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An artificially-intelligent biomeasurement
system for total hip arthroplasty patient
rehabilitation

Ewan James Law



ROBERT GORDON
UNIVERSITY•ABERDEEN

This thesis is presented as part of the requirements of the
Robert Gordon University
for the degree of Doctor of Philosophy

November 2012

Declaration

I confirm that the material presented in this thesis is my own work and that all sources of material have been properly acknowledged.

Ewan James Law
12th November 2012

Abstract

This study concerned the development and validation of a hardware and software biomeasurement system, which was designed to be used by physiotherapists, general practitioners and other healthcare professionals. The purpose of the system is to detect and assess gait deviation in the form of reduced post-operative range of movement (ROM) of the replacement hip joint in total hip arthroplasty (THA) patients.

In so doing, the following original work is presented: Production of a wearable, microcontroller-equipped system which was able to wirelessly relay accelerometer sensor data of the subject's key hip-position parameters to a host computer, which logs the data for later analysis. Development of an artificial neural network is also reported, which was produced to process the sensor data and output assessment of the subject's hip ROM in the flexion/extension and abduction/adduction rotations (forward and backward swing and outward and inward movement of the hip respectively). The review of literature in the area of biomeasurement devices is also presented.

A major data collection was carried out using twenty-one THA patients, where the device output was compared to the output of a Vicon motion analysis system which is considered the 'gold standard' in clinical gait analysis. The Vicon system was used to show that the device developed did not itself affect the patient's hip, knee or ankle gait cycle parameters when in use, and produced measurement of hip flexion/extension and abduction/adduction closely approximating those of the Vicon system. In patients who had gait deviations manifesting in reduced ROM of these hip parameters, it was demonstrated that the device was able to detect and assess the severity of these excursions accurately.

The results of the study substantiate that the system developed could be used as an aid for healthcare professionals in the following ways:

- To objectively assess gait deviation in the form of reduced flexion/extension and abduction/adduction in the human hip, after replacement,
- Monitoring of patient hip ROM post-operatively
- Assist in the planning of gait rehabilitation strategies related to these hip parameters.

Keywords/phrases: Biomeasurement system, Total hip arthroplasty, Artificial neural network, Accelerometer, Physiotherapy, Gait analysis

Dedication

In loving memory of my dear Mother, Irene Elizabeth Leach; a brave lady and a model human being. It is because of you I am here, in every definition of that statement. You will forever be my hero.

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I would like to thank my directors of studies:

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Non-academically, I would also like to acknowledge the tremendous emotional support of my beloved Amy McMillan as well as James and Isobel Law, who have encouraged me to do my best, for as long as I can remember.

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Publications

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Contents

Leading Pages	i
Declaration	i
Abstract	ii
Dedication	iv
Acknowledgements	v
Publications	vi
Contents	vii
List of figures	xii
List of tables	xv
Chapter 1: Introduction	1
1.1 Background	1
1.2 Overview of the study	3
1.3 Facets of the study and thesis overview	4
1.4 Research objectives	5
1.5 Chapter summary	8

Chapter 2: Literature Review	9
2.1 Introduction.....	9
2.2 Literature review methodology	10
2.3 Hip revision surgery & post-operative gait	12
2.4 Gait analysis review.....	13
2.5 Biomechanical device review.....	14
2.6 Patent search.....	15
2.7 Artificial intelligence and ANNs in clinical applications	20
2.8 Chapter summary.....	23
Chapter 3: Methods	24
3.1 Scope of research.....	25
3.2 Recruitment of participants.....	26
3.3 Data collection phases	28
3.4 The use of Vicon MX Motion Analysis System	29
3.5 Live-action video cameras	31
3.6 Vicon MX control unit	31
3.7 Vicon system software	32
3.8 Gait laboratory preparation.....	33
3.9 System calibration.....	33
3.10 Measurement device initialisation	35
3.11 Subject arrival	35
3.12 Session preparation	35
3.13 Session execution.....	36
3.14 Subject debriefing	38
3.15 Data collection and processing protocol.....	39

3.16	Data integrity.....	40
3.17	Chapter summary.....	41
Chapter 4: Instrumentation Development.....		42
4.1	Introduction.....	42
4.2	Methodology	44
4.3	System development	45
4.4	Microcontroller interfacing	47
4.5	Microcontroller code development.....	47
4.6	Developed device sampling rate	48
4.7	Software methodology	49
4.8	Chapter summary.....	50
Chapter 5 Artificial Neural Network Development.....		51
5.1	Introduction.....	51
5.2	Software methodology	52
5.3	ANN data pre-processing	53
5.4	Neural network design	55
5.5	Training sets.....	57
5.6	Training algorithm	58
5.7	Training algorithm	59
5.8	Chapter summary.....	60

Chapter 6: Results	61
6.1 Introduction.....	61
6.2 Repeatability study	62
6.3 Main data collection	66
6.4 Assessment of the effect of the developed device on gait	68
6.5 Correlation of Vicon output compared to the developed device	72
6.6 Means of Vicon system output compared to developed device	80
6.7 Artificial neural network results	84
6.8 Vicon and developed device data comparison.....	88
6.9 Chapter summary.....	109
Chapter 7: Discussion	110
7.1 Introduction.....	110
7.2 Controller design & implementation	112
7.3 Software coding	114
7.4 Effectiveness of the presented system in identifying altered gait	118
7.5 Suitability of use as a physiotherapy aid for hip range of motion	128
7.6 Chapter summary.....	132
Chapter 8: Conclusions	133
8.1 Conclusions	133
8.2 Strengths and limitations of the study.....	134
8.3 Suggestions for follow on/future work.....	135

References:	136
Appendix 1: Patient Information Sheet	145
Appendix 2: Patient Consent Form	148
Appendix 3: Patient Reply-paid Envelope	149
Appendix 4: Summary Request Sheet	150
Appendix 5: Patient Travel-Expense Claim Form	151
Appendix 6: NHS Research and Development Approval	152
Appendix 7: Research Ethics Committee Approval	153
Appendix 8: Marker Placement Protocol	156
Appendix 9: Microcontroller Software Listing	157
Appendix 10: Microcontroller program flow diagram	161
Appendix 11: Vicon "Workstation" Operating Guide	162
Appendix 12: Control Unit Development	166
Appendix 13: Developed device User Manual	170
Appendix 14: Artificial Neural Network Software Listing ...	177
Appendix 15: Hardware prototype development	186

List of figures

<i>Figure 1.4.1: Thesis Map</i>	6
<i>Figure 1.4.2: Appendix list</i>	7
<i>Figure 2.2.1: Literature search and review strategy</i>	10
<i>Figure 3.1: Methodology-contributing factors.</i>	24
<i>Figure 3.4.1: The Human Performance Laboratory</i>	29
<i>Figure 3.4.2: Vicon Motion Analysis Camera</i>	29
<i>Figure 3.4.3: Kistler 9281B Force Plate</i>	31
<i>Figure 3.9.1.1: Force plates, 'L'-frame placement and calibration volume</i> .	34
<i>Figure 3.13.1: Data collection flowchart</i>	36
<i>Figure 3.13.2: C++ code segment for random number generation</i>	36
<i>Figure 3.13.3: Graphic of acceptable gait trial</i>	37
<i>Figure 4.1.1: Hip axes</i>	43
<i>Figure 4.2.1: Design Methodology for System Development</i>	44
<i>Figure 4.3.1: The Dimension Engineering 3-axis accelerometer</i>	45
<i>Figure 4.7.1: System block diagram</i>	49
<i>Figure 5.2.1: Software composition method</i>	52
<i>Figure 5.3.1: Sample data stream</i>	53
<i>Figure 5.3.2: Divided trial logs</i>	53
<i>Figure 5.3.3: Excel imported data</i>	54
<i>Figure 5.4.1: ANN topology</i>	56
<i>Figure 5.6.1: Backpropagation algorithm</i>	58
<i>Figure 5.7.1: Software testing overview</i>	59
<i>Figure 6.5.1: Flexion/extension scatter plot Device Vs Vicon</i>	77
<i>Figure 6.5.2: abduction/adduction scatter plot Device Vs Vicon</i>	78
<i>Figure 6.6.1: Flexion/extension waveform landmarks</i>	80
<i>Figure 6.6.2: abduction/adduction waveform landmarks</i>	82
<i>Figure 6.7.1: Hip peak flexion event ANN output histogram</i>	85
<i>Figure 6.7.2: Hip peak extension event ANN output histogram</i>	85

<i>Figure 6.7.3: Hip peak abduction event ANN output histogram</i>	87
<i>Figure 6.7.4: Hip peak adduction event fitness score histogram</i>	87
<i>Figure 6.8.1: Patient 1 hip flexion/extension waveforms</i>	88
<i>Figure 6.8.2: Patient 1 hip abduction/adduction waveforms</i>	88
<i>Figure 6.8.3: Patient 2 hip flexion/extension waveforms</i>	89
<i>Figure 6.8.4: Patient 2 hip abduction/adduction waveforms</i>	89
<i>Figure 6.8.5: Patient 3 hip flexion/extension waveforms</i>	90
<i>Figure 6.8.6: Patient 3 hip abduction/adduction waveforms</i>	90
<i>Figure 6.8.7: Patient 4 hip flexion/extension waveforms</i>	91
<i>Figure 6.8.8: Patient 4 hip abduction/adduction waveforms</i>	91
<i>Figure 6.8.9: Patient 5 hip flexion/extension waveforms</i>	92
<i>Figure 6.8.10: Patient 5 hip abduction/adduction waveforms</i>	92
<i>Figure 6.8.11: Patient 6 hip flexion/extension waveforms</i>	93
<i>Figure 6.8.12: Patient 6 hip abduction/adduction waveforms</i>	93
<i>Figure 6.8.13: Patient 7 hip flexion/extension waveforms</i>	94
<i>Figure 6.8.14: Patient 7 hip abduction/adduction waveforms</i>	94
<i>Figure 6.8.15: Patient 8 hip flexion/extension waveforms</i>	95
<i>Figure 6.8.16: Patient 8 hip abduction/adduction waveforms</i>	95
<i>Figure 6.8.17: Patient 9 hip flexion/extension waveforms</i>	96
<i>Figure 6.8.18: Patient 9 hip abduction/adduction waveforms</i>	96
<i>Figure 6.8.19: Patient 10 hip flexion/extension waveforms</i>	97
<i>Figure 6.8.20: Patient 10 hip abduction/adduction waveforms</i>	97
<i>Figure 6.8.21: Patient 11 hip flexion/extension waveforms</i>	98
<i>Figure 6.8.22: Patient 11 hip abduction/adduction waveforms</i>	98
<i>Figure 6.8.23: Patient 12 hip flexion/extension waveforms</i>	99
<i>Figure 6.8.24: Patient 12 hip abduction/adduction waveforms</i>	99
<i>Figure 6.8.25: Patient 13 hip flexion/extension waveforms</i>	100
<i>Figure 6.8.26: Patient 13 hip abduction/adduction waveforms</i>	100
<i>Figure 6.8.27: Patient 14 hip flexion/extension waveforms</i>	101
<i>Figure 6.8.28: Patient 14 hip abduction/adduction waveforms</i>	101
<i>Figure 6.8.29: Patient 15 hip flexion/extension waveforms</i>	102
<i>Figure 6.8.30: Patient 15 hip abduction/adduction waveforms</i>	102
<i>Figure 6.8.31: Patient 16 hip flexion/extension waveforms</i>	103
<i>Figure 6.8.32: Patient 16 hip abduction/adduction waveforms</i>	103
<i>Figure 6.8.33: Patient 17 hip flexion/extension waveforms</i>	104

<i>Figure 6.8.34: Patient 17 hip abduction/adduction waveforms</i>	104
<i>Figure 6.8.35: Patient 18 hip flexion/extension waveforms</i>	105
<i>Figure 6.8.36: Patient 18 hip abduction/adduction waveforms</i>	105
<i>Figure 6.8.37: Patient 19 hip flexion/extension waveforms</i>	106
<i>Figure 6.8.38: Patient 19 hip abduction/adduction waveforms</i>	106
<i>Figure 6.8.39: Patient 20 hip flexion/extension waveforms</i>	107
<i>Figure 6.8.40: Patient 20 hip abduction/adduction waveforms</i>	107
<i>Figure 6.8.41: Patient 21 hip flexion/extension waveforms</i>	108
<i>Figure 6.8.42: Patient 21 hip abduction/adduction waveforms</i>	108
<i>Figure 7.2.1: Final accelerometer-based device, as presented</i>	112
<i>Figure 7.3.1: Patient 8 hip flexion/extension waveforms</i>	116
<i>Figure 7.3.2: Patient 15 hip abduction/adduction waveforms</i>	117
<i>Figure 7.4.1.1: Device Vs Vicon comparison</i>	122
<i>Figure 7.4.1.2: Device Vs Vicon trend lines</i>	123
<i>Figure 7.4.1.3: Device Vs Vicon trend lines on grid</i>	125
<i>Figure 7.5.1: Patient 5 hip flexion/extension waveforms</i>	129
<i>Figure 7.5.2: Patient 19 hip flexion/extension waveforms</i>	130
<i>Figure 7.5.3: Patient 19 hip abduction/adduction waveforms</i>	130

List of tables

<i>Table 2.2.1: Keyword list</i>	11
<i>Table 6.2.1: Z-Scores of static marker placement repeatability</i>	64
<i>Table 6.2.2: Z-Scores for static marker placement repeatability</i>	64
<i>Table 6.2.3: Overall Homogeneity of Variances</i>	65
<i>Table 6.2.4: Analysis of variances</i>	65
<i>Table 6.3.1: Patient demographic data</i>	66
<i>Table 6.4.1: Comparison of means P-value</i>	70
<i>Table 6.5.1: Developed device hip flexion/extension normality scores</i>	73
<i>Table 6.5.2: Vicon system hip flexion/extension normality scores</i>	74
<i>Table 6.5.3: Developed device hip abduction/adduction normality scores</i>	75
<i>Table 6.5.4: Vicon system hip abduction/adduction normality scores</i>	76
<i>Table 6.5.5: Pearson correlation coefficient in hip flexion/extension</i>	79
<i>Table 6.5.6: Pearson correlation coefficient in hip abduction/adduction</i>	79
<i>Table 6.6.1: Paired samples statistics output: hip flexion/extension</i>	81
<i>Table 6.6.2: Paired samples T-test output: hip flexion/extension</i>	81
<i>Table 6.6.3: Paired samples statistics output: hip abduction/adduction</i>	83
<i>Table 6.6.4: Paired samples T-test output: hip abduction/adduction</i>	83
<i>Table 6.7.1: Artificial neural network peak flexion/extension output</i>	84
<i>Table 6.7.2: Artificial neural network peak abduction/adduction appraisal</i>	86
<i>Table 7.4.1: Marker placement Z-Score range</i>	119

Chapter 1

Introduction

Chapter Overview

This chapter describes the background and purpose of the study: the motivating factors for its inception and the associated research topics – both clinical and technical. In addition, this chapter describes the objectives used to validate the system which was developed to address the previously-unmet clinical need of a low-cost and portable system, able to detect gait abnormality in a patient which originates from reduced hip range of motion during walking, using artificial intelligence. The chapter concludes with a map of the thesis structure, giving a brief overview of the content of each chapter.

1.1 Background

Osteoarthritis (OA) currently affects around 3.4 million individuals over 65 in the United Kingdom, requiring an annual budget of £5.5 billion in care services, with an estimated 66% increase in OA-related disability by 2020 (Arthritis Research Campaign 2006). OA of the hip affects in excess of 150000 of these individuals in the United Kingdom, resulting in an estimated total health and social services cost of around £250M per year (Arthritis Research Campaign 2006). Total hip arthroplasty (THA) is one of the most commonly and widely used surgical procedures (Jan et al. 2004) in patients with advanced arthritic disorders of the hip where OA is the most common preoperative diagnosis in individuals between the ages of 65 to 74 years (Bertocci et al. 2004). THA has become successful in allowing people to enjoy an improved quality of life (Shelton 1996, Laupacis et al. 1993).

Physiotherapy plays an important role in the rehabilitation of THA patients with the main aims of regaining muscle strength, range of motion and

function (Jesudason and Stiller 2002). The effectiveness of these interventions will become increasingly important as the number of THA procedures performed grows, in accordance with a demographically older population.

Although THA usually results in a decrease of pain, improved function and more efficient gait, abnormal gait patterns have been reported in patients months and years following THA (Perron et al. 2000, McCrory, White and Lifeso 2001, Vogt et al. 2003).

If gait abnormalities are not treated, they degenerate and also affect the contralateral hip, through mechanical dysfunction (Loizeau et al. 1995), (Perron et al. 2000), or even to the point where a revision prosthesis is required, as a consequence of altered biomechanics (Madsen et al. 2004). Additionally, it has been demonstrated that atypical or pain-negating 'assumed' gait variations increases energy expenditure and can increase the risk of the person falling (Vogt et al. 2003).

As an effect of more THAs being performed, the demand on healthcare services will similarly increase, and, consequently, patients may not receive *any* physiotherapy input. Subsequently, there will be an impetus to more efficiently assist patients who present with gait deviations associated with THA and even in the encouragement for patients to take responsibility for their own management (Madsen et al. 2004, Miki et al. 2004).

The application of an artificial neural network, an example of an Artificial Intelligence software algorithm, has been shown to effectively model gait variables (Sepulveda, Wells and Vaughan 1993). Whereas many existing re-education tools are purely software-based, such as the system developed by (Mihailidis, Fernie and Barbenel 2001), the device presented here uses an artificial neural network within the biomeasurement system. The benefit of this is that actual, real-world data from the subject is collected and then processed, in order to evaluate hip ROM, which could then be used by a healthcare professional to relate the assessment data to the responsible muscle-groups which gave rise to the deviation. The advantage of using an

artificial neural network is that it is able to identify meaningful patterns in subtle, masked, and 'noisy' data sets, which a human observer may overlook. Artificial Intelligence has been shown to be useful for processing large-volume time-sensitive signals of this nature, such as the work of (BALLARD, D. 1995), in dynamic real-time expert systems in robotics.

1.2 Overview of the study

It was hypothesised that a device, such as that presented, could be useful in detecting muscle imbalance soon after hip-replacement. Any imbalance could give rise to undesirable hip-positioning and therefore altered gait pattern. This can result in dislocations, or eventual prosthesis damage which would require invasive maintenance or complete removal of the implanted joint and replacement with a new prosthesis (Morgan et al. 2004), which can only be performed a limited number of times.

The biomeasurement system which is presented in this thesis would allow healthcare professionals to objectively assess patients' hip flexion/extension and abduction/adduction, following THA. Should these parameters be measured to be abnormal in range, the purpose of the system is to identify the parameter responsible, producing quantitative data relating to the magnitude of lack of range of movement which intimate which mode of retraining would be required to progress towards an acceptable gait. It was theorised that this would have the effect of providing better quality of life for patients in terms of improved efficiency of locomotion and reduced risk of falls, with the associated preclusion of any further healthcare intervention and associated cost savings thereof.

1.3 Facets of the study and thesis overview

Following the literature-review, detailed in Chapter 2, the research objectives were formulated in order to identify those features which would be required to ascertain if a system could be used as a gait retraining tool. Following review of physiological and anatomical features associated with gait with the examination of relevant pathologies, an experimental design was formed, the method of which is detailed in Chapter 3.

The design and development of a biomeasurement device in Chapter 4 describes the hardware system and microcontroller code design. This software allows the microcontroller to use the sensors to gather the necessary data to allow the ANN in the system to recognise deviated hip flexion/extension and abduction/adduction, based on training sets (examples of extreme cases), which it has been programmed to recognise.

Chapter 5 details the design of the analysis mechanism for the system, an ANN. This software is an example of an artificial intelligence algorithm which was designed to recognise and infer abnormal features in the gait pattern of the subject.

In addressing the following research objectives, the suitability of use of the developed device was assessed, as a clinical tool which would allow physiotherapists to aid patients in facilitating the adoption of favourable hip positioning, consistent with the mechanical design of their implanted prosthesis.

An overview of the thesis layout and appendix overview is shown in Figures 1.4.1 and 1.4.2.

1.4 Research Objectives

Informed by gaps identified in current literature and clinical practice, the device was developed to meet the unmet clinical need for a low-cost, instrumented and portable device which healthcare professionals could use, to allow targeted rehabilitation and physiotherapy strategies to be formulated, based upon objective measures and artificial neural network (ANN) processing of hip movement following total hip arthroplasty.

Distilling these requirements into a deliverable system specification, the following research objectives were developed as the foundation of the study:

1. To design and implement an electronic controller for the system using suitable sensors and components, for the purpose of gathering hip-position data.
2. To code the necessary ANN to be able to recognise altered pattern of motion of the hip.
3. To critically assess the effectiveness of the system in identifying altered patterns of gait.
4. To test the system on a suitable number of subjects in order to evaluate if the system is suitable for use as a physiotherapy diagnostic and detection aid for gait, based on Vicon and qualitative analysis.

Thesis Map and Appendix Overview

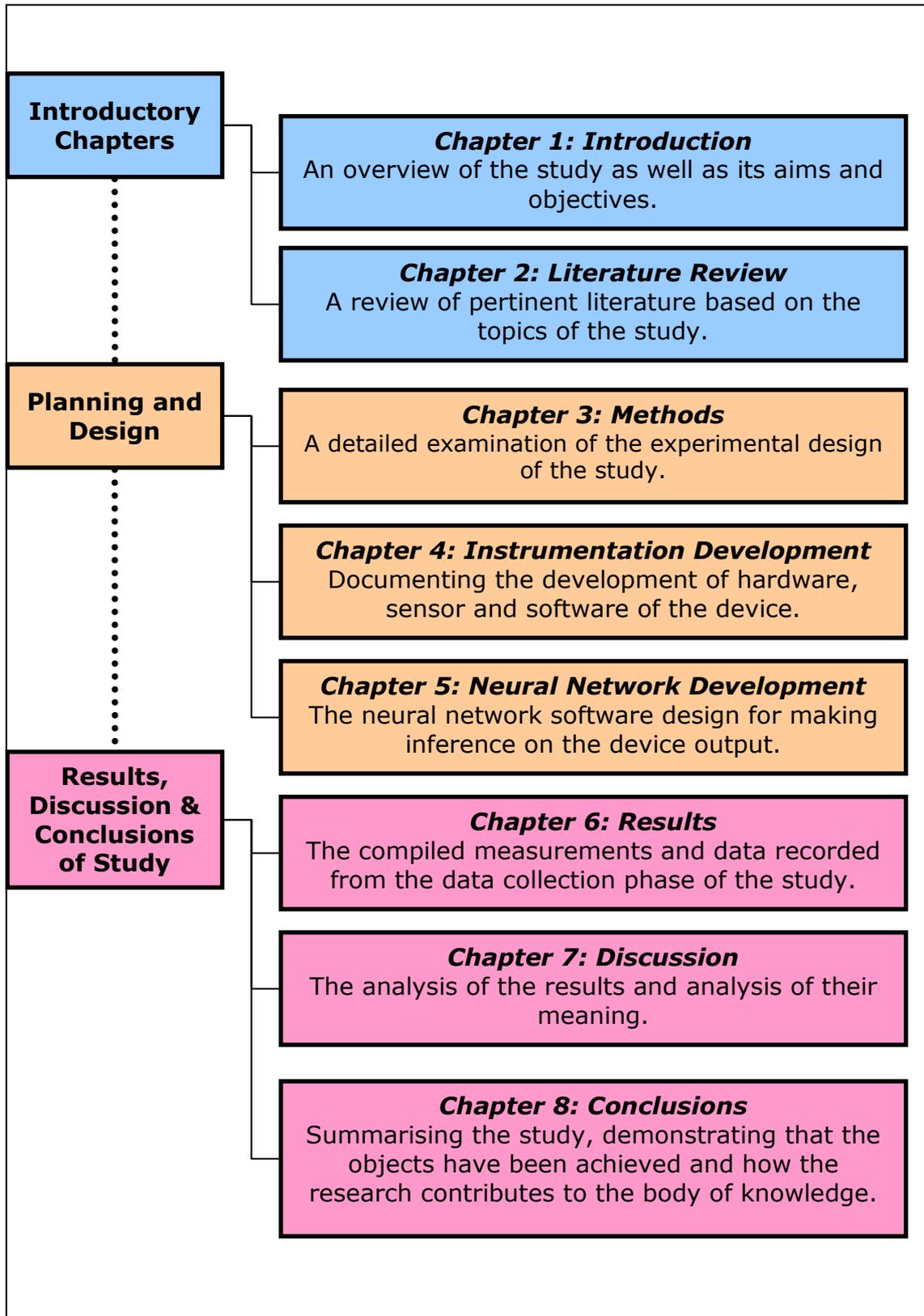


Figure 1.4.1: Thesis map

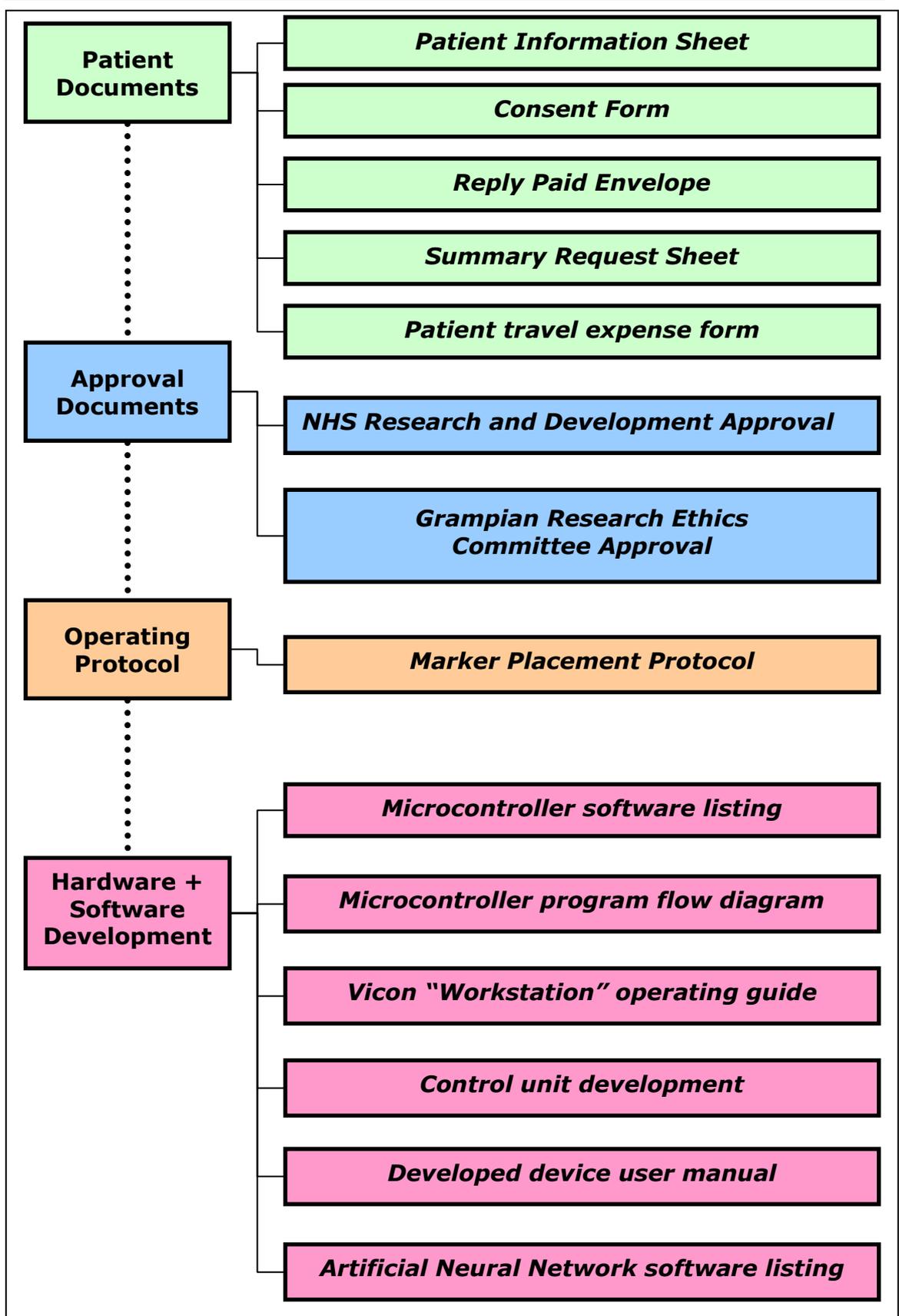


Figure 1.4.2: Appendix list

1.5 Chapter summary

This chapter has described the study in terms of scope and objectives, as well as the physical layout of the thesis. Following formulation of the aims and objectives, a review of current literature was undertaken, as described in the following chapter, so that previous work in this area could be evaluated.

Chapter 2

Literature Review

Chapter Overview

This chapter describes how the review of literature was performed on the main topics of the research. These topics were critically examined and discussed in order to discover what previous work, if any, had been undertaken.

2.1 Introduction

Due to the interdisciplinary nature of the study, literature from biomechanics, clinical studies, artificial intelligence applications, specifically artificial neural networks and existing biomedical devices was reviewed in order to assess what mechanisms and systems are currently in place for hip replacement patients. This information was used to make informed decisions on all aspects of the study such as experiment and methodology design, hardware and software composition as well as the interpretation and evaluation of data in order to optimise both the study and the system design so as to best serve its purpose.

2.2 Literature Review Methodology

Due to the substantial volume of literature for the technological, biomechanical and physiological facets of this research subject, it was decided from the outset that a filtering and review methodology be adopted as described on the following pages to manage the throughput and topics of the information concerned, as summarised in Figure 2.2.1.

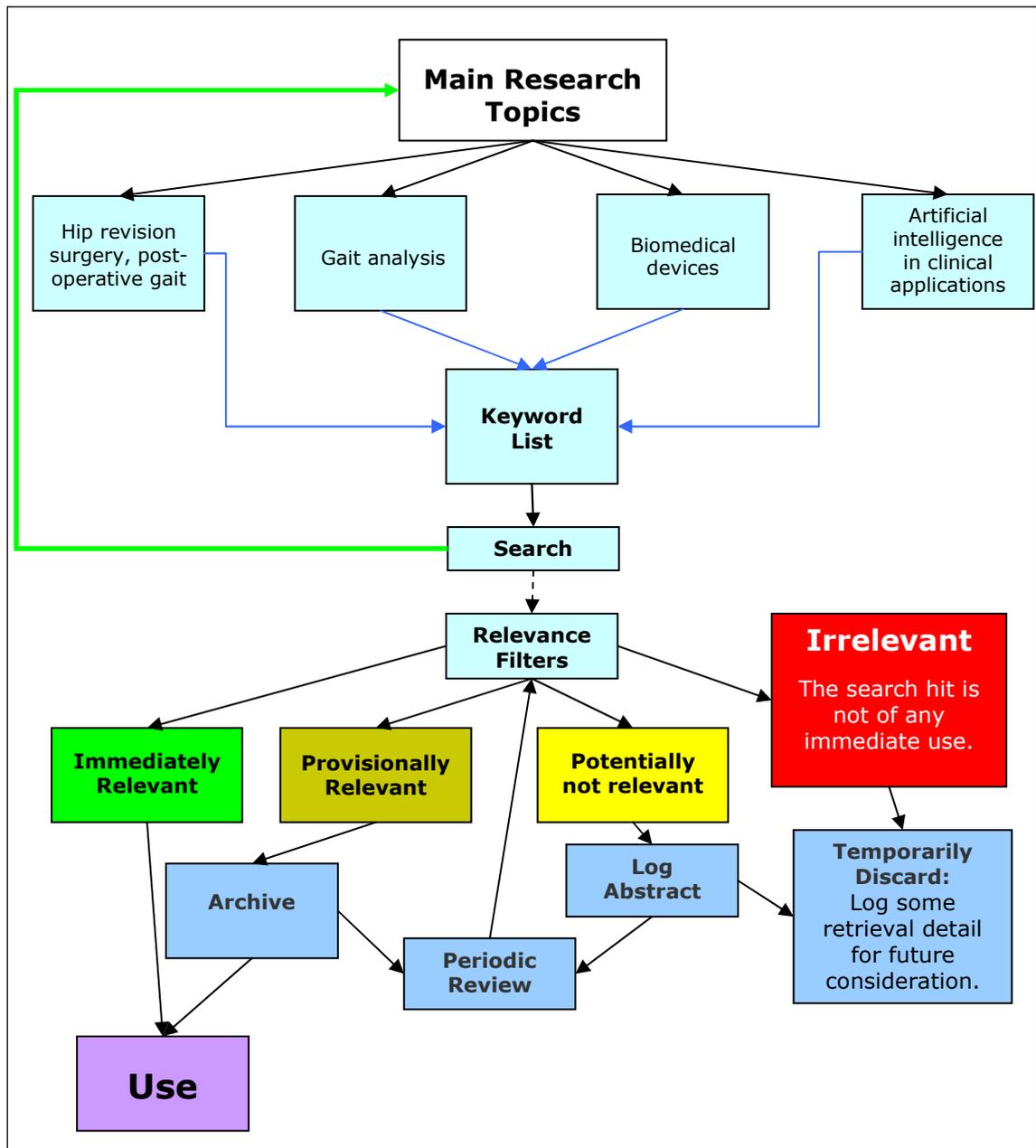


Figure 2.2.1: Literature search and review strategy

With reference to Figure 2.2.1, the main research facets were identified to be:

- Hip revision surgery & post-operative gait
- Gait analysis
- Biomedical devices
- Artificial intelligence in clinical applications

Using each of these headings, keywords were derived which were relevant to each super-topic and to interdisciplinary areas. The search itself was then performed using library and internet resources in order to find work published in the English language, related to these topics and using the keywords shown in Table 2.2.1. The literature which was found was then subject to a check against the main areas for relevance and specificity, in order to evaluate its usefulness and to be considered for use in the literature review. As shown, this was graded from being of *immediate* use, to being of *potential* use in the review. Online databases were used for the search involving technical, engineering and life science journals as well as conference and workshop proceedings.

This process passed through several iterations until a satisfactory depth and breadth of information was gained; the stopping point for the literature review was identified to be where the study was underpinned soundly in all regards with respect to current literature.

LITERATURE DATABASE SEARCH TERMS AND KEYWORDS		
Biomeasurement devices	Artificial neural networks	hip structure & function
Sensor technologies	Architectures	pathologies of the hip
Portable designs	Training methods	Hip prostheses
Sensor interfacing	Healthcare applications	Hip Orthotics
Microcontroller selection	Advantages of use	biofeedback systems
		A.I. augmentation of biofeedback systems
		Biomechanics of gait
		Gait analysis

Table 2.2.1: Keyword list

2.3 Hip revision surgery & post-operative gait

In reviewing hip pathology and anatomy with respect to this research, the biomechanics of the human hip as well as its structure and function were investigated. In addition, the topics of hip failure and gait abnormality following surgery were also examined.

THA is the normal surgical intervention and amongst one of the most common surgical procedures (Jan et al. 2004). Ackerman and Bennel 2004, McCrory, White and Lifeso 2001, Madsen et al. 2004 and, Perron et al. 2000 have shown that arthroplasty may afford pain-relief and increase range of motion, which has the effect of increasing the mobility for the patient, as well as decreasing the risk of falls, as reported by Trudelle-Jackson, Smith 2004 and Brander, Mullarkey and Stulberg 2001).

However, post-operatively, it has been observed that gait can become affected in terms of altered (pain-lessening) pattern of gait (Oken et al. 2010, Sariali et al. 2009) and it is thought that the choice of surgical technique may have a bearing on the degree to which pathologies will manifest, depending on what approach is adopted (Whatling et al. 2006, Jolles and Bogoch 2006).

The purpose of physiotherapy following total hip arthroplasty is to assist in the relief of pain, improve function and provide stability (Lombardi, Berend and Mallory 2005, Shelton 1996, Jesudason and Stiller 2002). The device developed in this study was designed to more quantitatively inform healthcare professionals if hip parameter(s) (flexion/extension/abduction/adduction) in a patient are sub-normal.

Gait abnormalities that may present postoperatively may affect patients in the mid to long term (Perron et al. 2000). If left untreated, these abnormalities may lead to deterioration of gait, increased risk of falls and eventually the need for revision (Loizeau et al. 1995). This, coupled with the fact that a larger number of replacements are performed in line with an increasingly aging population, as reported by (Casiano et al. 2002),

suggests that an increasingly efficient aftercare attitude must be adopted to cater for these individuals and the associated patient throughput rate (Freburger 2000, Heine, Koch and Goldie 2004).

2.4 Gait analysis review

Should gait become altered following THA, gait analysis may be used in order to detect the severity and the nature of the underlying problem and be used to formulate a strategy for physiotherapy or other remedial intervention.

Visual observation of gait tends to be the in-field choice for physiotherapists, who use their own subjective methods to assess gait quality (Toro, Nester and Farren 2003). Although the reliability of visual gait appraisal has been shown to increase with clinical experience, patients with orthopaedic disorders, THA patients in this case, are not routinely studied, as described by (Brunnekreef et al. 2005).

Microprocessor-based systems on the other hand are known to produce valid and reliable output for THA measures. Perron's work for example evaluated hip extension using an Optotrak system (Perron et al. 2000) demonstrates this.

The drawbacks of instrumented gait analysis, although considered the gold standard, are high cost, dedicated laboratory space, as well as trained operatives (Toro, Nester and Farren 2003).

Consequently, there exists an unmet clinical need for a low-cost, portable system which features some form of biomeasurement device, with output analysis to assess hip range of movement.

2.5 Biomechanical device review

Literature pertaining to current biomedical devices was reviewed in order to establish if any devices existed which would be capable of providing the data for this study. In reviewing these devices, factors such as the sensors, signal processing techniques and interpretation of the output data were appropriate for use either directly, or as having favourable attributes which would be useful in the design of a custom device.

In addition to this, the use of such devices as physiotherapy tools and practices were examined to determine how current devices have been integrated into clinical use and their practical effectiveness when compared to human interpretation alone (Genet et al. 2007).

Biomeasurement systems and devices have been used to infer gait parameters by using laboratory-based systems (Zijlstra and Hof 2003) as well as portable devices (Moe-Nilssen and Helbostad 2002). The application of accelerometry in these studies has been used as the sensing technology in the detection of the gait cycle events and shown to produce useful graph-based output which would, however, require analysis and interpretation.

A system which was designed to appraise rehabilitation progress using unspecified kinematics sensors has proven effective in a longitudinal study of shoulder pathology following surgery (Coley et al. 2004). Angular velocities and range of movement were used in healthy versus pathological side comparison and produces a more objective output in the form of logs corresponding to the measured values.

An intelligent knee, ankle and foot orthotic has been developed which uses a sensor network to detect the positioning of the lower leg and features actuators to physically limit how far the user can move. This approach was used in order to re-familiarise the patient to a prescribed range of motion (Moreno, Brunetti and Pons 2004). However, this presents a potential safety and therefore ethical issue of the application of this device to a clinical

setting since the use of abrupt decelerative forces to hard-limit movement may present a tripping or falling hazard as a result.

In terms of passive devices and systems specific to THR, a lab based system has been shown to produce highly accurate results using correlated motion capture and Computer Tomography (CT) (Hagio et al. 2003); however, this device was lab-bound and expensive due to the use of CT technology.

A device which addresses the issue of portability and has also been shown to remove the subjectivity from visual appraisal is Physilog[®] (Aminian et al. 2004). This device consists of a frame which the subject moves inside and which produces tabulated output of gait parameters, which may not be appropriate in the clinical environment, due to the interpretation of the output, which requires time to decode and evaluate.

This labour-intensive, subjectively-interpreted approach would seem to suggest a need for a more practical, portable system comprising a passive sensing architecture for clinical use, which will produce informed, unambiguous and automatic analysis of output from the biomeasurement sensing component.

2.6 Patent search

As part of the instrumented gait analysis review, an examination of pertinent patent applications was conducted to determine what pre-existing devices were available, their operating principles and if any functionality deficiencies could be catered for in the device to be constructed in the study. The patent application review covered not only entire systems, but also novel and emergent sensor technologies which could be utilised in the device design phase. Other key attributes of the systems under review included portability, data output mode, subject interface and general user-friendliness.

Several gait related bio-measurement and rehabilitation-assistive devices reviewed consist of stationary measurement apparatuses, wherein the individual under test is asked to perform movement(s) within some prescribed capture volume. Matjacic and Sinkjaer's balance re-trainer system, for example, uses a fixed framework which the subject is fastened into and a two-degrees-of-freedom assembly is utilised in order to measure, and retrain the knee extensor muscles (Matjacic, M. and Sinkjaer, T. 2003). The patent alludes to a computerised system to which the balance rig is attached, but does not explicitly describe the operating principal. The benefits of this system are noted to be that the subject is physically supported within the apparatus, allowing isolated training of the knee extensors. However, the system design has removed the feasibility of it being used as a mobile, multipurpose platform for gait retraining.

