP as an indicator of balance. This balance measurement system contains a hardware based setup of four force sensors and a unit to send the sensor information to a PC as well as a program in Matlab to analyse the data. In addition the program gives visual feedback to warn a user of a potential unstable posture as well as allowing automatic analysis of COP parameters based on recorded data.

A clinical study was undertaken among 14 patients with neuropathy and 5 control subjects testing the effect of the developed EFS for posture control in different scenarios. The tested scenarios included balancing during eyes open (EO), eyes closed (EC), on foam pad (OF) and walking. Participants improved their balance significantly during balancing with eyes open, while neither decline nor an improvement was observed in the other scenarios.

In conclusion the wearable EFS was suitable for force magnitude estimation and improved posture control in patients with neuropathy when they had their eyes open. The current study significantly contributed to the field of electrotactile feedback systems and showed that this technology can have a positive impact in improving the life quality of people suffering from neuropathy in their feet.

1.4. Outline

The thesis is divided into eight chapters. Further in the appendix a CD is provided containing programming code in C and Matlab, in addition to an ethical approval application for a clinical study and publications resulting from this research.

Chapter 2 explains the background for the design of an electrotactile feedback system. At first the somatosensory system is explained to give an overview of the physiological processes within the nervous system, as well as how tactile and proprioceptive perception works and how it is used in balance. Further the basic principles of electrocutaneous stimulation are explained. Finally a literature review of current research in the field of electrotactile feedback systems is presented.

Chapter 3 explains the design process, prototyping and testing of the EFS. The functional principles of force sensing technologies are explained and different, modelling touch sensation, sensors are analysed, with a focus on piezoresistive force sensors. Then components of the device that was developed for this research are

[13] A power function is a function often used to fit data to a curve of the form $y = b*x^m$ and can be used to describe the sensitivity in a magnitude estimation experiment (Marcus and Fuglevand 2009).

[14] Pulse-amplitude modulation (PWM) is the change of voltage and consequently current of a pulse, while pulse-width modulation changes the time period that a pulse is applied.

described. The chapter finishes with the presentation of some preliminary test results to demonstrate the functionality of the developed EFS.

In Chapter 4 the software architecture of the device is discussed. The software is explained in (Unified Modelling Language) UML diagrams[15]. First the training routine is shown. Then the intelligent agent based principle of the program is explained and the rule base is discussed.

Chapter 5 evaluates force magnitude estimation with the device that was developed. In this chapter a pilot study with the device is presented. Pulse width modulation was evaluated concerning accuracy and sensitivity when used for electrotactile feedback.

Chapter 6 explains how the balance analysis system was developed. It discusses the methods to analyse balance and explains the real time system for the visualisation of balance movement and balance parameters.

Chapter 7 presents the clinical study carried out at Royal Bournemouth Hospital and results are presented. The measurement system from Chapter 6 was used to verify and analyse the balance of the study participants while performing several tasks designed to test their postural control.

Chapter 8 summarises the work, explains the contributions in more detail and gives an insight in prospective future research projects.

[15] UML diagrams are used to describe abstract relationships between objects when explaining software or processes

"We see with our brains not eyes."

Paul Bach-y-Rita

Chapter 2 Research background

2.1. Abstract

The somatosensory system is essential for motor control and underpins the capture and transmission of information about touch, movement, position sense and orientation of body parts (proprioception), to the brain. The loss of somatosensation, caused by nerve damage, leads to an inability to move as well as absence of cutaneous sensation and consequently strong limitations in activities of daily life (ADL). Biofeedback with electrocutaneous stimulation can potentially support sensory substitution to improve ADL. The understanding of the underlying physiological aspects of the sensory system is essential for the design of a wearable electrotactile feedback system (EFS) which might help to compensate for absent sensation.

This chapter explains the somatosensory system and its importance in maintaining balance, as well as the functional principles of electrical stimulation and its applications for sensory substitution. A systematic literature research was carried out to summarise related work in the field and previous studies were evaluated and discussed. Little research exists in the design and testing of EFS and there remain open questions in the usage of a wearable EFS for magnitude estimation and as a means to improve balance and walking.

The literature research carried out in this chapter forms a basis for the design and study of a wearable EFS and justifies further research, as EFS has the potential to improve the quality of life of people with sensation loss in the feet.

2.2. Somatosensory system

2.2.1. Neural Information Processing

To explore the physical environment, the human body has sensory receptors that process and conduct information to the brain, where the information is decoded and elaborated into perception (Kandel et al. 2000). The nervous system consists of two cell types: the neurons, also called nerve cells, and the glial cells. The glial cells are not directly involved in information processing, but they have several functions to support the neurons, e.g. producing myelin used to insulate nerve cells.

The human brain contains at least 10^{11} neurons of various types. Sensory neurones are essential for information processing in the nervous system, transmitting sensory signals as well as muscle stretch signals through an electrical charge. The neuron consists of the cell body, dendrites, the axon, and presynaptic terminals (Fig. 2.1). There are different kinds of neurons in the nervous system, which are adapted to their function, but all of them work with the same basic principle.

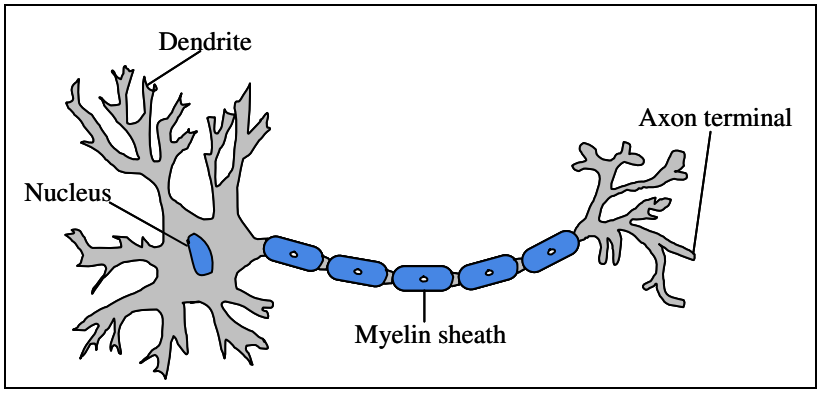

Fig. 2.1: Neuron Basic structure of a neuron[16]

Two types of cell processes arise from the cell body, axons and dendrites. Axons are the transmitting element of neurons with a length of up to over a meter within the body and a diameter between 0.2 µm and 20 µm (Freberg 2009). The neurons with the largest diameter in a peripheral nerve are called A-α fibres and are usually the motor nerves, while the slightly smaller A-β fibres are the sensory nerves. Both of these large neurons are insulated by myelin, a fatty sheet that surrounds the axon which allows fast conduction velocities of ~ 50m/s. A-δ fibres, though slightly smaller are also involved in sensory transmission. The smallest myelinated and unmyelinated C fibres subserve pain and temperate perception and conduct at 0.2 - 1.5 m/s (Marcus et al. 2006; Johnson 2001). Electrotactile feedback targets the sensory nerve fibres, so that no motor activation is triggered.

2.2.1.1 Neurotransmission

The cell conducts a signal that travels along the axon through an electrical impulse called an action potential. The action potential exits the neuron at the axon terminal and is conducted via synapse and neurotransmitters to the cell body and dendrites of the next cell, which can have several connections to other axon terminals. One neuron can have up to 150.000 connections with other nerve cells (Chorost 2011).

The process that causes this process between neurones is called neurotransmission. When an action potential arrives at the axon terminal, it triggers the release of neurotransmitter molecules that open ion channels in the next nerve cell (Fig. 2.2). Only certain ions can go through these channels inside the cell and change the potential between both sides of the cell membrane, which results in the triggering of a new action potential.

[16] Image based on Wikipedia article: Neuron (www.wikipedia.de, accessed 05/11/2010).

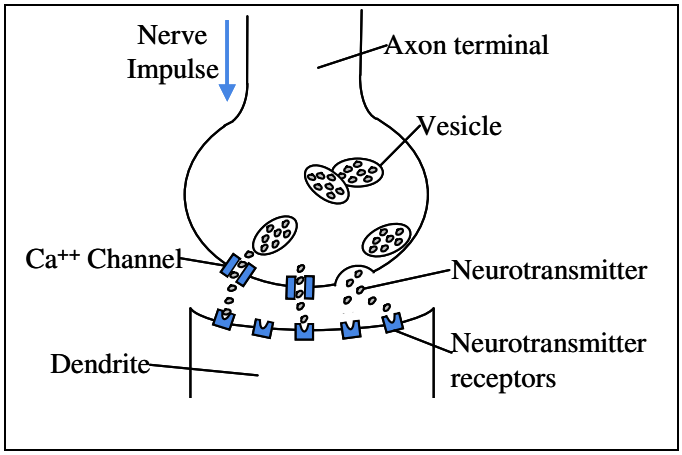

Fig. 2.2: Synaptic transmission and neurotransmitters (Julien 2005)

2.2.1.2 Action Potential

In a neutral state all cells have a difference in the electrical potential on either side of the cell membrane, the resting membrane potential (V_m) which is defined as

$$V_m = V_{in} - V_{out}, \quad (1)$$

where V_{in} is the potential on the inside of the cell and V_{out} the potential on the outside. The electrical difference within a resting neuron is about – 65 mV (Bray et al. 1999). The current that flows into and out of the cells is carried by sodium and potassium ions (NA+ and K+) through the mentioned ion channels. When the depolarization reaches a certain threshold (around -55 mV) the cell opens voltage gated ion channels which produces an all-or-none action potential. All-or-none in this context means that action potentials have the same duration and amplitudes, so the information is encoded by frequency and number of spikes.

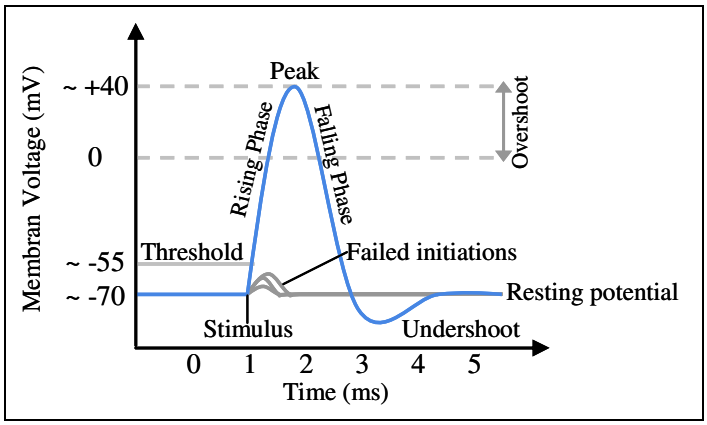

Fig. 2.3: Schematic of an action potential[17]

When an action potential is triggered, the membrane potential reaches a value of about +40 mV at its peak, and then falls back into an undershoot before returning to the resting level (Fig. 2.3). The period before a new potential can be fired is called refraction period and usually lasts for 1 ms. The continuation of the triggering action potential along the pathway of our nervous system allows signals to be transported

[17] Image based on Wikipedia article: Neuron (www.wikipedia.de, accessed 05/11/2010).

throughout the body. Axons can be myelinated or unmyelinated. The propagation along a myelinated axon is called saltatory conduction and is faster than for unmyelinated axons. The signal moves with a speed of up to 50-60 meters per second in an adult's largest fibres. The trigger which causes action potentials to process tactile information is the physical deformation of the skin (Kandel et al. 2000).

2.2.2. Sensation of touch

Skin can be seen as a hybrid system of a viscoelastic media including the dermis, active sensors and the mechanoreceptors (Maheshwari and Saraf 2008). These Mechanoreceptors are located very close to the first layer of the skin, the epidermis. A tactile stimulus is transformed by mechanoreceptors into electrical impulses which travel through the neural pathways to the brain. The area in the brain that is decoding the information for touch sensation is called somatosensory cortex (Fig. 2.4-A). The cortical homunculus in Fig. 2.4-B shows the anatomical divisions by various body parts in the somatosensory cortex for sense information (Penfield and Jasper 1954).

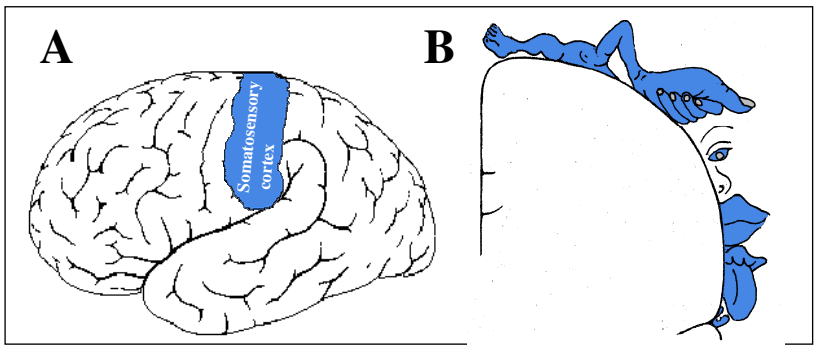

Fig. 2.4: Somatosensory cortex: Brain with somatosensory cortex (A) and sensory homunculus (B) (Penfield & Jasper, 1954)

2.2.2.1 Mechanoreceptors

Mechanoreceptors are nerve endings that create an electrical impulse when they are transformed. They are mainly embedded in the skin. Fig. 2.5 shows the location of mechanoreceptors in the human skin (Kandel et al. 2000), which are located at the meeting point of epidermis (the first layer of the skin) and dermis (the second layer of the skin).

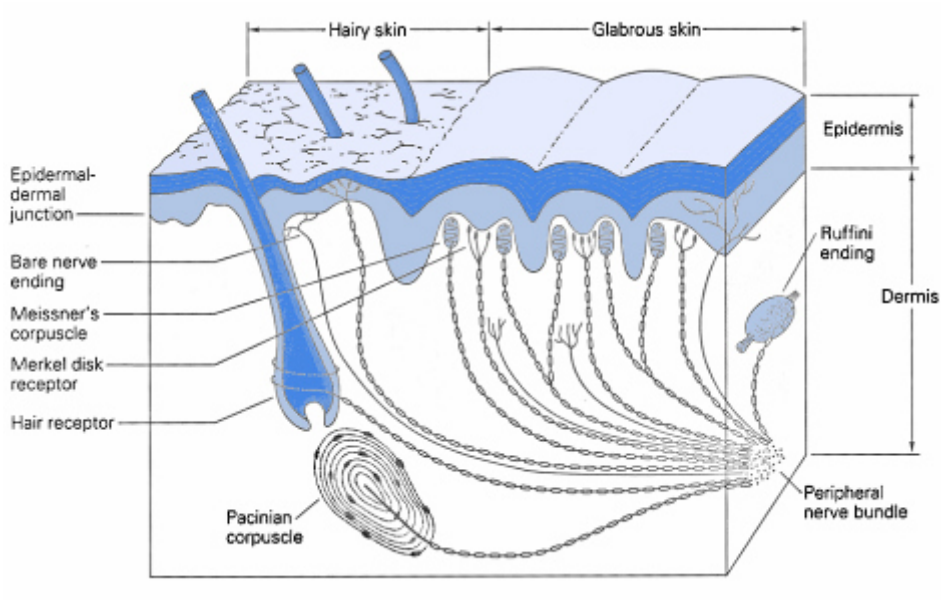

Fig. 2.5: Receptors in the skin : Model of the skin showing different receptors and their location[18]

There are several mechanoreceptors in the human skin that underpin the perception of contact with an object (Tab. 2.1)

- Meissner's corpuscle: sensitive to changes in texture
- Pacinian corpuscle: sensitive to gross pressure changes and vibrations
- Ruffini's end organ: sensitive to tension, shear forces, deep in the skin
- Merkel's disc: sensitive to touch and pressure
- Bare nerve endings and hair receptors

These end organs have differing sensitivities to tactile pressure and have differing receptive field sizes, some being small and therefore underpinning localisation whereas others are larger with lower forces required and so bring attention to an area. Electrical stimulation of mechanoreceptors creates the same feeling as a physical stimulation (Macefield 2005).

Merkel cells and Meissner's corpuscles are the primary receptors involved in tactile perception. The sensations elicited by artificial stimulation differ from each other. When Meissner's and Pacinian corpuscle are stimulated a frequency dependent sensation of vibration is perceived (Macefield 2005). The stimulation of Merkel disks produces the sensation of a constant pressure on the skin.

Merkel cells are associated with large and myelinated Aβ fibres, which have a diameter of 7-12 µm and conduct at velocities of 30-70 m/s. (Marcus et al. 2006; Darian-Smith 1984; Johnson 2001). The receptors are classified as slowly adapting type I (SAI) receptors. SAI receptors respond to several aspects of a mechanical stimulus and are sensitive even to a small stimulus (Johnson 2001).

[18] Adapted from Kandel (2000) and Marcus (2006).

Receptor type	Fiber group	Modality	Fibre diameter (µm)	Conduction velocity (m/s)
Mechanoreceptors				
Meissner's corpuscle	Aα, β	Stroking, fluttering	12-20 (α), (6-12) (β)	72-120 (α), (36-72) (β)
Merkel disk receptor	Aα, β	Pressure, Text	"	"
Pacinian corpuscle	Aα, β	Vibration	"	"
Ruffini ending	Aα, β	Skin stretch	"	"
Hair-tylotrich	Aα, β	Stroking, fluttering	"	"
Hair-down	Aδ	Light stroking	1-6	4-36
Field	Aα, β	Skin stretch	12-20 (α), (6-12) (β)	72-120 (α), (36-72) (β)
Nocireceptors				
Mechanical	Aδ	Sharp	1-6	4-36
Thermal-mechanical	Aδ	Burning pain	1-6	4-36
Thermal-mechanical	C	Freezing pain	0.2-1.5	0.4-2.0
Polymodal	C	Slow burning pain	0.2-1.5	0.4-2.0

Tab. 2.1: Mechanoreceptors and Nociceptors : Receptors showing their fibre group, sensation modality, size and conduction velocity [19] . Thermal receptors and muscle and skeletal mechanoreceptors are not listed as they are not relevant for the presented approach.

Meissner's corpuscles are primarily found in glabrous[20]skin (McGlone et al. 2012). They are specialised for detection of phasic signals such as identification of motion across the skin or vibration (Darian-Smith 1984). They respond to deformation of skin in the range of 100 µm and at frequencies between 2-300 Hz (Marcus 2006). Similar to the Merkel cells, they are associated with Aβ fibres and therefore conduct action potentials at 30-70 m/s (Birder and Perl 1994).

Pacinian corpuscles are fluid filled lamellae and are very sensitive to vibration exceeding the sensitivity of Meissner's corpuslces as they respond to deformations of only a few micrometers and are located deeper in the skin than Merkel cells or Meissner's corpuslces. They are slow adapting receptors (SAII) (Darian-Smith 1984). Ruffini endings are similar to Pacinian corpuscles SAII fibres and they are primarily sensitive to skin stretch and play a substantial role in proprioception particularly in the hand (Johansson and Vallbo 1983). The hair receptors are likely to be in the location of electrical stimulus. Their afferent nerve endings are similar in morphology to Meissner's and Merkel afferent and they are sensitive to light touch or vibration (Anstis et al. 1978; Darian-Smith 1984; Birder and Perl 1994).

Reception of pain and discomfort is processed by Nociceptors, classified in two categories. The Aδ fibres, conducting at 4-30 m/s are associated with sharp and fast occurring pain, while the thin and unmyelinated C fibres transmit the information at a much lower speed of 0.2-4 m/s, creating a long lasting or burning pain (Marcus et al. 2006). The stimulation of nociceptors should try to be avoided when applying electrical stimulation with an EFS to make the stimulus as comfortable as possible. This can be done by detecting the threshold of stimulation intensity that activates the nociceptors set this as the upper boundary when applying electrical stimulation. Since the threshold of stimulation intensity for nociceptors is higher than for mechanoreceptors stimulation stays in a non harmful range.

[19] Adapted from Kandel (2000).

[20] Glabrous skin is external skin with no hair.

2.2.2.2 Information pathway

The information pathway of a tactile stimulus is shown in Fig. 2.6. As soon as an action potential in a perceptual sensor was triggered e.g. in the feet or the leg the signal conveys through the larger nerves in the leg, namely the femoral nerve, sciatic nerve, tibial nerve and common fibular nerve (Grey 2008) leading into the spinal cord. After travelling through the spinal cord the signal enters the cerebral cortex through the dorsal column medial leminiscal pathway for tactile and proprioceptive perception, and the anterolateral system for pain perception. The signals leaves the spinal cord and synapse through the medulla into the dorsal column nucleus and continue to the contralateral thalamus. From there the nerve signal projects into the primary somatosensory cortex (Fig. 2.4) (Jones and Powell 1973) where the stimulus is interpreted as touch (Kaas 1983). The intensity of a stimulus arriving from the information pathway is encoded in two different ways. Firstly, through the number of nerve fibres involved and secondly through the firing rate of the action potentials (Knibestöl and Vallbo 1980).

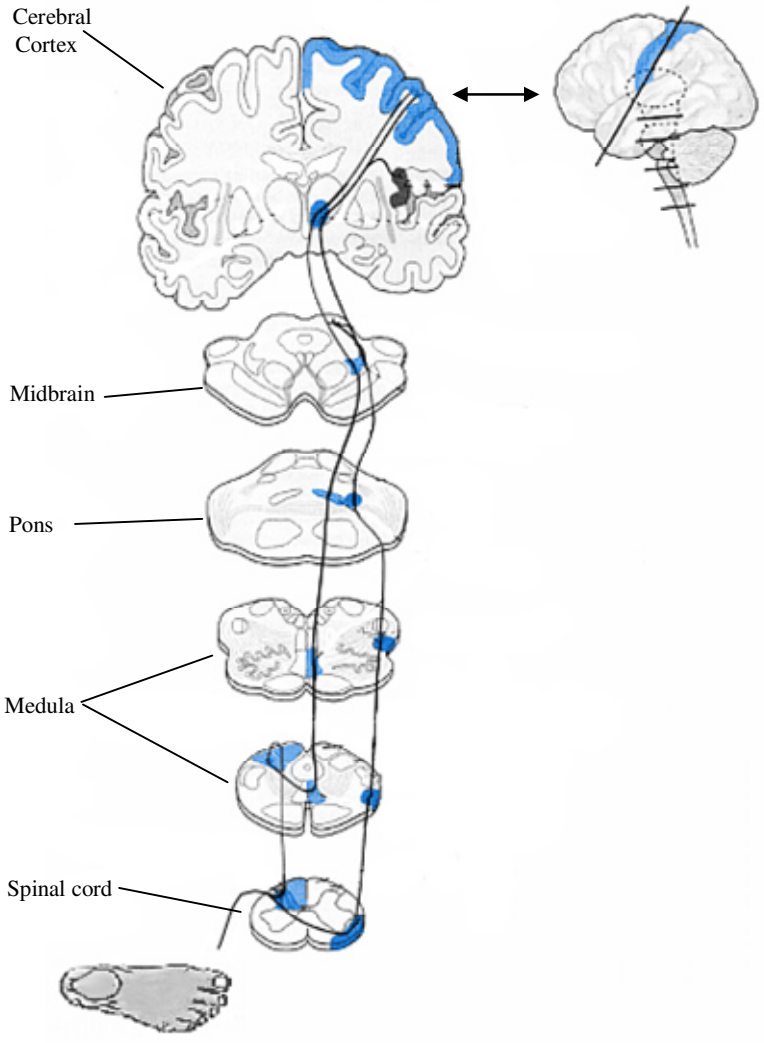

Fig. 2.6: Information pathway: Information is processed from the feet to the somatosensory cortex[21].

[21] Adapted from Kandel (2000).

2.2.2.3 Peripheral neuropathy

Peripheral neuropathy means the damage of nerves resulting in partial or total loss of functionality or sensation. There are over 160 Million people worldwide with a prevalence of peripheral neuropathy and the number is on the rise, while diabetes mellitus is the most common cause of it (Bales and Meals 2009). Several other diseases and comorbidities can also cause damage to the nerves:

- Cancer (nerve damage after chemotherapy)
- Idiopathic polyneuropathy
- Infectious diseases (Typhus, Aids)
- Diseases after toxication (Alcohol, other toxics)
- Leprosy

Different patterns of peripheral neuropathy affect different parts of the body while the most common one is peripheral polyneuropathy, which mainly affects the feet and legs. Symptoms of peripheral neuropathy encompass loss of sensation and movement and position sense or proprioception. With no sensation feedback, daily tasks like driving a car, become extremely difficult due to the lack of force feedback. Other problems are the lack of pressure estimation that results in balance instability (Kanade et al. 2008) and a lack of awareness of harmful pressure in the feet, which can lead to tissue damage. Patients are often present with numbness or tingling and have difficulties walking in the dark.

Neuropathy is either primary axonal or primary demyelinating (Bromberg 2013). Diabetes leads to axonal neuropathy. The high glucose levels associated with diabetes lead to microvascular damage of the axons (Malik 2005) which causes a disconnection of the fibres from the sensory nerves or motor nerves. On the other hand damage to the myelin sheet in demyelinating neuropathy limits the cable properties of the nerves and slows down or blocks conduction in affected fibres (Waxman 1982).

2.2.3. Balance and posture

Balance, also called postural stability, is a term that describes the dynamics that are involved in the process of changing the body posture to prevent a fall during standing and walking. It is an essential task in locomotion and allows one to explore its environment. Balance can be classified into dynamic stability as in walking, and in static stability as in standing. For the latter one, stable stance or body equilibrium, are terms that are used to describe a stable condition when standing still. For analysing balance the forces acting on the body and characteristics of body segments are studied, while the body posture describes the orientation of different parts of the body relative to the gravitational vector (Winter 1995). Usually the centre of pressure (COP) or the centres of mass (COM) or gravity (COG) are used to describe balance. The difference between COM and COG has been recognized (Spaepen et al. 1977) and should not be confused.

The centre of mass (COM) describes the location of the average weight of all body parts in a 3 dimensional space. It is a passive variable that is controlled by the active change of posture. The vertical projection on the ground is called centre of gravity (COG) and is measured in metres in a two dimensional coordination system (Winter 1995).

The COP is the location of the vertical ground reaction forces that are acting on the base of support (BAS), which is the area of the body that is in contact with the support surface (Shumway-Cook et al. 2000). The COP represents a weighted average of all pressures on the surface that are in contact with the ground. If one foot is on the ground and the other one is lifted then the COP value relates to the foot in contact with the ground. Often a single force platform is used to measure the COP and in that case net COP is measured, which is the combined COP of both feet. To measure the COP of each respective foot, when both feet are on the ground, two force platforms are needed. The COP under each foot is a direct reflection of the neural control for changing the position of the body and ankle on the foot. Movements involving plantar flexion and dorsiflexion result in a COP movement in the anterior posterior (AP) direction while movements in a right angle to the AP direction result in a COP movement in the medial lateral direction (ML). The COP is measured in metres (Winter 1995). When the body is kept in equilibrium during balancing the COP movement is minimal. A lower COP movement is therefore an indication for stable stance. During walking the COP travels from the heel over the midfoot to the big toe before the foot is lifted (Rodgers 1988). Balance involves several neural processes working in coordination which each other. Sensory and perceptual processes involve:

- Vestibular: System in the inner ear to detect position changes
- Vision: Eyesight provides detection of the surrounding environment
- Somatosensory system: Uses proprioception and the sensation of touch to feel a change in posture

Furthermore the motor processes are necessary to perform the posture control action. This includes the organisation of muscles throughout the body by coordinating several neuromuscular processes. Motor information is coming from the cerebral cortex and transmitted through the spinal cord to activate muscles (Kandel et al. 2000). The reaction time to a stimulus is dependent on the modality of the stimulus.

2.2.4. Reaction time

There are higher level processes involved in posture control which are essential for responding to sensational information in the form of an action, such as the modification of a motor task in response to a changing environment (adaptive) or based on previous learning experiences (anticipatory) (Shumway-Cook et al. 2000). It was shown that anticipatory response time can be increased significantly by learning (Nashner 1976). While a countermeasure for imbalance involving a supporting step can start at 600 ms before the foot is lifted, other tasks such as tilting an ankle to react to a moving surface can be as short as 75 ms (Kandel et al. 2000). A balance aid can inform its user of his current state of balance. The time it takes until a stimulus causes a voluntary reaction is dependent on several factors. According to (Kandel et al. 2000) reaction time to a proprioceptive stimulus can range from 80-120 ms, while the shortest latency for a mono-synaptic reflex is 40 ms. This difference in latency is mainly as a result of the synapses being involved in the afferent input and the motor output. The reaction time to visual input is between 150-180 ms, due to the amount of synapses in the retina (Kandel et al. 2000). It is not possible to calculate more accurate reaction times because the summation time of synapses varies too much and the reaction time also increases with the choice of

alternatives. The repetition of a certain task decreases the reaction time as stimuli become predictable (Kandel et al. 2000; Nissen and Bullemer 1987).

The reaction to a tactile or electrotactile stimulus, e.g. to change the body posture, is a cognitive process. The sensory information is processed in the cerebellum cortex before an action is triggered (Ivorra et al. 2008). The total reaction time to a tactile stimulus performing a cognitive action was found to be 300 ms. Learning to improve reaction times for balancing can be necessary when sensation loss appears in the feet or occurs suddenly such as after a stroke (Geurts et al. 2005). Especially if only one foot is affected, a person may be hesitant to shift weight to the affected limb which, in turn, limits balance control (Turnbull et al. 1996). In such cases balance training is an important rehabilitation procedure (Winter 1995). The aim of such balance training is to compensate for the impairment of a sensing modality involved in balance with the use of other sensory information.

2.2.5. Biofeedback and sensory substitution

Sensory substitution means the compensation for sensory loss by using sensory information from another functioning sensory modality instead. It is very much related to the term neuroplasticity which refers to the ability of the human brain to change and strengthen the connections of nerve cells. Research in sensory substitution goes back to the year 1969, when Bach-y-Rita et al. studied visual substitution by tactile image projection (Bach et al. 1969). Visually impaired people were equipped with a device that transferred visual information into tactile information. The authors use 400 solenoid vibrators[22] arranged in a grid (Fig. 2.7-A) to project a video with a resolution of 400 points (Fig. 2.7-B) on the back of the test subjects. The study participants could differentiate between objects, and reported to perceive the sensory information as coming from the front rather than coming from the back where the actual feedback unit was placed.

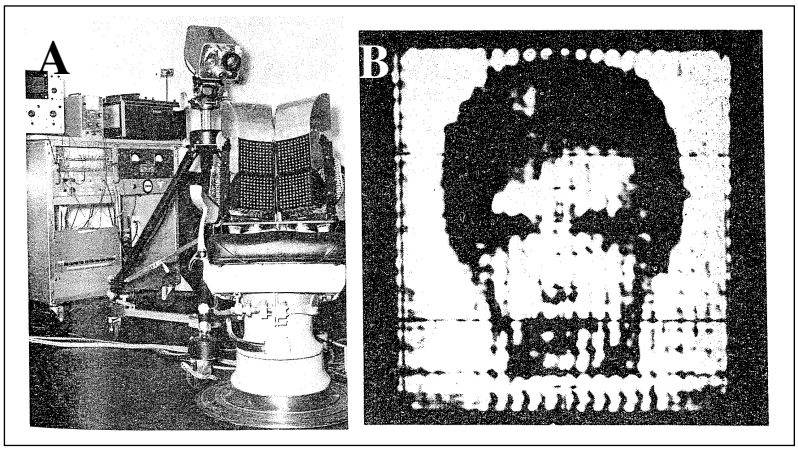

Fig. 2.7: Vision substitution system (A) and woman image with a 400 point resolution (B) (Bach y Rita 1969)

Recently the term biofeedback has become more popular to describe systems that allow sensory substitution or sensory enhancement by detecting the environment with sensors and giving feedback via audio, visual or tactile signals. Audio and

[22] Solenoid vibrators are spinning magnet based motors

visual systems were tested previously evaluating its effects on balance improvement. Chiari et al. (2005) presented an audio based biofeedback system that measured the horizontal trunk acceleration with accelerometers. They converted the movement of the trunk into audio signals by modulating the sound frequency. Their results showed that subjects improved their balance by using the audio-feedback system. Barclay-Goddard et al. (2004) analysed 7 trials with 246 participants that were using visual and audio feedback for the improvement of balance in patients after a stroke. They came to contradictive results and concluded that balance improvement was not significant in the analysed studies where audio and visual based biofeedback was used for rehabilitation of patients after a stroke.

Tactile feedback can, amongst other modalities, be based on vibration which affects the mechanoreceptors or electrical stimulation (Kaczmarek, Webster, et al. 1991). The present study aims to design and develop a wearable EFS for the compensation of sensory loss in the feet by redirecting and creating electrotactile feedback to sensing skin. This compensation is related to sensory substitution, since the brain also needs to reinterpret the redirected signals. Electrical stimulation of the skin is used to transmit feedback information.

2.3. Electrical Stimulation

An electrotactile feedback system uses electrical stimulation of the skin to stimulate nerve cells for the simulation of touch sensation. The underlying principles of electrical stimulation has been recognised since 400 BC when the torpedo fish was used in different illnesses. It is now widely used in clinical contexts for pain reduction, functional muscle stimulation and neurophysiological tests (Geddes 1994). Electrical stimulation can be percutaneous (leads that penetrate the skin) or transcutaneous (leads that are connected to the skin surface) (Kuiken et al. 2007). Percutaneous stimulation is invasive and electrotactile devices use transcutaneous stimulation to give feedback.

2.3.1. Transcutaneous Electrical Nerve Stimulation

Transcutaneous Electrical Nerve Stimulation (TENS) is often used to describe wearable devices with pulsed current in the frequency range of 1 to 120 Hz and a pulse duration of about 50-200 micro sec. Stimulus voltage is usually in the range of 10 V to 100 V or more in clinical treatments. At a certain intensity a nerve impulse or muscle contraction occurs. For this purpose up to 100 Hz are used. Stimulus current is usually in the range of 10 mA to 100 mA for clinical treatments (Robertson et al. 2006).

2.3.2. Functional principle of Electrical Stimulation

The basic principle of electrical stimulation is the application of an electrical potential difference to the surface of the skin via electrodes. The electrical balance across the nerve membrane between the location of stimulation is disturbed, which can then trigger an action potential in the nerves that are in the area between the electrodes (section 2.2.1.2). As shown in Fig. 2.8 the electrical potentials that are applied to the skin are defined by the parameters frequency (f), pulse width (w) and amplitude (voltage or current) (section 2.3.3).

The response of different nerve fibres is based on the parameters of the applied pulses (Kajimoto et al. 2003). The relation between pulse width and amplitude (voltage) plays an important role in this context. For pulses with a short pulse width a high current is necessary to create a response and pulse; whereas long pulse width requires a lower amplitude. Larger A fibres are the easiest to stimulate (Tsui 2008), while the smaller C fibres carrying information from the nociceptors need higher current densities.

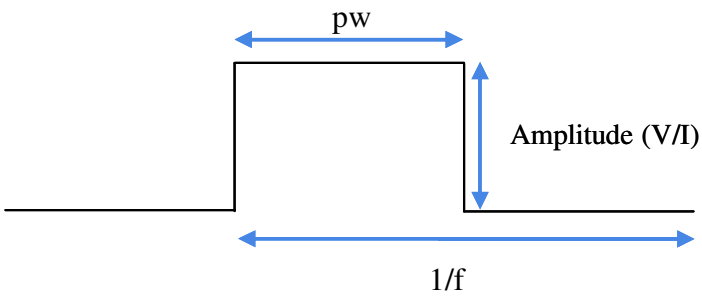

Fig. 2.8: Pulse parameters: Pulse is defined by frequency (1/f), pulse width (pw) and amplitude (V/I). Higher pulse amplitude and pulse width result in a stronger activation of sensory and motor nerves while the change of frequency results in a change of the received sensation.

The response for short pulses is the activation of sensory nerves which is defined by the sensory threshold. With higher currents, above the motor threshold or longer pulse width, muscles are activated. Stronger pulses result in pain. If the frequency of the stimulation is too high, nerves can not respond anymore, because a subsequent action potential can only be triggered after a period of time, called refractory period (Ward and Lucas-Toumbourou 2007). The maximum frequency for nerves to react is in the range of 4-5 kHz (Ward et al. 2009).

2.3.3. Parameters

To create a feedback system that uses electrical stimulation, it is essential to choose the right parameters for the pulses (Fig. 2.8). The parameters of the pulse consist of the pulse amplitude (voltage and current), the pulse frequency, pulse width and pulse shape.

2.3.3.1 Voltage and current

To stimulate nerve fibres electrodes are attached to the skin. The current that flows has to change its direction or intensity steadily, since nerve fibres adapt to a direct current (DC) within milliseconds and no action potentials can be triggered.

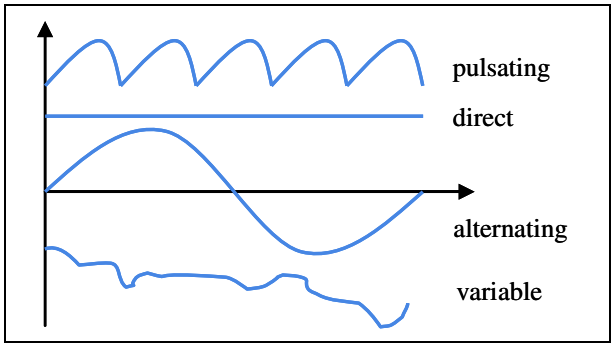

Fig. 2.9: Current modality: Different kinds of current shapes (Kandel et al. 2000)

Therefore, the current has to be pulsating current (PC) or alternating current (AC). (Fig. 2.9). The amount of current that flows from one electrode to another is dependent on the voltage on the electrodes and the resistance of the skin since,

$$V = I \cdot R\,. \qquad (2)$$

Stimulus voltage is usually in the range of 10 V to 100 V or more, and stimulus current is in the range of 10 mA to 100 mA for clinical treatments. To reach this high voltage, usually the electrical stimulation systems have a transformer integrated into their design (Cheng et al. 2004).

Skin can be seen as a circuit of a capacitor and a resistor (Dorgan and Reilly 1999) with the highest layer of the skin (epidermis) being the capacitor, and the dermis and lower subcutaneous tissue acting as a resistor (Fig. 2.10). The capacitor charges during pulse and discharges afterwards. In this model, it is not considered that skin can change its resistance over time. When electrodes are attached to the skin, it becomes slightly more moist under the area of contact and leads to a higher conductivity. The natural impedance of the skin lies between 50 -200 kΩ and drops down to about 10 kΩ when it is moistened (Tregear 1966). The high current tends to flow through low impedance pores with no moistening. Current is evident where the current density (current per unit Area ($^{mA}/_{cm^{-2}}$)) is greatest so that smaller electrodes lead to a higher density. The nerves which are close to the electrodes are more affected by the stimulation. Consequently, if low current density stimulation is applied to the skin the nerve fibres which normally respond to touch and pressure are the first to be stimulated. With higher current density, nerves which are located more deeply in the skin, like the efferent nerve fibres which activate muscle fibres can be stimulated. If Electrodes are too small (< 1 mm^2) or too large (> 100 mm^2) electrical stimulation tends to create a prickly or painful sensation (Marcus et al. 2006; Szeto and Saunders 1982).

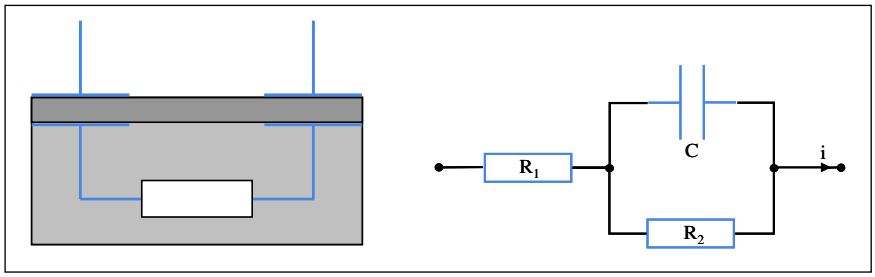

Fig. 2.10: Electronic model of the skin and circuit (Dorgan and Reilly 1999)

2.3.3.2 Pulse width and pulse frequency

A certain pulse width has to be applied to the electrodes to cause an action potential. The pulse width in medical treatment is usually in the range between 5 µs and 1000 µs. The shorter the pulse width, the higher the current must be to trigger the same response. Alon et al. (1983) tested which pulse width leads to painful motor activation. A motor response between 300 to 600 µs is more likely to be comfortable than if a longer pulse of 1 ms or more, is used. With longer pulse duration the range of the upper and lower threshold of comfortable sensation becomes smaller.

Tab. 2.2 shows the relationship between pulse width, voltage and the response thresholds. A pulse width below 5 µs does not trigger any reaction since the nerve fibres cannot respond to such fast changes of potentials (Alon et al. 1983).

The time between two pulses defines the kind of feeling that is produced. A variable related to the pulse frequency is duty cycle

$$D = f \cdot w . \quad (3)$$

The duty cycle D is the product of frequency f and pulse width w and describes how much current flows.

Pain tolerance limit		Sensory threshold		Motor threshold	
Voltage	t_{Pulse} (µs)	Voltage	t_{Pulse} (µs)	Voltage	t_{Pulse} (µs)
400	5	100	5	200	9
250	10	50	10	120	11
150	30	20	30	80	25
100	80	10	80	60	75
80	100	5	100	50	100
70	300	3	300	30	200
60	800	2	800	20	800
50	1000	1	1000	1	1000

Tab. 2.2: Thresholds for motor functions and perception: Threshold concerning pain, sensory and motor stimulation (Robertson et al. 2006) for rectangular pulses of different length

2.3.3.3 Pulse shape

For most applications a rectangular stimulus pulse is used. If the pulse is not rectangular, but rises slowly instead, the nerve fibres can adapt to the pulse. The triggering of an action potential is less likely in that case because the threshold for the trigger is not reached. When starting with an electrical stimulation session, the amplitude of the pulse is usually ramped and started low and then raised to a certain level to avoid startled reactions.

The polarity of the pulse plays an important role when considering toxic accumulations. If a pulse is not unipolar the area under the cathode becomes more alkaline and the area under the anode becomes more acidic. A bipolar pulse is therefore recommended if electrical stimulation is applied for a longer duration (Szeto and Saunders 1982).

2.3.4. Psychophysics in electrical stimulation

The science of Psychophysics goes back to the year 1860 when Fechner described the relationship between the subjective psychophysical experience of a stimulus and the objective applied value of this stimulus (Fechner 1860).

2.3.4.1 Sensory Thresholds

There are three thresholds that need to be considered for the use of an electrotactile feedback system:

- Absolute threshold
- Difference threshold
- Pain threshold

The absolute threshold describes the intensity of stimulus

$$p = k \ln \frac{S}{S_0}, \quad (4)$$

that is detectable by a subject, with a p value of 0.5, while the difference threshold, also known as the just-noticeable difference, describes the intensity variation between two stimuli that are detected as different stimuli. According to the Weber-Fechner law (Weber 1851) the just-noticeable difference of a stimulus in relation to the stimulus intensity can be described asWhere p is the change in perception, S is the increase of the stimulus and S_0 is the absolute threshold. The factor k is an individual factor. The law states that the perception of a stimulus is proportional to the logarithm of the intensity of the stimulus divided by the initial absolute threshold (Weber 1851). However, newer findings suggest that the logarithmic function is one of several possibilities and generally a powerfunction is a more realistic relationship (Murray 1993; Ross and Murray 1996).

2.3.4.2 Detection of thresholds

There are several methods to detect sensory thresholds that can be considered when designing an EFS. The most established methods are the method of limits and the staircase adaptation (Ehrenstein and Ehrenstein 1999). The method of limits involves the change of a stimulus whether by raising the intensity starting with a very low undetectable value or by lowering the intensity starting from a clear detectable value. In the first case, the subject whose threshold is to be defined gives feedback as soon as a stimulus is perceived which is then signed as the threshold. For the lowering method, the subject gives feedback as soon as a stimulus is not detectable anymore. Since the two possibilities for the method of limits, raising and lowering the stimulus can lead to different results it was proposed to mix both methods and average the resulting threshold to give more accurate values (Ehrenstein and Ehrenstein 1999).

Another possibility to detect the absolute threshold is the staircase method (Bekesy 1947). This method builds on the methods of limits. First a value is found with ascending and lowering a stimulus and then an alternating stimulus close to the detected threshold is applied. Data is gathered over a period of time to obtain an average value of the detected stimuli resulting in finding the threshold.

2.3.4.3 Magnitude estimation

Magnitude estimation experiments consist of several stimulus levels which are applied to a subject in random order and the subject has to rate the perceived stimulus. This method was proven to be reliable and repeatable (Marks 1974; Ehrenstein and Ehrenstein 1999; Knibestöl and Vallbo 1980). To improve the consistency of an experiment involving several subjects, a standard stimulus is applied to a subject before a trial starts and is asked to scale subsequent magnitude estimates according to this initial stimulus (Marcus and Fuglevand 2009).

To describe and predict the relationship between the perceived stimulus and the subjective assigned value a physiological power function,

$$\psi = k \cdot \phi^{\beta}, \quad (5)$$

was used previously, where ψ is the perceived magnitude, ϕ is the magnitude of the applied stimulus, k is the initial gain of the power function (Marks 1974; Stevens

1957; Ehrenstein and Ehrenstein 1999) and β is the sensitivity to different stimulation magnitudes (section 5.2.2). Since the absolute threshold does not correspond with the zero of the power function, the outcome of the function deviates for low stimuli but can be adopted by subtracting the initial threshold S_0 from ϕ,

$$\psi = k(\phi - S_0)^{\beta}. \quad (6)$$

The power function for mechanical stimuli is generally a decelerating function (Marks 1974; Johansson and Vallbo 1983). While the one for electrical stimulation depends on the modality and can be accelerating or decelerating (Marcus and Fuglevand 2009).

2.3.5. Electrode shape

The shape and surface area of electrodes in touch with the skin has an effect on the evoked sensation. Rounded electrodes are more comfortable because current peaks can occur on the corner of rectangular electrodes leading to an uncomfortable sensation (Fig. 2.11).

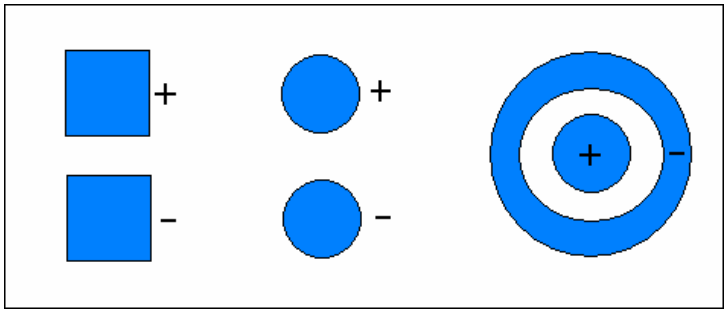

Fig. 2.11: Different shaped electrodes with Cathode and Anode.

Electrodes with a small surface below 1 mm^2 or with a surface area above 100 mm^2 can cause a sensation which is described as prickly or painful when used for electrocutaneous stimulation (Marcus et al. 2006; Szeto and Saunders 1982). Small electrodes result in a high current density on the surface of the skin which triggers the uncomfortable sensation (Prior and Lyman 1974). Nobel metals, such as gold, silver or platinum have been proposed as electrode coatings to prevent any electrochemical process that could lead to cell damage where the electrodes are attached (Brummer and Turner 1975). However these electrodes are rather expensive. More commonly used are pregelled AG/AgCl (silver / silver chloride) or carbon based electrodes, which have been proven to be suitable for electrocutaneous stimulation (Kaczmarek, Webster, et al. 1991).

2.4. Electrotactile feedback systems

A electrotactile feedback system uses electrocutaneous stimulation as a means to create a tactile sensation. Areas of the body with little or no sensation, in this case the feet, are equipped with force sensors, and these can be integrated into support structures such as a shoe insole, which are then connected to the feedback system, enabling the device to “redirect” the force by transmitting a electrotactile sensation (Rollman 1969). The wearer of the device learns to interpret the feedback thus gaining better control over his limbs.

2.4.1. Origins of electrotactile feedback

The first record of using electrocutaneous or electrotactile stimulation to create the sensation of touch was described by Rollman (1969). It was a couple of years later when several other research groups started to explore the parameters and the possible use of electrotactile feedback as a sensory substitution technology (Solomonow and Lyman 1980; Szeto and Saunders 1982). It was also proposed as a feedback system for neural prosthesis (Saunders 1977) and for a variety of applications such as a speech processor (Cowan et al. 1995; Blamey et al. 1988), substitution of touch (Lundborg, Rosén, Lindström, et al. 1998; Carpaneto et al. 2003) as well as a tactile display for vision substitution (Kajimoto 2006). Electrocutaneous stimulation research continues to be a field of interest as new tests on the characteristics of electrotactile feedback have been recently published (Warren et al. 2008; Marcus and Fuglevand 2009; Buma et al. 2007; Geng et al. 2012). Specifically relevant to this research is the approach of Matjacic et al. (2000) and Vuillerme et al. (2007) as Matjacic is applying electrocutaneous stimulation on the back as a source of feedback in supporting paraplegic standing, while Vuillerme uses a tongue based electrotactile device for balance improvement. Depending on the application of the electrotactile feedback an EFS has different characteristics that need to be considered.

2.4.2. Characteristics of electrotactile devices

Electrocutaneous stimulation can be used in various applications and with different intentions. One application is to use it as a feedback for a certain magnitude, like pressure, distance or temperature. The feedback is given by changing the intensity of an occurring stimulus when applied to the skin. Another application is the use of a matrix of multiple electrodes to form a display, called electrotactile display (Jeffs and Warwick 2013) which can be used to transfer visual information to different areas of the body. This is similar to the concept by Bach y Rita but uses electrotactile technology instead of vibrotactile technology (Bach y Rita 1969). Dependent on use and approach the electrotactile system can be placed on different locations of the human body.

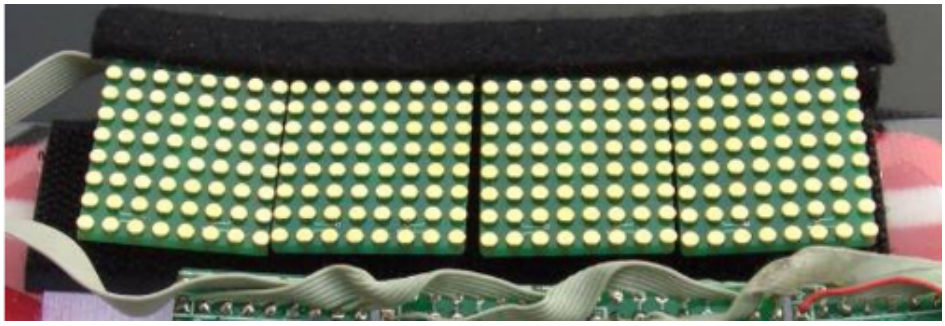

Fig. 2.12: Electrotactile display on the forehead[23]. Each electrode in the matrix can be activated separately to transmit information, e.g. edges of an object or letters (Jeffs and Warwick 2013).

2.4.2.1 Location of electrocutaneous stimulation

Different location sites ability to provide information when using electrotactile feedback technologies have been studied. Fig. 2.12 shows an electrotactile display

[23] Image source is the image of a Forehead Retina System (FRI) from (Kajimoto, 2000)

that is used on the forehead to transmit picture information similar to Bach y Rita (1969) study. An array of 512 electrodes was placed on the forehead and an image captured with a video camera was converted into a tactile pattern on the electrotactile stimulator matrix.

A similar array of electrodes was used by Jeffs and Warwick (2013) where it was placed on the tongue allowing information to transmit in the form of letters and directions, while Vuillerme (2007) used this approach on the tongue to give feedback to improve balance and gesture. An initial study on lip perception of electrotactile array stimulation, Liu and Tang (2005) concluded that the lips have a high sensitivity to electrical stimulation and excellent spatial discrimination capability. Geng et al. (2012) created an overview of the evoked sensation modality when applying different stimulation patterns to the forearm in different modalities. Neither of those location areas are suitable for a wearable EFS because of practical reasons, since the cables for the electrodes could hinder its user during daily use. The upper leg might be a practical and more discrete location for electrotactile feedback. Electrodes can be placed under the trousers and would therefore be not visible from the outside.

2.4.2.2 Parameters for electrocutaneous stimulation

Waveform

There is a controversy in the literature regarding which type of waveform is the most practical for electrotactile feedback. According to (Szeto 1977) a monopolar pulse can be more effective because lower current levels need to be applied to produce the same sensation than in a bipolar pulse and they were used before in electrotactile feedback systems (Prior and Lyman 1974).

On the other hand Szeto (1982) suggests that a monophasic pulse can lead to toxification and irritation of the skin, by unbalanced accumulation of positive ions at the electrodes. This is further backed up by Brummer and Turner (1975) and Kaczmarek et al. (1991) who suggest that a biphasic pulse can prevent the risk of toxication as the symmetry of charge injection maximises the likelihood of a reaction reversal (Marcus 2006). Additionally biphasic waveforms create a more comfortable sensation for the individual than monophasic pulses. A bipolar pulse consist of a primary pulse and secondary pulse with opposed polarity (Szeto and Saunders 1982). Van den Honert and Mortimer (1979) indicated that the secondary pulse would partially negate the primary pulse. Therefore they proposed a delay between the first and second polarized pulse. On the other hand Kaczmarek et al. (1992) stated that altering the time between a bipolar pulse creates no difference in the perceived sensation. A time delay seems therefore not necessary for the design of a wearable EFS.

Pulse modulation method

To change the magnitude of a pulse of an EFS several modulation methods can be considered (Kaczmarek et al. 1992), namely frequency modulation (FM), pulse amplitude modulation (PAM) and pulse width modulation (PWM). FM was studied by Marcus (2009) where the stimulation frequency varied between 20 and 200 Hz. Most studies use PAM commercial available stimulators usually PAM as the custom modulation modality. However, the superiority of PAM to PWM was not shown before. If PAM is used, the skin adapts fast to the stimulation (Buma 2007) which might limit the possibilities to control the pulse intensity.

Frequency and burst rate

The frequency for electrotactile feedback usually lies within the range of 2-100 Hz. (Szeto 1985; Saunders 1977) which is the natural stimulus range for receptors involved in tactile perception (Knibestöl and Vallbo 1980; Poulos et al. 1984). According to Marcus et al (2009) who experimented with higher frequencies, the estimation of perceptual magnitude drops notably when frequencies above 200 Hz are used. Frequency modulation is not suitable for magnitude estimation as the perceptual sensitivity is significantly lower than other forms of modulation (and Fuglevand 2009). The frequency also plays an important role when it comes to adaptation. A pulse frequency higher than 60 Hz leads to a rapid adaptation to stimulation (Collins et al. 2009) and becomes more prominent among higher frequencies, while lower frequencies near 10 Hz show only a minor adaptation to the stimulation (Kaczmarek 2000).

2.4.2.3 Adaptation time to electrocutaneous stimulation

When electrocutaneous stimulation is applied over a longer period of time the skin adapts to the stimulation so that the evoked sensation becomes less noticeable. Adaptation in this case is defined as "a changing response to a constant stimulus, i.e. a decrease of action potential frequencies in sensory nerve fibres" (Buma et al. 2007). Buma et al. (2007) studied this effect and performed a sensation decay measurement. The result was the creation of a curve representing how a subject adopts to a constant stimulus in relation to the time of stimulation.

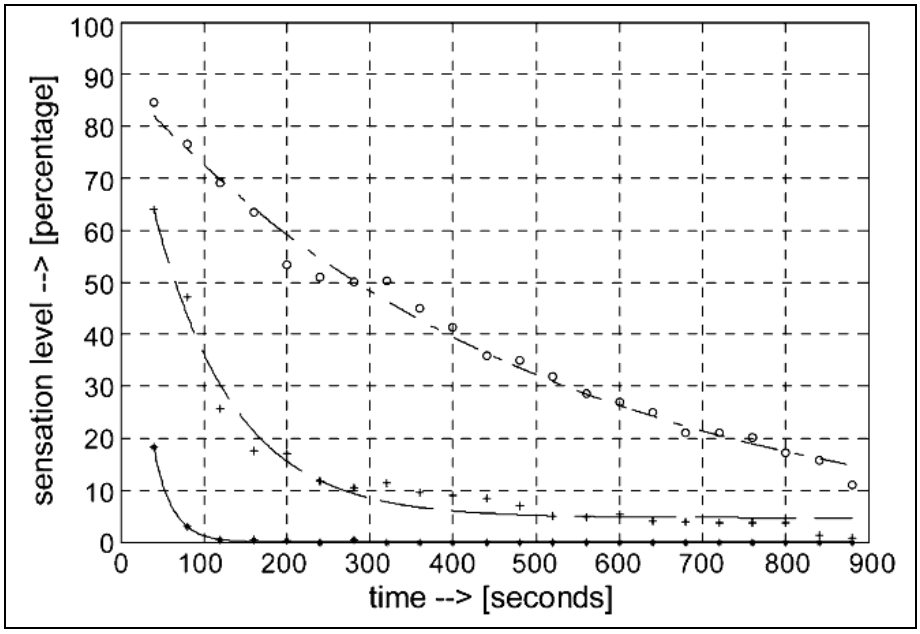

Fig. 2.13: Time-sensation level relationship - The measurements of one subject reporting about the subjective sensation levels is shown. The curves demonstrate adaptation to continuous electrical stimulation at levels adjusted to 20% (*), 50% (+) and 80% (o) of the range for sensation and pain thresholds (Buma et al. 2007).

