A PERVASIVE BODY SENSOR NETWORK FOR MONITORING POST-OPERATIVE RECOVERY

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This thesis is submitted to the University of London in partial fulfilment of the requirements for the degree of Doctor of Philosophy. Except for where indicated, it presents entirely my own work and describes the results of my own research.

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Abstract

Over the past decade, miniaturisation and cost reduction brought about by the semiconductor industry has led to computers smaller in size than a pin head, powerful enough to carry out the processing required, and affordable enough to be disposable. Similar technological advances in wireless communication, sensor design, and energy storage have resulted in the development of wireless "*Body Sensor Network*" (BSN) platforms comprising of tiny integrated micro sensors with onboard processing and wireless data transfer capability, offering the prospect of pervasive and continuous home health monitoring. In surgery, the reduced trauma of minimally invasive interventions combined with initiatives to reduce length of hospital stay and a socioeconomic drive to reduce hospitalisation costs, have all resulted in a trend towards earlier discharge from hospital. There is now a real need for objective, pervasive, and continuous post-operative home recovery monitoring systems. Surgical recovery is a multi-faceted and dynamic process involving biological, physiological, functional, and psychological components. Functional recovery (physical independence, activities of daily living, and mobility) is recognised as a good global indicator of a patient's post-operative course, but has traditionally been difficult to objectively quantify.

This thesis outlines the development of a pervasive wireless BSN system to objectively monitor the functional recovery of post-operative patients at home. Biomechanical markers were identified as surrogate measures for activities of daily living and mobility impairment, and an ear-worn activity recognition (e-AR) sensor containing a three-axis accelerometer and a pulse oximeter was used to collect this data. A simulated home environment was created to test a Bayesian classifier framework with multivariate Gaussians to model activity classes. A real-time activity index was used to provide information on the intensity of activity being performed. Mobility impairment was simulated with bracing systems and a multiresolution wavelet analysis and margin-based feature selection framework was used to detect impaired mobility. The e-AR sensor was tested in a home environment before its clinical use in monitoring post-operative home recovery of real patients who have undergone surgery. Such a system may eventually form part of an objective pervasive home recovery monitoring system tailored to the needs of today's post-operative patient.

Acknowledgements

"Your reason and your passion are the rudder and the sails of your seafaring sole.

If either your sails or you rudder be broken, you can but toss and drift, or else be at a standstill in mid-seas.

For reason, ruling alone is a force confining; and passion, unattended, is a flame that burns to its own destruction.

Therefore let your soul exalt your reason to the height of passion, that it may sing;

And let it direct your passion with reason, that your passion may live through its own daily resurrection, and like the phoenix rise above its own ashes."

From "The Prophet" by Kahlil Gibran

During the four-year journey that has led to the completion of this thesis, there have been numerous times where I have felt either my reason or passion tested, but throughout I have had the tremendous support of those around me to keep my rudder and sail intact. I would like to thank Professor the Lord Darzi of Denham and Professor Guang-Zhong Yang for providing me with amazing opportunities, resources, and guidance to embark upon this thesis. I am honoured to have contributed to their vision of pervasive healthcare.

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To Kishwer and Aslam,

for being my constant source of inspiration

CONTENTS

Abstract 2

List of Figures 10

List of Tables 23

List of Acronyms 24

1 Introduction 27

2 Wireless Body Sensor Networks (BSN) 35

2.1 Wireless Sensor Networks (WSN) 35

2.1.1 History of wireless sensor networks 35

2.1.2 Key components of WSNs 37

2.1.3 Existing applications for WSNs 38

2.2 Body Sensor Networks 40

2.3 Applications for BSN in Healthcare 41

2.3.1 Monitoring chronic diseases 44

2.3.2 Monitoring hospitalised patients 46

2.3.3 Monitoring vulnerable patient groups 48

2.4 Existing Pervasive Patient Monitoring Systems 51

2.4.1 Integrated fabrics and clothing embedded systems 52

2.4.2 Wireless body sensor networks 53

2.4.3 Sensor fusion with wearable and ambient sensing 54

2.4.4 Implantable sensing 54

2.5 Technical Challenges Facing Body Sensor Networks 56

2.5.1 Improved sensor design 56

2.5.2 Biocompatibility 57

2.5.3 Energy supply and demand 58

2.5.4 System security and reliability 59

2.5.5 Context awareness 62

2.5.6 Integrated therapeutic systems 63

2.6 Personalised Healthcare 64

2.7 Conclusions 67

3 Pervasive Monitoring in Surgery 69

3.1 Introduction 69

3.2 Trends Leading to Earlier Home Discharge following Surgery 70

3.2.1 Enhanced recovery programs 71

3.2.2 Specialist discharge nurses 71

3.2.3 Ambulatory surgery 72

3.2.4 *Home Wards* 72
3.2.5 *Socio-Economic Drivers for Home Recovery* 73
3.3 Monitoring Post-operative Recovery 74
3.3.1 *Biological recovery and wound healing* 74
3.3.2 *Physiological recovery* 77
3.3.3 *Post-Operative Complications* 78
3.3.1 *Psychological recovery* 83
3.3.2 *Functional Recovery* 84
3.4 Biomechanical Parameters for Measuring Functional Recovery 87
3.5 Sensor Node Design for Pervasive Functional Recovery Monitoring 93
3.5.1 *System overview* 93
3.5.2 *Key features* 94
3.5.3 *Sensor selection* 96
3.5.4 *Using accelerometers to monitor functional recovery* 97
3.5.5 *Using pulse oximeters to monitor activity-related physiology* 99
3.6 The ear-worn activity recognition (e-AR) sensor 102
3.6.1 *Key Components* 102
3.6.2 *The head as a site for accelerometer placement* 104
3.6.3 *The ear-lobe as a site for pulse oximeter placement* 105
3.6.4 *Regulatory approval* 106
3.7 Conclusions 107
4 Home Activity Monitoring 108
4.1 Introduction 108
4.2 Materials and Methods 111
4.2.1 *Overview* 111
4.2.2 *Pilot study* 111
4.2.3 *Simulated home environment* 112
4.2.4 *Data Collection* 112
4.2.5 *Ethical approval and Informed consent* 115
4.2.6 *Participant Questionnaires* 115
4.2.7 *Data analysis: accelerometer trace morphology* 115
4.2.8 *Data analysis: Activity classification and Index* 116
4.3 Results 118
4.3.1 *Pilot study: biomechanical evaluation of ADLs* 118
4.3.2 *Activity classifier and index* 130
4.3.3 *Simulated home activities circuit* 134

4.4 Discussion 141
5 Detecting Impairments in Mobility 145
5.1 Introduction 145
5.1.1 Truncal mobility impairment following abdominal surgery 145
5.1.2 Lower limb mobility impairment following abdominal surgery 146
5.1.3 Changes in gait following surgery 148
5.1.4 Measuring changes in gait following surgery 148
5.1.5 Using head-worn accelerometers to evaluate gait changes *149*
5.2 Materials and Methods 151
5.2.1 Overview 151
5.2.2 Simulating impaired lower limb mobility 151
5.2.3 Simulating impaired truncal mobility 152
5.2.4 Data Collection 154
5.2.5 Mobility impairment detection 154
5.2.6 Ethical approval and informed consent 158
5.3 Results 158
5.3.1 Detecting lower limb mobility impairment 158
5.3.2 Detecting lower limb mobility impairment: achieving optimal separation 161
5.3.3 Detecting impaired truncal mobility 162
5.3.4 Detecting truncal mobility impairment: achieving optimal separation 170
5.4 Discussion 171
6 Monitoring Functional Post-Operative Recovery in the Real Home 174
6.1 Introduction 174
6.1.1 Challenges of continuous home activity monitoring 174
6.1.2 Wearable activity sensing systems 176
6.1.3 Ambient activity sensing systems 177
6.1.4 Wearable and ambient sensor fusion 177
6.2 Methods 178
6.2.1 Overview 178
6.2.2 Mobility Impairment 178
6.2.3 Data Collection 179
6.2.4 Ethical Approval and Informed Consent 179
6.2.5 Data Analysis 180
6.3 Results 181
6.3.1 Unsupervised home ADL classification 181
6.3.2 Unsupervised home activity index 185

6.3.3 Logistic regression of diary card activity versus activity index data 188
6.3.4 Unsupervised home mobility impairment detection 189
6.4 Discussion 195
7 Home Vital Signs Monitoring in the Context of Activity 198
7.1 Introduction 198
7.1.1 Normal and abnormal variations in HR and SpO_2 198
7.1.2 Context awareness in home vital signs monitoring 201
7.2 Methods 202
7.2.1 Overview 202
7.2.2 Ethical approval and Informed consent 202
7.2.3 Regulatory approval 202
7.2.4 Data collection 202
7.2.5 Scenarios 203
7.2.6 Data Analysis 204
7.3 Results 206
7.3.1 Increasing walking intensity treadmill circuit 206
7.3.2 Scenario-based normal ADLs circuit 209
7.3.3 Real Home Environment 212
7.4 Discussion 215
8 e-AR Sensor Patient Trial 220
8.1 Introduction 220
8.2 Methods 222
8.2.1 Post-operative home recovery study 222
8.2.2 Ambulatory surgery mobility impairment study 223
8.2.3 Outcome measures 224
8.2.4 Ethical approval and Informed consent 225
8.2.5 Regulatory approval 225
8.2.6 e-AR sensor data collection 225
8.2.7 Data Analysis 226
8.3 Results 227
8.3.1 Post-operative home recovery 227
8.3.2 Post-operative mobility following ambulatory surgery 252
8.4 Discussion 258
9 Conclusions and Future Work 263
Appendix A: Pre-Study Questionnaire 268
Appendix B: Post-Study Questionnaire 273

Appendix C: Real-time Classifier 277
Appendix D: Truncal Immobility Brace 284
Appendix E: Mobility Impairment 288
References 295

List of Figures

Figure 2.1 A proposed solar-powered mote (left) and its magnified structural field-of-view (right) (courtesy of Professor K. Pister, University of California at Berkeley).

Figure 2.2 Examples of WSN hardware platforms developed in recent years.

Figure 2.3 Diagrammatic representation of the BSN architecture with wirelessly linked context aware 'on body' (external) sensors and its seamless integration with home, working, and hospital environments.

Figure 2.4 (Left) EC "Wealthy" project sensors embedded in clothing (courtesy of Rita Paradiso, Smartex Italy). (Right) "MIThril" tunic, (courtesy of Professor Alex Pentland, MIT Media Laboratory).

Figure 2.5 (Left) The CardioMEMS Endosure wireless aneurism pressure sensing device, Courtesy of CardioMEMS Inc. and Professor Mark Allen, Georgia Institute of Technology. (Right) Medtronic "Reveal Insertable Loop Recorder", Courtesy of Medtronic Inc.

Figure 2.6 (Left) Examples of an implantable device (sacral nerve stimulator) in current clinical use. (Bottom right) Deep brain stimulators, (courtesy of the Radiological Society of North America). (Above right) Implantable Synchromed® II drug delivery system for chronic pain, (courtesy of Medtronic Inc).

Figure 2.7 A picture from the 1918 influenza epidemic is an extreme example of the number of hospital patients that can be present close proximity (courtesy of the National Museum of Health and Medicine, Armed Forces Institute of Pathology, Washington, D.C., NCP 1603).

Figure 2.8 (Left) An integrated insulin drug-delivery system consisting of two communicating skin patches, one monitoring blood subcutaneous glucose, and the other delivering insulin (courtesy of Professor Adam Heller and John Wiley & Sons Inc).

Figure 2.9 (Left) the first prototype ring sensor with RF transmitter powered by a coin-sized battery (courtesy of Professor Harry Asada, MIT). (Right) a FitSense sensor attached to an athlete's shin enabling measurement of stride length, step

rate, instantaneous speed, distance, and acceleration (courtesy of Tom Blackadar, FitSense Inc).

Figure 3.1 An open midline laparotomy incision (top left) with resulting wound (top right). Laparoscopic ports inserted for a minimally invasive procedure (bottom left) with resulting wounds (bottom right).

Figure 3.2 Normal flow of faeces following a bowel anastomosis (left). The flow of faeces into the peritoneal cavity in the case of an anastomotic leak (right) often as a result of poor healing leading to sepsis.

Figure 3.3 The post-operative 'Active Tracer (AC-301)' accelerometer motion tracking system as proposed by Inoue et al. (Surgical Endoscopy 2003).

Figure 3.4 The human body's functional locomotor units shown diagrammatically with the subject in a natural position during walking.

Figure 3.5 During a stepping movement, the hip is flexed through a combination of hamstrings and gluteus maximus muscle. Initially the strength of movement is provided by the hamstrings, however towards the end the gluteus takes over.

Figure 3.6 The Cartesian coordinate system demonstrating movement of the head in x, y, and z directions.

Figure 3.7 Anatomical terms used to describe relative position.

Figure 3.8 Anatomical terms used to describe basic movements of the human body.

Figure 3.9 A diagrammatic representation of the BSN system worn by the patient and connected wirelessly to central servers where this information can be accessed by the clinician.

Figure 3.10 The Imperial college BSN node comprising of the above-mentioned components on a circuit board (right) compared in size to a fifty pence coin (left).

Figure 3.11 Common sensors that may be used with a BSN, namely 3-lead ECG (left), trunk accelerometers (centre), and finger-worn pulse oximeters (right).

Figure 3.12 The sensor system described by Kavanah et al (2006) which consisted of three triaxial accelerometers, each connected to a processor box worn on the subject's waist. The accelerometers were fixed to the head, C7 spinous process, L3 spinous process, and the lateral malleolus of the ankle.

Figure 3.13 The sigmoidal haemoglobin-oxygen dissociation curve. It can be seen that there is little variation in the pO2 between SpO2 values of 90-100% (above the dotted

line). Below this a small drop in SpO2 results in a large drop in pO2.

Figure 3.14 The e-AR sensor comprising of a BSN node connected to an ADXL330 accelerometer, ChipOx© pulse oximeter with ear clip and power supply (left). The device casing itself that is designed to be worn on the outer ear (middle and right).

Figure 3.15 e-AR sensor components: the BSN node on a circuit board (left), MCC ChipOx® pulse oximeter module (centre), and light weight polymer lithium-ion battery (right).

Figure 3.16 Wearing the ear-worn activity recognition sensor by hooking it around the base of the ear cartilage and clipping the pulse oximeter sensor on the earlobe.

Figure 3.17 The X, Y, and Z accelerometer axes in the e-AR sensor.

Figure 3.18 Common sites for pulse oximeter sensor placement in clinical practice.

Figure 4.1 Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk.

Figure 4.2 Floor plan of simulated home environment, with activities performed in each room labelled numerically as in table 4.1

Figure 4.3 BSN Signal Editor Version 1.1 graphical user interface (GUI) used in this study demonstrating accelerometer outputs from Z (ADC0-top trace), Y (ADC2-middle trace) , and X (ADC3-bottom trace) axes.

Figure 4.4 The seated (above) and stance (below) phases of the STS activity

Figure 4.5 Accelerometer traces showing the transition from sitting to standing positions. The purple trace represents x axis displacement (forward-backward), the green coloured trace represents z axis displacement (up-down), and the yellow trace represents y axis displacement (side-side) of the e-AR sensor.

Figure 4.6 Accelerometer traces showing the transition from standing to sitting down and reading. The purple trace represents x axis displacement (forward-backward), the green coloured trace represents z axis displacement (up-down), and the yellow trace represents y axis displacement (side-side) of the e-AR sensor.

Figure 4.7 Combined movements of the pelvis and trunk during the 'sit up' phase of the LTS activity. Initial flexion at the lumbar spine is followed by full flexion at the hip.

Figure 4.8 Accelerometer traces showing the transition from lying down to standing. The purple trace represents x axis displacement, the green coloured trace represents

z axis displacement, and the yellow trace represents y axis displacement of the e-AR sensor.

Figure 4.9 Accelerometer traces showing the transition from standing to lying down. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement of the e-AR sensor.

Figure 4.10 Stages of the gait cycle observed in subjects as they walked with conventionally used terminology marked at the appropriate points.

Figure 4.11 Accelerometer traces for walking on a treadmill at 5km/h whilst wearing the e-AR sensor. The trace shows the accelerometer trace over 40 steps with the purple trace representing x axis displacement, the green coloured trace representing z axis displacement, and the yellow trace representing y axis displacement.

Figure 4.12 The accelerometer trace for a single gait cycle with corresponding images of the subject as they undertake this. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement.

Figure 4.13 The accelerometer traces for a subject walking at 5km/h (left) and 2.5 km/h (right) with marked change in amplitude of accelerometer trace visible. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement.

Figure 4.14 Stance phase of the gait cycle observed in subjects as they were running. This phase is described by the limb marked X.

Figure 4.15 Swing phase of the gait cycle observed in subjects as they were running. This phase is described by the limb marked X.

Figure 4.16 Accelerometer traces for running on a treadmill at 8km/h whilst wearing the e-AR sensor. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement.

Figure 4.17 Clustering and classification of reading, walking and running for all subjects whilst wearing the e-AR sensor during the pilot study. This classification system was based on the signal variance across 3 accelerometer axes.

Figure 4.18 Clustering and correct classification of these activities into 'Class 0', 'Class 1',

and 'Class 2' activities during the pilot study.

Figure 4.19 (a) Graph showing the raw accelerometer data from a subject in the 5-activity pilot study. (b) The activity index for the above subject showing the levels of variance as an activity is undertaken. (c) Results of the classifier on the accelerometer data.

Figure 4.20 Accelerometer traces for one of the subjects undertaking the 34 activity simulated home trial. The activities are labelled from 1-34 at the bottom of the diagram a marked by the study coordinator during the trial. It should be noted that marker 35 signifies the end of the study and is not a distinct activity.

Figure 4.21 Average variances for each activity for one participant in the scenario-based activity circuit

Figure 4.22 Clustering and correct classification of these activities into 'very low', 'low', 'medium' and 'high' levels during scenario-based activity circuit across all subjects.

Figure 4.23 Accelerometer trace for one participant in the scenario-based simulated home circuit (above), with associated activity classification results from 0-3.

Figure 4.24 Accelerometer trace for one participant in the scenario-based simulated home activity circuit (above), with associated activity index results.

Figure 4.25 The mean variance for each activity for all 22 Participants in the circuit. Error bars represent standard deviation. Legend shows activity description

Figure 5.1 Muscle layers of the anterior abdominal wall affected by surgical incisions.

Figure 5.2 Thrombosis of the deep veins (left) results in swelling of the leg, causing pain and immobility. Ultimately a fragment of the clot may dislodge and become free-flowing within the blood stream, becoming an embolus.

Figure 5.3 The subject is wearing a knee brace whilst walking on the treadmill.

Figure 5.4 Subject shown wearing a truncal immobility brace system, with the components labelled. Please note that the subject in this figure was asked to wear a headband to secure the e-AR sensor.

Figure 5.5 The recovered ICA components of an accelerometer trace from a subject when walking. The upper component indicates the running pace, whilst the lower component represents high frequency components.

Figure 5.6 Stages of a wavelet filter composed of high pass and low pass filters at each stage.

Figure 5.7 An example multi-resolution DWT of an acceleration signal.

Figure 5.8 The DWT coefficients (above) for the ICA component of the accelerometer trace representing the walking pace (middle), with the high frequency component separated (below).

Figure 5.9 Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally (above) versus with moderate lower limb mobility impairment (below)

Figure 5.10 Results of using a KNN 5-fold cross validation on 10 subjects using DWT. Colours represent the number of features selected by Simba varying from 1 (blue) to all features (red). Percentage correct classification of normal versus moderately impaired lower limb mobility is shown.

Figure 5.11 Results of using a KNN 5-fold cross validation on 10 subjects using DWT when ICA was used for source separation before the feature extraction step. Colours represent the number of features selected by Simba varying from 1 (blue) to all features (red). Percentage correct classification of normal versus moderately impaired lower limb mobility is shown.

Figure 5.12 The impact of ICA and increasing number of selected features on correct data classification rates for impaired lower limb mobility.

Figure 5.13 Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally (above) versus with truncal mobility impairment (below). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.

Figure 5.14 The impact of ICA and increasing number of selected features on correct data classification rates when the e-AR sensor was used to detect normal versus impaired truncal mobility when walking on treadmill at varying speeds and incline.

Figure 5.15 Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally across a corridor (left) versus with truncal mobility impairment (right). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.