Einav has similarly patented a system for holistic lower-body balance retraining (Einav, O. 2005). In this chair-based system, the legs of the subject are mechanically moved alternately resulting in postural changes that are claimed to manipulate and rehabilitate the spine and other lower-body faculties with the intention of improving muscle tone and range of movement within the subject. Although this system, by design, would be suitable for highly immobile persons, the delivery of the therapy offered by the system appears to be largely untargeted; the manipulation of the subject by the controller is arbitrary. A more targeted, multijoint system was designed by Scott (Scott, S.H. 1999). This system is capable of offering a resistive load to the joints of the subject and the angular position of each is able to be monitored. This system provides multiple configurations for exercise and monitoring of different joints and so is a more general, multi-use system, but one which offers targeted rehabilitation to the user. The system is confined to a stationary apparatus, so its use in dynamic gait is not possible. In addition, the patent makes no mention of automated or computerised interfaces for measurement readout or control so it is unclear if this device must be used and adjusted by a supervising individual. The final static system reviewed was a hip-flexion measurement device proposed by Mora (Mora, V.J. 2004). The form factor of the device is a stand with a single-axis joint which is overlaid on the hip centre of

flexion/extension of the subject under test. This device is very specific in application, passively measuring the flexibility of the ischiotibial muscles while the subject flexes the hip and displaying the peak flexion angle on a mechanical, graduated dial. This device is simple in operation, but affords a very functional appraisal of a key component of gait which affects such gait-cycle parameters as step and stride length. Being that this device is not automated, it relies on a third-party for measurement and analysis of the result.

Portable devices for gait retraining also exist and differ widely in design, purpose and target environment. For example, a wearable electrogoniometer patent has been filed by Raftopoulos (Raftopoulos, D.D. 1981) which features a pedometer and angle display of the joint under test. The measuring element is an encoder whose output is used to calculate relative position of the goniometer arms. The nature of the encoder is not explicitly stated, but due to the fact that its function is to measure angular position, the choice of sensing element is limited to either potentiometer, Gray wheel or slotted optical disk technologies. The main drawbacks of this system are twofold: firstly, the design of the goniometer hinge is extremely bulky and restrictive, which would almost certainly introduce asymmetrical loads to the wearer and also interfere in arm swing and femoral musculature operation due to its necessary restrictive design. Secondly, although there are ball-joints mentioned in the patent for the purpose of absorbing cross-axis movement, there is no axial travel afforded by the device. Consequently, this design is fraught with the same issue that was apparent in the first generation device in this study, namely, that as hip flexion increases, the angle between thigh and trunk diminishes and as does the distance between the femoral and abdominal coupling elements also decreases resulting in the hinge arms having no escape path and tending to collapse into the wearer. The invention of Lissek et al is a computerised, one degree of freedom hinge-based system for orthopaedic measurement of full range or relative point-to-point joint angle measurement (Lissek, K. 2004). The instrumentation aspects of the patent are only very loosely referred to, the patent concentrating on a more methodological description and application of the device submitted.

Although not associated with gait, the operating principal of Kramer's device for measuring animate links of the human finger is noteworthy in design and operation as it is able to measure multi-joint angular position in multiple axes (Kramer, J. 2000). The device features an instrumented armature in which all joints of the finger are replicated and whose joint centres are equipped with (undisclosed) sensing elements. The readings of these sensors can be used to calculate relative segment angles of the finger. The aforementioned joint compression issue would also affect this device as there appears to be no linear extension and compression aspect to the inter-joint couplings.

Electromagnetic joint angular position is used in the invention by Reis (Reis, M.T. 1998). In this system, a transmitter is used to track the position of two wired sensors in three-dimensional space, in order to provide both angular and translational data of each. By placing one sensor on a fixed position, adjacent to the joint of interest, and one adjacent to the joint where the segment movement will give rise to a differential output with respect to the other sensor, the data from the system can then be used to calculate relative joint position. True portability of the device is negated by the existence of the sensor wiring, although the transmitter range and long sensor connections would allow somewhat remote data capturing. A commercial application of this technology exists in the "Fastrak" system, manufactured by Polhemus (Polhemus, Michigan, 2002).

A truly portable, instrumented system was registered by Prichard (Prichard, R. 2005). This device uses a single accelerometer in order to measure and display, onboard the device, accelerative and decelerative magnitudes of the segment to which the device is attached. Since it does not translate this magnitude into tilt, the applications of this device may be limited to pedometry, activity monitoring or similar general measurements. In addition, the device offers no data logging or broadcast features: the only output information is via a single-row, text LCD readout where the device displays peak and current acceleration/deceleration encountered. A system submitted by Song, et al (Song, C.G., Seo, J.H., Kim, D.W., et al. 2003) uses bio-impedance measurement of muscles attributable to joint

movement. The method is described where a low current source is applied across muscles adjacent to the joint of interest and voltage-measuring electrodes to measure the potential difference across the joint. No publication on the accuracy or implied safety issues of this device are available. A more passively-operating system was submitted by Sihvonen (Sihvonen, T. 2004) . This device uses electromyography (EMG), an approach which uses electrical activity in muscles, in order to measure joint movement and function. This device is designed to be used before and after an intervention has taken place in order to compare pre and post intervention data. Strictly speaking, this system does not act as a motion capture system, as the EMG signal can not be used to directly infer resultant joint position, but as a retraining or rehabilitation device, it provides a useable benchmark for a healthcare professional to work towards.

For almost all of the patents under review, a high-level description of the underlying technologies is omitted in the patent listing in order to increase the security of the intellectual property of the inventor. However, the review of existing devices serves as a useful starting point and afforded an opportunity to develop a device for this study which could be used in three-dimensional position measurement of the human hip.

2.7 Artificial intelligence and artificial neural networks in clinical applications

The application of artificial intelligence (A.I.) software techniques in medical applications was explored in order to assess their suitability for use as bio-measurement device controllers and in pattern recognition of biological processes.

The benefits of using A.I. in such a system were also reviewed as well as the more practical aspects such as selection of A.I. technique to be used, interfacing the real-world quantities measured by the system sensors and how inferences, based on these values, could be made.

In terms of re-education tools, pure software-based systems are currently in existence. Mihailidis developed a program designed for individuals affected with dementia. The program runs a personal computer and aids the user in performing a series of motions associated with completing a task. Apparent limitations of this are portability (which could be overcome with more portable hardware), and the ability of the novice user, or subject themselves, to operate the program and interpret its responses (Mihailidis, Fernie and Barbenel 2001).

In the area of biofeedback, orthotics and intelligent systems, one current approach is Dynamic Real-Time Expert Systems. Ballard's work in this field concerns processing of large-volume time-sensitive signals in robotics (Ballard, D. 1995). Applying this type of system to an orthotic has distinct advantages in terms of processing speed and scalability; additional system hardware components or functionality may be added and the system need only be retrained.

The application of an artificial neural network (ANN) software algorithm has been shown to effectively model gait variables also (Sepulveda, Wells and Vaughan 1993), specifically, temporal gait patterns. Chau reports that the analysis and classification of gait data is enabled by ANNs as they are highly flexible and have the ability to model non-linear data, unlike other approaches (Chau, 2001). Furthermore, Yoo describes how the backpropagation algorithm was successfully used to train an ANN to recognise an individual's gait pattern using computer vision as the input. This suggested that a network designed to process gait waveforms would be feasible (Yoo et al, 2008).

Gait data has also been studied using an ANN by Barton and Lees (2005). In it, hip-knee joint angles from an optical motion capture system were retroactively processed with the neural network in order to classify patterns into normal and pathological groups. Consequently, the ANN output did not form any kind of continuous rating on the data that were captured, only broad classification and, additionally, the system used a lab-confined signal source.

ANNs have also been used successfully in signal processing applications in biometric measurement analysis, for example, using neural networks in predictive detection of respiratory disorders in premature babies (Dybowski and Gant 2001). This has overcome the problem that previously-existing techniques were unable to identify easily.

Frederic's work examines how a human and an ANN interpret EEG (electroencephalogram) output in sleep disorders and describes how a sleep pathology was investigated, with the ANN frequently out-performing the expert (Frederic and Nizar 2006).

Further studies on ANNs processing EEG signal characteristics appear in Tagluk's experiment of Sleep Apnea Syndrome (SAS). The results were suggest that the use of an ANN could speed throughput time in identifying SAS from EEG signals (Tagluk, Akin and Sezgin 2010).

In other bio-signal processing applications, Cathers's work describes how the noise emitted by the heart (cardiac auscultation) can provide information on how healthy it is, and that this method is often used by doctors but can take significant time, in the order of years, to master (Cathers 1995). He comments that a combination of signal processing techniques and ANNs could produce an automated heart sound classification and this would be very useful in diagnosing such heart conditions. In a related study, Akhbardeh focuses on the detection of heart problems, but using ballistocardiography (BCG) where ANNs can provide automatic signal classification and, since no electrodes need to be attached to the body during measurement, the patient could be potentially monitored in their home environment (Akhbardeh, Junnila and Koivistoinen 2007). Further examples include work by Liang and also Guler, who use artificial intelligence in surface electrogastrograms (EGG) for studying the electrical activity of the stomach (Liang, Lin and McCallum 2000) and for reduced blood vessel diameters (Guler and Derya 2003).

Following the review, it was decided that, due to their success in these applications, the logical choice for signal analysis in the study was an artificial neural network.

2.8 Chapter summary

In reviewing the relevant literature, potential gaps in both research and product markets were identified, allowing the objectives of the study to focus on the target application.

From a product development point of view, re-affirming the purpose of the 'product' assisted in the design of its functionality and afforded a view of the scope and plan of the research as a whole.

Chapter 3

Methods

Chapter Overview

Following the review of literature, the knowledge gained was used in the experimental design, with the purpose of addressing the aims of the study. This chapter describes and justifies the selection processes for the conceptualisation, execution and analysis phases of the research. Figure 3.1: *Methodology-contributing factors*. shows the main elements contributing to, and developing from the study methodology.

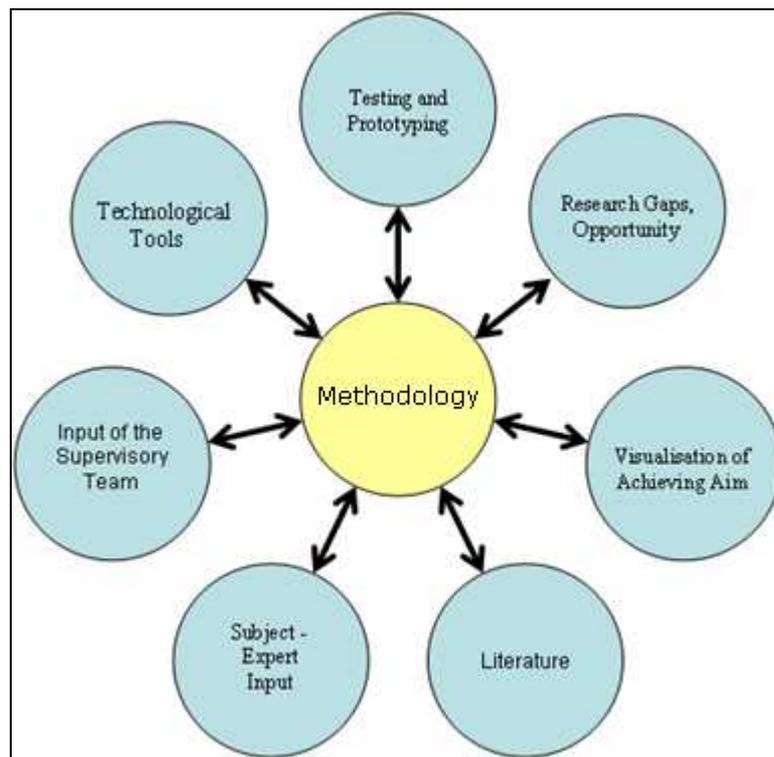


Figure 3.1: *Methodology-contributing factors*.

3.1 Scope of research

Financial Resources

The main financial resource of the project was supplied in the form of the Research Development Initiative budget allocation of £450 per year of study. This amount was used to purchase all of the tools, components and equipment which were required to construct the hardware elements of the research. Reimbursement of the subjects' travel expenses (if required), as well as the commercial orthotic from Orthomerica, were approved for purchase using the School of Health Sciences departmental budget.

Human Resources

The human resource requirements of the study involved the following groups of people:

- A convenience sample of MSc Physiotherapy students ($n = 12$) for initial performance evaluation of the device- field testing, debug, software and hardware refinement.
- The hip-replacement subjects (inclusion and exclusion attributes detailed in 3.2.2), which were used to assess the performance of the final revision system in detecting gait deviation consisted of two sub-groups:
 - Ten individuals for a pilot study
 - Eleven additional individuals for the main study
- The principal investigator of this study, as motion capture equipment operator, during the data collection phases of the study.

3.2 Recruitment of Participants

3.2.1 Recruitment personnel

A consultant orthopaedic surgeon at Woodend Hospital, Aberdeen was approached to refer THA patients for the purposes of study. A meeting with the consultant orthopaedic surgeon was organised in order to develop comprehensive patient inclusion and exclusion criteria, ensuring a standardised framework to match to potential patients.

A research nurse was identified to examine the medical records of pre-operative total hip arthroplasty candidates and issue them with a copy of the pre-prepared information document, shown in Appendix 1 and the reply-paid envelope shown in Appendix 3. The information sheet included a study overview in straightforward, basic terms as well as a detailed description of what their participation will entail and finally a reply slip to indicate interest in the study, either to request contact for additional information and/or to participate in the study.

3.2.2 THA Subject inclusion and exclusion criteria

Inclusion criteria:

- Primary total hip arthroplasty patients.
- Patients who received the procedure as a result of osteoarthritis.
- Patients who received an Exeter-type prosthesis (the hip device used in the majority of THAs) by anterolateral surgical technique.
- Female patients aged between 60 and 70 years (chosen to maximise the strength of statistical tests as they are more prevalent than male patients).
- Patients who were comfortable to wear shorts and the Vicon retro-reflective markers attached with double-sided, hypoallergenic adhesive tape and an unobtrusive waist and thigh-worn orthotic (see Patient Information Sheet, Appendix 1).
- 6 to 10 week post-operative patients.

Exclusion Criteria:

- Subjects who had previous hip pathologies resulting in surgical intervention.
- Subjects who had gait deviations not immediately related to the hip.

The exclusion criteria were selected to discount other effects, from previous hip-related issues, from potential gait-affecting interaction with the most surgery.

3.2.3 Ethical Approval

Prior to receiving patients who had undergone total hip arthroplasty, ethical approval was sought in order to evaluate the study in terms of its ethical management and highlight any areas which could have compromised patient safety, integrity or confidentiality. Approval was granted by Grampian Research Ethics Committee on the 4th January 2007 (reference number 06/S0802/125) and NHS Research and Development registration of the study was confirmed on the 18th January 2007 (reference number 2007RG002). The documents are shown in appendices 6 and 7.

3.3 Data collection phases

Pre-pilot data collection

This data collection was a full hardware test in order to establish if the system were capable of capturing the desired data. The subject set consisted of the 2006/2007 MSc Physiotherapy cohort (age range 20 to 41, 23 female, 4 male) in order to obtain a sample data set to assess and develop the instrumentation and data capturing protocol.

Pilot study

The pilot study consisted of ten individuals, from a population of total hip arthroplasty patients, recruited from NHS Grampian, who satisfied the criteria described in section 3.3.2. They were subjected to the operating protocol described in section 3.8.

Main Study

Following analysis of the pilot study data, the main data collection phase was then carried out using an additional 11 subjects of the same criteria as the pilot study.

3.4 The use of Vicon MX Motion Analysis System

The Robert Gordon University Human Performance Laboratory, within the school of Health Sciences was the venue for the testing phase of the research (Figure 3.4.1).



Figure 3.4.1: The Human Performance Laboratory

The Laboratory is equipped with a Vicon MX three-dimensional motion analysis system, which was used to capture the movement data from both the subjects. The laboratory set-up includes the items of equipment which appear in the following sections.

Vicon Cameras

Associated with the system were seven infra-red sensitive video cameras. These cameras were interfaced with the control unit using a *Vicon MX Net* unit.



Figure 3.4.2: Vicon Motion Analysis Camera

With reference to Figure 3.4.2:, each camera consists of a ring of Infra-Red (I.R.) Light-emitting Diode (LED) strobe ring, which pulses IR light, which reflects off the markers attached to the subject, back to the IR-transmissive lens filter of the camera, before being acquired by the Charge-Coupled Device (CCD) at the centre of the strobe ring.

Ground reaction force sensing plates

The laboratory is also equipped with two Kistler 9281B force-platforms, as shown in Figure 3.4.3 (Kistler, Hampshire, UK), which are used to measure ground reaction forces in order for the system to calculate the kinetic data parameters of the subject.



Figure 3.4.3: Kistler 9281B Force Plate Source:Kistler

The force plates contain piezoelectric sensing elements which output a magnitude of charge representative of the applied force. The output of the force plates is amplified by *Kistler type 9865B 8-channel charge amplifiers* in order to obtain a useful signal before passing to the Vicon Control Unit.

3.5 Live-action video cameras

The laboratory features one Panasonic M10 and one F10 live-action video cameras to capture footage of the subject during the motion capture session. This video footage provides coronal and sagittal plane reference for visual appraisal and corroboration with the system output. The signals from the cameras are mixed using a *Panasonic WS-MX12 Digital Production Mixer* and displayed on a *Panasonic TX21T1 television*.

3.6 Vicon MX Control unit

The role of the Control Unit in the Vicon system is to interface and synchronise the camera feeds, force place data and the live reference video from the live-action cameras.

3.7 Vicon system software

A *Dell Workstation PWS470*¹ was used to execute the software associated with data collection and results processing, and consisted of the following:

Workstation (Version 5.2.7)

The Workstation software allows the system to monitor the hardware described above, calibrate the system and to capture data. The program also allows for databases to be made and sub-trees for each project, subject set and individual participant. Appendix 11 details the operating procedure used to capture data using the system.

Polygon Authoring Tool (Version 3.1, Build 2.1)

The Polygon software package allows access to the subject database and is able to import data from it allowing for the creation of gait analysis reports for plotting, manipulation and export.

¹ Contains Intel 3.2GHz Xeon Processor, 1Gb RAM and uses Microsoft Windows XP operating system with Service Pack 2.

3.8 Gait laboratory preparation

The gait laboratory was prepared by ensuring all materials, such as tapes, markers, batteries, etc, were in abundant supply. To negate session disruption, "no-entry" signage was attached to the laboratory doors to ensure no disruptions or breach of subject privacy. The floor of the laboratory was swept to ensure that no debris was present that could pose a health and safety risk to the participant, who was bare-footed throughout the session.

3.9 System Calibration

The Vicon system was powered on and calibrated in the manner described overleaf, in line with the system operating manual.

3.9.1 Static Calibration

An 'L'-Frame, featuring retro reflective markers, was placed on the force-plate farthest from the workstation (Y+ axis), at lower left-hand corner (shown in red in Figure 3.9.1.1):

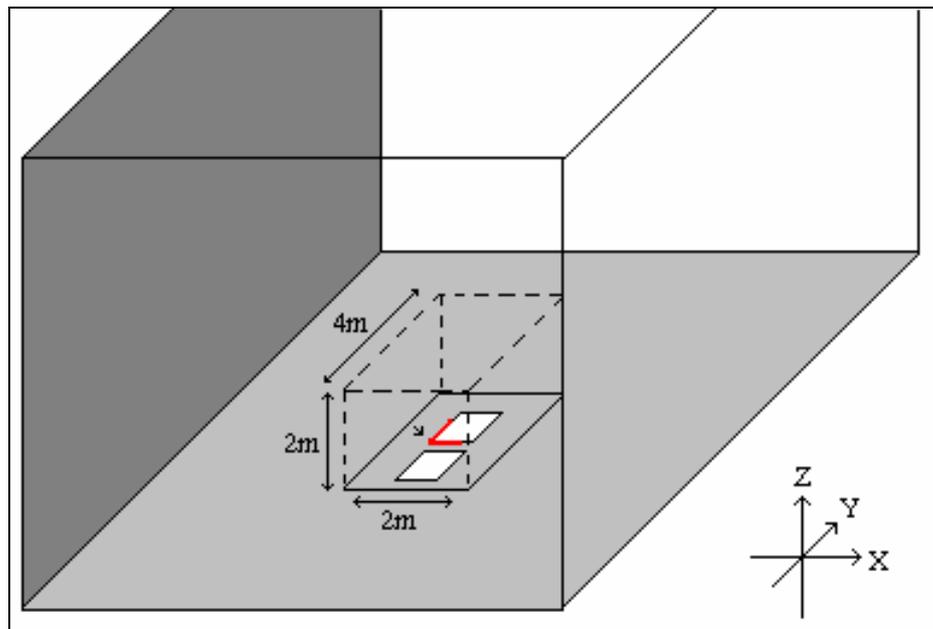


Figure 3.9.1.1: Force plates, 'L'-frame placement and calibration volume

3.9.2 Dynamic Calibration

To define the operating envelope of the system, the calibration wand was waved throughout the calibration volume (dotted outline in Figure 3.9.1.1) for approximately sixty seconds, until the automated camera calibration routine showed a residual error of $<2\text{mm}$. If the residual error exceeded 2mm , the dynamic calibration was repeated until it did so.

3.10 Measurement device initialisation

The accelerometer-based measurement device was powered up and initialised. The host PC was booted and the data recording program was loaded to the microcontroller in the development system, ready for the start command to be issued. Vicon and device session files were created, with an identifier for the subject. The system was then ready to start collecting data. The full operating manual written for the developed device is given in Appendix 13.

3.11 Subject arrival

The subject was greeted in reception area of the University and thanked for their participation before being escorted to the gait laboratory and briefed on what was required of them during the data collection session. The consent form (Appendix 2) was read through with the subject and opportunity for questions was invited.

3.12 Session preparation

If consent was granted, the subject was asked to retire to a changing facility to don either the supplied, or the subject's own, gymware, which is necessary to allow attachment and camera visibility of the self-adhesive Vicon retro-reflective markers. The height of the subject was found using a stadiometer, their weight using a digital set of scales and their leg lengths using a plastic measuring tape. Finally, the subject's knee and ankle widths were measured using a sliding calliper.

3.12.1 Retro-reflective marker application

These markers (ten sphere type and five sphere-on-wand type) were attached to the bare skin using hypoallergenic adhesive tape in line with the Helen Hayes Modified marker placement protocol, shown in Appendix 8 (lower body marker set only). Appendix 11 may be referenced at this point, which details Vicon system software operations of the data collection.

3.13 Session execution

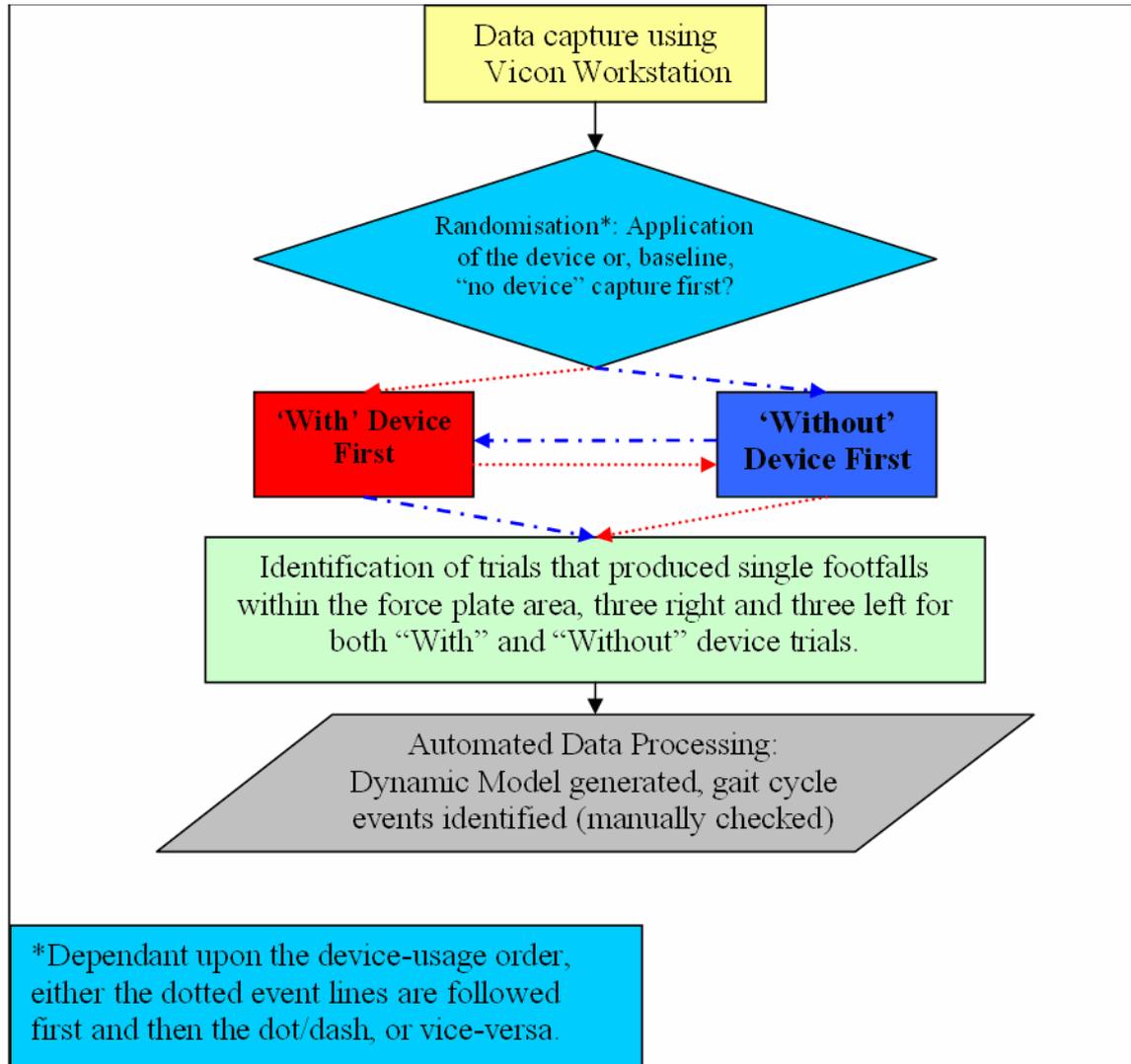


Figure 3.13.1: Data collection flowchart

Figure 3.13.1 shows the overall process of data collection. Whether the subject was fitted with the developed device first, or if they are asked to walk without the device first, was a randomised outcome. A random number generator application was composed in Borland C++, as shown in Figure 3.13.2, where the software's underlying "rand()" function uses a "multiplicative congruential" generator with period 2^{32} (Borland C++ Builder, Version 6, 2002).

```

float r;          // The randomised number
r = random(2001); // Generate large-ranged value
r = (r/1000) - 1; // Scale this value to the 'milli' range;
                // the '-1' allows for negative values.
  
```

Figure 3.13.2: C++ code segment for random number generation

If the value of “r” was positive, the device was worn after successful collection of three acceptable Vicon trials; if “r” was negative, the device would be applied first.

After the subject was prompted to do so, they walked the length of the lab so that kinetic and kinematic data of their gait was collected by the Vicon 3d motion analysis system. This process was repeated until three satisfactory trials are collected for each foot. A satisfactory trial is achieved when the subject made one foot fall within the measuring surface region of (at least) one force plate, as shown in Figure 3.13.3.

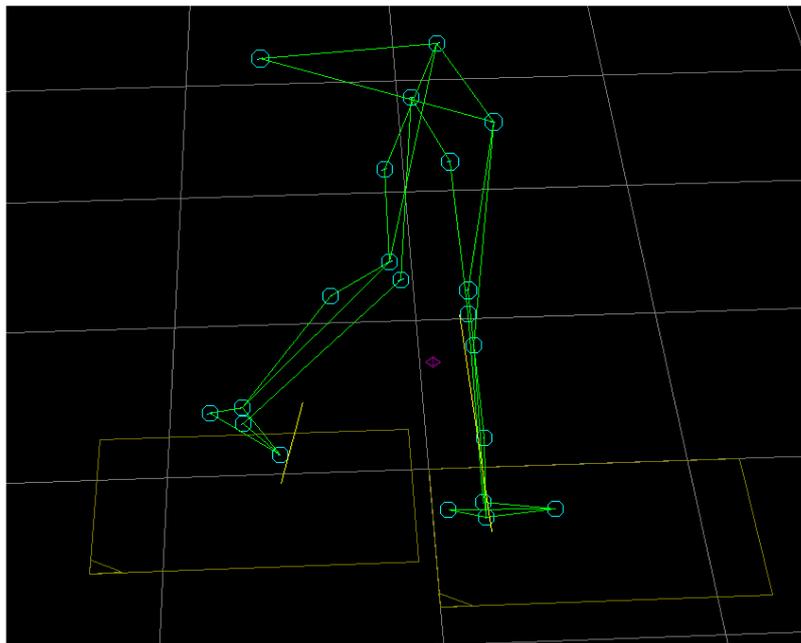


Figure 3.13.3: Single force plate trial signifying an acceptable trial

The developed device was then fitted to, or removed from, the subject, depending on the random-order for device/no device previously discussed. The subject was again asked to walk the length of the lab several times so that gait analysis for both ‘with’ and ‘without’ device trials were then be collected.

3.14 Subject debriefing

The Vicon markers and any other apparatus were carefully removed from the subject, after which they were directed to the changing facility. Once the subject was ready to leave, a summary report request form (Appendix 4) was offered, should the subject have wished to be sent a one-page summary of the completed study at its conclusion. Travel expense reimbursement was also offered (Appendix 5). The subject was then escorted back to the reception area and thanked for their participation, whereupon they were free to leave.

3.15 Data collection and processing protocol

Once the data from both the Vicon system and the developed device was collected, processing² (in the form of tabulation and import to the SPSS software package) was required to ensure the data was presented in a manner which would facilitate validation of:

- All gait-cycle parameters when using the developed device compared to when no device was used, to assess if the device itself affected gait.
- Comparison of the specific gait cycles selected using the Polygon software with those of the developed device; their degree of matching was an indicator of device accuracy. This was to statistically validate the developed device output, compared to that of the Vicon system.
- The performance of the neural network in detecting gait abnormalities in terms of reduced hip ROM, in order to determine if the device could be used by a healthcare professional in the clinical environment for this purpose.

² Chapter 5 describes the developed device post-processing operations

3.16 Data Integrity

In order for valid, robust conclusions to be drawn, the processing and analysis stages of the study were designed to be as free as possible from sources of error and bias. Anticipated and actively-minimised occurrences of these phenomena in the study included:

Transcription errors: where the physical reproduction of data from one location to another potentially introduced displaced, incorrect or corrupt data values, which could have lead to misinterpretation of data. This was minimised by using automated techniques of data recording and tabulating, in the form of Microsoft Excel Macros for row and column stacking operations.

Processing errors: where data required pre/post-processing to produce the required format for presentation, numerical and/or typographical errors can be introduced. In order to minimise this, these processes were automated by further use of macros. This ensured that repetitive tasks were carried out without fatigue or loss in accuracy for uniform, consistent processing.

Data handling

Capturing, logging and backup: in obtaining the data, errors may have been present in the form of frame 'drop' (loss of an instance of sensor-read values). This is a physical limitation in the operating system on the host PC which can be compounded by serial communication. In order to combat this, high-specification components and handshaking and in-built transmission-error checking were investigated and implemented to minimise data loss and corruption and ensure reliable communication.

3.17 Chapter summary

This chapter has described how the study was devised, that is, how the aims of the research could be addressed and by what means, so that valid and scientifically rigorous conclusions could be drawn when the results were discovered. In order for a comparison of artificial intelligence-based assessment of gait to be performed, a device which was capable of measuring the key parameters was required. The following chapter describes the hardware development phase of the research.

Chapter 4

Instrumentation Development

Chapter Overview

This chapter details the development of the sensors, microcontroller, interfacing electronics and software required for gathering and logging of the sensor data for hip flexion/extension and abduction/adduction ROM measurement.

4.1 Introduction

The role of the hardware in this system is to measure and record rotational angles of the human hip with respect to the torso. In order to describe and measure this motion, the biomechanical properties of the hip must be considered and understood.

The hip joint consists of a 'ball and socket' type joint formed by the femoral head and the acetabulum of the pelvis, which allows movement in three dimensions.

As shown in Figure 4.1.1, the synergy of these muscle groups gives rise to the degrees of freedom shown.

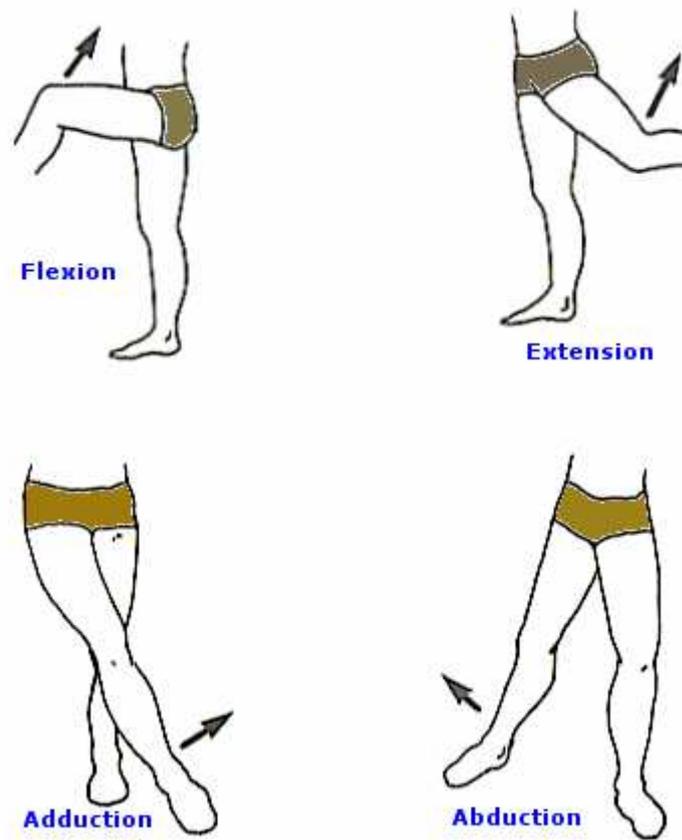


Figure 4.1.1: Hip axes. Source: *Principles of Anatomy and Physiology, 6th Edition*.

The degrees of freedom include (normal range shown in brackets)

Flexion/extension – the forward (135°) and backward (25°) swing of the leg.

Adduction/abduction – the inwards (25°) and outward (45°), side to side movement of the leg.

The following section details how the system was designed to measure these movements.

4.2 Methodology

Once the purpose and requirements of the biomeasurement system were known, the development was undertaken using the methodology shown in Figure 4.2.1.

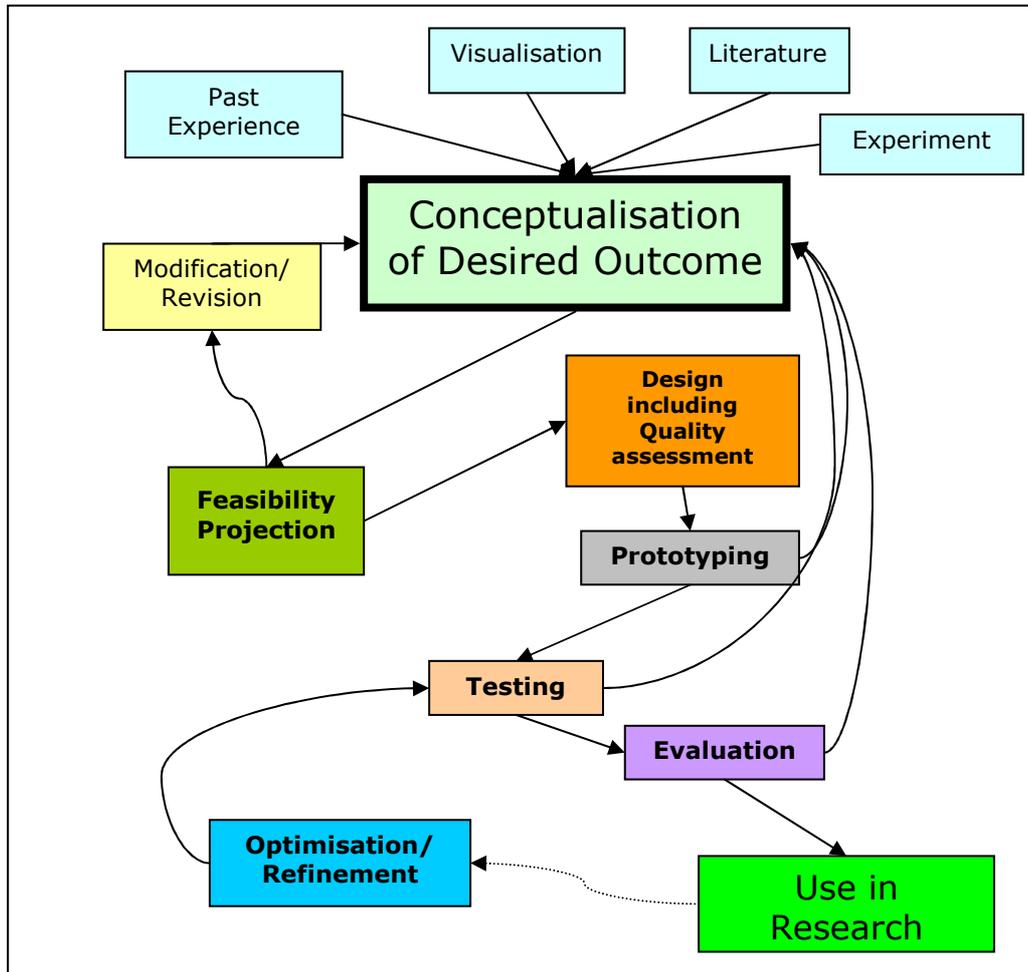


Figure 4.2.1: Design Methodology for System Development

With continued reference to Figure 4.2.1, the factors shown in light-blue assist in the precipitating of an initial concept. From this point, a feasible design is developed and then manufactured as a prototype which is then tested and evaluated. Once a working system is obtained, it may be subject to periodic, in-use, optimisation and refinement as its real-world behaviour is observed.

Appendix 15 describes the prototype devices which were developed prior to the final device presented on the following pages.

4.3 System development

The developed device uses two Dimension Engineering (USA) three-axis accelerometer; a modular device which contains the "Analog Devices ADXL330" sensing elements and also the required ancillary components which facilitates rapid prototyping and evaluation of the device. The sensor uses the Earth's gravitational field as a datum for calculating tilt using coils, which are sensitive to position within this field.

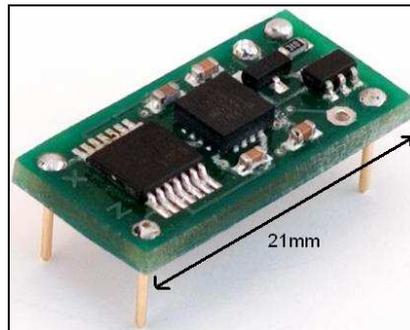


Figure 4.3.1: The Dimension Engineering 3-axis accelerometer

Source: Dimension Engineering data sheet

This device was tested and found to provide a highly accurate output with a rapid response time and convenient facilities for interfacing and operation. An advantage of this type of sensor is its ability to easily detect heel-strike gait events associated with the start and end of one complete gait cycle from the decelerative sensor responses.

The module also gives convenient connectivity to external controllers with only five electrical connections to be made – two for power supply and a further three for each accelerative plane it measures.

In order to negate the need to use mounting hardware such as hinges or armatures, the modules are capable of being placed with few restrictions; their relative readings allow the thigh-mounted device data to be compared with that of the torso in order to calculate the hip angle relative to it.

The new sensor components require little in terms of ancillary components, with the majority of the electrical connections being of the same type as

those of the previous devices, in the form of analogue input. The modules were placed in enclosures for electrical insulation, mechanical protection and to provide a mounting surface for attachment to the subject.

The removal of the mounting hardware dependency also has the secondary benefit of eliminating the single-joint application of the device and allows it to be considered as a more abstract tool for measuring relative motion of any two body segments.

Once the final hardware design was constructed, an interface was required to connect the device to a computer so that the sensor data could be obtained. The following section describes how a microcontroller was integrated into the system to fulfil this role

4.4 Microcontroller interfacing

Since the system must perform many co-ordinated tasks, from the reading of the sensor outputs to conversion of these values and tabulating text output, as well as serial communications of this data, it was pertinent to use a microcontroller in the system. The Freescale MC68HC12 (contracted to HC12 hereafter) microcontroller installed in an Elektronikladen HC12Compact was first choice as the controller as it offers appropriate design architecture in its input/output (I/O), processing and memory capabilities.