Different stimulation magnitudes in the range of the threshold for sensation and discomfort were applied (Fig. 2.13). After about 50 seconds the lower electrical stimulation levels are not detectable anymore. This is similar to a natural sensory input as humans adopt to all kinds of sensory stimulations over time, which includes the natural sensation of force from the feet. The time of recovery back to the original level of sensation occurs within minutes (Kaczmarek 2000; Buma et al. 2007).

Another form of adaptation over time is the change of threshold. Kaczmarek (1990) stated that the electrotactile sensation threshold varied periodically with time and that the fluctuations were as much as 25% of the average threshold. The study also showed that when testing the threshold several times over a period of 30 minutes the threshold did not exceed 25% of the average threshold.

2.4.3. Development of wearable electrotactile feedback systems

Only a few portable systems have been designed. A stimulator by Onesti (1989) had a very short operation time because of the use of a high voltage operational amplifier. The device also did not implement the possibility to analyse sensor data or individualise the device to a user's psychophysical requirements. A wearable EFS was proposed by Vuillerme et al. (2007). However, their system used the tongue as the area of feedback which is not a practical location for using the feedback system for ADL, due to the user's inability to speak when using the device. In addition wires connected to the tongue and coming out of the mouth limit the wearing comfort and may be disturbing in a day to day scenario. Another portable feedback system has been developed by Kajimoto (2006). In this approach the feedback is transmitted via electrocutaneous stimulation of the forehead. Again the practicability is limited by cables limiting the freedom of head movement and the system's overall indiscreetness by covering large parts of the face.

2.4.4. Electrotactile feedback for magnitude estimation

Lundborg et al. (1998) described artificial sensation based on the use of piezoresistive sensors and provide some preliminary observations on their results. Piezoresistive force sensors are used to detect forces on the fingertips (Fig. 2.14). Electrical impulses with pre-gelled skin electrodes at the upper arm were used to simulate tactile sensing.

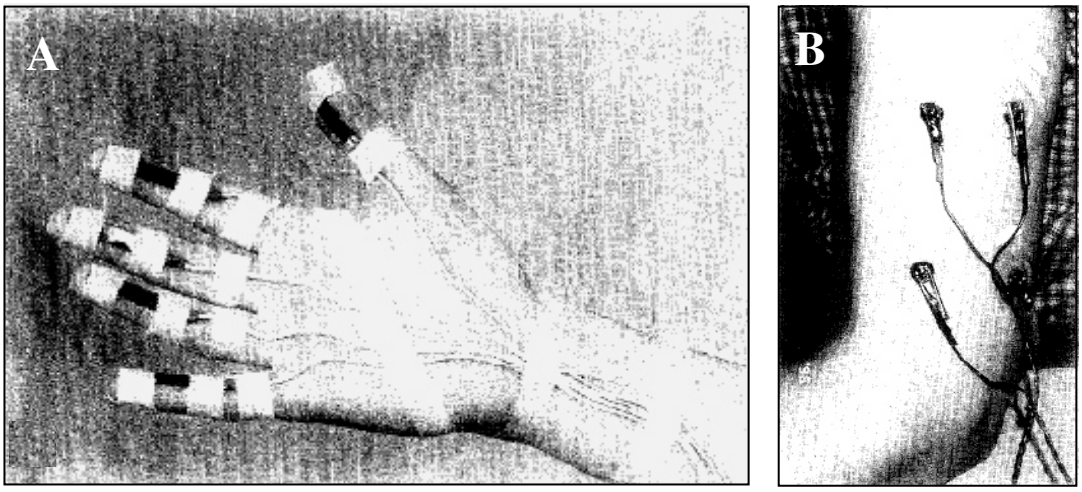

Fig. 2.14: Electrotactile force feedback system for the hand by Lundborg, Rosén and Lindström (1998). The force sensors are attached to the finger tips to detect the pressure applied with the hand (A). Electrodes are attached to the upper arm giving feedback when pressure is applied with the fingers (B).

The differentiation of pressure levels was tested and showed good results. Experiments in a set-up of five test subjects showed that different pressure levels could be discriminated with the help of the electrical impulses that were transferred to the upper arm.

However the study did not investigate the psychophysical power function for each participant. Also the system that was proposed did not consider individual sensation thresholds, nor was it designed as a portable device. Furthermore a portable electrotactile feedback device for the feet has different requirements in terms of weight and the electrical stimulation parameters. Also in their design they used current modulation and did not consider other modulation methods.

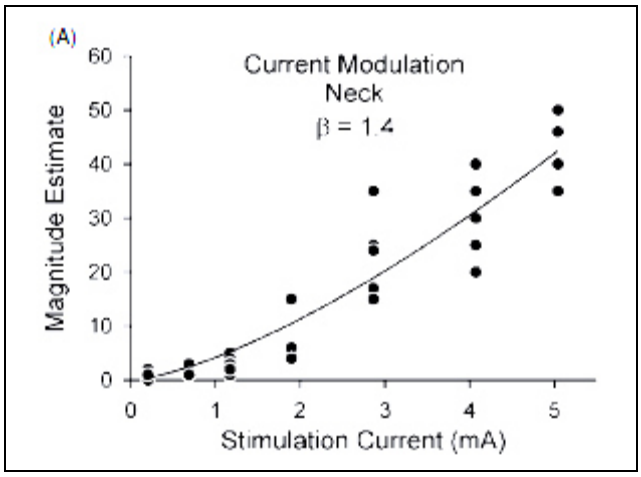

Fig. 2.15: Relationship between stimulation current and magnitude estimate (Marcus and Fuglevand 2009). The β value was found to be 1.4 indicating that sensitivity for higher magnitudes is better than for lower magnitudes.

Marcus and Fuglevand (2009) compared mechanical and electrical stimulation to study if a relationship exists between the two when applied to the neck (Fig. 2.15). The graph shows the averaged power function for all study participants. The study tested magnitude estimation with PAM and FM on the neck as a location of stimulation, but PWM was not considered as a stimulation modality (Chapter 5).

2.4.5. Electrotactile Feedback for balance improvement

Currently limited research and literature exist in the field of electrotactile feedback for balance improvement. The two-dimensional electrotactile feedback system by Matjacic et al. (2000) has been developed for use in paraplegic standing. In their system information about the moving COP was projected onto the back of a person (Fig. 2.16.) and measured the change in COP movement with and without applying electrotactile feedback (Chapter 1). Three individuals with no sensation in their legs were studied and it was found that they could correctly interpret information about their posture when encoded in different stimulation patterns after a certain learning period. It helped the person to identify the posture and adjust their body position. However this feedback system seems not useful in a daily environment since it is not designed to be portable.

A tongue-placed electrotactile feedback system for balance improvement by Vuillerme et al (2007) was tested with six healthy test participants who used the system. The plantar pressure was given as a feedback to the individuals through a tongue placed tactile biofeedback system. The results showed an improvement of balance parameters analysing the sway area with and without using the device. Unfortunately the study does not specify how the surface area of sway was calculated. Also tests with impaired individuals were not performed with the feedback system.

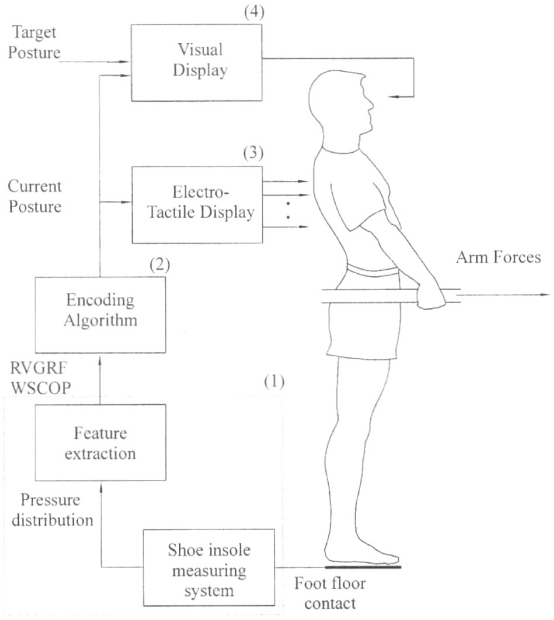

Fig. 2.16: Electrotactile display transmitting posture information to improve balance (Matjacic et al. 2000)

2.4.6. Walking speed with electrotactile feedback

People with neuropathy have problems in walking because the awareness of the position of the foot in relation to the ground is not sensed. An EFS which gives feedback about the COP movement can indicate during walking when the heel strikes the ground and can forward the information about the COP movement during ground contact to its wearer which potentially improves the confidence in walking. To test the improvement in quality of walking a timed up and go test (TUG) is usually carried out which measures several times the time a person needs to stand up and walk for a certain distance while the time is recorded. The TUG test was used previously for testing the effects of a tongue based biofeedback system for patients following a stroke (Badke et al. 2011). In a clinical study of 29 stroke patients the study revealed that the time to complete the TUG test decreased from 24.7s to 20.7s (16.2%). No study tested yet the effects of a wearable EFS that uses the leg as a stimulation location.

2.5. Conclusions

The underlying principles of the nervous system and electrical stimulation were explained and previous work on electrotactile feedback was evaluated. Several gaps of knowledge were identified.

The majority of EFS systems use modified commercially available stimulators rather than designing and tailoring a device that is more practical in daily life, i.e. portable and robust. This facts lead to the objective to design a wearable EFS in the current work. Additionally there is a clear lack of an in-depth description of software architecture and the design of EFS, which was addressed in this study.

Even though electrical stimulation was tested in several locations of the human body there are still some locations that could be very useful for future design

considerations such as the upper leg. Most studies discussed the use of FM or PAM for magnitude modulation, but did not consider using another modulation such as PWM, while several findings suggest that PWM has advantages over PAM and FM. The adaptation to stimulation of the skin for FM occurs after several seconds for high frequencies and also changes for different amplitudes when PAM is used (Buma et al. 2007) which makes the control of the pulse more difficult.

Even though electrotactile feedback was used previously for analysis of balance the scope of those studies is limited as the sample size was very small and an electrotactile display was used instead of a simpler approach, such as a small array of electrodes. Furthermore the presented studies did not consider the legs as an appropriate area for electrotactile feedback testing. In addition to that the discussed studies did not give a detailed description which measurement system was used for the evaluation of balance. Therefore it was aimed to develop a measurement system for the analysis of balance and use it in a study to determine which effect a wearable EFS can have on posture control. The objective was to test the hypothesis that the wearable EFS would improve balance parameters based on the COP movement in balancing and improve walking speed in a timed up and go test.

In conclusion the literature showed that EFS have a high potential to improve the living conditions of people suffering from peripheral neuropathy justifying the current work and investigation of wearable EFS. The design of hardware and software of the EFS were the first steps in addressing the identified gaps of knowledge.

"Any sufficiently advanced technology is indistinguishable from magic."

Arthur C. Clarke (1962)

Chapter 3 Hardware Design

3.1. Abstract

An electrotactile feedback system (EFS) is a specific form of biofeedback using electrocutaneous stimulation as a means to give information to its wearer. This can help people with problems of pressure estimation caused by a sensation loss in their feet to maintain their balance when standing and walking. Previous studies tested the use of electrotactile feedback to improve activities of daily life (ADL). However the proposed systems tested were mainly stationary devices and there is only limited work available about the design concepts of a wearable EFS.

A wearable medical device needs to fulfil several design criteria, such as safety to the user, individualised customization of device parameters, practicability and low cost. This chapter investigates the hardware requirements for a wearable EFS and presents a novel design concept. Different force sensor technologies were considered for the use in the wearable EFS design, as well as hardware solutions to fulfil the design criteria.

The proposed design is composed of three main units: sensor unit, pulse creation unit and electrical stimulation unit. The sensor unit consists of four force sensors integrated in a shoe insole to detect forces applied to the sole of the feet. The pulse creation unit has a microcontroller for sensor data processing and pulse creation which is transmitted to the four-channel electrical stimulation unit, creating electrical feedback through electrodes placed on a user's skin.

The portable device design proposed in this study considers individual parameters and safety aspects and contributes to the development of wearable medical equipment that can improve ADL of people with sensation loss in their feet.

3.2. Technical background

3.2.1. Components

An electrotactile feedback system (EFS) is a biofeedback system that allows sensory substitution by replacing a lost or damaged sensory into another (Kaczmarek, Webster, et al. 1991). This may help people with a dysfunction of a certain sensory modality, e.g. tactile sensation, compensate for their impairment. Most EFS used in previous studies are designed as stationary devices (Matjacic et al. 2000; Kaczmarek, Kramer, et al. 1991) impeding the user's mobility. Only a few portable systems have been designed (Onesti et al. 1989; Vuillerme et al. 2007; Kajimoto 2006) (Chapter 2).

An EFS consists of three main parts, which can be classified in the following categories:

- Sensor unit
- Pulse creation unit
- Stimulation unit (electrical)

The sensor unit can detect forces and obtains pressure information with a suitable sensor technology and forwards this information to the pulse creation unit. The pulse creation unit interprets the information and triggers a stimulation that is forwarded to the wearer of the device via skin over a proximal area not affected by sensory loss. The technology for the sensor unit needs to allow the detection of forces that are applied to a foot insole.

3.2.2. Tactile sensing technology

The electrotactile feedback system designed in this research aims to redirect touch sensation from the feet to the upper leg and needs a sensor unit to detect pressure applied to the feet. Several sensors are able to detect force and pressure (Maheshwari and Saraf 2008). A sensor detects tactile information that is applied and transforms it into a signal which is then interpreted by a computational device or circuit that uses the information to create a further action, e.g. giving feedback to the user. Therefore a sensing device must be composed of two elements: the tactile-sensitive element producing a signal according to the physical stress and an information-processing element which receives the signal and processes it. Different techniques for tactile sensing can be used

- Capacitive: Change of capacitance (Neumann et al. 2004)
- Air pressure (Kyoungchul Kong et al. 2008)
- Piezoelectric: Production of a charge (Cotton et al. 2007)
- Piezoresistive: Change of resistance (Rubio et al. 2007)

Capacitive sensors use the characteristics of two conducting materials changing their capacity in relation to their distance to each other (Neumann et al. 2004). Another method for pressure detection is using a ground contact force sensor based on air pressure (Kyoungchul Kong et al. 2008). These sensors are bulky and more expensive than the other sensors. Piezoelectric force sensors use an effect in which the application of stress to a certain crystal polarizes the crystal and generates voltage (Ma 2010). This voltage can be measured and used as a reference of the force applied to the sensor. However the voltage can only be measured over a short period of time and is not suitable to measure static pressure. Piezoresistive sensors change their resistance during the time a force is applied.

3.2.2.1 Piezoresistive force sensors

The functional principle of a piezoresistive force sensor is based on quartz crystals. The crystals have the characteristics that when mechanical stress is applied the material changes its resistivity, with higher pressure levels lowering the resistivity. This change of resistivity can be measured by applying an electrical potential and using Ohm's Law (Sze 1994). The change of resistance comes with a slight shift when pressure is applied over a longer time period, but compared to piezoelectric

sensors it is more suitable to detect static pressure on the feet. If compared to capacitive sensors, piezoresistive sensors have the advantage of being smaller in size and having a higher sensitivity (Neumann et al. 2004). To some extent all force sensors have the problem of non-linearity as the force versus voltage curve is not a perfect straight line. Also there is a form of hysteresis as the curve is not the same during loading as it is when removing the force.

For biomedical applications it is important to have a tactile device that has high sensitivity to deformation, which is the case for piezoresistive sensors (Herrera-May et al. 2009). If mechanical stress is applied to a semiconductor, it changes its resistivity. Piezoresistivity ρ_σ is defined as

$$\rho_\sigma = \frac{\left(\frac{\partial_\rho}{\rho}\right)}{\varepsilon}, \qquad (7)$$

where $\partial\rho$ is the change in resistivity, ρ the original resistivity and ε the strain. The resistivity is inversely proportional to the strain (see Equ.(7)). Therefore a current that flows through the semiconductor is also proportional to the strain and can be measured, which gives a indication of the pressure. Piezoresistive force sensors are widely used to measure pressure applied to the feet (Rana 2009; Kajimoto et al. 2004). The same configuration can be used to detect gait. Chen et al. (2008) developed shoes for abnormal gait detection using piezoresistive sensors (Fig. 3.1). Their system succeeded in detecting several gait abnormalities.

Fig. 3.1: Shoe system for abnormal gait detection. An insole with several force detection sensors attached was placed in a shoe (Chen et al. 2008) and was used for data analysis.

Different companies offer force sensors which can be used for the balance analysis such as Interlink, LuSense or F-Scan (Hollinger and Wanderley 2006). F-Scan sensors have an advantage over other force sensors as they are very thin and flexible. They were used previously for gait analysis but also for in-shoe-pressure analysis of patients with diabetic feet (Arnold et al. 2010; Pitei et al. 1999; Frykberg et al. 1998).

3.2.2.2 Sensor placement

Several sensor arrangements have been used in previous studies for detecting and analysing foot pressure. Simple arrangements only use one (Hargreaves and Scales 1975) or two force sensors on each foot to differentiate between gait cycles (Miyazaki and Iwakura 1978), while other systems involve at least four force sensors on each foot (Kong et al. 2008). The recommended location for the sensor placement is the big toe, heel, first metatarsal and fifth metatarsal (Kajimoto and Kawakami 2004; Williams 1997; Granat et al. 1996), because those are the locations of the highest pressure during standing and walking. More sensors were used by Pollard et

al. (1983) with similar results, which demonstrates the reliability of this form of foot pressure analysis.

3.2.3. Data processing

The selection of an appropriate microprocessor for data processing is mainly dependent on the requirements of the pulse creation unit. The microprocessor of the EFS should be able to transform analogue sensor feedback into digital values for processing and analysing the data. Furthermore it should also include the capacity of storing individual parameters to allow a comfortable feedback which is not harmful to the wearer. Another requirement is the microprocessor's need for enough processing power to modify each pulse of each channel resulting from the centre of pressure information gathered from the sensors. Commonly used microprocessors for data processing tasks are usually from PIC or AVR and both were used in previous studies involving electrical stimulation (Marcus et al. 2006; Carpaneto et al. 2003). The two microprocessors showed sufficient processing power to handle several sensor data streams.

3.2.4. Electrical stimulation

The pulse can be controlled by the microcontroller and therefore an adequate method of power amplification is needed to create sensation in the human skin (Szeto and Saunders 1982). Usually the stimulation voltage lies between 10 Volts and 100 Volts for applications of electrical stimulation (Cheng et al. 2004). To reach this amount of voltage with a 9 Volt battery, a transformer needs to amplify the voltage by a factor of 10. The current is transferred to the user's skin via electrodes. The shape and material of the electrodes also has an effect on the evoked sensation (Chapter 2). Rounded AG/AgCl (silver / silver chloride) based electrodes were used in previous studies for electrotactile feedback (Lundborg, Rosén and Lindström 1998). They were found suitable and were selected for the present study.

3.3. Schematic planning

3.3.1. Development process

The development of the device was divided into two main steps. First, an analogue device has been developed, to test if the system allows feedback when pressure is applied to the sensor system. In the second step a digital device has been developed which served as a basis for a wearable EFS. The analogue device was mainly build to gain experience with the construction of electrotactile force feedback devices as there is little literature available on the design of an EFS. The aim was to develop the sensor unit and the electrical stimulation unit, while the pulse creation unit could be replaced in a later stage of the development with a digital pulse creation unit.

3.3.2. Analogue device design

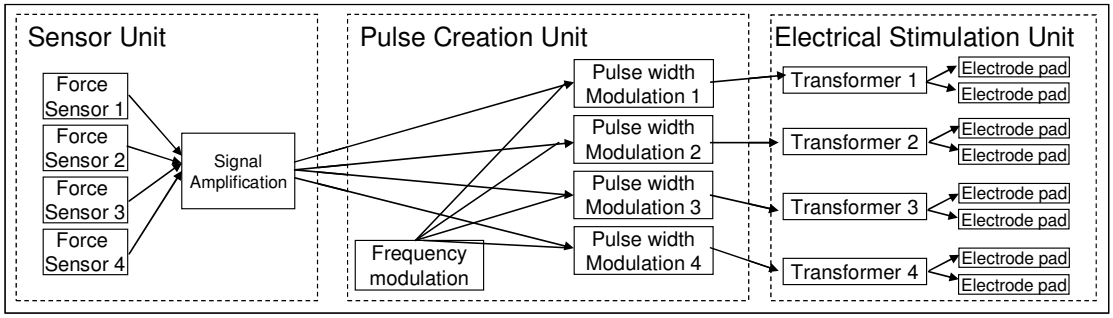

Fig. 3.2: Block diagram of the analogue device design

The analogue device design consists of a sensor unit, a pulse creation unit and an electrical stimulation unit. The device also has a power unit that serves as a power supply. The Sensor Unit of the device consists of four piezoresistive force sensors for the detection of pressure. An operational amplifier amplifies the sensor response and forwards the signal to the Pulse Creation Unit. The pulse in the Pulse Creation Unit has a variable frequency between 15 and 30 Hz and a maximum amplitude of 100 V. When the device is in operation the pulse frequency and pulse amplitude are fixed, and only the pulse width changes. The Pulse Creation Unit uses the output of the sensor unit to modulate the pulse width of the pulse proportional to the output with a pulse width modulator. The pulse lies within a range of 50-400 μs and is dependent on the amplified signal of the Sensor Unit. The pulse controls a transformer which is part of the Electrical Stimulation Unit. The transformers amplify the pulse from the pulse creation unit and transfer the pulse through electrodes to the skin. The loop connected to the skin is galvanically isolated from the controlling circuit.

3.3.3. Digital device design

The digital prototype developed in this research extends the design of the analogue prototype adding a microcontroller to the pulse creation unit. The digital device was designed to fulfil the following requirements:

- Transforming analogue sensor feedback into digital values for processing and analysis
- Storing calibration data for the time period of the device usage to allow feedback individualised to each user
- Ability to modify the pulse of each channel as an result of the changing centre of pressure information (Chapter 4)

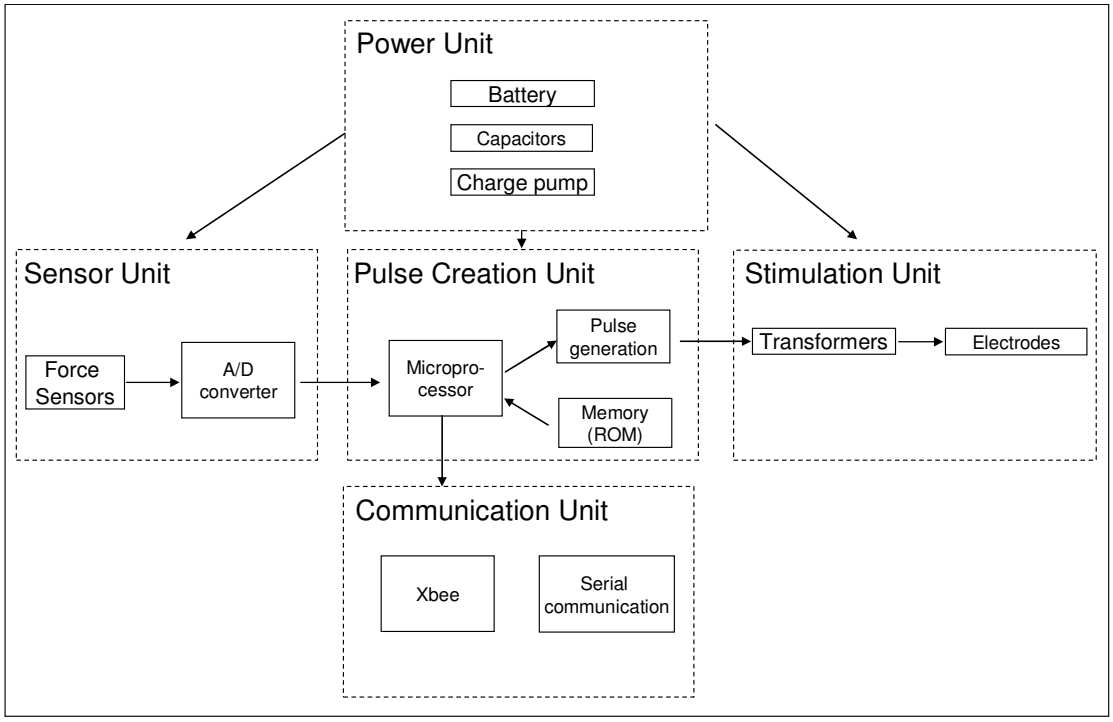

Fig. 3.3: Block diagram of the digital prototype design with all component units of the EFS. In addition to the analogue design the digital design incorporates a microcontroller in the Pulse Creation Unit, which allows to save individual parameters of the user and sending data via the Communication Unit.

The output of the sensor unit is transformed with an analogue-digital-transformer, which can be used to process the sensor data on a microcontroller. This approach offers more flexibility than the analogue device design.

The digital prototype also has a power unit for power supply. In addition the device has a communication unit for serial cable and wireless communication which allows for a collection of sensor data with a connected PC.

3.3.4. Device setup

The EFS is installed on both legs of a wearer. Fig. 3.4 shows the final setup of the device in a schematic diagram.

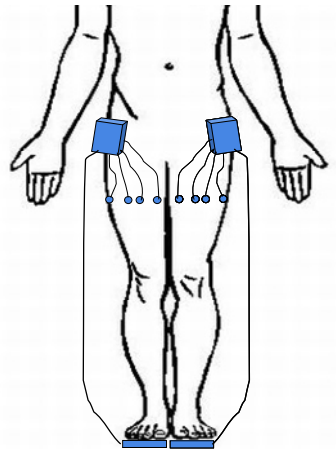

Fig. 3.4: Schematic diagram of the prototype. Eight electrodes are placed on each leg (only four are visible on each side in the diagram). The electrodes are connected to the processing unit which has the sensor unit connected through cables. The sensor unit is an insole that is placed in a shoe.

The force sensors are integrated onto an insole that can be placed in a shoe. The sensors are connected with a housing that contains the amplification part of the sensor unit, the pulse creation unit, the power unit, communication unit and the electrical stimulation unit. Leads are connected to the box allowing electrodes to be placed at the user's upper leg.

3.4. Developed Components

3.4.1. Power Unit

3.4.1.1 Battery and Power source

The power source of the device is designed to deliver current to the electrical components and the transformers for pulse amplification. If the transformer is sinking[24] the current directly from the battery, the pulse might be delayed since the response time of the battery is not fast enough. A capacitor can solve this problem and can serve as the power source for the pulse. The battery loads the capacitor when no pulse is present and when the transformer is sinking the current from the capacitor completes the circuit instead of the battery. Two capacitors of 470 µF and 10 µF (C1 and C2) compensate the response time of the battery. The device is designed for a maximum current of 1 A in the primary winding of the transformer by putting a 9 Ohm resistor between the battery (with 9 Volt) and the transformer. The capacitor has to have a capacitance to serve a charge (Q) of 1 Ampere for a maximum time of 500 µs using a 9 Volt battery for four transformers. The capacitance for the capacitor can be calculated by

$$I = \frac{dQ}{dt} \text{ and } C = \frac{Q}{V}. \quad (8)$$

The charge Q is 500 µC (Coulomb) and the Capacitance (C) is 55 µF for 1 Transformer and 220 µF for 4 transformers. To create a sufficient buffer the capacitance was doubled and a 470 µF capacitor was used.

The linear regulator L7805 (Texas instruments, 2002) gives 5 V as an output which is needed for the sensor system to power the other components in the circuit, C_3 functions as a buffer for the linear regulator (Fig. 3.5) but also as a potential power source. The same value as of C_1 was used, to keep the possibility open to use the output current of the linear regulator with 5 V for the transformer.

The power consumption of all electrical components is about 100 mAh. With a 9 Volt battery with 750 mAh the device can be operated for about 7.5 hours. The battery has to be loaded every 7.5 hours or sooner before the device can be used again. This ratio can be improved by using less power consuming components or by putting the microcontroller into sleep mode when the device is not used, or by using a battery with higher mAh.

[24] Sinking in this context means that an electronic component is using the current from a power source

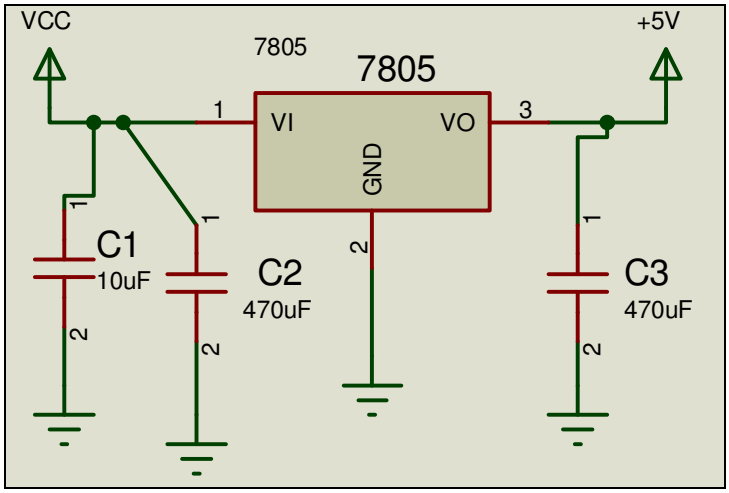

Fig. 3.5: Power source design with linear regulator and capacitors.

3.4.1.2 Charge Pump

A charge pump is a DC to DC converter. It uses capacitors to store energy and can be used, amongst other functionalities, to invert a voltage power source. The charge pump is used for the sensor signal amplification by providing a -5 V output. To realise the charge pump the microchip ICL 7660 (Texas Instruments 1997) was used which is a common chip component for designing a charge pump circuit (Fig. 3.6).

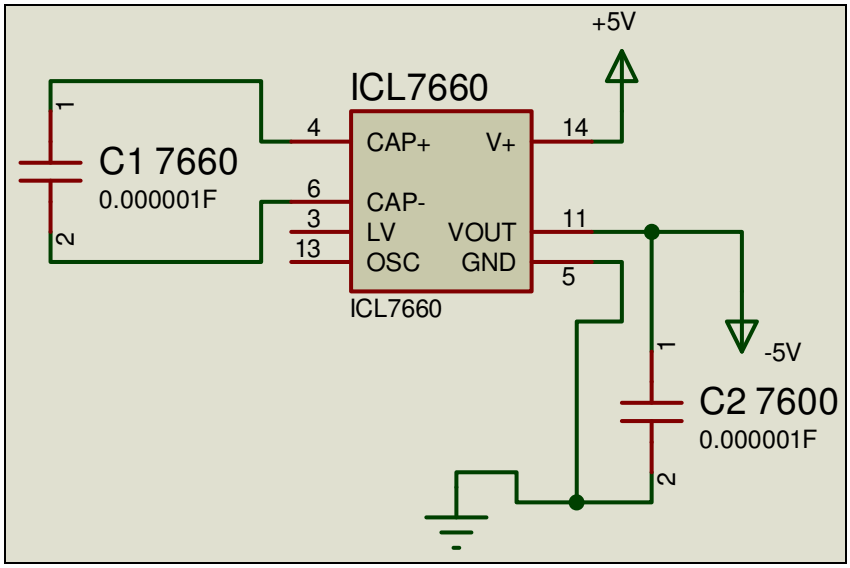

Fig. 3.6: Charge pump circuit with an ICL 7660 (Texas Instruments 1997))

3.4.2. Sensor Unit

The Sensor Unit consists of piezoresistive sensors of the type FlexiForce (Tekscan 2006) and a LM358 (Texas Instruments 2000) operational amplifier. The force sensor changes its resistance when load is applied. The operational amplifier compares the voltage coming from the -5 V source, $V_{(compare)}$ with the output voltage from the force sensor (Fig. 3.7). The outgoing Voltage, $V_{(out)}$, is proportional to the force applied to the force sensor and lies between 0 and 5 Volts. It can be calculated by

$$V_{(out)} = -V_{(compare)} \cdot \frac{R1}{R_{(Sensor)}}, \quad (9)$$

where $R_{(Sensor)}$ is the resistance of the force sensor and R1 is the compare resistor (Fig. 3.7).

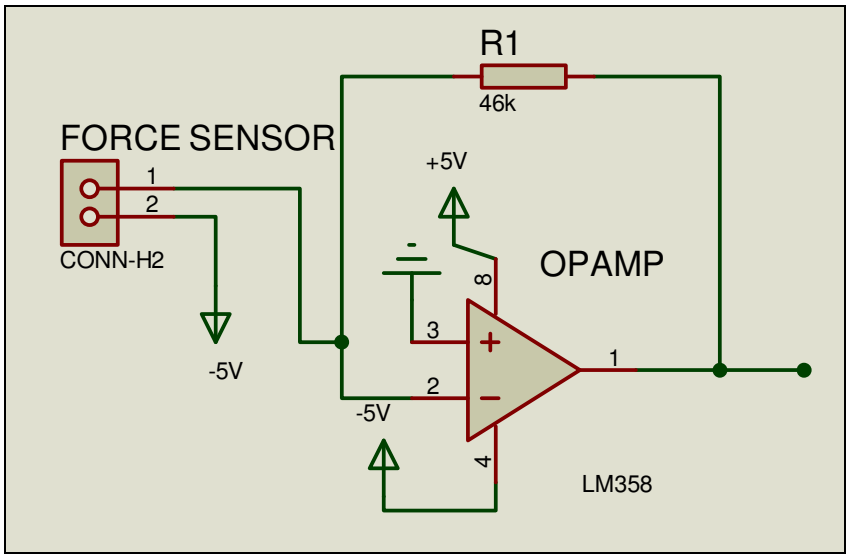

Fig. 3.7: Force sensor and operational amplifier.

An arrangement of four force sensors was used as it could be easily incorporated in an insole and still offers accurate pressure detection on the foot. Fig. 3.8 shows a foot insole that consists of four force sensors which are located at the front, back, left and right of a foot insole. The specific sensor locations are four main pressure points at the big toe, the first metatarsal, the fifth metatarsal and heel.

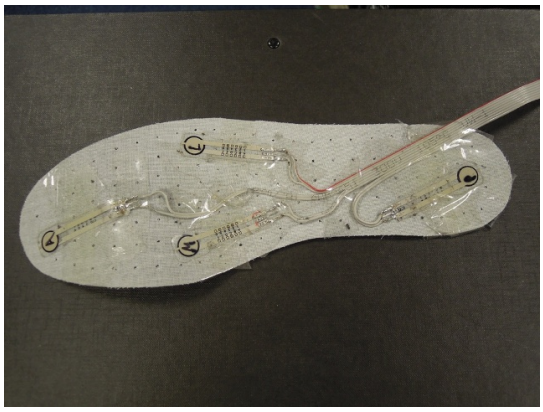

Fig. 3.8: Sensor unit shoe insole developed as part of this research

3.4.3. Analogue Pulse Creation Unit

The pulse creation unit build in this research was an analogue circuit first. In this circuit a NE555 chip is used to create pulses and to control the pulse widths with the voltage coming from the sensor unit. The NE555 (Texas Instruments 2010) is a widely used circuit component to create pulses in electrical circuits. The frequency of the pulse was set to 30 Hz (Chapter 2). The pulse width was set to a range between 100 µs and 139 µs (Chapter 2). The analogue pulse creation unit was replaced in the next design step by a digital pulse creation unit.

3.4.4. Digital Pulse Creation Unit – Microprocessor Atmega32

Instead of an astable operator and a pulse width modulator circuit with the NE555 a microcontroller was integrated for the management of the pulse width. Both, astable modulator and pulse width modulator were replaced by a software based algorithm.

The microcontroller used is an Atmel Atmega 32 which is a 32 bit processor with 32KB self-programming Flash Program Memory with 2KB SRAM and 1KB EEPROM (Texas Instruments 2011). The Atmega32 was chosen because it has 8 Channel 10-bit A/D-converters which are needed as sensor input since the sensors deliver analogue input that has to be converted into digital values. The Atmega32 has up to 16 MIPS throughput at 16 MHz. An external 16 MHz clock is used. The operation voltage is between 2.7 - 5.5V. Once the development software was programmed and tested it could be uploaded to the microprocessors internal memory to function as a self governing unit (Chapter 4).

3.4.5. Electrical Stimulation Unit

The electrical stimulation unit in the analogue device was designed for outputting a unipolar pulse. It consists of a transformer of the type Miniature Audio Transformer LT700 (Stortech Electronics 2012) to amplify the battery voltage and the electrodes which are attached to the user's skin and connected with wires to the transformers. The transformers are directly connected to the battery. The resistor R_1 is located between the pulse creation unit and the transistor. Without this resistor, back flowing current could limit the transistor's function. When the output of the pulse creation unit is high the current can flow through the primary winding from the battery to ground and the transformer will amplify the pulse and deliver to the electrodes connected to the person's skin (Fig. 3.9). A diode prevents the current from floating back after a pulse to prevent unwanted current fluctuations.

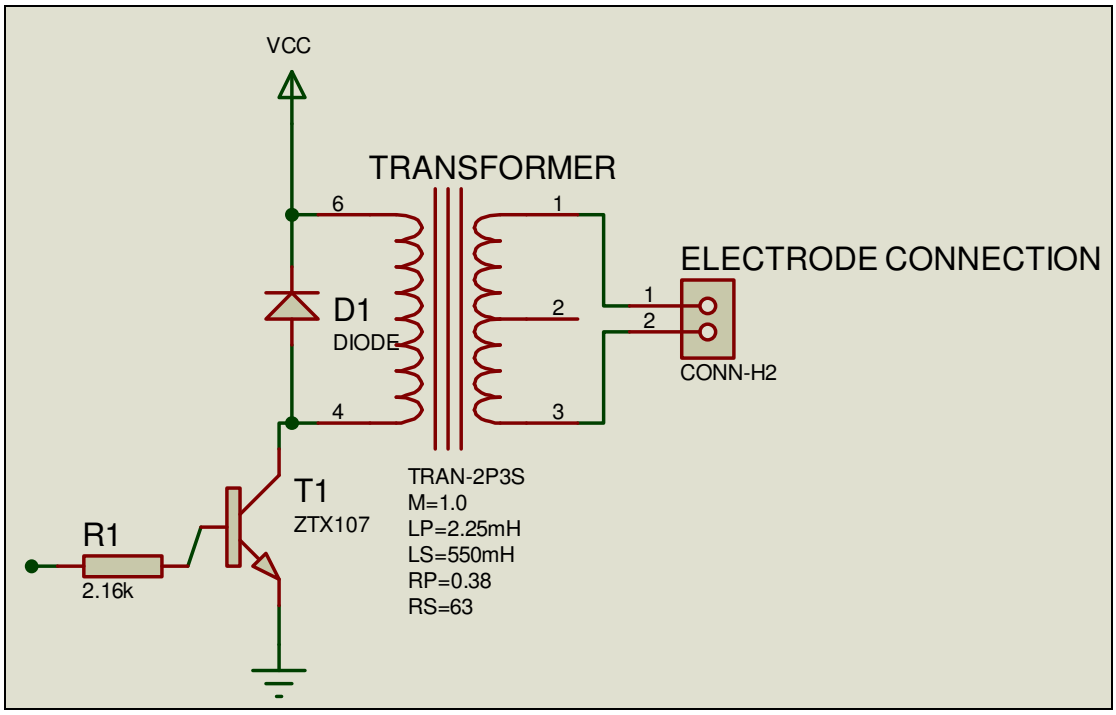

Fig. 3.9: Transformer circuit with electrode connection in the analogue prototype

As described previously the use of a unipolar electrical impulse can cause reddening of the skin if applied over a long period of time. To avoid or reduce this a bipolar pulse was used. To achieve a bipolar pulse an H-bridge was integrated into the circuit design. The principle of an H-Bridge combined with a J-Type FlipFlop (Philips Semiconductors 1997) as a one bit memory was used to switch the direction of the current after each pulse to create a bipolar pulse. Fig. 3.10 shows the principle of the H-Bridge. When S1 and S4 are closed the Mass or Load, M, has a positive voltage. If S2 and S3 are closed then M has a negative voltage.

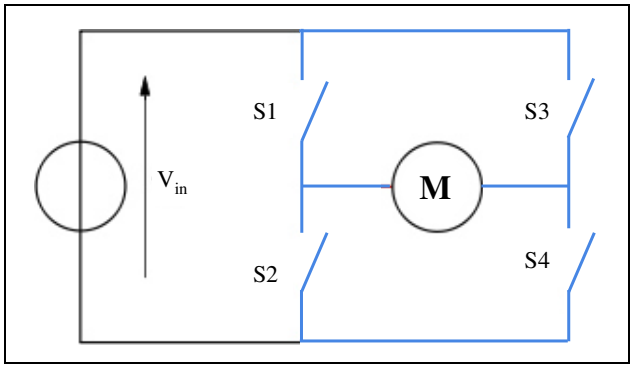

Fig. 3.10: H-bridge principle

The H-Bridge was integrated into the circuit as shown in Fig. 3.11. The flip flop switches the H-bridge transistors and the resistor R5 at the same time which closes the connection of the transformer to ground.

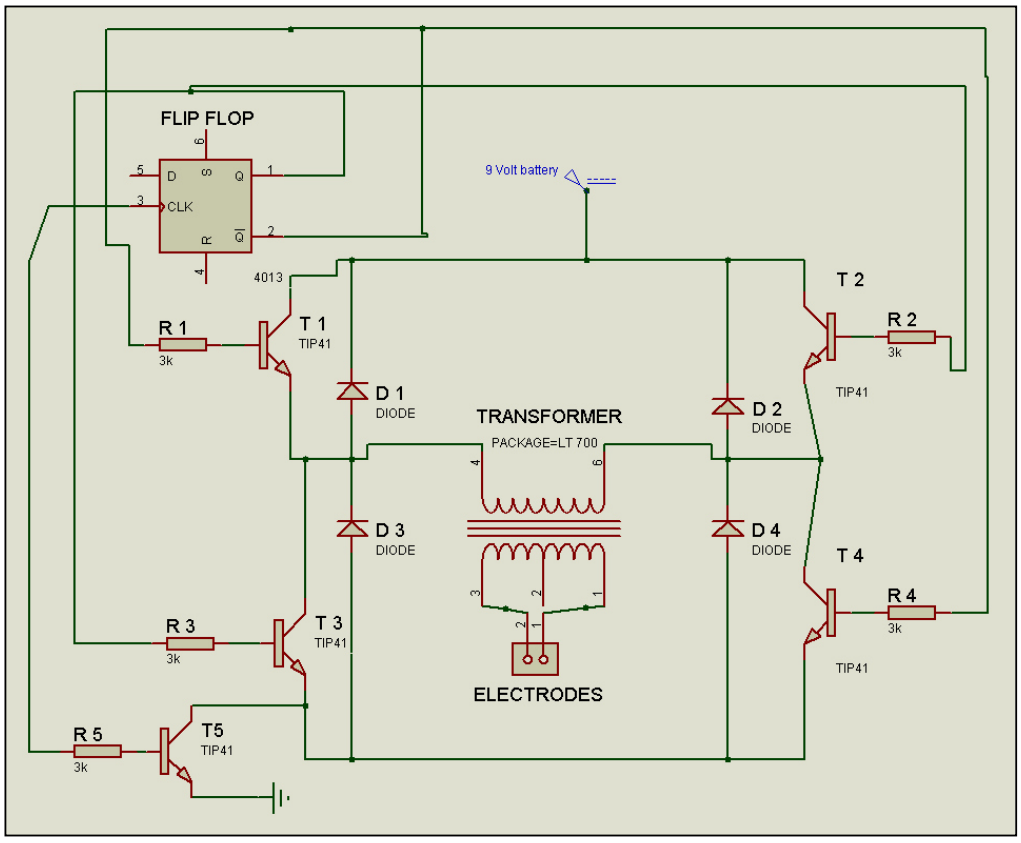

Fig. 3.11: Final electrical stimulation unit design: The Flip flop is controlled by the pulse signal coming from the microcontroller into Pin 5 and switches the transformer pairs T1-T4 or T2-T3 on and off so that the current from the battery flows in a bipolar manner through the transformer thus creating a bipolar pulse.

In the final design setup a 9 Ohm resistor was put in place between the power unit and the transformer thus limiting the maximum current in the primary winding to 1 A. With the winding ration of 9.3 the maximum current in the secondary winding is therefore limited to 107 mA. The link between the transformers and the skins are electrodes of the type Ambu Neuroline 700 (Ambu 2012) with a Ag/AgCl interface.

3.4.6. Communication unit

The wireless communication unit consists out of 3 communication channels, via a cable or wireless. The 3 communication channels are:

- ISP Programming Interface for flashing the microcontroller ROM
- XBee Wireless Communication for sending sensor data to the computer for data logging
- Wired Communication over RS232 as a backup possibility for sending sensor data

The ISP programmer allows accessing the microcontrollers fuse bits and programming the internal ROM with the software which was designed with AVR Studio 4 (GNU License).

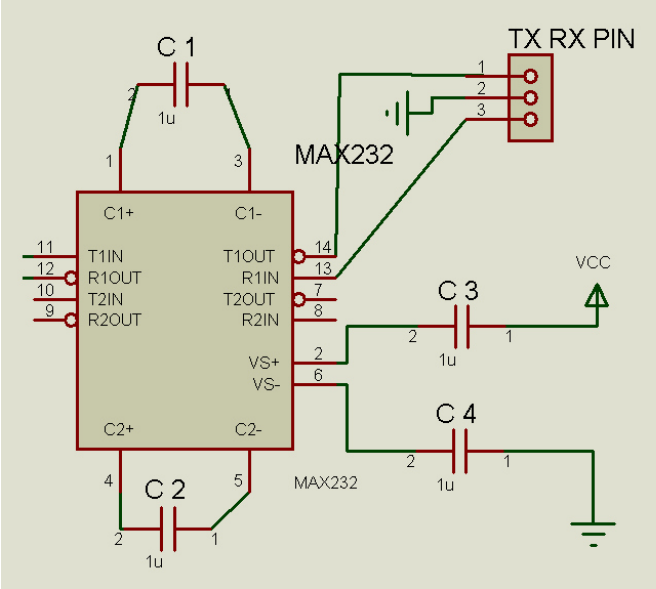

Fig. 3.12: Communication unit for the RS232 interface

To connect the microcontroller via the RS232 interface with a computer a MAX232 component (Texas Instruments 2004) was integrated into the design. Since the voltage levels for sending signals to the computer RS232 interface are higher than 5 Volts the MAX232 regulates the voltage. The Max232 exchanges data with the microcontroller via the Receive (R) and Transfer (T) pin. The XBee-module has a voltage level converter to 3 V integrated and can be connected with the T and R pins of the microcontroller to send and receive data wirelessly.

3.5. PCB-Design process and assembly

The facilities at Bournemouth University were used for designing the feedback device's circuit. The circuit design has been developed in Proteus – ISIS, a computer program for designing and simulating circuits (Appendix D). The circuit was tested via breadboarding. The design of the circuit board was done in Proteus – ARES (Appendix E). Fig. 3.13 shows the 3D visualization in Proteus ARES.

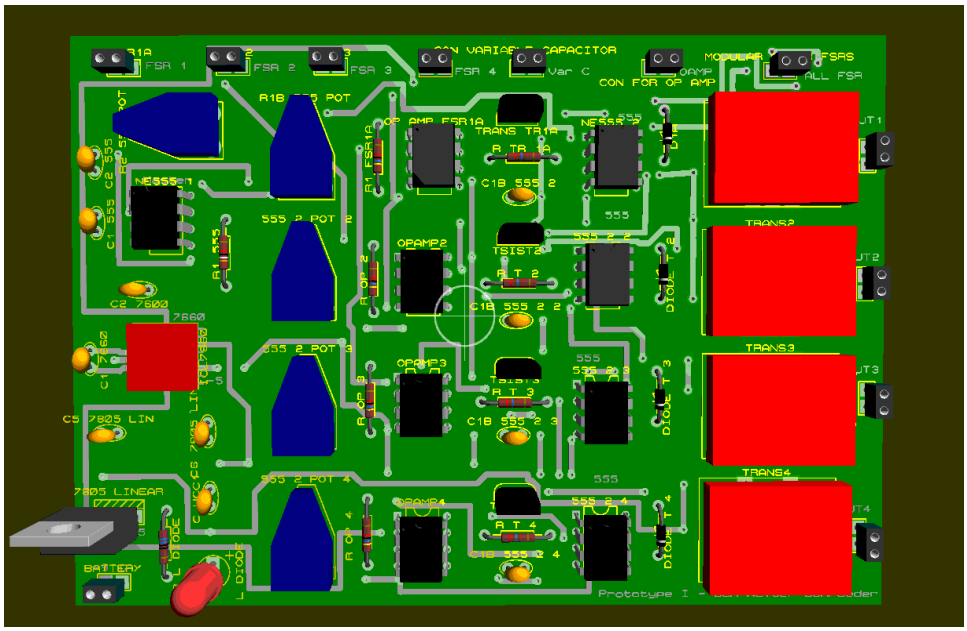

Fig. 3.13: 3D visualization of analogue device created with ARES

Fitting the printed circuit board involved the soldering of the components to the circuit board. A printing circuit machine in the laboratory for Electrical Engineering in the School of Design, Engineering and Computing was used to create the PCB as seen in Fig. 3.14.

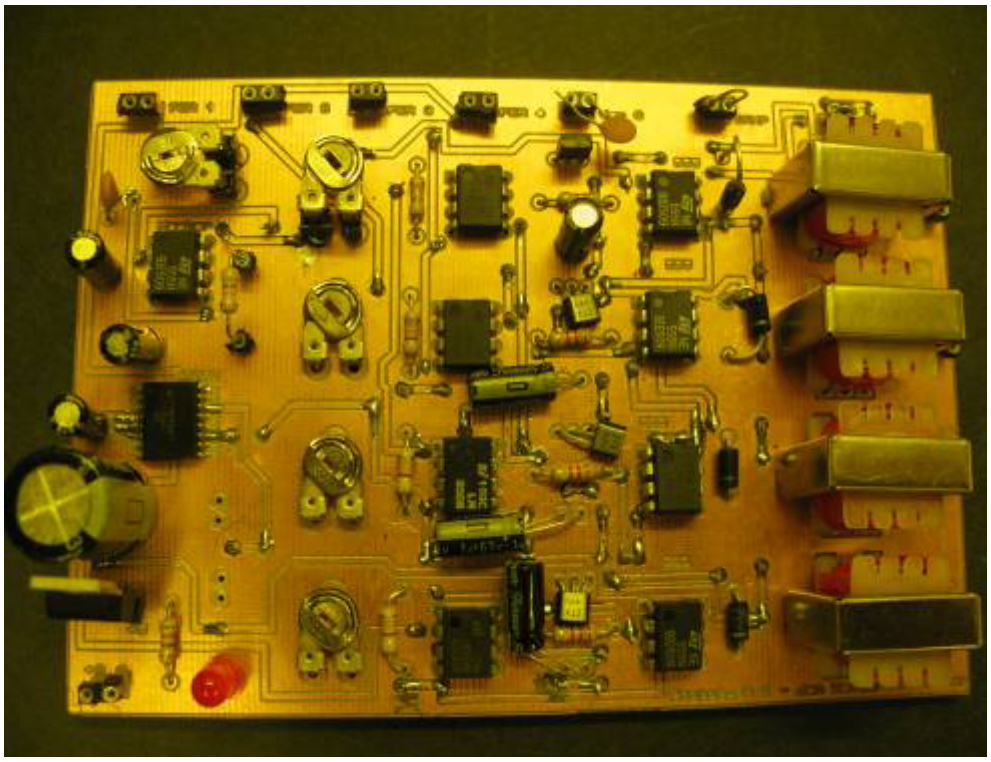

Fig. 3.14: PCB of the analogue device built at Bournemouth University

The digital prototype was designed in a 2-level design to keep the space the PCB needs smaller so that it can be fitted into a reasonable sized housing. The 2-level design separates the sensor, power and communication units from the pulse creation and electrical stimulation units. The two PCBs are connected via a bus cable.

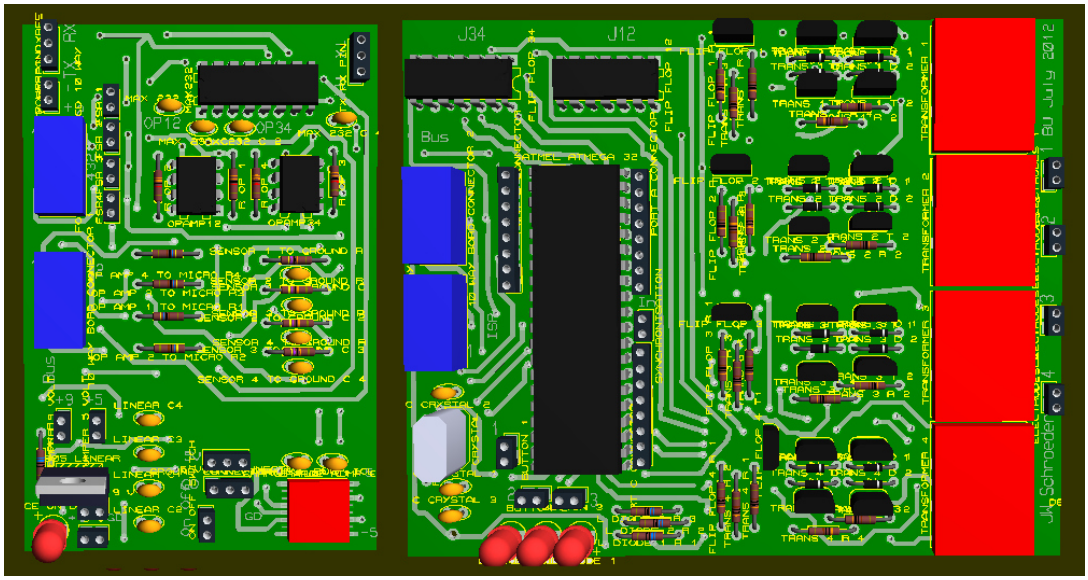

Fig. 3.15: 2-level design of the digital device: sensor unit, communication unit and power unit (left) and pulse creation unit and electrical stimulation unit (right). Both PCBs are connected with a bus cable (via the blue box representing a connector) to deliver sensor information and power to the microcontroller and electrical stimulation unit and to deliver communication information to the communication unit.

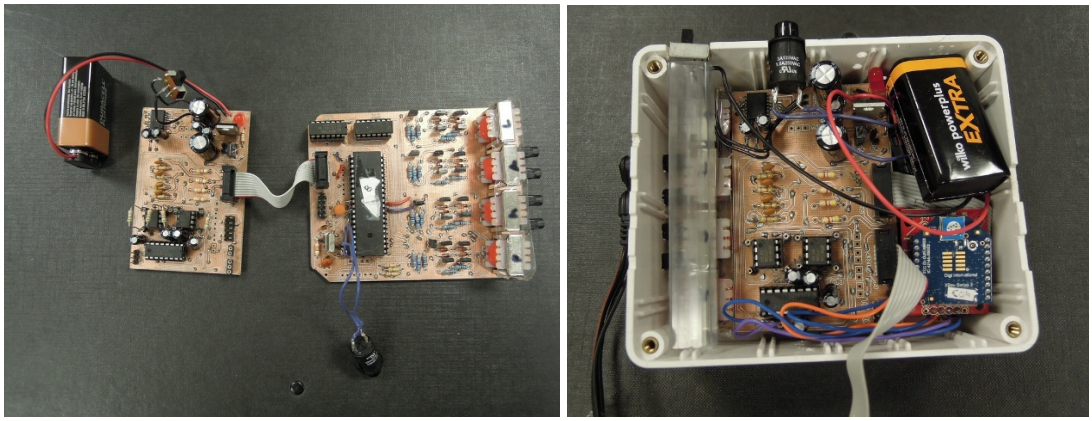

Fig. 3.16: Printed circuit board and installation in housing - The image on the left shows the two levels before they are placed on top of each other in the housing as it can be seen on the right picture.

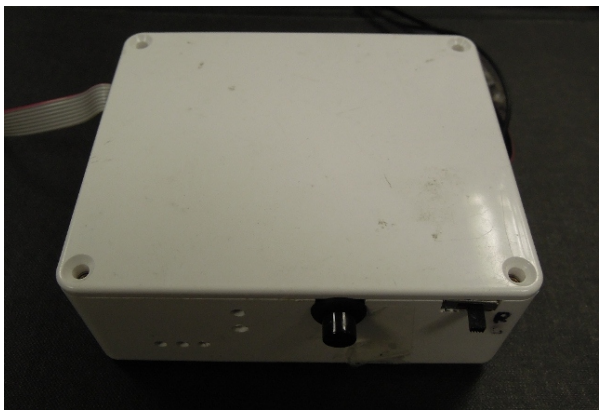

Fig. 3.17: Closed device housing and sensor unit showing the button that was used for user input.

The PCB was assembled and put into a housing for easier handling and for safety reasons. Fig. 3.16 and Fig. 3.17 show the installation of the circuit board in the housing. The housing has an on and off switch as well as a button to allow starting the calibration process and start and stop the device if needed. The cables for the sensor unit are attached via a 8 pin bus cable and the electrodes of the type Ambu Neuroline 700 are connected via standardized leads to the user's skin.

3.6. Functionality test

A test was conducted with three test participants to test the functionality of the sensor unit and electrical stimulation unit and to further test if differentiation of sensor stimulation location is possible.

