

University of Strathclyde

Department of Bioengineering

Development and Evaluation of Free-Living
Physical Activity Monitoring Devices for
Application in Clinical Populations

By
Kit Tzu TANG

A thesis presented in fulfilment of the requirements for the degree of
Doctor of Engineering in Medical Devices

2010

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

The copyright of this thesis belongs to the author under the terms of the United Kingdom Copyright Acts as qualified by University of Strathclyde Regulation 3.50. Due acknowledgement must always be made of the use of any material contained in, or derived from, this thesis.

Acknowledgement

Firstly I would like to thank all my supervisors, Ben Stansfield, Bill Spence and David Simpson for all their time, support and guidance throughout my EngD.

I would especially like to thank all the participants (and their parents) who took part in the studies.

I am very grateful for the support from PAL Technologies Ltd in the form of loaned devices, technical support and advice throughout the study.

My very sincere thanks to the staff at the Anderson Gait Laboratory (Alison Richardson, Jan Herman and Ben Cox) for help in the recruitment process and to allow me to collect data concurrently with their clinical gait analysis sessions.

Endless gratitude to my parents for their love and support and special thanks to my sister, Tina, without her, I would not have applied for the EngD course. I was fortunate indeed to be supported by some wonderful friends, particularly Julie who encouraged me through my stressful times and Chak who helped me out with all my IT issues.

Thanks also to all staff at the Bioengineering Unit, especially Stephan who lent me calibration equipments and provided me with his many words of wisdom.

Finally, I am very grateful for the funding from EPSRC.

Content

Acknowledgement

Contents.....	i
Abstract.....	vi
Glossary of terms.....	v
Figure list.....	ix
Table list.....	xii

1 INTRODUCTION1

1.1 Thesis Overview.....	2
1.2 Involvement of PAL Technologies Ltd.....	3

2 PHYSICAL ACTIVITY AND REHABILITATION4

2.1 Introduction.....	4
2.2 Activity Monitoring Techniques.....	6
2.2.1 Questionnaires and diaries.....	7
2.2.2 Observational techniques.....	8
2.2.3 Gait Analysis.....	8
2.2.4 Methods for measuring energy expenditure.....	9
2.2.4.1 <i>Doubly labelled water (DLW)</i>	10
2.2.4.2 <i>Oxygen cost measurements</i>	10
2.2.4.3 <i>Heart rate monitoring</i>	11
2.2.4.4 <i>Summary</i>	11
2.2.5 Ambulatory monitoring devices.....	11
2.2.5.1 <i>Pedometers</i>	11
2.2.5.2 <i>Foot switches, goniometers and gyroscopes</i>	12
2.2.5.3 <i>Accelerometer based devices</i>	13
2.2.6 Issues associating with activity monitoring techniques.....	17
2.2.7 Summary – Activity monitoring techniques.....	18

3 CEREBRAL PALSY19

3.1 Introduction.....	19
3.2 Classification of CP.....	20
3.2.1 Physiological classification.....	20
3.2.2 Topographical classification.....	21
3.2.3 Gross Motor Function Classification Systems (GMFCS).....	22
3.2.4 Summary.....	22
3.3 Assessment methods of CP.....	22

3.4	Cerebral palsy management	24
3.5	Activity monitoring for people with CP.....	24
3.6	Summary	26
4	LOWER LIMB PROSTHETICS	27
4.1	Introduction.....	27
4.2	Prosthetic requirements and components.....	28
4.3	Problems encountered by lower limb amputees.....	29
4.4	Outcome measurement - Activity monitoring and prosthetic use.....	30
4.5	Compliance monitor for amputees	32
4.5.1	Stump/socket interface pressure measurements.....	33
4.6	Summary	36
5	CEREBRAL PALSY – VALIDATION STUDY	37
5.1	Introduction.....	37
5.2	Methods.....	39
5.2.1	Introduction.....	39
5.2.2	The activPAL device and data analysis algorithms	39
5.2.2.1	<i>ActivPAL proprietary signal analysis algorithm</i>	<i>40</i>
5.2.3	Subjects.....	43
5.2.4	Evaluation study context.....	44
5.2.4.1	<i>Routine Gait Analysis session at the Anderson Gait Laboratory.....</i>	<i>46</i>
5.2.5	Protocol for activPAL use.....	47
5.2.6	Protocol for video recording	48
5.2.7	Protocol for synchronization of activPAL and video.....	48
5.2.8	activPAL data output	49
5.2.9	Video classification protocol and data output.....	49
5.2.9.1	<i>Video analysis 1</i>	<i>49</i>
5.2.9.2	<i>Video analysis 2</i>	<i>50</i>
5.2.10	Comparison of activPAL and video analysis outputs	51
5.3	Results	52
5.3.1	Posture categorization comparison	52
5.3.1.1	<i>ActivPAL analysis compared with video analysis 1.....</i>	<i>52</i>
5.3.1.2	<i>ActivPAL analysis compared with video analysis 2.....</i>	<i>54</i>
5.3.2	Stride counts comparison.....	63
5.3.3	Statistical analysis.....	65
5.3.3.1	<i>Correlations between activPAL and video data</i>	<i>65</i>
5.3.3.2	<i>Reliability Analysis</i>	<i>69</i>
5.3.3.3	<i>Agreement between video and activPAL data.....</i>	<i>69</i>

5.4	Discussion	75
5.4.1	ActivPAL posture categorization and stride count	76
5.4.1.1	<i>Walking and standing categorization</i>	76
5.4.1.2	<i>Walking categorization</i>	78
5.4.1.3	<i>Upright and non-upright categorization</i>	78
5.4.1.4	<i>Setting for minimum sitting and upright periods</i>	83
5.4.1.5	<i>Counting strides</i>	85
5.5	Summary	88
6	CEREBRAL PALSY – 7 DAYS FREE-LIVING ACTIVITY MONITORING	90
6.1	Introduction.....	90
6.2	Methods.....	91
6.3	Data Analysis	92
6.4	Results	94
6.4.1	Functional assessment questionnaire	94
6.4.2	ActivPAL results.....	95
6.4.2.1	<i>Effect of minimum setting for upright (sitting/lying) and sitting/lying (non-upright) period duration in the activPAL software</i>	98
6.4.2.2	<i>Sit-to-stand transitions</i>	100
6.5	Discussion	102
6.5.1	Functional assessment questionnaire	102
6.5.2	Free-living activPAL data.....	104
6.5.3	Effects of minimum setting for upright and sitting periods	106
6.5.4	Number of sit-to-stand transitions	108
6.5.5	Activity patterns of people with CP using activPAL with diary.....	109
6.5.6	Summary.....	113
7	AMPUTEES STUDY – ACTIVITY MONITORING FOR TRANS-TIBIAL SUCTION SOCKET USERS.....	115
7.1	Introduction.....	115
7.2	Device development.....	116
7.2.1	PressurePAL	117
7.2.1.1	<i>Calibration of pressurePAL</i>	118
7.2.2	ForcePAL.....	120
7.2.3	Calibration of forcePAL	122
7.3	Laboratory based validation study	125
7.3.1	Subjects.....	126
7.3.2	Methods	127

7.3.2.1	<i>Attachment methods</i>	128
7.3.2.2	<i>Video recordings</i>	129
7.3.2.3	<i>Synchronization</i>	129
7.4	Free-living multi-days monitoring using the pressurePAL	130
7.5	Data Analysis	131
7.5.1	Development of the pressurePAL signal analysis algorithm	131
7.5.1.1	<i>Decompressing the raw pressure signals</i>	134
7.5.1.2	<i>Categorization of static and dynamic events</i>	135
7.5.1.3	<i>Identify the ‘off’ periods</i>	136
7.5.1.4	<i>Algorithm to count strides</i>	137
7.5.1.5	<i>Activity summary generation</i>	138
7.5.1.6	<i>Summary</i>	138
7.5.2	Developing data analysis algorithm for the forcePAL	138
7.5.2.1	<i>Decompressing the raw pressure signals</i>	140
7.5.2.2	<i>Categorization of upright and non-upright events</i>	141
7.5.2.3	<i>Categorization of walking and standing events</i>	142
7.5.2.4	<i>Identify the ‘off’ periods</i>	143
7.5.2.5	<i>Stride counts</i>	144
7.5.2.6	<i>Activity summary generation</i>	144
7.5.2.7	<i>Summary</i>	145
7.5.3	Comparing video data to pressurePAL or forcePAL algorithm	145
7.5.4	Data analysis for free-living monitoring	147
7.5.4.1	<i>pressurePAL data</i>	147
7.5.4.2	<i>LAM data</i>	148
7.6	Results – PressurePAL validation study	148
7.6.1	Activity categorization comparison	148
7.6.2	Statistical analysis	150
7.6.2.1	<i>Correlation between pressurePAL and video data</i>	150
7.6.2.2	<i>Reliability Analysis</i>	151
7.6.2.3	<i>Agreements between pressurePAL and video data</i>	152
7.7	Results – ForcePAL validation study	156
7.7.1	Activity categorization comparison	156
7.7.2	Statistical analysis	157
7.7.2.1	<i>Correlation between forcePAL and video data</i>	157
7.7.2.2	<i>Reliability Analysis</i>	159
7.7.2.3	<i>Agreement between video and forcePAL data</i>	159
7.8	Results – Free-living monitoring using the pressurePAL	164
7.9	Discussion	166
7.9.1	Subject population	166

7.9.2	PressurePAL	166
7.9.2.1	<i>Calibration of device</i>	166
7.9.2.2	<i>Development of the signal analysis algorithm and its limitations</i>	167
7.9.2.3	<i>Disagreement between video and pressurePAL data</i>	168
7.9.2.4	<i>Statistical analysis</i>	172
7.9.2.5	<i>Long term monitoring using pressurePAL</i>	172
7.9.2.6	<i>Summary</i>	174
7.9.3	ForcePAL	174
7.9.3.1	<i>Calibration of forcePAL</i>	174
7.9.3.2	<i>Limitations of the forcePAL</i>	175
7.9.3.3	<i>Development of signal analysis algorithm and its general limitations</i> ..	176
7.9.3.4	<i>Disagreement between video and forcePAL data</i>	177
7.9.3.5	<i>Statistical analysis</i>	180
7.9.3.6	<i>Summary</i>	180
7.10	Summary	181
8	CONCLUSION	183
8.1	ActivPAL for use with the CP population.....	183
8.2	Quantifying amputees' activity patterns with pressurePAL and forcePAL	184
9	RECOMMENDATIONS FOR FUTURE WORK.....	186
9.1	Cerebral Palsy Study	186
9.2	Amputees study	187
	REFERENCES.....	189
	APPENDICES	207

Abstract

Objective measurement of physical activity provides evidence of actually free-living mobility and insight into the efficacy of interventions in clinical populations. Free-living activity monitoring is not used routinely as an outcome assessment in the population of children with cerebral palsy. Similarly there is a lack of quantification of physical activity level for lower limb amputees, leaving a gap in clinicians understanding of the suitability of prescribed prostheses.

For this thesis, an uniaxial accelerometer based device, activPAL, was evaluated for use in children with cerebral palsy and to objectively measure their free-living activity levels. The study group consisted of 19 subjects with varying degree of mobility impairment. ActivPAL data were compared with video recordings which acted as the gold standard for activity categorization and stride count. There was lack of agreement in activity categorization and stride count between activPAL and video based data. Potential sources of errors were investigated. Subjectivity in definitions of physical activity and adoption of postures that are not conveniently characterized proved to be the main sources of discrepancy between the activPAL and video based activity classification. The second part of this study was to quantify free-living activity levels of people with cerebral palsy. 15 subjects took part and their activity levels were measured using the activPAL. Results showed that activPAL with the use of simple diary offers a valuable tool for assessing physical activity in a free-living environment for this clinical population.

To quantify trans-tibial amputees' free-living physical activity levels and prosthetic usage, two monitoring devices (pressurePAL and forcePAL) were developed and evaluated. Data analysis algorithms were developed to automatically classify time spent in different activity states and count the number of strides made with the prosthesis. Reasonable accuracies were shown when data were compared to video recording for activity categorization, but further studies are required.

Glossary of Terms

Angle of foot progression – angle between a reference line along the midline of the foot and the direction of progression.

Ataxia – the shaky movements and unsteady gait that result from the brain's failure to regulate the body's posture and the strength and direction of limb movements. It may be due to disease of the sensory nerves or the cerebellum. In cerebellar ataxia there is clumsiness of willed movements. The patient staggers when walking and may not be able to pronounce words properly.

Athetoid – a writhing involuntary movement especially affecting the hands, face, and tongue. It impairs the ability to speak or use his hands; intelligence is often unaffected.

Cadence – the number of steps taken in a minute. The average for a person without any gait disorder is around 113 steps per minutes.

Chorea – a jerky involuntary movement particularly affecting the head, face, or limbs. Each movement is sudden but the resulting posture may be prolonged for a few seconds. The symptoms are usually due to disease of the basal ganglia.

Diplegia – paralysis involving both sides of the body and affecting the legs more severely than the arms. Cerebral diplegia is a form of cerebral palsy in which there is widespread damage, in both cerebral hemispheres, of the brain cells that control the movements of the limbs.

Dysaesthesias – the abnormal and sometimes unpleasant sensations felt by a patient with partial damage to sensory nerve fibres when his skin is stimulated.

Dyskinesia – a group of involuntary movements that appear to be a fragmentation of the normal smoothly controlled limb and facial movements.

Dyssynergia – lack of coordination, especially clumsily uncoordinated movements found in patients with disease of the cerebellum.

Dystonic – a postural disorder often associated with disease of the basal ganglia in the brain. There may be spasm in the muscles of the face, shoulders, neck, trunk, and limbs. The arm is often held in a rotated position and the head may be drawn back and to one side.

Hemiplegia – paralysis in one side of the body. Movements of the face and arm are often more severely affected than those of the leg. It is caused by disease affecting the opposite hemisphere of the brain.

Hypertonic – describing a solution that has a greater osmotic pressure than another solution.

Muscle tone – the normal state of partial contraction of a resting muscle, maintained by reflex activity.

Paralysis – muscle weakness that varies in its extent, its severity, and the degree of spasticity or flaccidity (decrease in muscle tone) according to the nature of the underlying disease and its distribution in the brain, spinal cord, peripheral nerves, or muscles.

Quadriplegia – paralysis/weakness in all four limbs.

Spasticity – resistance to the passive movement of a limb that is maximal at the beginning of the movement and gives way as more pressure is applied. It is a symptom of damage to the corticospinal tracts in the brain or spinal cord. It is usually accompanied by weakness in the affected limb.

Spastic paralysis – weakness of a limb or limbs associated with increased reflex activity. This results in resistance to passive movement of the limb. It is caused by disease affecting the nerve fibres of the corticospinal tract, which in health not only initiate movement but also inhibit the stretch reflexes to allow the movements to take place.

Step length – distance by which the named foot moves forward in front of the other one.

Stride length – distance between two successive placements of the same foot, consisting of two relatively similar step lengths in normal individuals.

Stride width – the perpendicular distance between the mid-point of the heel for consecutive steps.

List of Figures

Chapter 2

Figure 2.1: World Health Organization model for International Classification of Functioning, Disability and Health (WHO 2001)..... 6

Chapter 5

Figure 5.1: ActivPAL professional physical activity monitor 39

Figure 5.2: ActivPAL docking station with USB interface 40

Figure 5.3: An example of the recorded raw acceleration signal from the activPAL and the filtered signal with an indication of upper and lower thresholds for posture classification. 41

Figure 5.4: General aspects of classifying walking episode and stride counts from the raw acceleration signal with the number of strides counted by the activPAL algorithm.42

Figure 5.5: Orientation blocks position for observational analysis (a) and retroreflective marker placement for computerised gait analysis (b). 47

Figure 5.6: Calculated percentage discrepancy for each subject (except sub 8 and 13 as the % discrepancies were over 10%) analysed by different minimum setting for upright periods in the activPAL software 60

Figure 5.7: Calculated percentage discrepancy for each subject (except subject 13 as % discrepancies were over 15%) analysed by different minimum setting for sitting periods in the activPAL software. 63

Figure 5.8: The total durations recorded from the video (video analysis 2) for walking periods plotted against total duration from the activPAL output..... 66

Figure 5.9: The total durations recorded from the video (video analysis 2) for standing periods plotted against total duration from the activPAL output..... 66

Figure 5.10: The total durations recorded from the video (video analysis 2) for sitting/lying periods plotted against total duration from the activPAL output 67

Figure 5.11: The total durations recorded from the video (analysis 2) for upright periods plotted against total duration from the activPAL output 67

Figure 5.12: The total stride counts recorded from video (all counts and forward counts only) plotted against the total stride counts from the activPAL software for each subject68

Figure 5.13: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total walking durations of each subject..... 70

Figure 5.14: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total standing durations of each subject 71

Figure 5.15: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total sitting/lying durations of each subject 71

Figure 5.16: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total upright durations of each subject 72

Figure 5.17: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total stride counts (all counts) of each subject 73

Figure 5.18: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total stride counts (forward counts only for video analysis) of each subject..... 73

Figure 5.19: An example of misclassified periods for subject 13. For the activity classifier 0, 1 and 2 for the activPAL data and 3, 4 and 5 for the video data representing sit/lie, stand and walk respectively. 76

Figure 5.20: An example of the raw activPAL output plotted against time showing a misclassification of sitting event with activPAL units between 40 and 90. 81

Chapter 6

Figure 6.1: Average quiet standing times, stepping times and number of steps per day over 7 consecutive days for 15 subjects 96

Figure 6.2: Relationship between mobility score and average daily step count and average upright time per day for all subjects. 97

Figure 6.3: Relationship between mobility score and average cadence and average daily step count for all subjects.	97
Figure 6.4: Relationship of average laboratory based cadence with average upright time and average step count per day for all subjects.	98
Figure 6.5: An example of average number of upright events per day categorized into different durations during free-living monitoring (subject 1) for 3 settings of minimum sitting/lying and standing/walking times.	99
Figure 6.6: An example of average number of non-upright (sedentary) events per day categorized into different durations during free-living monitoring (subject 1) for 3 settings of minimum sitting/lying and standing/walking times.	99
Figure 6.7: The average number of sit-to-stand transitions per day for each subject that were analysed using 10, 5 and 3 seconds as the minimum setting for upright and sitting/lying periods.	100
Figure 6.8: Mobility score plotted against average number of sit-to-stand transitions (minimum duration of upright and sitting/lying events =10 seconds) per day performed by each subject.	101
Figure 6.9: Subject's age plotted against average number of sit-to-stand transitions (minimum duration of upright and sitting/lying events =10 seconds) per day performed by each subject.	102

Chapter 7

Figure 7.1: A photograph of the pressurePAL with the T-piece connector (5p coin of 170mm diameter included to indicate scale)	118
Figure 7.2: U-tube mercury manometer configuration for the calibration of the pressurePAL	119
Figure 7.3: PressurePAL readings with the corresponding pressure values in kPa.	120
Figure 7.4: ForcePAL with the FlexiForce as the sensing element	121
Figure 7.5: Flat bed calibration device connected to the mercury manometer	123
Figure 7.6: Calibration graph – forcePAL readings with the corresponding pressure values (mmHg)	123
Figure 7.7: The pressurePAL attached to the pressure relief valve of a trans-tibial suction socket with a T-piece connector and plastic tubing	128
Figure 7.8: Attachment of the ForcePAL to the prosthesis. The lead and data logger were securely attached with tapes over the top during the validation study.	129
Figure 7.9: Long-term Activity Monitor, LAM (PAL Technologies Ltd, UK).....	130
Figure 7.10: An example of a subject's (sub 7) pressure profile performing different activities using a suction socket with the pressurePAL attached.....	131
Figure 7.11: Flow chart for the pressurePAL signal analysis algorithm	134
Figure 7.12: Moving standard deviation pressure signal (grey) and the smoothed signal (black) for first 1500 seconds of recording from one of the subjects (Figure 7.10). The threshold of the smoothed standard deviation signal is shown to distinguish static and dynamic events.	136
Figure 7.13: Example of cyclical signals representing walking, the number of peaks that pass both upper and lower thresholds were counted as strides by the data analysis algorithm.....	137
Figure 7.14: An example of a subject's (sub 10) pressure profile recorded using the forcePAL, while performing different activities.....	138
Figure 7.15: Flow chart for the forcePAL signal analysis algorithm	140
Figure 7.16: Raw forcePAL data (grey), with the moving averaged data (black) for subject 5. Threshold of the filtered moving average signal is shown to distinguish upright and non-upright events.	142
Figure 7.17: Stage 1 moving standard deviation (grey) and stage 2 smoothed (black) standard deviation data for subject 5. A threshold of the stage 2 signal is shown to distinguish walking and standing activities for the upright events.	143
Figure 7.18: Cyclical signal representing walking, number of peaks that passes both upper and lower thresholds were counted as stride by the data analysis algorithm.....	144

Figure 7.19: An example of the video and pressurePAL data using the general Matlab algorithm for activity categorization. For the activity classifier 0, 1 and 2 for the video data and 3, 4 and 5 for the pressurePAL data representing ‘off’ state, static and dynamic events respectively.....	146
Figure 7.20: An example of the video and forcePAL post-processed data using the Matlab algorithm for activity categorization. For the activity classifier 0, 1, 2 and 3 for the video data and 4, 5, 6 and 7 for the forcePAL data representing ‘off’ state, sitting/lying, standing and walking events respectively.	146
Figure 7.21: The total durations recorded from the video for dynamic (walking), static (standing and sitting) and ‘off’ events plotted against total duration from the pressurePAL post-processed output.	150
Figure 7.22: The total number of strides found from the video compared with the number of strides computed from the pressurePAL data.....	151
Figure 7.23: Bland-Altman plot for the agreement between video and pressurePAL for the total dynamic durations for all subjects.	153
Figure 7.24: Bland-Altman plot for the agreement between video and pressurePAL for the total static durations for all subjects.	153
Figure 7.25: Bland-Altman plot for the agreement between video and pressurePAL for the total ‘off’ durations for all subjects.....	154
Figure 7.26: Bland-Altman plot for the agreement between video and pressurePAL for the total stride counts for all subjects.	154
Figure 7.27: The total durations recorded from the video for walking, standing, sitting/lying and ‘off’ events plotted against total duration from the forcePAL post-processed output for all subjects.....	158
Figure 7.28: The total number of strides found from the video compared with the number of strides computed from the forcePAL data for all subjects.	159
Figure 7.29: Bland-Altman plot of percentage agreement between video and forcePAL classification of total walking duration for all subjects.	160
Figure 7.30: Bland-Altman plot of percentage agreement between video and forcePAL classification of total standing duration for all subjects.	161
Figure 7.31: Bland-Altman plot of percentage agreement between video and forcePAL classification of total sitting/lying duration for all subjects.....	161
Figure 7.32: Bland-Altman plot of percentage agreement between video and forcePAL classification of total ‘off’ duration for all subjects.....	162
Figure 7.33: Bland-Altman plot of percentage agreement between video and forcePAL classification of total stride count for all subjects.....	162
Figure 7.34: Active free-living monitoring results for subject 3 and subject 10 using the pressurePAL, shown as time spent in dynamic activities and stride counts per day...	166

List of Tables

Chapter 2

Table 2.1: Examples of general health questionnaires and specific activity questionnaires	7
---	---

Table 2.2: Examples of commercially available accelerometer based activity monitoring devices	14
---	----

Chapter 5

Table 5.1: Information on CP subjects (M = Male, F = Female, AFO = Ankle Foot Orthosis)	44
---	----

Table 5.2: ActivPAL analysis and video analysis 1 - Percentage sensitivities and discrepancies for posture categorization time for each subject	53
---	----

Table 5.3: Total time spent in each activity state measured by the activPAL and video analysis 2 for each subject	54
---	----

Table 5.4: ActivPAL analysis and video analysis 2 - Percentage sensitivities and discrepancies for posture categorization of each subject, with stand times that were less than 6 seconds between stepping periods classified as continuous walking activities in the video data	55
--	----

Table 5.5: Percentage sensitivity and discrepancy for upright and non-upright postures of each subject using the default minimum sitting and upright setting (10 sec) for activPAL analysis	56
---	----

Table 5.6: Percentage sensitivities for upright classification of each subject for different minimum setting for upright periods in the activPAL analysis compared with video analysis 2	58
--	----

Table 5.7: Percentage discrepancies for upright classification of each subject for different minimum setting for upright periods in the activPAL analysis compared with video analysis 2	59
--	----

Table 5.8: Percentage sensitivities for non-upright classification of each subject for different minimum setting for sitting periods in the activPAL analysis compared with video analysis 2	61
--	----

Table 5.9: Percentage discrepancies for non-upright classification of each subject for different minimum setting for sitting periods in the activPAL analysis compared with video analysis 2	62
--	----

Table 5.10: Stride counts comparison between video and activPAL data with calculated percentage sensitivities and discrepancies for each subject.....	64
---	----

Table 5.11: The calculated mean of the percentage difference between video (video analysis 2) and activPAL data and limits of agreement calculated according to Bland & Altman (1986, 1999) for each activity categorization.	74
--	----

Table 5.12: The 95% confidence interval for the lower and upper limits of agreement for all activity categories.	75
---	----

Table 5.13: Sources of disagreement between the activPAL physical activity classification and that observed from video analysis 2.....	82
--	----

Table 5.14: Sources of disagreement between the activPAL stride count and that counted from the video when only forward strides were counted.....	87
---	----

Chapter 6

Table 6.1: Information on subjects who took part in this study	91
--	----

Table 6.2: Mobility score of each subject using the Edinburgh mobility questionnaire	94
--	----

Table 6.3: Number of complete free-living activity monitoring days for each subject.	95
--	----

Chapter 7

Table 7.1: RS Component gauge piezo-resistive sensor (24PC Series) characteristics	117
--	-----

Table 7.2: FlexiForce, A201 sensor characteristics	121
--	-----

Table 7.3: The recorded forcePAL unit with correlated pressure data for the drift test using the FlexiForce as a pressure sensor	125
--	-----

Table 7.4: Amputee subjects' information	127
--	-----

Table 7.5: Time spent in each activity state found by video recordings and pressurePAL data for each subject	148
Table 7.6: Percentage sensitivities and discrepancies for activity categorization and stride count of each subject.....	149
Table 7.7: The calculated mean of the percentage difference between video and pressurePAL data and limits of agreement calculated according to Bland & Altman (1986, 1999) for dynamic, static, off and stride counts.	155
Table 7.8: The 95% confidence interval for the lower and upper limits of agreement for all activity categories.	156
Table 7.9: Time spent in each activity state found by video recordings and forcePAL data for each subject.....	156
Table 7.10: Percentage sensitivities and discrepancies for activity categorization and stride count of each subject.....	157
Table 7.11: The calculated mean of the percentage difference between video and forcePAL data and limits of agreement calculated according to Bland & Altman (1986, 1999) for walking, standing, sitting/lying, off events and stride counts.....	163
Table 7.12: The 95% confidence interval for the lower and upper limits of agreement for all activity categories	164
Table 7.13: Time spent in different activity states and stride counts by pressurePAL and LAM for subject 3. (Day 2 to 8).....	164
Table 7.14: Time spent in different activity states and stride counts by pressurePAL and LAM for subject 10 (Day 2 to 8).....	165

1 INTRODUCTION

In clinical practice, there has been an increasing need to provide evidence based practice on the effectiveness of interventions in patient care. This had led to the development of various outcome measurement techniques for assessing intervention/treatment progress on the patient. Outcome measurements could be both physical and or psychological and one of the main outcomes in rehabilitation is their mobility level. For the monitoring of rehabilitation progress of these clinical groups of patient to be successful, their activities of daily living should be quantified in their home, educational/work and leisure environments as well as in a laboratory based settings.

It is possible to study the free-living physical activity levels of different patient group in a number of ways. Questionnaires or interviews could take place, but might be biased and often non quantitative. Computerised gait analysis techniques could determine the walking ability of each person, however there is no clear link between walking ability and amount of actual walking performed in free-living environments. Energy expenditure measurements such as exchange of doubly labelled water (DLW), oxygen consumption and heart rate could offer characterizations of activity level of a person. Some of these methods such as DLW are very expensive to administer and would not be practical on a large scale or in routine measurement. In addition, these techniques measure energy expenditure which would not be useful in populations with various mobility levels, as one person might spend more energy in performing the same amount of stepping activities compared to another person.

Small low cost devices with long term data recording capacity are needed to allow friendly physical activity monitoring. One example of a technology to do this is accelerometry. Accelerometer based devices could be used for routine monitoring of clinically relevant populations. Some accelerometer based devices provide outputs that have been linked to energy expenditure while others quantify time spent in different activity states by the individual, which would be more useful in patient populations with varying levels of mobility. Alternative technologies exist that potentially also offer the possibility for long term monitoring of physical activity in specific populations. The use of a device to record pressure and/or force at the stump socket interface within prosthetic sockets also offers this possibility.

Although it is useful to objectively document free-living physical activity level for all clinical rehabilitation groups, it is of paramount importance for people with mobility difficulties, such as people with cerebral palsy, stroke patients, people with multiple sclerosis and lower limb amputees. The quantification of free-living physical activity level in these clinical populations could be used to verify the effectiveness of the chosen intervention/prescription and also to document their rehabilitation progress.

For this thesis, investigations into the physical activity monitoring of two populations of subjects (people with cerebral palsy and lower limb amputees) were performed. There appear to be no commercially available devices or studies reporting the use of experimental devices to monitor the quantity of lower limb amputees' physical activity as well as the amount of prosthetic usage. The free-living physical activity level of this subject group could be indicative of correct prosthetic prescription and successful rehabilitation progress.

People with cerebral palsy have varying degrees of mobility impairment, making it important to validate any monitoring device that relies on movement patterns for successful operation. There appear to be no studies demonstrating the ability of commercially available devices to accurately monitor physical activity in this population.

In this thesis, subjects with cerebral palsy were examined using an accelerometer based device. The validity of device output was investigated and data from multi-day records of physical activity reported. Secondly subjects with trans-tibial amputations and prosthetic limbs were studied using pressure and force measuring devices. Physical activity monitoring methods were developed for this population to allow the characterization of posture and stepping events.

1.1 Thesis Overview

Throughout the thesis, where appropriate, reference has been made to the literature. Terms in italics are defined in the glossary. Information on physical activity and rehabilitation with different methods of monitoring activity are discussed (Chapter 2). A description of aspects of cerebral palsy (CP) relevant to the thesis is included (Chapter 3). Details of prosthetic use and design are provided as a background for the reader (Chapter 4).

A description of the validation study on the use of an accelerometer based activity monitor, activPAL, for use with the CP population (Chapter 5), with details on the 19 subjects studied (Section 5.2.2), methods (Section 5.2.3) and the equipment used are included. Data analysis procedures (Section 5.3) and results are presented for the comparison between activPAL and video recordings (Section 5.4) with statistical analysis. The relationship between the video and activPAL data is discussed (Section 5.5) with possible areas of misclassification explored. A multi-day study of physical activity in people with CP in their free-living environment is included (Chapter 6). A comparison of multi-day activity with diary based physical activity logs and mobility levels of the subjects are made (Section 6.4).

Two monitoring devices, the pressurePAL and forcePAL, for monitoring trans-tibial amputees' activity levels and prosthetic usages (Chapter 7) are described and formal calibration results are given for both devices (Section 7.2). The details of the method of the validation studies are presented (Section 7.3), including details on the 10 subjects. Extensive details of the data analysis algorithms for activity categorization and stride identification are given (Section 7.5) for both the pressurePAL and forcePAL. Results are presented of the comparison between pressurePAL/forcePAL and video data (Section 7.6 and 7.7). Free-living activity monitoring using the pressurePAL is presented in Section 7.8, including comparison results with the LAM (Long-term Activity Monitor). Discussion of the results incorporates the possible errors in the data analysis algorithm to categorize activities for trans-tibial amputees using the pressurePAL and forcePAL (Section 7.9).

Overall conclusions are drawn (Chapter 8) and recommendations made for further studies in this area of free-living activity monitoring for people with CP and in the amputee population (Chapter 9).

1.2 Involvement of PAL Technologies Ltd

This work was performed as part of Engineering Doctorate studies under the Doctoral Training Centre at the University of Strathclyde's Bioengineering Unit. As part of this programme an industrial collaborator may be engaged. For the work reported in this thesis PAL Technologies Ltd, Glasgow, UK, was the named industrial collaborator. PAL Technologies Ltd provided standard activPAL devices and also custom modified devices (pressurePAL, forcePAL) at no cost to the project. No payment was made to the thesis author, Kit Tzu Tang, or the supervisory team for involvement with this work.

2 PHYSICAL ACTIVITY AND REHABILITATION

2.1 Introduction

The work reported in this thesis is concerned with the monitoring of physical activity. It is necessary to establish the importance for this type of monitoring before the more specific elements of the work performed is detailed.

In our modern society, active lifestyle is thought to be important for all age groups. As sedentary way of life has been demonstrated to be detrimental as it increases the risk of developing many health problems (Lee and Skerrett 2001; Argiropoulor et al 2004; Berentzen and Sorensen 2007; Kamphuis et al 2007; Van der Horst et al 2007), such as cardiovascular diseases (Kohl 2001; Chen and Wu 2008), obesity (Chakravarthy et al 2002; Officer 2004), type 2 diabetes mellitus (Lynch et al 1996; Smith and McFall 2005; Chyun et al 2006) and certain types of cancer (Thune and Furberg 2001). People with disabilities are as likely as people in the general population to develop health problems associated with inactivity.

Physical activity is an essential part of daily functioning and there is increasing evidence to support its positive association with quality of life (Brown et al 2004; Bize et al 2007). Rehabilitation progress of patients after surgery or intervention may be best described by their level of physical activity in a free-living environment (Lyons et al 2005). For the chronically diseased population, their health related quality of life is correlated with their level of physical activity (Nelson et al 2007). According to a review of 24 studies (Coumeya and Friedenreich 1999), it was found that increased levels of physical activity could improve cancer patients' quality of life. In addition, most chronic disease groups comprised of mainly older individuals, and in general the elderly population usually present poorer physical health or lack physical strength when compared to the younger age groups (Hopman et al 2000). Therefore, they require specific attention in the recommendation of physical activity to maintain health. In 2002, statistics showed that inactivity was estimated to cost the NHS over £8.2 billion per year in England (Department of Culture 2002), consequently it is necessary to provide both healthy individuals as well as persons with chronic disease with a motivation to become more physically active to maintain their quality of life.

In accordance with the American College of Sports Medicine (ACSM) and American Heart Association (AHA) guidelines for healthy adults under the age of 65, the

recommendation for reducing the risk of chronic disease is to perform either moderate intense physical activity 30 minutes a day, 5 days a week or 20 minutes vigorously intense exercise for 3 days a week. In addition to these physical activities, a person should carry out 8-10 strength-training exercise, 8-12 repetitions of each exercise twice a week. For the 30 minutes moderate activity, it can be accumulated throughout a day in 10 minutes bouts (Haskell et al 2007; Nelson et al 2007).

Stamatakis et al (2007) suggested that adults' participation in sports had increased between 1991 and 2004 while their occupational physical activity had decreased during the same period. There is a general tendency for individuals to overestimate their activity level and underestimate the health related risk when asked to self-report, hence quantitative measurement of physical activity is needed. It is desirable to have reliable and objective techniques for measuring and monitoring physical activity in free-living environments.

The problem of inactivity does not only occur in adults, it has also become of paramount importance in children. In fact, the levels of activity for those between the age of 9 to 18 years old can significantly predict adult physical activity (Telama et al 2005). Studies have shown that inactive youths were at risk of becoming inactive and overweight in their adulthood, with increasing risk for developing numerous health problems (Van der Horst et al 2007; Chen and Wu 2008). The U.S. Physical activity guidelines state that adolescents should accumulate at least 60 minutes of moderate physical activity in most, if not all, days of the week (Physical Activity Guidelines Advisory Committee 2008). Although boys are generally more active than girls (Ridgers et al 2005; Butcher et al 2008), the majority of adolescents do not meet the above recommendation (Butcher et al 2008).

With the increasing interest to improve health related quality of life, measurements of physical activity have become more important and widespread. First, it is necessary to understand the terms mobility and physical activity. Mobility is defined as 'the individual's ability to move about effectively in his surrounding' (WHO 1980). Physical activity is any bodily movement produced by skeletal muscles that result in an energy expenditure and physical activity level is the ratio of total energy expenditure to basal energy expenditure.

The World Health Organization model of the International Classification of Functioning, Disability and Health (ICF) provided a framework to define the

components of health and some health-related components of well-being, which include body function and structure (impairments), activities, and participation (Figure 2.1). Both ‘activities and participation’ are main components within the model (Figure 2.1). The ICF defined activity as the execution of a task or action by an individual, and participation is defined as involvement in a life situation.

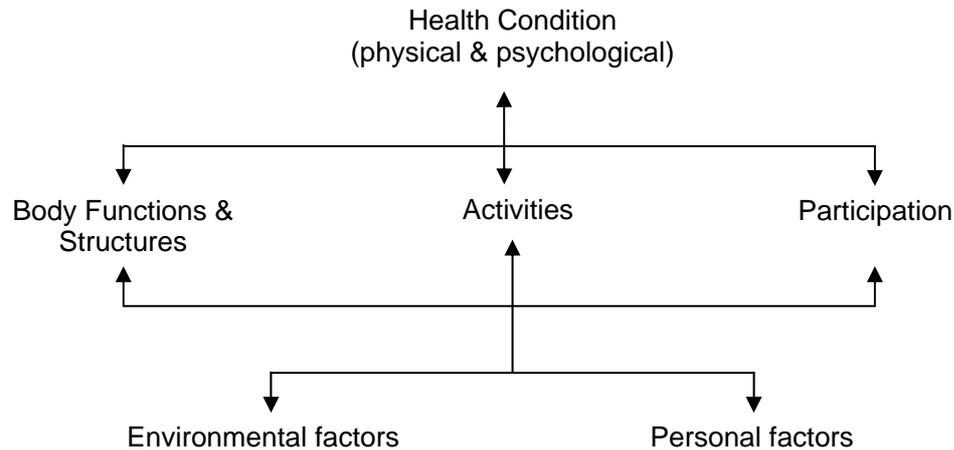


Figure 2.1: World Health Organization model for International Classification of Functioning, Disability and Health (WHO 2001).

The ICF stated that activity can be measured through the constructs of capacity and performance, where capacity is the implementation of a task in a controlled environment showing what the person is ‘capable’ of doing when asked in a clinical situation; and performance is the execution of a task in a natural environment, which would show what the person ‘really does’ in the free-living setting. From the ICF model, intervention in one component may, potentially, have influence on one or more of the other entities. Therefore performance is as important as capacity for an individual with or without disabilities. In view of rehabilitation issues, the ability to monitor patients’ levels of activity can provide useful quantitative information about their physical activity patterns, including any changes. This would enable clinicians to make more informed decisions about diagnosis, choice of appropriate treatment and the evaluation of progress (Lincoln 1990; Geurts et al 1991; Keith 1994).

2.2 Activity Monitoring Techniques

Physical activity is theoretically a single entity, but extremely difficult to be measured as such. During any type of movement, more than one set of skeletal muscles would be working and the total work done by both arms and legs has to be found. In practice, it

would be very difficult to measure every aspect which contributes to physical activity, therefore a choice must be made based upon which component of physical activity is most relevant to the research or clinical question.

2.2.1 *Questionnaires and diaries*

A convenient and inexpensive way to monitor physical activity is to use questionnaires or diaries. A diary is usually given to the subject to be completed at the time of activity or at the end of the day during daily free-living monitoring. However, the individual has to be motivated to keep full descriptions of his/her activity level at predetermined time intervals (Sirard et al 2000).

For activity level assessment, a general health questionnaire with a mobility part or specific activity questionnaires could be used (Washburn and Montoye 1986; Panesar et al 2001; van der Dussen et al 2001; Meriwether et al 2006). Examples of these questionnaires can be seen in Table 2.1. These questionnaires usually have a scoring procedure to assess a person’s overall activity level. Although questionnaires are still one of the main techniques for assessing physical activity, their reliability and responsiveness remains problematic.

Table 2.1: Examples of general health questionnaires and specific activity questionnaires

General health questionnaires	Reference
Medical Outcome Study Short Form 36 (SF-36)	Ware 1993
World Health Organization quality of life questionnaire – brief version (WHOQOL-BREF)	World Health Organisation 2004
Nottingham Health Profile	Hunt et al 1980
Functional Independence Measure (FIM)	Maynard et al 1997
Specific activity questionnaires	
Physical activity assessment tool (PAAT)	Meriwether et al 2006
International Physical Activity Questionnaire – Long Form (IPAQ-Long)	Craig et al 2003
Barthel Index	Mahoney & Barthel 1965

Questionnaires can provide useful information and have been widely used successfully in both clinical and research settings throughout the world for assessing free-living physical activity monitoring and many of these questionnaires have been validated for use in various clinical populations. However, questionnaires and diaries could be

subjective and prone to human errors. It is also possible that the accuracy of a questionnaire can be biased by leading or closed ended questions, which may contribute to errors in results interpretation. An interview may be required to improve the quality and reliability of the information.

2.2.2 Observational techniques

Observational gait analysis is a qualitative method of assessing walking patterns by identifying gait deviations in people through visual observation. However, good knowledge of normal gait and extensive experience of pathological gait is necessary to allow valuable observations to be made. There is no universal system for standardising observational gait analysis, causing difficulties with comparison between studies.

Observational means of assessment have several problems. Performing this type of observation purely by eye limits the number of 'pictures' seen per second to only 16 rendering events that last less than 1/16th of a second uncharacterisable. Also during gait, many events occur simultaneously making interpretation with no replay facility very difficult. The use of video technology clearly overcomes this issue and provides the capability for slow motion and pause during play back, allowing repeat viewing without fatiguing the patient. Advantages of observational assessment are that no extra external attachments to the patient are required therefore reducing the possibility of gait modification. However, it is a time consuming task and some important underlying causes for gait deviation may not be detected even by trained observers.

Observational gait analysis can also be used outside the laboratory, where an observer with or without the aid of video equipment, registers a person's activity levels in a given time period. However, this may influence the subject's behaviour with the awareness of being observed and this procedure is very time-consuming both for data collection and the interpretation that follows.

2.2.3 Gait Analysis

Instrumented gait analysis is the study of walking that involves a detailed examination of movements of the limbs while a person walks, normally through the use of some form of motion analysis system. This type of analysis is useful for identifying the underlying causes for walking abnormalities in patients (Cappozzo 1984, Kirtley 2006, Perry 1992, Zanchi et al 2000). The results from gait analysis can be used to aid

planning of the most appropriate treatment for people with a gait deviation (Gage 1991). Motion analysis coupled with force plate data (a record of the forces acting between the foot and the ground during walking) can provide information on both the kinematic and kinetic events throughout the gait cycle (Simon 2004, White 1999).

Kinematic is the term used to describe the geometric description of motion and information such as the position and orientation of body segment and angles of joints. The kinematic data is normally acquired using a body mounted marker system. The markers used can either be active, i.e. LEDs (e.g. CODA Motion Analysis (Dexterity Research Ltd, UK)) or passive reflective markers (e.g. ELITE system, BTS SrL, Milan, Italy, VICON, Oxford Metrics Ltd, Oxford, UK). The markers are placed in such a way as to allow the tracking of all body segments of interest. (Gage 1991, Perry 1992)

On the other hand, kinetic events are those relating to the forces and the effects of these forces on the body, especially at the joints. The most commonly used method to gain kinetic information is by the use of a force recording device (force plate) with either piezoelectric or strain gauged instrumentation, that is embedded in the walkway flush with the surrounding floor. The ground reaction forces (vertical, anterior/posterior and medio-lateral components) between the foot and the ground are measured when a person steps onto the force plate. (Gage 1991, Perry 1992)

The combination of kinematic and kinetic data allows the calculation of several key elements of activity performance throughout the observed movement including; joint angles, ground reaction forces, joint forces and joint moments.

Other spatial parameters such as stride length and width, step length and angle of foot progression can be found using an instrumented gait analysis system. These temporal variables in turn reflect events throughout the gait cycle (e.g. stance time, swing time, single and double support times). Cadence and walking velocity can also be calculated from these temporal parameters. It has to be noted that the velocity of gait will alter the dynamic joint ranges, therefore gait with similar velocities should be used for comparison purposes.

2.2.4 *Methods for measuring energy expenditure*

The minimum amount of energy that is required to keep the body alive is termed the basal metabolic rate, which can be estimated in a quiet and restful environment for an

individual after at least 8 hours sleep the previous night and approximately 12 to 14 hours since the last meal. Any energy expended over this basal metabolic rate is required to perform various physiological tasks (such as food digestion), may be associated with change in emotional state or could be required to perform physical activity. A key element of energy expenditure is the requirement to meet demands of physical activity. There are a number of methods which can be used to measure energy expenditure and the most widely used techniques include the use of doubly labelled water, the measurement of oxygen consumption or heart rate monitoring.

2.2.4.1 Doubly labelled water (DLW)

The doubly labelled water method is considered to be the gold standard for measuring energy expenditure under free-living conditions (Westerterp and Kester 2003; Plasqui and Westerterp 2007). Both the hydrogen and oxygen atoms of the water molecule are tagged with stable isotopes (^{18}O and deuterium, ^2H) in DLW for tracking purposes to assess energy expenditure (Lof et al 2003). The basis of the DLW method is to follow the decline in the stable isotopes in the body after the initial labelling, over time, through regular sampling of urine. This method can be used for both free-living and hospitalised patients, however, this technique is only accurate for average daily energy expenditure and cannot provide a temporal breakdown of activity. Also the labelled isotopes are very expensive, therefore not suitable for large scale studies.

2.2.4.2 Oxygen cost measurements

During physical activities, muscles are required to perform work using energy. By directly measuring the caloric expenditure at these sites of metabolism, the amount of physical activity can be determined (Maltais et al 2005). However, this has proved to be difficult to carry out, therefore an indirect measurement of the metabolic by-products was adopted. By sampling respiratory gases (relative proportion of O_2 and CO_2) in expired air, by portable systems such as the Cosmed K4b2 (Rome, Italy), energy expenditure during physical activities could be determined (Corry et al 1996; Littlewood et al 2004; Fredrickson et al 2007). However, the validity of these measurements can be adversely affected by environment conditions such as temperature and pressure, diet, prior exercise and intake of food. Another disadvantage linked to this method is the need to wear at least a nose clip and mouthpiece or a full face mask to collect the expired air, which could prove cumbersome and may result in the inhibition

of movements precluding certain activities. Therefore this method may not be feasible for use in free-living environments.

2.2.4.3 Heart rate monitoring

Heart rate monitoring is not a direct measure of physical activity, but provides an indication of the relative stress placed upon the cardiopulmonary system by the performed activity. Recordings of heart rate can be used to estimate oxygen consumption, which in turn determines energy expenditure (Bussmann et al 2004, Rowlands et al 1997). Oxygen uptake and heart rate have a linear relationship for a wide range of aerobic activities, with the exception at the resting heart rate and at the high end where maximal heart rate occurs for the anaerobic pathway. Heart rate data collected at specific time intervals can also provide information on the frequency, intensity and duration of the physical activity being performed. However, for the use of heart rate monitoring to be useful as a tool for activity monitoring purposes, the system has to be calibrated for each individual because heart rate varies from person to person and physical activity is not the only factor that affects the changes in heart rate. Other factors that could affect heart rate include emotional stress, medication, anxiety, level of fitness, hydration and environmental differences.

2.2.4.4 Summary

Although these methods for measuring energy expenditure are well established, they can present problems in practicality and the accuracy in the free-living situations. Furthermore, it is difficult to compare energy expenditure results between subjects, especially people with chronic disease or gait disorders, as these groups of patients may use more energy for the same physical activity when compared to an individual without any health problems. It is therefore more appropriate to characterize actual physical activity undertaken using methods other than energy consumption measurement.

2.2.5 *Ambulatory monitoring devices*

2.2.5.1 Pedometers

A pedometer is an objective, cheap, unobtrusive device which counts the number of steps the wearer takes and is usually worn at the ankle or the hip. It is ideal for a large population survey for activity level as step counts. Although a pedometer can count the

number of steps and the information can be used to assess activity, some early studies have suggested that pedometers can be inaccurate in both step counting and measuring distance walked (Gayle et al 1977; Washburn et al 1980). As technology improved in the past decade, evidence from recent studies showed the reliability and validity of electronic pedometers to be good (Foster et al 2005; Tudor-Locke et al 2005; Crouter et al 2006), but still varying greatly depending on the brand of the device (Schneider et al 2004; Tudor-Locke et al 2005). One other shortcoming of a pedometer is that it records the total count of stepping activity, therefore results have to be collected at the end of each day during free-living monitoring and participants may be able to check on the step count throughout the day (unless blinded), leading to exaggeration of activity to improve on the score of the pedometer. Furthermore, no information on posture or other physical activities performed is possible (e.g. cycling, work with the arm, sitting etc.).

2.2.5.2 Foot switches, goniometers and gyroscopes

Footswitches count the number of times the foot make contact with the ground (on/off), in effect counting steps. Footswitches normally use a pressure sensitive resistor as the sensing element to record heel strike and toe-off (Granat et al 1995). Analysis of the data obtained could be used to distinguish between continuous walking activities and small movements in standing.

Goniometers measure joint angle and by knowing the position and actions of lower limb joints, posture and activities can be determined. Goniometer measurements have been used extensively around the knee joint to document the apparent range of knee motion, especially to assess the efficacy of surgery or other forms of therapy to improve mobility or reduce painful movements. (Piriyaprasarth and Morris 2007; Rowe et al 2001) Goniometers can provide accurate measurement of angles, however the information obtained may not be useful in determining posture or activity level of people with gait deviations. For example, the range of knee joint angle for people who walk with flexed knees (crouch gait) or stiff knees might be small, making it difficult to distinguish standing episodes from walking periods.

Gyroscopes measure orientation of the segment based on the principles of conservation of angular momentum, hence body position can be determined and postural information could be obtained (Aminian et al 2002, Scapellato et al 2005, Tong et al 1999).

Although these devices have been used widely in studies to provide information on gait events, little research has been done for measuring activity levels directly or to estimate energy expenditure with a single device. Some researchers examined the feasibility of using a combination of these mechanical tools with accelerometer based devices to identify gait events, hence activity levels (Lau and Tong 2007).

2.2.5.3 Accelerometer based devices

Accelerometer based devices have become widely used for physical activity monitoring, allowing assessment of temporal patterns and intensity of activity as well as total accumulated activity (Morris 1973; Kavanagh and Menz 2008). These devices can be sensitive to accelerations in one to three orthogonal planes (vertical, mediolateral and anteroposterior). Due to the design of accelerometers this output is typically a combination of acceleration along the sensitive axis and orientation with respect to gravity. It is likely that the output signal would be affected by other factors such as external vibration and acceleration due to jolting of the sensor on the body from a loose attachment leading to overlaying of errors on the signal. As accelerometers respond to both frequency and intensity of movement, they provide additional information compared to actometers or pedometers, which are attenuated by impact or tilt only. Uniaxial accelerometer based devices can provide valid and useful information on posture and stepping activities if positioned appropriately. Triaxial accelerometer based devices would be sensitive to a wider range of body movements/activities, as they can detect acceleration changes in all three planes.

These devices are divided into two broad categories, those which estimate energy expenditure and those which classify posture and activity types. The commercially available accelerometers most frequently referred to in the literature are shown in Table 2.2. These devices are generally easy to fabricate, relatively cheap and small in size, therefore suitable for free-living activity monitoring, allowing unrestricted and minimally encumbered movement.

Table 2.2: Examples of commercially available accelerometer based activity monitoring devices

Accelerometer based monitoring devices	Type of accelerometer	Main Measure Outcomes	Other characteristics	References
Actical (Mini-Mitter Co., Sunriver, OR, USA)	Uniaxial; Dual-axial	Energy expenditure, step counts	Worn at waist using a belt; 28x27x10mm; weighs 17.5g	Welk et al 2004; Leenders et al 2006; Esliger et al 2007
Actigraph (also known as CSA, MTI, WAM) (Fort Walton Beach, FL, USA)	Uniaxial	Energy expenditure, activity intensity and step counts	Worn at waist using a belt; 53x50x20mm ; weighs 42.5g	Hendelman et al 2000; Sirard et al 2000; Metcalf et al 2002; Crouter et al 2006; Leenders et al 2006; Ham et al 2007; McClain et al 2007a
Actitrac (IM Systems, Baltimore, MD, USA)	Bi-axial	Activity counts	Worn at waist; 56x38x13mm; weighs 34g	Welk et al 2003
ActivPAL (PALtechnologies, UK)	Uniaxial	Time spent in different posture and step counts	Worn on the thigh; 50x35x7mm; weighs 20g	Grant et al 2006; Harris et al 2006; Ryan et al 2006
ActiWatch (Cambridge Neurotechnology Ltd, UK)	uniaxial Dual-axis	Energy expenditure	Hip or wrist worn; 39x32x9mm; weighs 11g	Finn et al 2000; Puyau et al 2002
Biotrainer (IM Systems, Baltimore, MD, USA)	uniaxial	Energy expenditure; activity counts	Worn at waist; 76x50x22; weighs 51g	Welk et al 2003
Caltrac (Sports Research Corporation, CA, USA)	Uniaxial	Energy expenditure	Worn at the waist; weighs 78g	Sallis et al 1990; Johnson et al 1998; Going et al 1999

DynaPort (McRoberts BV, Netherlands)	Triaxial	Time spent in different activities and body position	Worn around the waist; 62x41x18mm; weighs 53g	Bussmann et al 1995; Uiterwaal et al 1998; Van Lummel et al 2002
IDEEA (Minisun, Fresno, CA)	5 sets of accelerometers	Energy expenditure	Sensors placed at 5 different locations; weighs 200g	Sun & Hill 1993; Sun et al 1994; Zhang et al 2003
PAM (Ossur, Iceland and Dynastream Innovations, Inc, Canada)	Uniaxial	Step counts and time in different posture	Worn at the ankle; 85x38x32mm; weighs 50g	Bussmann et al 2004; Ramstrand and Nilsson 2007
StepWatch Activity Monitor, SAM (Cyma, WA, USA)	Dual-axis	Step counts and time spent stepping	Worn just above the ankle; 65x50x15mm; weighs 65g	Coleman et al 1999; Foster et al 2005; McDonald et al 2005; Boone and Colemann 2006
Tracmor (Philips Research, Netherlands)	Triaxial	Energy expenditure	Worn at the lower back; 72x26x8mm; weighs 22g	Levine et al 2001
Tritrac-R3D /RT3 (Stayheathy, Monrovia, CA, USA)	Triaxial	Energy expenditure	Worn at the waist; 71x56x28mm; weighs 65g	Jakicic et al 1999; Nichols et al 1999; Hendelman et al 2000; Campbell et al 2002; Powell et al 2003; Rowlands et al 2004; Leenders et al 2006
3dNX (BioTel Ltd, Bristol, UK)	Triaxial	Energy expenditure	Worn at waist using a belt; 125x58x8mm; weighs 93g	Carter et al 2008

The most commonly used accelerometers consist of a piezoelectric element with a seismic mass and when acceleration is detected by the seismic mass, it causes the piezoelectric element to bend and record a voltage signal that is proportional to the applied acceleration. There are also piezoresistive or strain gauge based accelerometers. Piezoresistive accelerometers use a piezoresistive substrate such as polysilicon in place of the piezoelectric element and the acceleration is detected as the inertial effect on the seismic mass changes its electrical resistance, which is proportional to the applied acceleration. A strain gauge based accelerometer uses a strain gauged element to detect the deflection of the seismic mass with a Wheatstone bridge network. The deflection is also directly proportional to the applied acceleration.

In general, the commercially available devices have sufficient onboard data storage capacity for prolonged recording (more than 7 days), which is useful for free-living measurement. In addition, with the advancement in technology, continuous time based sampling is possible, therefore output can be saved and downloaded to computers for post-processing to identify duration, frequency and intensity of the physical activity performed, hence energy expenditure can be estimated.

The output of an accelerometer based physical activity monitoring device is dependent upon the location of the monitor; its orientation; the posture of the subject and the movement/activity being performed. If the subject is at rest, the accelerometer output is determined by its inclination relative to the gravitational field. If the orientation of the accelerometer relative to the person is known, the posture of the subject relative to the gravitational field can then be determined by the accelerometer signal.

The most commonly used interpretation of accelerometer signals include simple mathematical operations such as means and standard deviations in conjunction with thresholds to determine periods of static and dynamic events. Another frequently adopted method for data analysis is the use of simple integration to determine the relationship between the integral of absolute accelerometer output and energy expenditure. More recently there are other signal analysis techniques such as frequency spectrum analysis, multi-resolution analysis, wavelets analysis, pattern recognition and neural networks, which could be used for accelerometer signal analysis.

Apart from the commercially available accelerometer based devices for monitoring activity level (Table 2.2), there are others which have been developed over the past decade and used in different research studies. Moe-Nilssen (1998) validated a triaxial accelerometer based device placed over the lumbar spine for standing balance and walking activity monitoring in the healthy adult population (Moe-Nilssen 1998a; Moe-Nilssen 1998b). In another study, Moe-Nilssen et al (2002) used the same device to measure balance control during quiet standing in the elderly population and later they used the monitor to estimate gait cycle characteristics such as cadence, step length and measures of gait regularity and symmetry (Henriksen et al 2004; Moe-Nilssen and Helbostad 2004).

Gait temporal parameters such as stance/swing relationship could be obtained from placing accelerometers on both legs (Aminian et al 1999) or different positions of the same leg (Willemsen et al 1990). Additional information on posture and activities can be found by placing more than one set of accelerometers on different body segments, such as on the trunk and legs (Veltink et al 1996; Bussmann et al 1998b; Bussmann et al 2000; Zhang et al 2003; Culhane and Lyons 2004; Lyons et al 2005; Lord et al 2007; White et al 2007). When a sensor is also placed on a segment of the upper limb, activity of the upper limb could also be detected (Foerster et al 1999; Schasfoort et al 2002).

Apart from general physical activity level, balance and fall detection can also be measured using triaxial accelerometer based devices (Lotters et al 1998; Mayagoitia et al 2002; Bourke et al 2006). Some research studies used accelerometers as well as gyroscopes to quantify posture and or activity levels and gait events (Najafi et al 2003; Paraschiv-Ionescu et al 2004; Jasiewicz et al 2006; Lau and Tong 2007). A combination of accelerometers with goniometers were used to assess gait events, while other studies used accelerometers with heart rate monitoring devices (Perkins et al 1995) to obtain data for physical activity level.

2.2.6 *Issues associating with activity monitoring techniques*

Nonetheless, with all kinds of free-living monitoring methods, problems with sampling size exist. The level of activity may vary greatly from day to day for most people and it is difficult to determine how many days to measure for an acceptable representation of daily physical activity for each individual. Another issue is that any attempt to measure physical activity may, alter the person's mobility level. People may become self-conscious and

over-exaggerate their physical activity during the monitored period. Studies suggested that 7 days monitoring would provide reliable estimates of daily activity level for both adults and children that would account for the potential differences in activities between weekdays and weekends (Trost et al 2000; Matthews et al 2002). Furthermore, each activity monitoring based device should be validated for each patient group before free-living monitoring.

2.2.7 Summary – Activity monitoring techniques

There are numerous types of instruments that are available to measure or assess aspects of physical activity. The choice of measurement technique will inevitably be dependent upon factors such as clinical needs and restrictions, related research questions, mobility aspects of interest, required methodological strength, cost and availability.

Physical activity monitoring may be performed using a number of methods each with their own advantages and disadvantages. To monitor for periods of time extending to several days it is necessary to use subject feedback via questionnaire or to adopt techniques that offer the possibility of either automatic activity detection using worn devices. Objective measurement using worn devices overcomes the difficulty of subjectivity and recall bias in questionnaire based records. Accelerometry is one technology that fulfils most of the requirements for long term monitoring of physical activity in a free-living environment and these requirements include; acceptability by the subject (size and appearance); ease of attachment and reattachment; robust to withstand wear in all anticipated environments and for all activities; sufficient data storage capacity for prolonged, multi-days, recording (more than 7 days) with adequate battery lifespan; appropriate frequency response. Any other techniques adopted must be minimally encumbering (to maximise compliance) and provide feedback on critical aspects of posture and stepping.

This thesis presents work based on the recording of accelerometer output as well as exploring the possibility of using pressure and force measurement for monitoring activity in the specific population of prosthetic users.

3 CEREBRAL PALSY

3.1 Introduction

One of the subject populations chosen for study in the work reported in this thesis, was that of people with cerebral palsy. It is important to understand the condition of cerebral palsy and its potential influence on a person's mobility, to appreciate the need for work to specifically validate activity monitors in this group of subjects.

Although cerebral palsy (CP) has probably existed since there have been children, it was not until the 1860s, when an English orthopaedic surgeon, Dr. William Little, first described it as a neuro-developmental condition and the term 'cerebral palsy' was introduced by Dr. William Osler in 1888. CP is the term used for referring to a group of non-progressive central nervous system (CNS) deficits, caused by an injury to the immature brain which usually occurs during or shortly after birth (Badawi et al 1998; Koman et al 2004). CP is thought to be one of the most common life-long developmental disabilities, causing considerable problems to individuals and their families. The worldwide reported prevalence in children with CP is 1 to 2.4 per 1000 live births (Murphy and Such-Neibar 2003; Koman et al 2004). The incidence and most important risk factors seem to be prematurity and low birth weight (Murphy and Such-Neibar 2003; Sankar and Mundkur 2005). CP can be developed prenatally, during birth or postnatally. The age until which CP can be acquired is uncertain as it is difficult to determine the exact time when the brain develops fully. Hereditary, prenatal infections, foetal anoxia and placenta mal-development are some examples of prenatal causes of CP. During birth the damage to the brain can be initiated by asphyxia or trauma. Whereas postnatal factors include vascular accidents, intraventricular haemorrhage and head trauma while the brain is still developing.

The motor cortex is believed to be the most vulnerable part of the brain in people diagnosed with CP, therefore almost all patients with CP have problems with movement. However, all other functions of the brain may also be affected due to the possibility of multiple lesions. Damage to the motor cortex usually leads to a loss of selective control of muscles, so contraction of these muscles may not be adequate at the appropriate time during specific movement such as walking. *Spasticity* and primitive patterns of contraction can also occur. Depending on the area of brain injuries, sensation which leads to a lack of balance, speech and posture may be impaired as well. CP affects many areas of the body, therefore there is

a need for a multidisciplinary approach to manage people with CP and the main fields include physiotherapy, speech therapy, orthopaedics and other associated rehabilitation specialists. Epilepsy (35-62%) and mental retardation (around 60%) are common in the CP population (Sankar and Mundkur 2005) along with other behaviour and neurological problems that can occur, depending on the extent of the defects in the brain.

An early diagnosis of CP is important as this could reveal significant delays in growth of the child. Initial problems that might be associated with CP include abnormalities of tone and patterns of motor behaviour related to the control of the body in space affecting the ability to interact with the environment. These motor difficulties may eventually lead to fixed deficits reducing function. Hence appropriate treatment/intervention is essential to help the individual to maintain mobility.

3.2 Classification of CP

Cerebral palsy is a diverse condition where the type of motor deficit may take several forms, which leads to problems when classifying the type of CP. There are currently two main methods to classify CP patients, the physiological and the topographical (Liptak and Accardo 2004). Another system, Gross Motor Function Classification Systems, GMFCS, is also used by some professions to classify different types of CP (Oeffinger et al 2007). A classification system for CP is used to clarify the extent of the disorder in a patient.

3.2.1 Physiological classification

This system classifies CP patients by the physiological characteristics of their abnormality and there are four main types of CP in this group, which are spastic, dyskinetic, ataxic and mixed (Murphy and Such-Neibar 2003; Sankar and Mundkur 2005).

Spastic CP is the most common type accounting for approximately 75 – 80% of the CP population. This type of CP usually correlates with a fixed lesion in the motor portion of the cerebral cortex, in which certain muscles are continuously contracted causing tightness or stiffness of these muscles, therefore affecting movement and gait.

Dyskinetic CP is classified as those who present problems maintaining posture and show fragmented involuntary movements of the limbs which would normally be controlled smoothly. Damage to the cerebellum and basal ganglia is the cause of dyskinetic CP.

Ataxic CP is when a patient shows low *muscle tone* and poor coordination of movements, which include shaky movements and unsteady gait that result from the brain's failure to regulate the body's posture and the strength and direction of limb movements. Affected children usually have a wide-based gait for balance as they tend to sway when walking and a mild intention tremor can also be seen.

The mixed type CP have damage to both the pyramidal and extrapyramidal portions of the brain, leading to both tight muscle tone seen in spastic CP and involuntary movements seen in *athetoid* CP. Children who fall into the mixed group have a more global neurological injury and so are more likely to have quadriplegia as opposed to diplegia and likely to present other forms of neurological disorders.

3.2.2 *Topographical classification*

The topographical classification was established using anatomical distribution of the deformity or abnormality. *Monoplegia*, *diplegia*, *hemiplegia*, *quadriplegia* and *double hemiplegia* (triplegia) are the terms used within this system. It is very rarely that children are diagnosed with monoplegic or double hemiplegic CP. Monoplegia refers to single limb involvement, whereas double hemiplegia relates to the involvement of all four limbs with both arms more severely affected.

Diplegia, accounting for around 40-45% of the CP population, is paralysis involving both sides of the body and affecting the legs more severely than the upper body. When only one side of the body is paralysed, it is termed hemiplegia (approximately 20-30%). In this group, movements of the face and arm are usually more severely affected than those of the legs and it is caused by damage affecting the opposite hemisphere of the brain. Quadriplegia (15-20%) defines the condition involving weakness/paralysis in all four extremities affecting the lower limbs more severely.

3.2.3 Gross Motor Function Classification Systems (GMFCS)

In 1997 another system, the Gross Motor Function Classification System (GMFCS), was developed to classify CP by their age-specific gross motor activity as well as their limitations (Palisano et al 1997). The GMFCS has five levels for describing the severity of motor disability, with level I as the more able-bodied, i.e. walks without limitations, and children in the level V category are those requiring a manual wheelchair for transportation. This system is reliable and valid, containing definitions and distinctions between levels.

3.2.4 Summary

The topographical classification is simple, therefore widely used. However by applying the topographical classification alone, limited information is given from the classification about the patient, therefore a combination of the physiological and topographical systems is usually used to describe a patient with CP, e.g. spastic diplegia, so that a more detailed diagnosis could be available.

The GMFCS is a more specific classification system based on gross motor activities in relation to age, however, it is still not widely used in a clinical setting, which may be due to the possibility of reclassification as the child grows and extensive knowledge about the system is required for the clinician to use it correctly.

3.3 Assessment methods of CP

The features that are most commonly seen with CP are:

- loss of selective muscle control
- dependence on primitive reflex patterns for ambulation such as mass limb flexion or extension which leads to abnormal movements in gait
- abnormal muscle tone
- relative imbalance between muscle agonists and antagonists across joints

A complete history, physical examination and ancillary investigation such as gait analysis are required for a full diagnosis of CP and its progression. Although the primary lesion in CP is non-progressive, the effects on the musculoskeletal system develop with growth. Therefore it is necessary to repeat these examinations at regular intervals to determine the rehabilitation progress of each patient.

During physical examination, different aspects of motor impairments are measured when the patient is in the prone and supine position. Range of motion (ROM) for both static and dynamic conditions are evaluated in all three planes (flexion/extension; abduction/adduction; internal/external rotation) by visual observations and measurement of angles. Muscle strength and selective control is tested. Muscle tone is rated and determined whether it is spastic, athetoid or mixed. Torsional deformation of bones and/or fixed foot deformities is assessed. Balance and equilibrium are appraised in both sitting and standing positions.

Physical examination is thought to be more useful in the evaluation of torsional deformities, equilibrium and balance, and muscle strength compared to gait analysis. However, it does not provide all the information required for a full assessment on its own. Therefore observational and computerised gait analyses are performed to complete the assessment. (See Chapter 2.2.2 and 2.2.3 for observational techniques and gait analysis). Desloovere et al (2006) concluded from their study that both clinical examination and gait analysis provided important information for delineating problems in children with CP. Although gait analysis alone gives valuable data, it cannot replace the information gained from clinical examination. DeLuca (1991) reported that computerised gait analysis information modified the surgical treatment recommendations made by experienced clinicians for patients with CP in 52% of the patients evaluated, indicating the importance of performing gait analysis. However, gait analysis only provides information on the person's capability of motion and no data are given for their physical activity outside the laboratory environment.