Figure 5.16 The impact of ICA and increasing number of selected features on correct data classification rates when the e-AR sensor was used to detect normal versus impaired truncal mobility walking along a corridor.

Figure 5.17 The normal pattern of stair climbing

Figure 5.18 Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally up a flight of stairs (left) versus with truncal mobility impairment (right). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.

Figure 5.19 The impact of ICA and increasing number of selected features on correct data classification rates for impaired truncal mobility in all subjects when walking up stairs.

Figure 5.20 The normal pattern of stair descent

Figure 5.21 Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally down a flight of stairs (left) versus with truncal mobility impairment (right). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.

Figure 5.22 The impact of ICA and increasing number of selected features on correct data classification rates for impaired truncal mobility when walking down stairs.

Figure 6.1 The three types of immobility simulated in the home environment during this study namely no impairment (a), impaired truncal mobility through a spinal brace (b), and impaired truncal and limb mobility through a spinal and limb brace (c).

Figure 6.2 The accelerometer trace (above) and accompanying activity classifier (below) for subject 1 in their home environment. A timeline (middle) indicating the events in the diary card of this subjects is included and labelled as follows: 1=Walking around the living room tidying up; 2=Sitting down and talking on the phone; 3=Tidying up the bedroom; 4=Sitting and working in front of a computer; 5=Getting up and eating a packet of crisps.

Figure 6.3 The accelerometer trace (above) and accompanying activity classifier (below) for subject 4 whilst at home for one leg of this study. The timeline (middle) is labelled as follows: 1=Making food in the kitchen; 2=Sitting, eating and watching television; 3=Washing up the dishes.

Figure 6.4 The accelerometer trace (above) and accompanying activity classifier (below) for subject 7 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card as follows: 1=Tidying up and organising bags; 2=Cooking dinner; 3=Sitting and eating dinner.

Figure 6.5 The accelerometer trace (above) and accompanying activity index (below) for subject 1 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card kept by the subject as follows: 1=Walking around the living room tidying up; 2=Sitting down and talking on the phone; 3=Tidying up the bedroom; 4=Sitting and working in front of a computer; 5=Getting up and eating a packet of crisps.

Figure 6.6 The accelerometer trace (above) and accompanying activity index (below) for subject 4 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card kept by the subject as follows: 1=Making food in the kitchen; 2=Sitting, eating and watching television; 3=Washing up the dishes.

Figure 6.7 The accelerometer trace (above) and accompanying activity index (below) for subject 7 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card kept by the subject as follows: 1=Tidying up and organising bags; 2=Cooking dinner; 3=Sitting and eating dinner.

Figure 6.8 The mean activity index during periods of high and low level activities recorded by subjects in this study.

Figure 6.9 A graph showing the mean activity index for the 9 subjects during low and high level activities in their own unsupervised home environments. Error bars represent two standard deviations of this mean.

Figure 6.10 The accelerometer traces for unsupervised walking in the home environment for subject 2 with 'normal mobility' (top), 'mildly impaired mobility' (middle), and 'moderately impaired mobility (bottom).

Figure 6.11 Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for all 9 subjects when wearing the e-AR sensor in their unsupervised home environment.

Figure 6.12 Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject 4 whilst wearing the eAR sensor in the unsupervised home. Accelerometer traces are shown on the left. Normal walking is seen to cluster between the two types of impairment.

Figure 6.13 Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject 5 whilst wearing the e-AR sensor in the unsupervised home. Accelerometer traces are shown on the left. Normal walking is seen to cluster between the two types of impairment.

Figure 6.14 Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject7 whilst wearing the eAR sensor in the unsupervised home environment. Accelerometer traces are shown on the left.

Figure 6.15 Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject 8 whilst wearing the eAR sensor in the unsupervised home environment. Accelerometer traces are shown on the left. Clustering does not occur in this case.

Figure 7.1 Normal physiological response to exercise and its impact on HR and SpO2. CO=Cardiac output, SV=Stroke volume.

Figure 7.2 The HR, SpO2, and X-Y axis accelerometer outputs for a subject as they undertook the treadmill circuit. The walking speeds are also labelled on this graph.

Figure 7.3 Mean HR (bpm) collected using the e-AR sensor with increasing treadmill walking intensity for each of the 44 volunteer samples.

Figure 7.4 Mean HR (bpm) with increasing treadmill walking intensity (standard deviations shown as arrows either side of the mean). Statistically significant results from the one-away ANOVA test are also shown.

Figure 7.5 The HR and SpO2 data for a subject 12 as they undertook the scenario-based home ADL circuit.

Figure 7.6 Mean HR (bpm) collected using the e-AR sensor after 5 activities in the scenario-based ADL circuit. Results of the one-way ANOVA test are shown, showing statistically significant differences between the activities of sitting, eating, and sleeping when compared to walking and climbing stairs. Associate p values are shown.

Figure 7.7 A pie chart showing the activities involving an SpO2 reading below 90% during the scenario-based ADL circuit.

Figure 7.8 The HR, SpO2, and activity index for a subject undertaking unsupervised activities in their own home environment.

Figure 7.9 Mean HR for each of the 27 samples during home activity circuit for low and high level activities. Overall means for high and low level activities are also shown.

Figure 7.10 A scatter plot showing the activity index during periods where SpO2 was <90%

according to the e-AR sensor for the 27 home ADL datasets. A line marking the point where activity index was 5 and the proportion of readings above and below this is also shown.

Figure 8.1 A picture of patient 1 wearing the e-AR sensor in their home with a close-up view (bottom right inset) of the patient's right ear.

Figure 8.2 A graph showing patient 1's mean resting heart rate (HR), peak HR at AI>5, and resting SpO2 during the pre- and post-operative period.

Figure 8.3 A bar chart showing the mean number of steps per hour taken by patient 1 during pre- and post-operative periods at home.

Figure 8.4 A graph showing the mean activity index per hour for patient 1 during pre- and post-operative periods at home.

Figure 8.5 The activity classification per hour profile for patient 1 during pre- and post-operative periods.

Figure 8.6 The mobility impairment classification results for patient 1 during the pre- and post-operative periods.

Figure 8.7 A picture of patient 2 wearing the e-AR sensor whilst standing in his living-room. The insets show a close-up view of the patient's right ear (top left), she subject sitting and watching television (top middle), and the subject cooking in his kitchen (top right).

Figure 8.8 A graph showing patient 2's mean resting heart rate (HR), peak HR at AI >5, and resting SpO2 during the pre- and post-operative period.

Figure 8.9 A bar chart showing the mean number of steps per hour taken by patient 2 during pre- and post-operative periods at home.

Figure 8.10 A graph showing the mean activity index per hour for patient2 during pre- and post-operative periods at home.

Figure 8.11 The activity classification per hour profile for patient 2 during pre- and post-operative periods.

Figure 8.12 The mobility impairment classification results for patient during pre- and post-operative periods.

Figure 8.13 A picture of patient 3 wearing the e-AR sensor in her home with a close-up view (top left) of the subject's ear.

Figure 8.14 A graph showing patient 3's mean resting heart rate (HR), peak HR with AI >5, and resting SpO2 during the pre- and post-operative period.

Figure 8.15 A bar chart showing the mean number of steps per hour taken by patient 3 during pre- and post-operative periods at home.

Figure 8.16 A graph showing the mean activity index per hour for subject 3 during pre- and post-operative periods at home.

Figure 8.17 The activity classification per hour profile for patient 3 during pre- and post-operative periods.

Figure 8.18 The mobility impairment classification results for patient 3 during the pre- and post-operative periods.

Figure 8.19 A picture of patient 4 wearing the e-AR sensor in their home with a close-up view (top right inset) of the subject's ear.

Figure 8.20 A graph showing patient 4's mean resting heart rate (HR), peak HR at activity index (AI) >5, and resting SpO2 during the pre- and post-operative period.

Figure 8.21 A bar chart showing the mean number of steps per hour taken by patient 4 during pre- and post-operative periods at home.

Figure 8.22 A graph showing the mean activity index per hour for patient 4 during pre- and post-operative periods at home.

Figure 8.23 The activity classification per hour profile for patient 4 during pre- and post-operative periods.

Figure 8.24 The mobility impairment classification results for patient 4 during the pre- and post-operative periods.

Figure 8.25 A picture of patient 5's living room. The inset (tops left) shows the patient wearing the e-AR sensor whilst resting in her bedroom, and a close-up view of her ear whilst wearing the sensor. The patient had to wear a headband with the sensor to prevent slippage on the ear during the day.

Figure 8.26 A graph showing patient 's mean resting heart rate (HR), peak HR at AI >5, maximal HR with activity, and resting SpO2 during the pre- and post-operative period.

Figure 8.27 A bar chart showing the mean number of steps per hour taken by patient 5 during pre- and post-operative periods at home.

Figure 8.28 A graph showing the mean activity index per hour for patient 5 during pre- and post-operative periods at home.

Figure 8.29 The activity classification per hour profile for patient 5 during pre- and post-operative periods.

Figure 8.30 The mobility impairment classification results for patient 5 during the pre- and post-operative periods

Figure 8.31 Mobility impairment classification (without ICA) for pre- vs. post-op walking in 5 subjects who underwent abdominal wall surgery. Axes represent the most discriminant features selected by feature selection.

Figure 8.32 Mobility impairment classification (with ICA) for pre- vs. post-op walking in 5 subjects who underwent abdominal wall surgery. Axes represent the most discriminant features selected by feature selection.

Figure 8.33 Mobility impairment detection classification (without ICA) results for pre- versus post-operative walking in 5 subjects who underwent day surgery peri-anal procedures. The axes represent the 3 most discriminant features as selected by feature selection.

Figure 8.34 Mobility impairment detection classification (with ICA) results for pre- versus post-operative walking in 5 subjects who underwent day surgery peri-anal procedures. The axes represent the 3 most discriminant features as selected by feature selection.

Figure 8.35 Mobility impairment detection classification (without ICA) for pre- versus post-operative walking in all 10 subjects. The axes represent the 3 most discriminant features as selected by feature selection.

Figure 8.36 Mobility impairment detection classification (with ICA) results for pre- versus post-operative walking in all 10 subjects. The axes represent the 3 most discriminant features as selected by feature selection.

Figure 8.37 The results for correct classification of mobility impairment and the impact of using an increasing number of features is shown for patient who had abdominal wall surgery, those who had peri-anal surgery, and both groups combined.

Figure A1 Question 1a – What is your level of anxiety for wearing the vital body sensors over the next 2 hours? Question 1b – What is your level of anxiety for being monitored in a simulated home environment? Question 1c -- What is your level of anxiety for taking the sensors off and putting them back on again?

Figure A2 Question 2a – Imagine you were a postoperative patient would you like to have your vital signs monitored continuously at home? Question 2b – Imagine you were a postoperative patient would you like to have your vital signs measured 4 times a day

Figure A3 Question 3a – Does wearing body sensors make you feel more secure at home? Question 3b – Will wearing body sensors lead to problems being picked up quicker?

Figure B1 Question 1 – During this study you have been given the opportunity to use a wearable body sensor. Did you find this sensor comfortable?

Figure B2 Question 2 – Do you think that wearing the sensor affected your activities in the scenario?

Figure D1 Result from patient questionnaire survey

Figure D2 Questionnaire results from the truncal mobility impairment brace.

List of Tables

Table 2.1 Differing challenges faced by Wireless Sensor Networks as compared to Body Sensor Networks

Table 2.2 Disease processes and parameters commonly used to monitor these diseases. Suggested sensor types for measurement of these parameters are listed in brackets. All of these conditions currently place a heavy administrative and financial burden on healthcare systems, which may be reduced if picked up.

Table 3.1 Typical post-operative lengths of stay for common general surgical procedures

Table 3.2 Clinical Manifestations of general post-operative complications, their causes, and the available current monitoring systems used to detect these. DVT=deep vein thrombosis, PE=pulmonary embolus, HR=heart rate, BP=blood pressure.

Table 4.1 List of activities performed in the simulated home with command and task description

Table 4.2 Activity classification results from the pilot study.

Table 5.1 The results of using KNN with 5-fold cross validation on the normal versus impaired lower limb mobility dataset.

Table 5.2 The results of using KNN with 5-fold cross validation on the subjects walking along a corridor with and without impaired truncal mobility.

Table 7.1 The effect of common post-operative complications during the early home recovery period on HR and SpO2 measurements.

Table 8.1 Demographics for patients who were selected for the post-operative home recovery study. HT=hypertension, IHD=ischaemic heart disease, COPD=Chronic obstructive pulmonary disease, IDDM=Insulin-dependent diabetes mellitus, NIDDM=Non-insulin dependent diabetes mellitus.

Table 8.2 Demographics for the 10 patients selected for the post-operative mobility following ambulatory surgery study.

Table D1 Truncal Immobility Patient Questionnaire Statements

Table D2 Summary of Mann-Whitney test

List of Acronyms

ADC0	Analogue to Digital Converter *z*-axis accelerometer trace
ADC2	Analogue to Digital Converter y-axis accelerometer trace
ADC3	Analogue to Digital Converter *x*-axis accelerometer trace
ADL	Activity of Daily Living
AF	Atrial Fibrillation
AI	Activity Index
BFFS	Bayesian Framework for Feature Selection
BI	Barthel Activities of Daily Living Index
BP	Blood Pressure
BPM	Beats per minute
BSN	Body Sensor Network
CARS-C	Computer Anxiety Rating Scale
CO	Cardiac Output
COPD	Chronic Obstructive Pulmonary Disease
COTS	Commercial Off-The-Shelf
CT	Computer Tomography
CTS-C	Computer Thoughts Survey Scale
DARPA	Defence Advanced Research Projects Agency
DVT	Deep Vein Thrombosis
DWT	Discrete Wavelet Transform
EADL	Extended Activities of Daily Living scale
e-AR	Ear-worn Activity Recognition Sensor
ECG	Electrocardiography
EEG	Electroencephalogram
EGF	Epidermal Growth Factor
EMG	Electromyography
EMS	Elderly Mobility Scale
EQ-5D	EuroQuol Group questionaire

GATC-C	General Attitude Towards Computer Scale
GPRS	General Packet Radio Service
GPS	Global Positioning System
GSM	Global System for Mobile Communications
GUGT	Get Up and Go Test
GUI	Graphical User Interface
Hb	Haemoglobin
HbA1c	Glycated haemoglobin
HDU	High Dependency Unit
HR	Heart Rate
ICA	Independent Component Analysis
ICD	Implantable Cardioverter-Defibrillator
KNN	K Nearest Neighbour
LAN	Local Area Network
LED	Light Emitting Diode
LPU	Local Processing Unit
LREC	Local Research and Ethics Committee
LTS	Lying-to-standing
MCU	Micro-controlling Unit
MEMS	Micro-electrical Mechanical System
MHRA	Medicines and Healthcare Regulatory Agency
MI	Myocardial Infarction
MIT	Massachusetts Institute of Technology
MRSA	*methicillin resistant Staphylococcus aureus*
NHS	National Health Service
NICE	National Institute of Clinical Excellence
OS	Operating System
PATHOS	Pervasive At Home Sleep Monitoring System
PC	Personal Computer
PDA	Personal Digital Assistant
PDGF	Platelet-Derived Growth Factor
PE	Pulmonary Embolus

PIR	Passive Infrared
pO2	Partial Pressure of Oxygen
QoR-40	Quality of Recovery questionnaire
RAM	Random Access Memory
RF	Radio Frequency
Rfab	Reconfigurable Fabric
RFID	Radio Frequency Identification
RISc	Reduced Instruction Set Computer
RMS	Root Mean Square
SAM	Step-watch Activity Monitor
SD	Standard Deviation
SF36	Short Form 36 questionnaire
SpO2	Oxygen Saturation
STS	Sitting-to-standing
SV	Stroke Volume
TCP	Transmission Control Protocol
TinyOS	Tiny Micro-threading Operating System
UC	University of California
UCLA	University of California at Los Angeles
UK	United Kingdom
VIP	Visual Image Processing
WAMAS	Wearable Accelerometer Motion Analysis System
WBAN	Wireless Body Area Network
WLAN	Wireless Local Area Network
WSN	Wireless Sensor Network
24hFAQ	24-hour Functional Ability Questionnaire
3-D	Three Dimensional

1 Introduction

Wireless *Body Sensor Networks* (BSN) is a new and evolving technology that for the first time offers the prospect of completely pervasive monitoring of patients in any environment. This translates to the ability to deliver continuous and objective home monitoring to a population of patients who could otherwise only receive this in the hospital setting. In a medical environment where decisions are currently made based on 'snapshots' of isolated information, the ability to look at a continuous stream of patient data has obvious advantages. This also has important implications for patients who wish to exercise choice over where they recover, with many choosing to go home earlier than ever before from hospital following surgery. *Personalised healthcare* is a term that is being mentioned more than ever in the context of medical care because it is tailored to an individual's needs. Patients also require their monitoring systems to be flexible and non-restrictive to their activities rather than confining themselves to serve the purpose of monitoring. With an aging and increasingly dependent population, recovering from acute illness or surgery at home alone, technologies that automate and improve the safety of current labour-intensive home monitoring systems are likely to be of tremendous value.

The advances in wireless technology mentioned above come at a time when surgical practice has itself progressed dramatically through a better understanding of surgical disease combined with improvements in surgical device technology. New anaesthetic techniques, analgesics, and the development of tailored goal-directed recovery programs have meant that patients recover from the trauma of surgery quicker than ever before. In general surgery, minimally invasive technologies such as laparoscopy and robotics have significantly reduced the wound size required to access the operative site, and in many cases have improved the quality of its visualisation. This has also had a dramatic impact in the reduction of the trauma of surgery to further minimise the length of hospitalisation. We find ourselves in a situation therefore, where the need for post-operative home monitoring is set to rise, with the technological solutions to meet this need now being in existence. The next step is the marriage of wireless technologies to the post-operative needs of the patient through the creation of a pervasive body sensor network to monitor post-operative recovery at home.

Post-operative recovery is a multi-faceted process, with healing involving a number of components. *Biological recovery* involves the processes of inflammation, tissue regeneration, and remodelling of the wounds created by the trauma of surgery itself. *Physiological recovery* involves the return of the body's major homeostatic systems (for example cardiopulmonary, renal, respiratory, and gastro-intestinal systems) to their normal steady state of functioning and interaction. *Functional recovery* involves a return to normal mobility and as a result the ability to perform activities of daily living effectively. Finally, it is important to appreciate that *psychological recovery* from the trauma of surgery can impact a number of aspects of an individual's personal and professional life. As a result, whilst there are a number of outcome measures that may be used to monitor home post-operative recovery, it is important to choose parameters that give a global yet objective indication of a patient's progress. In addition to this, the pervasive monitoring system developed to monitor post-operative recovery at home must be non-invasive, have a high level of compliance, and be simple to use.

Of the parameters mentioned above, functional recovery following general surgery is perhaps the most relevant to measure in a home environment for a number of reasons. First, a return to normal mobility and physical independence are outcome measures that are important components of quality of life and quality of recovery questionnaires used to evaluate the post-operative recovery of patients at home. Second, functional recovery is a good global measure because order to return to normal activity and mobility, a subject will need to show adequate biological, physiological, and psychological recovery. Finally, an outcome measure that shows when a patient has safely returned to their normal function can ultimately determine when it is time to stop monitoring them at home.

This thesis tests the original hypothesis that 'biomechanical data collected using an ear-worn activity recognition (e-AR) BSN device can be used as a surrogate marker of functional recovery'. Through its experimental chapters, this thesis aims to:

- Identify biomechanical parameters relating to functional recovery in terms of activities of daily living and mobility impairment that may be objectively and continuously monitored using wearable sensors in the home environment.

- Use a pervasive wireless ear-worn activity recognition (e-AR) device comprising of low power accelerometers, pulse oximeter, BSN node, wireless data transfer capability, and energy power source to collect this biomechanical raw data.

- Test a series of original hypotheses linking these biomechanical markers to outcomes of functional recovery through experiments conducted in the simulated and real home environments.

- Analyse this biomechanical data and convert it into surrogate markers of functional recovery through a series of frameworks, thereby objectively quantifying activity and mobility.

- Demonstrate the use of the e-AR BSN sensor, data analysis framework, and biomechanical markers of functional recovery to pervasively monitor post-operative recovery in the homes of real patients who have recently undergone general surgical procedures.