3.6.1. Methods

First the stimulation functionality was tested by using two pressure scenarios. In the first scenario no load was applied and in the second scenario a load of 500 grams was applied. For this test one electrode pair was connected to the participants' skin and the voltage applied to the skin was measured at the connection of electrodes and skin using a U81B oscilloscope (Tursdale Technical Services Ltd 2013). The oscilloscope was connected via a USB cable to a PC and the voltage was plotted with the U81B software. After this test four electrode pairs were connected to the participants' upper leg with each electrode pair being 5 cm apart from the next electrode pair. The four

force sensors were applied in random order and the test participants were asked to confirm the location of stimulation. The test was repeated 15 times.

3.6.2. Results

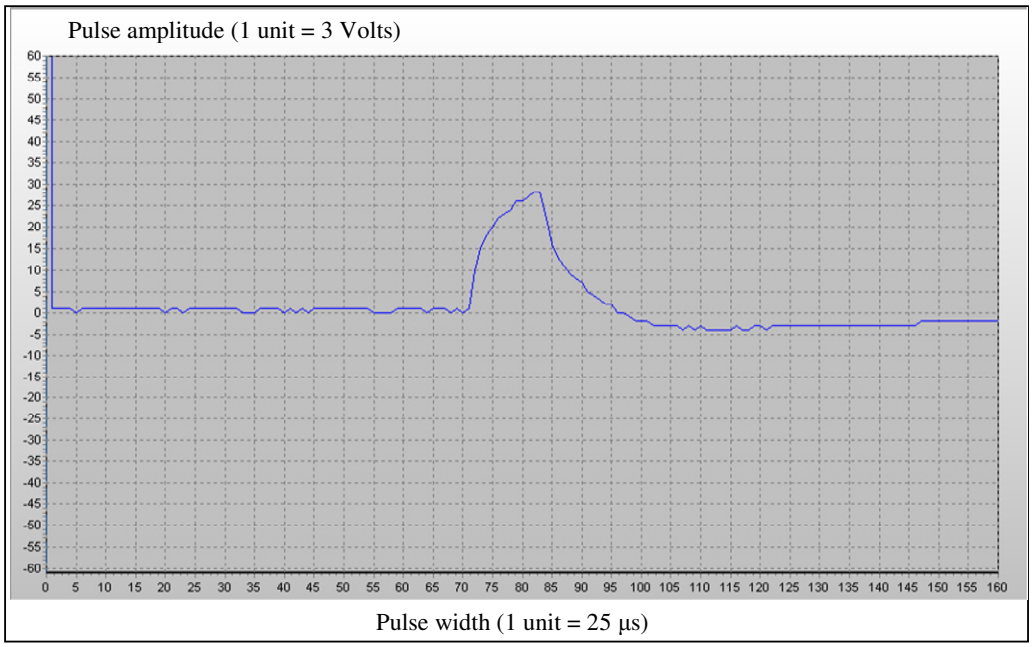

Fig. 3.18: Pulse measured on human tissue at minimum load measured on an oscilloscope, 1 unit equates 25 µs on the x-axis and 3 Volt on the y-axis.

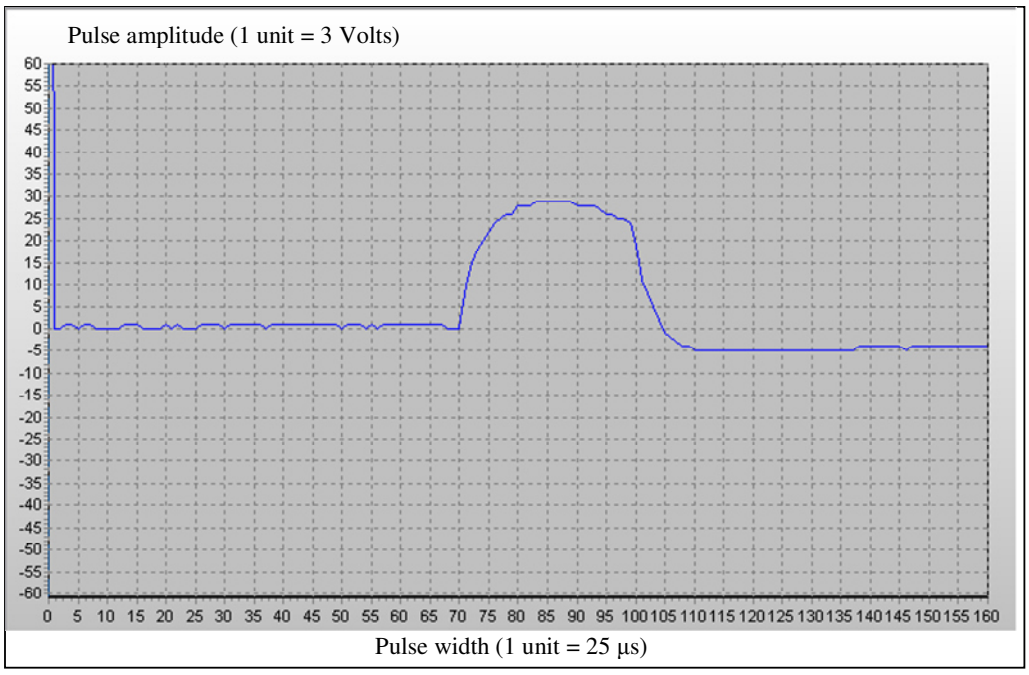

Fig. 3.19: Pulse measured on human tissue at maximum load.

Fig. 3.18 and Fig. 3.19 show the pulse applied through the electrodes measured with the oscilloscope. The maximum Voltage was 90 Volt. The length of the pulse was between 100 µs at minimum load and 140 µs at maximum load and the frequency was 28 Hz. The shape shows the behaviour of the skin acting like a capacitor which

is charged and discharged. Fig. 3.19 also shows that the pulse coming from the transformer does not stay stable but declines because of the saturation[25] of the transformer. It was found that the transformer is saturated at a pulse width of around 500-550 µs if a bipolar shape pulse is used. For uni-polar pulses the transformer is expected to be saturated for shorter pulses in the range of 250-300 µs.

In the location differentiation test the three test participants could name the correct location of stimulation in all 15 repetitions. The possibility of differentiation between four pairs of electrodes was therefore 100%. However, this might change for longer exposure and if pulses are applied over a longer period of time as adaptation to the stimulus might limit the ability to correctly differentiate between electrode pairs.

3.6.3. Discussion

Pulse amplitude and pulse width were in the expected range. However the frequency was expected to be 31 Hz based on the datasheet of the NE555 but is around 28 Hz. The saturation of the transformer limits the range of the pulse width that can be applied through the electrodes.

This preliminary test confirmed the working principle of the designed EFS. The application of load on a force sensor changed the output stimulation according to the weight applied. Further it was possible for the participants to differentiate which sensor was pressed and correctly name the location of stimulation.

3.7. Reliability test of force sensor system

A preliminary study was conducted to evaluate the behaviour of the piezoresistive force sensors when load is applied.

The reliability of the sensor system is a critical component in the design of an EFS to assure a flawless functionality of the device. To give appropriate electrotactile feedback the sensor system needs to be well understood. As the behaviour of force sensors under load can vary (Hollinger and Wanderley 2006) the study aimed to test different parameters of the piezoresistive force sensors used in this work.

3.7.1. Methods

A load-resistance relationship test was conducted. One force sensor was loaded with loads 50 g – 700 g in steps of 50 g and the resistance was measured for each step. Following this the relationship between load and voltage was derived using the circuit design in subchapter 3.4.2. (Fig. 3.7). The load-voltage relationship was tested for five resistors: 3.3 kΩ, 9.82 kΩ, 33 kΩ, 47 kΩ and 98.81 kΩ. In addition to that a repeatability test (Hall et al. 2008) was conducted loading seven force sensors with 50 g and 300 g while recording the resistance of the sensors. Finally a sensor drift test was carried out where a test participant was standing on a single force sensors over a period of 10 minutes and data was recorded at a frequency of 1 Hz.

[25] Saturation means that the magnetic field between the 2 windings of the transformer is not changing anymore and therefore voltage and current in the secondary winding declines

3.7.2. Results

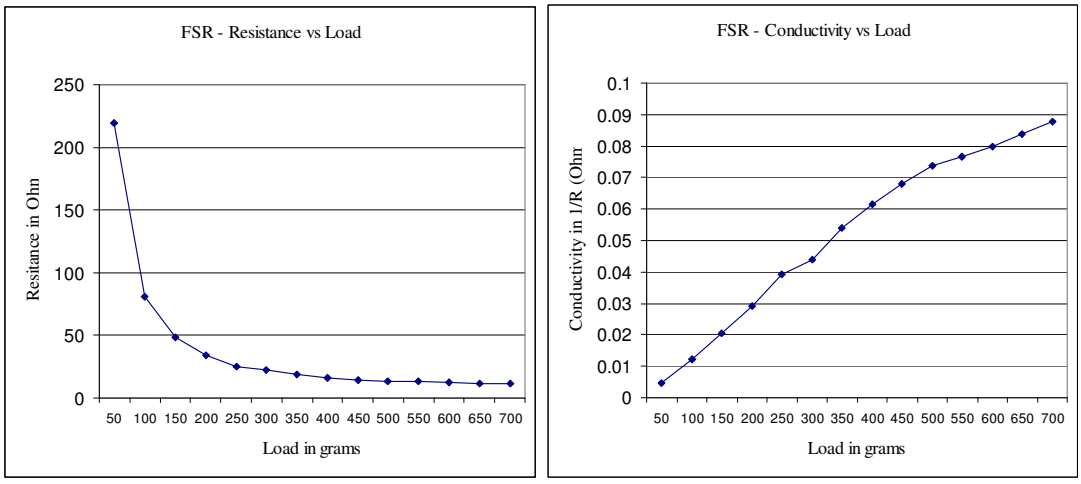

Fig. 3.20: Resistance/Conductivity vs. Load comparison for consecutive force sensor measurements. The Conductivity vs Load curve shows almost linear behaviour.

The calibration measurement shows the behaviour of the resistance and conductivity of the sensor against the load for one sensor (Fig. 3.20). Five different resistors were tested in the sensor unit circuit (see 3.4.2) and the output voltage was plotted against the load for all resistors.

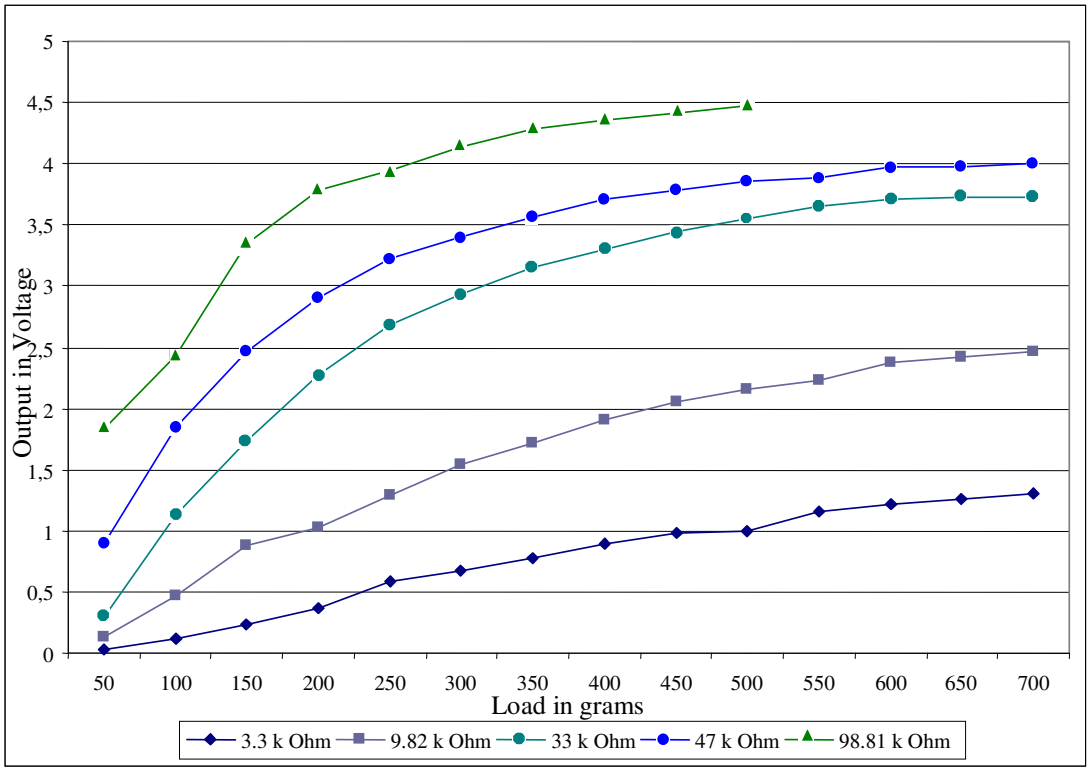

Fig. 3.21: Voltage output for different resistors in V (y-axis) vs. Load in grams (x-axis) comparison for Interlink FSR. According to the manufacturer the conductivity of the sensors should be almost linear. The figure shows that this is not the case for higher resistors.

Another calibration test done was the comparison of different sensors to define their deviation to each other when the load is applied. The arithmetic mean μ, standard deviation σ and maximum deviation δ were calculated.

Load in g	μ_R in kΩ	σ (Stdev)	δ_{Max}	δ_{Max} in %
50	26.9	1.5	4.2	15.6
300	259.1	18.7	55	21.2

Tab. 3.1: Deviation test for 7 force sensing devices

Tab. 3.1 shows that the deviation for different sensors and two loads of 50 grams and 300 grams was up to 15.6% for a low load and 21.2% for a high load.

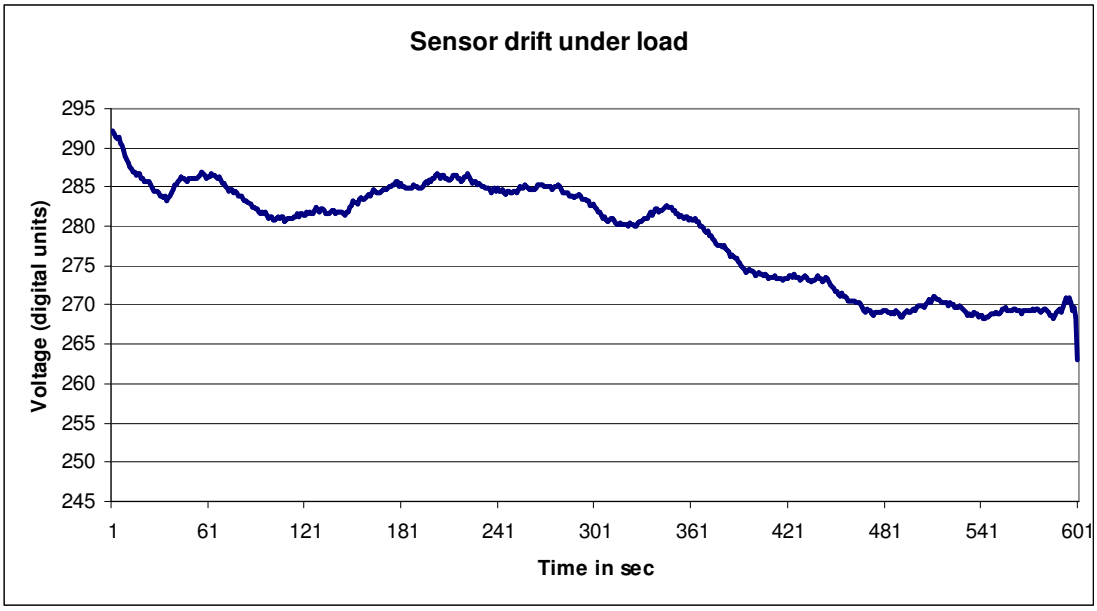

Fig. 3.22: Sensor drift under load. The figure shows the time over a period of 10 min and the voltage reading recorded by the processing unit. A moving window average filter was applied with a window size of 30 measurements.

The loading over a longer period of time revealed that the force sensor drift over a period of 10 min. was 3.8%.

3.7.3. Discussion

According to the manufacturer the conductivity of the sensor is almost linear and it is directly proportional to the reciprocal of the resistance. However, when evaluating the force output for different resistors in the sensor unit circuit the voltage output of the sensor unit shows a slightly non-linear behaviour, especially for higher resistor values used. If a higher resistor is used then the curve has to be taken into consideration for the calculation of stimulation feedback. In addition to that the deviation between different sensors is high and therefore it is recommended to calibrate each force sensor before it is used. The sensor drift was relatively low if compared to other factors but needs to be considered if a load is applied over a longer period of time.

The reliability of the sensor system in an EFS is a critical factor. Several parameters of the force sensors used in the design of the EFS were therefore evaluated. The force – voltage relationship was found to be almost linear for low resistors but became logarithmic for higher resistors. Different sensors show high variations of up to 21.2%. Sensor drift was found to be relatively low, but should be countermeasured if the force sensor is loaded over a longer period of time. This can be done by recording the drift curve of each sensor before the sensor is used in the EFS. Then

the curve can be used to correct sensor reading at a specific time. However, this might only be necessary if the device is continuously used over a longer period of time. In conclusion the preliminary test suggests that each force sensor needs to be calibrated before it is used in an EFS.

3.8. Conclusion

The current chapter presented the hardware design and development of a wearable EFS to be used by people with sensation loss in their feet. The hardware design of the current research incorporated the requirements of an electrotactile force feedback system (Chapter 1). The development process of the device is explained, starting with a device concept, an analogue prototype design, then a digital prototype design, followed by preliminary tests of the device and sensor system components.

The presented device meets safety requirements such as galvanic separation of the power source and it uses bipolar pulses to avoid any tissue damage due to accumulation of toxics in the area where the electrodes are placed. The EFS offers the possibility to individualise parameters through the integration of a microcontroller and can easily be adapted to the user's needs. Depending on the nature of the user's impairment, e.g. if only one leg is affected due to sensation loss, the design allows to equip only the affected leg with the device. The EFS is wearable and off-the-shelf components were used for the assembly to keep the overall costs low.

The sensor system was tested towards reliability. The test showed that the force sensors vary between each other and need to be calibrated. The force-voltage relationship showed approximated linearity for resistors below 33k. The functionality of the device was demonstrated and it was shown that the pulse width changed according to the force applied to the sensors.

The design has its limitations regarding usage in daily life as it is still bulky. This was necessary due to the restrictions for the PCB manufacturing at Bournemouth University. This could be improved further by outsourcing the manufacturing of the EFS to an external company with advanced production capabilities allowing a smaller and more practical device design.

In conclusion the designed hardware meets the requirements for the use in a wearable EFS. The device needs appropriate software to complete the EFS.

3.9. Acknowledgements

I would also like to thank the supervisors of the electrical engineering facilities at the Bournemouth University for their help in the design and the manufacturing of the circuit board in particular to Adam Wright and Christopher Benjamin. Furthermore thanks to Salisbury NHS Foundation Trust and their working group, namely Duncan Wood and Rod Lane, for providing useful support and the electrodes that were used for some of the experiments, as well as Odstock Medical who supported this research with a Functional Electrical Stimulator ODFSIII.

**"Reading computer manuals without the hardware
is as frustrating as reading manuals
without the software."**

Arthur C. Clarke

Chapter 4 Software Architecture

4.1. Abstract

There is only limited research dealing with the programming of algorithms that incorporate the technical and individual variables of an electrotactile feedback system (EFS). This fact limits the progress of development of wearable EFS.

In this research project embedded software has been developed for a portable EFS that tackles the problem of improving balance control for impaired individuals. The program has several novel features. An intelligent agent was implemented to process information from the sensor system and taking an action in the form of electrocutaneous stimulation. In a training routine the force sensor system is calibrated and COP information obtained. Furthermore the software detects individual parameters of the wearer by testing the sensation threshold for electrocutaneous stimulation using an established procedure, the method of limits (Chapter 2 and 5).

After the training routine the program uses the gathered information to calculate the ideal pulse width based on the calibrated values, so that the electrotactile feedback given to its wearer is always in a comfortable range of sensation and that the feedback is based on the COP information detected beforehand. The system uses artificial intelligence (AI), in form of a simple reflex agent (SRA) to prevent harmful or unwanted feedback. A preliminary test was performed to test the repeatability of the sensory threshold detection and showed a high repeatability.

The key features of the software are: 1) Individual customization of sensory threshold, 2) Automatic sensor calibration and COP detection, 3) Knowledge base with individual parameters, 4) Time efficient pressure-feedback calculation, 5) Intelligent agent to regulate electrotactile feedback, 6) Detection of sensor and data transmission error and prevention of harmful stimulation

The developed software has several novel features and can be integrated in the innovative portable EFS that can be used by people with sensory impairment as a reference to improve their ability of controlling their balance and thus preventing the risk of falls.

4.2. Introduction

4.2.1. Motivation

Most electrotactile feedback systems are static and cannot be worn during activities of daily life (Matjacic et al. 2000; Kaczmarek, Kramer, et al. 1991). Even though portable devices have been studied before (Onesti et al. 1989) no digital device development allowing the implementation of an intelligent algorithm was studied

yet. The previous chapter explained the hardware for the development of a portable EFS with an integrated microcontroller to implement an algorithm to improve the usefulness of the EFS. The software on a portable EFS should fulfil several requirements to assure a useful feedback such as calibrating the force sensors and the individual thresholds for comfortable sensations stored in a knowledge base. A rule base then should assure that the requirements are met. An intelligent agent can fulfil those tasks and interact with its environment, in this case, the centre of pressure movement on the foot sole, and trigger an action, here in form of the electrotactile feedback.

4.2.2. Intelligent agents

Artificial intelligence involves the design and study of intelligent agents (Russell and Norvig 2009). Intelligent agents are autonomous entities that detect changes in their environment and trigger an action based on condition-action rules (Fig. 4.1).

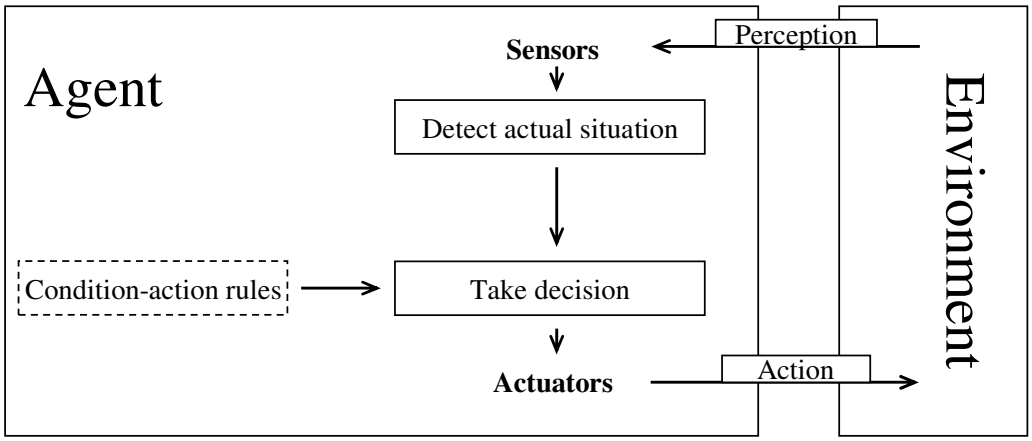

Fig. 4.1: Principle of simple reflex agent

There exist several types of agents which can be considered in the design of an EFS. Most intelligent agents need high processing power between the perception of a sensory input and the performance of an action. On the other hand a simple reflex agent (SRA) uses a rule base that is trained or defined before the agent starts to interact with the environment (Russell and Norvig 2009). This allows the implementation of a fast decision making process. For the developed EFS the rules must be based on the parameters of the system which includes the force sensor validation, centre of pressure detection and identification of sensory thresholds. Further all actions, in form of electrical feedback, must stay in a comfortable range of stimulation.

4.2.3. Piezoresitive force sensor validation

Different piezoresistive force sensors, even when of the same manufacturing, can have a high variability if the same load is applied (Chapter 3). While the linearity of change of resistance measured against different loads is quiet stable (Tekscan 2006), the resistance for the same load on different force sensors and under different conditions can vary significantly. A possibility to calibrate force sensors is by putting controlled loads on them and recording the force-resistance or force–voltage curve (Hollinger and Wanderley 2006). Theoretically this is necessary before every use of a force sensor, as it changes its resistance over time based on temperature and

location (Meyer et al. 2006). However this procedure is very time consuming and, is therefore not practical. By detecting the minimum and maximum force sensor value and assuming an almost linear behaviour between them, the time for calibration could be reduced significantly. The software developed in this work should allow an appropriate method to detect the minimum and maximum force sensor values as information for the electrotactile feedback.

4.2.4. Centre of Pressure

The centre of pressure is commonly used to describe the quality of balance (Turcot et al. 2009). The COP can be detected via force sensors allocated in a shoe insole (Biswas et al. 2008). Feedback about the COP can be supportive for improving the ability to actively controlling balance when it is limited, e.g. due to impairment (Kanade et al. 2008). As the goal of the device is to help people with impaired ability to stand stable by actively controlling their centre of balance, the software should be able to detect the COP in a stable situation for a user and store this information to detect when a person becomes unstable. The COP can be obtained with a simple learning algorithm by measuring the force distribution under people's feet (Morin et al. 2002) and the information can be saved in a knowledge base. Several indicators of balance can be derived from the COP such as the displacement in the anterior-posterior (AP) and the medial-lateral direction (ML) (Chapter 6).

4.2.5. Threshold procedure

The range of comfortable sensation differs between each individual. This is due to the sensitivity of a person (Marcus and Fuglevand 2009), the placement of the electrodes (Geng et al. 2012) and the skin condition (Tregear 1966) leading to a higher or lower resistance for the current to pass through. By detecting the thresholds of the person before electrotactile feedback is applied it can be assured that the feedback is always in a comfortable range. An appropriate method for the detection of thresholds is the method of limits (Chapter 2 and 5). In this method the lower threshold is detected by slowly raising a pulse until a test subject confirms that he or she can feel the stimulus. The same is done for the higher threshold, where the test subject confirms once the stimulus becomes uncomfortable. This method shows a high repeatability when used several times (Appendix H). Therefore the software developed in this work should implement the methods of limits in the calibration procedure for detecting the thresholds for comfortable sensation.

4.2.6. Pulse characteristics

Another requirement of the program is to deliver pulses with the appropriate characteristics (Chapter 2). The frequency for electrotactile feedback usually lies within the range between 2 and 100 Hz (Szeto 1985; Szeto and Saunders 1982) and the pulse width lies between 0 and 1000 μs (Robertson et al. 2006). The program should be able to deliver those pulse characteristics. A unipolar pulse can lead to toxication of the skin (Marcus et al. 2006) and the software should allow creating a bipolar pulse to avoid this unwanted effect.

4.3. Technical methods

4.3.1. Development Environment

The development environment AVR Studio was used for the embedded programming. The software has been developed in the programming language C (Appendix J). The program was compiled and a hex[26] file was created and loaded onto the ROM (memory) of the microcontroller using an AVR MKII programmer connected with the ISP interface on the microcontroller.

4.3.2. Analogue to digital conversion of sensor data

The Atmel Atmega 32 microcontroller has an integrated analogue to digital converter (ADC), which allows interpreting the information from the sensor unit. The sensor unit sends a voltage with the minimum Voltage, V_{min} = 0 V and V_{max} = 5 V, depending on the force that is applied to the force sensor. The ADC is able to convert this voltage into an 10 bit-value between 0 and 1024 leading to a resolution of

$$f = \frac{V_{\max}}{1024}. \qquad (10)$$

This value represents the force, further called force value *f*. The force value can be read by calling the appropriate command in the program. Since the ADC has a limited accuracy it is necessary to use an average filter to have a more representative force value at a given time, $f_{(i}$,

$$f_{(t)} = \frac{1}{3}\sum_{i=1}^{3} \Delta f_{(i)}, \qquad (11)$$

where $\Delta f_{(i)}$ is a single reading of the ADC. Before three values are averaged a first reading is undertaken to warm up the ADC, which is not used for the averaging method. This is a commonly used method to countermeasure electronic induced noise of the sensory system. The whole process of warming up the ADC and averaging over three values was measured and takes ~ 500 µs per reading.

4.3.3. Data transfer

For communication and debugging purpose the device is able to send data via the TxD pin of the microcontroller to the COM-port of the PC. This can be done by initializing the UART interface of the microcontroller and sending continuously data of the type “Character” (Char) to the UART interface. Since a UART can only send one char at a time a small routine was programmed to send strings through this interface, such as the sensor values. Another communication channel is a XBee-module that enables the EFS to send data wirelessly to a PC. This communication channel is also used in the training routine to communicate with the user and define the parameters for the simple reflex agent.

[26] A hex-file is a program converted into machine code that can be interpreted by the microcontroller

4.3.4. Timers

The microcontroller that was used is an Atmel Atmega 32 (Texas Instruments 2011). This microcontroller only has two hardware pulse width modulators (PWMs) available. Since the device was designed with four transformers a software PWM needed to be implemented as part of this work. A software PWM was implemented by using the internal timers, also called counters, of the microcontroller. The Atmel Atmega 32 has three internal timers with different characteristics. Two timers were used to build a software PWM: One timer that sets the frequency of the pulses and a second timer to control the pulse width. Both timers were initialised during the initialization process (Fig. 4.2) of the program running on the microcontroller. The first timer was set to 50 Hz and the interrupt frequency was divided into three cycles. Two cycles were reserved to send sensor data wirelessly and one cycle was reserved to give feedback. This resulted in a data acquisition rate and a pulse frequency of 16.6 Hz.

4.3.5. Pulse control

The pulse was controlled by setting four output pins of the microcontroller HIGH or LOW. A port pin which was set to HIGH had a stable voltage of 5 V. Once the voltage was set LOW the voltage dropped to 0. By connecting an output pin to a J-type Flipflop that is itself connected to the transformer switches, it was possible to control the bipolar pulses' frequency and width through this output pin by using the software PWM to change the state of the pin.

4.4. Program structure

This section describes the software architecture of the program for the electrotactile feedback device that was designed and implemented for this work. Unified Modelling Language (UML) diagrams were used to demonstrate the working principles of the software (Hamilton 1999). The programming code for the device can be found on the CD (Annex J).

4.4.1. Main routine

The main routine of the program is shown in Fig. 4.2. The different routines can be entered on the device by pressing the function button on the device.

After the device starts up the input ports and output ports of the microcontroller are initialized. The input ports use an ADC as described above. After the initialization the program enters the training routine where the feedback parameters are derived and the condition-action rules are defined. Then the program goes into the feedback routine where the sensor data is read and the implemented simple reflex agent decides on an action based on the input data. The sensory input results in a pulse that drives the transformers (Chapter 3). By pressing the button the device can now switch between the feedback routine, during which the SRA is active and data is send wirelessly for recording or a no-feedback mode, where the device only sends the data from the force sensors for recording, but no feedback in form of electrical stimulation is activated. This switch is useful when using the device for study purposes if one wants to compare the effects on balance with and without the device giving feedback, but also in daily operations to turn the device into a less energy consuming mode when it is not needed.

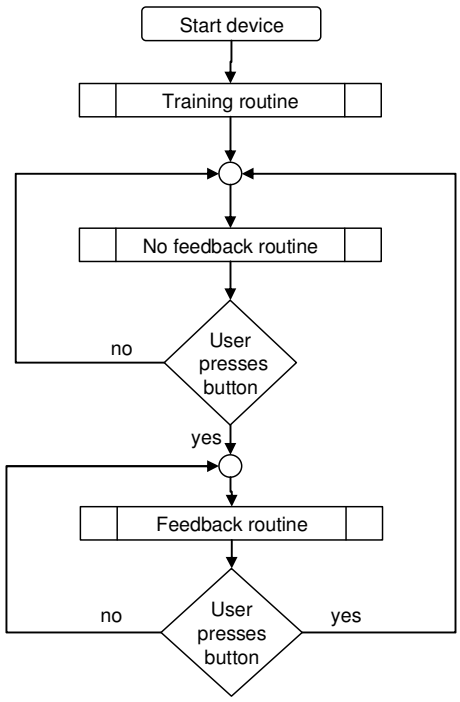

Fig. 4.2: Flow chart of Main routine. After the training routine the user can switch between the "No feedback routine" and the "Feedback routine" by pressing a button attached to the device. In the No feedback routine the device only sends the pressure sensor data, while in the Feedback routine the Simple Reflex Agent is active, initialising electrotactile feedback, before the pressure data is sent.

4.4.2. Training routine

The training routine of the feedback parameters was necessary to save individual parameters in a knowledge base and to create a condition-action rule base for the intelligent agent. There are three main variables that are detected in the developed software: the force sensor values, the COP during quiet stance and the sensory threshold for the electrotactile feedback. During the training routine a user interface communicates wirelessly with the user via the RS232 interface and an XBee-module of the EFS and instructions are given on a computer screen.

The force sensor maximum and minimum values are obtained by recording the sensor input for about 30 seconds while force is applied to the sensors. The force sensors are attached to the user's insole placed in a shoe and the user is asked to sway back and forth and left and right during that time. The algorithm then assigns values for the minimum and maximum force values, f_{min} and f_{max}, for each force sensor during that time. If the current sensor value is higher than the current maximum sensor value, f_{max} the current sensor value becomes the new f_{max} and vice versa for f_{min}. These values are stored for each force sensor in a knowledge base on the microcontroller's memory.

The centre of pressure information was detected by analysing a balanced stand for five seconds. The user was asked to stand still and the centre of pressure information was recorded at 2 Hz, and averaging over those values resulting in a COP force value, f_{COP}, for each sensor. This information is added to the knowledge base on the internal memory.

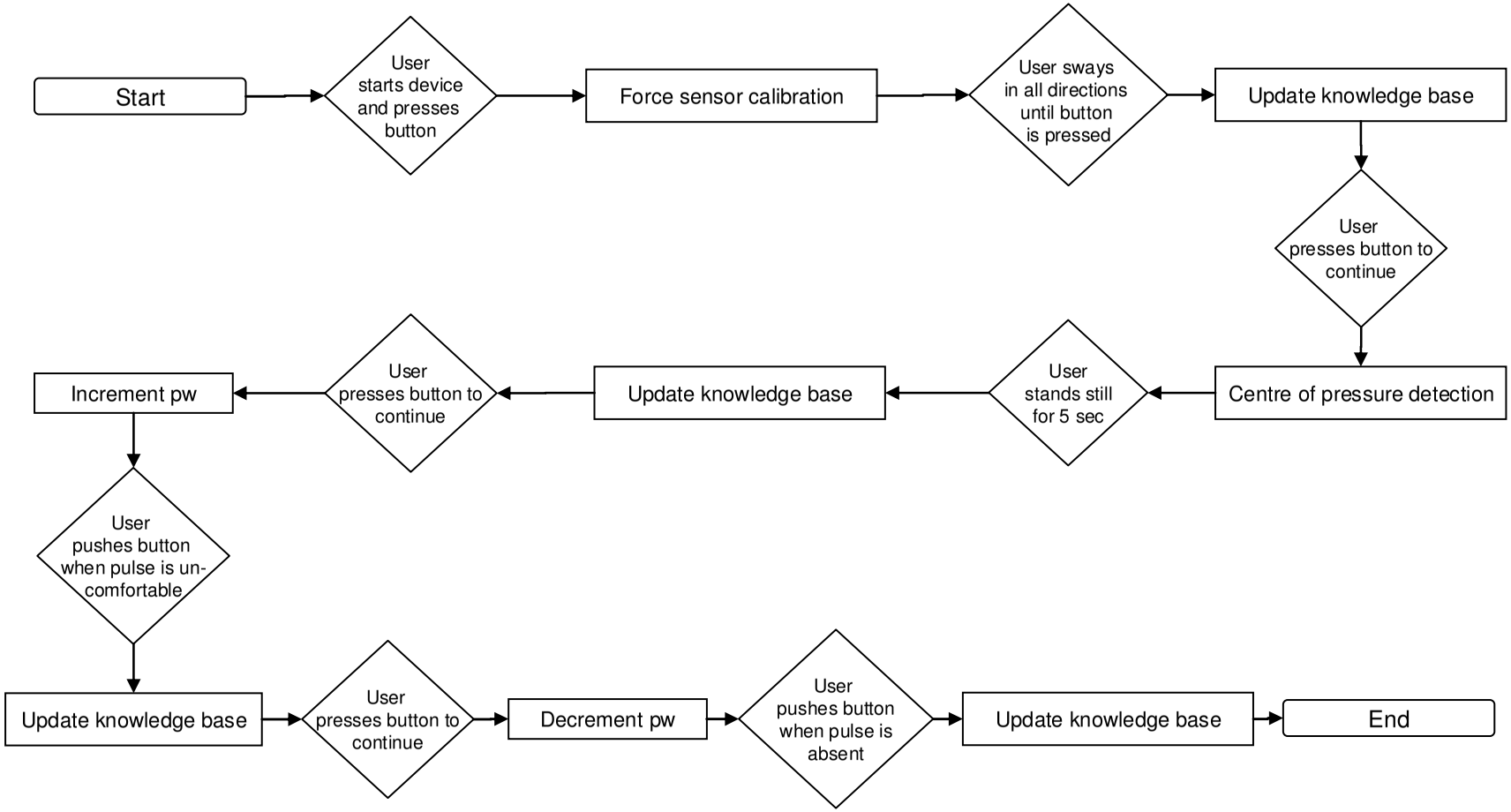

Fig. 4.3: Flow chart of the Training routine. The user starts the device and presses a button on the device to start the force sensor calibration. The user sways in different directions and during that time the device detects the minimum and maximum force sensor value of each sensor, which are then saved in the knowledgebase. The user then continues by pressing the button on the device and the centre of pressure is detected while the user is standing still for 5 seconds. In the next step the user starts the incrementation of the pulse width by pressing a button stops once the pulse feels uncomfortable. The lower threshold is then detected by lowering the pulse and detecting the value once the user finishes the training routine by pressing the button again.

The sensory thresholds were detected for each individual. The procedure included the testing of the transformer output on a pair of electrodes to define the threshold for sensing and discomfort. These thresholds were then used as the minimum and maximum range of pulse width. The training routine (Fig. 4.3) uses a frequency timer to create pulses at a rate of 16.6 Hz. Another timer was used to vary the pulse width. The reliability of this method was tested in a preliminary study prior during the design process of the software and was found to be suitable for the use in EFS. (Appendix H).

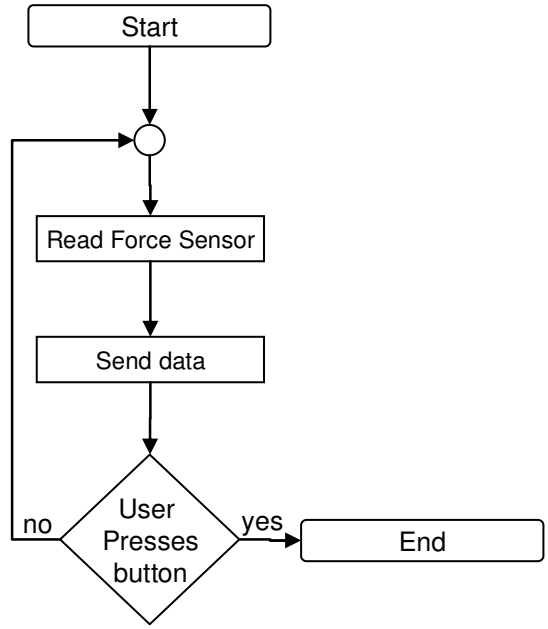

Fig. 4.4: Flow chart of No feedback routine. The routine reads the force sensor data and sends the data. No electrotactile feedback is given in this device modus.

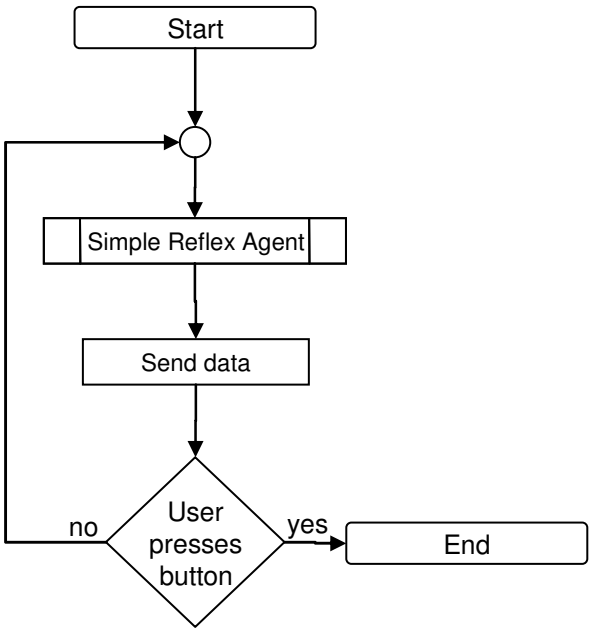

Fig. 4.5: Flow chart of Feedback routine using Simple Reflex Agent (SRA). In the Feedback routine the Simple Reflex agent is activated and electrotactile feedback is given to the user before data is sent.

The first loop of the Training routine (Fig. 4.3) aims to obtain the pulse width that creates discomfort to the participant. Therefore the pulse width starts from 0 and increments by 4 µs every 0.3 s. The pulse rises until a button is pressed by the user. The pulse width value is then saved in a variable resulting in the upper threshold for comfortable sensation, pw_{max}. Then the pulse width starts to decrease by 4 µs every 0.3 s. Once the pulse width reaches the sensation threshold and the calibration button is pressed again the value is saved as the threshold variable for the minimum pulse width, pw_{min} in the microcontroller's knowledgebase. The calibration procedure contains a software based limitation for the maximum pulse width as well as a software based limit for safety reasons. If the pulse width reaches 600 µs the software detects this as the maximum pulse width and does not raise the pulse width anymore. The hardware limit is the saturation of the transformer. The transformer saturates at a pulse width of roughly 500 – 550 µs, thus longer pulses than that are not received as being stronger in magnitude (Chapter 3).

4.4.3. Feedback routine and No-feedback routine

The Feedback routine (Fig. 4.4) handles the main function of the electrotactile feedback system. First a timer is started to define the pulse frequency. The timer allows using an interrupt routine to read the sensor data and give electrotactile feedback. The sensor data is then sent via XBee or RS232 with a frequency of 16.6 Hz to a computer where the sensor data can be logged and analysed later on or displayed in real time (Chapter 6). At this point the Feedback routine calls the SRA before sending the data, while the no-feedback routine stops here and loops back to reading the sensor data again.

The SRA (Fig. 4.6) checks the conditions of the rule base (subchapter 4.5.2). Condition 1 is triggered if the sensor value is higher than the previously detected maximum force value and results in setting the pulse width to pw_{max}. Condition 2 is triggered if the sensor value is in the expected range and results in the calculation of the pulse width using the transfer function (subchapter 4.5.1). Condition 3 is triggered if the sensor value is smaller than the previously detected minimal force value and results in the end of a pulse by setting the pulse width to 0.

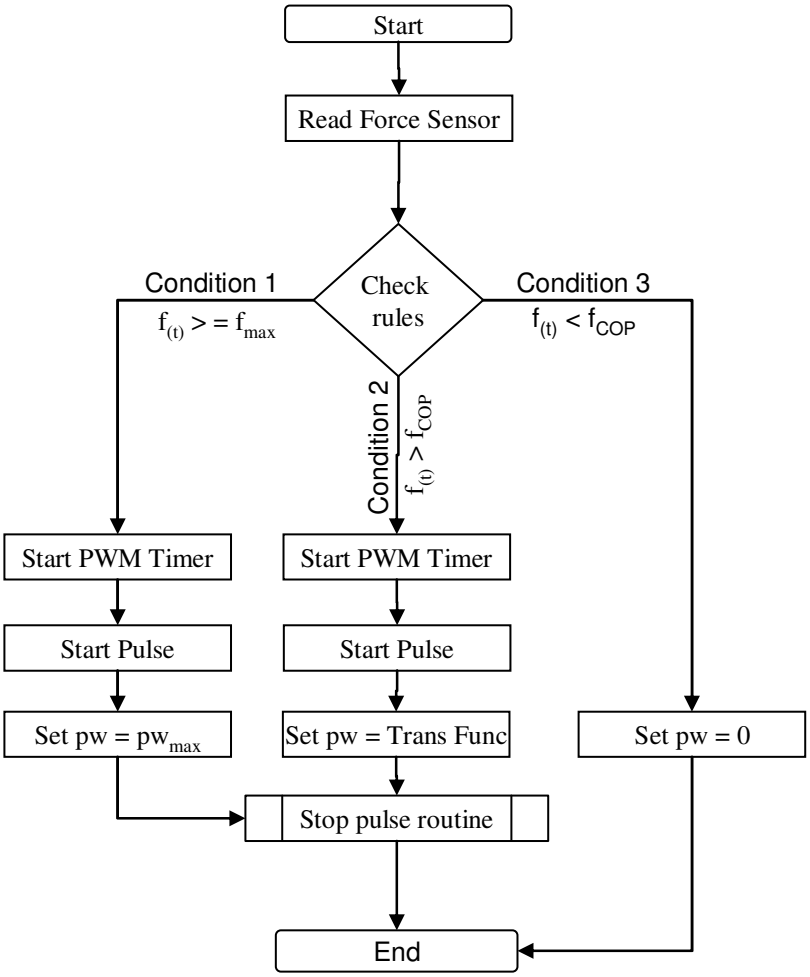

Fig. 4.6: Flow chart of simple reflex agent. The intelligent agent checks the rule base before the feedback stimulation is triggered. If condition 1 is detected then the pulse width (pw) is set to the maximum threshold pulse width, if condition 2 is detected then the pulse width is calculated by using the transfer function (section 4.5.1) and if condition 3 is detected then no pulse is triggered.

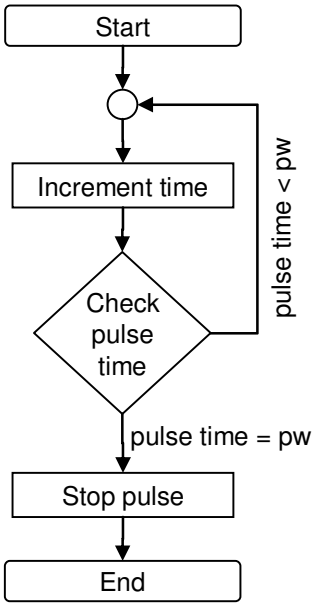

Fig. 4.7: Flow chart of the Stop Pulse Routine. The routine tests if the current pulse time is equal the pulse width defined by the Simple Reflex Agent and stops the pulse if the pulse width is reached.

A pulse is started by setting the output pin to HIGH. In the Stop pulse routine (Fig. 4.7) the program increases the current pulse with a resolution of 4 µs.

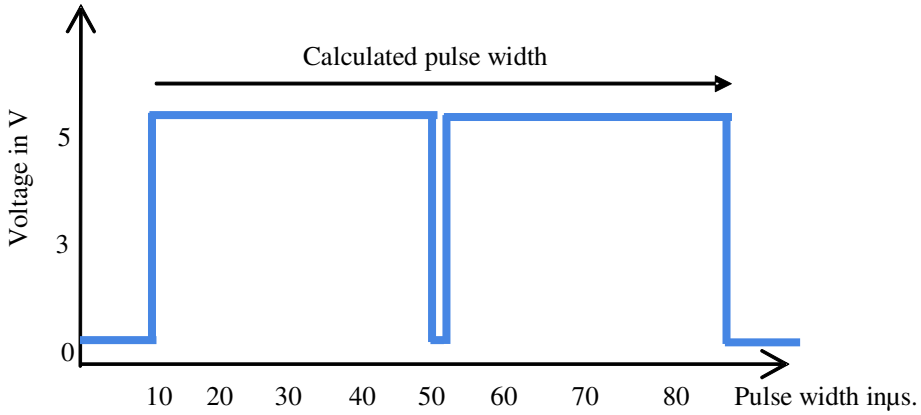

Fig. 4.8: Bi-shaped pulse sent to Flip-Flop for H-Bridge control. The Flop-Flop in combination with the H-Bridge inverts the second pulse thus creating a bi-shaped at the electrodes that are attached to the user.

If the current pulse width matches half of the value of the pulse width set by the SRA, then the pulse at the output pin is set to LOW and is set to HIGH directly after that (Fig. 4.8). The pin is then set to LOW again when the current pulse width reaches again half of the calculated pulse width value resulting in a bi-shaped pulse with a total length of the set pulse width. Since the pulse is sent to the J-type Flip-Flop the pulse triggers the Flop-Flop to switch between the two statuses to control the H-bridge of the transformer, thus leading to a bipolar pulse in the electrical stimulation units output.

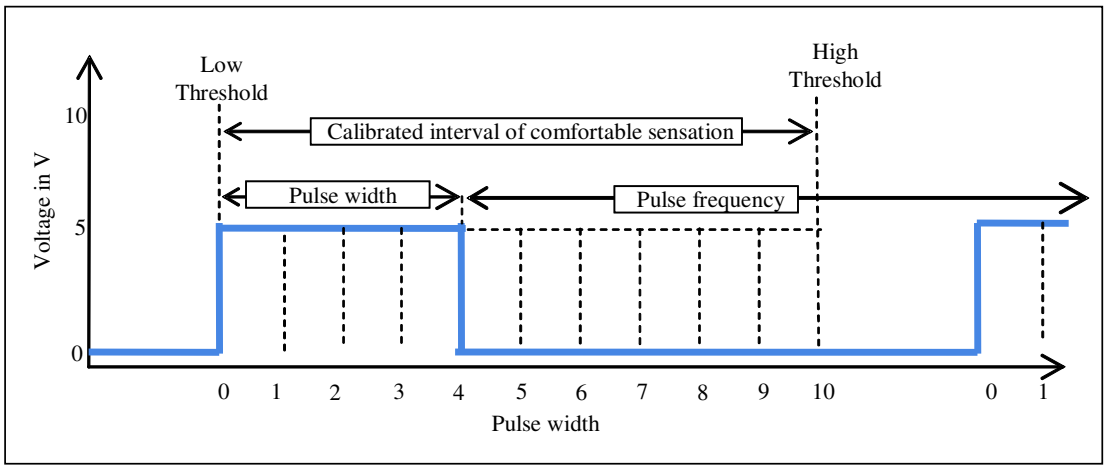

Fig. 4.9: Range of pulse width. The pulse width lies within the interval of lower and higher threshold as obtained in the calibration procedure

The formula used to calculate the pulse width $pw_{(t)}$ for a specific sensor value $f_{(t)}$, representing the voltage coming from the sensor unit, is based on the two pulse width thresholds for sensation and discomfort that were obtained in the training routine (Fig. 4.3).

4.5. Transfer function and rule base

4.5.1. Transfer function between COP movement and pulse width

The transfer function aims to relate the magnitude of COP displacement with the strength of the electrocutaneous stimulation. During the training routine the interval for comfortable sensation is obtained by determining the minimum pulse width, pw_{min}, and maximum pulse width, pw_{max}. The COP, f_{COP}, is obtained by averaging the force sensor readings received over a period of 5 seconds as described above for each sensor,

$$f_{COP} = \frac{1}{10}\sum_{t=1}^{10} \Delta f_{(t)} \,. \qquad (12)$$

The outcome is an equivalent digital value for f_{COP} between 0 and 1024. The values f_{max}, f_{min} and f_{COP} are saved during the training routine in the knowledge base and are used by the intelligent agent for the calculation of the pulse width. To calculate the displacement of the current COP to the COP during body equilibrium at a given time into the AP or ML direction, the current force value needs to be subtracted from the force value representing the COP. To calculate the time dependent pulse width for this deviation, $pw_{(t)}$, for a measured single force sensor value, $f_{(t)}$, the intervals for the pulse width must be matched to the interval of the force sensor values. To do this firstly the force sensor values are normalized by dividing through the length of the interval $[f_{COP}, f_{max}]$,

$$\frac{f_{(t)} - f_{COP}}{f_{\max} - f_{COP}}, \text{ where } f_{(t)} \in [f_{COP}, f_{\max}]. \qquad (13)$$

The same is done for the pulse width where pw_{min} is the pulse width for the lower sensation threshold in µs. pw_{max} is the pulse width for the discomfort threshold in µs,

$$\frac{pw_{(t)} - pw_{\min}}{pw_{\max} - pw_{\min}}, \text{ where } pw_{(t)} \in [pw_{\min}, pw_{\max}]. \qquad (14)$$

Then the force sensor value interval needs to be matched with the pulse width interval,

$$\frac{f_{(t)} - f_{COP}}{f_{\max} - f_{COP}} = \frac{pw_{(t)} - pw_{\min}}{pw_{\max} - pw_{\min}} \,. \qquad (15)$$

To calculate the pulse width at a given time, $pw_{(t)}$, for a given electrode location (l), the equation is solved for

$$pw_{l(t)} = pw_{\min} + (pw_{\max} - pw_{\min}) \cdot \frac{f_{(t)} - f_{COP}}{f_{\max} - f_{\min}} \,. \qquad (16)$$

This formula consists of division operation which is time consuming. By transforming the formula into a simpler form calculation time can be saved. The linear equation

$$x_{(y)} = \mathrm{a} \cdot y + \mathrm{b}\,, \qquad (17)$$

contains no division and the equation for the pulse width can be transformed into a linear equation

$$pw_{l(t)} = \mathrm{k}_{\mathrm{d1}} \cdot 10^{-2} \cdot \mathrm{f}_{(t)} - \mathrm{k}_{\mathrm{d2}} . \quad (18)$$

The two factors k_1 and k_2 can be calculated directly after the training routine and before the program enters the feedback routine, so no more division is necessary during the feedback routine,

$$k_1 = \frac{pw_{\max} - pw_{\min}}{f_{\max} - f_{COP}} \cdot 10^2 . \quad (19)$$

The multiplicator 10^2 is used to avoid rounding errors and is later reversed by multiplying with 10^{-2} (see eq. (18)). The second factor is

$$k_2 = pw_{\min} + \frac{f_{COP} \cdot (pw_{\min} - pw_{\max})}{f_{\max} - f_{COP}} . \quad (20)$$

The calculation for the coefficient has to be done for each force sensor separately and directly after the training routine. This leads to a total of eight coefficients that are stored in the knowledge base on the microcontroller's internal memory. By using equation (17) the pulse width is always in the range of the lower threshold and the maximum threshold (Fig. 4.9 and Fig. 4.10).

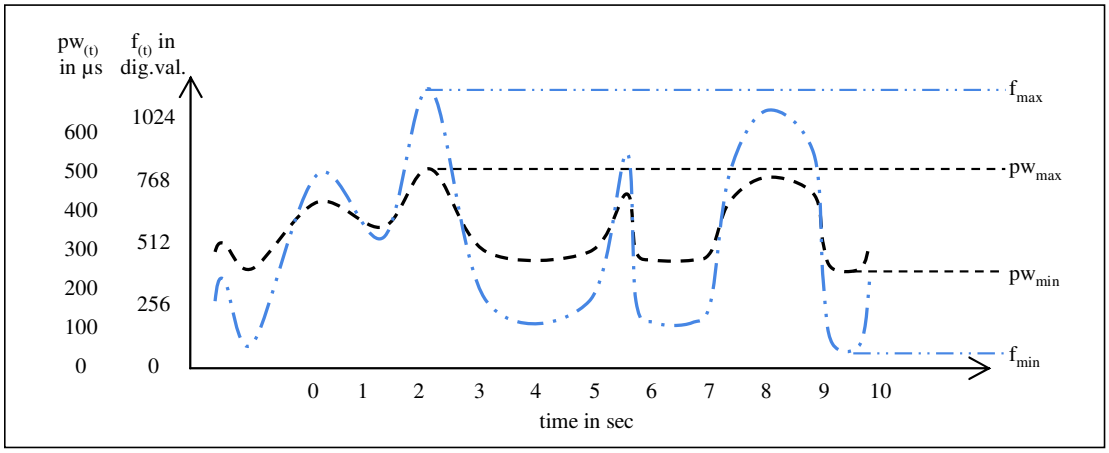

Fig. 4.10: Relationship between pulse width value and COP displacement (Line: . . . . . .) and pulse width (Line: - - - - -).

However there are several exceptions to this, such as a faulty sensor value, a malfunction of one of the sensors or another circuit component. The simple reflex agent detects these situations that could be potentially harmful to the wearer by applying the condition-action rule base before an action in form of electrical stimulation is triggered.

4.5.2. Definition of rule base for intelligent agent

The rule base used by the intelligent agent prevents pulses which are higher than pw_{max} but also assures that feedback on a certain electrode is only given when a force sensor value is within the force sensor value interval [f_{COP} f_{max}]. Three conditions are tested before any pulse command is sent:

Condition 1) If $f_{(t)}$ is greater than or equals f_{max} then $pw_{(t)}$ is set to pw_{max}

Condition 2) If $f_{(t)}$ is greater than f_{COP} then pulse is calculated according to pulse transfer function ($pw_{d(t)} = k_{d1} \cdot 10^{-2} \cdot f_{(t)} - k_{d2}$)

Condition 3) If $f_{(t)}$ is smaller than f_{COP} then $pw_{(t)}$ is set to 0

Condition number 2 indicates that all values are in the estimated range and the pulse width can be calculated by the transfer function. The rule base assures that no uncomfortable sensation is given to the wearer.

4.6. Discussion and conclusions

4.6.1. Motivation

Electrotactile feedback systems have the potential to improve balance and walking for people with sensation loss in their feet. The software of an EFS needs to fulfil certain requirements to assure that the usage of the device is safe and considers individual parameters. Further the embedded software needs to make use of the COP information to provide feedback to the user and enables the user to better control his/her posture. Therefore the aim was to develop an intelligent system that can be trained with device and user specific parameters to optimize the effectiveness of the EFS.