A compact, lightweight enclosure was developed to house the electrical components as well as to provide electrical insulation, mechanical support and user controls, the development of which can be seen in Appendix 12. An Initium Promi-SD202 Bluetooth transceiver was used to provide a high quality communication link between the device and the data-logging PC. This device was selected since it provides secure, error-correcting and wireless connectivity.

4.5 Microcontroller code development

To control the embedded system, code was written to facilitate the data capture and hardware control requirements of the system (source code shown in Appendix 9, flow diagram of operation in Appendix 10). This software was responsible for reading the values of the analogue to digital ports to which the sensors were connected, format and output these values to the terminal window where the values are recorded for later processing.

4.6 Developed device sampling rate

The sample rate of the developed device was calculated thus:

Serial Baud rate of 6812 Compact board: 19200 (wireless serial transceiver set to match).

Serial mode utilised: 8-N-1 mode; one byte requires ten $1/19200$ periods. (8 data bits, one start bit and one stop bit).

Therefore the serial transmission time was $\sim 521\mu\text{s}$ /byte

Sending the data (3 ASCII chars. Plus the '\t' formatting command) required four bytes to be sent over the wireless link.

These four bytes, each with 6 ADC readings to transmit, each taking $521\mu\text{s}$
= $\sim 12.5\text{ms}$ or $\sim 80\text{Hz}$.

4.7 Software methodology

The programming language 'C' was chosen to devise the control application, since it is the main supported high-level language used with the MC68HC12 microcontroller and which allows the intended functionality to be realised.

Imagecraft ICC12 V6, the program supplied with the microcontroller, was used to input and compile the code as well as allow communication with the microcontroller via the terminal facility of the software.

Figure 4.7.1 shows a block diagram of the final system for reference henceforth to the contents of this chapter.

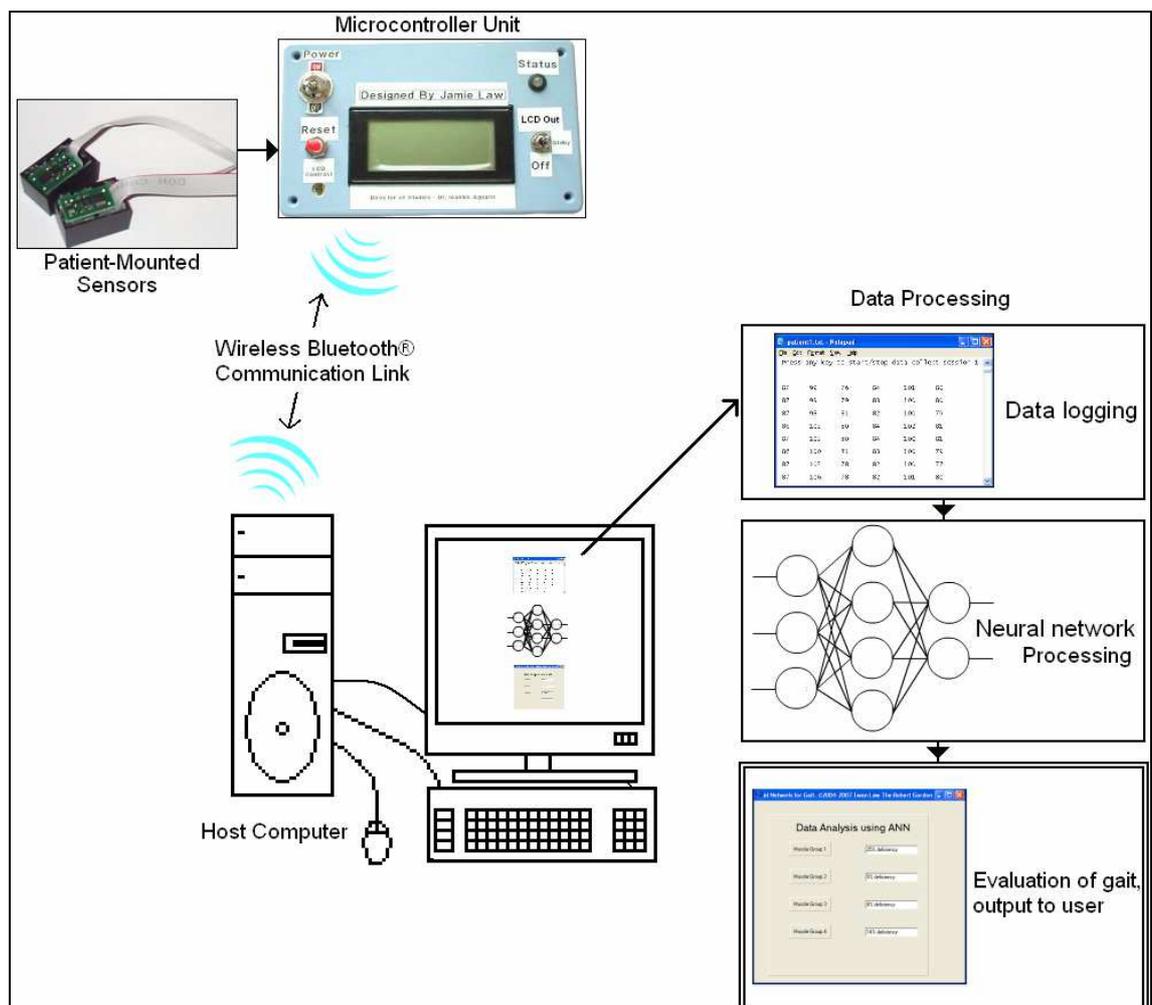


Figure 4.7.1: System block diagram

4.8 Chapter summary

This chapter has covered all of the aspects of the evolution of the developed device as used within the study as well as the reasons for key design choices used in its production.

In order for the device to be used in its intended role, to infer gait deviation based upon reduced hip ROM, the following chapter details how this was achieved.

Chapter 5

Artificial Neural Network Development

Chapter Overview

This chapter describes the development of the Artificial Neural Network algorithm, designed to recognise gait deviation from altered range of movement (ROM), based on the system sensor inputs read by the hardware elements of the developed device.

5.1 Introduction

Following the capture of the live hip flexion/extension and abduction/adduction data using the developed device, the role of the artificial neural network algorithm was to infer which, if any, ranges of motion were abnormal. The network was exposed to training sets consisting of normative gait examples from a library of normal subjects, supplied with the Vicon system, prior to processing the actual developed device data values. Following processing of the device sensor values, the network then output analyses of the subject's hip flexion/extension and abduction/adduction ROM.

5.2 Software methodology

Borland C++ (Borland, Cupertino, California) was used to code the network, since the features it offers were complementary to the data encountered and suitable for use in the following respects:

- Choice of variables
- Mathematical functions
- Ease of use of the language
- Debug features

Figure 5.2.1 shows the development methodology for composing the code:

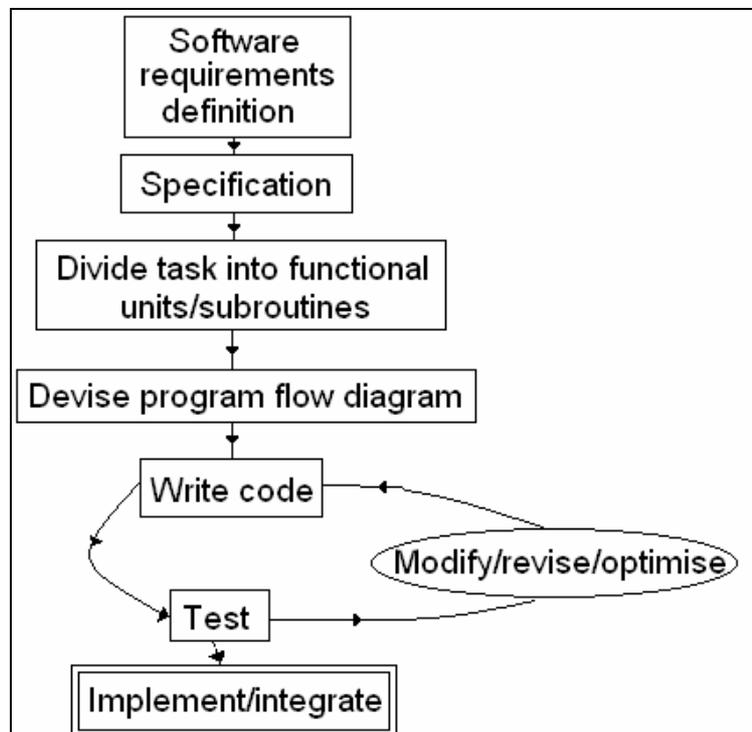


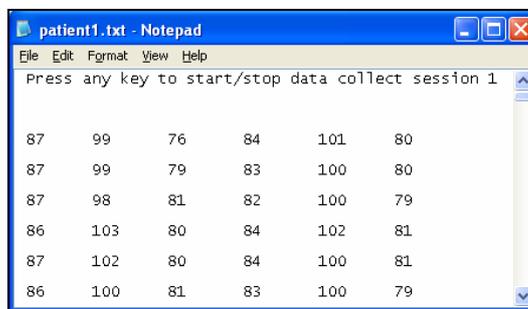
Figure 5.2.1: Software composition method

A full listing of the artificial neural network software can be found in Appendix 14.

5.3 ANN Data pre-processing

The sensing elements, as discussed in Chapter 4: Hardware Development consisted of two DE-ACCM3D tri-axis accelerometer modules, one worn on the subject's abdomen, on the anterior superior iliac spine (ASIS) and the other on the femoral midline, 15cm below the ASIS (please refer to Appendix 13 for the operating protocol of the developed device).

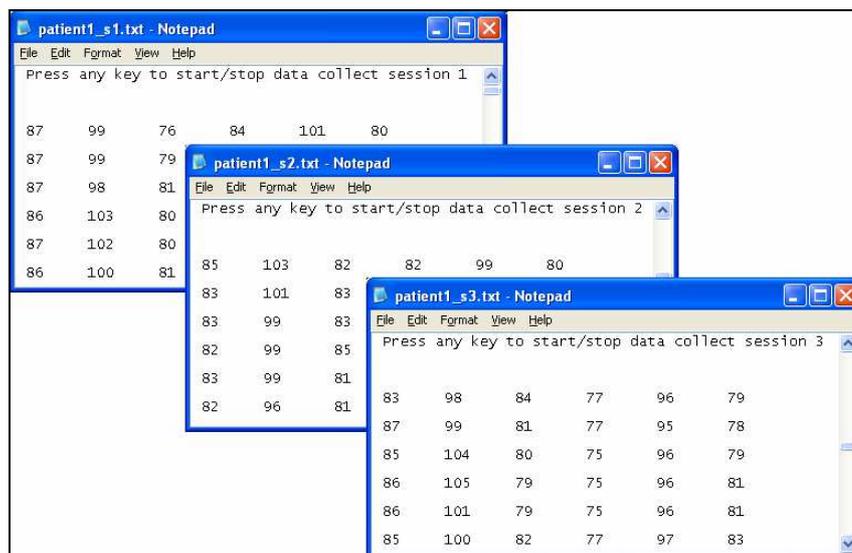
Prior to inputting the motion capture data from the developed device into the ANN, the data required pre-processing. With reference to Figure 5.3.1, an example raw stream is shown; each axis of tilt is represented by a column of values.



patient1.txt - Notepad						
Press any key to start/stop data collect session 1						
87	99	76	84	101	80	
87	99	79	83	100	80	
87	98	81	82	100	79	
86	103	80	84	102	81	
87	102	80	84	100	81	
86	100	81	83	100	79	

Figure 5.3.1: Sample data stream

Each trial (a single-direction gait capture along the length of the laboratory) is divided into different text files so that individual trial logs may be studied, as shown in Figure 5.3.2.



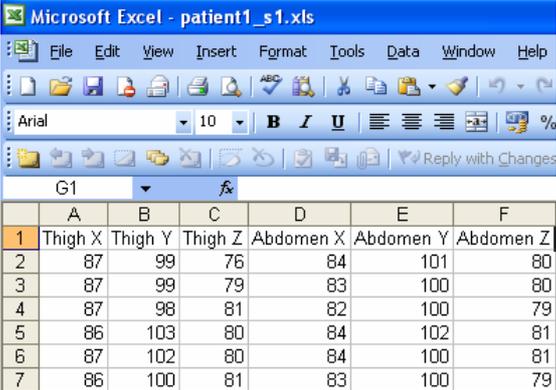
patient1_s1.txt - Notepad						
Press any key to start/stop data collect session 1						
87	99	76	84	101	80	
87	99	79				
87	98	81				
86	103	80				
87	102	80				
86	100	81				

patient1_s2.txt - Notepad						
Press any key to start/stop data collect session 2						
85	103	82	82	99	80	
83	101	83				
83	99	83				
82	99	85				
83	99	81				
82	96	81				

patient1_s3.txt - Notepad						
Press any key to start/stop data collect session 3						
83	98	84	77	96	79	
87	99	81	77	95	78	
85	104	80	75	96	79	
86	105	79	75	96	81	
86	101	79	75	96	81	
85	100	82	77	97	83	

Figure 5.3.2: Divided trial logs

All text elements were removed from the text file when imported into Excel (column identifiers added):



	A	B	C	D	E	F
1	Thigh X	Thigh Y	Thigh Z	Abdomen X	Abdomen Y	Abdomen Z
2	87	99	76	84	101	80
3	87	99	79	83	100	80
4	87	98	81	82	100	79
5	86	103	80	84	102	81
6	87	102	80	84	100	81
7	86	100	81	83	100	79

Figure 5.3.3: Excel-imported data

Peaks in the accelerometer output occurred when the heel of the subject striking the laboratory floor. This property was exploited as consecutive gait cycles could be located and separated (the peak values themselves were discarded as they can not be used to find tilt).

The Vicon system output was then used to identify which gait cycle in a particular trial corresponded to the same gait cycle from the device, so that the comparison of outputs was carried using equivalent data (the other gait cycles were discarded for the comparison, but would be useful in assessing the subject clinically).

Flexion/extension and ab/ad-duction ADC sensor values are converted to voltage: $(\text{ADC Value} \times 5 \text{ Volts}) \div 255$ (which is the port full-scale deflection) , the calibration measures taken at the outset of the data collection were then subtracted from this and the difference between the abdomen and femur was found.

Using the standard sensitivity setting of the accelerometer, 0.333V/g the resultant g-attributed tilt is: $(\text{value} \div 0.333)$

In order to find the resultant tilt, the inverse sine function is applied to this value before being converted into degrees (this protocol was given in the sensor module application note).

A simple rolling mean finite impulse response (FIR) filter was then used on the accelerometer data points, as suggested by Kavanagh and Menz 2008, to remove frequency components >15Hz, the normal frequency range of human gait (Lord et al. 2008). The optimised period of five points for the filter moving average was found by experimentation when initial testing of the accelerometer was undertaken.

The Vicon system outputs a set-sized fifty-frame graph of each gait cycle parameter. To achieve this with the developed device, Microsoft excel was used to resample the waveform at 2% intervals of the gait cycle, so that it also yielded a fifty-frame graph. This then allowed direct comparison of each system. This method allowed unconstrained-size data captures to be fitted to a common, fifty-frame template, to allow comparison of subjects who have very low step cadence, as well as normal.

5.4 Neural network design

The use of a neural network allowed the system to infer the severity of reduced ROM gait deviation, based on combinations of inputs which the network had not, necessarily, explicitly been trained to recognise. With reference to Figure 5.4.1, the network inputs relates to the number of sensor inputs that are interfaced with the hardware, in this application, six continuous accelerometer values which were logged from the data collection phase.

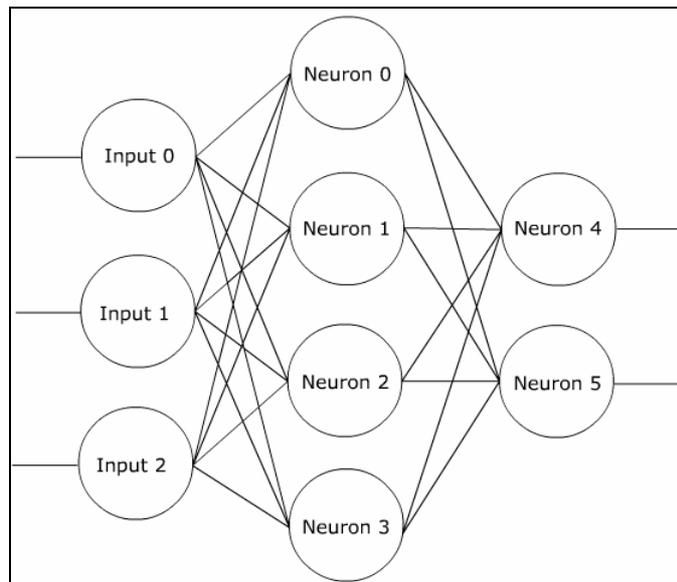


Figure 5.4.1: Artificial neural network topology

The number of hidden layers as well as neurons in each was chosen based upon the design guides discussed by (Hagan, Demuth and Beale 1996, Rafiq, Bugmann and Easterbrook 2001), using the following parameters:

- Number of training sets used to train network
- Network sensitivity to different gait deviations
- Network performance

The number of neurons in the output layer were chosen to form a coded output where neurons 4 and 5 in Figure 5.4.1 relate to hip flexion extension normality ratings respectively. As the same network architecture was used to evaluate hip adduction/abduction also, neurons 4 and 5 related to these parameters respectively.

5.5 Training sets

Prior to processing actual sensor values, the network was exposed to simulated data of idealised cases in order to train it (Hopfield 1982). The training sets consisted of patterns of existing data which corresponded to normal and deviated gait, based upon the normative range given in the Vicon system.

Where the measured values deviated from the normative ranges, a training target output of '1' indicated that the subject had a value which lay at the centre of the normative range (35° for flexion, -10° extension, 5° peak adduction and -8° peak abduction). An output of '0' indicated a $\leq -20^\circ$ excursion from normal range, indicating greatly deviated magnitudes.

5.6 Training algorithm

The Backpropagation algorithm was implemented, as discussed by Negnevitsky 2005 and Bryson and Ho 1969 in order to train the network. With reference to Figure 5.6.1, this process is repeated for each pattern. The absolute threshold value for network error was specified as 1%:

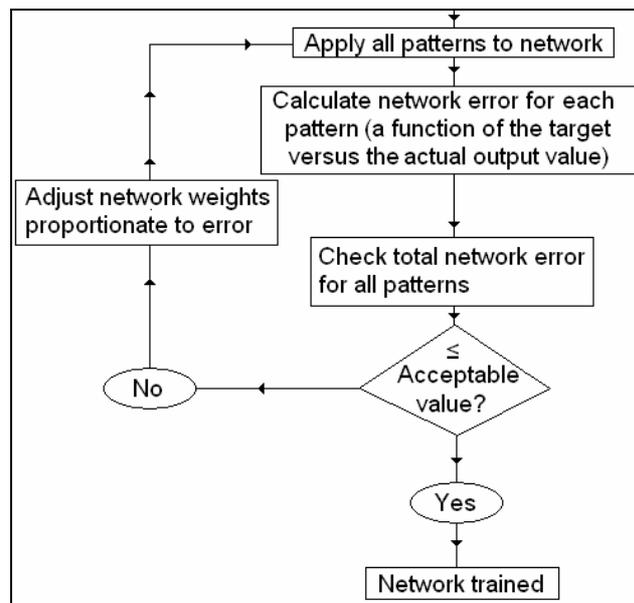


Figure 5.6.1: Back-propagation algorithm overview

5.7 Testing

The network was extensively tested using the approach shown in Figure 5.7.1

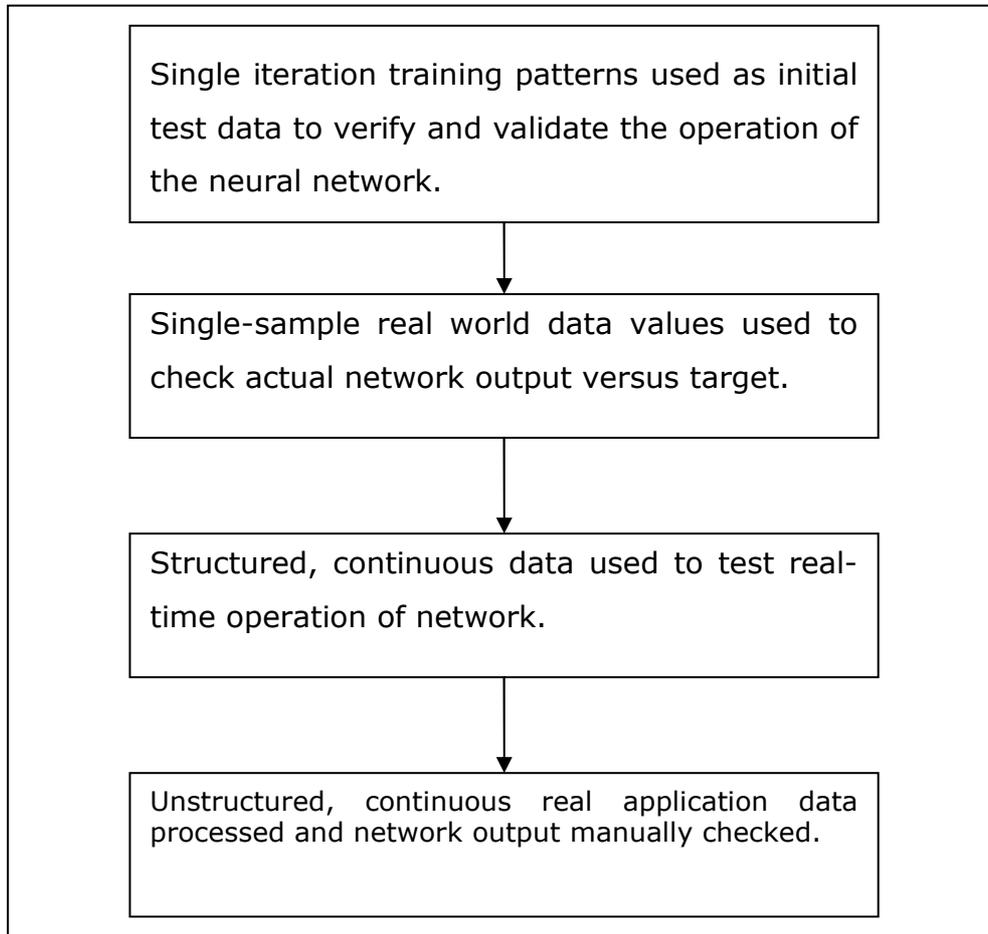


Figure 5.7.1: Software testing overview

5.8 Chapter summary

This chapter has described the neural network software development which was coded to infer hip flexion/extension and abduction/adduction ROM deficiency, retroactively processed from the developed device in post-operative THA patient gait. Following processing of the collected data, the results chapter shows the outcome of these inferences as well as direct comparison of the developed device with the clinical gold-standard, motion capture, Vicon system.

Chapter 6

Results

Chapter Overview

This chapter presents the results of the various data collection phases of the research.

6.1 Introduction

In order to validate the performance of the device and in so doing, meet the research objectives, a major data collection was undertaken, with subsequent data processing. This consisted of the following stages:

Marker placement repeatability analysis

Firstly, the repeatability and placement accuracy of the Vicon marker set was assessed, which is paramount to the accuracy of the system as a whole (Kirtley 2002). Therefore a measure of this was taken to ensure valid conclusions could later be drawn between subjects' data sets as well as in comparing the developed device against Vicon data directly. Section 6.2: Repeatability, describes the execution of this phase of the research and presents the results.

6.2 Repeatability study

Methodology

The purpose of the repeatability study was to ensure that by accurately identifying the anatomical landmarks by palpation, consistency, precision and accuracy of measurement was attainable when applying the retro-reflective markers.

In order to test the repeatability of the marker placement, a convenience-sampled individual was asked to attend five separate motion capture sessions in order to be outfitted with the aforementioned lower body marker set. The sessions were conducted over a five day period within the same week and at the approximately same time on each occasion, to minimise subject variation.

- The sessions were conducted at the Human Performance Laboratory at the School of Health Sciences within the Robert Gordon University.
- Following palpation of the anatomical landmarks, markers were placed as described in Appendix 8: Marker Placement Protocol. Static subject captures were obtained which consist of a three-second automatically-timed capture of the subject standing in the anatomical position.
- The markers were then removed and the subject was free to leave.

A total of five iterations of this procedure were undertaken so that a comparison of each session's readings could be used as an indication of marker placement reliability, which is fundamental to accurate Vicon software output.

The following distances were obtained from the Workstation motion capture program by selecting two points and then choosing the *Graph → Distance Between* command:

- The inter-anterior superior iliac crest distance.
- Left and right lateral epicondyle of the femur to lateral malleolus.
- Left and right foot length - heel to second metatarsal head.

The command returns the distance, in millimetres, between the two selected points as a mean over the three second capture time. These parameters were chosen as Vicon Workstation uses these parameters in the calculation of kinetic and kinematic data relating to hip flexion/extension and abduction/adduction and it was therefore decided to use these as they were the principal parameters of the study.

Since the segment lengths measured pertain to different segments, Z-Scores (Larsen et al, 2000) were calculated for each parameter, thus normalising each value to a directly-comparable form.

A one way analysis of variance was conducted to compare the variance within each parameter as well as between each parameter and a homogeneity score and its significance level was obtained. The variance in the measurement results within the five sessions is a key indicator of marker placement accuracy.

Repeatability results for marker placement

Body Segment	Measurement Instance	ZScores (mm)
Pelvis	1	-0.5241
	2	-0.4128
	3	0.3016
	4	0.6192
	5	1.0161
Left Knee to Ankle	1	-0.7322
	2	0.4798
	3	0.0125
	4	0.6044
	5	0.6356
Left Foot Length	1	0.4363
	2	0.4363
	3	1.1134
	4	-0.5416
	5	-1.4444
Right Knee to Ankle	1	-0.7023
	2	-0.2431
	3	0.6753
	4	1.006
	5	-1.0805
Right Foot Length	1	0.5116
	2	-1.0682
	3	0.4143
	4	-0.7673
	5	-0.0903

Table 6.2.1: Z-Scores of static marker placement repeatability

Descriptives

ZScore	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
					Pelvis	5		
Left Knee to Ankle	5	.200020	.5778685	.2584306	-.517498	.917538	-.7322	.6356
Left Foot Length	5	.000000	.9999996	.4472134	-1.241664	1.241664	-1.4444	1.1134
Right Knee to Ankle	5	-.068920	.8893986	.3977511	-1.173254	1.035414	-1.0805	1.0060
Right Foot Length	5	-.199980	.7020281	.3139565	-1.071663	.671703	-1.0682	.5116
Total	25	.026224	.7311432	.1462286	-.275577	.328025	-1.4444	1.1134

Table 6.2.2: Descriptive statistics of Z-Scores for static marker placement repeatability

Test of Homogeneity of Variances

ZScore

Levene Statistic	df1	df2	Sig.
.865	4	20	.502

*Table 6.2.3: Overall Homogeneity of Variances***ANOVA**

ZScore

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.607	4	.152	.248	.907
Within Groups	12.223	20	.611		
Total	12.830	24			

Table 6.2.4: Analysis of variances

Z-scores for marker placement repeatability were computed, where a 'zero' value score indicates that the measurement equals that of the mean of the body segment in question (Table 1). Table 2 gives the descriptive statistics based thereupon. Table 3 gives Levene's test for homogeneity of variances. As $p > 0.05$, the Z-scores can be considered homogeneous. The results of the one-way ANOVA shows that there is no significant difference in mean scores within the individual trial, nor across the parameter set: $F(4,20)$, $p > 0.05$.

6.3 Main data collection

Main Study Results Overview

The main data collection phase of the study was then carried out using a sample of THA patients (n=21), recruited from NHS Grampian, who satisfied the inclusion criteria described in Chapter 3: Research Methodology, who were then subjected to the operating protocol also described in Chapter 3. Table 6.3.1: **Participating patient data** describes patient demographic data.

	Range	Minimum	Maximum	Mean	Std. Deviation
Age in years	9	60	69	65.29	2.667
Mass in KG	56.4	52.3	108.7	80.786	15.9419
Height in cm	24.5	151.1	175.6	162.086	5.9014

Table 6.3.1: Participating patient data

Main Study Methods

Each patient had data collected using:

1. Only the Vicon system.

and

2. From both the developed device **and** the Vicon system simultaneously.

The latter data were captured simultaneously for direct comparison. The Vicon data was captured using its proprietary software and the developed device data was captured using OC Console (Elektronikladen, Germany) terminal emulator, which featured serial output recording functionality. The developed device wirelessly transmitted text strings containing the accelerometer sensor readings. These text-based sensor logs were collated in a single computer directory, for each participant.

6.4 Main study results: assessment of the effect of the developed device on gait

Overview

The first stage of the developed device validation concerned the comparison of gait cycle parameters of the patient when wearing the developed device, versus not wearing it.

Methods

After the data was collected, as described in section 6.3.2, the Vicon elements were transcribed to SPSS, and divided into separate Workbooks by:

- Patient number (n=21)
- Trial (n=3),
- Operated/non-operated side(n=2)
- With/without developed device(n=2)
- Gait cycle parameter(n=12):
 1. Pelvic tilt
 2. Pelvic obliquity
 3. Pelvic rotation
 4. Hip flexion and extension
 5. Hip abduction and adduction
 6. Hip mediolateral rotation
 7. Knee flexion and extension
 8. Knee abduction and adduction
 9. Knee mediolateral rotation
 10. Ankle dorsiflexion and plantarflexion
 11. Ankle mediolateral rotation
 12. Foot progression angle
- Data Frame(n=50)

The number appearing in brackets shows the number of levels of each dimension, i.e. total Vicon dataset size was the product of these; 151200 elements.

The effect of the developed device on gait cycle parameters

In order to establish which statistical test of means, parametric or non-parametric, was suitable for examining Vicon output for the “with versus without” developed device comparison, tests of normality were carried out on each waveform peak and trough (which were used as landmarks of interest).

Vicon data normality tests were carried out using averaged data:

- For each side, operated and non-operated
- With and without developed device fitment
- With peak and trough values for each of the patients’ three trials

As $n=21$, the Shapiro-Wilk normality test significance was undertaken (D’Agostino, Belanger and D’Agostino 1990). Where normal distribution of data was found ($\text{sig} > 0.05$) in the waveform landmark maximum/minimum, a Paired Samples T-Test was undertaken; otherwise, if $\text{sig} < 0.05$, the Wilcoxon Signed Rank test was used in order to compare the waveforms’ discrete landmarks of interest.

<i>Gait cycle parameters "with Vs without" developed device</i>		
Parameter	Test Type T = Paired Samples T-Test W = Wilcoxon Signed Rank Test	p-value for all pairs
Pelvic tilt	W	>0.05
Pelvic obliquity	W	>0.05
Pelvic rotation	T	>0.05
Hip flexion and extension	T	>0.05
Hip abduction and adduction	T	>0.05
Hip mediolateral rotation	T	>0.05
Knee flexion and extension	T	>0.05
Knee abduction and adduction	T	>0.05
Knee mediolateral rotation	T/W	>0.05/>0.05
Ankle dorsi/plantar-flexion	T	>0.05
Ankle rotation	T/W	>0.05/>0.05
Foot progression angle	T/W	>0.05/>0.05

Table 6.4.1: Comparison of means p-value outcomes

With reference to Table 6.4.1, it can be observed that:

1. 58% of parameters have waveforms with entirely normally distributed landmarks:

- Pelvic rotation
- Hip flexion and extension
- Hip abduction and adduction
- Hip rotation
- Knee flexion and extension
- Knee abduction and adduction
- Ankle dorsi/plantar-flexion

2. 25% have some elements which are normally and others which are not normally distributed:

- Knee rotation
- Ankle rotation
- Foot progression angle

3. The remaining 17% have purely not normally distributed waveform components:

- Pelvic tilt
- Pelvic obliquity

Table 6.4.1 also shows a summarised view of the comparison of means for each gait cycle parameter. With all p-value >0.05 , the data suggests that the null hypothesis can be accepted; there is no significant difference between gait cycle parameter rotations when wearing the developed device compared to not wearing it.

Where both tests are shown for a parameter, elements of the underlying waveform landmarks (maximum/minimum) were normally distributed while others were not normally distributed.

The different tests show different points on the waveform. For example ankle rotation – the first waveform landmark may be normally distributed, but the next may not be, so the appropriate test was chosen.

After establishing that the developed device did not appear to significantly affect the gait cycle parameters studied, the next stage of the validation was to directly compare the output of the device itself with the Vicon motion capture system.

6.5 Main study results: the correlation of Vicon data output compared to the developed device

The aim of the second phase of results processing was to establish whether the developed device output and those from Vicon were quantitatively comparable in the gait cycle parameters of interest, namely hip flexion/extension and hip adduction/abduction. This was done by:

1. Examining the descriptive statistics from the output of the Vicon system and the device.
2. Calculating the Pearson's correlation coefficient between the device output and the Vicon system to assess system agreement.
3. Performing a Paired-samples T-Test on the mean of the major data landmarks from both systems in order to test that the mean data values of both systems agreed.

Table 6.5.1 to Table 6.5.4 show the Kolmogorov-Smirnov, as discussed by (Beitz 2008). For the test, data frames $n=50$ (where each frame comprised of sixty-three averaged points – three trials for each of the twenty-one patients for each parameter and for each of the two system outputs). As all p -values > 0.05 , it can be concluded that the data were normally distributed, allowing parametric statistical tests to be conducted.

**Developed device hip flexion/extension tests of Normality
(n=63/data frame)**

DATA FRAME	Kolmogorov-Smirnov(a)		
	Statistic	df	Sig.
01	.131	63	.050
02	.110	63	.057
03	.078	63	.200(*)
04	.068	63	.200(*)
05	.066	63	.200(*)
06	.098	63	.200(*)
07	.100	63	.188
08	.078	63	.200(*)
09	.066	63	.200(*)
10	.078	63	.200(*)
11	.079	63	.200(*)
12	.087	63	.200(*)
13	.085	63	.200(*)
14	.064	63	.200(*)
15	.083	63	.200(*)
16	.078	63	.200(*)
17	.081	63	.200(*)
18	.074	63	.200(*)
19	.076	63	.200(*)
20	.087	63	.200(*)
21	.079	63	.200(*)
22	.101	63	.182
23	.117	63	.053
24	.076	63	.200(*)
25	.089	63	.200(*)
26	.059	63	.200(*)
27	.054	63	.200(*)
28	.064	63	.200(*)
29	.067	63	.200(*)
30	.070	63	.200(*)
31	.067	63	.200(*)
32	.092	63	.200(*)
33	.080	63	.200(*)
34	.097	63	.200(*)
35	.114	63	.064
36	.104	63	.091
37	.117	63	.063
38	.101	63	.184
39	.083	63	.200(*)
40	.110	63	.058
41	.115	63	.054
42	.095	63	.200(*)
43	.091	63	.200(*)
44	.088	63	.200(*)
45	.090	63	.200(*)
46	.057	63	.200(*)
47	.058	63	.200(*)
48	.078	63	.200(*)
49	.094	63	.200(*)
50	.085	63	.200(*)

* This is a lower bound of the true significance.

Table 6.5.1: Developed device hip flexion/extension normality scores

**Vicon system hip flexion/extension tests of Normality
(n=63/data frame)**

DATA	Kolmogorov-Smirnov		
	Statistic	df	Sig.
01	.060	63	.200(*)
02	.097	63	.200(*)
03	.094	63	.200(*)
04	.125	63	.057
05	.116	63	.056
06	.076	63	.200(*)
07	.115	63	.051
08	.125	63	.052
09	.137	63	.058
10	.120	63	.051
11	.096	63	.200(*)
12	.090	63	.200(*)
13	.084	63	.200(*)
14	.103	63	.092
15	.125	63	.051
16	.117	63	.052
17	.084	63	.200(*)
18	.077	63	.200(*)
19	.083	63	.200(*)
20	.093	63	.200(*)
21	.103	63	.091
22	.077	63	.200(*)
23	.087	63	.200(*)
24	.090	63	.200(*)
25	.101	63	.182
26	.102	63	.172
27	.110	63	.058
28	.121	63	.053
29	.130	63	.052
30	.123	63	.052
31	.093	63	.200(*)
32	.106	63	.078
33	.107	63	.070
34	.128	63	.052
35	.153	63	.056
36	.136	63	.052
37	.108	63	.066
38	.101	63	.178
39	.093	63	.200(*)
40	.114	63	.052
41	.118	63	.059
42	.121	63	.052
43	.098	63	.200(*)
44	.119	63	.056
45	.103	63	.094
46	.100	63	.186
47	.098	63	.200(*)
48	.106	63	.074
49	.094	63	.200(*)
50	.089	63	.200(*)

* This is a lower bound of the true significance.

Table 6.5.2: Vicon system hip flexion/extension normality scores

**Developed device hip abduction/adduction tests of Normality
(n=63/data frame)**

DATA FRAME	Kolmogorov-Smirnov		
	Statistic	df	Sig.
01	.059	63	.200(*)
02	.087	63	.200(*)
03	.086	63	.200(*)
04	.073	63	.200(*)
05	.084	63	.200(*)
06	.101	63	.181
07	.080	63	.200(*)
08	.096	63	.200(*)
09	.088	63	.200(*)
10	.093	63	.200(*)
11	.093	63	.200(*)
12	.118	63	.053
13	.079	63	.200(*)
14	.097	63	.200(*)
15	.106	63	.075
16	.091	63	.200(*)
17	.095	63	.200(*)
18	.086	63	.200(*)
19	.097	63	.200(*)
20	.129	63	.051
21	.134	63	.062
22	.100	63	.190
23	.122	63	.052
24	.119	63	.056
25	.104	63	.087
26	.100	63	.188
27	.079	63	.200(*)
28	.069	63	.200(*)
29	.081	63	.200(*)
30	.097	63	.200(*)
31	.133	63	.072
32	.138	63	.054
33	.140	63	.054
34	.154	63	.076
35	.124	63	.062
36	.098	63	.200(*)
37	.104	63	.089
38	.114	63	.051
39	.082	63	.200(*)
40	.077	63	.200(*)
41	.068	63	.200(*)
42	.062	63	.200(*)
43	.057	63	.200(*)
44	.056	63	.200(*)
45	.061	63	.200(*)
46	.065	63	.200(*)
47	.069	63	.200(*)
48	.078	63	.200(*)
49	.080	63	.200(*)
50	.100	63	.196

* This is a lower bound of the true significance

Table 6.5.3: Developed device hip abduction/adduction normality scores

**Vicon system hip abduction/adduction tests of Normality
(n=63/data frame)**

Data Frame	Kolmogorov-Smirnov		
	Statistic	df	Sig.
01	.086	63	.200(*)
02	.074	63	.200(*)
03	.081	63	.200(*)
04	.077	63	.200(*)
05	.060	63	.200(*)
06	.084	63	.200(*)
07	.079	63	.200(*)
08	.066	63	.200(*)
09	.075	63	.200(*)
10	.083	63	.200(*)
11	.089	63	.200(*)
12	.072	63	.200(*)
13	.076	63	.200(*)
14	.067	63	.200(*)
15	.067	63	.200(*)
16	.080	63	.200(*)
17	.067	63	.200(*)
18	.072	63	.200(*)
19	.073	63	.200(*)
20	.074	63	.200(*)
21	.072	63	.200(*)
22	.091	63	.200(*)
23	.086	63	.200(*)
24	.081	63	.200(*)
25	.094	63	.200(*)
26	.101	63	.183
27	.073	63	.200(*)
28	.070	63	.200(*)
29	.092	63	.200(*)
30	.097	63	.200(*)
31	.119	63	.061
32	.146	63	.062
33	.139	63	.054
34	.133	63	.057
35	.111	63	.053
36	.106	63	.076
37	.096	63	.200(*)
38	.090	63	.200(*)
39	.088	63	.200(*)
40	.071	63	.200(*)
41	.071	63	.200(*)
42	.078	63	.200(*)
43	.089	63	.200(*)
44	.089	63	.200(*)
45	.071	63	.200(*)
46	.074	63	.200(*)
47	.086	63	.200(*)
48	.104	63	.085
49	.101	63	.184
50	.091	63	.200(*)

* This is a lower bound of the true significance.

Table 6.5.4: Vicon system hip abduction/adduction normality scores

After establishing that both the Vicon system output and developed device measurements were normally distributed, tests of comparison were performed. Figure 6.5.1 shows a scatter plot of the developed device hip flexion/extension data with respect to the Vicon output across all patients' 50-point hip flexion/extension full waveforms.