Furthermore, electromyography (EMG) recordings can be used to show the activation of skeletal muscles during movement (Ricamato et al 2005). The net EMG signal is the summation of all the electrical potentials from the generation of motor unit action potentials when a muscle contracts. Surface or indwelling electrodes can be applied to obtain EMG signals. These signals are very difficult to interpret as it is hard to distinguish noise or artefacts from real data. However, clinically, dynamic EMG is the only method available to determine which muscles are active during movement and the duration of the activation.

3.4 Cerebral palsy management

Abnormalities in cerebral palsy gait rarely occur in isolation, they normally consist of both primary and secondary anomalies. Primary deviations are directly due to the damage in the CNS, whereas secondary anomalies are those coping strategies used by individuals to get around the primary gait deviations. It may be difficult to distinguish between the primary and secondary abnormalities, but it is important to identify between the two and correct only the primary anomaly, which in effect abolishes the compensatory mechanisms as they are no longer required by the patient. Any gait impairments usually lead to reduced efficiency, requiring more energy compared to normal gait, therefore by giving the patient appropriate treatment/intervention, their physical capability should be maintained or improved.

Early diagnosis of CP is essential to allow an opportunity to assess and initiate rehabilitation for any mobility difficulties, which may result in fixed deficits as the child grows reducing their functions. In normal children gait matures by 5 years old (Davies et al 1997). However, children with CP in comparison with healthy children vary considerably in the nature and timing of the developmental changes in their walking abilities. Full examinations must be carried out to guide treatment plans, as it is likely that no two persons with CP will have exactly the same abnormalities. Therefore, intervention planning should be individualised, based on specific problems, taking physical and cognitive development into account and ensuring carer involvement. For motor difficulties, the appropriate options should reduce the deficits but help to maintain levels of mobility and physical fitness.

3.5 Activity monitoring for people with CP

In general, children with CP exhibit a higher energy cost for walking compared to healthy children and an increase of energy cost for ambulatory activities is seen as the child grows (Johnston et al 2004; Maltais et al 2005). In addition, the level of independence for people with CP decreases as the child develops (Johnston et al 2004; Day et al 2007). These limitations in walking skills and increased energy cost for ambulatory movements could lead to a decline in their ability to participate in day-to-day activities (Beckung and Hagberg 2002; Steenbergen and Gordon 2006). Bjornson et al (2007) reported that children with CP were less active compared to a group of age matched healthy children. It is important to document physical activity in CP children to assess if interventions are helping to maintain an active life style.

For people with the condition of CP, it is believed that those who are ambulatory would show limitations in their walking capacity, which might lead to implications for performance in the free-living environment. However, in clinical practice the main focus for assessment of people with CP has been measures of their walking capacity (e.g. gait analysis and tests on energy cost for walking). These methods are time consuming and high levels of skills are required to analyse the data. Usually no quantitative measurements are collected for activity levels within the context of the daily lives of people with CP, though questionnaires can be used (Graham and Harvey 2007; Maher et al 2007; Oeffinger et al 2007), they can be subjective and may be biased. A better understanding of physical activity in a free-living context for children with CP is warranted to enhance the perceptions of interventions aimed at mobility limitations and aid treatment decision making.

Chapter 2.2.5 discussed the different types of devices available to monitor activity levels in the general population and specific adult patient groups. Most changes in the mobility of people with CP are generally in the growth phase, i.e. childhood. To use accelerometer based devices to monitor asymptomatic children's activity levels, these devices must be sensitive enough to detect the highly transitory, short bursts and spontaneous movements that characterize children's play behaviours (Rowlands et al 2007). This leads to difficulties in energy expenditure prediction for children when using accelerometer based devices (Rodriguez et al 2002; Puyau et al 2004; Trost 2006).

Toschke et al (2007) used the Actigraph to monitor activity level in 205 asymptomatic children aged between 5 and 6, they found that low reliability might be caused by variable placement of the accelerometer device and the use of an elastic belt might cause slipping of the device. On the other hand, some validation studies in asymptomatic children have been carried out for different commercially available accelerometry devices and most studies reported good validity under supervised field conditions (Sallis et al 1990; Busser et al 1997; Trost et al 1998; Ekelund et al 2001; Argiropoulor et al 2004; Puyau et al 2004; Freedson et al 2005; McDonald et al 2005; Brandes et al 2006; Pfeiffer et al 2006; Chu et al 2007; Hussey et al 2007). The use of accelerometer devices for gaining information on the correlations between different interventions to increase activity level in asymptomatic children has been studied (Trost et al 1999; Ridgers et al 2005; Hager 2006; Heitzler et al 2006; Butte et al 2007). However, each accelerometer based device should be validated

before measuring physical activity especially if applied in a group with mobility related symptoms.

3.6 Summary

Cerebral Palsy can affect the mental and physical development of children and therefore has an impact on the child's ability to perform activities and on the likelihood that they will engage in community based physical activity. Children with cerebral palsy have a large range of mobility impairments and therefore to fully characterize the effect of the cerebral palsy on an individual it is necessary to perform an extensive assessment.

Intervention is often aimed at reducing the effect of the condition on walking capability, either preventing deterioration or enhancing this ability. The ability to walk might be linked to actual performance of physical activity in a free-living environment. However, it is not possible to characterize actual physical activity unless this is measured. The use of accelerometer based devices offers the possibility of quantifying free-living physical activity in this population, but there is no evidence that valid or reliable data can be obtained using this method in this highly variable mobility impaired population.

4 LOWER LIMB PROSTHETICS

4.1 Introduction

The second subject population studied for the work reported in this thesis was that of lower-limb amputees. As people in this population wear prosthetic devices during walking activity a number of alternative monitoring methods might be used to quantify free-living physical activity. Aspects of amputation and the use of prosthetic devices are introduced in this chapter to provide insight into the requirements for development of techniques for free-living physical activity monitoring in this population.

The earliest known prosthetic device was found in a tomb and was dated back to around 300BC. However, it was not until World War II that rehabilitation services for amputees became visible, because of the high demand from returning veterans. In addition, the polio epidemic in the 1940's and 1950's added to the need for restorative care. With the advancement in medical technology and the universal trend towards health consciousness, life expectancy has increased which leads to a growing population of the elderly. This increased age brings a concomitant increase in the potential for disease and injury, hence increases the incidence of amputations (Pernot et al 1997) and therefore expands the need for rehabilitation, especially in the prosthetic area. In a global study, the incidence of lower limb amputation was shown to range from 3.7 – 88.7 per 100,000 men and from 0.5 – 32 per 100,000 women (The Global lower extremity amputation study group 2000).

The major indications for performing amputation are: vascular diseases, trauma or injury, congenital limb deficiency, tumours and chronic infection. The typical age for lower limb amputation is 51-69 years old (Esquenazi and Meler 1996) and the highest prevalence for lower limb amputation in North America and Europe is through vascular disease with approximately 70% of all amputations (Pernot et al 1997; Mayfield et al 2000). However, the frequency of prosthetic use is lowest among this group because of co-morbidities. Fletcher et al (2002) showed that the amputation rates in the US between 1956 and 1995 declined, however, the total number of amputees increased due to the aging population (Fletcher et al 2002) and advancement in medical technology. Therefore, there is a clear need for effective ongoing prosthetic services.

Once the clinical evaluation and diagnostic techniques prove the necessity of amputation, it then becomes the goal of the rehabilitation team to ensure optimal recovery, restore function to the individual and to enable resettlement in society with an acceptable level of function. An artificial limb is used to replace the amputated part of the limb to restore functional losses and the main focus in the rehabilitation program for lower limb amputees is on standing and walking ability while using the prosthesis. The time from surgery to the first prosthesis fitting had been thought to contribute a significant effect on the frequency of prosthetic use and attainment of satisfactory walking ability with the prosthesis. Pezzin et al (2004) showed that those who were fitted at a later stage after amputation (>60 days) were less likely to be satisfied with the prosthesis fit, comfort, appearance, and overall performance, when compared to the persons with early prosthesis fitting (<30 days). However, early fitting may not always be feasible with the presence of non-healing wounds; infection; friable skin grafts or other co-morbidities and limb injuries that preclude ambulation. Well-fitting, comfortable, and easy-to-use prosthetic devices enable a patient to perform daily activities and maintain independence, which are of paramount importance for mental and physical health.

Lower limb amputations cause a loss of physical function, a change in weight distribution, interference in coordination and proprioception, and a disturbance of balance. The common levels of amputation in the lower limb are hindquarter, hip disarticulation, trans-femoral, knee disarticulation, trans-tibial, syme, and partial foot. An amputee's mobility level is influenced by the level of amputation and age (Holden and Fernie 1987). People with hip disarticulation and hind-quarter amputations have been shown to have reduced levels of independence. Trans-femoral amputees, with the loss of their nature knees, usually exhibit higher energy cost gait and are therefore less efficient with poorer quality of gait compared to trans-tibial amputees (Holden and Fernie 1987).

4.2 Prosthetic requirements and components

The essential elements of successful lower limb prosthesis are:

- a good fit of socket onto the residual limb stump
- alignment which positions the socket correctly in relation to the artificial foot
- suitable artificial joints as required
- some means of suspending the prosthesis on the stump
- a total weight within clinical requirements

- a functional device within a cosmetically acceptable package

The most common forms of lower limb amputations are either trans-femoral or trans-tibial, and for both types of amputations, the prosthesis would typically be composed of a prosthetic foot, a shank element, a custom made socket and some form of suspension. A suitable artificial knee joint would also be needed for trans-femoral prostheses. The prosthetic foot is designed to provide a base of support and shock absorption during ambulation. The shank corresponds to the anatomical lower leg and is used to connect the socket to the prosthetic foot. The custom made socket is in contact with the residual limb and disperses pressure around it. Suspension devices should keep the prosthesis firmly in place during use and prevent excessive relative motion between the residual limb and socket during walking.

4.3 Problems encountered by lower limb amputees

Van Velzen et al (2006) reviewed 48 studies and found that many factors (disease characteristics, personal and external factors) would influence a person's walking ability after amputation (van Velzen et al 2006). These concerns could cause gait abnormalities in amputees which may lead to less use of the prostheses and eventually not using the prescribed prosthesis at all. Condition of the stump, problems due to the prosthesis itself and amputees' reactions towards the use of an artificial limb could all lead to a decrease in the frequency of prosthetic use and physical activity of the individual, thus reduced quality of life.

The effective use of any stump depends largely on the operative technique performed and thus on the residual muscles left after the amputation and the condition of the skin (or soft tissue envelope). The prosthesis itself generally has no activity functional capacity and is controlled by the stump and its muscles. Good amputation procedures may lead to improved stump condition and therefore improved transfer of loads between stump and socket allowing better control of the prosthesis and therefore improved ability in walking.

Inadequate maintenance of hygiene levels and stump volume fluctuations are examples of other general stump problems which lower limb amputees can encounter. If the socket and or the stump are not cleaned regularly, debris accumulates causing skin irritation. On the other hand, volume fluctuation adds to the difficulty in providing the best socket fit. After

amputation the stump swells, especially distally as oedema occurs. This swelling can take up to 18 months to subside, but as mentioned previously it is best to fit an amputee with a prosthesis as soon after the amputation as possible (Pezzin et al 2004), so stump socks are added when the stump decreases in size. When the stump volume stabilises, the socket is recast to ensure adequacy of fit. Small volume fluctuations can also occur daily.

Ill-fitting sockets, bad alignment and incorrect length all lead to abnormalities in amputee gait, which may lead to infrequent use of the prosthesis. Badly fitting sockets can create excessive pressure causing pain, irritation or skin ulcers, and therefore patients would not be able to use the prosthesis until the skin is healed and pain is relieved. In addition, phantom pain may occur, which can be disabling (Dillingham et al 2001). Lower limb amputees normally rank socket fit and comfort as the most important issue influencing prosthesis acceptability (Legro et al 1999). For good functional outcome it is important to ensure correct socket alignment, positioning the stump to allow the wearer efficient performance of functional tasks. The socket of the prosthesis must be well fitted and be comfortable in order for the user to wear it. The weight of the prosthesis is also important as patients would find it difficult to walk with a heavy prosthesis. The socket should support the patient's weight comfortably including loads experienced during gait.

For amputees the initial rehabilitation training tends to have long term aims; however the motivation of the patient is the main factor towards good progress. It is important to distinguish the non-wearers who experience uncomfortable gait due to problems with the prosthesis itself or the stump condition, from those who have no interest in using the artificial limb. When a person is not motivated, he/she will not wear the prescribed prosthesis at all. On the other hand, if a prosthesis causes discomfort to the patient, the amputee may wear the prosthesis when necessary such as moving around in the house, and they would use it when first received, but once the discomfort begins, the amount of wear may decrease. It might be expected that the activity levels for those who have prostheses with bad alignment or of incorrect length would be less compared to those patients who have been properly fitted.

4.4 Outcome measurement - Activity monitoring and prosthetic use

The expectations of successful rehabilitation and level of outcome after amputation vary greatly between amputees. From one end of the scale, Para-Olympic participants are able to

run 100 metres in under 11 seconds, but on the other hand a successful outcome might be for the amputee to be able to take a few steps to assist a carer during transfer. Therefore the assessment of outcome measures should be individualised and evaluated in relation to pre-morbid function. The success of prosthetic fitting as well as prosthetic usage and amputees' overall functional ability in a community setting must be considered in their rehabilitation progress.

Pernot et al (1997) suggested that 'knowledge of daily functioning of amputees can enhance our understanding of the optimal care needed for amputees in our health care system'. Their review also found that the outcomes of studies showing the extent of prosthetic use cannot be compared as different selection criteria were used between studies and there were differences in the definition of functional walking (Pernot et al 1997). Therefore it would be useful to have an objective method to measure prosthetic usage that could be comparable between studies.

Most outcome measures for amputees are based on a variety of scoring techniques from questionnaires or interviews (See Chapter 2.2.1) (Kegal et al 1978; Narang et al 1984; Johnson et al 1995; Leung et al 1996; Uiterwijk et al 1997; Fletcher et al 2001; Panesar et al 2001). However, the use of a questionnaire/ interview could be biased and subjective. It would be difficult to determine the efficacy of the prosthesis from questionnaires, especially if the recipients were not motivated in using the prosthesis in the first place or if they believed that an indication of non-use could lead to support services being withdrawn. Also they may not know or remember exactly how active they had been while using the prosthesis. A more quantitative assessment method is the 10-metre walk; when an amputee is asked to walk 10 metres in a laboratory based setting. Full-time prosthetic users usually complete the task in less than 30 seconds and longer time is required for partial users. Some might not be able to finish the 10 metres walk. Collin et al (1992) used the Barthel index to assess functional outcome of lower limb amputees with peripheral vascular disease, which showed correlation with their walking speed and three distinct subgroups identified as walkers, partial walkers and non-walkers (Collin et al 1992).

In a study (Pezzin et al 2004), 960 amputees were interviewed to examine their prosthetic use and satisfaction with prosthetic limb devices. This survey showed that 94.5% surveyed used their artificial lower limb extensively and most people (75.7%) were satisfied with the overall performance of their prosthesis. In another study (Pohjolainen et al 1990), only 68%

of the amputees interviewed were extensive users of their prosthesis. Results from these studies cannot be compared as different methods of assessments were used.

Successful outcome measurements should be based on the amputees' performance and not just their capability. Furthermore, measures of mobility and independence may be useful in quantifying amputees' quality of life. Regular assessment is desirable for lower limb amputees as active prosthetic users may deteriorate into non-wearers because of their ongoing pathology. Hence, a long-term monitor for quantifying the amount of wear and activity levels in the free-living environment would be a useful device in order to document the rehabilitation progress and effectiveness of the prosthesis in restoring mobility to the amputee.

4.5 Compliance monitor for amputees

Chapter 2.2.5 discussed the different types of ambulatory activity monitors available for use in the general population. However, for activity monitoring in the amputees population, it is not only important to document their activity levels on a day-to-day basis, but also to quantify prosthetic usage. Therefore it is desirable to have a device that monitors the amount of prosthetic use as well as activity level for lower limb amputees. The ideal compliance monitor should be concealed within the prosthesis; the battery life time must be relatively long (>3 months), so that it can monitor a representative free-living period. Long battery life would be required because exaggeration of activity may occur at the beginning of the monitoring period (Ross and Reece 2006). The device must be discrete, unobtrusive and must not affect the function of the prosthesis.

There have been several attempts to develop devices to determine the wearing times for different types of orthosis and or prostheses. Holden and Fernie (1987) measured the extent of prosthetic use in 104 lower limb amputees from the onset of inpatient gait training up to 2 years post discharge. Footswitches were used as an electronic counter of steps to document objective measurement of actual use of the artificial leg as well as patients' ability in stepping (Holden and Fernie 1987). However, for the less active amputees, this method did not give any indication of the amount of prosthetic use and also counting steps did not describe the total activity level of a person. Holden and Fernie (1987) suggested that at least 600 steps per day were necessary for an amputee to manage a one-level home with moderate support (Holden and Fernie 1987).

Stam et al (1995) developed a device for continuous ambulatory monitoring of prosthetic walking (CAMP) in trans-tibial amputees. The device was attached around the shank element of the prosthesis and had a capacity to measure the walking time and number of walking periods per day for up to 5 days. However, this method only provided limited information towards activity level and prosthetic usage as only stepping activities were recorded (Stam et al 1995) and no information on prosthetic usage was given.

Bussmann et al (1998a) validated and tested the reliability of an accelerometer based activity monitor, which was able to detect several types of activities/postures (lying, sitting, standing, transitions, movement-related activities) for people with and without amputation. A high correlation was found between the output from the activity monitor and data obtained from video recordings (Bussmann et al 1998a). Since this study, the activity monitor had been developed further and validated in different groups of people (Bussmann et al 1998b; Bussmann et al 2004). However, this device did not give any information on the frequency of prosthetic use.

PAL Technologies Ltd (Glasgow, UK) developed a Long-term Activity Monitoring (LAM) device for use with lower limb amputees to document their stepping activities by counting steps. The LAM monitor consists of an uniaxial accelerometer and the device is placed inside the shank element of lower limb prostheses and is capable of recording for up to one year (Ross and Reece 2006). The outputs from the LAM include number of steps taken each day and were found that by using the LAM in conjunction with a validated prosthetic evaluation questionnaire, amputee's free-living mobility level and success of rehabilitation could be provided.

4.5.1 *Stump/socket interface pressure measurements*

When a stump is placed inside the socket, pressure should be distributed in such a way as to off load sensitive areas and transfer load through only those areas that have high pressure tolerance. Some sockets are designed to have equal pressure over the stump/socket interface, while others were designed to have high pressure areas over those tissues which could bear load. However, it is difficult to achieve ideal pressure distribution practically.

Many studies have used the measurements of stump/socket interface pressure to identify areas of high pressure, hence determining prosthetic fit and comfort. However, currently no ideal transducer exists for these measurements. Ferguson-Pell and Bain (1980) and Grant et al (1985) stated that an ideal interface transducer should be:

- small with thickness/diameter ratio of 1:10
- highly flexible without distorting the readings
- uniformly sensitive over the measuring surface
- capable of collecting continuous electrical output
- able to withstand ambient moisture and temperature of the body
- inexpensive to build
- highly sensitive, have negligible hysteresis, good linearity, negligible long term drift, suitable measuring range and good accuracy

There have been suggestions that only thin sensors such as the diaphragm deflection strain-gauge sensors (Rae et al 1971; Pearson et al 1973), fluid-filled transducers (VanPijkeren et al 1980), pneumatic transducers (Kroupskop et al 1987) and printed circuit sheet sensors (Engsborg et al 1992; Houston et al 1994; Zhang et al 1996; Convery and Buis 1998; Zhang et al 1998) are suitable for insertion between the skin and socket. Mounting of these devices should be relatively easy, but due to the sensors finite thickness, the pressure pattern may be disturbed when a sensor is placed at the stump/socket interface (Appoldt et al 1968).

For trans-femoral stump/socket interface measurements, Appoldt et al (1968) used four semiconductor strain gauges bonded on to a pressure sensitive diaphragm. They showed that the interface pressure can vary significantly from day to day due to donning of the prosthesis in a different position, fatigue, volumetric changes of the stump, and subject's gait variation (Appoldt et al 1968). Van Pijkeren et al (1980) used a hydraulic pressure transducer where the sensing element was a PVC bag filled with silicon oil and was connected to a National Semiconductor pressure transducer with an oil filled tube. They found that this method was affected by the variation of the radius of curvature of the measurement surface (VanPijkeren et al 1980). Lee et al (1997) measured the stump/socket interface pressure using strain gauged load cells which were integrated with the socket, with the transducer face flush with the socket's inner wall. The sockets used were made specifically with openings to allow the pressure transducers to make contact with the stump

(Lee et al 1997), therefore would not be ideal for quantifying daily use of the prosthesis and activity level.

For trans-tibial stump/socket interface pressure measurements, various force transducers were developed using strain gauges, mounted on the socket so the transducer face was flushed with the liner (Appoldt et al 1968; Sanders et al 1997; Zhang et al 1998; Sanders and Daly 1999; Goh et al 2003). These required the sockets to be made specifically and the transducers were cumbersome, therefore not suitable for free-living monitoring. Another commonly used method to measure stump/socket interface pressure was by force sensitive resistors (FSR) (Buis and Convery 1997; Convery and Buis 1998; Beil et al 2002). Although inaccuracies have been reported for the use of FSR technology (Cavanagh et al 1992; Ferguson-Pell et al 1992; Sanders 1995), Buis and Convery (1997) suggested some techniques to improve reliability with a strict calibration procedure and test protocol to be followed. A commercially available transducer, the F-socket (Tekscan Inc., Boston, USA) consisting of 96 FSR sensor cells, was used to measure pressure distribution at the prosthetic socket-stump interface.

For suction sockets, air pressure transducers connected to the one-way valve could also be used to determine pressure profiles during ambulation (Beil et al 2002). This allows the characterization of the negative pressure that occurs during the swing phase of a gait cycle.

Interface pressure data could also be used for evaluation of stump/socket finite element models, which are computer-based analysis tools that calculate interface stresses based on residual limb and prosthesis geometries and material properties as well as the loading conditions specified at the model boundaries (Jia et al 2004, 2005).

From the numerous studies on stump/socket interface pressure measurements, it was hypothesised that by determining pressure profile at the stump/socket interface, prosthetic usage and amputees' activity levels could be quantified, as distinct pressure patterns could be seen during different activities. For the purpose of developing a compliance monitor to measure the pressure profile, a site at the stump/socket interface where contact always occurred when a prosthesis is being worn should be chosen for the point of application of the pressure transducer.

4.6 Summary

Amputees are offered the opportunity to regain mobility through the use of prosthetic devices. The exact type of device and the fit are determined for each patient individually. There are, however, characteristics of the devices that provide the opportunity for monitoring of both prosthesis wearing times and physical activity. The published work on the variation of pressure profiles at the stump socket interface indicates that monitoring of this pressure would provide sufficient information to allow characterization of physical activity state. This promising route for physical activity characterization is explored in this thesis with both interface pressure and suction socket pressure relief valve pressure signals used.

5 CEREBRAL PALSY – VALIDATION STUDY

5.1 Introduction

Activity monitoring in the home, education and leisure environments can provide invaluable information on the rehabilitation progress for people with cerebral palsy (CP). This requires a wearable device that may be worn for multi-day periods and does not impair mobility. Physical activity is complex with many variables and it is therefore difficult to measure all aspects of physical activity with a single monitoring device. Depending on the reason for activity monitoring, it may be desirable to measure activity in various contexts. It is possible that the aim of measuring activity may be to obtain information on the energy expended by a subject to correlate with obesity levels. However, the fundamental quantity addressed in this thesis is activity patterns during daily living, characterized by standing and stepping phases with number of strides performed.

Due to the heterogeneous nature of the CP population it was recognised that although subjects may have had gait deviations in common with one another, no two subjects would be exactly the same. The severity of, and the underlying reason for, a particular abnormality may differ greatly between subjects. By performing gait analysis only, a patient's walking ability and the underlying causes of the disability may be determined, however, their walking activity during normal daily life is unknown.

The activPAL (PAL Technologies Ltd, UK) is an uniaxial accelerometer based device, that is commercially available for monitoring activity level in a free-living environment. However, the device had not been validated for use with younger subjects (children), especially those with mobility difficulties. The current study was carried out to validate the activPAL for people with CP and to establish whether the proprietary activPAL algorithm for data analysis could be used to categorize posture and count strides in the CP population. It was hypothesised that the activPAL could accurately categorize posture (sitting/lying, standing and walking) and strides detection using a general algorithm and hence provides useful free-living activity data to document the activity patterns and rehabilitation progress of people with CP and to aid clinicians in decision making towards treatment planning.

The abilities of the activPAL to characterize free-living activity into periods spent sitting/lying, standing and walking using a proprietary algorithm has been validated in

healthy adult populations (Jamieson 2002; Godfrey et al 2007; Grant et al 2008) and results showed that overall agreement between observer and activPAL were 95.9%-98% with excellent inter-device reliability (ICC ranged from 0.79-0.99). Studies also demonstrated the use of the activPAL to characterize free-living physical activity levels of older adults (Egerton 2005), stroke patients (Egerton et al 2002; Harris et al 2006) and people with heart disease (Lean et al 2007). However, subjects with CP may have altered anatomy and motion patterns, therefore it was important, before using the activPAL in this subject population, to validate the output under controlled conditions.

The activPAL outputs should be validated against a 'gold standard' test in order to examine its ability to accurately classify posture and count strides for people with CP. 'Gold standard' is the term used as a benchmark that is regarded as definitive for the required measurements and a hypothetical ideal gold standard test has a sensitivity or statistical power, of 100%, however this is very difficult to achieve. Doubly labelled water, DLW, (see Chapter 2.2.4.1) is thought to be the 'gold standard' to validate accelerometry based activity monitoring devices which are used to infer energy expenditure. For the current study the aim was to evaluate the ability of the activPAL to characterize physical activity state. The widely used 'gold standard', observation by means of video recorder, was employed to validate the accuracy of the activPAL outputs for use with the CP population. An observer can distinguish postures and count the number of steps that the wearer performs. Visual analysis provides a gold standard for data on posture and movement patterns.

This validation study was carried out at the Anderson Gait Laboratory, Edinburgh, which specialises in gait analysis for people who show a wide range of gait disorders and thus provided the ideal setting for recruitment of subjects with CP and conducting data collection. Clinical gait analysis is routinely performed at the Anderson Gait Laboratory for treatment planning and review of rehabilitation progress for people with gait disabilities. The process involved each patient being evaluated individually through physical examination, observational and computerised gait analysis in a single visit to the centre.

Evaluation of the ability of the activPAL general analysis algorithms to correctly characterize physical activity state and stepping activity in a CP population is reported in this chapter.

5.2 Methods

5.2.1 Introduction

The activPAL was used in this study to attempt to characterize physical activity. To understand the way in which this evaluation study was carried out, the device and the proprietary data analysis algorithms are first described (section 5.2.2). The subject population is detailed and then the context in which the evaluation was conducted is given (section 5.2.3). Specific aspects of the experimental protocol are covered (sections 5.2.4 to 5.2.10).

5.2.2 The activPAL device and data analysis algorithms

The activPAL (Figure 5.1) is an uniaxial accelerometer based activity monitoring device worn on the thigh. It is a lightweight device of approximately 20g with a dimension of 50x35x7mm. A range of sampling frequency 0-100Hz is available, and 10Hz is normally used for daily activity recording. The uniaxial accelerometer used in the activPAL was an ADXL31 (Analog Devices, Inc.).



Figure 5.1: ActivPAL professional physical activity monitor

For standard use, it is advocated that the activPAL is attached to the anterior mid thigh, which was the position used in this study. The activPAL has a sensitive axis aligned with the long axis of the thigh, which is affected by both gravity and movement of the lower limb. Although the device output is referred to as ‘acceleration’ from an ‘accelerometer’, the signal output is actually a combination of acceleration and also orientation with respect to gravity. In this thesis the output from the device will be referred to as ‘acceleration’ although there is some ambiguity in the use of this term unless the gravitational component is also considered to be due to the potential acceleration effect that would arise in a gravitational field.

The difference between signals produced when the activPAL is placed statically (i.e. with only orientation effect due to gravity and no acceleration effect) in a horizontal and then a vertical position was equivalent to 1g (g = acceleration due to gravity). Hence, the acceleration signal measured from the activPAL could be calculated (Equation 5.1).

$$Acc_{PAL} = \left(\frac{PALsignal - PALsignal_H}{PALsignal_V - PALsignal_H} \right) \times 9.81 \quad \text{[Equation 5.1]}$$

Where $PALsignal$ = output signal, $PALsignal_H$ = output signal with device horizontal, $PALsignal_V$ = output signal with device vertical.

Within the activPAL, the signal noise was reduced by using an anti-aliasing low pass filter with a cut-off at 5Hz and then the signal was digitised (8bits) by internal microprocessors and information stored on the internal memory. The microprocessor controlled the processing and recording of the sensor signal and communication with a host computer. The device was capable of recording for in excess of 7 days continuously and it recorded the acceleration signal, which was then downloaded to a computer for analysis. A serial cable linked the docking station (Figure 5.2) to the USB port of a computer with the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd), which was used to analyse the data.



Figure 5.2: ActivPAL docking station with USB interface

5.2.2.1 ActivPAL proprietary signal analysis algorithm

The interpretation of the activPAL signal by the proprietary algorithm allowed the categorization of posture as sitting/lying, standing and walking periods with the number of strides determined. Although the author does not know the exact algorithm that was used

by the activPAL software, general aspects of the acceleration signal interpretation were known.

Sitting/lying and upright posture classification

The proprietary algorithm first employed some form of filtering techniques, possibly a 10 second moving average filter and then two thresholds were identified for the filtered signal (Figure 5.3), an upper threshold for the classification of upright postures and a lower threshold to distinguish sedentary events. Hence for a change in activity state, it is necessary for the signal to go through both thresholds. For example, when a person is in an upright state, a change of activity would not occur until the filtered acceleration signal passed through the lower threshold, and if in a sitting posture a change would not occur unless the upper threshold was crossed.

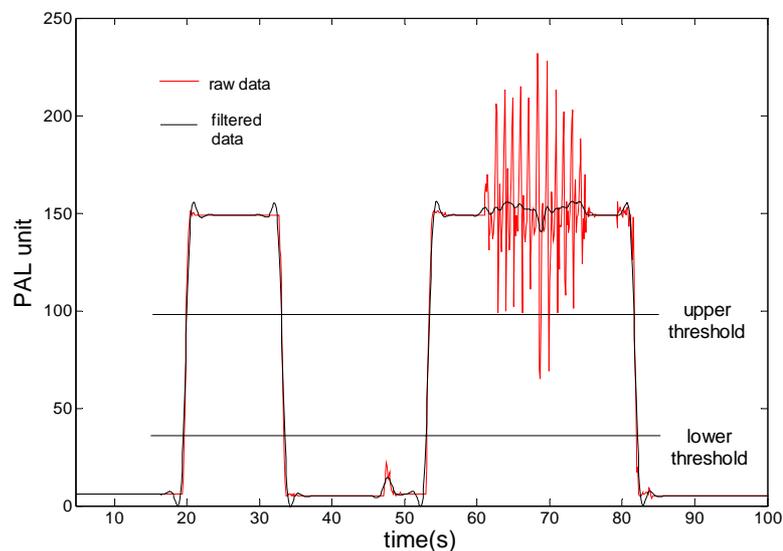


Figure 5.3: An example of the recorded raw acceleration signal from the activPAL and the filtered signal with an indication of upper and lower thresholds for posture classification.

Stepping classification

After the classification of upright and non-upright events, the algorithm then identified stepping activities within the upright posture. When a cyclical signal was detected within the upright events, it was expected to be stepping episodes. The start time of each stepping activity was recognised by the first trough in a cyclical signal after a small peak was detected (Figure 5.4). This trough was considered as the first stride within this walking period. The number of every other trough within the stepping activity was counted to represent the number of strides performed. The last trough was used as the finish time of

the associated stepping episode, which did not seem to be counted as a stride. As the exact algorithm was unknown, information was only obtained from data collected to determine when a stride was counted. A diagrammatic summary of the general aspects of the classification of walking period and stride counts from the acceleration signal recorded by the activPAL are presented in Figure 5.4 with the number of strides counted by the activPAL algorithm.

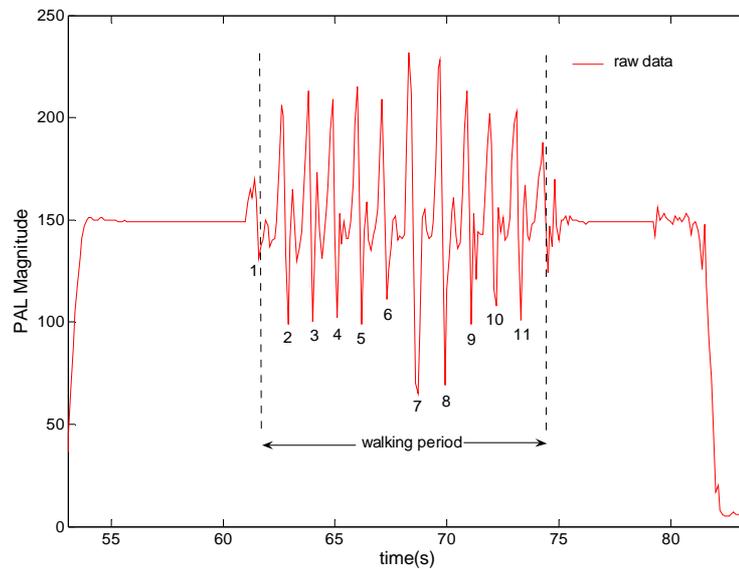


Figure 5.4: General aspects of classifying walking episode and stride counts from the raw acceleration signal with the number of strides counted by the activPAL algorithm.

Energy expenditure analysis

The activPAL post-processing software was capable of maintaining a running count of the number of strides the device wearer took, providing estimates of energy expenditure and producing cadence data associated with the stepping activities. Energy expenditure is often expressed as multiples of resting metabolic rate termed MET (metabolic equivalents), which is defined as ‘the ratio of the work metabolic rate to the resting metabolic rate’.

1 MET is the rate at which adult burns 1 kcal at rest. In general, sitting quietly and other sedentary activities have MET values close to 1 as these activities do not require any more kcal than one would burn at just resting. The default estimated energy expenditure in the activPAL software used 1.25 METs, 1.4 METs and 4 METs for sitting/lying, standing and stepping (at 120 steps per minute) respectively. These energy values could be changed manually in the activPAL professional software.

Minimum duration of events

The activPAL proprietary signal analysis algorithm included a minimum setting for the duration of sitting/lying and upright events, which was set at a default of 10 seconds. I.e. it was not possible to record a transition to a sitting/lying posture from an upright posture unless the posture lasted for in excess of 10s. If the sitting/lying period was less than 10s then the posture was recorded as continuous upright time and the person was characterized as being in continuous stepping if stepping occurred both before and after this short sedentary period (less than 10s).

The minimum sitting/lying and upright duration could be changed from 1 to 100 seconds in the activPAL professional software. The setting of this time would affect the interpretation of the data stream if short periods of activity were undertaken. 10 seconds was chosen as the default, but it is not clear why this setting is chosen as it would be ideal to be able to detect all instances of posture change no matter how rapid these were. Ideally it would be possible to detect changes in posture that lasted for only very short periods, e.g. less than a second.

The author assumes that this element of the proprietary algorithm was implemented based purely on the assumption that such short transitions would not occur in free-living activity. It might be anticipated that if this parameter was set to as low as 1 second that errors may arise in the signal analysis due to the use of smoothing of the signal to detect posture transitions. However, the value of 10s seems to be very high if all periods of posture change are to be characterized correctly. For this study the default value of 10s was used except specifically to examine the affect of this parameter on the results of the validation study where the value was varied between 1 and 10s.

5.2.3 *Subjects*

Prior to data collection for the validation study, ethical approval was granted through the NHS Lothian local research ethics committee (LREC3) and the University of Strathclyde Ethics Committee. Written consent was routinely obtained for all subjects who undergo gait analysis at the Anderson Gait Laboratory, and also covers the use of data for research purposes and for publication. A separate consent form was provided for the use of the activity monitor, activPAL, for each subject prior to their routine gait analysis session.

19 subjects in the age range of 5 to 17 years old (mean age of 11) with the condition of CP (Table 5.1), who attended for routine gait analysis at the Anderson Gait Laboratory, took part in this study. No attempt was made to identify subjects within particular pathological groups or with particular pathological patterns. The sample was taken by convenience from those attending for gait analysis. For subjects under the consent age of 16 years old, their parents/guardians were informed and consent obtained. If the subjects were over the age of 16 years old, but were unable to give informed consent they were excluded from the study.

Table 5.1: Information on CP subjects (M = Male, F = Female, AFO = Ankle Foot Orthosis)

Subject number	Age	Sex	Type of CP	Mobility aids currently used
1	5	M	Diplegic	Bilateral AFO
2	5	M	Diplegic	Left AFO
3	6	M	Right hemiplegic	Left AFO
4	6	F	Diplegic	K-walker
5	7	F	Diplegic	None
6	7	F	Left hemiplegic	Right AFO
7	8	M	Diplegic	Bilateral AFO
8	9	M	Right hemiplegic	Wheelchair
9	10	M	Spastic diplegic	Bilateral AFO
10	12	M	Spastic diplegic	None
11	13	F	Quadriplegia	Bilateral AFO, walking frame, wheelchair
12	13	F	Diplegic	Bilateral AFO
13	14	F	Spastic diplegic	Bilateral AFO, insoles, K-walker, wheelchair
14	14	M	Spastic quadriplegia	Bilateral AFO, K-walker, wheelchair
15	15	M	Spastic diplegic	None
16	15	M	Left hemiplegic	None
17	15	M	Diplegic	None
18	17	M	Mild diplegic	Insoles
19	17	M	Right hemiplegic	Left AFO

5.2.4 Evaluation study context

Details of the routine gait analysis are included here to establish the context in which the validation exercise was implemented. The gait analysis sessions involved sets of short

activity sequences with time spent in the different postures that could be used to validate the activPAL data analysis algorithm, which was of primary importance for the current thesis.

The procedures were completed concurrently with a routine gait analysis session, which consisted of observational and computerised gait analyses and physical examination performed by trained physiotherapists. The existing facilities at the Anderson Gait Laboratory included a three dimensional (3D) motion analysis system (VICON 460 datastation (Oxford Metrics Ltd, Oxford, UK)), 2 floor mounted force plates (AMTI BP400600 Force platform) and planar video. The motion analysis system comprised of 6 wall mounted cameras (VICON MCam2 cameras, 100Hz, 1.3 mega pixels, 12.5mm lens) which tracked and recorded the 3D coordinates of the retro-reflective markers placed on the lower limbs and pelvis of an individual to quantify walking ability. The markers used were 14mm in diameter, lightweight polystyrene spheres covered with highly retro-reflective tape and mounted on plastic bases. These were either directly stuck onto the skin with double sided tape, or were mounted on wands before being attached to the limbs to improve visibility and facilitate determination of the segment axes. Forces on the feet of the subject were recorded with the 2 floor mounted force plates (AMTI BP400600 Force platform, 1000lb capacity). The motion and the forces on the lower limb were recorded and by combining the motion and force plate data, quantification of the kinematic and kinetic information could be performed by using the Vicon Workstation, BodyBuilder and Polygon software packages (Oxford Metrics Ltd, Oxford, UK).

Observational gait analysis was carried out using a planar video for each person when they walked both the length and width of the laboratory for observing the coronal and sagittal views of gait patterns. Sometimes EMG data on muscle activities during gait were also collected by the Motion Lab Systems MA-100. Typically a written functional assessment questionnaire (Appendix I) was used to gain information on the subject's activity/ability outside of the gait laboratory environment; however no monitoring of activity levels outside of the gait laboratory was performed at the Anderson Gait Laboratory. The questionnaire used at the Anderson Gait Laboratory was the Gillette Functional Assessment Questionnaire (Novacheck et al 2000), which was a 10 level scale to evaluate walking ability with an additional assessment questionnaires on 22 higher level skills, such as stair climbing and navigating curbs.

For this study, an additional activity monitor, the activPAL was introduced during the routine gait analysis procedures. The validation of the accuracy of the activPAL analysis algorithms in the CP population was achieved by comparing the activPAL data with video recordings, which acted as the ‘gold standard’.

5.2.4.1 Routine Gait Analysis session at the Anderson Gait Laboratory

For a routine gait analysis session at the Anderson Gait Laboratory (Edinburgh), a patient was required to walk set distances during both the standard video and computerised gait analysis parts. The procedure for routine gait analysis was as follow:

1. Observational gait analysis (Figure 5.5a)
 - a. Orientation blocks were placed at both thighs and the trunk while subjects were either seated or standing.
 - b. Both patellae were marked using marker pencil when the patient was either seated or standing. Then both heels were marked when subjects were in the standing position.
 - c. Subjects walked the length of the gait laboratory at least 6 times (approximately 10m long) for anterior/ posterior observations.
 - d. Subjects walked the width of the laboratory at least 6 times (approximately 5m wide) for lateral observations.
 - e. Subjects were seated while orientation blocks were removed.
2. Computerised gait analysis
 - a. Retro-reflective markers were placed at anatomical landmarks (Figure 5.5b) while subjects were seated.
 - b. A static test was carried out when the subject was asked to stand quietly for a few seconds in the centre of the gait laboratory.
 - c. Subjects were asked to walk the length of the gait laboratory at least 6 times depending on the number of strides that made contact with the force plates.
 - d. After the standard motion analysis, all markers were removed.
3. Physical examination
 - a. Subjects were asked to lie on a plinth for testing of *muscle tone*, muscle strength and lower limb joints range of movements.

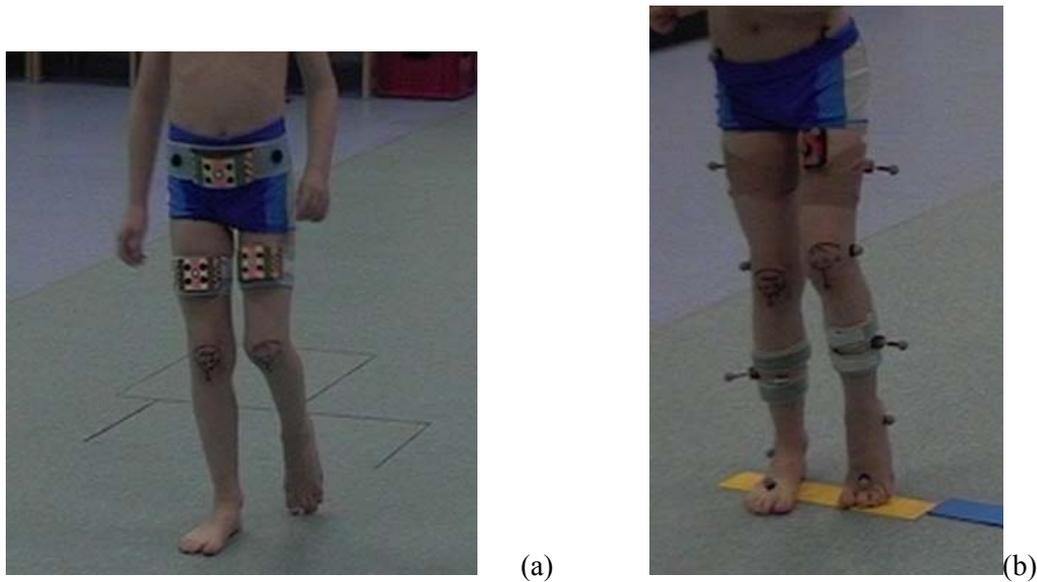


Figure 5.5: Orientation blocks position for observational analysis (a) and retroreflective marker placement for computerised gait analysis (b).

If the subject usually wears Ankle-foot orthoses (AFO), procedure 1 and 2 were repeated with the use of the AFO. Subjects were allowed to rest as required during the routine gait analysis session and resume when they were ready.

The following procedures were developed to allow the validation of the activity monitor on the activities a subject undertook as part of a routine gait analysis session. The subject did not perform any additional walking over and above that required during normal routine gait analysis. Each subject walked several hundreds steps with start and stop phases during a routine gait analysis session allowing for evaluation to take place. Also throughout the session, there were periods spent sitting/lying, standing and walking to enable the validation of the proprietary signal analysis algorithm's ability to accurately categorize the type of postures of the subject.

5.2.5 Protocol for activPAL use

The following default values were set in the PAL professional software to configure the activPAL before use:

Sampling frequency – 10Hz

Minimum upright and sitting/lying period – 10 seconds

Default estimated energy expenditure - 1.25 METs, 1.4 METs and 4 METs for sitting/lying, standing and stepping activity respectively.

At the beginning of each routine gait analysis session, the activPAL was switched on before attaching to the anterior mid thigh segment of each subject (Figure 5.5b), either on the leg with more pronounced gait abnormality or the right thigh if both limbs had similar mobility difficulties. The recommended PALstickies (PAL Technologies Ltd) were used to attach the activPAL to each subject. The PALstickies employed a patented dual layer hydrogel to provide optimum skin adhesion without the need to shave the skin surface. The direct attachment of the device onto skin as compared to clothing was aimed at reducing any error that might be associated with relative motion of clothing to underlying skin.

On the completion of the gait analysis session, the activPAL was removed from the subject, and the data were downloaded directly onto a laptop using the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd).

5.2.6 *Protocol for video recording*

A digital video camera (Model GR-DVX509SH, JVC, Japan) was used to provide a visual record of the subjects' posture, stride counts and rate of stepping during the routine gait analysis sessions. The camera was placed at one end of the laboratory. The zoom was set at the widest angle in order to ensure the subject was in view at all times. Recording started before any procedures took place. On the completion of each testing session the digital video recorder was turned off after the monitoring device was switched off. The video tapes were stored for later analysis.

5.2.7 *Protocol for synchronization of activPAL and video*

The video and the activPAL were not electronically linked therefore there was a requirement to develop a method to synchronise the two sets of data. The solution chosen was to set the digital video camera to record first, and then switch on the activPAL in front of the video camera so that the time at which the activPAL was switched on could be noted. It was not clear as to the exact instant of initiation of data recording on the activPAL. The flashing green light (5 flashes indicated data collection initiation) on the activPAL was used to set the time of activPAL data collection starting. The last flash was used to set the time

point at which data collection commenced. There remained an uncertainty in synchronisation due to video frame rate resolution and time at which the activPAL deemed to start recording.

5.2.8 *activPAL data output*

The proprietary algorithm used by the activPAL software categorized posture and counted strides (1 stride = 2 steps). Two files were generated automatically from the activPAL software when the recorded data were retrieved. One of the files was an activity profile with a break down of hourly events (time spent in sit/lie, stand and walk) and total hourly step counts. The second file was an activity summary profile with the accumulated time spent in each posture and step counts for the entire recording session. (See Appendix II for an example of the activity profile and activity summary profile generated from the activPAL software.)

For further information on the activity profile, an event file (.csv file) was retrieved for each recording using the activPAL software, which provided the initial time (sampling data point) at which a change of posture or a stride took place. The durations for each of these activities were also shown with corresponding activity code and an accumulated stride count. The activity code adopted in this file was 0 for sitting/lying, 1 for standing and 2 for stepping activities. From the .csv event file, the sampling data points were used to calculate the time at which a change of posture took place. The calculated times with the corresponding activity codes were then saved as a .txt file for later comparison purposes with the video data.

5.2.9 *Video classification protocol and data output*

5.2.9.1 *Video analysis 1*

The first video analysis was used to provide a classification of posture and stepping that best matched the observer's (author) understanding of physical activity state (sitting/lying, upright) and stepping. This did not take into account certain elements of the way in which the activPAL interpreted the data stream to classify physical activity.

From the continuous video recording, the time for each change in posture was noted with the associated activity code (sit/lie as 3, stand as 4 and walk as 5) and the information was

saved as a .txt file for use to compare with the .txt file created from the activPAL data. The total number of strides that each subject took during the gait analysis session was also counted.

In order to reduce error and misclassification for the analysis of the video data it was necessary to provide a definition of physical activity state and what constituted a stride. The following definitions were used in video analysis 1:

1. Subjects were classified as sitting only when it appeared that the gluteus muscle region was in contact with the intended seat. When the gluteus muscle region lost contact with the seat, posture was classified as upright, either standing or walking depending on whether a stride was taken.
2. The time at which a change of activity occurred was noted to the nearest twentieth of a second, which was determined as the start point of the transition in posture.
3. Two methods were used for the classification of a stride:
 - a. All counts – This method counted a stride when the foot (ipsilateral to actiPAL attachment) struck the ground after having been lifted from it in the upright posture. This count included small side steps and turning steps.
 - b. Forward counts – A stride was only counted when a forward progression had been produced as a result of the foot (ipsilateral to activPAL attachment) striking the ground after having been lifted from it.

5.2.9.2 Video analysis 2

It was recognised that the activPAL data analysis algorithms contained mechanisms to minimise misinterpretation of data that might affect classification of the data. Video analysis 2 was implemented to provide a set of posture and stepping classifications that might match the characterization as provided by the activPAL.

The activPAL did not register stand times which were less than 6 seconds between walking periods. Although the minimum sitting and upright period could be altered, the minimum duration for standing events could not be changed in the proprietary algorithm. These intervals of standing between walking episodes were classified as continuous stepping activities in the activPAL output. Consequently, for the validation of the activPAL algorithm to categorize activities, an extension of video analysis 1 was carried out to match

the activPAL categorization criteria. The stand times that were less than 6 seconds between walking periods were re-classified as continuous stepping activities.

5.2.10 Comparison of activPAL and video analysis outputs

The video data was manually coded and entered into a spreadsheet with the initial time for each change in posture and its associated activity code. This information was saved as a .txt file for comparison with the activPAL data using a Matlab program.

5.2.10.1 Posture categorisation comparison

A software program was written using Matlab (student version 7.1, the MathWorks Inc) to automatically compare the activPAL and video data (See Appendix III for the Matlab code). The Matlab program imported the .txt files for the video and activPAL data. Continuous time lines for both data sets with corresponding activity codes were created based on the .txt files. The total times spent in each posture were found for both data sets and the percentage sensitivity and discrepancy for each subject's activity profile were calculated using equation 5.2 and 5.3 respectively.

$$sensitivity(\%) = \frac{time_{PAL}}{time_{video}} \times 100 \quad \text{[Equation 5.2]}$$

$$discrepancy(\%) = \left(\frac{abs(time_{PAL} - time_{video})}{time_{video}} \right) \times 100 \quad \text{[Equation 5.3]}$$

In equation 5.2 and 5.3, $time_{PAL}$ and $time_{video}$ are the duration of each posture registered by the activPAL and video recordings respectively.

The calculated percentage sensitivities showed whether the activPAL over- or under-estimated time spent in each posture and the calculated percentage discrepancies showed the accuracy of the activPAL to categorize posture, which would be easier to compare between subjects. This evaluation of the activPAL output is based on the assumption that the video data presents a 'gold standard' for the characterization of physical activity data.

The percentage sensitivities and discrepancies were first found between activPAL and video data (using both video analysis 1 and video analysis 2) for time spent in walking, standing and sitting/lying events. Additional analysis was carried out to compare the activPAL and video data (analysis 2) for upright (walking and standing) and non-upright (sitting/lying) activities. It was thought that younger subjects/ children would have more frequent short bouts of activities compared to adults, therefore it would be important to determine whether shorter minimum sitting/lying and upright times were required to analyse young subjects' free-living behaviours. The activPAL software had a default setting of 10 seconds for minimum sitting/lying and upright periods for posture categorization. For further analysis, the percentage sensitivities and discrepancies were calculated for each subject with a range of minimum setting for sitting and upright periods (1-10 seconds) in the activPAL software, and compared to video data (video analysis 2).

5.2.10.2 Stride count comparison

The 'all counts' and 'forward counts' found from the video recordings for each subject were compared with the activPAL total stride counts from the event summary files, and percentage sensitivity and discrepancy were calculated using equations 5.2 and 5.3, with the number of stride counts replacing time in both equations.

5.3 Results

The general gait pattern of each subject was observed within the video data and brief description can be found in Appendix IV with information on the leg to which the activPAL was attached during the validation study. In this section, first the posture classification results are presented followed by the stride count results. Also results from variation in the minimum times of sitting/lying and upright duration are included.

5.3.1 *Posture categorization comparison*

5.3.1.1 ActivPAL analysis compared with video analysis 1

For posture categorization comparison between the activPAL algorithm and the video data (video analysis 1), the percentage sensitivities and discrepancies for each subject are presented in Table 5.2.

Table 5.2: ActivPAL analysis and video analysis 1 - Percentage sensitivities and discrepancies for posture categorization time for each subject

subject number	sensitivity (%)			discrepancy (%)		
	walk	stand	sit	walk	stand	sit
1	110.70	96.74	98.97	10.70	3.26	1.03
2	150.95	81.78	98.63	50.95	18.22	1.37
3	158.11	80.93	99.56	58.11	19.07	0.44
4	128.34	90.85	98.45	28.34	9.15	1.55
5	103.52	97.81	100.41	3.52	2.19	0.41
6	105.55	100.37	97.38	5.55	0.37	2.62
7	112.92	94.41	97.40	12.92	5.59	2.60
8	106.61	120.76	87.62	6.61	20.76	12.38
9	98.41	101.01	98.02	1.59	1.01	1.98
10	142.09	89.99	89.21	42.09	10.01	10.79
11	101.46	104.35	98.88	1.46	4.35	1.12
12	97.77	102.14	98.82	2.23	2.14	1.18
13	101.53	295.20	77.82	1.53	195.20	22.18
14	132.75	94.77	98.00	32.75	5.23	2.00
15	95.25	101.94	94.73	4.75	1.94	5.27
16	115.83	96.32	96.28	15.83	3.68	3.72
17	82.55	107.86	95.29	17.45	7.86	4.71
18	110.22	96.48	96.68	10.22	3.52	3.32
19	116.90	92.76	97.53	16.90	7.24	2.47
average	114.29	107.71	95.77	17.03	16.88	4.27

Table 5.2 shows activPAL data compared to video analysis 1, the activPAL generally over-estimated the walking periods and under-estimated time spent in sedentary events. The percentage sensitivities for walking were over 100% for all subjects, except subject 9, 12, 15 and 17, while the percentage sensitivities for sitting/lying were less than 100% for all subjects except subject 5. The average percentage discrepancies for walking and standing were 17.03% and 16.88% respectively, which indicated differences between the video and the activPAL data for these events. On the other hand, an average discrepancy of 4.27% was found for the sitting/lying periods. Although this was a lower percentage discrepancy compared to the walking and standing events, subject 8, 10 and 13 showed percentage discrepancies over 10% for the sitting periods (Table 5.2). The calculated percentage sensitivity (295.2%) and discrepancy (195.2%) for standing posture

categorization of subject 13 were very high in comparison to other subjects' results. This indicated a high level of misclassification occurred for subject 13 between standing and sitting states.

5.3.1.2 ActivPAL analysis compared with video analysis 2

Table 5.3 shows the total time spent in each activity state measured by the activPAL and video recording for each subject, after setting extra criteria for analysing the video data by classifying stand times that were less than 6 seconds between walking activities as continuous stepping activities (video analysis 2). Table 5.4 details the percentage sensitivities and discrepancies for posture classification of each subject.

Table 5.3: Total time spent in each activity state measured by the activPAL and video analysis 2 for each subject.

subject	walk duration (sec)		stand duration (sec)		sit duration (sec)		upright duration (sec)	
	video	PAL	video	PAL	video	PAL	video	PAL
1	575.8	618.7	1868.7	1824.4	1829.4	1810.6	2444.5	2443.1
2	442.1	582.5	1019.6	881.1	1466.6	1446.5	1461.7	1463.6
3	643.5	892.7	1636.9	1389.6	2245.7	2235.9	2280.4	2282.3
4	314.2	372.3	847.6	792.5	1013.4	997.7	1161.8	1164.8
5	324.0	317.9	503.4	509.2	1196.1	1201.0	827.4	827.1
6	335.2	329.2	791.7	816.6	1289.7	1257.9	1126.9	1145.8
7	1028.4	1033.3	1411.8	1443.2	1292.3	1258.7	2440.2	2476.5
8	397.9	401.7	398.3	507.2	952.2	834.3	796.2	908.9
9	286.2	266.3	919.4	944.7	1019.1	998.9	1205.6	1211.0
10	503.3	515.8	808.2	807.1	694.5	619.5	1311.5	1322.9
11	604.5	603.1	361.6	388.2	2341.8	2315.5	966.1	991.3
12	486.9	451.9	1174.5	1225.5	1980.1	1956.8	1661.4	1677.4
13	585.4	590.4	387.6	1156.0	3501.9	2725.1	973.0	1746.4
14	393.5	506.7	933.0	895.9	4083.7	4001.9	1326.5	1402.6
15	148.2	138.3	414.9	426.1	104.4	98.1	563.1	564.4
16	429.9	450.8	1053.1	1054.5	803.4	773.5	1483.0	1505.3
17	339.5	273.0	927.1	1009.8	515.4	491.1	1266.6	1282.8
18	698.3	712.1	1113.4	1126.1	940.6	909.4	1811.7	1838.2
19	967.2	1045.8	1648.7	1601.2	1978.2	1929.4	2615.9	2647.0
average	500.2	531.7	958.9	989.4	1539.4	1466.4	1459.1	1521.1

Table 5.4: ActivPAL analysis and video analysis 2 - Percentage sensitivities and discrepancies for posture categorization of each subject, with stand times that were less than 6 seconds between stepping periods classified as continuous walking activities in the video data.

subject number	sensitivity (%)			discrepancy (%)		
	walk	stand	sit	walk	stand	sit
1	107.45	97.63	98.97	7.45	2.37	1.03
2	131.76	86.42	98.63	31.76	13.58	1.37
3	138.73	84.89	99.56	38.73	15.11	0.44
4	116.56	94.08	98.45	16.56	5.92	1.55
5	98.12	101.15	100.41	1.88	1.15	0.41
6	98.21	103.43	97.38	1.79	3.43	2.62
7	100.48	102.22	97.40	0.48	2.22	2.60
8	100.96	127.34	87.62	0.96	27.34	12.38
9	93.05	102.75	98.02	6.95	2.75	1.98
10	102.48	99.86	89.20	2.48	0.14	10.80
11	99.77	107.36	98.88	0.23	7.36	1.12
12	92.81	104.34	98.82	7.19	4.34	1.18
13	100.85	298.25	77.82	0.85	198.25	22.18
14	128.77	96.02	98.00	28.77	3.98	2.00
15	93.32	102.70	94.73	6.68	2.70	5.27
16	104.86	100.13	96.28	4.86	0.13	3.72
17	80.41	108.92	95.29	19.59	8.92	4.71
18	101.98	101.14	96.68	1.98	1.14	3.32
19	108.13	97.12	97.53	8.13	2.88	2.47
average	105.19	111.36	95.77	9.86	15.98	4.27

By performing video analysis 2 for the video recordings, the average percentage discrepancies for walking and standing periods were reduced from 17.03% and 16.88% (video analysis 1) to 11.14% and 16.70% (analysis 2) respectively. From Table 5.4, it can be seen that for subject 13, the percentage discrepancy for standing and sitting/lying posture was 212.36% and 23.96% respectively, which indicated a high level of misclassification for this subject that affected the average discrepancy greatly, and therefore should be investigated separately. When subject 13 was removed from the calculation, the average percentage sensitivity and discrepancy for standing was reduced to 101.20% and 5.66% respectively. The average percentage discrepancy for sitting/lying was reduced to 3.60%. The large change in average percentage sensitivity and discrepancy were due to the

large amount of misclassification between sitting/lying and standing postures for subject 13 using the general activPAL algorithm for activity categorization.

Upright and non-upright events

Upright (stand and walk periods) and non-upright (sit and lie events) times recorded from the video and activPAL data were compared to determine the accuracy of the activPAL algorithm (default setting for minimum sitting/lying and upright period – 10 seconds) to categorize upright events without the needs to distinguish between standing and walking activities. The percentage sensitivities and discrepancies for upright and non-upright events for each subject are presented in Table 5.5.

Table 5.5: Percentage sensitivity and discrepancy for upright and non-upright postures of each subject using the default minimum sitting and upright setting (10 sec) for activPAL analysis

subject number	sensitivity (%)		discrepancy (%)	
	upright	non-upright	upright	non-upright
1	99.93	98.97	0.07	1.03
2	100.02	98.63	0.02	1.37
3	100.03	99.56	0.03	0.44
4	100.21	98.45	0.21	1.55
5	99.93	100.41	0.07	0.41
6	101.80	97.38	1.80	2.62
7	101.34	97.40	1.34	2.60
8	114.07	87.62	14.07	12.38
9	100.42	98.02	0.42	1.98
10	100.80	89.21	0.80	10.79
11	102.58	98.88	2.58	1.12
12	100.93	98.82	0.93	1.18
13	179.47	77.82	79.47	22.18
14	105.70	98.00	5.70	2.00
15	100.21	94.73	0.21	5.27
16	101.44	96.28	1.44	3.72
17	101.26	95.29	1.26	4.71
18	101.37	96.68	1.37	3.32
19	101.00	97.53	1.00	2.47
average	105.92	95.77	5.94	4.27

Although the average percentage discrepancies for upright and non-upright activities were low, 6.70% and 4.59% respectively, results showed that sometimes misclassifications of posture took place. For most subjects, the percentage discrepancies for upright events were less than 5% (Table 5.5), with the exceptions of subject 8, 13 and 14. For the non-upright classifications, the percentage discrepancies for subject 8, 10, 13 and 15 were higher than 5%. From table 5.5, only results for subject 13 had percentage discrepancies over 20% for both upright and non-upright events when compared to video data. These high percentages indicated misclassification occurred and would affect the overall average calculated percentage sensitivity and discrepancy. When subject 13 was removed from the calculations, the average percentage discrepancies for upright and non-upright events were reduced to 2.30% and 3.51% respectively.

Effect of variation in minimum sitting/lying and upright times

The standard setting for the minimum sitting/lying and upright times of 10s was systematically varied to assess its effect on the activPAL results generated in comparison with video analysis 2 output.

Although video analysis 2 was chosen, it would be the same results as video analysis 1 as the change in setting was used for distinguishing upright and non-upright periods and the extra criteria for video analysis 2 was performed for upright periods to categorize standing activities less than 6 seconds between walking episodes as continuous stepping, therefore this would not affect the overall upright times.

The effect of changing the minimum setting for upright and sitting/lying periods is investigated in this study.

The calculated percentage sensitivities and discrepancies for upright events are shown in Table 5.6 and 5.7 respectively. A graphical representation of the percentage discrepancy for each subject with 1-10 seconds setting for minimum upright periods is shown in Figure 5.6 (except subject 8 and 13 as the percentage discrepancies were much higher (over 10%) than the other subjects).

Table 5.6: Percentage sensitivities for upright classification of each subject for different minimum setting for upright periods in the activPAL analysis compared with video analysis 2

subject	upright % sensitivity									
	1 sec	2 sec	3 sec	4 sec	5 sec	6 sec	7 sec	8 sec	9 sec	10 sec
1	100.16	100.16	100.16	100.16	100.16	99.94	99.94	99.94	99.94	99.94
2	102.21	102.07	102.07	102.07	102.07	101.70	101.70	101.70	101.70	101.05
3	101.38	101.38	101.48	101.48	101.48	101.48	101.48	101.82	101.43	101.43
4	99.77	99.86	100.26	100.26	100.26	100.26	100.26	100.26	100.26	100.26
5	100.41	99.86	99.93	99.93	99.26	99.96	99.96	99.96	99.96	99.96
6	103.35	103.22	102.99	102.68	102.30	102.30	101.68	101.68	101.68	101.68
7	101.50	101.38	101.38	101.38	101.49	101.49	101.49	101.49	101.49	101.49
8	115.47	115.27	115.27	114.86	114.86	114.86	114.04	113.07	114.15	114.15
9	100.59	100.45	100.45	100.45	100.45	100.45	100.45	100.45	100.45	100.45
10	105.12	105.12	105.12	105.12	105.12	105.12	105.12	105.12	105.12	105.12
11	101.68	101.45	101.54	101.15	101.15	101.95	101.95	101.95	102.78	102.78
12	102.22	102.55	102.55	101.75	101.73	101.35	101.35	100.49	100.96	100.96
13	183.99	183.63	183.62	183.62	183.62	183.62	185.51	184.74	184.74	185.89
14	107.86	107.92	107.92	107.08	107.08	107.08	107.08	107.06	107.06	105.74
15	100.23	100.23	100.23	100.23	100.23	100.23	100.23	100.23	100.23	100.23
16	101.13	101.13	100.94	100.94	100.94	100.94	100.94	100.94	101.50	101.50
17	101.13	101.13	101.34	100.87	101.25	101.25	101.25	101.88	101.88	101.88
18	101.35	101.46	101.32	101.13	101.13	101.13	101.13	100.58	101.47	101.47
19	101.36	101.36	101.36	101.36	101.19	101.19	101.19	101.19	101.19	101.19
average	106.89	106.82	106.84	106.66	106.62	106.65	106.67	106.56	106.74	106.69

Table 5.7: Percentage discrepancies for upright classification of each subject for different minimum setting for upright periods in the activPAL analysis compared with video analysis 2

subject	upright % discrepancy										max deviation
	1 sec	2 sec	3 sec	4 sec	5 sec	6 sec	7 sec	8 sec	9 sec	10 sec	
1	0.16	0.16	0.16	0.16	0.16	0.06	0.06	0.06	0.06	0.06	0.10
2	2.21	2.07	2.07	2.07	2.07	1.7	1.7	1.7	1.7	1.05	1.16
3	1.38	1.38	1.48	1.48	1.48	1.48	1.48	1.82	1.43	1.43	0.10
4	0.23	0.14	0.26	0.26	0.26	0.26	0.26	0.26	0.26	0.26	0.12
5	0.41	0.14	0.07	0.07	0.74	0.04	0.04	0.04	0.04	0.04	0.70
6	3.35	3.22	2.99	2.68	2.3	2.3	1.68	1.68	1.68	1.68	1.67
7	1.5	1.38	1.38	1.38	1.49	1.49	1.49	1.49	1.49	1.49	0.12
8	15.47	15.27	15.27	14.86	14.86	14.86	14.04	13.07	14.15	14.15	2.40
9	0.59	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.14
10	5.12	5.12	5.12	5.12	5.12	5.12	5.12	5.12	5.12	5.12	0.00
11	1.68	1.45	1.54	1.15	1.15	1.95	1.95	1.95	2.78	2.78	1.63
12	2.22	2.55	2.55	1.75	1.73	1.35	1.35	0.49	0.96	0.96	1.59
13	83.99	83.63	83.62	83.62	83.62	83.62	85.51	84.74	84.74	85.89	2.27
14	7.86	7.92	7.92	7.08	7.08	7.08	7.08	7.06	7.06	5.74	2.18
15	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.00
16	1.13	1.13	0.94	0.94	0.94	0.94	0.94	0.94	1.5	1.5	0.56
17	1.13	1.13	1.34	0.87	1.25	1.25	1.25	1.88	1.88	1.88	1.01
18	1.35	1.46	1.32	1.13	1.13	1.13	1.13	0.58	1.47	1.47	0.34
19	1.36	1.36	1.36	1.36	1.19	1.19	1.19	1.19	1.19	1.19	0.17
average	6.91	6.85	6.85	6.67	6.7	6.66	6.68	6.57	6.75	6.7	0.86

From Tables 5.6 and 5.7 and Figure 5.6, it could be seen that there were no general trends for all subjects when the minimum upright setting was changed from 1 to 10 seconds. The percentage discrepancies for each setting were constant for subject 10 and 15. For subject 1, 2, 5, 6, 8, 9, 12, 14 and 19 the percentage discrepancies increased when the minimum setting was changed from 10 to 1 second. On the other hand, the percentage discrepancies decreased when the minimum setting was changed from 10 to 1 second for subject 4, 7, 11, 13, 16, 17 and 18.