The layout of this thesis and the interdependence of its chapters are outlined below:

- **Chapter 2** reviews the origins and development of BSNs, outlining their potential applications in the delivery of pervasive healthcare for the management of both acute and chronic conditions, in both hospital and community settings. A number of other strategies and platforms for pervasive healthcare monitoring are discussed, including proprietary designed WSNs, clothing-embedded systems, environmental sensors, and implantable devices, all of which go some way to meet the challenges of delivering truly pervasive and ubiquitous healthcare monitoring. Future areas of focus are highlighted including improving sensor design, biocompatibility, energy supply, power scavenging, secure information transfer, and context awareness all of which must be overcome before such a system is fully effective.

- **Chapter 3** reviews the technological, clinical, and socioeconomic trends in modern surgical practice that have led to earlier discharge from hospital following an operation, and highlights the need for pervasive post-operative recovery monitoring in this setting. The different types of recovery that a patient may experience are classified into biological, physiological, functional, and psychological categories with means of monitoring these explored. Functional recovery is identified as a good

global indicator of patient's progress, with 'activities of daily living' (ADLs) and 'mobility' as important components of this that would be suited to pervasive monitoring in the home. The use of biomechanical markers to quantify ADLs and mobility is explored, and a number of methods to measure functional recovery reviewed including the use of accelerometers and pulse oximeters. The sensor node design and wireless BSN platform that are key to the success of such a system are described and packaged into an ear-worn Activity Recognition (e-AR) device that is to be worn by the patient at home during their post-operative recovery period.

- **Chapter 4** tests the hypothesis that '*The e-AR sensor can be used to measure the changes in head acceleration that occur with varying postures and movements during key ADLs. This biomechanical information can then be analysed using an activity classification framework and used as the basis for inferring the ADLs being performed. In this way, the biomechanical information captured by the e-AR sensor can be used to objectively quantify functional recovery.*' An experiment comprising of five key ADLs was undertaken to determine the biomechanical changes that occur during these activities and correlate them to the accelerometer outputs from the e-AR sensor. An activity classification framework was then used to analyse these biomarkers and tested on a larger dataset of thirty-four activities undertaken in a simulated home environment. In this way, the ability of the e-AR sensor to correctly classify home ADLs was evaluated.

- **Chapter 5** tests the hypothesis that '*The e-AR sensor can be used to collect raw biomechanical data to detect impairments in human gait due to truncal and limb immobility. These parameters can then be converted using a spatiotemporal analysis framework into surrogate markers of normal and impaired mobility*'. In order to achieve this, truncal and limb immobility was simulated using bracing systems and subjects asked to mobilise in a simulated home environment whilst wearing the e-AR sensor to collect raw biomechanical data. A multi-resolution spatiotemporal framework software was used to analyse the e-AR sensor's accelerometer data which instead of using fixed measures (such as gait cycle) that generally do not take into account of 3-D motion, used multi-resolution wavelet features across all directions of motion. This technique used automatic margin-based feature selection to select the frequency bands of the wavelet transform that provide discrimination between classes

of motion, and Independent Component Analysis (ICA) as a means of source separation for 3-D acceleration.

- **Chapter 6** tests the hypothesis that: '*The e-AR sensor and its biomechanical data analysis frameworks can be used to quantify the intensity and type of activity being performed by a subject in their normal home, and detect any impairment in their mobility in this completely unsupervised environment*'. Accelerometer data was collected using the e-AR sensor, worn by healthy volunteers in their own homes. In order to simulate mobility impairment, subjects were asked to take part in three separate legs of the study where they were either wearing an abdominal bracing system (simulating impaired truncal mobility), an abdominal and knee bracing system (simulating truncal and lower limb mobility impairment), or no bracing system at all (normal mobility). The activity classification framework and index, mobility impairment detection framework, and accelerometer trace morphology assessment tools developed to date were then used to analyse this data.

- **Chapter 7** tests the hypothesis that: '*Activity classification information obtained from the e-AR sensor may be used to provide the context in which a patient's physiology may be interpreted. This physiology monitoring was in the form the e-AR sensor's wearable pulse oximeter which was used to measure a subject's heart rate and oxygen saturation.*' Data obtained from volunteers wearing the e-AR sensor in both simulated and real home environments was used to evaluate the performance of context-aware pulse oximetry over a range of activity types and determine its role in pervasive post-operative home monitoring.

- **Chapter 8** is a clinical pilot study demonstrating the use of the e-AR sensor and its activity classification, mobility determination, and pulse oximeter to monitor functional and physiological aspects of recovery in 15 post-operative patients. The e-AR sensor was worn by 5 patients undergoing elective surgery in the pre-operative period to evaluate their baseline home function and mobility, which was compared to their functional recovery and mobility during the first ten days that they spent at home after surgery. To further test the e-AR sensor's mobility impairment framework, the gait of 10 patients undergoing ambulatory surgery was evaluated pre- and post-operatively using the device.

- **Chapter 9** concludes the thesis, summarises its findings, and discusses its future limitations, outlining the future directions that this research may take.

The work undertaken in this thesis relied on the development of the wireless BSN node and its operating system, the e-AR sensor, data visualisation software, and analysis frameworks by the pervasive computing team at the Institute of Biomedical Engineering at Imperial College. My original contribution to this thesis is outlined below:

- Identification of activities of daily living and mobility impairment as important parameters of functional post-operative home recovery, and the determination of biomechanical components of these parameters that were objectively monitored with the e-AR sensor.

- Contributing towards the development of the data analysis frameworks used to convert raw biomechanical data into surrogate markers that could be used to provide continuous and objective measurement of activity and mobility impairment.

- Generation of the original hypotheses to be tested, experimental design, ethical approval, regulatory approval, data collection, data analysis, and interpretation of results for the experiments presented in this thesis.

- Clinical evaluation of the e-AR sensor and its data analysis framework to monitor post-operative patients in their homes including patient selection, education, home visits, hardware setup and installation, data collection, and analysis.

The contents of this thesis have resulted in the following book chapters, publications, conference proceedings and prizes:

- *Book Chapter:* Introduction to Body Sensor Networks. Aziz O, Lo B, Darzi A, Yang GZ. Body Sensor Networks. Ed Guang-Zhong Yang. Springer 2006. 1846282721

- *Conference presentation:* Aziz O, Lo B, King R, Yang GZ, Darzi A. Pervasive Body Sensor Network: An Approach to Monitoring the Post-operative Surgical Patient. IEEE: BSN 2006.

- *Conference presentation:* Aziz O, Lo B, Yang GZ, Darzi A. Pervasive Healthcare: Clinical Drive, Technological Innovations, and Socio-Economic Benefits. IEE: Perspectives in Pervasive Computing 2006.

- *Conference presentation:* Aziz O, Lo B, Yang GZ, Darzi A. Body Sensor Networks, The ultimate diagnostic tool? IEE: BSN 2005.

- *Conference presentation:* A Pervasive Body Sensor Network for Monitoring the Post-operative Surgical Patient. Aziz O, Lo B, Atallah L, Yang GZ, Darzi A. UK-Ubinet Workshop, 2006, July. London.

- *Conference presentation:* Developing a Pervasive Monitoring System for the post-operative surgical patient. Aziz O, Lo B, Yang GZ, Darzi A. Institute of Biomedical Engineering: Network for Bioinformation Technology. 2006, Jan. London

- *Conference presentation:* Pervasive Healthcare: Clinical Drive, Technological Innovations, and Socio-Economic Benefits. Aziz O, Lo B, Yang GZ, Darzi A. Institute of Electrical Engineers Interface Event: Perspectives in Pervasive Computing. 2005, October. London.

- *Publication:* Aziz O, Lo B, Pansiot J, Atallah L, Yang GZ, Darzi A. From computers to ubiquitous computing by 2010: health care. Philos Transact A Math Phys Eng Sci. 2008 Oct 28;366(1881):3805-11.

- *Publication:* Aziz O, Atallah L, Lo B, Elhelw M, Wang L, Yang GZ, Darzi A. A pervasive body sensor network for measuring postoperative recovery at home. Surg Innov. 2007 Jun;14(2):83-90.

- *Publication:* Lo B; Atallah L; Aziz O; El Elhew M; Darzi A; Yang GZ. Real-time pervasive monitoring for postoperative care. 4th International Workshop on Wearable and Implantable Body Sensor Networks. 2007 13:122-127.

- *Publication:* Aziz O, Lo B, King R, Darzi A, Yang GZ. Pervasive body sensor network: an approach to monitoring the post-operative surgical patient. Wearable and Implantable Body Sensor Networks, 2006 April:18-21.

- *Publication:* Atallah L, Aziz O, Lo B, Yang G Z. Detecting Walking Gait Impairment with an Ear-worn Sensor. Proceedings of the 2009 Sixth International Workshop on Wearable and Implantable Body Sensor Networks, 2009: 175-180.

- *Prize:* Institute of Biomedical Engineering: Network for Bioinformation Technology: Poster Competition Prize. 2006

2 Wireless Body Sensor Networks (BSN)

2.1 Wireless Sensor Networks (WSN)

Over the past decade, the miniaturisation and cost reduction brought about by the semiconductor has made it possible to create computers that are smaller in size than a pin head, powerful enough to carry out the processing required, and affordable enough to be considered disposable. It is thought that this reduction in size and increase in processing capability is likely to continue over the next two decades, with the computers becoming even smaller and cheaper year by year [1]. Similarly, advances in wireless communication, sensor design, and energy storage technologies have meant that the concept of a truly pervasive "*Wireless Sensor Network*" (WSN) is rapidly becoming a reality [2]. Integrated microsensors no more than a few millimetres in size, with onboard processing and wireless data transfer capability are the basic components of such networks, which are already in existence [3, 4]. Thus far a range of applications have been proposed for the use of WSNs and they are likely to change every aspect of our daily lives.

2.1.1 History of wireless sensor networks

One of the first applications developed to utilize large-scale pervasive wireless sensor networks was *'Smart Dust'*. This was developed at the *University of California* (UC) at Berkeley and funded by the *Defence Advanced Research Projects Agency* (DARPA). The aim of this project was to produce a self-contained, millimetre-scale sensing and communication platform for massively distributed sensor networks [4]. Primarily meant as a military application, the *Smart Dust* concept involved the use of thousands of tiny wireless sensor "motes" that could be spread over a large battlefield area, allowing enemy movements to be monitored in a covert manner. In addition to its military application, *Smart Dust* may eventually be used in a number of different environments ranging from the atmosphere, where they may be deployed for weather condition monitoring, to factories, where they may be used to track productivity and output. In both these examples, the wireless nature of the network is absolutely crucial. As an example, Figure 2.1 illustrates two images of the optical *Smart Dust* motes currently being developed. It is interesting to note that researchers have

also approached *Smart Dust* from a biotechnology perspective to produce motes from chemical compounds rather than electric circuitry[5].

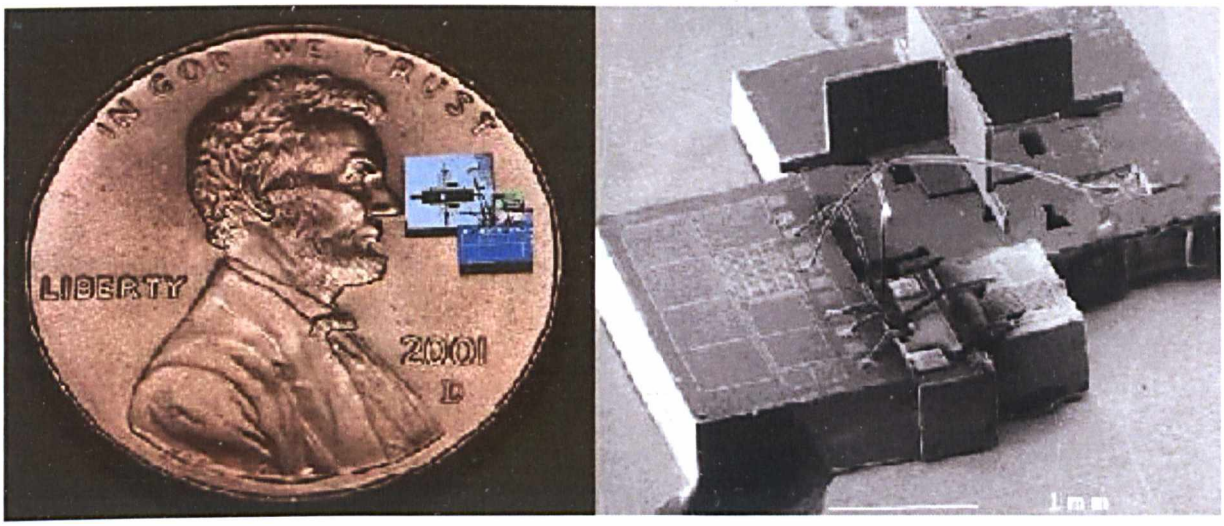


Figure 2.1 *A proposed solar-powered mote (left) and its magnified structural field-of-view (right) (courtesy of Professor K. Pister, University of California at Berkeley).*

In the early stages of the *Smart Dust* project, the team gained experience by building relatively large "motes" using *Commercial Off-The-Shelf* (COTS) components. With cooperation from Intel® Corporation (California, USA), these motes were created as an open-source hardware and software platform, combining sensors, low power wireless communication, and processing onto a single architecture. The motes were also designed to have the ability to "self-organize" (resulting in a self-configuring WSN), and carry out onboard signal processing and distributed inferencing tasks prior to sending relevant information to a central control. Whilst the concept of tiny, ubiquitous, low cost, *Smart Dust* motes has not yet been fully realised, many reasonably small motes are now commercially available. The flurry of activity in this area is best illustrated below in Figure 2.2, which shows some of the WSN mote hardware platforms developed over the last five years.

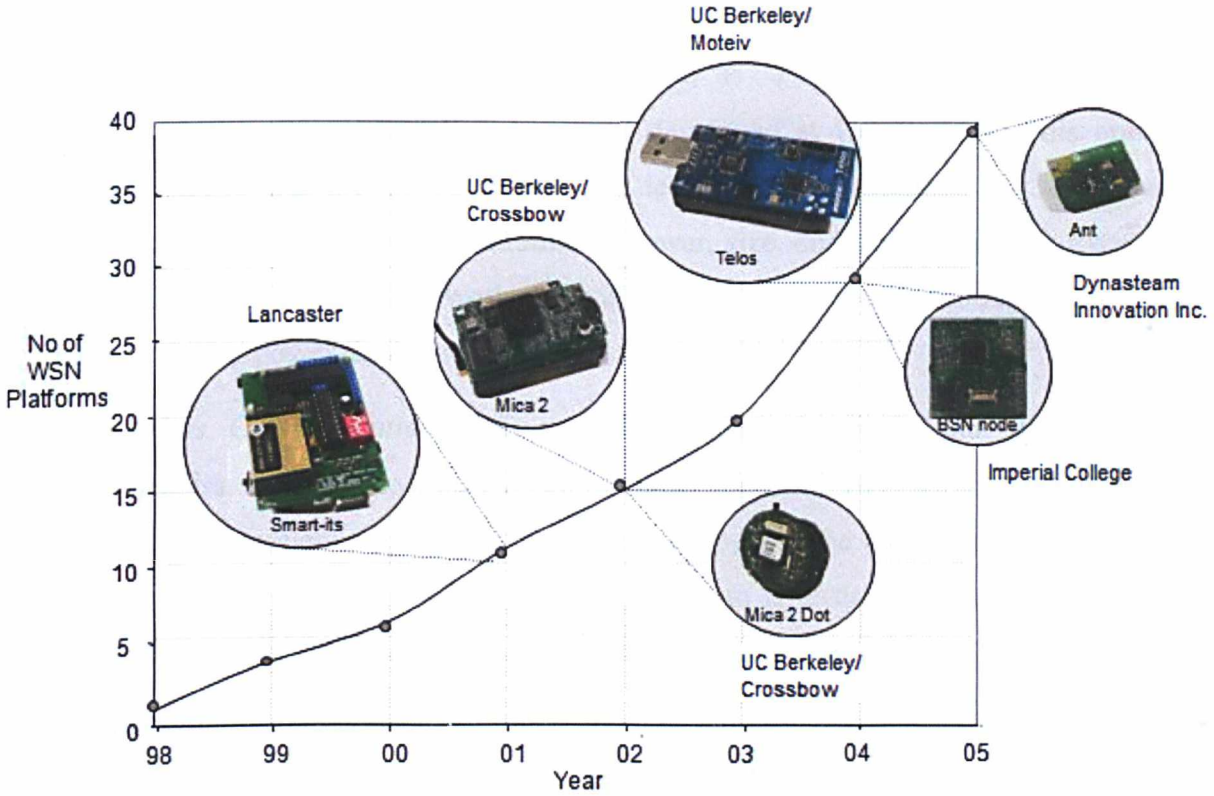


Figure 2.2 *Examples of WSN hardware platforms developed in recent years.*

2.1.2 Key components of WSNs

The architecture of WSN mote hardware platforms consists of six major components namely:

- *Processor* – This is the 'brain' of the mote, overseeing all the other components. Processors used in WSNs have lower processing demands than those used in personal computers (PC) and also have tight constraints on power consumption due to battery size restrictions. As a result, they are based on *Micro-controlling Units* (MCUs) as opposed to conventional PC-type processors.
- *Memory* – This provides storage of both raw and processed data from sensors. MCU-based processors provide limited *Random Access Memory* (RAM), meaning the WSN platforms need to use external flash memory.
- *Operating System (OS)* – This is the software that manages the wireless network and mote resources. The processing power and memory limitations of WSN hardware mentioned above, mean that convention embedded operating systems (e.g. Microsoft ® Corporation's Windows XP) are not suitable for WSN platforms. A key

development for WSNs has been the small, open source (freely available) energy efficient software operating system known as '*Tiny Micro-threading Operating System*', or 'TinyOS', which has been developed at UC Berkley. This operating system provides a basic framework and development environment for WSNs, and it functions well under the constraints of power, size, and cost. TinyOS software runs both the hardware and network, making sensor measurements, routing decisions, and controlling power dissipation.

- *Wireless Communication* – This connects multiple motes and allows wireless transmission of data to where it can be used. The three main components that afford the mote wireless communication in this setting are the radio transceiver, antenna, and communication protocols. It is important to note that wireless communication usually carries the greatest power demand of all WSN components.
- *Sensor Interface* – This allows the mote to be connected to either a digital (e.g. 3-axis accelerometers) or an analogue (e.g. thermistors or photo resistors) sensor. A number of WSN mote designs contain integrated sensors that monitor a variety of environmental factors including temperature, humidity, barometric pressure, light intensity, tilt and vibration, and magnetic field [6].
- *Power Supply* – This is a crucial part of any WSN mote, currently consisting primarily of batteries and fuel cells. The miniaturization of power sources for sensors and mote components as well as the development of energy harvesting systems are key considerations and are mentioned later on in this chapter.

2.1.3 Existing applications for WSNs

Currently, new applications for WSNs can be categorised into three types: those used for monitoring environments (indoor, outdoor, urban or countryside), those used for monitoring objects (such as machines and buildings) and those for monitoring the interaction of these objects with environments [7].

An example of WSNs monitoring environments is a sensor network being used to monitor the impact of a wind farm off the coast of England on the structure of the ocean bed [8]. Here, sensor nodes are deployed on the ocean bed by dropping them from a ship at selected positions. Each sensor mote is fixed on the ocean bed by an anchor, and connected via a cable to a buoy on the ocean surface that contains the radio equipment and Global Positioning

System (GPS). The WSN is used to measure temperature, pressure, conductivity, current, turbidity, and ultimately through these the influence of the wind farm on formation of sand banks tidal activity. In Briksdalsbreen in Norway, a WSN is being used to monitor sub-glacier environments [9]. Here, motes equipped with pressure, temperature, and tilt sensors are placed at the bottom of drill holes in the glacier ice and communicate with a base station placed on top of the glacier. This is in turn used to measure supra-glacial displacements using differential GPS and transmit the data collected via the Global System for Mobile communications (GSM). The system aims to enable observation of displacements and the dynamics inside the glacier over a lengthy (months to years) period.