Developed device Vs Vicon hip flexion/extension output

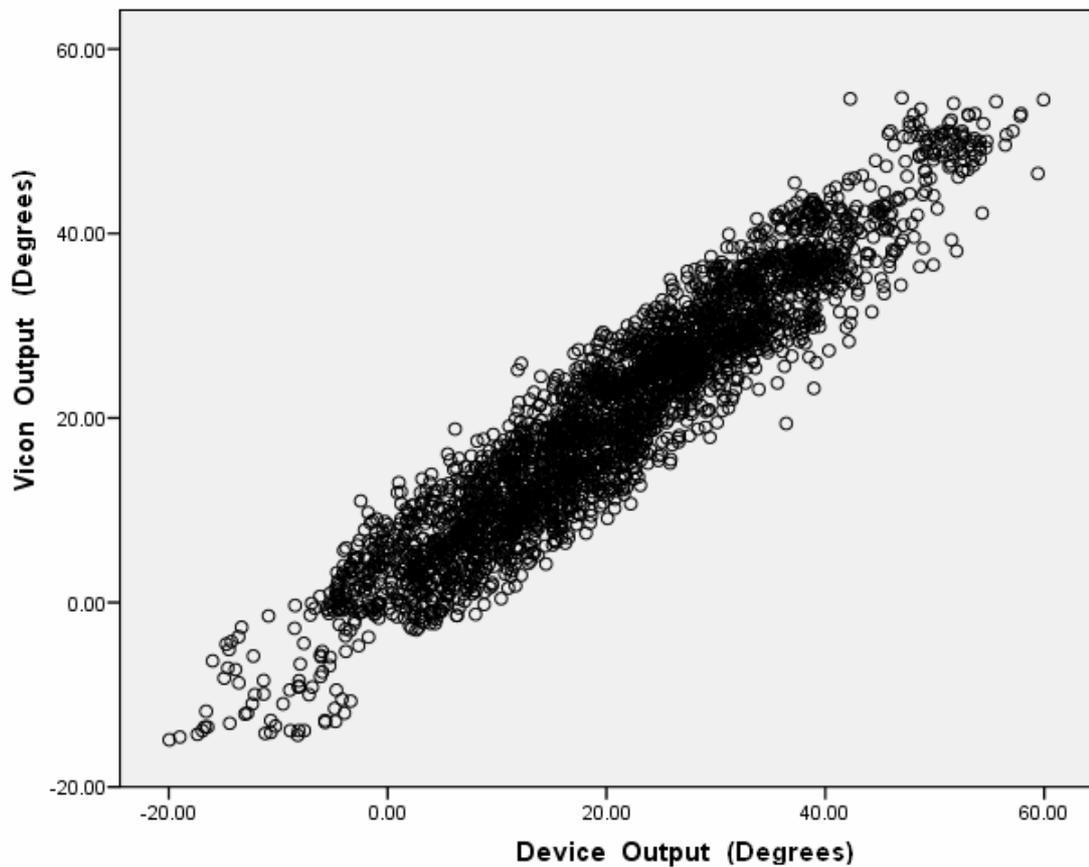


Figure 6.5.1: Scatter plot of device output with respect to Vicon for hip flexion/extension

As can be observed in the figure, the distribution of the data points and conformity to an overall linear, positive-gradient trend; the developed device output would appear to be valid in comparison to the Vicon system, the gold standard of motion analysis.

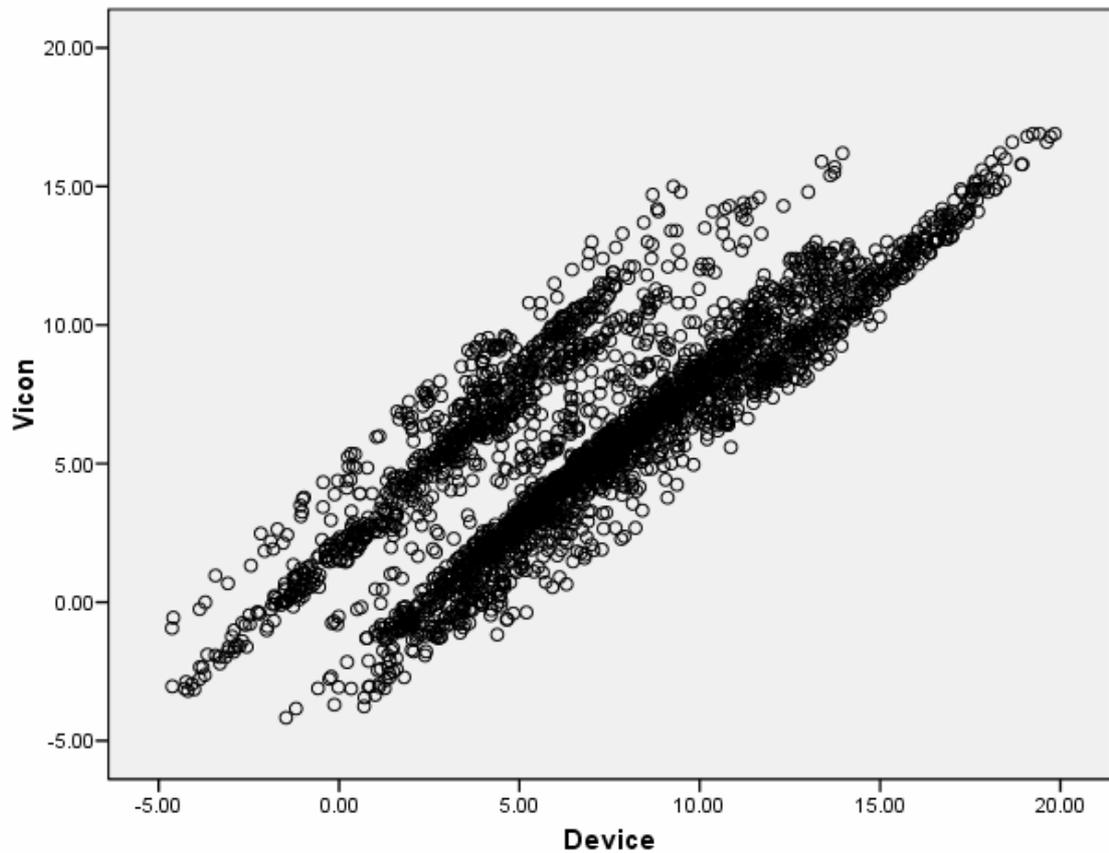
Developed device Vs Vicon hip abduction/adduction output

Figure 6.5.2: Scatter plot of device output with respect to Vicon for hip abduction/adduction

In hip abduction/adduction parameter (Figure 6.5.2), although there is overall linearity in the distribution of data points, the majority of which lie in a common framework, there are also secondary, tertiary and evidence of quaternary distributions, which will be addressed in the discussion chapter.

After establishing that there was no violation of the assumption of normality, a Pearson product-moment correlation coefficient was then obtained, based upon the two systems' three-thousand and fifty element data set (twenty-one patients, multiplied by three trials and fifty data frames per trial), in order to quantitatively assess the degree to which systems outputs were correlated. The result of which can be seen in tables 6.6.1 and 6.6.2

**Pearson product-moment correlation
coefficient in hip flexion/extension**

		Vicon	Device
Vicon	Pearson Correlation	1	.946(**)
	Sig. (2-tailed)		.000
	N	3150	3150
Device	Pearson Correlation	.946(**)	1
	Sig. (2-tailed)	.000	
	N	3150	3150

** Correlation is significant at the 0.01 level (2-tailed).

Table 6.5.5: Pearson correlation coefficient in hip flexion/extension

**Pearson product-moment correlation
coefficient in hip abduction/adduction**

		Vicon	Device
Vicon	Pearson Correlation	1	.824(**)
	Sig. (2-tailed)		.000
	N	3150	3150
Device	Pearson Correlation	.824(**)	1
	Sig. (2-tailed)	.000	
	N	3150	3150

** Correlation is significant at the 0.01 level (2-tailed).

Table 6.5.6: Pearson correlation coefficient in hip abduction/adduction

With an r value of 0.946 for hip flexion/extension and 0.824 for abduction/adduction, and using the correlation strength guide proposed by Cohen (1988), there is a large, positive correlation ($r > 0.5$) between the Vicon system output and that of the developed device, where $n = 3150$ and $p < 0.005$. This equates to a coefficient of determination of 89.49% shared variance for hip flexion/extension and 67.90% shared variance for hip abduction/adduction.

6.6 Main study results: comparing means of the Vicon system output compared to the developed device

In order to compare the means of waveform landmarks of interest namely the peak and trough points of hip flexion/extension and abduction/adduction parameters, and in so doing, compute inferential statistics based on projected true population, a paired-samples T-test was executed using the mean of each patient's three trials (from both the developed device and the Vicon system).

For the hip flexion/extension Paired Samples T-Test, "pair 1" relates to the 1st maxima in the waveform from the developed device and Vicon system (i.e. the peak hip flexion), "pair 2" relates to the trough of the flexion/extension waveform (i.e. the peak hip extension) and "pair 3" relates to the second maxima, as shown in Figure 6.6.1.

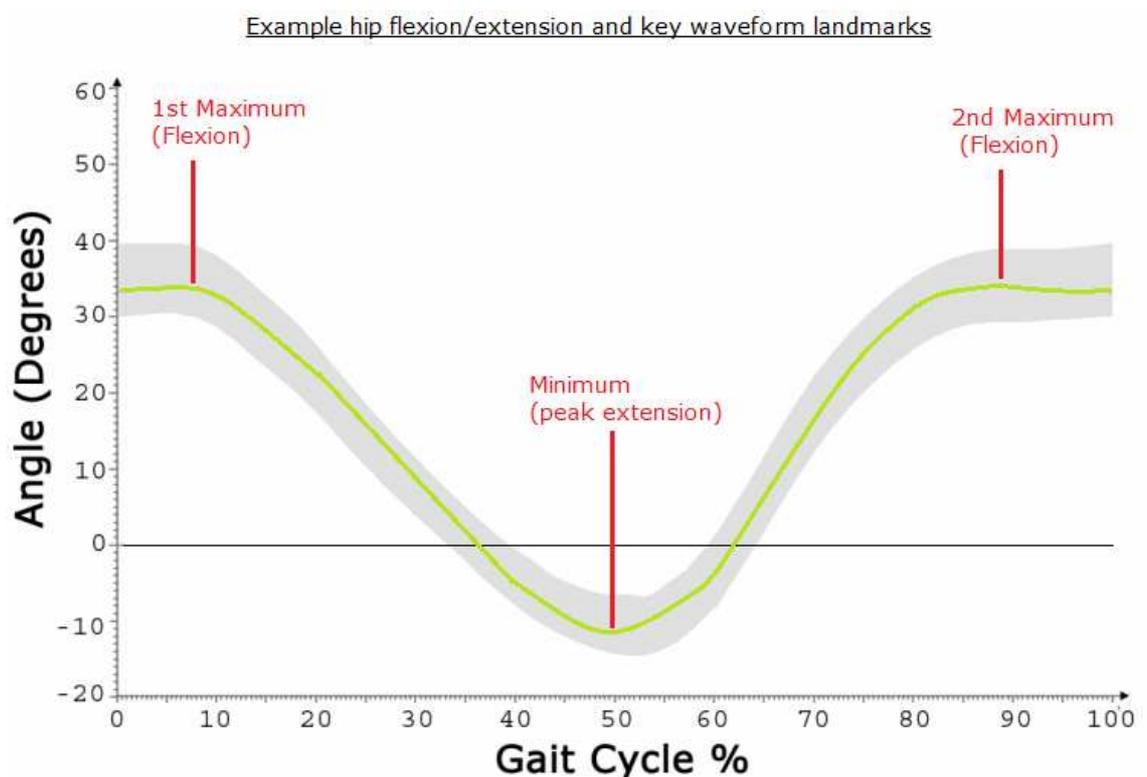


Figure 6.6.1: Hip flexion/extension waveform landmarks of interest

The output for the hip flexion/extension paired-samples T-Test was as follows:

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Max1Device	33.7308	21	9.86263	2.15220
	Max1Vicon	33.5444	21	9.41742	2.05505
Pair 2	Min1Device	5.4285	21	7.38271	1.61104
	Min1Vicon	4.6910	21	7.86563	1.71642
Pair 3	Max2Device	34.7932	21	8.10728	1.76915
	Max2Vicon	34.7754	21	8.10134	1.76786

Table 6.6.1: Paired samples statistics output: hip flexion/extension

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	Max1Device - Max1Vicon	.18632	2.40679	.52521	-.90924	1.28188	.355	20	.726
Pair 2	Min1Device - Min1Vicon	.73751	2.25911	.49298	-.29082	1.76585	1.496	20	.150
Pair 3	Max2Device - Max2Vicon	.01785	1.67683	.36591	-.74543	.78114	.049	20	.962

Table 6.6.2: Paired samples T-test output: hip flexion/extension

Table 6.6.1 gives the general statistics for the data and Table 6.6.2 demonstrates that there was no statistically significant difference in means of the patient's hip flexion/extension between the developed device and the Vicon system:

First maxima: developed device $M = 33.73^\circ$, $SD = 9.86$ and Vicon system $M=33.54^\circ$, $SD=9.41$, $t(20) = 0.355$, $p = > 0.05$ (two tailed). The mean difference between the developed device and the Vicon system was 0.186° with a 95% confidence interval ranging from -0.91 to 1.28 .

Minimum: developed device $M = 5.43^\circ$, $SD = 7.38$ and Vicon system $M=4.69^\circ$, $SD=7.86$, $t(20) = 1.496$, $p = > 0.05$ (two tailed). The mean difference between the developed device and the Vicon system was 0.738° with a 95% confidence interval ranging from 0.02 to 1.68 .

Second maxima: developed device $M = 34.79^\circ$, $SD = 8.11$ and Vicon system $M=34.77^\circ$, $SD=8.10$, $t(20) = 0.49$, $p = > 0.05$ (two tailed). The mean difference between the developed device and the Vicon system was 0.186° with a 95% confidence interval ranging from 0.02 to 1.68 .

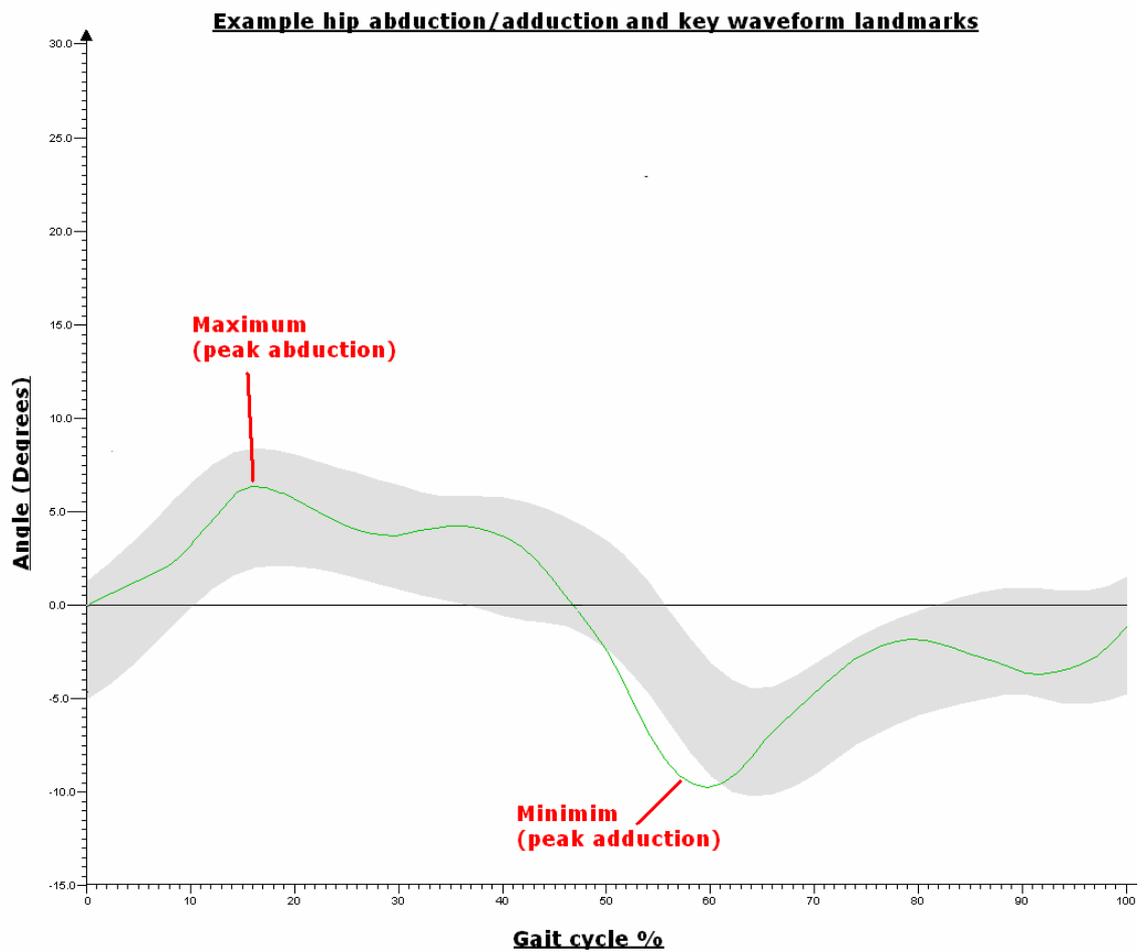


Figure 6.6.2: Hip abduction/adduction waveform landmarks of interest

For the hip abduction/adduction Paired Samples T-Test, "pair 1" relates to the peak abduction from the developed device and Vicon system, while "pair 2" relates to the peak adduction, as shown in Figure 6.6.2.

The output for the hip abduction/adduction paired-samples T-Test was as follows:

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MaxDevice	10.5197	21	3.87412	.84540
	MaxVicon	9.7498	21	3.22967	.70477
Pair 2	MinDevice	2.8762	21	4.02273	.87783
	MinVicon	1.3930	21	3.24087	.70721

Table 6.6.3: Paired samples statistics output: hip abduction/adduction

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	MaxDevice - MaxVicon	.76987	2.44386	.53329	-.34256	1.88231	1.444	20	.164
Pair 2	MinDevice - MinVicon	1.48320	2.40554	.52493	-.38821	2.57819	2.826	20	.500

Table 6.6.4: Paired samples T-test output: hip abduction/adduction

Table 6.6.3 gives the general statistics for the data and Table 6.6.4 demonstrates that there was no statistically significant difference in means of the measurement value in patient's hip abduction/adduction between the developed device and the Vicon system:

Maximum: developed device $M = 10.52^\circ$, $SD = 3.87$ and Vicon system $M=9.75^\circ$, $SD=3.23$, $t(20) = 1.444$, $p = > 0.05$ (two tailed). The mean difference between the developed device and the Vicon system was 0.77° with a 95% confidence interval ranging from -0.34 to 1.88 .

Minimum: developed device $M = 2.88^\circ$, $SD = 4.02$ and Vicon system $M=1.39^\circ$, $SD=3.24$, $t(20) = 2.826$, $p = > 0.05$ (two tailed). The mean difference between the developed device and the Vicon system was 1.48° with a 95% confidence interval ranging from 0.39 to 2.58 .

6.7 Artificial neural network results

After establishing that the developed device and Vicon system outputs were directly comparable, the mean of each patient's three trials, from both the developed device and the Vicon system, were processed using the artificial neural network.

Hip flexion/extension ANN-processed output

Table 6.8.1 shows the artificial neural network output for each patient's flexion and extension parameters. The ANN output is based upon training sets of normative data. Restated for convenience - a training set target output of '1' indicated that the subject had a value which lay at the centre of the normative range (35° for flexion, -10° extension, 5° peak adduction and -8° peak abduction). An output of '0' indicated a -20° excursion from normal range, indicating greatly deviated magnitudes.

Patient	Peak Flexion 1 Rotation (Degrees)	Peak Flexion 2 Rotation (Degrees)	Peak Extension Rotation (Degrees)	ANN Hip flexion output	ANN Hip extension output
1	27.57	24.03	-9.92	0.83	0.94
2	29.54	29.14	-4.47	0.87	0.43
3	20.45	22.17	-6.10	0.82	0.77
4	20.47	14.23	-7.94	0.69	0.91
5	21.1	25.76	-3.57	0.87	0.27
6	24.95	29.23	-3.77	0.90	0.28
7	10.39	15.80	-5.81	0.57	0.78
8	8.56	9.33	-6.80	0.32	0.87
9	32.44	30.49	-8.68	0.91	0.91
10	29.22	25.73	-9.67	0.86	0.94
11	37.88	34.28	-7.56	0.93	0.85
12	30.8	29.52	-8.52	0.90	0.91
13	38.41	38.03	-6.90	0.94	0.79
14	35.02	31.28	-6.43	0.92	0.76
15	19.85	20.99	-6.71	0.80	0.84
16	18.18	20.42	-7.87	0.74	0.90
17	22.14	22.03	-7.85	0.81	0.90
18	21.07	26.16	-6.24	0.86	0.78
19	24.59	27.89	-8.32	0.86	0.91
20	16.78	22.01	-8.04	0.73	0.91
21	23.95	27.90	-7.94	0.87	0.89

Table 6.7.1: Artificial neural network peak flexion/extension output

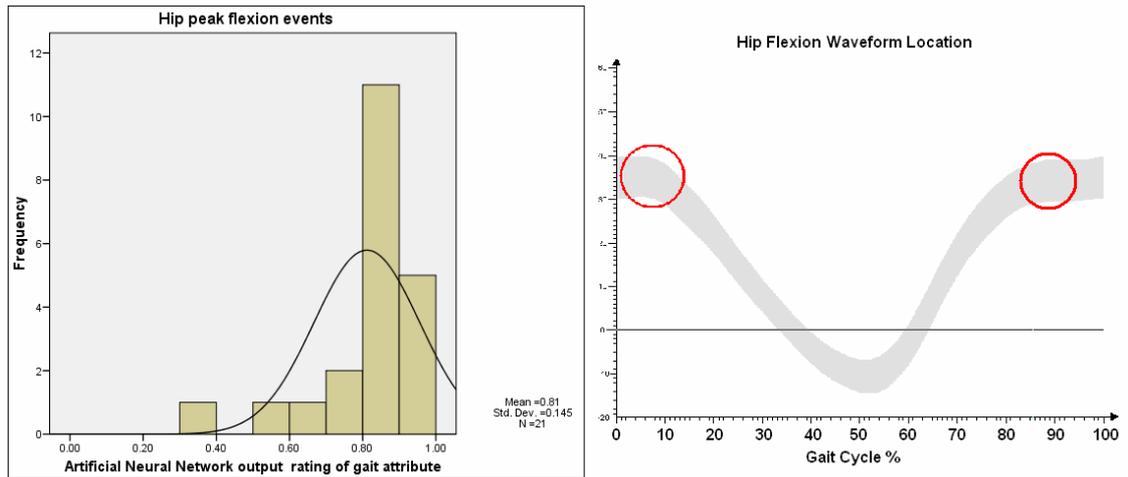


Figure 6.7.1: Hip peak flexion event ANN output histogram

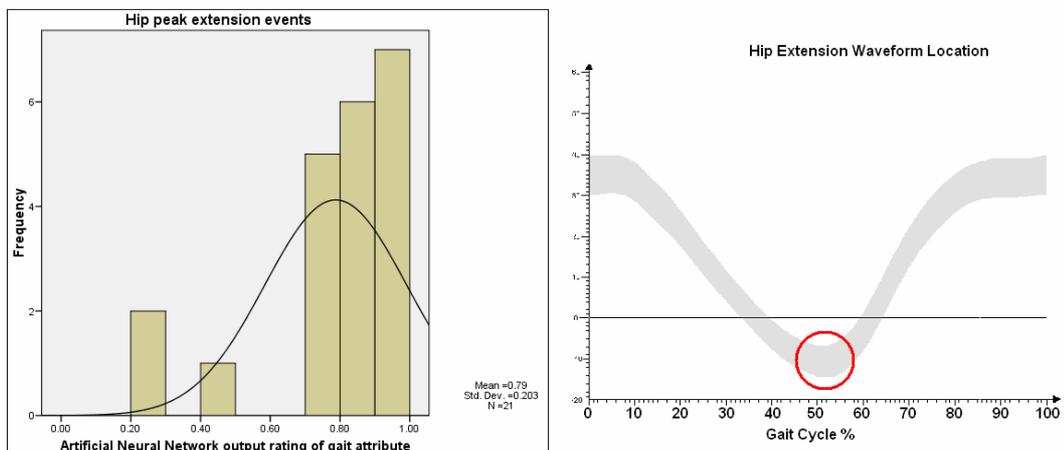


Figure 6.7.2: Hip peak extension event ANN output histogram

The fitness score means for the peak flexion and extension events are 0.81 (SD = 0.145) and 0.79 (SD = 0.203) respectively (Figures 6.7.1 and 6.7.2). This data would suggest that the sample's peak flexion and extension are approximate normal magnitudes, with the exception of two outlying values in peak extension arising from patients seven and eight.

Hip flexion/extension ANN-processed output

Table 6.7.2 shows the artificial neural network appraisal of each patient's abduction and adduction parameters.

Patient	Peak abduction rotation (degrees)	Peak adduction rotation (degrees)	ANN Hip abduction output	ANN Hip adduction output
1	6.07	-3.63	0.92	0.74
2	1.56	-2.38	0.64	0.76
3	0.57	-3.38	0.44	0.86
4	5.81	-4.99	0.89	0.85
5	2.34	2.05	0.81	0.10
6	4.86	-2.39	0.90	0.65
7	2.58	-1.9	0.78	0.67
8	4.49	-4.25	0.85	0.84
9	1.85	-3.84	0.62	0.87
10	2.44	-3.26	0.71	0.82
11	7.52	-4.77	0.94	0.78
12	4.63	-2.87	0.89	0.72
13	1.69	-7.39	0.42	0.96
14	7.85	-2.28	0.96	0.51
15	-2.2	-3.73	0.10	0.88
16	2.52	-4.18	0.68	0.88
17	4.11	-2.39	0.87	0.68
18	8.25	-2.87	0.96	0.59
19	4.64	-4.02	0.86	0.82
20	4.12	-0.33	0.90	0.35
21	3.03	-0.41	0.84	0.40

Table 6.7.2: Artificial neural network peak abduction/adduction appraisal

With reference to Figures 6.7.3 and 6.7.4, the peak abduction/adduction ANN outputs were 0.76 (SD = 0.219) and 0.70 (SD = 0.211) respectively; ANN outputs suggest the parameters are deviated with respect to normal values. The meaning of this, as well as the flexion and extension appraisals is explored in the discussion chapter.

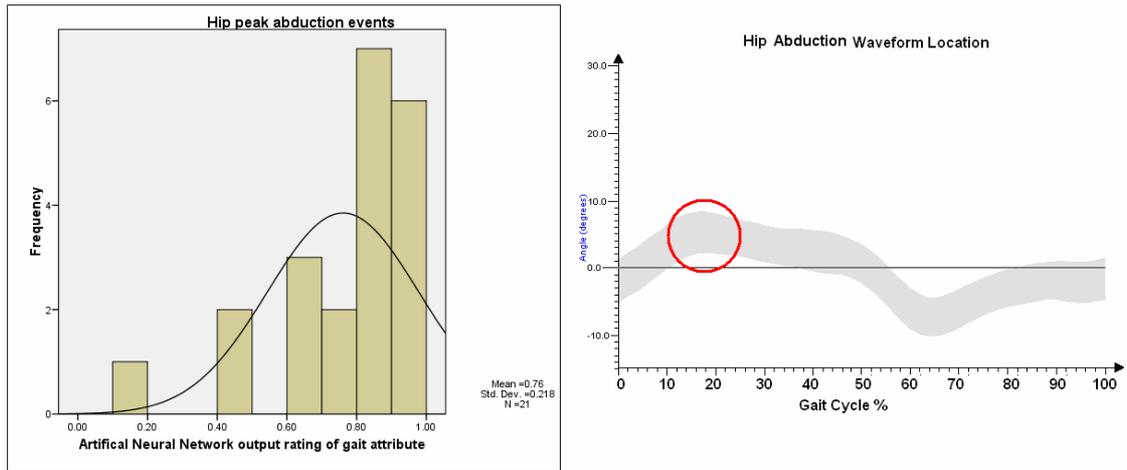


Figure 6.7.3: Hip peak abduction event ANN output histogram

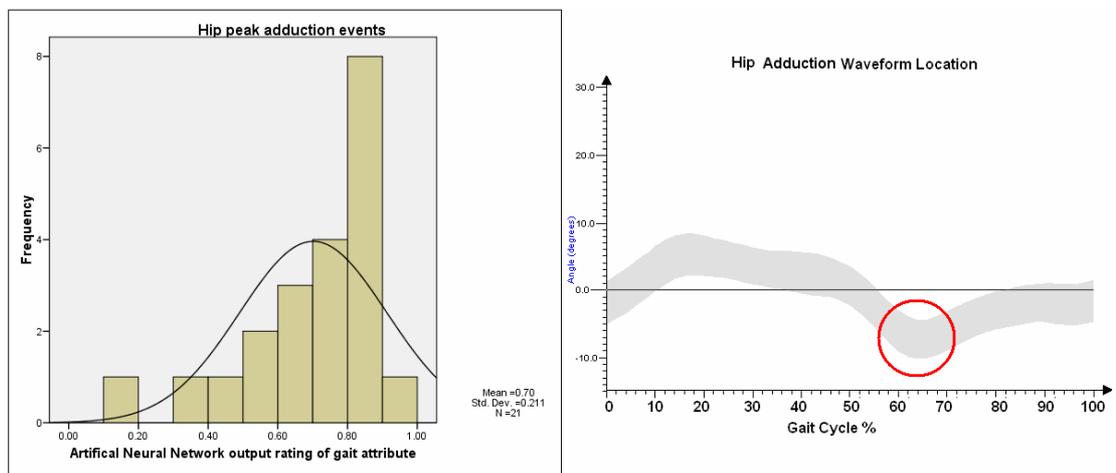


Figure 6.7.4: Hip peak adduction event fitness score histogram

6.8 Vicon and developed device data comparison

The following section gives a direct graphical comparison of the developed device output against the Vicon system, along with the artificial neural network output. In each case, the normative range from the Vicon software is shown in grey with the Vicon and developed device traces overlaid in pink and blue respectively.