4.6.2. Results & Implications

The software that has been developed in this study uses an intelligent agent, a simple reflex agent, to take decisions based on a predefined rule base. The rule base is obtained by using a novel training routine that detects the COP information, the minimum and maximum sensor values, and the sensory thresholds of the user for electrocutaneous stimulation. The approach for the detection of sensory thresholds in this work is based on the method of limits and offers a fast way to train the system. A preliminary test confirmed the repeatability of the method for detecting sensory thresholds. A transfer function between the COP displacement and the magnitude of electrocutaneous stimulation was derived.

The embedded software solution presented in this chapter is a major contribution to the development of a portable EFS. Existing EFS or new concepts can make use of the software and integrate it into their solution.

4.6.3. Limitations

Several parts of the program could be improved if more calculation power was available. An example is the robustness of the system towards sensor drift. Force sensors can change their behaviour over time, through change of temperature and natural erosion. A dynamic algorithm could be investigated in further research to solve this problem by detecting and countermeasuring the sensor drift.

The developed software does incorporate the sensory threshold of the user, but it does not incorporate the change of those thresholds during the usage of the device. The human skin can adapt to electrical stimulation over time (Buma et al. 2007). A possible solution for this is to study the adaptation of each individual and use the adaptation curve to counter measure against the adaptation when calculating the pulse width. Nevertheless this might not necessarily be useful as the adaptation to stimulation is a natural behaviour which also occurs for normal touch.

4.6.4. Future work

Further investigations should be considered for improving the detection of sensory thresholds in the training routine. A possible improvement is slowing down the increase or decrease of the pulse width when it reaches the area where it is more likely to have a threshold and accelerate the increase and decrease for pulse widths that are expected to be in between the two thresholds. This approach would allow finding the thresholds faster and is more practical.

Further work could be done in extending the knowledge base. A look up table which stores the equivalent pulse width pattern for each COP value could be useful for future design concepts that require a less time consuming approach for determining the pulse width. Additionally a more complex intelligent agent could be considered in future design concepts. The system could use artificial neural networks to learn the balance behaviour of the wearer of the device during its usage. Another possibility is the use of fuzzy logic to correctly detect and classify sensor or device errors and warn the user of a failure of the device.

Another considerable psychophysical fact for future studies is that each person has an individual psychophysical power function for magnitude estimation with electrotactile stimulation. The individual preference and the placement of the electrodes play an important role on how this function looks like for each individual. The information about the psychophysical power function could be integrated in the transfer function between COP information and pulse width. An evaluation of the psychophysical power function at upper legs as an area of stimulation is studied in the next chapter.

4.6.5. Conclusions

After the hardware design of an EFS was described in the last chapter, this chapter focused on software and novel algorithms which have been developed in this work. The main requirements on the software for an EFS were summarized and justified the need for an AI based approach by using an intelligent agent to communicate between the perceptive sensor unit and the active stimulation unit.

A simple reflex agent was implemented. A rule base was defined which uses the information obtained in a training routine. The rule base is created in three steps. Firstly the system is trained to detect the sensor characteristics by saving the minimum and maximum force values in a knowledge base. Then the COP information is detected by analysing the stable stance of the user. Finally the method of limits was implemented using an accelerated time saving approach to detect sensory thresholds of electrocutaneous stimulation. The rule base prevents harmful feedback in case of a sensor or data transmission error and automatically limits the pulse width to a comfortable range.

This AI approach allows the calculation of the ideal pulse width for electrotactile feedback and assures through a transfer function that the magnitude of the feedback is according to the placement of the COP information. The calculation of the pulse width is fast and was optimized for the implementation on a microcontroller. The presented software can be integrated into new concepts of electrotactile feedback devices and improve the quality and usability of EFSs. Since the software can be used for embedded programming on a microcontroller, because of its size, it is suitable for portable systems, which can easily be carried around by people with

sensory impairment. This portable system has been developed to improve the ability to judge the magnitude of COP displacement which can help to control balance and to reduce the risk of falling.

**"Vision without implementation
is hallucination."**

Benjamin Franklin

Chapter 5 Study on Sensitivity and Accuracy

5.1. Abstract

The aim of the study presented in this chapter was to investigate if the upper leg is suitable for magnitude estimation with electrocutaneous stimulation and if pulse width modulation has drawbacks in comparison to other stimulation modalities. A study was undertaken with 11 participants using an electrocutaneous stimulation device built at Bournemouth University. This involved applying 25 randomised magnitude values of electrocutaneous stimulation through electrodes that were placed on the upper leg. Participants were asked to gauge on a scale of 0 to 9, the level of stimulation applied. The test was repeated twice. Based on the results a psychophysical power function (PPF) was derived for each participant. The mean β-value, which is the power of the PPF, was $\beta=1.17 \pm 0.35$. The accuracy of magnitude estimation was measured by averaging the mean absolute error (μ_{MAE}) for all test subjects, which was $\mu_{MAE} = 1.14 \pm 0.33$. Considering a scale of 10 magnitude levels, this location was found to be considerably accurate for the use in feedback systems for people with sensory impairment. The findings suggest that PWM is beneficial over other stimulation modalities, like pulse amplitude modulation (PAM) and can be considered for future design concepts of electrotactile feedback systems and improve the efficacy of sensory communication based on electrocutaneous stimulation to benefit people with sensation loss.

5.2. Introduction

Tactile feedback can be based on vibration (Kaczmarek, Webster, et al. 1991) or electrocutaneous stimulation (Szeto and Saunders 1982). Electrotactile feedback devices use electrical stimulation of the skin through electrodes to create a stimulus. Changing the magnitude of a stimulus can be done by pulse width modulation (PWM), pulse amplitude modulation (PAM) or frequency modulation (FM) (Kaczmarek et al. 1992). FM is not considered as a useful modality for electrotactile feedback (Marcus and Fuglevand 2009) because of the reduced sensitivity range but also because adaptation of the skin for higher frequencies appears very rapid (Buma et al. 2007). Commercially available electrical stimulators usually use the stimulation modality PAM. However, the superiority of PAM over PWM was not shown before. It was shown that the skin adapts to electrical simulation rapidly when PAM is used at lower intensities. Furthermore the impedance of the electrode-skin connection increases for lower currents (Kaczmarek, Webster, et al. 1991), which makes accurate control of the stimulus more difficult.

Electrocutaneous stimulation has been tested in several areas of the human body (Chapter 2). The medial part of the thigh is an intuitive choice for electrotactile feedback as the upper leg is close to the feet allowing several device design possibilities when developing an electrotactile feedback system. However, research

on this location for feedback is limited. Buma et al. (2007) studied sensation decay during electrocutaneous stimulation on the knee angle. The study however did not evaluate this location with regard to its accuracy and sensitivity to magnitude estimation and the stimulation modality PWM.

Previous research evaluated magnitude estimation where several stimulus levels were applied to a subject and the estimated values, as well as the true values, were recorded. Results of those experiments have been proven to be reliable and repeatable (Ehrenstein and Ehrenstein 1999; Knibestöl and Vallbo 1980). Using curve fitting in those experiments, a psychophysical power function can be achieved. The power (β) of this function is used to describe the sensitivity to stimulation (Marks 1974), while different stimulation modalities result in different β values. The β value in previous work was found to be $\beta = 0.57 \pm 0.24$ for frequency modulation, and $\beta = 1.14 \pm 0.37$ (Marcus and Fuglevand 2009) and $\beta = 1.2$ (Tashiro and Higashiyama 1981) for pulse amplitude modulation. A β value above 1 means that subjects have in average a higher sensitivity to high input stimuli, while a β value below 1 means that the subjects have a higher sensitivity to low input stimuli (Marcus and Fuglevand 2009). Although β values for FM and PAM have been evaluated the β value for PWM has not been studied yet in previous research.

The locations for testing the magnitude estimation of electrocutaneous stimulation use the neck (Marcus and Fuglevand 2009) and the underside of the wrist (Tashiro and Higashiyama 1981) while there is a lack of knowledge about magnitude estimation at other parts of the body including the upper leg. In addition to studying the sensitivity through the power function, the accuracy of magnitude estimation experiments can be measured by calculating the absolute mean error of psychophysical judgements (Res et al. 2005; Wever and Zener 1928) and testing how many levels allow reliable classification. Previous work was done on testing magnitude estimation with electrocutaneous stimulation. It was shown that four different pressure levels could be discriminated reliably using electrical impulses that were transferred to the upper arm (Lundborg, Rosén and Lindström 1998). However, no data exists about the accuracy of electrocutaneous stimulation on the upper leg. The present research investigates magnitude estimation using pulse width modulation to the upper leg. By supplementing the knowledge about PWM as a stimulation modality on another location, the upper leg, the design possibilities for electrotactile feedback systems can be extended.

5.3. Methods

The test population comprised of eleven control subjects: ranging in age from 18 to 56, with the average age being 41 years ± 11.3. Four of the eleven test persons were female. The ethics committee of Bournemouth University approved the trial. All test subjects gave written consent before the experiment. The experiment lasted for 50 minutes. Established psychophysical models were used to retrieve thresholds for the sensation and discomfort of the participating subjects (Marks 1974) as well as for the procedure of magnitude estimation (Stevens 1957).

5.3.1. Device description

5.3.1.1 Components

For this study, a device that has been developed for this research at Bournemouth University was used (Chapter 3). In contrast to older design proposals for electrocutaneous stimulation devices using only analogue circuits (Prior and Lyman 1974; Kaczmarek, Kramer, et al. 1991) in this study digital components were used (section 3.4.4). The system used has a pulse creation unit with an Atmel Atmega 32-bit Microcontroller. The pulses were transformed into bipolar pulses to counteract toxication (Szeto and Saunders 1982) and then amplified to reach the required value to trigger a sensation (Fig. 5.1). The pulse was then directed via electrode leads to electrodes on the surface of the skin.

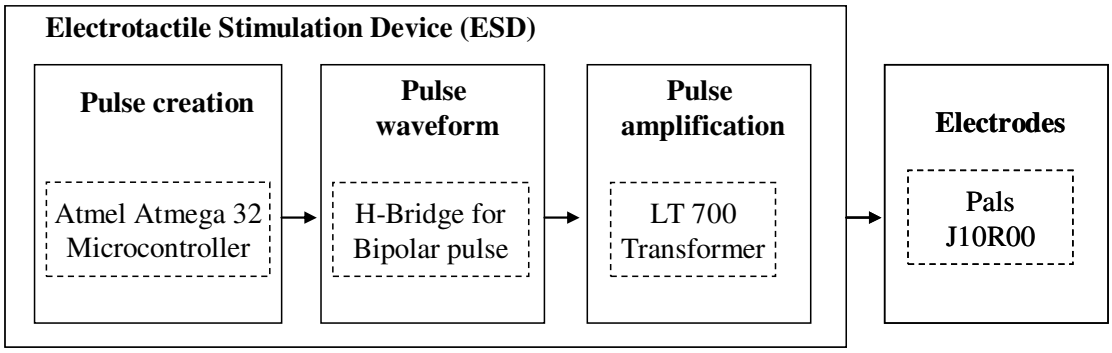

Fig. 5.1: Device architecture of Electrical Stimulation Device: The electrical stimulation device (ESD) consisted of a pulse creation unit, a circuit to transform the monophasic pulse into a bipolar pulse and then amplify it in a pulse amplification unit. The ESD is galvanically isolated from the electrodes which are connected to the test participant.

The electrodes used were self-adhesive pre-gelled electrodes of the type Platinum J10R00 by Pals with a size of 2.5 cm in diameter. The current was limited to 38 mA by placing a resistor in the primary winding of a transformer that was used to amplify the pulses. The use of a transformer assured galvanic isolation of the test participant.

5.3.1.2 Parameters

The device built creates a pulse with a fixed frequency and amplitude. It was decided to set the pulse at 50 Hz, as this frequency was previously used for the evaluation of electrocutaneous stimulation (Lindenblatt and Silny 2006). The voltage for electrocutaneous stimulation usually lies within the range of 50 - 200 Volts, while a voltage between 50 and 100 V is detectable at pulse durations of 5 - 10 µs. (Robertson et al. 2006). The maximum amplitude of the pulses in the present experiment was limited due to the transformer specifications to 84 V.

For safety reasons a maximum pulse width was set in the embedded program of 600 µs which was chosen in accordance with Alon et al. (1983), who found that a pulse width below 600 µs is more likely to evoke a comfortable sensation.

The formula to calculate the pulse width $pw_{(\phi)}$ for a given input magnitude ϕ, representing one of 10 stimulation levels was

$$pw_{(\phi)} = pw_{\min} + (pw_{\max} - pw_{\min}) \cdot \frac{\phi}{10}, \qquad (21)$$

where pw_{min} is the pulse width for the sensation threshold in µs, pw_{max} is the pulse width for the threshold of discomfort and ϕ is the randomized true magnitude level between 0 and 9.

5.3.1.3 Experimental setup

The test participants were seated comfortably on a chair. Two electrodes were placed on their upper leg (Fig. 5.2) on a controlled location, which was the middle of the femur bone above the femoral nerve (Standring 2008).

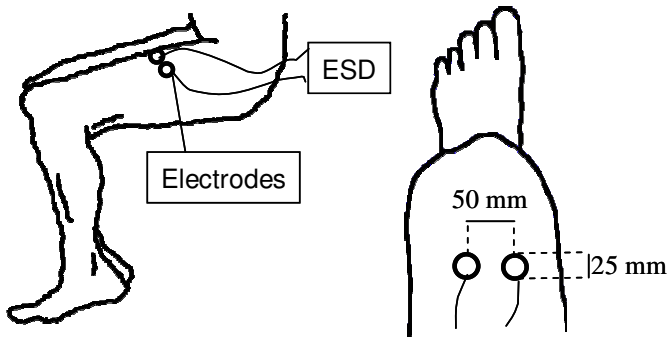

Fig. 5.2: Setup of magnitude estimation experiment: The electrodes were placed at the left hand side of the upper leg (left). The diameter of the electrodes was 25 mm and they were placed 50 mm to each other (right).[27]

This position in the upper leg is an intuitive choice for feedback because of its comparable sensitivity with the feet (Kandel et al. 2000).

5.3.2. Sensation thresholds

Several methods for threshold detection have previously been proposed (Ehrenstein and Ehrenstein 1999; Bekesy 1947; Corso 1963). The method of limits is well established and used in most experiments involving psychophysics. It involves the detection of a stimulus by starting from a very low value or by starting from a high stimulus and gradually lowering the value. Usually, the procedure is repeated several times until a final threshold can be set. In the present experiments, with a view to offsetting the effects of adaptation to electrical stimulation, which can occur quite rapidly (Buma et al. 2007), the descending method was chosen over the ascending method, and by starting with the higher threshold it was assured to have an interval where stimulation could be sensed. The pulse width started to rise from 0 and increased by 4 µs every 0.3 s. The pulse intensified until a button was pressed by the user. The pulse width value was then saved as a variable. Then, the pulse width started to decrease by 4 µs every 0.3 s. Once the pulse width reached the threshold where sensation was absent, a button was pressed again and the value was saved as the threshold variable for the minimum pulse width. During the experiment, the test subjects were asked to say "Stop" once the threshold of discomfort was reached and press the button. The same procedure was used for the lower threshold. If the participant misunderstood the instructions and asked for a repetition the procedure was repeated in order to find an interval for comfortable sensation prior to initiating

27 Adapted from http://www.kneeguru.co.uk/ and http://clipart4all.blogspot.co.uk/

the experiment. Depending on the thresholds of the test subject the procedure for threshold detection took between 3-5 minutes.

5.3.3. Estimation of magnitude

After the assignment of the thresholds, the interval of comfortable sensation was divided into sensation levels. The number of absolute levels which can be reliably classified in psychophysical experiments varies. Miller (1982) finds that different proprioceptive tasks can be classified reliable between 5 to 10 times of magnitude. Tashiro and Higashiyama (1981) used 10 stimulation levels with pulse amplitude modulation in an electrocutaneous stimulation experiment, but the individual thresholds were not taken into account. 10 stimulation levels were chosen for the presented approach with 9 representing the highest stimulation magnitude and 0 representing little or no stimulation. Similar to (Marcus and Fuglevand 2009) who used 80% of the maximum threshold as the highest stimulation level, and to avoid any discomfort 90% of each person's maximum stimulus threshold for discomfort was used. This was to assure that the test participant would not receive an uncomfortable stimulus.

In a psychophysical magnitude experiment the term "psychophysical judgement" describes the action of a test participant to decide which magnitude the subject thinks was received. The number of psychophysical judgements in an experiment for magnitude estimation depends on the number of different stimuli that are used. Ideally each magnitude level is applied once or twice. However, if the number of psychophysical judgements exceeds 60 repetitions, the subject's performance is likely to deteriorate (Marks 1974). Therefore, it was aimed to stay below that number in order to avoid signs of fatigue in the later parts of the session and decided for 50 psychophysical judgements in two successive parts of the experiments, meaning 25 psychophysical judgements in each part. This also allowed us to have a comparable number of judgments with Marcus and Fuglevand (2009) where 36 repetitions were used. To avoid any effects dependent on the order of applied stimuli the stimulation levels were generated randomly.

To be in line with the aforementioned experiments on electrocutaneous stimulation (Tashiro and Higashiyama 1981; Marcus and Fuglevand 2009) it was decided to not use a visual analogue scale but entering the stimulation levels on a keyboard. The test participant was asked to assign the magnitude level on a keyboard using the numbers 0 to 9 after each psychophysical judgement describing his or her subjective sensation. In an experiment involving the estimation of magnitude, a reference pulse is usually transmitted to the test participant before the starting the estimation procedure. Since the reference stimulus can have an effect on the shape of the psychophysical function, it is debatable which one should be used and options include the lower threshold or the higher threshold (Stevens and Poulton 1956; Beck and Shaw 1962). Before the experiment started, it was decided to use three different stimuli, using the magnitude levels 1, 5 and 9, as a reference point for each subject. This was done to help minimize the influence of the reference stimulus given to the test subjects on the results of the experiment.

Each test subject was given an instruction before the experiment started. The wording of the instruction to the test subject was based on previous work (Marks 1974) and adapted to the specifications of the present study:

A number of stimuli will be transmitted to your leg. Your task is to judge how strong each stimulus feels by assigning a number that corresponds with the degree of magnitude. The first three stimuli provide a reference and have a magnitude of 1, 5 and 9. For the succeeding stimuli that will have randomized magnitudes, assign other numbers in proportion to the magnitude and type them on the keyboard in front of you. You can assign any whole number ranging from 0 to 9 to describe the magnitude with 9 being the highest magnitude and 0 being the lowest.

The test participant then did 25 successive psychophysical judgements in the first part of the experiment after which there was a break of five minutes. The true values and estimated values were shown to the test participants followed by the second part of the experiment with 25 more successive psychophysical judgements.

5.3.4. Data analysis

5.3.4.1 Sensitivity

MATLAB® (The MathWorks Inc.) was used to fit the sample data to a standard power function of the form

$$\psi = k \cdot \phi^{\beta}, \tag{22}$$

as introduced by Stevens (1955), where ψ represents the estimated psychological magnitude and ϕ is the true magnitude of the stimulus intensity (Marks, 1974). k is the initial gain of the power function (Marcus, 2009) and the β value is used to describe the sensitivity. If β is set to 1, the function becomes a linear function with the inclination k. Bootstrapping was used with a sample size of 1000 to compare the first and second part of the experiment with a paired test towards the β values to test if the sensitivity for each subject is correlated between the first and second part of the experiment.

5.3.4.2 Accuracy

To estimate the accuracy the average of all mean absolute errors, μ_{MAE} (Armstrong 2001) and their standard deviation, was calculated. MAE is the mean absolute error between the true magnitude ϕ and estimated magnitude ψ for 25 successive psychophysical judgements. This measure was used in previous work to measure the accuracy of using electrocutaneous stimulation as a method of feedback (Collins et al. 2009). It can be calculated by

$$\mu_{MAE} = \frac{1}{11}\sum_{i=1}^{11}\frac{1}{25}\sum_{j=1}^{25}\left|\phi_{(ij)} - \psi_{(ij)}\right|, \tag{23}$$

where MAE is the mean absolute error between the true magnitude ϕ and estimated magnitude ψ for 25 successive psychophysical judgements.

The improvement of accuracy was tested by comparing the mean absolute error for each subject between the first and second part of the trial. The t-test for matched pairs with $p < 0.05$ (Wilcoxon 1945) was performed to test the significance of the Null Hypothesis, that subjects do improve their ability to estimate magnitude after the first test. This test was done previously in electrocutaneous stimulation experiments to compare stimulation magnitude (Geng et al. 2012).

5.4. Results

5.4.1. Sensation Thresholds

The interval of comfortable electrocutaneous stimulation varies for each individual. The longest pulse width that created a comfortable sensation for one test subject was found to be 558 μs, The shortest pulse width that could be detected was 26 μs.

The arithmetic mean of the pulse widths were calculated and found to be μ_{Min} = 96.1 ± 50.7 μs for the minimum pulse widths, and μ_{Max} = 331 ± 148 μs for the maximum pulse widths. It was found that the ratio of the maximum pulse width and the minimum pulse width was on average 3.74, but also with a relatively high standard deviation of 1.2. The relatively high standard deviations demonstrate the high dispersion supporting the necessity to calibrate the range of an EFS system for each individual.

5.4.2. Estimation of magnitude

5.4.2.1 Sensitivity with psychophysical power function

A comparison of the best fitting power function retrieved from one subject in the two parts of the trial is shown in Fig. 5.3. The constant factor k and the exponent β value of the power function are shown in the graph. In the figure presented here the β value is above 1.0 which means that this particular subject has a higher sensitivity to high input stimuli.

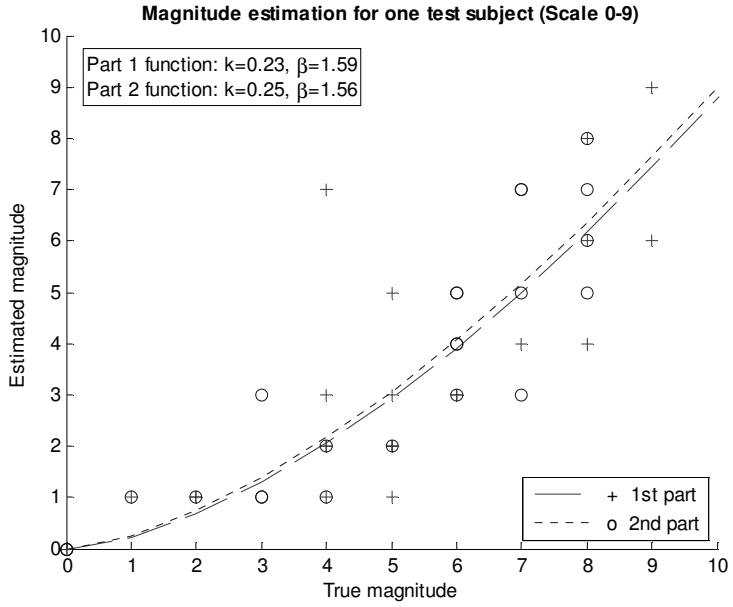

Fig. 5.3: Magnitude estimation plot for one subject. The axis show magnitude levels from 0-9. In the case of subject one the interval for comfortable pulse was 47 μs – 168 μs. The graph shows 50 psychophysical judgements for magnitude estimation against true magnitude for the 2 parts of the trial (each part had 25 psychophysical judgements). The curve represents the resulting two power functions using curve fitting. Even though all 50 values were plotted there appear to be fewer than 50 values in this figure, which is due to the fact that the same magnitude levels were applied several times in random order and overlay with each other.

The same procedure was applied to all 11 subjects as shown in Fig. 5.4. The graph shows the k and β value for each participant in the two parts for the trial and the resulting power fitting curves.

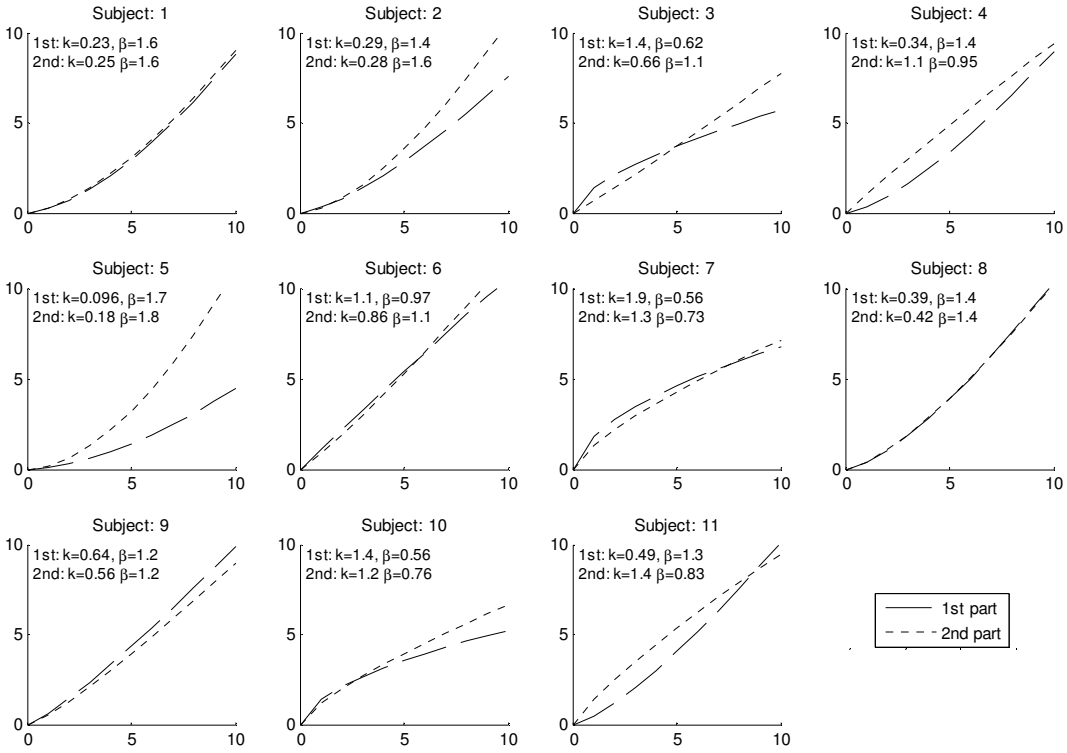

Fig. 5.4: Magnitude estimation for all 11 subjects. Each graph shows the psychophysical power function curve for the first and second part of the trial and the individual k and beta value of the power functions with the estimated magnitude value in the y axis and the true value in the x axis.

The average power of the psychophysical functions for all subjects in the first part of the trial was $\beta = 1.15 \pm 0.41$ for the first part and $\beta = 1.17 \pm 0.35$ for the second part of the trial.

The β values for pulse width modulation found in this trial were compared with those of pulse amplitude and frequency modulation found by Marcus & Fuglevand (2009) as shown in Fig. 5.5. One can see that pulse width modulation and pulse amplitude modulation have similar characteristics, as the β-value for pulse amplitude modulation was $\beta = 1.14 \pm 0.37$ in Marcus experiment. In contrast, the β value for frequency modulation, $\beta = 0.57 \pm 0.24$, indicates a poor sensitivity towards the differentiation of magnitude for higher frequencies thus limiting the range for useful feedback (Marcus & Fuglevand 2009). The findings suggest that there is no drawback of PWM over PAM in the context of sensitivity. Both methods offer enough range for feedback.

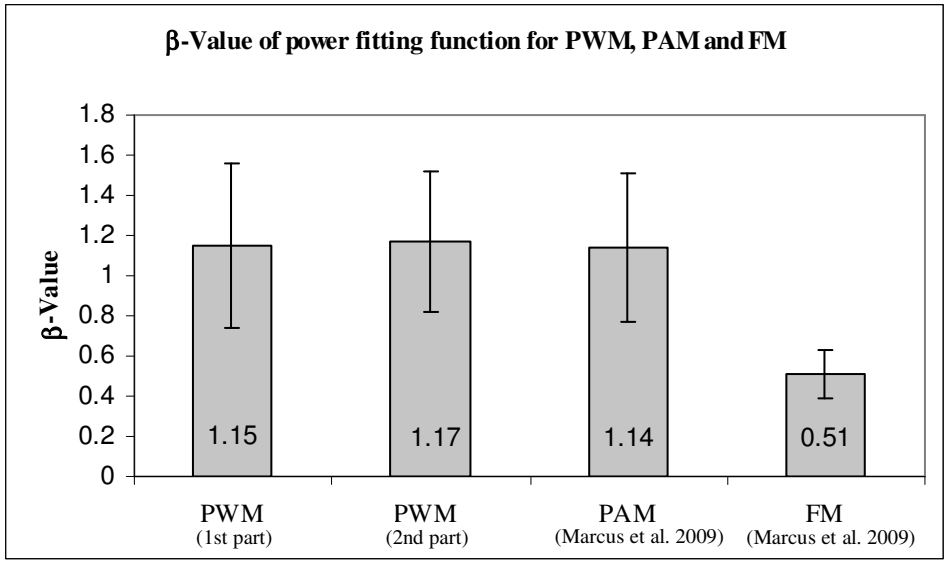

Fig. 5.5: β-Value for power fitting function - Comparison between pulse-width-modulation (PWM) as found in the two parts of the presented study and for pulse amplitude modulation (PAM) and frequency modulation (FM) as found by Marcus et al (2009). The low β-Value for FM indicates a limitation of feedback for higher frequencies.

5.4.2.2 Accuracy of pressure estimation

The arithmetic mean for the mean absolute error in the first part of the trial was $\mu_{MAE(1)} = 1.6 \pm 0.73$ and $\mu_{MAE(2)} = 1.14 \pm 0.33$ for the second part (Tab. 5.1). These values show that the absolute estimation of magnitude is fairly accurate, 84% in the first and 88.6% in the second part, when compared to the scale of 10 possible values (0-9). However, the ability of measuring an absolute magnitude is below 95% which suggests that the scale for the absolute levels which can be reliably classified ($p>0.95$) is less than 10.

Subject	1	2	3	4	5	6	7	8	9	10	11	Mean
Mean Absolute Error												
Part 1	1.84	2.32	1.80	1.48	3.16	0.84	1.20	1.12	0.88	2.12	0.88	1.60
σ	± 1.40	± 1.52	± 1.71	± 0.92	± 2.06	± 0.69	± 1.29	± 0.88	± 0.83	± 1.69	± 0.78	± 0.73
Part 2	1.48	1.16	1.48	0.48	1.32	0.80	1.44	0.92	1.00	1.52	0.96	1.14
σ	± 1.26	± 1.11	± 1.39	± 0.77	± 1.31	± 0.65	± 1.42	± 0.91	± 0.82	± 1.00	± 0.84	± 0.34
Mean Error												
Part 1	-1.60	-2.16	-1.40	-1.40	-3.16	0.36	-0.64	-0.88	-0.56	-1.80	-0.56	-1.25
σ	± 1.68	± 1.75	± 2.06	± 1.04	± 2.06	± 1.04	± 1.66	± 1.13	± 1.08	± 2.04	± 1.04	± 0.95
Part 2	-1.48	-0.84	-1.24	-0.16	-1.08	0.40	-0.96	-0.76	-1.00	-1.28	0.24	-0.74
σ	± 1.26	± 1.37	± 1.61	± 0.90	± 1.53	± 0.96	± 1.79	± 1.05	± 0.82	± 1.31	± 1.27	± 0.63

Tab. 5.1: Mean absolute error (MAE) and mean error (ME) of magnitude estimation for all 11 test subjects. For improved visability the grey coloured fields show where the mean error for each subject was below 0 indicating that the subject on average estimated a value below the true value.

The grey coloured fields show that most test subjects tended to estimate values lower than the true values, with the exception of subject 6 and 11, who slightly overestimated the magnitude. The underestimation of the magnitude was related to the magnitude of the stimulus. The higher the true stimulus was the higher was the mean error of the estimated stimulus.

Most test subjects showed a significant improvement in estimating the magnitude of stimulation between the first and second part of the trial. The Wilcoxon signed ranked statistic W was found to be 10, which showed that the Null Hypothesis had to be rejected and it can be stated with at least 95% certainty that any subject would

improve their ability of estimating the magnitude of the stimulation with higher accuracy when they perform the test the second time.

5.5. Discussion

The presented work aimed to evaluate the accuracy and sensitivity of electrocutaneous stimulation using pulse width modulation on the upper leg. The method of limits (Ehrenstein and Ehrenstein 1999) was used to detect sensation thresholds for each of the 11 study participants. Then several tests for magnitude estimation were carried out and accuracy and sensitivity were evaluated.

5.5.1. Findings and implications

During the calibration procedure a large variation between the minimum and maximum pulse width was detected for each individual. This is the result for a variety of reasons such as the condition of the skin (Tregear 1966), electrode placement (Geng et al. 2012) and the individual's sensory thresholds in general. Since the electrode placement was controlled and the electrodes were pregelled, leading to a higher conductivity, the individual's sensitivity to stimulus was considered as the main reason for this finding. It is assumed that the first two aspects, electrode location and skin condition would not have played a major role in the variation of thresholds. This is also consistent with previous threshold experiments with electrocutaneous stimulation (Marcus and Fuglevand 2009; Lund et al. 2005). No significant correlation could be found between sensory thresholds and factors such as age and sex in the examined population. Without an individual identification of sensation thresholds, it is very likely that fixed pulse width values for the lower and higher thresholds would not use the full range of comfortable electrocutaneous stimulation or even exceed the threshold for discomfort leading to an uncomfortable feedback. The method used was helpful to identify the thresholds, which allowed pulse widths in a comfortable range of stimulation. It is a fast and valuable method for calibration of an EFS.

The results show that the psychophysical power function with PWM is comparable with PAM in sensitivity, while it is superior to frequency modulation because of the extended range. PWM and PAM are the preferred methods in this context, because the sensitivity of FM is degrading rapidly for higher magnitudes (Marcus and Fuglevand 2009).

The average error for estimating absolute values was found to be 1.14± 0.33 in the second part of the trial. Considering the fact that the scale consisted of 10 values, these results indicate a fairly good level of absolute differentiation. However, the confidence of estimating the absolute value was below 95%, showing that a smaller scale with fewer levels might be needed for higher significance.

The results showed that subjects improved their accuracy when performing the magnitude estimation test a second time. The reasons for this were probably that test subjects got used to the stimulation in the first part of the trial and could therefore make more accurate psychophysical judgements in the second part.

All subjects underestimated the magnitudes of the stimulation on average. The underestimation is linked to the curve form of the psychophysical power function. A reason for this underestimation could be the reference pulse. Even if it was tried to minimize the effects of the reference stimulus, this could be an effect that influenced

the psychophysical judgement, as it was shown in previous work (Stevens 1957; Beck and Shaw 1962). An indication of this is that the subjects reported that it was difficult to remember the maximum level of stimulation which was perceived in the beginning as a reference pulses, meaning that a judgment was usually based on comparing with the magnitude of the previous pulse rather than the reference pulse.

Another reason for the underestimation of magnitudes could be the adaptation to stimulation as it was described previously (Buma et al. 2007)(Chapter 2). However no evidence was found that the growth of the mean absolute error was time related.

5.5.2. Limitations

A limitation is that the presented results were compared with those available in the literature and did not test PAM or FM in this trial. However, the applied methods were very similar to those of the associated experiments and the results were found to be comparable.

A limitation of the presented trial was that people with sensory problems in their feet might also have loss of sensation in their upper leg, which was not considered. In that case the electrodes may have to be placed in an area with sensing skin, e.g. the stomach, chest or the back (Kaczmarek 2000; Matjacic et al. 2000). Then it should be considered that the changed location of the electrodes might also change the sensitivity and accuracy.

5.5.3. Future work

The findings support the use of pulse amplitude modulation for the future development of new electrotactile devices, while the upper leg is a suitable location. Devices that help to estimate magnitudes of pressures can be useful for individuals suffering from sensation loss or reduced sensation in their feet but also for individuals with other impairments. It could be well suited on a prosthesis allowing the wearer to feel the force which is applied to the artificial limb. The sensory information given by an electrotactile feedback system could increase the acceptance of a hand or leg prostheses (Schulz et al. 2007) and enables its wearer to accurately apply pressure based on the magnitude of the feedback stimulation.

The sensitivity test showed that magnitude estimation becomes in average worse for higher pulse width or higher amplitudes. Therefore future research could investigate to countermeasure this fact by developing an algorithm that makes pulses representing higher magnitudes stronger then pulses representing lower magnitudes. This might help to make the curve of the psychophysical power function more even which might be useful for some tasks that require magnitude estimation.

Further research should also investigate the use of magnitude estimation for the improvement of balance and walking (Chapter 7). The aim is to prove how an electrotactile feedback system can help to improve pressure estimation and balance for people who suffer from sensation loss in their feet with the vision of improving daily life activities for impaired individuals.

5.5.4. Conclusions

The rationale for this investigation was to examine the use of pulse width modulation at the upper leg as a modulation option for electrotactile feedback systems. Accuracy and sensitivity were found to be suitable for magnitude estimation and the resulting

curve of the psychophysical power function for magnitude estimation can be used to improve the efficiency of future sensory communication. No drawback was found when comparing the sensitivity of PWM with previous research on the sensitivity of PAM or FM in electrocutaneous stimulation (Marcus and Fuglevand 2009). Since PWM has advantages over PAM such as the slower adaptation to stimulation (Buma et al. 2007) it may be beneficial over PAM when designing new electrotactile feedback devices. It was also shown that the upper leg is an appropriate area for the location of electrotactile feedback. These aspects are valuable for future design considerations.

5.6. Acknowledgements

I would like to thank Prof. Dr. Demian Fay and Patrick Schroeder to help with the statistical analysis of the results obtained for the magnitude estimation experiments. Furthermore I would like to express my gratitude to the study participants that contributed to the outcome of this research.

**"Every line is the perfect length
if you don't measure it."**

Marty Rubin

Chapter 6 Measurement System for Balance Analysis

6.1. Abstract

This chapter describes a measurement system that has been developed for determining balance control. This system is based on four force sensors integrated in a plantar shoe insole. A novel standardised foot model is presented allowing comparison of COP parameters amongst individuals with different foot dimensions. Force sensor data was sent to a computer where analysis was performed via Matlab[28]. Several problems of the data acquisition process were solved by applying data cleansing algorithms and outlier detection. Four different COP measurement values were integrated: COP velocity, AP Velocity, ML velocity and sway area. The system was tested with predefined balance patterns, and an offline analysis was performed to prove the functionality of the plantar measurement system. Additionally, a real-time analysis of balance is presented allowing visualisation of the current position of the COP and information about COP parameters. In combination with a wearable electrotactile feedback system this tool might also be helpful for people with balance problems looking at the screen of a PC or tablet allowing them to assess their balance behaviour in real time which in turn, enables them to respond by correcting their body posture and improving balance.

The developed system was verified with controlled data and can be used for the evaluation of balance parameters.

6.2. Introduction

6.2.1. Motivation

The loss or reduction of sensation in the legs caused by morbidities that result in nerve damage leads to problems when it comes to posture control (Turcot et al. 2009). Previous research indicated that biofeedback systems can support active posture control for people with balance problems. The rehabilitation process can be accelerated and patients can relearn or improve their balance. Such systems can help patient with balance problems after a stroke (Nichols 1997; Moreland et al. 1998), Parkinson (Chiari et al. 2005) or in amputees (Carpaneto et al. 2003). Several biofeedback systems have been proposed for this purpose.

Positive effects on balance have been measured when using electrocutaneous stimulation to give feedback about the centre of pressure movement to the tongue of test participants (Vuillerme et al. 2007) or through audio and vision (Milosevic et al.

[28] Matlab®, The MathWorks Inc., Novi, MI

2011). To measure the effects of biofeedback on posture control it is necessary to develop an appropriate model for balance analysis.

6.2.2. Posture control measurement system

Postural control describes the tasks involved to prevent the body from falling during standing and walking (Chapter 2). To determine balance several indicators can be determined, such as the centre of pressure (COP), the centres of mass (COM) or gravity (COG) (Winter 1995). The stability of stable stance can be measured using different techniques. Besides measuring COP with force plates, COM and COG can be determined with video based postuography. Another method is using electromyography (EMG) (Shumway-Cook et al. 2000). For the latter, an electromyography is used to measure the muscle activities usually at the lower legs. Further methods involve the use of accelerometer sensors to detect sway in different parts of the body (Turcot et al. 2009). This method was tested on diabetic patients with peripheral neuropathy and was found to be suitable to evaluate balance skills of diabetic patients. However, the most established method is using a plantar measurement system with force sensors or force plates (Winter 1995; Bamberg et al. 2008; Zhu et al. 1990)) for the detection of COP and related parameters to describe balance. There are several commercial measurement platforms available such as the Chattecx system (Grabiner et al. 1993), Tekscan pressure system (Bachus et al. 2006) and Kistler force platform (Lackner et al. 1999; Jeong 1994).

The disadvantage of a force measurement platform is that it cannot be integrated in a shoe insole and does not allow the design of a wearable device. Insole systems involve one or more force sensors to detect pressure applied to the feet. If the sensor system analyses stability in gait, one or two sensors are considered useful because the different gait cycles can be detected (Hargreaves and Scales 1975; Miyazaki and Iwakura 1978). Alternatively more sensors are needed for accurate analysis of the COP. Usually, at least four sensors are used for COP analysis. Sensor systems with more force sensors showed similar results to systems with four sensors demonstrating the reliability of plantar measurement systems for balance analysis with four sensors (Pollard et al. 1983). The placement of the force sensors is usually at the area of highest pressure.

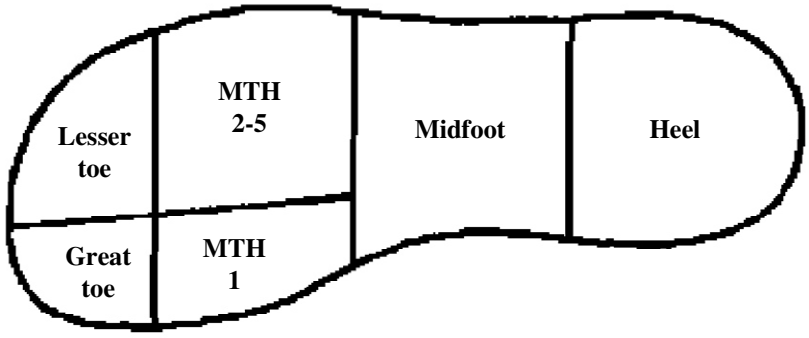

Fig. 6.1: Segments of the feet

The least amount of pressure is distributed among the Midfoot and Lesser Toes (Fig. 6.1). Thus a suitable positioning of force sensors is located along the other four segments as the pressure on those points is the highest in relation to the rest of the

feet. In previous research, the sensors have been placed under the 1st metatarsal (MHT) and 5th metatarsal and at the heel and big toe (Hallux) (Granat et al. 1996; Williams 1997). The same arrangement of mentioned locations was also implemented in newer studies (Rana 2009). Unfortunately, previous studies do not provide a detailed description about which foot model was used, which is considered to be a major drawback when interpreting COP information.

The most common indicator for analysing balance with the sensor systems is the aforementioned COP. Based on the displacement and movement of the COP, several parameters can be calculated to describe the measured balance and analyse balance control (Winter 1995).

6.3. COP parameters

6.3.1. Centre of pressure calculation

To measure the COP, force sensors have to be placed in different positions of the foot to detect the change of direction in medial-lateral (ML) and anterior-posterior (AP) direction. The COP can be calculated by summing up each force *f* multiplied by its location co-ordinates at the lateral position (1st metatarsal), medial position (5th metatarsal), anterior (toe) and posterior (heel) and divided by the sum of the forces. The coordinates are measured beforehand and are then used to calculate the centre of pressure,

$$COP_{(x,y)} = \frac{f_p \cdot p_{(x,y)} + f_l \cdot l_{(x,y)} + f_m \cdot m_{(x,y)} + f_a \cdot a_{(x,y)}}{f_p + f_l + f_m + f_a}. \quad (24)$$

where *p, l, m* and *a* are the sensor channels, representing the locations of the sensors. The COP can be calculated for each sensor reading and stored for further analysis of the calculation of the following parameters.

6.3.2. Path length of COP Displacement

The path length of COP displacement is the path that the centre of pressure travels during a defined time period. The length *l* of the COP displacement between two COP coordinates pairs ($x_{COP(i)}$, $y_{COP(i)}$) and ($x_{COP(i-1)}$, $y_{COP(i-1)}$) can be derived using Pythagorean theorem,

$$l_{(x_i,y_i)} = \sqrt{(x_{COP(i)} - x_{COP(i-1)})^2} + \sqrt{(y_{COP(i)} - y_{COP(i-1)})^2}. \quad (25)$$

Summing up over those values gives the path length of COP displacement. This is mainly an indicator of how far a subject was swaying during the period when the data was recorded.

The path length of COP displacement,

$$l_\mu = \sum_{i=1}^{t} l_{(x_i,y_i)}, \quad (26)$$

is measured in mm. For a more specific analysis of sway behaviour the path length of the COP displacement in AP or ML direction can be calculated.

6.3.3. Path length of COP displacement in AP and ML direction

AP is the path in vertical y-direction considering only the posterior and anterior change in direction, while the ML is the vertical x-direction as in medial-lateral. The calculation of the COP displacement in AP and ML direction gives a better indication in which direction balance problems have occurred when compared to the path length of the COP displacement in all directions. The path length of COP displacement in AP direction l_{AP} is calculated by summing up over each COP displacement in AP direction for the time of the measurement,

$$l_{AP} = \sum_{i=1}^{t} \sqrt{(y_{COP(i)} - y_{COP(i-1)})^2} \,. \tag{27}$$

where y_{COP} is the value of the COP position on the y axis. For the calculation of the COP displacement in ML direction, $l_{\mathrm{ML.}}$ x_{COP} is used respectively. The path length of COP displacement and COP displacement in AP or ML direction are used to calculate the mean velocity of COP displacement.

6.3.4. Mean velocity of COP Displacement

To calculate the mean velocity of COP displacement v_{μ} the sections of COP displacements $l_{(x,y)}$ for each timestamp need to be summed up and then divide it by t,

$$v_{\mu} = \frac{l_{\mu}}{t} \,. \tag{28}$$

The mean velocity of the COP displacement is an indicator of the overall sway. To analyse the sway in a certain direction, the velocity in AP and ML direction are calculated.

6.3.5. Root Mean Square COP velocity in AP and ML Direction

The root mean square COP velocity is a commonly used indicator to measure the quality of balance used in several studies on balance improvement. The path length in one direction is measured and divided by the time,

$$v_{RMSx} = \sum_{i=1}^{t} \sqrt{(\frac{l_{(x_i)}}{t})^2} \,. \tag{29}$$

The COP velocity v_{RMSy} in ML direction is calculated respectively using the path length in ML direction, $l_{(y)}$.

6.3.6. Sway Area using convex hull

The sway area can be approximated by determining the convex hull[29] as an indicator of the surface of the sway area. The convex hull is defined as the set which includes all points a_i in the observed area,

$$\left\{ \sum_{i=1}^{|S|} a_i x_i \,\middle|\, (\forall i : a_i \geq 0) \wedge \sum_{i=1}^{|S|} a_i = 1 \right\}. \tag{30}$$

[29] The convex hull of a set of points is the smallest convex set that contains all those points.

Several other algorithms exist for the calculation of the sway area but require a longer calculation time. The convex hull can be calculated quickly and is suitable for real-time analysis.

6.4. Foot model for balance assessment

6.4.1. Foot dimensions

In this work a novel standardized foot model is proposed to assure that COP analysis is comparable between different studies and individuals. The foot model developed focuses on the standardization of foot dimensions, force sensor placement and foot position.

The standardized foot dimensions are based on previous work on foot dimensions (Wunderlich et al. 2001). In their work, the authors analyze the difference in foot shape for men and woman. Their findings related to the difference are not of particular relevance when creating a foot model. However since 293 men and 491 women were studied, their measurements in terms of foot length and width represent a good average of a common sized foot for the creation of a foot model. The values which are of most importance for the purpose of designing the foot model were foot length and the width of the ball of the foot and the relation of the two to each other (see Fig. 6.2).

The average width of the ball of a man's foot was determined to be 100.89 mm and 91.39 mm for a woman (Wunderlich et al. 2001). The average foot length for a male was found to be 269.82 mm for males and 243.83 mm for female participants. The relation between length and width for both genders is 0.375. This ratio was used for the foot model in the presented approach.

For the foot model the mean values for the length and breadth of men and women were used resulting in the standardized measurements for the foot of 256.82 mm in length and a width of 96.18 mm. Based on those values, a coordination system was created placing the foot within a rectangular reaching from the coordinates 0, 0 to 97, 257 (see Fig. 6.2).

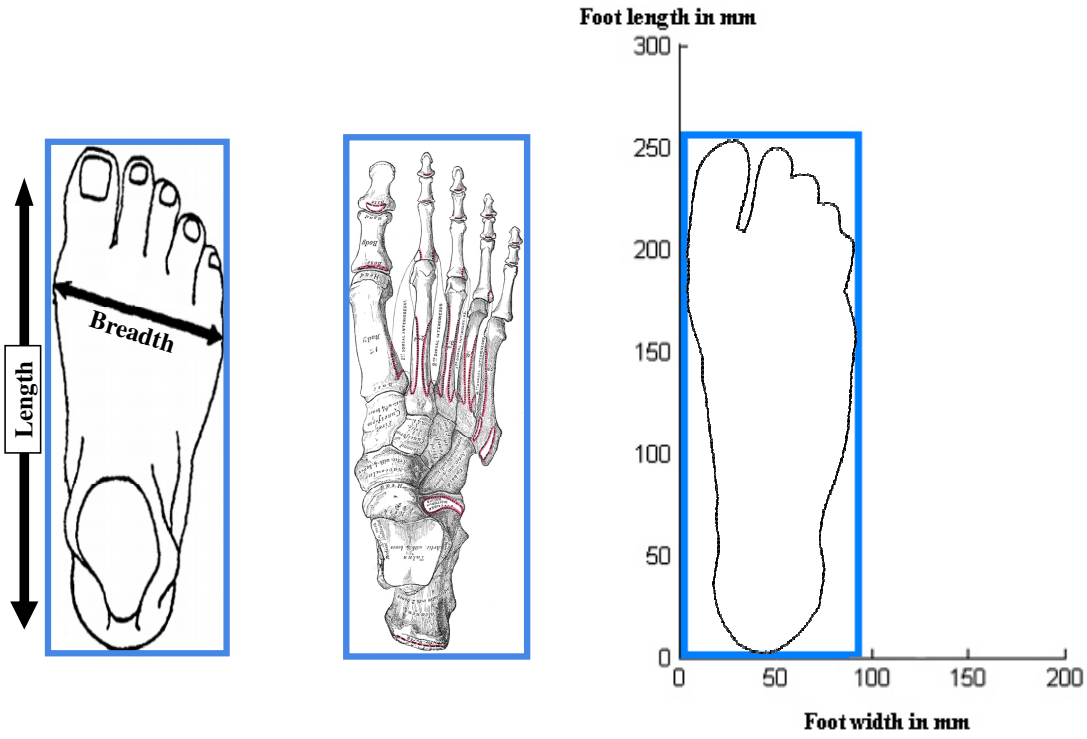

Fig. 6.2: Foot dimensions: Length and breadth of foot (left) [30], skeletal model of foot (middle)[31], foot model dimensions in coordination system (right). The coordination system is based on the standard foot size as described above.

Based on the anatomy of the human feet the sensor locations need to be integrated in the foot model.

6.4.2. Model for sensor placement

As mentioned above, the force sensors used for pressure analysis in previous studies were often placed at the 1st metatarsals, 5th metatarsals, the heels and the big toes (Rana 2009; Kyoungchul Kong et al. 2008; Granat et al. 1996; Williams 1997). In those research projects the exact position of the force sensor is not mentioned. Also it is not clear which anatomical assumptions were used to place the force on aforementioned locations. To avoid any lack of clarity, an anatomical model was used in the current work to define the location of force sensor placement. After studying a skeletal model of the foot, it was decided to place the sensor at the toe, heel and joints of medial Cuneiforms and 1st metatarsals cuboid and 5th metatarsals (see Fig. 6.2), because it is expected to have the highest pressure at these joint points. The coordinates of the sensor placement based on the foot dimensions in mm were:

- Lateral sensor: 80, 167
- Anterior sensor: 35, 251
- Medial sensor: 21, 175
- Posterior sensor: 38, 22

[30] Based on Wunderlich et al. (2001)

[31] Adopted from Grey anatomy (2010)

The same sensor placement was used for both feet. These coordinates were used to define a standardized foot when visualizing the COP movement. In the case that the coordinates need to be matched to the values of a subject's actual foot the coordinates need to be multiplied by the factor s,

$$p_{(x,y)}, l_{(x,y)}, m_{(x,y)}, a_{(x,y)} = s \cdot p_{(x,y)}, s \cdot l_{(x,y)}, s \cdot m_{(x,y)}, s \cdot a_{(x,y)}, \quad (31)$$

where *s* is a number derived from dividing the a subjects actual foot length by 256.82 mm, which represents the average foot length.

6.4.3. Foot position

As for the standing position of the two feet relative to each other, findings by (McIlroy and Maki 1997) were used. In their study, 22 people were tested to find their natural foot position when standing comfortably. It was found that the average preferred foot position was 0.17 m between heel centres, with an angle of 14° between the long axes of the feet. Since the original foot model above used the long axis vertically to the x-axis, a rotation was performed using

$$x' = x \cdot \cos(\alpha) + y \cdot \sin(\alpha)$$

and (32)

$$y' = x \cdot \sin(\alpha) + y \cdot \cos(\alpha),$$

where x' and y' are the new coordinates. This calculation was performed for each coordinate of the force sensors, setting α equals 7° for the right foot and -7° for the left foot, resulting in the foot positions and sensor placements. The foot model was used for the visualization of the COP and the calculation of the force sensor placement which is described in the next sub section. The position information and foot standardisation was used in the clinical study as described later and in the analysis of pressure data from the force sensors. The force sensors in respect to the feet are placed at a distance of 170 mm and an angle of 14° (Fig. 6.3).

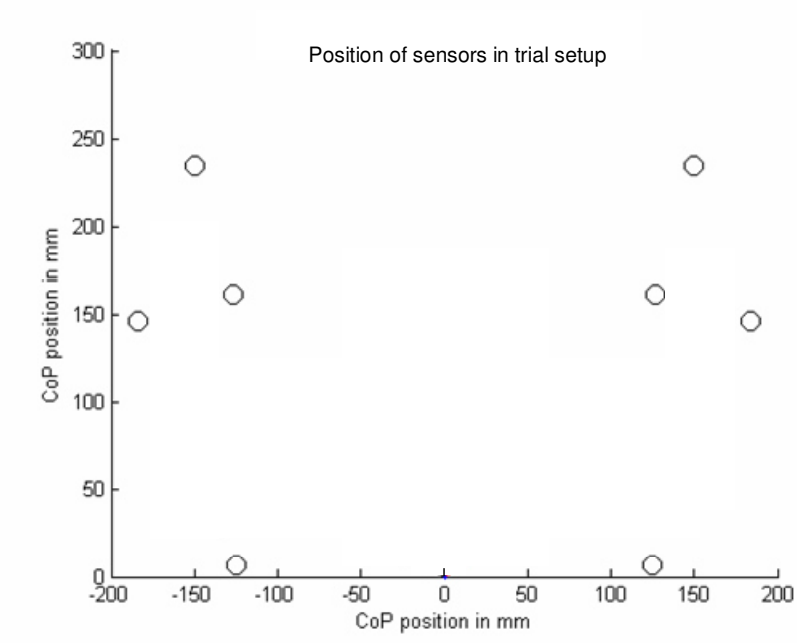

Fig. 6.3: Position of force sensors - The figure shows the left and right foot.

6.5. Data acquisition

6.5.1. Data stream overview

An automatic data acquisition system was implemented (see Fig. 6.4). The sensor data was converted into an 10-bit value by an analogue digital converter (ADC). A microcontroller decoded the sensor data, and sent it via XBee wirelessly to a serial port of the PC. The data was logged and sent to Matlab where corrupted data was detected and interpolation was used to replace the detected data points. If pre-recorded data was used then additional filters were applied to detect outliers. Then the COP parameters were calculated in Matlab and the software that has been developed automatically produced visualizations of COP parameters and wrote numerical values in an Excel file. For the real-time visualization, the COP parameters were visualized without outlier detection and presented on a screen.