An example of a WSN for monitoring objects is a system developed by *British Petroleum*, who have picked up on the huge potential offered by WSN technology and have recently embarked on a program to develop its large-scale use. One application they are testing is the establishment of a WSN that monitors refinery equipment for faults. Here a number of wireless sensors that detect abnormal vibration are attached a large range of factory equipment. Abnormally or unusually high levels of machinery vibration are used to alert engineers to a potentially malfunctioning piece of equipment before it actually breaks down. *British Petroleum* also aims to use a long-distance WSN to remotely monitor customers' liquefied petroleum gas tank fill levels. They intend to place ultrasonic sensors at the base of the tanks to detect the fill level, which is then transmitted via a low earth orbit satellite to a control station [2]. As a result their customers may be alerted to the need to refill their tanks, before the fuel actually runs out. Achieving this level of sensor coverage in both these examples with wired sensors would be impossible to set up, maintain, and be very expensive.

Finally, an example of a WSN monitoring the interaction of these objects with environments is the "Zebranet" project based at Princeton University. Used at the Mpala Research Center in Kenya, this WSN is used to observe the behaviour of wild horses, zebras, and lions over hundreds square kilometres. Animals are fitted with sensor nodes containing an integrated GPS receiver to obtain an estimate of their position and movement speed. Light sensors are used to give an indication of the environment that the animals are in. As a result, the WSN is able to determine grazing activity patterns, inter- and intra- species interactions, and the impact of human development. Each mote logs readings from its sensors every three minutes and exchanges identities whenever it enters the communication range of another mote. At regular intervals, a mobile base station (e.g., a car or a plane) moves through the observation

area and collects the recorded data from the animals it passes [10]. In this example it is impossible to imagine how this type of monitoring could be achieved without the use of a WSN.

2.2 Body Sensor Networks

Whilst WSN technology continues to evolve for the broad range of indications and settings described above, it does not specifically tackle the challenges associated with human body monitoring. The human body consists of a complicated internal environment that responds to and interacts with its external surroundings, but is in a way "separate" and "self contained". Human body monitoring using a network of wireless sensors may be achieved by attaching these to the body surface as well as implanting them into tissues. In essence, the human body environment is not only on a smaller scale, but also requires a different type and frequency of monitoring, with appreciation of different challenges than those faced by WSN. The realisation that proprietary designed WSNs are not ideally suited to monitoring the human body and its internal environment has led to the development of a wireless "*Body Sensor Network*" (BSN) platform.

Specifically designed for the wireless networking of implantable and wearable body sensors, the BSN architecture aims to set a standard for the development of a common approach towards pervasive monitoring. Figure 2.3 is a diagram illustrating a simplified example of such an architecture. It represents a patient with a number of sensors attached to their body, each sensor also being connected to a small processor, wireless transmitter, and battery pack, all together forming a 'BSN Node complex' capable of seamlessly integrating with home, office, and hospital environments. The BSN node ensures the accurate capture of data from the sensor to which it is connected, carries out low level processing of this data, and then wirelessly transmits this information to a Local Processing Unit (LPU). The data from all the sensors is in this way collected by the LPU, processed further, and fused before being wirelessly transmitted to a central monitoring server either via a wireless Local Area Network (LAN), blue-tooth, or mobile phone (General Packet Radio Service - GPRS or 3G) network[11].

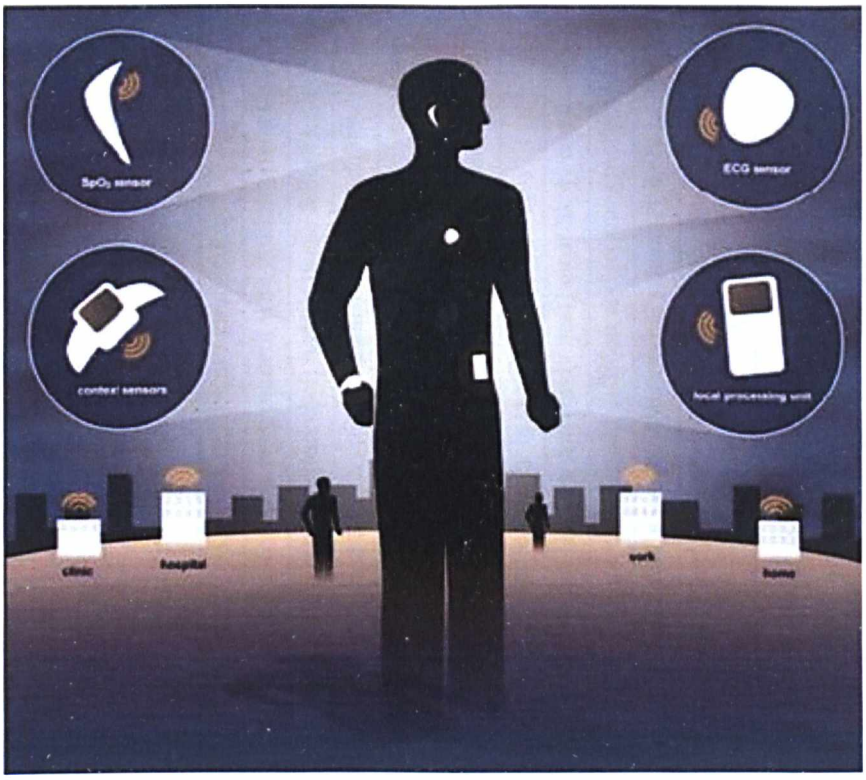


Figure 2.3 *Diagrammatic representation of the BSN architecture with wirelessly linked context aware 'on body' (external) sensors and its seamless integration with home, working, and hospital environments.*

Although the challenges faced by BSNs are in many ways similar to WSNs, there are intrinsic differences between the two which require special attention. Some of these differences are shown in Table 2.1.

2.3 Applications for BSN in Healthcare

The observations by Hippocrates (460–380 B.C.) the Greek founder of modern medicine, that audible sounds emanating from the chest were produced by the heart and lungs, ultimately led to the development of the stethoscope by René Théophile Hyacinthe Laënnec in 1816. The name stethoscope was chosen because it is derived from the Greek *stethos* (meaning chest), and *skopein* (meaning to observe). At the time Laënnec describes using a 1 foot long, 1.5 inch wide cedar tube ¼ inch in diameter, with a central channel [12]. Today the acoustic stethoscope looks markedly different, and has evolved into a device has been carefully engineered to accurately relay heart and chest sounds through its diaphragm through to the physician's ear. More recently electronic stethoscopes that convert acoustic sound waves to electrical signals have emerged. These work by amplifying and processing heart and breath sounds thereby optimising auscultation (listening), and have the added advantage of being able to record and thereby transmit the information they record. Electronic stethoscopes

Table 2.1 *Differing challenges faced by Wireless Sensor Networks as compared to Body Sensor Networks*

Challenges	WSN	BSN
Scale	As large as the environment being monitored (metres/kilometres)	As large as human body parts (millimetres/centimetres)
Node Number	Greater number of nodes required for accurate, wider area coverage.	Fewer, more accurate sensors nodes required (limited by space).
Node Function	Multiple sensors, each perform dedicated tasks.	Single sensors, each perform multiple tasks.
Node Accuracy	Large node number compensates for accuracy and allows result validation.	Limited node number with each required to be robust and accurate.
Node Size	Small size preferable but not a major limitation in most cases.	Pervasive monitoring and need for miniaturisation
Dynamics	Exposed to extremes in weather, noise, and asynchrony.	Exposed to more constant environment with motion artefact is a challenge
Event Detection	Early adverse event detection desirable; failure often reversible.	Early adverse events detection vital; human tissue failure irreversible
Variability	Much more likely to have a fixed or static structure.	Biological variation and complexity means a more variable structure.
Data Protection	Lower level wireless data transfer security required.	High level wireless data transfer security required to protect patient information.
Power Supply	Accessible and likely to be changed more easily and frequently.	Inaccessible and difficult to replace in implantable setting.
Power Demand	Likely to be greater as power is more easily supplied.	Likely to be lower as energy is more difficult to supply.
Energy Scavenging	Solar, and wind power are most likely candidates.	Motion (vibration) and thermal (body heat) most likely candidates.
Access	Sensors more easily replaceable or even disposable.	Implantable sensor replacement difficult and requires biodegradability.
Biocompatibility	Not a consideration in most applications	A must for implantable and some external sensors. Likely to increase cost
Context Awareness	Not so important with static sensors where environments are well defined	Very important because body physiology is very sensitive to context change
Wireless Technology	Blue-tooth, Zigbee, GPRS, and wireless LAN, and Radio Frequency (RF) already offer solutions.	Low power wireless required, with signal detection more challenging
Data Transfer	Loss of data during wireless transfer is likely to be compensated by number of sensors used.	Loss of data more significant, and may require additional measures to ensure Quality of Service and real-time data interrogation capabilities.

achieve their function by a number of means including microphones in the chest piece, piezoelectric crystals, or a stethoscope diaphragm with an electrically conductive inner surface forming a capacitive sensor [13]. The emergence of this technology has made remote cardiopulmonary examination into a reality with some groups demonstrating the reliable use of 'telestethoscopy' to monitor vulnerable patients with cardiovascular diseases such as heart failure, in their home environments [14]. The path is now paved for wireless continuous telestethoscopy for monitoring heart and breath sounds, in a way that Hippocrates himself could never imagine.

Like stethoscopes, a number of other diagnostic tools have continued to evolve, revolutionising medical practice by allowing doctors to extract more and more important information about their patients' physiological states. Electrocardiography (ECG) has made the diagnosis of myocardial infarction immediate, respirometry has allowed us to quantify and monitor the progress of chronic pulmonary disease, and pulse oximetry has meant we can acutely monitor a patient's oxygen saturation thereby indirectly monitoring their respiratory function. Whilst these diagnostic tools continue to develop and improve, their use to offer a 'snapshot' of information at the time of patient examination by a physician does not accurately reflect the monitoring needs of disease processes which are continuous. No matter how sophisticated and complex the monitoring equipment gets, the next great challenge for core diagnostic devices lies in being able to monitor a patient's physical parameters, physiology and biochemistry continuously and with the patient in any environment.

The impact of the environment a patient is in on their physiology is well known. Perhaps the best example of this is the '*white coat syndrome*' which results in patients' recorded blood pressures being much higher when visiting their physicians in clinics or in the hospital [15]. For chronic diseases where deterioration is more gradual, being able to monitor a patient in their own environment, be it home, work, or outdoors is therefore key. In the case of hypertension (a raised blood pressure), ambulatory blood pressure monitoring would result not only in more accurate diagnosis, but also more effective monitoring of response to therapy. For acute diseases requiring hospital admission, patients go from being monitored intensively in the hospital ward, to a completely unmonitored home environment when they have shown a certain degree of recovery and stability in their condition. On many occasions a patient is kept in hospital slightly longer than absolutely necessary just to allow the physician to monitor them for a certain period of time before being confident of their discharge. Having

the ability to monitor patients at home would be invaluable in both acute and chronic disease states, allowing safe early discharge to a monitored home environment (something that does not currently exist). The development of wireless BSNs offers a platform to establish such a health monitoring system, and represents the latest evolution of diagnostic tools. BSN patient monitoring systems promise to provide information that is likely to be as important, dramatic and revolutionary as those initial observations made by Hippocrates himself.

2.3.1 Monitoring chronic diseases

The scale of the requirement for patient monitoring in healthcare systems can only be appreciated once the magnitude of human disease processes requiring early diagnosis and treatment is considered. Several examples illustrate this need, but none as dramatically as cardiovascular related illnesses:

Abnormalities of heart rhythm (arrhythmias) such as *atrial fibrillation* (AF) are commonly encountered in clinical practice, occurring in as many as 4% of the population over the age of 60, increasing with age to almost 9% in octogenarians[16]. Early symptoms of atrial fibrillation include fatigue and palpitations, and often lead to the patient seeking medical advice. Electrocardiography (ECG) is eventually performed along with other investigations, and as soon as the diagnosis is made treatment is begun to try and prevent the longer-term complications of tachycardia-mediated cardiomyopathy (a high heart rate ultimately resulting in heart failure) and stroke. The patient is often placed on anticoagulant (blood thinning) medication such as Warfarin to prevent them having a stroke, but this in turn places them at risk of potentially serious bleeding complications from the drug. Ultimately, patients with AF have a two-fold increase in mortality independent of other risk factors[17]. Apart from early detection of this condition using ECG so that prompt treatment can be initiated, regular monitoring is required to ensure heart rate is controlled through drugs such as Digoxin or Amiodarone. Monitoring this often episodic condition with conventional means through snapshots of information is very difficult and often unable to give the clinician a feel for its severity. Whilst the use of 24-hour holter ECG monitoring does help, continuous and pervasive monitoring of heart rate using miniaturised and BSN technology worn by the patient during their day offers the chance to diagnose abnormalities in cardiac rhythm earlier than ever before. Ultimately this guides therapy to control cardiac rate and rhythm, thereby preventing many of the complications of AF. In at high risk groups such as elderly patients

with AF on Warfarin, BSN's would offer a means of determining the effectiveness of therapy and the need for the patient to remain on the drug.

Hypertension (high blood pressure) is another cardiovascular disease thought to affect approximately 1 billion individuals worldwide [18]. The diagnosis of this disease is often made in an otherwise asymptomatic patient who has presented to their doctor for other reasons. This condition can if left untreated, result in end-organ failure and significant morbidity; ranging from visual impairment to coronary artery disease, heart failure, and stroke. *Heart failure* in turn affects up to 10% of patients above the age of 65 [19]. Early diagnosis of hypertension is important so that the long-term effects of this disease can be prevented by controlling risk factors such as smoking and high cholesterol, and also initiating antihypertensive treatment early. In order to make the diagnosis, a patient has to undergo a series of blood pressure (BP) measurements taken during visits to their doctor, which if consistently high, diagnose the condition. Anti-hypertensive treatment can then be commenced and is titrated to the required effect by monitoring the patient's BP over a period of weeks or months following initiation of therapy. The whole process requires regular visits to the doctor to take serial BP measurements and ensure adequacy of therapy. Once the patient's blood pressure reaches a steady, desired state, their monitoring requirements reduce but do not stop altogether. This is because as people age, their response to medication may change as well as the properties of their cardiovascular system, meaning that over a patient's life, their hypertension pharmacotherapy may be altered many times. One can therefore imagine the labour-intensive nature of this blood pressure monitoring. Although home BP testing kits have been made available, limitations of these devices are their dependence on the operator and patient motivation. To complicate matters further, recently a new precursor to hypertension termed "*prehypertension*" has been identified, and research suggests treating this may result in even earlier initiation of treatment[20]. The continuous monitoring that BSNs aim to provide seems ideally suited to not only diagnosing hypertension, but also to deciding the timing and nature of therapy. Once the patient was on antihypertensive medication, BSNs designed to monitor BP would be able to provide continuous surveillance, thereby monitoring the response to therapy. Hypertension is a condition that is ideally suited to the model of monitoring that pervasive BSNs offer.

Diabetes mellitus is a well-known chronic progressive disease resulting in several end organ complications. It is a significant independent risk factor for hypertension, peripheral vascular, coronary artery, and renal disease amongst others. The prevalence of diabetes mellitus has increased dramatically over the past four decades, mainly due to the increase in prevalence of obesity[21]. It is estimated that annually 24,000 cases of diabetes induced blindness are diagnosed, and 56,000 limbs are lost from peripheral vascular disease in the United States alone. The diagnosis is often made from measuring fasting blood glucose (which is abnormally raised) either during a routine clinical consultation, or as a result of complications of the condition for which the patient is admitted to hospital. Once such acute complication is diabetic keto-acidosis which can be life-threatening, and can occur not only in newly diagnosed diabetics, but also in those with poor blood sugar control due to reduce compliance with medication[22]. Once diagnosed, patients with Type I Diabetes Mellitus (insulin dependent) require regular administration of insulin at several times during the day, with blood glucose "pinprick" testing used to closely monitor patients' blood sugar in between these injections. This need for repeated drawing of blood is invasive and therefore undesirable for many patients, yet there is at present no clear reliable alternative. As previously mentioned, variable treatment compliance rates (60-80% at best) in these patients are made worse the fact that they are on multiple medications[23]. BSN technology in this group would allow the networking of wireless implantable and attachable glucose sensors not only to monitor patient glucose levels but could also be used in "closed feedback loop" systems for drug (insulin) delivery, as described later on in this chapter.

Although the three chronic conditions mentioned above illustrate the need for continuous physiological and biochemical monitoring, there other examples of diseases processes that would also benefit from such monitoring. Table 2.2 lists some of these processes and the parameters that may be used to monitor them.

2.3.2 Monitoring hospitalised patients

The hospital infrastructure required to treat acute medical conditions and provide elective interventions represents a significant cost to most healthcare systems across the world. Whilst in hospital, patients receive monitoring of various levels of intensity ranging from *intermittent* (four to six times a day in the case of those with stable conditions), to *intensive* (every hour), and finally to *continuous* (invasive and non-invasive) such as that seen in an

intensive care unit. The level of monitoring often changes depending on both the nature of their illness, and their level of recovery. A significant level of staffing is required to administer this monitoring and record its outcomes, ranging from one nurse for six patients on the general ward, to one nurse for two patients on a high dependency unit, and finally one nurse for one patient on the intensive care unit. Basic constituents of patient monitoring include vital signs (blood pressure, heart rate, oxygen saturation, respiratory rate, and temperature), visual appearance, level of consciousness, urine output, and pain level. Further aspects that may be monitored include surgical drainage, wounds, electrocardiography, blood testing, and radiographic imaging amongst others. Most of these monitoring systems represent snapshots in time that a subject is observed in, with a series of these snapshots resulting in observation of a trend. In the case of vital signs monitoring, the frequency of these snapshots is what will ultimately determine whether an adverse event is picked up early.

Patients undergoing surgery for example are a group who's monitoring starts off in the *pre-operative period* when their operative risk is evaluated in a clinic setting. This pre-assessment clinic offers a 'snap shot' view of the patient's health and physiology and is used to pass the patient 'fit for surgery'. Once this is done, they are admitted for surgery and during the *peri-operative period* (from the time they are put to sleep to the time they wake up after surgery) their monitoring needs are highly intensive (the patient is under general anaesthesia at this time). Once the patient wakes up and is stable, their recovery during the *early post-operative period* is monitored intermittently on the ward. Aside from being restrictive and "wired", hospital ward-based patient vital signs monitoring systems tend to be very labour intensive, requiring manual measurement and documentation, and are prone to human error. Automation of this process along with the ability to pervasively monitor patients wherever they are in the hospital (not just at their bedside), is desirable not only to the healthcare provider, but also to the patient.

The next step for any "hospital of the future" would be to adopt a ubiquitous and pervasive in-patient monitoring system enabling carers to predict, diagnose, and react to adverse events earlier than ever before. BSNs offer a platform for this, thereby improving the efficiency of hospital systems in treating patients with acute diseases. An additional benefit may also be the ability through sensors to determine the movements of patients through hospital wards, clinics, emergency departments, and operating theatres, thereby allowing more rapid

streamlining of resources where they are needed the most. Efficient hospitals would thereby maintain optimal capacity to cater for elective (planned) admissions whilst maintaining the capacity to admit patients with acute illnesses. Finally it is important to note that many hospitalised patients are not sent home early because the infrastructure to safely monitor them there and respond quickly to any adverse events that may occur does not exist. In the case of patients undergoing surgery for example, pervasive wearable BSNs offer the opportunity to seamlessly integrate hospital discharge to safe home monitoring during peri-operative period where patients are still at risk of developing complications. In many cases these patients are kept in hospital to monitor them over this period. The post-operative patient group is the focus of this thesis and is discussed in more detail in Chapter 3.

Once a patient is discharged from hospital they are often asked to attend outpatient clinics to monitor their overall clinical progress. Due to the episodic and subjective nature of outpatient clinic review, it is often difficult to objectively determine how a patient is recovering from their diagnosis. The advent of implantable sensors through which information regarding the operative of disease site can be determined may represent a significant step in solving this problem. An example of this is the use of a implantable micro machined wireless sensor to monitor patients undergoing abdominal aortic aneurism surgery has already begun [24]. Here, one of the major abdominal arteries is found to be abnormally dilated, making it prone to rupture and death. A repair with a synthetic graft is required to prevent this, and during the procedure a sensor is placed at the site of surgery, thereby allowing the measurement of pressure around the aorta. In the clinic the patient is asked to lie down and a radiofrequency reader is 'swiped' over their abdomen, allowing the clinician to measure the pressure in the sack, thereby evaluating the status of the aneurism repair. From examples such as this it can be envisaged that continuous and pervasive BSN patient monitoring has a clear role in providing accurate objective information about a patient's health in the outpatient setting.