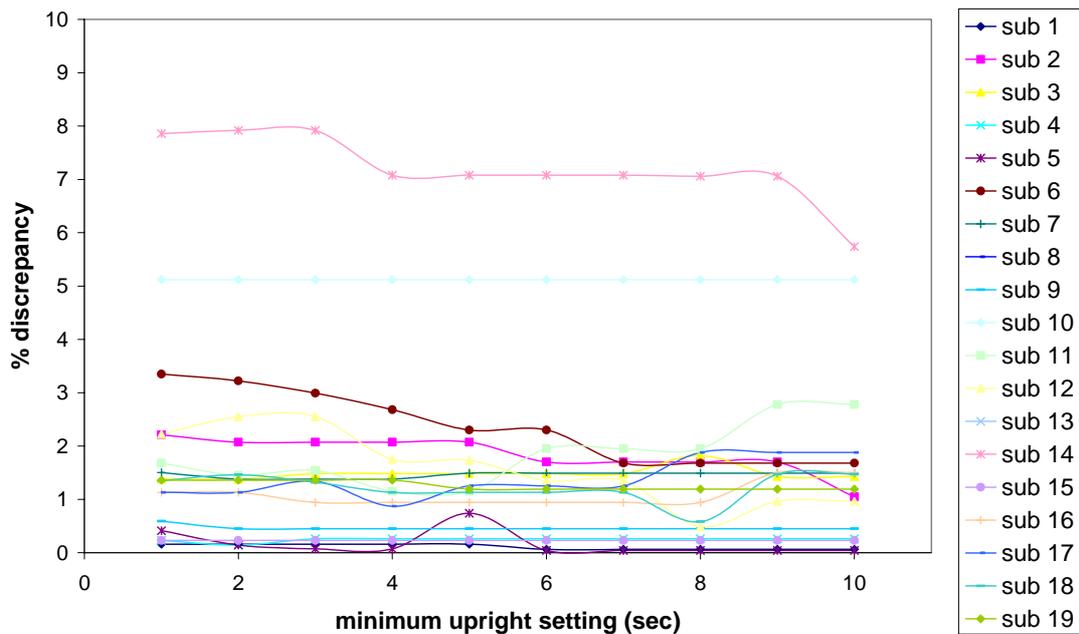


Figure 5.6: Calculated percentage discrepancy for each subject (except sub 8 and 13 as the % discrepancies were over 10%) analysed by different minimum setting for upright periods in the activPAL software.

The overall outputs for most of the other subjects did not appear to change more than a small amount (average 0.86%) when the minimum threshold was changed, the differences between the maximum and minimum percentage discrepancies for subjects 1, 3, 4, 5, 7, 9, 16, 18 and 19 were within 1%, whereas the differences between maximum and minimum percentage discrepancies for subjects 2, 6, 8, 11, 12, 13, 14 and 17 were between 1 and 3%.

For sitting/lying events comparison, the calculated percentage sensitivities and discrepancies for sitting events are shown in Table 5.8 and 5.9 respectively. A graphical representation of the percentage discrepancy for each subject (except subject 13 with percentages discrepancy over 15%) with 1-10 seconds setting for minimum sitting periods is shown in Figure 5.7.

Table 5.8: Percentage sensitivities for non-upright classification of each subject for different minimum setting for sitting periods in the activPAL analysis compared with video analysis 2

subject	sitting % sensitivity									
	1 sec	2 sec	3 sec	4 sec	5 sec	6 sec	7 sec	8 sec	9 sec	10 sec
1	98.68	98.68	98.68	98.68	98.68	98.68	98.97	98.97	98.97	98.97
2	96.56	96.70	96.70	96.70	96.70	96.70	97.07	97.07	97.07	97.71
3	98.25	98.25	98.14	98.14	98.14	98.14	98.14	97.80	98.19	98.19
4	99.01	98.90	98.45	98.45	98.45	98.45	98.45	98.45	98.45	98.45
5	100.10	100.48	100.29	100.29	100.89	100.29	100.41	100.41	100.41	100.41
6	96.07	96.19	96.39	96.66	96.99	96.66	97.53	97.53	97.53	97.53
7	97.51	97.74	97.74	97.74	97.40	97.74	97.40	97.40	97.40	97.40
8	86.52	86.68	86.68	87.03	87.03	87.03	87.71	88.52	87.62	87.62
9	97.85	98.02	98.02	98.02	98.02	98.02	98.02	98.02	98.02	98.02
10	89.21	89.21	89.21	89.21	89.21	89.21	89.21	89.21	89.21	89.21
11	105.50	105.60	105.56	99.48	99.48	99.48	99.15	99.15	98.80	98.80
12	97.77	97.40	97.40	98.08	98.09	98.08	98.50	98.38	98.82	98.82
13	76.74	76.84	76.84	76.84	76.84	76.84	76.14	76.36	76.36	76.04
14	97.31	97.29	97.29	97.56	97.56	97.56	97.56	97.57	97.57	98.00
15	94.73	94.73	94.73	94.73	94.73	94.73	94.73	94.73	94.73	94.73
16	96.98	96.98	97.31	97.31	97.31	97.31	97.31	97.31	96.28	96.28
17	95.65	95.65	95.13	96.29	95.36	96.29	95.36	93.81	93.81	93.81
18	96.36	96.15	96.42	96.80	96.80	96.80	96.80	97.85	96.14	96.14
19	97.31	97.31	97.31	97.31	97.53	97.31	97.53	97.53	97.53	97.53
average	95.69	95.73	95.70	95.54	95.54	95.54	95.58	95.58	95.42	95.46

Table 5.9: Percentage discrepancies for non-upright classification of each subject for different minimum setting for sitting periods in the activPAL analysis compared with video analysis 2

subject	% discrepancy sitting										max deviation
	1 sec	2 sec	3 sec	4 sec	5 sec	6 sec	7 sec	8 sec	9 sec	10 sec	
1	1.32	1.32	1.32	1.32	1.32	1.32	1.03	1.03	1.03	1.03	0.29
2	3.44	3.3	3.3	3.3	3.3	3.3	2.93	2.93	2.93	2.29	1.15
3	1.75	1.75	1.86	1.86	1.86	1.86	1.86	2.2	1.81	1.81	0.45
4	0.99	1.1	1.55	1.55	1.55	1.55	1.55	1.55	1.55	1.55	0.56
5	0.1	0.48	0.29	0.29	0.89	0.29	0.41	0.41	0.41	0.41	0.79
6	3.93	3.81	3.61	3.34	3.01	3.34	2.47	2.47	2.47	2.47	1.46
7	2.49	2.26	2.26	2.26	2.6	2.26	2.6	2.6	2.6	2.6	0.34
8	13.48	13.32	13.32	12.97	12.97	12.97	12.29	11.48	12.38	12.38	2.00
9	2.15	1.98	1.98	1.98	1.98	1.98	1.98	1.98	1.98	1.98	0.17
10	10.79	10.79	10.79	10.79	10.79	10.79	10.79	10.79	10.79	10.79	0.00
11	5.5	5.6	5.56	0.52	0.52	0.52	0.85	0.85	1.2	1.2	5.08
12	2.23	2.6	2.6	1.92	1.91	1.92	1.5	1.62	1.18	1.18	1.42
13	23.26	23.16	23.16	23.16	23.16	23.16	23.86	23.64	23.64	23.96	0.80
14	2.69	2.71	2.71	2.44	2.44	2.44	2.44	2.43	2.43	2	0.71
15	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	0.00
16	3.02	3.02	2.69	2.69	2.69	2.69	2.69	2.69	3.72	3.72	1.03
17	4.35	4.35	4.87	3.71	4.64	3.71	4.64	6.19	6.19	6.19	2.48
18	3.64	3.85	3.58	3.2	3.2	3.2	3.2	2.15	3.86	3.86	1.71
19	2.69	2.69	2.69	2.69	2.47	2.69	2.47	2.47	2.47	2.47	0.22
average	4.9	4.91	4.92	4.49	4.56	4.49	4.46	4.46	4.63	4.59	1.09

From Table 5.9 and Figure 5.7, it could be seen that there were no general trends for all subjects when the minimum sitting period setting was changed from 1 to 10 seconds. The percentage discrepancies for each setting were constant for subjects 10 and 15. For subject 1, 2, 6, 8, 9, 11, 12, 14 and 19 the percentage discrepancies increased when the minimum setting was changed from 10 to 1 second. However, the percentage discrepancies decreased for subject 4, 7, 13, 16, 17 and 18.

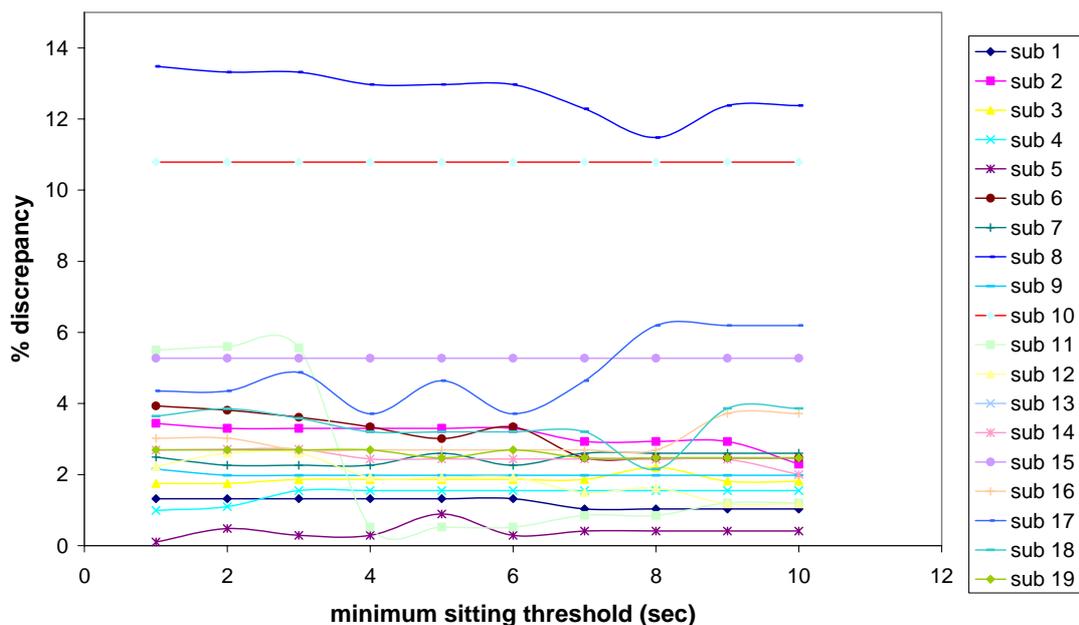


Figure 5.7: Calculated percentage discrepancy for each subject (except subject 13 as % discrepancies were over 15%) analysed by different minimum setting for sitting periods in the activPAL software.

The overall outputs for most of the other subjects did not appear to change more than a small amount (average 1.09%) when the threshold was changed, the differences between the maximum and minimum percentage discrepancies for subjects 1, 3, 4, 5, 7, 9, 13, 14 and 19 were within 1%. Whereas the differences between maximum and minimum percentage discrepancies for subjects 2, 6, 8, 11, 12, 16, 17 and 18 were between 1% and 5.5%.

5.3.2 Stride counts comparison

Within the walking periods, the total strides made by each subject during their routine gait analysis sessions were counted from the video recordings using two methods, ‘all counts’ and ‘forward counts’. ‘All counts’ included all movements of the leg with the activPAL attached and ‘forward counts’ only included forward progression movement of the leg with the activPAL attached. These stride counts from the video data were compared to the output from the event summary profiles obtained from the activPAL software. The number of strides from the activPAL software, video ‘all counts’ and video ‘forward counts’ with associated percentage sensitivities and discrepancies are presented in Table 5.10.

Table 5.10: Stride counts comparison between video and activPAL data with calculated percentage sensitivities and discrepancies for each subject.

subject number	activPAL stride counts	video all counts	video forward counts	sensitivity (%)		discrepancy (%)	
				all counts	forward counts	all counts	forward counts
1	557	661	605	84.27	92.07	15.73	7.93
2	409	497	409	82.29	100.00	17.71	0.00
3	710	722	642	98.34	110.59	1.66	10.59
4	243	286	267	84.97	91.01	15.03	8.99
5	218	281	249	77.58	87.55	22.42	12.45
6	301	321	284	93.77	105.99	6.23	5.99
7	739	828	782	89.25	94.50	10.75	5.50
8	289	307	248	94.14	116.53	5.86	16.53
9	163	224	196	72.77	83.16	27.23	16.84
10	358	366	310	97.81	115.48	2.19	15.48
11	373	394	355	94.67	105.07	5.33	5.07
12	363	422	365	86.02	99.45	13.98	0.55
13	324	345	303	93.91	106.93	6.09	6.93
14	298	312	278	95.51	107.19	4.49	7.19
15	104	135	103	77.04	100.97	22.96	0.97
16	347	412	358	84.22	96.93	15.78	3.07
17	234	307	263	76.22	88.97	23.78	11.03
18	473	491	418	96.33	113.16	3.67	13.16
19	756	807	635	93.68	119.06	6.32	19.06
average	382	427	372	88.04	101.82	11.96	8.81

For all subjects, the percentage sensitivities for ‘all counts’ were below 100%, indicating the activPAL under estimated the stride counts for all the subjects when compared to strides counted from the video recordings, which included side steps and small steps for turning. This shows the activPAL might not include all the small side steps and turning steps that an individual took. For the ‘forward counts’ comparison, the activPAL sometimes under estimated stride counts and occasionally over estimated the stride counts, which led to average percentage sensitivity of 101.82% that indicates high average sensitivity.

The average percentage discrepancy for ‘forward counts’ was lower than ‘all counts’ (8.81% and 11.96% respectively), however it appeared that the activPAL included the small side and turning steps for 7 subjects (subjects 3, 8, 10, 13, 14, 18 and 19), with the percentage discrepancies for ‘forward counts’ higher than the ‘video all counts’. The percentage sensitivities for these subjects were closer to 100% when the ‘video all counts’ were used for comparison.

5.3.3 *Statistical analysis*

For the following statistical tests only results from the activPAL analysis using the default setting of 10 seconds for minimum upright and sitting/lying periods were used and compared to video analysis 2 data as the default setting would normally be used for free-living monitoring. For every subject, the total time spent in each posture during the gait analysis session was found for both the video (video analysis 2) and activPAL data using the Matlab program (Appendix III). These computed times were used for statistical testing. For stride count analysis, both ‘all counts’ and ‘forward counts’ from the video analysis were compared to the activPAL output.

5.3.3.1 **Correlations between activPAL and video data**

For each subject, the total durations from the video and activPAL data for each posture were found and graphs were plotted to find the correlations between the two data sets (Figure 5.8-5.11 for walking, standing, sitting/lying, and upright durations respectively). Correlation coefficients were calculated using equation 5.4, where x and y were video and activPAL times for each posture respectively, n was the number of subjects and SD represents standard deviation. A significance test was performed using equation 5.5 to evaluate whether the association between the two sets of data was apparent.

$$r = \frac{\sum xy - n\bar{x}\bar{y}}{(n-1)SD(x)SD(y)} \quad \text{[Equation 5.4]}$$

$$t = r\sqrt{\frac{n-2}{1-r^2}} \quad \text{[Equation 5.5]}$$

The correlation coefficients r were calculated as 0.9599, 0.9004, 0.9867 and 0.9576, $t = 13.42, 8.53, 25.03$ and 13.70 ($p < 0.001$) for walking, standing, sitting/lying and upright posture respectively, indicating highly significant positive correlations between the video and activPAL outputs.

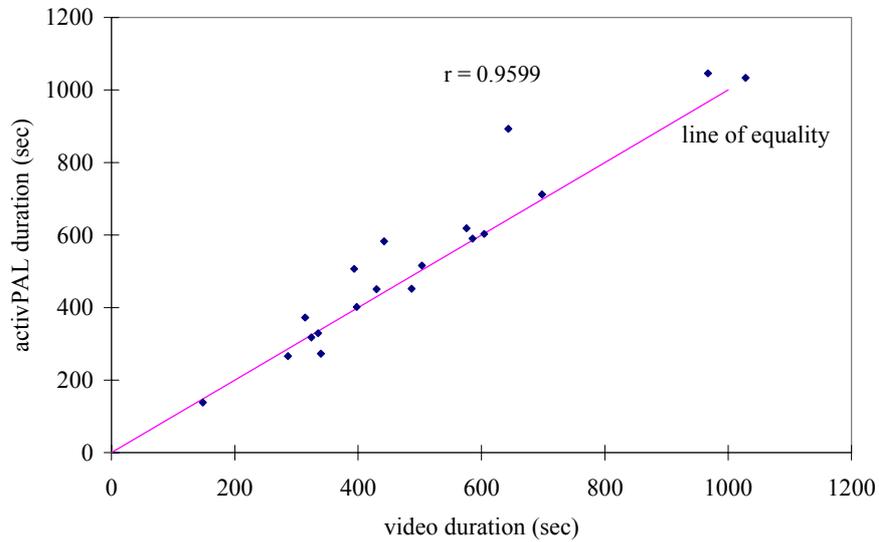


Figure 5.8: The total durations recorded from the video (video analysis 2) for walking periods plotted against total duration from the activPAL output

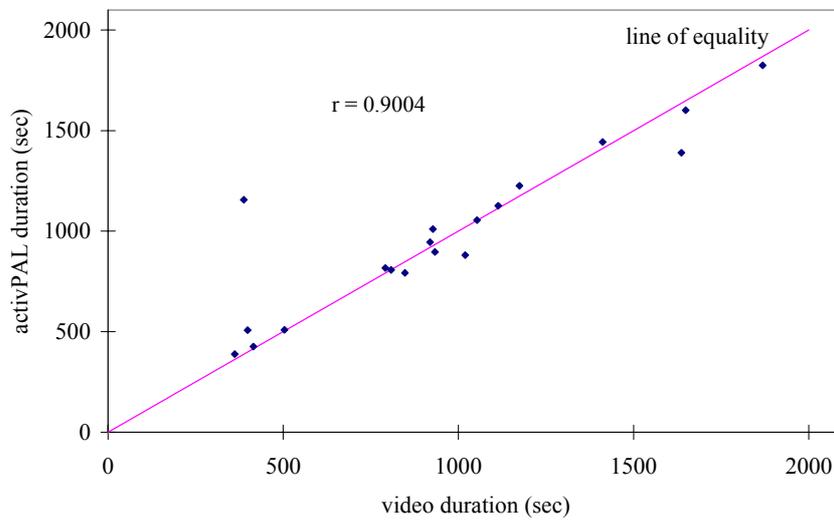


Figure 5.9: The total durations recorded from the video (video analysis 2) for standing periods plotted against total duration from the activPAL output.

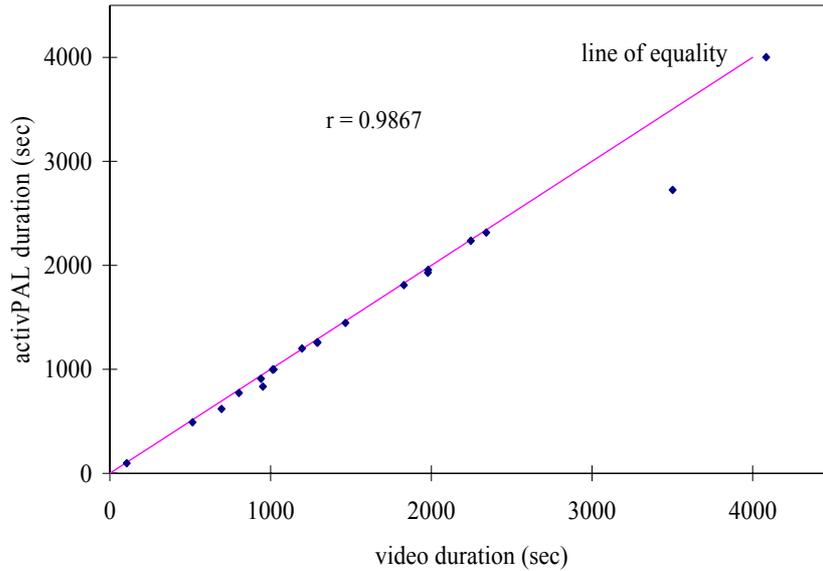


Figure 5.10: The total durations recorded from the video (video analysis 2) for sitting/lying periods plotted against total duration from the activPAL output

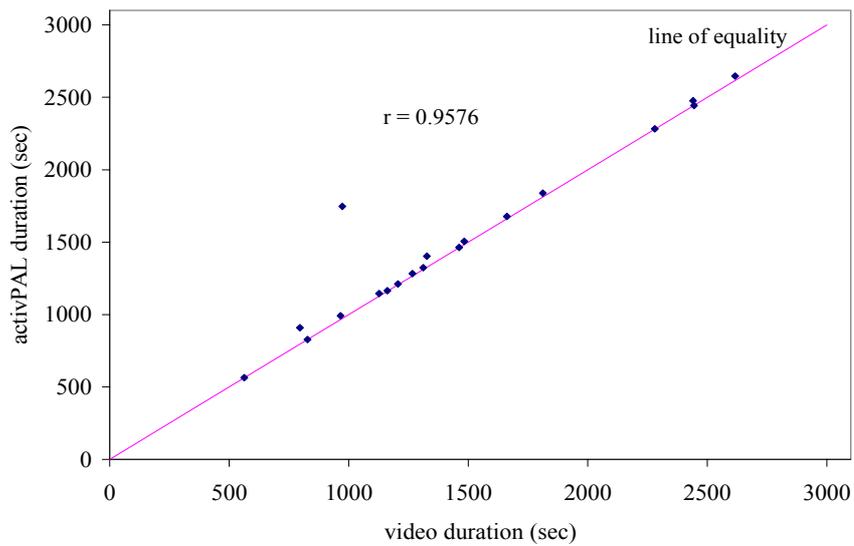


Figure 5.11: The total durations recorded from the video (analysis 2) for upright periods plotted against total duration from the activPAL output

For sitting/lying and upright comparisons (Figure 5.10 and 5.11), good correlations were found between the video (video analysis 2) and activPAL outputs, with only one outlier (subject 13) and most of the data points very close to the line of equality. However, Figure 5.8 and 5.9 seem to be more scattered for the durations in walking and standing time

comparisons. The outliers, data points which were not close to the trend lines, would affect the average percentage discrepancies. These outliers with higher percentage discrepancies indicated misclassification between postures that occurred for some subjects during this validation study.

For the correlation of stride counts between activPAL and video data, Figure 5.12 shows the total strides counted from the video recordings ('all counts' and 'forward counts') with the total number of strides from the activPAL algorithm. The correlation coefficient, r , were calculated as 0.9886 and 0.9742, $t = 27.07$ and 17.80 ($p < 0.001$) for 'all counts' and 'forward counts' respectively, showing highly significant positive correlation between both data sets compared with the activPAL output.

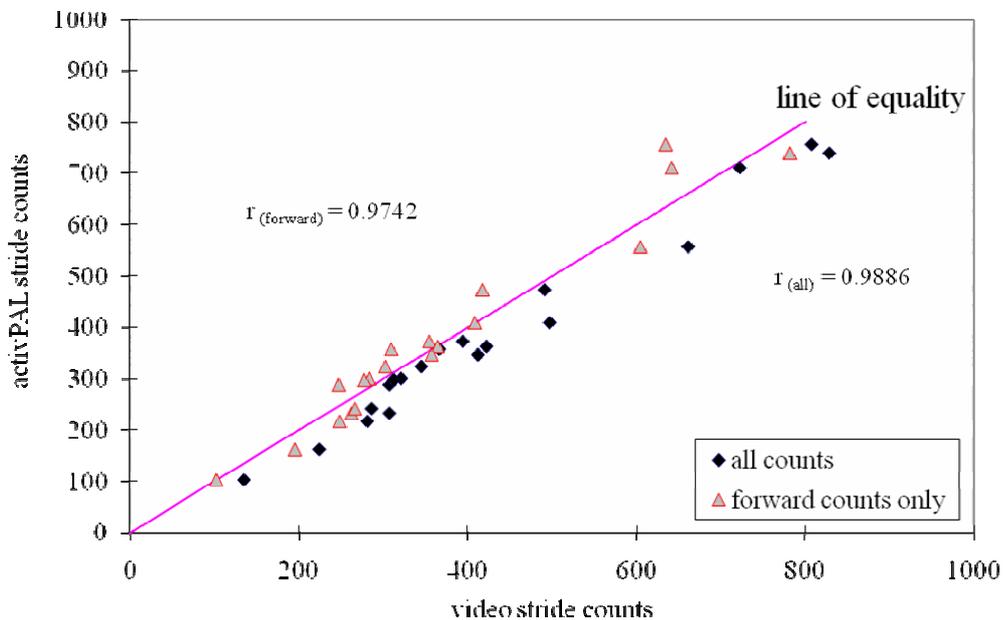


Figure 5.12: The total stride counts recorded from video (all counts and forward counts only) plotted against the total stride counts from the activPAL software for each subject

Although all the calculated r values showed highly significant positive correlation between the video and activPAL data for stride counts and posture categorization, r only measured the strength of relation between two variables, and not the agreement between them. The calculated correlation coefficients, r (Figure 5.8 – 5.12) show data points in relation to lines of best fit and not line of equality. Perfect agreement between the two data sets could only be achieved when points lay perfectly on the line of equality. Therefore further statistical tests were required to investigate the limits of agreements between the two methods as the

primary aim of comparison studies would be to determine whether two methods agree sufficiently to be used interchangeable.

5.3.3.2 Reliability Analysis

The intraclass correlation coefficient (ICC) is a measure of correlation, consistency or conformity for a data set when it has multiple groups (Strout and Fleiss 1979). Reliability analysis was carried out to find the ICC(2,1) using an absolute agreement definition, that was based on a two-way random effects model, with the measuring methods and subjects considered as random variables, which measured agreement emphasizing the interchangeability of the measuring methods. ICC(2,1) was computed using a statistical analysis software, SPSS Statistics (Version 16, SPSS Inc, USA) and an ICC value of ≥ 0.75 was considered to be good and ≥ 0.9 was deemed excellent.

The calculated ICC(2,1) were 0.976, 0.944, 0.992 and 0.978 for walking, standing, sitting/lying and upright classification respectively. For stride count, when all the strides were counted from the video ICC(2,1) was found to be 0.994 and when only forward progression stride were counted ICC(2,1) was 0.986. ICC(2,1) was >0.9 for all activity categorization and stride count, which demonstrated excellent reliability and that the video and activPAL measurements were interchangeable.

5.3.3.3 Agreement between video and activPAL data

It was hypothesised that although both methods measured the same data (duration of activity), they would not agree exactly in their measurements as measurement errors exist in both methods. Furthermore, time is a continuous parameter and both video and activPAL measurements of duration would contain errors as the precise times at which an activity was deemed to be initiated and terminated were difficult to define.

It was thought that statistical analysis to determine the agreement between the two methods would be more appropriate to identify how much activPAL results might differ from the video data. For this study, the method for assessing agreement between the two activity monitoring techniques was based on Bland and Altman statistical method (Bland & Altman 1986, 1999). Agreement between video and the activPAL was assessed by comparing the mean value of total time spent in each posture for video and activPAL with the percentage

difference between the two data sets for each subject. Agreement was defined as the percentage difference between the video and activPAL and calculated using the equation 5.6.

$$[(\text{activPAL duration} - \text{video duration}) / \text{mean duration} \times 100\%] \quad [\text{Equation 5.6}]$$

The mean of such differences indicates the estimated bias (difference between methods) and the standard deviation (SD) of the different measures random fluctuations around this mean. If the ‘limits of agreement’ (mean percentage difference $\pm 2\text{SD}$) between two methods are not clinically important or significant, the two methods could be used interchangeably. Graphical representation of the data of percentage differences plotted against the average value allows the evaluation of relationship between measurement error and assumed value. Confidence intervals (CI) values for mean -2SD and mean $+2\text{SD}$ in Bland & Altman analysis showed a range of values based on the observed data with a specified probability, the population value lies.

Figures 5.13 – 5.16 illustrate the Bland & Altman plots for the level of agreement between video analysis 2 and the activPAL for the total time spent in each activity during the gait analysis session. Values above zero represented the activPAL over-estimated the time spent in the activity state and values below zero showed under-estimation of time spent in the activity.

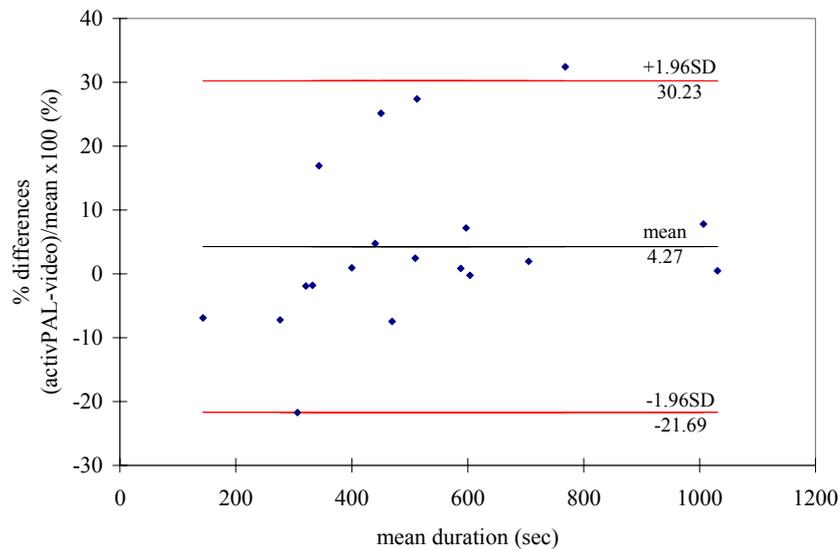


Figure 5.13: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total walking durations of each subject

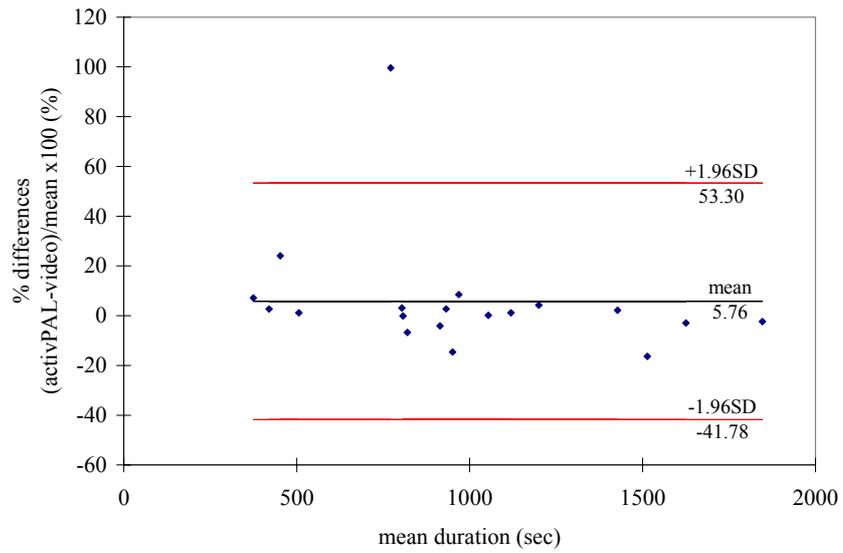


Figure 5.14: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total standing durations of each subject

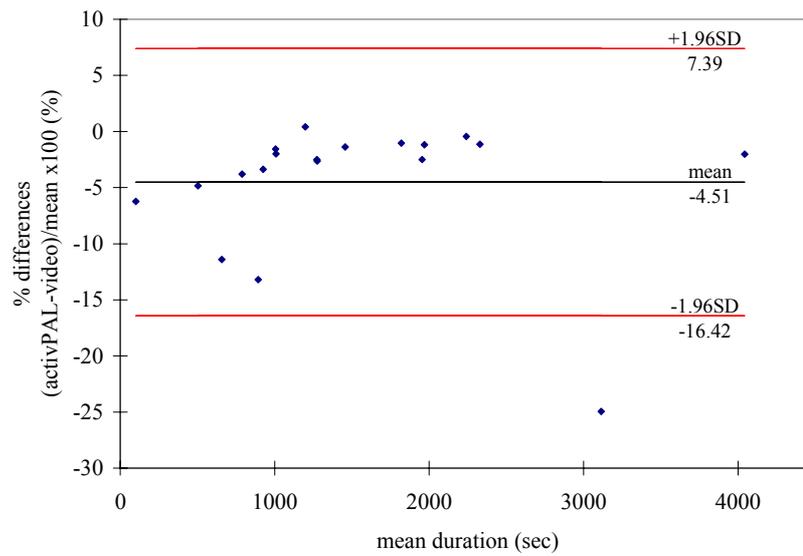


Figure 5.15: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total sitting/lying durations of each subject

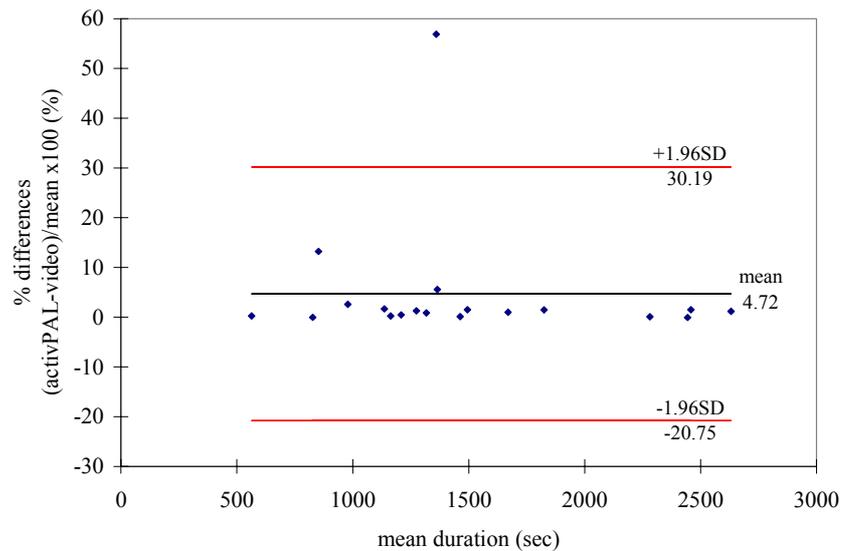


Figure 5.16: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total upright durations of each subject

The ranges of the percentage differences between subjects were -21.7 to 32.4% for walking (Figure 5.13), -16.3 to 99.6% for standing (Figure 5.14), -25.0 to 0.4% for sitting/lying (Figure 5.15) and -0.04 to 56.9% for upright (Figure 5.16).

Figure 5.17 and 5.18 show the Bland & Altman plots for the level of agreement between video and activPAL for stride counts during the testing sessions for each subject. The range of the percentage differences between subjects were -31.55 to -2.2% for all stride counts and -18.4 to 17.4% for forward counts only.

For durations of walking, standing, sitting/lying events and stride count, there are no obvious relation between the differences and mean from the video and activPAL data. The activPAL over-estimated time spent in each activity category for some subjects while under-estimating for others. From Figure 5.17, it could be noted that the activPAL under-estimated strides when all small strides were counted from the video as all values were below 0%. However, this effect was removed when only forward progression stride counts were recorded from the video to compare with activPAL data.

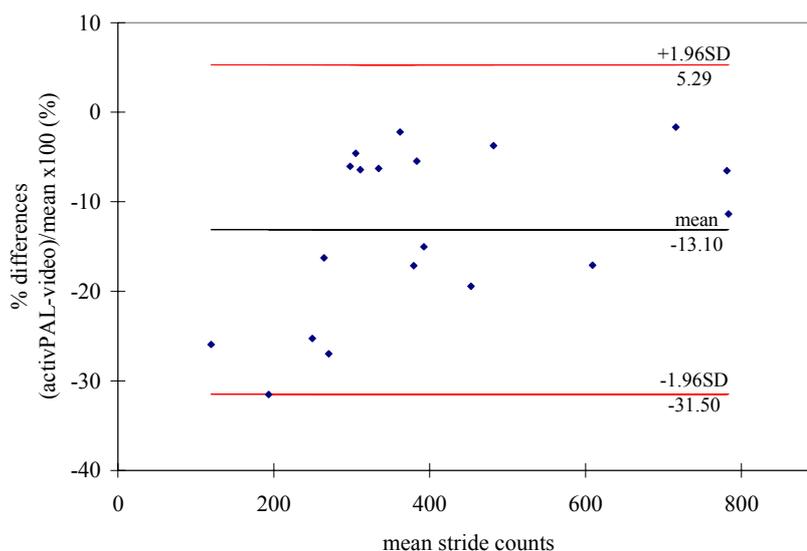


Figure 5.17: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total stride counts (all counts) of each subject

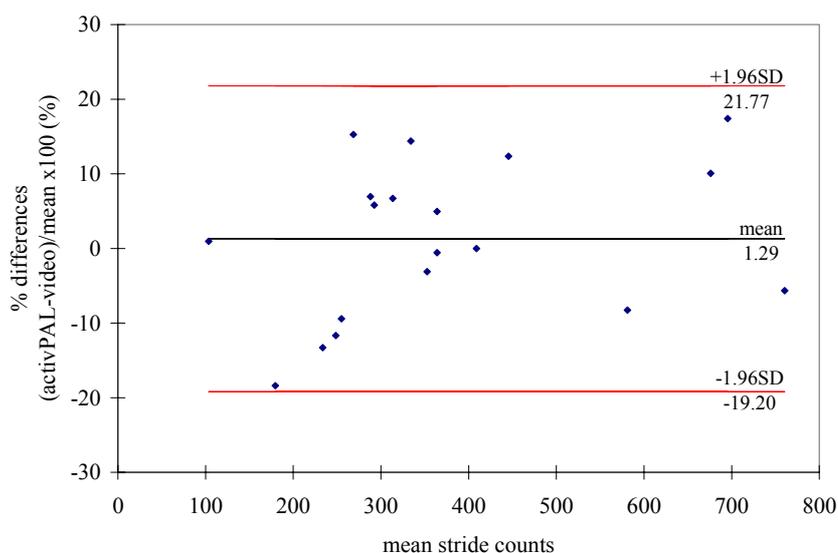


Figure 5.18: Bland-Altman plot for the agreement between video (video analysis 2) and activPAL for the total stride counts (forward counts only for video analysis) of each subject

It was assumed that the percentage differences were Normally distributed (Gaussian), hence 95% of the differences should be expected to lie between ± 1.96 standard deviation from the mean and these were called the limits of agreement (Bland and Altman 1986, 1999). Table 5.11 shows the calculated limits of agreements with the mean value. The limits of agreements lie between -21.69 to 30.23% for walking events (Figure 5.13), -41.78

to 53.30% for standing activity (Figure 5.14), -16.42 to 7.39% for sitting/lying episodes (Figure 5.15), -20.75 to 30.19% for upright periods and -31.50 to 5.29% for all stride counts (Figure 5.16) and -19.20 to 21.77% for forward stride counts only (Figure 5.17).

Table 5.11: The calculated mean of the percentage difference between video (video analysis 2) and activPAL data and limits of agreement calculated according to Bland & Altman (1986, 1999) for each activity categorization.

Activity category	Mean (%)	Lower limit of agreement (%)	Upper limit of agreement (%)
Walking	4.27	-21.69	30.23
Standing	5.76	-41.78	53.30
Sitting/lying	-4.51	-16.42	7.39
Upright	4.72	-20.75	30.19
Stride (All counts)	-13.10	-31.50	5.29
Stride (forward counts)	1.29	-19.20	21.77

However, these limits of agreement are only estimates of the values for this particular set of data. Hence standard errors (SE) and confidence intervals were used to determine the accuracy of these estimates. SE was calculated using the equation 5.7. The 95% confidence intervals for the bias were calculated using equation 5.8 with 18 degrees of freedom, $t = 2.101$ was found. Hence 95% confidence intervals for the bias were -2.11 to 10.65%, -5.93 to 17.45%, -7.44 to -1.59%, -1.54 to 10.98%, -17.63% to -8.58% and -3.75 to 6.33% for walking, standing, sitting/lying, upright and stride count (all) and stride count (forward) respectively.

$$SE(\bar{d}) = \frac{SD}{\sqrt{n}} \quad \text{[Equation 5.7]}$$

$$\bar{d} \pm (t \times SE) \quad \text{[Equation 5.8]}$$

The standard error of the limits (equation 5.9) and 95% confidence interval (equation 5.10) were calculated. Table 5.12 shows the 95% confidence interval for the lower limits of agreement, which were -24.72 to -18.65%, -45.89 to -37.67%, -18.47 to -14.36%, -23.76 to -17.74%, -34.05 to -28.94% and -21.89 to -16.50% for walking, standing, sitting/lying, upright, all stride count and forward stride count respectively. The 95% confidence interval for the upper limits of agreement were found to be 27.19 to 33.26%, 49.19 to 57.41%, 5.33

to 9.45%, 27.18 to 33.20%, 2.73 to 7.85% and 19.07 to 24.47% for walking, standing, sitting/lying, upright, stride count (all) and stride count (forward) respectively.

$$\bar{d} \pm 2SD \approx \sqrt{3SD^2 / n} \quad [\text{Equation 5.9}]$$

$$(\text{lower or upper limits} \pm (t \times \sqrt{3SD^2 / n})) \quad [\text{Equation 5.10}]$$

Table 5.12: The 95% confidence interval for the lower and upper limits of agreement for all activity categories.

Activity category	95% CI for lower limits of agreement		95% CI for upper limits of agreement	
	lower value	upper value	lower value	upper value
walking	-24.72	-18.65	27.19	33.26
standing	-45.89	-37.67	49.19	57.41
sitting/lying	-18.47	-14.36	5.33	9.45
upright	-23.76	-17.74	27.18	33.2
stride (all)	-34.05	-28.94	2.73	7.85
stride (forward)	-21.89	-16.5	19.07	24.47

5.4 Discussion

This study attempted to validate the activPAL as an activity monitor for people with CP. Video recordings of posture and stride count acted as the ‘gold standard’ for comparison with the activPAL data to validate its use for the CP population.

The exact proprietary algorithm used by the activPAL was not known, therefore the classification criteria for the video data could not be matched fully for ideal analysis. However, the general aspects of the activPAL proprietary algorithm suggested that the acceleration signals were classified into upright and non-upright events first by identifying threshold levels. Then within the upright periods, the activPAL algorithm would detect cyclical signals to identify walking episodes. The algorithm counts the number of troughs to represent strides. It was also believed that a minimum cadence was set by the activPAL algorithm. However, it was not known whether a threshold was set for the amplitude of the cyclical signal to classify each trough as a stride. It appeared that the algorithm counted every other trough to represent one stride during the walking episodes (Figure 5.4).

The identifiable misclassification periods were established from the graphs of continuous timelines against activity codes/classifiers for the activPAL and video data (video analysis 2) using the Matlab program (Appendix III). An example of the misclassified periods is shown in Figure 5.19 for subject 13. The pattern of the activity codes against time should be identical if 100% accuracy was achieved. In Figure 5.19, it can be seen that there were periods classified as standing by the activPAL algorithm that were seen as sitting events in the video recording.

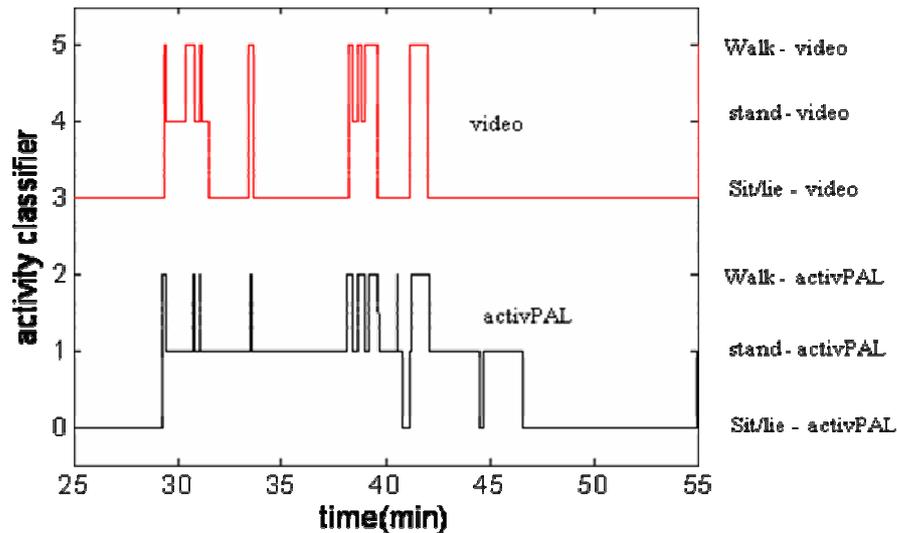


Figure 5.19: An example of misclassified periods for subject 13. For the activity classifier 0, 1 and 2 for the activPAL data and 3, 4 and 5 for the video data representing sit/lie, stand and walk respectively.

For the misclassified episodes the raw activPAL acceleration signals were exploited and the videos were re-examined to determine the position of the activPAL during these occurrences.

5.4.1 *ActivPAL posture categorization and stride count*

5.4.1.1 Walking and standing categorization

Misclassification between standing and walking times were seen in all subjects. The average percentage discrepancies between video analysis 1 and 2 and the activPAL data for the walking and standing times were much higher than those associated with sitting/lying periods (Table 5.2 and 5.4). In comparison to video analysis 1, video analysis 2 (performed to match the characterization that would have resulted from the activPAL) did lead to

decreased average percentage discrepancies for both standing and walking periods. However, the discrepancies in standing and walking classification were not removed completely. One reason for this was that it was still difficult to determine the exact duration of standing and walking episodes from the video data. This difficulty arose due to the complexity of the subject's movements which were highly individual specific.

Standing is defined as a human position in which the body is constantly in an orthostatic state. However, this does not clearly distinguish standing periods, as it is difficult to identify a minimum duration to classify standing episodes, which would also lead to the problem of classifying walking periods. If 100% accuracy for non-upright classification was achieved, the error in categorizing standing and walking episodes would be related as over-estimation of time spent in standing would lead to under-estimation of time spent in walking. Furthermore, it was unclear as to how many strides were required for the activPAL to classify a period as stepping activity and whether there was a requirement to exceed a certain speed (cadence) of such events. The followings are some examples of activities that would contribute to the classification complications between standing and walking occurrences:

- A period of quiet standing (i.e. legs not moving) interrupted by the person taking one step forward with both legs, then standing quietly again.
- Very low cadence stepping activities such as taking a step every 5 second.
- In the upright posture, small movements of the lower limbs to maintain balance.
- Side steps or shuffling gait.

In addition, standing posture relies on dynamic balance as the human centre of mass is situated in front of the ankle and the base of support of the two feet is narrow, therefore humans would fall forward during static upright posture without muscle action. Constant external and internal perturbations such as breezes and respiration also lead to the necessity for dynamic balance during standing. Internal mechanisms that are not obvious to the human eyes (e.g. spring action in muscles and higher control from the nervous system or core muscles) prevent a person from falling forward while standing. However, these mechanisms might be disrupted in people with CP, which leads to the use of other coping strategies such as small amounts of leg movement. This would make these events appear as perturbations in the activPAL data stream hence making classification of these events more challenging. For this study these episodes were categorized as standing in the video data and not walking. However, it was not known exactly how these activities would be

classified by the activPAL algorithm. Discrepancies of both walking and standing times would increase if the activPAL classified these incidents as walking activities.

5.4.1.2 Walking categorization

Apart from the misclassification between walking and standing events, another type of error for the durations of walking periods was due to the activPAL being attached to one leg only, therefore when a person started or ended a walking episode with the opposite leg, the time for that walking event would be less than it should be. In this validation study, it was seen that the subjects with gait affected on one side would start their walking episodes with the affected limb. However, when both limbs were affected, there was no dominant starting leg.

In a free-living environment, the percentage of this error would be small if the individual being monitored was active with long walking periods. Nonetheless, the error would increase for people with higher mobility difficulties as they might only perform household walking distances involving only small amounts of short walking periods per day.

5.4.1.3 Upright and non-upright categorization

The complications associated with the separation of walking and standing events discussed in the previous sections would not have affected the calculated total times spent in the upright posture. An examination of the total time spent upright, i.e. including both walking and standing should remove this element of potential misclassification from the comparison between the activPAL and the video analysis 2.

Analyses were carried out for upright and non-upright events (Table 5.5 page 55). The average percentage discrepancies calculated for all subjects were much lower for upright events (5.9%) compared to 9.9% for standing and 16.0% for walking activities. In a free-living environment, therefore it might be best to consider the average daily time spent in the upright posture rather than attempting to separate standing and walking times when using the activPAL and to use stride/step counts to determine amount of stepping activities performed.

Any errors in the classification of walking time would affect the classification of standing time as upright time could be accurately distinguished from non-upright time. For the majority of subjects it appeared that this was the case. In general non-upright and upright total times were correctly determined. Misclassification was occurring between standing and walking times (Table 5.4, page 54) more apparently.

For subject 10 and 15, the percentage discrepancies for non-upright events were much higher than for upright episodes. This was caused by the short overall duration spent for sitting/lying events during the laboratory validation study for these two subjects, hence a small discrepancy in the total duration caused a large percentage difference compared to the relatively longer time spent in upright activity.

The use of the gait laboratory visit as the validation period presented both advantages and disadvantages to the study. It was possible to study the subjects performing a range of activities in a limited environment, thus allowing continuous video recording. The subjects performed a range of activities with various postures. There were periods where posture was not prescribed, allowing the signal analysis algorithms to be tested in self selected postures. Also the transition from walking to standing to sitting and general movements in the upright posture were not prescribed allowing examples of movement patterns to occur that might also occur in a free-living environment. Although the activity classification that is adopted in this thesis appears straightforward and unambiguous, the video records demonstrated that the subjects adopted postures and executed movements that could not be easily classified. This difficulty in activity classification using video was reflected in the variability in interpretation of posture and stepping by the activPAL.

An alternative method of performing a validation study might have been to prescribe set periods of activity, i.e. sitting/lying, standing and walking with set stepping pattern and distance. It is possible that this would have lead to a 100% agreement between video analysis and activPAL data interpretation, however, this would not have reflected the classification that would occur when applying the instrument in a free-living context. It was considered essential that the validation study include elements of subject choice in posture adoption and movement to obtain insight into the ability of the activPAL algorithms to classify physical activity. A rigid protocol would not have achieved this. Perhaps the ideal setting for a validation study would be free-living community based. However, continuous video recording in a free-living environment presents problems of consent (where other

people are interacting with the subject of study) and basic logistical difficulties. The use of the laboratory based session was considered a suitable compromise.

One type of misclassification that appeared to occur was that the activPAL categorized sitting events as standing episodes (Figure 5.19). This type of misclassification was seen specifically in subject 13. It was noted that for these periods, the raw acceleration signals from the activPAL were between 40 and 90 activPAL units (Figure 5.20), whereas the general quiet sitting posture should have generated signals below 10 as the activPAL should have been in a horizontal orientation and quiet standing should have been around 150 as the activPAL would have been in a vertical orientation. From the video recordings for these misclassification events it was observed that the activPAL was generally slightly at an angle and not horizontal. There were two ways in which this occurred. Firstly, some of the small subjects tended to perch on the side of chairs rather than sit completely on the seat. This resulted in their thighs being inclined to the horizontal even though in the video they might be classified as sitting. This may have been a preference for the subjects rather than a necessity. There would be no way of knowing if this type of perching would lead to misclassification of the activPAL if the current proprietary algorithms were used for signal analysis. Secondly due to the variation in anatomy of the subjects, it was possible for the activPAL to be placed such that it was not entirely horizontal when the subjects were sitting. The activPAL was placed on the anterior mid thigh. The geometry of the thigh varied between individuals, potentially leading to changes in orientation in sitting. Also any misalignment around the axis of the thigh would have altered the signal output.

Although full instructions on the placement of the activPAL could be given to participants and their parents for free-living monitoring, the actual position of the device for each monitoring day would be unknown, therefore misclassification due to this problem could not be eliminated completely.

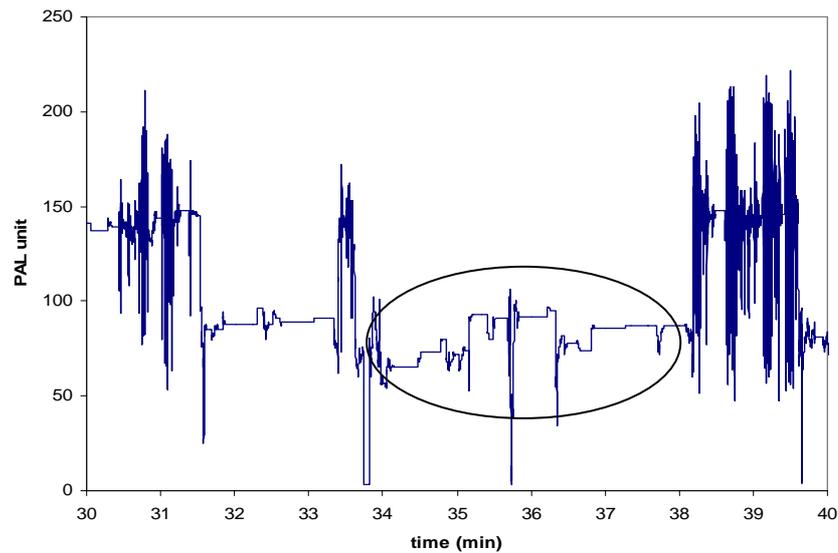


Figure 5.20: An example of the raw activPAL output plotted against time showing a misclassification of sitting event with activPAL units between 40 and 90.

It was believed that the activPAL software employed a moving average filter before identifying threshold levels to distinguish upright and non-upright events. One solution to improve the misclassification of sitting with legs at a slight angle would be to increase the lower threshold, so that it could include a wider range of sitting postures. However, this might be problematic with other gait abnormalities that could be seen in people with CP such as crouch gait, when knees are flexed during walking. Hence thighs would not be in a vertical orientation.

Another possible misclassification was caused by people with very limited mobility that required to be lifted for change of posture, such as from a seated position to standing. For example Subject 14 could not stand or walk without support. For the video data, standing was not classified until the subject's feet were in contact with the ground, however vertical thighs were seen during transfer between the sitting and standing postures as the subject was lifted with support under their arms. Hence a difference in classification occurred.

A summary of differences between activPAL interpretation of physical activity and that derived from video analysis 2 are summarised in Table 5.13. The misclassification caused by sitting in a non-horizontal position occurred in 8 subjects. The uncategorized differences between walking and standing events were not taken into account in Table 5.13 (except for subject 6 when a longer period of misclassification occurred). The error of misclassification

between standing and walking occurred in all subjects, as it was difficult to interpret real standing times as discussed previously.

Table 5.13: Sources of disagreement between the activPAL physical activity classification and that observed from video analysis 2.

subject	sitting in a non-horizontal position n (sec)	total sitting time (sec)	% error for sitting in horizontal position (%)	Uncategorizable differences
1		1829.4	0.0	
2	20	1466.6	1.4	10s Walking categorized as Sitting
3	46	2245.7	2.0	9s Standing categorized as Sitting
4		1013.4	0.0	
5		1196.1	0.0	
6		1289.7	0.0	4s Standing categorized as Sitting 136s Walking categorized as Standing
7		1292.3	0.0	
8	8	952.2	0.8	
9		1019.1	0.0	
10	65.6	694.5	9.4	
11	35.9	2341.8	1.5	
12	26	1980.1	1.3	34.3s Standing categorized as Sitting 13s Walking categorized as Sitting
13	361.4	3501.9	10.3	
14		4083.7	0.0	10s Standing categorized as Sitting
15		104.4	0.0	
16	24.9	803.4	3.1	
17		515.4	0.0	14s Standing categorized as Sitting
18		940.6	0.0	
19		1978.2	0.0	

Although from Table 5.13 some subjects did not have any misclassification between activity states, there were small percentage discrepancies when compared to the video data, which were mainly caused by error in identifying the exact time when an activity changed occurred. Furthermore, standing posture was always seen before and after sitting periods in the activPAL algorithm. However, in the video if the subject was seated straight after a walking episode or vice versa, then no standing times would be included in the video data.

Once again, this error was introduced by the difficulties in the interpretation of standing posture.

5.4.1.4 Setting for minimum sitting and upright periods

The activPAL algorithm used a default setting of 10 seconds for minimum sitting and upright periods to categorize activity. One of the main classification problems noted from the activPAL software using the default setting was its inability to categorize activities that were less than 10 seconds in duration, with a change in posture (i.e. from upright to non-upright and vice versa). For example, the activPAL default algorithm did not pick out events when an individual was seated for less than 10 seconds between two upright events (occurred in subject 2, 3, 11, 12, 14 and 17), and standing for less than 10 seconds between two seated periods (occurred in subject 3). In subject 12, the activPAL classified two stepping episodes that were less than 10 seconds in duration between seated events as continuous sedentary periods.

Furthermore, the activPAL default setting was not able to detect falls when subjects took less than 10 seconds to return back to an upright posture. Subject 12 fell over after a walking period, sat on the floor for approximately 7 seconds before getting back on her feet with some help and then stood quietly following the incident. The activPAL classified this fall episode as a standing event. On the other hand subject 2 fell forward during walking and was in the prone position for approximately 5 seconds before getting up and started to walk again. For this subject, the activPAL classified the fall period as continuous walking activity.

By using the default setting on the activPAL algorithm, the need for posture changes to be longer than 10 seconds in duration clearly limits the ability of the activPAL data analysis algorithm to correctly categorize the subjects' activities even though the raw acceleration signals clearly indicated postural change. Orendurff et al (2009) found that 17% of adult walking bouts during free-living monitoring were less than 5 steps. It might be hypothesised that younger subjects (children) generally perform more frequent short bouts of activities compare to adults. Therefore further data analyses were carried out for a range of minimum upright and sitting periods in the algorithm, so events that were less than 10 seconds in duration could be included in the activPAL analysis. The setting of 1 to 10 seconds for minimum upright and sitting periods were investigated and results were

compared to the video data (video analysis 2). Table 5.6-5.9 (pages 57 to 61) and Figure 5.6 and 5.7 showed that there were no general patterns to the effect of changing the minimum sitting and upright periods in the activPAL software on the sensitivity of classification of posture. The percentage discrepancy/sensitivity for some subjects seemed to increase as the minimum setting for upright and sitting periods were increased from 1 to 10 seconds, but for other subjects these percentages decreased. Some subjects had fluctuating sets of results when the minimum threshold was changed, however two subjects (10 and 15) had constant percentage sensitivity for all minimum settings indicating that they did not perform activities that were less than 10 seconds during the gait analysis sessions and no difference was introduced when the minimum setting was reduced from 10 seconds for these two subjects. The fluctuation in percentage sensitivity indicated that there may have been additional misinterpretation of the signal induced by changing the minimum setting, however, the cause of this change could not be determined as there were no consistent patterns in the data. It is possible that a combination of signal filtering to determine posture and the minimum settings being too low could lead to misclassification. It was not possible to determine any distinct pattern in this misclassification.

By changing the default setting to 1 second for minimum sitting and upright periods, the problem with the misclassification for sitting events that were less than 10 seconds should be removed. Also the activPAL was able to detect falls and correctly classified those periods as sitting/lying events. However, for subject 5, this did not eliminate the misclassified periods of stepping activities that were less than 10 seconds between two seated events, which indicated that the activPAL algorithm was unable to identify short stepping activities between seated periods although the default setting was changed to its lowest value of 1 second.

Overall, the average percentage discrepancy was greater when results were analysed using 1 second setting for minimum upright and sitting/lying events, indicating errors in the analysis when the algorithm becomes more sensitive to changes of posture. From the set of data collected, setting of 7 or 8 seconds for minimum upright and sitting/lying events were found to have the lowest average discrepancy when compared between video and activPAL data. However, the real effects of decreasing the minimum upright and sitting/lying periods were not known and further investigation is required.

The default setting of 10 seconds for minimum sitting and upright periods in the activPAL software clearly limits its ability to accurately classify activities that were less than 10 seconds in duration. By reducing the setting on the activPAL software, short bouts and spontaneous movements could then be monitored. Although most events less than 10 seconds were correctly classify when the default setting was changed from 10 to 1 second, the accuracy of the activPAL data did not increase when compared to the video data. The overall outputs for percentage discrepancy did not appear to change more than small amount (approximately 1%) when the minimum threshold was altered. This might be due to only small amount of short transitions being performed in the laboratory for routine gait analysis procedures. The number of short bouts of activity (< 10 seconds) might be expected to be significant for children in a free-living environment. The fluctuation of percentage discrepancy might be caused by errors in the analysis when the algorithm became more sensitive to small changes in the acceleration signals with a reduced minimum threshold for sitting and upright periods, hence creating misclassified activities.

5.4.1.5 Counting strides

The stride count algorithm employed by the activPAL software looked for the number of troughs during the upright posture, as stepping activities were represented by cyclical signals with one cycle corresponding to one stride (Figure 5.4). The activPAL algorithm under-estimated the stride counts when all strides and turning steps were counted from the video recording for all subjects indicated that the activPAL might not always include small side or turning steps. For counting forward strides only in the video data, comparison with activPAL data showed that some subjects had percentage discrepancies that were higher compared to the percentage discrepancies for counting all strides in the video data. This occurred in almost half of the subjects (subject 3, 8, 10, 13, 14, 18 and 19).

The video recordings were analysed with a stride by stride comparison to the activPAL outputs and it was found that miscounts occurred at the end of walking episodes, especially if the subject was required to turn round 180° to walk back to the other side of the laboratory. There might be a small amount of discrepancy between video and activPAL data for the time at which a change of posture occurred. The video analysis protocol used did not classify sitting/lying events until the gluteus muscle was in contact with the intended seat, and vice versa for upright categorization. However, people with lower limb disabilities, may take a longer time for transition between postures. It was not known from

the activPAL algorithm the exact time at which posture change was deemed to occur, hence time discrepancy between video and activPAL data might exist.

When all strides were counted from the video, the activPAL under-estimated for all subjects as end strides for most walking episodes were not counted. It was found that when the last step of a walking episode was the leg with the activPAL attached, this stride was not counted by the activPAL algorithm. However, if the last step was produced by the opposite leg, the last stride was counted. Hence it showed that a complete gait cycle was required for the last stride to be counted by the activPAL algorithm.

When only forward progression strides were counted from the video, the activPAL sometimes over-estimated, which indicated that small turning and side steps were included for some subjects (e.g. subject 8 and 18). In spite of this, the activPAL occasionally did not include these small steps (e.g. subject 12 and 15). At times, the activPAL missed out the end stride that caused a stopping action (e.g. subject 1 and 17). Sometimes there were extra strides which were random, such that there might be a stride counted from a seated position to a standing posture or extra strides being counted within a walking episode. By looking at the video recordings, there was no consistent pattern to indicate when the activPAL would count the small steps. By examining the raw acceleration signals, large amplitude of acceleration signal was seen indicating movement of the lower limb, however these were not seen in the video recordings. The exact algorithm employed by the activPAL software was not known, it was therefore difficult to understand the exact criteria used to classify a stride.

Table 5.14 summarised the differences between the activPAL interpretation of stride count and that derived from the video analysis. In general, the misclassification of first and last stride within walking episodes came from the difficulty in identifying what were a real first and last stride and the motion of turning round 180°. From the activPAL accelerometer signals, it could be seen that slow turning was not counted as a stride, whereas large movement of the thigh while turning was included as a stride.

Table 5.14: Sources of disagreement between the activPAL stride count and that counted from the video when only forward strides were counted.

subject	last stride not counted	first stride not counted	additional end stride counted	additional first stride counted	Total Additional first and last strides	Mid posture extra strides	Mid posture missing strides	Total additional mid posture strides	Total additional strides	total strides counted from video	total walking episodes
1	37	15	1	2	-49	15	14	1	-48	605	81
2	8	9	15	11	9	31	40	-9	0	409	57
3	10	5	27	11	23	46	1	45	68	642	81
4	17	1	2	3	-13	17	28	-11	-24	267	33
5	9	9	3	6	-9	18	40	-22	-31	249	30
6	7	3	11	2	3	17	3	14	17	284	37
7	24	5	4	8	-17	20	46	-26	-43	782	78
8	1	2	12	9	18	25	2	23	41	248	31
9	12	12	4	1	-19	9	23	-14	-33	196	24
10	5	1	16	8	18	30	0	30	48	310	48
11	7	2	13	2	6	18	6	12	18	355	29
12	12	1	8	4	-1	17	18	-1	-2	365	48
13	10	2	5	3	-4	35	10	25	21	303	25
14	5	11	4	1	-11	37	6	31	20	278	32
15	3	5	2	3	-3	6	2	4	1	103	15
16	21	3	9	3	-12	11	10	1	-11	358	57
17	28	2	0	0	-30	4	3	1	-29	263	39
18	7	2	24	0	15	46	6	40	55	418	54
19	7	2	27	43	61	62	2	60	121	635	79

For mid posture misclassification of a stride, this usually occurred when leg movements were seen during standing periods with no forward progression. For example, with toe walkers (people who cannot put down their heels due to tight gastronomies) they have lack of balance and small movements could be seen when they tried to stand still. Additional strides were counted in the activPAL algorithm for some subjects as the acceleration signals had additional peaks and troughs, which may be due to the gait pattern of those

individuals. However, there was no general trend and errors seemed to be random which might be representative of real error that could occur in free-living monitoring and would be difficult to eliminate for this population.

For the Bland & Altman agreement plots, the mean percentage difference was 1.29% for ‘forward count’, which was closer to 0% compared to -13.1% for ‘all count’. Hence it was shown that there was better average agreement between video data with ‘forward count’ results, which indicated that the activPAL generally did not count small side and turning strides. It was thought that this might be due to another threshold level being used, and the troughs in the cyclical signal had to pass through this threshold in order to be counted as a stride. Therefore, a slow small stride with small changes in the activPAL acceleration signal would not be considered as a stride by the activPAL algorithm. This might lead to error when gait abnormalities are present, e.g. for toe walkers who do not have heel strike and, therefore, have acceleration profiles that might be different to those of ‘normal’ gait. However, when gait patterns of each subject were investigated (Appendix IV), no general relationship could be identify between gait patterns (toe walkers, foot flat walkers, walking on lateral border and relatively normal gait) and percentage discrepancy for counting strides.

5.5 Summary

The validation study of the activPAL as an activity monitor for use in the CP population was carried out concurrently with gait analysis sessions that involved many short periods of walking and sitting with numerous transitions between postures and activity states, thus providing challenging conditions for the implementation of the proprietary signal processing algorithm employed by the activPAL. Determination of events from the video recording was not straightforward and it was necessary to prepare clear definitions of what was considered to be a stride and at what time a transition should be precisely defined. Attempts were made to match the characterization that would result from ideal analysis of the thigh worn activPAL output. From this study, it was found that the activPAL could count the number of strides a person took (101.82% average sensitivity for forward counts only) and categorize activity into periods spent in sitting/lying, standing and walking with a reasonable accuracy (105.19%, 111.36% and 95.77% respectively). Misclassification could be seen and wide intervals for Bland & Altman agreement plots were found indicating large variations between subjects.

Direct comparison of the activPAL output with the video analysis allowed examination of discrepancies in classification that occurred. The classification of rapid changes from one posture/activity state to another and then back again were affected by the minimum settings of parameters within the activPAL software. It is therefore, important that these parameters are set appropriately. For this validation study there were only a small number of these short posture/activity states so there was not a large effect on outcomes when the parameters were modified. However, if physical activity involved many of these short postural/activity states then there is a possibility that the setting of the minimum allowable duration in the activPAL software would become critical for accurate classification.

Discrepancies between classifications also occurred for activities that were not easily categorized. This included non-forward stepping and sitting with thighs in an orientation other than horizontal, i.e. perching on the side of a chair. It was not possible to identify clear patterns within or between subjects as to the occurrence of these types of discrepancy in classification between the activPAL and video based analyses.

From this laboratory based validation study, it was difficult to predict the effects of changing the minimum upright and sitting thresholds on the output of the activPAL for free-living activity monitoring. It was believed that the discrepancies observed in the validation study might be under-estimates of those that might occur in the community/home environment as there were restrictions on the activities performed by the subjects in the laboratory. It is possible that in a free-living environment the subjects would perform activities that did not fit the standard classifications of activity used and would therefore potentially be misclassified. Particularly short bursts of activity and regular rapid transitions may be expected in a population of younger subjects (children).

Although there were identified limitations in the physical activity characterization that the activPAL produced, with careful setting of the software parameters for minimum event duration it would be possible to gain insight into free-living physical activity levels.