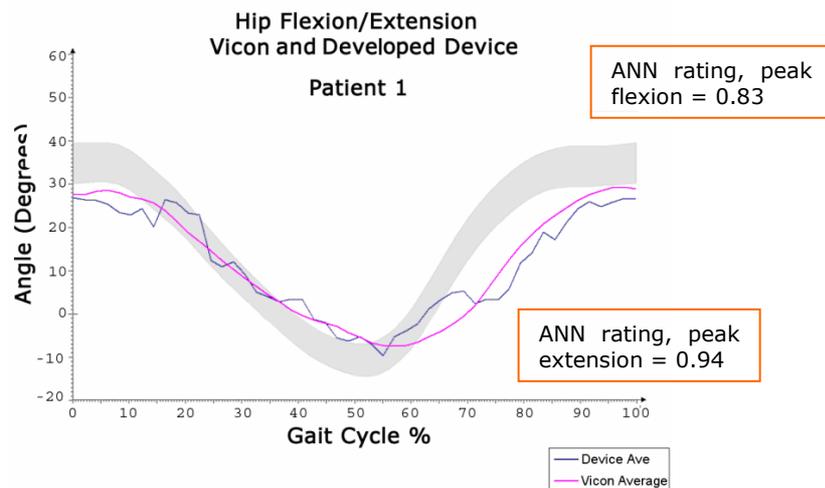


Figure 6.8.1: Patient 1 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

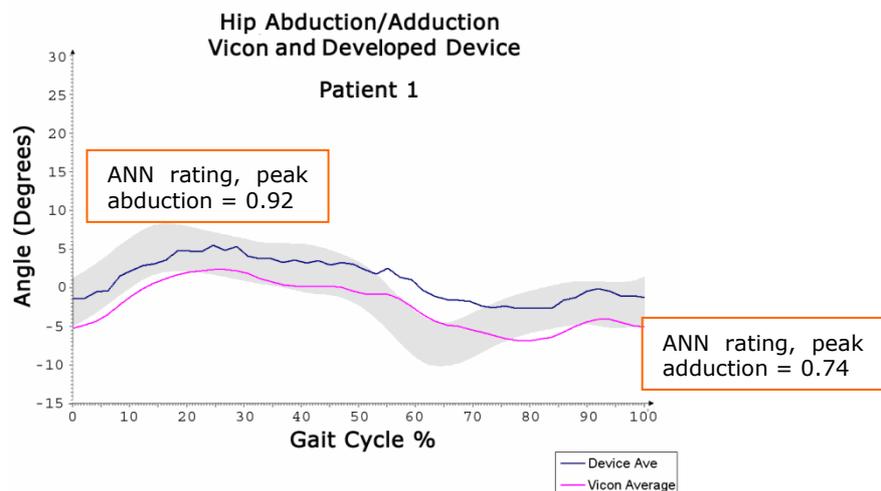


Figure 6.8.2: Patient 1 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

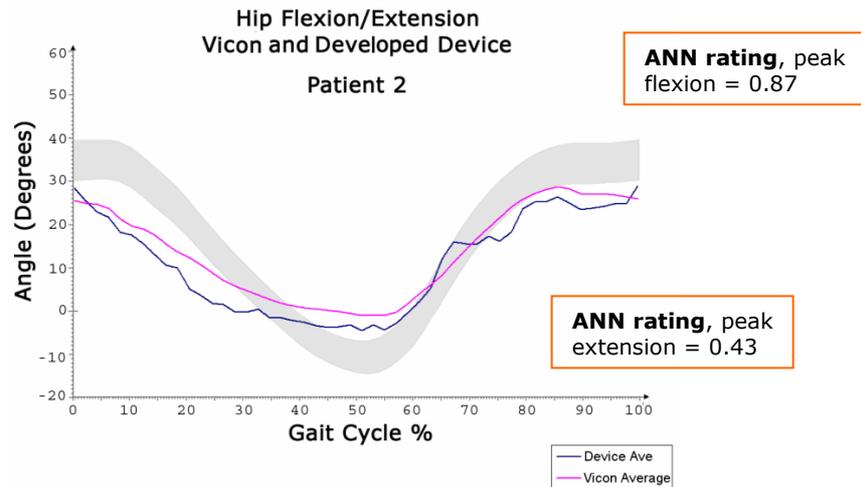


Figure 6.8.3: Patient 2 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

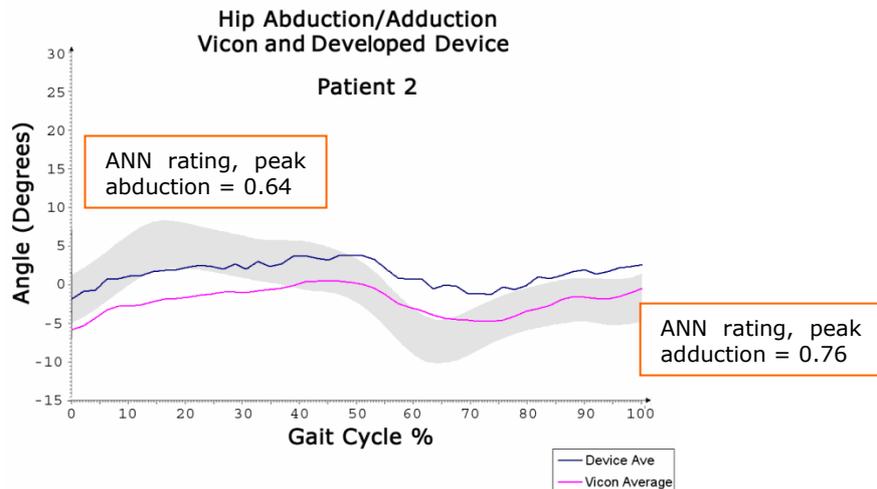


Figure 6.8.4: Patient 2 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

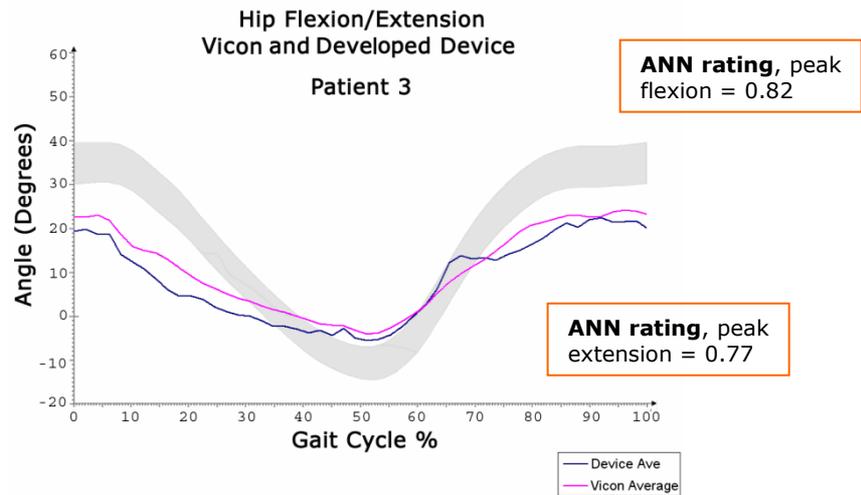


Figure 6.8.5: Patient 3 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

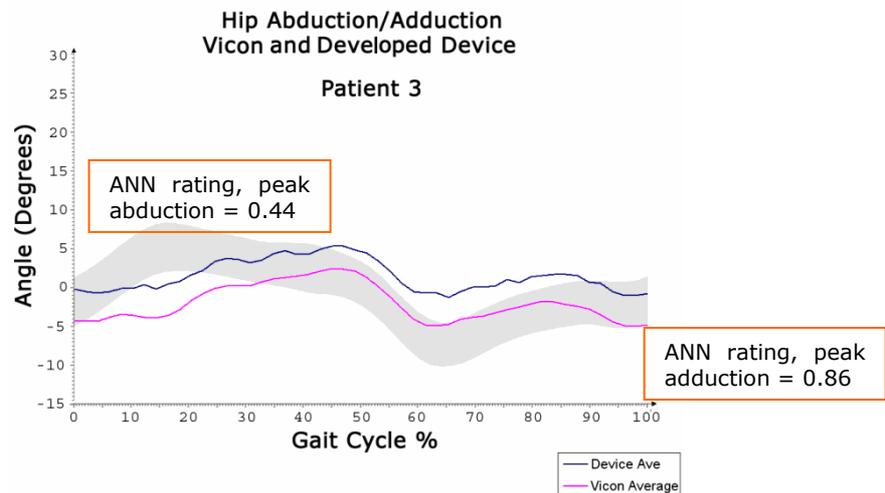


Figure 6.8.6: Patient 3 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

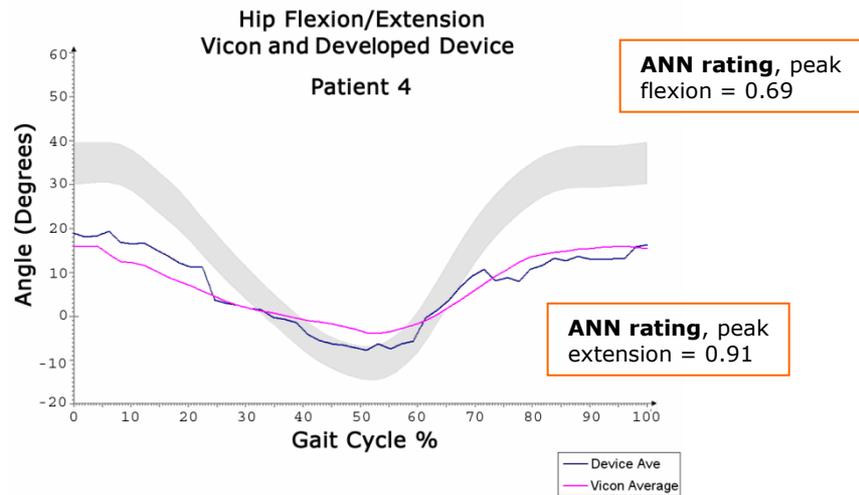


Figure 6.8.7: Patient 4 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

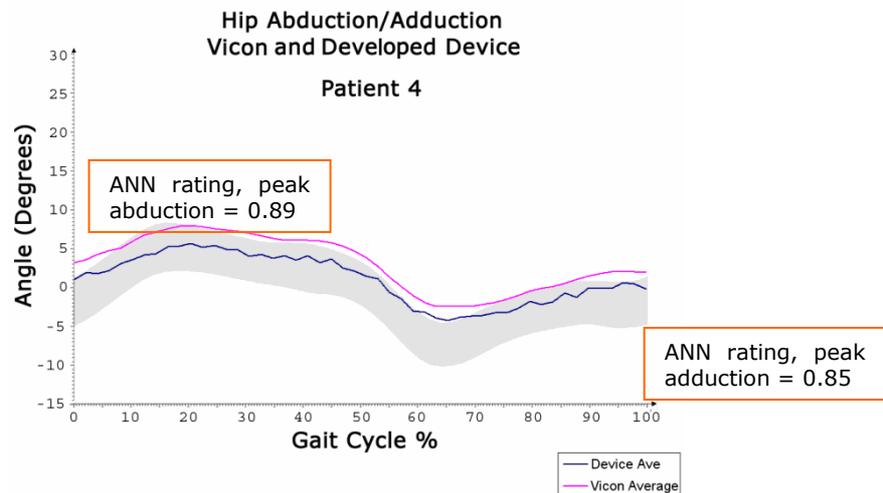


Figure 6.8.8: Patient 4 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

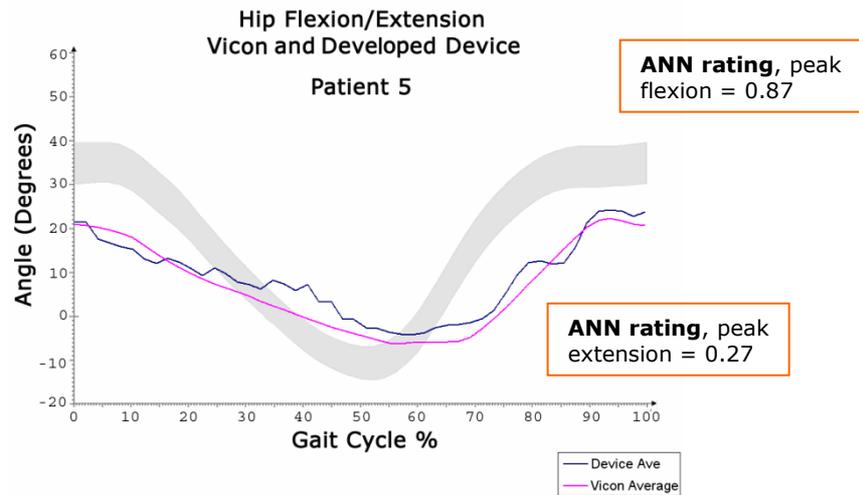


Figure 6.8.9: Patient 5 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

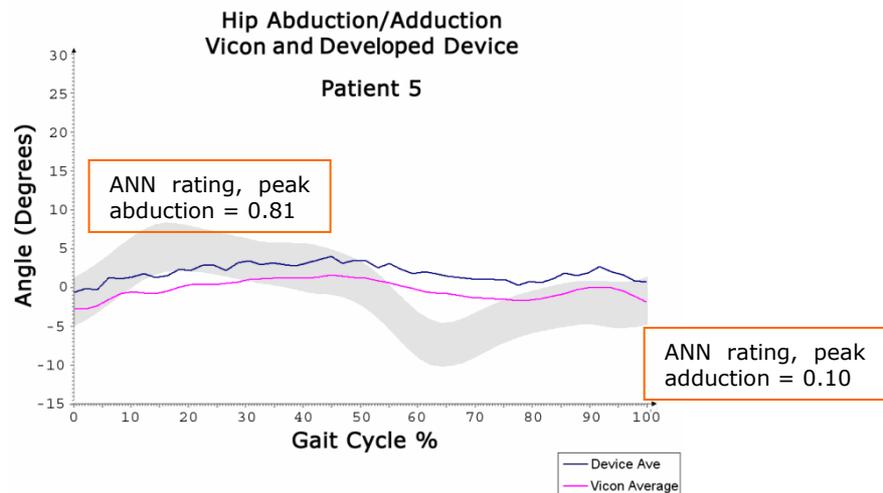


Figure 6.8.10: Patient 5 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

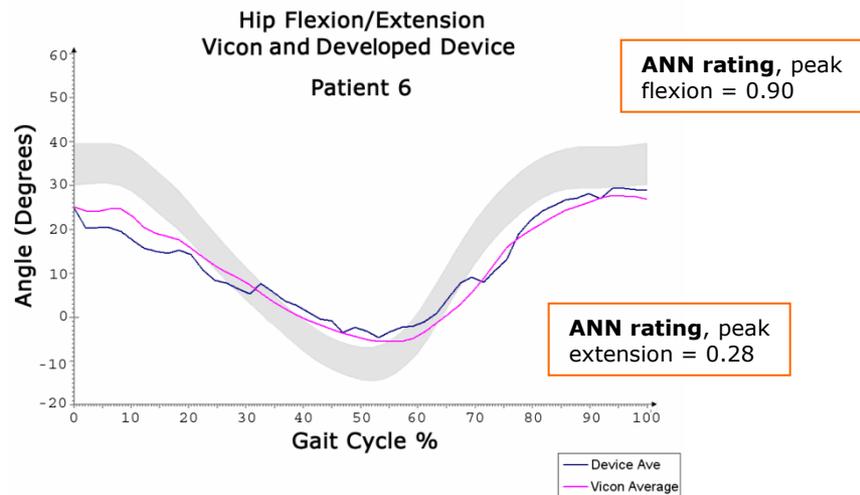


Figure 6.8.11: Patient 6 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

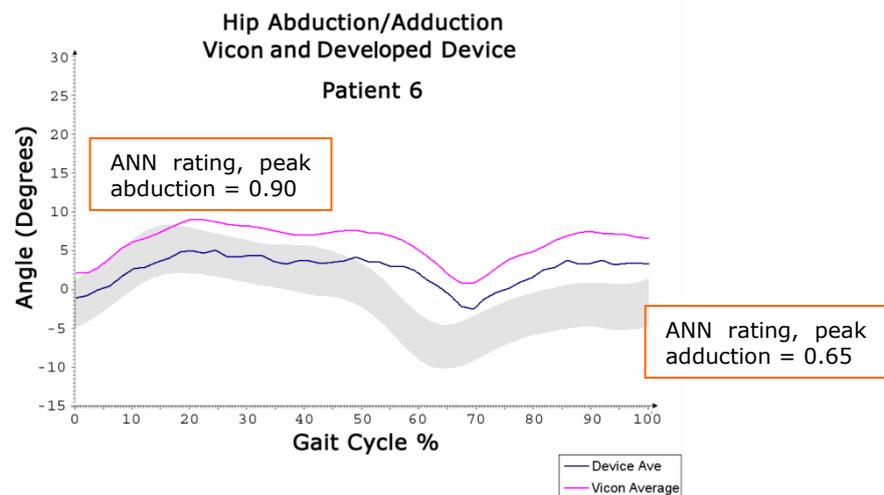


Figure 6.8.12: Patient 6 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

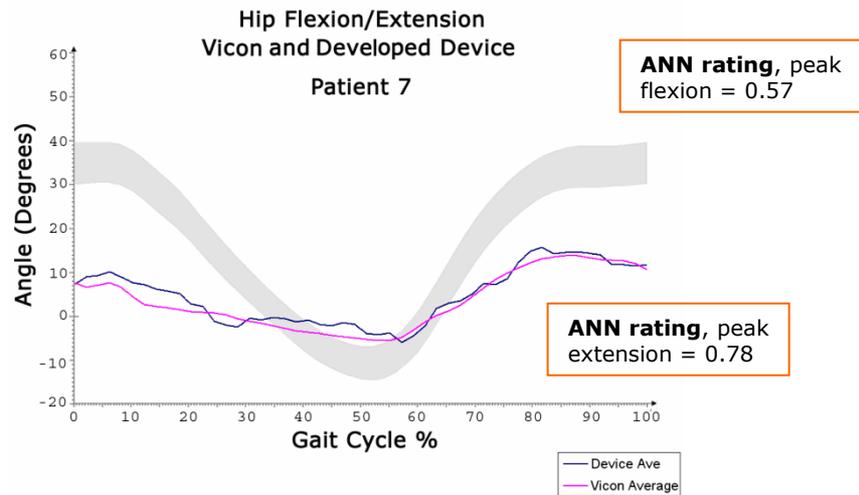


Figure 6.8.13: Patient 7 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

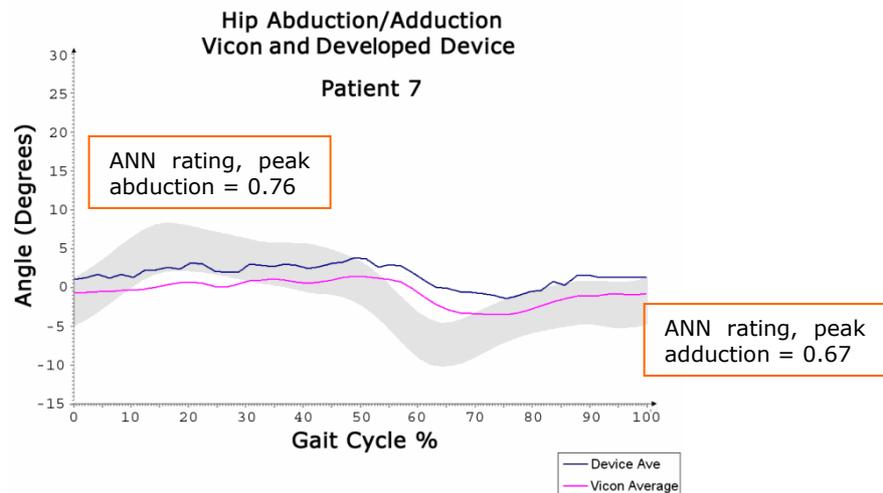


Figure 6.8.14: Patient 7 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

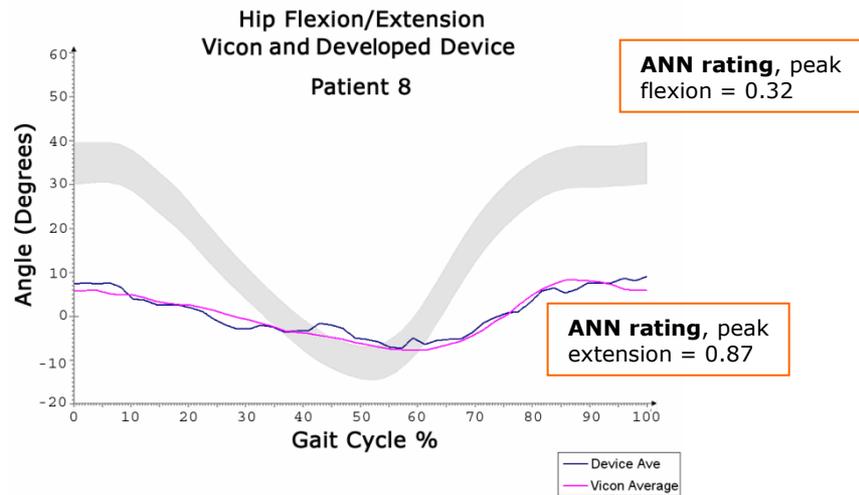


Figure 6.8.15: Patient 8 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

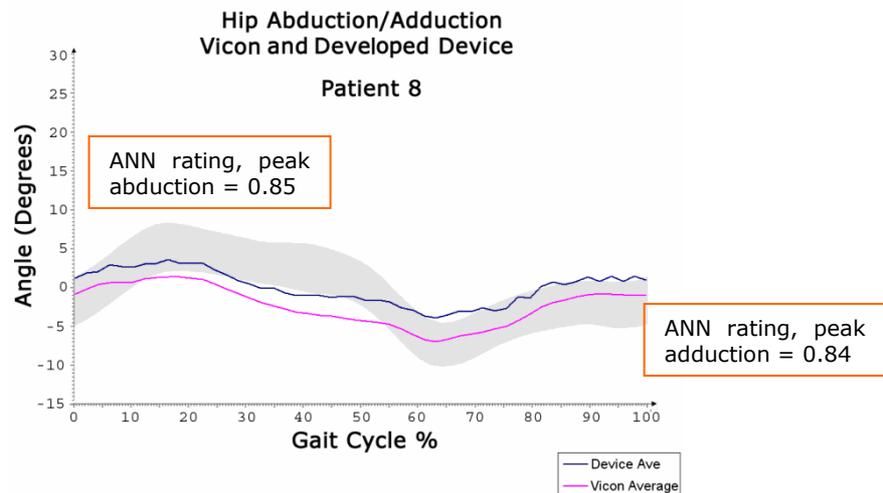


Figure 6.8.16: Patient 8 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

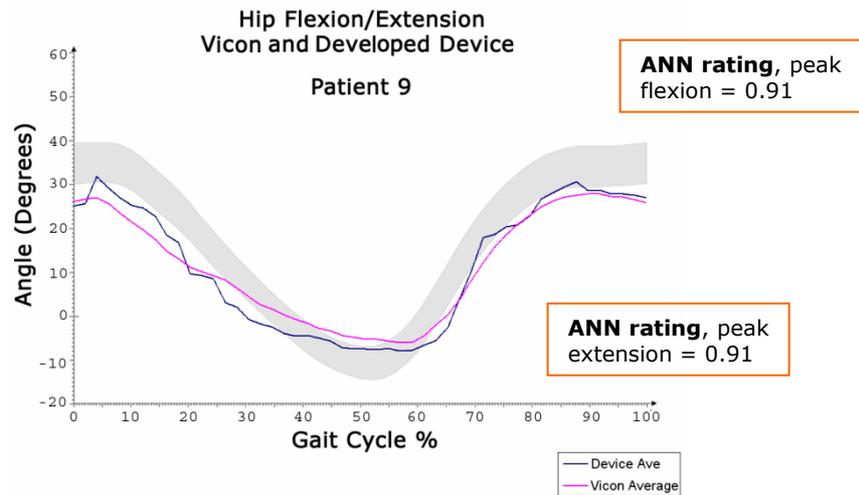


Figure 6.8.17: Patient 9 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

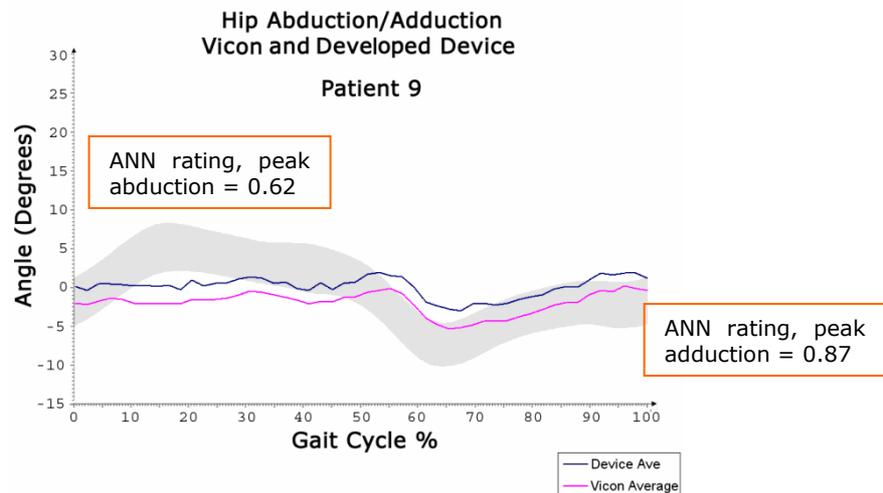


Figure 6.8.18: Patient 9 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

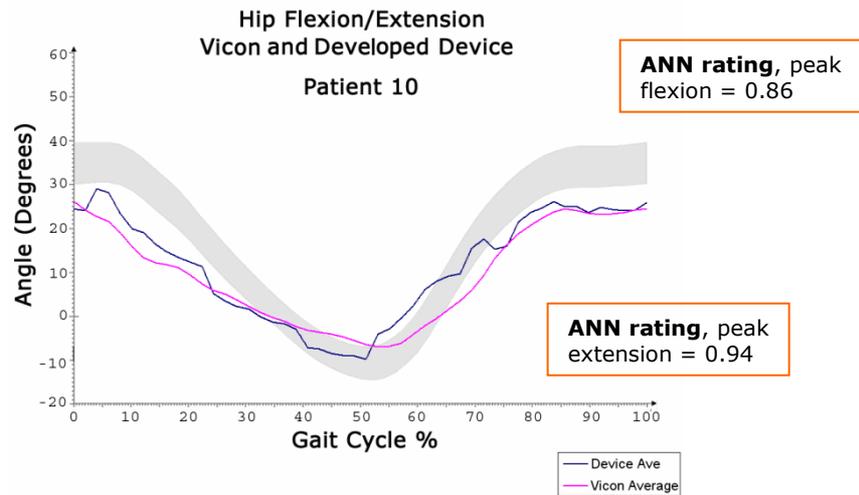


Figure 6.8.19: Patient 10 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

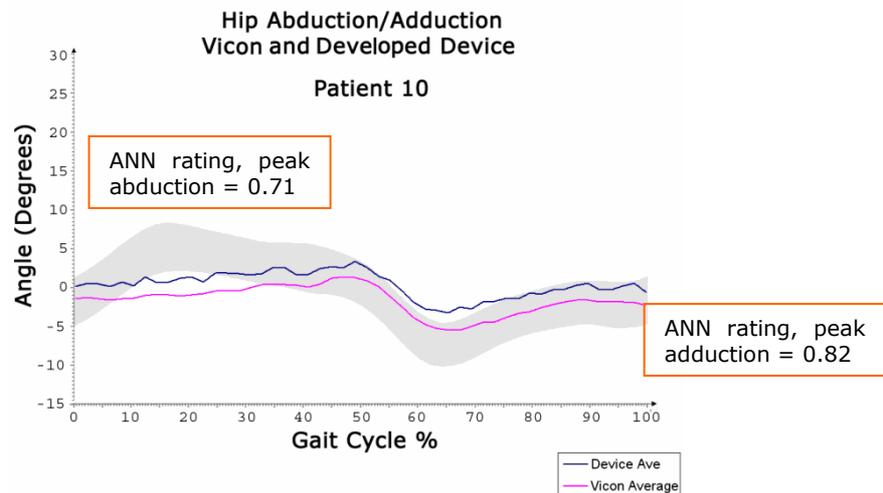


Figure 6.8.20: Patient 10 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

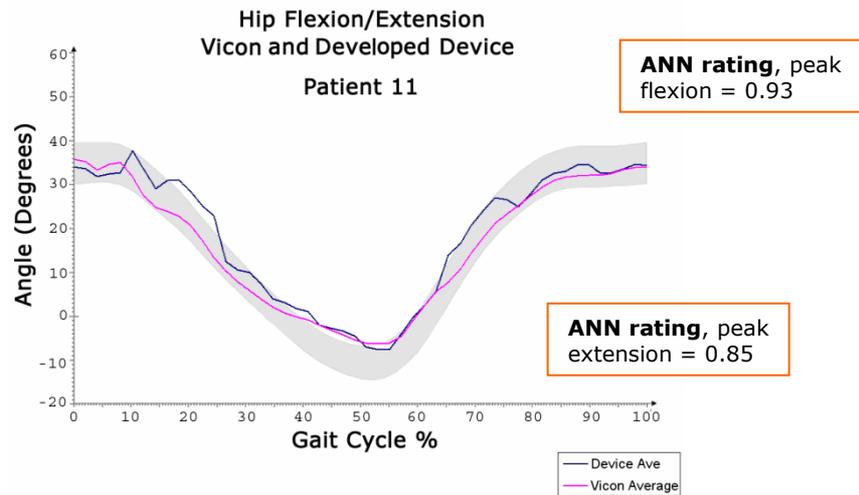


Figure 6.8.21: Patient 11 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

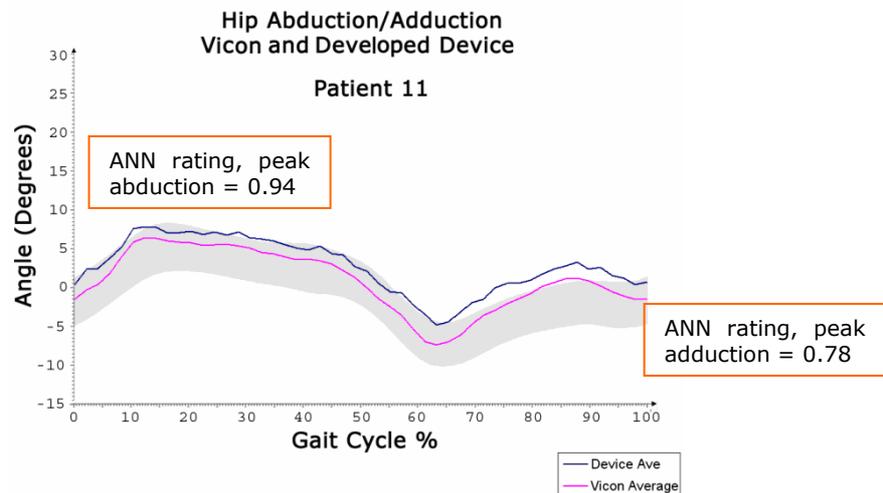


Figure 6.8.22: Patient 11 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

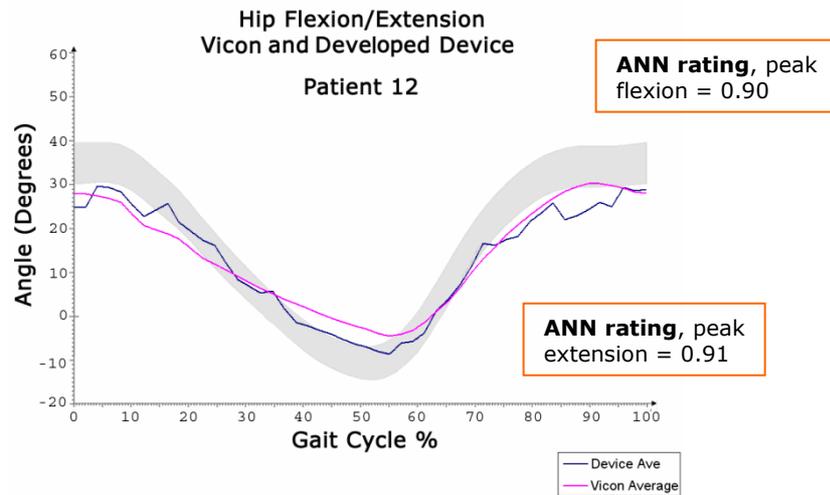


Figure 6.8.23: Patient 12 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

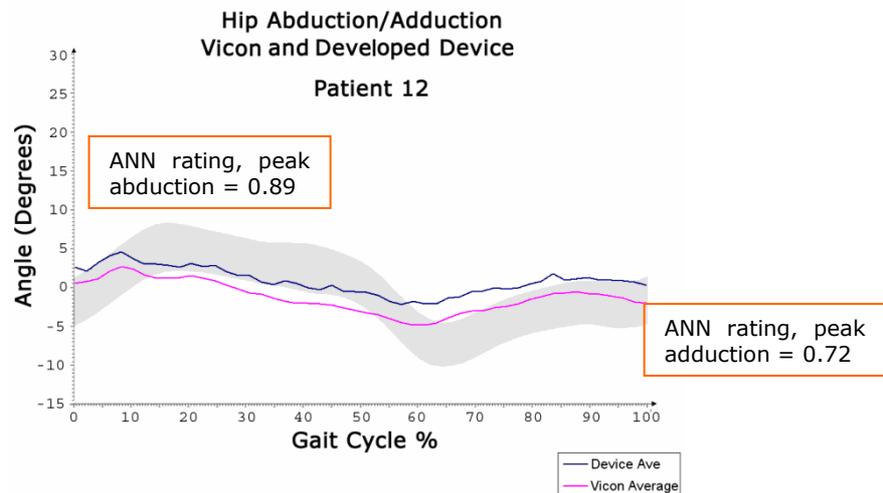


Figure 6.8.24: Patient 12 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

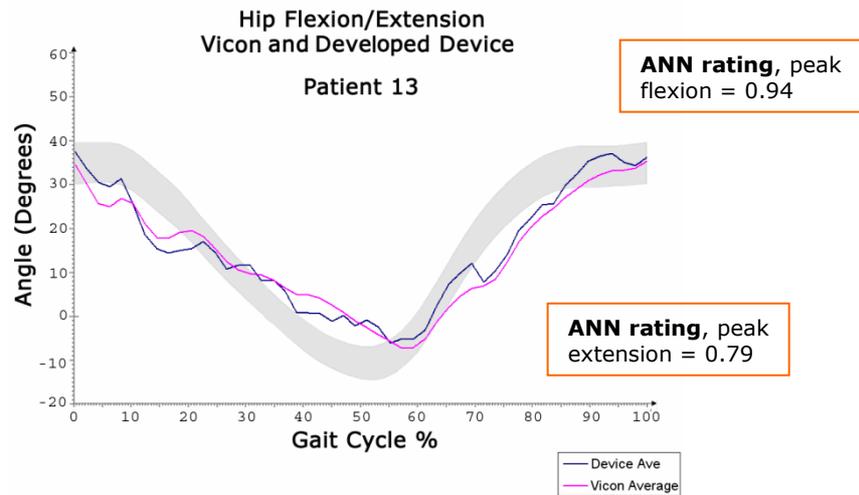


Figure 6.8.25: Patient 13 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

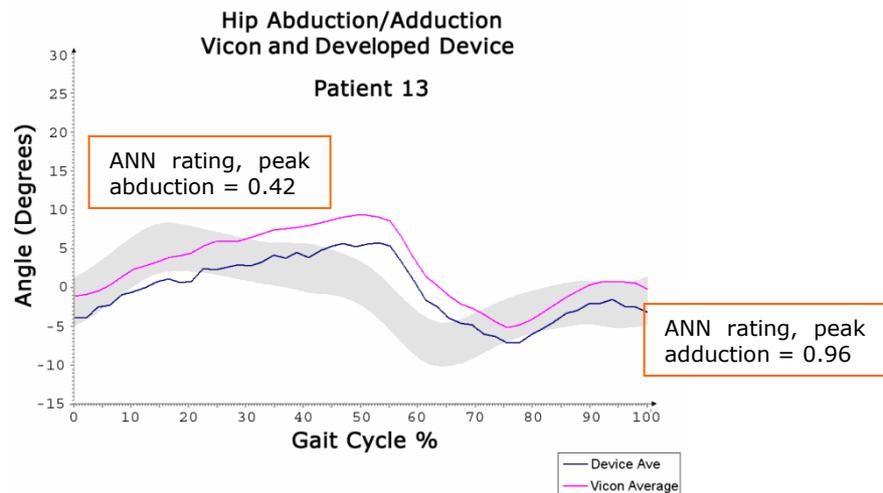


Figure 6.8.26: Patient 13 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

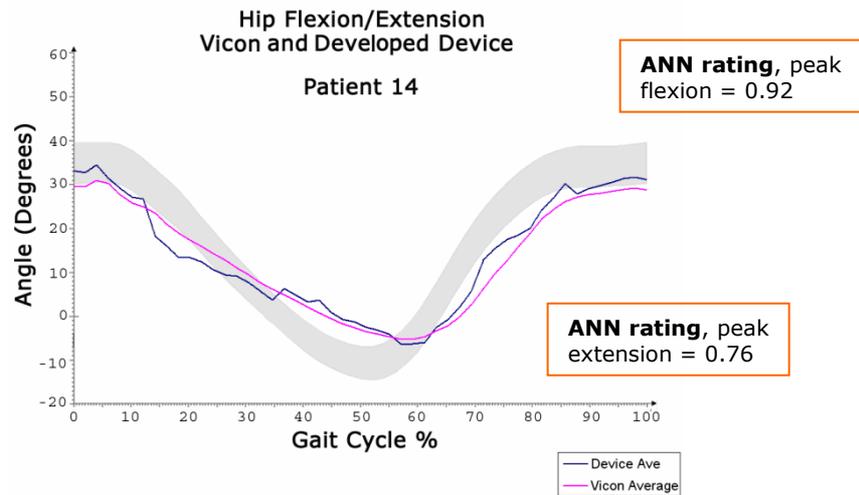


Figure 6.8.27: Patient 14 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

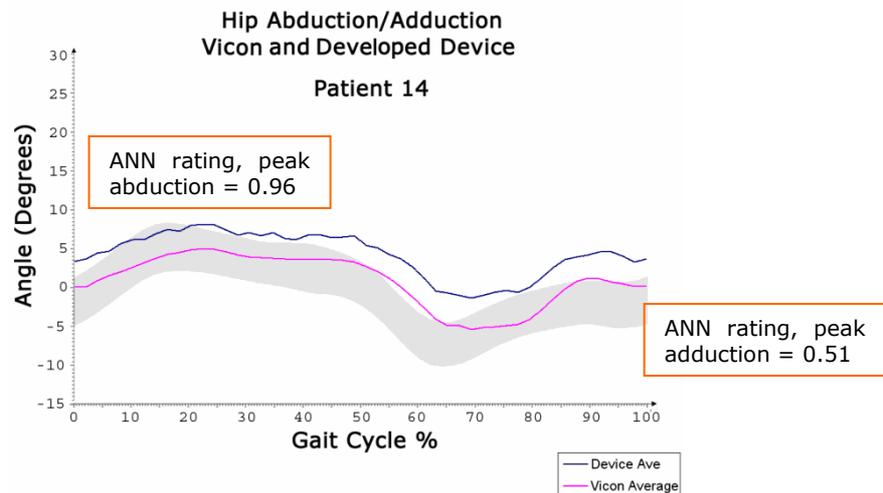


Figure 6.8.28: Patient 14 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

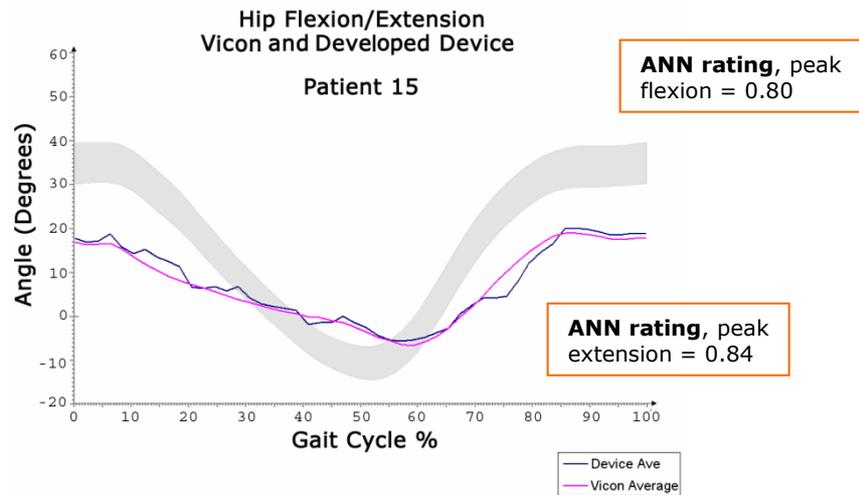


Figure 6.8.29: Patient 15 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

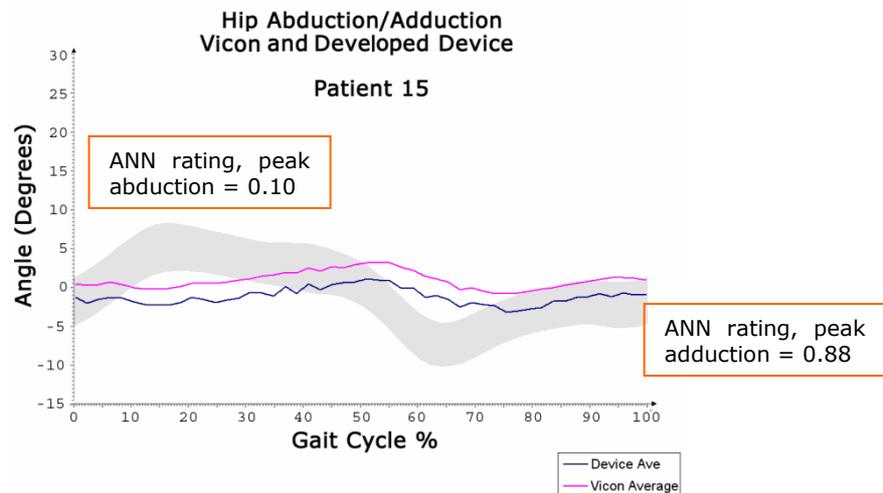


Figure 6.8.30: Patient 15 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

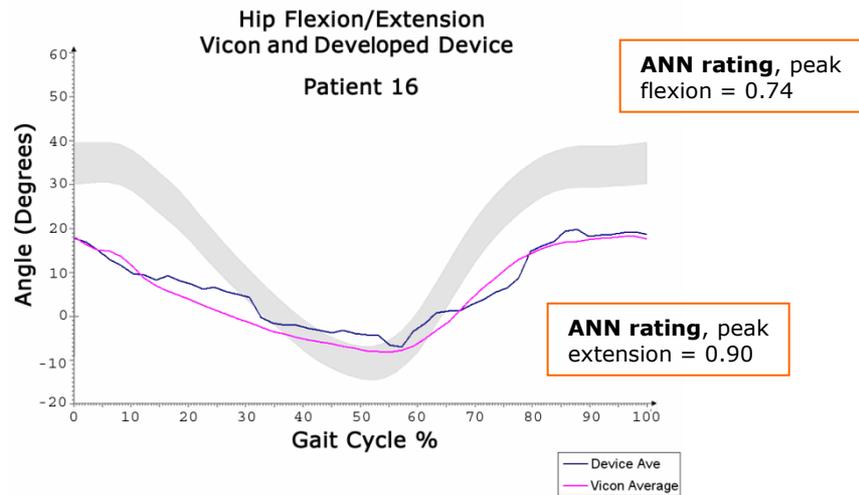


Figure 6.8.31: Patient 16 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

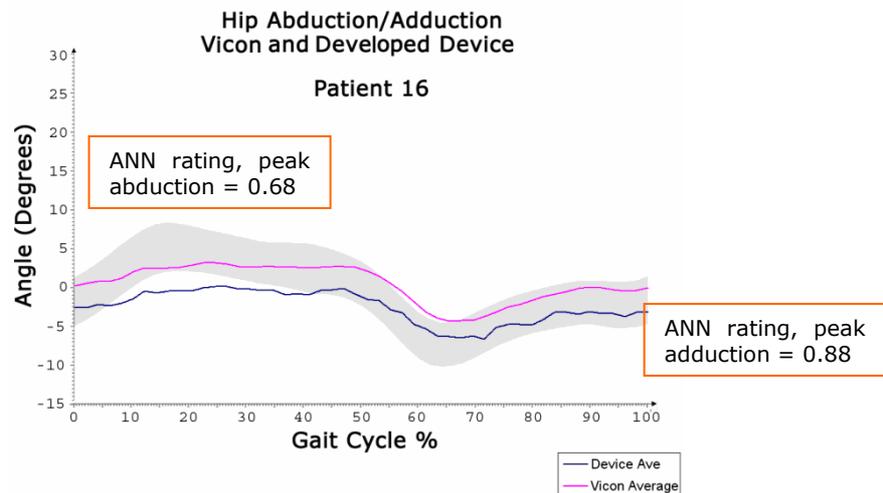


Figure 6.8.32: Patient 16 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

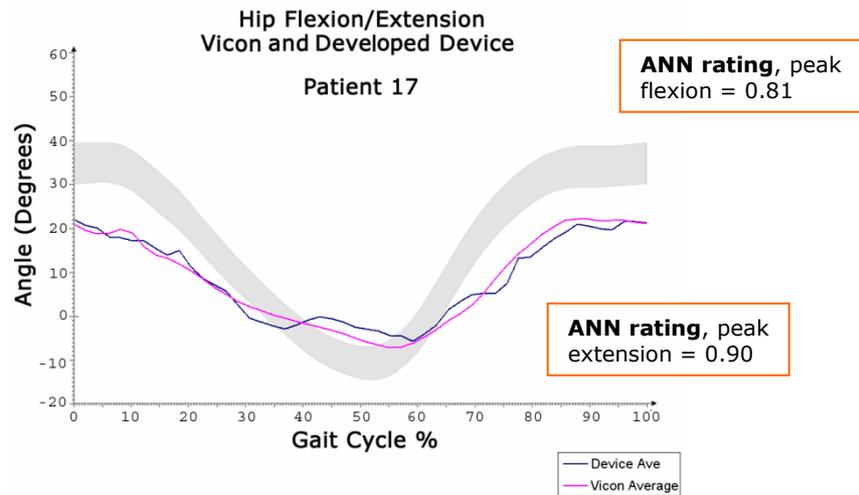


Figure 6.8.33: Patient 17 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

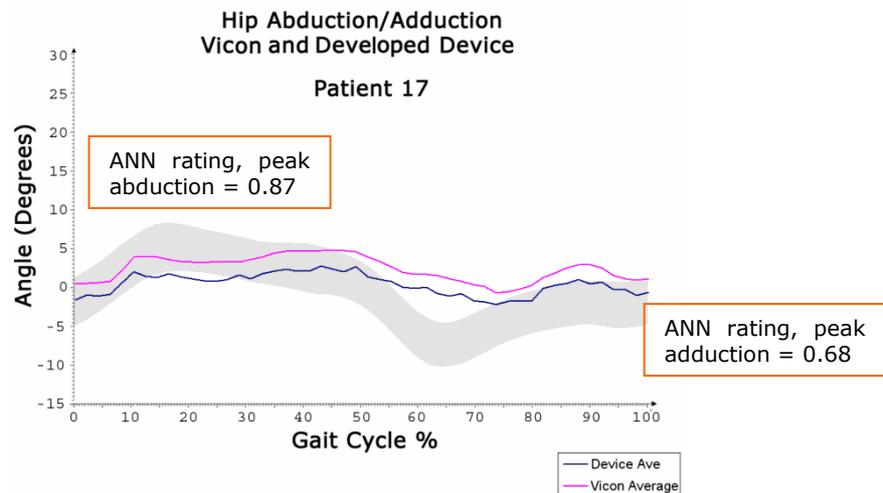


Figure 6.8.34: Patient 17 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

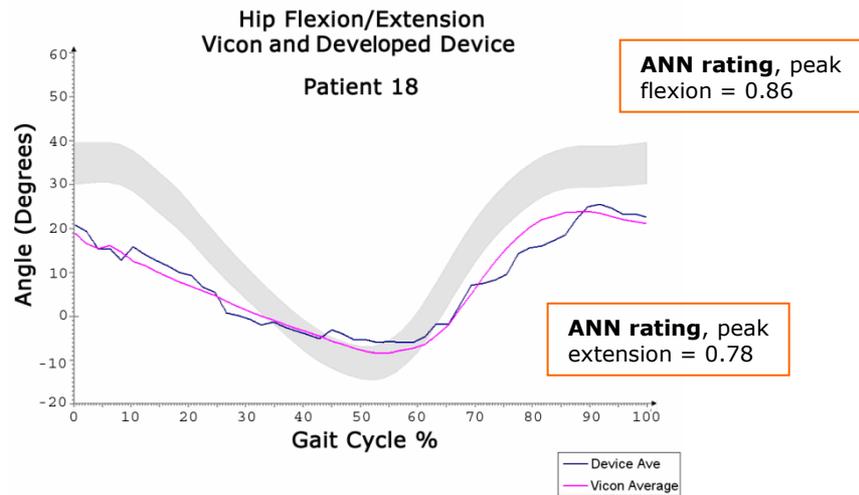


Figure 6.8.35: Patient 18 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

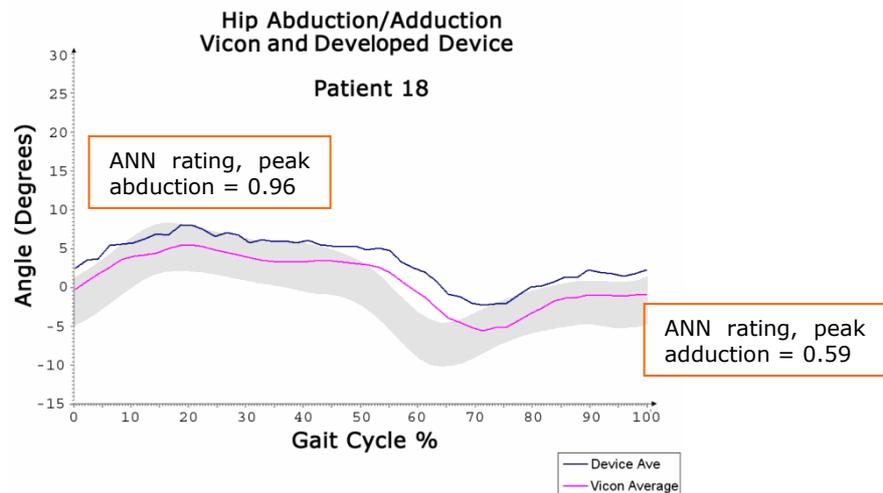


Figure 6.8.36: Patient 18 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

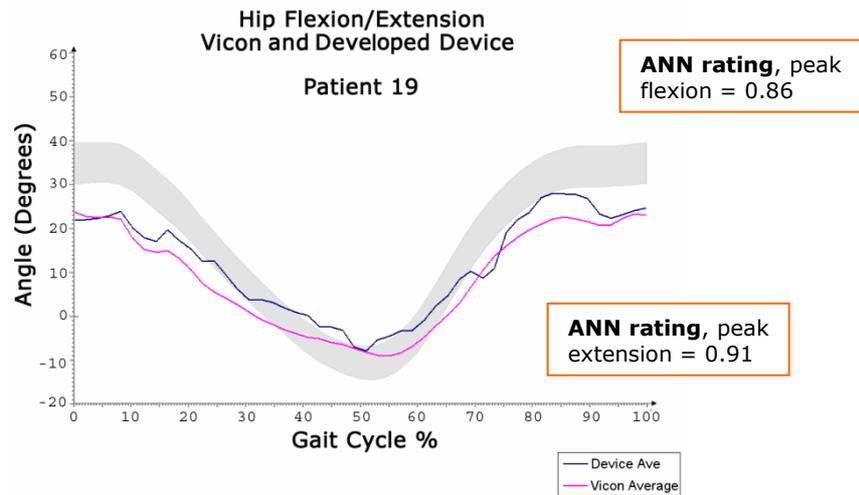


Figure 6.8.37: Patient 19 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

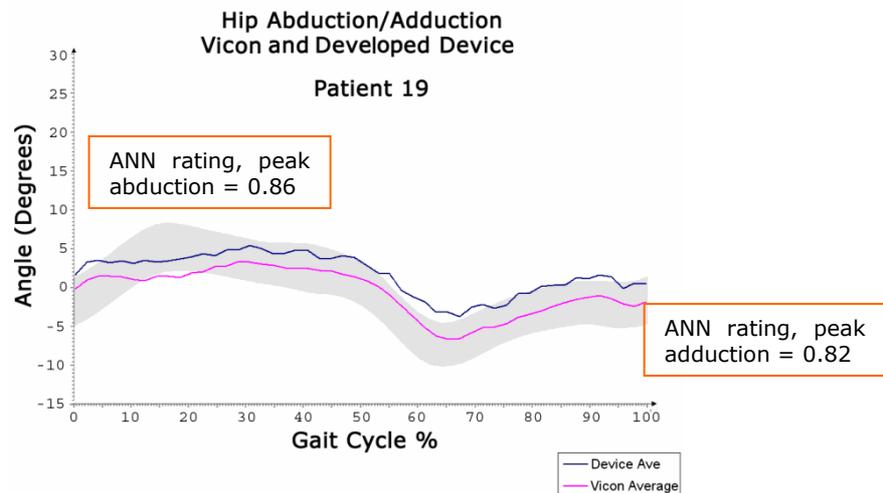


Figure 6.8.38: Patient 19 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

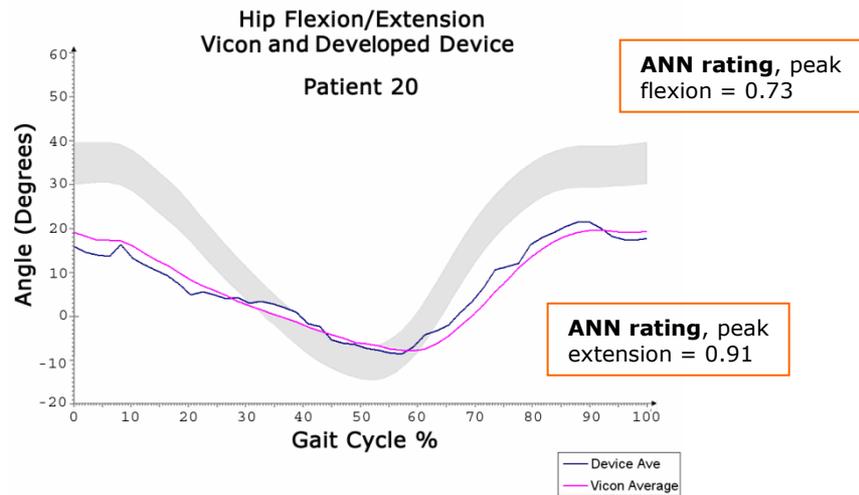


Figure 6.8.39: Patient 20 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

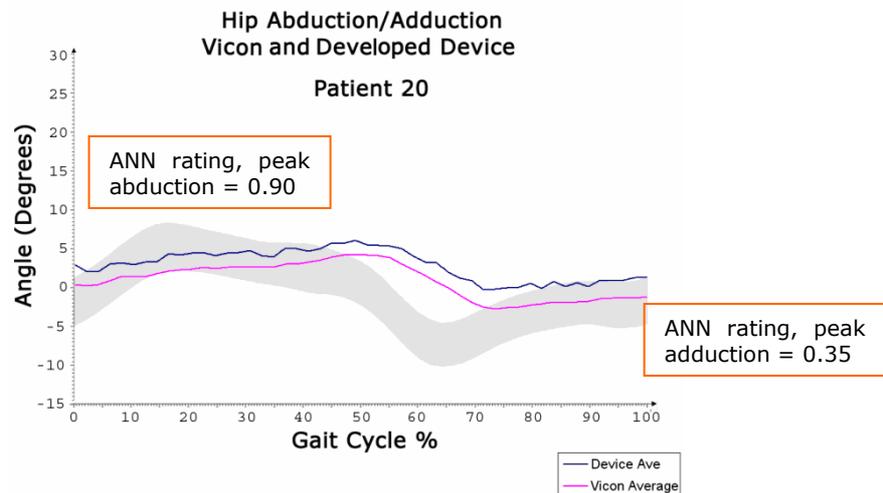


Figure 6.8.40: Patient 20 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

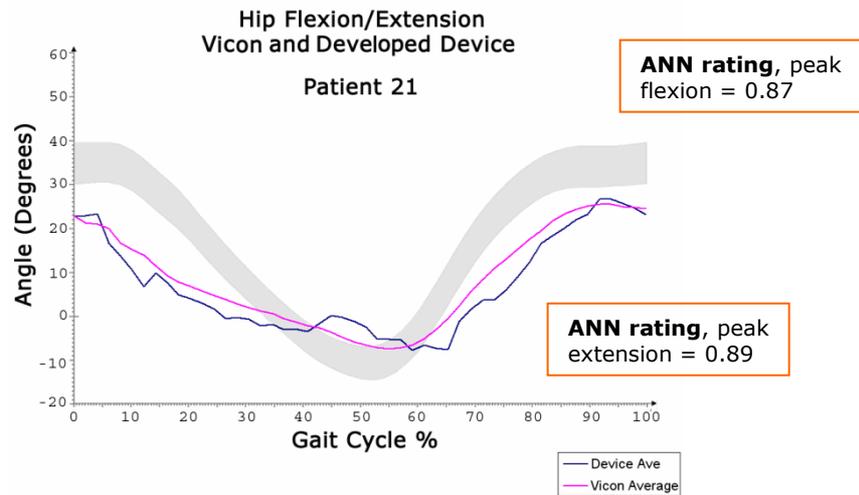


Figure 6.8.41: Patient 21 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

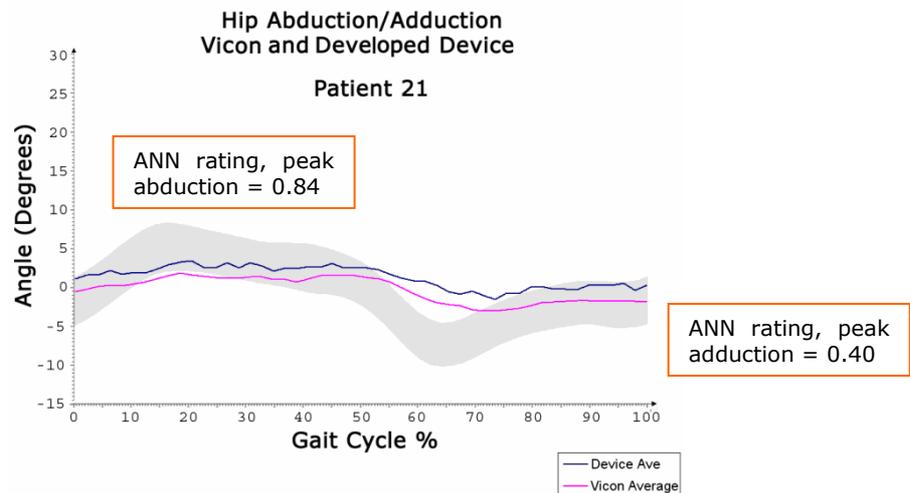


Figure 6.8.42: Patient 21 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

6.9 Chapter summary

This chapter has presented the results from the various data collection phases of the study using tables and figures to demonstrate the developed device output and the artificial neural network of the system compared to the Vicon system. The next chapter will discuss the meaning of the results and contextualise them using the framework of the study objectives and overall aim.

Chapter 7

Discussion

Chapter Overview

This chapter examines the objectives established in Chapter 1 and discusses how the study has been undertaken to address them and establish if they have been achieved. In so doing, the objectives and overall aim of the research are revisited and aligned to explore the overall aim of the study: the development, validation and verification of a device to aid healthcare professionals in detecting deviated hip position in post-operative THA patients; to inform rehabilitation strategies based upon objective measures made by the device and its output. Culminating in the production of the results presented in Chapter 6, this chapter concludes with discussion of the possible meanings, relationships, as well as the performance of the developed device as an instrumented biomeasurement system.

7.1 Introduction

To address this overall aim of the study, a principal objective set was developed at its commencement, to clearly define its scope and purpose, and to form a robust plan of work in the pursuit of the aim.

To reiterate the objectives of the study were:

1. To design and implement an electronic controller for the system using suitable sensors and components, for the purpose of gathering hip-position data.
2. To code the necessary software to be able to recognise altered pattern of motion of the hip.
3. To critically assess the effectiveness of the system in identifying altered patterns of gait.
4. To test the system on a suitable number of subjects in order to evaluate if the system is suitable for use as a physiotherapy diagnostic and detection aid for gait, based on Vicon and qualitative analysis.

7.2 Controller design & implementation

Following the review of literature and investigating the nature of normal and deviated gait, the developed device data acquisition system was developed. The evolution of the hardware measurement system underwent three iterations, as detailed in Appendix 15, to inform the design of the final device (Figure 7.2.1) which is described in Chapter 4.

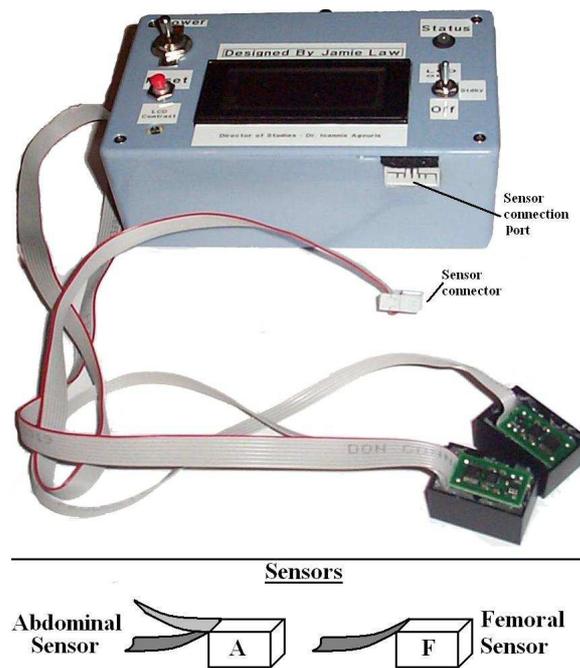


Figure 7.2.1: Final developed device, as presented

The electronics controller, its wireless communication module and data logging software running on the host computer software were the same for each of the devices; the sensing apparatus which the subject wore with its interfacing circuit and its embedded pre-processing code differed for each. The 'generalised controller' design strategy was adopted so that modifications, revisions and entirely different sensing units could be connected to the unit, assuming they produced an analogue response, otherwise additional hardware and software interfacing would also be required.

On the selection of accelerometers as the measurement sensors: their choosing for the presented system, as well as their quality output for biomeasurement applications, is in agreement with such work as Choquette, Hamel and Boissy 2008, Turcot et al. 2008. However, the developed device and system differs from the former, in which the accelerometers served as the basis of data collection system for body-segment-specific activity monitoring and, in the latter, used as sensing elements in a lab-based system and were successful in discrimination knee pathologies. No system encountered at the time of writing appeared to be designed or constructed with the function of hip flexion/extension and abduction/adduction data acquisition in a portable, clinical context.

7.3 Software coding

The next goal of the study involved creating software to drive the hardware and software processing tasks.

There were four software layers developed in the study, which were necessary to gather and process data. These were:

1. Microcontroller-resident sensor driver, interfacing and processing code.
2. Microcontroller-resident data tabulating and transmission code and host computer-resident.
3. Computer-resident Visual Basic (VB) Microsoft Excel macro scripts, developed to process repetitive, high-volume and high-criticality.
4. Computer-resident artificial neural network, coded in Borland C++, developed to process the developed device accelerometer data.

With reference to appendices 9 and 10, detailing the microcontroller-resident code, this software was capable of carrying out its tasks of acquiring accelerometer sensor data, via its analogue to digital converter (ADC) port, processing the signal data and handling wireless serial communication to the host computer. Third-party terminal software was used on the host computer to data-log the microcontroller communication stream.

Extensive use of the Microsoft Excel macro function was employed to write VB scripts to automate, as much as possible, the data handling and post-processing operations, such as data division into patient/trial/gait cycle parameter/data frame and data source (the developed device or Vicon system). This allowed the ~1 million data elements of the study to be manipulated, minimising the risk of manual transcription errors post-processes, such as data normalising, averaging and plotting operations.

The neural network software was developed in C++ and training sets were synthesised based upon normal hip patterns, with the network being trained to recognise deviations from the range and making inferences of magnitude and direction of this deviation.

The artificial neural network output shown in Chapter 6.8 details the data output from the Vicon system plotted alongside the waveform from the developed device, for each subject. In addition, the artificial neural network scores for each of the developed device waveform landmarks are shown next to the plots. These scores reflect the degree to which each of the waveform landmarks, for each parameter and each patient, subscribe to the normative range. If the ANN score was close to the value '1', it would have suggested, based upon the data gathered, that the particular gait cycle event in question observes normal magnitude. Conversely, a low score indicated reduce magnitude and therefore could be used as an indicator of deviation or pathology.

Using selected examples from the data set, using subjects 8 and subject 15 as examples of abnormal and normal ROM (Figures 7.3.1 and 7.3.2 respectively), the ANN scoring can be observed with respect to the developed device and Vicon system graphs.

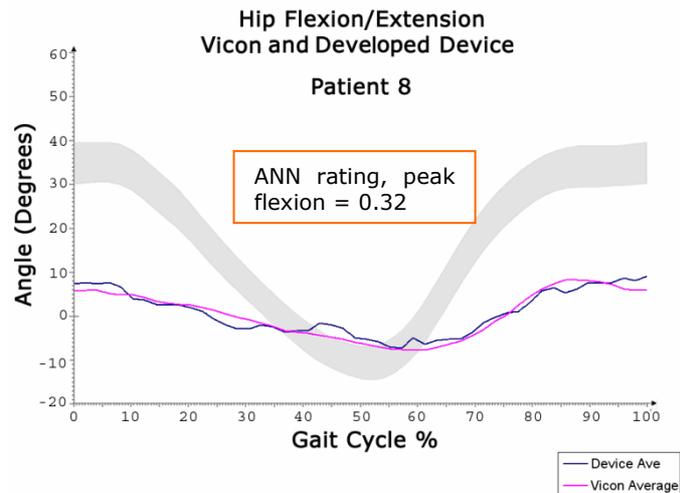


Figure 7.3.1: Patient 8 hip flexion/extension waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

The data of subject 8 demonstrates significantly decreased hip flexion, as supported by the data from the developed device and the Vicon system; a primary peak flexion of 8.56° and a secondary of 9.33° , compared to central normative range of 35° . Correspondingly, the artificial neural network output a flexion score of 0.32, as opposed to a normative rating of '1'.

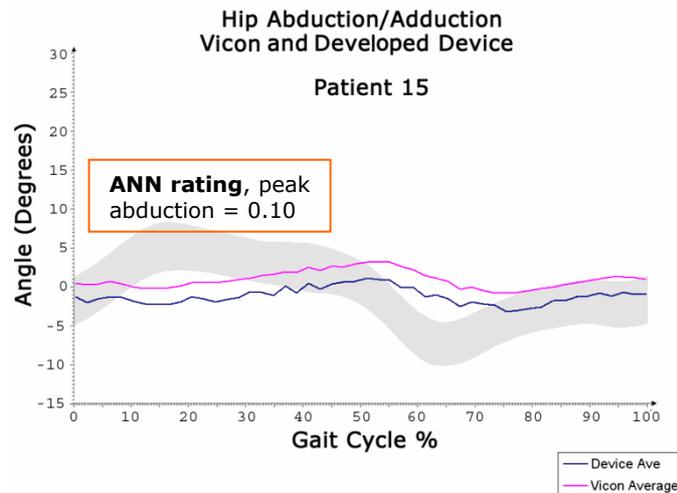


Figure 7.3.2: Patient 15 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

Patient 15 presented with a peak hip abduction of -2.2 , as opposed to a normative $+4^{\circ}$. Consequently, the artificial neural network scoring for this magnitude of rotation is 0.1.

The outputs of the network could be used as indicators of deviation or reduced range of motion in the clinical setting. If the device were used for repeated measures of a subject before, during and after a rehabilitation treatment, it is conceivable that the output of the device could be used as a benchmark and biomeasurement system for assessing the effectiveness of a certain intervention.

Overall, based upon the operation of the software for the developed device during the study, it operated as designed and expected, allowing the system to function, data to be collected, sorted, processed and analysed in a manner allowing the developed device to be validated against the Vicon system.

7.4 Effectiveness of the system in identifying altered patterns of gait

For the developed device, data were collected in order to establish if the developed device developed in the study was effective in detecting gait abnormality in THA patients with respect to hip flexion/extension and abduction/adduction range of motion and pattern. This data collection consisted of a multi-phase data acquisition, processing and analysis architecture:

1. Marker repeatability study outcome.
2. Assessing the effect of the developed device on gait.
3. Comparing the developed device hip flexion/extension and hip abduction/adduction output with that of the Vicon system.