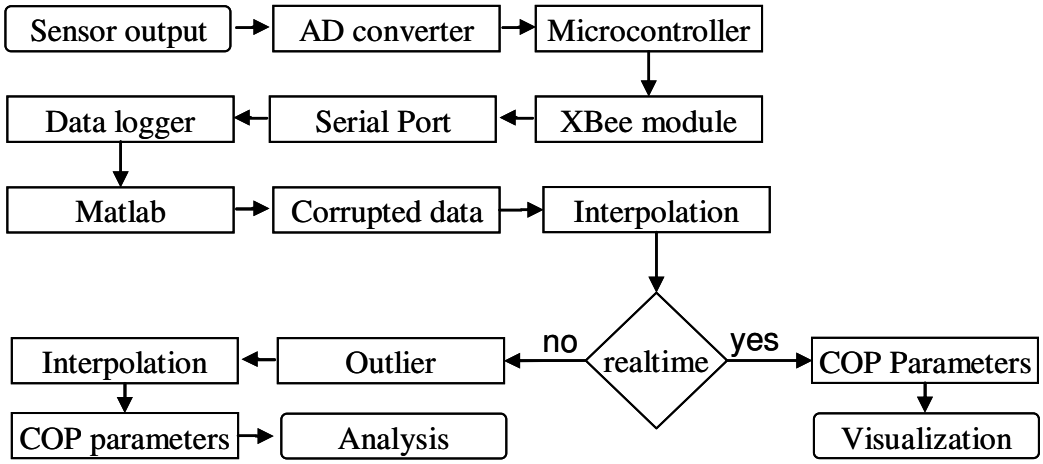

Fig. 6.4: Flow chart of the data stream of the analysis process

6.5.2. Protocol for reading data

The analogue sensor data, which is a change of voltage if pressure is applied to the force sensor, was converted into a digital value in the ADC of the microcontroller. The microcontroller creates a data string based on a specific data protocol before sending the data to the serial port. The data protocol is a string divided into five fields, with each field separated by a semicolon:

- Device name: The value is A, B or C to differentiate between the devices and identification of left and right placed location
- Multiplier: A multiplier to keep the timer value below 30000 on the microcontroller to prevent memory problems and stack overflow
- Counter: Counter at 16.6 Hz for the amount of sensor readings
- Sensor name: L, A, M or P to separate the sensor values in the analysis
- Sensor value: Digital converted sensor reading (10-bit value)

Each field is separated with a semicolon to make separation of the fields easier once the data is processed in Matlab. An example String is: B;1;160;A;120. In this example the device name is “B” indicating that the device was placed on the right

foot. The multiplier is 1 and the Counter is 160, which means that the total counter is 1 · 30000 + 160 which is the 30160's representing the sensor reading at 1809 seconds (30160/16.6 Hz). The sensor name is A which stands for the anterior sensor and the sensor reading is 120 which represents a voltage of 0.59 V (5V / 1024 · 120 = 0.59 V).

The microcontroller sends the data via XBee to the serial port of the computer. The data logger program Hercules[32] can open any serial port on the computer and show the received data. It was used to show the incoming data in real-time, as well as storing the data in a log file.

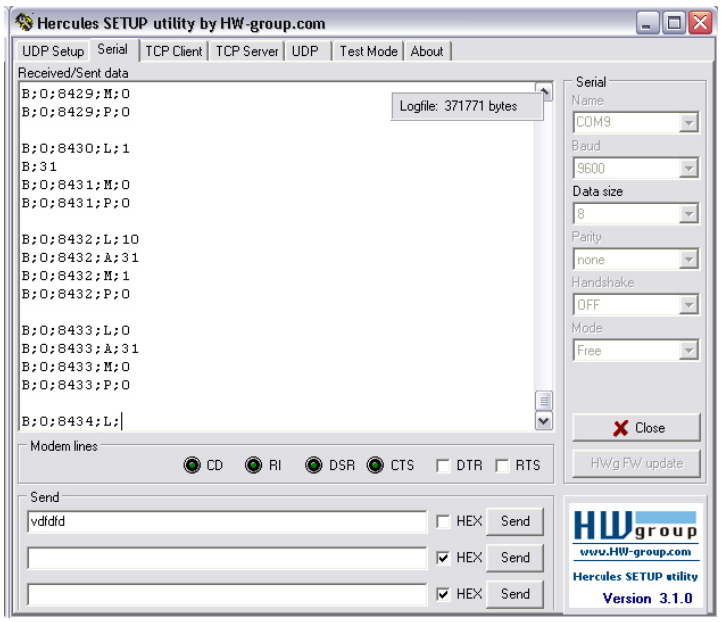

Fig. 6.5: Screen shoot of Hercules interface while logging data from the sensor system

After all data is collected and stored in a logfile, the logfile is read into Matlab. Hercules was only used for the pre-recorded data analysis. For the dynamic real-time system the communication with the Serial port was directly realised with Matlab.

6.5.3. Interpolation between data points

Matlab identifies corrupted data points by testing each of the fields of each protocol string and tests the following rules

1. Multiplicator is a number and is smaller than 20
2. Counter is a number and is smaller than 30001
3. Sensor Values is a number and is smaller than 550
4. Device Name is A,B or C
5. Sensor name is L,A,M or P

The maximum counter value of 30001 was chosen to avoid stack overflow which occurred on the microcontroller when this variable was not controlled. As described

[32] Hercules is a serial port setup utility program by HW-group.com

above the data from the feedback device which is collected during the usage of the device is sent via the XBee wireless communication module to a PC and then saved to a log file using the serial port terminal software, Hercules. The data is saved in log files and then read into Matlab for further analysis. Due to sending data via a wireless module, data arriving in Matlab can be corrupted. An algorithm in Matlab has been developed in this work that detects all data points which are corrupted and uses a linear interpolation (see Fig. 6.6) algorithm to interpolate for missing data points using

$$y = y_0 + (y_1 - y_0)\frac{x - x_0}{x_1 - x_1}, \qquad (33)$$

where y is the new coordinate for the value x at a missing data point.

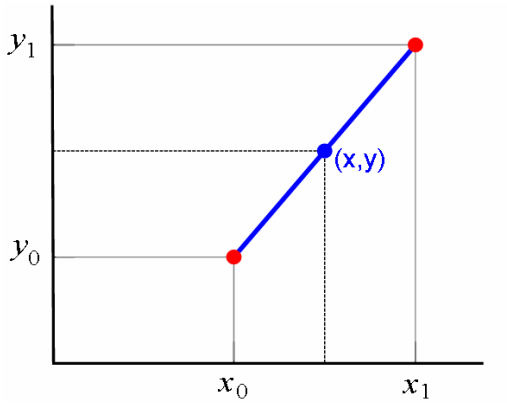

Fig. 6.6: Linear interpolation: The new data point (x,y) which is missing in the data collection is calculated by linear interpolation.

Once the corrupted data points are detected and interpolated for, the data set still contains some outliers that occur because of wrong sensor readings.

6.5.4. Outlier detection

To detect outliers or corrupted data that were not detected by previous detection algorithm a standard Hampel Filter was used which is a robust filter which uses the Median of a data set to detect outliers (Pearson 2005). It is a moving window filter and detects outliers based on the median of the current window. The window size is variable and includes between 6 to 18 data points. Any detected outlier was discarded and replaced by the median of the window (Liu et al. 2004). The standard value for the threshold was not changed and is three times the median of the given window. [33]. The outliers were treated as corrupted data points and were replaced with linear interpolation as described above.

[33] Using Matlab Library from Ronald K. Pearson (www.ronald.com). Code and detailed description can be found in Apendix J: CD /Software/Matlab/hampel.m

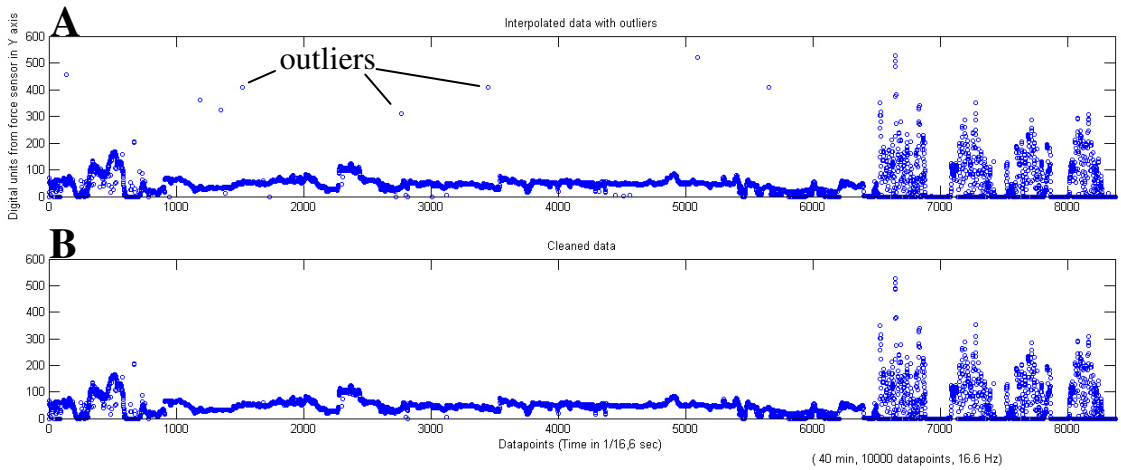

Fig. 6.7: Hampel filter outlier detection - Data set for one force sensor before (A) and after (B) execution of the Hampel filter. It is shown that the date around the outliers is interpolated after the filter process.Fig. 6.7 shows a data set of the posterior force sensor of the right foot for one test participant over a period of 9 minutes. Before analyzing the balance parameters the data is filtered using the Hampel filter to detect outliers (Liu et al. 2004).

6.5.5. Calculation of balance parameter

All COP parameters were calculated using the formulas described in section 6.3. Matlab has an interface that allows communication with Microsoft Excel files. The developed software calculates all values automatically and stores them in an excel file. The software also automatically creates visualization of the force sensor readings and COP movements and saves them in a separate folder for later analysis.

6.6. Pretest with controlled data

A control subject was asked to perform several simulated balance situations and conditions to evaluate the balance analysis system that has been developed in this work. To visualize the distribution of forces, the force sensor values are given in Newton. The force indicated in the graphs is an estimation of the force in Newton since the value has a deviation of about +/- 2.5%[34] when compared to the actual force applied on that particular sensor, due to the placement of the foot and differences between individual force sensors. The forces which are shown in the graphs show the load of that particular sensor which is only a fraction of the force that is acting on the whole foot as the forces are distributed across the foot. AP movements are shown in mm representing the real world movements based on the foot model that has been developed and described in section 6.4. If not otherwise indicated the analysis and visualization is based on measurements of the test subject's right foot.

[34] The Repeatability of +/- 2.5% is according to the specifications of the force sensors by Tekscan. More information can be found in subchapter 3.3.1. Force sensor calibration.

6.6.1. Sensor position verification

To test the sensor positioning, the insole was put in a shoe and the control subject was asked to stand still and keep his body in equilibrium while recording data.

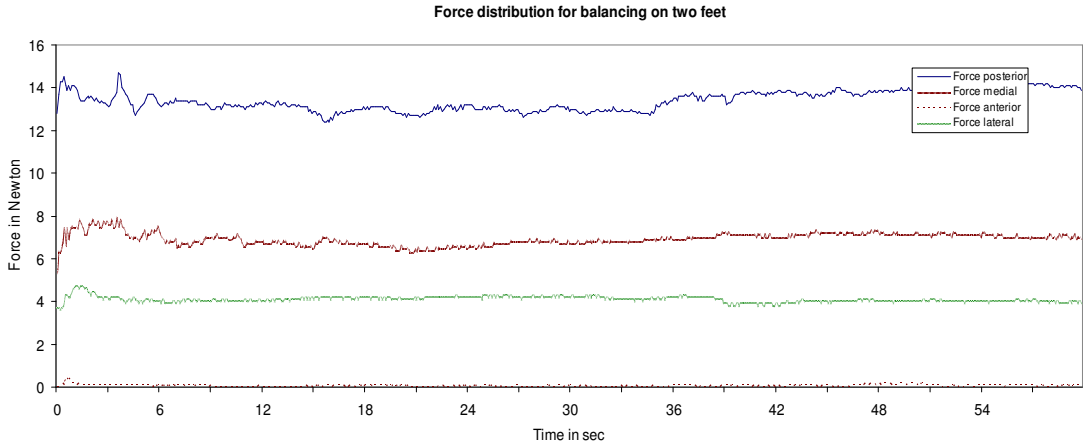

Fig. 6.8: Force sensor output in Newton over 60 seconds.

Data was recorded over a time period of 60 seconds (Fig. 6.8). The force sensor values show only small variations in the forces which indicate a stable stance. Evidently, most of the force is focused on the posterior force sensor, $F_{p,}$ with a force of around 14 Newton. However, the force sensor on the great toe represented through the force F_a is very low, as the COP points towards the posterior direction when the body is in equilibrium. The medial force sensors show a force of 7 Newton with small variations and the lateral force sensor shows an acting force of 4 Newton on average.

Fig. 6.9 shows the outcome of continuous measurements for leaning in different directions for a couple of seconds. Within 60 seconds the leaning was carried out in the following order: posterior, lateral, anterior and medial. The angle of inclination was approximately 10° towards the vertical for each direction. A change of posture was performed every four seconds with a short period of stable stance for two seconds in between. Fig. 6.9 shows the force distribution in each direction. As can be seen the anterior force is the smallest on average. This is dependent on the placement of the anterior force sensor under the big toe. The force sensor at the heel (posterior) experiences the highest forces.

The graphs show that the force F_p in the posterior direction has the highest force value when leaning to the front in a posterior direction (20 Newton), while there is still a resting force when leaning in a lateral direction. The medial forces F_m have their highest value of about 15 Newton when leaning to the medial direction. However there is still some force when leaning to the front (anterior) or to the side (lateral).

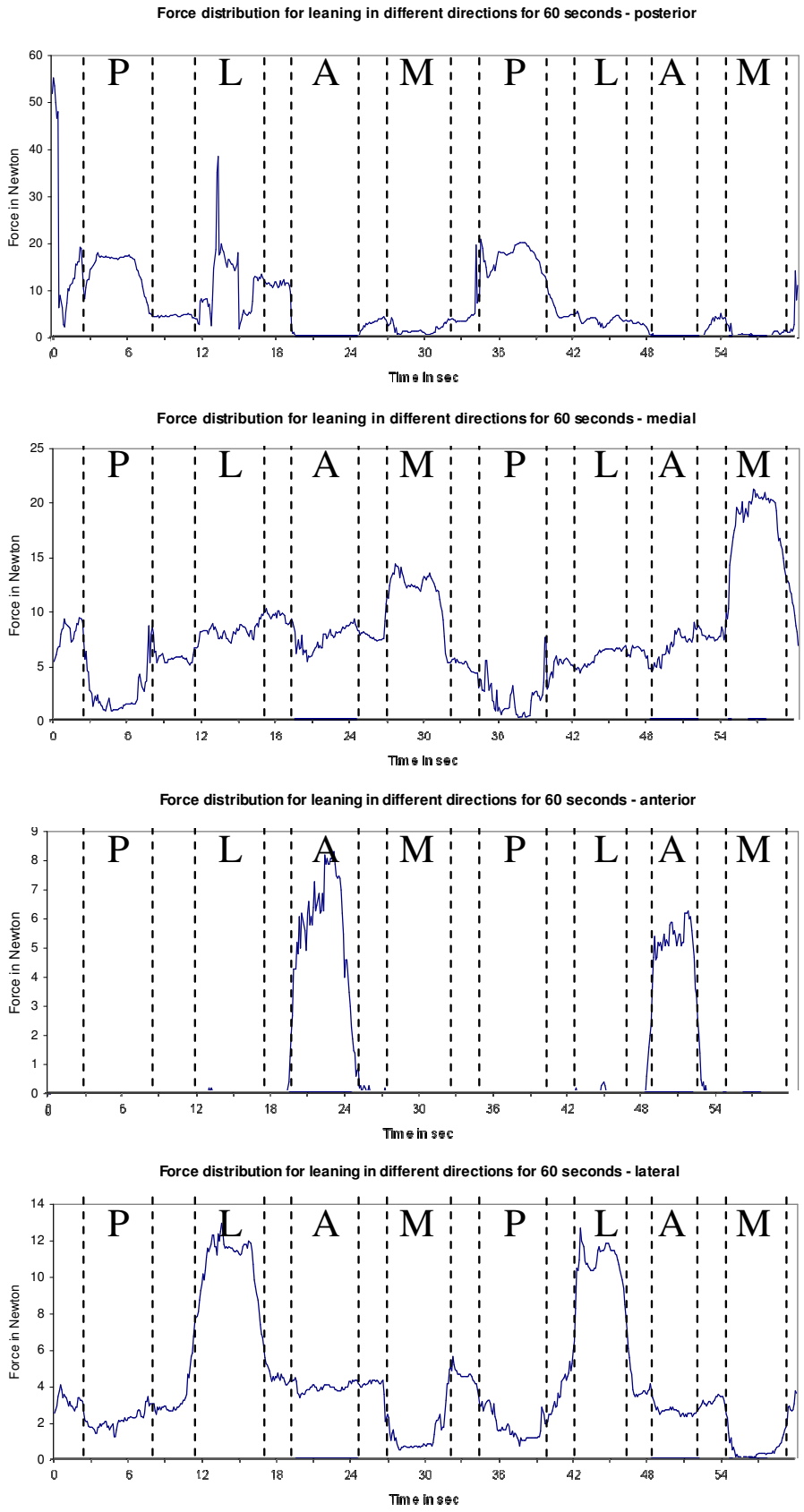

Fig. 6.9: Leaning in different directions of showing each force sensor output separately (f_p, f_m, f_a, f_l). The letters above each column indicate the direction the test subject was leaning with an inclination of approximately 10°: Posterior (P), Anterior (A), Lateral (L), and Medial (M). The y axis for all 4 graphs is not the same. The posterior sensor experiences the highest force on average.

6.6.2. COP calculation verification

To verify the calculation and visualization of the COP movements an unstable condition was simulated by asking the control subject to balance on his left foot for 20 seconds during the recording of the data. By using the foot model described above the path of COP was visualized (Fig. 6.9).

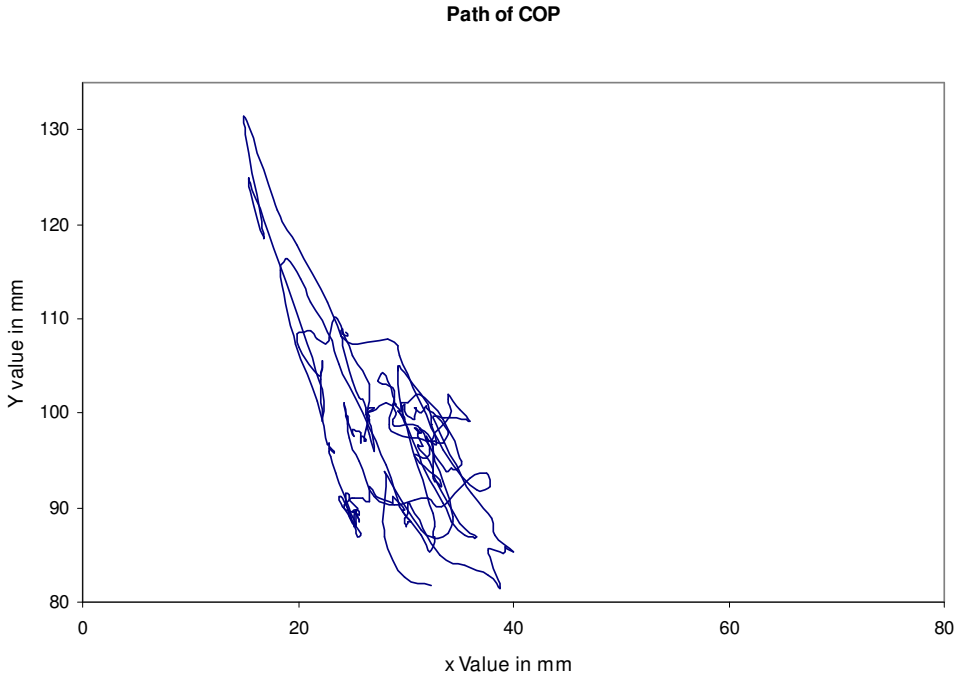

Fig. 6.10: Path of COP during balancing on one foot using all 4 channels for calculation

Fig. 6.10 shows the path of the COP while balancing on one foot. The figure shows the path that the COP took under the insole of the test participant. Since the figure shows the path while balancing on the left foot, the COP tends to swing more in the lateral direction. The figure visualizes a strong sway because of the instable condition.

6.6.3. AP movement verification

COP movement in AP direction is commonly used to analyse and visualize postural control. To verify the usability of the developed plantar sensor system for AP movement analysis, several predefined scenarios were tested. The angle of sway was approximately 10° in each direction.

1) No signal: Simulation of no load applied to all sensors

2) Anterior sway: Simulation of a stable stance for ~5 seconds, then leaning forward for ~5 seconds, then returning into stable stance

3) Posterior sway: Simulation of a stable stance for ~5 seconds, then leaning backwards for ~5 seconds, then coming back into stable stance

4) Lateral sway: Simulation of a stable stance for ~5 seconds, then leaning in lateral direction for ~5 seconds, then coming back into stable stance

5) Medial sway: Simulation of a stable stance for ~5 seconds, then leaning in medial direction for ~5 seconds, then coming back into stable stance

6) AP sway: Stable stance for ~5 seconds, then swaying back and forth in anterior and posterior direction for 20 sec

7) ML sway: Stable stance for ~5 seconds, then swaying back and forth in medial and lateral direction for 20 sec

Before and after the experiment, the plantar measurement system was recorded with no load applied. The COP movement in AP direction showed a linear line indicating that no static noise was present when no load was applied (Fig. 6.11)

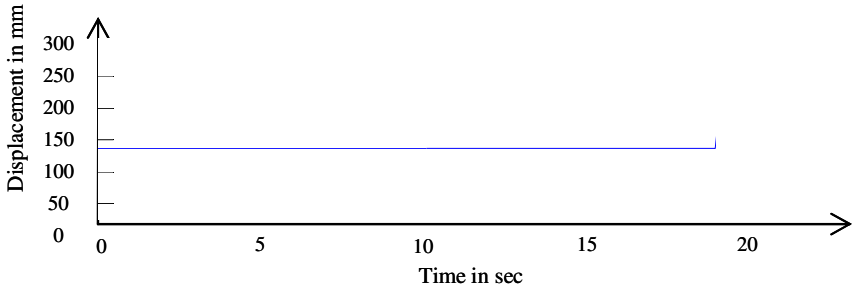

Fig. 6.11: No signal - In a neutral position the AP displacement of the COP is at 128.5 mm in the centre of the foot.

The anterior sway can be seen in Fig. 6.12. In the first couple of seconds, the test participant was a bit unstable before starting to focus on the task. At the eight second mark the test participant was leaning forward with an approximated inclination of 10° displacing his COP by 150 mm towards the front and returned into a stable condition after seven more seconds.

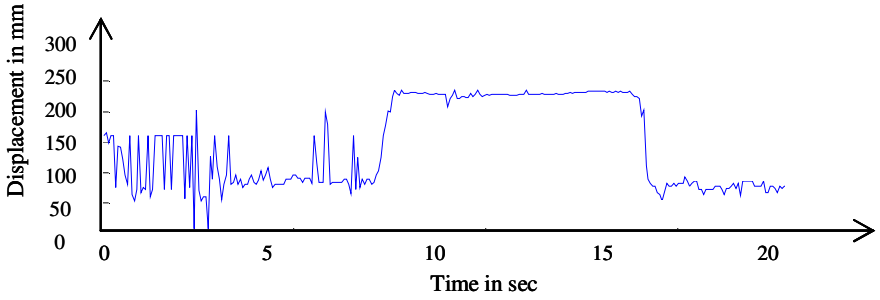

Fig. 6.12: Anterior sway - The COP displacement in AP direction is 150 mm when swaying in the lateral direction.

The second scenario was leaning in the posterior direction (see Fig. 6.13). The test participant started leaning backwards after 8 seconds and staid in this position for eight seconds before returning into a stable stance. Apparently, there are two outliers that were not detected by the filter algorithm. The possibility of having undetected outliers needs to be considered for the interpretation of the data in later trials.

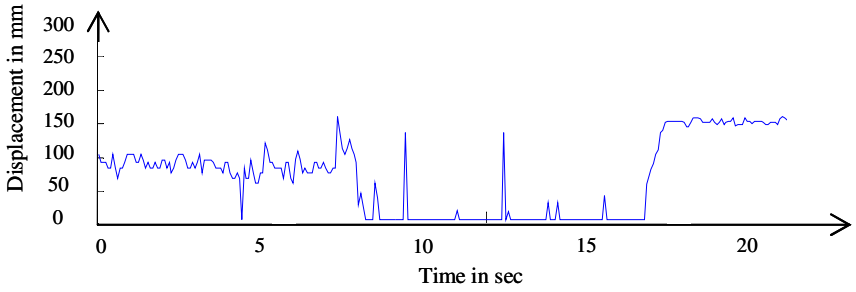

Fig. 6.13: Posterior sway - The AP displacement of the COP for a posterior sway shows a displacement of approximately 100 mm in the posterior direction.

Swaying in lateral direction (see Fig. 6.14) created a minimal COP movement in the AP direction.

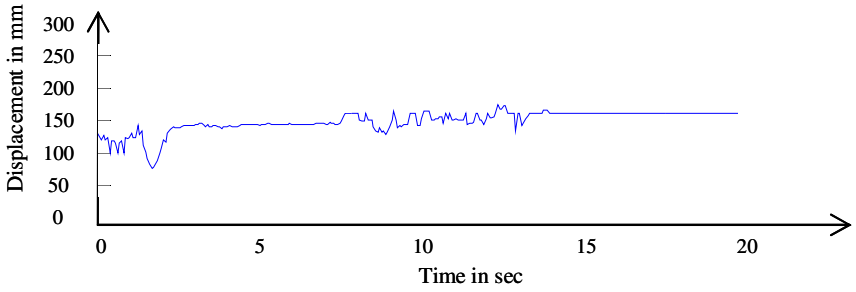

Fig. 6.14: Lateral sway - The AP displacement of the COP is minimal for lateral sway.

The medial sway also did not show any specific AP movement (Fig. 6.15) as expected.

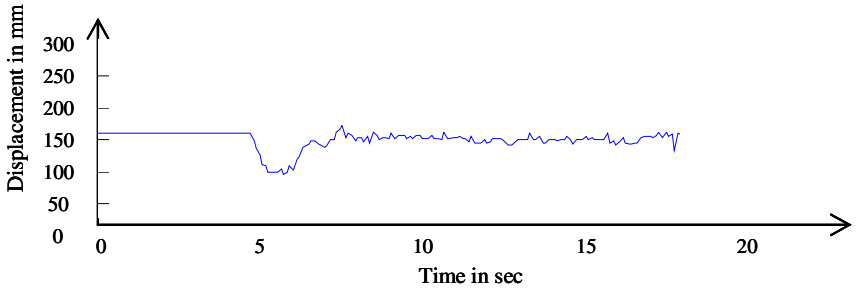

Fig. 6.15: Medial sway - The AP displacement is approximately 50 mm for the medial sway.

When swaying back and forth one can see that the COP is swinging in the AP direction with a frequency of 0.4 Hz based on the movement of the test participant performing eight AP-sways within 20 seconds (see Fig. 6.16).

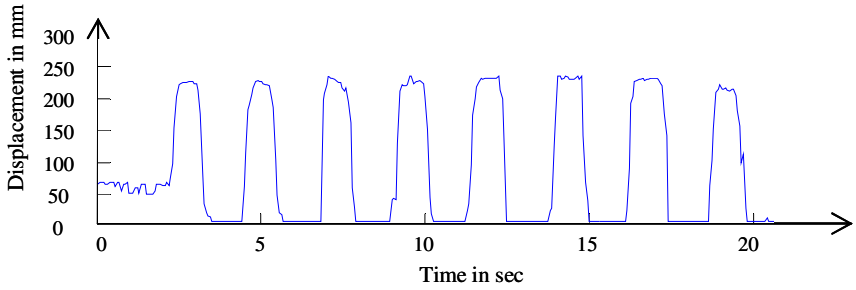

Fig. 6.16: AP sway - The AP movement is shown for swaying in AP direction. The amplitude of the COP displacement is 240 mm and the frequency is 0.4 Hz

Swaying left and right continuously for 15 seconds created a COP movement in AP direction, however it is clearly visible that AP sway created a much higher displacement of the COP in AP direction than the ML sway (see Fig. 6.17).

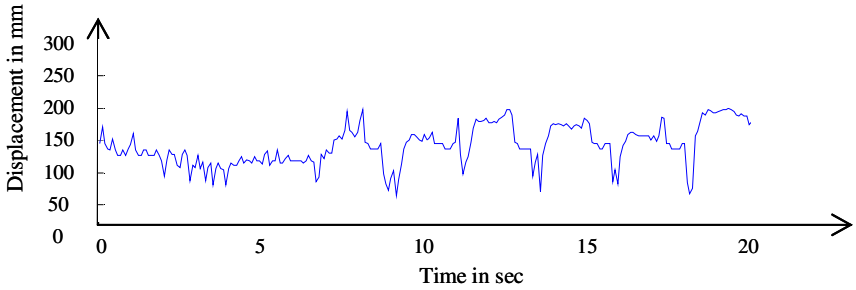

Fig. 6.17: ML sway - The AP displacement is shown for swaying in ML direction.

The COP movement in the scenarios 3 (Posterior sway), 4 (Lateral sway) and 6 (AP sway) were visualized with the developed foot model (Fig. 6.19).

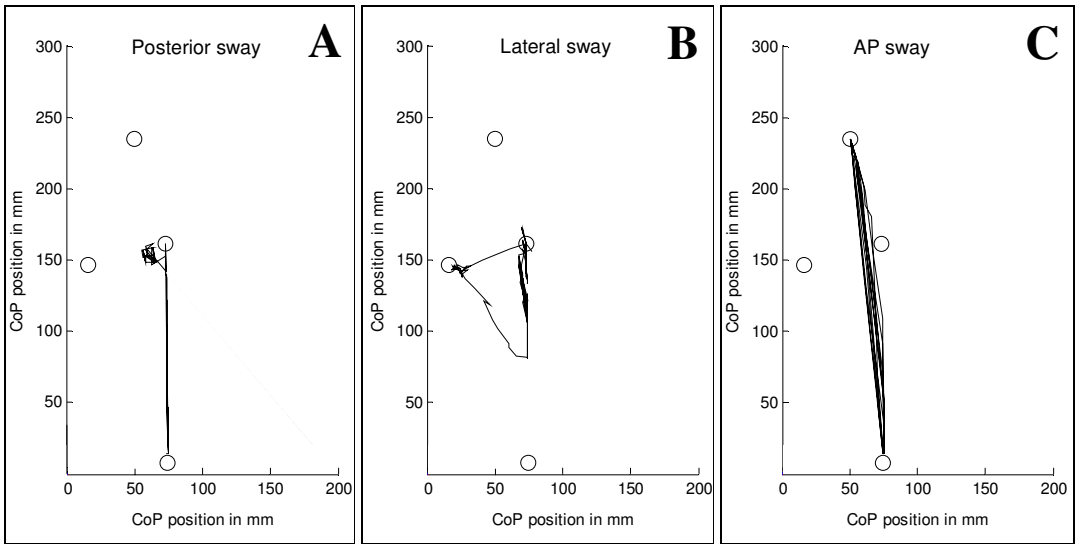

Fig. 6.18: COP movement for different sway scenarios - During the posterior sway (A) the COP is moving in between the four force sensors and moves to the posterior sensor when the subject sways in the posterior direction. During the lateral sway (B) the COP moves to the lateral sensor. During the anterior-posterior (AP) sway (C) the subject sways back and forth several times resulting in a movement of the COP between the anterior and posterior sensor.

In summary, it can be stated the observed COP movement in AP direction behaved as expected in this scenario where a test participant performed predefined movements. The system was also tested for its ability to verify gait cycles for further analysis via visual analysis (Appendix I). In addition to the analysis described in this section, it is necessary to analyse the values of the COP parameters that were automatically calculated in Matlab and saved in an Excel file.

6.6.4. Numerical Analysis

The Excel file created, lists the performed procedures and calculates the COP parameters (Tab. 6.1).

Procedure	$MV_{COP\ (mm/s)}$	$RMSV_{AP\ (mm/s)}$	$RMSV_{ML\ (mm/s)}$	$SA_{(cm^2)}$
No signal	0	0	0	0
Anterior sway	0.69	0.8	1.92	38.95
Posterior sway	0.77	0.83	2.16	95.25
Medial sway	0.52	1.01	1.26	32.55
Lateral sway	0.33	0.49	0.82	93.73
AP sway	1.04	1.7	2.59	123.35
ML sway	0.75	1.02	1.91	65.4

Tab. 6.1: Numerical analysis of test scenarios - The table shows the values for mean velocity (MV), root-mean-square of the velocity (RMSV) in anterior-posterior (AP) direction and root-mean-square of the velocity (RMSV) in medial-lateral (ML) direction as well as the surface area (SA) for the predefined balance scenarios

The parameters shown are the COP movement velocity, MV_{COP}, the mean velocity in AP direction, $RMSV_{AP}$, and ML direction, $RMSV_{ML}$, measured in mm/s and the sway area, SA, measured in cm^2. The table shows that COP movement velocity for anterior and posterior sway is higher than for medial or lateral sway. Also the overall AP sway creates more movement than the average ML sway. Furthermore, it is shown that the test participant performing the AP sway scenario creates a higher sway area than the ML sway.

6.7. Real-Time Visualisation of balance parameters

6.7.1. Interface

A novel graphical interface has been developed in Matlab which plots balance information in real time for one foot (Fig. 6.19). The graphical interface has a plotting window at the top that shows the force values of all four force sensors in digital units representing the voltage after the analogue-to-digital conversion in real time. Each force sensor is plotted in another color to distinguish between them. The data point in the middle of the plot is the most recent read value. The x-axis shows the timer value at 16.6 Hz as it is sent by the microcontroller. A second overview shows the COP path under the foot. The current COP is calculated by using the equation stated in subchapter 6.3 and is based on the foot model described above. The circles represent the location of the sensors as described above. The COP is visualized by plotting the COP movement over a predefined time period. A third overview calculates several balance parameters in real time, such as the COP path length in AP and ML direction ant the mean COP movement velocity, as well as the sway area (see subchapter 6.3). All COP values are background colored to allow a faster presentation of higher or lower values. Low values are represented by a yellow

background color while high values are represented with a red background color so that red is representing the maximum value for a COP parameter and yellow represents zero. If the dynamic COP analysis system is used in combination with electrotactile feedback, the developed visualisation also allows integrating an overview of the pulse width of the electrical stimulators (see Appendix I).

6.7.2. Real time adjustment of COP parameters

The system that has been developed continuously measures the balance measurement values (COP parameters) and adjusts their maximum values in real time. When starting the program all COP parameters are set to zero. A training time of 10 seconds is foreseen in which the user sways in different directions. During that time, an algorithm detects if a COP parameter is higher than the assigned maximum value to that COP parameter. If the current value is higher then that COP parameter, it gets the current value assigned. The colors that are assigned to each value of each COP parameter are adequately matched to the interval of minimum and maximum COP value. Different scenarios were tested to demonstrate the functionality of the system.

6.7.3. System in motion

When the device is in use, force sensor values are sent to the interface. In a scenario where the user was leaning forward (Fig. 6.19) the path length in AP direction and COP mean velocity were high, while the Sway area was low. The darker colored values indicate the higher values.

The lateral sensor value equals zero over the time period shown, as there is no pressure applied to that part of the foot when performing a forward lean in this particular scenario. Another scenario is shown in Fig. 6.20 where a user was slightly swaying in different directions.

As it can be seen, there are no fast forward or backward movements and all force sensors indicate the application of a force during the period of measurement. The overall sway area is higher than in the previous example which is visualised by having a darker coloured background of the sway area value in the balance measurement values section.

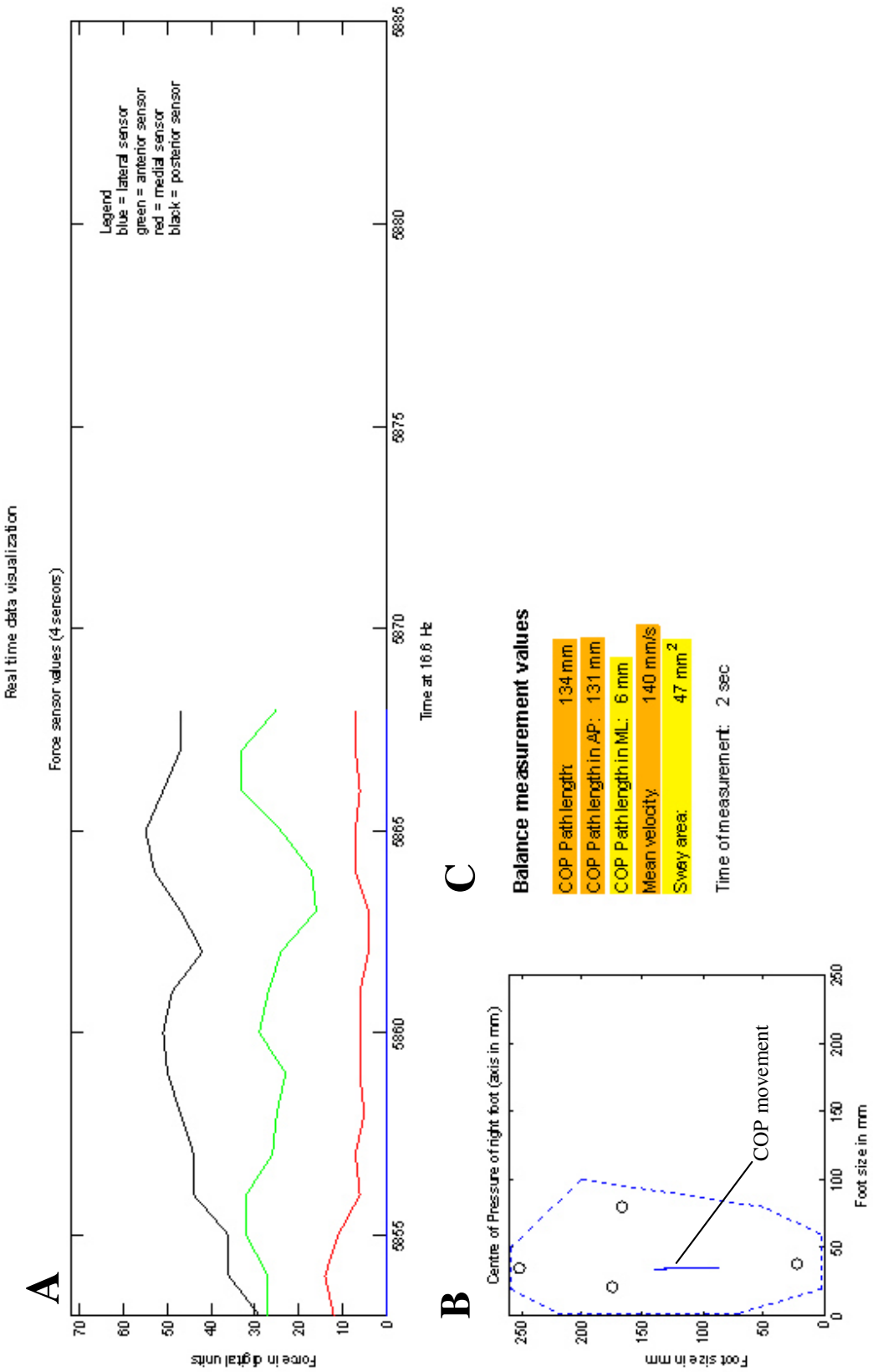

Fig. 6.19: Screenshot of analysis system for leaning forward: The force sensor values (A), the movement of the COP with a line (B) and the balance measurement values (C).

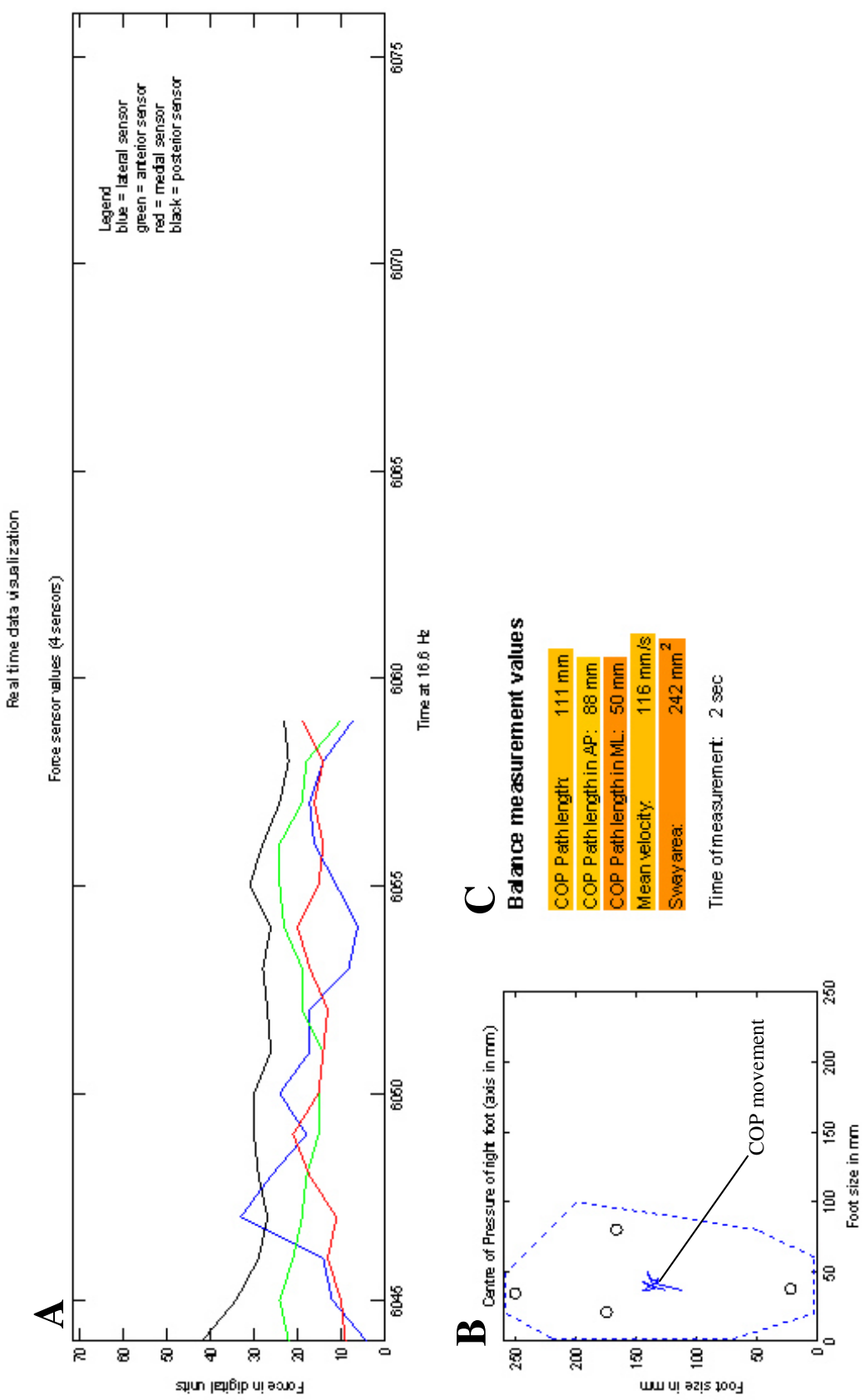

Fig. 6.20: Screenshot of analysis system for unsteady stand: The force sensor values (A), the movement of the COP with a line (B) and the balance measurement values (C).

6.8. Discussion

A measurement system for the analysis of balance parameters to study the effects of a wearable EFS for posture control has been developed and tested in the current work. The system was designed and implemented to serve as an analysis tool in a clinical study to test if EFS improves posture control in patients with sensation loss in their feet.

6.8.1. Findings

A plantar balance measurement system for posture control analysis and visual balance feedback has been developed in this work and several test scenarios were analysed. The most commonly used COP parameters were summarized and the COP movement in the AP direction was identified as an indicator for posture control. A novel foot model was presented that incorporates standardised foot measurements and foot positions. The model also involves the placement of four force sensors at locations of high pressure on the feet. It allows easy comparison between different balance assessments in future trials. The presented foot model saves time when performing a study with several participants, as the measurement of individual foot parameters, such as foot deformation or other anomalies, is a time consuming process.

The data acquisition process for the data from the measurement system was described. Several filters help to identify corrupted data points and outliers. An automatic analysis approach for pre-recorded data was presented that automatically creates several useful visualisations of AP movement, as well as automatically calculating balance parameters and then saves them in an Excel file for later analysis. The system was tested with several predefined scenarios and posture control could successfully be demonstrated. However, using predefined scenarios does not allow comparing the ability to control posture when a balance aid like an electrotactile feedback is used. Therefore, a study described in chapter 7 uses the visual analysis and numerical analysis in a clinical trial to compare different balance scenarios using electrotactile feedback.

In addition to the pre-recorded data analysis system a dynamic real time COP analysis system has been developed that can be used as a balance training aid. This real-time system is using the same acquisition process like the pre-recorded data analysis system, with the limitation that it does not detect outliers since the filter process mentioned above (see section 6.5.3) is a time consuming procedure and can not be implemented in real time.

The dynamic COP analysis system is useful to visually test the installation of the force sensors. It quickly determines if all force sensors give accurate values, in terms of representing the ground reaction forces that occur when a person is swaying in different directions. The developed interface shows a user's moving centre of pressure but also displays balance parameters in real time. A user is warned via changing colours of situations that could lead potentially to a fall.

6.8.2. Implications

The presented plantar balance measurement system has advantages over other systems. The presented system uses a specific foot model which was not used in

other studies involving the use of force sensors (Bamberg et al. 2006). Further the position of the feet was standardized which also helps to improve the comparability between different study participants.

The balance behaviour is visualised and can be useful when analysing COP movement and other balance parameters in real time. The developed colour visualization for values might be useful for people with balance problems to see movements or balance behaviours that are critical which could lead to a fall. Simple instructions, such as keeping all the colours in the yellow range might be sufficient as a motivation to actively control balance for people that have balance problems. The training of balance is an important stage in the rehabilitation process which can be continued by using an EFS as a follow up rehabilitation measure.

6.8.3. Future Work

Individuals with sensory impairment after stroke or with prosthesis can benefit from training during rehabilitation. A future study with the developed feedback system might reveal significant improvement in the rehabilitation process when the EFS is used in combination with the visualization of the centre of pressure movement and balance parameters. When using the system to train balance in rehabilitation a useful extension could be adding a reward system to it for motivational reasons. The developed tool can have a significant impact in balance training facilities for rehabilitation, because the plantar measurement system can be easily integrated into a shoe insole and implemented on any computer or tablet, allowing a high flexibility in several training scenarios.

The developed foot model uses certain assumptions about the anatomy of the human foot which might not always be accurately matching with the feet of a study participant. In the case of foot deformations the system might therefore lack the generalisation of results. It might be necessary to improve the model by taking common foot deformations into consideration to keep the model more flexible.

6.8.4. Conclusion

The motivation for the development of the presented plantar balance measurement system was the usage in a clinical trial to test if a wearable EFS can improve posture control for impaired individuals. A measurement system has been developed that allows tracking and analysis of balance parameters. Further the system allows visualizing COP movement and parameters on a screen and could potentially be used as a training device in rehabilitation. It was shown that the developed system allows balance analysis in predefined scenarios, but it has yet to be tested in a real world scenario with patients. A clinical trial was carried out using the developed measurement method for balance analysis.

"The quality of life is more important than life itself."

Alexis Carrel, 1952

Chapter 7 Clinical Trial on Posture Control

7.1. Abstract

This chapter presents the design and results of a clinical study which was carried out at the Royal Bournemouth Hospital to test the feasibility of an electrotactile feedback system (EFS) for improving posture control during standing and walking. The study design was approved by the National Research Ethics Service.

In this study, a biofeedback system examining the effects of electrocutaneous stimulation (ES) on an individual's ability to actively control their posture was tested in a clinical environment. In total 14 participants with sensory impairment took part in the study. They were observed performing a variety of balance tests with eyes open (EO), eyes closed (EC) and on a foam pad (OF), as well as walking tests while using the electrotactile feedback system (EFS). The EFS detected the centre of pressure (COP) using a shoe insole equipped with force sensors and giving feedback to the upper leg in the form of electrical stimulation based on the change of COP. The recorded COP movement was used as an indicator of the balance behaviour of the participants, where the COP velocity in Anterior-Posterior (AP) direction, Medial-Lateral (AP) direction and Sway Area was tested. Furthermore the study examined if the usage of the device would improve walking speed in a Timed-Up-and-Go (TUG) test.

Balancing results showed that patients significantly improved their velocity in AP direction during balancing with eyes open, suggesting less sway and a more stable stand during the use of the EFS. A case analysis of one participant revealed that the subject adapted the angle of one foot to bring his/her body position in equilibrium while maintaining the other foot in a neutral position.

In a timed-up-and-go (TUG) test it was shown that when the EFS was used the average time to complete the test improved significantly by 7.2% ($p < 0.05$). The time improvement was not related to the use of the EFS suggesting that participants improved because of repetition of the task. However the results suggest that participants were not hindered by the device while performing the TUG test.

Even though significant improvement was only shown for balance during eyes open the current study showed that study participants successfully used the electrotactile feedback system to change their foot position and posture. It was concluded that EFS can be a supportive tool for aiding balance provided that the user has enough time to learn to use the device.

7.2. Introduction

7.2.1. Background

The usage of systems which give biofeedback information about the centre of pressure movement has been previously studied. Barclay-Goddard et al. (2004) compared seven trials under similar conditions with a total amount of 246 participants using audio- and visual-based biofeedback to improve their balance after a stroke. They concluded that the feedback did not improve the sway in standing individuals, nor their walking speed in a Timed-up-and-go-test. On the other hand studies with less participants using audio (Chiari et al. 2005), or a combination of vision and audio feedback (Milosevic et al. 2011) showed a positive effect on balance. Chiari et al. (2005) uses audio-sound to give feedback about the trunk acceleration and concluded that study participants reduced their trunk movement when using the feedback system. Milosevic et al. (2011) examined postural stability when audio-visual biofeedback was provided while balancing on a balance board. The decrease of the balance board movement radius was tested and participants showed significant decrease ($p < 0.0001$) in all directions during balancing tasks when audio-visual biofeedback was used indicating that the feedback helped in maintenance and recovery of dynamic balance. Using electrotactile feedback as a means to give biofeedback showed as well positive effects on balance control (Vuillerme et al. 2007; Bajd et al. 2002) (Chapter 2). In the studies of Vuillerme et al. (2007) and Matjacic et al. (2000) feedback about the COP movement was given to the back and tongue of study participants and in both studies the balance parameters improved. Dozza (2006) explains this lack of conclusive results, in studies involving usage of biofeedback systems, to be as a result of the difficulties in integrating biofeedback information into the existing natural way of processing sensory information. There still remain several open questions in determining how posture control changes when electrotactile feedback is used by individuals suffering from sensation loss. The lack of understanding in how EFS affect posture control makes it difficult to design such systems. In this study several aspects of an EFS are discussed to foster the development of biofeedback systems so that more people with sensory impairment can benefit from using such devices.

The different methods to determine the quality of balance have been previously discussed (Chapter 2 and 6). Balance describes the dynamics that are involved in the process of changing the body posture to stand and prevent a fall reference. Video based measurements systems (Wang et al. 2010), record the body posture and track the centre of mass. Accelerometer and inertial sensor based measurement system can detect movements of different body parts (Chiari et al. 2005; Turcato and Ramat 2010), while force sensor based systems are commonly used to track the centre of pressure (COP) movement for balance analysis (Bamberg et al. 2006). The COP movement can be used to calculate, amongst other indicators of balance, the velocity of the Anterior-Posterior (AP) or medial-lateral (ML) sway and the sway area of the COP. These are common indicators for balance. A lower value in the AP and ML velocity and a lower sway surface area is indicating better balance (Winter 1995). AP and ML velocity can be calculated by summing up the overall travelled distance of the COP in one direction and dividing it by the time. The sway area can be calculated by determining the convex hull of all COP measurements. AP and ML velocity are robust if outliers are in the dataset, while the sway area may increase significantly with a single outlier making it more sensitive to outliers. Additionally to test the

efficiency of walking and balancing aids, a Timed Up and Go (TUG) test is commonly carried out. The TUG test is a standardised procedure to determine the quality of walking. A participant of the TUG test has to sit on chair, walk 3 metres, then come back to the chair and sit again (Podsiadlo and Richardson 1991). The time for performing the TUG is directly related to the risk of falls (Shumway-Cook et al. 2000) as well as impairment of mobility and was found to be a sensitive (sensitivity = 87%) and specific (specificity = 87%) measure for identifying elderly individuals who are prone to falls.

The time to complete the test has the following relation to mobility:

- Less than 10 seconds: Freely mobile
- Less than 20 seconds: Mostly independent
- Between 20-29 seconds: Variable mobility
- Higher than 29 seconds: Impaired mobility

So far no TUG was reported to measure the effects of electrotactile feedback on walking speed for individuals with sensory impairment and it remains unclear if walking speed changes when electrotactile feedback is applied to body parts other than the tongue (Badke et al. 2011)(Chapter 2).

7.2.2. Objectives

The primary goal of this study was to investigate the feasibility of using a wearable EFS and its effects on COP movement by applying different balance scenarios to determine whether EFS improves balance parameters. The walking speed was examined in a TUG test to investigate if the usage of a wearable EFS improves walking speed. Furthermore it sought to examine participants' experience of using the EFS.

7.3. Methods

7.3.1. Participant population

A total of 23 patients were involved in the screening for the study. Five individuals were excluded from the study due to having early stage neuropathy and no report of an effect on balance. Four participants withdrew before the trial commenced. Eight female and six male patients with an average age 64 ± 12 years participated in the study. The youngest patient was 43 years old and the oldest patient was 89 years old. The control group consisted of five healthy individuals with an average age of 52 ± 18 years.

The candidates for the clinical trial were preselected by a Diabetic Consultant and screened further by the investigator. Among the group four patients had total sensation loss in their feet; four had partial sensation loss and six suffered from painful neuropathy. All patients signed an informed consent form. The study design was submitted to the National Research Ethics Service and favourable opinion was granted.

7.3.2. EFS device and measurement system

A wearable electrotactile feedback device that was designed and built at Bournemouth University for this research was used to carry out the study (Fig. 7.1) (Chapter 3). The device consists of a sensor, processing and stimulation unit. The sensor unit is an insole equipped with four force piezo-resisive sensors to detect the ground reaction forces on the feet.

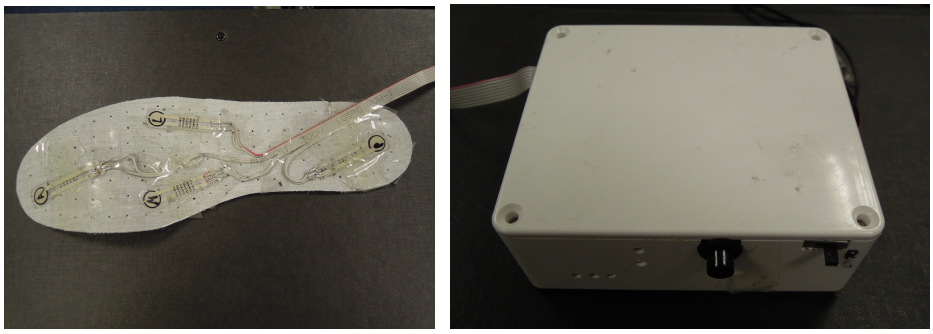

Fig. 7.1: Force sensor unit and device housing designed and developed at Bournemouth University for this research project.

The force sensor information is transmitted via a cable to the processing unit where the device calculates the centre of pressure and indicates the movement of centre of pressure by sending electrical impulses to the electrodes. Four electrode pairs are placed around the upper leg in anterior, posterior, lateral and medial positions. When the centre of pressure moves to the front, then the electrodes in the front are activated with the same responses occurring in the other directions. The strength of the stimulus is proportional to the movement of the COP. The further the user leans in one direction, the stronger the feedback stimulus is.

Stimulus frequency, pulse amplitude and pulse width were chosen according to previous studies using electrotactile feedback (Robertson et al. 2006; Szeto 1985) (Chapter 5). In this study a pulse frequency of 17 Hz, pulse amplitude of 84 V and a maximum pulse width of 600 µs were used. The device was calibrated for each test participant. During the calibration process the device detected the minimal and maximal force sensor values. The centre of pressure was then determined by recording the force sensor information for five seconds while the participant kept his/her body posture in equilibrium. To keep the stimulation in a comfortable range the sensation thresholds of each participant were determined.

The device has two modes. The first mode only records data (no feedback-mode) and does not evoke any electrical stimulus (Chapter 4). The second mode (with feedback-mode) creates electrotactile feedback according to the COP information whilst simultaneously recording data. The stimulus is calculated by the following force transfer function,

$$pw_{l(t)} = pw_{\min} + (pw_{\max} - pw_{\min}) \cdot \frac{f_{(t)} - f_{COP}}{f_{\max} - f_{COP}}, \qquad (34)$$

Where the pulse width at any given time, $pw_{(t)}$, is dependent on the force sensor value, f_t, the force value for the COP, f_{COP}, the maximum force f_{max} and the minimum and maximum pulse widths, pw_{min} and pw_{max} (see Eq.(34)). The force sensor values were sent wirelessly using the Zigbee standard to a password protected PC and stored in a log file for later analysis.