2.3.3 Monitoring vulnerable patient groups

In addition to the above-mentioned scenarios, BSNs may also prove invaluable for regular and non-intrusive monitoring of "at risk" population groups such as the elderly. With people in industrialised nations living longer than ever before and an increase in average life expectancy of more than 25 years, the size of this group is set to increase, along with their demand on healthcare resources [25].

Identifying ways of monitoring this aging population in their home environment is therefore very important, with one key example of the usefulness of this approach being the vulnerable periods during months of non-temperate weather. There is evidence to suggest that at times of the year where weather conditions are at their extremes (either very cold or very hot), elderly patients are at increased risk of requiring hospital admission[26, 27]. They are at risk because they are not able to seek medical help early enough for simple and treatable conditions, which eventually may lead to significant morbidity. An example of this is an elderly individual who lives alone and suffers a chest infection which he fails to identify and seek help for until the infection requires hospital admission, or even ventilator support. This could all be potentially avoided if the infection, or change in patient habit as a result of this infection was picked up early and antibiotic therapy initiated.

Examples of how people behave differently at the onset of illnesses include a decrease in appetite, a reduction in movement, and likelihood to stay indoors. When correlated with physiological vital signs measurement, this system has the potential to clearly identify those most at risk. It also demonstrates an instance in which a WSN (set up in the patient's home) and BSN (on the patient's body) may overlap in their applications. It may be therefore that monitoring elderly patients in their home environment during non-temperate weather months will allow earlier detection of deterioration in their condition for which prompt treatment may reduce the need for hospital admission, associated morbidity and even mortality.

The concept of an unobtrusive "home sensor network" to monitor an elderly person's social health (giving feedback not only to the carers and family of that elder, but also to the elder individual themselves), is one that is being developed by companies such as the Intel[28]. Whilst such a sensor network attempts to monitor social well-being by identifying the individual and the level of activity they are undertaking, it is easy to see how this network could communicate with a body sensor network relaying physiological data about the individual. Combining these two networks would allow for a much better appreciation of the context in which the sensing is taking place.

Table 2.2 outlines some of the common disease processes and patients groups encountered in daily healthcare practice, and outlines the parameters that a BSN for the monitoring of these conditions would be required to be able to detect.

Table 2.2 *Disease processes and parameters commonly used to monitor these diseases. Suggested sensor types for measurement of these parameters are listed in brackets. All of these conditions currently place a heavy administrative and financial burden on healthcare systems, which may be reduced if picked up.*

Disease Process	Physiological Parameter (BSN Sensor Type)	Biochemical Parameter (BSN Sensor Type)
Hypertension	Blood pressure (*implantable/ wearable mechano-receptor*)	Adrenocorticosteroids (*implantable biosensor*)
Ischaemic Heart Disease	Electrocardiogram (ECG), cardiac output (*implantable/ wearable ECG sensor*)	Troponin, Creatine Kinase (*implantable biosensor*)
Cardiac Arrhythmias/ Heart Failure	Heart rate, blood pressure, ECG, cardiac output (*implantable/wearable mechano-receptor and ECG sensor*)	Troponin, Creatine Kinase (*implantable biosensor*)
Cancer (Breast, Prostate, Lung, Colon)	Weight loss (body fat sensor) (*implantable/ wearable mechano-receptor*)	Tumour markers, Blood detection (urine, faces, sputum), Nutritional albumin (*implantable biosensors*)
Asthma / COPD	Respiration, peak expiratory flow, oxygen saturation (*implantable/ wearable mechano-receptor*)	Oxygen partial pressure *(implantable/wearable optical sensor, implantable biosensor*)
Parkinson's Disease	Gait, tremor, muscle tone, activity (*wearable Electroencephalography-EEG, accelerometer, gyroscope*)	Brain dopamine level (*implantable biosensor*)
Alzheimer's Disease	Activity, memory, orientation, cognition (*wearable accelerometer, gyroscope*)	Amyloid deposits (brain) (*implantable biosensor/EEG*)
Stroke	Gait, muscle tone, activity, impaired speech, memory (*wearable EEG, accelerometer, gyroscope*)	
Diabetes	Visual impairment, sensory disturbance (*wearable accelerometer, gyroscope*)	Blood glucose, glycated haemoglobin (HbA1c). (*implantable biosensor*)
Rheumatoid Arthritis	Joint stiffness, reduced function, temperature (*wearable accelerometer, gyroscope,thermistor*)	Rheumatoid factor, inflammatory and autoimmune markers (*implantable biosensor*)
Renal Failure	Urine output *(implantable bladder pressure/volume sensor)*	Urea, creatinine, potassium. (*implantable biosensor*)
Vascular Disease (Peripheral & Aneurisms)	Peripheral perfusion, blood pressure, aneurism sac pressure. *(wearable/implantable sensor)*	Haemoglobin level (*implantable biosensor*)
Infectious Diseases	Body temperature (wearable thermistor)	Inflammatory markers, White cell count, Pathogen metabolites (*implantable biosensor*)
Post-operative Monitoring	Heart rate, blood pressure, ECG, oxygen saturation, temp (implantable /wearable and ECG sensor)	Haemoglobin, blood glucose, monitoring the operative site. (implantable biosensor)

2.4 Existing Pervasive Patient Monitoring Systems

In most healthcare systems spiralling costs, inadequate staffing, medical errors, and an inability to get to hospital in time in rural areas is placing a tremendous burden on the provision of care. The concept of "ubiquitous" and "pervasive" human well-being monitoring with regards to physical, physiological, and biochemical parameters in any environment and without restriction of activity [29, 30] has only recently become a reality with the important advances in sensor, miniaturised processor, and wireless data transmission technologies described earlier [31, 32]. Whilst external (attachable) sensors such as those for measuring vital signs, have continued to improve, it is the areas of implantable sensors and more recently biosensors that have generated much interest [33, 34]. Advances in key areas such as power supply miniaturization, increased battery duration, reduced energy consumption, and power scavenging are eagerly awaited and will be an essential part of any system that makes pervasive monitoring possible, particularly with regards to implantable sensors [35]. *Micro Electro-Mechanical System* (MEMS) technology is another area which has offered the prospect of sophisticated sensing using a miniaturized sensor device [36]. Pervasive healthcare systems utilising large-scale BSN and WSN technology will allow access to accurate medical information at any time and place, ultimately improving the quality of the service provided.

With these important advances taking place, the clinician is for the first time able to explore the prospect of not only monitoring patients more closely, but also in an environment where they have never been able to be monitored before. The chronic conditions of diabetes mellitus and hypertension mentioned previously in this chapter are currently managed basis of a series of "snapshots" of information, obtained in a clinic setting which is artificial to the patient's normal environment. The long-term management of these conditions would clearly benefit from any technology which would result in a more tailored treatment being offered to the patient. The treatment of AF, which as previously mentioned is associated with episodic rather than continuous abnormalities such as blood pressure surges, paroxysmal arrhythmias or episodes of myocardial ischaemia best illustrates this, as at present much time is wasted in trying to "capture an episode" of these abnormalities. As all of these episodes would be picked up using basic vital signs monitoring and as their timing cannot be predicted, a wireless, pervasive, and continuous monitoring system is ideally suited to diagnosing and monitoring the progress of such a disease.

Additionally, better and earlier detection is likely to result in earlier administration of the appropriate treatment, and the prevention of disease-related morbidity. In the more acute hospital setting, the ability to continuously capture data on patient well-being has the potential to facilitate earlier adverse event detection and ultimately treatment. In such a system the patient would not be required to stay at their bedside for monitoring to take place, increasing their mobility and return to activity in the hospital. In addition to this, patient physiological data would be obtained either continuously or at shorter time intervals, picking up deterioration more quickly. At present, much of the data captured even with continuous patient monitoring is lost, but with an automated pervasive monitoring system this could be stored for later review and trend-analysis.

In order to achieve the goal of truly pervasive monitoring, a number of research platforms have emerged over the past decade. Broadly speaking these platforms employ one of four strategies namely: integrated fabrics and clothing embedded systems, wireless body sensor networks, sensor fusion with the use of ambient and wearable sensors, and implantable sensing. Each of these strategies is considered in turn below with examples of currently available systems utilising them given.

2.4.1 Integrated fabrics and clothing embedded systems

The concept of a 'wearable motherboard' was first realised in 1999 at Georgia Institute of Technology for military applications, but it soon became clear that such technology could lead to a pervasive 'Smart Shirt' to monitor health [37]. Factors that have been identified as being of importance for the wide-stream uptake of this technology include wearability, durability, manufacturability, maintainability, connectivity, and affordability. A number of newer strategies for embedding sensors in clothing to make them more pervasive have since been employed either through integrating them with a textile platform such as in the European Commission "Wealthy" project [38], or by embedding them into clothes with integrated electronics resulting in "intelligent biomedical clothes" such as in the European Commission "MyHeart" Project [39]. The "MIThril" project based at Massachusetts Institute of Technology (MIT) Media Lab, has developed a body-worn sensing computation, and networking system, integrated in a "tunic" [40], with proposed body-worn applications including "memory glasses" that aim to provide a context-aware memory aid to the wearer. The Reconfigurable Fabric (RFab) project underway at University of California at Los Angeles (UCLA) aims to develop an intelligent fabric that uses woven wires within a

garment to connect sensors but if the garment is damaged, is also able to find new interconnection pathways [41]. Figure 2.4 shows some of the devices assembled through the research platforms mentioned above.

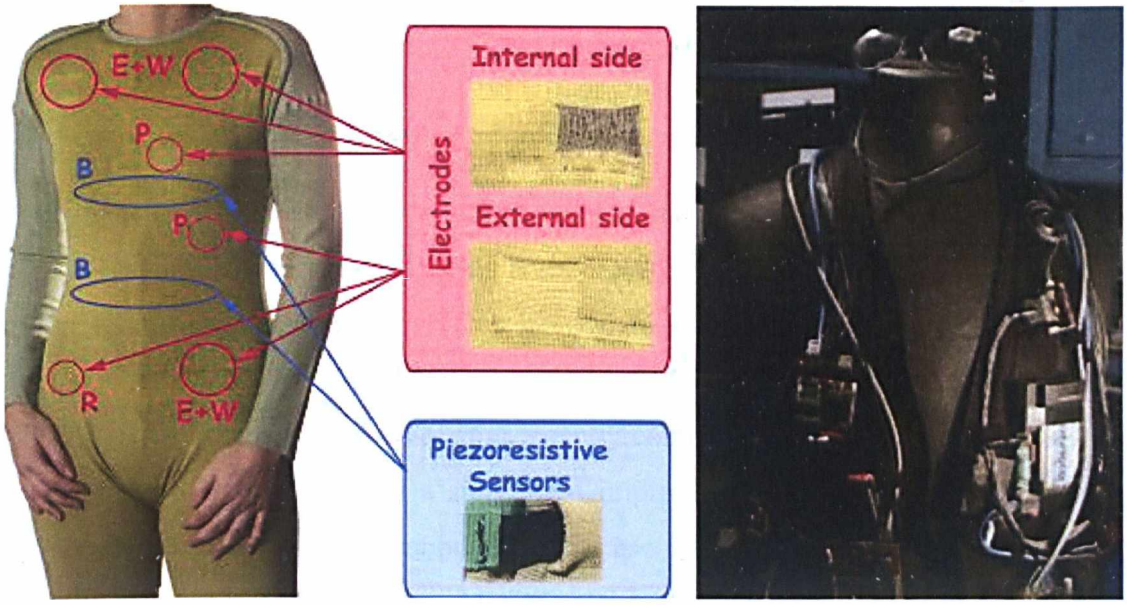


Figure 2.4 *(Left) EC "Wealthy" project sensors embedded in clothing (courtesy of Rita Paradiso, Smartex Italy). (Right) "MIThril" tunic, (courtesy of Professor Alex Pentland, MIT Media Laboratory).*

2.4.2 Wireless body sensor networks

Unlike the systems embedded within clothing, wireless body sensor networks allow the placement of sensors at their required sites with wireless communications between them. Whilst a large number of platforms are emerging, a few important examples are mentioned in this section. Targeted to a population of patients with cardiac disease, "CardioNet" is a mobile outpatient telemetry system consisting of a three-lead electrocardiogram wirelessly connected to a *Personal Digital Assistant* (PDA)-sized processing, display, and power unit, that aims to provide continuous real-time ECG monitoring, analysis and response for patients with suspected heart rhythm disturbances in their home, work or travelling environment [42]. At the Mayo Clinic College of Medicine in Rochester, Jovanov et al have developed a Wireless Body Area Network (WBAN) that uses off the shelf sensors, a Zigbee compliant radio, and a range of motion sensing and physiological sensors to provide unsupervised ambulatory monitoring during normal activities for long periods of time [43]. The "Code Blue" project based at Harvard University has developed a medical sensor network using pulse oximeter, ECG, and motion activity sensor motes based on MicaZ and Telos designs [44]. More recently, the Mercury sensor network platform at Harvard

University is being designed for data-intensive applications such as high-fidelity motion analysis in patients with Parkinson's Disease and Epilepsy at home [45]. Finally, Dexternet is a three-layer wireless body sensor network platform developed at UC Berkeley, comprising of body sensor, personal network, and global network layers, with sensors designed to detecting body motion, ECG, and respiratory patterns [46].

2.4.3 Sensor fusion with wearable and ambient sensing

The accuracy of many of the wearable body sensing systems mentioned above may be affected by a number of factors such as ambiguous data, errors in data transmission, poor compliance, and sensor inaccuracy. This has led to some groups exploring the impact of combining wearable and ambient environmental sensors to see if there is a complementary relationship between the two. Pansiot et al recently combined a wearable activity sensor with an ambient 'blob sensor', finding a significant improvement in activity classification with integration of the two sensors as opposed to the use of either system alone [47]. Using the same ambient and wearable sensors, Atallah et al have demonstrated the use of an activity grid that determines the amount of time a subject spends in any particular room in their house, whilst the wearable sensor determines what activity they are actually performing when in that room [48]. These findings suggest that sensor fusion may be the key to overcoming many of the limitations of wearable body sensor network systems.

2.4.4 Implantable sensing.

The development of implantable sensors offers BSN one of its most exciting components. The European Commission project "Healthy Aims" has been focussing on specific sensor applications namely for hearing aids (cochlear implant), vision aids (retinal implant), detecting raised orbital pressure (glaucoma sensor), and intracranial pressure sensing (implantable pressure sensor) [49]. Other implantable devices include Medtronic's "Reveal Insertable Loop Recorder", which is a fully implantable cardiac monitor used to record the heart's rate and rhythm at the time of unexplained fainting, dizziness, or palpitations. The device provides the clinician with an ECG that can be used to identify or rule out an abnormal heart rhythm as the cause of these symptoms [50]. As previously mentioned, CardioMEMS is a company that produces an implantable pressure sensor developed at Georgia Institute of Technology, that can pressure readings following implantation into an aneurism sac at the time of endovascular repair [24]. This implanted sensor then provides a means of monitoring the repair over the following years. Given Technologies has developed

and endoscopy capsule that transmits images of the small bowel as it travels through the gastrointestinal tract, allowing the detection of disease in a part of the body that is otherwise difficult to access [51]. Finally more recently, a knee replacement prosthesis is being developed to measure six components of tibial force that are important in evaluating effective biomechanics of the knee joint. It is hoped that if this technology can be embedded into knee replacements, it may be used to deliver focussed rehabilitation to allow the maximal beneficial effect of the procedure [52]. Figure 2.5 below shows some of these implantable body cavity sensing technologies mentioned in this section that may ultimately form part of an implantable wireless BSN.

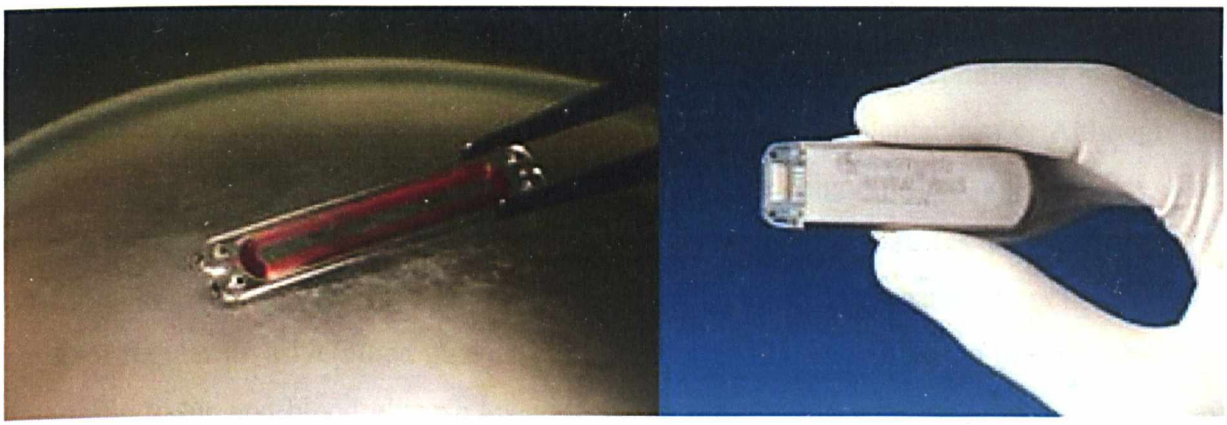


Figure 2.5 *(Left) The CardioMEMS Endosure wireless aneurism pressure sensing device, Courtesy of CardioMEMS Inc. and Professor Mark Allen, Georgia Institute of Technology. (Right) Medtronic "Reveal Insertable Loop Recorder", Courtesy of Medtronic Inc.*

Each of the four strategies mentioned above share a common aim in providing unobtrusive, pervasive human monitoring irrespective of geographical location. In the case of external sensors, whilst embedding these into a garment does provide a more convenient wearable system, it lacks flexibility for the addition and relocation of sensors as dictated by patient size and shape. With implantable sensors, wiring is impractical and to large extent can limit sensor placement. A wireless platform specifically designed to network external and implantable sensors on the human body is desirable not only because it allows these various sensors to be networked in a less bulky and intrusive way, but also because it allows the potential to add and remove sensors as required. Wireless sensor networking, data acquisition, data capture, and low power transmission all offer the prospect of flexible body sensor networks that are truly pervasive and non-obtrusive.

2.5 Technical Challenges Facing Body Sensor Networks

Although the BSN platform aims to provide the ideal wireless setting for the networking of human body sensors and the setting up of pervasive health monitoring systems, there are several other technical challenges that lie ahead. These include the need for better sensor design, MEMS integration, biocompatibility, power source miniaturisation, low power wireless transmission, context awareness, secure data transfer, and integration with therapeutic systems, each of which are mentioned briefly below, and covered in more detail throughout this thesis.

2.5.1 Improved sensor design

Advances in biological, chemical, electrical, and mechanical sensor technologies have led to a host of new sensors becoming available for wearable and implantable use. Although the scope of these sensors is very wide, the following examples highlight the potential they offer to pervasive patient monitoring. In the case of patients with diabetes mellitus, trials of implantable glucose sensors are underway in an attempt to rid this patient population of the need for regular invasive blood glucose pinprick testing[53]. In addition to this, the ability to determine tissue and blood glucose levels using an implantable wireless glucose sensor may also form the sensing part of a "closed feedback loop" system. The other half of this loop would consist of a drug delivery pump which would continuously infuse a variable amount of fast-acting insulin based in their glucose level[54]. This concept effectively results in the closed feedback loop system acting as an "artificial pancreas", which maintains blood glucose within a closely defined reference range. As a result diabetics may be able to avoid not only the complications of an acutely uncontrolled blood sugar (hypo- or hyperglycaemia), but also much of the end organ damage associated with the condition (retinopathy, cardiac, renal, and peripheral vascular disease). Reliability is a very important requirement of sensors in closed feedback loop systems such as this because they ultimately guide treatment delivery. It may be therefore that in this case an implantable biosensor array offers a more accurate result that one isolated sensor[55].