6 CEREBRAL PALSY – 7 DAYS FREE-LIVING ACTIVITY MONITORING

6.1 Introduction

The population of people with cerebral palsy (CP) has varying levels of mobility impairments (van der Dussen et al 2001) and one of the primary aims of clinical interventions in CP is to maintain and improve mobility. Therefore knowledge of daily activity levels will provide critical information about the success of the clinical intervention. However, there is limited information pertaining to the mobility of people with CP in their free-living environments (Bjornson et al 2007) and typically no routine monitoring of activity levels is performed. Questionnaires are sometimes used to obtain information on free-living activity levels for people with CP, but this method could be subjective. CP is diagnosed in young children, therefore questionnaires would normally be completed by their parents. This might lead to errors in reporting as the parents may not be with the child all the time, hence parents might not document all the activity performed by their child. Furthermore, people with CP may have cognitive difficulties due to lesions in the brain, therefore even when the child grows up, information obtained from questionnaires completed by them may not be reliable.

Activity monitoring in a free-living environment may be used to assess the effectiveness of interventions aimed at increasing activity, and to quantify rehabilitation progress for people with CP. There are many commercially available activity monitors that could be used to assess daily activity levels for people with CP (examples of commercially available activity monitors are listed in Table 2.2, Chapter 2). However, most of the monitors' measure outcomes are in terms of energy expenditure. This information has limited applicability in a CP population due to the large range of mobility impairment and altered gait patterns in this population. Daily activity patterns in the CP population would provide more useful information than measures of energy expenditure.

The activity monitor, activPAL, can be worn for multi-day periods and potentially provides a useful tool for physical activity monitoring. The validation study reported in Chapter 5 indicates that, although there are limitations in use of this device in this population, it can be used to monitor physical activity in the free-living environment as long as the results are interpreted taking into account potential misclassification.

The work reported in this thesis was aimed at characterising the activity patterns of people with CP throughout daily living, as quantified by stepping, standing and sedentary phases of activity.

The application of the activPAL in the free-living environment is explored with the activity of a group of children with CP being monitored over multi-day periods. The absolute values of physical activity recorded are reported and the effect of modification of activPAL software settings on results quantified.

6.2 Methods

15 participants (Table 6.1) who took part in the validation study (Chapter 5) agreed to wear the activPAL in their free-living environments to monitor their daily activity levels. All subjects were of school age, hence required to attend school during weekdays. However, it was half term or holiday periods for subject 2, 6 and 11 during part or whole of their free-living monitoring week. Subject 15 and 17 worked after school on certain days of the week.

Table 6.1: Information on subjects who took part in this study

Subject number	Age	Sex	Type of CP	Mobility aids currently used
1	5	M	Diplegic	Bilateral AFO
2	5	M	Diplegic	Left AFO
3	6	M	Right hemiplegic	Left AFO
5	7	F	Diplegic	None
6	7	F	Left hemiplegic	Right AFO
7	8	M	Diplegic	Bilateral AFO
8	9	M	Right hemiplegic	Wheelchair
10	12	M	Spastic diplegic	None
11	13	F	Quadriplegia	Bilateral AFO, walking frame, wheelchair
12	13	F	Diplegic	Bilateral AFO
14	14	M	Spastic quadriplegia	Bilateral AFO, K-walker, wheelchair
15	15	M	Spastic diplegic	None
17	15	M	Diplegic	None
18	17	M	Mild diplegic	Insoles
19	17	M	Right hemiplegic	Left AFO

Subjects or their parents completed the standard functional assessment questionnaire (Appendix I) during their routine gait analysis sessions. The questionnaire used at the Anderson Gait Laboratory was the Gillette Functional Assessment Questionnaire (Novacheck et al 2000), which is a 10 level scale to evaluate walking ability with an additional assessment questionnaires on 22 higher level skills, such as stair climbing and navigating curbs. A comparison was made between the physical activity characterization accomplished with the activPAL and the outcome of the functional assessment questionnaire.

Subjects were asked to attach the activPAL to the same thigh throughout the 7 day monitoring period, either on the leg with more pronounced gait abnormality or the right thigh if both legs showed similar gait difficulties. This was the same thigh as used during the laboratory based evaluation study. Subjects were instructed to remove the activPAL during any water-based activities (e.g. bathing and swimming), and the device could be removed for over nights periods when the subject was sleeping. Full instructions on the attachment methods of the activPAL using the PALstickies (PAL Technologies Ltd) were given to each subject and their parents.

Each subject and their parents were also asked to keep a simple diary/timetable of the activities that the subject performed within the 7 days monitoring period, so that comparison of the collected data with the diaries could be achieved. A timetable with hourly slots (Appendix V) was given to each subject and they were asked to record the activities they performed during the 7 day monitoring period. The timetable could be completed by either the subjects themselves or their parents (especially for younger subjects and those who had cognitive difficulties). Instructions were given to record where they were during the day and any physical activities performed (e.g. sporting activities, shopping, walking the dogs etc). Each subject was provided with a stamped addressed envelope, so the activPAL could be posted back to the researcher with the diary/timetable after the monitoring period.

6.3 Data Analysis

The activPAL data were downloaded onto a computer using the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd). Data was first analysed using the default setting of 10 seconds as the minimum duration for sitting and upright periods. The total

time spent in each activity (sitting/lying, standing and walking with total step count) for each monitored day was found using the activPAL professional software. The average times spent in stepping, quiet standing and numbers of steps per day were calculated.

Further analysis of the activPAL data were carried out to determine the most appropriate setting for the minimum duration of upright and sitting periods. The activPAL data analysis algorithm first employed some form of filtering techniques and two thresholds were identified to distinguish upright and non-upright (sedentary) events. The algorithm then associated stepping episodes with cyclical signals within upright periods and counted the number of strides (See Section 5.2.1.1 for details of the activPAL signal analysis algorithm). For upright and non-upright (sedentary) classification, the activPAL algorithm set a minimum duration for which sitting/lying and standing period had to last in order that a change in posture state might be registered. The default setting in the activPAL professional software was 10 seconds for the minimum duration of sitting/lying and standing periods, and this setting could be changed manually in the software from 1 to 100 seconds.

In the activPAL software the default setting for the minimum upright and sitting periods were set as 10 seconds. Although it was shown that altering these values between the values of 1 and 10 seconds did not have a major impact on the results of the validation study it was not possible to know how these setting might affect free-living activity. The type of activity engaged by the subjects in their free-living environment could have been very different to that of the semi-prescribed and observed laboratory based environment. Interpretation of the acceleration signal by the activPAL software was made using a smoothing filter to establish posture. If very short postural events occurred, i.e. less than 3s in duration, it is possible that these would not be characterized correctly. Also it might be questioned whether a change of activity that occurred for less than 3 seconds should be counted as important activity change in the context of multi-day physical activity monitoring. It was believed that activity performed in the validation study did not represent the full range of children's activity patterns. It was not possible to determine whether the proportion of time spent in short posture events in the laboratory were good representations compared to daily life situations. Hence different settings of minimum duration for sitting and upright periods were investigated (3, 5 and 10 seconds) for the free-living activPAL data. A minimum of 3 second was chosen to avoid potential errors associated with the smoothing algorithm implemented in the activPAL software.

The data were analysed using a Visual Basic program using the .pal files created from the activPAL software and all activity events were identified. For each minimum setting of upright and sitting period (3, 5 and 10 seconds), the durations for each sedentary and upright event were established for each day for each subject and the average number of events per day were categorized into different bins (< 20, 20-60, 60-120, 120-300, 300-600, 600-1800, 1800-3600, 3600-7200 and >7200 seconds). These ranges were chosen so that good representations of the number of events could fall within each category, as it was assumed that there would be more short periods of activity during free-living monitoring.

The average numbers of sit-to-stand transitions per day were also identified for each subject, which would provide information on the subject's ability to perform sit-to-stand transitions, which could give extra indication to the mobility level of an individual.

6.4 Results

All subjects were of school age, and free-living monitoring were carried out during school weeks except for subject 2, 6 and 11 who wore the activPAL during holiday weeks. Therefore physical activity levels were expected to be different compared to normal school weeks. Subject 15 and 17 worked after school on certain days of the week.

6.4.1 Functional assessment questionnaire

The mobility score (Table 6.2) described the subject's typical walking ability with the use of any assistive devices. The scores were found from the standard functional assessment questionnaire used in the Edinburgh Gait Laboratory (Appendix I). The scale ranged from 1 to 10, where 10 described the more mobile subjects who would be able to run without any difficulties or assistance and 1 indicated the subject could not take any steps at all, therefore dependent on wheelchair for mobility.

Table 6.2: Mobility score of each subject using the Edinburgh mobility questionnaire

subject number	1	2	3	5	6	7	8	10	11	12	14	15	17	18	19
mobility score	8	8	8	8	8	8	6	9	5	7	5	9	9	9	6

The mobility scores for the 15 subjects ranged from 5 to 9. Subject 10, 15, 17 and 18 had the highest mobility score of 9 indicating they were able to perform general activities

without any difficulties or assistance. Subject 11 and 14 had the lowest mobility score of 5, which showed that they had mobility difficulties that correlated to the use of wheelchair (Table 6.1).

6.4.2 *ActivPAL results*

ActivPAL data was obtained from the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd) and an example of a subject’s activPAL free-living 7 days results can be found in Appendix VI, which included the weekly summary data and activities broken down for each day with annotated information from their diary.

Although each subject was asked to wear the activPAL for 7 consecutive days, some subjects forgot to put it on or did not want to wear it on certain days. Table 6.3 shows the number of complete days (midnight to midnight), of which each subjects worn the activity monitor. Although subjects did not wear the device during overnight sleeping, the activPAL was placed horizontally to represent sitting/lying events, hence indicating time spent in sedentary events. This ranged from 1 to 7 days. The activPAL was switched on and attached to each subject after their routine gait analysis sessions, usually between 11am – 1pm. Therefore only half a day of activity could be recorded during this first day. This was not used in data analysis presented here.

Table 6.3: Number of complete free-living activity monitoring days for each subject

subject number	1	2	3	5	6	7	8	10	11	12	14	15	17	18	19
Monitoring days	6	6	7	6	3	5	1	5	2	5	7	6	6	6	7

Figure 6.1 shows the range of activity levels for the 15 subjects during free-living monitoring, indicating the average quiet standing times, stepping times and number of steps per day (2 steps = 1 stride). The standard deviations for the average quiet standing, stepping and number of steps per day are also shown in Figure 6.1.

The activPAL data for each subject were used to calculate the average quiet standing, stepping and number of steps per day. There was no standard deviation for subject 8 as only one full day of activPAL data was recorded.

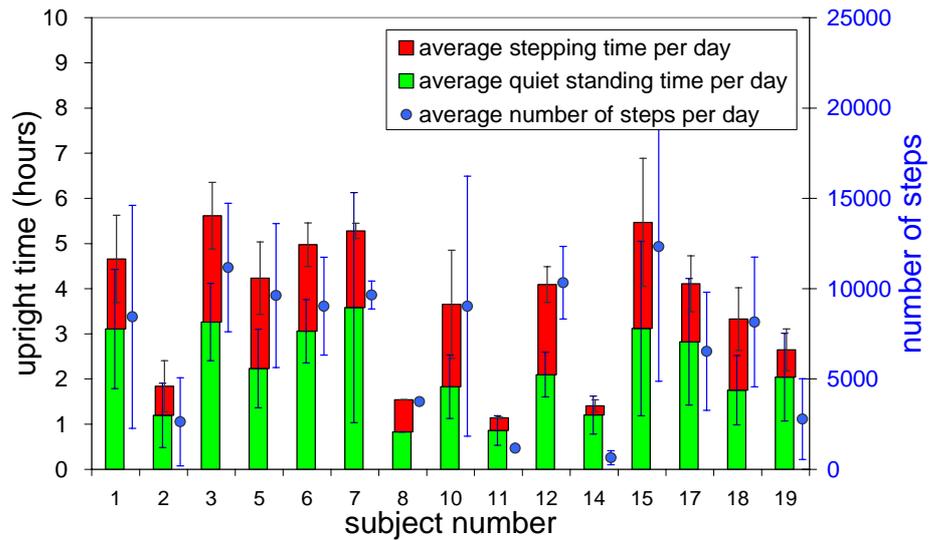


Figure 6.1: Average quiet standing times, stepping times and number of steps per day over 7 consecutive days for 15 subjects.

There were large variations in the average daily step count (642 to 12330 steps per day) and upright time (0.89 to 5.67 hours per day) of subjects. Figure 6.1 indicates that subject 14 had step counts below 1000 per day and subject 2, 8, 11 and 19 had step counts below 5000 per day. All other subjects had step counts over 5000 per day. For free-living activity monitoring of people with CP, the average quiet standing times ranged from 0.4 to 2.57 hours per day and the average stepping times ranged from 0.29 to 2.94 hours per day (Figure 6.1), indicating the wide range of daily activity performed by each individual.

Different parameters were investigated against mobility scores from the questionnaire. The relationship between mobility scores, average daily step count and average upright time per day is illustrated in Figure 6.2 and the relationship between mobility scores and average cadence and average daily step count is shown in Figure 6.3.

From Figure 6.2 it could be seen that subjects with mobility scores of 5 and 6 had lower average step count and upright time per day than those with higher mobility scores. Subjects with mobility score of 5 had the lowest average cadence (Figure 6.3).

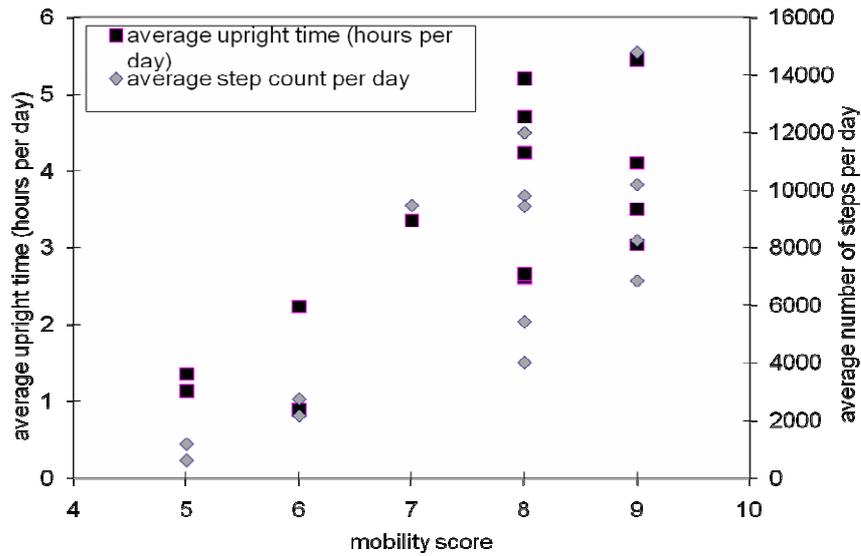


Figure 6.2: Relationship between mobility score and average daily step count and average upright time per day for all subjects.

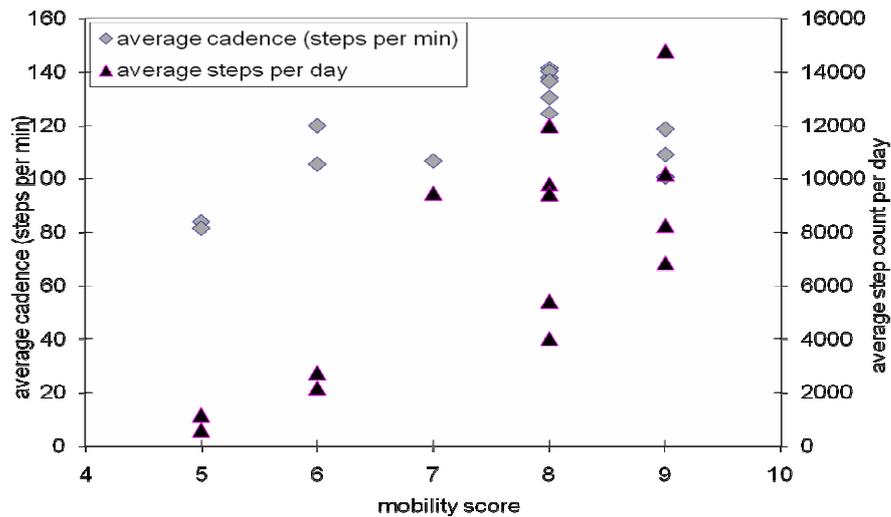


Figure 6.3: Relationship between mobility score and average cadence and average daily step count for all subjects.

The correlation coefficient, r , were calculated as 0.767, 0.767 and 0.483 for average upright time per day, average step count per day and average cadence per day respectively with mobility score, showing strong positive correlation between average upright time and average step count per day compared with mobility score. There was only medium positive correlation between average cadence per day compared with mobility score.

Apart from this small pattern, there was no other general trend between mobility scores and average upright times, average daily step count or average cadence for the subject population (Figure 6.2 and 6.3).

Laboratory based average walking cadence is plotted against average step count per day and upright time per day in Figure 6.4.

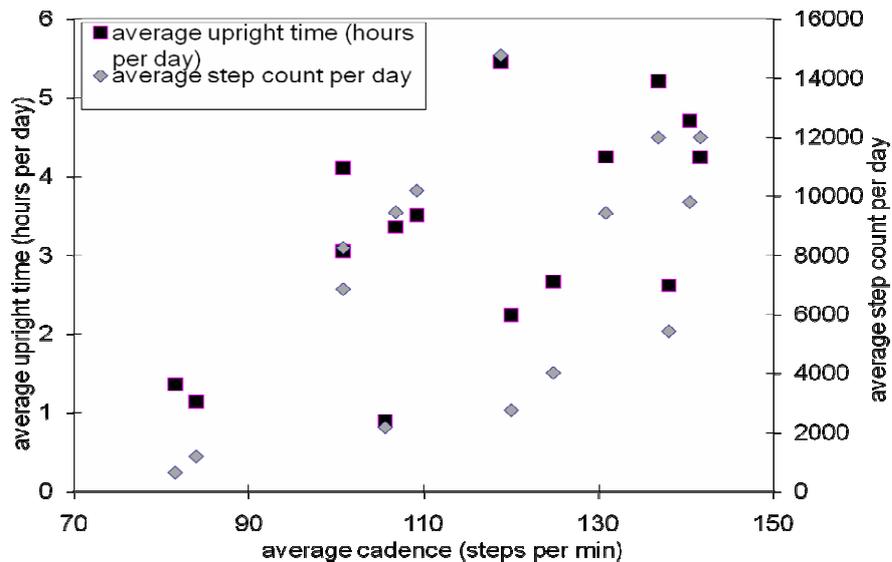


Figure 6.4: Relationship of average laboratory based cadence with average upright time and average step count per day for all subjects.

The correlation coefficients, r , were calculated as 0.560 and 0.615 for average step count per day and average upright time per day respectively against average cadence. No other general trend could be seen from Figure 6.4 for any relationships between average cadence with average upright time and average step count per day for the subject population.

6.4.2.1 Effect of minimum setting for upright (sitting/lying) and sitting/lying (non-upright) period duration in the activPAL software

Different settings of the minimum duration for sitting/lying and upright (standing/walking) periods were investigated, as it was hypothesised that in this subject population short bursts of activity might occur frequently. Children’s free-living physical activity might consist of many spontaneous changes in posture and short transitory activity bursts. It was not possible to know if this was true for this population of children unless the minimum

settings for upright and sitting/lying period duration within the activPAL software were reduces below 10s. Figure 6.5 and 6.6 show examples of a subject’s free-living monitoring results, with the average number of upright and non-upright (sedentary) events per day respectively, which were categorized into different bins (< 20, 20-60, 60-120, 120-300, 300-600, 600-1800, 1800-3600, 3600-7200 and >7200 seconds) for data analysis using 3, 5, and 10 seconds for the minimum setting of upright and sitting/lying periods. Appendix VII and VIII show the average number of upright and sedentary events per day categorized into different bins for all subjects.

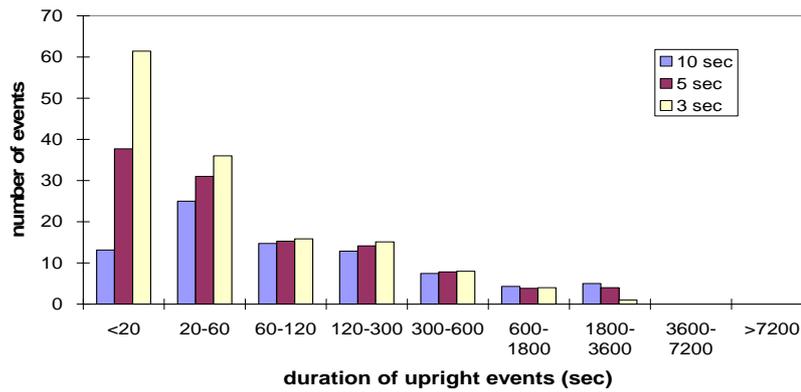


Figure 6.5: An example of average number of upright events per day categorized into different durations during free-living monitoring (subject 1) for 3 settings of minimum sitting/lying and standing/walking times.

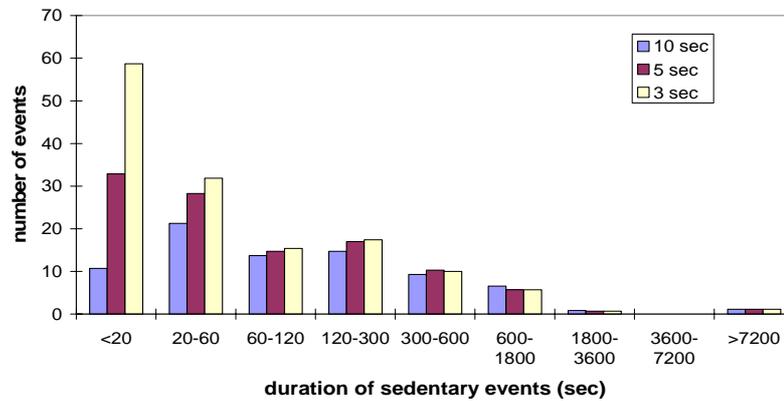


Figure 6.6: An example of average number of non-upright (sedentary) events per day categorized into different durations during free-living monitoring (subject 1) for 3 settings of minimum sitting/lying and standing/walking times.

For both upright and non-upright (sedentary) analysis with all the subjects, as the minimum setting for sitting and upright period reduced from 10 seconds to a lower value (i.e. 5 and 3),

the average number of events that occurred less than 20 seconds in duration increased. For sedentary analysis, the average numbers of events that were longer than 2 hours (7200 seconds) for all 3 settings were the same for subject 1, 5, 6, 10, 11, 15 and 17, but different for subject 2, 7, 8, 12, 14, 18 and 19. These longer sedentary events usually indicated overnight sleeping episodes, as subjects placed the device on a horizontal surface during overnight sleeping periods.

Apart from the trend seen in the <20 seconds bin, there was no general pattern for the number of events within each bin when the minimum setting for upright and sitting were changed from its default of 10 seconds to 5 and 3 seconds. Also the number of events increased for 20-60 second duration bin as the minimum setting decreased, apart from subject 2, 3, 6 and 8.

6.4.2.2 Sit-to-stand transitions

The average number of sit-to-stand transitions per day for each subject for the 3 settings of minimum upright and sitting/lying periods (10, 5 and 3 seconds) are shown in Figure 6.7, which indicates that as the minimum setting for upright and sitting periods decreased, the average number of transitions per day increased. For the setting of 10, 5 and 3 seconds of minimum sitting/lying and upright periods, the average number of sit-to-stand transitions per day ranged from 31-101, 35-147 and 39-185 respectively.

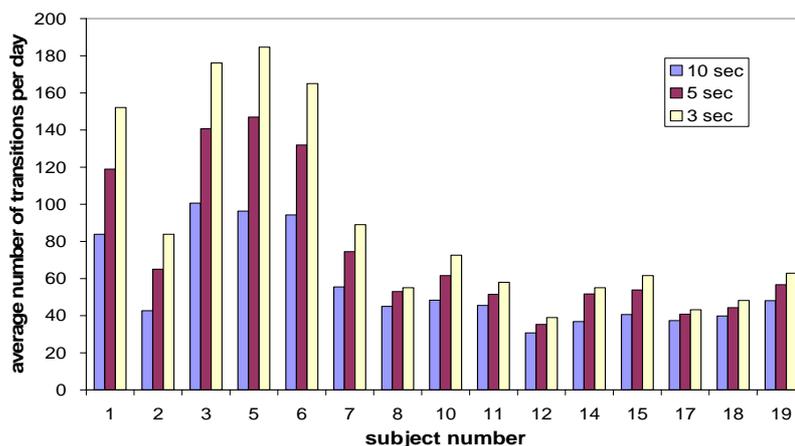


Figure 6.7: The average number of sit-to-stand transitions per day for each subject, analysed using 10, 5 and 3 seconds as the minimum setting for upright and sitting/lying periods.

Subject 1, 3, 5 and 6 appeared to perform over 80 sit-to-stand transitions per day for all three settings of minimum upright and sitting/lying periods in the activPAL software for the data analysis algorithm. The percentage change resulting from a shortening of the minimum times from 10 seconds to 3 seconds ranged from a 14% to a 49% increase.

The relationship between mobility scores with the average number of sit-to-stand transitions is illustrated in Figure 6.8. No general pattern could be noted from Figure 6.8 for correlation between number of sit-to-stand transitions and mobility level. It showed that the daily average sit-to-stand transitions ranged from 31 to 101, indicating the range of activity level for the subject population in this study.

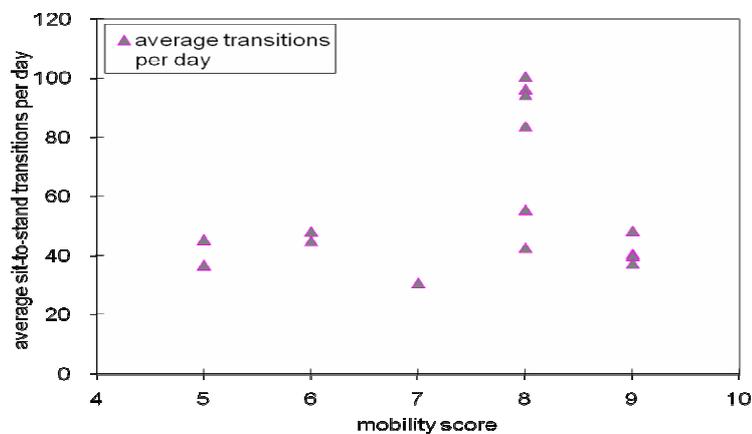


Figure 6.8: Mobility score plotted against average number of sit-to-stand transitions (minimum duration of upright and sitting/lying events =10 seconds) per day performed by each subject.

The relationship between the ages of each subject with corresponding average number of sit-to-stand transitions per day during free-living monitoring is shown in Figure 6.9.

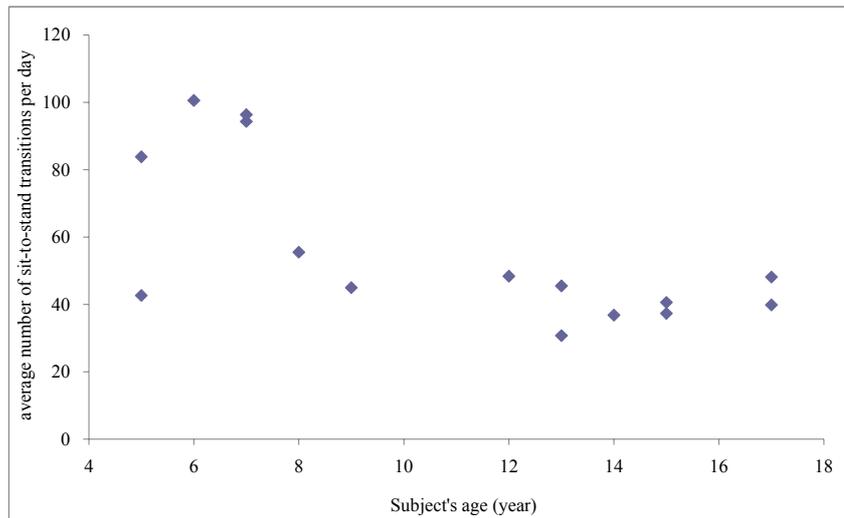


Figure 6.9: Subject's age plotted against average number of sit-to-stand transitions (minimum duration of upright and sitting/lying events =10 seconds) per day performed by each subject.

It could be seen that there was a threshold of average sit-to-stand transition per day that is around 40. Only the younger subjects (5 to 7 years old) performed more than 60 average sit-to-stand transitions per day.

6.5 Discussion

6.5.1 *Functional assessment questionnaire*

The mobility scores (Table 6.2) were either the subjects' or their parents' perception of the subjects' ability to perform daily physical activities with the use of any assistive devices, which could be subjective. The Gillette Functional Assessment Questionnaire used at the Anderson Gait Laboratory was a 10 level parent/patient reporting scale encompassing a range of walking abilities with additional assessment questions on higher level skills. Parents could be biased as they might mislead the clinical staff by under- or over-estimating the subject's mobility status. Table 6.2 showed that the mobility score ranged from 5 to 9 for the subjects who took part in this study. Although the walking ability for people with CP could range from 1 to 10, the lowest mobility score obtained from subjects who took part in this study was 5 because subjects were recruited when they attended routine gait analysis sessions, and for a person with CP to be able to have clinical gait assessment, the minimum requirement would be the ability to walk with assistance. Hence it was unlikely that subjects with a mobility score below 3 would have been recruited to this study, as these people with CP would have been dependent on the use of a

wheelchair and could not have walked or stood unaided, therefore would not have been assessed in routine gait analysis sessions and would not have been in an unsupported upright posture in daily situations.

Although the questionnaire consisted of other parameters, only the overall mobility score was used to compare between subjects. The higher level mobility skills within the questionnaire were not used as these activities might be related to developmental age at which children normally acquire the skills. For example, younger subjects (< 5 year old) might not be able to carry a fragile object or a glass of water because they were too young and had not yet developed these skills. Also a subject might not have performed other activities such as riding a two wheeler bike or a trike and ice skating because they never had the opportunity or did not enjoy such activity, and not because of their ability. Hence only their general mobility skills were used as mobility scores to compare with activPAL data.

Furthermore, the functional assessment questionnaire only provided information on the capability of each individual with CP and did not give any indications on their free-living activity patterns or the amount of daily activity being performed. A subject might be able to perform all activity types stated on the questionnaire but could choose to have a sedentary lifestyle. For example, subject 2 had a mobility score of 8 but had average step count of <5000 per day.

The mobility scores were used and it was established that although there was correlation between mobility score (range from 4 to 10) with average upright time and average step count per day, mobility score could not be used to predict free-living physical activity due to the variability of the measures within the scores (Figure 6.2 and 6.3). There were no other general relationships between functional mobility levels attained from subjects/parents and parameters measured in the free-living environment such as average upright times per day, average daily step count and number of sit-to-stand transitions. Figures 6.2 and 6.3 indicate that for lower mobility scores of 5 and 6, subjects had the lowest average number of steps per day, however for mobility score of 7 or higher, the range of daily average step count increased. The range of average daily step count for subjects with higher mobility varied greatly from 4011 to 12330.

From the activPAL free-living data, it could be seen that results could be useful to predict mobility level into 2 groups, either below 7 (< 3000 steps per day) or above 7 (> 3000 steps per day). However, it is more ambiguous for people with mobility score of 7 as they might fall into either category. It was seen that if mobility score was below 7, these subjects tended to have limited mobility, hence lower level of daily activities. Free-living activity results showed that although a subject might have high mobility skills, they might not carry out high amount of physical activity.

The results demonstrate that to determine free-living physical activity level it is not possible to use the mobility score derived from a questionnaire alone, and that it would be necessary to make direct measurement with an objective monitor such as the activPAL.

6.5.2 Free-living activPAL data

General activity patterns of people with CP

Complete days of no data (i.e. sedentary event for 24 hours), were not included in the calculation of averaged time spent in each activity state and stride count, as this was taken to indicate that the subject was not wearing the activPAL.

By identifying the average quiet standing times, stepping times and number of steps per day for people with CP, their general daily activity patterns could be evaluated. It can be hypothesised that people who walk only short distances, i.e. have only short walking bouts, are only walking within the home or for short transits to transport etc. To extend physical activity beyond the home it would be necessary to undertake longer periods of walking and to stay upright for longer. It can be hypothesised that those with poor walking ability might only perform essential walking to allow independence during daily activities. Those with greater walking ability might tend to perform voluntary physical activity in addition to this essential walking activity. This additional physical activity would involve both increased stepping and increased standing times.

From the results (Figure 6.1) it can be seen that subjects 11 and 14 perform only a small number of steps per day and that they might therefore be classed as ‘household’ walkers performing only essential stepping to maintain independent within indoor environment but would require assistance for outdoor activities. This is in contrast to other subjects (subject 1, 3, 5, 6, 7, 10, 12, 15, 17 and 18) who performed over 5000 steps per day, above the level

required for performance of essential daily tasks, and so indicating additional activity that might be classified as 'community' based walking. Subject 2, 8 and 19 might fall in between these two groups as they appeared to perform more steps or upright time per day than those who were 'household' walkers, however not as many as those who were 'community' walkers. Three categorisations of physical activity level are proposed, those involving household stepping; short community based stepping; and active community based stepping.

ActivPAL activity patterns corresponded to the mobility scores from the functional assessment questionnaire. Subjects 8, 11, 14 and 19 had the lowest mobility scores, 5 or 6, which matched with the activPAL results as they exhibited the lowest average step counts. However, subject 2 had a mobility score of 8 but had an average step count below 5000. This suggested that the functional assessment questionnaire might only indicate a person's capability and not their actual daily activity levels. Free-living activity levels not only include ability to perform such activities, but are also influenced by other factors such as motivation, environment, family circumstances and possibly economical constraints.

There was a wide range of step counts per day for the more active subjects as characterized by large standard deviations of the data. This variation could have been due to a wide number of factors including general fatigue, weather, visiting friends, scheduled activity sessions, confined sitting (e.g. watching films), etc. Less active subjects with CP might need support in stepping activities; the lower variation in step count within this group was probably caused as these subjects only performed essential activities such as toileting, walk to transportation and indoor activities. Also those steps recorded might be due to daily exercise prescribed by physiotherapists, therefore less variation in the number of steps was seen for the less active subjects.

The average quiet standing times ranged from 0.83 to 3.58 hours per day and the average stepping times ranged from 0.21 to 2.35 hours per day. All subjects seemed to spend more times in the quiet standing posture compared to stepping activities, with the exception of subject 8. There might be many reasons for higher standing times, for example, subject 15 and 17 worked in a shop that involved a lot of standing. Also the use of walking frames would increase time spent in quiet standing posture (e.g. subject 11 and 14), as these subjects might need assistance to move in and out of their walking frame, so once in the frame they might remain in an upright position until they were helped back into a seated

posture. In addition, physiotherapy programs varied from person to person. Some people with CP might be required to perform daily exercise in the quiet standing position, while others might need to carry out these exercises in a prone or supine position for muscle stretching/strengthening.

To maintain good health, it is recommended in U.S Dietary guideline that children engage in at least 60 minutes of moderate to vigorous physical activity per day (2008 Physical Activity Guideline for Americans). For adults, the well known 10,000 steps per day is indicative of an active lifestyle (Tudor-Locke and Bassett 2004; Le Masuier et al 2003), but this recommendation is likely to be too low for children who are more active than adults.

From the activPAL results, most subjects who took part in this study had an average of over 60 minutes of stepping activity per day (subject 1, 3, 5, 6, 7, 10, 12, 15, 17 and 18). These were the more active ‘community’ walkers who engaged in higher amounts of physical activity. However, for the recommended step count of 10,000, only 4 subjects achieved this (subject 3, 5, 10 and 15). This indicated that although the subjects studied are engaging in stepping activity, they are not performing to the recommended levels for maintenance of good physical health.

6.5.3 *Effects of minimum setting for upright and sitting periods*

3, 5 and 10 second settings of minimum upright and sitting/lying periods were investigated for its effect on free-living activity monitoring outcomes. 10s was chosen as this was the default setting for the activPAL software. It was hypothesised, however, that there might be a number of posture bouts shorter than 10s as children/younger subjects have a tendency for engaging in play activity with a significant physical activity component. It is commonly observed that this play activity involves many posture changes in short periods of time. The two settings of 5 and 3 seconds were chosen to provide examples of the effect of this setting on the data characterization. 5 second was half the value of the default setting. 3 second was chosen as the shortest time that it was considered a meaningful event would last. It would have been possible to use 1 second as the minimum, however it was not felt that this would offer a meaningful interpretation of the data as it may have lead to error in classification of rapid transitory motions as posture state changes. Hence a longer duration of 3 seconds was used instead of the lowest minimum setting.

The time bins were selected pragmatically to ensure a manageable number of bins and a suitable spread across the duration span. The longest duration bin was set as over 7200 seconds (2 hours) to provide information on any times where no change in physical state was made for what was considered a 'long time'. The shortest durations was set as less than 20 seconds so that it could include events for the default setting (10 seconds). For a 10 second setting of minimum sitting/lying and upright times there would have been no events less than 10 seconds making it unreasonable to use a bin of 10 seconds and less. After preliminary analysis the following data bin sizes were used: 20 seconds to 1 minute, 1 – 2 minutes, 2-5 minutes, 5-10 minutes, 10-30 minutes, 30-60 minutes, 1-2 hours and then over 2 hours. Although it might have been possible to use different bin sizes, there was no clear logic to choosing alternative values.

For the default minimum setting of upright and sitting period of 10 seconds, any events that occurred with durations less than 10 seconds would not be categorized correctly. Therefore as the setting was reduced, the number of events that were less than 20 seconds increased. Although the number of episodes for less than 20 seconds was expected to increase when the minimum setting of upright and sitting periods decreased, it was not known whether the increased was errors caused by the activPAL analysis algorithm, or whether these episodes were real in the free-living data.

The increase in the number of episodes that were less than 20 seconds resulting from changing the minimum time for upright and sitting/lying events would affect the durations of other events to an unknown extent, as it was not known whether this short transition occurred in a previously categorized longer period of activity (e.g. >7200 seconds) or whether it occurred within a shorter period of activity (e.g. 60-120 seconds). There was no general trend for the effect of reducing the minimum setting for upright and sitting period on other duration bins except that of less than 20 seconds. This indicated that the extra periods detected were not systematically within any particular length of bout as characterized with a longer minimum time setting. In addition, when the data was analysed using a minimum setting for upright and sitting period of 3 or 5 seconds, the difference of number of events compared to those analysed using a minimum setting of 10 seconds could not be predicted. For example, an episode of sedentary activity that was 1800 seconds long when using the default setting might contain one or more very short periods of upright activity of less than 5 seconds, thus when analysed with a 5 seconds minimum period would be split into perhaps three shorter duration elements. (e.g. 1800 seconds with the

default setting, the same period of activity might be split into 95 seconds and 1700 seconds of sedentary with 5 seconds upright period, or 600, 600 and 590s sedentary periods and two 5s upright periods). This effect might explain why for some subjects, there were increases in number of events when minimum duration setting changed from 10 to 5 seconds, but then decreased numbers when the setting was changed from 5 to 3 seconds. More than one short transition could occur within a previously categorized long period of posture.

One way to reduce this unknown effect would be to modify the bins so that each bin would be shorter and that the maximum value would not be larger than twice the lower value of that bin so that when a short transition occurred, only one episode would remain in the same bin and the other would fall into a lower bin. This would make sure, when the activity was split into shorter periods, the number of events would always increase in the lower bins and would not split into 2 or more events within the same bin. However, this method would increase the number of bins and there might be no event in some bins.

If it is assumed that all the transitions that were detected using the 3s setting were real then it must be considered that this setting was the best to use for the free-living data. It is difficult to say if a setting less than 3 seconds would have been better as this might have lead to erroneous interpretation of the data. A possible way to validate the effect of changing the minimum upright and sitting threshold for free-living monitoring was to video record each subject's activity patterns during their daily lives. However this would have been extremely time consuming and a large amount of data analysis would have been required. Furthermore, subject's activity patterns might not be true when an observer was noting down their daily life activities.

6.5.4 *Number of sit-to-stand transitions*

Although there was no general relationship seen between mobility level and number of average daily sit-to-stand transitions per day, it appeared that there was a 'threshold' number of sit-to-stand transitions of approximately 40 per day, indicating functional task performances only such as toileting and bathing. There was however four younger subjects (subject 1, 3, 5 and 6) who performed over twice the number indicating engagement with additional discretionary activity. From Figure 6.9, it could be seen that generally younger active subjects with CP (aged 5 to 7) performed higher number of sit-to-stand transitions, which might be indicating younger children's play behaviour. However, if their mobility is

reduced, the average number of sit-to-stand transitions per day might reduce to functional task performance only.

Short bouts and spontaneous activities might represent young children's activity pattern, however when a child grows, this characteristic of activity pattern might change with less short bouts and spontaneous transitions between activity states, hence decreasing the number of transitions as age increases.

The less active younger household walkers performed similar sit-to-stand transitions compared to the older active community walkers. For the age range in this study, all subjects were required to go to school during week days, which would be included in their daily activity routine. Subject 15 and 17 worked after school during certain days of the week, hence this information has to be taken into account when analysing the data, as rigid lifestyle might influence free-living physical activity level.

6.5.5 *Activity patterns of people with CP using activPAL with diary*

By combining the activPAL results with the diary, it could be seen that the more active subjects usually carried out some form of outdoor sporting activities, such as football (subject 3, 10, 15, 17 and 18). The less active household walkers were limited by their mobility, hence could not take part in many sporting activities, which were confirmed by their diaries (e.g. subject 2, 8, 11, 14 and 19). Subject 11 and 14 required a walking frame for stepping activities and usually used a wheelchair for mobility in the community. Subject 8 also used a wheelchair for long distance community travel. Subject 2 normally stayed at home during leisure times, indicating household activities rather than long periods of stepping episodes. Subject 19 was 17 years old and preferred to stay at home and did not do any outdoor activities, apart from travelling to school on the bus.

Although all subjects were of school aged, their weekly activity pattern would include school days, but part or all of the monitoring weeks for subjects 2, 6 and 11 were during the holidays, hence their activity patterns might have been different compared to the normal school week. This information has to be taken into consideration when assessing their free-living activity levels and such information would be missing if the activPAL was the only method used for monitoring free-living activity levels.

Without the addition of a diary, information such as reasons for fewer activities on certain days would not be revealed. For example, subject 15 went paint balling on Saturday but did not wear the activPAL as he was worried that it might fall off, hence no activity was recorded for that day. The subject then stayed at home on the following day to relax after a full day of activity the previous day. However, with activPAL information alone, it showed that the subject was less active over the weekend. Subject 17 stated he was less active because of injuries, hence less badminton was played during the monitoring week compared to his normal week.

Nonetheless, some activities such as playing football and snooker were correctly identified by the activPAL algorithm, where high cadence stepping periods were seen while playing football (subject 3, 10, 15, 17 and 18) and standing periods with occasional stepping activities were recorded for snooker playing (subject 15).

Only 2 full days of results were found for subject 11, which was due to the activPAL being placed inside a washing machine by mistake on the evening of the third day of monitoring. The activPAL stopped automatically and saved the recorded data. Although the subject wore the device again after the incident, no additional data was logged.

With the activPAL recordings alone, some information might be missing such as times at which the device was not worn but activities took place (e.g. swimming for subject 5 and 18) or activPAL misclassified the active events such as cycling (subject 5), horse riding (subject 12) and wheelchair tennis (subject 12). ActivPAL results showed horse riding and wheelchair tennis as continuous sitting/lying events, while cycling was classified as either standing or sitting/lying episodes. These types of misclassification indicated limitation for the activPAL. It was also not possible to monitor upper limb activity levels and activities performed in a seated posture.

Some movements performed by people with CP might not be registered by the activPAL (e.g. compensatory or coping strategies such as crawling and moving around on the knees) even though these allowed change of location. It was noted from the validation study that subject 14 had limited mobility and required to be lifted between activity states, for example from wheelchair to walking frame, and these lifting movements would have been classified as sit-to-stand transitions. However no work was done by the subject himself for the change in posture.

The diary revealed that sometimes subjects did not wear the activPAL for either a whole day (e.g. subject 6) or just part of a day (e.g. subject 7, 10), as these subjects forgot to put the monitor on. Subject 2 did not want to wear the device at school indicating compliance issues with device wear. Subject 8 only had one full day of activPAL data, as he did not want to have the activPAL attached to his leg. This subject had cognitive difficulties and required longer periods to accommodate changes. When this subject visually noticed the activPAL device on the third day of monitoring he took it off and did not want to wear it again. Hence only one complete day of data was collected with 2 half days for the first and third day.

It was noted that sometimes the activPAL was placed incorrectly even though full instructions on its placement were given to each subject and their parents. It was seen that for subject 12, even though the subject's diary revealed the use of the activPAL, no activity data were recorded for day 3 and 5 during the free-living monitoring. It was assumed that this was a result of placing the monitor upside down. If the device was placed upside down, sitting/lying events would have been registered throughout the recording times. It was not possible to automatically tell when the activPAL was being worn. It was necessary to use the diary to ensure that wear times were correctly identified. Examination of the activPAL output could be used to identify very long periods of non-compliance, but short periods when the monitor was not worn could not be identified from the output data as these could have been genuine sitting/lying times. A number of the subject demonstrated poor levels of compliance with monitor wear (subjects 2, 6, 7 and 10).

A possible way to overcome misplacement of the activPAL was to place the device inside a discrete pocket of a tightly fitted pair of shorts. This would remove the problem of incorrect attachment of the activPAL and also other people could not see the device and no contact of the skin would be required. However, people might still forget to put on the shorts in the morning and compliance would still be an issue.

Limitations to diary reporting alone

Each subject was asked to write a simple diary/timetable of the activities they performed throughout the monitoring period. Apart from subject 1 who forgot to complete a diary/timetable of activities, all subjects posted back their timetable of activities along with the activPAL device after the monitoring period. Although verbal instructions were given to each subject and/or their parents for recording information onto the timetable, the

contents of the diary for each subject varied in its quantity and quality. Some subjects only wrote down the time the activPAL was attached or took off or days at which they wore the device, while others wrote down more detail such as events broken down hourly. Appendix VI shows an example of activPAL data with annotated notes from each subject's diary/timetable.

Some methods for diary reporting require the subject to write down extensive details of daily activities in 10 minutes intervals with the type of activity (e.g. occupation, sport, walking, house/yard, inactive, personal care, transportation); a brief description; estimated intensity (low, medium or high); position of activity (lying, sitting, standing or moving around); and time spent (Eason et al 2002). This type of diary reporting would be very time consuming and subjects might not be compliant in including all details. Other studies relied on subjects to rate the intensity of their activity level using a numeric activity code such as the Bouchard activity diary (Bouchard et al 1983). For this method, subjects might be biased or over-exaggerate intensity of all active periods.

The timetable/diary given to each subject in this study was broken down into hourly event, so that subjects/carers would not be required to spend excessive amounts of time completing the diary each day and they were only asked to write down brief descriptions of the activity performed, as this would provide information on the posture and activity intensity for comparison with the activPAL data. However, the information obtained varied greatly between subjects with valuable information only collected for some subjects.

Limitations to activPAL monitoring alone

People with CP have a wide range of gait abnormalities that are different between individuals, and each individual may have their own coping strategies to overcome their mobility difficulties. Activities such as moving around using their knees (kneel walking) and crawling might not be categorized appropriately by the activPAL algorithm, even though functional movement is achieved and high levels of energy might be expended during these actions. In addition, it is commonly observed that children tend to engage in a wider range of 'activities' than adults, such as jumping, skipping and hopping during play. Although the activPAL was found to reliably categorize activity into sitting/lying, standing and walking for people with CP, it would be best to develop the activPAL algorithm further in order to include a wider range of activities, so that an accurate representation of daily physical activities could be monitored for this group of people.

It might be difficult to interpret the data if the activPAL was only worn for part of the day, as it might be mistaken that the subject was inactive (sitting/lying events only) for long period of time, but in fact the activPAL was not worn at all. Information from a diary would be useful to exclude these data for which the activPAL was not worn.

The periods for which the device was not worn might be identified from the activPAL data where continuous sedentary or quiet upright events were seen. However, it would be difficult to note a specific cut-off point for non-wear periods. For example, a subject could be sleeping during the day if not feeling well, which would lead to long sedentary periods during the day time when activity was expected, but on the other hand this long sedentary period might be due to the device not being worn for part of the day. Therefore it would be difficult to find out non usage of the monitoring device and this might contribute to errors in the data analysis process.

6.5.6 *Summary*

The activPAL could provide information on activity patterns for people with CP in their free-living environment and could be used to distinguish the more active ‘community’ walkers from those limited ‘household’ walkers. However, some activities such as cycling, crawling, moving with knees and falls might not be classified by the activPAL data analysis algorithm. Furthermore, activities such as swimming and wheelchair tennis would be shown as inactive periods as the activPAL would classify these periods as sedentary events.

Compliance issues were also noticed as some subjects did not wear the device on certain days so that 24 hours of sedentary activity was recorded. There was also indication of misplacement of the device. Fitting the monitor inside a discrete pocket of a pair of tightly fitted shorts might reduce these compliance problems.

The subjects’ activities were often in short bouts, which could be seen in the analysis of sitting and upright durations. A large number of events occurred for less than 20 seconds in duration, showing the short bouts of activity performed by the children. It was shown that short bouts of activity could only be seen in the more active subjects with CP, those who were less active spent longer time in each posture perhaps indicating their reluctance or inability to perform transitions between postures.

There was no clear relationship between laboratory based cadence or questionnaire derived mobility score and free-living physical activity. These results indicate that a typical gait laboratory assessment does not allow full characterization of mobility and could not predict free-living physical activity level. It is therefore desirable to include objective free-living monitoring as a component of typical mobility assessment to provide evidence of actual daily mobility of each subject.

By using a diary in addition to the activPAL, a better understanding of the results could be achieved as some information could not be seen with the activPAL data alone. Furthermore, a short description of the monitoring week would also provide additional information such as the general health of the individual, as a person might be less active with an illness (e.g. cold or flu). This information could not be found by the activPAL results alone.

Information gained from the diary may have been subjective and dependent upon memory if it was completed at the end of each day, possibly leading to errors in reporting, but this information still provided some useful insight and provided useful information for interpretation of the activPAL data. Hence standard diary reporting method should have been used in conjunction with activPAL to achieve full detailed free-living activity of people with CP.

The results of this study indicate the wide range of physical activity levels exhibited by this population of subjects and highlights the importance of device software parameter settings on signal interpretation outcomes.

The information gained on the daily activity levels of subjects with CP, especially for the monitoring of pre- and post-intervention physical activity levels obtained from an activPAL device could provide invaluable insight into the efficacy of the treatment and the rehabilitation progress of the individual. The level of mobility in a free-living environment could also aid clinicians in decision making towards the most appropriate treatment planning.

7 AMPUTEES STUDY – ACTIVITY MONITORING FOR TRANS-TIBIAL SUCTION SOCKET USERS

7.1 Introduction

The goal of rehabilitation for amputees is to foster a rapid return to activities of daily living, including the ability to walk and independently perform social and physical tasks. In order to achieve this goal, a comfortable, effective and easy-to-use prosthesis is essential. Currently, observations and gait analysis are carried out in gait laboratory environment for capability based assessment to determine rehabilitation progress. However, this is time consuming and does not give an insight into the day-to-day activities of amputees within the environment they live. Questionnaires (Rommers et al 2001, Leung et al 1996, Panesar 2001) are sometimes used to establish amputees' quality of life. Nonetheless, the use of questionnaires is subjective and there is a lack of free-living monitoring devices which can quantify the amount of prosthetic use and activity levels of amputees. Therefore, device development must be undertaken to allow the quantification of prosthetic use, giving insights into the rehabilitation progress of amputees. It is essential to separate those functional wearers from those partial and non wearers in order to determine rehabilitation progress and aid prosthetic prescription and treatment planning.

The fundamental issue addressed in this study was activity patterns during daily living of trans-tibial amputees, characterized by stepping activities and amount of prosthetic usage. There are several types of suspension methods available for trans-tibial sockets, and the best way to achieve suspension varies from person to person, which is influenced by body contours, climate, activity level and personal preferences. One of the commonly used methods is called the suction suspension, which is based on the creation of a seal between the stump and the prosthesis so a partial vacuum is formed, thus atmospheric pressure keeps the socket in place on the stump. The simplest method to create a seal is to apply an external sleeve over the prosthesis which extends from the socket to mid-thigh. Another method of creating a seal against the skin is the use of a roll-on elastomeric liner that fits inside the socket. Once the system is sealed, the one-way valve situated at the distal end of the socket allows air to be expelled during weight bearing, facilitating the development of a partial vacuum such that atmospheric pressure holds the prosthesis securely against the residual limb. Other types of suspension includes those that are based on anatomical contour such as the supracondylar suspension (SC) where the medial and lateral brims of

the socket extend higher and fully encompass the femoral condyles holding the stump itself; and the supracondylar suprapatellar suspension (SCSP) socket, where the anterior, medial and lateral walls are higher, encompassing the patellar and femoral condyles to hold the stump. Straps and the use of metal side hinges are other forms of suspension methods for trans-tibial sockets. The work reported in this thesis focused on trans-tibial amputees using suction sockets as this is one of the main types and widely used suspension method.

Chapter 4.5.1 discussed the different stump/socket interface pressure measurement techniques for the measurement of socket comfort. By determining pressure profile at the stump/socket interface, prosthetic usage and amputees' activity levels could, potentially, be quantified. Distinct pressure patterns are seen during different activities. For suction socket users it was hypothesised that the amount of prosthetic wearing times and activity levels could be quantified by measuring the pressure profile at the suction valve or at the stump/socket interface.

The aim of this study was to develop activity monitoring devices with a general signal analysis algorithm that could describe trans-tibial suction socket usage as well as amputees' free-living activity levels. Hence, clinicians and prosthetists could be able to document the rehabilitation progress of amputees, incorporating changes to the prosthesis when necessary.

7.2 Device development

This project was performed with collaboration from PAL Technologies Limited (Glasgow, UK). Two activity monitors, the pressurePAL and the forcePAL were developed for use with trans-tibial amputees to quantify their prosthetic usage and free-living activity levels. The pressurePAL measured pressure profile at the pressure relief valve and the forcePAL measured pressure profile at the stump/socket interface of trans-tibial amputees. Detailed descriptions of the two devices and the output signal analysis algorithms developed to characterize physical activity and prosthesis wearing times are given in the following sections.

7.2.1 *PressurePAL*

As discussed previously, suction sockets are based on atmospheric pressure, therefore a gauge piezoresistive pressure transducer (24PC Series, RS Components, UK) with its reference as atmospheric pressure, was used as the sensing element to monitor prosthetic usage. Hence atmospheric pressure is recorded as 0psi/Pa. It measured both vacuum and positive pressure in the range of ± 15 psi (103.4kPa), which was within the range (-30 to 70kPa) expected at the pressure relief valve of trans-tibial suction sockets (Beil 2002). The piezoresistive pressure transducer (24PC Series, RS Components, UK) specifications stated that it could provide a highly accurate and linear voltage output, which was directly proportional to the applied pressure. The 24PC Series piezoresistive pressure transducer characteristics are shown in Table 7.1.

Table 7.1: RS Component gauge piezo-resistive sensor (24PC Series) characteristics

Excitation	10V (dc)
Full scale span	Min 165mV , typical 225mv, max 285mV
Pressure range	-15 to +15psi
Input resistance	5k Ω
Output resistance	5k Ω
Linearity	± 0.25 % Span
Repeatability & Hysteresis	± 0.15 % Span
Response time	1ms
Sensitivity	15 mV/psi
Stability over one year	± 0.5 % Span
Operating temperature range	-40 to +85 $^{\circ}$ C

The pressurePAL (Figure 7.1) was a lightweight (approximately 25g) device with dimensions 50x50x7mm, which was designed to monitor trans-tibial suction socket users' activity levels and prosthetic usage. The microprocessor controlled the processing and recording of the sensor signal and communication with a host computer when connected for parameter setting and data download. A sampling frequency of 10Hz was selected to record pressure profile during daily activities, the signal was digitised (8 bits) by internal microprocessors and information stored on the internal memory. The pressurePAL was capable of recording continuously for over 7 days. A custom built serial cable linked the device to the USB port of a computer and the recorded data could be retrieved using the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd). Four files

(.dat, .pal, .cfg and .def) were created from the activPAL professional software. These files contained different formats of the data which could be used for signal post-processing to determine time spent in different activity states and count the number of strides an amputee performed during the recorded period.



Figure 7.1: A photograph of the pressurePAL with the T-piece connector (5p coin of 170mm diameter included to indicate scale)

7.2.1.1 Calibration of pressurePAL

Meaningful interpretation of the pressure recorded by the pressurePAL could only be achieved if the device was calibrated appropriately. Hydrostatic calibration was possible and involved placing the sensor under a column of water. The height of the water column above the sensor would provide an accurate measure of hydrostatic pressure acting on it. To calculate pressure, equation 7.1 could be used, where p was the pressure, ρ the density of the medium, g gravitational acceleration and h the height difference between the sensor and the top of the water column. However, this method was height limited as water has a density of 998.2kg/m^3 at 20°C , therefore with a maximum possible height of 2 metres, the measured pressure was limited to 20kPa (3psi) which did not reach the range (-30 to 70kPa) required for the pressure measurements for trans-tibial suction sockets at the suction valve during ambulation (Beil 2002).

$$p = \rho gh \quad \text{[Equation 7.1]}$$

Mercury with a density of 13524kg/m^3 was therefore used in a U-tube manometer configuration (Figure 7.2) to calibrate the pressurePAL, which was connected to one end of the mercury U-tube (the reservoir side). A syringe was used to introduce air into the system creating a positive pressure leading to a rise of mercury at the open end of the U-tube manometer (Figure 7.2). For negative pressure measurements, the syringe was connected to

the open end and air was extracted from the system. The pressure was increased or decreased from atmospheric in steps of approximately 100mmHg and was repeated 5 times. The height differences, h , between the two mercury levels were noted for each change of pressure, so that pressure values could be calculated using equation 7.1.

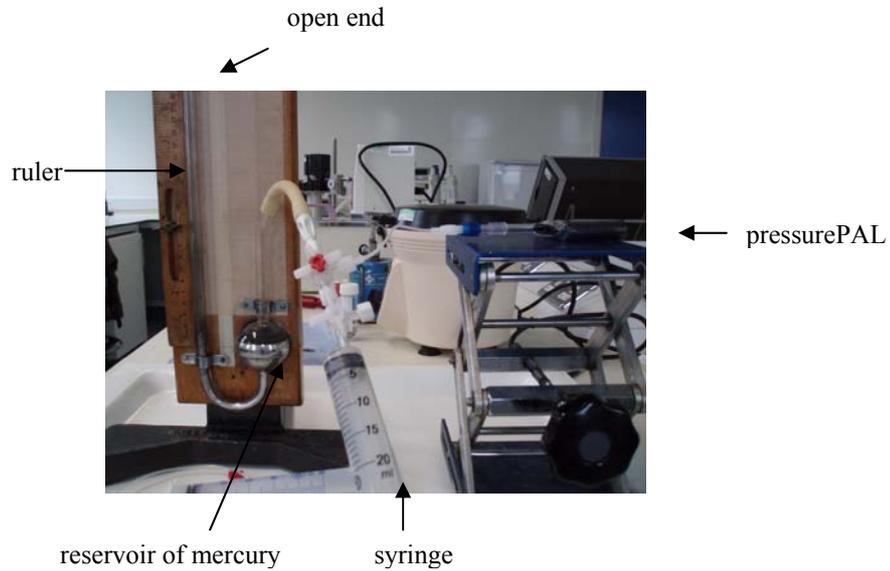


Figure 7.2: U-tube mercury manometer configuration for the calibration of the pressurePAL.

The range of the pressurePAL readings with the corresponding pressure measurements are presented in Figure 7.3. Zero value on the y-axis in Figure 7.3 represents atmospheric pressure, which was the reference for the gauge piezoresistive transducer. Values in the negative pressure range indicated the system was in vacuum creating a suction effect and values above atmospheric pressure indicate positive pressure being applied to the system. A linear relationship was found between the pressurePAL outputs and the pressure values. The calibration equation to obtain pressure value was found to be $pressure = (0.4853 \times PAL_{output}) - 59.43$ with correlation coefficient $r = 0.9999$ indicating a strong positive correlation for the calibration data.

The pressure sensor had an analog output which was sampled by the analog to digital (A/D) converter onboard. The A/D converter used in the pressurePAL was 8 bits, containing a maximum number of 256 values. Figure 7.3 shows saturation of the pressurePAL device before the full range of the pressure sensor was reached, therefore limited by its gain. The maximum range of the pressure recorded on the device before saturation was shown to be

± 60 kPa (10psi) in Figure 7.3, which was within the range required for pressure measurement at the trans-tibial suction valve for ambulatory activities (Beil 2002). By matching the range of the device to the expected signal range the maximum sensitivity could be achieved.

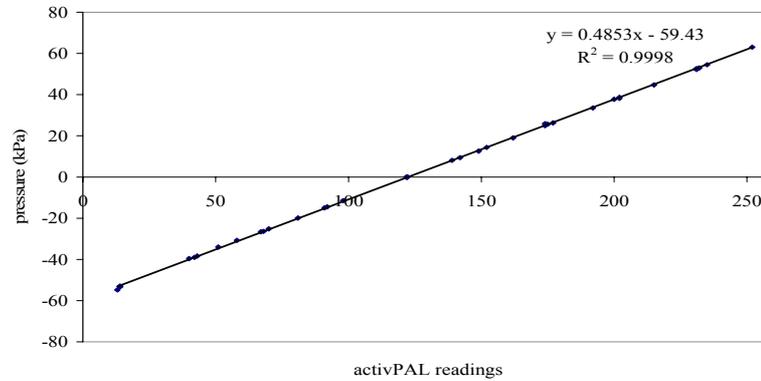


Figure 7.3: PressurePAL readings with the corresponding pressure values in kPa.

7.2.2 ForcePAL

Another activity monitor was developed using a force sensing resistor (FSR), which could be placed at the stump/socket interface to measure pressure profile, hence quantifying prosthetic usage and amputees' activity levels.

The monitor is referred to in this thesis as the ForcePAL. It used a force sensitive element that measured average pressure over the sensor element. For convenience the term 'force' is used to refer to this monitor configuration.

FlexiForce (A201, Tekscan, Boston, MA, USA) was used as the sensing element, which was an ultra-thin, flexible printed circuit that sensed contact force, as the resistance changed inversely with the applied force and the conductance ($1/R$) varied proportionally with the applied force. The FlexiForce sensor was constructed from two layers of polyester film and on each layer, a conductive material (silver) was applied, followed by a layer of pressure-sensitive ink. The two layers were laminated together using adhesive to form the sensor, which acted as a force sensing resistor in an electrical circuit. The FlexiForce, A201 sensor's performance characteristics are shown in Table 7.2.

Table 7.2: FlexiForce, A201 sensor characteristics

Linearity	±5%
Repeatability	±2.5% of full scale
Hysteresis	<4.5% of full scale
Drift	<3% per logarithmic time scale
Operating range	-9 to +60°C

The FlexiForce (Figure 7.4b) used was 8" (203mm) in length, 0.55" (14mm) wide and 0.005" (0.127mm) thick with an active sensing area of 0.375" (10mm) in diameter, hence $7.8 \times 10^{-5} \text{m}^2$.

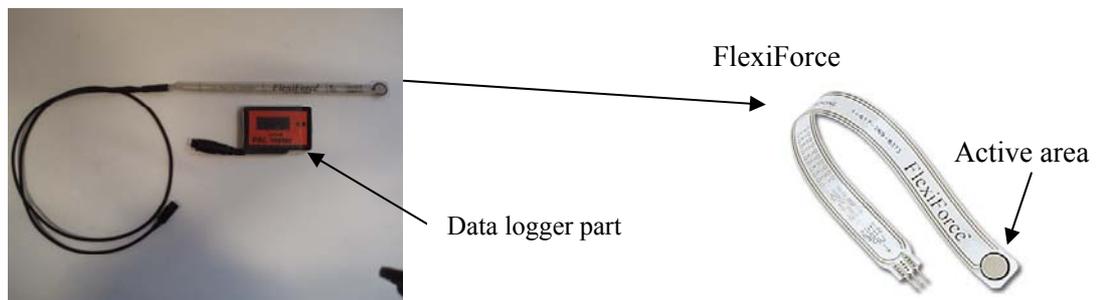


Figure 7.4: ForcePAL with the FlexiForce as the sensing element

The FlexiForce was linked to the data logger part of the monitoring device, which contained the microprocessor that controlled the processing and recording of the sensor signal and the communication with the host computer. A sampling frequency of 10Hz was selected to record the pressure profile at the stump/socket interface during daily activities, the signal was digitised (8 bits) by internal microprocessors and information stored on the internal memory. The combination of the FlexiForce and the data logger was called the forcePAL (Figure 7.4), which was a lightweight (approximately 20g) device with dimensions 50x35x7mm for the data logger part. The forcePAL was designed to monitor trans-tibial amputees' activity levels and prosthetic usage for all socket types. The forcePAL was capable of recording continuously for over 7 days. A custom built serial cable linked the docking station to the USB port of the computer and the device was placed at the docking station for the retrieval of recorded data using the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd). Four files (.dat, .pal, .cfg and .def) were created from the activPAL professional software. These files contained different formats of the data being stored in the internal memory of the device.

The forcePAL could potentially be used with all types of lower limb prostheses to quantify the duration of wearing times and not be limited for use with suction sockets only. The active part of the FlexiForce could be placed anywhere at the stump/socket interface to record pressure profile during different activities.

The suitability of the FlexiForce for low interface pressure measurement was evaluated by Ferguson-Pell (2000) demonstrating that the sensor had acceptable static loading drift, repeatability, linearity and hysteresis for measurement of low interface pressure such as might occur at the stump bandage interface.

Although Ferguson-Pell (2000) suggested that the FlexiForce was best used under static conditions and that the accuracy might be reduced for measurement of force during dynamic events, the FlexiForce was chosen as the stump/socket interface pressure measurement sensor as it provided sufficient accuracy for the purpose of this study to determine postural state of an amputee while using the prosthesis. The FlexiForce provided the range required for the pressure measurement and was simple to integrate with the data logger part of the monitoring device. It was noted that interpretation of the signal could not rely on high levels of accuracy, hence only ranges of signal were used to identify activity/postural status and not the absolute values..

7.2.3 Calibration of forcePAL

The forcePAL was calibrated using a flat bed device which was initially used to calibrate the F-scan socket in the Bioengineering Unit. Dick (2003) used the device to calibrate a FlexiForce based sensor for bandage pressure measurements. The flat-bed device (Figure 7.5) had 2 outlet nozzles, nozzle A which was connected to the mercury manometer and nozzle B was blocked to create a sealed environment. The FlexiForce part of the sensor was placed between the two flat surfaces and bolted down to ensure no air could escape or enter.

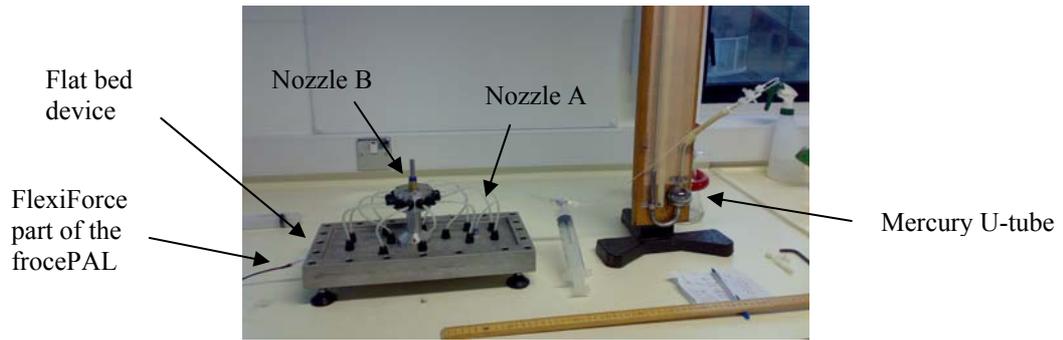


Figure 7.5: Flat bed calibration device connected to the mercury manometer

A syringe was used to introduce air into the system, hence increasing pressure, which would be evenly distributed along an air tight film that applied pressure evenly to the FlexiForce active area and the mercury U-tube. The pressure was increased to 650mmHg and then decreased back to zero in steps of 50mmHg. The height differences between the mercury levels were noted each time a change of pressure was achieved, while the ForcePAL was set to record continuously. This was repeated 5 times.