4. Performing inferential statistical tests on the key waveform features of interest in hip flexion/extension and hip abduction/adduction.
5. Artificial neural network assessment of these parameters.

It can be seen from Table 6.2.1, on page 73, that the raw repeated measures Z-scores are, in 76% of the cases, sub-millimetre in magnitude and, in the worst case, -1.44mm deviated from the measurement distance mean.

From the descriptive statistics, Table 6.2.2, the Z-score across all five measures shows the "mean of means" (i.e. the average of all parameter means) to be 0.026mm. This value is an indicator of the overall data set variance; the lower this value, the more accurate the whole marker set was placed throughout the repeatability study (Charlton et al. 2004). In addition, the ranges of the measures can be observed in Table 7.4.1.

Body segment	Z-Score range across five measures
Pelvis	1.5415
Left knee to ankle	1.3678
Left foot length	2.5578
Right knee to ankle	2.0865
Right foot length	1.5798
Mean Range	1.82668

Table 7.4.1: Marker placement Z-Score range

Concluding the marker placement repeatability, the computed Levene statistic of 0.865 ($p > 0.05$) reflects homogeneity of variance. At this level the Z-scores are evidently homogeneous, meaning that markers placed with this low level of variance will be subject to minimal marker placement error. This results in optimised data capture and consequently higher-quality of data output from the Vicon system software which relies on absolute marker placement accuracy for joint centre interpolation and extrapolation in gait cycle parameter output (Agouris 2002).

A conceivable limitation of this technique exists in the eventuality that if the segment endpoint markers were persistently displaced by the same magnitude and direction as one another, the resultant relative distance measure could still seem accurate, but the absolute marker placement would not be.

It is more likely, however, that repeated palpation-application cycles would emphasize errors of this nature in the form of spurious, or highly disparate, segmental measurement readings (Kadaba et al. 1989).

In order for the developed device to be used as a system for hip position measurement, it was imperative to assess if the device induced any functional impairment in gait cycle parameters. This was tested by using the Vicon system to capture data with and without the developed device being worn by the patient. Thereafter, a comparison of means of the maxima and minima of each gait cycle parameter waveform was conducted. The Vicon system waveform landmark data frame number was used in the selection of the developed device data frame, i.e. a like-for-like waveform comparison was drawn at the same point of both devices so that waveform pattern/phase was also compared.

For the gait cycle parameters featuring waveform landmarks not following normal distribution, it is theorised that the natural variation within the sample (n=21) is very diffuse for some individuals, due to the effect of the THA procedure itself (Sariali et al. 2009); the patient alters their range of movement and assumes a pain-reducing/relieving range of movement, as shown in the non-normal distribution in waveform landmarks.

Whether the waveform landmarks in each gait cycle parameter are normally distributed or not, the comparison of means tests which were undertaken (with reference to Table 6.4.1) show no significant difference in the patients studied, when wearing the developed device, compared to not wearing the device. Therefore their gait was altered with respect to normal parameters, but not altered as a result of wearing the device

The clinical relevance of having a system, which is used for the purpose for detection of abnormalities in gait, which does not *itself* contribute an effect, is clear: it is adverse to the study to have a piece of instrumentation which alters the quantities which are being studied (Faruqui and Jaeblon 2010). More specifically, the results suggest that the developed device may be used on the THA subject population generally, with unknown gait deviations

resulting from hip positioning, without the requirement of considering if the device would be destructive, obtrusive or producing a negative effect on the patient's gait cycle parameters; the output of the device relates entirely to any detected, patient-originating deviation only.

7.4.1 Comparing the developed device hip flexion/extension and hip abduction/adduction output with that of the Vicon system

For the purpose of comparing the developed device to the Vicon system output, scatterplots were generated to give a qualitatively-assessable means of agreement of the two systems.

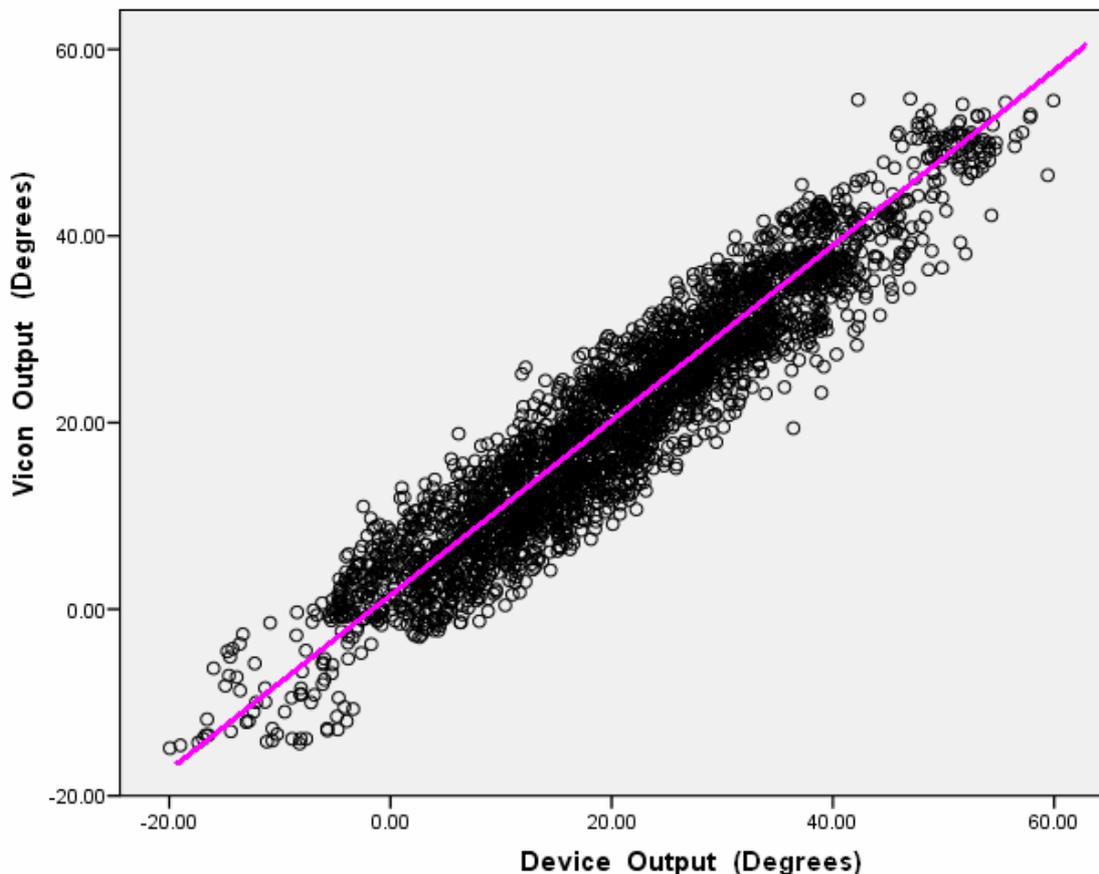


Figure 7.4.1.1: Scatter plot of device output with respect to Vicon, with centre of mass shown, for hip flexion/extension

With reference to Figure 7.4.1.1, which shows all patient hip flexion extension measures of all data frames and across all trials; the strong, positive correlation of the scatter plot illustrated that values output from the developed device and the Vicon system agree, from a qualitative appraisal, very closely and with little variance/divergence (evident from the tight formation of points with a low proportion of outliers); the points distribution followed an essentially singular body grouping. Quantitatively, the large and positive Pearson product-moment correlation coefficient of $r = 0.946$ underpinned this appraisal, based upon Cohen's r-value evaluation

guidelines (Table 6.5.5). From the clinical viewpoint, the data suggested that the developed device described patient hip flexion/extension across the full waveform, to a level comparable with the Vicon system.

Hip abduction/adduction measures of all data frames and across all trials:

With reference to Table 6.5.6, again there was strong, positive correlation shown by the r-score of 0.824, however, with reference to Figure 7.4.1.2, the hip abduction/adduction and hip flexion/extension scatter plots differed in appearance:

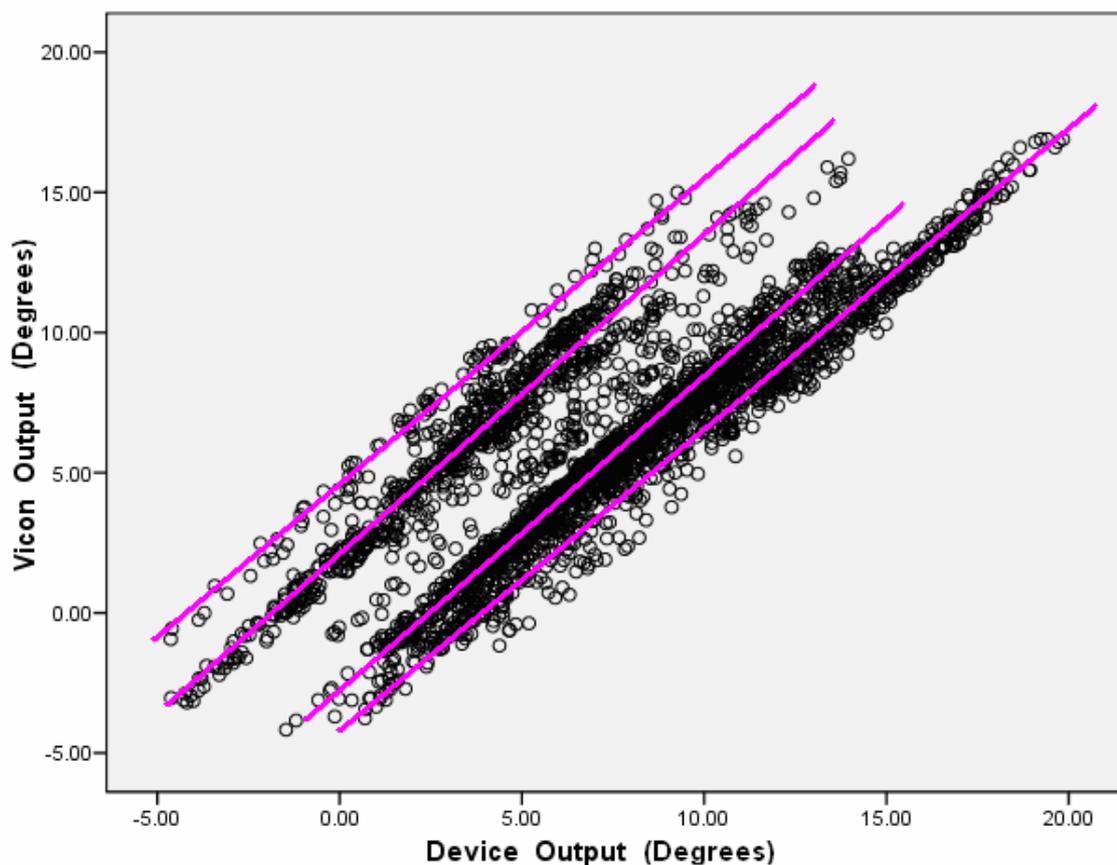


Figure 7.4.1.2: Scatter plot of device output with respect to Vicon for hip abduction/adduction

Qualitatively, there were three main parallel and distinct clusters of points, with a fourth set evident, which comprised a much smaller percentage of points than the other three series.

The two main bodies of points were heavily engaged across the data set, indicating close agreement; it is from this bulk agreement of the vast majority of which give rise to the resultant r-value indicator of large, positive correlation.

The third densest trend was separated from the main pair by approximately 4° ; the area of separation containing a spread of intermediate points.

Lastly, a small but definite grouping of points comprised the sparsely populated fourth grouping. The separation of these points from the third most dense trend suggest that they are not outliers of it, but have a unique significance.

The parallel nature of the data suggested mildly (considering the correlation coefficient and scatterplot scale) discordant output between the developed device and the Vicon system. Specifically, several offsets of one system with respect to the other, which were not constant across the entire dataset (otherwise the whole plot would show a common displacement on one axis). A grid was added to the scatterplot, along with a zero-degree difference baseline (Figure 7.4.1.3), so that the nature of the offset can be further analysed:

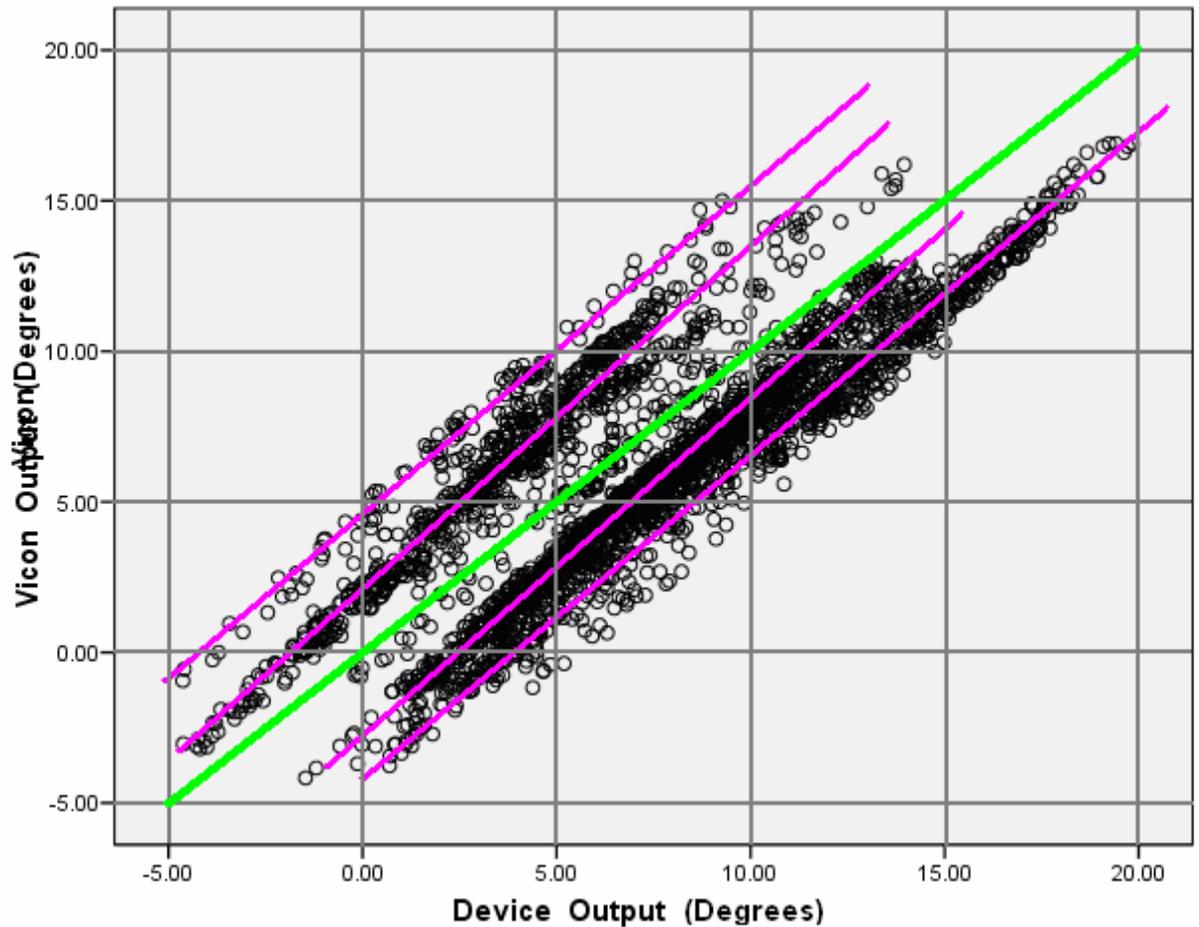


Figure 7.4.1.3: Gridline enhanced scatter plot of device output with respect to Vicon for hip abduction/adduction

On the 'Device' output axis, from approximately -2° to $+5^{\circ}$, there appears to be a small, bipolar distribution of points at $\pm 2.5^{\circ}$ from the zero-degree difference baseline (which is represented by the green trace). After $+5^{\circ}$, the two major trends tended towards convergence. At above fifteen degrees, there is no evidence of parallel discordance.

The reasons for the offsets could have, in theory, arisen from:

1. Vicon marker placement error

As previously stated, precise positioning of the Vicon system retroreflective markers is vital, in order for its software to compute accurate output (Kirtley 2002). If there was an error in placement of one or more of the markers which are used to derive hip abduction/adduction, then an effect such as that presented in Figure 7.4.2.2 could conceivably occur. However, since this scatterplot shows all patients' hip abduction/adduction data, this error would need to have been repeated a number of times to give such a consistent distribution formation.

2. Vicon marker occlusion/disturbance

If the device sensors or control unit were to have disturbed the thigh wand and/or ASIS marker(s), which are instrumental in hip abduction/adduction calculation, it is a possibility that this parameter would be affected when the device was worn. However, this is unlikely to be the cause of the phenomenon, as the data studied in the test of functional impairment when using the developed device would show differences when wearing the device compared to not wearing it (assuming the error would cause the statistical test to reveal this magnitude of error as significant) (McClelland et al. 2010).

3. Developed device hardware measurement error or limitation

The accelerometer sensor itself could theoretically have given incorrect values, perhaps as a result of its intrinsic accuracy, microcontroller analogue to digital converter (ADC) resolution (i.e. a bit-step separation) (DeBusschere and Kovacs 2001) or a fault in the sensing element itself. Alternatively, the assumed aberration may have arisen in the conversion of tilt data from the device, although this seems less likely as the processing methodology for both sensors was precisely the same and conducted in the same automated data batch-processing (Lord et al. 2008, Boonstra et al. 2006).

4. Developed device sensor disturbance during data capture

A repetitive/persistent disturbance of one of the accelerometer sensors could potentially give rise to a highly-consistent error across the test population during data capture. For example, upon heel strike, soft tissue artefacts and/or inertial effects, as described by (Wren et al. 2006) could affect either the accelerometer(s) and/or the Vicon system markers (although the latter hypothesis would carry the same caveat as described in part 2, above). The mechanical attachment of the accelerometers to the patient (by means of double-sided hypoallergenic tape) could have allowed transmission of ground-reaction forces through adipose tissue and the relatively-mobile abdomen or thigh attachment sites, to give rise to reverberations in the sensor itself.

It is theorised that the error can most likely be attributed to this mechanical resonance of the accelerometer(s), which is more apparent in the small-range parameter of hip abduction/adduction, compared to the relatively larger-ranged hip flexion/extension. Although this error is small, and has not manifested a statistically significant difference in Vicon system against the developed device, this effect could be investigated as part of a follow on study.

7.5 Suitability of the system for use as a physiotherapy diagnostic and detection aid

Examining the validity of the data produced by the present device, Paired Samples T-Tests were applied to the maxima and minima waveform landmarks of the hip flexion/extension and hip abduction/ adduction, in order to test if the means of the measurement values from the Vicon system and developed device agreed.

As described in Chapter 6.6, there was no statistically significant difference in the means of hip flexion/extension, nor hip abduction/adduction, between the developed device and the Vicon system. In appraising the data for each patient from both the Vicon system as well as the presented system (device and artificial neural network stages as a whole), it can be observed that the developed device output and the Vicon system show statistically no difference in their output means. Therefore, it can be inferred that the developed device is at least as useful as the Vicon system is for that purpose. Furthermore, the presented system offers the additional benefits of:

- User friendliness in terms of a complete biomeasurement system for hip flexion/extension and abduction/adduction, with a software results analysis tool in the form of an artificial neural network, which is able to rate these parameters deviation from normative range.
- A low cost tool to build, operate and maintain.
- A portable device that can be used in many settings (Genet et al. 2007).

Taking selected examples of the THA patient subjects:

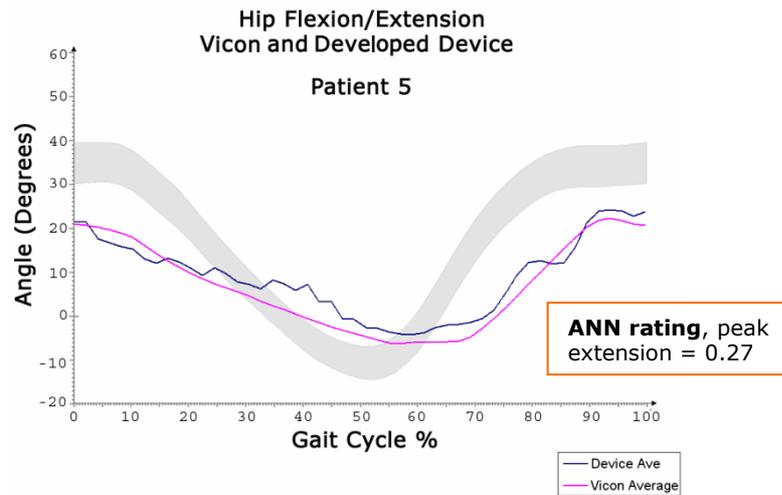


Figure 7.5.1: Patient 5 hip flexion/extension waveform with ANN appraisal of extension

Patient 5 exhibits markedly reduced hip extension, as can both be seen from the Vicon "gold standard" and developed device output graphs, and, moreover in the correspondingly low ANN appraisal score of this parameter; this is a unique and novel outcome of this study.

Patient 19 (Figure 7.5.2, Figure 7.5.3) shows fairly normal hip flexion, extension and abduction/adduction; the graph traces from the measurement systems both show that this patient's waveforms overlay a good proportion of the normal ranges. Again, the ANN appraisal of these parameters would also confirm this.

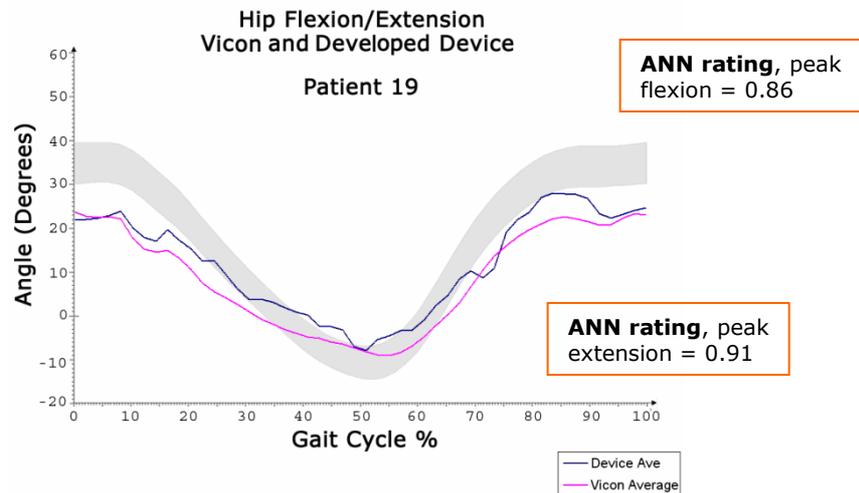


Figure 7.5.2: Patient 19 hip flexion/extension with ANN key landmark ratings at peak/trough values

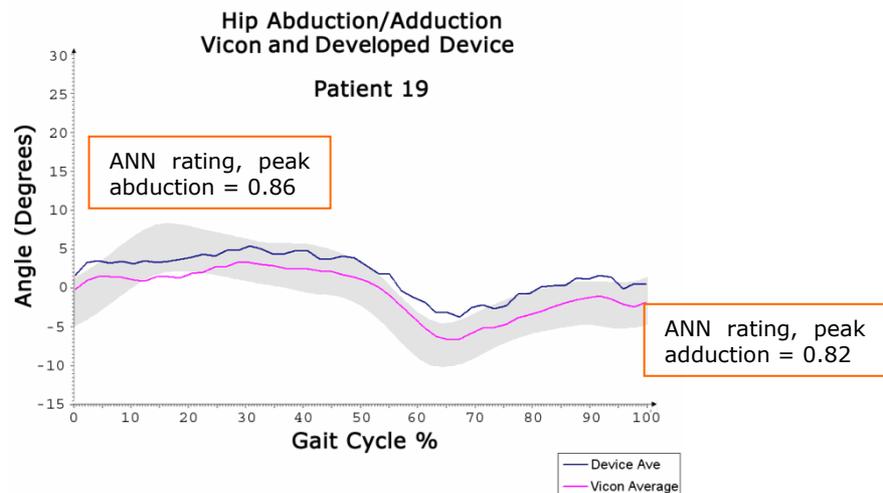


Figure 7.5.3: Patient 19 hip abduction/adduction waveform from developed device, Vicon system, and with ANN key landmark ratings at peak/trough values

In the clinical setting, the results imply that healthcare professionals could use the developed device as a logging, graphing and semi-automated diagnosis tool, which would save time and give objective and consistent measurements and analyses, when compared to visual appraisal.