Improvements in sensor manufacturing and nano-engineering techniques, along with parallel advances in MEMS technology offer the potential of producing even smaller implantable and attachable sensors than were previously possible. An example of one such miniaturized nano-engineered sensor currently under development is a fluorescent hydrogel alginate microsphere optical glucose sensor[56]. Physiological sensors benefiting from MEMS

technology integration include the micro needle array and the implantable blood pressure sensor[57]. Although much of this is still experimental, it is not inconceivable that over the next decade these sensors will guide therapy for chronic conditions such as hypertension and congestive cardiac failure. MEMS devices in particular may prove pivotal in the drug delivery part of any closed feedback loop[58]. In addition, when mass-produced, MEMS technology offers the prospect of delivering efficient and precise sensors for no more than a few dollars. This is well illustrated in the case of accelerometers, which were used by the automobile industry to efficiently and reliably trigger car airbag release during an accident.

2.5.2 Biocompatibility

Implantable sensors and stimulators have had to overcome the problems of long-term stability and biocompatibility, with perhaps one of the most successful examples of this being the cardiac pacemaker and the *implantable cardioverter-defibrillator* (ICD)[59]. The scale of implantable ICD use is best demonstrated by the fact that in 2001, a total of 26,151 were implanted at 171 centres in the United Kingdon (UK) and Ireland[60]. One of the main indications for an ICD is sudden cardiac death, which affects approximately 100,000 people annually in the UK, demonstrating the size of the patient population that may benefit from this device[61]. Other implantable devices currently used in clinical practice include implantable drug delivery systems for chronic pain[62], sacral nerve stimulators for anal incontinence[63], and high frequency brain (thalamic) stimulation for neurological conditions such as Parkinson's disease[64] and refractory epilepsy[65]. Figure 2.6 shows a range of these implantable devices currently in clinical use.

The fact that large groups of the patients already carry implanted devices such as those mentioned above, means that many of the lessons learnt from their use can be extended to any proposed implantable biosensor research. In addition to this, the integration of these already implanted sensors and effectors into a larger wireless body sensor network is something that deserves consideration. With regards to this last statement, power consumption is obviously an important issue, and until this is addressed it is unlikely that for example pacemakers would be used to monitor the cardiovascular status as part of a body sensor network. Interference of these devices with each other as well as with day to day technologies used by patients such as the mobile phones, is a concern that has been noted, and must be addressed [66]. The concern here is that interference may result in not only sensor malfunction, but also might affect implanted drug delivery systems and stimulators.

This supports the call for a new industrial standard for the wireless transmission frequency used in body sensor networks.

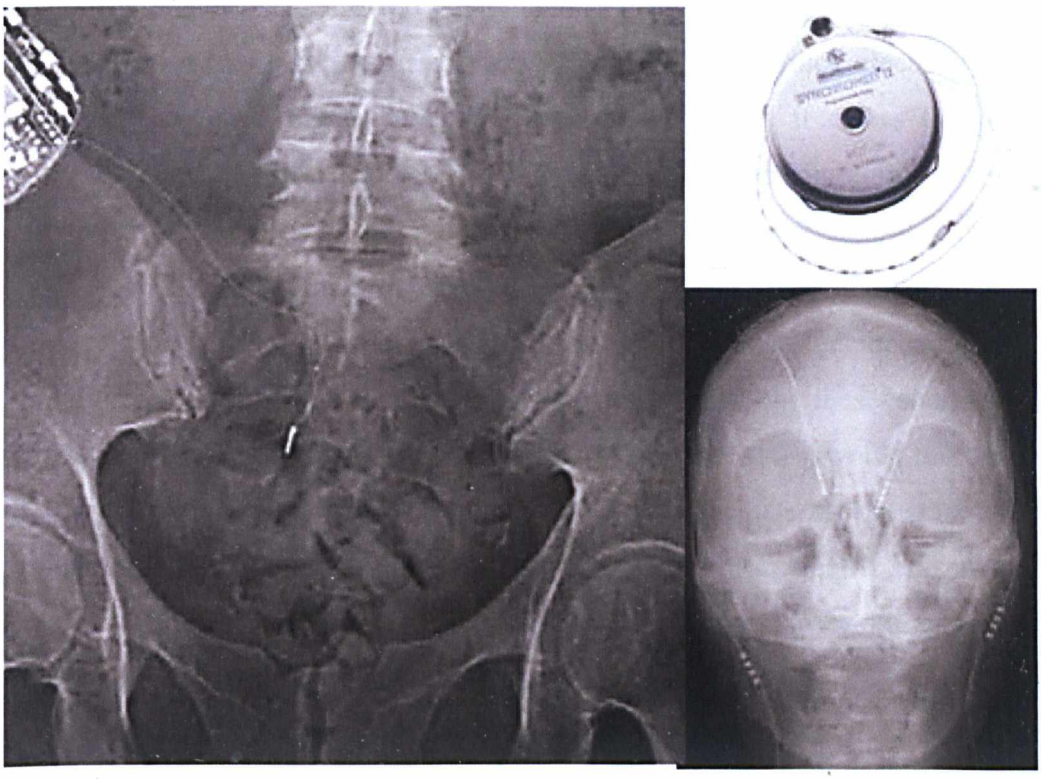


Figure 2.6 *(Left) Examples of an implantable device (sacral nerve stimulator) in current clinical use. (Bottom right) Deep brain stimulators, (courtesy of the Radiological Society of North America). (Above right) Implantable Synchromed® II drug delivery system for chronic pain, (courtesy of Medtronic Inc).*

2.5.3 Energy supply and demand

One of the key considerations for BSNs is power consumption. This is because power consumption determines not only the size of the battery required but also the length of time that the sensors can be left *in situ*. The size of battery used to store the required energy is in most cases the largest single contributor to the size of the sensor apparatus in term of both dimensions and weight. These factors are important not only in the implantable but also the external sensor settings because they determine how "hidden" and "pervasive" the sensors are. Several strategies have been employed to achieve this miniaturisation of power source. One such strategy is the development of micro-fuel cells that could be used in the case of implantable sensors, reducing the size of the power supply whilst increasing the lifetime of the battery and therefore the sensor. Characteristics that render fuel cells highly attractive for portable power generation include their high energy efficiency and density, combined with the ability to rapidly refuel [67, 68]. Polymer-electrolyte direct methanol [69] and solid-oxide

fuel cells [70] are examples of two such technologies that have been suggested as alternatives to Lithium ion batteries in portable settings.

An alternative approach is to use bio catalytic fuel cells consisting of immobilized micro organisms or enzymes as catalysts, and glucose as a fuel to produce electricity [71]. This concept of an "enzymatic micro battery" is attractive because it offers the prospect of dramatically reducing the size of the sensor apparatus and is ideally suited to implantable devices to the point that it has even been suggested as a power supply for a proposed "microsurgery robot" [71]. Miniaturising the packaging required to hold a battery's chemical constituents, which currently consists of strong metals such as steel because the battery houses highly corrosive chemicals, is also important. Replacing these chemicals with a substance that is much less corrosive (for example oxygen and water) would therefore require less bulky packaging[72]. Another interesting strategy is the use of acoustic (ultrasound) power transmission into an implantable device, with piezoelectric discs as power transducers[73]. Challenges faced in this case include increasing power storage capability as well as controlling the acoustic beam to achieve maximal efficiency.

Finally reducing battery consumption through the increased use of power scavenging from on-body sources such as vibration and temperature, is a strategy being developed to enhance battery life especially in the case of implantable sensors[74, 75]. At present, a large proportion of the electrical power consumed by biosensors goes towards the measurement circuit. In a wireless BSN system the wireless communication link is likely to be the greatest consumer of power. The development of low-power wireless data paths is therefore key to the successful development of the wireless BSN systems. Reducing the power consumption of the radiofrequency transceiver may be one way this can be achieved[76, 77]. Ultra wideband radio has also been suggested as a mode of short-range wireless communication with relatively high data rates and low power consumption[78]. Self-configuring networks carry the advantage of reducing energy consumption from unnecessary nodes classified as "redundant", thereby increasing the system lifespan.

2.5.4 System security and reliability

Figure 2.7 is a historic photograph showing mass crowding in the healthcare environment. Although this is not representative of the clinical setting in modern hospitals, it highlights the importance of secure and reliable data transfer for BSNs. Security and reliability of the

network are two of the crucial elements of the BSN design, as sensitive patient information is being transmitted through the wireless network. Unlike typical wired or wireless network architectures in which the network configuration is mostly static and very little constraint on resources, the architecture for BSN is highly dynamic, placing more rigorous constraints in power supply, communication bandwidth, storage and computational resources.

In terms of security, BSN data must be secured with strong cryptography to protect the patient's privacy. However, strong cryptography requires extensive computation and resources. Considering the limited resources that a BSN node can have, a compromised approach has to be taken to maximise security whilst minimising resource utilisation. Furthermore, the highly dynamic nature of BSN means that typical static network authentication methods will not be applicable. Even methods proposed for *ad-hoc* networks such as the asymmetric cryptography technique, would be computationally too expensive for BSN applications [79]. As such, a robust, efficient and light weighted security infrastructure is required for the practical deployment of BSN applications.



Figure 2.7 *A picture from the 1918 influenza epidemic is an extreme example of the number of hospital patients that can be present close proximity (courtesy of the National Museum of Health and Medicine, Armed Forces Institute of Pathology, Washington, D.C., NCP 1603).*

The reliability of the network, on the other hand, directly affects the quality of patient monitoring, and in a worst case scenario, it can be fatal when a life-threatening event has gone undetected. However, due to the constraints on communication bandwidth and power consumption, traditional network reliability techniques such as the re-transmission mechanism for Transmission Control Protocol (TCP), may not be practical for BSN applications. With similar constraints on WSNs, researchers have proposed several methods for improving its reliability. One simple approach is to use limited retransmission where packets are retransmitted for a fixed number of times until the reception of the acknowledgement; however, retransmission often induces significant overhead to the network. Another approach is to form a multi-path network and exploit the multiple routes to avoid disrupted links [80]. It is expected that this will be an area that will attract significant research interest in the coming years, partially in exploring the autonomous sensing paradigm for developing self-protecting, self-healing, self-optimising, and self-configuring BSNs.

Thus far most security and network reliability techniques aim to provide maximum security and reliability for generic wireless sensor network applications. However, in the case of BSNs, instead of relying solely on the low level network infrastructure, high level context information can be used to reinforce the security and reliability of the system. An example of this is the use of biometric information for enhancing the inherent security of the network [81]. Furthermore as multiple sensors are often used in a BSN application to measure or infer the same physiological parameters, the use of intelligent multi-sensor data fusion techniques can significantly enhance the reliability of the system.

Other implications of deploying BSNs include the appreciation of the long-term consequences of their effect on the body, particularly in the case of implantable sensors. This is likely to govern the materials and manufacturing process used to construct BSN nodes, their battery supply, and the type of wireless data transfer used. In the case of WSN, where the effect of large number redundant energy-depleted nodes is likely to be detrimental on the environment [2], these nodes must be re-usable or in some way biodegradable. For BSN, both biodegradability and inertness of materials offer potential solutions, but finding the right material to manufacture the nodes from is likely to pose an important challenge.

2.5.5 Context awareness

In addition to being able to monitor physiological parameters, research on BSN has identified the importance of the context (environment) the person being monitored is in when interpreting these parameters. Simple activities such as "sleeping" and "walking" have an affect on not only vital signs such as heart rate and blood pressure, but also on any measure of activity and mobility that is being used. This "context awareness" can also help account for motion artefacts and errors detected by the sensors. Under normal conditions visual monitoring provides this contextual information most effectively, but in the pervasive healthcare monitoring setting this is not possible. It is therefore important to identify methods of "inferring" context using techniques such as "Naïve Bayesian" classifiers [82] and "hierarchical hidden semi-Markov models" [83] for activity recognition and tracking daily activities. Fusion of data from multiple sensors may provide this contextual information, with selected classifiers designed to yield optimal results based on fusing all the sensor readings.

Several types of sensors have been used to try and develop this context awareness. Accelerometers have been suggested as appropriate candidates for determining activity state (driving, sleeping, exercising) and posture (lying, sitting, standing), although the technical challenge of sensor placement in order to achieve the ideal result is one that is still being addressed [84, 85]. Audio sensors that act by determining either the level of environmental noise or whether the subject is talking to anyone or not, have also showed potential[86]. Changes in temperature and heat flux may be able to not only determine whether the subject is active or at rest, but also when the subject moves from a warmer indoor to a colder outdoor environment [85]. Skin conductance (affected by sweat gland activity) may be measured using galvanic skin response, with an electrode in contact with the skin surface[87]. Integration of several of these context-sensing modalities is a strategy used by SenseWear™ (BodyMedia Inc.), who have produced a device consisting of a multi-sensor array that is worn on the upper arm and includes a 2-axis accelerometer, heat flux sensor, galvanic skin response sensor, skin temperature sensor, and near-body ambient sensor [87]. Researchers at MIT have developed a modified ring sensor that uses photoplethysmography to detect a person's pulse rate and blood-oxidation level. They have built "context awareness into this ring using photocells to detect ambient light, thermistors to detect temperature, and accelerometers to detect motion, all of which may interfere with readings and must therefore be accounted for [88].

2.5.6 Integrated therapeutic systems

Integrating sensors and therapeutic systems and thereby "closing the feedback loop", is likely to play a major part in defining the role for BSN in clinical practice[89]. This is particularly well illustrated in the delivery of pharmacotherapy where currently drugs are administered at doses and frequencies that are based on average sizes, and metabolic rate. When considering that for an individual patient, who has an individual size and metabolism, this optimal dosage is likely to vary considerably from the "average", it is clear that individualised dosing is preferable. In addition to this, a patient's drug requirement may temporarily change during an illness, or for example when they are on other medications such as antibiotics. Whilst under dosing in these situations will result in inadequate treatment (for example seizures in patients on anti-epileptic medication), overdosing will result in an increased risk of the patient suffering unwanted side-effects. Drug-delivering medical feedback loops consist of miniaturised sensors that continuously monitor a drug's effect and through medical control algorithms, adjust its delivery from miniaturised drug pumps. The dosage of the drug would therefore be individualised to the patient.

An example of integrated drug-delivering therapeutic system for fast-acting insulin in diabetics shown in Figure 2.8 [89]. This proposed system consists of two patches on the skin. One is an implanted sensor-amplifier-transmitter which may be replaced by the user every few days. The other patch would be an insulin-delivering system comprising of a calibrator, *Radio frequency* (RF) receiver, drug reservoir, pump, battery, and miniature subcutaneously inserted drug inlet. The RF signal from the "sensor" patch would be received by the "insulin delivery" patch and translated through a medical algorithm, to a series of micro-doses of insulin. Like the "sensing" patch, the "insulin delivery" patch would also be replaced by the user every few days.

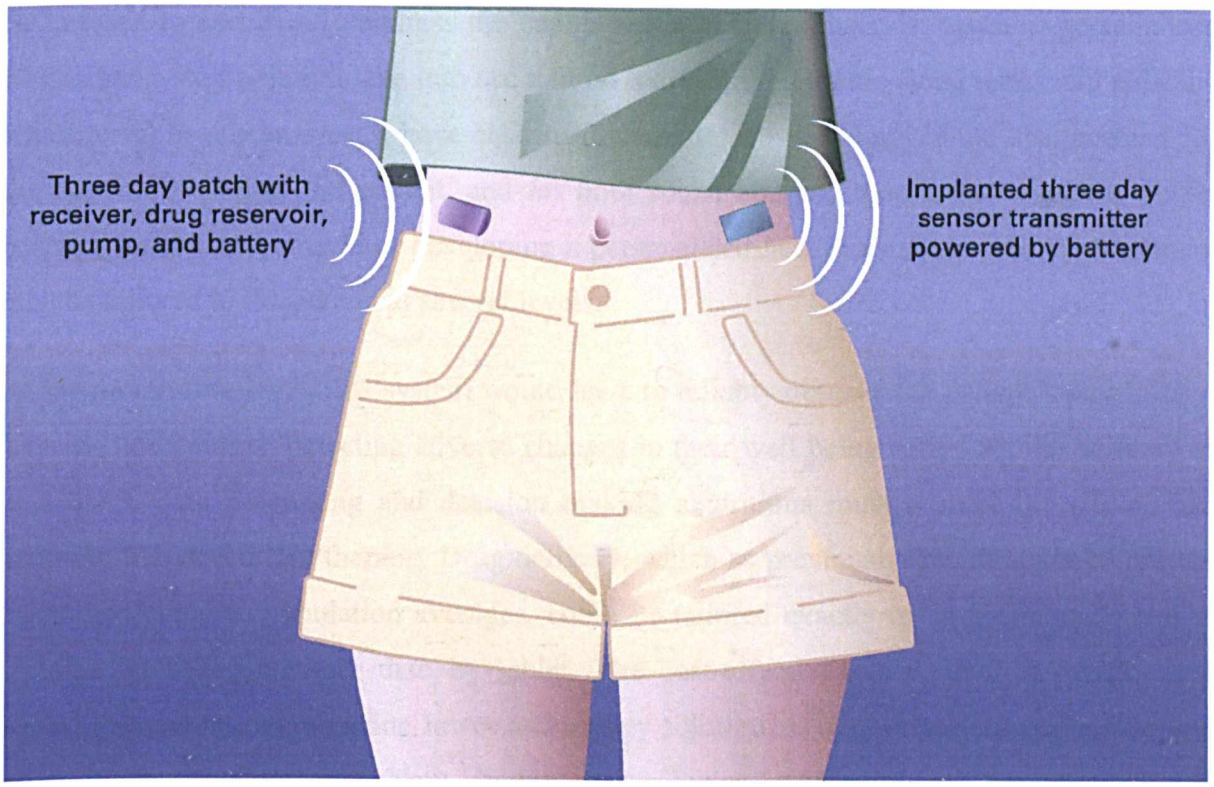


Figure 2.8. *(Left) An integrated insulin drug-delivery system consisting of two communicating skin patches, one monitoring blood subcutaneous glucose, and the other delivering insulin (courtesy of Professor Adam Heller and John Wiley & Sons Inc).*

The other disease processes (some of which have been mentioned earlier in this chapter) that would benefit from a similar integrated drug delivery process include epilepsy, hypertension, ischemic heart disease, and conditions requiring blood anticoagulation. All these disease processes currently require "average dosing" and their efficacy is currently monitored by measuring their drug level in patient's blood, or in the case of hypertensives, their blood pressure when attending to their health clinic. It is important to remember that drug delivery may not be the only stimulus that is delivered by such integrated feedback systems, with electrical stimuli, for example to brain, nerves, and muscle being other important examples. Whatever the application, it is clear that the pace at which these integrated feedback systems develop is dependent largely on the development of suitable components and medical control algorithms to construct the miniature subsystems.

2.6 Personalised Healthcare

In a population consisting of several vulnerable groups such as those with chronic disease and the elderly, the need for effective individualised health monitoring and delivery has resulted in the concept of "personalised healthcare". Such a system is expected to be 'dynamic' and

customised to specifically address the health needs of individuals. In essence, personalised healthcare systems should take into account an individual's chronic (long term) and episodic (short term) healthcare needs, have clear healthcare objectives. They should also account for the cognitive level of the patient, and for both social and community factors. BSNs offer perhaps the greatest chance of developing a personalised healthcare system where treatment may be tailored to the patient at several levels.

At the monitoring level, this system would have to reliably observe the patient's physiology, activity, and context, detecting adverse changes in their well being early. At the delivery of care level, data processing and decision making algorithms must prompt the appropriate action to deliver correct therapy. Drug delivery, which as previously mentioned is at present dosed according to population averages, could be tailored exactly to an individual's needs, perhaps by infusion rather than by tablet. The cost-effectiveness of such a personalised healthcare system over existing lower technology solutions is also important and is likely to drive their development. New bionic technologies such as neuromodulation and neurostimulation devices are likely to enable BSNs to interact with and control a patient's physiological systems themselves. Ultimately these devices could use information from BSN sensors to control the human body's musculoskeletal system itself. Perhaps one of the most successful examples of a bionic device in clinical use is the cochlear implant, which has had tremendous impact on patient's lives [90].

At the research level, pervasive healthcare systems will allow doctors to learn much more about the disease processes they commonly see in clinical practice. Finally at the information delivery level, giving the patient personalised information (according to their healthcare needs) is likely to help them understand and self-manage their conditions more appropriately [91]. The ultimate aim of all this is the early detection of disease leading to an early intervention, both of which are attribute that may make personalised healthcare-based treatment the next best thing after prevention itself.