Figure 7.6 shows the recorded outputs from the forcePAL plotted against the applied pressure (mmHg), the blue data corresponded to the readings for increasing pressure from 0 to 650mmHg and red data corresponded to the decreasing pressure from 650 to 0mmHg. The averages for forcePAL readings for each pressure were found and a linear relationship was apparent (Figure 7.6).

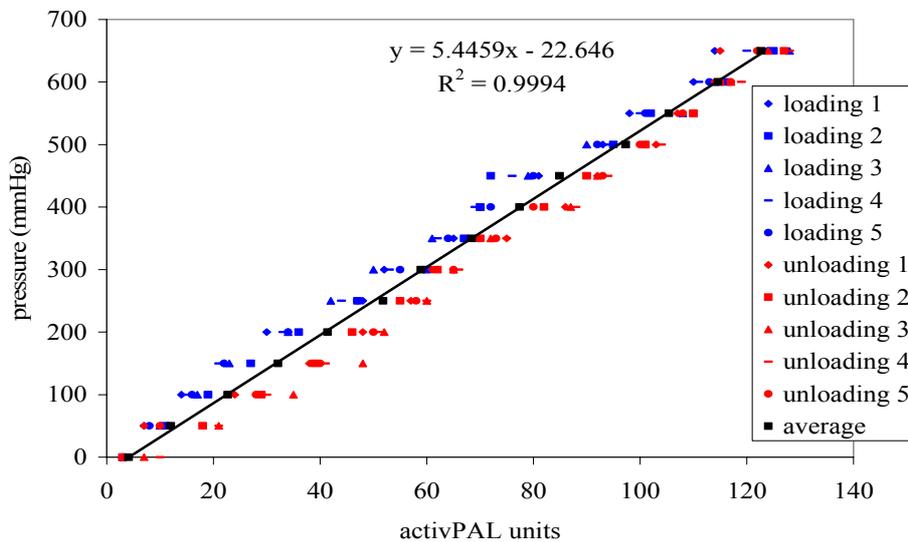


Figure 7.6: Calibration graph – forcePAL readings with the corresponding pressure values (mmHg).

The calibration equation to obtain pressure value in mmHg for any forcePAL unit was found using the following equation:

$$pressure(mmHg) = (5.4459 \times PAL_{output}) - 22.646$$

with correlation coefficient $r = 0.9997$, indicating a strong positive correlation between the two data sets. Pressure measured in mmHg was converted to kPa or psi (1mmHg = 0.133kPa = 0.0193psi).

The maximum height of mercury for the calibration study of the forcePAL was set at 650mmHg as the peak stump/socket interface pressure measured by Beil et al (2000) was 85kPa (640mmHg) The range of pressure calibration was set within the range required for pressure measurement at trans-tibial stump/socket interface during ambulation activities.

Hysteresis

From Figure 7.6, it could be seen that the FlexiForce exhibited the characteristic of hysteresis. Hysteresis was calculated from the largest difference in the readings between increasing and decreasing output values at the same applied force and divided by the maximum output reading in the range of loading. It can be seen that the FlexiForce had a high degree of hysteresis. The maximum difference in the output reading between increasing and decreasing forcePAL output for the same applied pressure was ± 16 PAL unit on average, with the percentage hysteresis being higher for lower pressure measurements.

Drift

Drift was tested by taping the FlexiForce part of the sensor securely to a flat surface, and a constant weight was applied to the active area for 60 minutes continuously. The forcePAL reading was noted every 5 minutes. The weight was made of brass with a diameter of 10mm, which was the same as the FlexiForce active area, and weighed 366g, which was equivalent to 45.7kPa (343mmHg).

Table 7.3 shows the recorded forcePAL units with corresponding pressure in kPa for the drift test that was noted every 5 minutes for one hour. When the constant force was applied to the FlexiForce, small random drift occurred as no pattern for the drift was noted.

Table 7.3: The recorded forcePAL unit with correlated pressure data for the drift test using the FlexiForce as a pressure sensor.

Time (min)	Applied pressure (kPa)	forcePAL unit	Recorded pressure (kPa)
0	45.7	60	40.41
5	45.7	62	41.86
10	45.7	68	46.20
15	45.7	68	46.20
20	45.7	66	44.76
25	45.7	67	45.48
30	45.7	68	46.20
35	45.7	63	42.58
40	45.7	68	46.20
45	45.7	67	45.48
50	45.7	66	44.76
55	45.7	67	45.48
60	45.7	69	46.93
Mean	45.7	66.08	44.81
(std)		(2.72)	(1.97)

The forcePAL provided the means of measuring the interface loading between the prosthesis and the stump. The calibration indicated that there might be considerable error present in the output signal from the forcePAL being affected by hysteresis and drift. This measurement solution provided a relatively simple means of measuring interface loading, but its use required the acceptance of errors in the signal output.

7.3 Laboratory based validation study

The first part of the study was to perform a laboratory based validation of the pressurePAL and the forcePAL as activity monitoring devices for trans-tibial suction socket users and to establish whether generalised algorithms for data analysis could be used to categorize activity events and count strides. The second part of the study (reported in subsequent sections) was to quantify trans-tibial amputees' activity level and prosthetic usage in their free-living environment.

The use of video recording provided visual identification of posture and stride count. This video record was used to inform the interpretation of the synchronised pressure profiles to

allow physical activity classification. Features of the pressure profiles that were repeatable within and across the subjects studied were used to characterize activity. A general data analysis algorithm for each monitoring device was developed to interpret the data and to automatically categorize activities and count strides. The accuracy and reliability of the signal analysis codes were explored using a comparison with video data, which acted as a 'gold standard' for activity categorization and stride count.

It was hypothesised that a general data analysis algorithm for each monitoring device could be developed that would accurately categorize activities, detect strides and quantify prosthetic usage, hence providing useful free-living activity data to document trans-tibial amputees' rehabilitation progress.

7.3.1 *Subjects*

Prior to data collection for the validation study, ethical approval was granted through the University Ethics Committee and written, informed consents were obtained from all participants who took part. Selection of subjects with trans-tibial amputation was based on a number of criteria. Only those subjects who had been an amputee for at least one year, with a prescribed prosthesis and good stump condition were selected. They were able to perform all activities comfortably including stair climbing. The use of walking stick by subject 4 was the only support used by any of the subjects. All other subjects were able to perform activities with no requirement for additional support.

10 trans-tibial amputees (Table 7.4) participated in this study, which was carried out at the Human Performance Laboratory, Bioengineering Unit, University of Strathclyde. The mean age of subjects was 57 years old and all were unilateral trans-tibial amputees except for subject 3 who was a bilateral trans-tibial amputee. All 10 subjects took part in the pressurePAL validation study and only 8 subjects (Sub 1, 2, 3, 5, 6, 7, 9 and 10) participated in the forcePAL validation study. Subject 4 and 8 did not participate in the forcePAL validation study because the device was not available during those sessions due to malfunction (damage).

Table 7.4: Amputee subjects' information

Subject number	Age	Sex	cause of amputation	Years since amputation
1	32	M	trauma	7
2	47	F	tumour	4
3	49	M	vascular	9
4	55	M	vascular	10
5	56	M	trauma	15
6	59	M	trauma	27
7	60	M	trauma	11
8	63	M	vascular	2
9	71	M	vascular	14
10	76	M	vascular	11

7.3.2 Methods

Each subject was required to visit the Bioengineering Unit at least twice. On their first visit, casting of the residual limb was carried out, so that custom suction sockets could be made. Each suction socket was fabricated following normal procedures with an air expulsion adaptor fitted to the standard centre hole and a valve to allow air expulsion, but prevent air ingress during unloading.

Subjects tried on their custom made suction sockets at their second visit to the Bioengineering Unit and necessary alignment and adjustments were performed until they were comfortable with the prosthesis. If subjects did not feel comfortable with the custom made suction sockets, they were asked to revisit after further alterations were carried out to the socket.

Testing of the monitoring devices did not take place until subjects had familiarized themselves with the prosthesis and felt secure and comfortable walking with the artificial limb. This usually took approximately 5 to 15 minutes.

When the subject was comfortable with their custom made lower limb prosthesis, the pressurePAL or the forcePAL was attached to the socket. Subjects were then asked to don the prosthesis in their usual manner and to perform activities such as sitting, standing, walking in the laboratory, stair ascending and descending, doffing of the prosthesis and

sitting without the artificial limb for different lengths of time while they were being video recorded. The testing of each device did not last longer than 1 hour and participants were allowed to rest as required during the session and resume when they were ready. The durations of each activity were dependent upon the capability of each individual as some subjects required to rest for longer period after walking episodes.

On the completion of each testing, the pressurePAL/forcePAL was removed from the socket and the data was downloaded directly to a computer using the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd).

7.3.2.1 Attachment methods

The pressurePAL was attached securely to the prosthesis and connected via plastic tubing to the pressure relief valve with an additional T-piece connector (Figure 7.7). Any change in air pressure inside the socket adjacent to the valve was therefore detected by the pressurePAL when amputees performed different activities.

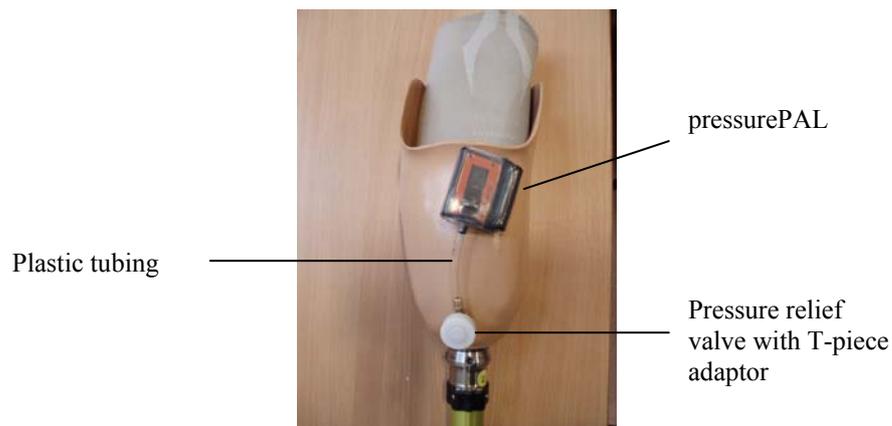


Figure 7.7: The pressurePAL attached to the pressure relief valve of a trans-tibial suction socket with a T-piece connector and plastic tubing.

For the attachment of the forcePAL, the FlexiForce part of the sensor was attached securely with micropore tapes at the mid-anterior socket/stump interface with no irritation to the subjects. The FlexiForce was connected externally to the main data logger part of the device (Figure 7.8) with a long lead that ran over the anterior socket brim. The main data logger part of the device was attached externally to the anterior of the socket.

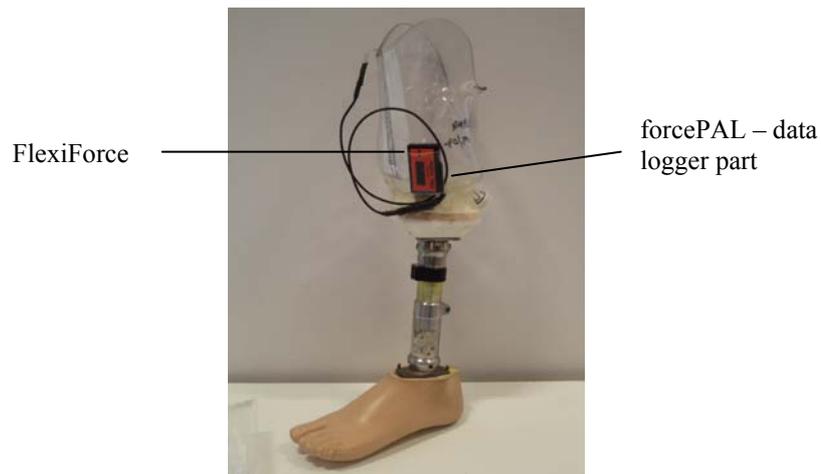


Figure 7.8: Attachment of the ForcePAL to the prosthesis. The lead and data logger were securely attached with tapes over the top during the validation study.

7.3.2.2 Video recordings

A digital video camera (Model GR-DVX509SH, JVC, Japan) was used to provide a visual record of the subject's types of activities and stride counts during the testing sessions. The camera was held by an operator and the zoom was set at its widest angle in order to ensure the subject was in view at all times. Recording started before any procedures took place. On the completion of each testing session the digital video recorder was turned off after the monitoring device was switched off. The video tapes were stored for later analysis.

7.3.2.3 Synchronization

The video and the pressurePAL/forcePAL were not linked therefore there was a need to provide a means of synchronizing the two sets of data. The solution opted for was to set the digital video camera to record first, and then to switch on the pressurePAL/forcePAL in front of the video camera, so that the time at which the monitoring devices were switched on could be noted. The pressurePAL had a visible red light that flashed when sampling began. This red flash was used to indicate time zero on the video data. The forcePAL had a visual indicator which flashed green light 5 times when sampling began, so the last flash on the forcePAL was used to indicate time zero on the video data. For this solution, a small error remained as the time between the red/green flash and the commencement of data recording was still unknown. However, this small error would be consistent throughout all the data sets.

7.4 Free-living multi-days monitoring using the pressurePAL

After the pressurePAL was validated in a laboratory based setting, the second part of the study was performed to determine the efficacy of the pressurePAL data analysis algorithm to categorize activity and count strides for trans-tibial suction socket users over extended periods of time (multiple days). Free-living activity monitoring with the additional information on prosthetic usage could provide clinicians and prosthetists with invaluable insights into amputees' activity patterns and their rehabilitation progress which could aid decision makings towards treatment planning (e.g. training, physiotherapy) and assessment of prosthetic prescription.

Two participants who took part in the validation study (subject 3 and 10) agreed to use their own prostheses with the pressurePAL attached to the pressure relief valve for 7 days, so their free-living activity levels and prosthetic usage could be monitored.

An extra monitoring device, the Long-term Activity Monitor, LAM (PAL Technologies Ltd) (Figure 7.9) was also mounted in the shank element of the prosthesis near the distal end. The LAM is a commercially available accelerometer based device, specifically designed for use with lower limb prostheses to document amputees' stepping activities with the number of strides performed by the individual.



Figure 7.9: Long-term Activity Monitor, LAM (PAL Technologies Ltd, UK)

The LAM is capable of recording continuously and gathering stride information over a one-year period, with graphical overview of daily stepping information once the data is downloaded onto a computer. The use of the LAM in this study provided information on amputees' free-living stepping activities to compare with the stride counts obtained from the pressurePAL during long term monitoring. The LAM was validated by Ross and Reece (2006), who found that the use of information gathered using the monitor together with that from a validated prosthetic evaluation questionnaire could be provide valuable insight into the success of rehabilitation protocols.

In the laboratory, the LAM was inserted into the shank tube near the distal end and the pressurePAL was attached to the pressure relief valve with an additional T-piece and plastic tubing (as described in Chapter 7.3.2.1). Subjects were asked to perform activities as they normally would throughout the 7 days monitoring period and both devices were removed to facilitate data download after the 7 days.

7.5 Data Analysis

The recorded suction socket pressure and stump/socket interface pressure profiles for each subject were downloaded to a computer using the activPAL professional software (version 5.8.1.6), which automatically created 4 files (.dat, .cfg, .pal and .def files).

7.5.1 *Development of the pressurePAL signal analysis algorithm*

The raw pressure signals measured from the pressurePAL were retrieved using the activPAL professional software with the .pal files. The pressurePAL raw pressure data was plotted against time for each subject. An example is presented in Figure 7.10.

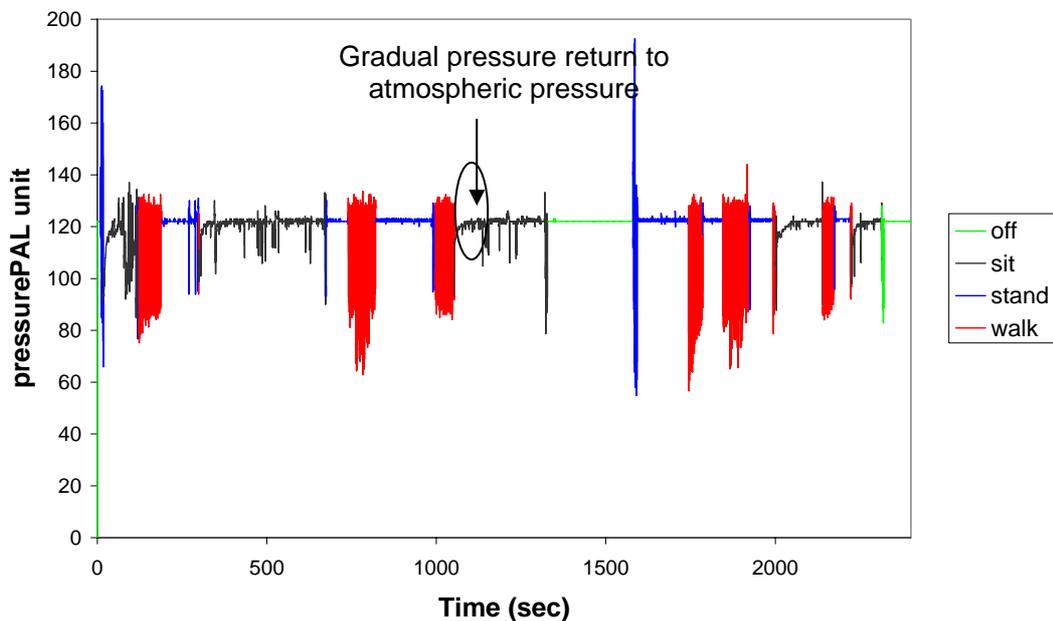


Figure 7.10: An example of a subject's (sub 7) pressure profile performing different activities using a suction socket with the pressurePAL attached.

By inspecting the pressure profiles of each subject with different lengths of time spent in various activities, it could be seen that certain features were consistent across all of the subjects' pressure profiles when compared to the time of each activity found from the video recordings. Constant atmospheric pressure was noted when amputees were not wearing their prostheses and cyclical signals represented stepping activities. The pressure profiles for standing and sitting postures were similar in some subjects, while having some distinguishing features in other subjects' pressure profiles. The pressure profile at the beginning of each sitting episode consisted of repeatable patterns (Figure 7.10) for all subjects except for subjects 1, 3 and 7. This feature is noted in Figure 7.10 as the pressure gradually returned back to atmospheric pressure. This might be caused as the seal between the stump and socket not being complete leading to air leaking out allowing equilibration with atmospheric pressure. The pressure profiles for subjects 3 and 7 did not contain this pattern as pressure immediately returned to atmospheric pressure for all sitting and standing episodes. Subject 1 had distinct threshold levels for sitting and standing events, indicating a strong seal was created and partial vacuum was achieved without leaking of air quickly into the atmosphere. This would be an ideal situation for identifying an appropriate data analysis algorithm, however only one subject had distinct thresholds for different postures.

It was not possible to develop a reliable technique to distinguish between sitting and standing times due to the variability of the signals between individuals. The difference in pressure profile for the sitting and standing episodes between subjects was probably due to the different amount of pressure exhibited at the pressure relief valve by each amputee. Some amputees might not weight bear on their prostheses before sitting down, hence the pressure would return back to atmospheric pressure instantly, without a 'leaking' effect that would be seen in other subjects who would weight bear on the prosthesis before sitting down.

It was observed from examining all the pressure profiles that if an amputee sat very quietly without any stump movement inside the socket, the pressure recorded at the suction valve would be recorded as atmospheric pressure.

It was decided to develop a general data analysis algorithm to determine its sensitivity for quantifying prosthetic usage and amputees' activity level. The need of a customised algorithm for each amputee would not be required if the general data analysis algorithm was sufficiently accurate.

A signal analysis software, Matlab (Student version 7.1, MathWorks Inc) was used to develop a general algorithm that could be used to identify activity levels and prosthetic usage for trans-tibial amputees using the pressurePAL for suction socket users. In order to automatically categorize activity levels and prosthetic use, different filtering techniques (e.g. Butterworth high pass and low pass filter and convolution) and methods such as pattern recognition or wavelet analysis were explored to identify a suitable solution for data analysis. Pattern recognition and wavelet analysis were not chosen because they were complex to perform and furthermore gait patterns for amputees could vary dramatically from individual to individual, leading to the difficulty of identifying a pressure profile to represent a general gait cycle of an amputee. Also, it was thought that a simple method should be employed to reduce processing time. Filtering of data signals was necessary to reduce noise and therefore produce a smoother signal for implementation of any analysis algorithm.

It was difficult to distinguish activities into walking, standing, sitting with and without prosthesis, as the pressure signals after filtering were still similar for standing and sitting periods. However, it was seen that repeatable signal components could be interpreted into period spent in dynamic, static and 'off' periods to quantify prosthetic usage and amputees' activity levels. Walking, including stair ascend and descend, could be classified as dynamic episodes, while standing and sitting with prosthesis could be categorized as static when only small amount of stump movement occurred inside the socket. The time spent when the prosthesis was not worn could be found by identifying periods of constant atmospheric pressure.

Although many filtering techniques had been trialled, a simple and effective way to distinguish between dynamic and static events was to use a moving window to calculate standard deviations, so that high variability in the data was expected for dynamic activities (e.g. walking), and low variability for static events. The Matlab signal analysis program can be found in Appendix IX. A summary of the program control flow is shown in Figure 7.11 with the following descriptions.

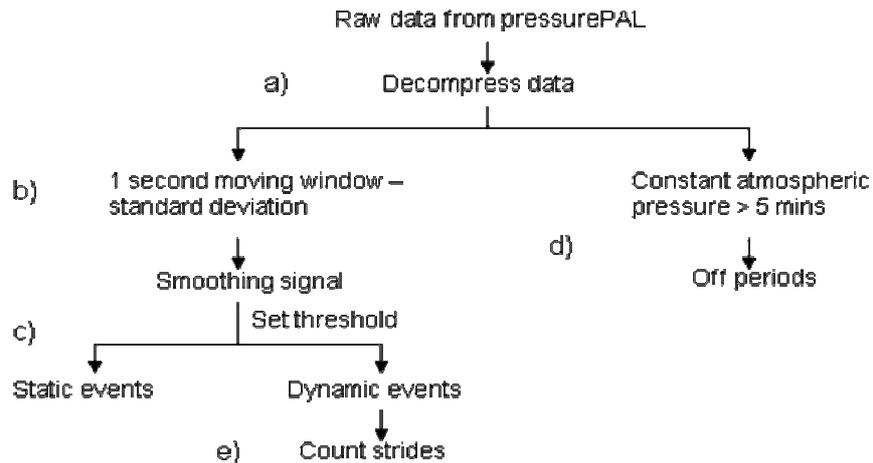


Figure 7.11: Flow chart for the pressurePAL signal analysis algorithm

- a. The Matlab program first read in the .dat file created from the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd). An algorithm was used to decompress the signals, as the .dat files contained compressed raw pressure data.
- b. A 1 second window was moved over the decompressed signal to calculate the corresponding standard deviation for each window, which was then smoothed using a 5 seconds average moving window.
- c. Static and dynamic events were distinguished using a set threshold for the filtered standard deviation signal.
- d. The ‘off’ state was identified by recognising signals that were constant atmospheric pressure for longer than 5 minutes.
- e. Strides were counted by identifying the number of peaks during the dynamic periods identified in (c).
- f. A computer-generated summary of the detected activities was created and saved.

7.5.1.1 Decompressing the raw pressure signals

The Matlab analysis code first read in the .dat files created by the activPAL professional software (version 5.8.1.6). The .dat files consisted of raw pressure signals that were compressed to decrease the number of data points stored in the internal memory of the device. The data had to be decompressed before any post-processing of the signal could be performed. The algorithm for decompressing the data was that when zero was seen in the data set, the value before the zero was repeated, and the algorithm used the number after the

zero for the number of repeats. This method was based on information obtained from PALTechnologies Ltd for their compression algorithm.

7.5.1.2 Categorization of static and dynamic events

A 1 second window (11 data points) was employed to move over the decompressed pressure signal, the standard deviation, for that second, was computed. The function used in Matlab analysis code was ‘movingstd (x, k, window mode)’, where x was the data series and k was the size of the moving window. The function ‘movingstd’ used filter to compute the standard deviation, using equation 7.2 where x represented the data point and \bar{x} was the mean for the data series and n the number of data points. The window mode chosen for this data analysis algorithm was the central window mode, which was a sliding window centred on each point, with k points on each side and the total width was (2k +1). In the algorithm k = 5, so a 1 second window was produced. There was no phase shift with this function and the output contained the same number of data points as the input series and because the total width was (2k+1), therefore 11 data points were included as 10 Hz sampling frequency was used (1 data point correspond to 0.1 second).

$$SD = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}} \quad \text{[Equation 7.2]}$$

The standard deviation signal was then smoothed using a moving average filter and the function used in Matlab analysis code was ‘moving_average (x, f)’, where x was the data series and f was the number of elements on each side of the data point. The function ‘moving_average’ smoothed the data series via averaging each element with f number of data points on each side of it. In the algorithm, f = 50, so a 10 seconds window was produced to move over the data series. Figure 7.12 shows the standard deviation of the pressure signal in grey and the smoothed standard deviation signal in black for one of the subjects during part of the testing session.

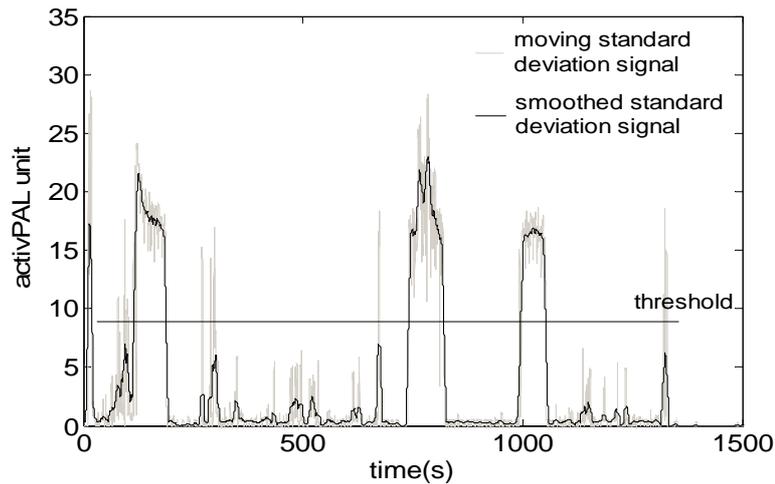


Figure 7.12: Moving standard deviation pressure signal (grey) and the smoothed signal (black) for first 1500 seconds of recording from subject 7 (Figure 7.10). The threshold of the smoothed standard deviation signal is shown to distinguish static and dynamic events.

From Figure 7.12, it could be seen that if the signal was not smoothed by the use of a moving average window, some periods would be classified incorrectly. The variability of the decompressed pressure signal was seen from the filtered standard deviation signal, where high variability was expected during dynamic activities and low variability for static events. A static/dynamic threshold was determined and applied to the filtered standard deviation signals. If the signals were above the threshold, the activity was considered to be dynamic and if it was below the threshold, the activity was deemed static (Figure 7.12). The threshold was determined based on all the pressure profiles. The most suitable threshold appeared to require an element of adaption to the individual. This was achieved by using a multiple of the standard deviation signal. The static/dynamic threshold which was set at $2/5$ of the maximum value for each filtered standard deviation signal.

7.5.1.3 Identify the ‘off’ periods

When the lower limb prosthesis was not worn, constant atmospheric pressure was detected. The algorithm classified ‘off’ periods when constant atmospheric pressure was recorded for over 5 minutes. Periods that were less than 5 minutes would be categorized as static events.

7.5.1.4 Algorithm to count strides

For counting the number of strides within the dynamic periods, initially only one threshold was used but it was seen that there were small peaks that were above the thresholds which should not be counted as strides. The cycles representing strides were not identical and so it was difficult to detect peaks that correspond correctly to each stride by setting only one threshold. Therefore it was decided to set 2 thresholds to count the peaks that would correspond to the number of strides performed, as the signal had to pass through both thresholds.

During the dynamic periods, cyclical signals were seen in the decompressed pressure data. A peak in the cyclical signal that passed through both the lower and upper thresholds was counted as a stride (Figure 7.13) Two thresholds were set so that any small amplitude pressure signal cycles which were probably due to small movements of the stump that were not corresponded to strides would not be miscounted. In some amputees, double pressure peaks could be seen in a gait cycle (e.g. stride 3 in Figure 7.13), similar to forces measured at a ground based force plate during a normal gait cycle. However, other amputees only had one pressure peak corresponding to a gait cycle. Therefore by setting 2 thresholds, the percentage miscount was expected to decrease, hence increasing accuracy for counting the number of strides from the pressure signal. The upper and lower thresholds were decided after all the pressure profiles were investigated for best thresholds to be used.

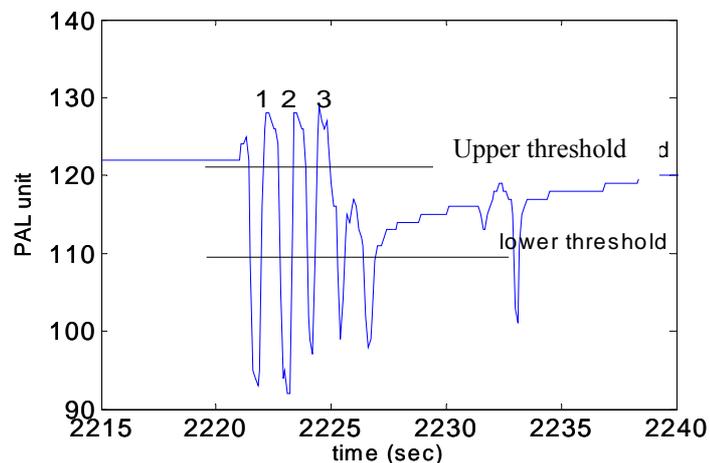


Figure 7.13: Example of cyclical signals representing walking, the number of peaks that pass both upper and lower thresholds were counted as strides by the data analysis algorithm.

7.5.1.5 Activity summary generation

For each subject, the associated activity codes ('off' state = 3, static (sitting and standing) = 4, dynamic (walking) = 5) were created and saved as an activity summary.

7.5.1.6 Summary

The developed signal analysis algorithm was based on visual examination of all of the pressure profiles recorded for the subject group. It was designed to allow static and dynamic event characterization with steps counted and any off periods identified. Although it might have been possible to develop algorithms that were tailored to individuals using some form of calibration process, this was not desired and completely automatic algorithms were developed. The validation of the suitability of the developed algorithm is detailed in the following sections.

7.5.2 *Developing data analysis algorithm for the forcePAL*

The raw stump/socket interface pressure signals recorded from the forcePAL were retrieved using the activPAL professional software with the .pal files. The forcePAL raw pressure data was plotted against time for each subject. An example is shown in Figure 7.14.

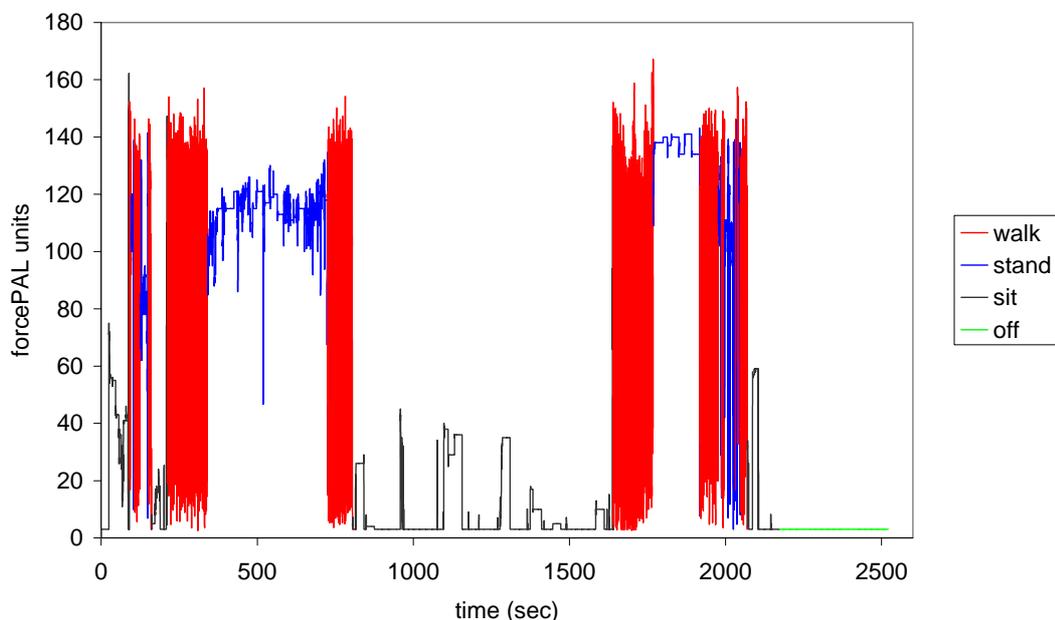


Figure 7.14: An example of a subject's (sub 10) pressure profile recorded using the forcePAL, while performing different activities.

Similar to the pressurePAL data, by inspecting the stump/socket pressure profiles of each subject recorded by the forcePAL, it could be seen that certain features were consistent across all of the subjects' pressure profiles for the different activities/postures when compared to the time at which each activity was performed that was found from the video recordings. Constant zero pressure was noted when amputees were not wearing the prosthesis as there would have been no contact force acting against the sensor at the stump/socket interface. Upright and non-upright events could be distinguished from the different range of forcePAL units as the pressure acting on the FlexiForce was higher during upright activities compared to non-upright events. Within the upright episodes, cyclical signals were seen, which represented stepping activities. By identifying the time at which each stride (heel strike) occurred in the video, it was found that by counting signal cycles, the number of strides could be determined. These repeatable signal components could be interpreted as activity, which allowed automatic detection of walking, standing, sitting and 'off' events to take place.

In order to automatically categorize amputees' activity levels and prosthetic usage, different filtering techniques were explored to identify the best but yet simple solution for data analysis. It was decided that a general algorithm should be developed first to determine its sensitivity for use to quantify amputees' activity levels and prosthetic use. The development of customised algorithms for individuals might have provided improved results, but would have required subject specific calibration. Although many filtering techniques (e.g. Butterworth) and methods such as pattern recognition and wavelet analysis could be used, a simple and effective algorithm using moving window techniques was developed. Pattern recognition and wavelet analysis could only be used to identify walking periods. To use these techniques to identify steps it would have been necessary to have been able characterize a typical stepping signal profile. However, signals generated during gait appeared to vary considerably between subjects making it difficult to identify a single representative wave form representing an amputee's stride..

A custom designed signal analysis code was implemented using Matlab (Student version 7.1, MathWorks Inc) to allow activity categorization and stride counts. The Matlab signal analysis program can be found in Appendix X. A summary of the program control flow is shown in Figure 7.15 with the following descriptions.

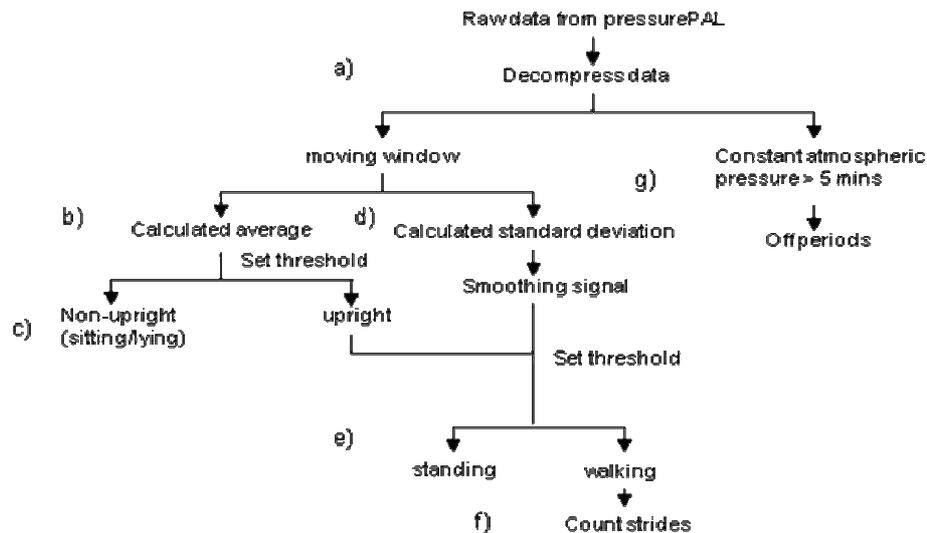


Figure 7.15: Flow chart for the forcePAL signal analysis algorithm

- a. The Matlab program first read in the .dat file created from the activPAL professional software (version 5.8.1.6, PAL Technologies Ltd). An algorithm was used to decompress the signals, as the .dat files contained compressed raw data.
- b. The raw data was passed through a 20 seconds moving window to calculate average of each window.
- c. Upright and non-upright events were distinguished using set threshold for the averaged signal.
- d. The raw signal was passed through a 2 second moving window to calculate its standard deviation (stage 1). The standard deviation signal was then smoothed using a 10 second moving average window (stage 2).
- e. For the upright periods, walking and standing events were separated using set threshold for the smoothed standard deviation signal (stage 2).
- f. The ‘off’ state was identified by recognising signals that were zero constant pressure for longer than 5 minutes.
- g. Strides were counted by identifying the number of peaks within cyclical signals that represented walking activities.
- h. A computer-generated summary of the detected activities was created and saved.

7.5.2.1 Decompressing the raw pressure signals

The Matlab analysis code first read in the .dat files created by the activPAL professional software (version 5.8.1.6). The .dat files consisted of raw pressure signals that were

compressed to decrease the number of data points stored in the internal memory of the device, therefore the data had to be decompressed before any post-processing of the signal could be performed. The algorithm for decompressing the data was that when zero was seen in the data set, the value before the zero was repeated, and the algorithm used the number after the zero for the number of repeats.

7.5.2.2 Categorization of upright and non-upright events

A 20 second window (201 data points) was used to move over the decompressed pressure signal, the mean for each window was computed. Figure 7.16 shows the raw forcePAL signal and the averaged signal for subject 5. The Matlab analysis code was the 'moving_average (x, f)', where x was the data series and f was the number of elements on each side of the data point. The function 'moving_average' smoothed the data series via averaging each element with f number of data points on each side of it, f = 5, while for stage 2, f=100 in the data analysis algorithm.

Figure 7.16 shows the raw forcePAL data and moving average forcePAL pressure data for one of the subject. It could be seen that distinct levels of upright and non-upright events could be determined from the amplitude of the moving average signal. As the amplitude of upright moving average signals varied between subjects, it was decided to use a threshold which was calculated dependent upon the maximum value of the averaged signal. It was found that a threshold set at 1/2.8 of the maximum value of the averaged signal of each subject could be used to identify upright from non-upright episodes. For the moving averaged signal, if data were above the threshold, the activity was considered to be upright (walking and standing) and if it was below the threshold, the activity was deemed non-upright (sitting/lying and 'off).

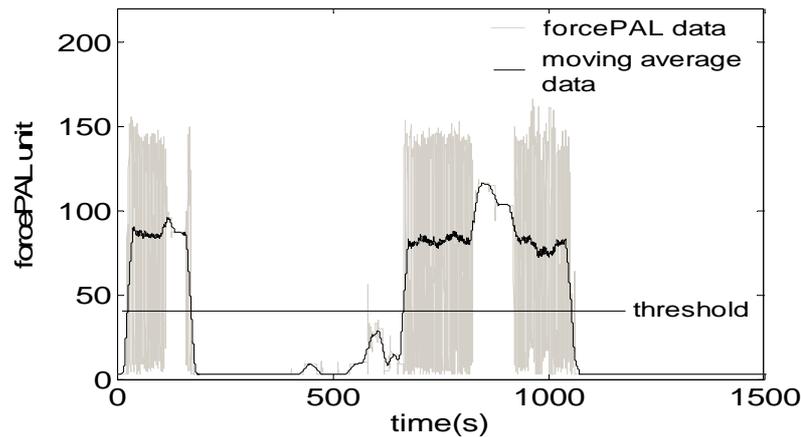


Figure 7.16: Raw forcePAL data (grey), with the moving averaged data (black) for subject 5. Threshold of the filtered moving average signal is shown to distinguish upright and non-upright events.

7.5.2.3 Categorization of walking and standing events

During upright events, it was necessary to separate walking and standing activities. This was accomplished in two states. For stage 1, a 2 second window (21 data points, $f = 10$) was moved over the decompressed pressure signal and its standard deviation calculated. The function used in Matlab analysis code was ‘movingstd (x, k, window mode)’, where x was the data series and k was the size of the moving window. The function ‘movingstd’ used equation 7.2 to compute the standard deviations of each window. The window mode chosen for this data analysis algorithm was the central window mode, which was a sliding window centred on each point, with k points on each side and the total width was $(2k + 1)$. In the algorithm $k = 10$, so a 2 second window was produced. There was no phase shift with this function and the output contained the same number of data points as the input series.

The standard deviation signal was then smoothed using a moving average filter (stage 2) with a 10 second window ($f=50$) with the Matlab code ‘moving_average (x, f)’. Figure 7.17 shows the standard deviation of the pressure signal in grey and the filtered standard deviation signal in black for subject 5.

The variability of the decompressed pressure signal was seen from the smoothed standard deviation signal (stage 2), where high variability was expected during stepping activities and low variability for standing periods during the upright events. A walking/standing threshold was determined and applied to the smoothed standard deviation signals. If the

signals were above the threshold, the activity was considered to be walking and if it was below the threshold, the subject was deemed to be in a standing posture (Figure 7.17). The threshold was set at a fixed level of 22 for all subjects, as this threshold was found to be suitable for all subjects.

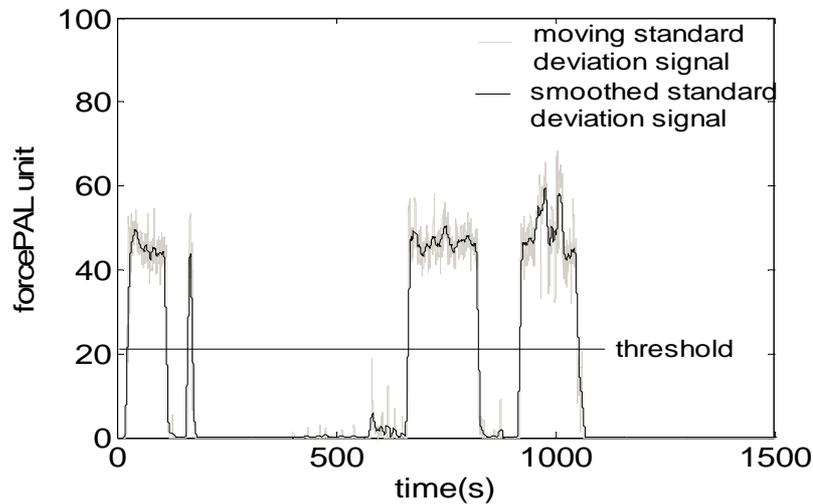


Figure 7.17: Stage 1 moving standard deviation (grey) and stage 2 smoothed (black) standard deviation data for subject 5. A threshold of the stage 2 signal is shown to distinguish walking and standing activities for the upright events.

7.5.2.4 Identify the ‘off’ periods

When the lower limb prosthesis was not worn, no force would be acting on the sensor at the stump/socket interface, hence zero pressure was recorded by the forcePAL. The algorithm classified ‘off’ periods when zero pressure was recorded for over 5 minutes. Periods that were less than 5 minutes would be categorized as sitting/lying events. It was assumed that sitting and lying would produce similar pressure profiles, therefore they were categorized into the same posture. However, lying events were not included in the protocol for the validation study due to laboratory constraints.

Drift occurred for the FlexiForce (see Section 7.2.3), however, when it was tested with no force acting on the active area, the sensor signal remained constant. Hence constant zero pressure would be seen when the prosthesis was not worn, even during longer periods such as during the nights and this characteristic of pressure profile was used to identify times as ‘off’ periods.

7.5.2.5 Stride counts

For counting the number of strides within the dynamic periods, initially only one threshold was used but it was seen that there were small peaks that were above the thresholds which should not be counted as strides. The cycles representing each stride were not identical and it was difficult to detect peaks that corresponded correctly to each stride by setting one threshold. Therefore it was decided to set 2 thresholds to count the peaks that would correspond to the number of strides performed, as the signal had to pass through both thresholds.

The number of peaks in the cyclical signal that passed through both the lower and upper thresholds was counted as the number of strides (Figure 7.18). Two thresholds were set so that any small amplitude cycles which were probably due to small movements of the stump inside the socket, that did not correspond to strides would not be counted. The upper and lower thresholds were decided based on data from all subjects.

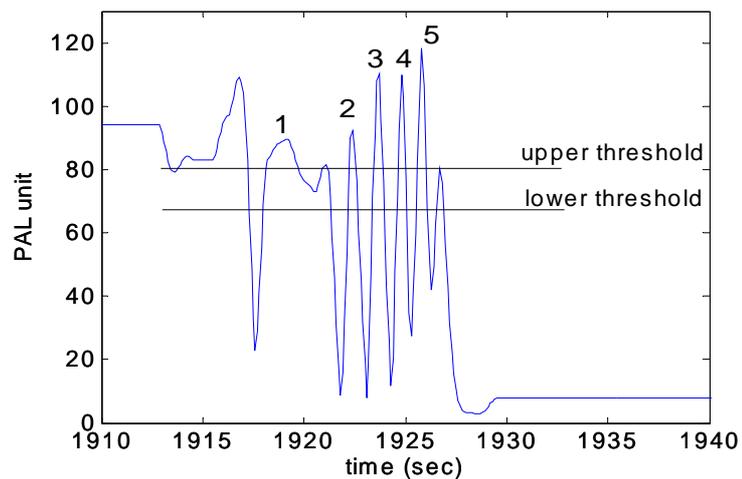


Figure 7.18: Cyclical signal representing walking, number of peaks that passes both upper and lower thresholds were counted as stride by the data analysis algorithm.

7.5.2.6 Activity summary generation

For each data set, the associated activity codes ('off' state = 4, sitting = 5, standing =6 and walking =7) were created and saved as an activity summary.

7.5.2.7 Summary

The forcePAL signal output analysis algorithm was designed to be able to automatically analyse all subjects' data with no requirement for individual calibration. The algorithms were developed to allow characterization of prosthesis wearing times and to divide this into sitting, standing and walking with stride counted. The developed algorithms were then validated as detailed in the following sections.

7.5.3 *Comparing video data to pressurePAL or forcePAL algorithm*

Reference data for the activity status and stride count was obtained using video recording. From the continuous video recording, the initial time for a change in activity was noted with the associated activity code. For the pressurePAL study, the activity classifiers for the video recordings were 0 = 'off' state, 1 = static (sitting and standing) and 2 = dynamic (walking). For the forcePAL study, the video activity classifiers were 0 = 'off' state, 1 = sitting/lying, 2 = standing and 3 = walking. This information was saved as .txt files. The total number of strides that each subject took during the testing session was also counted from the video recordings.

In order to reduce error and misclassification for the analysis of the video data clear definitions of activity state and stride were used:

1. Subjects were classified as sitting only when it appeared that the gluteus muscle region was in contact with the intended seat. When the gluteus muscle region lost contact with the seat, posture was classified as upright, either standing or walking depending on whether a stride was taken.
2. The classification of a stride was made when the artificial limb struck the ground each time after having been lifted from it in the upright posture. Strides were also counted for stair ascending and descending. Each stride was counted at the instance of first contact of the prosthesis with the floor after been lifted from it. (This is equivalent to all counts as stated in the CP validation study.)
3. The time at which a change of activity occurred was noted to the nearest twentieth of a second, which was determined as the start point of the transition in that activity.

An additional Matlab algorithm (Appendix XI) was used to compare the post-processed pressurePAL/forcePAL data with the associated activity codes to the video data (.txt files)

automatically. The Matlab program imported the .txt files for the video data and created continuous time lines with corresponding activity codes. Figure 7.19 and 7.20 are example graphs computed using the Matlab algorithm to compare the post-processed pressurePAL and forcePAL data respectively with the results obtained from the video recordings for activity categorization.

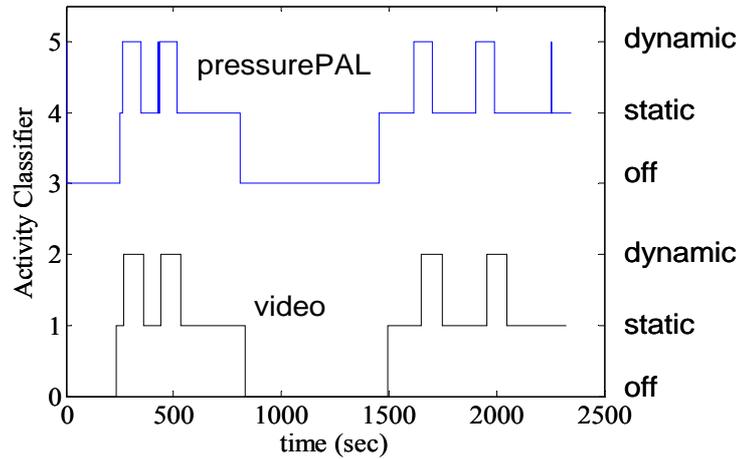


Figure 7.19: An example of video and pressurePAL data using the general Matlab algorithm for activity categorization. For the activity classifier 0, 1 and 2 for the video data and 3, 4 and 5 for the pressurePAL data representing ‘off’ state, static and dynamic events respectively.

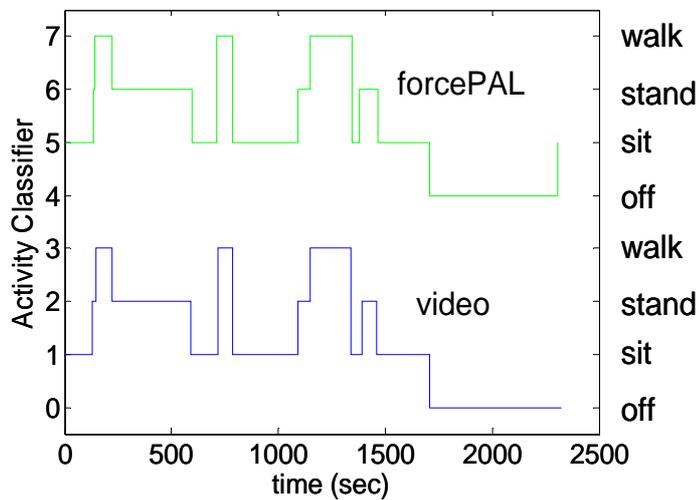


Figure 7.20: An example of the video and forcePAL post-processed data using the Matlab algorithm for activity categorization. For the activity classifier 0, 1, 2 and 3 for the video data and 4, 5, 6 and 7 for the forcePAL data representing ‘off’ state, sitting/lying, standing and walking events respectively.

The total times spent in each activity were found for both the video and post-processed pressurePAL/forcePAL data and the percentage sensitivity and discrepancy for each subject's activity profile were calculated using equations 7.3 and 7.4, which were included in the Matlab analysis code.

$$sensitivity(\%) = \frac{time_{PAL}}{time_{video}} \times 100 \quad \text{[Equation 7.3]}$$

$$discrepancy(\%) = \left(\frac{abs(time_{PAL} - time_{video})}{time_{video}} \right) \times 100 \quad \text{[Equation 7.4]}$$

In equations 7.3 and 7.4, $time_{PAL}$ and $time_{video}$ are the duration of each activity as determined by the pressurePAL/forcePAL and video recordings respectively.

The total number of strides counted from the video recordings was also compared to the computed number of peaks in the pressurePAL/forcePAL signals and percentage sensitivity and discrepancy were calculated using equation 7.3 and 7.4 respectively (time was replaced with count in both equations).

The calculated percentage sensitivities showed whether the pressurePAL/forcePAL over- or under-estimated time spent in each activity or stride count in comparison with the video based classification and the calculated percentage discrepancies showed the accuracy of each device to categorize activity and count strides, which would be easier to compare between subjects.

7.5.4 Data analysis for free-living monitoring

7.5.4.1 pressurePAL data

The free-living pressurePAL recorded data were analysed using the Matlab algorithm (Appendix IX) to categorize activity into period spent as dynamic (walking) events, static (standing and sitting/lying) episodes and 'off' periods when the prescribed prosthesis was not worn. Also the number of strides undertaken by the subject with the artificial limb during the free-living monitoring period was counted. The .dat file from the pressurePAL

was analysed using the Matlab data analysis code and the time spent in each activity per day was found.

7.5.4.2 LAM data

The .dat and .cfg files created from the activPAL professional software were used in a Visual Basic program written by PAL Technologies Ltd (UK) to analyse the LAM data. The program produced a graphical overview of daily walking activity as stride counts per day with associated cadence for each walking episode. The daily stride count was compared to the outcome from the pressurePAL recordings.

7.6 Results – PressurePAL validation study

7.6.1 Activity categorization comparison

The pressurePAL algorithm (see Appendix IX) classified activity into period spent in the ‘off’ state when the prosthesis was not worn, static events which included both sitting and standing activities, dynamic episodes such as walking, and the number of strides taken. For activity categorization, the total time spent in each activity was compared between the pressurePAL algorithm and the video data (Table 7.5).

Table 7.5: Time spent in each activity state found by video recordings and pressurePAL data for each subject

subject	dynamic time (sec)		static time (sec)		off time (sec)		stride count	
	video	PAL	video	PAL	video	PAL	video	PAL
1	374.5	366	1058.1	1087.2	891.2	891.8	299	296
2	548.1	539.6	2488.7	2572.5	228.2	218.3	423	414
3	889.6	872.8	1617.5	1668.1	187	175.1	552	540
4	621.9	682.4	2322.4	2266.5	267.1	266.7	463	482
5	149.2	147.3	3391.2	3399.6	0	0	116	116
6	720	586.4	1974.3	2117.1	1387.1	1302.5	542	404
7	357.3	383.1	1706.7	1723	251.1	251.5	301	309
8	671.2	689.5	2013.8	1987.6	552.2	550.9	451	448
9	443.3	464.6	1445.8	1447.4	280.1	266.1	241	244
10	426.1	390.1	1443.5	1483.7	131.1	126.6	269	278

Additional Matlab code (see Appendix XI) was used to calculate percentage sensitivity and percentage discrepancy for each subject, which are presented in Table 7.6.

Table 7.6: Percentage sensitivities and discrepancies for activity categorization and stride count of each subject

subject number	sensitivity (%)				discrepancy (%)			
	dynamic	static	off	strides	dynamic	static	off	strides
1	93.5	104.2	100.1	99.0	6.5	4.2	0.1	1.0
2	92.2	104.7	95.7	97.9	7.8	4.7	4.3	2.1
3	97.3	103.6	93.6	97.8	2.7	3.6	6.4	2.2
4	107.0	97.9	99.9	104.1	7.0	2.1	0.1	4.1
5	94.5	105.2	N/A	100.0	5.5	5.2	N/A	0.0
6	91.8	102.9	93.9	93.0	8.2	2.9	6.1	7.0
7	106.9	101.0	100.2	102.7	6.9	1.0	0.2	2.7
8	99.4	99.8	99.8	99.3	0.6	0.2	0.2	0.7
9	92.4	103.9	95.0	101.2	7.6	3.9	5.0	1.2
10	91.2	102.9	96.6	103.3	8.8	2.9	3.4	3.3
Average (sd)	96.6 (6.02)	102.6 (2.34)	97.2 (2.80)	99.8 (3.27)	6.2 (2.59)	3.1 (1.60)	2.9 (2.72)	2.4 (2.04)

The pressurePAL data were analysed by a generalised algorithm which classified an amputee's activity into dynamic (walking), static (standing and sitting) and 'off' (prosthesis not worn) periods with average sensitivities of 96.6%, 102.6% and 97.2% respectively for the 10 subjects who took part in this study. The calculated average discrepancies for activity categorization were found to be 6.2%, 3.1% and 2.9% for dynamic, static and 'off' events respectively. No subjects had a percentage discrepancy over 10% for any event categorization. For subject 5, there were no 'off' periods information from the pressurePAL as the device's battery ran out in the middle of the testing session, hence only approximately 20 minutes of pressure data was recorded.

The Matlab algorithm counted the number of peaks within the dynamic periods to correlate with stride counts. The average sensitivity of 99.8% and average discrepancy of 2.4% were found for stride count comparison between the video and pressurePAL data.

7.6.2 Statistical analysis

7.6.2.1 Correlation between pressurePAL and video data

For each subject, the total durations for each activity category from the video and pressurePAL data were computed using the Matlab algorithm. Figure 7.21 shows the correlations between the two data sets for dynamic, static and ‘off’ durations. Correlation coefficient, r , was calculated using equation 7.5, where x and y were video and pressurePAL times for each activity respectively, n was the number of subjects and SD represents standard deviation. Significance test, t , was calculated using equation 7.6 to evaluate whether the association between the two sets of data was apparent.

$$r = \frac{\sum xy - n\bar{x}\bar{y}}{(n-1)SD(x)SD(y)} \quad [\text{Equation 7.5}]$$

$$t = r\sqrt{\frac{n-2}{1-r^2}} \quad [\text{Equation 7.6}]$$

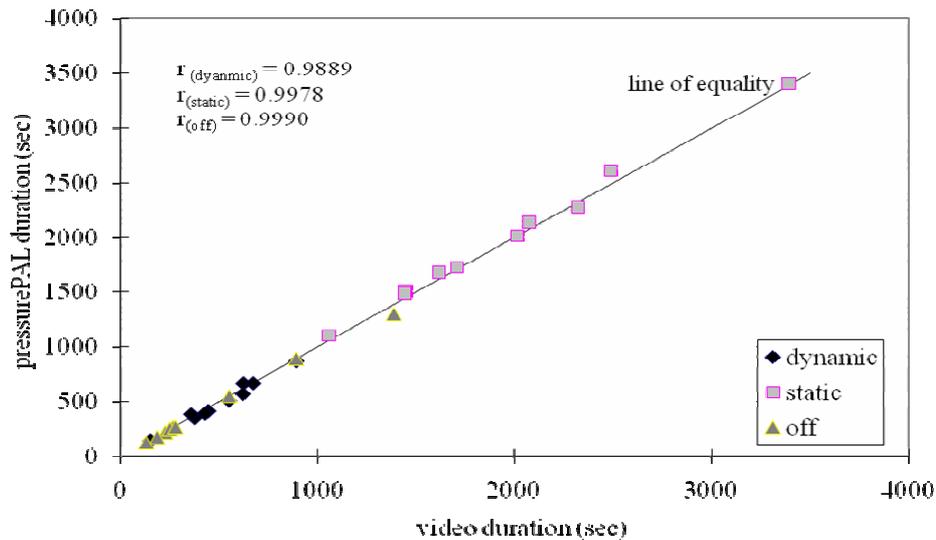


Figure 7.21: Total durations recorded from the video for dynamic (walking), static (standing and sitting) and ‘off’ events plotted against total duration from the pressurePAL post-processed output.

The correlation coefficients r were calculated as 0.9889, 0.9978 and 0.9990, with $t = 18.81$, 42.07 and 63.18 ($p < 0.001$) for dynamic, static and ‘off’ events respectively, indicating highly significant positive correlations between the video and pressurePAL outputs.

Figure 7.22 shows correlation between video total stride counts and pressurePAL stride counts using the Matlab algorithm for the 10 amputees in this study. The correlation coefficient, $r = 0.9950$ with $t = 28.14$ ($p < 0.001$), indicating a strong positive correlation between the two data sets.

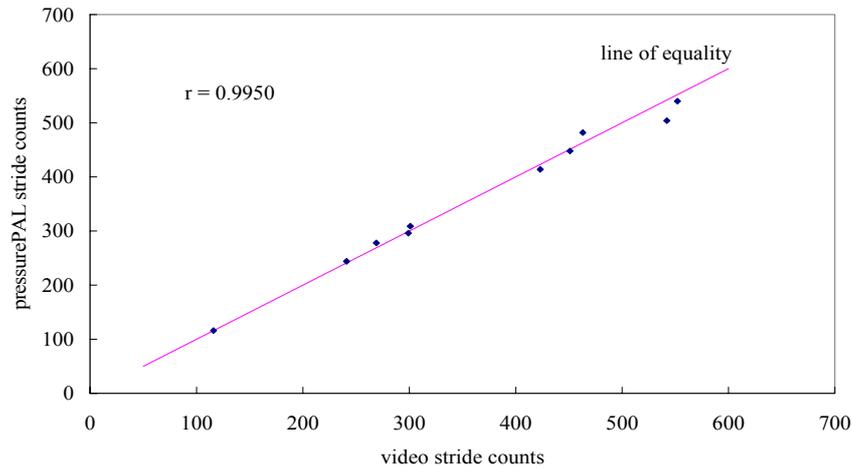


Figure 7.22: The total number of strides found from the video compared with the number of strides computed from the pressurePAL data.

Although all the calculated r values showed highly significant positive correlation between the video and pressurePAL data for activity categorization and stride count, r only measured the strength of relation between two variables, and not the agreement between them. As both video and pressurePAL measured the same variables, they should be correlated. The calculated correlation, r values (Figure 7.21 and 7.22), relates to the fit of data points to lines of best fit and not lines of equality. Perfect agreement between the two data sets could only be achieved if all points lay perfectly on a line of equality. Therefore further statistical tests were required to investigate agreements between the pressurePAL results and video data.

7.6.2.2 Reliability Analysis

The intraclass correlation coefficient (ICC) is a measure of correlation, consistency or conformity for a data set when it has multiple groups (Strout and Fleiss 1979). Reliability analysis was carried out to find the ICC(2,1) using an absolute agreement definition, that was based on a two-way random effects model, with the measuring methods and patients

considered as random variables, which measured agreement emphasizing the interchangeability of the measuring methods. ICC(2,1) was computed using a statistical analysis software, SPSS Statistics (Version 16, SPSS Inc, USA) and an ICC value of ≥ 0.75 was considered to be good and ≥ 0.9 was deemed excellent.

The calculated ICC(2,1) were 0.994, 0.999, 0.999 and 0.997 for dynamic, static, off events and stride count respectively. ICC(2,1) was >0.99 for all activity categorization and stride count, which demonstrated excellent reliability and that the video and pressurePAL measurements were interchangeable.

7.6.2.3 Agreements between pressurePAL and video data

It was hypothesised that although both methods measured the same variables (duration of activities and stride count), they would not agree perfectly, as measurement errors exist in both methods. In addition, time is a continuous parameter and both video and pressurePAL measurements would contain errors in regards to the precise time of event occurrence. However, it was hypothesised that the limits of agreements for the percentage difference between video and pressurePAL data would not be clinically significant.

It was thought that statistical analysis to determine the agreement between the two methods would be more appropriate to identify how much the pressurePAL results might differ from the video data. Agreement between video and the pressurePAL was assessed by comparing the mean value of total time spent in each posture for video and pressurePAL with the percentage difference between the two data sets for each subject. Percentage difference was calculated using the equation 7.6.

$$[\{(pressurePAL\ duration - video\ duration)/mean\ duration\} \times 100\%] \quad [Equation\ 7.6]$$

Figure 7.23 – 7.26 illustrate the level of agreement according to the method of Bland and Altman (1986, 1999) between video and pressurePAL for the total time spent in each activity (dynamic, static, off and stride count) during the testing session. Values above zero represented that the pressurePAL over-estimated the time spent in the activity state and values below zero showed under-estimation of time spent in the activity compared to the video record.

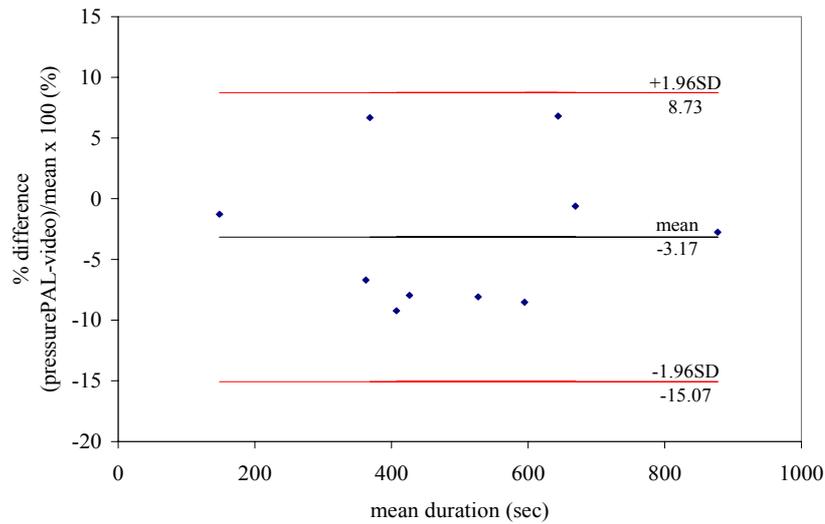


Figure 7.23: Bland-Altman plot for the agreement between video and pressurePAL for the total dynamic durations for all subjects.

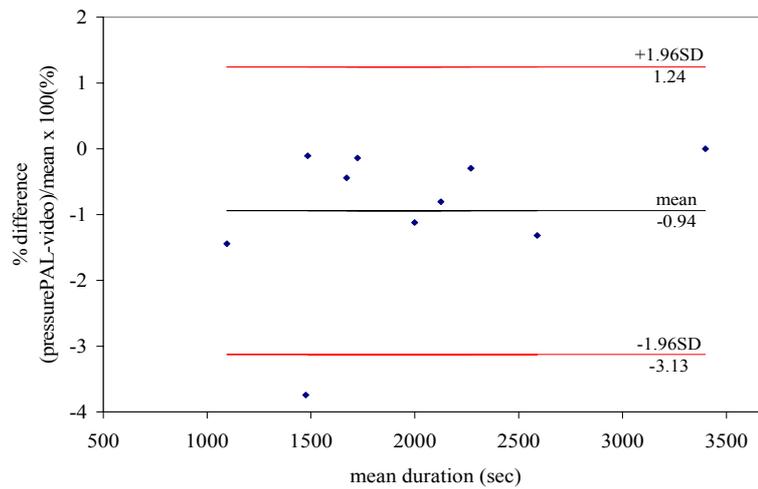


Figure 7.24: Bland-Altman plot for the agreement between video and pressurePAL for the total static durations for all subjects.

From Figure 7.23 to 7.26, it can be seen that the pressurePAL over-estimated for some subjects while under-estimating for others for activity categorization for dynamic classification and stride counts. However, the pressurePAL algorithm under-estimated time spent in static postures for all subjects and also under-estimated time spent in the ‘off’ state for all subjects except subject 7 and 10, which were only over-estimated by 0.2% and 0.1% respectively.

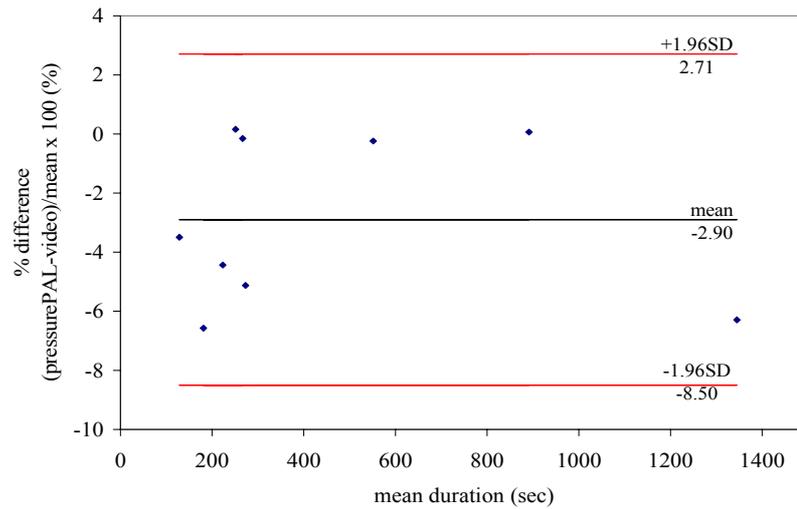


Figure 7.25: Bland-Altman plot for the agreement between video and pressurePAL for the total ‘off’ durations for all subjects.