Additionally, the developed device could save the time of patients as well as potential travelling inconveniences or difficulties, and would represent a good financial saving to the healthcare service, rather than attend a gait laboratory, should a hip flexion/extension/abduction /adduction appraisal be needed.

As a result of these highly-favourable attributes, the objective of the study, to assess the suitability of the developed device as a physiotherapy diagnostic and detection aid for gait, has been addressed.

7.6 Chapter summary

This chapter has discussed the results and findings arising from the data collection made with the developed device. In summary, the outcome of this is that all of the objectives established at the outset of the study have been addressed and the overall aim of the research has been achieved:

To develop a patient-worn system, which is able to measure, wirelessly-transmit and record real-time data about hip flexion/extension and abduction/adduction parameters during walking, whilst not affecting movement when in use. This system may be able to be used to automate diagnoses associated with the hip, post-THA, and better inform rehabilitation strategy compared with current subjective analysis, and at considerably lower operating and ownership cost than methods which are currently employed.

In the intended clinical application, it is now envisaged and conceivable that a patient would, as part of their routine THA aftercare, visit a healthcare professional, such as their general practitioner or a physiotherapist (Gocen et al. 2004). The healthcare professional could then use the developed device with the patient to gather data on the hip flexion/extension and abduction/adduction parameters during normal gait, or indeed during other activities (discussed in the suggestions for future work section of the next chapter) and use this data to detect any deviation in these parameters. Informed, objective rehabilitation strategies could then be devised so as to minimise the highly unfavourable risks associated with THA (discussed in Chapter 1), namely, falls and incorrect positioning of the patient's hip, which could affect the longevity of the prosthesis by altering mechanical loading (Birrell, Johnell and Silman 1999). The device could also be used as tool for monitoring progress of prescribed exercise or the effectiveness of interventions such as physiotherapy and exercise.

Chapter 8

Conclusions, strengths and limitations of the study and suggestions for future work

Chapter Overview

This chapter presents the conclusions that were drawn from analysis of the data from the study. In addition, this chapter describes elements of the study that were considered strengths and limitations. The chapter concludes with suggestions for work which could logically follow that which was undertaken in the study.

8.1 Conclusions

Following presentation and statistical analysis of the results, the meaning and implications of the data were investigated. The subject matter of this multidisciplinary study was found to be unique; no other study encountered to date has concerned the development of a device, such as that presented for the purpose of hip position recording and artificial neural network data analysis of range of motion in hip flexion/extension and abduction/adduction.

Specifically an electronic controller was designed and implemented, using suitable sensors and components, for the purpose of gathering hip flexion/extension and abduction/adduction position data. In addition, software was developed which was able to detect decreased ROM and, thereafter, the developed device was compared to the motion analysis gold standard in the form of the Vicon system using a cohort of THA patients.

8.2 Strengths and limitations of the study

The strengths of the study are:

- The production of a wireless hardware biomeasurement system (including software) which could be used as a platform technology for other joints or multiple joints.
- The study benefitted greatly by having the Human Performance lab of the School of Health Sciences available.
- The cross-correlation strategy of the developed device and Vicon systems presents a re-usable method for future biomeasurement device validation work.
- The developed device is capable of giving an interpreted, functional assessment of hip flexion/extension and abduction/adduction whereas the Vicon system gives graphical output of the parameters only, which requires assessment by a highly-trained individual in order to draw conclusions of their meaning.

In a clinical or home setting, the device could be used by a healthcare professional to gather data on how a patient moves their hip during gait. The artificial neural network could then give a objective measure of extent to which range(s) of motion were normal, or pathological.

In a wider sense, it is also conceivable that the developed device could be used for non-gait hip-monitoring applications such as sports and exercise science, where hip position during an activity could be measured.

Other applications could include using the device to monitor recovery after injury, or the efficacy of a particular treatment, intervention or strategy on injury.

Limitations of the study are:

- The lack of a mediolateral rotation axis. This is a drawback of accelerometers, but could be overcome using a single-axis addition to the system.
- The number of participants recruited would have preferably been greater than 21, so as to give even stronger statistical test validity.

8.3 Suggestions for future work

For a follow-on study, it would be most interesting to carry out a longitudinal study whereby patient hip ROM would be measured pre-operatively and repeated measures would be made post-operatively, using an experimental design which featured a group who received assessment and physiotherapy strategies informed by the device, compared to a group who received normal review and intervention.

Associated with this, it would be fascinating to employ the prediction qualities of an artificial neural network to detect hip ROM deviation in a predictive capacity.

Since the original prototype manufacture, alternative and new components of which the system is comprised, have been released. Therefore, it would be pleasing to refine and miniaturise the system using such parts.

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Appendix 1

Patient Information Sheet



THE
ROBERT GORDON
UNIVERSITY
ABERDEEN

Patient information sheet (Study number 06/S0802/125)

Title

Evaluation of a device to assist recognition and re-education of walking pattern following total hip Replacement

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of this study?

The purpose of this study is to look in depth at the movements and muscles working around your hip when you walk. Sometimes after hip replacement surgery the muscles can be weak and people alter their normal pattern of walking. We are trying to develop a device which will recognise this altered pattern and assist physiotherapists to treat patients more effectively. The device measures angles and movement and consists of a belt worn around the waist and a small device on the thigh. We will be comparing the information from the device against physiotherapist observation and a computerised, video-based motion analysis system.

Why have I been chosen?

You have been chosen because you have had, or will have, a total hip replacement.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet and be asked to sign a consent form. You will be given a copy of both forms to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. **Withdrawal will not affect your future treatment in any way** and your details will not be kept, or used, in any other respect.

What will happen to me if I take part?

The session will take part at The Robert Gordon University, Faculty of Health and Social Care at Garthdee, Aberdeen. You will be asked to bring shorts, or these can be provided for you, which you will wear during the session. There are changing facilities on the premises and the laboratory that the study will be carried-out in, is private. You are of course welcome to bring another person with you for company.

Next, small, self-adhesive ten-pence-sized markers will be placed at the centre of your knees, ankles and feet. These markers are attached using hypoallergenic double-sided tape and are easily removed afterwards.

You will then be asked to simply walk, at a pace which suits you, along the length of the lab which is around 23 feet (7 meters) so that information on how you move your hip can be collected. This is repeated several times until an accurate record is collected. The sessions are video-recorded to compare measurements to the corresponding hip movements that are made.

Next, you will then be assisted to put the device around your waist and repeat the above steps.

Finally, the device and markers will be removed and you are free to go. It is anticipated that this will take approximately 1 hour of your time

Are there any risks in taking part?

Nothing in the trial can hurt you. There is nothing invasive; the data is collected using reflected light. The marker removal is like taking off a ½" circular plaster (and the markers are only put on once). The new device has a belt-worn part and a small self adhesive part. It is **not possible** that the session could damage your new hip – You will not be asked to move your hip to any extreme positions. You will simply be asked to walk at a pace which is comfortable to you.

What are the possible benefits of taking part?

This study may not benefit you directly. It is hoped that the knowledge gained will assist rehabilitation of patients with total hip replacements in the future.

Will my taking part in the study be kept confidential?

Your name will be replaced with a code. All data will be kept in digital form in a computer with restricted access. After 5 years, the data will be destroyed

What will happen to the results of the research study?

The results themselves will be published in biomechanics, artificial intelligence and engineering-related journals, and presented at a professional conference. You will not be identified in any reports or publications. You will receive a summary of the findings and how the information you provided is being used.

Who is organising and funding the research?

The research has been funded by the Research Developments Initiative (RDI), conducted in The Robert Gordon University with collaboration with NHS Grampian.

Who has reviewed the study?

The Grampian Research Ethics Committee and Mr. Paddy Ashcroft, consultant orthopaedic surgeon from Woodend Hospital, Aberdeen have approved the study.

Travel Expenses

Reasonable travel expenses will be reimbursed to you and parking facilities are available at the university campus.

What do I do now?

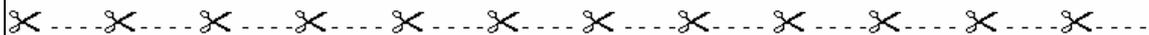
You can register your interest in taking part by mailing the slip below in the included reply-paid envelope. The principal researcher will then telephone you at the time you specify to be convenient. This is done to answer any questions you may have and/or arrange the best date and time for you to attend the measurement session at the university.

You are also free to contact the principal researcher at any time at the details below with any questions you may have. Please remember you are free to withdraw at any time and if you are not interested in taking part in the study, please discard this document.

Thank you for taking the time to read this and considering taking part in this research study. Please discuss this information with anyone you wish prior to making a decision.

Jamie Law BSc(Hons.)
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Please complete the following in block capitals:

Name: _____
 Contact phone number
 (including area code): _____
 Best day to call: _____
 Best time to call: _____ am/pm

Tick as appropriate:

I would like more information
 on the study, please contact me
 and/or
 I am interested in taking part
 in the study, please contact me

Appendix 2

Patient Consent Form

	THE ROBERT GORDON UNIVERSITY ABERDEEN	
Study Number: 06/S0802/125	30/11/06 – Version 2	
Patient Identification Number for this trial:		
CONSENT FORM		
Title of Project:	Validation of Walking-Appraisal Tool for Physiotherapists.	
Name of Researcher:	Mr Jamie Law	
	Please initial box	
1. I confirm that I have read and understand the information sheet dated..... (version) for the above study and have had the opportunity to ask questions.	<input type="checkbox"/>	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	<input type="checkbox"/>	
3. I understand that this is part of a research project designed to investigate differences between how a computer program and a human evaluate movement information of the hip after replacement, and that it may be of no benefit to me personally.	<input type="checkbox"/>	
4. I consent to the sessions being video-recorded (to compare measurements to the corresponding hip movements which are being made).	<input type="checkbox"/>	
5. I agree to take part in the above study.	<input type="checkbox"/>	
_____ Name of volunteer	_____ Date	_____ Signature
_____ Name of Person taking consent (if different from researcher)	_____ Date	_____ Signature
_____ Researcher	_____ Date	_____ Signature
Top copy for patient – lower copy for researcher		

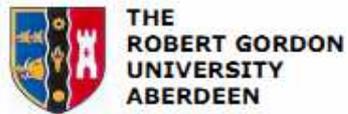
Appendix 3

Patient Reply-Paid Envelope

**The Robert Gordon University
Jamie Law
School of Health Sciences
FREEPOST AB313
ABERDEEN
AB10 7QG**

Appendix 4

Summary Request Sheet



Report Request Sheet (Study number 06/S0802/125)

Upon conclusion of the above study, I would like a summarised copy of the main findings*.

Please send this to:

Name: _____

Address: _____

Postcode: _____

* Please note that the report will show the general findings of the study and not be an individualised report on your specific lab session. Any questions you may have on its content may be asked of the principal researcher, Jamie Law, at the details supplied on the Patient Information Sheet.

Appendix 5

Patient Travel-Expense Claim Form

Miscellaneous Payment Voucher
(To be used where a formal supplier invoice is not available)


THE ROBERT GORDON UNIVERSITY ABERDEEN

To the Finance Officer **Sample** From **Sample** School **Sample**
 Please make the following payment(s) and charge the expenditure to the accounts as indicated Date **Sample**

Pay	Address	In respect of	Amount			Financial code														
			£	p		Objective	Subj	Alt												
Sample	Sample	Travel expenses incurred during participation in data collection of Jamie Law.																		
		Goods/Services received in good order																		

Payment authorised by (Signature)

Appendix 6

NHS Research and Development Approval

Research and Development

Foresterhill House Annexe
Foresterhill
Aberdeen
AB25 2ZB



Date 18/01/07
Ethics 06/S0802/125
R&D Ref: 2007RG002

Mr Ewan J. Law
Faculty of Health and Social Care
The Robert Gordon University
Room H302
Garthdee Road
AB10 7QG

Enquiries to Katy Booth
Extension 54656
Direct Line 01224 554656
Email k.booth2@nhs.net

Dear Mr Law,

Project title: Evaluation of a device to assist recognition and re-education of walking pattern following total hip replacement.

Thank you very much for sending all relevant documentation. I am pleased to confirm that the project is now registered with the NHS Grampian Research & Development Office. The project has R & D Management Approval to proceed locally.

Please note that if there are any other researchers taking part in the project that are not named on the original Ethics application, please advise the Ethics Committee in writing and copy the letter to us so that we may amend our records and assess any additional costs.

Wishing you every success with your research

Yours sincerely

A handwritten signature in black ink, appearing to read 'KB' followed by a flourish.

Katy Booth
Data Co-ordinator

Appendix 7

Research Ethics Committee Approval



Grampian Local Research Ethics Committee (2)

Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558503
Facsimile: 01224 558609

4 January 2007

Mr Ewan J Law
Research Development Initiative (RDI) Studentship
The Robert Gordon University
Room H302
Faculty of Health and Social Care
Garthdee Road
ABERDEEN
AB10 7QG

Dear Mr Law

Full title of study: Evaluation of a device to assist recognition and re-education of walking pattern following total hip replacement
REC reference number: 06/S0802/125

Thank you for your letter of 4 January 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out. You are advised to study the conditions carefully, in particular:

Condition 1: Annual Progress Report

Under the Central Office of Research Ethics Committees (COREC) regulations NHS Research Ethics Committees are required to monitor research with a favourable opinion. This is to take the form of an annual progress report which should be submitted to the Grampian Research Ethics Committee 12 months after the date on which the favourable opinion was given. Annual reports should be submitted thereafter until the end of the study.

Points to note:

- The first annual progress report should give the commencement date for the study. This is normally assumed to be the date on which any of the procedures in the protocol are initiated. Should the study not commence within 12 months of approval a written explanation must be provided in the 1st annual progress report.
- Progress reports should be in the format prescribed on the COREC website (www.corec.org.uk/applicants/apply/progress.htm).
- Progress reports must be signed by the Principal Investigator/Chief Investigator.
- Failure to submit a progress report could lead to a suspension of the favourable ethical opinion for the study.
- Please note the Annual Progress Report is a short 3 page form which is extremely easy to complete.

Condition 2: Notification of Study Completion/Termination

Under the Central Office of Research Ethics Committees (COREC) regulations researchers are required to notify the Ethics Committee from which they obtained approval of the conclusion or early termination of a project and to submit a Completion/Termination of Study Report. Researchers should follow the instructions on the COREC website (www.corec.org.uk/applicants/apply/endofproject.htm).

Points to note:

- For most studies the end of a project will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol.
- Final analysis of the data and report writing is normally considered to occur after formal declaration of the end of the project.
- A Final Report should be sent to the GREC within 12 months of the end of the project.
- The summary of the final report may be enclosed with the end of study declaration, or sent to the REC subsequently.
- There is no standard format for final reports. As a minimum we should receive details of the end date and information on whether the project achieved its objectives, the main findings and arrangements for publication or dissemination of research, including any feedback to participants.
- Please note the Completion/Termination of Study Report need only be a summary document and should, therefore, be easy to prepare.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application		24 October 2006
Investigator CV		24 October 2006
Protocol	2	14 December 2007
Covering Letter		4 January 2007
Covering Letter		24 October 2006
Covering Letter		30 November 2006
Summary/Synopsis	3	1 September 2006
GP/Consultant Information Sheets	2	
Participant Information Sheet	4	
Participant Consent Form	2	30 November 2006
Response to Request for Further Information		30 November 2006
Response to Request for Further Information		4 January 2007
Application Pages		
Operating Protocol Flowchart	1	
Summary CV for Supervisor - Ioannis Agouris		24 October 2006

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/S0802/125

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

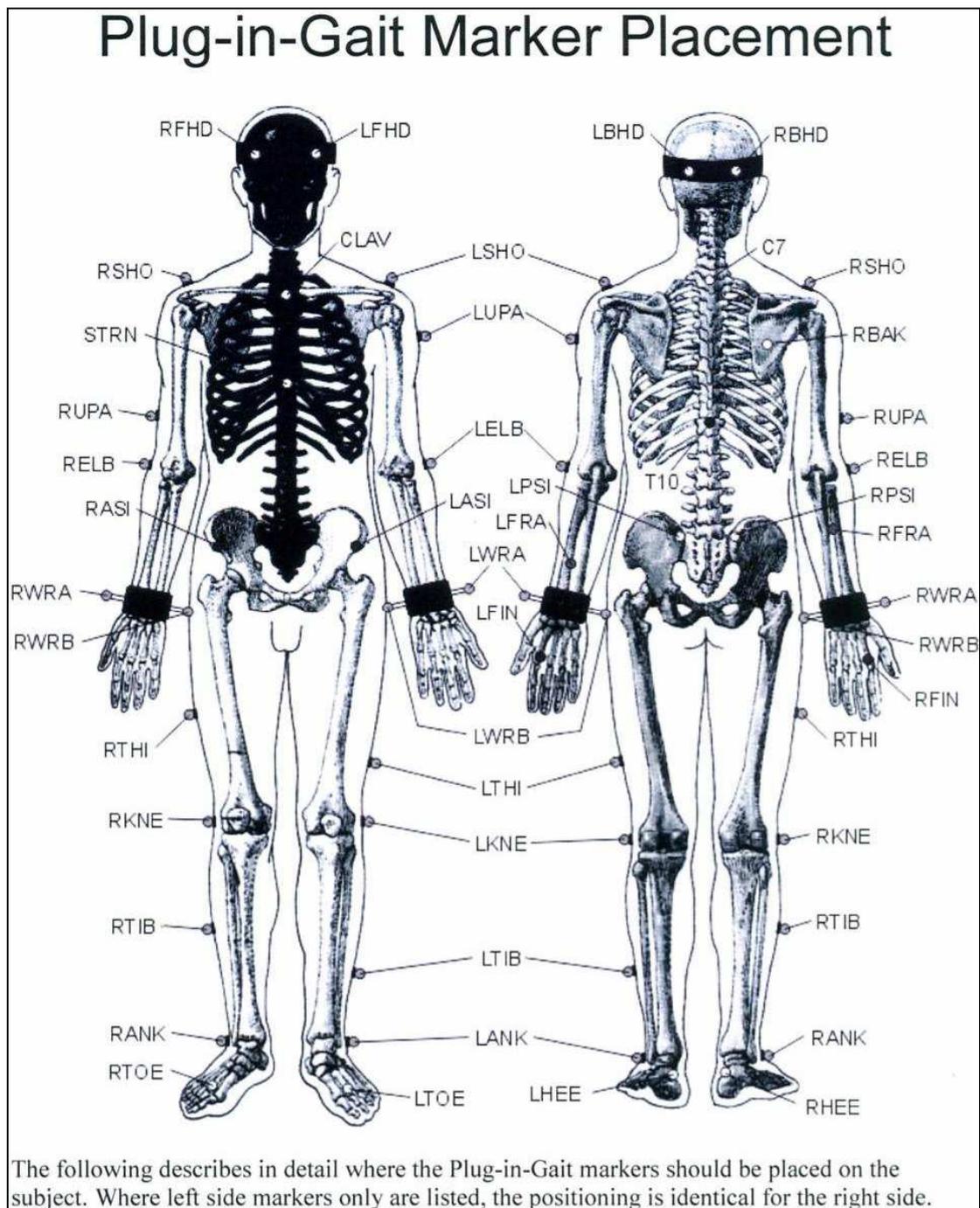
Yours sincerely

Caro Bai

Dr Sheila A Simpson
Chair

Appendix 8

Marker Placement Protocol



Appendix 9

Microcontroller Software Listing

```

/*;*****
;*
;*          The Robert Gordon University, Aberdeen
;*
;*****
;*          File name:          Hip-logV5.c
;*          Author:            Jamie Law
;*          Created:           Started:    3rd May 2006
;*                               This Revision    18th Nov 2006
;*
;*****
;*          M68HC12  C Source File
;*
;* Description: This program reads tilt information from two, 3-axis
;*              DE-ACCM3D accelerometers. The data that is read is displayed
;*              on the terminal, toggling collection at a key stroke.
;*
;*****
/

#include <ctype.h>
#include <hcl2.h>
#include <stdio.h>

void adcport(void); // Prototype for adcport subroutine.
void splashscreen(void); // Prototype for "off" mode startup screen routine.
void datacollect(void); // Prototype for data capture/log subroutine.

unsigned char thigh_x; // Abdominal sensor X-axis component (Flex/Extension).
unsigned char thigh_y; // Abdominal sensor Y-axis component (Ad|Abduction).
unsigned char thigh_z; // Abdominal sensor Z-axis component (Axial
translation).

unsigned char abdomen_x; // Femoral sensor X-axis component, Flex/Extension.
unsigned char abdomen_y; // Femoral sensor Y-axis component, Ad|Abduction.
unsigned char abdomen_z; // Femoral sensor Z-axis component, Axial translation

unsigned char session = 1; // Patient Session Counter.
unsigned char keypress = 0; // Start/stop data collect.
unsigned char mode = 0; // Mode select switch initialised to a known
value.
unsigned char firsttime = 1; // First data collect loop-iteration indicator.
unsigned char modechange = 1; // Change of mode indicator for LCD status.

```

```

int main( )
{
    DDRJ = 0xF5;                // Set up Port J as:
                                // |Bit| 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 |
                                // |I/O|OUT|OUT|OUT|OUT|IN |OUT|IN |OUT|
    DDRT = 0xFF;                // Set up Port T as:
                                // |Bit| 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 |
                                // |I/O|OUT|OUT|OUT|OUT|OUT|OUT|OUT|OUT|
    ATDCTL2 = 0x80;             // Enable ADC hardware.
    ATDCTL4 = 0x67;             // set sample rate.
    ATDCTL5 = 0x70;             // Enable all channels.

    while (1)                  // Run program continuously...
    {
        mode = PORTJ;           // Check "mode" switch position.
        switch ( mode )        // Undertake selected mode.
        {
            case 0x02:         // Switch set to "Off" mode.
                splashscreen(); // Display front-end screen.
                modechange = 1; // Mark change of mode
                break;

            case 0x0A:         // Switch in "Stand By" (to collect) mode.
                datacollect(); // Execute data-logging subroutine
                modechange = 1;
                break;
        }
    }

    return 0;
}

/*****
 *
 * Name:          adcport
 * Parameters:    none
 * Returns:       none
 * Globals:       none
 * Description:   This funtion polls each of the 3 ADC channels and writes the
 *                value into that axis's respective variable
 *
 *****/

void adcport(void)
{
    abdomen_x = ADR3H;         // Sample Abdominal sensor, X-component.
    abdomen_y = ADR5H;         // Sample Abdominal sensor, Y-component.
    abdomen_z = ADR7H;         // Sample Abdominal sensor, Z-component.

    thigh_x = ADR0H;          // Sample Femoral sensor, X-component.
    thigh_y = ADR1H;          // Sample Femoral sensor, Y-component.
    thigh_z = ADR2H;          // Sample Femoral sensor, Z-component.
}

```

```

/*****
*
* Name:          splashscreen
* Parameters:    none
* Returns:       none
* Globals:       none
* Description:   This routine shows a user-defined message.
*
*****/

void splashscreen(void)
{
    PORTT = 0x00;
    // |0123456789ABCDEF| // LCD column number guide
    lcd_putxy(0,0, "System Designed ");
    lcd_putxy(1,0, " and Built by ");
    lcd_putxy(2,-4, "-= Jamie Law -= ");
    lcd_putxy(3,-4, "(C)2006 Ver. 1.2 ");
}

/*****
*
* Name:          datacollect
* Parameters:    d - delay loop counter
*               firsttime -
* Returns:       none
* Globals:       keypress - Start/stop data collect.
*               trial - Patient trial count.
* Description:   This routine toggles the data capture sequence while the mode
*               selection is set to "stand-by"
*
*****/

void datacollect(void)
{
    unsigned char d; // Delay counter variable.
    unsigned char NO; // Keypress register result (dummy-read
                    // to clear keystroke register).

    for(d = 0; d < 5000; d++) // Keypress debounce delay loop.
    {
    }

    if(modechange == 1) // On mode change, display status on LCD
    {
        // |0123456789ABCDEF|
        lcd_putxy(0,0, "Data Capture ");
        lcd_putxy(1,0, " Mode: Press any");
        lcd_putxy(2,-4, " key to begin ");
        lcd_putxy(3,-4, " data capture");

        modechange = 0; // Reset mode change flag, stops LCD strobe.
        PORTT = 0x04; // Show red "standby" LED colour
    }

    if (firsttime == 1) // On 1st iteration, the on/off toggle loop is not
    { // accessed to give this message; so is done here.

        printf("\r \n");
        printf("Press any key to start/stop data collect trial 1");
        firsttime = 0;
        PORTT = 0x04;
    }

    if( (SC0SR1 &0x20) != 0) // If keypress detected...
    {
        keypress++; // Increment keypress count.

        if (keypress == 10) // Reset at 10 presses to limit count.

```

```

    {
        keypress = 0;
    }

    NO = SC0DRL; // Clear keyboard register.
    printf("\r \n"); // Carridge return & line feed for tabulation.

    if(keypress % 2 == 0) //Remainder toggles start/stop data collection
    {
        trial++; // New trial I.D.

        PORTT = 0x04; // Show red "standby" LED colour
        // |0123456789ABCDEF|
        lcd_putxy(0,0, "Data Capture ");
        lcd_putxy(1,0, " Mode: Press any");
        lcd_putxy(2,-4," key to begin ");
        lcd_putxy(3,-4," data capture");

        printf("\r \n"); // Carridge return + line feed for tabulation

        printf("Press any key to start/stop data "
               "collect trial " "%d", trial);
    }
}

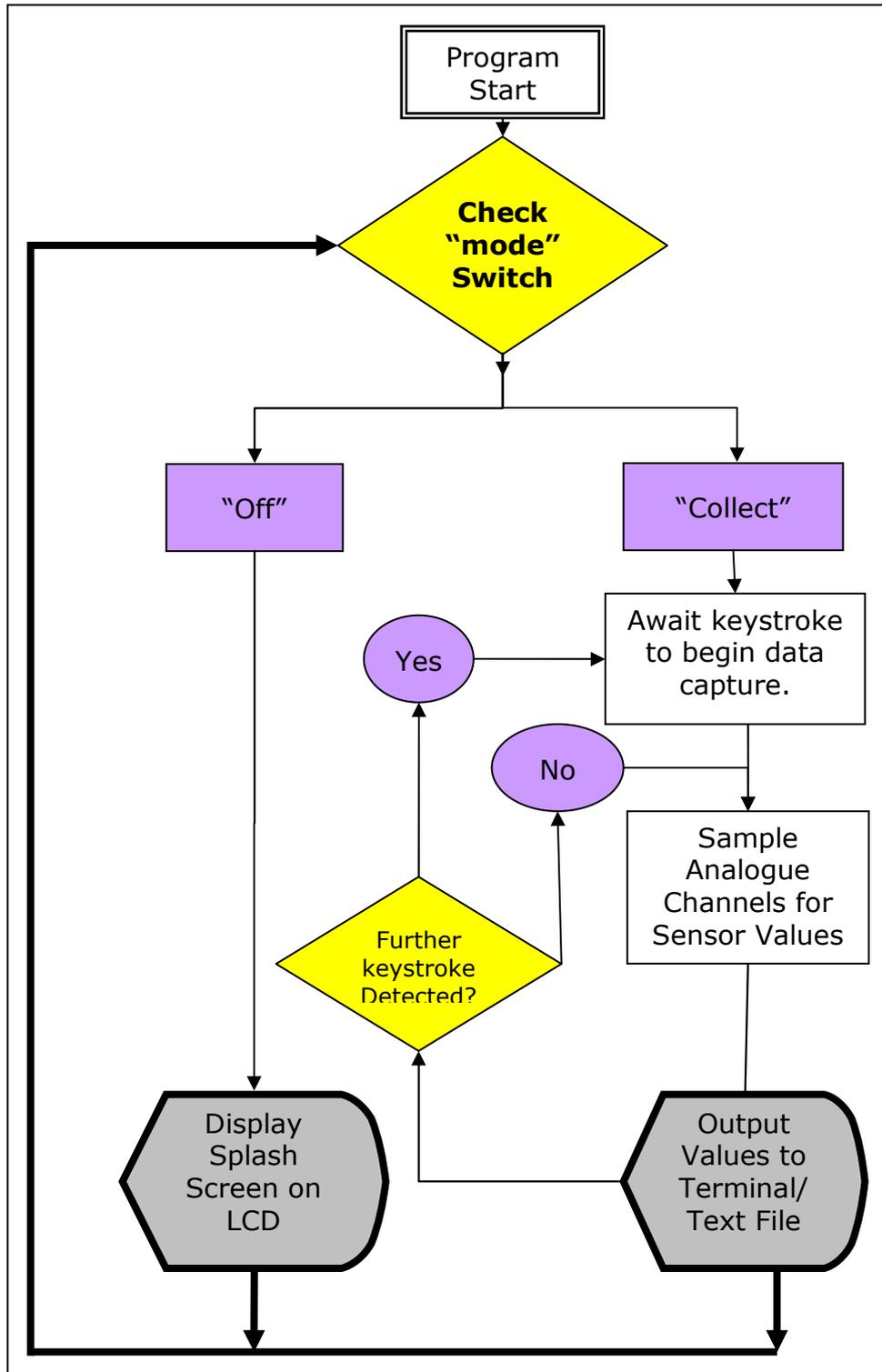
if(keypress % 2 == 1) //keypress to start data-logging
{
    PORTT = 0x01; // Show green "collect" LED colour
    adcport(); // Obtain ADC readings
    printf("\r \n"); // Tabulate output to terminal.
    printf("%d",thigh_x);
    printf("\t");
    printf("%d",thigh_y);
    printf("\t");
    printf("%d",thigh_z);
    printf("\t");
    printf("%d",abdomen_x);
    printf("\t");
    printf("%d",abdomen_y);
    printf("\t");
    printf("%d",abdomen_z);

    // |0123456789ABCDEF|
    lcd_putxy(0,0, "Data Capture ");
    lcd_putxy(1,0, " Mode: Press any");
    lcd_putxy(2,-4," key to end ");
    lcd_putxy(3,-4," data capture");
}
}

```

Appendix 10

Microcontroller program flow diagram



Appendix 11

Vicon "Workstation" Operating Guide



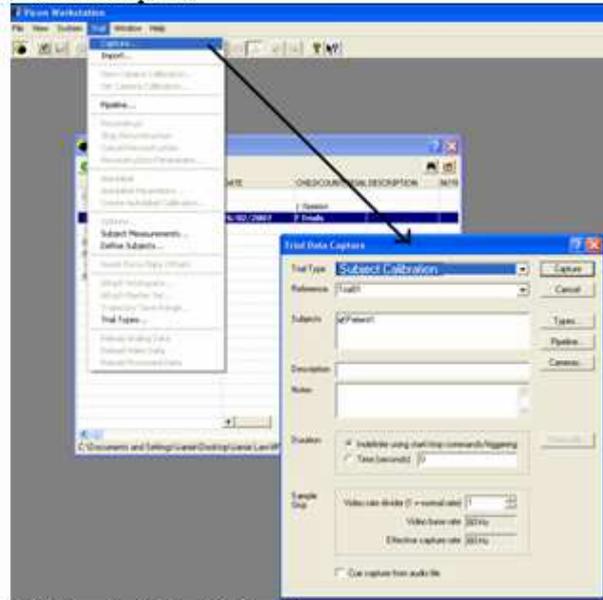
Vicon Workstation operation guide

By Jamie Law

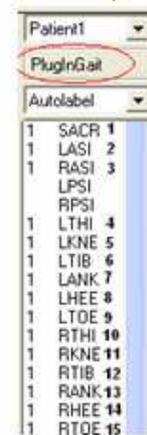
v.3.0

*Document prepared by Jamie Law, School of Health Sciences B0/11/07.
Page 1 of 4*

1. Measure Subject height, weight, leg lengths, knee and ankle widths.
2. Enter this data - Trial → *Subject Measurements*. → → →
3. Apply markers in line with protocol.
4. Ask subject to stand in the middle of the lab (for consistency, astride force plates).
5. Trial → Capture:

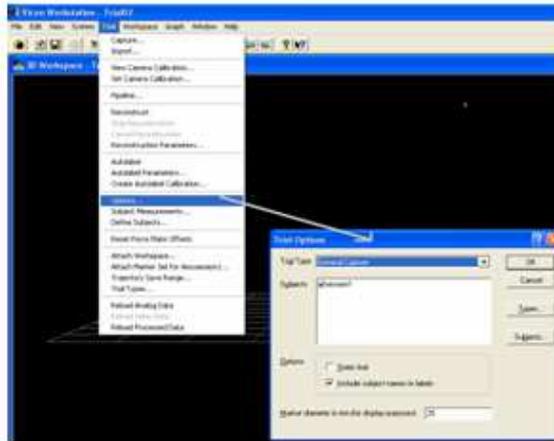


6. Set trial type to *Subject Calibration*
 - Capture... Start... *Auto-stop* Close
7. Check for presence of all markers (press 'play' button to advance time if needed).
8. Left click markers and select name SACR → LASI → RASI → Left... →Right...
9. File → Save

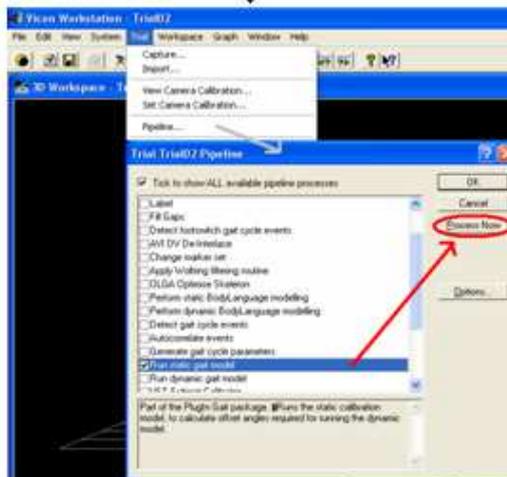


10. Check for "plug in gait" (see red circled area in marker name diagram ↑)

11. Trial → *Options...* ensure subject name is checked ↓



12. Trial → *Pipeline...* check "run static gait model" → click *process now*:



13. Verify that stick-figure is now constructed of double lines:



...File → Save.

14. Trial → *Create Autolabel Calibration* → → → →

15. File → Save.

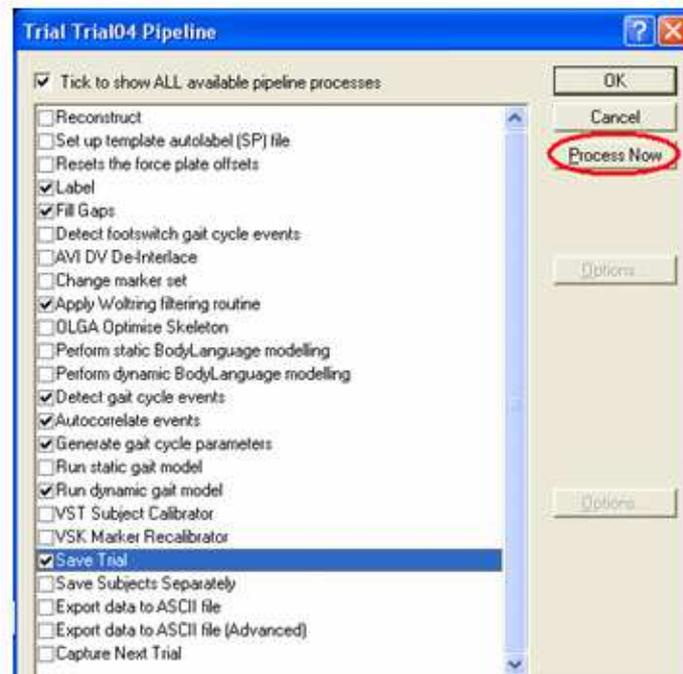
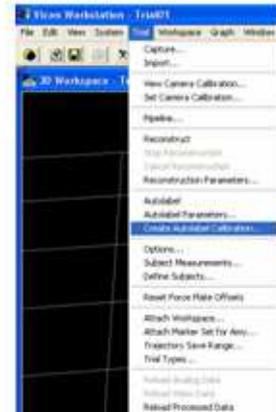
16. Trial → Trial Types... check all 'capture' boxes

17. Trial → Capture... "Trial Type" *General Capture...*
Capture

18. Collect Sessions. Check for complete, connected model, otherwise there is marker occlusion or another problem.

19. F2 to bring up database containing trials. Highlight all trials and press *Space* to "mark node" (or right-hand click then select).

20. Trial → Pipeline... check the following:



...Process now.. Close

Appendix 12

Control Unit Development

The purpose of the control unit is to allow the various parts of the system to be conveniently housed and, from a health and safety standpoint, mechanically and electrically secured.

Prior to purchasing the enclosure for the control unit, the microcontroller, battery pack, wireless module, LCD panel and other controls were measured; their volume was used as the main selection criteria.



Figure 1: The enclosure selected for the system

Figure 1 shows the “Universal Project Box”, model PX-3 which was selected and purchased from Maplin. The enclosure lid is screw-fitting allowing access for battery installation and any servicing. Plastic was chosen as the preferred box material since it is electrically insulating, lightweight, easy to cut when forming apertures and is low in cost.



Figure 2: Enclosure interior, lid markings shown

Figure 2 shows the interior layout of the enclosure. The markings on the lid represent the centre line and LCD panel width, shows the display. The internal wall surfaces feature channels which facilitate the securing of components. Figure 3 shows the lid of the enclosure marked to accept the LCD panel.



Figure 3: LCD panel with respect to enclosure lid

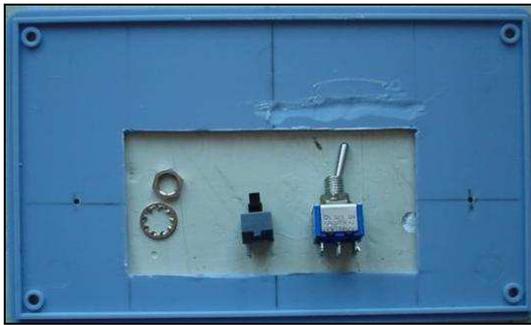


Figure 4: LCD panel aperture



Figure 5: Control devices trial fitted

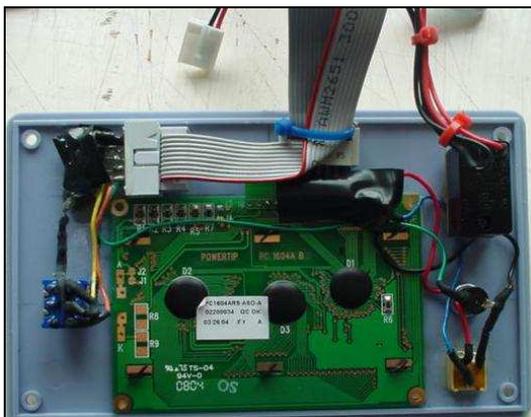


Figure 6: control devices fully installed



Figure 7: Microcontroller and battery pack test fit

Figure 4 shows the aperture, through which the LCD bezel is mounted. The mode selection double pole, triple throw switch can be seen as well as an early version of the “reset” momentary push button. Equidistant markings for the control locations and abraded material to accommodate the LCD header solderwork can also be seen.

The fitment of the various control panel devices and LCD panel, prior to wiring is shown in Figure 5.

In Figure 6, the wiring harness is installed. One ten and one fourteen-way ribbon cable take the switch state signals to the microcontroller and also control the LCD.

Figure 7 shows the microcontroller and battery pack fitment. The device uses four, “AA” 2300 mAh Nickel Metal-hydride batteries as the power source. 3M double-sided adhesive pads were used to secure the microcontroller as well as provide a degree of shock-dampening.



Figure 8: Wiring harness

Figure 8 shows the microcontroller wiring harness in the process of being installed. For safety, all solder joints were terminated with insulating heat-shrink tubing. The use of connectors allows removal of the lid for ease of access to the main compartment.