In order to deliver truly personalised healthcare, BSN sensors have to become invisible to the patient, thereby avoiding activity restriction or behaviour modification. Whilst sensor miniaturisation and implantability are potential solutions to this, another option being explored is the integration of the sensor into non-clothing items that patients already wear. The ring sensor developed at MIT for example, can act as an ambulatory telemetric continuous health monitoring device [88]. This wearable biosensor uses advanced

photoplethysmographic techniques to acquire data on the patient's heart rate, heart rate variability and oxygen saturation. This ring sensor contains an optical sensor unit, an RF transmitter, and a battery, connected to a microcomputer in the ring itself. This ensures onsite low-level signal processing, data acquisition, filtering, and bidirectional RF communication with a cellular phone which can access a website for data acquision and clinical diagnosis.

There are ofcourse, other areas aside from clinical practice were wireless BSN surveillance may be useful in monitoring people and their activity. Professional groups such as fire-fighters and paramedics, who commonly face hazardous situations, as well as policemen and soldiers, may all be monitored with such a system. Fitsense is a company that has developed a system known as 'The BodyLAN™'. This uses low power wireless body monitoring sensors for a variety of physiological and environmental parameters, which via a proprietary wireless personal area network collect and send data to its users. They can then assess their fitness and performance [92]. Figure 2.9 below shows some of these monitoring systems.



Figure 2.9 (Left) the first prototype ring sensor with RF transmitter powered by a coin-sized battery (*courtesy of Professor Harry Asada, MIT*). (Right) a FitSense sensor attached to an athlete's shin enabling measurement of stride length, step rate, instantaneous speed, distance, and acceleration (*courtesy of Tom Blackadar, FitSense Inc*).

One of the challenges of a personalised healthcare system is the wealth of information that the system is going to generate for the healthcare provider above and beyond what is currently available. How this information will be accumulated, stored, and interpreted, and

how healthcare systems will respond to adverse events must all be considered. It is important to appreciate that at present whilst much patient information is collected by continuous monitoring, for example during hospital admission, most of this information is lost. Although personalised pervasive healthcare systems will collect a vast amount of information, separating this into "important" and "non-important" is going to require very accurate context sensing. Mining this data to separate 'true' from 'false positive' events, and representing it to a user is yet another challenge. Finally, as previously mentioned, reacting to this information is going to require major process automation and structural change to existing healthcare systems.

2.7 Conclusions

This chapter has reviewed the origins and development of BSNs, outlining their potential applications in the delivery of pervasive healthcare for the management of both acute and chronic conditions, in both hospital and community settings. A number of other strategies and platforms for pervasive healthcare monitoring have also been discussed, including proprietary designed WSNs, clothing-embedded systems, environmental sensors, and implantable devices, all of which go some way to meet the challenges of delivering truly pervasive and ubiquitous healthcare monitoring. Future areas of focus include improving sensor design, biocompatibility, energy supply, power scavenging, secure information transfer, and context awareness all of which must be overcome before such a system is fully effective.

Each of the pervasive monitoring strategies mentioned above have their own merits and limitations. This thesis focuses on the development, testing, and deployment of a specialised wireless BSN platform comprising of hardware, software, and a wearable sensor to pervasively monitor the recovery of patients at home following general surgical procedures. The vast majority of these patients are currently discharged from the highly supervised hospital environment to the completely unsupervised home once they have shown adequate recovery and demonstrated the ability to independently perform their activities of daily living. Without effective means of monitoring patients in their home environment, there is a risk of either keeping these patients in hospital too long, or their re-admission of hospital because they were discharged too early. Both these outcomes are undesirable because they result in increased patient morbidity and a rise in the overall cost of care. A pervasive BSN device that enables the continuous and objective monitoring of functional recovery in the

early post-operative period following home discharge would be an invaluable tool for modern post-surgical care.

This thesis is designed to test the hypothesis that 'a pervasive BSN device can be used to quantify functional post-operative recovery in the home environment'. The need for pervasive home monitoring in surgery and drivers towards early post-operative discharge are reviewed in the Chapter 3. Components of functional recovery are identified, and the sensor types that could be used to measure these reviewed. The architecture of a specialised BSN platform and an ear-worn Activity Recognition (e-AR) sensor used to capture biomechanical data relating to measures of functional recovery is presented. Chapters 4 and 5 present the results of experiments undertaken using the e-AR sensor in the simulated home environment, designed to test a series of data analysis frameworks that convert biomechanical data into objective surrogate markers of functional recovery. Chapter 6 tests the use of the e-AR sensor and its analysis frameworks in the real home environment, and Chapter 7 tests the ability of the e-AR sensor to provide physiological data in the presence of contextual information. Chapter 8 presents the results of a pilot study using this system to pervasive monitor post-operative recovery in patients who have undergone general surgical procedures. Finally Chapter 9 concludes the thesis outlining the future for pervasive monitoring systems in surgical practice.

3 Pervasive Monitoring in Surgery

3.1 Introduction

Since the emergence of surgery as a specialty in the latter part of the 19th century, advances in the fields of anaesthesia, microbiology, anti-sepsis, and surgical instrumentation have not only dramatically improved post-operative outcome, but have also allowed increasingly complicated surgical procedures to be undertaken with relatively low peri-operative risk. In general surgery, the advent of laparoscopic (keyhole) and robotic (master-slave device) procedures has meant that a surgeon's fingers have been replaced by much smaller diameter instruments that enter the peritoneal cavity through 5-12mm incisions and themselves are not in direct contact with the operative tissues. The impact that this has had on the reduction of wound size is dramatic, and shown below in Figure 3.1.

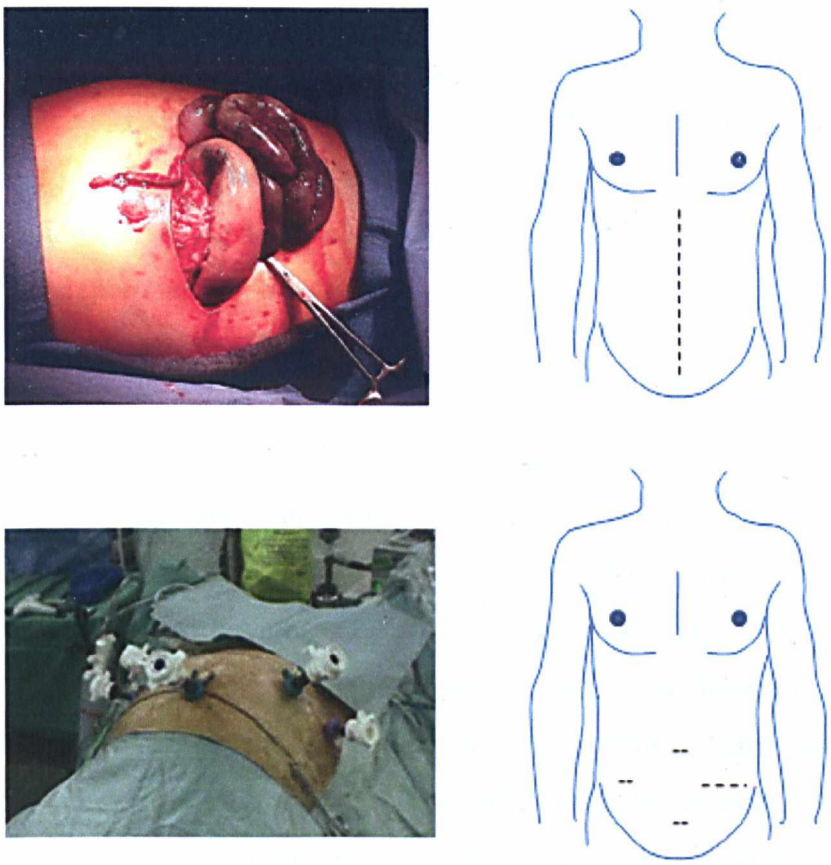


Figure 3.1 *An open midline laparotomy incision (top left) with resulting wound (top right). Laparoscopic ports inserted for a minimally invasive procedure (bottom left) with resulting wounds (bottom right).*

As a result, patients who have undergone these procedures experience less post-operative pain (lower requirement for analgesia), mobilise earlier, and have a reduced hospital length of stay [93, 94]. With patients returning to their homes earlier than ever before, there is now a real need to provide high quality post-operative care in this environment. The ability to monitor post-operative recovery ubiquitously and pervasively at home for a period of time following an operation is an essential part of this post-surgical care. Existing patient monitoring systems are not well suited to fulfil this role either because they lack objectivity, are labour intensive, or only offer a view of a patient's health at a particular instant in time. BSN technology is ideally suited to this as it enables a means of monitoring a dynamic recovery process when compared to the snapshot view provided by existing systems.

This chapter aims to outline the changes in surgical management that have resulted in a reduction in hospital stay, together with the socioeconomic drivers that have promoted this for reasons of cost and patient choice. It goes on to describe the different components of post-operative recovery and identify a number of direct and indirect parameters through which the post-operative recovery can be measured. Functional recovery is identified as an important parameter to measure in the early post-operative period when the patient is at home, and the use of biomechanical parameters as indirect measures of this proposed. Finally sensors suited to monitoring these biomechanical parameters are presented, and a wireless BSN sensor node design and architecture to enable the collection of this data is described. An ear-worn Activity Recognition (e-AR) device encapsulating these components is introduced and used as the basis for the experiments in this thesis.

3.2 Trends Leading to Earlier Home Discharge following Surgery

In addition to the advances in surgical technology such as minimally invasive surgery, the past two decades have seen the emergence of a number of strategies aimed at promoting a patients' return to normal activities as early as possible following surgery. Initiatives such as 'ambulatory' or 'day' surgery have been established for low/medium complexity operations, offering short operative times, lighter anaesthesia, and same-day discharge [95]. For more complex operations, 'enhanced recovery programs' (also known as 'fast-tracking' and 'goal directed recovery'), have been introduced so that patients can be motivated to return to their normal functional levels and therefore are discharged home safely as early as possible [96]. Rising healthcare cost and failure of economies to meet this rise is another driver for early discharge, as the financial burden of hospital admission can be reduced by initiatives that

promote early recovery. Finally, there is every indication that when given the choice, most patients prefer to recover at home as compared to being in hospital [97]. This section reviews the ways in which these initiatives reduce the length of post-operative stay and promote early home discharge. When sending a patient home, there is an overwhelming need to ensure that they are safe to do so, able to cope, and recovering as would be expected. Objective markers of post-operative home recovery are required before this can be achieved.

3.2.1 Enhanced recovery programs

Enhanced recovery programs in such as '*fast tracking*' in general surgery begin in the peri-operative period and are aimed at improving recovery whilst reducing the stress response following surgery, and ultimately shortening hospital stay [98]. The main elements of these programs include extensive peri-operative counselling, avoiding bowel preparation (thereby avoiding dehydration and altered biochemistry), allowing the patient to have carbohydrate-loaded liquids up until 2 hours before surgery, anaesthesia tailored to be short-acting and including epidural analgesia, high inspired peri-operative oxygen concentrations, avoidance of peri-operative fluid overload, small incisions, non-opiate based pain management, early removal of catheters, and enhanced post-operative feeding and mobilisation. Recent evidence suggests that enhanced recovery programs result in quicker post-operative recovery, reduced morbidity, and hospital stay compared to traditional recovery programs [99]. Whilst these programs aim to maximise a patient's recovery following surgery, they are often unable to extend into the home environment where the patient may still be within the first post-operative week of their operation and therefore would ideally require some surveillance. A system that would allow home monitoring of such patients with early intervention is ideally suited to the concept of enhanced recovery and would improve not only its outcomes but also allow it to be used in a more widespread fashion. The use of a wrist-worn 'Actigraph' device as part of a functional recovery program to monitor physical activity in the post-operative has been demonstrated but this has largely been as a retrospective research tool as opposed to a real-time activity monitoring system [100]. Finally, enhanced recovery programs have been shown to have a higher re-admission rate to hospital following discharge [101], suggesting the need for improved monitoring of patients on these programs once they leave the hospital.

3.2.2 Specialist discharge nurses

The creation of the 'specialist discharge nurse' role has in recent times been used to prepare patients for their post-operative course from an early stage before surgery. These nurses

maintain continuity with patients, education them about their post-operative care and ensuring their chances of uneventful steady recovery are maximised. Dawes et al (2006) successfully demonstrated this role for patients undergoing major abdominal and pelvic gynaecological surgery, demonstrating earlier hospital discharge, better information delivery, and patient satisfaction with such a program in place [102]. The importance of home visits by specialist nurses to improve continuity of care and address information needs of patients discharged home after primary angioplasty for myocardial infarction (heart attacks) has been re-iterated in a recent study by Astin et al (2008) [103]. Finally, in the case of breast surgery, nurse-specialist led discharge is has been shown to be effective in the management of surgical drains in the home environment [104]. The creation of the specialist discharge nurse role has meant that there is now an opportunity to provide outreach care in the home environment, although this remains labour-intensive and expensive for large-scale use.

3.2.3 Ambulatory surgery

Improvements in anaesthesia and surgical techniques have resulted in a large number of 'ambulatory' or 'day' surgical procedures being undertaken every year in healthcare systems across the world [105, 106]. This type of surgery is geared towards safely discharging patients home on the day of their operation, so that almost their entire post-operative course is spent there. In 2007, the UK Audit Commission (an independent healthcare watchdog), identified 25 operations or admissions which could be carried out as day cases ranging from inguinal hernia repair and excision of breast lumps, to laparoscopic cholecystectomies [107]. It also recommended that 75% of these operations or admissions should be carried out as day cases. As a result, it is estimated that if all UK National Health Service (NHS) trusts achieved an average of 75% day cases across the 25 procedures, then at least 390,000 bed days could be freed up, saving the UK NHS £78 million per annum. Day surgery is an initiative that not only benefits the patient, but also the healthcare systems as a whole. As a result, patients undergoing these procedures currently recover in an almost completely unsupervised manner at home.

3.2.4 Home Wards

There are at present a number of initiatives in post-operative surgical care targeted at offering acutely unwell patients the option to recover at home following a range of elective and emergency procedures [108, 109]. These initiatives offer to provide safe home recovery by increasing the intensity of nursing to that similar to a hospital ward. In such an initiative,

patients may be visited 4-6 times a day by mobile nursing teams to monitor their vital signs, review their clinical progress, offer them physiotherapy, and administer both oral and intravenous medication. This represents a labour-intensive process that is too expensive for most healthcare systems to implement. It is also important to note that episodic patient monitoring employed by home ward systems shares many of the limitations of current hospital ward monitoring systems. Whilst it is not yet clear whether these types of home recovery systems are cost-effective compared to existing hospital-based recovery, enabling these with technologies that allow remote patient recovery measurement and monitoring is likely to increase their efficiency. It is also important to note that any proposed post-operative recovery monitoring system must be integrated with primary care as in the UK, General Practitioners (GPs) and community health staff are responsible for management of patients in ambulatory care settings.

3.2.5 Socio-Economic Drivers for Home Recovery

The spiralling cost of healthcare provision in the western world is due to a rise in the adoption of new technologies and treatment modalities, combined with screening and health promotion programs that detect disease at an earlier stage than even before, has led to a drive to seek more efficient means of patient care. The per capita expenditure on health for most countries has risen dramatically over the past decade, with the United States of America leading the way at approximately $6500, and countries such as the United Kingdom further behind on approximately $2700 per capita [110]. In the United Kingdom, the National Institute of Health and Clinical Excellence (NICE) is an institution that has been set up to evaluates the incremental cost of a new technology per quality-adjusted life year and make recommendations to the UK NHS on which new technologies it should provide its patients. The current threshold for cost-effectiveness used by NICE is at $50,000 per quality-adjusted life-year [111].

Hospitalisation is perhaps one of the most expensive parts of a patient's care, and therefore minimising this cost has been the stimulus for many of the initiatives such as fast tracking and goal-directed recovery mentioned above. Restructuring of healthcare institutions through financial pressures in many countries has lead to a significant reduction in the number of available inpatient hospital beds [112, 113]. Another driver for minimising the length of stay has been the need to prevent the spread of hospital-acquired (nosocomial) infections such as *methicillin resistant Staphylococcus aureus* (MRSA) and *Clostridium difficile*, both of which

can cause significant morbidity [114]. These factors, combined with a shortage of appropriately trained clinical staff in most healthcare systems [115] means that there is a real need to improve the efficiency of patient management, and where appropriate, use novel solutions and technologies to reduce unnecessary workload without compromising patient safety. Finally, their preference for home recovery means that patients are likely to receive such initiatives positively. Table 3.1 below shows some typical lengths of post-operative stay following surgery for common general surgical procedures. This gives an indication that whilst a patient may be at home the day of minor surgery, for intermediate and complex cases this can range from 3-10 days post-operatively.

Procedure	Expected post-operative length of stay
Laparoscopic Cholecystectomy	0-36 hours
Open Cholecystectomy	4-5 days
Laparoscopic Colectomy	4-7days
Open Colectomy	7-10 days
Open inguinal hernia repair	0-24 hours
Laparoscopic Appendicectomy	1-2 days
Open Appendicectomy	1-3 days

Table 3.1 *Typical post-operative lengths of stay for common general surgical procedures*

3.3 Monitoring Post-operative Recovery

Post-operative recovery is a multifaceted entity that involves the biological processes of wound healing, the physiological processes of the body compensating for the trauma it has been exposed to, the ability to overcome post-operative complications, the physical process of returning to normal function, and the psychological process of resuming a normal life. In devising a strategy for post-operative home monitoring it is important to understand each of these components and the parameters that could be used to monitor them.

3.3.1 Biological recovery and wound healing

At the biological level, wound healing following surgery is a complex process that involves the following phases:

The *inflammatory phase* of wound healing lasts 0-4 days and represents the initial response to the trauma of surgery. It is initiated by the exposure of collagen at the time when a wound is

created and characterised by haemostasis (the cessation of bleeding) followed by inflammation, thereby sealing the wound surface. Surgical wounds cause injury to tissues and cell membranes, resulting in the release of inflammatory mediators such as thromboxane A2 and prostaglandin 2-alpha. These are both potent vasoconstrictors (producing a contraction in vessel size) and prevent haemorrhage (blood loss) [116]. After a period of time, cells at the site of the wound release histamine which causes vasodilatation (widening of capillaries) thereby helping inflammatory cells reach the site of healing. Platelets are amongst the first cells to respond, releasing a large number of inflammatory factors and chemokines, namely epidermal growth factor (EGF), fibronectin, fibrinogen, histamine, and platelet-derived growth factor (PDGF). The result of this is the formation of a clot, controlling bleeding and limiting the extent of injury. Platelets also activate the complement cascade resulting in the release of mediators that attract neutrophils (a type of white blood cell) through chemotaxis (the release of a chemical substance attracting the neutrophil to the site of the operation). As a result, more and more immune response cells migrate to the wound. These include neutrophils that kill bacteria and decontaminate the wound from foreign debris and macrophages that secrete a number of enzymes and cytokines [116].

The *proliferative phase* lasts between 2-22 days and represents the process of tissue reconstruction. As the inflammatory phase comes to end, wound repair can now begin with angiogenesis (the growth of new blood vessels), fibroplasia, and epithelialisation resulting in the formation of granulation tissue. Angiogenesis is important as it allows the delivery of nutrients to the wound and helps to maintain the granulation tissue bed. Fibroplasia involves the migration of fibroblasts into the wound where they proliferate, deposit extracellular matrix including collagen, and give the wound its strength. Epithelialisation occurs and is characterised by the migration of epithelial cells across the wound. In the skin for example, this results in the re-formation of the epidermis barrier.

The *Maturation Phase* (lasting 21 days to 2 years) represents the final phase of healing and is characterised by wound contraction, resulting in increased wound strength without an increase in collagen content, ultimately resulting in a smaller amount of apparent scar tissue. Maximal wound strength is ultimately reached at about a year. It is important to appreciate that the process outlined above is dynamic, ultimately involving some overlap of each phase and continued remodelling of the wound.

Wound healing can be influenced by a number of 'local' and 'systemic' factors [117]. Local factors that may have a negative impact on wound healing include: poor blood supply resulting in inadequate wound perfusion; the presence of a foreign body (for example excess suture material) at the operative site resulting in chronic inflammation; infection impairing the normal healing process; and post-operative bleeding which can compromise not only the local blood supply of the wound, but also can act as a focus for infection in the case of haematoma formation. The following systemic factors result in impaired wound healing:

- *Diabetes* resulting in peripheral vascular disease (poor blood supply), neuropathy (poor skin sensation), and poor white blood cell function (poor inflammatory response), all of which translate to globally poor wound healing.