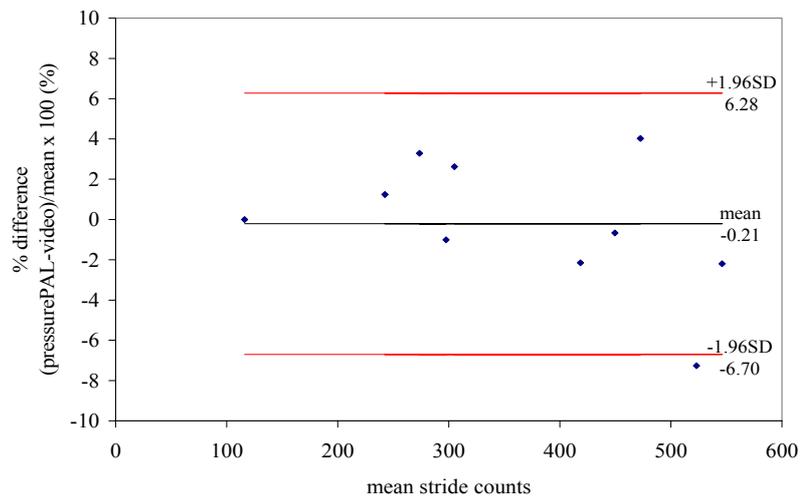


Figure 7.26: Bland-Altman plot for the agreement between video and pressurePAL for the total stride counts for all subjects.

It was assumed that the percentage differences were Normally distributed (Gaussian), hence it would be expected that 95% of the differences should lie between ± 1.96 standard deviation from the mean and these were called the limits of agreement (Bland and Altman 1986, 1999). Table 7.7 shows the calculated limits of agreements with the mean value. The limits of agreements were -15.07 to +8.73% for dynamic events (Figure 7.23), -3.13 to +1.24% for static activity (Figure 7.24), -8.50 to 2.71% for off periods (Figure 7.25) and -6.70 to +6.28% for stride count (Figure 7.26).

Table 7.7: The calculated mean of the percentage difference between video and pressurePAL data and limits of agreement calculated according to Bland & Altman (1986, 1999) for dynamic, static, off and stride counts.

Activity category	Mean (%)	Lower limit of agreement (%)	Upper limit of agreement (%)
Dynamic	-3.17	-15.07	8.73
Static	-0.94	-3.13	1.24
Off	-2.90	-8.50	2.71
Stride	-0.21	-6.70	6.28

However, these limits of agreement were only estimates of the values for this particular set of data. Hence standard error (SE) and confidence intervals were used to determine the accuracy of these estimates. SE was calculated using equation 7.7. The 95% confidence intervals for the bias were calculated using equation 7.8, with 9 degrees of freedom, $t = 2.262$ was found. Hence 95% confidence intervals for the bias were -7.51 to 18.67, -1.74 to 11.48, -4.94 to 16.47 and -2.58 to 10.80 for dynamic, static, off events and stride count respectively.

$$SE(\bar{d}) = \frac{SD}{\sqrt{n}} \quad \text{[Equation 7.7]}$$

$$\bar{d} \pm (t \times SE) \quad \text{[Equation 7.8]}$$

The standard error of the limits (equation 7.9) and 95% confidence interval (equation 7.10) were calculated. Table 7.8 shows the 95% confidence interval for the lower limits of agreement, which were -22.59 to -7.54, -4.51 to -1.74, -12.04 to -4.96 and -10.80 to -2.60 for dynamic, static, off periods and stride count respectively. The 95% confidence interval for the upper limits of agreement were found to be 1.21 to 16.25, -0.14 to 2.62, -0.83 to 6.25 and 2.18 to 10.38 for dynamic, static, off periods and stride count respectively (Table 7.8).

$$\bar{d} \pm 2SD \approx \sqrt{3SD^2 / n} \quad \text{[Equation 7.9]}$$

$$(\text{lower or upper limits} \pm (t \times \sqrt{3SD^2 / n})) \quad \text{[Equation 7.10]}$$

Table 7.8: The 95% confidence interval for the lower and upper limits of agreement for all activity categories.

Activity Category	95% CI for Lower limits agreement (%)		95% CI for Upper limits of agreement (%)	
	Lower value	Upper value	Lower value	Upper value
Dynamic	-22.59	-7.54	1.21	16.25
Static	-4.51	-1.74	-0.14	2.62
Off	-12.04	-4.96	-0.83	6.25
Stride	-10.80	-2.60	2.18	10.38

7.7 Results – ForcePAL validation study

7.7.1 Activity categorization comparison

The forcePAL algorithm (see Appendix X) classified activity into four categories – walking, standing, sitting/lying and ‘off’ states (when the prosthesis was not worn). The algorithm also counted the total number of strides performed with the prescribed prosthesis. For activity classification, the time spent in each activity was compared between the forcePAL and video data (Table 7.9).

Table 7.9: Time spent in each activity state found by video recordings and forcePAL data for each subject

subject	walk time (sec)		stand time (sec)		sit time (sec)		off time (sec)		stride count	
	PAL	video	PAL	video	PAL	video	PAL	video	PAL	video
1	687.8	701.4	436.3	471.6	1353.4	1319.1	869.0	841.2	474	444
3	406.5	381.0	139.6	151.1	520.6	521.3	869.1	871.0	254	237
5	292.6	302.8	148.0	161.0	408.0	390.4	1046.1	1033.0	205	201
6	547.9	561.3	207.2	198.1	993.5	991.4	343.7	341.1	331	357
7	720.9	714.2	706.6	696.7	928.0	904.3	580.4	603.2	486	562
8	505.4	487.5	187.3	206.1	493.6	484.4	374.1	366.9	328	271
9	355.6	338.0	516.7	529.5	900.8	891.2	325.5	334.9	279	266
10	504.6	471.5	606.5	624.6	1035.3	1077.3	343.1	349.0	374	344

Additional Matlab code (see Appendix XI) was used to calculate percentage sensitivity and discrepancy for each subject, which are presented in Table 7.10.

Table 7.10: Percentage sensitivities and discrepancies for activity categorization and stride count of each subject

subject	sensitivity (%)					discrepancy (%)				
	walk	stand	sit	off	stride	walk	stand	sit	off	stride
1	104.0	102.2	97.0	97.6	101.5	4.0	2.2	3.0	2.4	1.5
2	98.7	105.0	97.0	104.7	97.4	1.3	5.0	3.0	4.7	2.6
3	100.4	105.3	98.7	101.5	93.3	0.4	5.3	1.3	1.5	6.7
5	101.6	101.8	98.4	102.2	104.7	1.6	1.8	1.6	2.2	4.7
6	93.5	101.0	97.2	103.1	94.0	6.5	1.0	2.8	3.1	6.0
7	94.4	95.0	103.0	104.2	93.9	5.6	5.0	3.0	4.2	6.1
9	103.7	95.6	99.6	101.2	94.9	3.7	4.4	0.4	1.2	5.1
10	102.1	98.5	100.5	101.0	105.9	2.1	1.5	0.5	1.0	5.9
Average	99.8	100.5	98.9	101.9	98.2	3.2	3.3	2.0	2.5	4.8
(std)	(3.99)	(3.88)	(2.09)	(2.23)	(5.13)	(2.15)	(1.80)	(1.14)	(1.38)	(1.84)

The forcePAL data were processed using a general algorithm and then compared with video data, the average percentage sensitivities of 99.8%, 100.5%, 98.9% and 101.9% were found for walking, standing, sitting/lying and ‘off’ events respectively for the eight subjects who took part in the study. The calculated average percentage discrepancies for activity categorization were found to be 3.2%, 3.3%, 2.0% and 2.5% for walking, standing, sitting/lying and ‘off’ periods respectively. The percentage discrepancy for each subject was below 5% for all activity categories.

The total number of strides were counted from the video recordings and compared to the number of peaks found within the walking periods using the Matlab algorithm, which represented stride counts. The average percentage sensitivity and discrepancy for stride count were found to be 98.2% and 4.8% respectively.

7.7.2 Statistical analysis

7.7.2.1 Correlation between forcePAL and video data

For each subject, the total durations of each activity category from the video and forcePAL data were found and Figure 7.27 was plotted to show the correlations between video and forcePAL data for walking, standing, sitting/lying and ‘off’ events. Correlation coefficient,

r, was calculated using equation 7.5 and significance test, t, was calculated using equation 7.6 to evaluate whether the association between the two sets of data was apparent.

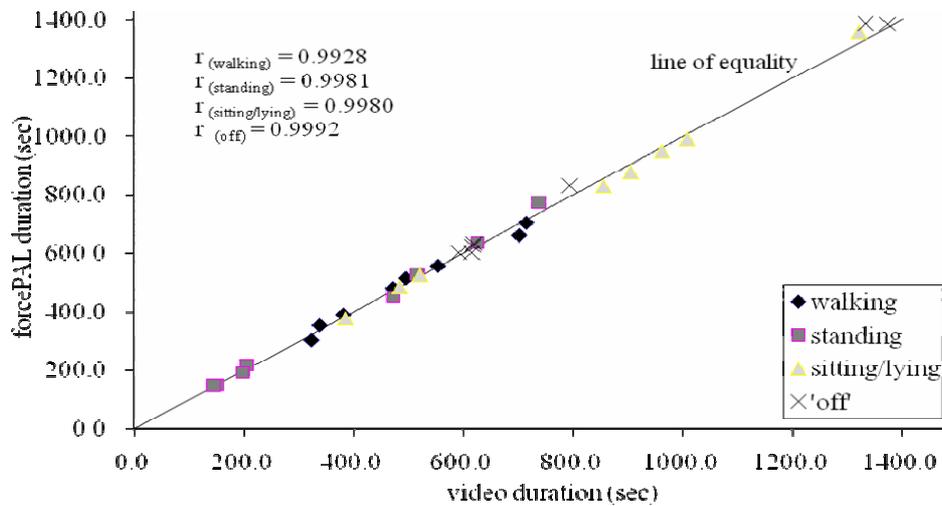


Figure 7.27: Total durations recorded from the video for walking, standing, sitting/lying and ‘off’ events plotted against total duration from the forcePAL post-processed output.

The correlation coefficients, r, were calculated as 0.9928, 0.9981, 0.9980 and 0.9992, with $t = 20.27, 39.66, 39.14$ and 61.12 ($p < 0.001$) for walking, standing, sitting/lying and ‘off’ events respectively, indicating highly significant positive correlations between the video and forcePAL outputs.

Figure 7.28 shows correlation between video and forcePAL total stride counts using the Matlab algorithm for 8 amputees in this study. The correlation coefficient, $r = 0.9857$ with $t = 14.33$ ($p < 0.001$), indicating a strong positive correlation between the two data sets.

Although all the calculated r values showed highly significant positive correlations between the video and forcePAL data for activity categorization and stride count, r only measures the strength of the relationship between two variables, and not the agreement between them. The calculated correlation coefficients, r values, were in relation to a line of best fit and not to a line of equality. Perfect agreement between the two data sets could only be achieved when all points were perfectly on the line of equality. Therefore further statistical tests were required to investigate the agreements between the forcePAL results and video data.

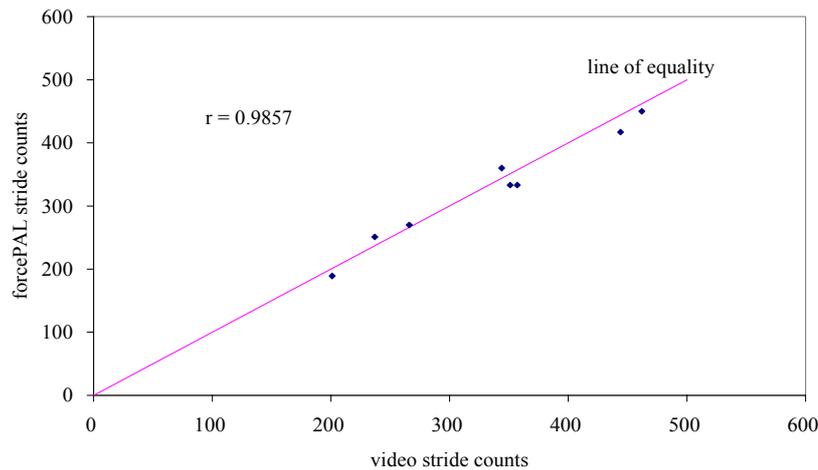


Figure 7.28: The total number of strides found from the video compared with the number of strides computed from the forcePAL data for all subjects.

7.7.2.2 Reliability Analysis

The intraclass correlation coefficient (ICC) is a measure of correlation, consistency or conformity for a data set when it has multiple groups (Strout and Fleiss 1979). Reliability analysis was carried out to find the ICC(2,1) using an absolute agreement definition, that was based on a two-way random effects model, with the measuring methods and patients considered as random variables, which measured agreement emphasizing the interchangeability of the measuring methods. ICC(2,1) was computed using a statistical analysis software, SPSS Statistics (Version 16, SPSS Inc, USA) and an ICC value of ≥ 0.75 was considered to be good and ≥ 0.9 was deemed excellent.

The calculated ICC(2,1) were 0.996, 0.999, 0.999, 0.999 and 0.991 for walking, standing, sitting/lying, ‘off’ events and stride count respectively. ICC(2,1) was >0.99 for all activity categorization and stride count, which demonstrated excellent reliability and that the video and forcePAL measurements were interchangeable.

7.7.2.3 Agreement between video and forcePAL data

It was hypothesised that although both methods measured the same variables (duration of activities and stride count), they would not agree perfectly, as measurement errors exist in both methods. In addition, time is a continuous parameter and both video and forcePAL measurements would contain errors as the precise time at which an activity was deemed to

happen could not be identified. However, it was hypothesised that the limits of agreements for the percentage difference between video and forcePAL data would not be clinically significant.

It was thought that statistical analysis to determine the agreement between the two methods would be appropriate to identify how much the forcePAL results might differ from the video data. Agreement between video and the forcePAL was assessed by comparing the mean value of total time spent in each posture for video and forcePAL with the percentage difference between the two data sets for each subject. Percentage difference was calculated using the equation $[(\text{forcePAL duration} - \text{video duration})/\text{mean duration} \times 100\%]$.

Figures 7.29 – 7.33 illustrate the level of agreement according to the method of Bland and Altman (1986, 1999) between video and forcePAL for the total time spent in each activity (walking, standing, sitting/lying, off periods and stride count) during the testing session. Values above zero represented the forcePAL over-estimating the time spent in the activity state and values below zero showed under-estimation of time spent in the activity compared to the video based record.

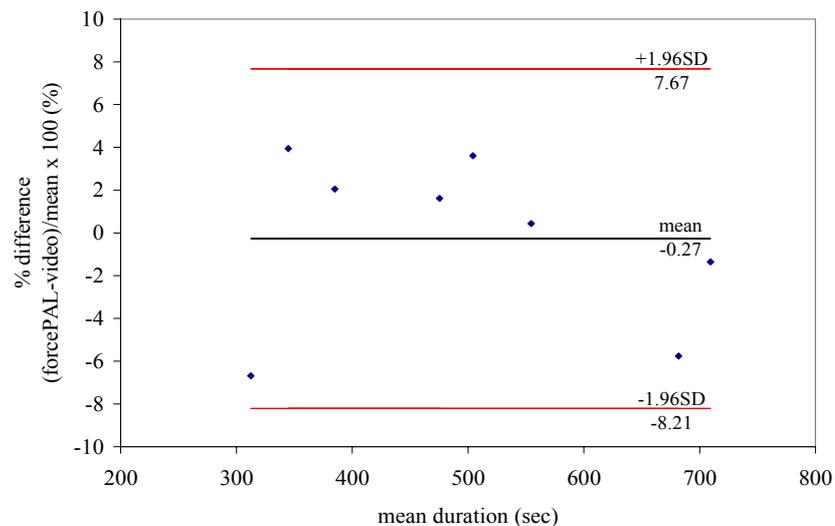


Figure 7.29: Bland-Altman plot of percentage agreement between video and forcePAL classification of total walking duration for all subjects.

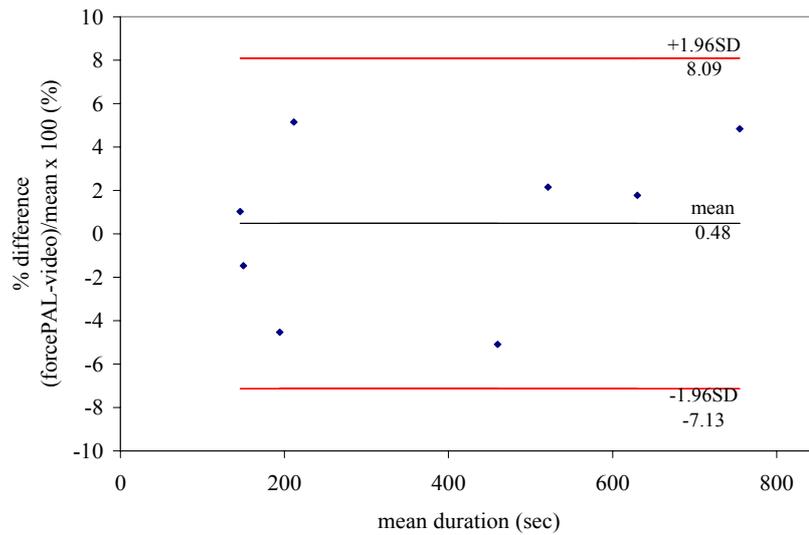


Figure 7.30: Bland-Altman plot of percentage agreement between video and forcePAL classification of total standing duration for all subjects.

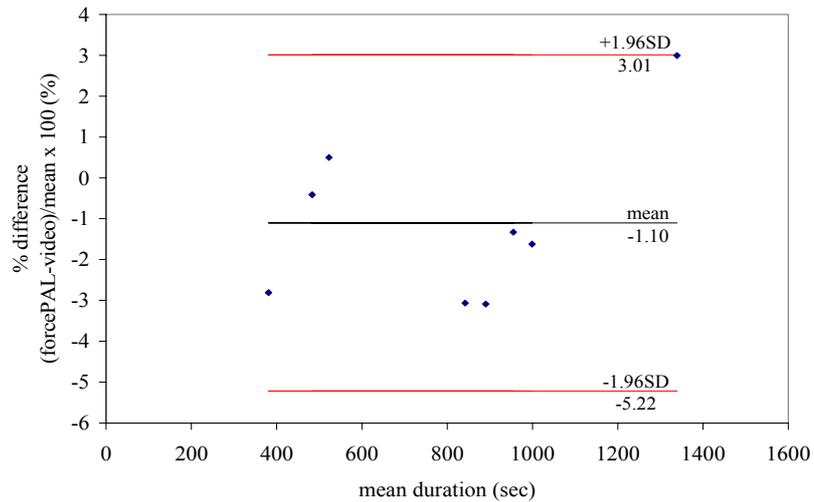


Figure 7.31: Bland-Altman plot of percentage agreement between video and forcePAL classification of total sitting/lying duration for all subjects.

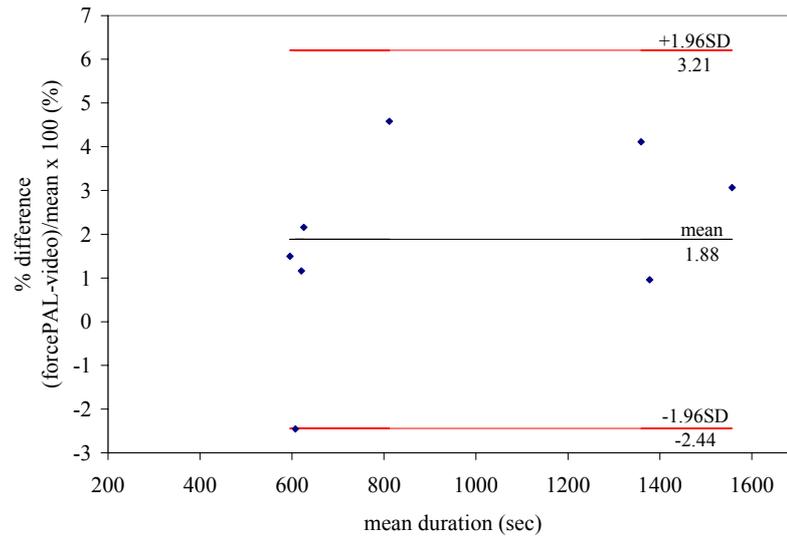


Figure 7.32: Bland-Altman plot of percentage agreement between video and forcePAL classification of total ‘off’ duration for all subjects.

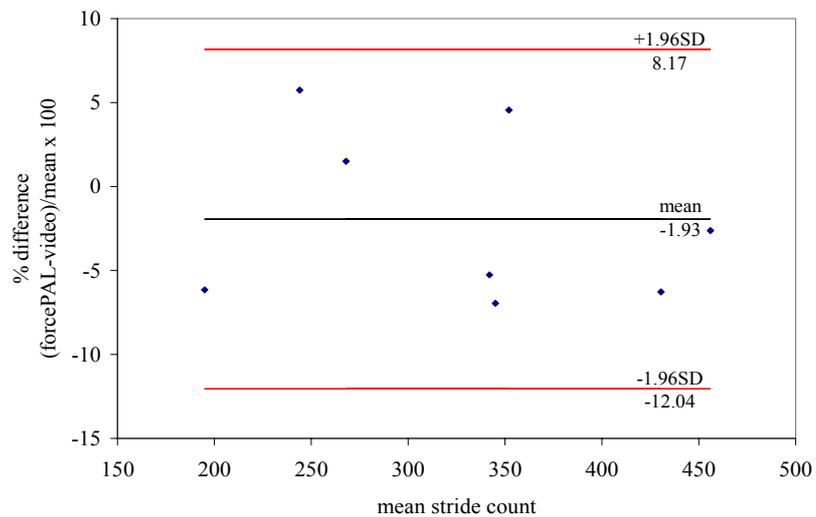


Figure 7.33: Bland-Altman plot of percentage agreement between video and forcePAL classification of total stride count for all subjects.

Figures 7.29 to 7.33 illustrate that the forcePAL over-estimated for some subjects while under-estimating for others for all activity categories and stride count, except ‘off’ period classification. The forcePAL over-estimated time spent in the ‘off’ state for all subjects except for subject 1, which under-estimated by 2.5%.

It was assumed that the percentage differences were Normally distributed (Gaussian), hence 95% of the differences should be expected to lie between ± 1.96 standard deviation from the mean and these were called the limits of agreement (Bland & Altman 1986, 1999). Table 7.11 shows the calculated limits of agreements with the mean values. The limits of agreement were -8.21 to 7.67% for walking (Figure 7.29), -7.13 to 8.09% for standing (Figure 7.30), -5.22 to 3.01% for sitting/lying (Figure 7.31), -2.44 to 6.21% for off periods (Figure 7.32) and -12.04 to 8.17% for stride count (Figure 7.33).

Table 7.11: The calculated mean of the percentage difference between video and forcePAL data and limits of agreement calculated according to Bland & Altman (1986, 1999) for walking, standing, sitting/lying, off events and stride counts.

Activity category	Mean (%)	Lower limit of agreement (%)	Upper limit of agreement (%)
Walking	-0.27	-8.21	7.67
Standing	0.48	-7.13	8.09
Sitting/lying	-1.10	-5.22	3.01
Off	1.88	-2.44	6.21
Stride	-1.93	-12.04	8.17

However, these limits of agreement were only estimates of the values for this particular set of data. Hence standard error (SE) and confidence intervals were used to determine the accuracy of these estimates. SE was calculated using equation 7.7. The 95% confidence intervals for the bias was calculated using equation 7.8 with 7 degrees of freedom, $t = 2.365$ was found. Hence 95% confidence intervals for the bias were -3.66 to 3.12, -2.76 to 3.73, -2.86 to 0.65, 0.04 to 3.73 and -6.25 to 2.37 for walking, standing, sitting/lying, off periods and stride count respectively.

The standard error of the limits (equation 7.9) and 95% confidence interval (equation 7.10) were calculated. Table 7.12 shows the 95% confidence interval for the lower limits of agreement, which were -14.08 to -2.34, -12.75 to -1.5, -8.26 to -2.18, -5.63 to 0.76 and -19.51 to -4.57 for walking, standing, sitting/lying, off periods and stride count respectively. The 95% confidence interval for the upper limits of agreement were found to be 1.80 to 13.54, 2.47 to 13.71, -0.03 to 6.05, 3.01 to 9.40 and 0.70 to 15.63 for walking, standing, sitting/lying, off periods and stride count respectively (Table 7.12).

Table 7.12: The 95% confidence interval for the lower and upper limits of agreement for all activity categories

Activity Category	95% CI for Lower limits agreement		95% CI for Upper limits of agreement	
	Lower value	Upper value	Lower value	Upper value
Walking	-14.08	-2.34	1.80	13.54
Standing	-12.75	-1.50	2.47	13.71
Sitting/lying	-8.26	-2.18	-0.03	6.05
Off	-5.63	0.76	3.01	9.40
stride	-19.51	-4.57	0.70	15.63

7.8 Results – Free-living monitoring using the pressurePAL

For free-living data collected using the pressurePAL, the total times spent per day in dynamic, static and ‘off’ states are shown in Table 7.13 and 7.14 for subject 3 and 10 respectively. Only full days of collected data are shown in Tables 7.13 and 7.14. Data for the first and last days of monitoring were excluded from the results as only part of these days were monitored. 9 days of data were collected for both subjects, hence 7 full days of data are shown in Table 7.13 and 7.14.

Table 7.13: Time spent in different activity states and stride counts by pressurePAL and LAM for subject 3. (Day 2 to 8)

Day	time (hr)			Stride count	
	Dynamic	Static	Off	pressurePAL	LAM
2	1.72	12.18	10.11	3718	4350
3	1.30	13.02	9.66	3026	2959
4	2.30	12.79	8.92	4885	3401
5	1.49	11.84	10.68	3071	2500
6	1.54	11.53	10.94	3252	1892
7	1.04	11.28	11.70	2220	1761
8	1.30	13.50	9.20	3263	3058
average	1.53	12.31	10.17	3348	2846

Table 7.14: Time spent in different activity states and stride counts by pressurePAL and LAM for subject 10 (Day 2 to 8)

Day	time (hr)			stride count	
	Dynamic	Static	Off	pressurePAL	LAM
2	0.45	10.18	13.42	110	83
3	0.87	17.11	6.03	1967	1200
4	0.62	17.32	6.11	1720	1605
5	1.33	12.91	9.76	2128	2369
6	0.55	10.41	13.03	853	897
7	0	0	24.00	0	0
8	0	0	24.00	0	2
Average (exclude day 7 and 8)	0.76	13.59	9.67	1356	1231

It was found that for subject 3, an average of 1.53 hours, 12.31 hours and 10.17 hours were spent in dynamic, static and ‘off’ activity per day respectively. For subject 10, 24 hours of ‘off’ periods were recorded for day 7 and day 8. The subject used a different prosthesis on these two days. Averages of 0.76 hours, 13.59 hours and 9.67 hours per day were spent in dynamic, static and ‘off’ activity respectively, when day 7 and 8 were excluded from the calculation.

Strides were counted using the pressurePAL algorithm and compared to the LAM stride count data (Table 7.13 and 7.14). For pressurePAL data, subject 3 had an average 3348 strides per day and subject 10 had an average of 1356 strides per day, indicating subject 3 was more active compared to subject 10. Figure 7.34 shows the total time spent each day in the dynamic state with stride count from the pressurePAL for the two subjects. It can be seen that subject 3 was more active compared to subject 10 as subject 3 spent more time in the dynamic state with higher stride count compared to subject 10.

Figure 7.34 is a graphical representation of the time spent in dynamic activity and number of strides performed by subject 3 and 10 during the free-living monitoring period. It could be seen that subject 3 was more active compared to subject 10 as subject 3 spent more time in the dynamic state each day (moving the stump inside the prosthesis) and higher stride count per day was recorded for subject 3.

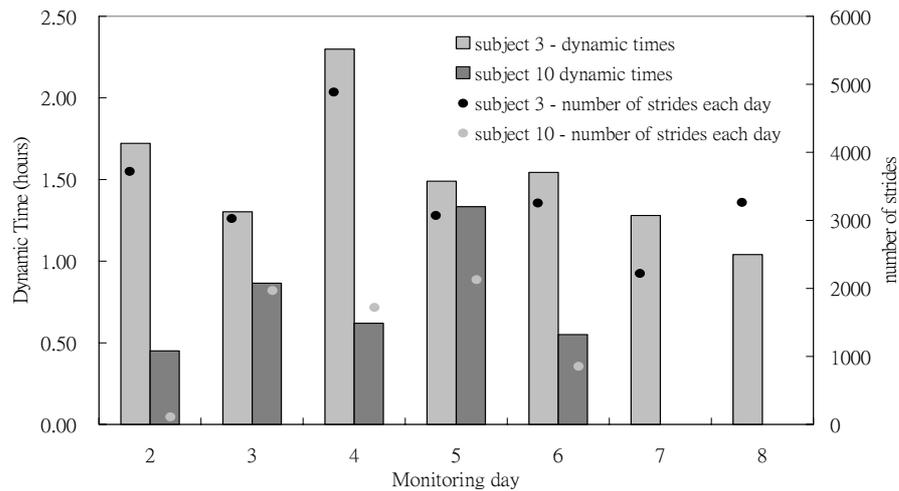


Figure 7.34: Active free-living monitoring results for subject 3 and subject 10 using the pressurePAL, shown as time spent in dynamic activities and stride counts per day.

7.9 Discussion

7.9.1 Subject population

Although the size of subject sample was small, the subjects recruited for this study represented a range of trans-tibial amputees as they had different indications for amputation and the duration of being an amputee ranged from 2 to 27 years. In addition, not all subjects were prescribed with the use of suction sockets but they were comfortable and able to carry out activities with their custom made suction sockets in the laboratory for the validation of the pressurePAL and forcePAL.

7.9.2 PressurePAL

7.9.2.1 Calibration of device

The pressurePAL was found to have a linear relationship to pressure readings without hysteresis and no drift was seen when the pressurePAL was tested at constant atmospheric pressure. Therefore drift should not pose any problems or cause errors in the identification of ‘off’ periods when the prosthesis was not worn.

7.9.2.2 Development of the signal analysis algorithm and its limitations

The signal analysis algorithm was based upon certain consistent features that were seen in the pressure profiles for all subjects. Originally, it was thought that amputees' activities could be categorized into walking, standing, sitting/lying and 'off', with the number of stride counts within the walking activities. Although different filtering techniques were considered, it was decided to use a moving window to compute averages and standard deviations of the pressure signal, which were then used to identify thresholds for activity categorization. It was not possible to distinguish between standing and sitting events due to the similarity in pressure profiles obtained from both standing and sitting postures. When amputees did not move their residual limb during standing, sitting or lying periods, the pressure profile was close to constant atmospheric pressure. Therefore, it was decided to use an algorithm that grouped standing and sitting/lying events into 'static' activity. This constraint on activity characterization would be difficult to eliminate as the amputees did not exhibit identical trends in relief valve pressure. Difficulties with signal interpretation may arise for a number of reasons including the fact that amputees would have individualised movement inside the socket depending on the fit and comfort of the prosthesis. It is also likely that the amount of soft tissue and general health of the amputee would affect pressure within the socket. Lying events were not included in the protocol for the validation study, but it was thought that the pressure profile for lying events would be similar to sitting episodes and therefore it would be necessary to group lying events into the static category.

Another limitation of the algorithm for categorization of the amputees' activity was that it required a minimum of 5 minutes of constant atmospheric pressure to characterize the 'off' state. The algorithm classified any times that an amputee removed the prosthesis for less than 5 minutes as static events. When the 'off' times were less than 5 minutes, these usually represent the need to perform some alteration to the placement of the stump inside the socket or adding stump socks, therefore classifying these periods as static would not be misleading.

For discrimination between dynamic and static events, the filtering techniques used in the data analysis algorithm contained two stages. The first stage was a moving window of 1 second to compute the standard deviation and the second stage was a 10 second moving average window. A threshold was then identified which was dependent upon the maximum value of the data after stage 2 filtering. The time at which an activity change occurred

might not be exactly determined depending on the location of the threshold. A small error (< 1 second) was expected for the time of activity change as the threshold was 2/5 of the maximum value. It was believed that this would not cause large amounts of misclassification during free-living monitoring as amputees do not generally perform short bouts of activities (less than 5 seconds), hence the error caused, in proportion of time spent in short periods of transition, would not be significant in daily life situations. Furthermore, no phase shift occurred with the use of the moving window to calculate standard deviation and average with the Matlab code used, therefore once an appropriate threshold was identified, accurate duration of each activity would be categorized.

7.9.2.3 Disagreement between video and pressurePAL data

For the validation of the data analysis algorithm for quantifying amputees' activity levels and prosthetic usage with the pressurePAL data, pressure results were compared with the video data. Pressure profiles at the pressure relief valve were dependent upon movement of the stump inside the socket as this in turn altered the air distribution of the socket creating pressure difference. Although all the average sensitivities were close to 100%, the pressurePAL sometimes over-estimated time spent in an activity state, while under-estimating for other subjects, which made the average sensitivities close to 100%. On the other hand, the average discrepancies were below 10%, but there were still misclassification between activity states. By comparing the post-processed pressurePAL data to the video data, the misclassified periods were identified.

For the video data analysis, the amputees' activities were originally categorized into walking, standing, sitting with and without prosthesis. Walking activities included both stair ascend and descend. As the pressurePAL data analysis algorithm could only distinguish dynamic and static events (with and without prosthesis), the video data were re-classified accordingly, by categorizing all walking activities (include stair ascend and descend) as dynamic events, and both standing and sitting periods shown in video were categorized as static episodes.

'Off' periods

The average percentage discrepancy was 2.9% for 'off' categorization. Although this percentage was low, small amounts of misclassification occurred. It was found that the pressurePAL under-estimated time spent in the 'off' state prior to the device being switched

off. This error could have been caused by the method adopted for synchronising the video and pressurePAL data. Although a visual indicator was used to identify device on/off, it did not diminish error as it required the observer to determine the exact time for this to occur. However, this type of error would not affect free-living monitoring as the device only required to be switched off once and would only under-estimate by a very small amount, < 1 second within a much longer total daily 'off' period of approximately 8 hours.

Static categorization

One type of misclassification that was seen between the video and pressurePAL data arose as a result of differences in donning procedure used by amputees. There were two types of suspension used to create a seal between the stump and the prosthesis. Apart from subject 7 who used the silicone liner with a ring at the distal end, all other subjects used sleeve suspension to create a seal between the stump and the socket. For subject 7, who used a silicone liner with the suction socket, during donning procedures the amputee was required to push the stump inside the socket so any excess air could be expelled through the one-way pressure relief valve and a seal between the stump and the prosthesis could be created. The procedure sometimes required the amputee to push the stump into the socket a few times during the donning process, causing cyclical pressure signals to be recorded at the pressure relief valve, which would be classified as dynamic activity and strides might also be counted. However, if a suspension sleeve was used, amputees were only required to place their stump inside the socket and then roll the sleeve over the socket to mid thigh to create an air tight situation. Therefore with the sleeve suspension method, the donning procedure was usually classified as static event by the algorithm. Hence amputee's donning method had to be considered as well.

Another type of misclassification was found as the algorithm categorized static events as dynamic. This was seen in subject 4, 5, 7 and 9. Noise in the pressure signal was reduced by using a moving average window. However, when large movements of the stump occurred while the amputee was in a 'static' posture, misclassification would take place as these signals were above the dynamic threshold. This indicated that the 'dynamic' category potentially contained non-walking stump-socket relative movements. It could be argued that categorization of stump movements in a 'static' posture as dynamic event is reasonable if general physical activity is being characterized. For this study, all standing and sitting events were classified as 'static' activities.

Small single pressure peaks would not cause misclassification as the standard deviation signal would not be above the dynamic threshold after a 10 second moving average window was used. However, for larger pressure changes inside the socket which lasted for 5 seconds or longer, misclassification might have occurred, as a 10 seconds moving average would still produce signal above the dynamic threshold. On the other hand, a real single stride would not be categorized correctly as the signal would be reduced to below the dynamic threshold after the average window was used.

Furthermore it was noted that amputees might sit or stand very still, e.g. subject 4, which led to almost constant atmospheric pressure being recorded during sitting periods. Although constant atmospheric pressure signals would be possible during quiet standing when no stump movement occurred, it would be unlikely that an amputee would stand over 5 minutes without any movement of the lower limbs. Weight shift between legs generally occur during long standing episodes. Subject 4 was the only amputee who walked with support using a walking stick, it was thought that subject 4 might not have put any weight onto the amputated leg during standing, leading to the measurement of near constant atmospheric pressure during these episodes. This might lead to misclassification of the 'off' events for long term monitoring, as the classification of 'off' periods relied on constant atmospheric pressure being recorded over a longer period of time. However, if an amputee sat or stood without any stump movement for a long time, these periods might be misclassified as 'off'. The discrepancy caused by this could be altered as the minimum duration for 'off' period could be changed in the algorithm. Therefore for long term monitoring, the minimum duration for 'off' period could be changed to a longer time, as in general when amputees do not wear their prosthesis, it would be for longer period (i.e. 30 minutes or more). Originally 5 minutes was chosen for identifying 'off' events as the validation study could not be excessively long, hence the 'off' periods during the testing sessions were limited.

It is questionable whether it was correct to categorize all standing periods as static events. Short standing occurrences might involve some leg movements or stump movements as even with normal populations, quiet standing involved internal muscle movements and it would be difficult to examine the strategy adopted by each amputee to remain in a quiet standing position, as this could vary between amputees. All standing periods were classified as static for the video data in this validation study, and hence an algorithm which could distinguish between standing and sitting episodes would be desirable. Nonetheless

due to the similar pressure profiles of these events with the use of the pressurePAL, this caused limitation in the data analysis algorithm, which could not be improved upon.

Dynamic activity and stride count

It was found that the ability of the data analysis algorithm to determine stair ascend and descend was 100% as these activities were always between level ground walking during the validation study. Hence initial and end stride for stair activities would not be misclassified. However, in free-living situation, amputees might stop and stand quietly at the end of stair walking activities and the effect of this was unknown. Furthermore, the high accuracy for identifying stair activities as dynamic events was because higher pressure amplitudes were seen during stair ascends and descends. As standard deviations were used to distinguish between static and dynamic events, larger amplitude for the pressure cycles would lead to larger standard deviation in the signal. It might be hypothesised that larger amplitudes of pressure cycles were created during stair activities because amputees were required to lift their prosthesis to reach the next step, therefore creating larger pressure changes as movement of the stump inside the socket increased. Hence signals for these periods would always be above the dynamic threshold.

When the total strides counted from the video data were compared with stride count from the pressurePAL data an average discrepancy of 2.4% was found. The number of peaks within the pressure cyclical signal was used to represent the number of strides an amputee performed. The pressure signal had to pass through 2 thresholds in order for the algorithm to count the peak as a stride. Two thresholds were set to minimise small peaks being counted as strides, as the gait cycle was characterized by a double peak in some subjects. Occasionally the last stride in a stepping sequence was not counted by the data analysis algorithm as the pressure amplitude was not high enough to pass the upper threshold. This was due to the last step sometimes being small and slow with partial weight bearing, leading to the generation of pressure profiles that would not correspond to a gait cycle. This type of miscount mainly occurred for subject 3 and 6 and was thought to be associated with their walking patterns, however the exact reason could not be identified.

On the other hand, additional strides were sometimes counted by the pressurePAL data analysis algorithm. This occurred when dynamic activities were misclassified due to large pressure signals during static events. If it was possible to reduce this type of dynamic misclassification, additional strides would not be included.

It is possible that individualised threshold values could be identified to improve the sensitivity of stride count, as developed algorithm used set thresholds value for all subjects to count peaks within cyclical signals. It would be more time consuming to find individualised stride count threshold as each amputee would be required to perform a set activity sequence in a controlled environment before an appropriate algorithm could be identified. This sequence would have to include set walking distances and times spent in each activity. However, activities performed in a laboratory might not be representative of free-living activity.

Another method to improve stride count accuracy was to use pattern recognition or wavelet analysis. However with wavelet analysis, a template of stride waveform has to be known. For amputees, their gait varies from person to person, therefore it would be difficult to identify a general waveform to represent a general gait cycle. These methods are explained in Chapter 9.

7.9.2.4 Statistical analysis

From the statistical analysis, 95% confidence interval for the lower and upper limits of agreement between video and pressurePAL data were calculated according to Bland & Altman (1986, 1999), for activity classification and the range of the intervals were -15.07 to 8.73, -3.13 to 1.24, -8.50 to 2.71 and -6.70 to 6.28 for dynamic, static, 'off' and stride count respectively. The intervals were relatively narrow for static and 'off' events, indicating that the degree of agreement would be clinically acceptable for these events using the general data analysis algorithm for the pressurePAL. However, the intervals for dynamic classification and stride count were wider, reflecting the large variations within data set, as the sample size was relatively small.

7.9.2.5 Long term monitoring using pressurePAL

The pressurePAL could be used to quantify prosthetic usage and categorize amputees' activity into period spent in dynamic or static events with the number of stride counts performed, however some differences were seen when compared to the LAM data. This information gained by the pressurePAL could aid clinicians or prosthetists to determine amputees' rehabilitation progress and the effectiveness of the prescribed prosthesis. For the two subjects who had worn the pressurePAL for 9 consecutive days, only subject 3 used the

prosthesis for the full 9 days. Although the pressurePAL data showed subject 10 did not use the prosthesis for the full 9 days, it was known that subject 10 had another prosthesis which he used occasionally when he felt uncomfortable with one prosthesis. This showed that subject 10 might not have felt comfortable wearing the same prosthesis continuously, which the subject agreed with and reported that he could not find a suitable socket that he could use continuously. The LAM data corresponded with the pressurePAL data as no stride count was recorded for subject 10 on day 7. However 2 strides were counted on day 8 on the LAM, which was miscounted as the subject did not use the prosthesis at all on day 8. On day 9, subject 10 wore the prosthesis with the pressurePAL attached for returning to the laboratory, but only half a day of data was recorded and therefore not used in the data analysis comparison. The LAM device could only count the number of steps an amputee performed and no additional information on activity level or prosthetic usage was possible. From the study, it could be found that subject 3 was more active with more strides and time spent in dynamic state compared to subject 10.

Discrepancies in the number of stride counts were seen between the LAM and the pressurePAL data. The LAM has been validated (Ross and Reece 2006), however, this validation was in a laboratory based environment. It was not known how well the LAM would characterize small or incomplete steps or prosthesis movement other than stepping, all of which might occur in the free-living environment. As noted previously, the LAM measured 2 steps for subject 10 on day 8, however the subject did not use the prosthesis on that day, hence exhibiting error. It was not possible to be sure whether the inconsistency between the data was caused by miscounting of strides by the pressurePAL algorithm or the LAM data or errors in both sets of data. It was noted from the pressurePAL validation study that improvement to the pressurePAL algorithm was necessary for 100% accuracy for stride count, hence this could have contributed to the differences between the two data sets. From this study, it was difficult to conclude how accurate the pressurePAL was when used in a free-living context. A possible way to validate free-living monitoring using the pressurePAL was to video record each subject's activity patterns during their daily lives. However, this would be time consuming for both data collection as well as data analysis. In addition subjects might exaggerate their activity levels when an observer is present.

The pressure data recorded would be a true representation of any stump movement inside the socket during amputees' daily activities. It would be difficult to change the pressure measurement without the stump being inside the socket. The types of activities are limited

with standard lower limb prosthesis, as running or other sporting activities would require another type of prosthesis. Although additional categories such as time spent in sitting and standing could add value to these data by knowing the posture of the amputee, the pressurePAL provided useful information for time spent in dynamic, static and off events. Further study with more subjects was required to examine the effectiveness of the pressurePAL as a free-living monitoring device.

7.9.2.6 Summary

It was necessary to attach the pressurePAL to the pressure relief valve of a suction type socket. There were therefore clear limitations in the use of the device to a subgroup of the amputee population. Within this group such a device would offer minimal interference with use of the prosthesis and no adaptations in prosthetic design are required. The signal analysis algorithms developed allowed high levels of accuracy in the characterization of physical activity into periods spent in dynamic and static states with stride counts. This method of using the pressurePAL presents the opportunity for long term monitoring of prosthetic use.

7.9.3 *ForcePAL*

7.9.3.1 Calibration of forcePAL

The forcePAL was found to exhibit hysteresis as loading and unloading the sensor did not produce the same forcePAL units with the same applied pressure. Although hysteresis occurred in the FlexiForce, it was anticipated that this would not adversely affect the chances of being able to use the device to quantify prosthetic usage as accurate pressure readings were not required. For activity categorization, only the relative changes and general magnitude of the pressure profiles were needed to classify posture, hence if the range of pressure units was known for each activity, an appropriate data analysis algorithm could be used for activity categorization.

Drift was also found for the forcePAL as pressure measurements did not remain constant when a constant weight was applied to the active area of the FlexiForce. However, drift appeared to be random as forcePAL measurements fluctuated around the applied pressure by small amounts ($\pm 2\text{kPa}$). It was anticipated that this random fluctuation in pressure

measurements would not cause problems in the quantification of prosthetic usage and amputees' activity levels, as it was small compared to the overall signal range. The data analysis algorithm used a moving window to calculate averages and standard deviations to identify thresholds for activity categorization. The only possible error that the characteristics of drift or hysteresis could cause was in the identification of 'off' periods, as this relied on constant atmospheric pressure being recorded for over 5 minutes. However, when the forcePAL was left at atmospheric pressure with no force acting on the active area of the FlexiForce, constant measurements were recorded, hence no drift occurred at atmospheric pressure, which allowed the data analysis algorithm to categorize 'off' durations.

7.9.3.2 Limitations of the forcePAL

The placement of the FlexiForce at the stump/socket interface caused some problem during the validation study. It was essential that the active area of the FlexiForce was placed at the stump/socket interface where contact of the stump would take place when it was worn. For the validation study, the sensor was placed at the anterior mid-thigh so that the wire could run over the brim of the socket without interference with the amputee, especially during ambulation. However, the amount of soft tissue around the stump would be different from amputee to amputee, hence the contact force with the FlexiForce sensor would be different between subjects. This led to difficulty in locating the sensor in an area that would produce the same pressure profile patterns for all subjects. The popliteal area was considered as a potential location for the sensor due to high pressure is typically generated here. However, placement of the FlexiForce sensor in this location might interfere with gait.

Another limitation of the forcePAL would be the need to carry out alteration to the socket in order to accommodate the sensor and a way to run the connected lead to the outside of the socket to connect the FlexiForce with the data logger. A hole in the socket wall would be needed to allow the wire connection between the FlexiForce and the main part of the forcePAL. This was not performed for this current study, as the focus for the validation study was to determine whether the forcePAL would produce pressure profiles that allowed the use of a general data analysis algorithm to categorize trans-tibial amputees' activity and prosthetic usage. However, for free-living monitoring to take place using the forcePAL, alterations to the socket would have been necessary.

7.9.3.3 Development of signal analysis algorithm and its general limitations

The forcePAL data analysis algorithm was developed and was based upon certain consistent features that were seen in the pressure profiles of each subject. It was thought that a general algorithm could be developed to quantify trans-tibial amputees' activity levels into time spent in walking, standing, sitting/lying and 'off' when the prosthesis was not worn. Throughout the process of developing the data analysis algorithm for analysing the forcePAL data, different filtering techniques were considered and it was decided to use moving window to compute standard deviation and average for the pressure signal, which was then used to identify thresholds for activity categorization. This method was chosen as it did not require long data processing time and no exact pattern of pressure profile for each activity state was required.

Limitation of data analysis algorithm

One of the limitations of the data analysis algorithm was that to detect times when the prosthesis was not worn it was required that a constant atmospheric pressure was recorded for a period longer than 5 minutes. The algorithm categorized any times that an amputee removed the prosthesis for less than 5 minutes as sitting/lying events. 'Off' periods less than 5 minutes were normally associated with the need to perform some alteration to the stump position inside the socket or to add stump socks as stump volume changed throughout the day. It might be considered therefore that classifying these periods as sitting would not be misleading.

Lying events were not included in the validation protocol as it was thought that the amputees would usually remove their prostheses when carrying out lying episodes, therefore pressure profiles at the stump/socket interface for lying with prosthesis were not known. However, it was thought that sitting and lying should have similar pressure profiles as only small stump movements would occur inside the socket during these events and stump contact force would be similar for each subject. Furthermore, similar energy expenditure would be expected for sitting and lying events, therefore grouping the two activities would be appropriate as it provides equivalent information on free-living activity patterns of amputees.

As a threshold was used to identify the transition from one activity state to the next it is possible that errors occurred in determining the precise time instant of transition. These errors might have been up to ± 1 second and the exact threshold for activity change could be

different between subjects. It was believed that these would not cause large amounts of misclassification during free-living monitoring as it is unlikely that amputees would perform lots of short burst, spontaneous activity, hence the number of transitions would be relatively low.

7.9.3.4 Disagreement between video and forcePAL data

For the validation of the data analysis algorithm for quantifying amputees' activity levels and prosthetic usage with the forcePAL, pressure results were compared to video data which acted as the gold standard for activity categorization in this study. Pressure profiles at the stump/socket interface were dependent upon movement of the stump inside the socket as this in alters the force acting on the sensitive area of the FlexiForce.

The general data analysis algorithm categorized the recorded pressure data into walking, standing, sitting and 'off' events and average sensitivities of 99.8%, 100.5%, 98.9% and 101.9% were found respectively. For stride count comparison 98.2% average sensitivity was found. Although average sensitivities for all classification were close to 100%, the forcePAL sometimes over-estimated time spent in an activity state, while under-estimated for other subjects, which were averaged together to produce sensitivity that were close to 100%.

Misclassification between activity states occurred. Average discrepancy of 3.2%, 3.3%, 2.0% and 2.5% were found respectively for walking, standing, sitting and 'off' periods. For stride count, 4.8% average discrepancy was found.

'Off' periods

The average percentage discrepancy was 2.5% for 'off' categorization, although the percentage was low, small amounts of misclassification occurred. It was found that the pressurePAL under-estimated time spent in the 'off' state prior to the device being switched off. This error might have been caused by the method adopted for synchronising the video and pressurePAL data. Although a visual indicator was used to identify device on/off, it did not diminish error as it required the observer to determine the exact time for this to occur. If the forcePAL were to be used in as free-living monitor, this type of error would not affect the outcomes as the device only required to be switched off once giving a very small percentage error in outcomes.

Sitting classification

Constant zero pressures were seen for some subjects during sitting episodes, which were caused by no forces acting on the sensor during these times. This would cause misclassification between sitting/lying and 'off' events. It was thought that sitting without any stump movement would not be likely to occur for a long period in the free-living environment, hence reducing the error caused by this type of misclassification. The discrepancy caused by this error was also reduced by setting a minimum duration for constant zero pressure measurement before it could be categorized as 'off' events, so that if there were small movements in between constant zero pressure, these periods would be classified as sitting/lying.

Although the average percentage discrepancy was low and the Bland & Altman agreement test showed good agreement between video and forcePAL data for sitting classification, some misclassification did occur. It was seen that sometimes sitting events were misclassified as standing. This was seen in subjects 2, 3, 5, 6 and 9 with short periods (<5 seconds) of misclassification. This occurred when large pressure signals were detected and also large movement of the limb was seen on the video data. These movements caused higher stump/socket pressure compared to quiet sitting episodes. This type of misclassification would only be seen when amputees performed large amounts of leg movement during seated periods, such as lifting the leg and placing it down on the floor. From the validation study, the amount of this type of error was low (2.5%), hence should not cause high amount of misclassification for free-living monitoring.

Standing classification

When large movements of the stump were created during standing, the algorithm would misclassify these periods as walking episodes because the standard deviation signal would be high if movement of the stump occurred. However, this type of misclassification would not take place unless the movement of the stump produced high pressure signals. Random short periods of pressure changes inside the socket would be considered as noise when the standard deviation of the pressure signals were smoothed using the moving average filter and would therefore be correctly classified as standing events.

Walking classification and stride counts

It was found that the ability of the data analysis algorithm to determine stair ascend and descend was 100% as these activities were always between level ground walking during the validation study. Hence initial and end stride for stair activities would not be misclassified. However, in a free-living situation amputees might stop and stand quietly at the end of stair walking activities and the effect of this was unknown. Furthermore, the high accuracy for identifying stair activities as dynamic events was because higher pressure amplitudes were seen during stair ascends and descends. As standard deviations were used to distinguish between static and dynamic events, larger amplitude for the pressure cycles would lead to larger standard deviation in the signal. Larger amplitudes of pressure cycles were created during stair activities than in level walking as amputees were required to lift their prosthesis to reach the next step. This would have led to larger force acting on the active area of the FlexiForce at the stump/socket interface and, therefore, signals for these periods would always have been above the dynamic threshold.

For stride count comparison between the forcePAL and video data, average sensitivity of 98.2% and average discrepancy of 4.8% were found. The number of peaks within the pressure cyclical signal was used to represent the number of strides an amputee performed. The pressure signal had to pass through two thresholds in order for the algorithm to count the peak as a stride. Miscount could occur when movements of the stump take place in the standing position. It was difficult to determine the thresholds for the data analysis algorithm for use with all subjects as gait varied from amputee to amputee. Variability in gait or stump condition (e.g. stump volume) on a daily basis might affect pressure. For example, when stump volume increases throughout the day, the force acting on the sensor would increase. This would lead to the problem of identifying a correct threshold to be used.

Individualised threshold values could potentially be used to reduce the error for stride count. The current algorithm used set threshold values for all subjects to count peaks within cyclical signals. It would be more time consuming to find individualised stride count threshold as each amputee would be required to perform set activities in a controlled environment/ laboratory before an appropriate algorithm could be identified. The activities might include a set walking distance and time spent in each activity. However, activities performed in a laboratory might not be representative of free-living activity.

Another method to improve stride count accuracy was to use pattern recognition or wavelet analysis. However with wavelet analysis, a template of stride waveform has to be known. For the amputees studied, the pressure profiles varied from person to person and it was therefore difficult to identify a specific waveform to represent a general gait cycle. These methods are explained in Chapter 9.

7.9.3.5 Statistical analysis

From the statistical analysis, 95% confidence interval for the lower and upper limits of agreement between video and forcePAL data were calculated according to Bland & Altman (1986, 1999), the range of intervals were -8.21 to 7.67, -7.13 to 8.09, -5.22 to 3.01, -2.44 to 6.21 and -12.04 to 8.17 for walking, standing, sitting, 'off' and stride count respectively. The intervals were relatively narrow for sitting/lying and 'off' periods, indicating the agreement was acceptable for these activity categorization, with small variation within the data sets. However, for walking, standing and stride count, the range of the intervals of agreement were wider, reflecting the variation within the data sets, as the sample size was relatively small.

7.9.3.6 Summary

The forcePAL offered a solution for monitoring the use of all types of sockets. In this thesis details of work with trans-tibial amputees is presented indicating the possibility of characterising walking, standing, sitting and 'off' times and stride counts with good levels of accuracy. The algorithms developed allowing automatic analysis of the pressure signals recorded by the forcePAL. The forcePAL does not present such a user friendly device as the pressurePAL as its sensing element must be placed within the socket and this must be connected via a wire to the outside of the prosthesis and the data logging element of the device. However, the forcePAL does offer the possibility of free-living physical activity classification over extended periods of time providing valuable information on all type of lower limb prosthetic use.

7.10 Summary

Suction suspension of trans-tibial sockets is based on atmospheric pressure by creating a seal between the stump and the prosthesis. A one-way pressure relief valve at the distal end of the socket expels air automatically during weight bearing, thus removing trapped air from the socket leading to the creation of a partial vacuum to hold the socket on the stump when weight bearing is reduced on the limb. The pressure at the pressure relief valve is influenced by the loading on the stump socket interface and therefore on the activity that the amputee is performing. For this thesis the pressure at the pressure relief valve was monitored using the pressurePAL and an algorithm developed to characterize physical activity state and stepping from this signal. The interpretation of the pressurePAL signal by a general algorithm (Appendix IX) allowed the categorization of activity into dynamic (walking) with the number of strides, static (standing and sitting/lying with the use of the prosthesis) and 'off' periods (prosthesis not worn) with good accuracy (average percentage discrepancies less than 6% for activity categorization). The pressurePAL was externally attached, without the need to alter the prosthesis itself and therefore did not interfere with the amputees' gait and the device had no contact with the skin. The pressurePAL could be attached to the prosthesis when free-living monitoring was required and removed easily after the monitoring period, as shown in the long term monitoring study with 2 subjects.

The pressurePAL was only suitable for suction socket users. Although suction suspension is a widely used method to suspend trans-tibial sockets, there are other types of suspension used by amputees. The forcePAL was developed to allow the monitoring of physical activity in users of other types of socket. For the forcePAL an FSR sensor was placed at the stump/socket interface to allow pressure measurement. The interpretation of the forcePAL signal by a general algorithm (Appendix X) allowed the categorization of amputees' activities into periods spent in walking with the number of strides, standing, sitting/lying and 'off' (when prosthesis was not worn), with good accuracy (average percentage discrepancies were below 5% for activity categorization). However, for the forcePAL to be implemented, alteration to the socket was required, which would not be ideal for free-living monitoring.

The signal analysis algorithms did not provide results that were in 100% agreement with a video based record of physical activity and it is clear that they could be developed further using observation of a larger study population in a free-living environment.

Both the pressurePAL and the forcePAL allowed the collection of signals that could be used to characterize the physical activity that the amputees were undertaking. The signal analysis algorithms that were developed as part of this work provided accurate information on physical activity state and stride count. Both monitors present promise for long term physical activity monitoring in this population of subjects.

8 CONCLUSION

This work was conducted in two study populations, those subjects with CP and adults with trans-tibial amputation. The aim of the work performed in both groups was to examine the efficacy of monitoring devices to characterize physical activity with the overall aim of providing devices that could be used for free-living community based physical activity monitoring. For both populations it was important that a validation study of the device being used was performed to provide insight into its value as a clinical monitoring tool.

8.1 ActivPAL for use with the CP population

The uniaxial accelerometer based activPAL was validated in a laboratory environment concurrent with a clinical gait analysis session to determine its efficacy for use to monitor activity patterns for people with CP. Video recording of activity was used to act as the ‘gold standard’ to compare with the activPAL data, poor agreement (Bland & Altman agreement test) was found indicating misclassification between activity states and count strides. The validation study showed that the range of limits of agreements between the video and activPAL data were wide, indicating the lack of agreement between activPAL and video data. Although there was lack of agreements in activity categorization and stride count, there were potential sources of error in both video measurements as well as the activPAL proprietary algorithm. Reasons for poor agreement might be due to gait abnormalities of the subject group, difficulty in identifying exact time at which an activity change occurred on the video and the exact activPAL algorithm for activity categorization was not known. Furthermore, high discrepancy between video and activPAL data was found in some cases due to short total duration in an activity state, so small time deviation (a few second) would lead to large percentage error.

Most studies used a set physical activity sequence to validate an accelerometer based device, which would diminish the problem with different total duration in each activity state between subjects. However, a set protocol of activities would not represent daily activity patterns, especially for younger subjects as they tend to perform short bouts of activity. Video based validation study in the subjects’ free-living environment should be carried out for a better understanding of the validity of activPAL for use with people with CP and data should be analysed by 3 or more assessor to remove any bias or error when only one person evaluates the video recordings.

The activPAL was used to assess free-living activity patterns of people with CP. Despite the lack of agreements between video and activPAL data, the activPAL was able to distinguish the more active community walkers from those limited household walkers in their free-living environment. The information gained from the daily activity levels of subjects with CP, especially for the monitoring of pre- and post-intervention physical activity levels obtained from activPAL devices could provide invaluable insight into the efficacy of the treatment and the rehabilitation progress of the individual. The level of mobility in a free-living environment could also aid clinicians in decision making towards the most appropriate treatment planning.

There was no clear relationship between laboratory based cadences or questionnaire derived mobility score and free-living physical activity. These results indicate that a typical gait laboratory assessment does not allow full characterization of mobility and could not predict free-living physical activity level. It is therefore desirable to include objective free-living monitoring as a component of typical mobility assessment to provide evidence of actual daily mobility of each subject. However, it would be essential to combine accelerometry based activity monitoring with other forms of self-reporting (e.g. diary) as information could be missing or misleading without some description of subject's daily activity pattern.

Overall, if the misclassification of perching against a seat could be resolved by increasing the upright threshold in the data analysis algorithm and providing researchers or clinicians understood the other limitations in the activPAL algorithm for use in people with cerebral palsy, the activPAL could be a useful tool to quantify free-living activity patterns of people with CP in conjunction with one form of self-reporting method such as diary.

8.2 Quantifying amputees' activity patterns with pressurePAL and forcePAL

For the quantification of trans-tibial amputees' activity levels and prosthetic usages, the pressurePAL and the forcePAL were developed with customised data analysis algorithm to categorize activities. The pressurePAL was connected to the suction valve of suction sockets and the forcePAL measured stump/socket interface pressure. The data were analysed using a customised signal analysis algorithm that classified pressurePAL signals into dynamic, static, off events and stride counts; and forcePAL data into periods spent

walking, standing, sitting, 'off' and count strides. Video recordings acted as the 'gold standard' for comparison to the monitoring devices and good agreement was found for static and 'off' events using the pressurePAL and sitting and 'off' for the forcePAL. Although the intervals for limits of agreement for stride count and dynamic/walking events were wider for both devices, the discrepancies were relatively low for all activity categorization (< 6%). The wide intervals might be due to large deviation within a relatively small sample. A larger number of subjects would inevitably provide a greater range of signal types to test the generated algorithms.

The pressurePAL was also tested for use in the free-living environment and was able to quantify periods spent in different activity states with the number of stride counts. Although stride count could be compared to LAM data for validation, the error in the LAM data was unknown as a free-living activity monitoring tool, hence only a comparison and not a validation was possible. Video based validation study in the subjects' free-living environment should be carried out for a better understanding of the validity of pressurePAL and video data should be analysed by 3 or more assessors to remove any bias or error when only one person evaluates the video recordings.

Both the data analysis algorithm for pressurePAL and forcePAL could potentially be improved by identifying individualised thresholds to count the number of strides a subject performed, as the amplitudes of the pressure cycles representing walking were subject dependent. In addition, other data analysis algorithms should be explored to determine the best solution with the least error.

Overall, both the pressurePAL and forcePAL could quantify amputees' activity level and prosthetic usage with reasonable accuracy. Clinicians may find the forcePAL more useful as it could potentially be used with all types of lower limb prostheses and could classify activities into off periods, sitting/lying, standing, walking and count the number of strides, whereas the pressurePAL could only be used with suction sockets and also pressurePAL would not be able to distinguish between sitting/lying and standing events.

9 RECOMMENDATIONS FOR FUTURE WORK

9.1 Cerebral Palsy Study

The activPAL was validated for use to monitor activity levels in people with CP. The validation study was carried out concurrently with a clinical gait analysis which involved many short periods of walking, standing and sitting with numerous transitions between postures and activity states. This combination of functional physical activity provided challenging conditions for the implementation of the activPAL proprietary signal processing algorithm and posed difficulties for visual, video based characterization of physical activity.

Young subjects are likely to engage in play activity and no attempt has been made in the present study to provide characterization of non-functional motions. An alternative evaluation protocol might have used a standard walking track with set periods of sitting and quiet standing. However, this might be too restrictive for subjects to adopt their preferred body position as in free-living related poses. Perhaps an ideal evaluation would have been based on multiple long periods (e.g. 8 hours) of video based analysis in the subjects' free-living environment. This form of evaluation was unfortunately beyond the scope of this work, but may be pursued for future study.

Device variability (i.e. inter-device differences) was not tested in the current study, this could be investigated to determine whether there would be any significant differences between different activPAL monitoring devices.

Although the activPAL was found to be able to categorize activity into sitting/lying, standing and walking for people with CP, it would be best to develop the activPAL algorithm further in order to include a wider range of activities (e.g. crawling, cycling), so that an accurate representation of daily physical activities could be monitored for this group of people. Furthermore, it would be beneficial to develop the data analysis algorithm to identify intervals of non device usage, so that data collected from those periods could be discarded and hence reasons for compliance might be recognized.

It would also be useful to carry out a study to monitor free-living activity levels pre- and post-intervention (Botulinum toxin injection, surgical intervention) for subjects with CP

using the activPAL, to determine the effects of different forms of interventions to improve mobility level of people with CP.

9.2 Amputees study

The testing procedures for the validation of both pressurePAL and forcePAL were carried out in a purpose built laboratory and subjects followed set protocols (small variation between subjects due to their walking abilities), hence they might not be able to adopt their preferred body position as in their free-living environment. Perhaps again an ideal evaluation would have been based on multiple long periods (e.g. 8 hours) of video based analysis in the subjects' free-living environment. This form of evaluation was unfortunately beyond the scope of this study and would be time consuming, but might be investigated in future study. In addition, the number of subjects for the amputee study was small, and so recruiting more subjects and repeating the validation study would be valuable, especially to the statistical analysis.

Only two subjects were tested in a free-living environment using the pressurePAL and no subjects were tested using the forcePAL and it would be best to collect free-living data for amputees using these monitoring devices. However, the forcePAL would need to be developed further before it could be used in the community. A method to incorporate the forcePAL to the prosthesis would be needed and it would be ideal if no alteration to the prosthesis was necessary. It may be possible to manufacture each socket with the pressure sensor (FlexiForce) attached to reduce external alteration to the prosthesis and the data logger part could be attached when monitoring is required.

Both the data analysis algorithms for the pressurePAL and forcePAL could be improved by identifying individualised threshold for counting the number of strides that a subject performed. A few possible solutions would be pattern recognition or wavelet analysis, however, the pressure signals obtained from either the pressurePAL or the forcePAL for a gait cycle have to be investigated closely, as not all amputees adopt the general gait pattern, hence it might be difficult to identify a general pattern to represent a typical amputee gait cycle. Furthermore, the current signal analysis code was written using Matlab (Matlab Inc) and investigation into possibility to convert into a Visual Basic program would be beneficial to PALtechnologies Ltd, as this is the software they use to analysis activPAL data.

An ideal device to quantify prosthetic usage and amputees' activity levels should not require alteration to the socket and simple attachment method that could be carried out in a clinical setting and patients could then be monitored in their free-living environment before returning for removal of device. Other possible sensors could be used to measure stump/socket interface pressure, such as a fluid filled pressure bag placed at the distal end of the socket. This type of sensor could be used with all lower-limb prostheses for both trans-tibial and trans-femoral amputees. However, once again alterations of the socket would be required as a hole would be needed at the distal end to connect the sensor to the external electronic components of an activity monitoring device, but might be investigated in future study to determine its efficacy for use to monitor amputees' activity level and prosthetic usage.

For the pressurePAL or the forcePAL to be viable for use in a clinical setting, a study with an increased number of subjects (at least 30 subjects) should be carried out to validate the data analysis algorithm for activity categorization and then the devices should be evaluated in free-living environment.

REFERENCES

- Aminian, K., Najafi, B., Bula, C., Leyvraz, P.F., Robert, P. (2002) "Spatio-temporal parameters of gait measured by an ambulatory system using miniature gyroscopes" Journal of Biomechanics **35**: 689-699
- Aminian, K., Rezakhanlou, K., De Andres, E., Fritsch, C., Leyvraz, P.F., Robert, P. (1999). "Temporal feature estimation during walking using miniature accelerometers: an analysis of gait improvement after hip arthroplasty." Medical and Biological Engineering and Computing **37**: 686-691.
- Appoldt, F., Bennett, L., Contini, R. (1968). "Stump-socket pressure in lower extremity prostheses." Journal of Biomechanics **1**: 247-257.
- Argiropoulou, E. C., Michalopoulou, M., Aggeloussis, N., Avgerinos, A. (2004). "Validity and reliability of physical activity measures in Greek high school age children." Journal of Sports Science and Medicine **3**: 147-159.
- Badawi, N., Watson, L., Petterson, B., Blair, E., Slee, J., Haan, E., Stanley, F. (1998). "What constitutes cerebral palsy?" Developmental Medicine & Child Neurology **40**: 520-527.
- Beckung, E., Hagberg, G. (2002). "Neuroimpairments, activity limitations, and participation restrictions in children with cerebral palsy." Developmental Medicine & Child Neurology **44**: 309-316.
- Beil, T. L., Street, G.M., Covey, S.J. (2002). "Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets." Journal of Rehabilitation Research & Development **39**(6): 693-700.
- Berentzen, T., Sorensen, T.I.A. (2007). "Physical inactivity, obesity and health." Scandinavian Journal of Medicine & Science in Sports **17**: 301-302.
- Bize, R., Johnson, J.A., Plotnikoff, R.C. (2007). "Physical activity level and health-related quality of life in the general adult population: A systematic review." Preventive Medicine.
- Bjornson, K. F., Belza, B., Kartin, D., Logsdon, R., McLaughlin, J.F. (2007). "Ambulatory physical activity performance in youth with cerebral palsy and youth who are developing typically." Physical Therapy **87**(3): 248-260.
- Bland, J.M., Altman, D.G. (1986). "Statistical methods for assessing agreement between two methods of clinical measurement" Lancet **i**: 307-310.
- Bland, J.M., Altman, D.G. (1999). "Statistical methods in medical research" Statistical Methods in Medical Research **8**: 135-160
- Boone, D. A., Colemann, K.L. (2006). "Use of a step activity monitor in determining outcomes." Journal of Prosthetics and Orthotics **18**(Supplement): 86-92.