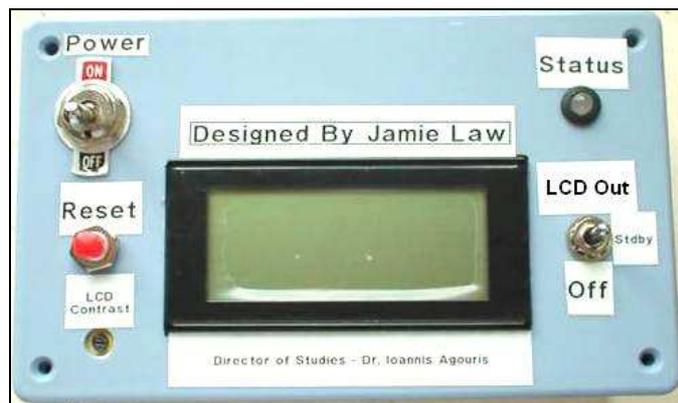


Figure 9: Completed control unit

The user controls were labelled using DYMOtape (Newell Rubbermaid, Connecticut, 2005). As shown in Figure 9, the controls/indicators consist of:

Power: Isolates battery from the system

Reset: Resets the MC68HC12 Microcontroller (pin 23 of connector ST5)

LCD Contrast: Adjusts the contrast of the panel for various viewing angles.

Status: This bi-colour LED indicates data collection condition

Mode: This double pole-triple throw switch is set to the desired mode.

Appendix 13

Developed device User Manual

Introduction

The accelerometer-based device is a two-node, three axis angular position measuring and logging system. Each of the two sensor nodes is capable of capturing coronal, sagittal and axial accelerations which can then be used together with a calibration reading to calculate tilt in each axis of rotation, with regards to the Earth's gravitational field.

Parts

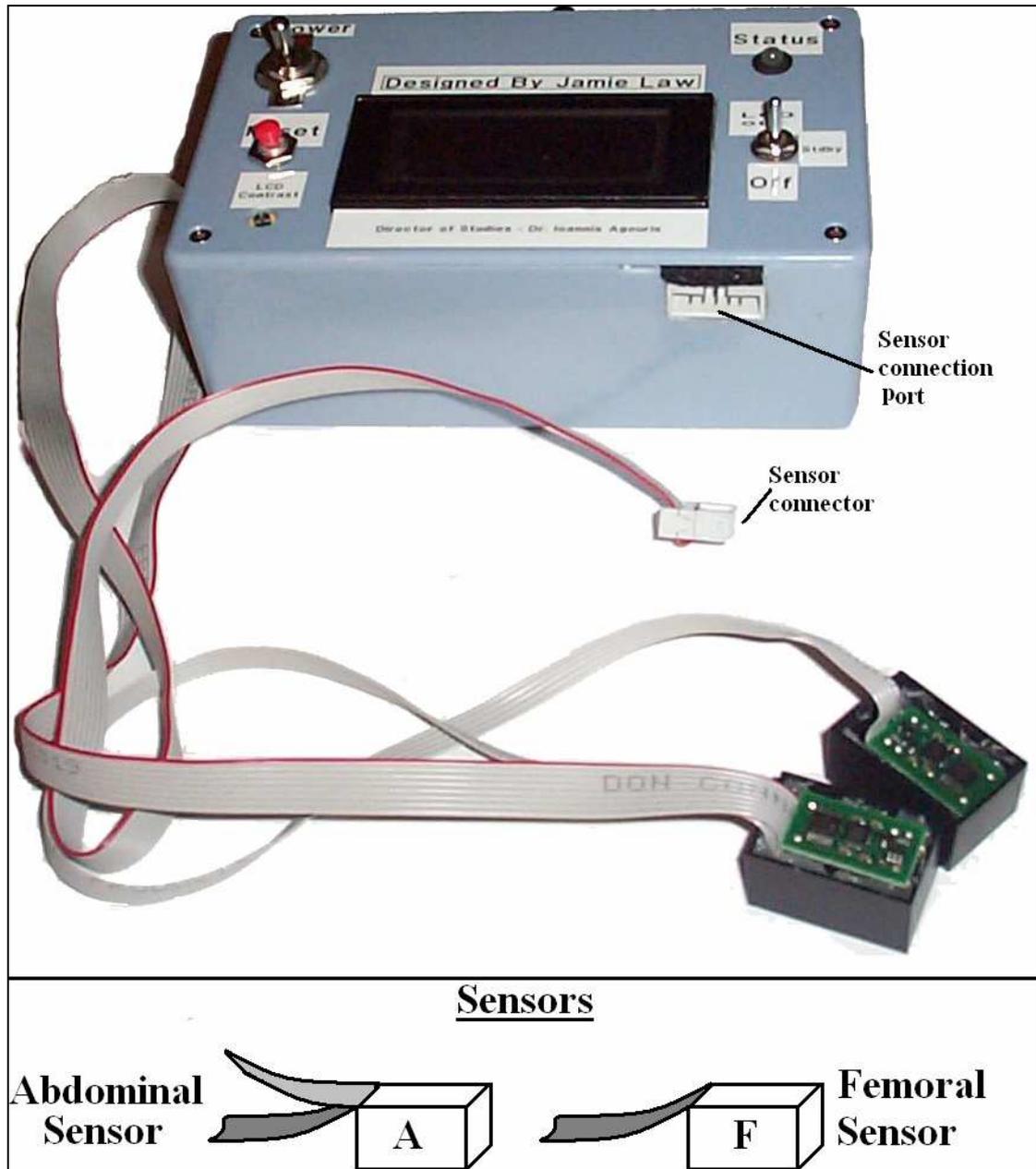


Figure 1: System parts

With reference to Figure 1, the system comprises the parts listed overleaf

Control unit

The control unit features the user controls and LCD panel. The purpose of the controls are as follows:

Power: Isolates battery from the system

Reset: Resets the MC68HC12 Microcontroller (pin 23 of connector ST5)

LCD Contrast: Adjusts the contrast of the panel for various viewing angles and ambient lighting conditions.

Status: This bi-colour LED indicates data collection condition

Mode: This double pole-triple throw switch is set to the desired mode.

Sensors

The sensors consist of one abdominal and femoral node, each containing a Dimension Engineering "DE-ACCM3D Buffered 3D Accelerometer" (Dimension Engineering, Ohio, 2005), in turn each featuring an Analog Devices ADXL330 accelerometer integrated circuit (Analog Devices, Massachusetts, 2006).

Wireless communication

Wireless communication within the system is accomplished using a Promi SD 202 serial cable replacement pair, each featuring a Class 1 Bluetooth transceiver assembly (Initium Co., Ltd., Korea, 2005).

Setup

Setting up the control unit

1. Remove the four screws securing the lid of the control unit and carefully open.
2. Fit four 'AA' sized batteries, as per the diagram on the battery pack holder, before each data capture session.
3. Refit the lid and securing screws and then power the unit on – the status LED should be showing both the red and green elements simultaneously and the LCD panel should be showing faint blocks.
4. Turn the control unit off.

Setting up the communication software

1. Plug in the Promi Bluetooth module into the host computer serial port, and its power cable into a spare USB (universal serial) port, but do not power it yet.
2. Power on the control unit whilst simultaneously powering on the Host computer Promi module. The module should display a green status and power LED.
3. Set the Mode selection switch to stdby (standby to collect data).

Logging Software setup

1. Run OC Console.exe and press the reset button on the control unit.
At the prompt, type l (lowercase 'L') then press the return key, before clicking on "Download".
2. Choose the correct path to the file "DataCapture.S19", this is the compiled microcontroller C code. A status bar shows the progression of the file transfer from the host PC to the microcontroller inside control unit – this will take approximately twenty seconds.
3. Once the download is complete, click "logfile" and enter a meaningful name for the data capture session, appended with the .txt file extension. Type g2000 at the prompt.
4. The LCD panel on the control unit should now show a "data capture" message and the status LED should display red, indicating that data collection is pending a key press.

The unit is now ready to begin capturing data

Subject preparation

1. Ensuring that the subject has been briefed on the goals of the study, what is expected of them during the session, the consent form should be read and, if approval is granted, signed.
2. The subject should be wearing gymware and adjusted, if necessary, so that the sensor nodes can be placed free from areas of clothing that could strike or otherwise disturb their readings.

3. The control unit is belt-mounted and is worn diagonally across the shoulder, in a fashion analogous to an automotive three-point seatbelt. The belt features Velcro adjustment and clip fitting.
4. The sensors are attached using double-sided, hypoallergenic tape, affixed to the base of the sensor, opposite the accelerometer board.
 - a. The abdominal sensor (double ribbon cable output) is attached on the ASIS on the side of interest.
 - b. The femoral sensor (single ribbon cable output) is placed on the mid-line of the thigh, 15cm below the abdominal marker, on the thigh midline.

The ten-way sensor cable is then connected into the port on the bottom face of the control unit.

Collecting data

Firstly, the subject is asked to stand as still as possible in the centre of the laboratory while a timed ten-second calibration reading is taken. The dynamic data trials can then be captured

After cueing the subject to begin walking, they are observed to walk 3m, and/or are assuming "normal" gait, any key can be pressed on the keyboard to toggle data collection. The status LED changes to green for a remote check that the device is collecting data. The data will also be displayed on the terminal window of the OC Console software.

Pressing a key a second time will stop data collection and automatically increment the trial number, ready for the next gait data capture. The status LED will revert to red, signifying that capture has been halted.

This process can be repeated until a suitable quantity of data has been collected. Clicking on the logfile button of OC Console again will close the

text file and prompt the user with the option of displaying the recording immediately.

Subject Debriefing

The device is removed from the subject in the following manner:

1. Power the control unit down and unplug the ten-way sensor cable from the port on the bottom face of the control unit.
2. Unfasten the clip on the control unit belt and remove the system to a safe location.
3. While securely holding the femoral sensor body and the edge of the hypoallergenic tape, rotate both sideways off the subject's thigh while simultaneously separating the thigh skin away from the sensor. The subject may perform this action themselves, so long as care of the sensor is observed. The tape should be carefully removed from the sensor, to prevent it adhering to other objects before being disposed of.
4. The abdominal sensor is removed in the same fashion.

The subject is then thanked for their participation and they are escorted to the exit of the building.

Appendix 14

Artificial Neural Network Software Listing

```

/*****
*
*           School of Electronic & Electrical Engineering
*
*           The Robert Gordon University, Aberdeen
*
*****/
*
*           File name:           HipFE-AdAb.cpp
*           Author:             Jamie Law
*           Created:            02/11/09
*
*****/
*
* Description:
*
* This program is an artificial neural network which can recognise altered
* ROM from the presented hardware device
*****/
/* Included libraries */

#include<iostream.h>
#include<conio.h>
#include<stdlib.h>
#include<math.h>
#include<iomanip.h>
#include<fstream.h>

/* Constants */

#define PATTERNS 4 // Number of training patterns for the network
#define IN_NEURONS 3 // Number of input layer neurons in the network
#define HID_NEURONS 4 // Number of hidden layer neurons in the network
#define OUT_NEURONS 2 // Number of processing neurons in the network
#define WEIGHTS 20 // The number of weights there are in the network
#define ACCEPTABLE_ERROR 0.1 //

/* Variables */

float weight[WEIGHTS]; // The network weight values
float sensor[PATTERNS][IN_NEURONS]; // Network inputs (or training pattern)
float output[PATTERNS][(HID_NEURONS+OUT_NEURONS)]; // Outputs from each neuron
float target[PATTERNS][OUT_NEURONS]; // Target for each pattern for each
output neuron
float error[PATTERNS][(HID_NEURONS+OUT_NEURONS)]; // Error from each op neuron
float abs_error[PATTERNS][(HID_NEURONS+OUT_NEURONS)]; // Absolute of above
float network_error = 0; // Total error per training cycle after processing
of pattern
int pattern; // Current Pattern to be processed
long int count = 0; // Count of pattern iterations
int flag = 0; // Set if network trained to instigate interface

/* Function prototypes */

float set_random_weights(void); // Random weight assignment function.
float get_data(void); // Obtain targets/patterns & inputs.
float generate(void); // Random weight generator.
int forward_pass(void); // Perform forward pass calculations.

```

Appendix 14: Artificial Neural Network Software Listing

```
int find_error(void); // Assess network error values.
int reverse_pass(void); // Modifies the weights to train
network.

float r; // The random weight generated.

char filename[20] = "c:/weightlog.txt";
int mode = ios::out;
fstream fout ( filename, mode );

// ***** Main Loop *****
int main (void)
{
    int wgt; // Weight log counter

    randomize(); // Mandatory function call for random-number generation.
    set_random_weights(); // Initialise network weights to random values
                        // in the range -1.000 to 1.000.
    get_data(); // Obtain user-entered training data

again:

    count++; // count number of pattern-passes

    for (pattern = 0; pattern < PATTERNS; pattern++)
    {
        forward_pass(); // Perform forward pass of network
        find_error(); // Find the error in the network
        reverse_pass(); // Modify weights if network is not yet
                        // trained
    }

    if ( network_error > ACCEPTABLE_ERROR)
    {
        network_error = 0;
        goto again;
    }

    if ( network_error < ACCEPTABLE_ERROR)
    {
        flag = 1;
        pattern = 0;

        cout << "NETWORK TRAINED!! in " << count << " passes!"
        << endl
        << "Press any key to use network";

        getch();
        clrscr();

use:
input1:        cout << endl << "enter input for neuron 0 (0.000
                - > 1.000): ";
                cin >> sensor[0][0];
```

Appendix 14: Artificial Neural Network Software Listing

```

if ( sensor[0][0] > 1.0 )
    {
        cout << endl << "input too large!";
        sensor[0][0] = 0;
        goto input1;
    }

input2:    cout << endl << "enter input for neuron 1 (0.000 - > 1.000): ";
           cin >> sensor[0][1];

           if (sensor[0][1] > 1.0)
           {
               cout << endl << "input too large!";
               sensor[0][1] = 0;
               goto input2;
           }

input3:    cout << endl << "enter input for neuron 2 (0.000 - > 1.000): ";
           cin >> sensor[0][2];

           if (sensor[0][2] > 1.0)
           {
               cout << endl << "input too large!";
               sensor[0][2] = 0;
               goto input3;
           }
           forward_pass();
           goto use;

    }

    getch();

    return(0);

}

//
*****

/*****
* Name:                set_random_weights
* Parameters:          g - the loop counter.
* Returns:              nothing
* Globals:              r, the random weight.
* Description:          assigns random, floating point values in the
order of
*                       +/- 1.00 to network weight array .
*****/

float set_random_weights(void)
{
    int g;

    //fout << " Original weights  " << endl << " =====" << endl;

    for ( g = 0; g < WEIGHTS; g++ )        // ..for each weight..
    {
        generate();                        //.. generate a random weight..
        weight[g] = r;                     //.. and assign it.
        // fout << "Weight " << g << " = " << weight[g] << endl;
    }

    return(0);
}

/*****
* Name:                generate
* Parameters:          r - the random number process variables.
* Returns:              r - the random weight.
* Globals:              r
* Description:          generates a random, floating point number of range -
1 to 1.
*****/

float generate(void)

```

Appendix 14: Artificial Neural Network Software Listing

```
{
    r = random(2001); // Generate large ranged value (good random spread).
    r = (r/1000) - 1; // Scale this value to the 'milli' range, the '-1'
                    // allows for negative weight values.
    return(r);
}

/*****
* Name:                get_data
* Parameters:
* Returns:
* Globals:
* Description:        Debug routine for entering of specific weights
*****/

float get_data(void)
{
    int i, j, k, l;

    for (i = 0; i < PATTERNS; i++)
    {
        for (j = 0; j < IN_NEURONS; j++)
        {
            cout << "enter input pattern "<< i << " for neuron "
                 << j << ":" << endl;

            cin >> sensor[i][j];

        }
        cout << endl << "and the next pattern..." << endl<< endl;
    }

    clrscr();

    for (i = 0; i < PATTERNS; i++)
    {
        for (j = 0; j < IN_NEURONS; j++)
        {
            cout << endl << "input pattern "<< i << ", for neuron " << j
                 << " is: " << sensor[i][j];

        }

        cout << endl;
    }
    cout << endl << endl;
}
```

Appendix 14: Artificial Neural Network Software Listing

```
for (k = 0; k < PATTERNS; k++)
{
    for (l = 0; l < OUT_NEURONS; l++)
    {
        cout << "enter the target of neuron "<< l << " for pattern "
        << k << ":" << endl;

        cin >> target[k][l];
    }
    cout << endl << "and for pattern " << (k+1) << endl<< endl;
}

return(0);
}

/*****
* Name:                                forward_pass
* Parameters:
* Returns:
* Globals:
* Description:
*****/

int forward_pass(void)
{

    // outputs from 'hidden' layer:

    output[pattern][0] = ( 1 / ( 1 + exp ( -
    (
    ( sensor[pattern][0] * weight[0] ) +
    ( sensor[pattern][1] * weight[4] ) +
    ( sensor[pattern][2] * weight[8] )
    )
    ) ) );

    output[pattern][1] = ( 1 / ( 1 + exp ( -
    (
    ( sensor[pattern][0] * weight[1] ) +
    ( sensor[pattern][1] * weight[5] ) +
    ( sensor[pattern][2] * weight[9] )
    )
    ) ) );

    output[pattern][2] = ( 1 / ( 1 + exp ( -
    (
    ( sensor[pattern][0] * weight[2] ) +
    ( sensor[pattern][1] * weight[6] ) +
    ( sensor[pattern][2] * weight[10] )
    )
    ) ) );

    output[pattern][3] = ( 1 / ( 1 + exp ( -
    (
    ( sensor[pattern][0] * weight[3] ) +
    ( sensor[pattern][1] * weight[7] ) +
    ( sensor[pattern][2] * weight[11] )
    )
    ) ) );

    // outputs from 'output' layer:

    output[pattern][4] = ( 1 / ( 1 + exp ( -
    (
    ( output[pattern][0] * weight[12] ) +
    ( output[pattern][1] * weight[14] ) +
    ( output[pattern][2] * weight[16] ) +
    ( output[pattern][3] * weight[18] )
    )
    ) ) );
}
```

```

output[pattern][5] = ( 1 / ( 1 + exp ( -
(
( output[pattern][0] * weight[13] ) +
( output[pattern][1] * weight[15] ) +
( output[pattern][2] * weight[17] ) +
( output[pattern][3] * weight[19] )
)
) ) );

if (flag == 1)
{
/*
if (output[pattern][4] >= 0.5) //un-comment to implement rounding
{
    output[pattern][4] = 1;
}

if (output[pattern][4] < 0.5)
{
    output[pattern][4] = 0;
}

if (output[pattern][5] >= 0.5)
{
    output[pattern][5] = 1;
}

if (output[pattern][5] < 0.5)
{
    output[pattern][5] = 0;
}
*/

cout << endl << endl << "Abduction output = " << output[pattern][4];
cout << endl << "Adduction output = " << output[pattern][5];
getch();
clrscr();
}

return(0);
}

```

Appendix 14: Artificial Neural Network Software Listing

```
*****
* Name: find_error
* Parameters:
* Returns:
* Globals:
* Description: after all patterns are forward-passed, the error check is done
*****/
int find_error(void)
{
    int err; //loop counter

    /* cout << endl << "output 4 with pattern " << pattern << " = "
    << output[pattern][4];
    cout << endl << "Target 4 with pattern " << pattern << " = "
    << target[pattern][0];
    cout << endl << "output 5 with pattern " << pattern << " = "
    << output[pattern][5];
    cout << endl << "Target 5 with pattern " << pattern << " = "
    << target[pattern][1];
    */

    // Output layer errors

    error[pattern][4] = ( output[pattern][4] *
                        ( 1 - output[pattern][4] )
                        )
                        * (target[pattern][0]- output[pattern][4]);

    error[pattern][5] = ( output[pattern][5] *
                        ( 1 - output[pattern][5] )
                        )
                        * (target[pattern][1]- output[pattern][5]);

    // cout << endl << "error for neuron 4, with pattern " << pattern
    // << " = " << error[pattern][4];
    // cout << endl << "error for neuron 5, with pattern " << pattern
    // << " = " << error[pattern][5];

    //

```

Appendix 14: Artificial Neural Network Software Listing

```
*****
//hidden layer error:
error[pattern][0] = ( output[pattern][0] * ( 1 - output[pattern][0] ) )
                    *
                    (
                    (error[pattern][4] * weight[12]) +
                    (error[pattern][5] * weight[13])
                    );

error[pattern][1] = ( output[pattern][1] * ( 1 - output[pattern][1] ) )
                    *
                    (
                    (error[pattern][4] * weight[14]) +
                    (error[pattern][5] * weight[15])
                    );

error[pattern][2] = ( output[pattern][2] * ( 1 - output[pattern][2] ) )
                    *
                    (
                    (error[pattern][4] * weight[16]) +
                    (error[pattern][5] * weight[17])
                    );

error[pattern][3] = ( output[pattern][3] * ( 1 - output[pattern][3] ) )
                    *
                    (
                    (error[pattern][4] * weight[18]) +
                    (error[pattern][5] * weight[19])
                    );

//
*****

for (err = 0; err < ( HID_NEURONS + OUT_NEURONS ); err++)
{
    abs_error[pattern][err] = error[pattern][err];
    //transfer the error array to copy for
    //calculation of absolute error without
    //affecting originals before weight change.

    if (abs_error[pattern][err] < 0)
    {
        (abs_error[pattern][err] *= -1); //find absolute error value
    }

    network_error += abs_error[pattern][err]; // total error for each
    // neuron (absolute error
    // sum from all patterns)

    fout << endl << network_error;
}

return(0);
}
```

Appendix 14: Artificial Neural Network Software Listing

```

/*****
* Name:                                reverse_pass
* Parameters:
* Returns:
* Globals:
* Description:
*****/
int reverse_pass(void)
{
    // Hidden-to-output weight changes

    weight[12] = weight[12] + ( error[pattern][4] * output[pattern][0] );
    weight[13] = weight[13] + ( error[pattern][5] * output[pattern][0] );
    weight[14] = weight[14] + ( error[pattern][4] * output[pattern][1] );
    weight[15] = weight[15] + ( error[pattern][5] * output[pattern][1] );
    weight[16] = weight[16] + ( error[pattern][4] * output[pattern][2] );
    weight[17] = weight[17] + ( error[pattern][5] * output[pattern][2] );
    weight[18] = weight[18] + ( error[pattern][4] * output[pattern][3] );
    weight[19] = weight[19] + ( error[pattern][5] * output[pattern][3] );

    // Input-to-hidden weight changes

    weight[0] = weight[0] + ( error[pattern][0] * sensor[pattern][0] );
    weight[1] = weight[1] + ( error[pattern][1] * sensor[pattern][0] );
    weight[2] = weight[2] + ( error[pattern][2] * sensor[pattern][0] );
    weight[3] = weight[3] + ( error[pattern][3] * sensor[pattern][0] );

    weight[4] = weight[4] + ( error[pattern][0] * sensor[pattern][1] );
    weight[5] = weight[5] + ( error[pattern][1] * sensor[pattern][1] );
    weight[6] = weight[6] + ( error[pattern][2] * sensor[pattern][1] );
    weight[7] = weight[7] + ( error[pattern][3] * sensor[pattern][1] );

    weight[8] = weight[8] + ( error[pattern][0] * sensor[pattern][2] );
    weight[9] = weight[9] + ( error[pattern][1] * sensor[pattern][2] );
    weight[10] = weight[10] + ( error[pattern][2] * sensor[pattern][2] );
    weight[11] = weight[11] + ( error[pattern][3] * sensor[pattern][2] );

    return(0);
}
*****/
```

Appendix 15

Hardware prototype development

15.1 System sensing devices

Many sensors were considered before the final type was chosen. The suitability of each device considered was measured using the following criteria:

- Output signal characteristics.
- Electronic interface requirements.
- Mechanical operating requirements.
- Response characteristics.

The following sections briefly outline the sensors considered for the angular measurement.

Optical encoder sensor

A shaft encoder is a device consisting of a light source that is reflected from, or transmitted through, an optical disk to a detector such as that shown in Figure 1. It was theorised that such a device could be incorporated into a system made to reproduce and measure hip rotation. The output yields either a pulse series or absolute position indicator depending on the variety chosen.



Figure 1: Example of a forty-eight segment disk (left) and three-bit Gray code disk (right).

Source: Mobile Robots: Inspiration to Implementation.

The segmented disk was not developed to prototype stage since it would necessitate calibration on each use due to the relative nature of its output i.e. the disk describes no unique datum from which measurements are taken. The coded disk, although allowing absolute position of the hinge to be found (due each area of the disk being unique), was not developed either, since the physical size requirement of the disk would not be convenient in a system with low physical size restraints.

Stretch Sensor

The second type of sensor considered for use in the system was the Merlin Robotics (Staffordshire, United Kingdom) stretch Sensor, which varies resistance with applied tensile force.

A sensor of this type could be used for each degree of freedom associated with the hip and arranged in an armature in a fashion analogous to biological tendons; with elongation being a function of the rotational angle.

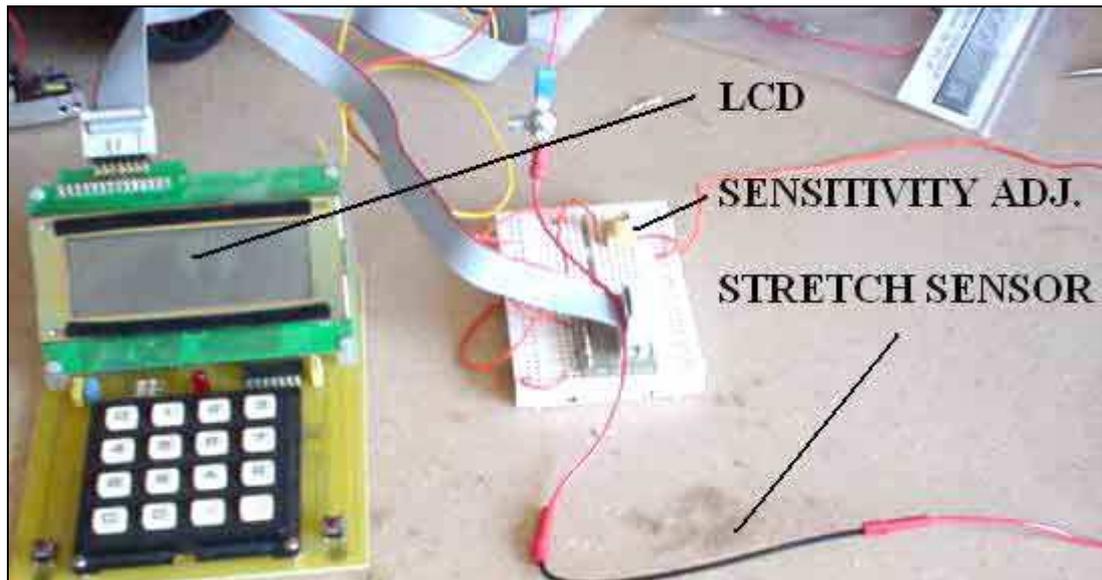


Figure 2: Test apparatus for stretch sensor

Figure 2 shows a test-bed built to evaluate the sensor. As an axial load is applied to the sensor, the proportional change in voltage is measured by an analogue to digital converter. This value is then displayed on a Liquid Crystal Display (LCD) panel, using a microcontroller. Although capable of measuring displacement, the time constant of the sensor was in excess of one second – too large to capture the gait cycle.

Resistive Bend Sensor

Flexpoint Sensor Systems (UK) manufacture a bend sensor which varies its resistance as the device is bent.

It was envisaged that this sensor could be incorporated into a mechanical rig which could follow the movements of the hip as a person walked. The device characteristics showed an acceptable response time, a low magnitude of overshoot and a negligible settling time of around a few hundred milliseconds.

However, the shortfall of this sensor technology was that it would require to be positioned flat against the thigh and the device would not be able to 'twist' as the thigh rotated medially and laterally.

Rotational potentiometer

The next logical device to consider was the rotational potentiometer. NTE Electronics Incorporated (USA) manufacture these devices (Figure 3) in small, lightweight packages featuring a sweep of 270° - satisfactory to describe any of the degrees of freedom during normal hip operation as shown in Figure 3.

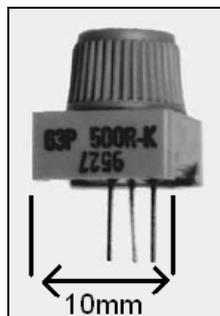


Figure 3: The Spectrol 63P rotational potentiometer

Source: Spectrol data sheet, NTE Electronics, Inc.

When a voltage is applied across the device, rotation gives rise to a specific voltage at the output pin. The device characteristics are fast response time and small overshoot as well as no perceptible settling time, favourable physical attributes and absolute positional data output. In view of these attributes, it was decided that this device would be one used in the initial prototype phase.

15.2 Sensor mounting development

Once each of these sensing technologies was evaluated and their operating characteristics known, the next phase of the hardware development involved the development of a mechanically-supportive mounting apparatus for the chosen device so that it was able to be mounted and articulate with a human hip. It was envisaged that a commercially-available device or piece of attire would be sourced which would allow mounting of the sensors and follow the hip-movement of the wearer.

Orthomerica Newport® device

The first device that was identified for this purpose was the Orthomerica Newport® 4 hip orthotic . This device is designed to physically hard-limit the hip movement of the wearer in flexion and extension and prevent movement altogether in abduction/adduction and medial/lateral rotational planes. This device was favoured since its design affords a good structural base for mounting other components. However, since this study concerns measurement and not limitation of the hip, it was decided that the hinge would require modification to mimic the hip's degrees of freedom and form the measurement armature.

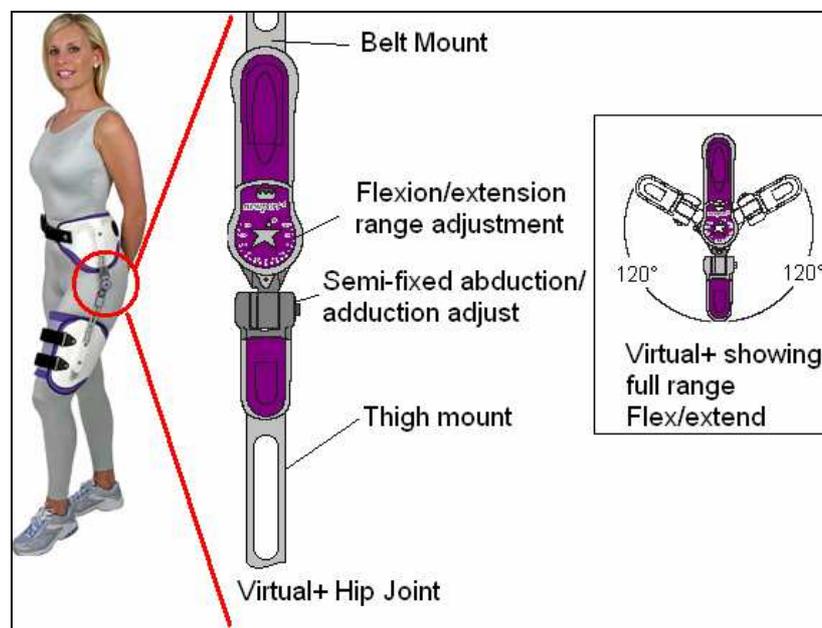


Figure 4: The unmodified "Virtual® +" Hinge.

Source: Customised Orthomerica promotional material

Figure 4 shows the product in its intended use as a movement-limiting device. The limits of the single degree of freedom are shown.

The locking gear of the hinge was first removed to increase the swing of flexion/extension and a potentiometer was added to measure rotation Figure 5.



Figure 5: the flexion/extension axis parts

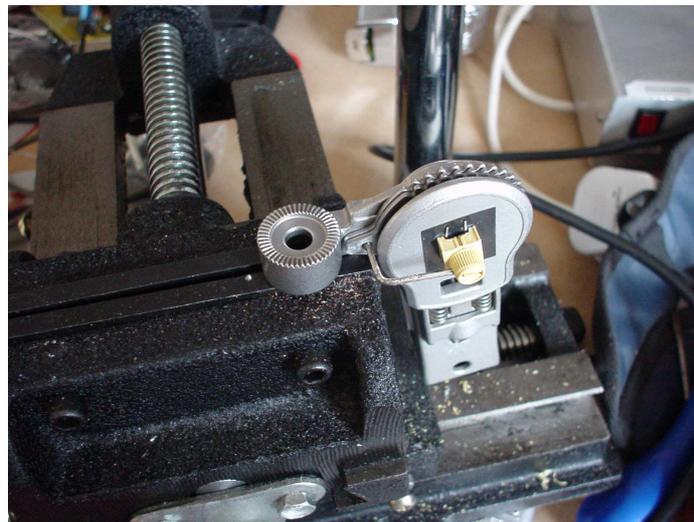


Figure 6: the adduction/abduction axis

A second modification allowed adduction and abduction. The toothed locking ring was separated from its counterpart Figure 6. This was accomplished by placing spacing shims at the centre of this ring so that the teeth no longer engaged. Once reassembled, the joint operated freely.



Figure 7: sensor anchorage

Figure 7 shows the abduction and adduction sensor placement prior to final fixture. Once the operation of the modified joints were verified, the electrical connections were made and epoxy resin was used to permanently attach the sensors.

The final modification to the hinge was the addition of the medial/lateral rotational axis. This proved the most challenging to realise, since rotation in this axis was not a function of the commercial hinge in any way. In order to allow rotation in this plane, a custom hinge sub-assembly was designed.

Since the shape of this sub-assembly is highly intricate, a drawing package was used to model its components and investigate the dimensions and shape to allow the desired articulation.

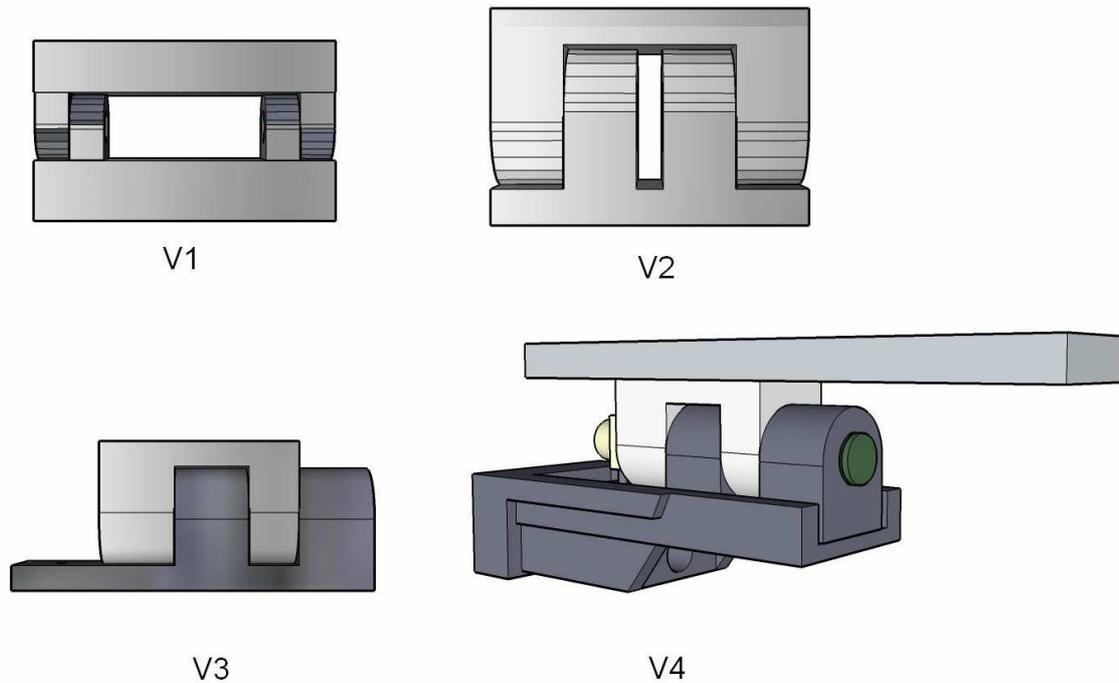


Figure 8: The evolution of the medial/lateral hinge

With reference to Figure 8, the hinge mechanism itself went through four main stages of evolution:

V1 represents the first iteration of design but resulted in too narrow a material thickness. Version 2 was devised to correct this, but the base thickness was too slight (4mm) to accept mounting hardware. Version 3 compensated for this by having both thick hinge halves and the mounting points located coincident with these to give maximum thread depth.

Version 4 shows this final hinge installed in the modelled surroundings of the hinge. The software was also used to give accurate simulation of the hinge during operation.

The final version was then manufactured by the mechanical engineering workshop in the University; the resulting assembly fitted precisely and was able to perform the action it was designed to accomplish. Figures 8 and 9 show the designed piece and the final item respectively.

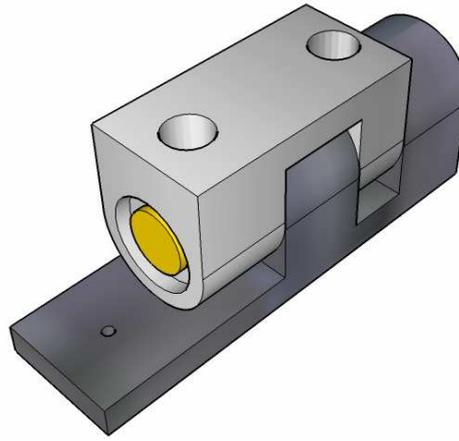


Figure 8: Final, rendered 3D Model



Figure 9: completed and assembled metalwork

Once the orthotic has been assembled (Figure 10) its electrical and mechanical characteristics were assessed before testing within the motion capture laboratory using a convenience-sampled volunteer.

1st generation prototype (modified orthotic hinge)

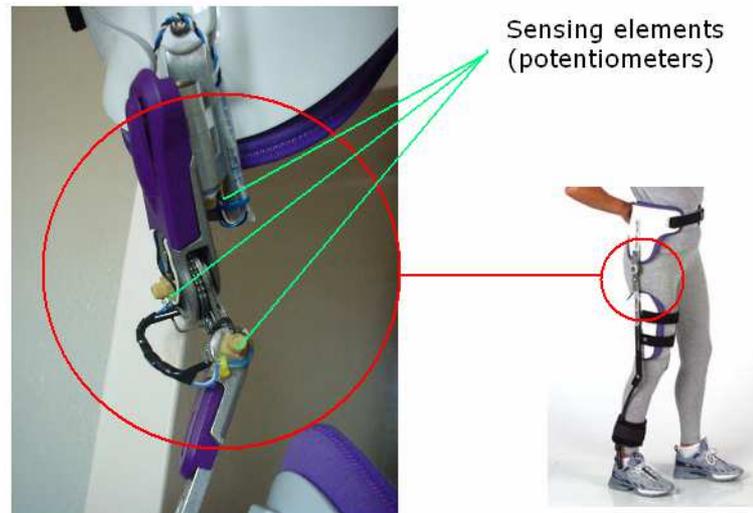


Figure 10: Instrumented hinge prototype system

During testing, it became apparent that the hinge was detrimental to gait since the thigh-cuff interfered with the adjacent thigh due to its location. In addition, the extension of the hinge while attached to the contoured section of the belt meant that normal arm swing was not possible without contact with the hinge body.

Although these effects would not be of concern while using the device for its originally-designed purpose of limiting motion; when using it in a system whose function is to passively monitor and measure, these gait-destructive elements are not favourable.

An investigation into modifying the device to circumvent these issues yielded no clear opportunity for further design to take place. Consequently, it was decided to prototype a second hinge using the advantageous aspects of the first system in order to overcome the shortcomings.

15.2.1 Development of 2nd generation sensor-replete armature

Continuing the use of a hinge-based device, similar to the first design would still allow the same sensing elements to be used, but with a newly-designed armature. A prototype of a lower-profile hinge was devised and built using construction blocks. This allowed rapid refinement of the design to allow rotation at key locations to follow hip movement.

In order to eliminate the potential of arm-swing contact with the device, it was decided that the design should support anterior fitment as opposed to lateral. Designing a custom armature also allowed the removal of the right-hand side only usage of the commercially-available orthotic.

15.2.2 Testing the 2nd generation device

The testing phase of the revised device was carried out in the motion capture laboratory using students as subjects, as detailed in the pre-pilot phase in chapter 3. The sessions also acted as refinement opportunities to streamline the fitment and data collection processes.

The Vicon MX system was used to capture the movements of the subjects with and without the device in order to establish the impact of the device on gait. The subjects were asked to walk at their normal pace until three trials were obtained giving a single-footfall, on a single force plate for each side.

Although data from fourteen students was recorded, only eight students' data was useable due to an unforeseen effect of using the hinge attached directly to the abdomen. This method of attachment was found to cause the armature to incorrectly flex during the gait cycle with some abdominal physiologies.

The data from an additional two students was missing a great proportion of values and so were discarded. It was hypothesised that this was due to the partial overshadowing of the right anterior superior iliac spine (ASIS) processes whilst using the belt component and this Vicon retro-reflective marker was occluded from the cameras during certain gait actions.