7.3.3. Experimental Setup and Calibration

The tests were performed in a private clinic room in the Diabetes and Endocrine Centre at the Royal Bournemouth Hospital by two investigators. Prior to the experiment the participants had to answer several questions regarding demographics and their neuropathic condition. Following that a monofilament touch test was performed in adherence to the Trust's Departmental Guidelines. A 10 g monofilament was used on 10 different locations on each foot to determine the level of sensory loss due to the neuropathy in each participant. Another monofilament test was performed on the upper leg to ensure that the patient had no sensory loss in this area. The shoe size of the test person was measured and the force sensors system was attached to a shoe insole, at the area of highest pressure including the 1st metatarsal, 5th metatarsal, heel and big toe (Granat et al. 1996; Williams 1997). The force sensing unit was then installed in the participant's shoe. The force sensors were connected to the device that was then mounted on a belt around the participant's waist. The test person was asked to wear shorts prior to the experiment in order to easily attach the electrodes to the upper leg. Electrodes of the type J10R00 were used with a diameter of 2.5 cm. Altogether 16 electrodes were placed in a circular manner around the upper part of the left and right leg (Fig. 7.2)

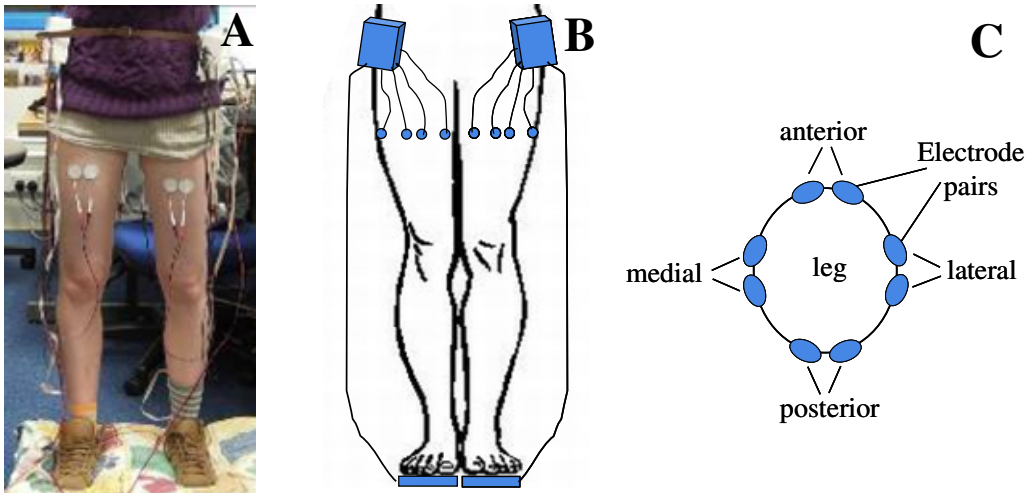

Fig. 7.2: Device attachment and installation on a test participant(A). Four electrodes pairs were placed on each leg of the test participants (B) resulting in 8 electrodes on each leg and 16 electrodes in total (C).

The calibration method consisted of three parts: Threshold calibration, force sensor value detection and the centre of pressure detection during body equilibrium. The "method of limits", an established method for threshold detection, was used for the calibration of sensory thresholds, for each participant (Stevens 1957)(Chapter 5). The experiment commenced with the calibration procedure in order to define the sensation thresholds for the electrical stimulation of the test participant. When the calibration button of the device was pressed a pulse started to rise. The test subject was asked to say "Stop" when the pulse started to feel uncomfortable, then the calibration button was pressed. The pulse now started to descend, when the test person did not feel the pulse anymore the procedure was stopped again. This procedure was repeated for both legs stimulating the anterior electrode. The minimum and maximum values were recorded and saved. This indicated the range of electrical stimulation pulse width that could be applied without causing harm to the

individual. The force sensors and maximum COP values were calibrated by recording the participants' movement over a period of 5 seconds. During that time the subject was asked to sway in different directions by moving his/her hips in a circle. The force sensor values were continuously recorded and a minimum and maximum value for each force sensor was detected. This procedure detected which force sensor value had to be matched to the maximum COP movement value representing the range of movement, which was necessary to match the force values to the interval of pulse widths. Next, the centre of pressure based on the force sensor readings was recorded. The test participant was asked to maintain body equilibrium for five seconds while the pressure information was recorded and the average COP value was determined. To secure the functionality and correct setup of the parameters the device was then briefly turned on for 30 seconds using the with-feedback mode. Then the patient was asked to confirm that he/she could feel stimulation when leaning in different directions. The procedure for calibration took between 7-10 minutes.

7.3.4. Test procedure

The experiment was divided into two parts. A balance test under different conditions (Winter 1995) and a standardised timed-up-and-go test (TUG) (Podsiadlo and Richardson 1991). The balance test involved balancing with eyes open (EO), eyes closed (EC) and on a foam pad (OF). Each of the three scenarios was conducted with and without giving electrocutaneous stimulation. The (TUG) test was conducted four times. First the TUG test was conducted with no feedback (TUG-no) and then with feedback (TUG-with), then the same procedure was repeated again after the first TUG test (see Fig. 7.3).

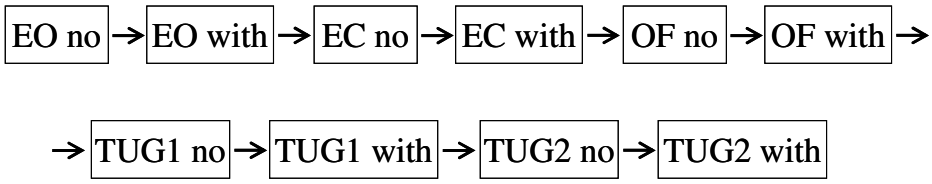

Fig. 7.3: Sequence of test procedure: Eyes open, no feedback (EO no), Eyes open, with feedback (EO with), Eyes closed, no feedback (EC no), Eyes close, with feedback (EC with), on foam pad, no feedback (OF no), on foam pad, with feedback (OF with), each test was conducted for 1 minute. The procedure was followed by a time-up-and-go- test (TUG) without feedback (TUG1 no), followed by a TUG with feedback (TUG1 with), and the same sequence for TUG2 no and TUG2 with.

During the balance tests the patient was told to maintain his or her body in a stable position and to avoid swaying. The following instructions were read to the study participant:

You will start to feel electrical stimulation on your left and right leg. The stimulation will change according to your body posture, which means that when you lean forward, you will feel an electrical stimulus on the front part of your leg and similarly for the back, right and left side. Try to use this information to maintain your balance and a stable position.

Each of the tests was started by pressing two buttons on the two devices on the left and right foot to trigger the transmission of sensor data. Each balance test lasted for 55 seconds. This time frame was selected based on the recommended time period for

balance tests (de Freitas et al. 2009; Słomka et al. 2013). During all balance tests the participants were observed by both investigators.

For the timed-up-and-go test an established test procedure for TUG was used (Podsiadlo and Richardson 1991) and the participant was asked to sit comfortably on a seat, then rise and walk 3 m towards a small object on the ground, come back to the seat and sit down again. The time was recorded with a stopwatch from the moment the person stood up to the moment the participant sat back down. The TUG was repeated four times. Before the TUG the following sentences were read to the participant:

Please stand up and walk to the object, then turn around and walk back to the chair. When you are back to the chair, sit down again. Don't rush, just walk with a normal pace.

To avoid stress to the participant and prevent the onset of fatigue the whole experimental procedure including balance and TUG test was kept within a time frame of 60 minutes. After the test procedure, each participant was asked to complete an evaluation questionnaire, rating their perceived discomfort using the comparative pain scale from 0 – 10 (Chen 2010).

To conclude all participants were interviewed to determine the subjective impression of the participant concerning improvement of balance, comfort of the electrocutaneous stimulation and overall impression of the comfort of wearing the device.

7.3.5. Analysis

7.3.5.1 Data collection

The data from the calibration and force sensor readings during the trial were recorded wirelessly and saved in a log file. The data sets were conditioned by replacing corrupted or missing data, mainly caused by the wireless transmission, via linear interpolation (Chapter 6). To detect outliers or corrupted data that was not detected by previous detection algorithm a standard Hampel Filter was used (Liu et al. 2004) (Chapter 6). The standard window size was set to 18 data points were used as the standard window size. Wider window sizes are more robust to outliers. In cases where strong artefacts falsified the data set a lower window size was selected. The detected outliers were replaced via linear interpolation.

7.3.5.2 Balance and TUG test analysis

The data analysis of the balance tests was divided into two sections. In the first section the data of all patients was analysed. The AP and ML velocity and sway area using the convex hull were presented for each test. Further a quotient was formed between COP movement values to study the effect of the usage of electrotactile feedback. This procedure was chosen based on the Romberg Quotient which is an established value used to compare COP movement values for studies that involve experiment where the patient has to balance with eyes open or eyes closed (Turcot et al. 2009). The quotient was formed between the COP movement value with feedback and without feedback. In accordance with the Romberg quotient a value above one indicates an improvement in balance and a quotient below one indicates a decrease in balance.

The second section used a detailed individual analysis of one subject to observe posture control. Visual inspection of the graphic presentation of the AP movement and COP movement was used to determine how the EFS affected the balance behaviour of the participant. To improve the accuracy and reliability of the plotted data a quantitative analysis of previously describes balance parameters was used to support the visual inspection (Ottenbacher 1986).

Not all data sets for each test could be included in the balance analysis. In cases where the sensor system could not collect sufficient data to allow analysis the data set was excluded from the study. This was due to sensor system error, when having no values or corrupted values in the log file. More data errors occurred when the feedback was turned on, since the algorithm for the calculation of the pulse width slowed down the microcontroller leading to corrupted data transmission via XBee. Another source of error was the connection of the force sensors. Before each trial the cables connecting the force sensors with the device were checked, but it happened that a cable connection got disconnected during the performance of the test which resulted in missing data from one sensor. Due to the different sources of error this part of the analysis could not be automated.

If not indicated otherwise, all tests for significance were conducted using a standard t-test with a confidence value of $p > 0.95$ using the statistical analysis software Stata (StataCorp LP).

7.4. Results

7.4.1. Sensation loss related problems

Patients were asked to rate their level of difficultly in undertaking daily activities as a result of their reduced sensitivity and balance instability (Fig. 7.4). The activities listed were scaled from 0 to 10, with 0 representing no impact on that particular activity and 10 representing a high negative impact.

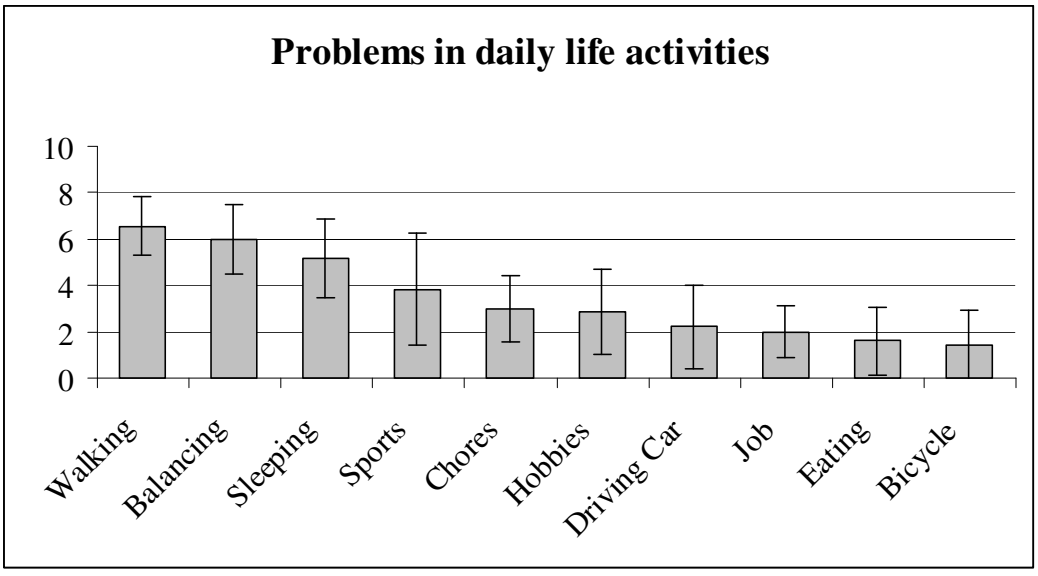

Fig. 7.4: Average rating of problem level on a scale from 0-10 for daily life activities related to sensation lost in the feet (n=16, 0 = low impact, 10 = high impact)

Most participants reported having problems with walking and balancing and the averaged rating was 6.6 ± 2.5 for walking and 6 ± 3 for balancing. Patients were also asked if they had suffered a fall as a result of poor balance. Four patients had previously experienced a fall confirming the high risk that is associated with neuropathy in the feet. The results substantiate the need for an aid to compensate for balance problems.

7.4.2. Numerical analysis on COP movement velocity and sway area

For all tests completed by the participants the quotient value when electrotactile feedback was turned on and when it was turned off was calculated (Tab. 7.1), which is similar to the Romberg quotient (section 7.3.5.2). This involved dividing the value where no feedback was obtained by the value where feedback was received. The table shows all quotients for the mean AP velocity (v_{AP}), mean ML velocity (v_{ML}) and the sway area (A_{SWAY}) for each participant. In addition the p-value was determined for each scenario testing the hypothesis that the mean of all patients is higher than one.

Relation quotient for patients

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	$p_{(\mu>1)}$
v_{AP} - EO	x	1.12	0.73	1.62	1.84	0.74	1.20	1.21	0.87	1.65	1.35	0.95	1.03	1.35	0.03
v_{AP} - EC	x	0.81	1.33	0.91	0.88	1.27	0.50	1.06	0.68	0.99	0.74	1.26	1.09	0.95	0.72
v_{AP} - OF	x	0.74	1.57	1.66	0.92	0.68	0.95	1.11	0.50	4.30	0.86	x	1.20	x	0.17
v_{ML} - EO	x	1.01	0.66	1.51	1.16	0.72	1.56	3.60	0.89	1.30	1.16	1.09	0.69	1.19	0.11
v_{ML} - EC	x	0.97	1.02	1.17	0.83	1.06	0.81	0.84	0.84	1.00	0.77	1.22	1.40	1.24	0.41
v_{ML} - OF	x	0.93	1.09	1.15	0.59	0.79	0.61	1.00	0.64	2.00	1.00	0.82	0.87	0.28	0.79
A_{sway} - EO	x	0.99	0.30	x	6.12	0.27	0.33	0.69	0.80	x	x	0.88	0.70	x	0.36
A_{sway} - EC	x	1.13	1.00	1.06	1.00	0.46	0.80	0.82	0.92	x	0.40	0.89	0.98	0.44	0.98
A_{sway} - OF	x	0.69	0.61	2.50	0.47	0.79	1.81	3.33	x	4.51	0.48	x	0.96	x	0.10

Tab. 7.1: Relation quotients for mean AP velocity (v_{AP}) and the sway area (A_{SWAY}) is shown. The quotient is formed by dividing the value of area or velocity with feedback by the value of the area or velocity without feedback. The same calculation is done for each of the three test scenarios (eyes open (EO), eyes closed (EC), on foam (OF)) and each patient (n=14). Fields filled with an x are values that had to be excluded from the analysis.

A value above one (Tab. 7.1) indicates that the feedback device helped to reduce AP movement and the sway area (marked darker). With eyes open 69.2% of the patients improved their AP velocity, while with eyes closed the AP velocity improved for 38.5% and on a foam pad for 45.5%. The ML velocity decreased for 69.2% during balancing with eyes open, 46.2% during balancing with eyes closed and 30.8% for on a foam pad when the EFS gave feedback. 11.1% of participants showed less sway area when the EFS was in feedback mode for balancing with eyes open. During balancing with eyes closed 16.7% of the participants improved their sway area and 40% during the balance test on a foam pad.

Tests for significance were performed for each scenario using a one-tailed t-test with the hypothesis that the quotient is greater than one. During balancing with eyes open the EFS significantly improved the AP velocity among the participants ($p < 0.05$). No other scenario showed a significant improvement in balance parameters within the confidence interval of $p < 0.05$. On the other hand, contrary to the hypothesis that

the EFS reduces the sway area, it was discovered that during balancing with eyes closed the sway area significantly increased ($p < 0.05$).

Relation quotient for control group

	1	2	3	4	5	$p_{(\mu>1)}$
v_{AP} - EO	1.01	4.75	2.67	1.06	0.98	0.11
v_{AP} - EC	2.79	1.01	0.98	1.01	0.59	0.26
v_{AP} - OF	0.47	0.43	0.28	0.92	1.01	0.97
v_{ML} - EO	0.97	1.06	1.23	1.04	0.98	0.15
v_{ML} - EC	1.13	1.49	0.88	2.15	0.68	0.18
v_{ML} - OF	1.09	0.50	0.94	1.13	1.08	0.66
A_{sway} - EO	0.49	2.11	1.15	x	x	0.32
A_{sway} - EC	0.94	0.31	0.98	x	x	0.82
A_{sway} - OF	0.58	0.49	x	0.85	1.07	0.92

Tab. 7.2: The relation-quotient for mean AP velocity (v_{AP}), mean ML velocity (v_{ML}) and the sway area (A_{SWAY}) for the control group. The quotient is formed by dividing the value of area or velocity with feedback by the value of the area or velocity without feedback. The same calculation is done for each of the three test scenarios (eyes open (EO), eyes closed (EC), on foam (OF)) and each control subject (n=5). Fields filled with an x are values that had to be excluded from the analysis.

The control group (Tab. 7.2) showed an improvement in AP velocity among 80% of the participants during balancing with eyes open, 60% for balancing with eyes closed and 20% for balancing on foam. ML velocity improved for 60% during balancing with eyes open, 60% during balancing with eyes closed and 60% during balancing on a foam pad. The sway area improved for 50% during balancing with eyes open, 0% for balancing with eyes closed and 25% for balancing on a foam pad. A t-test among the control group did not show any significant values. Even though four out of five patients showed an improvement with eyes open and three out of five with eyes closed, the sample size was too small to reach significance.

Overall the results indicate that participants suffering from sensation loss did improve their AP velocity significantly when the EFS was used during balancing with eyes open. However, no other scenario showed significant improvement when comparing the COP parameters with and without using electrotactile feedback, while the sway area increased when the EFS was used during balancing with eyes closed.

7.4.3. Case analysis

The COP parameters of one patient were studied in more detail and selected COP movement parameters were calculated and visualised. The selected patient reported having difficulties in balancing during standing and walking. The patient, with the identification number 005, had total sensation loss in both feet reaching from the lower limb to the foot insole. In the monofilament test he detected none of the contacts on the feet. An overview of the AP movement for this patient during each part of the experiment is shown in Fig. 7.5. The length of movement was matched to a standardised foot model as described above (see Chapter 6). The patient data indicates a strong periodic sway with eyes open and not using the feedback system in the left and right foot. The graph in Fig. 7.5 shows the sway in anterior and posterior direction over the course of 55 seconds.

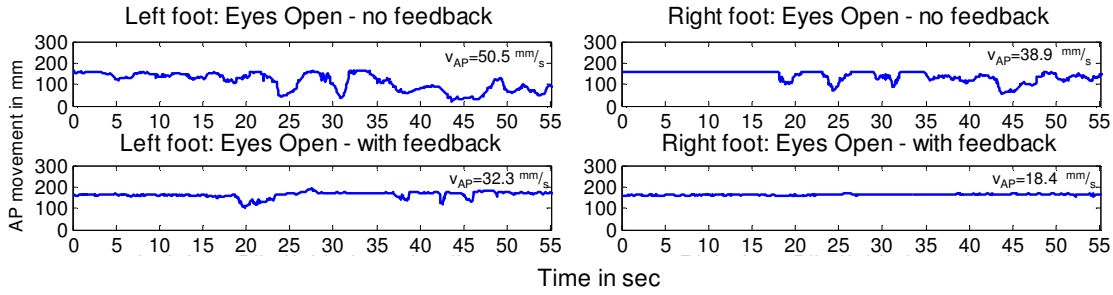

Fig. 7.5: COP movement in AP direction during balancing with eyes open for test participant 005

The frequency of this supposing systematic AP movement was 0.25 Hz with a total amplitude of 160 mm between 20 mm and 180 mm in relation to the foot. When using the device the systematic AP movement disappeared and the patient's control of balance appeared much more stable. This observation is supported by comparing the mean velocities, since the mean velocity in AP direction is 50.5 mm/s (left) and 38.9 mm/s (right) without receiving feedback and 31.5 mm/s (left) and 18.3 mm/s (right) with the continuous feedback. The range for the AP movement for the left foot of 160 mm without receiving feedback if compared to 80 mm with feedback also indicates less movement.

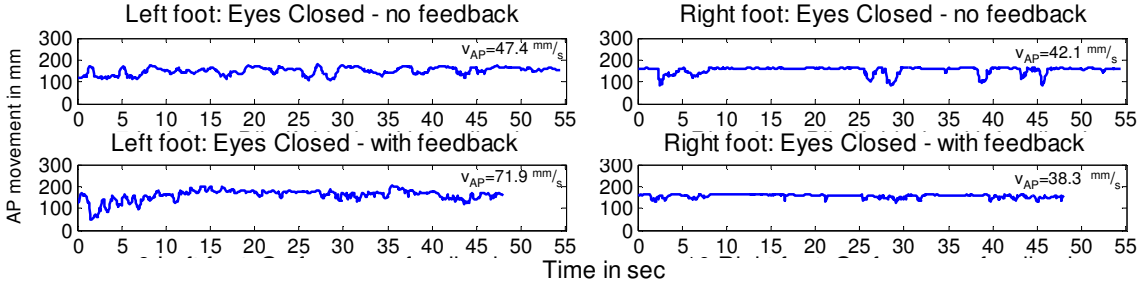

Fig. 7.6: COP movement in AP direction during balancing with eyes closed for test participant 005

With eyes closed (EC) the AP movement again suggests a systematic sway frequency with an approximated frequency of 0.3 Hz (Fig. 7.6). The AP sway stays continuously within the duration of the experiment and does not change significantly.

Once the electrotactile feedback is used the patient needs a couple of seconds to adopt and then the sway movement is stabilised at a higher frequency of about 0.65 Hz. The sway amplitude decreases indicating that the subject uses the feedback to control their posture to countermeasure extensive sway. The mean velocity in AP movement is in this case higher because of the faster swing frequency. However, this does not necessarily result in less stability because the total amplitude is less if compared to the eyes closed test without feedback.

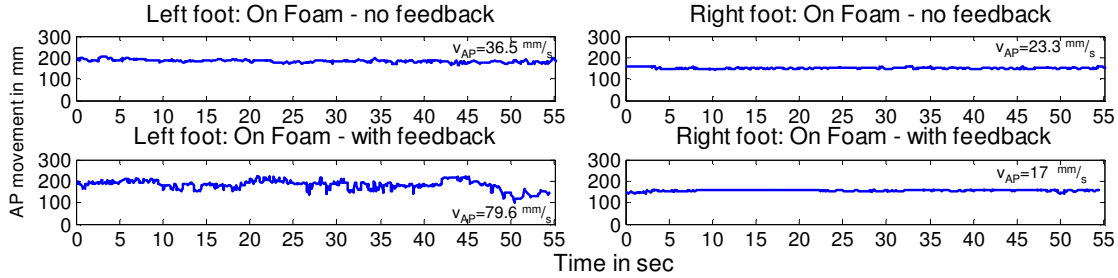

Fig. 7.7: COP movement in AP direction during balancing on a foam pad for test participant 005

While balancing on a foam pad the test participants performance declines when the EFS is used. The AP velocity is 79.6 mm/s compared to 36.5 mm/s indicating a higher sway in the AP direction. This suggests that the patient did not benefit from the feedback on foam.

Another indicator showing a change in posture control is the visual inspection of the sway path for the left and right foot and the averaged COP for both feet (Fig. 7.8). Looking at the sway path and the resulting sway area (Fig. 7.9) during balancing with eyes open it shows less sway when the device gives electrotactile feedback to the user. The sway area is 1557 mm^2 (left) and 1332 mm^2 (right) without using the feedback and 1506 mm^2 (left) and 119 mm^2 (right) while receiving feedback.

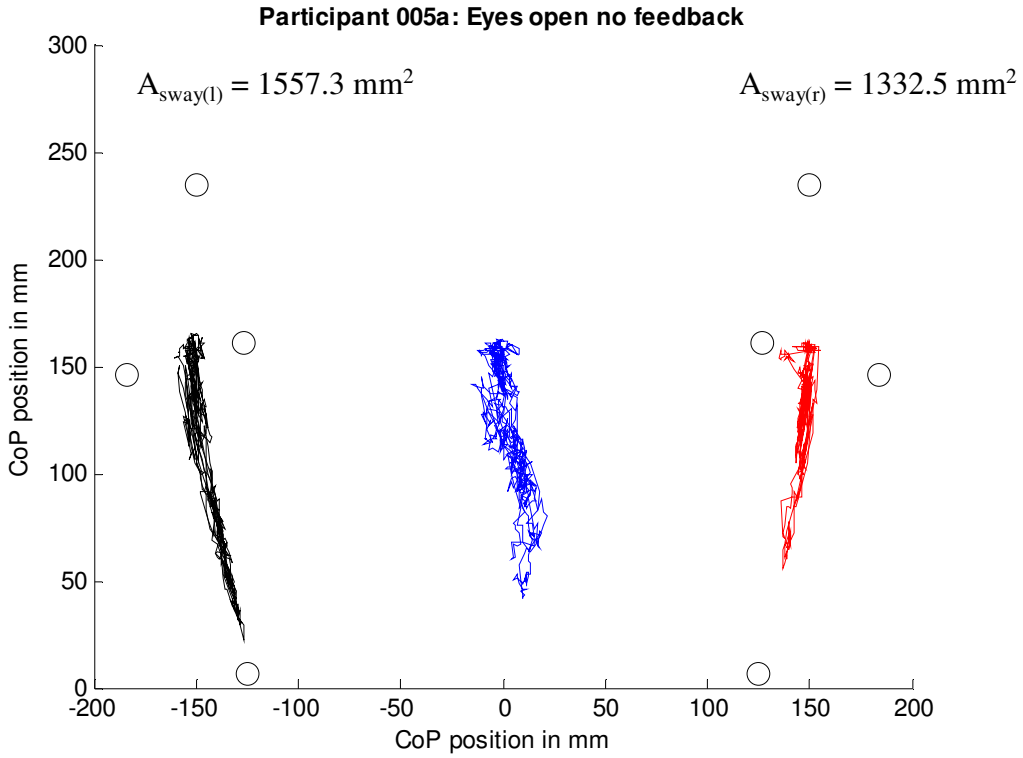

Fig. 7.8: COP for balancing with eyes open with no feedback: Sway path for left and right foot as well as averaged sway path with no electrotactile feedback during balancing with eyes open. The circles represent the force sensor placement in the shoe insole.

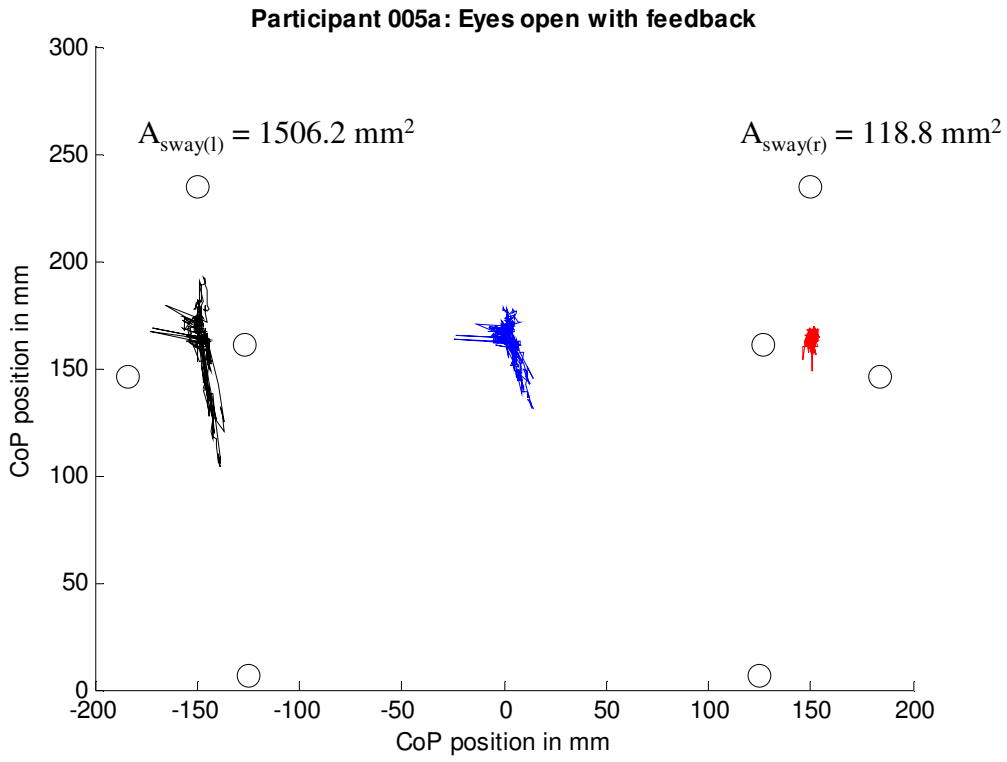

Fig. 7.9: COP for balancing with eyes open with feedback: Sway path for left and right foot as well as averaged sway path with electrotactile feedback during balancing with eyes open

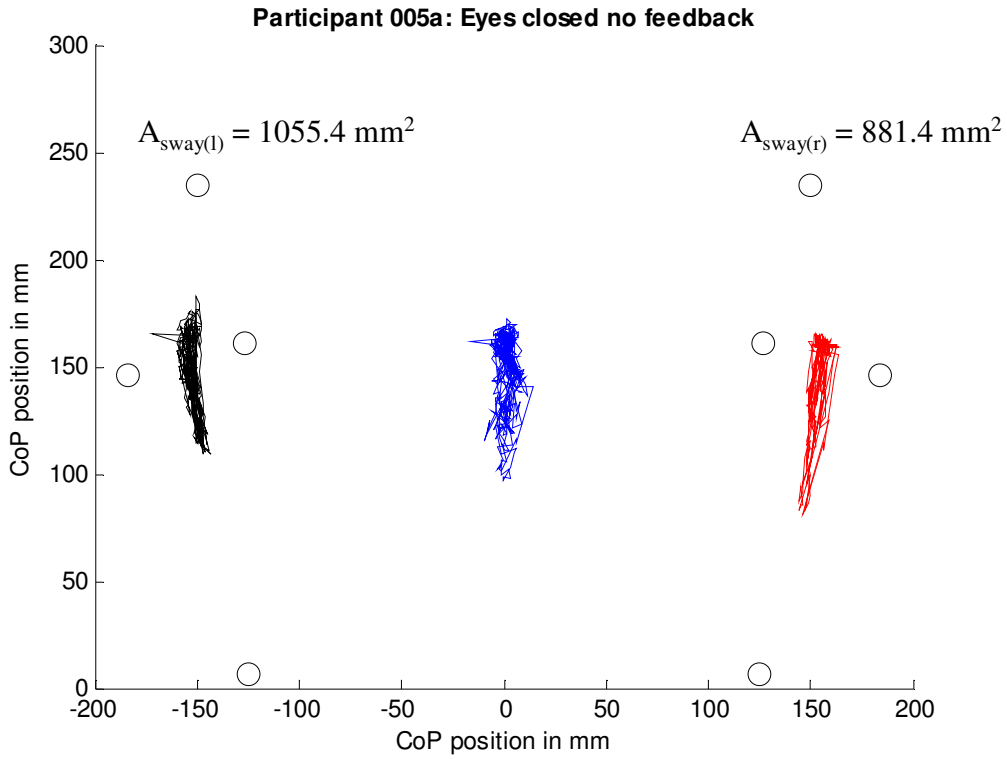

Fig. 7.10: COP for balancing with eyes closed with no feedback: Sway path for left and right foot as well as averaged sway path with no electrotactile feedback during balancing with eyes closed

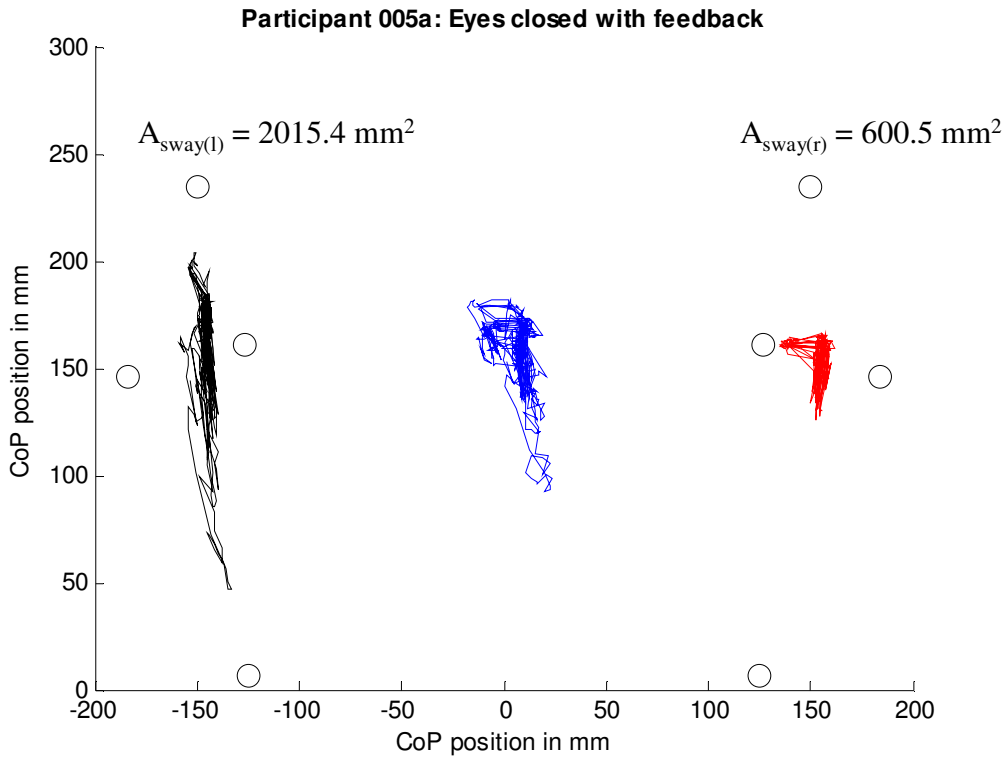

Fig. 7.11: COP for balancing with eyes closed with feedback: Sway path for left and right foot as well as averaged sway path with electrotactile feedback during balancing with eyes closed

A specific pattern was observed when the participant was using the EFS with feedback. During balancing with eyes closed the participant moves his/her right foot in a different way than the left foot. The right foot shows a higher sway in the ML direction than the left foot. The participant stated after this exercise that he/she tried to minimize the feedback stimulation on the lateral placed electrode pair by tilting his/her ankle more towards the medial direction. If the accumulated averaged COP is used for the analysis (Fig. 7.11) this specific behaviour can not be observed. A conclusion from this observation is that the centre of pressure needs to be analysed separately for both feet.

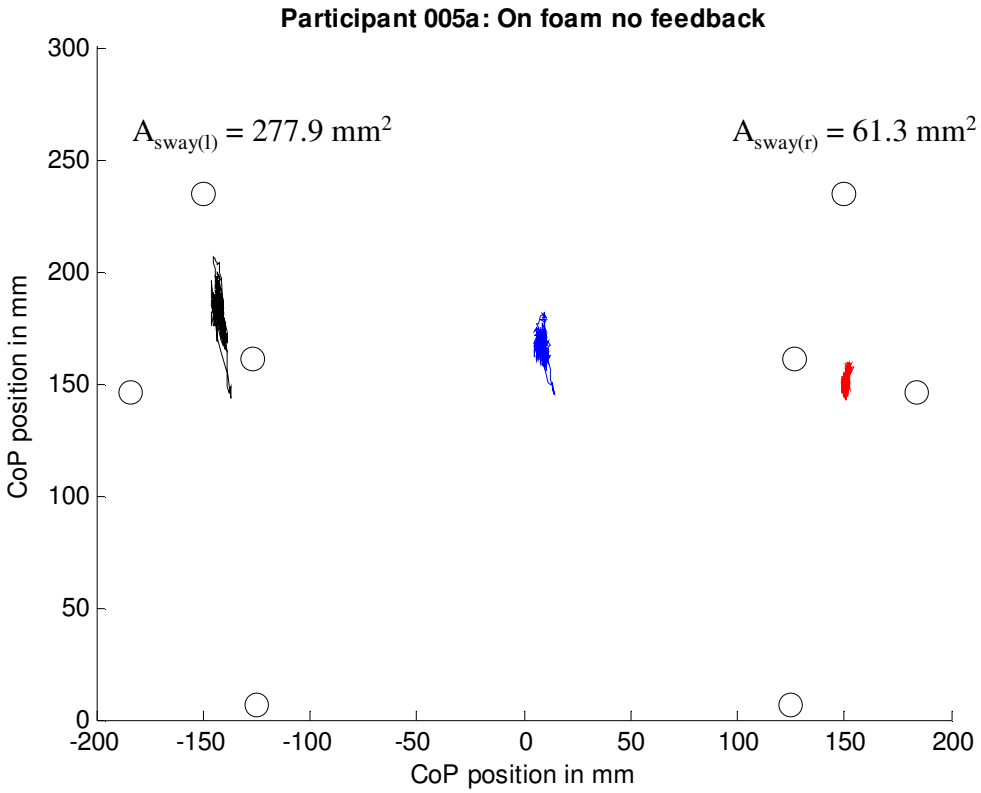

Fig. 7.12: COP for balancing on foam with no feedback: Sway path for left and right foot as well as averaged sway path with no electrotactile feedback during balancing on foam

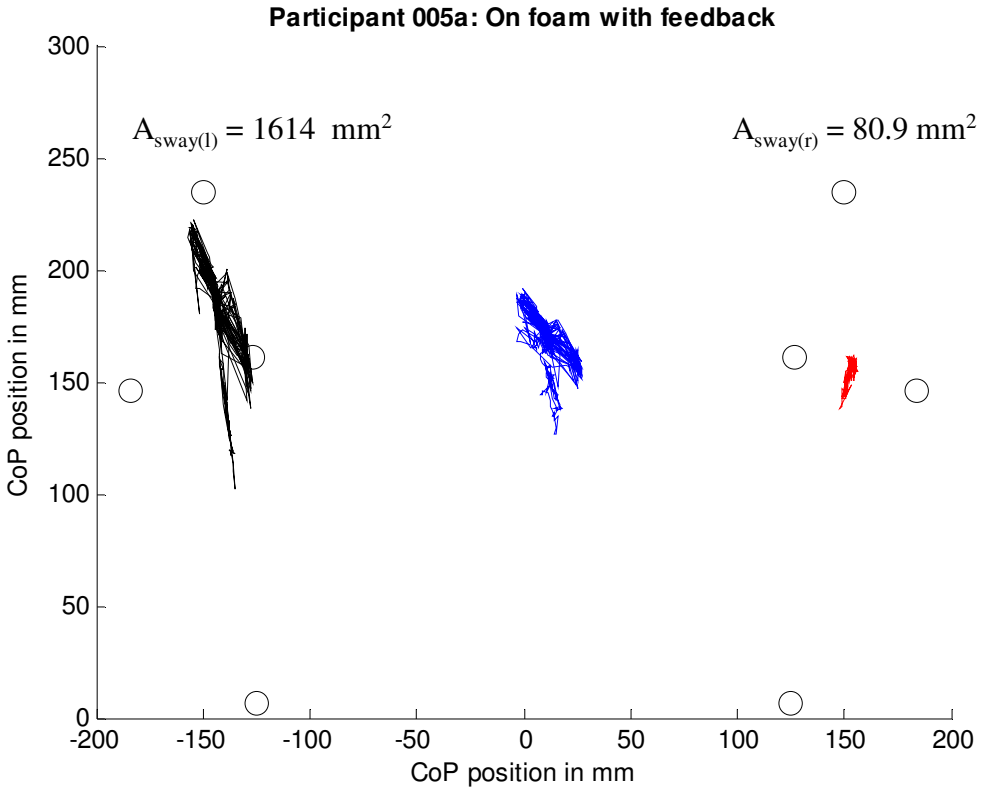

Fig. 7.13: COP for balancing on foam with feedback: Sway path for left and right foot as well as averaged sway path with electrotactile feedback during balancing on foam

During eyes closed the sway area of the subject increased from 277.9 mm^2 (left) and 61.3 mm^2 (right) to 1614.0 mm^2 (left) and 80.9 mm^2 (right). This further demonstrates that the participant did not benefit from the feedback when balancing on foam.

7.4.4. Timed up and go test

A timed-up-and-go (TUG) test (section 7.3.4) was conducted with 14 patients. One patient showed strong signs of fatigue during TUG1 and could not complete the TUG2 test. This data was therefore excluded from the analysis.

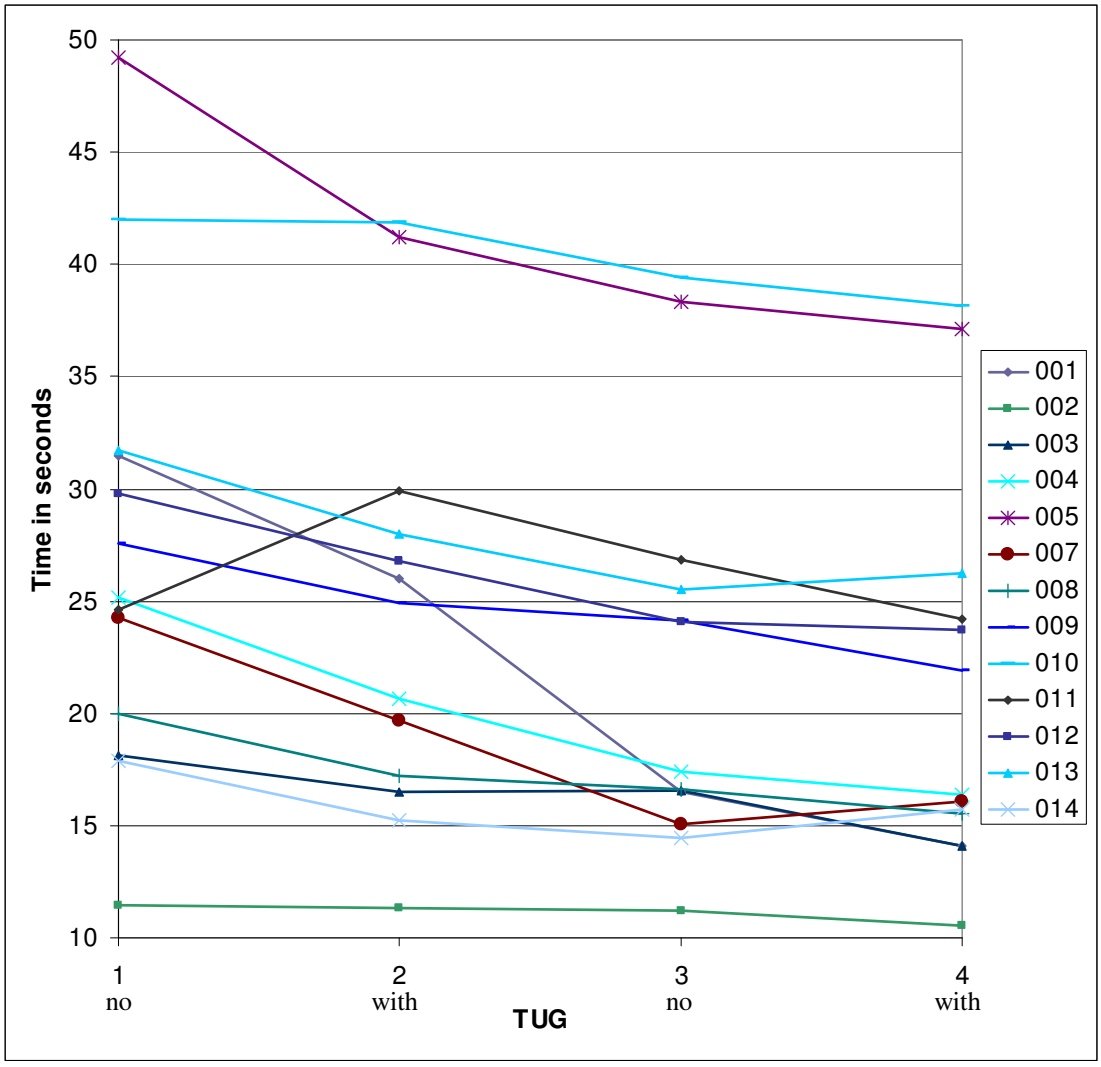

Fig. 7.14: Timed-up-and-Go test for all participants. The plot shows the times for each TUG (n=13). TUG 1 and TUG 3 involved no feedback, while TUG 2 and TUG 4 were performed with feedback. The patient with the identification number 006 could not participate in this trial due to tiredness.

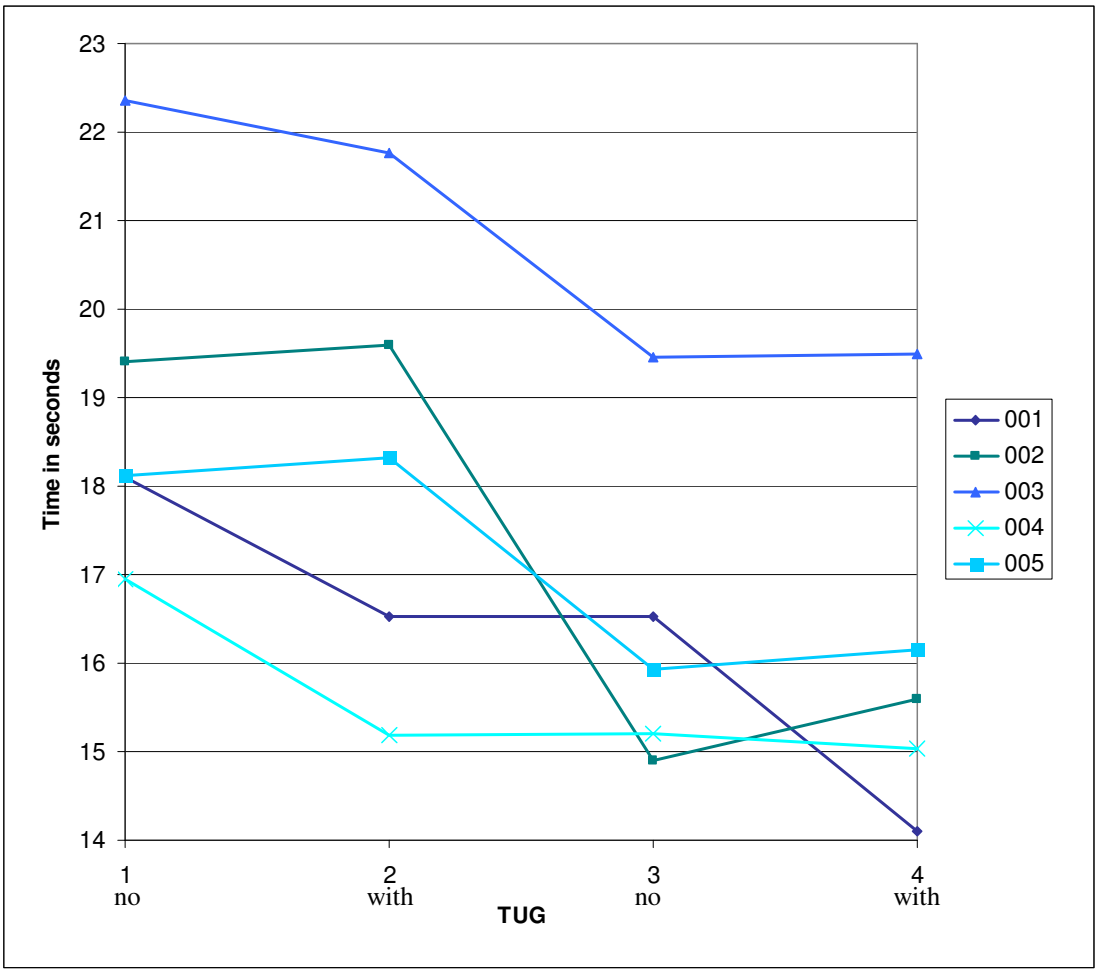

Fig. 7.15: Timed-up-and-Go test for the control group. The plot shows the times for each TUG (n = 5). TUG 1 and TUG 3 involved no feedback, while TUG 2 and TUG 4 was performed with feedback.

All time measurements were plotted and the graph shows that on average the time to complete the TUG with feedback decreased from 24.6 s without feedback to 22.8 s with feedback (7.2%) for patients Fig. 7.14) and from 17.7 s without feedback to 17.2 s with feedback (2.9%) for the control group (Fig. 7.15).

When using the TUG scale (section 7.2.1) as introduced by Podsiadlo and Richardson (1991) six patients had “mostly independent mobility” (time to complete TUG test below 20 s), five had “variable mobility” and two had “impaired mobility” (time to complete TUG test above 30 s). The graph is showing a steady improvement in times between the TUG tests (Fig. 7.16) and the t-test revealed that the improvement over the course of trial for all participants was significant. The average improvement in the 1st TUG between no EFS and with EFS was 2.4 ± 3.2 s ($p = 0.006$) and 0.8 ± 3.2 s ($p = 0.012$) in the 2nd TUG between no EFS and with EFS. The improvement between TUG1 with EFS and TUG2 no EFS was 2 ± 1.4 s ($p = 0.002$). Significance was also tested for the hypothesis that the time improvement with EFS was higher than the time improvement without EFS and the hypothesis was rejected.

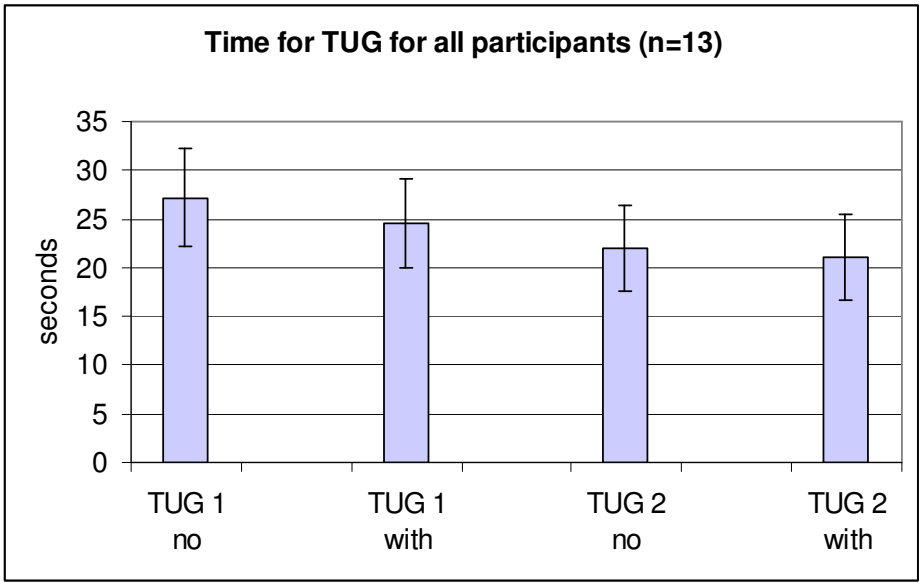

Fig. 7.16: Graph of Timed up and go test showing the total time of TUG with the electrotactile feedback system (EFS) and without for all participants (n=13). One patient could not participate in the TUG test.

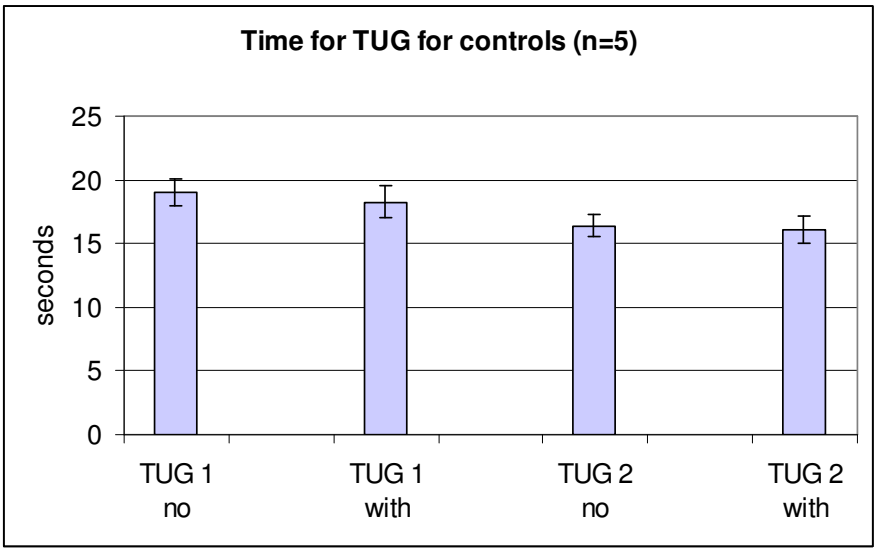

Fig. 7.17: Graph of Timed up and go test showing the total time of TUG with the electrotactile feedback system (EFS) and without for controls. (n=5)

In the control group the time improvements with and without feedback were less than in the patient group (Fig. 7.17) and not significant for all scenarios ($p > 0.05$). Control subjects improved 0.7 s and 0.3 s in the two TUG tests and 1.9 s between TUG1-with and TUG2-no. However the time improvement with EFS for both groups was not significantly higher than the improvement with no EFS meaning that the improvement in time is likely to be a result of repetition.

7.4.5. Feedback on device performance

After the trial participants were asked to evaluate their impression concerning the performance of the EFS. Firstly the participants were asked to rate the overall comfort of the device, including the comfort from wearing the device and from

receiving the electrical stimulation on a scale from 0 to 10 with 0 being not comfortable and 10 being very comfortable. The average rating was 7.7 ± 2.7 (n= 14), indicating that using the device felt comfortable (Fig. 7.18). When asked if the usage of the device created any pain the average rating was 1.5 ± 2.5 (n=15), showing that the stimulation felt fairly comfortable for the participants. One patient did not feel pain but reported wearing and using the device as uncomfortable.

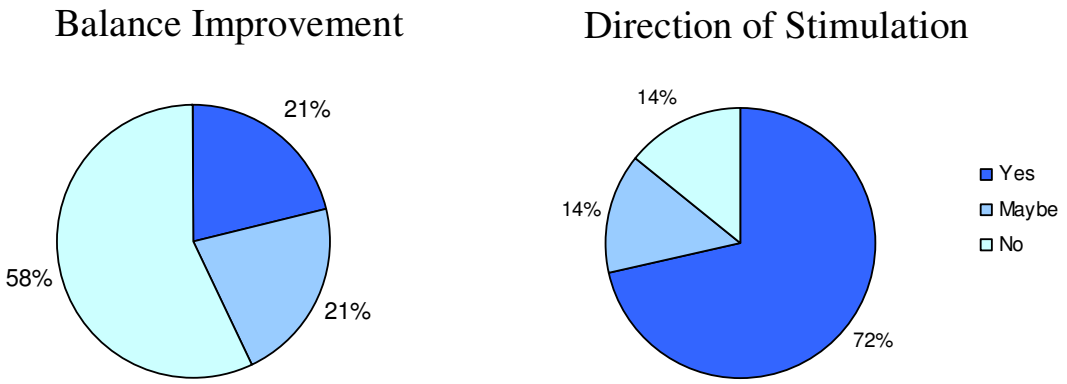

Fig. 7.18: Pie presentation of feedback from patients concerning performance of the device. On top: More than half of the participants did not have the impression that the device improved their awareness of balance. Below: Most participants can feel from which direction the stimulus is coming from while using the device

When asked if the device helped to improve balance more than half of the test participants had the impression that it did not help them while 21% had the feeling that the device improved their ability to control their balance. 14% of the participants emphasised the usefulness in improving awareness of balance when using the device with eyes closed. 72% of the patients said that it is possible to differentiate between the positions of the activated electrodes and as such define the direction of sway. The other patients were not sure which direction the stimulation was coming from or did not perceive the stimulation strong enough to distinguish the direction.

7.5. Discussion

This chapter gives an account of the effects of an electrotactile feedback system on posture control when used by individuals with sensation loss. A study with 14 participants and five control subjects was conducted where it was evaluated how individuals use the feedback for posture control based on the centre of pressure movement and for walking based on the time for a TUG. The study contributed to the understanding of the effects of an EFS on balancing and walking by people with sensation loss.

7.5.1. Findings and implications

The present study was designed to determine the feasibility of electrotactile feedback on improving posture control and to study the influence of electrotactile feedback during timed walking tests. The study also aimed to explore the difficulties encountered with sensation loss and to evaluate the acceptance of a wearable electrotactile feedback system and its comfort.

Study participants with neuropathy reported having major problems with maintaining balance during standing and walking, which supports the necessity to use a balance aid in assisting standing and walking.

The numerical analysis of all participants revealed that the patients with sensation loss significantly improved their balance when they used the EFS during the eyes open balance test. The trend for improvement did not continue in the consecutive scenarios with eyes closed and on a foam pad. Therefore the observed improvement is not related to a learning effect. This finding is representative of previous studies that found that electrotactile feedback improves balance parameters (Vuillerme et al. 2007; Matjacic et al. 2000). However those studies did not test electrotactile feedback during balancing with eyes closed. In the present study the sway area increased significantly during balancing with eyes closed suggesting that in average it was more difficult for the participants to use the EFS during balancing with eyes closed than balancing with eyes open. A possible reason is that participants with sensation loss in their feet use mainly vision and the vestibular system to control their posture and to compensate for the loss of the somatosensory feedback (Chapter 2). During balancing with eyes closed a patient is mainly dependent on the vestibular system. This might cause an overreaction to electrotactile feedback when patients use the system, resulting in a higher COP movement. Furthermore it was observed by the investigators that study participants initiated the electrotactile feedback either consciously or unconsciously when the instruction was to maintain body equilibrium, thus the COP based measurements increased. These random electrocutaneous stimulation activations were witnessed by the investigators during the study in several cases. This effect appeared to be greater when the participants had their eyes closed.