- Bouchard, C., Tremblay, A., Leblanc, C., Lorte, G., Savard, R., Theriault, G. (1983) "A method to assess energy expenditure in children and adults" American Journal of Clinical Nutrition **37** 461-437
- Bourke, A. K., O'Brien, J.V., Lyons, G.M. (2006). "Evaluation of a threshold-based tri-axial accelerometer fall detection algorithm." Gait & Posture.
- Brandes, M., Zijlstra, W., Heikens, S., van Lummel, R., Rosenbaum, D. (2006). "Accelerometry based assessment of gait parameters in children." Gait & Posture **24**: 482-486.
- Brown, D. W., Brown, D.R., Heath, G.W., Balluz, L., Giles, W.H., Ford, E.S., Mokdad, A.H. (2004). "Associations between physical activity dose and health-related quality of life." Medicine and Science in Sports and exercise **36**(5): 890-896.
- Buis, A. W., Convery, P. (1997). "Calibration problems encountered while monitoring stump/socket interface pressures with force sensing resistors: techniques adopted to minimise inaccuracies." Prosthetics and Orthotics International **21**: 179-182.
- Busser, H. J., Ott, J., Van Lummel, R.C., Uiterwaal, M., Blank, R. (1997). "Ambulatory monitoring of children's activity." Medical Engineering and Physics **19**: 440-445.
- Bussmann, J. B. J., Damen, L., Stam, H.J. (2000). "Analysis and decomposition of signals obtained by thigh-fixed uni-axial accelerometry during normal walking." Medical and Biological Engineering and Computing **38**: 632-638.
- Bussmann, J. B. J., Grootsholten, E.A., Stam, H.J. (2004). "Daily physical activity and heart rate response in people with a unilateral transtibial amputation for vascular disease." Archives of Physical Medicine and Rehabilitation **85**: 240-244.
- Bussmann, J. B. J., Reuvekamp, P.J., Veltink, P.H., Martens, W.L.J., Stam, H.J. (1998a). "Validity and reliability of measurements obtained with an 'activity monitor' in people with and without a transtibial amputation." Physical Therapy **78**(9): 989-998.
- Bussmann, J. B. J., Van de Laar, Y.M., Neeleman, M.P., Stam, H.J. (1998). "Ambulatory accelerometry to quantify motor behaviour in patients after failed back surgery: a validation study." Pain **74**: 153-161.
- Bussmann, J. B. J., Veltink, P.H., Koelma, F., Van Lummel, R.C., Stam, H.J. (1995). "Ambulatory monitoring of mobility-related activities: the initial phase of the development of an activity monitor." European Journal of physics medicine and rehabilitation **5**(1): 2-7.
- Butcher, K., Sallis, J.F., Mayer, J.A., Woodruff, S. (2008). "Correlates of physical activity guideline compliance for adolescents in 100 U.S. cities." Journal of Adolescent Health.

- Butte, N. F., Puyau, M.R., Adolph, A.L., Vohra, F.A., Zakeri, I. (2007). "Physical activity in nonoverweight and overweight hispanic children and adolescents." Medicine and Science in Sports and exercise **39**(8): 1257-1266.
- Campbell, K. L., Crocker, P.R.E., McKenzie, D.C. (2002). "Field evaluation of energy expenditure in women using Tritrac accelerometers." Medicine and Science in Sports and exercise **34**(10): 1667-1674.
- Cappozzo, A. (1984) "Gait analysis methodology" Human Movement Science **3**: 27-50
- Carter, J., Wilkinson, D., Blacker, S., Rayson, M., Bilzon, J., Izard, R., Coward, A., Wright, A., Nevill, A., Rennie, K., McCaffrey, T., Livingstone, B. (2008). "An investigation of a novel three-dimensional activity monitor to predict free-living energy expenditure." Journal of Sports Sciences **26**(6): 553-561.
- Cavanagh, P.R., Hewitt, F.G., Perry, J.E. (1992) "In-shoe plantar pressure measurement: a review" The Foot **2**(4) 185-194
- Chakravarthy, M. V., Joyner, M.J., Booth, F.W. (2002). "An obligation for primary care physicians to prescribe physical activity to sedentary patients to reduce the risk of chronic health conditions." Mayo Clin. Proc. **77**: 165-173.
- Chen, J. L., Wu, Y. (2008). "Cardiovascular risk factors in chinese american children: associations between overweight, acculturation, physical activity." Journal of Pediatric Health Care **22**(2): 103-110.
- Chu, E. Y. W., McManus, A.M., Yu, C.C.W. (2007). "Calibration of the RT3 accelerometer for ambulation and nonambulation in children." Medicine and Science in Sports and exercise **39**(11): 2085-2091.
- Chyun, D. A., Melkus, G.D., Katten, D.M. (2006). "The association of psychological factors, physical activity, neuropathy, and quality of life in type 2 diabetes " Biological Res Nurs **7**(4): 279-288.
- Coleman, K. L., Smith, D.G., Boone, D.A., Joseph, A.W., del Aguila, M.A. (1999). "Step activity monitor: long-term, continuous recording of ambulatory function." Journal of Research and Development **36**: 8-18.
- Collin, C., Wade, D.T., Cochrane, G.M. (1992). "Functional outcome of lower limb amputees with peripheral vascular disease." Clinical Rehabilitation **6**: 13-21.
- Convery, P., Buis, A.W.P. (1998). "Conventional patellar-tendon-bearing (PTB) socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of a trans-tibial amputee." Prosthetics and Orthotics International **22**: 193-198.

- Corry, I.S., Duffy, C.M., Cosgrave, A.P., Graham, H.K. (1996) "Measurement of oxygen consumption in disabled children by the COSMED K2 portable telemetry system" Developmental Medicine & Child Neurology **38**: 585-593
- Coumeya, K. S., Friedenreich, C.M. (1999). "Physical exercise and quality of life following cancer diagnosis: a literature review." Annals Behav. Med. **21**(2): 171-179.
- Craig, C.L., Marshall, A.L., Sjoström, M., Bauman, A.E., Booth, M.L., Ainsworth, B.E., Pratt, M., Ekelund, U., Yngve, A., Sallis, J.F., Pekka, O.J.A. (2003) "International Physical Activity Questionnaire: 12-country reliability and validity" Medicine & Science in Sports & Exercise **35**: 1381-1395
- Crouter, S. E., Clowers, K.G., Bassett, D.R. (2006). "A novel method for using accelerometer data to predict energy expenditure." Journal of Applied Physiology **100**: 1324-1331.
- Culhane, K. M., Lyons, G.M. (2004). "Long-term mobility monitoring of older adults using accelerometers in a clinical environment." clinical Rehabilitation **18**: 335-343.
- Davis, R.B., Ounpuu, S., Bell, K.J., DeLuca, P.A. (1997) "The long-term effects of orthopaedic surgery in children with cerebral palsy." Gait & Posture **5**: 82
- Day, S. M., Wu, Y.W., Strauss, D.J., Shavelle, R.M., Reynolds, R.J. (2007). "Change in ambulatory ability of adolescents and young adults with cerebral palsy." Developmental Medicine & Child Neurology **49**: 647-653.
- DeLuca, P.A. (1991) "The use of gait analysis and dynamic EMG in the assessment of the child with cerebral palsy." Human Movement Science **10**: 543-554
- Department of Culture (2002). Game Plan: A strategy for delivering the government's sport and physical activity objectives. Strategy unit. M. a. Sports. London, England.
- Desloovere, K., Molenaers, G., Feys, H., Huenaerts, C., Callewaert, B., Van de Walle, P. (2006). "Do dynamic and static clinical measurements correlate with gait analysis parameters in children with cerebral palsy?" Gait & Posture **24**(3): 302-313
- Dillingham, T. R., Pezzin, L.E., MacKenzie, E.J., Burgess, A.R. (2001). "Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study." American Journal of Physical Medicine & Rehabilitation **80**(8): 563-571.
- Eason, K.E., Masse, L.C., Kelder, S.H., Tortolero, S.R. (2002) "Diary days needed to estimate total activity and activity by dimension" Medicine & Science in Sports & Exercise **34** 1308-1315
- Egerton, T. (2005). Physical activity of older adults - a pilot study investigating actual upright activity. 27th International society for posture and gait research, Marseille, France.

- Egerton, T., Maxwell, D., Granat, M., Wellwood, I., Langhorne, P., McAlpine, C., McDonald, J. (2002). "Measurement of upright activity of patients in stroke units." Physiotherapy **88**(3): 176-177.
- Ekelund, U. L. F., Sjostrom, M., Yngve, A., Poortvliet, E., Nilsson, A., Froberg, K., Wederkopp, N., Westerterp, K. (2001). "Physical activity assessed by activity monitor and doubly labeled water in children." Medicine and Science in Sports and exercise **33**(2): 275-281.
- Engsberg, J. R., Springer, J.N., Harder, J.A. (1992). "Quantifying interface pressures in below-knee amputee sockets." Journal of Association of Child Prosthetic-Orthotics Clinic **37**(3): 81-88.
- Esliger, D. W., Probert, A., Gorber, S.C., Bryan, S., Laviolette, M., Tremblay, M.S. (2007). "Validity of the Actical Accelerometer step-count function." Medicine and Science in Sports and exercise **39**(7): 1200-1204.
- Esquenazi, A., Meler, R.H. (1996). "Rehabilitation in limb deficiency. 4. Limb amputation." Archives of Physical Medicine and Rehabilitation **77**: S18-24.
- Ferguson-Pell M, H. S., Bain D (2000). "Evaluation of a sensor for low interface pressure applications." Medical Engineering and Physics **22**: 657-663.
- Ferguson-Pell, M., Cardi, M. (1992) "Pressure mapping systems" Team Rehabilitation Report **3**(7) 28-32
- Finn, K.J. & Specker, B. (2000) "Comparison of Actiwatch activity monitor and childrens' activity rating scale in children." Medicine and Science in Sports Exercise **32**(10) 1794-1797
- Fletcher, D. D., Andrews, K.L., Butters, M.A., Jacobsen, S.J., Rowland, C.M., Hallett Jr, J.W. (2001). "Rehabilitation of the geriatric vascular amputee patient: a population-based study." Archives of Physical Medicine and Rehabilitation **82**: 776-779.
- Fletcher, D. D., Andrews, K.L., Hallett Jr, J.W., Butters, M.A., Rowland, C.M., Jacobsen, S.J. (2002). "Trends in rehabilitation after amputation for geriatric patients with vaascular disease: implications for future health resource allocation." Archives of Physical Medicine and Rehabilitation **83**: 1389-1393.
- Foerster, F., Smeja, M., Fahrenberg, J. (1999). "Detection of posture and motion by accelerometry: a validation study in ambulatory monitoring." Computers in Human Behavior **15**: 571-583.
- Foster, R. C., Lanningham-Foster, L.M., Manohar, C., McCrady, S.K., Nysse, L.J., Kaufman, K.R., Padgett, D.J., Levine, J.A. (2005). "Precision and accuracy of an ankle-worn accelerometer-based pedometer in step counting and energy expenditure." Preventive Medicine **41**: 778-783

- Fredrickson, E., Ruff, R.L, Daly, J.J. (2007) "Physiological cost index as a proxy measure for the oxygen cost of gait in stroke patients" Neurorehabilitation and Neural Repair **21**(5): 429-434
- Freedson, P., Pober, D., Janz, K.F. (2005). "Calibration of accelerometer output for children." Medicine and Science in Sports and exercise **37**(11suppl): S523-530.
- Functional independence measure (FIM): (1993) Developed by the Uniform Data System for Medical Rehabilitation, State University of New York at Buffalo, New York, USA.
- Gage, J.R (1991) "Gait analysis in cerebral palsy" London: MacKeith Press; Oxford: Blackwell Scientific Publishers; New York: Cambridge University Press.
- Gayle, R., Montoye, H.J., Philpot, J. (1977). "Accuracy of pedometeres for measuring distance walked." Research Quarterly for Exercise and Sport **48**: 632-636.
- Geurts, A. C. H., Mulder, T.H., Rijken, F.A.J., Nienhuis, B. (1991). "From the analysis of movements to the analysis of skills: bridging the gap between laboratory and clinic." Journal of Rehabilitation Science **4**: 9-12.
- Godfrey, A., Culhane, K.M., Lyons, G.M. (2007). "Comparison of the performance of the activPAL Professional physical activity logger to a discrete accelerometer-based activity monitor." Medical Engineering and Physics **29**(8): 930-934.
- Goh, J. C. H., Lee, P.V.S., Chong, S.Y. (2003). "Stump/socket pressure profiles of the pressure cast prosthetic socket." Clinical Biomechanics **18**: 237-243.
- Going, S.B., Levin, S., Harrel, J. (1999) "Physical activity assessment in American Indian schoolchildren in the Pathways study." American Journal of Clinical Nutrition **69** 788S-795S
- Graham, H. K., Harvey, A. (2007). "Assessment of mobility after multi-level surgery for cerebral palsy." Journal of Bone Joint Surgery - British **89**: 993-994.
- Granat, M. H., Maxwell, D.J., Bosch, C.J., Gerguson, A.C.B., Lees, K.R., Barbenel, J.C. (1995). "A body-worn gait analysis system for evaluating hemiplegic gait." Medical Engineering and Physics **17**(5): 390-394.
- Grant, P. M., Ryan, C.G., Tigbe, W.W., Granat, M.H. (2006). "The validation of a novel activity monitor in the measurement of posture and motion during everyday activities." British Journal of Sports Medicine **40**: 992-997.
- Hager, R. L. (2006). "Television viewing and physical activity in children." Journal of Adolescent Health **39**: 656-661.
- Ham, S. A., Reis, J.P., Strath, S.J., Dubose, K.D., Ainsworth, B.E. (2007). "Discrepancies between methods of identifying objectively determined physical activity." Medicine and Science in Sports and exercise **39**(1): 52-58.

- Harris, N., Britton, E., Morrell, E., Davis, L. (2006). "Evaluation of a single axis accelerometry system for monitoring sit to stand activity in stroke patients." Clinical Rehabilitation **20**: 637-643.
- Haskell, W. L., Lee, I.M., Pate, R.R., Powell, K.E., Blair, S.N., Franklin, B.A., Macera, C.A., Heath, G.W., Thompson, P.D., Bauman, A. (2007). "Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association." Medicine and Science in Sports and exercise **39**(8): 1423-1434.
- Heitzler, C. D., Martin, S.L., Duke, J., Huhman, M. (2006). "Correlates of physical activity in a national sample of children aged 9-13 years." Preventive Medicine **42**: 254-260.
- Hendelman, D., Miller, K., Baggett, C., Debold, E., Freedson, P. (2000). "Validity of accelerometry for the assessment of moderate intensity physical activity in the field." Medicine and Science in Sports and exercise **32**(9suppl): S442-449.
- Henriksen, M., Lund, H., Moe-Nilssen, R., Bliddal, H., Danneskiold-Samsøe, B. (2004). "Test-retest reliability of trunk accelerometric gait analysis." Gait & Posture **19**: 288-297.
- Holden, J. M., Fernie, G.R. (1987). "Extent of artificial limb use following rehabilitation." Journal of Orthopaedic Research **5**: 562-568.
- Hopman, W. M., Towheed, T., Anastassiades, T. (2000). "Canadian normative data for the SF-36 health survey." Can. Med. Assoc. J. **163**(3): 265-271.
- Houston, V. L., Mason, C.P., LaBlanc, K.P., Beattie, A.C., Garbarini, M.A., Lorenze, E.J. (1994). Preliminary results with the DVA-Tekscan below-knee prosthetics socket/residual limb stress measurement system. Proceedings of the 20th Annual Meeting & Scientific Symposium of the American Academy of Orthotists and Prosthetists.
- Hunt, S.M., McKenna, S.P., McEwan, J. (1980) "A quantitative approach to perceived health status: a validation study. Journal of Epidemiology Community Health **34** 281-286
- Hussey, J., Bennett, K., Dwyer, J.O., Langford, S., Bell, C., Gormley, J. (2007). "Validation of the RT3 in the measurement of physical activity in children." Journal of Science and Medicine in Sport.
- Hustvedt, B-E., Christophersen, A., Johnsen, L.R., Tomten, H., McNeill, G., Haggarty, P., Lovo, A. (2004) "Description and validation of the ActiReg: a novel instrument to measure physical activity and energy expenditure" British Journal of Nutrition **92**(6) 1001-1008
- Jakicic, J. M., Winters, C., Lagally, K., Ho, J., Robertson, R.J., Wing, R.R. (1999). "The accuracy of the TriTrac-R3D accelerometer to estimate energy expenditure." Medicine and Science in Sports and exercise **31**(5): 747-754.

- Jamieson, P. (2002). The validation of a novel activity monitor. Bioengineering Unit. Glasgow, University of Strathclyde. **MSc**: 72.
- Jasiewicz, J. M., Allum, J.H.J., Middleton, J.W., Barriskill, A., Condie, P., Purcell, B., Li, R.C.T. (2006). "Gait event detection using linear accelerometers or angular velocity transducers in able-bodied and spinal-cord injured individuals." Gait & Posture **24**: 502-509.
- Jia, X., Zhang, M., Li, X., Lee, W.C.C. (2004). "Load transfer mechanics between trans-tibial prosthetic socket and residual limb - dynamic effects." Journal of Biomechanics **37**: 1371-1377.
- Jia, X., Zhang, M., Li, X., Lee, W.C.C. (2005). "A quasi-dynamic nonlinear finite element model to investigate prosthetic interface stresses during walking for trans-tibial amputees." Clinical Biomechanics **20**: 630-635.
- Johnson, V. J., Kondziela, S., Gottschalk, F. (1995). "Pre and post-amputation mobility of trans-tibial amputees: correlation to medical problems, age and mortality." Prosthetics and Orthotics International **19**: 159-164.
- Johnson, R.K., Russ, J., Goran, M.I. (1998) "Physical activity related energy expenditure in children by doubly labeled water as compared with the Caltrac accelerometer." International Journal of Obesity Related Metabolic Disorders **22**(11) 1046-1052
- Johnston, T. E., Moore, S.E., Quinn, L.T., Smith, B.T. (2004). "Energy cost of walking in children with cerebral palsy: relation to the Gross Motor Function Classification System." Developmental Medicine & Child Neurology **46**: 34-38.
- Kamphuis, M., Geerlings, M.I., Tjhuis, M.A.R., Giampaoli, S., Nissinen, A., Grobbee, D.E., Kromhout, D. (2007). "Physical inactivity, depression, and risk of cardiovascular mortality." Medicine and Science in Sports and exercise **39**(10): 1693-1699.
- Kavanagh, J. J., Menz, H.B. (2008). "Accelerometry: A technique for quantifying movement patterns during walking." Gait & Posture.
- Kegal, B., Carpenter, M.L., Burgess, E.M. (1978). "Functional capabilities of lower extremity amputees." Archive of Physics Medicine and Rehabilitation **59**: 109-119
- Keith, R. A. (1994). "Functional status and health status." Archive of Physics Medicine and Rehabilitation **75**: 478-483.
- Kirtley, C. (2006) "Clinical gait analysis: theory and practice" Edinburgh: Elsevier
- Kohl, H. W. (2001). "Physical activity and cardiovascular disease: evidence for a dose response." Medicine and Science in Sports and exercise **33**(6): S472-483.
- Koman, L. A., Smith, B.P., Shilt, S. (2004). "Cerebral palsy." The Lancet **353**: 1619-1631.
- Krouskop, T.A., Brown, B.G., Winningham, D.J. (1987) "Interface pressure in above-knee sockets" Archive of Physics Medicine & Rehabilitation **68** 713-714

- Lau, H., Tong, K. (2007). "The reliability of using accelerometer and gyroscope for gait event identification on persons with dropped foot." Gait & Posture.
- Lean, M. E. J., Granat, M.H., Tigbe, W.W. (2007) "An investigation of the predictive value of the measurement of upright free-living physical activity in determining the risk factors of heart disease - a pilot study." Scottish Executive Health Department Chief Scientist Office: Focus on Research Executive Summary Report (CZG/2/80)
- Lee, I. M., Skerrett, P.J. (2001). "Physical activity and all-cause mortality: what is the dose-response relation?" Medicine and Science in Sports and exercise **33**(6): S459-471.
- Lee, V. S. P., Solomonidis, S.E., Spence, W.D. (1997). "Stump-socket interface pressure as an aid to socket design in prostheses for trans-femoral amputees - a preliminary study." Proceedings of the Institution of Mechanical Engineers Part H: Journal of Engineering in Medicine **211**: 167-180.
- Leenders, N. Y., Sherman, W.M., Nagaraja, H.N. (2006). "Energy expenditure estimated by accelerometry and doubly labeled water: do they agree?" Medicine and Science in Sports and exercise **38**(12): 2165-2172.
- Legro, M. W., Reiber, G., del Aguila, M., Ajax, M.J., Boone, D.A., Larsen, J.A., Smith, D.G., Sangeorzan, B. (1999). "Issues of importance reported by persons with lower limb amputations and prostheses." Journal of Rehabilitation Research & Development **36**(3): 155-163.
- Leung, E. C. C., Rush, P.J., Devlin, M. (1996). "Predicting prosthetic rehabilitation outcome in lower limb amputee patients with the functional independence measure." Archives of Physical Medicine and Rehabilitation **77**: 605-608.
- Levine, J. A., Baukol, P.A., Westerterp, K.R. (2001). "Validation of the Tracmor triaxial accelerometer system for walking." Medicine and Science in Sports and exercise **33**(9): 1593-1597.
- Lincoln, N. B. (1990). "Research methodology " Clinical Rehabilitation **4**: 91-93.
- Liptak, G. S., Accardo, P.J. (2004). "Health and social outcomes of children with cerebral palsy." Journal of Paediatrics **145**: S36-41.
- Littlewood, R.A., Davies, P.S., Cleghorn, G.J., Grote, R.H. (2004) "Physical activity cost in children following an acquired brain injury - a comparative study" Clinical Nutrition **23**: 99-104
- Lof, M., Hannestad, U., Forsum, E. (2003) "Comparison of commonly used procedures, including the doubly-labelled water technique, in the estimation of total energy expenditure of women with special reference to the significance of body fatness" British Journal of Nutrition **90**: 961-968

- Lord, S., Rochester, L., Baker, K., Nieuwboer, A. (2007). "Concurrent validity of accelerometry to measure gait in Parkinsons Disease." Gait & Posture.
- Lotters, J. C., Schipper, J., Veltink, P.H., Olthuis, W., Bergveld, P. (1998). "Procedure for in-use calibration of triaxial accelerometers in medical applications." Sensors and Actuators **68**: 221-228.
- Lynch, J., Helmrigh, S.P., Lakka, T.A., Kaplan, G.A., Cohen, R.D., Salonen, R., Salonen, J.T. (1996). "Moderately intense physical activities and high levels of cardiorespiratory fitness reduce the risk of non-insulin-dependent diabetes mellitus in middle-aged men." Arch. Intern. Med **156**: 1258-1354.
- Lyons, G. M., Culhane, K.M., Hilton, D., Grace, P.A., Lyons, D. (2005). "A description of an accelerometer-based mobility monitoring technique." Medical Engineering and Physics.
- Maher, C. A., Williams, M.T., Olds, T., Lane, A.E. (2007). "Physical and sedentary activity in adolescents with cerebral palsy." Developmental Medicine & Child Neurology **49**: 450-457.
- Mahoney, F.I. & Barthel, D.W. (1965) "Functional evaluation: The Bathel Index. A simple index of indepenence useful in scoring improvement in the relation of the chronically ill." Maryland State Medical Journal **14** 61-65
- Maltais, D. B., Pierrynowski, M.R., Galea, V.A., Bar-Or, O. (2005). "Physical activity level is associated with the O2 cost of walking in cerebral palsy." Medicine and Science in Sports and exercise **37**(3): 347-353.
- Matthews, C. E., Ainsworth, B.E., Thompson, R.W., Bassett, D.R. (2002). "Sources of variance in daily physical activity levels as measured by an accelerometer." Medicine and Science in Sports and exercise **34**(8): 1376-1381.
- Mayagoitia, R. E., Lotters, J.C., Veltink, P.H., Hermens, H. (2002). "Standing balance evaluation using a triaxial accelerometer." Gait & Posture **16**: 55-59.
- Mayfield, J. A., Reiber, G.E., Maynard, C., Czerniecki, J.M., Caps, M.T., Sangeorzan, B.J. (2000). "Trends in lower limb amputation in the Veterans Health Administration, 1989-1998." Journal of Rehabilitation Research & Development **37**(1): 23-30.
- Maynard, F.M et al (1997). International standard for Neurological and Functional Classification of Spinal Cord Injury **35**(5): 273
- McClain, J. J., Sisson, S.B., Tudor-Locke, C. (2007a). "Actigraph accelerometer interinstrument reliability during free-living in adults." Medicine and Science in Sports and exercise **39**(9): 1509-1514.

- McDonald, C. M., Widman, L., Abresch, R.T., Walsh, S.A., Walsh, D.D. (2005). "Utility of a step activity monitor for the measurement of daily ambulatory activity in children." Archives of Physical Medicine and Rehabilitation **86**: 793-801.
- Meriwether, R. A., McMahon, P.M., Islam, N., Steinmann, W.C. (2006). "Physical activity assessment: Validation of a clinical assessment tool." American Journal of Preventive Medicine **31**(6): 484-491.
- Metcalf, B. S., Curnow, J.S.H., Evans, C., Voss, L.D., Wilkin, T.J. (2002). "Technical reliability of the CSA activity monitor: the earlybird study." Medicine and Science in Sports and exercise **34**(9): 1533-1537.
- Moe-Nilssen, R. (1998a). "A new method for evaluating motor control in gait under real-life environmental conditions. Part 1: The instrument." Clinical Biomechanics **13**: 320-327.
- Moe-Nilssen, R. (1998b). "Test-retest reliability of trunk accelerometry during standing and walking." Archives of Physical Medicine and Rehabilitation **79**: 1377-1385.
- Moe-Nilssen, R., Helbostad, J.L. (2002) "Trunk accelerometry as a measure of balance control during quiet standing." Gait & Posture **16**: 60-68
- Moe-Nilssen, R., Helbostad, J.L. (2004). "Estimation of gait cycle characteristics by trunk accelerometry." Journal of Biomechanics **37**: 121-126.
- Morris, J. R. W. (1973). "Accelerometry - a technique for the measurement of human body movements." Journal of Biomechanics **6**: 729-736.
- Murphy, N., Such-Neibar, T. (2003). "Cerebral palsy diagnosis and management: The state of the art." Current Problem in Pediatric Adolescence Health Care: 146-149.
- Najafi, B., Aminian, K., Paraschiv-Ionescu, A., Loew, F., Bula, C., Robert, P. (2003). "Ambulatory system for human motion analysis using a kinematic sensor: monitoring of daily physical activity in the elderly." IEEE Transaction in Biomedical Engineering **50**: 711-723.
- Narang, I. C., Mathur, B.P., Singh, P., Jape, V.S. (1984). "Functional capabilities of lower limb amputees." Prosthetics and Orthotics International **8**: 43-51.
- Nelson, M. E., Rejeski, W.J., Blair, S.N., Duncan, P.W., Judge, J.O., King, A.C., Macera, C.A., Castaneda-Sceppa, C. (2007). "Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association." Medicine and Science in Sports and exercise **39**(8): 1435-1445.
- Nichols, J. F., Morgan, C.G., Sarkin, J.A., Sallis, J.F., Calfas, K.J. (1999). "Validity, reliability, and calibration of the Tritrac accelerometer as a measure of physical activity." Medicine and Science in Sports and exercise **31**(6): 908-912.

- Novacheck, T.F., Stout, J.L., Tervo, R. (2000) "Reliability and validity of the Gillette Functional Assessment Questionnaire as an outcome measure in children with walking disabilities" Journal of Paediatric Orthopaedics **20**(1) 75-81
- Oeffinger, D., Gorton, G., Bagley, A., Nicholson, D., Barnes, D., Calmes, J., Abel, M., Damiano, D., Dryscio, R., Rogers, S., Tylkowski, C. (2007). "Outcome assessments in children with cerebral palsy, Part I: descriptive characteristics of GMFCS Levels I to III." Developmental Medicine & Child Neurology **49**: 172-180.
- Officer, C. M. (2004). At least five a week: evidence on the impact of physical activity and its relationship to health. Department of Health. London, England.
- Orendurff, M., Schoen, J., Bernatx, G., Crass, S., Klute, G. (2009) "How humans walk: bout duration, steps per bout and rest duration." Journal of Rehabilitation Research and Development
- Palisano, R., Rosenbaum, P., Walter, S., Russell, D., Wood, E., Galuppi, B. (1997). "Development and reliability of a system to classify gross motor function in children with cerebral palsy." Developmental Medicine & Child Neurology **39**: 214-223.
- Panesar, B. S., Morrison, P., Hunter, J. (2001). "A comparison of three measures of progress in early lower limb amputee rehabilitation." Clinical Rehabilitation **15**: 157-171.
- Paraschiv-Ionescu, A., Buchser, E.E., Rutschmann, B., Najafi, B., Aminian, K. (2004). "Ambulatory system for the quantitative and qualitative analysis of gait and posture in chronic pain patients treated with spinal cord stimulation." Gait & Posture **20**: 113-125.
- Pearson, J. R., Holmgren, G., March, L., Oberg, K. (1973). "Pressure in critical regions of below-knee prostheses." Bulletin of Prosthetics Research **10**: 53-76.
- Perkins, M. A., Dicken, P., Hyde, D.J., Grant, L.J. (1995). "Two miniature monitors for long-term ambulatory studies." Medical Engineering and Physics **17**(6): 410-415.
- Pernot, H. F. M., de White, L.P., Linderman, E., Cluitmans, J. (1997). "Daily functioning of the lower extremity amputee: an overview of the literature." Clinical Rehabilitation **11**: 93-106.
- Perry, J. (1992) "Gait analysis: normal and pathological function" Thorofare, NJ: SLACK
- Pezzin, L. E., Dillingham, T.R., MacKenzie, E.J., Ephraim, P., Rossbach, P. (2004). "Use and satisfaction with prosthetic limb devices and related services." Archives of Physical Medicine and Rehabilitation **85**: 723-729.
- Pfeiffer, K. A., Mciver, K.L., Dowda, M., Almeida, M.J.C.A. (2006). "Validation and calibration of the Actical accelerometer in preschool children." Medicine and Science in Sports and exercise **38**(1): 152-157.

- Physical Activity Guidelines Advisory Committee. Report of the Physical Activity Guidelines Advisory (2008), DHHS website (<http://health.gov/paguidelines>)
- Piriyaprasarth, P., Morris, M.E. (2007) "Psychometric properties of measurement tools for quantifying knee joint position and movement: A systematic review" The Knee **14**: 2-8
- Plasqui, G., Westerterp, K.R. (2007). "Physical activity assessment with accelerometers: an evaluation against doubly labeled water." Obesity **15**(10): 2371-2379.
- Pohjolainen, T., Alaranta, H., Karkkainen, M. (1990). "Prosthetic use and functional and social outcome following major lower limb amputation." Prosthetics and Orthotics International **14**: 75-79
- Powell, S. M., Jones, D.I., Rowlands, A.V. (2003). "Technical variability of the RT3 accelerometer." Medicine and Science in Sports and exercise **35**(10): 1773-1778.
- Puyau, M.R., Adolph, A.L., Vohra, F.A., Butte, N.F. (2002) "Validation and calibration of physical activity monitors in children" Obesity Research **10**(3) 150-157
- Puyau, M. R., Adolph, A.L., Vohra, F.A., Zakeri, I., Butte, N.F. (2004). "Prediction of activity energy expenditure using accelerometers in children." Medicine and Science in Sports and exercise **36**(9): 1625-1631.
- Rae, J. W., Cockrell, J.L. (1971). "Interface pressure and stress distribution in prosthetic fitting." Bulletin of Prosthetics Research **10**(64-111).
- Ramstrand, N., Nilsson, K.A. (2007). "Validation of a patient activity monitor to quantify ambulatory activity in an amputee population." Prosthetics and Orthotics International **31**(2): 157-166.
- Ricamato, A.L., Hidler, J.M. (2005) "Quantification of the dynamic properties of EMG patterns during gait" Journal of Electromyography and Kinesiology **15**: 384-392
- Ridgers, N. D., Stratton, G., Fairclough, S.J. (2005). "Assessment physical activity during recess using accelerometry." Preventive Medicine **41**: 102-107.
- Rodriguez, G., Beghin, L., Michaud, L., Moreno, L.A., Turck, D., Gottrand, F. (2002). "Comparison of the TriTrac-R3D accelerometer and a self-report activity diary with heart-rate monitoring for the assessment of energy expenditure in children." British Journal of Nutrition **87**: 623-631.
- Rommers, G.M., Vos, L.D.W., Groothoff, J.W., Eisma, W.E. (2001) "Mobility of people with lower limb amputations: scales and questionnaires: a review. Clinical Rehabilitation **15**: 92-102
- Ross, J., Reece, A. (2006). A pilot study into the use of the long term activity monitor. British Association of Prosthetists and Orthotists Annual Conference, Glasgow 24-26 March, 2006.

- Rowe, P.J., Myles, C.M., Hillmann, S.J., Hazlewood, M.E. (2001) "Validation of flexible electrogoniometry as a measure of joint kinematics" Physiotherapy **87**(9): 479-488
- Rowlands, A.V., Eston, R.G., Ingledew, D.K. (1997) "Measurement of physical activity in children with particular reference to the use of heart rate and pedometry" Sports Medicine **24**(4): 258-272
- Rowlands, A. V., Pilgrim, E.L., Eston, R.G. (2007b). "Patterns of habitual activity across weekdays and weekend days in 9-11 year-old children." Preventive Medicine.
- Rowlands, A. V., Thomas, P.W.M., Eston, R.G., Topping, R. (2004). "Validation of the RT3 Triaxial accelerometer for the assessment of physical activity." Medicine and Science in Sports and exercise **36**(3): 518-524.
- Ryan, C. G., Grant, P.M., Tigbe, W.W., Granat, M.H. (2006). "The validity and reliability of a novel activity monitor as a measure of walking." British Journal of Sports Medicine **40**: 779-784.
- Sallis, J. F., Buono, M.J., Roby, J.J., Carlson, D., Nelson, J.A. (1990). "The Caltrac accelerometer as a physical activity monitor for school-age children." Medicine and Science in Sports and exercise **22**(5): 698-703.
- Sanders, J.E. (1995) "Interface mechanics in external prosthetics review of interface stress measurement techniques" Medical and Biological Engineering and Computing **33** 509-516
- Sanders, J. E., Daly, C.H. (1999). "Interface pressures and shear stresses: sagittal plane angular alignment effects in three trans-tibial amputee case studies." Prosthetics and Orthotics International **23**: 21-29.
- Sanders, J. E., Lam, D., Dralle, A.J., Okumura, R. (1997). "Interface pressures and shear stresses at thirteen socket sites on two persons with transtibial amputation." Journal of Rehabilitation Research & Development **34**: 19-43.
- Sankar, C., Mundkur, N. (2005). "Cerebral palsy - definition, classification, etiology and early diagnosis." Indian Journal of Pediatr **72**: 865-868.
- Scapellato, S., Cavallo, F., Martelloni, C., Sabatini, A.M. (2005) "In-use calibration of body-mounted gyroscopes for applications in gait analysis" Sensors and Actuators
- Schasfoort, F. C., Bussmann, J.B.F., Stam, H.J. (2002). "Ambulatory measurement of upper limb usage and mobility-related activities during normal daily life with an upper limb-activity monitor: a feasibility study." Medical and Biological Engineering and Computing **40**: 173-182.
- Schneider, P. L., Crouter, S.E., Bassett, D.R. (2004). "Pedometer measures of free-living physical activity: comparison of 13 models." Medicine and Science in Sports and exercise **36**(2): 331-335.

- Simon, S.R. (2004) "Quantification of human motion: gait analysis - benefits and limitations to its application to clinical problems" Journal of Biomechanics **37**: 1869-1880
- Sirard, J. R., Melanson, E.L., Li, L., Freedson, P.S. (2000). "Field evaluation of the computer science and applications, Inc. physical activity monitor." Medicine and Science in Sports and exercise **32**(3): 695-700.
- Smith, D. W., McFall, S.L. (2005). "The relationship of diet and exercise for weight control and the quality of life gap associated with diabetes." Journal of Psychosom. Res **59**(6): 385-392.
- Stam, H. J., Eijskoot, F., Bussmann, B.J. (1995). "A device for long term ambulatory monitoring in trans-tibial amputees." Prosthetics and Orthotics International **19**: 53-55.
- Stamatakis, E., Eklund, U., Wareham, N.J. (2007) "Temporal trends in physical activity in England: The health survey for England 1991-2004." Preventive Medicine **45**(6) 416-423
- Steenbergen, B., Gordon, A.M. (2006). "Activity limitation in hemiplegic cerebral palsy: evidence for disorders in motor planning." Developmental Medicine & Child Neurology **48**: 780-783.
- Strout, P. E., Fleiss, J. L. (1979) "Intraclass correlations: uses in assessing rater reliability" Psychological Bulletin **86**: 420-428
- Sun, M. & Hill, J. (1993) "A method for measuring mechanical work and work efficiency during human activities." Journal of Biomechanics **26** 229-241
- Sun, M., Reed, G.W., Hill, J. (1994) "Modification of a whole-room calorimeter for measuring of rapid changes in energy expenditure." Journal of Applied Physiology 2686-2691
- Telama, R., Yang, X., Viikari, J. (2005). "Physical activity from childhood to adulthood: a 21-year tracking study." American Journal of Preventive Medicine **28**: 267-273.
- The-Global-lower-extremity-amputation-study-group (2000). "Epidemiology of lower extremity amputation in centres in Europe, North America and East Asia." British Journal of Surgery **87**: 328-337.
- Thune, I., Furberg, A.S. (2001). "Physical activity and cancer risk: dose-response and cancer, all sites and site-specific." Medicine and Science in Sports and exercise **33**(6): S530-550.
- Tong, K., Granat, M.H. (1999) "A practical gait analysis system using gyroscopes" Medical Engineering and Physics **21**: 87-94
- Toschke, J.A., von Kries, R., Rosenfeld, E., Toschke, A.M. (2007) "Reliability of physical activity measures from accelerometry among preschoolers in free-living conditions." Clinical Nutrition **26**(4) 416-420

- Trost, S. G., Pate, R.R., Freedson, P.S., Sallis, J.F., Taylor, W.C. (2000). "Using objective physical activity measures with youth: How many days of monitoring are needed?" Medicine and Science in Sports and exercise **32**(2): 426-431.
- Trost, S. G., Pate, R.R., Ward, D.S., Saunders, R., Riner, W. (1999). "Correlates of objectively measured physical activity in preadolescent youth." American Journal of Preventive Medicine **17**(2): 120-126.
- Trost, S. G., Ward, D.S., Moorehead, S.M., Watson, P.D., Riner, W., Burke, J.R. (1998). "Validity of the computer science and applications (CSA) activity monitor in children." Medicine and Science in Sports and exercise **30**(4): 629-633.
- Trost, S. G., Way, R., Okely, A.D. (2006). "Predictive validity of three ActiGraph energy expenditure equations for children." Medicine and Science in Sports and exercise **38**(2): 380-387.
- Tudor-Locke, C., Burkett, L., Reis, J.P., Ainsworth, B.E., Macera, C.A., Wilson, D.K. (2005). "How many days of pedometer monitoring predict weekly physical activity in adults?" Preventive Medicine **40**: 293-298.
- Uiterwaal, M., Glerum, E.B.C., Busser, H.J., Van Lummel, R.C. (1998). "Ambulatory monitoring of physical activity in working situations, a validation study." Journal of Medical Engineering & Technology **22**(4): 168-172.
- Uiterwijk, A. E. M., Remerie, S.C., Rol, M., Sier, J.C., Stam, H.J., Terburg, M. (1997). "Routing through the health care system and level of functioning of lower limb amputees." Clinical Rehabilitation **11**: 253-262.
- van der Dussen, L., Nieuwstraten, W., Roebroek, M., Stam, H.J. (2001). "Functional level of young adults with cerebral palsy." Clinical Rehabilitation **15**: 84-91
- Van der Horst, K., Paw, M.J.C.A., Twisk, J.W.R., Van Mechelen, W. (2007). "A brief review on correlates of physical activity and sedentariness in youth." Medicine and Science in Sports and exercise **39**(8): 1241-1250.
- Van Lummel, R. C., Van der Slikke, R.M.A., Uiterwaal, M. (2002). "An objective clinical movement analysis concept for outcome reaserach: 'DynaPort'." Orthopadie-Technik Quarterly, English edition **7**: 6-15.
- van Velzen, J. M., van Bennekom, C.A.M., van der Woude, L.H.V., Houdijk, H. (2006). "Physical capacity and walking ability after lower limb amputation: a systematic review." Clinical Rehabilitation **20**: 999-1016.
- VanPijkeren, T., Naeff, M., Kwee, H.H. (1980). "A new method for the measurement of normal pressure between amputation residual limb and socket." Bulletin of Prosthetics Research **10**: 31-34.

- Veltink, P. H., Bussmann, H.B.J., Vries, W., Martens, W.L.J., Van Lummel, R.C. (1996). "Detection of static and dynamic activities using uniaxial accelerometers." IEEE Transactions on Rehabilitation Engineering **4**(4): 375-385.
- Ware, J.E. (1993) "SF-36 Health Survey: Manual & Interpretation Guide. Boston: The Health Institute, New England Medical Centre, USA.
- Washburn, R. A., Chin, M.K., Montoye, H.J. (1980). "Accuracy of pedometer in walking and running." Research Quarterly for Exercise and Sport **51**: 695-702.
- Washburn, R. A., Montoye, H.J. (1986). "The assessment of physical activity by questionnaire." American Journal of Epidemiology **123**: 563-576.
- Welk, G.J., Almeida, J., Morss, G. (2003) "Laboratory calibration and validation of the Biotrainer and Actitrac activity monitors" Medicine & Science in Sports and Exercise **35**(6) 1057-1064
- Welk, G. J., Schaben, J.A., Morrow, J.R. (2004). "Reliability of accelerometry-based activity monitors: a generalizability study." Medicine and Science in Sports and exercise **36**(9): 1637-1645.
- Westerterp, K. R., Kester, A.D.M. (2003). "Physical activity in confined conditions as an indicator of free-living physical activity." Obesity Research **11**: 865-868.
- White, R., Agouris, L., Selbie, R.D., Kirkpatrick, M. (1999) "The variability of force platform data in normal and cerebral plays gait" Clinical Biomechanics **14**: 185-192
- White, D. K., Wagenaar, R.C., Del Olmo, M.E., Ellis, T.D. (2007). "Test-retest reliability of 24 hours of activity monitoring in individuals with parkinson's disease in home and community." Neurorehabilitation and Neural Repair **21**(4): 327-340.
- WHO (1980). International classification of impairment, disabilities and handicaps; a manual of classification relating to the consequences of disease. W. H. Organization, Geneva.
- WHO (2001). International classification of functioning, disability and health. W. H. Organization. Geneva.
- Willemsen, A. M., Bloemhof, F., Boom, H.B.K. (1990). "Automatic stance-swing phase detection from accelerometer data for peroneal nerve stimulation." IEEE Transaction in Biomedical Engineering **37**: 1201-1208.
- Zanchi, V., Papic, V., Cecic, M. (2000) "Quantitative human gait analysis" Simulation Practice and Theory **8**: 127-139
- Zhang, K., Werner, P., Sun, M., Pi-Sunyer, F.X., Boozer, C.N. (2003). "Measurement of human daily physical activity." Obesity Research **11**: 33-40.
- Zhang, M., Turner-Smith, A.R., Roberts, V.C., Tanner, A. (1996). "Frictional action at lower limb/prosthetic socket interface." Medical Engineering and Physics **18**: 207-214.

Zhang, M., Turner-Smith, A.R., Tanner, A., Roberts, V.C. (1998). "Clinical investigation of the pressure and shear stress on the trans-tibial stump with a prosthesis." Medical Engineering and Physics **20**: 188-198.

<http://health.gov/paguidelines>

APPENDICES

- Appendix I Functional Assessment Questionnaire
- Appendix II Example of activity profile and activity summary obtained from activPAL data
- Appendix III Matlab algorithm for posture categorization comparison between video and activPAL data for people with CP
- Appendix IV CP subjects gait patterns
- Appendix V Example of timetable/diary given to subject with CP for 7 day activity self-reporting
- Appendix VI Example of a set of weekly CP results with annotated note from diary
- Appendix VII Average number of upright events per day for different minimum setting of upright times
- Appendix VIII Average number of sedentary events per day for different minimum setting of no-upright times
- Appendix IX Matlab algorithm for activity categorization with the pressurePAL data
- Appendix X Matlab algorithm for activity categorization with the forcePAL data
- Appendix XI Matlab code for comparison between video and pressure/forcePAL data

Appendix I – Functional Assessment Questionnaire

The following questionnaire was used to identify mobility level of individual attended for gait analysis at the Anderson Gait Laboratory, Edinburgh, UK. Higher levels of mobility skills are also indicated.

Functional Assessment Questionnaire

Date:.....

Mobility Levels

Choose the **one** answer below that best describes your child's typical walking ability (**with the use of any needed assistive devices**).

My child...

1. Cannot take any steps at all.
2. Can do some stepping on his/her own with the help of another person. Does not take full weight on feet; does not walk on a routine basis.
3. Walks for exercise in therapy and less than typical household distances. Usually requires assistance from another person.
4. Walks for household distances, but makes slow progress. Does not use walking at home as preferred mobility (primarily walks in therapy).
5. Walks more than 15-50 feet but only inside at home or school (walks for household distances).
6. Walks more than 15-50 feet outside the home, but usually uses a wheelchair or buggy for community distances or in congested areas.
7. Walks outside the home for community distances, but only on level surfaces (cannot manage kerbs, uneven ground, or stairs without assistance of another person).
8. Walks outside the home for community distances, is able to manage kerbs and uneven ground in addition to level surfaces, but usually requires minimal assistance or supervision for safety.
9. Walks outside the home for community distances, easily gets around on level surfaces, kerbs, and uneven ground, but has difficulty or requires minimal assistance with running, climbing, and/or stairs.
10. Walks, runs and climbs on level and uneven ground without difficulty or assistance.

Higher Level mobility skills

Please tick all the things your child is able to do:

- Walk carrying an object
- Walk carrying a fragile object or a glass of liquid
- Walk up and downstairs without using the banister
- Steps up and down a kerb independently
- Run
- Runs well including around a corner with good control
- Can take steps backwards
- Can manoeuvre in tight areas
- Able to get on/off the bus independently
- Able to jump over a rope
- Able to jump off a single step
- Hop on the right foot
- Hop on the left foot
- Kick a ball with the right foot
- Kick a ball with the left foot
- Ride a two wheeler bike
- Ride a trike
- Ice skate or roller skate/blade
- Ride an escalator, stepping on/off by her/himself

Appendix II – Activity profile and Activity summary generated by activPAL

For activPAL data retrieved using the activPAL software, two types of files are generated, the activity profile and the activity summary. For all activPAL data, yellow represents sedentary events (sitting/lying); green represents standing episodes and red corresponds to stepping activity. The intensity of the activity can be seen by the amplitude of the data in the activity profile graphs.

The start time and end time of the recording period is shown with the total monitoring duration. On the right hand side of the activity profile graph is a pie chart indicating the proportion of time spent in different activity in that hour and the total duration of time spent is also stated. The results are shown in hourly interval, so 24 similar graphs as Figure II.a would be found in a complete day of recording (midnight to midnight).

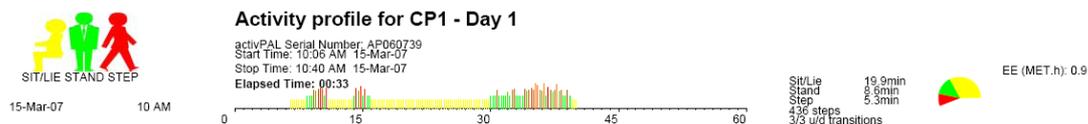


Figure II.a: Example of activity profile obtained from the activPAL

For the activity summary (Figure II.b), information on the number of steps performed within different cadence bands, number of upright events and number of sedentary events is presented. The overall time spent in each activity state is also noted. The total time spent in each activity state during either the recording time (if less than 24 hours) or daily (if multi-days were recorded) is shown in the activity summary, with a pie chart indicating the proportion of time spent in each activity state.



Activity summary for CP1 - Day 1

activPAL serial number: AP060739
 Start Time: 10:06:21 AM 15-Mar-07
 Stop Time: 10:40:16 AM 15-Mar-07

Elapsed Time: 00:33:55

TIME (h:m:s)			
00:20:01	(59%)	Sitting/Lying:	
00:08:36	(25%)	Standing:	
00:05:18	(16%)	Stepping:	



TOTAL NUMBER OF STEPS: 436

Energy Expenditure: 0.9 MET.h

Upright Events: 4

Seated/Lying Events: 3

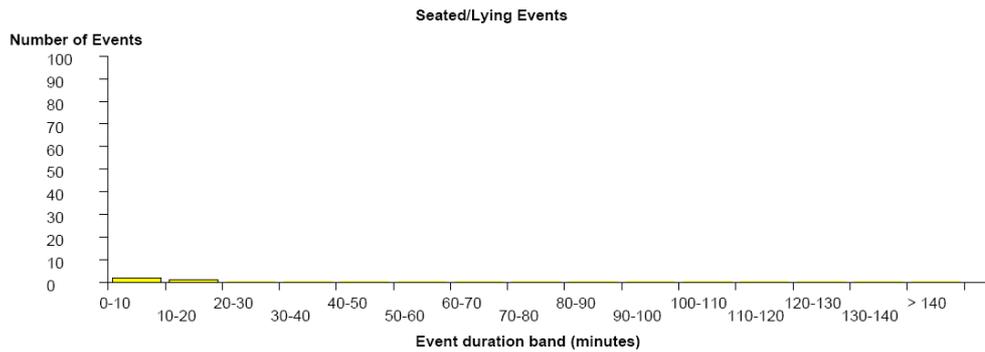
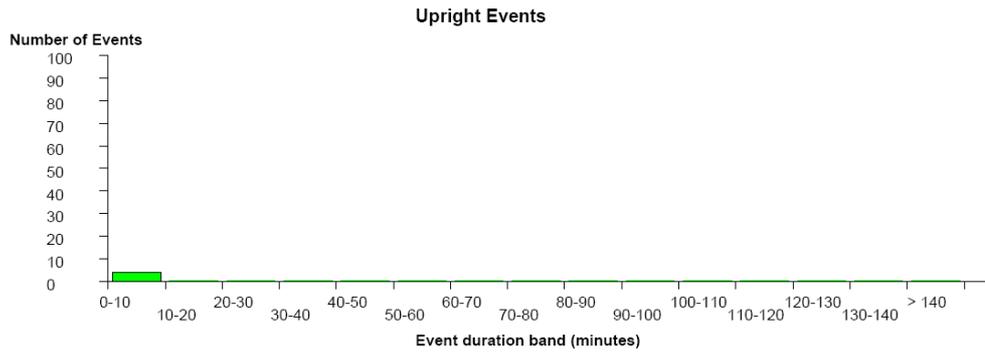
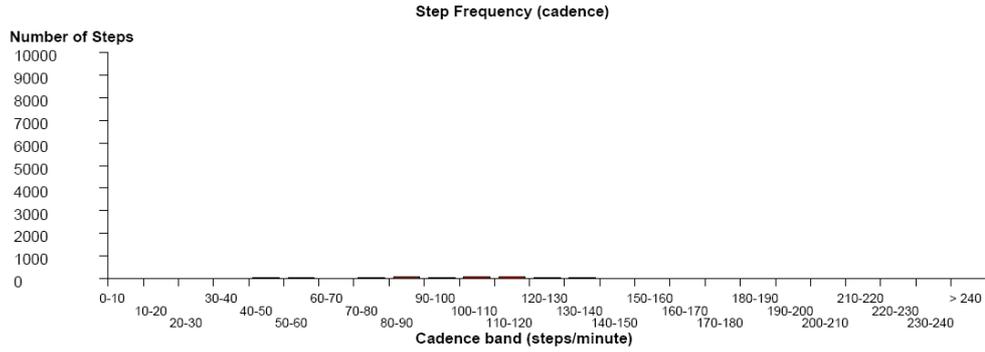


Figure II.b: Example of the activity summary obtained from the activPAL

Appendix III - Matlab code for posture categorization comparison between video and activPAL data

This is the data analysis algorithm written using Matlab for comparing video and activPAL data collected during the validation study. The duration of time spent in each activity state was found for both video and activPAL data and was compared. The percentage sensitivity and discrepancy were then calculated.

Within Matlab code ‘%’ indicates notes and hence not part of the algorithm itself.

```

clear all
% Load video data and create continuous time
line
load CPvideo.txt
A=CPvideo;
aa=diff(A(:,1));
time_continuous=[];
activity_code=[];
for i=1:length(A)-1
t_beg=A(i,1);
t_end=A(i+1,1);
time=t_beg:0.1:t_end;
time_continuous=[time_continuous; time'];
activity_beg(i)=A(i,2);
c=ones(size(time))*activity_beg(i);
activity_code=[activity_code;c'];
end

B=[time_continuous activity_code];
D=diff(B(:,1));
aa=find(D==0);
B(aa,:)=[];
Figure %plot video data
plot(B(:,1),B(:,2),'r')
hold on

% calculate time spent in each posture for video
data
C=B(:,2);
total_time_walk_video=length(find(C==5))/10
total_time_stand_video=length(find(C==4))/10
total_time_sit_video=length(find(C==3))/10

% load activPAL data
load CPPALprog.txt
Z=CPPALprog;
aa=diff(Z(:,1));
time_continuous=[];
activity_code=[];
for i=1:length(Z)-1
t_beg=Z(i,1);
t_end=Z(i+1,1);
time=t_beg:0.1:t_end;
time_continuous=[time_continuous; time'];
activity_beg(i)=Z(i,2);
f=ones(size(time))*activity_beg(i);

activity_code=[activity_code;f'];
end

Q=[time_continuous activity_code];
f=diff(Q(:,1));
aa=find(f==0);
Q(aa,:)=[];

plot(Q(:,1),Q(:,2),'k') %plot activPAL data
ylabel('activity classifier'), xlabel('time(s)')

% calculate time spent in each posture for
activPAL data
E=Q(:,2);
total_time_walk_PAL=length(find(E==2))/10;
total_time_stand_PAL=length(find(E==1))/10;
total_time_sit_PAL=length(find(E==0))/10;

% calculate percentage discrepancies
error_walk=((abs(total_time_walk_PAL-total_time_walk_video))/total_time_walk_video)*100;
error_stand=((abs(total_time_stand_PAL-total_time_stand_video))/total_time_stand_video)*100;
error_sit=((abs(total_time_sit_PAL-total_time_sit_video))/total_time_sit_video)*100;

% calculate percentage sensitivities
sensitivity_walk =
(total_time_walk_PAL/total_time_walk_video)*
100
sensitivity_stand =
(total_time_stand_PAL/total_time_stand_video)*
100
sensitivity_sit =
(total_time_sit_PAL/total_time_sit_video)*100

error_upright=((abs((total_time_walk_PAL+total_time_stand_PAL)-(total_time_walk_video+total_time_stand_video)))/
(total_time_walk_video+total_time_stand_video))*100;
sensitivity_upright =
((total_time_walk_PAL+total_time_stand_PAL)/
(total_time_walk_video+total_time_stand_video))*100;

```

Appendix IV - Gait patterns of subject with CP

subject	Leg attached to activPAL	Barefoot gait pattern
1	Right	For the right, no heel strike, sometimes toe walk, sometimes foot flat. The left gait is relatively normal.
2	Left	Bilateral toe walking and crouch gait
3	Left	Bilateral toe walking
4	Right	Bilateral toe walking
5	Right	Foot flat on right and relatively normal for left side gait
6	Right	Foot flat bilaterally
7	Right	Foot flat bilaterally
8	Right	Walk on lateral border of right foot and sometimes drag foot along the floor. Left side was foot flat
9	Right	Foot flat bilaterally, and drag foot on right
10	Left	Foot flat on right and relatively normal for left side gait
11	Right	Toe walking bilaterally and crouch gait
12	Right	Toe walking bilaterally and slight crouch gait
13	Right	Toe walking bilaterally and slight crouch gait
14	Right	Toe walking bilateral and crouch gait
15	Right	Foot flat bilaterally
16	Right	Foot flat and walk on lateral border on right foot, left gait was without major abnormality
17	Right	Relatively normal gait bilaterally
18	Right	Relatively normal gait bilaterally with slight flat foot
19	Left	Toe walking on left foot and flat footed on right

Appendix V – Example of timetable/diary given to each subject for recording hourly activity

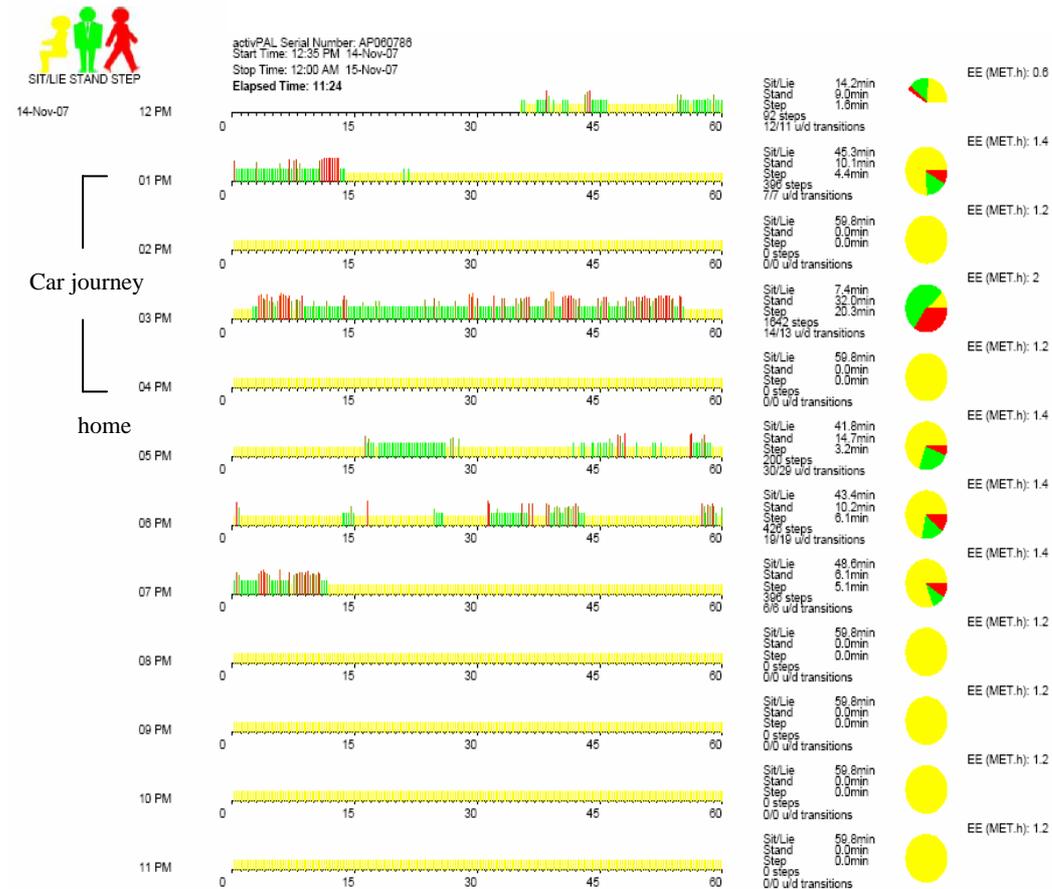
Time	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday
6.00								
7.00								
8.00								
9.00								
10.00								
11.00								
12.00								
13.00								
14.00								
15.00								
16.00								
17.00								
18.00								
19.00								
20.00								
21.00								
22.00								
23.00								

Appendix VI – Free-living activPAL results for people with CP annotated with notes from diary

Multi-day free-living activity monitoring for people with CP was recorded using the activPAL and hourly events for each subject were retrieved using the activPAL professional software. This Appendix shows the activPAL results broken down hourly for each subject. Notes from subject’s diaries for the monitoring periods are included alongside the activPAL results to enhance understanding of the collected data.

As mentioned in Appendix II, for activPAL activity profiles, yellow represents sedentary events, green correlates to standing episodes and red associates with stepping activity. The total duration of each activity state within each hour is shown on the right.