In an individual case analysis it was shown that electrotactile feedback can be used as a means to actively control body posture. The participant that was studied in more detail showed a reduction in AP velocity and sway area when using the device with eyes open and eyes closed. This indicates an improvement in posture control. However the subject could not benefit from the feedback while balancing on a foam pad. When validating the centre of pressure movement and sway path it was found that the participant changed their foot position according to the feedback received. The findings enhance our understanding of how electrotactile feedback is used, since a response for each foot separately was not expected. This is also an important fact when analysing the effects of EFS in other studies, since the calculation of the combined centre of pressure for both feet might not discover such behaviour. It is therefore recommended to always analyse both feet separately.

In a Timed-Up-and-Go test study participants showed an acceleration of 7.2% when using EFS. However the improvement was not significantly related to the use of the EFS but rather the repetition of the task.

The study also revealed that the participants perceived electrotactile feedback as comfortable. 72% of the participants could easily differentiate the direction that was indicated by the electrical stimulus, while 14% had difficulties to relate the stimulation to a direction, which suggests the suitability of this form of feedback for the transmission of directional information, such as the movement of the centre of pressure under the feet.

Whilst this study did not confirm an improvement in all balance tasks, it did show that for the specific task of balancing during eyes open the AP significantly

improved. This does substantiate the use of electrotactile feedback as a means of a balance aid, because the benefit during balancing with eyes open was evident. However no improvement could be shown with eyes closed and on a foam pad. With more training and use it may be possible for patients to correct their balance in the other scenarios as well.

7.5.2. Limitations of the study

The generalisation of these results is subject to certain limitations regarding the patient population, the measurement and feedback system, and the experimental design.

In this study the sample size was relatively small, due to the necessity of requiring participation from a very specific population group. In order to source the population group it required liaising with the Bournemouth Diabetes and Endocrine Centre, where the Consultant chose potential candidates who fitted the criteria i.e having neuropathy in the lower limbs. Furthermore there were constraints in arranging the trials around the hospital's pre-assigned appointments between the patient and the Diabetic Consultant. Due to the nature of the study, the trial required at least two meetings with the subject in order to gain consent, screen and finally undertake the test. Poor attendance at the initial face to face meeting and in addition, the failure of those who had consented to attend follow up meetings further impeded the study selection. This can be counter measured in the future by accessing a greater patient population group over a longer period of time.

The conducting of the tests was restricted to the hospital environment by the ethical board. Higher levels of participation could be achieved in future studies if the EFS is tested at the patients home thus reducing the need for participants to attend multiple appointments. Rather than being restricted to a very short training period this would also enable the participant to become more familiar to the EFS, which led to a greater benefit to the user concerning balance recovery in previous studies (Badke et al. 2011).

The physical condition of the individuals participating in the trial also had an impact on the study results. Even though the overall time of the test procedure was designed to be less than an hour and specific balance and walking tests less than 1 minute, patients tended to suffer from fatigue towards the end of the TUG test. As some subjects became tired during the first TUG test, two of them could not complete the second TUG test and this had a knock on effect on the result presented. In order to improve the reliability of the study and eliminate such variables that may influence the results, it may be more beneficial to arrange follow ups where the same TUG test could be repeated on the same subject.

It is also necessary to consider that among the participant group there may be other factors affecting balance, such as age related morbidities, resulting in an impairment of vision and vestibular senses (Spirduso et al. 2005). Furthermore, the participant group required prompting and were not always adhering to instructions given by the investigator and as a result electrotactile feedback impulses were initiated independent from their actual need for maintaining balance equilibrium. Therefore this also impacted upon the results obtained. A longer training period could countermeasure this effect as it was not reported in previous studies using electrotactile feedback with a longer training period (Badke et al. 2011).

Another limitation was the distribution of pressure under the patient's foot. Several patients showed foot deformations due to sensory loss (Munde et al. 2013; Schömig et al. 2000), which made it difficult to detect highest pressure points for setting up the force sensors and matching the foot model to the patients' feet. Additionally the individuals with foot deformations had to wear special designed shoes, which also influenced the sensor readings by distributing the pressure irregularly. Ideally having a negative imprint of the foot would be useful in adopting the sensor location for each individual.

7.5.3. Future Work

Investigations need to be done to establish how electrotactile feedback influences posture control when used over a longer period of time and during activities of daily life. This could include driving a car or a bicycle to see if user can benefit from the feedback. To test if patients improve their ability to walk in future research it is recommended to put an additional measurement system in place that allows analysing gait when an EFS is used. For this purpose video based methods could be used.

The observations suggest that participants initiated a sensation consciously or unconsciously since the electrical stimulation was perceived as comfortable. This fact could be proved in future studies by designing a trial which specifically evaluates this effect, as no information exists in the literature on the impact of reactive behaviour to electrotactile feedback when used by individuals with sensation loss in their feet and how this potentially influences the study results.

7.5.4. Conclusion

The presented study was designed to gain knowledge about the use of electrotactile feedback system for patients with sensation loss and balance problems. Balance assessment and walking test were performed in a clinical trial with patients suffering from neuropathy in their feet. In addition patients were asked to rate the efficiency of the EFS used.

The study revealed that patients improved their stability based on AP velocity measurements significantly during balancing with eyes open, but sway area reduced during balancing with eyes closed. Participants improved their walking speed in a TUG test by 7.2% in average. The improvement was not related to the use of feedback, but the results show that the patients were not hindered by wearing the device.

Despite its exploratory nature, this study offered some insight into the functionality and efficiency of electrotactile feedback. The study shows that a wearable EFS has the potential to improve posture control for patients with neuropathy. The findings could have significant implications in rehabilitation and treatment of individuals with sensation loss maximising safety and quality of life by helping the user to relearn posture control with an EFS and use it to reduce risk of falls.

7.6. Acknowledgements

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Steve Trowbridge. I also sincerely acknowledge the support of the research department at the Royal Bournemouth Hospital, in particular Laura Purandare and Robert Chapman, who helped with the clinical trial design and funding of the trial. Mahbub Chowdhury Mishu did an excellent job in supporting the study procedure and preparing the data analysis. Prof. Dr. Demian Fay and Patrick Schroeder contributed thankfully with their knowledge about statistics to the analysis of the study. Furthermore I express my gratitude to all study participants.

**"Still round the corner there may wait,
A new road or a secret gate."**

J. R. R. Tolkien

Chapter 8 Discussion and Conclusions

This dissertation has investigated the design and application of an electrotactile feedback system (EFS) for magnitude estimation with the objective of assisting those who suffer from poor postural control as a result of sensation loss in their feet to better support their balance while standing or walking.

The motivation for the present work was to improve the quality of life of people suffering from sensation impairment in their feet by developing a wearable electrotactile feedback system (EFS). Sensory loss in the feet can result from diseases such as Diabetes and HIV. Also side effects from treatments such as chemotherapy can cause damage to the sensory nerves (Tofthagen et al. 2012). This sensory loss leads to problems in balance and performance in everyday activities. As a result the risk of falls and injuries greatly increase (Cimbiz and Cakir 2005). By giving feedback, also called biofeedback, about the exact force or pressure applied to the feet, people should be able to compensate for their impairment, as the feedback is able to estimate the magnitude of force and pressure applied (Marcus et al. 2006). Estimating the magnitude of force and pressure in the feet has showed positive effects in improving postural control helping to maintain balance during standing (Matjacic et al. 2000) and improve confidence in walking (Badke et al. 2011). However, only a few wearable biofeedback systems using electrocutaneous stimulation were studied previously. Older systems lack flexibility due to the use of analogue circuit technology. Newer systems are not practical as they are applied to body parts such as the tongue, neck and forehead which are unsuitable for everyday use. Several open questions in the design of an EFS and testing of its usage remain which was the motivation for the present study.

8.1. Restatement of aims

The primary aim was to design and develop a wearable EFS that would suit people suffering from sensation loss that allows the estimation of pressure at the sole of foot. The device should be customised to the user's individual needs, which means that it would have to be adaptable to the different anthropometric measurements of each individual which included factors such as weight and shoe size. In addition, the design should consider the individual calibration of sensory thresholds for the electrical stimulation, as they can differ significantly between people (Lund et al. 2005). Furthermore, the study aimed to investigate the effect of the developed EFS on magnitude estimation, as sensory loss in the feet leads to reduced or non-existent awareness of the pressure and force that is applied to the feet. The hypothesis to be tested was that the developed system would have better sensitivity and accuracy for magnitude estimation when compared to previously reported systems. This study also aimed to undertake a clinical trial with patients suffering from neuropathy in their feet. Previously a portable system has not been tested on a population group suffering from sensation loss in their feet. The study also investigated if the EFS

could help to improve postural control during basic functions such as balancing and walking using established methods (Turcot et al. 2009; Manor and Li 2009).

A secondary aim of the study was to identify and implement a sensor system for a wearable EFS, since several systems that were used previously such as static force plates (Matjacic et al. 2000) are not suitable for a portable feedback system. Additionally, a measurement system was aimed to be developed that would visualise and analyse balance parameters based on the centre of pressure information.

8.2. Research Findings

Different sensor systems were compared based on previous studies and piezoresistive force sensor technology was selected for the EFS. A sensor unit has been developed using a voltage comparator circuit. Various resistors were tested in the sensor circuit and the power function between the circuit designs were compared with each other. This allowed designing a circuit with an approximated linear power function which could be suitable for body weights of the users between 50 kg and 120 kg.

A test-retest reliability using seven force sensors revealed high deviations of 5.1% between the different sensors. It was shown that the repeatability cannot be ensured and that each sensor requires calibration after every use. This was clearly supported by other research findings (Hollinger and Wanderley 2006). A test in Poole Hospital using a static electrical stimulation unit showed that pulse frequencies between 30 and 50 Hz create a comfortable sensation. Based on the experiments to define electrotactile pulse parameters the suitable range for the presented approach was found to be 15-50 Hz for the frequency, 0-600 µs for pulse width and 60-100 Volts for the pulse amplitude. Using these findings an electrotactile feedback system has been developed and parameters were set within this range. Besides the sensor unit, the EFS consisted of a stimulation unit for electrocutaneous stimulation of the skin and a processing unit for the handling of the sensor data. The proposed system considers safety, flexibility and portability as well as individual parameters, such as centre of pressure of the feet, maximum pressure of the feet and the minimum and maximum sensory threshold of each user (Chapter 3).

Software for magnitude estimation for force and pressure feedback based on the centre of pressure (COP) was programmed. The software incorporates a learning algorithm that saves patient and device specific parameters in a knowledge base. This includes the centre of pressure, maximum displacement in anterior-posterior (AP) and medial-lateral (ML) direction, and sensation thresholds. A psychophysical mapping function involving the parameters in the knowledge base was derived and implemented (Chapter 4).

The implemented calibration method was tested for repeatability in ten consecutive repetitions determining the minimum and maximum pulse width each time. It was found to be 53.6 µs ± 17.6 µs for the lower threshold and 322 µs ± 5.07 µs for the upper threshold.

A trial with eleven participants was carried out and magnitude estimation was studied with the EFS (Chapter 6) using pulse width modulation (PWM). Patients had to estimate randomised stimulation magnitudes with 10 different magnitude levels. The accuracy to estimate randomised magnitudes was high and it was found that the averaged mean absolute error, was $\mu_{MAE} = 1.14 \pm 0.33$. The sensitivity was studied by determining the averaged power function and was found to be $\beta = 1.17 \pm 0.37$.

The results were compared to previous research on magnitude estimation with a static EFS using pulse amplitude modulation (PAM) on the neck and was found to be comparable. It was concluded that no disadvantages of PWM can be seen over PAM, suggesting PWM as a suitable alternative for magnitude estimation. The study confirmed the potential of the EFS for feedback applications (Chapter 5).

In preparation for a clinical trial in Royal Bournemouth Hospital a measurement system for balance visualisation and analysis has been developed. A standardised foot model was presented for the measurement system and an analysis workflow was setup. The system was tested with predefined movement scenarios and functionality was confirmed. In addition a real time analysis tool was presented that allows visualisation of the centre of balance and real time calculation of balance parameters (Chapter 6).

A clinical trial of 14 patients with peripheral neuropathy in their feet and 5 control subjects was undertaken (Chapter 7). During the screening process patients reported having problems in walking and standing caused by their sensation loss. All participants undertook several balance tasks with eyes open (EO), eyes closed (EC) and on a foam pad (OF). Anterior-posterior (AP) and medial-lateral (ML) velocity as well as sway area was analysed. The study showed that the wearable EFS significantly improved the AP velocity for study participants when standing with eyes open ($p = 0.03$), although the sway area significantly reduced with eyes closed ($p = 0.02$). 21% of the participants stated that the device improved their balance during balancing and walking and 73% stated that they could use the device to process directional information from the electrodes. The average rating for comfort wearing and using the device on a scale from 0 to 10, with 10 being the most comfortable, was 7.7 ± 2.7 and the average pain rating on a comparative pain scale was 1.5 ± 2.5 indicating minor discomfort. The trial involved a timed-up-and-go (TUG) test and showed an improvement of walking speed through four consecutive repetitions. The improvement of walking was not significantly related to the use of electrotactile feedback.

8.3. Contributions and Implications

The findings from this study contribute to a more in-depth understanding of the design, use and efficacy of a wearable EFS. The procedure laid out; the results from the tests during hardware development and parameter tuning; as well as the experiments carried out with the device to test its feasibility, are valuable for future device developments. The study showed the potential of a wearable EFS for magnitude estimation and as a means to improve balance.

The developed sensor unit has several advantages compared to non-portable systems such as the force plate based EFS (Matjacic et al. 2000). The flexible piezoresistive force sensors can be comfortably integrated into shoe insoles giving information about the force and pressure distribution on the foot and do not hinder the user during walking. Also this form of the sensor system is lower in costs than comparable systems using a force plate.

A test with different force sensor circuits showed that linearity of the voltage reading can be approximated by selecting an appropriate resistor for the sensor circuit. The approximated linearity makes the sensor system suitable for the use of an embedded psychophysical mapping function of voltage reading to stimulation intensity, because

the algorithm needs less calculation power than a logarithmic relationship found in previous studies (Hollinger and Wanderley 2006). Even though single sensors showed sufficient repeatability, the precision between different sensors varied significantly, indicating that it is necessary to calibrate each single sensor before it is used in an EFS.

To prevent an unwarranted skin reaction caused by uni-polar pulses (Marcus et al. 2006), a pulse creation unit using J-type flip-flop together with an H-bridge was designed and integrated in the circuit for the creation of bipolar pulses. This construct makes the electrical stimulation safer and more comfortable for the wearer and thus more advantageous than using the uni-polar pulses (Lundborg, Rosén, Lindström, et al. 1998). Existing systems, e.g. the tongue stimulator created by Vuillerme et al. (2007) could be improved by adding the proposed bipolar stimulation circuit making it safer for the user. In addition the proposed designs by Vuillerme et al. (2007) and Matjacic et al. (2010) are based on static devices and could be made portable by applying the design components presented in this study. Therefore the findings enhance the development of an optimal wearable EFS.

The developed calibration method in this study is based on the method of limits (Marks, 1974), however it also incorporates a tested fast routine allowing a quick calibration of the sensory thresholds. The calibration method and the novel learning algorithm that has been developed can support future designs. Additionally the psychophysical mapping function, combining centre of pressure information and individualised thresholds, is valuable for embedded software design considerations since the developed algorithm was computationally fast. It does not use any division but calculates all constants after the sensory and force sensor parameters are determined and stored in a knowledge base. The process is resource saving and can be implemented in commercially available microcontrollers.

The empirical findings of the magnitude estimation experiment with the developed EFS provide a new understanding of how different pressure and force levels can be detected with EFS. The novelty of the study was to test pulse width modulation (PWM) as a means of modulating the magnitude intensity of the EFS. Previous studies on magnitude estimation used pulse amplitude modulation (PAM) (Marcus and Fuglevand 2009) but did not consider pulse width modulation (PWM). PWM has advantages over PAM because the skin adapts its ability to feel the stimulation at different intensity levels during PAM which was not reported for PWM (Buma et al. 2007). PWM can therefore be beneficial for the use in a EFS. Also the area on the upper leg was not used in previous magnitude estimation studies, which is a practical area when considering the design of an EFS for people with sensation loss in their feet. Although PWM was used as a stimulation modality in the current work and the upper leg was selected for placing the electrodes, the sensitivity was comparable to previous studies using PAM on the neck (Marcus and Fuglevand 2009). This suggests that the selected modulation type, PWM, is a valuable alternative to the ones tested by others, since no disadvantage could be shown. In addition to that it was found that the accuracy and sensitivity for magnitude estimation with PWM is better than methods using other stimulation modalities, namely audio and vibrotactile (Stevens 1956). The study has gone some way towards enhancing the understanding of how to design a wearable EFS to allow magnitude estimation for people with sensation loss by showing the accuracy and sensitivity of the proposed set up.

The developed measurement system may be applied to other studies involving the assessment of balance. Previous studies that measured the centre of pressure movement with a force sensor array (Bamberg et al. 2006) did not consider a specific foot model for their calculations of COP movement. This leads to a lack of comparability between the data sets of different study participants. By using standardised foot sizes (Wunderlich et al. 2001) and foot positions the comparability between feet, which do not differ significantly from the average, is given. The development of the measurement system also involved the implementation of a visualisation tool for balance. Such a tool can be extremely useful in rehabilitation for relearning or improving balance for people having sensation loss. (Nichols, 1995) (Moreland et al. 1998), Parkinson (Chiari et al. 2005) or in amputees (Carpaneto et al. 2003). In this study patients with sensation loss in their feet were asked about their difficulty in performing activities of daily life (ADL). The outcome of the questionnaire confirmed the necessity for a biofeedback system, as most individuals experience major limitations performing daily tasks, where balance and walking were the most affected.

The clinical study revealed that the participants significantly improved their AP velocity with eyes open. This suggests that the EFS is suitable to reduce the risk of a fall during standing. However the study also showed that the sway area increased with eyes closed. A longer learning period in using the EFS might be needed for this scenario so the participant can correctly use the feedback system when vision is restricted. Previous studies analysing the effects of biofeedback in motor control for stroke patients (Chiari et al. 2005; Moreland et al. 1998; Glanz et al. 1997) could not draw a clear conclusion of the positive effects of feedback on improving motor control. The lack of conclusive results is thought to be related to the difficulties in experimenting with biofeedback systems (Dozza 2006). One reason for these difficulties might be reactive behaviour of the study participants.

The results from the case study of one patient analysing his/her balance behaviour when using the EFS revealed that the patient reacted to the electrical stimulation by changing the foot position of each foot separately. Therefore it is recommended that future sensor systems should also use separate analysis of both feet when testing balance improvement of electrotactile feedback as both feet can show different behaviours as a result of the stimulation.

The present study provides additional evidence with respect to the effects of electrotactile feedback on posture control during walking. Participants improved walking speed in consecutive trials. Even though the improvement was not significantly related to the use of the EFS, but rather the improvement of a task by repetition (Dozza 2006), it revealed that the wearable EFS did not hinder the study participants when performing the walking task. This can be seen due to the participant increasing walking speed when electrotactile feedback stimulation was received. In conclusion the study could show that the developed wearable EFS is beneficial for balancing with eyes open and for magnitude estimation demonstrating a high accuracy and suitable sensitivity for tasks that require the estimation of pressure applied to the feet.

8.4. Limitations

There were a number of limitations identified in this study. As only one hardware system was designed, it may have been beneficial to design and trial alternative

systems as suggested in Chapter 3. One alternative could be testing a simplified version of the device, by using two electrode pairs on each leg for feedback rather than four. This would allow a less bulky and more portable design. Also having less information input for the user might be more intuitive to use and detect the direction of stimulation.

The device and stimulation parameters were confirmed in small case studies. Further experiments with a larger population of test participants could be done to evaluate the parameters with higher significance and test additional features like improved device intelligence. The developed algorithms do not consider all aspects of the EFS. Sensor drift and changing skin impedance was not considered for the development of the algorithm for not making the system unnecessarily complex, as the effects of sensor drift and changing skin impedance occur after longer use (Hollinger and Wanderley 2006; Tregear 1966) and the trials were conducted only over a short period of time.

The study on magnitude estimation has only examined subjects without sensation loss (Chapter 5). This could have an effect on the generalisation of the accuracy and sensitivity when using the developed EFS. Future studies on magnitude estimation with participants with loss of somatosensory feedback should be undertaken to test if this has any influence on the presented results.

The developed measurement system used a standardised foot model for the calculation of force and pressure distribution on the feet (Chapter 6). However the system does lack effectiveness and accuracy when the subjects have foot deformities. The visualisation and analysis of centre of pressure movement might therefore lack accuracy. A measurement system that can adjust to different centres of pressure more effectively would ensure more accurate results. A system that automatically detects foot deformations might help to compensate for this limitation in future studies.

A limitation of the study on posture control during balancing and walking is that the number of patients and controls were relatively small. A generalisation of the results is therefore not in all circumstances possible. The number of participants was mainly limited due to the terms and regulations of the hospital and difficulties in participant recruitment. However the involvement of additional research locations would allow accessing a larger population of patients so more participants could be included in the study.

An important limitation lies in the fact that the device could be only tested for a short period of time. Previous studies using EFS on the tongue reported that patients could improve their balance after three weeks of practicing with the device. This learning effect could not be studied in the current work. However for more complex and longer lasting studies MHRA [35] approval would have been needed, which goes beyond the scope of this research, as it takes a long time and involves high costs.

Notwithstanding these limitations, the presented work enhances the understanding of electrotactile feedback systems by proposing and evaluating a novel device design and testing the system for magnitude estimation, posture control and confidence in walking. While the developed EFS did not show significant improvements in balancing with eyes closed or balancing on foam it showed that patients significantly

[35] The MHRA is the governmental body of the United Kingdom for the verification of medical devices.

improved their AP sway when they had their eyes open. Additionally the EFS was found suitable for the use in magnitude estimation. The findings of this work lead to several recommendations for future work.

8.5. Recommendations for further work

Further research might explore the restoration of somatosensation for amputees, which are constantly rising in numbers (Murdoch et al. 1998). This concerns artificial legs to enhance gait and balancing with the external sensory feedback, but also other body parts. The use of an artificial limb only allows the improvement of motor function, but the wearer does not get any feedback from the prosthesis. In the case of a prosthetic hand the control of grasping is extremely difficult without sensory feedback (Monzée et al. 2003; Lafargue et al. 2003) and the presented system in this work could be modified so that it could be used for magnitude estimation in artificial hands (Kuiken et al. 2007; Schulz et al. 2007). To the individual user this would improve grasping tasks and activities of daily life (ADL) as the risk of dropping objects is reduced.

It is also recommended that further research is undertaken into rehabilitation of individuals with sensory impairment. For example after stroke individuals often have problems with balance and need to relearn how to walk and use their feet (Barclay-Goddard et al. 2004). The presented visualization tool and additional information about force and pressure with the described EFS could allow acceleration of the rehabilitation process by giving visual and electrotactile feedback which makes the user aware of the current balance situation.

Further studies in evaluating magnitude estimation (Chapter 5) and improvement in walking and balance (Chapter 6) with the EFS over a longer period of time would be beneficial. It could determine whether learning to use the device significantly changes the results on posture control and walking speed. More research into examining the effects of EFS when performing tasks that require a shift and change in foot pressure, such as driving a car or a bicycle would also be beneficial in helping individuals to improve their ability to perform ADL.

Further work would be beneficial in investigating ways to enhance the hardware and software components of the proposed EFS. Even though the current device was designed to be portable, when compared to Functional Electrical Stimulation devices that are available on the market, this device was heavier and less compact (Odstock Medical Ltd 2006). Further emphasis is required on creating a portable device that could be practical and comfortable for the user in the long-term. Using surface-mounting technology (SMT) instead of Through Hole Technology (THT) would help achieve this and make the device more compact. A more sophisticated microcontroller with more memory and calculation power would allow improved algorithms that include hardware and user specific parameters. The psychophysical mapping function (Chapter 4) could be extended by using user specific power functions of sensitivity for higher accuracy of magnitude estimation. More computation power could be also used to detect changing variables of the system such as, the drift of sensors (Goebel and Yan 2008) or changing resistance of skin (Sunyoung et al. 2010). By correcting those parameters the system becomes more robust for longer usage.

Also there is limited research in use of EFS in non health related fields such as augmented reality or space applications. Previous studies discuss electrotactile feedback as a means of simulating touch in augmented reality applications (Ku et al. 2003) and exploring this area further may be beneficial. The system developed in this study could be modified by replacing the sensor system with an augmented reality system that simulates touch or any application of force or pressure. This might be especially useful in the gaming industry (Eid et al. 2012) or augmented realities for the simulation of training situations (Xu et al. 2010) that require the application of pressure, such as assessment of patients in a hospital environment. A future study investigating the use of EFS in space related application is recommended. Astronauts have reduced sensory input during extravehicular activities and could benefit from additional sensory input (Schroeder et al. 2012). EFS could help to overcome problems caused by reduced somatosensory input from an astronaut suit when performing tasks in weightlessness.

8.6. Conclusions

The work presented in this thesis aimed to design and test a wearable electrotactile feedback system to improve the quality of life of people with loss of sensation in their feet.

The motivation was to help people with sensation loss caused by Diabetes. This required estimating foot pressure with a feedback system and reduce the risk of falls by using an EFS which redirects sensation from the non sensory area to an area with normal sensation. A literature review on electrotactile feedback systems revealed that current EFS designs lack portability and have limited possibilities to individualise the device parameters for the user. Also several open questions remained in the use of EFS for improving magnitude estimation and posture control. To address these questions a novel wearable EFS has been developed in this work which considers safety aspects and individual parameters of the user. The system is calibrated for its wearer by a learning algorithm that detects personalised sensory thresholds and the pressure distribution at the feet, using a piezoresistive force sensor unit. This information is combined in a psychophysical mapping function matching centre of pressure movement and electrotactile feedback. The EFS incorporates further features such as using pulse width modulation as stimulation modality and the upper leg as the stimulation location. It was tested for estimating the magnitude of forces and it was found that the proposed system allows high accuracy and sensitivity. In order to evaluate the improvement of posture control during standing a measurement system has been developed using a new standardised foot model and analysis of balance parameters that are based on the centre of pressure movement. The system allows visualisation of the balance parameters in real-time, but also to analyse balance behaviour and can be used a training aid in rehabilitation. The clinical study revealed that the electrotactile feedback system did significantly improve the sway velocity in anterior-posterior direction of patients with sensation loss when they have their eyes open. With eyes closed the sway area of the study participants increased, suggesting that a longer learning period is needed to efficiently use the EFS in other scenarios than with eyes open. A Timed-Up-and-Go test revealed that walking speed increases for consecutive trials. Although these are not significantly related the use of the feedback system, the study showed that the device did not hinder the patients to improve their walking speed by repetition of the task.

In summary the findings of this thesis are valuable for future developments of wearable electrotactile feedback systems proposing novel hardware and software solutions and answering several research questions concerning the use of an EFS in magnitude estimation and posture control. The findings contribute to the growing research field of feedback systems, which will allow people with sensation loss in their feet to get a chance for compensating their impairment and improving their living conditions. The study showed that EFS improves sway and therefore reduces the risk of falls and it certainly showed a high accuracy in magnitude estimation. Improving posture control and regaining the ability to estimate pressure applied to the feet will positively improve quality of life of people with sensation loss in their feet.

Appendices

Appendix A: NE555 Astable Operator Configuration

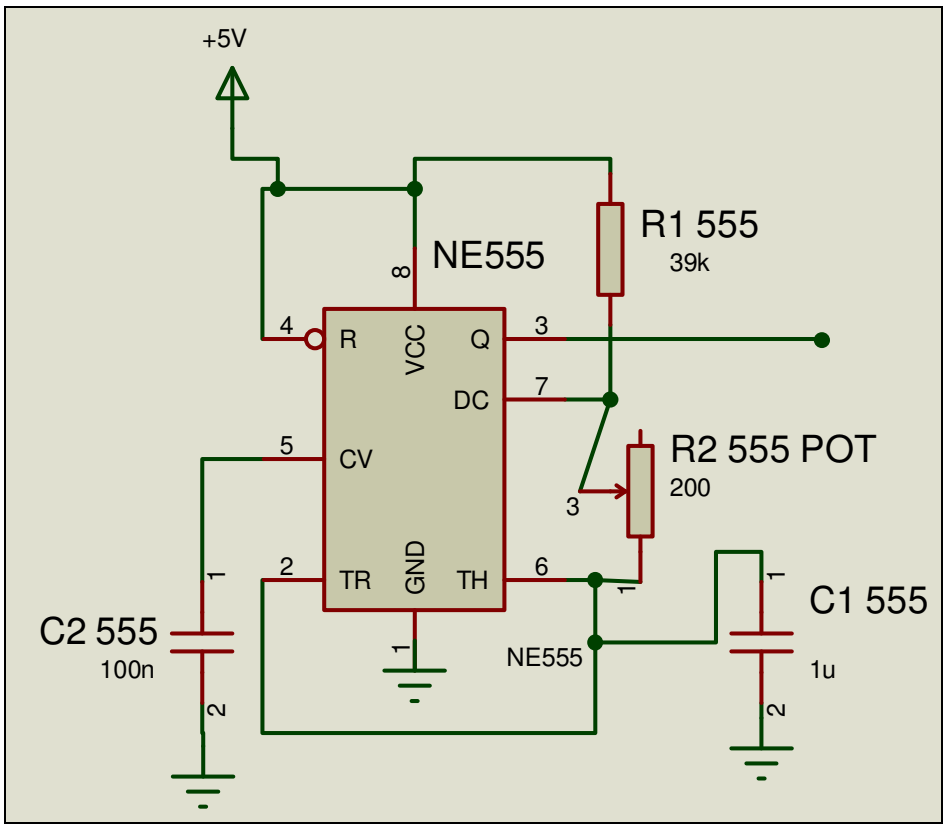


Fig. A.1: Astable Operator circuit with NE555 (Texas instruments, 2002)

In the Astable Operator Configuration (Fig. A.1) the NE555 creates a constant pulse. The components were chosen according the NE555 datasheet and equation for the astable operator [36] configuration (Texas Instruments 2010). Additionally a potentiometer (R_2 555 POT)[37] was integrated into the circuit to adapt the duty cycle of the pulse given by the astable operator (Fig. A.1).

[36] Astable operator means that the NE555 produces a constant pulse which can be used e.g. to open and close a current switch

[37] A potentiometer is a variable resistor that can be manually changed to a desired resistance to easier control circuit behaviors

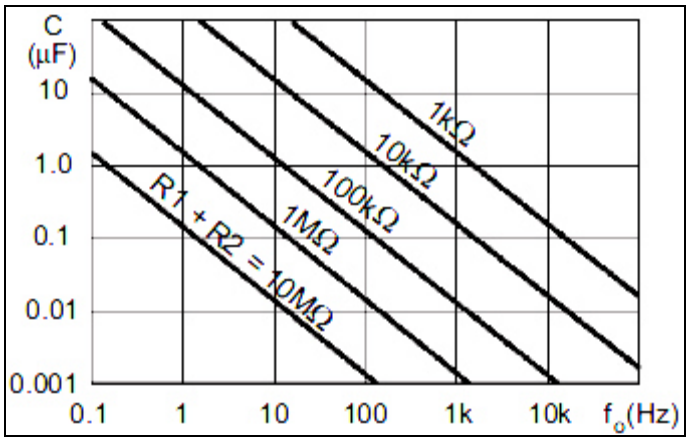


Fig. A.2: Relation of Resistance and Capacitance for different frequencies in an Astable Operator from the NE555 Data sheet (Texas Instruments 2010)

The frequency in this configuration is dependent on the resistor and capacitor used in the circuit (Fig. A.2). According to the data sheet of the NE555 the charge time (output HIGH)[38] of the NE555 is given by

$$t_1 = 0.693\ (R_1 + R_2)\ C_1, \qquad (35)$$

and the discharge time (output LOW) by

$$t_2 = 0.693\ (R_2)\ C_1. \qquad (36)$$

Thus the total period T is given by

$$T = t_1 + t_2 = 0.693\ (R_1 + 2R_2)\ C_1. \qquad (37)$$

The frequency of oscillation is then

$$f = 1/T = 1.44\ /\ (R_1 + 2R_2)\ C_1. \qquad (38)$$

In the case the presented prototype the frequency was supposed to be 30 Hz. To reach this frequency the components were selected as R1 = 128 Ω and R2 = 46.2k Ω and C1 = 1 µC. If these values are inserted into equation (38) the resulting frequency is f = 31 Hz.

The duty cycle is given by

$$D = R_2\ /\ (R_1 + R_2). \qquad (39)$$

Since the astable operator functions as a trigger for the pulse width modulator, the duty cycle has to be very high. So R_2 was chosen very low compared to R_1 resulting in a very high duty cycle so that the out-coming pulse at port 3 is low for 50 µs and the rest of the time for 322 µs high.

[38] The pulse has two status, high and low. High means that the voltage is 5 Volts on the output pin of the NE555, while low means 0 V on the output pin.

Appendix B: NE555 Pulse Width Modulator Configuration

Another configuration for the NE555 is the pulse width modulator configuration. The pulse width in this configuration is triggered by the astable operator with a frequency of roughly 31 Hz. The pulse width modulation is dependent on the control voltage at Pin 5 (CV) which is given by the output of the operational amplifier that depends on the sensor load. The circuit diagram is shown in Fig. B.1. The output of the pulse width modulator drives the transistor that controls the transformer as described below.

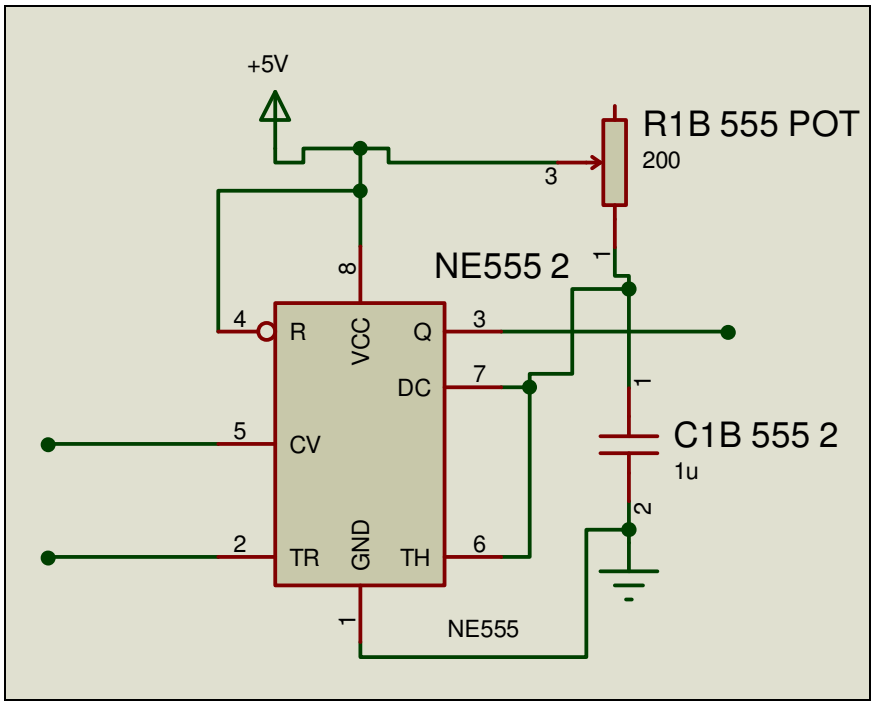


Fig. B.1: Pulse Width modulator circuit for NE555

The maximum pulse length is defined by the following equation

$$t = 1.1\, R_1 C_1. \qquad (40)$$

Since the analogue prototype was only used for test purposes a relatively low pulse width of t = 139 µs was set as the maximum pulse width by setting R1 = 139 Ω and C_1 = 1 µF. This is to ensure that the pulse driving the transformer on Pin 3 is between 50 µs and 139 µs because 50 µs is the minimum pulse width that could be chosen. The 50 µs are added to the 50 µs of the astable operator, so the final range of pulse width lied within 100 µs and 139 µs equivalent to a voltage of 0 to 5 V coming as input voltage to port 5 from the sensor unit.

Appendix C: Case study on frequency and pulse amplitude

A preliminary case study was carried out to test the parameters for electrocutaneous stimulation.

C.1. Methods

The parameters for frequency and amplitude were taken from literature (Chapter 2). A study with one test participant was performed in Poole Hospital with a static electrical stimulation unit. Electrodes were placed on the skin of the upper arm and 3 different frequencies were tested: 30 Hz, 50 Hz and 70 Hz. The device had 5 different pulse width adjustments (see Tab. C.1).

C.2. Results

Each pulse width in combination with the pulse amplitude was applied once and it was recorded when the sensing threshold and threshold of discomfort occurred.

	Sensing threshold		**Discomfort threshold**	
F in Hz	pw in ms	I in mA	pw in ms	I in mA
30	0.02	18	0.02	30
30	0.05	5.4	0.05	10
30	0.1	2.7	0.1	6
30	0.2	1.8	0.2	3.9
30	0.5	1.2	0.5	1.8
50	0.02	20	0.02	40
50	0.05	7.2	0.05	11
50	0.1	3	0.1	4.2
50	0.2	2.4	0.2	3.3
50	0.5	1.2	0.5	2.1
70	0.02	8.7	0.02	22
70	0.05	5	0.05	9.3
70	0.1	2.4	0.1	4.8
70	0.2	1.5	0.2	2.7
70	0.5	0.9	0.5	1.8

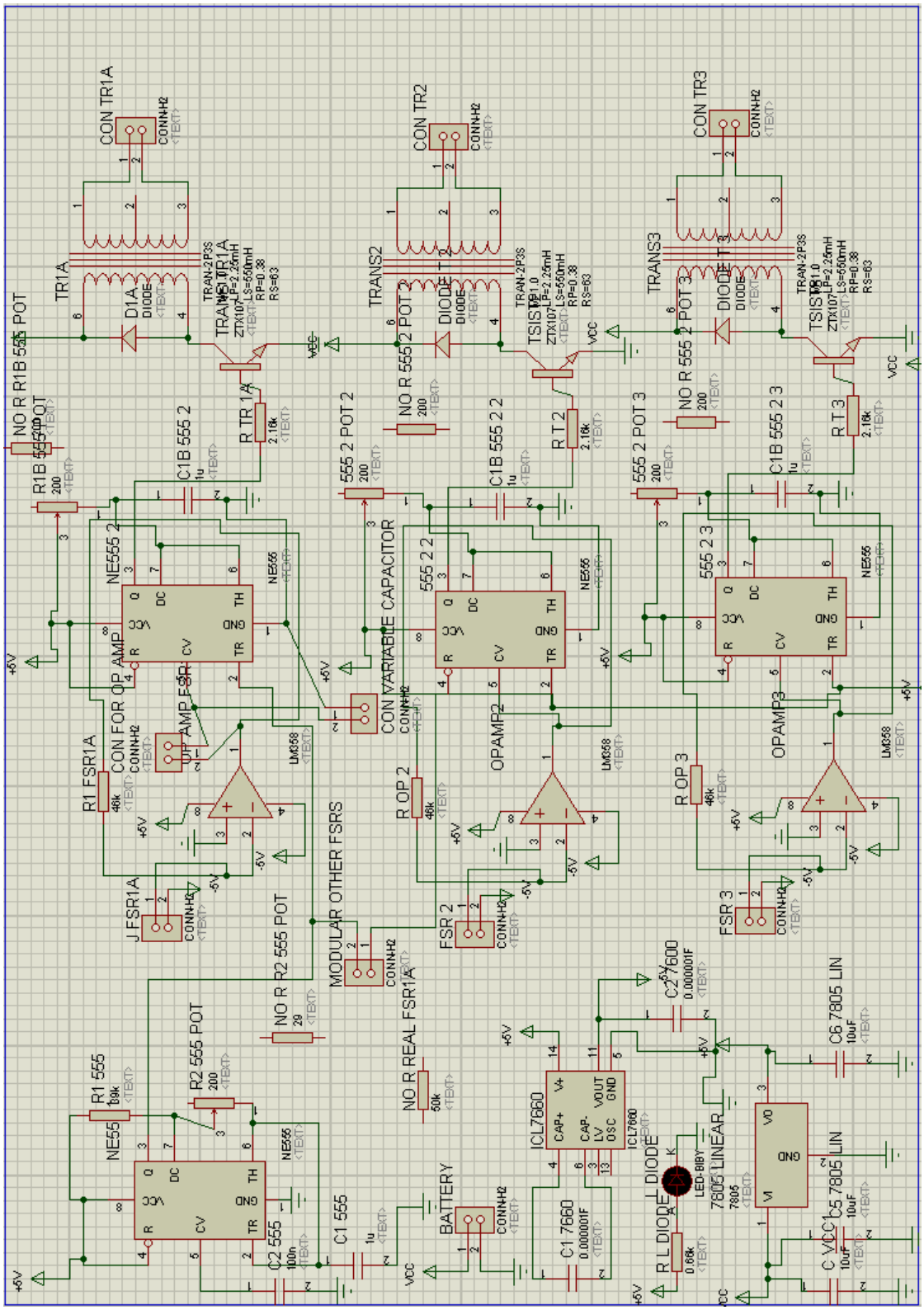
Tab. C.1: Sensation and discomfort threshold test

It was found that a frequency of 30 Hz and 50 Hz felt more comfortable than a frequency of 70 Hz. As mentioned in section 3.4.3 the transformer is limited to pulse widths up to 500 µs. Therefore a suitable current amplitude at 500 µs would be 2-3 mA in the developed EFS. Usually the current for electrocutaneous stimulation is much higher. It is assumed that the manufacturer of the static electric stimulator uses another measurement standard for the display on the device because based on literature and later tests with the developed device showed that the current should be much higher, up to 100 mA.

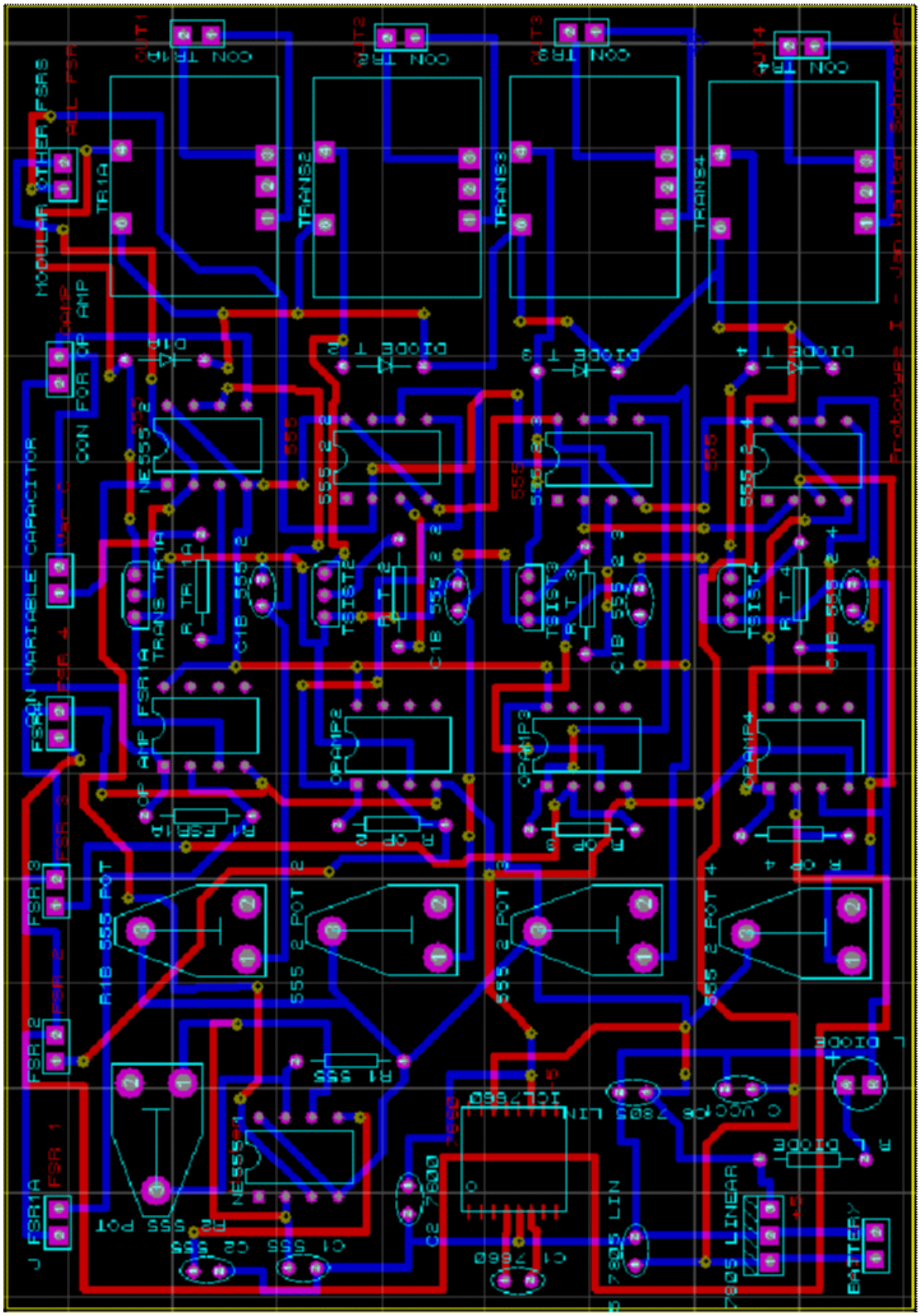
C.3. Discussion

The case study tested several balance parameters. The results are of limited scope as the display of current intensities of the electrical stimulator did not match those of previous studies found in the literature. However the study revealed that pulse frequencies over 50 Hz can lead to more uncomfortable stimulation than lower frequencies.

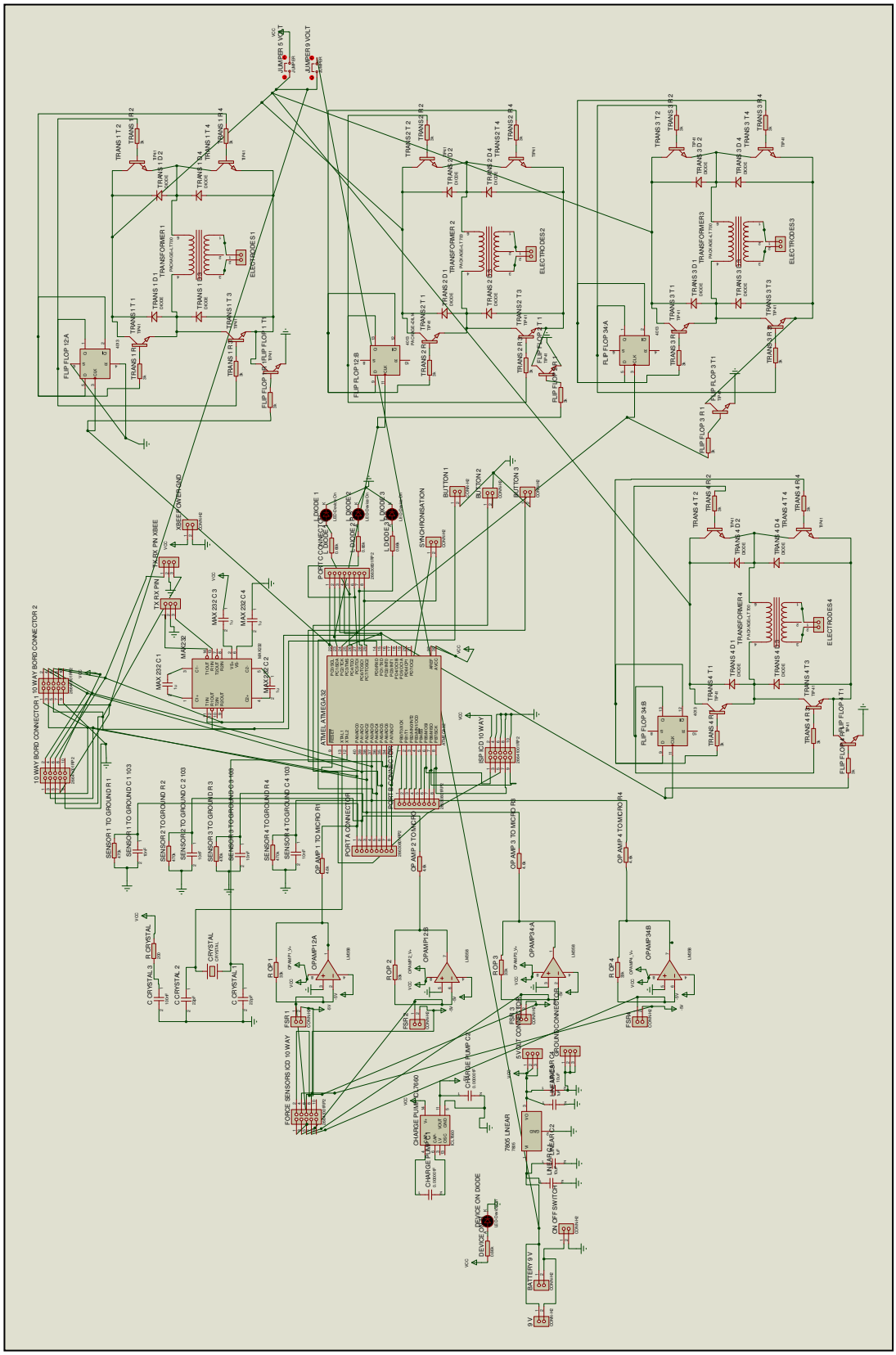
Appendix D: Circuit Design for analogue device created with Proteus IRIS



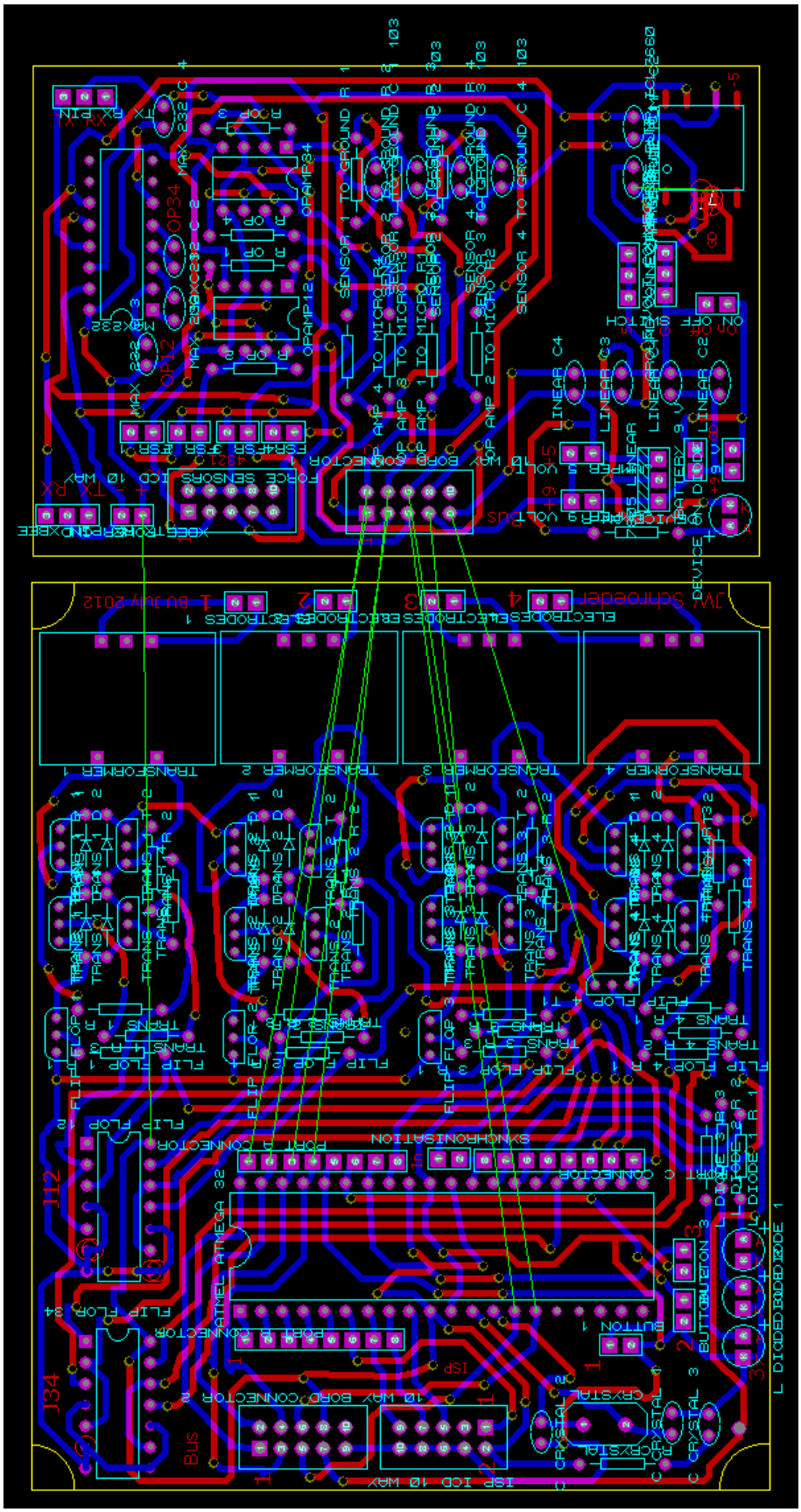
Appendix E: PCB design for analogue device created with Proteus ARES



Appendix F: Circuit Design for digital device created with Proteus IRIS



Appendix G: PCB design for digital device created with Proteus ARES



Appendix H: Repeatability test for threshold detection

A preliminary study with one male test person, aged 29, was performed to test the repeatability of the calibration method in terms of finding the thresholds for sensation and discomfort. This preliminary test was conducted to study if the method of limits can be used for the calibration procedure.

H.1. Methods

Two self-adhering electrodes of the type Platinium Blue by Pals with a size of 3 cm^2 were placed at the upper leg. The current was limited to 38 mA by using a 5 V power source and by putting a 14 Ω resistor in the primary winding of a transformer with a winding rate of 9.33. A test-retest was carried out with one test person (Rousson et al. 2002). Test person had to start the calibration method to define the sensation and discomfort thresholds as described in Chapter 4. The test was repeated 10 times for the test person.

H.2. Results

Tab. H.1 shows the distribution of pulse width in µs after 10 repetitions of the calibration with one test person.

1	2	3	4	5	6	7	8	9	10	µ	δ	δ in %
60	40	28	48	68	88	40	44	68	52	54	17.6	32.8
332	320	328	320	316	320	324	324	320	316	322	5.1	1.6

Tab. H.1: Values obtained from calibration procedure

For the discomfort threshold all values were within a range of 316 to 328 µs. The arithmetic mean µ was 322 µs and the standard deviation δ was 5.07 µs. For the sensation threshold values were within a range of 28 to 88 µs. The arithmetic mean µ was 53.6 µs and the standard deviation δ was 17.6 µs.

H.3. Discussion

A calibration method using the methods of limits was tested that allows calibration for different feedback systems. The standard deviation for the discomfort threshold of 5.07 µs was surprisingly good, considering that the step width was 4 µs. The standard deviation of 17.6 µs is still good, since the threshold for sensation is more difficult to detect.

As mentioned in Chapter 2 the specific threshold for sensation and discomfort vary between individuals. Without a personalised calibration it is very likely that fixed values for the pulse width thresholds would not use the full range of comfortable electrical stimulation or even exceed the discomfort threshold leading to an uncomfortable feedback. Tests with further subjects are needed to show the reliability over a larger group of test subjects.

Appendix I: Gait cycle differentiation

A plantar measurement system has been developed allowing balance analysis for impaired individuals. Gait analysis was not a major interest of the developed system.

However, the system offers the possibility to extract gait parameters such as gait cycles when used during walking.

I.1. Methods

One test subject, aged 28, performed a normal gait experiment to valuate the usability of the plantar measurement system for gait cycle differentiation. Gait can be separated in 2 gait cycles, the stance phase and the swing phase (Fig. I.1.)

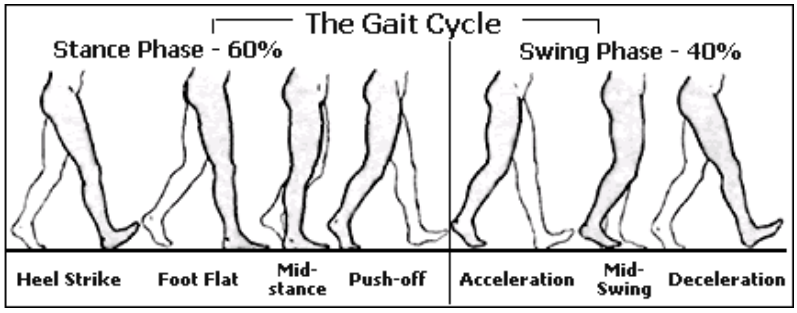


Fig. I.1: Gait cycles[39].

I.2. Results

To test the force sensors for its ability to identify gate patterns a normal walking pattern for 60 seconds was recorded.