Subject 3 – Day 1

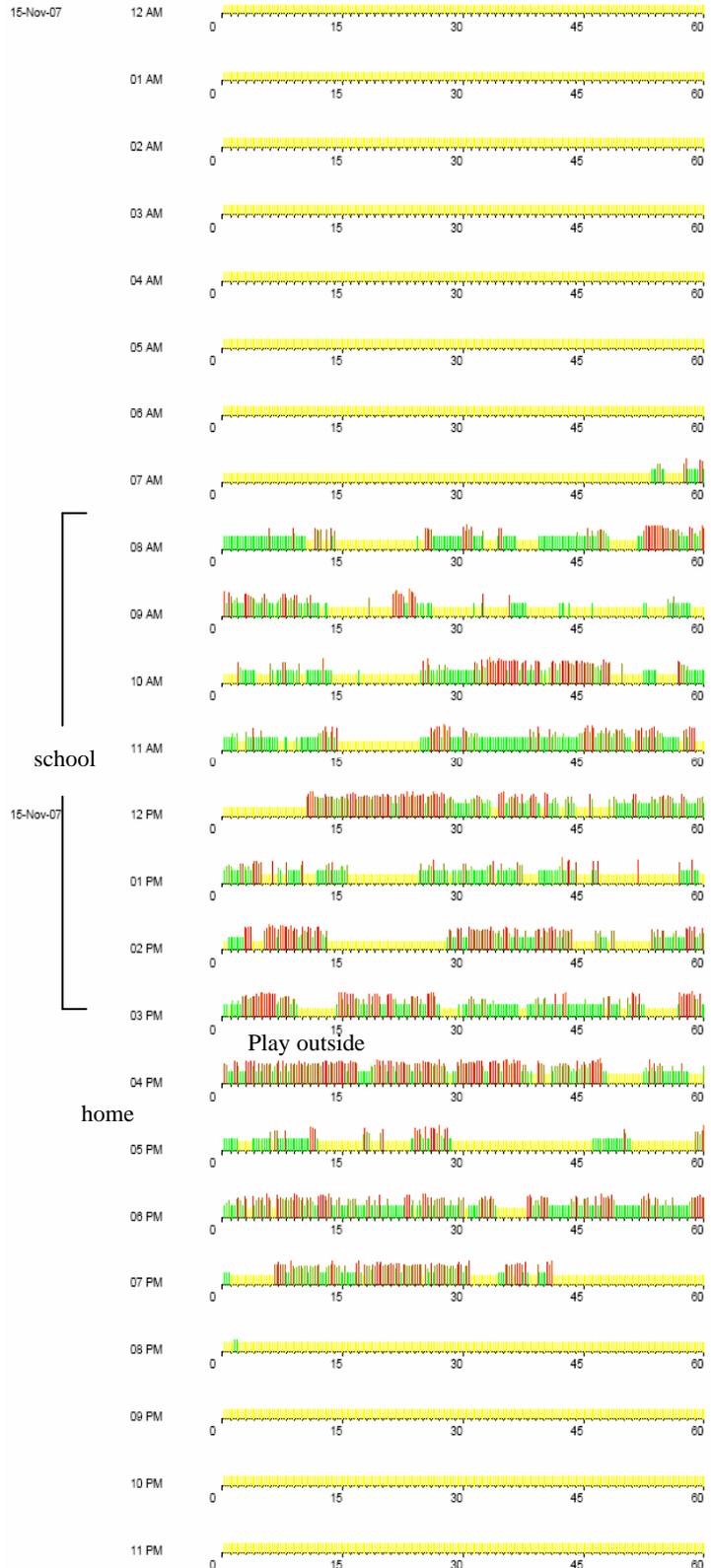


Subject 3 - Day 2



15-Nov-07

activPAL Serial Number: AP060788
 Start Time: 12:00 AM 15-Nov-07
 Stop Time: 12:00 AM 16-Nov-07
 Elapsed Time: 24:00



school

15-Nov-07

home

Play outside

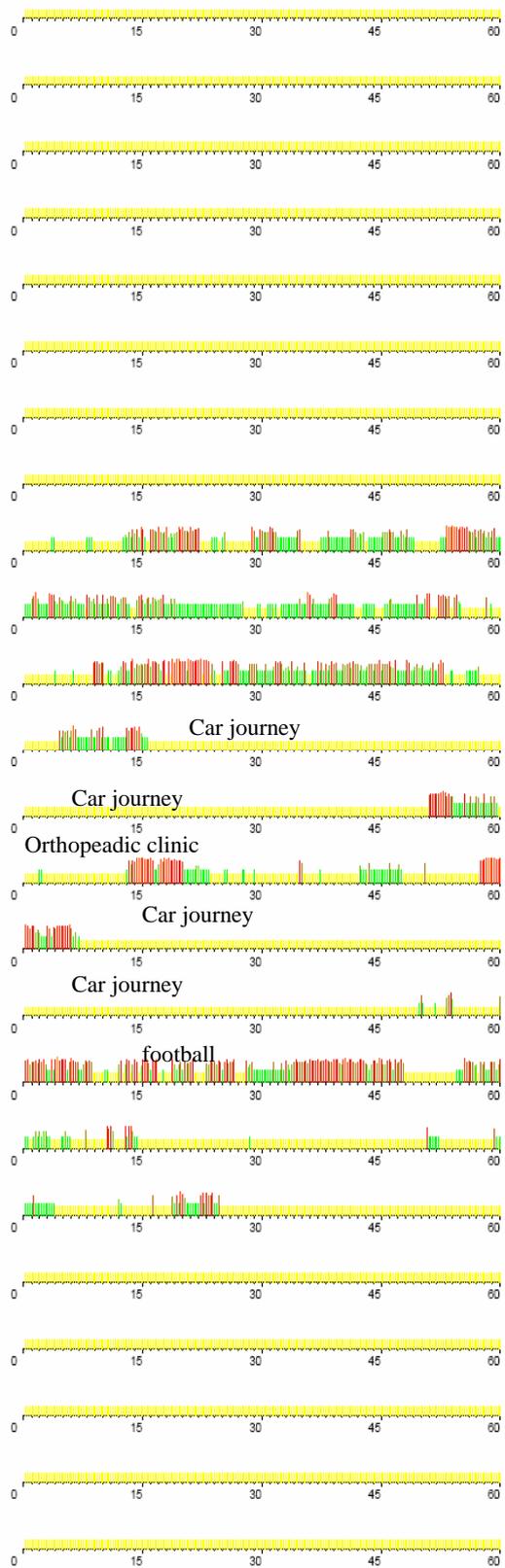
Time	Sit/Lie	Stand	Step	u/d transitions	EE (MET.h)
12 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.3
01 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.2
02 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.2
03 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.2
04 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.2
05 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.2
06 AM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.2
07 AM	56.6min	2.9min	1.5min	110 steps	EE (MET.h): 1.3
08 AM	20.3min	28.0min	11.7min	990 steps	EE (MET.h): 1.7
09 AM	38.8min	14.1min	6.1min	708 steps	EE (MET.h): 1.6
10 AM	22.7min	21.0min	16.3min	1392 steps	EE (MET.h): 1.8
11 AM	15.5min	29.1min	15.4min	1122 steps	EE (MET.h): 1.8
12 PM	17.7min	14.9min	27.4min	2172 steps	EE (MET.h): 2.1
01 PM	28.1min	23.6min	11.3min	778 steps	EE (MET.h): 1.6
02 PM	24.9min	14.7min	20.4min	1710 steps	EE (MET.h): 2
03 PM	13.8min	28.0min	20.1min	1692 steps	EE (MET.h): 2
04 PM	9.9min	16.7min	34.4min	264 steps	EE (MET.h): 2.4
05 PM	37.9min	18.6min	5.5min	432 steps	EE (MET.h): 1.5
06 PM	5.2min	28.4min	26.4min	1008 steps	EE (MET.h): 2.1
07 PM	29.9min	11.4min	18.7min	1410 steps	EE (MET.h): 1.8
08 PM	59.5min	0.4min	0.1min	4 steps	EE (MET.h): 1.3
09 PM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.3
10 PM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.3
11 PM	80.0min	0.0min	0.0min	0 steps	EE (MET.h): 1.3

Subject 3 - Day 3



16-Nov-07 12 AM

actvPAL Serial Number: AP060788
 Start Time: 12:00 AM 16-Nov-07
 Stop Time: 12:00 AM 17-Nov-07
 Elapsed Time: 24:00



Time	Sit/Lie	Stand	Step	Steps	u/d transitions	Activity State	EE (MET.h):
12 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
01 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
02 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
03 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
04 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
05 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
06 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
07 AM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
08 AM	22.8min	18.5min	17.6min	1424 steps	30/29	Green/Red	1.9
09 AM	12.2min	33.0min	14.8min	1070 steps	37/37	Green/Red	1.8
10 AM	18.0min	20.0min	21.4min	1742 steps	58/58	Green/Red	2
11 AM	48.1min	6.7min	4.2min	374 steps	11/10	Yellow/Red	1.4
12 PM	51.0min	4.5min	4.5min	424 steps	2/1	Yellow/Red	1.4
01 PM	37.8min	11.3min	10.8min	1132 steps	21/20	Green/Red	1.7
02 PM	53.3min	1.9min	5.1min	512 steps	3/3	Yellow/Red	1.5
03 PM	57.6min	1.1min	1.4min	100 steps	9/8	Yellow/Red	1.3
04 PM	14.6min	12.8min	32.7min	2569 steps	26/26	Green/Red	2.4
05 PM	49.7min	7.3min	3.0min	208 steps	15/16	Yellow/Red	1.4
06 PM	49.8min	7.9min	4.7min	220 steps	8/8	Yellow/Red	1.4
07 PM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
08 PM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
09 PM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
10 PM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3
11 PM	60.0min	0.0min	0.0min	0 steps	0.0	Yellow	1.3

school

home

Car journey

Car journey

Orthopaedic clinic

Car journey

Car journey

football

Subject 3 - Day 4

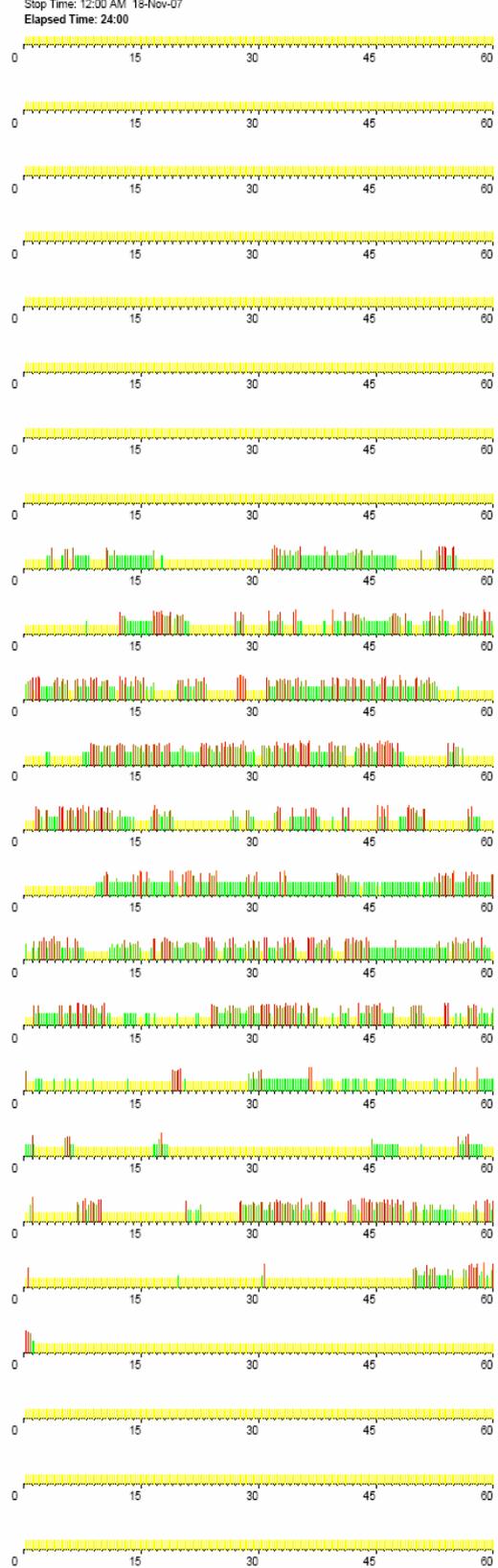


17-Nov-07

activPAL Serial Number: AP000766
 Start Time: 12:00 AM 17-Nov-07
 Stop Time: 12:00 AM 18-Nov-07
 Elapsed Time: 24:00

Home all day and
 play with friends

17-Nov-07



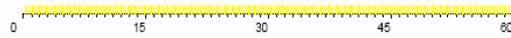
Time	Sit/Lie	Stand	Step	0 steps	0/0 u/d transitions	EE (MET.h)
12 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
01 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
02 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
03 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
04 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
05 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
06 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
07 AM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.2
08 AM	30.3min	22.0min	7.7min	624 steps	15/14 u/d transitions	1.5
09 AM	29.9min	18.2min	11.8min	880 steps	31/30 u/d transitions	1.6
10 AM	18.0min	22.7min	19.3min	1462 steps	18/18 u/d transitions	1.9
11 AM	18.1min	18.8min	22.1min	1728 steps	30/28 u/d transitions	2.0
12 PM	32.2min	14.8min	13.0min	1032 steps	38/37 u/d transitions	1.7
01 PM	10.8min	38.8min	9.8min	742 steps	9/8 u/d transitions	1.6
02 PM	11.4min	28.2min	20.4min	1508 steps	28/28 u/d transitions	1.9
03 PM	22.3min	21.1min	16.1min	1240 steps	38/37 u/d transitions	1.8
04 PM	38.8min	19.8min	3.7min	290 steps	60/60 u/d transitions	1.4
05 PM	49.0min	9.0min	2.0min	124 steps	7/7 u/d transitions	1.3
06 PM	31.1min	10.1min	18.8min	1410 steps	54/53 u/d transitions	1.8
07 PM	50.8min	4.3min	4.1min	390 steps	9/8 u/d transitions	1.4
08 PM	58.8min	0.5min	0.8min	68 steps	0/0 u/d transitions	1.3
09 PM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.3
10 PM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.3
11 PM	60.0min	0.0min	0.0min	0 steps	0/0 u/d transitions	1.3

Subject 3 - Day 5



18-Nov-07

12 AM

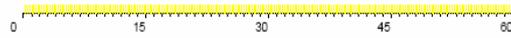


Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

01 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

02 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.2

03 AM

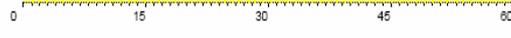


Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.2

04 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

05 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

06 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

07 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

08 AM

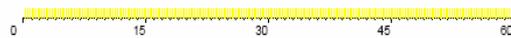


Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.2

09 AM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.2

10 AM



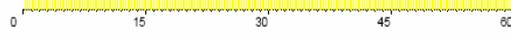
Sit/Lie 45.2min
Stand 8.4min
Step 8.4min
702 steps
38/38 u/d transitions



EE (MET.h): 1.5

home

11 AM



Sit/Lie 29.1min
Stand 23.1min
Step 10.8min
748 steps
54/54 u/d transitions



EE (MET.h): 1.8

18-Nov-07

12 PM

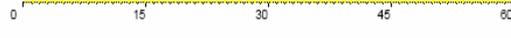


Sit/Lie 39.3min
Stand 10.6min
Step 10.1min
754 steps
41/40 u/d transitions



EE (MET.h): 1.8

01 PM



Sit/Lie 12.8min
Stand 28.3min
Step 21.1min
1783 steps
33/33 u/d transitions



EE (MET.h): 2

02 PM



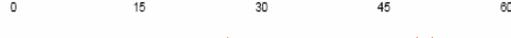
Sit/Lie 0.2min
Stand 17.5min
Step 42.8min
42/4 steps
2/2 u/d transitions



EE (MET.h): 2.9

home

03 PM

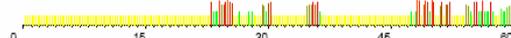


Sit/Lie 20.8min
Stand 12.8min
Step 28.8min
2100 steps
58/58 u/d transitions



EE (MET.h): 2.1

04 PM

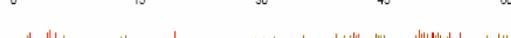


Sit/Lie 40.1min
Stand 8.7min
Step 11.2min
806 steps
31/30 u/d transitions



EE (MET.h): 1.8

05 PM



Sit/Lie 54.7min
Stand 1.9min
Step 3.4min
774 steps
5/5 u/d transitions



EE (MET.h): 1.4

06 PM

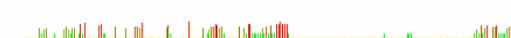


Sit/Lie 39.2min
Stand 15.8min
Step 4.9min
282 steps
18/18 u/d transitions



EE (MET.h): 1.4

07 PM

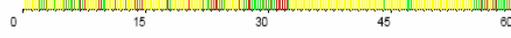


Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

08 PM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

09 PM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

10 PM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

11 PM



Sit/Lie 60.0min
Stand 0.0min
Step 0.0min
0 steps
0/0 u/d transitions



EE (MET.h): 1.3

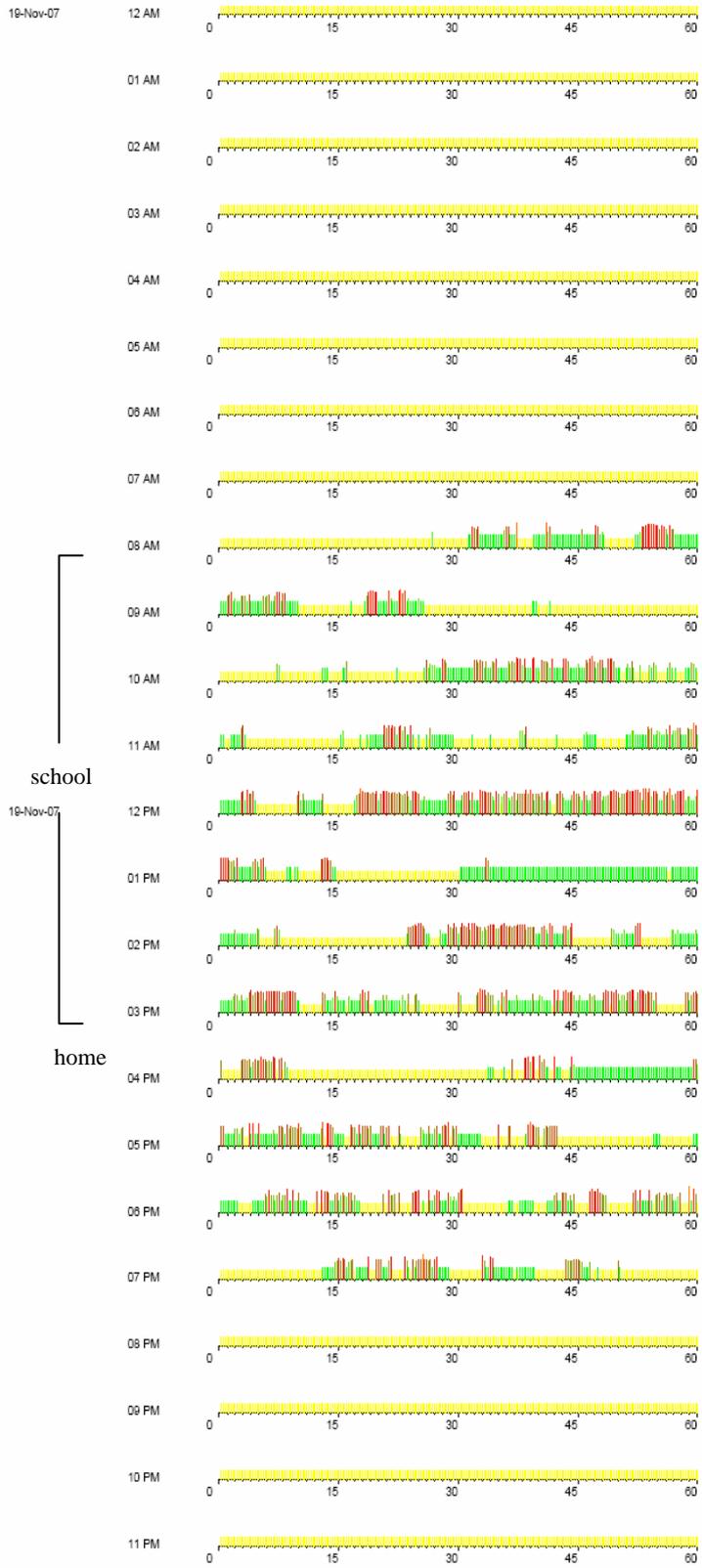
shopping
Practicing football at home

Subject 3 - Day 6



19-Nov-07

activPAL Serial Number: AP060766
 Start Time: 12:00 AM 19-Nov-07
 Stop Time: 12:00 AM 20-Nov-07
 Elapsed Time: 24:00



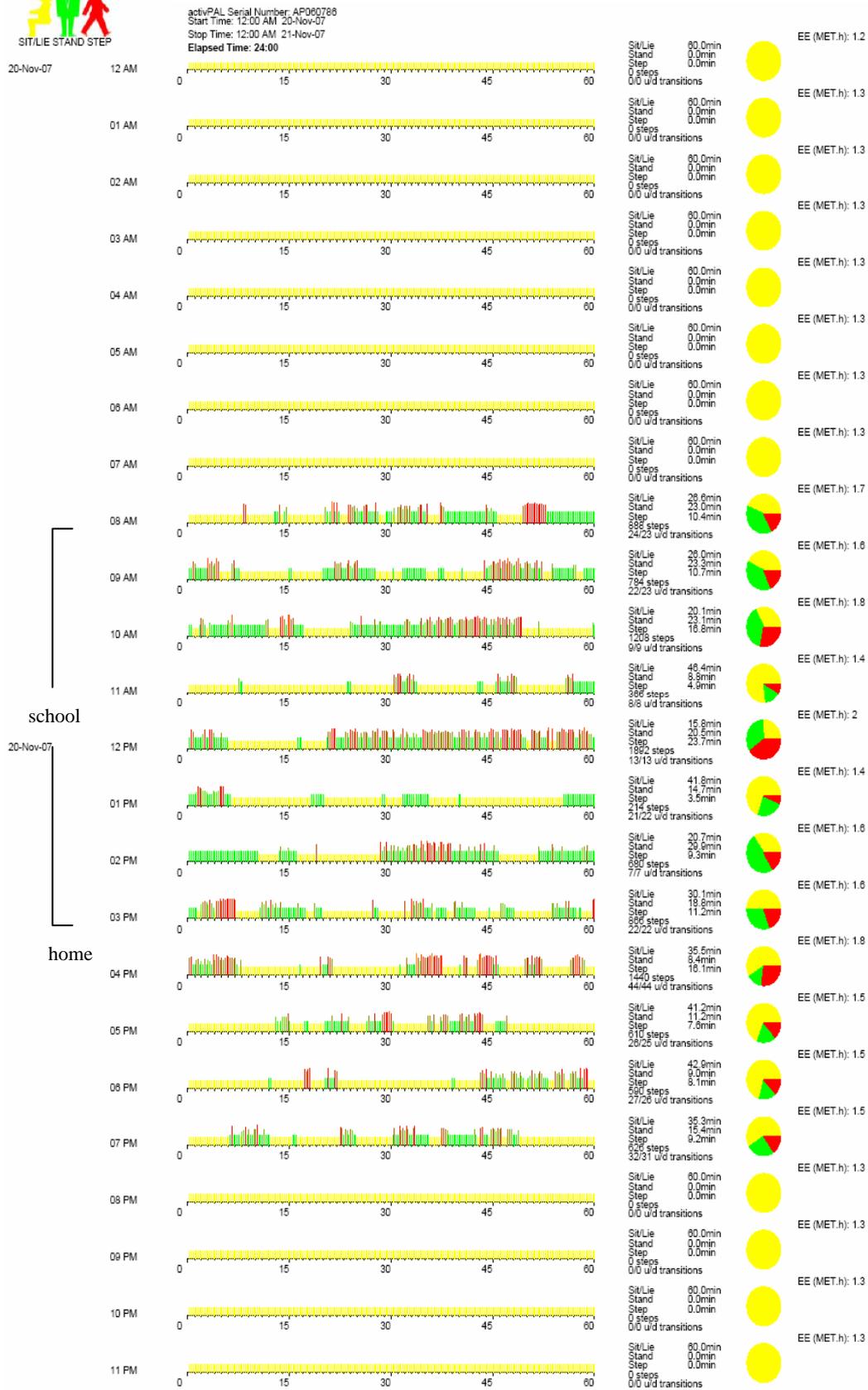
school

19-Nov-07

home

Time	Sit/Lie	Stand	Step	u/d transitions	EE (MET.h)
12 AM	60.0min	0.0min	0.0min	0 steps	1.3
01 AM	60.0min	0.0min	0.0min	0 steps	1.2
02 AM	60.0min	0.0min	0.0min	0 steps	1.2
03 AM	60.0min	0.0min	0.0min	0 steps	1.2
04 AM	60.0min	0.0min	0.0min	0 steps	1.2
05 AM	60.0min	0.0min	0.0min	0 steps	1.2
06 AM	60.0min	0.0min	0.0min	0 steps	1.2
07 AM	60.0min	0.0min	0.0min	0 steps	1.2
08 AM	38.0min	18.3min	7.7min	644 steps	1.5
09 AM	41.3min	12.0min	6.7min	548 steps	1.5
10 AM	28.3min	18.7min	13.0min	644 steps	1.7
11 AM	34.5min	18.5min	8.7min	520 steps	1.5
12 PM	9.8min	18.3min	31.1min	2568 steps	2.3
01 PM	21.6min	32.5min	6.1min	462 steps	1.5
02 PM	27.8min	14.0min	18.4min	1420 steps	1.8
03 PM	18.0min	21.0min	23.0min	1764 steps	2
04 PM	33.3min	18.4min	8.3min	644 steps	1.5
05 PM	26.9min	20.1min	14.0min	1082 steps	1.7
06 PM	23.8min	20.3min	16.0min	1220 steps	1.8
07 PM	36.4min	18.0min	8.6min	670 steps	1.6
08 PM	60.0min	0.0min	0.0min	0 steps	1.3
09 PM	60.0min	0.0min	0.0min	0 steps	1.3
10 PM	60.0min	0.0min	0.0min	0 steps	1.3
11 PM	60.0min	0.0min	0.0min	0 steps	1.3

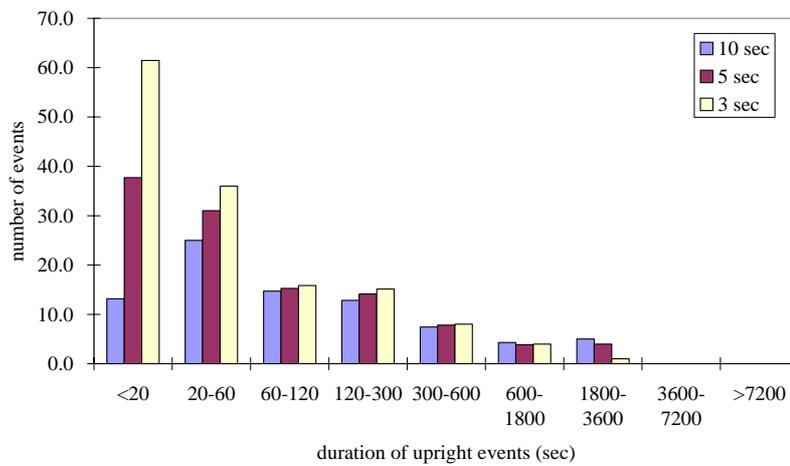
Subject 3 - Day 7



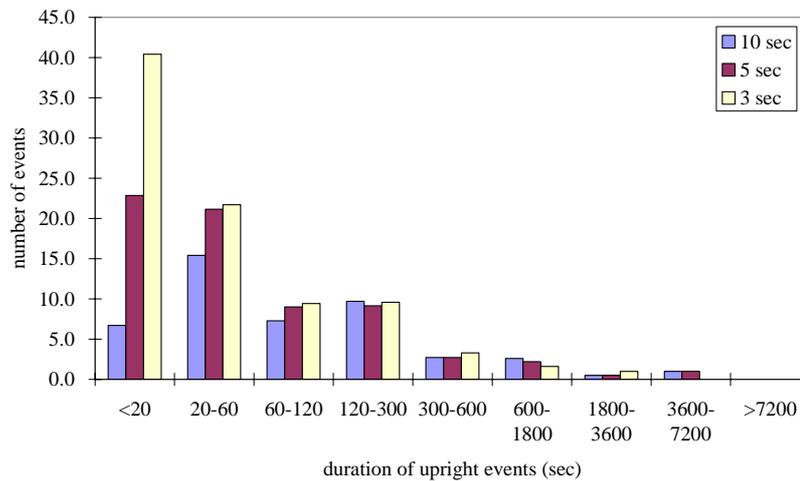
Appendix VII – Average number of upright events per day for 3 minimum settings for each subject

The average number of upright events per day for different minimum settings (3, 5 and 10 seconds) of upright periods in the activPAL software for each subject who took part in the free-living monitoring is shown in this Appendix. The number of events might not be whole numbers as the graphs show average number of events per day.

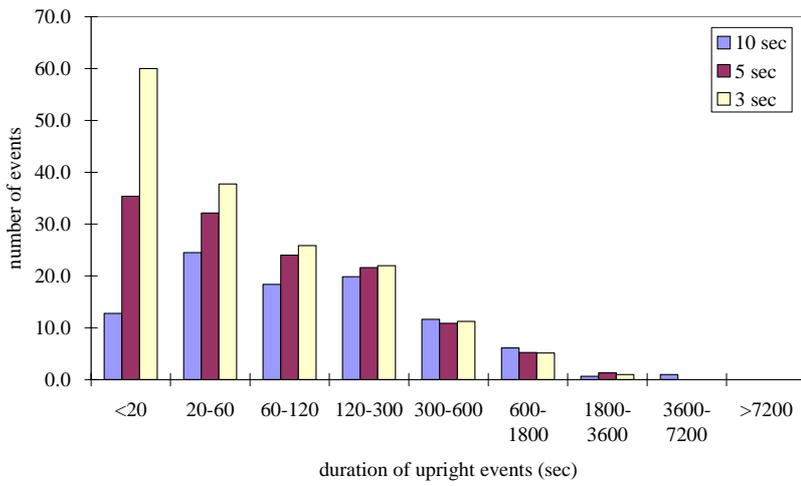
Subject 1



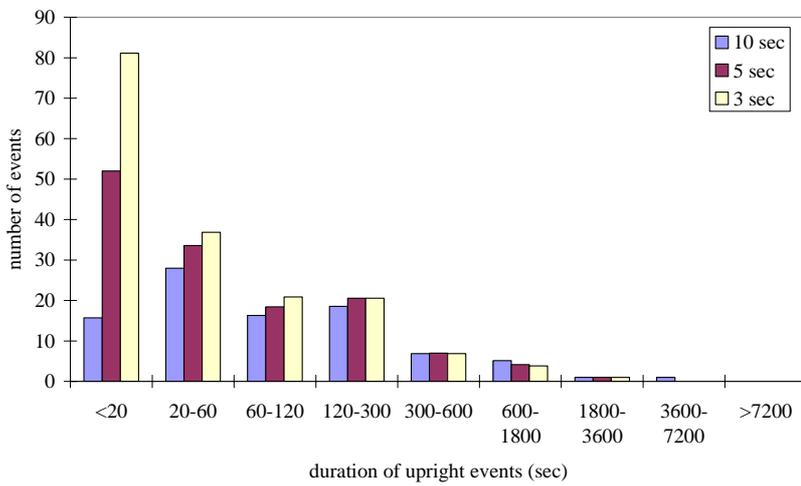
Subject 2



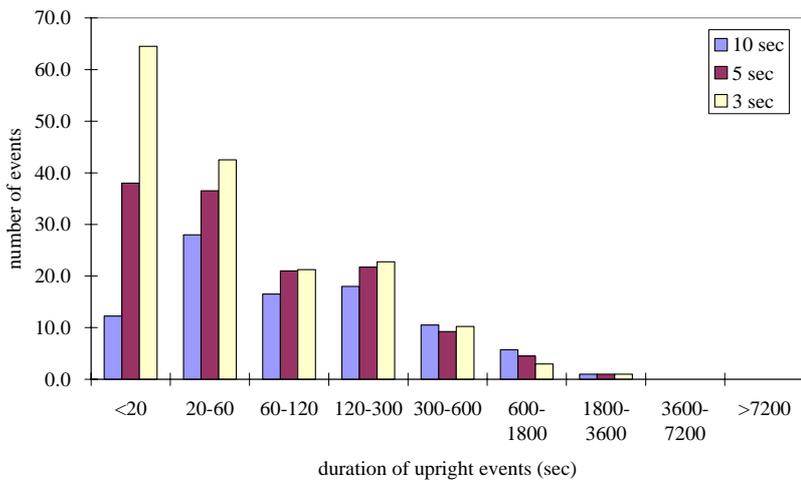
Subject 3



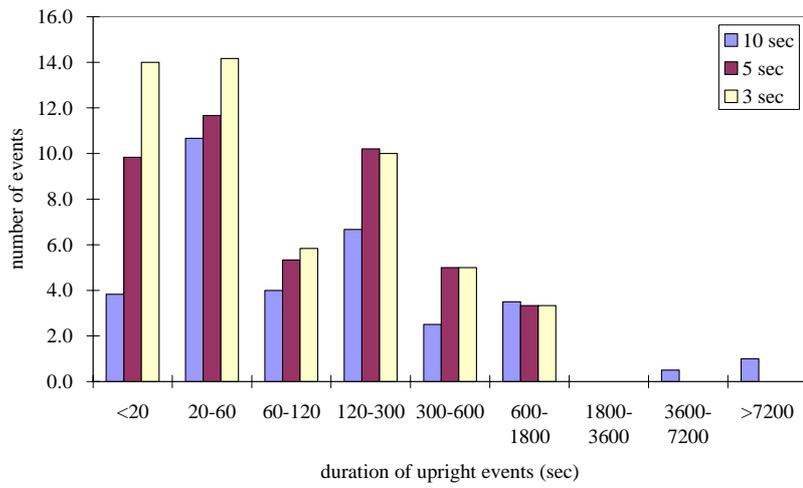
Subject 5



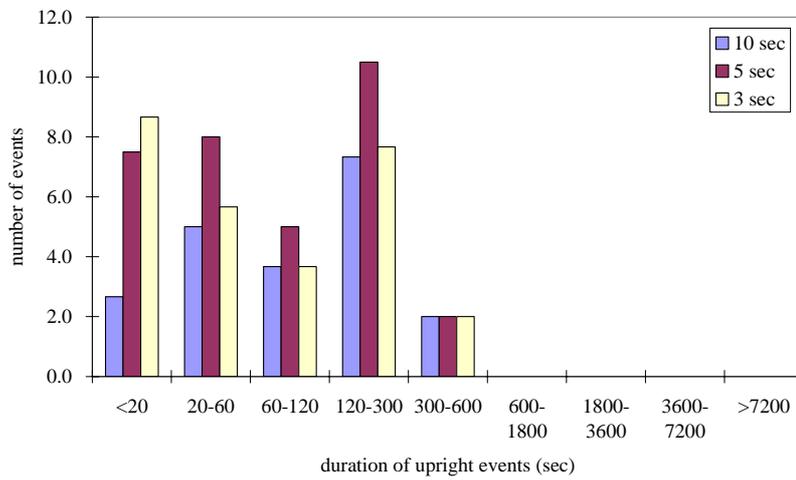
Subject 6



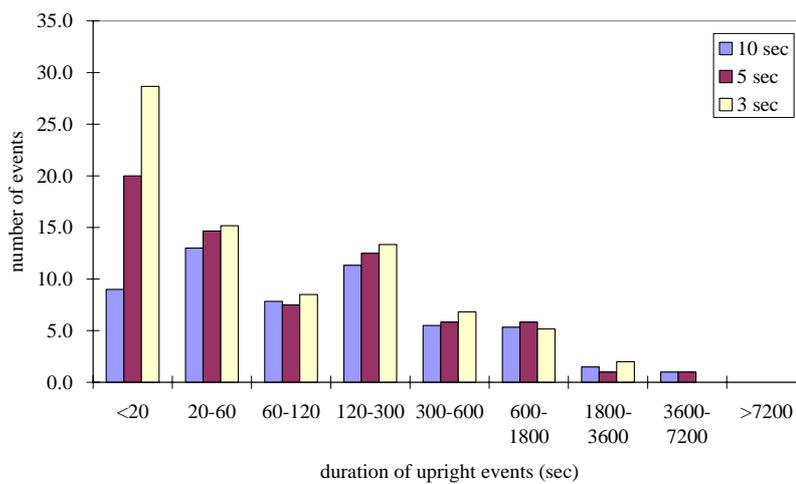
Subject 7



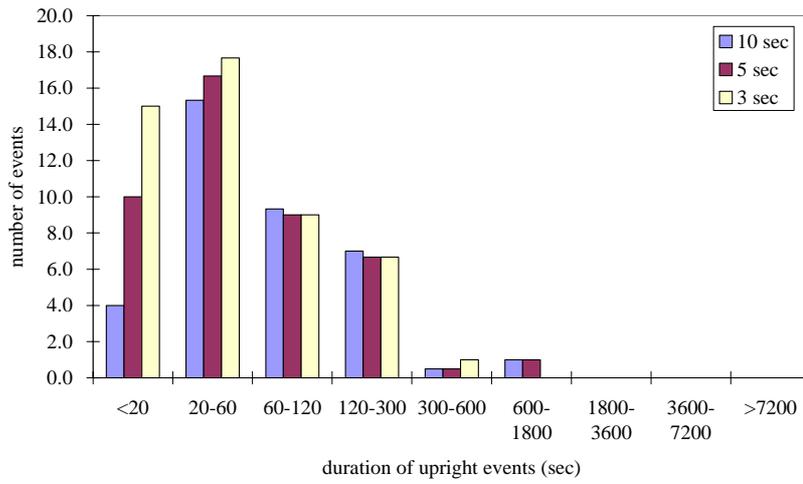
Subject 8



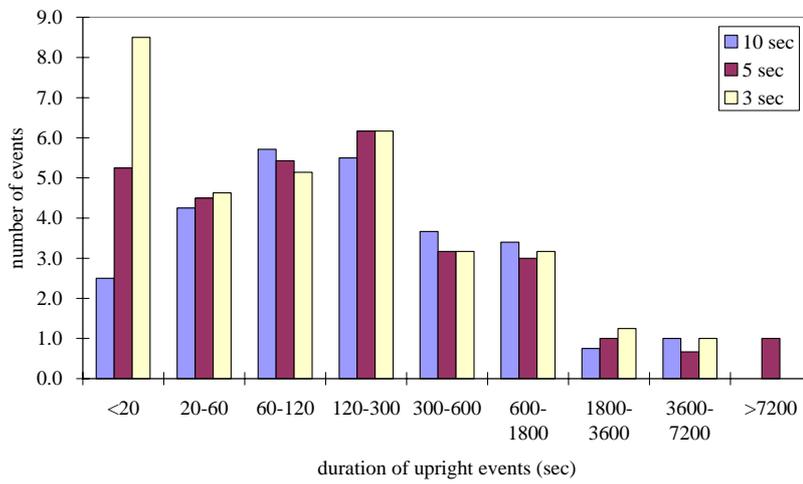
Subject 10



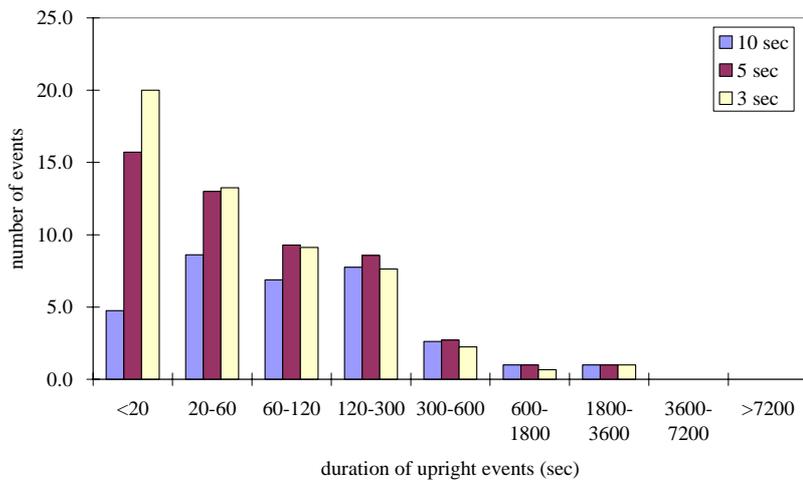
Subject 11



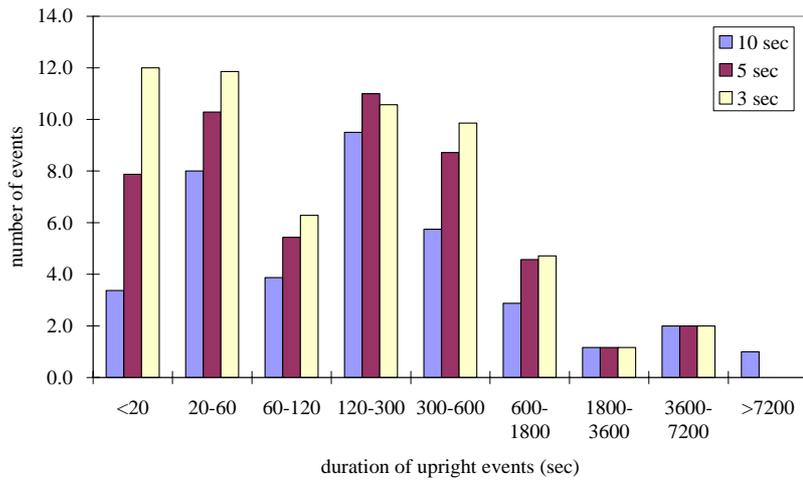
Subject 12



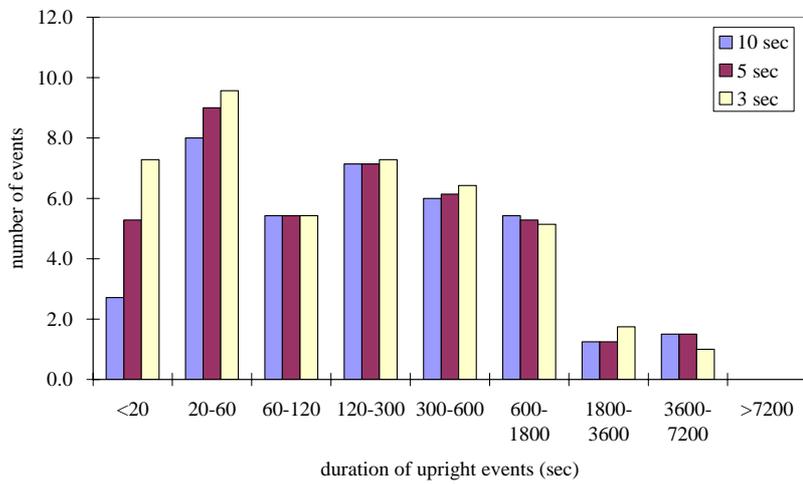
Subject 14



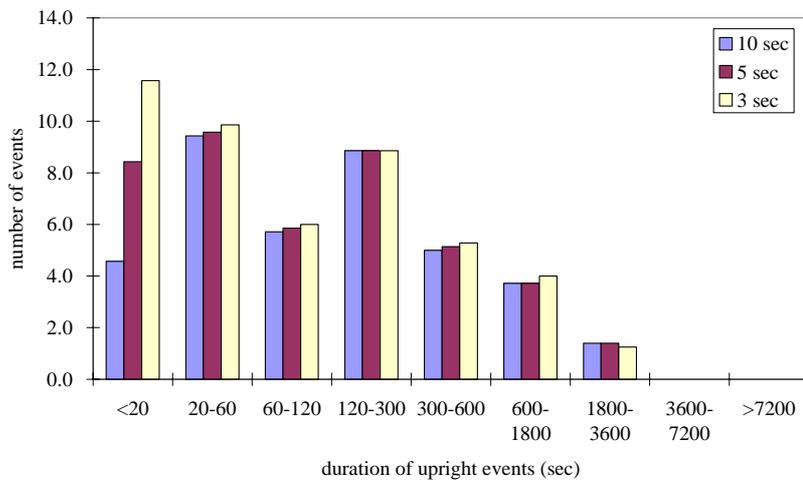
Subject 15



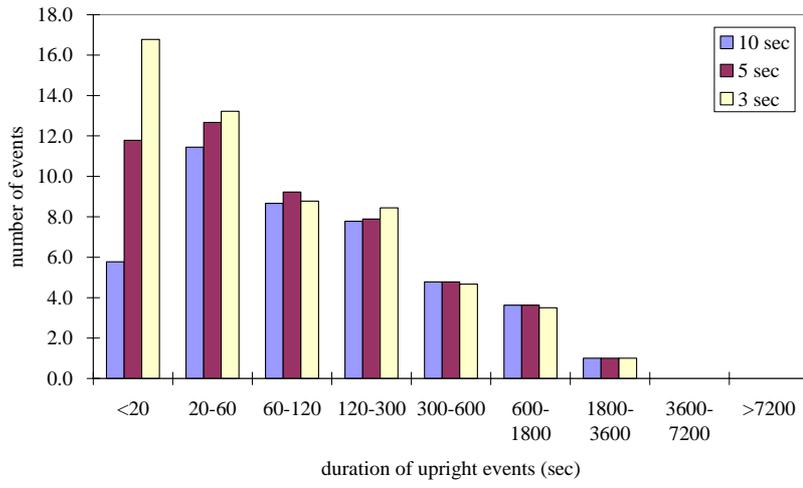
Subject 17



Subject 18



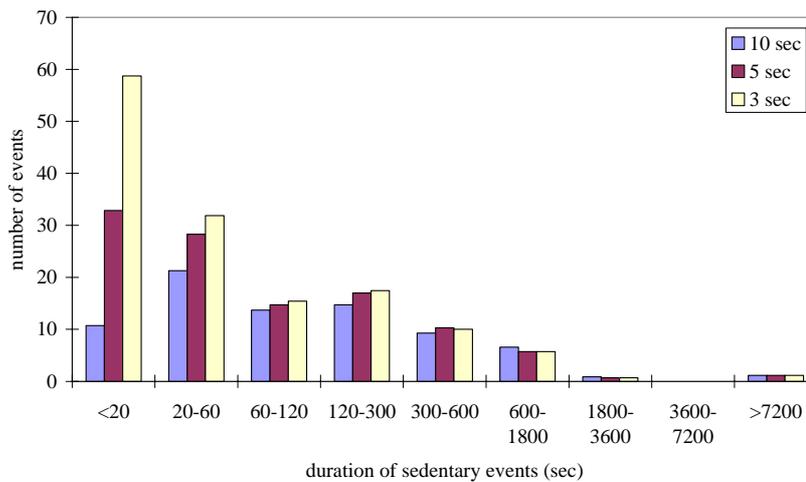
Subject 19



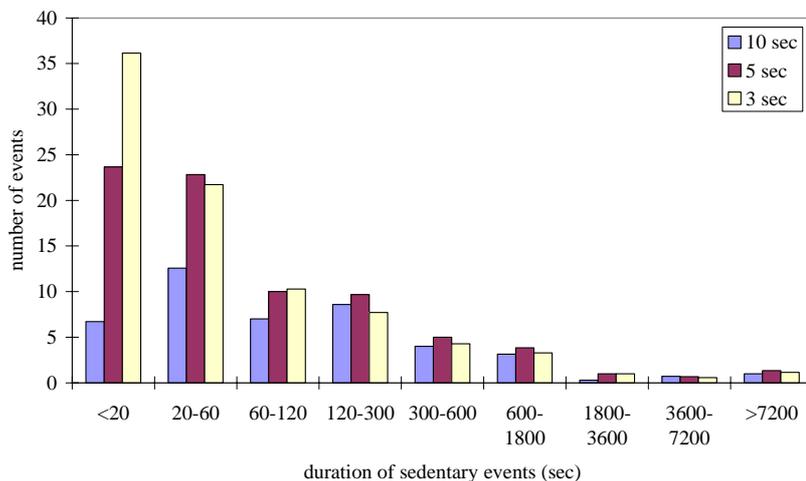
Appendix VIII – Average number of sedentary events per day for 3 minimum settings for each subject

Average number of sedentary events per day for different minimum settings (3, 5 and 10 seconds) of upright periods in the activPAL software for each subject who took part in the free-living monitoring is shown in this Appendix. The number of events might not be whole numbers as the graphs show average number of events per day.

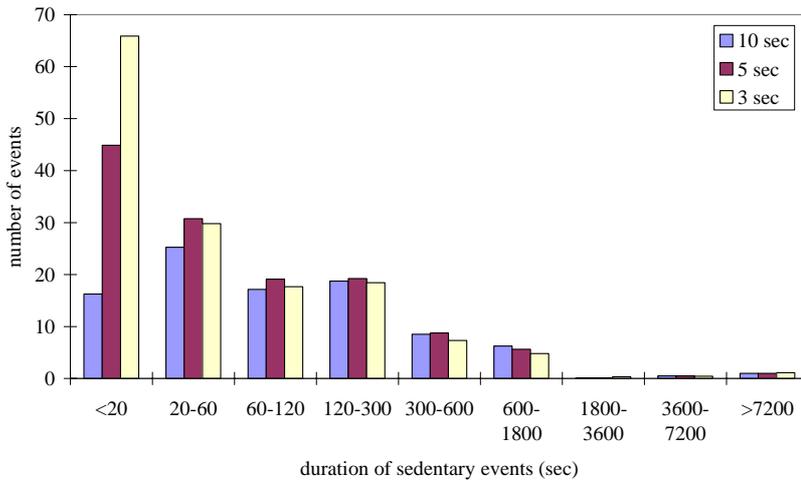
Subject 1



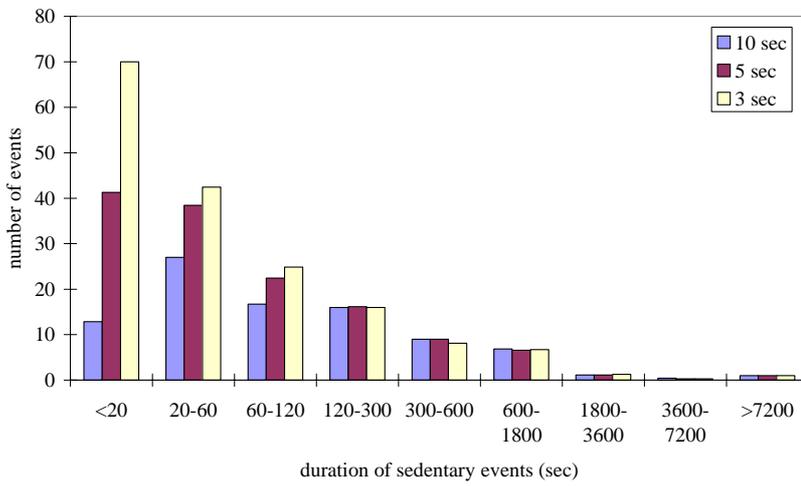
Subject 2



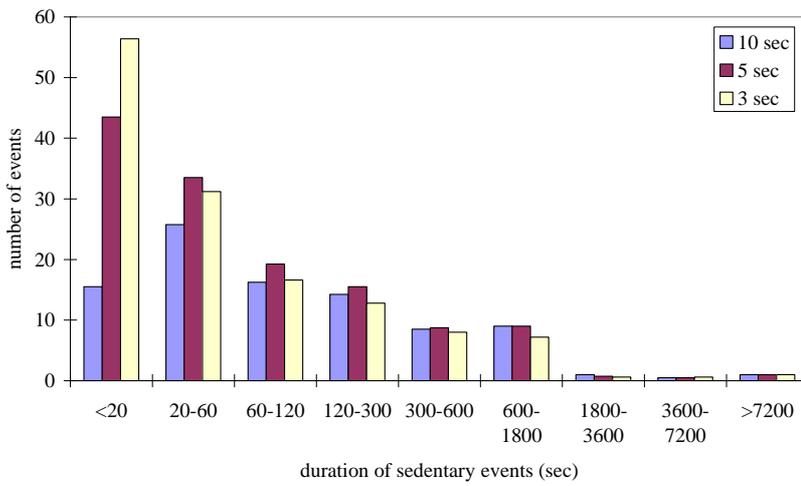
Subject 3



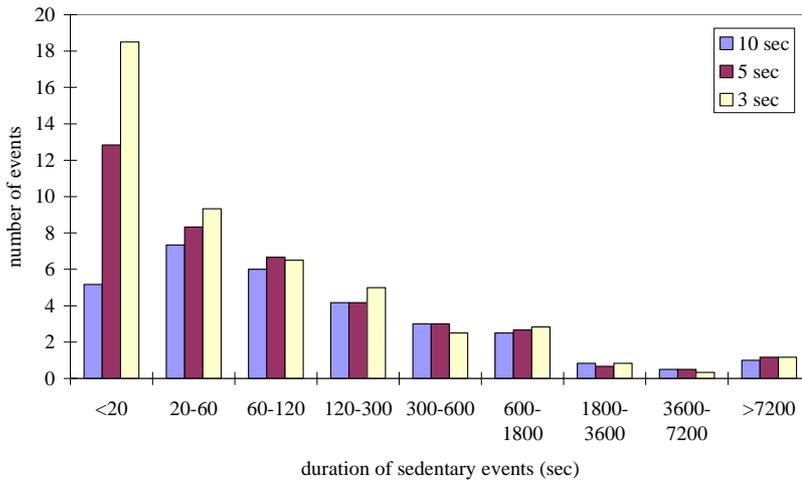
Subject 5



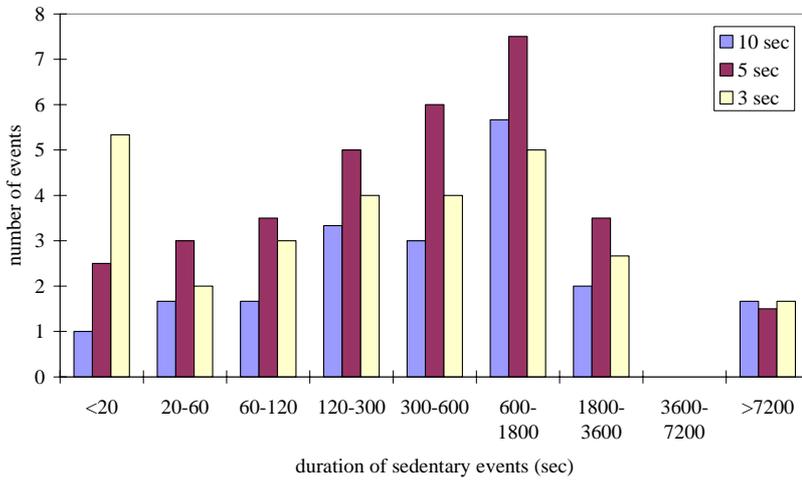
Subject 6



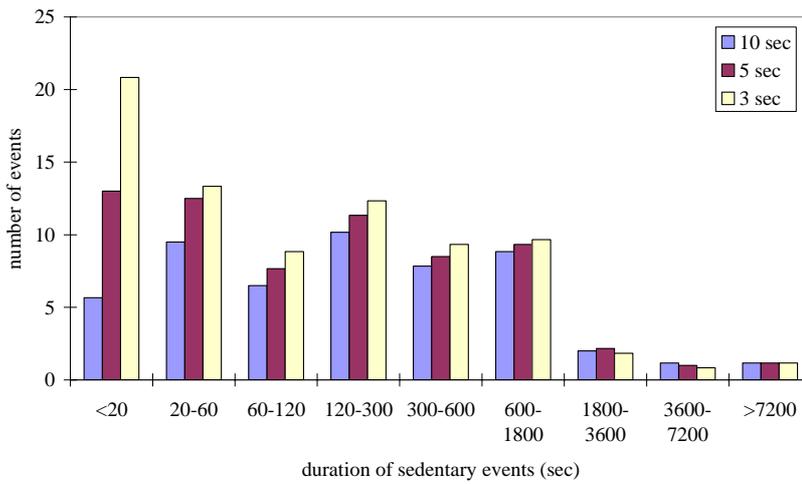
Subject 7



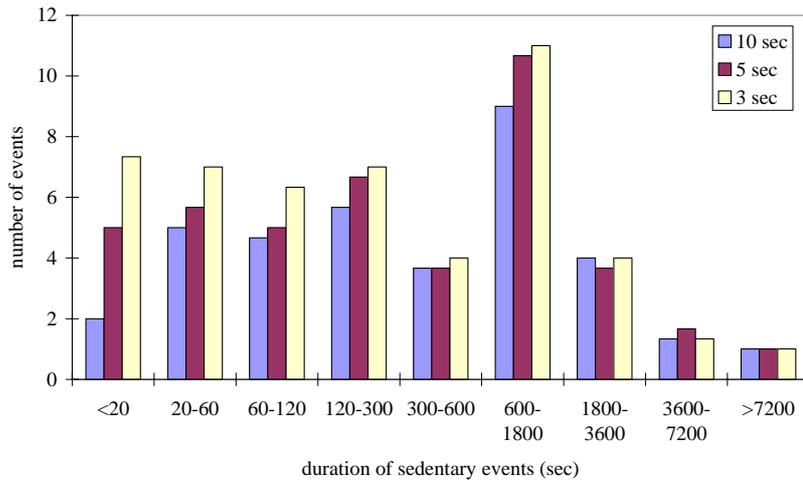
Subject 8



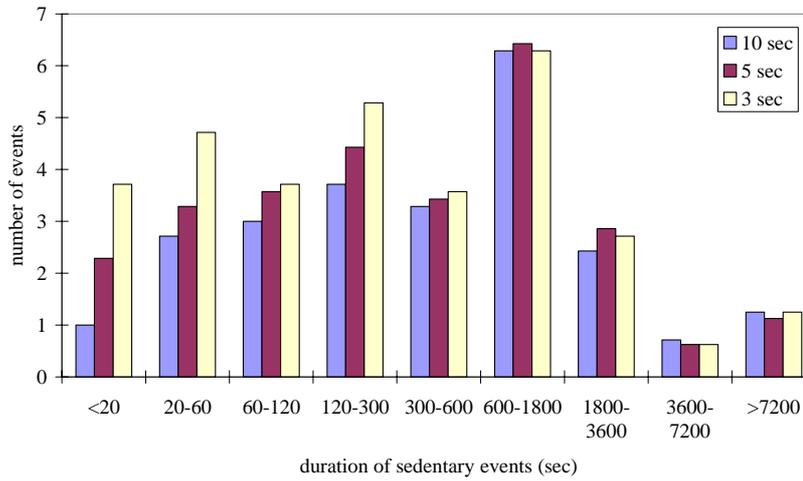
Subject 10



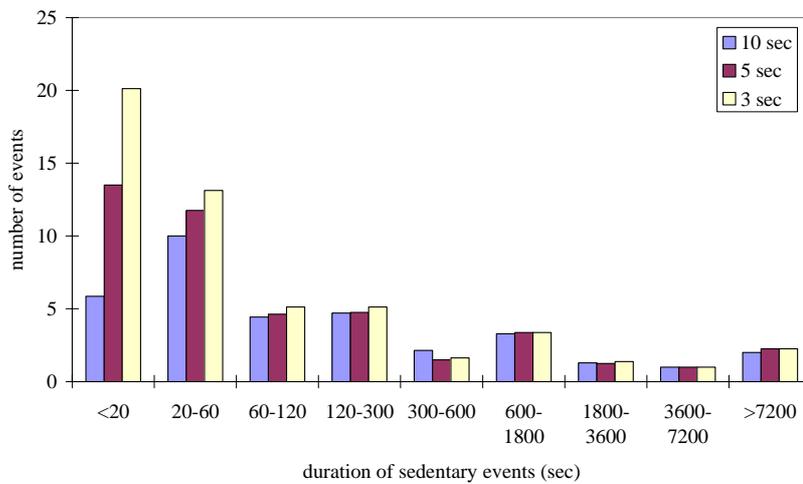
Subject 11



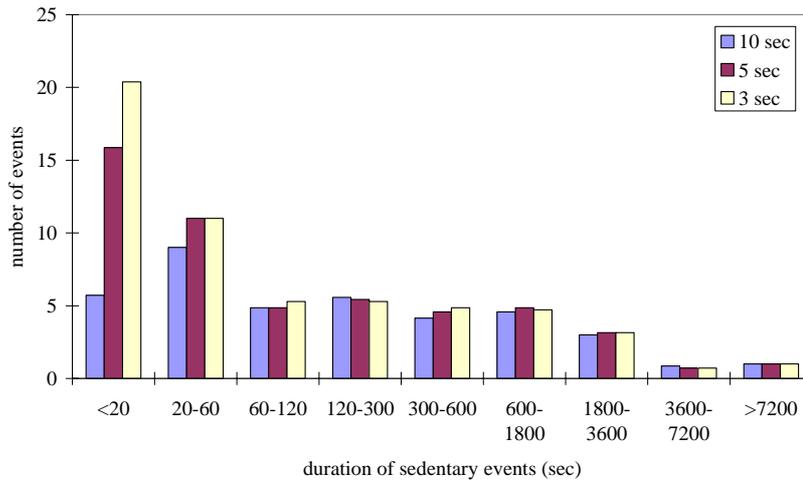
Subject 12



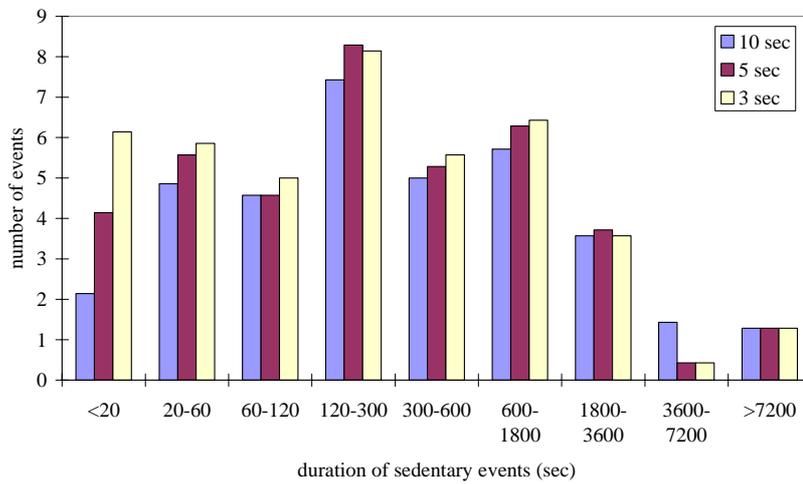
Subject 14



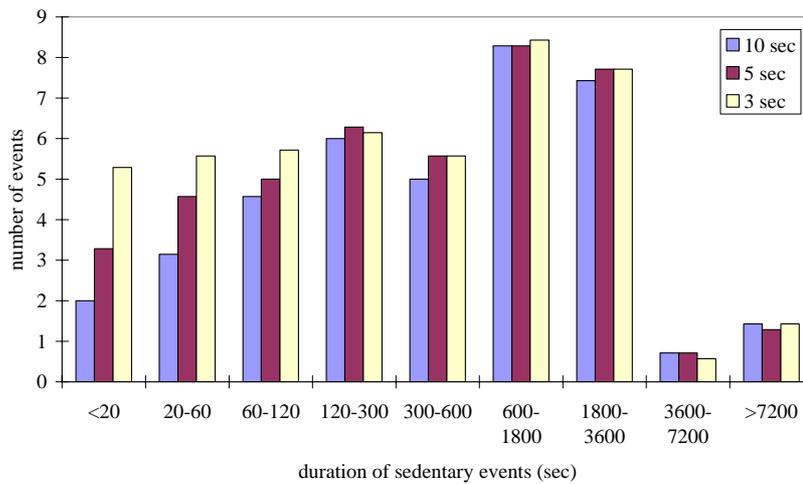
Subject 15



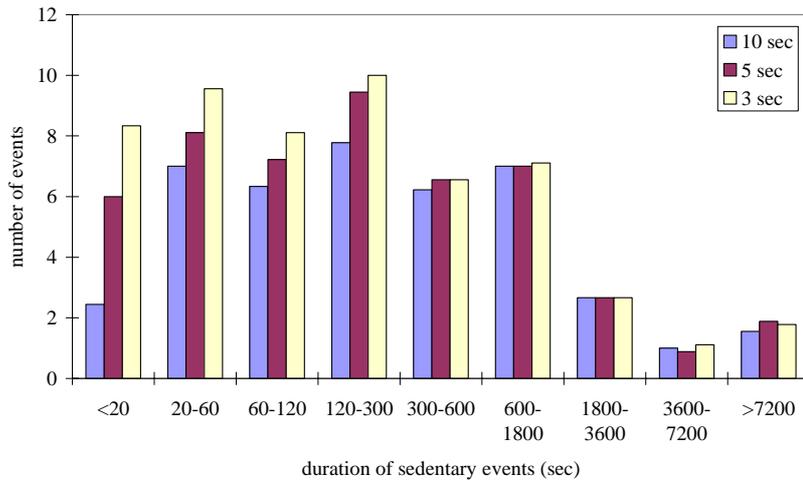
Subject 17



Subject 18



Subject 19



Appendix IX - Matlab data analysis algorithm for activity categorization of pressurePAL data.

The Matlab code categorized trans-tibial amputees' activity level using the pressure signal recorded at the pressure relief valve of a suction socket with the pressurePAL. The algorithm categorizes activity into time spent in dynamic, static and 'off' events; also strides performed by the amputee were counted.

Within Matlab code '%' indicates notes and hence not part of the algorithm itself.

```
Clear all                                continue
% GUI to prompt user to select desired PAL end
session for analysis                       k = k+1;
prompt ={'Enter program you wish to analyse end
e.g. filename.dat'};                     j = 0;
title = 'Input PAL session';              end
num_lines= 1;
file_name =                               % Calculate Sample times based on a sampling
char(inputdlg(prompt,title,num_lines));    rate of 10Hz
time_div=1/10;
% Load file into MATLAB workspace        n=length(y);
file_id=fopen(file_name,'r');             % Find number of samples
% Read File                               sample_num=size(y);
x=fread(file_id);                         t=sample_num(1:1);

% decompress data                         %Create matrix of time divisions
n = length(x);                            time_div_matrix=[0:time_div:time_div*(t-1)];
k = 1;                                    z=time_div_matrix';
j = 0;                                    % moving window of 1 second to compute
for i = 1:n                                standard deviation
if j == 0                                  a=movingstd(y,5);
y(k,1) = x(i,1);                           %Plot PAL values w.r.t. time
if x(i,1) == 0                              figure;
y(k,1) = x(i-1,1);                          plot(time_div_matrix,y,time_div_matrix,a,'k');
p = x(i-1,1).*ones(x(i+1,1),1);            xlabel('time(s)'), ylabel('PAL Magnitude')
y = [y(1:k,1); p];
k = k + x(i+1,1);                            % moving average window of 10 second
j = 1;                                       b=moving_average(a,50);
```

```

figure;
plot(time_div_matrix,b,'r');

t=b;
F=[z t];
% distinguish static and dynamic events
m=max(t);
threshold=(m/5)*2;
n=length(t);
for i=1:n;
if t(i,1)> threshold;
e(i,1)=5;
elseif t(i,1)<= threshold;
e(i,1)=4;
end
end

% count stride
f=min(y);
b = 1; %to indicate passing the baseline
peaks = 0; %counts the number of peaks >
threshold
threshold = 121; % threshold value
baseline = 110; % baseline value
ti = 0.1; %time to start counting
tf = time_div*(t-1); %time to finish counting
for i=ti*10:tf*10
if (y(i,1) > threshold) && (b == 1)
peaks = peaks+1;
j=i;
A=[j peaks];
b = 0;
end
if y(i,1) < baseline
b = 1;
end
end
peaks

% identify 'off' periods
n=length(y);
b = 1; c = 0; d = 0; k = 0;
for i = 1:n-1
if y(i,1) == y(i+1,1)
if b == 1
k = i; c = 1; b = 0;
else
c = c+1;
end
elseif (y(i,1) ~= y(i+1,1)) && (b == 0)
d = 1;
end
if (y(i,1) ~= y(i+1,1)) && (d == 1) && (b == 0)
&& (c > 1500)
y(k:k+c,1) = 1000*ones(c+1,1);
b = 1; d = 0; c = 0;
elseif (y(i,1) ~= y(i+1,1)) && (d == 1) && (b
== 0) && (c < 1500)
b = 1; d = 0; c = 0;
end
end

% doff event for any period which is static for
over 5 min
s=y;
n=length(s);
for i=1:n;
if s(i,1)==1000;
s(i,1)=3;
else s(i,1)=e(i,1);
end
end

figure
plot(time_div_matrix,s,'g') % graph of activity
pattern

```

Appendix X - Matlab data analysis algorithm for activity categorization from forcePAL data.

The Matlab code categorized trans-tibial amputees' activity level by stump/socket interface pressure measured using the forcePAL. The algorithm categorized activity into periods spent walking (with the number of strides performed), standing, sitting and 'off'.

Within Matlab code '%' indicates notes and hence not part of the algorithm itself.

```
clear all                                continue
                                          end
% GUI to prompt user to select desired PAL session for analysis
prompt = {'Enter program you wish to analyse e.g. filename.dat'};
title = 'Input PAL session';
num_lines = 1;
file_name = char(inputdlg(prompt,title,num_lines));
                                          % Calculate Sample times based on a sampling rate of 10Hz
                                          time_div=1/10;

% Load file into MATLAB workspace
file_id=fopen(file_name,'r');
                                          % Find number of samples
sample_num=size(y);
t=sample_num(1:1);

% Read File
x=fread(file_id);
% decompress data
n = length(x);
k = 1;
j = 0;
for i = 1:n
    if j == 0
        (k,1) = x(i,1);
        if x(i,1) == 0
            y(k,1) = x(i-1,1);
            p = x(i-1,1).*ones(x(i+1,1),1);
            y = [y(1:k,1); p];
            k = k + x(i+1,1);
            j = 1;
            % Create matrix of time divisions
            time_div_matrix=[0:time_div:time_div*(t-1)];
            z=time_div_matrix';
            %Plot PAL values w.r.t. time
            figure (2)
            plot(z,y,'k');
            xlabel('time(s)'), ylabel('PAL Magnitude')
            %title('PAL readings w.r.t. time of',file_id,'data')
            hold on;
            % moving average window of 20 second
            t=moving_average(y,100);
            figure(2);
            plot(z,t,'r')
```

```

hold on;

% distinguish upright and non-upright events
n=length(t);
q=max(t);
m=q/2.8;
for i=1:n;
if t(i,1)>52;
e(i,1)=6; % upright event e.g standing and
walking
elseif t(i,1)<=52;
e(i,1)=5; % non-upright event e.g sitting and
lying
end
end

% moving standard deviation of raw data
v=movingstd(y,10);
figure(2);
plot(z,v,'y')
hold on;

% moving average window of 10 second
u=moving_average(v,50);
figure(2);
plot(time_div_matrix,u,'b')

% distinguish dynamic and static events i.e.
separate standing and walking
n=length(u);
for i=1:n;
if u(i,1)>22;
u(i,1)=7; % dynamic event e.g walking
else u(i,1)=e(i,1);
end
end

%count steps

b = 1; % to indicate passing the baseline
peaks = 0; % counts the number of peaks >
threshold
threshold = 82; % threshold value
baseline = 70; % baseline value
ti = 0.1; %time to start counting
tf = time_div*(t-1); %time to finish counting

for i=ti*10:tf*10
if (d(i,1) > threshold) && (b == 1)
peaks = peaks+1;
b = 0;
end
if d(i,1) < baseline
b = 1;
end
end
steps=(peaks)

% separating the doff period
n = length(y);
b = 1; c = 0; d = 0; k = 0;
for i = 1:n-1
if y(i,1) == y(i+1,1)
if b == 1
k = i;
c = 1;
b = 0;
else
c = c+1;
end
elseif (y(i,1) ~= y(i+1,1)) && (b == 0)
d = 1;
end
if (y(i,1) ~= y(i+1,1)) && (d == 1) && (b == 0)
&& (c > 5000)
y(k:k+c,1) = zeros(c+1,1);
b = 1; d = 0; c = 0;

```

```
elseif (y(i,1) ~= y(i+1,1)) && (d == 1) && (b  
== 0) && (c < 5000)  
b = 1; d = 0; c = 0;  
end  
end
```

```
s=y;  
n=length(s);  
for i=1:n;
```

```
if s(i,1)==0;  
s(i,1)=4;  
else s(i,1)=u(i,1);  
end  
end
```

```
figure  
plot(time_div_matrix,s,'g') % graph of activity  
patterns
```

Appendix XI - Matlab code for posture categorization comparison between video and pressurePAL/forcePAL data

This is the data analysis algorithm written using Matlab for comparing video and pressurePAL/forcePAL data collected during the validation study. The duration of time spent in each activity state was found for both video and activPAL data and was compared. The percentage sensitivity and discrepancy were then calculated to evaluate the pressurePAL and forcePAL for use to quantify amputees' activity level and prosthetic usage. This part of the Matlab code was added at the end of Matlab algorithm for activity categorization (Appendix IX and X) for comparison between video and pressure/forcePAL data.

Within Matlab code '%' indicates notes and hence not part of the algorithm itself.

```
load video.txt
A=video;
A=A*10;
a=round(A);
A=A/10;
time_global=[];
action_global=[];
for i=1:length(A)-1
t_beg=A(i,1);
t_end=A(i+1,1);
time=t_beg:0.1:t_end;
time_global=[time_global; time'];
action_beg(i)=A(i,2);
c=ones(size(time))*action_beg(i);
action_global=[action_global;c'];
end

B(aa,:)=[];
figure;
plot(B(:,1),B(:,2),'k');
hold on;
figure;
plot(time_div_matrix,s,'b')
G=B(:,2);
% calculate error and sensitivity in each activity
group for pressurePAL data
walk=(length(find(s==5)))/10
static=(length(find(s==4)))/10
doff=(length(find(s==3)))/10

B=[time_global action_global];
D=diff(B(:,1));
aa=find(D==0);
walk_video=length(find(G==2))/10;
static_video=length(find(G==1))/10;
doff_video=(length(find(G==0))/10);
```

```

sensitivity_walk = (walk/walk_video)*100
sensitivity_static = (static/static_video)*100
sensitivity_doff = (doff/doff_video)*100

error_walk=((abs(walk-walk_video))/walk_video)*100;
error_static=((abs(static-static_video))/static_video)*100;
error_doff=((abs(doff-doff_video))/doff_video)*100;

% calculate error and sensitivity in each activity group for forcePAL data
walk=(length(find(s==7)))/10;
stand=(length(find(s==6)))/10;
sit=(length(find(s==5)))/10;
doff=(length(find(s==4)))/10;

walk_video=length(find(G==3))/10;
stand_video=length(find(G==2))/10;
sit_video=(length(find(G==1))/10);
doff_video=(length(find(G==0))/10);

sensitivity_walk = (walk/walk_video)*100
sensitivity_stand = (static/stand_video)*100
sensitivity_sit = (sit/sit_video)*100
sensitivity_doff = (doff/doff_video)*100

error_walk=((abs(walk-walk_video))/walk_video)*100;
error_stand=((abs(stand-stand_video))/stand_video)*100;
error_sit=((abs(sit-sit_video))/sit_video)*100;
error_doff=((abs(doff-doff_video))/doff_video)*100;

```