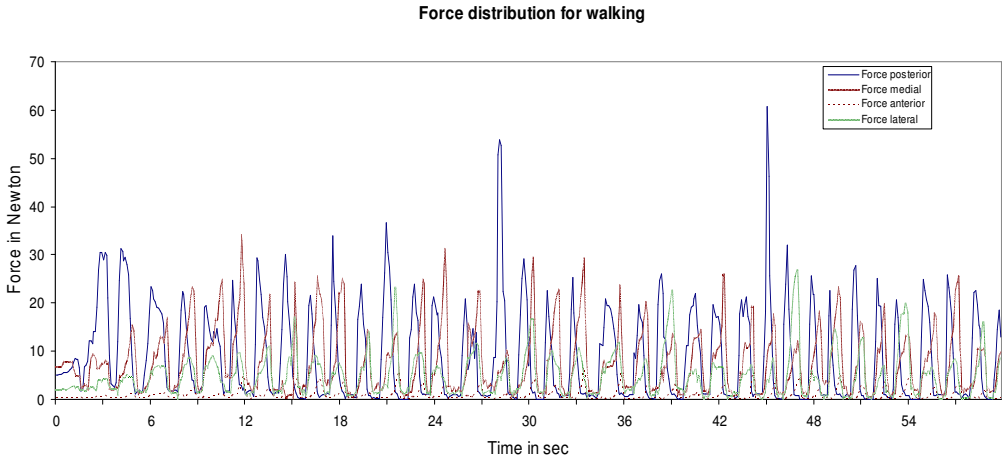


Fig. I.2: Force distribution over a time period of 60 seconds of walking

Fig. I.2 shows the measured force distribution over a time of 60 seconds. The heel strike is the strongest force with a maximum value of 60 Newton. When looking at a shorter time period the different gait cycles can be identified.

[39] Image source: www.root2being.com (25 May 2012)

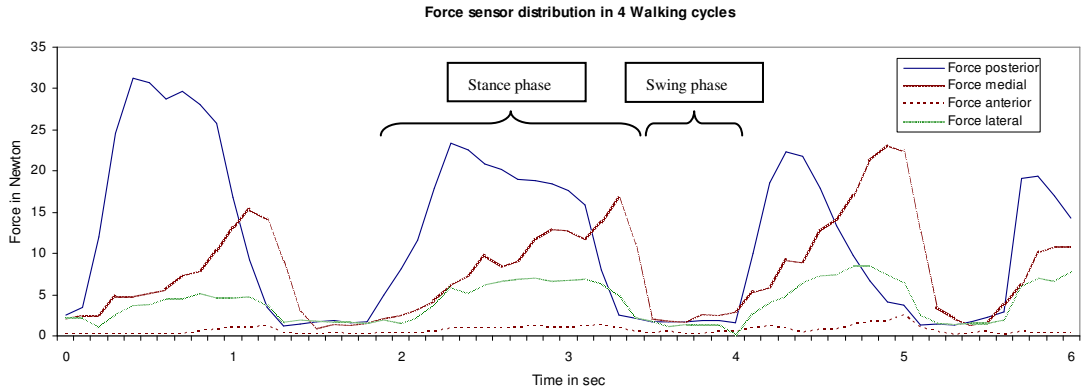


Fig. I.3: Force distribution over 10 seconds of walking

Fig. I.3. shows a shorter timeframe of 6 seconds. It is clearly visible that within the time of 6 seconds, 4 steps were recorded. The Stance phase and Swing phase can be distinguished. Further it is possible to see when the different stages of the gait cycle take place (e.g. heel strike and mid stance).

I.3. Discussion

The goal of this short experiment was to verify ability to identify gait cycles with the measurement system. It was shown that the system is able to do so which demonstrates the application possibilities of the developed system.

Appendix J: CD

The CD contains 5 folders:

Clinical Trial Data Analysis: Contains the anonymous trial data and Matlab files for data analysis

Ethical Approval: Contains all documents submitted to the NHS Ethics Committee

Device Software: Contains the device software that was implemented on the microcontroller

Publications: Contains journal and conference publications and the patent draft

Real-time Visualization Software: Contains the Matlab files for the real-time balance analysis tool

References

Alon, G., Allin, J. and Inbar, G.F. 1983. Optimization of pulse duration and pulse charge during transcutaneous electrical nerve stimulation. *Aust J Physiother.* 29(6), pp. 195–201.

Ambu 2012. Neuroline® 700. In: *Datasheet 700*.

Anon 2005. *Mosby's Medical, Nursing; Allied Health Dictionary - Revised Reprint [Hardcover]*. Mosby; 6th Book; CD-Rom edition.

Armstrong, J.S. 2001. *Evaluating forecasting methods*. Norwell: Kluwer Academic Publishers.

Arnold, J.B., Causby, R., Pod, G.D. and Jones, S. 2010. The impact of increasing body mass on peak and mean plantar pressure in asymptomatic adult subjects during walking. *Diabetic foot & ankle* 1(55518), pp. 1–8.

Bach, P., Collins, C.C., Saunders, F.A., White, B. and Scadden, L. 1969. Vision Substitution by Tactile Image Projection. *Nature* 221(5184), p. 963–&.

Bachus, K.N., DeMarco, A.L., Judd, K.T., Horwitz, D.S. and Brodke, D.S. 2006. Measuring contact area, force, and pressure for bioengineering applications: using Fuji Film and TekScan systems. *Medical engineering & physics* 28(5), pp. 483–8.

Badke, M.B., Sherman, J., Boyne, P., Page, S. and Dunning, K. 2011. Tongue-based biofeedback for balance in stroke: results of an 8-week pilot study. *Archives of physical medicine and rehabilitation* 92(9), pp. 1364–70.

Bajd, T., Mihelj, M. and Matjacic, Z. 2002. The biomechanics of standing and balancing in paralyzed people. *Cellular & Molecular Biology Letters* 7(1), pp. 74–77.

Bales, J.G. and Meals, R. 2009. Peripheral neuropathy of the upper extremity: medical comorbidity that confounds common orthopedic pathology. *Orthopedics* 32(10).

Bamberg, S.J.M., Benbasat, A.Y., Scarborough, D.M., Krebs, D.E. and Paradiso, J. a 2008. Gait analysis using a shoe-integrated wireless sensor system. *IEEE transactions on information technology in biomedicine: a publication of the IEEE Engineering in Medicine and Biology Society* 12(4), pp. 413–23.

Bamberg, S.M., Lastayo, P., Dibble, L., Musselman, J. and Raghavendra, S.K.D. 2006. Development of a quantitative in-shoe measurement system for assessing balance: sixteen-sensor insoles. *Conf Proc IEEE Eng Med Biol Soc* 1, pp. 6041–6044.

Barclay-Goddard, R., Stevenson, T., Poluha, W., Moffatt, M.E.K. and Taback, S.P. 2004. Force platform feedback for standing balance training after stroke. *Cochrane database of systematic reviews* 4, p. CD004129.

Beck, J. and Shaw, W.A. 1962. Magnitude estimation of pitch. *Journal of the Acoustical Society of America* 34, pp. 92–98.

Bekesy, G. V 1947. A new audiometer. *Acta Oto-laryngologica* 35, pp. 411–422.

Biswas, A., Lemaire, E.D. and Kofman, J. 2008. Dynamic gait stability index based on plantar pressures and fuzzy logic. *Journal of Biomechanics* 41(7), pp. 1574–1581.

Blamey, P.J., Cowan, R.S., Alcantara, J.I. and Clark, G.M. 1988. Phonemic information transmitted by a multichannel electrotactile speech processor. *Journal of speech and hearing research* 31(4), pp. 620–9.

Boućek, P., Pelikánová, T. and Saudek, F. 2007. Symptomatic diabetic neuropathy: irreversible nerve damage? *Prakt. Lék.* 87(2), pp. 82–85.

Bray, J., P. A., C., Macknight, A., R., M. and D., T. 1999. *Lecture Notes on Human Physiology*. 4th ed. Blackwell Science Ltd.

Bromberg, M.B. 2013. An electrodiagnostic approach to the evaluation of peripheral neuropathies. *Physical medicine and rehabilitation clinics of North America* 24(1), pp. 153–68.

Brummer, S.B. and Turner, M.J. 1975. Electrical stimulation of the nervous system: The principle of safe charge injection with noble metal electrodes. *Bioelectrochemistry and Bioenergetics* 2(1), pp. 13–25.

Buma, D.G., Buitenweg, J.R. and Veltink, P.H. 2007. Intermittent stimulation delays adaptation to electrocutaneous sensory feedback. *Ieee Transactions on Neural Systems and Rehabilitation Engineering* 15(3), pp. 435–441.

Carpaneto, J., Micera, S., Zaccone, F., Vecchi, F. and Dario, P. 2003. A. sensorized thumb for force closed-loop control of hand neuroprostheses. *Ieee Transactions on Neural Systems and Rehabilitation Engineering* 11(4), pp. 346–353.

Chen, H. 2010. Muscle Channel Technique for Peripheral Sensory Neuropathy. *Medical Acupuncture* 22(1), pp. 57–59.

Chen, M., Huang, B., Xu, Y.S., Motivation, A. and Ieee 2008. Intelligent shoes for abnormal gait detection. In: *2008 Ieee International Conference on Robotics and Automation, Vols 1-9*. New York: Ieee, pp. 2019–2024.

Cheng, K.W.E., Lu, Y., Tong, K., Rad, A.B., Chow, D.H.K., Sutanto, D. and Member, S. 2004. Development of a circuit for functional electrical stimulation. *IEEE Trans Neural Syst Rehabil* 12(1), pp. 43–47.

Chiari, L., Dozza, M., Cappello, A., Horak, F.B., Macellari, V. and Giansanti, D. 2005. Audio-Biofeedback for Balance Improvement: An Accelerometry-Based System. *IEEE Trans Biomed Eng.* 52(12), pp. 2108–2111.

Chorost, M. 2011. *World Wide Mind: The Coming Integration of Humanity, Machines, and the Internet*. Simon and Schuster.

Cimbiz, A. and Cakir, O. 2005. Evaluation of balance and physical fitness in diabetic neuropathic patients. *Journal of diabetes and its complications* 19(3), pp. 160–4.

Cole, J. 1995. *Pride and a Daily Marathon*. The MIT Press.

Collins, A.T., Blackburn, J.T., Olcott, C.W., Dirschl, D.R. and Weinhold, P.S. 2009. The effects of stochastic resonance electrical stimulation and neoprene sleeve on knee proprioception. *Journal of orthopaedic surgery and research* 4, p. 3.

Cornblath, D.R. and McArthur, J.C. 1988. Predominantly sensory neuropathy in patients with AIDS and AIDS-related complex. *Neurology* 38(5), pp. 794–6.

Corso, J.F. 1963. A theoretico-historical review of the threshold concept. *Psychological bulletin* 60, pp. 356–70.

Cotton, D.P.J., Chappell, P.H., Cranny, A., White, N.M. and Beeby, S.P. 2007. A novel thick-film piezoelectric slip sensor for a prosthetic hand. *Ieee Sensors Journal* 7(5-6), pp. 752–761.

Cowan, R.S., Galvin, K.L., Sarant, J.Z., Millard, R., Blamey, P.J. and Clark, G.M. 1995. Improved electrotactile speech processor: Tickle Talker. *The Annals of otology, rhinology & laryngology. Supplement* 166, pp. 454–6.

Darian-Smith, I. 1984. *The Sense of Touch: Performance and Peripheral Neural Processes*.

Dorgan, S.J. and Reilly, R.B. 1999. A model for human skin impedance during surface functional neuromuscular stimulation. *Rehabilitation Engineering, IEEE Transactions on* 7(3), pp. 341–348.

Dozza, M. 2006. Biofeedback Systems for Human. Università di Bologna.

Ehrenstein, W. and Ehrenstein, A. 1999. Psychophysical Methods Windhorst, U. and Johansson, H. eds. *Modern Techniques in Neuroscience Research*, pp. 1211–1241.

Eid, M., Issawi, A. and Saddik, A. 2012. Slingshot 3D: A synchronous haptic-audio-video game. *Multimedia Tools and Applications*.

Fechner, G.T. 1860. *Elemente der Psychophysik*. Breitkopf und Härtel.

Freberg, L. 2009. *Discovering Biological Psychology*. Cengage Learning.

De Freitas, P.B., Freitas, S.M.S.F., Duarte, M., Latash, M.L. and Zatsiorsky, V.M. 2009. Effects of joint immobilization on standing balance. *Human movement science* 28(4), pp. 515–28.

Frykberg, R.G., Lavery, L.A., Pham, H., Harvey, C., Harkless, L. and Veves, A. 1998. Role of neuropathy and high foot pressures in diabetic foot ulceration. *Diabetes care* 21(10), pp. 1714–9.

Fujita, T., Nakamura, S., Ohue, M., Fujii, Y., Miyauchi, A., Takagi, Y. and Tsugeno, H. 2005. Effect of age on body sway assessed by computerized posturography. *Journal of bone and mineral metabolism* 23(2), pp. 152–6.

Geddes, L.A. 1994. The first stimulators-reviewing the history of electrical stimulation and the devices crucial to its development. *Engineering in Medicine and Biology Magazine, IEEE* 13(4), pp. 532–542.

Geng, B., Yoshida, K., Petrini, L. and Jensen, W. 2012. Evaluation of sensation evoked by electrocutaneous stimulation on forearm in nondisabled subjects. *Journal of rehabilitation research and development* 49(2), pp. 297–308.

Geurts, A.C.H., de Haart, M., van Nes, I.J.W. and Duysens, J. 2005. A review of standing balance recovery from stroke. *Gait & posture* 22(3), pp. 267–81.

Glanz, M., Klawansky, S. and Chalmers, T. 1997. Biofeedback therapy in stroke rehabilitation: a review. *Journal of the Royal Society of Medicine* 90(1), pp. 33–9.

Goebel, K. and Yan, W. 2008. Correcting Sensor Drift and Intermittency Faults With Data Fusion and Automated Learning. *IEEE Systems Journal* 2(2), pp. 189–197.

Grabiner, M.D., Lundin, T.M. and Feuerbach, J.W. 1993. Converting Chattecx Balance System vertical reaction force measurements to center of pressure excursion measurements. *Physical therapy* 73(5), pp. 316–9.

Granat, M.H., Maxwell, D.J., Ferguson, A.C., Lees, K.R. and Barbenel, J.C. 1996. Peroneal stimulator; evaluation for the correction of spastic drop foot in hemiplegia. *Archives of physical medicine and rehabilitation* 77(1), pp. 19–24.

Gulbandilar, E., Cimbiz, A., Sari, M. and Ozden, H. 2008. Relationship between skin resistance level and static balance in type II diabetic subjects. *Diabetes research and clinical practice* 82(3), pp. 335–9.

Hall, R.S., Desmoulin, G.T. and Milner, T.E. 2008. A technique for conditioning and calibrating force-sensing resistors for repeatable and reliable measurement of compressive force. *Journal of biomechanics* 41(16), pp. 3492–5.

Hamilton, M. 1999. *Software Development: A Guide to Building Reliable Systems*. Prentice Hall Professional.

Hargreaves, P. and Scales, J.T. 1975. Clinical assessment of gait using load measuring footwear. *Acta orthopaedica Scandinavica* 46(6), pp. 877–95.

Herrera-May, A.L., Soto-Cruz, B.S., Lopez-Huerta, F. and Cortes, L.A.A. 2009. Electromechanical analysis of a piezoresistive pressure microsensor for low-pressure biomedical applications. *Revista Mexicana De Fisica* 55(1), pp. 14–24.

Hollinger, A. and Wanderley, M.M. 2006. Evaluation of Commercial Force-Sensing Resistors. , pp. 1–4.

Van den Honert, C. and Mortimer, J.T. 1979. The response of the myelinated nerve fiber to short duration biphasic stimulating currents. *Annals of biomedical engineering* 7(2), pp. 117–25.

Hughes, R.A.C. 2002. *Peripheral neuropathy*. BMJ.

Ivorra, A., Daniels, C. and Rubinsky, B. 2008. Minimally obtrusive wearable device for continuous interactive cognitive and neurological assessment. *Physiological measurement* 29(5), pp. 543–54.

Jeffs, A. and Warwick, K. 2013. Sensory Perception through an Electro-tactile Stimulus Array on the Tongue. In: *2013 IEEE International Conference on Systems, Man, and Cybernetics*. pp. 3549–3554.

Jeong, B.Y. 1994. Contour representation of sway area in posturography and its application. *Archives of physical medicine and rehabilitation* 75(9), pp. 951–6.

Johansson, R.S. and Vallbo, A.B. 1983. Tactile sensory coding in the glabrous skin of the human hand. *Trends in Neurosciences* 6, pp. 27–32.

Johnson, K.O. 2001. The roles and functions of cutaneous mechanoreceptors. *Current opinion in neurobiology* 11(4), pp. 455–61.

Jones, E.G. and Powell, T.P.S. 1973. Somatosensory System Handbook of Sensory Physiology. In: *Anatomical Organization of the Somatosensory Cortex*. pp. 579–620.

Julien, R.M. 2005. *A primer of drug action: A comprehensive guide to the actions, uses, and side effects of psychoactive drugs*. New York: Worth Publishers.

Kaas, J.H. 1983. What, if anything, is SI? Organization of first somatosensory area of cortex. *Physiological reviews* 63(1), pp. 206–31.

Kaczmarek, K.A. 2000. Electrotactile adaptation on the abdomen: Preliminary results. *Ieee Transactions on Rehabilitation Engineering* 8(4), pp. 499–505.

Kaczmarek, K.A., Kramer, K.M., Webster, J.G. and Radwin, R.G. 1991. A 16-channel 8-parameter waveform electrotactile stimulation system. *IEEE transactions on bio-medical engineering* 38(10), pp. 933–43.

Kaczmarek, K.A., Webster, J.G., Bachyrita, P. and Tompkins, W.J. 1991. Electrotactile and Vibrotactile Displays for Sensory Substitution Systems. *Ieee Transactions on Biomedical Engineering* 38(1), pp. 1–16.

Kaczmarek, K.A., Webster, J.G. and Radwin, R.G. 1992. Maximal Dynamic-Range Electrotactile Stimulation Wave-Forms. *IEEE Transactions on Biomedical Engineering* 39(7), pp. 701–715.

Kajimoto, H. 2006. Forehead Electro-tactile Display for Vision Substitution. *Proc. EuroHaptics*.

Kajimoto, H. and Kawakami, N. 2004. Electro-tactile display with tactile primary color approach. *Proc. of IEEE/RSJ Int Conf on Intelligent Robots*.

Kajimoto, H., Kawakami, N. and Tachi, S. 2003. Psychophysical evaluation of receptor selectivity in electro-tactile display. 13, pp. 83–86.

Kajimoto, H., Kawakami, N., Tachi, S. and Inami, M. 2004. SmartTouch: electric skin to touch the untouchable. *IEEE Computer Graphics and Applications* 24(1), pp. 36–43.

Kanade, R. V, Van Deursen, R.W.M., Harding, K.G. and Price, P.E. 2008. Investigation of standing balance in patients with diabetic neuropathy at different stages of foot complications. *Clinical Biomechanics* 23(9), pp. 1183–1191.

Kandel, E.R., Schwartz, J. and Jessell, T. 2000. *Principles of Neural Science*. 4th ed. Elsevier.

Kasthuri, A., S., S. and N., K. 2000. Somatic Neurophaty in Diabetes Mellitus. *Medical Journal Armed Forces India* 56(1), pp. 33–6.

Kim, S.S., Won, J.C., Kwon, H.S., Kim, C.H., Lee, J.H., Park, T.S., Ko, K.S. and Cha, B.Y. 2013. Validity of the medical outcomes study sleep scale in patients with painful diabetic peripheral neuropathy in Korea. *Journal of Diabetes Investigation* 4(4), pp. 405–409.

Knibestöl, M. and Vallbo, A.B. 1980. Intensity of sensation related to activity of slowly adapting mechanoreceptive units in the human hand. *The Journal of physiology* 300, pp. 251–67.

Kong, K., Member, S., Tomizuka, M. and Ieee 2008. Smooth and continuous human gait phase detection based on foot pressure patterns. In: *Ieee International Conference on Robotics and Automation*. New York: Ieee, pp. 3678–3683.

Kong, K., Tomizuka, M. and Ieee 2008. *Estimation of Abnormalities in a Human Gait Using Sensor-Embedded Shoes*. New York: Ieee.

Ku, J., Mraz, R., Baker, N., Zakzanis, K.K., Lee, J.H., Kim, I.N.Y., Kim, S.I., Graham, S.J., Jeonghun, K. and Jang Han, L. 2003. A Data Glove with Tactile Feedback for fMRI of Virtual Reality Experiments. *CyberPsychology & Behavior* 6(5), p. 497.

Kuiken, T.A., Marasco, P.D., Lock, B.A., Harden, R.N. and Dewald, J.P. a 2007. Redirection of cutaneous sensation from the hand to the chest skin of human

amputees with targeted reinnervation. *Proceedings of the National Academy of Sciences of the United States of America* 104(50), pp. 20061–20066.

Lackner, J.R., DiZio, P., Jeka, J., Horak, F., Krebs, D. and Rabin, E. 1999. Precision contact of the fingertip reduces postural sway of individuals with bilateral vestibular loss. *Experimental Brain Research* 126(4), pp. 459–466.

Lafargue, G., Paillard, J., Lamarre, Y. and Sirigu, A. 2003. Production and perception of grip force without proprioception: is there a sense of effort in deafferented subjects? *The European journal of neuroscience* 17(12), pp. 2741–9.

Lindenblatt, G. and Silny, J. 2006. Evaluation and comparison of 50 Hz current threshold of electrocutaneous sensations using different methods. *Journal of Zhejiang University Science. B* 7(12), pp. 933–46.

Liu, H., Shah, S. and Jiang, W. 2004. On-line outlier detection and data cleaning. *Computers & Chemical Engineering* 28(9), pp. 1635–1647.

Liu, T., Inoue, Y. and Shibata, K. 2010. A wearable ground reaction force sensor system and its application to the measurement of extrinsic gait variability. *Sensors (Basel, Switzerland)* 10(11), pp. 10240–55.

Liu, W. and Tang, H. 2005. An initial study on lip perception of electrotactile array stimulation. *The Journal of Rehabilitation Research and Development* 42(5), p. 705.

Lord, S.R., Clark, R.D. and Webster, I.W. 1991. Physiological factors associated with falls in an elderly population. *Journal of the American Geriatrics Society* 39(12), pp. 1194–200.

Lund, I., Lundeberg, T., Kowalski, J., Sandberg, L., Budh, C.N. and Svensson, E. 2005. Evaluation of variations in sensory and pain threshold assessments by electrocutaneous stimulation. *Physiotherapy Theory and Practice* 21(2), pp. 81–92.

Lundborg, G., Rosén, B. and Lindström, K. 1998. Artificial sensibility based on the use of piezoresistive sensors - Preliminary observations. *Journal of Hand Surgery-British and European Volume* 23B(5), pp. 620–626.

Lundborg, G., Rosén, B., Lindström, K. and Lindberg, S. 1998. Artificial Sensibility Based on the Use of Piezoresistive Sensors. *J Hand Surg Br.* 23(5), pp. 620–6.

Ma, W. 2010. Instrumentation of Gait Analysis. Kungliga Tekniska Högskolan.

Macefield, V.G. 2005. Physiological characteristics of low-threshold mechanoreceptors in joints, muscle and skin in human subjects. *Clinical and experimental pharmacology & physiology* 32(1-2), pp. 135–44.

Maheshwari, V. and Saraf, R.F. 2008. Tactile Devices to Sense Touch on a Par with a Human Finger. *Angewandte Chemie (International ed. in English)* 47(41), pp. 7808–7826.

Malik, R.A. 2005. Diabetic peripheral neuropathy: linking microvascular etiology to potential treatments. In: *Advanced Studies in Medicine*. pp. 144–149.

Manor, B. and Li, L. 2009. Characteristics of functional gait among people with and without peripheral neuropathy. *Gait & posture* 30(2), pp. 253–6.

Marcus, P.L. and Fuglevand, A.J. 2009. Perception of electrical and mechanical stimulation of the skin: implications for electrotactile feedback. *Journal of Neural Engineering* 6(6), p. 12.

Marcus, P.L., Mcnaughton, B. and Higgins, C. 2006. Electrotactile Feedback System Using Psychophysical Mapping Functions.

Marks 1974. *Sensory Processes: The New Psychophysics*. New York: Academic Press.

Matjacic, Z., Jensen, P.L., Riso, R.R., Voigt, M., Bajd, T. and Sinkjaer, T. 2000. Development and evaluation of a two-dimensional electrocutaneous cognitive feedback system for use in paraplegic standing. *Journal of Medical Engineering & Technology* 24(5), pp. 215–226.

McGlone, F., Olausson, H., Boyle, J.A., Jones-Gotman, M., Dancer, C., Guest, S. and Essick, G. 2012. Touching and feeling: differences in pleasant touch processing between glabrous and hairy skin in humans. *The European Journal of Neuroscience* 35(11), pp. 1782–8.

McIlroy, W.E. and Maki, B.E. 1997. Preferred placement of the feet during quiet stance: development of a standardized foot placement for balance testing. *Clinical Biomechanics* 12(1), pp. 66–70.

Meyer, J., Lukowicz, P. and Tr, G. 2006. Textile Pressure Sensor for Muscle Activity and Motion Detection. In: *10th IEEE International Symposium on Wearable Computers,*. pp. 2–5.

Miller 1982. The magical number 7, plus minus two, some limits on our capacity for processing information. *Psychological Review* 63, pp. 81–97.

Milosevic, M., McConville, K. and Valter, M. 2011. Audio-visual biofeedback system for postural control. *International Journal on Disability and Human Development* 10(4), pp. 321–324.

Miyazaki, S. and Iwakura, H. 1978. Foot-force measuring device for clinical assessment of pathological gait. *Medical & Biological Engineering & Computing* 16(4), pp. 429–436.

Monzée, J., Lamarre, Y. and Smith, A.M. 2003. The effects of digital anesthesia on force control using a precision grip. *Journal of neurophysiology* 89(2), pp. 672–83.

Moreland, J.D., Thomson, M. a and Fuoco, a R. 1998. Electromyographic biofeedback to improve lower extremity function after stroke: a meta-analysis. *Archives of physical medicine and rehabilitation* 79(2), pp. 134–40.

Morin, E., Reid, S., Eklund, J.M., Lay, H., Lu, Y., Stevenson, J. and Bryant, J.T. 2002. Comparision of Ground Reaction Forces Measured with a Force Plate, FScan and Multiple Individual Force Sensors. , pp. 57–58.

Munde, D.D., Karne, S. and Shah, N. 2013. Charcot Joints: A Case Study. *Indian Journal of Applied Research* 3(1), pp. 2012–2013.

Murdoch, G., Wilson, A.B. and Jr. 1998. *A Primer on Amputations and Artificial Limbs*. Charles C Thomas Pub Ltd.

Murray, D.J. 1993. A perspective for viewing the history of psychophysics. *Behavioral and Brain Sciences* 16(01), pp. 115–137.

Nashner, L.M. 1976. Adapting reflexes controlling the human posture. *Experimental brain research* 26(1), pp. 59–72.

Neumann, J.J., Greve, D.W. and Oppenheim, I.J. 2004. Comparison of Piezoresistive and Capactive Ultrasonic Transducers Liu, S.-C. ed. *Sensors and Smart Structures Technologies for Civil, Mechanical, and Aerospace Systems* 5391, pp. 230–238.

Nichols, D.S. 1997. Balance retraining after stroke using force platform biofeedback. *Physical therapy* 77(5), pp. 553–8.

Nissen, M.J. and Bullemer, P. 1987. Attentional requirements of learning: Evidence from performance measures. *Cognitive Psychology* 19(1), p. 32.

Ochs, A.L., Newberry, J.E., Lenhardt, M.L. and Harkins, S.W. 1985. Neural and vestibular aging associated with falls. In: *Handbook of the psychology of aging*. Van Nostrand Reinhold Co, pp. 378–399.

Odstock Medical Ltd 2006. The Odstock Dropped Foot Stimulator. In: *Datasheet ODFS III*.

Onesti, R.J., Tompkins, W.J., Webster, J.G., Wertsch, J.J. and Service, R.M. 1989. Design of a Portable Electrotactile Stimulator for Sensory Substitution Applications. *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society* 5, pp. 1439–1440.

Ottenbacher, K.J. 1986. Reliability and accuracy of visually analyzing graphed data from single-subject designs. *The American journal of occupational therapy: official publication of the American Occupational Therapy Association* 40(7), pp. 464–9.

Pearson, R.K. 2005. *Mining Imperfect Data: Dealing with Contamination and Incomplete Records*. SIAM.

Penfield, W. and Jasper, H.H. 1954. *Epilepsy and the functional anatomy of the human brain*. Boston: Little, Brown.

Philips Semiconductors 1997. Dual JK flip-flop with set and reset positive-edge trigger. *Datasheet 74HC/HCT109*.

Pitei, D.L., Lord, M., Foster, A., Wilson, S., Watkins, P.J. and Edmonds, M.E. 1999. Plantar pressures are elevated in the neuroischemic and the neuropathic diabetic foot. *Diabetes care* 22(12), pp. 1966–70.

Podsiadlo, D. and Richardson, S. 1991. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society* 39(2), pp. 142–8.

Pollard, J.P., Le Quesne, L.P. and Tappin, J.W. 1983. Forces under the foot. *Journal of biomedical engineering* 5(1), pp. 37–40.

Prior, R.E. and Lyman, J. 1974. Electrocutaneous feedback for artificial limbs. *Bull Prosthet Res* 24(10), pp. 3–37.

Rana, N.K. 2009. Application of Force Sensing Resistor (FSR) in Design of Pressure Scanning System for Plantar Pressure Measurement. In: *2nd International Conference on Computer and Electrical Engineering*. pp. 678–685.

Res, C., Willmott, C.J. and Matsuura, K. 2005. Advantages of the mean absolute error (MAE) over the root mean square error (RMSE) in assessing average model performance. *Climatic Research* 30(1), pp. 79–82.

Riskowski, J.L., Quach, L., Manor, B., Menz, H.B., Lipsitz, L. a and Hannan, M.T. 2012. Idiopathic peripheral neuropathy increases fall risk in a population-based cohort study of older adults. *Journal of Foot and Ankle Research* 5(1), p. 19.

Robertson, V.J., Ward, A., Low, J. and Reed, A. 2006. *Electrotherapy explained: principles and practice*. 4th ed. Elsevier, B. H. ed.

Robles-De-La-Torre, G. 2006. The importance of the sense of touch in virtual and real environments. *Ieee Multimedia* 13(3), pp. 24–30.

Rodgers, M.M. 1988. Dynamic biomechanics of the normal foot and ankle during walking and running. *Physical therapy* 68(12), pp. 1822–30.

Rollman, G.B. 1969. Electrocutaneous stimulation: Psychometric functions and temporal integration. *Perception & Psychophysics* 5(5), pp. 289–293.

Ross, H.E. and Murray, D.J. 1996. *E.H. Weber on the Tactile Senses*.

Rousson, V., Gasser, T. and Seifer, B. 2002. Assessing intrarater, interrater and test–retest reliability of continuous measurements. *Statistics in Medicine* 21, pp. 3431–3446.

Rubenstein, L.Z. 2006. Falls in older people: epidemiology, risk factors and strategies for prevention. *Age and ageing* 35(2), pp. 37–41.

Rubio, W.M., Silva, E.C.N. and Nishiwaki, S. 2007. Piezoresistive sensor design using topology optimization. *Structural and Multidisciplinary Optimization* 36(6), pp. 571–583.

Russell, S. and Norvig, P. 2009. *Artificial Intelligence: A Modern Approach*. Prentice Hall Press.

Saunders, F.A. 1977. Procedures for Electrocutaneous Displays. In: *Functional Electrical Stimulation: Applications in Neural Prostheses*. p. 303.

Schömig, M., Ritz, E., Standl, E. and Allenberg, J. 2000. The diabetic foot in the dialyzed patient. *Journal of the American Society of Nephrology* 11(6), pp. 1153–9.

Schroeder, J.W., Dubey, V.N., Hickish, T.F., Cole, J., M., C. and I., S. 2012. Applications of Electrical Stimulation and Electrotactile Feedback in Human Spaceflight. In: *63rd International Astronautical Congress*. p. IAC–12,A1,2,7.

Schulz, S., Pylatiuk, C., Kargov, A. and Werner, T. 2007. Design and evaluation of a multifunction myoelectric prosthetic hand with force feedback system and fluidic actuators for different grasping types. *Disability and Rehabilitation* 29(20-21), p. 1648.

Shumway-Cook, A., Brauer, S. and Woollacott, M. 2000. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. *Physical therapy* 80(9), pp. 896–903.

Słomka, K., Juras, G., Sobota, G. and Bacik, B. 2013. The reliability of a rambling-trembling analysis of center of pressure measures. *Gait & posture* 37(2), pp. 210–3.

Smith, B.H. and Torrance, N. 2012. Epidemiology of neuropathic pain and its impact on quality of life. *Current pain and headache reports* 16(3), pp. 191–8.

Solomonow, M. and Lyman, J. 1980. Electrotactile stimulation relevant to sensory-motor rehabilitation: a progress report. *Bulletin of prosthetics research* 10-33, pp. 63–72.

Spaepen, A.J., Vranken, M. and Willems, E.J. 1977. Comparison of the movements of the center of gravity and of the center of pressure in stabilometric studies. *Agressologie: revue internationale de physio-biologie et de pharmacologie appliquées aux effets de l'agression* 18(2), pp. 109–13.

Spirduso, Francis and MacRae 2005. *Physical Dimensions of Ageing*. 1st ed. Human Kinetics Pub Inc.

Standring, S. 2008. *Gray's Anatomy*. Churchill Livingstone.

Stevens, S. 1957. On the psychophysical law. *Psychological review* 64(3), pp. 153–81.

Stevens, S.S. 1955. The Measurement of Loudness. *The Journal of the Acoustical Society of America* 27(5), p. 815.

Stevens, S.S. and Poulton, E.C. 1956. The estimation of loudness by unpracticed observers. *Journal of Experimental Psychology* 51(1), pp. 71–78.

Stortech Electronics 2012. Low Voltage PCB transformer. In: *Datasheet LT-700*.

Sunyoung, K., Yazicioglu, R.F., Torfs, T., Dilpreet, B., Julien, P. and Van Hoof, C. 2010. A continuous-time electrode-skin impedance measurement circuit for motion artifact monitoring in ECG acquisition systems. In: *VLSI Circuits (VLSIC), 2010 IEEE Symposium on*. pp. 219–220.

Sze, S.M. 1994. *Semiconductor sensors*.

Szeto, A. 1985. Relationship between pulse rate and pulse width for a constant-intensity level of electrocutaneous stimulation. *Annals of Biomedical Engineering* 13(5), pp. 373–383.

Szeto, A. and Saunders, F.A. 1982. Electrocutaneous Stimulation for Sensory Communication in Rehabilitation Engineering. *IEEE Transactions on Biomedical Engineering* BME-29(4), pp. 300–308.

Szeto, A.Y. 1977. Comparison of codes for sensory feedback using electrocutaneous tracking. *Annals of biomedical engineering* 5(4), pp. 367–83.

Tashiro, T. and Higashiyama, A. 1981. The perceptual properties of electrocutaneous stimulation: sensory quality, subjective intensity, and intensity-duration relation. *Perception & psychophysics* 30(6), pp. 579–86.

Tekscan 2006. FlexiForce Sensor User Manual. In: *Datasheet A201*.

Texas Instruments 2004. Dual EIA-232 Drivers/Receivers. In: *Datasheet MAX232*.

Texas Instruments 2000. Low Power Dual Operational Amplifiers. In: *Datasheet LM358*.

Texas Instruments 2011. Microcontroller with 32KBytes In-System Programmable Flash. In: *Datasheet Atmega 32*.

Texas Instruments 2010. Precision Timer. In: *Datasheet NE555*.

Texas Instruments 1997. Switched Capacitor Voltage Converter. In: *Datasheet LMC 7660*.

Tofthagen, C., Overcash, J. and Kip, K. 2012. Falls in persons with chemotherapy-induced peripheral neuropathy. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer* 20(3), pp. 583–9.

Tregear, R. 1966. *Physical Functions of the Skin. Academic Press*. New York: Academic Press.

Tsui, B.C.H. 2008. Electrical Nerve Stimulation. In: *Atlas of Ultrasound and Nerve Stimulation-Guided Regional Anesthesia*. Springer, p. 11.

Turcato, A. and Ramat, S. 2010. Studying postural sway using wearable sensors: fall prediction. In: *XII Mediterranean Conference on Medical and Biological Engineering and Computing 2010*. Springer Berlin Heidelberg, pp. 620 – 623.

Turcot, K., Allet, L., Golay, A., Hoffmeyer, P. and Armand, S. 2009. Investigation of standing balance in diabetic patients with and without peripheral neuropathy using accelerometers. *Clinical Biomechanics* 24(9), pp. 716–721.

Turnbull, G.I., Charteris, J. and Wall, J.C. 1996. Deficiencies in standing weight shifts by ambulant hemiplegic subjects. *Archives of physical medicine and rehabilitation* 77(4), pp. 356–62.

Tursdale Technical Services Ltd 2013. Manual Handheld Oscilloscope. *User Manual PCE-UT81B*.

Vuillerme, N., Chenu, O., Pinsault, N., Moreau-Gaudry, A., Fleury, A., Demongeot, J. and Payan, Y. 2007. Pressure sensor-based tongue-placed electrotactile biofeedback for balance improvement--biomedical application to prevent pressure sores formation and falls. *Annual International Conference of the IEEE Engineering in Medicine and Biology Society* 2007(1), pp. 6114–7.

Wang, F., Skubic, M., Abbott, C. and Keller, J.M. 2010. Body sway measurement for fall risk assessment using inexpensive webcams. *Conference proceedings: Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Conference* 2010, pp. 2225–9.

Ward, A.R. and Lucas-Toumbourou, S. 2007. Lowering of Sensory, Motor, and Pain-Tolerance Thresholds With Burst Duration Using Kilohertz-Frequency Alternating Current Electric Stimulation. *Archives of Physical Medicine and Rehabilitation* 88(8), pp. 1036–1041.

Ward, A.R., Lucas-Toumbourou, S. and McCarthy, B. 2009. A comparison of the analgesic efficacy of medium-frequency alternating current and TENS. *Physiotherapy* 95(4), pp. 280–8.

Warren, J.P., Bobich, L.R., Santello, M., Sweeney, J.D. and Tillery, S.I.H. 2008. Receptive field characteristics under electrotactile stimulation of the fingertip. *IEEE transactions on neural systems and rehabilitation engineering* 16(4), pp. 410–5.

Waxman, S.G. 1982. Membranes, myelin, and the pathophysiology of multiple sclerosis. *The New England journal of medicine* 306(25), pp. 1529–33.

Weber, E.H. 1851. *Die Lehre vom Tastsinne und Gemeingefühle*.

Wever, E.G. and Zener, K.E. 1928. The method of absolute judgment in psychophysics. *Psychological Review* 35, pp. 466–93.

Wilcoxon, F. 1945. Individual Comparisons by Ranking Methods Frank Wilcoxon. *Biometrics Bulletin* 1(6), pp. 80–83.

Williams, J.R. 1997. Walking aids for stroke patients (BL). Univerity of Bath.

Winter, D.A. 1995. Human balance and posture control during staning and walking. *Gait & Posture* 3, pp. 193–214.

Wunderlich, Roshna, E., Cavanagh and Peter, R. 2001. *Gender differences in adult foot shape: implications for shoe design*. Hagerstown: Lippincott Williams Wilkins.

Xu, Z., Yu, H. and Yan, S. 2010. Motor rehabilitation training after stroke using haptic handwriting and games. In: *Proceedings of the 4th International Convention on Rehabilitation Engineering & Assistive Technology*. Singapore Therapeutic, Assistive & Rehabilitative Technologies (START) Centre, p. 31.

Zhu, H.S., Maalej, N., Webster, J.G., Tompkins, W.J., Bach-y-Rita, P. and Wertsch, J.J. 1990. An umbilical data-acquisition system for measuring pressures between the foot and shoe. *IEEE transactions on bio-medical engineering* 37(9), pp. 908–11.

Bibliography

The bibliography lists further work that was consulted during the course of this research.

Anon Rajeswaramma, Vermeriddi et al., 1973 Pressure-Sensitive Stump Sock, *Archives of Physical Medicine and Rehabilitation*, , pp. 142-144.

Arshak, K., Jafer, E. and Fox, A. 2005. Design of a new thick film capacitive pressure and circuitry interface. *Composites Science and Technology* 65(5), pp. 757–764.

Babkoff, H. 1977. Electrocutaneous input-output functions: magnitude estimation and reaction time. *The International journal of neuroscience.* 7(2), pp. 73–80.

Biddiss, E.A. and Chau, T.T. 2007. Upper limb prosthesis use and abandonment: A survey of the last 25 years. *Prosthetics and Orthotics International* 31(3), pp. 236–257.

Bottaro, A., Yasutake, Y., Nomura, T., Casadio, M. and Morasso, P. 2008. Bounded stability of the quiet standing posture: an intermittent control model. *Human movement science* 27(3), pp. 473–95.

Choi, C., Carpaneto, J., Lago, N., Kim, J., Dario, P., Navarro, X., Micera, S., 2007. Classification of afferent signals recorded with a single cuff electrode. In: Biol, S. ed. *29th Annual International Conference of the IEEE-Engineering-in-Medicine-and-Biology-Society*. Lyon, FRANCE: Ieee, pp. 2385–2388.

Cipriani, C., Antfolk, C., Balkenius, C., Rosen, B., Lundborg, G., Carrozza, M.C. and Sebelius, F. 2009. A novel concept for a prosthetic hand with a bidirectional interface: a feasibility study. *IEEE Trans Biomed Eng* 56(11 Pt 2), pp. 2739–2743.

Cooper, G., Barker, A.T., Heller, B.W., Good, T., Kenney, L.P.J. and Howard, D. 2011. The use of hydrogel as an electrode-skin interface for electrode array FES applications. *Medical engineering & physics* 33(8), pp. 967–72.

Corriveau, H., Prince, F., Hébert, R., Raîche, M., Tessier, D., Maheux, P. and Ardilouze, J.L. 2000. Evaluation of postural stability in elderly with diabetic neuropathy. *Diabetes care* 23(8), pp. 1187–91.

Cotton, D.P.J., Graz, I.M. and Lacour, S.P. 2009. A Multifunctional Capacitive Sensor for Stretchable Electronic Skins. *Ieee Sensors Journal* 9(12), pp. 2008–2009.

Cranny, a., Cotton, D.P.J., Chappell, P.H., Beeby, S.P. and White, N.M. 2005. Thick-film force and slip sensors for a prosthetic hand. *Sensors and Actuators A: Physical* 123-124, pp. 162–171.

Danilov, Y.P., Tyler, M.E., Skinner, K.L., Hogle, R.A. and Bach-y-Rita, P. 2007. Efficacy of electrotactile vestibular substitution in patients with peripheral and central vestibular loss. *Journal of vestibular research: equilibrium & orientation* 17(2-3), pp. 119–30.

Dawson, T.W., Stuchly, M.A., Kavet, R., W., D.T. and A., S.M. 2004. Evaluation of Interactions of Electric Fields Due to Electrostatic Discharge With Human Tissue. *Ieee Transactions on Biomedical Engineering* 51(12), pp. 2194–2198.

De Barros, P.G., Lindeman, R.W. and Ward, M.O. 2011. Enhancing robot teleoperator situation awareness and performance using vibro-tactile and graphical feedback. In: *2011 IEEE Symposium on 3D User Interfaces (3DUI). IEEE,* pp. 47–54.

Dubey, V.N. and Crowder, R.M. 2006. A dynamic tactile sensor on photoelastic effect. *Sensors and Actuators a-Physical* 128(2), pp. 217–224.

Dünser, A., Grasset, R. and Billinghurst, M. 2008. A survey of evaluation techniques used in augmented reality studies. *ACM SIGGRAPH ASIA 2008 courses on* - SIGGRAPH Asia '08, pp. 1–27.

Dyck, P.J., Kratz, K.M., Karnes, J.L., Litchy, W.J., Klein, R., Pach, J.M., Wilson, D.M., O'Brien, P.C., Melton, L.J. and Service, F.J. 1993. The prevalence by staged severity of various types of diabetic neuropathy, retinopathy, and nephropathy in a population-based cohort: the Rochester Diabetic Neuropathy Study. *Neurology* 43(4), pp. 817–24.

Geng, B., Yoshida, K. and Jensen, W. 2011. Impacts of selected stimulation patterns on the perception threshold in electrocutaneous stimulation. *Journal of Neuroengineering and Rehabilitation* 8(1), p. 9.

Genthon, N. and Rougier, P. 2005. Influence of an asymmetrical body weight distribution on the control of undisturbed upright stance. *Journal of biomechanics* 38(10), pp. 2037–49.

Ghulyan-Bedikian, V., Paolino, M. and Paolino, F. 2013. Short-term retention effect of rehabilitation using head position-based electrotactile feedback to the tongue: influence of vestibular loss and old-age. *Gait & posture* 38(4), pp. 777–83.

Goldberg, A., Russell, J.W. and Alexander, N.B. 2008. Standing balance and trunk position sense in impaired glucose tolerance (IGT)-related peripheral neuropathy. *Journal of the neurological sciences* 270(1-2), pp. 165–71.

Hampton, G.H. 1979. Therapeutic Footwear for the Insensitive Foot. *Physical Therapy* 59(1), pp. 23–29.

Hatzivasiliou, F. V and Tzafestas, S.G. 1994. Analysis and Design of a New Piezoresistive Tactile Sensor System for Robotic Applications. *Journal of Intelligent & Robotic Systems* 10(3), pp. 243–256.

Hayward, V., Astley, O.R., Cruz-Hernandez, M., Grant, D. and Robles-De-La-Torre, G. 2004. Haptic interfaces and devices. *Sensor Review* 24(1), pp. 16–29.

Hijmans, J.M., Geertzen, J.H.B., Zijlstra, W., Hof, A.L., Postema, K. and Neurosciences, C. 2008. Effects of vibrating insoles on standing balance in diabetic neuropathy. *Journal of Rehabilitation Research and Development* 45(9), pp. 1441–1449.

Ilic, M., Vasiljevic, D. and Popovic, D.B. 1994. A programmable electronic stimulator for FES systems. *IEEE Transactions on Rehabilitation Engineering* 2(4), pp. 234–239.

Ishida, A., Masuda, T., Inaoka, H. and Fukuoka, Y. 2008. Stability of the human upright stance depending on the frequency of external disturbances. *Medical; Biological Engineering; Computing* 46(3), pp. 213–221.

Jorgovanovic, N., Dosen, S., Djozic, D.J., Krajoski, G. and Farina, D. 2014. Virtual grasping: closed-loop force control using electrotactile feedback. *Computational and mathematical methods in medicine* 2014, p. 120357.

Judy, J.W. 2001. Microelectromechanical systems (MEMS): fabrication, design and applications. *Smart Materials &; Structures* 10(6), pp. 1115–1134.

Kaczmarek, K. a. A., Webster, J.G.G. and Radwin, R.G.G. 1990. Periodic Variations In The Electrotactile Sensation Threshold. [1990] *Proceedings of the Twelfth Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, pp. 1060–1061.

Kajimoto, H. 2012. Electrotactile Display with Real-Time Impedance Feedback Using Pulse Width Modulation. *IEEE Transactions on Haptics* 5(2), pp. 184–188.

Kaptchuk, T.J., Goldman, P., Stone, D. a and Stason, W.B. 2000. Do medical devices have enhanced placebo effects? *Journal of clinical epidemiology* 53(8), pp. 786–92.

Kim, S.S., Won, J.C., Kwon, H.S., Kim, C.H., Lee, J.H., Park, T.S., Ko, K.S. and Cha, B.Y. 2013. Validity of the medical outcomes study sleep scale in patients with painful diabetic peripheral neuropathy in Korea. *Journal of Diabetes Investigation* 4(4), pp. 405–409.

Lee, H.-M., Cheng, C.-K. and Liau, J.-J. 2009. Correlation between proprioception, muscle strength, knee laxity, and dynamic standing balance in patients with chronic anterior cruciate ligament deficiency. *The Knee* 16(5), pp. 387–91.

Lesniak, D.R. and Gerling, G.J. 2008. Modeling the data transformations underlying touch sensation to further tactile feedback in neural prosthesis. *AMIA Annu Symp Proc*, p. 1022.

Liu, T., Inoue, Y. and Shibata, K. 2009. Development of a wearable sensor system for quantitative gait analysis. *Measurement* 42(7), pp. 978–988.

Madigan, M.L., Davidson, B.S. and Nussbaum, M.A. 2006. Postural sway and joint kinematics during quiet standing are affected by lumbar extensor fatigue. *Human movement science* 25(6), pp. 788–99.

Maheshwari, V. and Saraf, R.F. 2006. High-Resolution Thin-Film Device to Sense Texture by Touch. *Science* . 312, pp. 1501–1504.

Martell, J.W.S. and Gini, G. 2007. Robotic Hands: Design Review and Proposal of New Design Process. In: Ardil, *C. ed. Conference of the World-Academy-of-Science-Engineering-and-Technology*. pp. 85–90.

Mascaro, S.A., Member, S. and Asada, H.H. 2001. Photoplethysmograph Fingernail Sensors for Measuring Finger Forces Without Haptic Obstruction. *IEEE Transactions on Robotics & Automation* 17(5), p. 698.

Mason, J.L. and Mackay, N. a 1976. Pain sensations associated with electrocutaneous stimulation. *IEEE transactions on bio-medical engineering* 23(5), pp. 405–9.

Maurer, C., Mergner, T. and Peterka, R.J. 2006. Multisensory control of human upright stance. Experimental brain research. *Experimentelle Hirnforschung. Expérimentation cérébrale* 171(2), pp. 231–50.

McCarney, R., Warner, J., Iliffe, S., van Haselen, R., Griffin, M. and Fisher, P. 2007. The Hawthorne Effect: a randomised, controlled trial. *BMC medical research methodology* 7(1), p. 30.

Menold, P.H., Pearson, R.K. and Allg, F. 1999. Online outlier detection and removal. *In proceeding of: Proc. Mediterranean Conference on Control and Automation*. (1981), pp. 1110–1133.

Merians, A.S., Tunik, E. and Adamovich, S. V 2009. Virtual reality to maximize function for hand and arm rehabilitation: exploration of neural mechanisms. *Stud Health Technol Inform* 145, pp. 109–125.

Micera, S., Navarro, X. and Yoshida, K. 2009. Interfacing With the Peripheral Nervous System to Develop Innovative Neuroprostheses. *Ieee Transactions on Neural Systems and Rehabilitation Engineering* 17(5), pp. 417–419.

Nagel, S.K., Carl, C., Kringe, T., Märtin, R. and König, P. 2005. Beyond sensory substitution--learning the sixth sense. *Journal of neural engineering* 2(4), pp. R13–26.

Navarro, X., Krueger, T.B., Lago, N., Micera, S., Stieglitz, T. and Dario, P. 2005. A critical review of interfaces with the peripheral nervous system for the control of neuroprostheses and hybrid bionic systems. *Journal of the peripheral nervous system*: *JPNS* 10(3), pp. 229–58.

Oddo, C.M., Beccai, L., Felder, M., Giovacchini, F. and Carrozza, M.C. 2009. Artificial Roughness Encoding with a Bio-inspired MEMS-based Tactile Sensor Array. *Sensors* 9(5), pp. 3161–3183.

Olson, J.M., Ieee and Ieee, P.A.C.I.E.T. dSPACE C.A.I.A. 2007. Tactile display technologies as an enabler for space exploration operations. In: *Astronaut*, *IEEE Aerospace Conference*, pp. 4385–4396.

Parham, K.R., Gordon, C.C. and Bensel, C.K. 1992. Anthropometry of the Foot and Lower Leg of U.S. *Army Soldiers: Fort Jackson, SC -- 1985*. , p. 360.

Puangmali, P., Althoefer, K., Seneviratne, L.D., Murphy, D. and Dasgupta, P. 2008. State-of-the-Art in Force and Tactile Sensing for Minimally Invasive Surgery. *IEEE Sensors Journal* 8(4), pp. 371–381.

Puig, J.E.P., Rodriguez, N.E.N. and Ceccarelli, M. 2008. A Methodology for the Design of Robotic Hands with Multiple Fingers. *International Journal of Advanced Robotic Systems* 5(2), pp. 177–184.

Rolke, R., Baron, R., Maier, C., Tolle, T.R., Treede, R.-D.D., Beyer, A., Binder, A., Birbaumer, N., Birklein, F., Botefur, I.C., Braune, S., Flor, H., Huge, V., Klug, R., Landwehrmeyer, G.B., Magerl, W., Maihofner, C., Rolko, C., Schaub, C., Scherens, a, Sprenger, T., Valet, M., Wasserka, B., Tölle, T.R., Bötefür, I.C. and Maihöfner, C. 2006. Quantitative sensory testing in the German Research Network on Neuropathic Pain (DFNS): standardized protocol and reference values. *Pain* 125(1-2), p. 197.

Romano, J.M., Gray, S.R., Jacobs, N.T., Kuchenbecker, K.J., Ieee and Robot, I. 2009. Toward Tactilely Transparent Gloves: Collocated Slip Sensing and Vibrotactile Actuation. In: *Automat Soc, I. T. C. H. ed. 3rd Joint EuroHaptics Conference Symposium on Haptic Interfaces for Virtual Environment and Teleoperator Systems. Salt Lake City, UT: Ieee*, pp. 279–284.

Rosen, B. and Lundborg, G. 2007. Enhanced sensory recovery after median nerve repair using cortical audio-tactile interaction. A randomised multicentre study. *Journal of Hand Surgery-British and European* 32E(1), pp. 31–37.

Rosen, B., Ehrsson, H.H., Antfolk, C., Cipriani, C., Sebelius, F. and Lundborg, G. 2009. Referral of sensation to an advanced humanoid robotic hand prosthesis. *Scand J Plast Reconstr Surg Hand Surg* 43(5), pp. 260–266.

Rougier, P., Burdet, C., Farenc, I. and Berger, L. 2001. Backward and forward leaning postures modelled by an fBm framework. *Neuroscience research* 41(1), pp. 41–50.

Rupert, A.H. 2000. Tactile situation awareness system: Proprioceptive prostheses for sensory deficiencies. *Aviation Space and Environmental Medicine* 71(9), pp. A92–A99.

Safin, D.R., Pilshikov, I.S., Urakseev, M. a. and Migranova, P.M. 2009. Problems in Design of Neuro-controlled Prosthetic Devices. *Biomedical Engineering* 43(4), pp. 167–170.

Sheffler, L.R. and Chae, J. 2007. Neuromuscular electrical stimulation in neurorehabilitation. *Muscle & Nerve* 35(5), pp. 562–590.

Sun, Y., Hollerbach, J.M. and Mascaro, S.A. 2008. Predicting Fingertip Forces by Imaging Coloration Changes in the Fingernail and Surrounding Skin. *Ieee Transactions on Biomedical Engineering* 55(10), pp. 2363–2371.

Szeto, A.Y.J., Lyman, J. and Prior, R.E. 1979. Electrocutaneous Pulse Rate and Pulse Width Psychometric Functions for Sensory Communications. *Human Factors: The Journal of the Human Factors and Ergonomics Society* 21(2), pp. 241–249.

Taylor, C.L. and Schwarz, R.J. 1955. The anatomy and mechanics of the human hand. *Artif Limbs* 2(2), pp. 22–35.

Vallbo, A.B., Hagbarth, K.E., Torebjork, H.E. and Wallin, B.G. 1979. Somatosensory, Proprioceptive, and Sympathetic Activity in Human Peripheral-nerves. *Physiological Reviews* 59(4), pp. 919–957.

Varoqui, D., Froger, J., Pélissier, J.-Y. and Bardy, B.G. 2011. Effect of coordination biofeedback on (re)learning preferred postural patterns in post-stroke patients. *Motor control* 15(2), pp. 187–205.

Wild, S., Roglic, G., Green, A., Sicree, R. and King, H. 2004. Global Prevalence of Diabetes: Estimates for the year 2000 and projections for 2030. *Diabetes Care* 27(5), pp. 1047–1053.

Xu, X., Graham, J., Zhu, J.J. and Starzyk, J.A. 2012. A Biopsychically Inspired Cognitive System for Intelligent Agents in Aerospace Applications. In: *Infotech@Aerospace 2012 Conference*. pp. 1–13.

Yoshimitsu, K., Shiba, N., Matsuse, H., Takano, Y., Matsugaki, T., Inada, T., Tagawa, Y. and Nagata, K. 2010. Development of a Training Method for Weightless Environment Using Both Electrical Stimulation and Voluntary Muscle Contraction. *The Tohoku Journal of Experimental Medicine* 220(1), pp. 83–93.

Zatsiorsky, V.M. and Duarte, M. 2000. rambling and trambling in quiet standing balance control cop. *Motor Control* 4, pp. 185–200.

Zhang, D., Guan, T.H., Widjaja, F. and Ang, W.T. 2007. Functional electrical stimulation in rehabilitation engineering. *Proceedings of the 1st international convention on Rehabilitation engineering & assistive technology in conjunction with 1st Tan Tock Seng Hospital Neurorehabilitation Meeting*, p. 221.

Zwislocki, J.J. 2009. Sensory Neuroscience: Four Laws of Psychophysics: Four Laws of Psychophysics (Google eBook). Springer.