- *Anaemia* (reduction in the amount of haemoglobin in the blood) which is associated with a decreased oxygen carrying capability of the blood stream, and poor perfusion (nutrient carrying ability) of tissues.

- *Steroid use* resulting in suppression of the inflammatory phase of wound healing.

- *Immunosuppressive drug use* such as those used to treat chronic conditions such as rheumatoid arthritis that can in turn dampen the body's normal healing response.

- *Malnutrition* resulting in poor healing due to deficiencies in the proteins, vitamins, minerals, and cofactors required for normal healing.

- *Obesity* which is associated with diabetes and immobility.

- *Increasing age* which is associated with poorer wound healing although this may not be an independent factor and may be related to chronic disease, whose incidence rises with age.

Visual inspection of healing skin wounds is used as a means of monitoring this biological recovery in the post-operative period. It is a subjective process that is often carried out by district or GP nurses undertaking dressing changes in the community. Attempts have been made to increase the objectivity of wound monitoring, through serial image capture [118] and the use of telemedicine [119], however it remains a very labour-intensive process that is not suited to pervasive monitoring. At the biological level, whilst detecting levels of inflammatory mediators is possible, interpreting this into relevant information on the progress

of a wound is difficult. It would also require invasive sampling of the tissues and fluids around the wound which is neither desirable to the patient nor suited to pervasive home monitoring.

3.3.2 Physiological recovery

Physiological recovery from general surgery is classically assessed non-invasively by the measurement of vital sign parameters such as heart rate (HR), oxygen saturation (SpO_2), temperature, and blood pressure. Patients undergoing major elective surgery currently experience four phases during which their physiology is assessed. In the '*pre-operative period*', they attend pre-assessment clinics where their anaesthetic risk is evaluated and minimised prior to surgery. The '*peri-operative period*' begins from the time they are anaesthetised for surgery to the time they wake up. The '*early post-operative period*' encompasses the first 3-5 days following surgery when they are usually recovering in the hospital ward. Finally the '*late post-operative period*' starts with discharge of the patient from hospital to their home environment. Because the patient is in hospital during the peri- and early post-operative periods, the monitoring they receive here is more labour-intensive and specifically designed to detect the body's response to blood loss (hypovolaemia from haemorrhage), poor oxygenation of tissues through lung collapse (atelectasis), and the presence of infections (wound infection or pneumonia). Although current hospital recovery monitoring systems are effective during peri- and early post-operative periods, they are not easy to use when the patient is at home. The infrastructure and equipment costs combined with the need for patient compliance makes this a less desirable across healthcare systems as a whole. Further details of the phases surrounding a surgical procedure during which patients are monitored are given below:

The *pre-operative* assessment period is aimed at identifying a patient's 'baseline' physiology as well as any co-existing conditions that could alter this and thereby increase their post-operative risk. As part of this, a patient's medical history is reviewed, they are examined, and investigations such as blood tests, radiological imaging (X-ray, ultrasound, echocardiography, Computer Tomography-CT scanning, etc.), ECG, and lung function tests are performed. The non-invasive vital signs measurements mentioned above are also taken during this period. If possible, the patient's health is optimised before surgery. Groups who are particularly at risk such as patients with ischaemic heart disease, chronic obstructive airways disease, or diabetes, are identified for closer supervision following surgery.

The *peri-operative* monitoring a patient receives during administration of general anaesthesia and throughout the operation until they are allowed to wake up includes continuous pulse oximetry, heart rate, ECG, temperature, and urine output measurement. Depending on the length of the anaesthetic and complexity of the case, they may also have invasive arterial blood pressure measurement and intermittent sampling to measure arterial oxygen content. Additionally being on a respiratory ventilator machine means their lung volumes and gases can be measured. After surgery some patients require an admission to an intensive care unit where they receive prolonged ventilation, systemic support, invasive monitoring, and one-to-one nursing, with their sedation gradually weaned as their body starts to function normally. Patients undergoing major surgery (such as simple bowel resections for cancer) are often admitted post-operatively to a high dependency unit (HDU) where they are more intensively nursed and monitored than a general ward, but do not require sedation and ventilation. For the vast majority of patients however, post-operative recovery monitoring takes place in a general ward where they receive intermittent observation and non-invasive vitals sign measurement that can vary in its frequency from every 30 min to every 6 hours.

Although the assessment of a patient's vital signs in the acute phase following surgery is both important and feasible, these parameters of physiological recovery are not so easy to measure continuously in the home. In addition to the technical challenges of continuous vital signs measurement, it is important to note that as part of normal human physiology, there are variations in heart rate and blood pressure that occur as a result of the activity being performed. If viewed in isolation therefore, vital signs monitoring in the home setting is almost un-interpretable because on would never know if for example a rise in HR was due to exercise, the emergence of an infection, or a primary arrhythmia involving the heart. Knowing the context in which physiology is measured is therefore extremely important.

3.3.3 Post-Operative Complications

Patients undergoing all types of surgery are prone to a range of post-operative complications in the *immediate* (within hours of surgery), *early* (within days of surgery) and *late* (usually beyond five days after surgery) time periods. These complications may also be classified as *general*, and therefore applicable to all types of surgery, or *specific* to the type of surgery in question [116]. In managing surgical patients, it therefore is important to consider these complications, some of which can be life-threatening, but in most cases have the potential to result in poor outcome such as pain, poor cosmesis, delayed healing, and ultimately

prolonged hospital stay. The care of these patients therefore involves firstly identifying those at risk of developing a complication due to the factors associated with poor wound healing discussed above, and then deciding the appropriate length and type of monitoring they require. Diabetics for example are a group that are often observed in hospital more closely and for longer a longer period of time, particularly after complex surgical procedures. The manifestations of common general complications following surgery are shown in Table 3.2, which also shows the types of parameters and sensors that may be used to detect them.

General and in particular gastro-intestinal surgery involves a range of procedures that may be performed laparoscopically (through keyhole incisions) or open. Table 3.3 shows the complications specific to patients undergoing laparoscopic or open gastro-intestinal surgery, and the monitoring systems used to detect these. It is important to note that in types of gastrointestinal surgery where a segment of bowel is resected (removed) and rejoined (anastomosed) as shown in Figure 3.1, one of the most serious complications that can occur is an '*anastomotic leak*'. Here, intestinal contents exude from the site of the surgical joining of two segments of bowel [120], resulting in sepsis (overwhelming infection), a marked systemic inflammatory response, and ultimately death. This complication is thought to occur in anywhere from 2-7% of patients undergoing bowel resections, and is associated with significant increase in morbidity, mortality, prolongation of hospital stay, and risk of local recurrence in colorectal cancer resections [121]. Although a number of risk factors predisposing to such a leak have been identified [122, 123], there remains an absence of information on the biochemical changes that occur at the anastomotic site as part of the healing process, which may have a profound effect on the tissue regeneration and remodelling that takes place at this site.

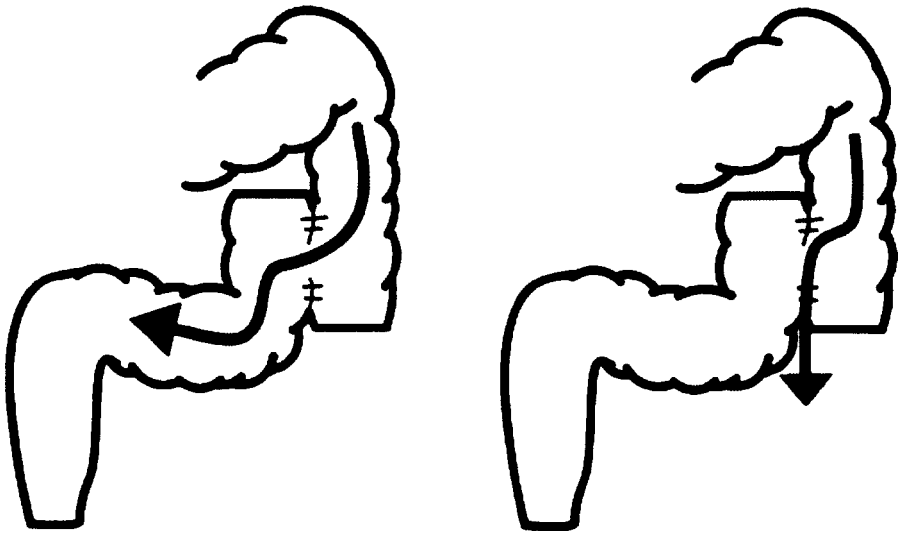


Figure 3.2 *Normal flow of faeces following a bowel anastomosis (left). The flow of faeces into the peritoneal cavity in the case of an anastomotic leak (right) often as a result of poor healing leading to sepsis.*

Risk factors that have thus far been identified as predisposing to anastomotic leak may be divided into *"patient-related"* and *"operative"* groups. Patient-related factors include the presence of diabetes, corticosteroid use, malnutrition, anaemia, and inflammatory bowel disease [124]. Operative factors include the type of surgical technique used, mode of anastomosis (hand sewn versus stapled), tension on the anastomosis, blood supply, and the use of surgical drains [125]. Clinical manifestations of anastomotic leaks may occur anytime following the operation but are most common between 2 and 10 days after abdominal surgery. The patient may complain of symptoms such as abdominal pain, fevers, and on examination may be febrile with a persistent tachycardia (rapid heart rate). The complication can ultimately result in the need for further major abdominal surgery and prolonged hospital admission. It is important to note that on enhanced recovery programs following minimally invasive surgery, patients are often sent home on the fifth post-operative day. They are therefore at risk of developing this complication when in the completely unsupervised home setting.

Table 3.2 *Clinical Manifestations of general post-operative complications, their causes, and the available current monitoring systems used to detect these. DVT=deep vein thrombosis, PE=pulmonary embolus, HR=heart rate, BP=blood pressure.*

Post-operative Manifestation	Timing and Possible causes	Type of Monitoring used to detect this
Post-operative Fever	Day 0-2: atelectasis (lung collapse), aspiration pneumonia. Day 3-5: urinary tract infection, wound infection, cannula/catheter-related sepsis. Day 5-10: wound infection, anastomotic leak, intra-abdominal abscess, DVT/PE Weeks/months: prosthesis/implant related infections, deep abscesses (infected collections)	Temperature measurement using sublingual or axillary thermometer
Post-operative Pain	Pain can significantly affect recovery by: impaired respiratory function (reduced breathing, coughing, and secretion clearance), reduced mobility (increases DVT/pressure sore risk), increased cardiac output (myocardial oxygen demand), impaired bowel function, urinary retention, and anxiety.	Subjective questioning or scoring on a 0-10 Likert scale
Poor Urine Output	Defined as a urine output of <30mL per hour. Most common causes include a blocked urinary catheter, poor fluid replacement (dehydration), or acute renal failure following direct renal injury due to drugs, prolonged hypoperfusion during surgery, transfusion or trauma.	Bladder palpation, cathetisation and washout, central venous pressure measurement, serum urea, creatinine and electrolyte measurement.
Shortness of Breath	Fluid overload, pneumonia, Pulmonary Embolus (PE), unrecognised chronic respiratory disease, pneumothorax (air in the pleural space causing lung collapse)	Chest auscultation (stethoscope), pulse oximetry, arterial blood sampling, chest x-ray.
Tachycardia (high HR)+/- Hypotension (low BP)	Postoperative bleeding, heart-related causes (Myocardial Infarction-MI, arrhythmia), PE, pain, anaphylaxis secondary to drugs (See Shock chapter).	Pulse oximetry, ECG, sphigmomanometer, invasive arterial blood pressure measurement
Confusion	Hypoxia (poor blood oxygenation), drug-related (opiate drug-related), infections, urinary retention, renal failure, hepatic disease, stroke, or an endocrine cause.	Pulse oximetry, patient history and examination, blood tests.
Chest pain	Angina, myocardial infarction, gastritis, gastric ulcer	Examination, ECG, and serum troponin/cardiac enzymes
Nausea and Vomiting	Paralytic postoperative Ileus (inability of the bowel to contract and empty normally), allergic drug reaction.	Examination, abdominal auscultation (stethoscope), abdominal X-ray, contrast study.
Wound Complications	Wound dehiscence, fluid discharge, or wound infection. An early warning sign is a serosanguinous (pink) discharge from wound followed by separation at days 7-10. This is a serious complication associated with significant mortality (up to 30%). Infections begin as erythema (redness) and cellulitis around wound, eventually resulting in purulent discharge associated with fever.	Examination, bacterial swabbing and microbiology culture
Post-operative bleeding	Primary Haemorrhage: starts during or very shortly after surgery, is directly from operative site usually due to inadequate haemostasis. Secondary Haemorrhage usually occurs after 7-14 days, often due to infection.	Examination, capillary refill time, central venous pressure, urine output, pulse oximetry (HR), sphigmomanometry (BP)

Table 3.3 *Post-operative complications specific to patients undergoing all types of gastro-intestinal surgery, as well as those specific to patients undergoing laparoscopic (keyhole) surgery. Their causes, and the available current monitoring systems used to detect these are also mentioned.*

Post-operative complication	Definition	Type of monitoring used to detect this
	LAPAROSCOPIC AND OPEN GASTRO-INTESTINAL SURGERY	
Anastomotic Leak	This can occur at the site where bowel is resected, the diseased segment removed, and continuity restored by rejoining the bowel. Bowel contents therefore have a potential route for entry into the abdominal (peritoneal) cavity). If small, this results in an abdominal abscess, but if severe can result in severe abdominal pain due to gross contamination of the peritoneal cavity and requires major surgery.	Vital signs monitoring (high HR, pyrexia), blood tests, contrast studies, CT scanning.
Intra-abdominal Abscess	A collection of pus within the abdominal cavity that occurs because of localised infection within the peritoneal cavity, usually as a result of contamination from bowel contents. This can cause abdominal pain and fever.	Vital signs monitoring (high HR, pyrexia), blood tests, contrast studies, CT scanning.
Incisional Hernia	The weakened abdominal wall results in the passage of abdominal contents through its covering layers into an abnormal position. This can be immediate, early, or late.	Clinical examination, ultrasound, or CT scanning
Disease recurrence (cancer)	The recurrence of disease either locally at the site of previous surgery, or at a different site in the body.	Contrast studies and CT scanning
	LAPAROSCOPIC SURGERY	
Air embolism	The accidental passage of air into the blood stream as a result of insufflation of carbon dioxide gas into the peritoneal cavity. The air can enter a blood vessel through inadvertent injury.	Clinical examination, auscultation, pulse oximetry (low SpO_2), chest X-ray, ECG, arterial blood gas.
Hypercapnoea/Acidosis	A rise in the carbon dioxide level in blood due to the insufflated gas being absorbed into the bloodstream. This can also result a drop in blood pH.	Clinical examination, pulse oximetry (low SpO_2), chest X-ray, ECG, arterial blood gas.
Arrhythmias/vagal reaction	Cardiac irritation caused by insufflating gas within the peritoneal cavity and the resulting distension.	Clinical examination, pulse oximetry, ECG.
Atelectasis	Lung collapse occurring because of the diaphragm being pushed upwards, causing pressure on lung bases and resulting in their collapse. This can result in difficult and inefficient breathing.	Clinical examination, auscultation, pulse oximetry (low SpO_2), chest X-ray, ECG, arterial blood gas

It can be seen from Tables 3.2 and 3.3 that the first manifestation of many of these post-operative complications is a change in vital signs such as a rise in heart rate, pyrexia, or a change in oxygen saturation. As with most illnesses, patients who develop post-operative complications are also likely to experience an associated change in their behaviour such as lethargy, changes in levels of activity, and the ability to mobilise. Developing a pervasive post-operative monitoring system that is able to directly detect such a broad range of complications is going to be almost impossible, but the use of surrogate markers that imply a change in behaviour associated with changes in physiology that occur in the context of inactivity is achievable. As a result, whilst such a pervasive system may not specifically identify the complication that has occurred, it will identify patients who are at risk of developing a complication early. In addition, whilst complications are episodic, a pervasive post-operating monitoring system would be expected to identify trends that may prevent a complications altogether. A simple example of this is encouraging mobilisation in a patient to reduce the risk of deep vein thrombosis (DVT) and ultimately pulmonary embolism (PE).

3.3.1 Psychological recovery

The impact that the trauma of major surgery can have on a patient's psychological wellbeing should not be underestimated. Post-operative depression and psychosocial distress are known phenomena that occur following several types of surgery, the risk of which increases with age and social isolation [126-128]. In patients undergoing cardiac surgery, post-traumatic stress is another factor that can adversely affect the psychological wellbeing of patients manifesting as severe symptoms such as avoidance and intrusion [129]. Pre-operative psychological features such as optimism and stress have been shown to predict patient's perception of pain severity following orthopaedic surgery [130]. Finally an important part of a patient's psychological recovery is their ability to return to their normal working lives. Pre-operative preparation and post-operative advice on likely impact of surgery on working life is an important way of reducing psychological trauma [131, 132]. Return to work is more difficult for those working in jobs requiring manual labour, those with disabilities such as stroke, and the elderly [133, 134]. Finally physiological factors such as reduction of blood loss have also been shown to impact the timing of patients' return to work following prostatic surgery [135]. Although it is an important aspect to consider in the post-operative period, psychological recovery is very difficult to measure objectively and does not lend itself well to continuous pervasive monitoring.

3.3.2 Functional Recovery

A patient's functional recovery following surgery is a multi-dimensional process that involves a return to physical independence, a normal quality of life, pre-operative levels of mobility, and activities of daily living. The quantification of each of these components with existing monitoring systems is considered in turn below:

To date, the gold standard methods of evaluating of physical independence and quality of life following surgery in the home or outpatient setting have involved the use of questionnaires such as the '*Short Form 36*' (SF36) and *EuroQol Group* EQ-5D [136, 137]. Whilst these attempt to measure post-operative quality of life objectively, they are designed to do so after a much longer time period (months) than would be required of a pervasive home recovery monitoring system (weeks). Example of this are studies such as that by Glassman et al (2006), who demonstrated the use of SF-36 in patients undergoing lumbar surgery comparing pre-operative and one-year post-operative results [138]. Dawes et al (2006) used the SF-36 score pre-operatively and at 6-weeks following gynaecological surgery [102], but again this time interval would not be suitable for monitoring early post-operative home recovery. In an attempt to address this, measurement tools such as the QoR-40 (quality of recovery) questionnaire have been developed to score patient daily with regards to physical comfort, emotional state, physical independence, psychological support, and pain [139, 140]. Although the QoR-40 has been shown to be a valid research tool for many patient groups [140-142], its limitations for routine practical use include dependence on patient recall and compliance. Another questionnaire designed to measure recovery and satisfaction from 24-hours following surgery is the '24-hour Functional Ability Questionnaire' (24hFAQ), comprising of questions that evaluate functional, physical, and satisfaction components of a patient's recovery [142]. Like the QoR-40 however, questionnaire-based strategies of recovery monitoring are effective in a research setting but likely to suffer from poor compliance rates by patients in widespread clinical practice.

A number of assessment scales have been designed to measure mobility as a global concept. The 'Get Up and Go Test' (GUGT) developed by Mathias et al (1986) requires a patient to stand up from a chair, walk for a short distance, turn around, return and sit down again [143]. It uses a 5-point ordinal scale to rank this mobility from normal (1) to severely abnormal (5). The 'Elderly Mobility Scale' (EMS) developed by Smith et al (1994) assesses lying to sitting, sitting to lying, sitting to standing, standing, gait, walking speed, and functional reach. Scores

range from 0, representing complete immobility, to 20, representing completely independent mobility [144]. The desire to automatically collect data on post-operative mobility has seen the emergence of mechanical motion sensors such as pedometers that determine step-counting and calorific burn. The major limitation of these technologies however, remains their inability to detect the intensity and exact nature of the movement that is being undertaken [145]. Electrical accelerometers are promising motion sensors for objective quantification of mobility because they may be used to detect both frequency and intensity of movement that occurs during a physical activity. Inoue et al (2003) designed a study measuring cumulative acceleration of body movement in 75 postoperative patients wearing an ankle accelerometer (Active Tracer AC-301) for 8 days after surgery as shown below in Figure 3.3 [146]. The cumulative acceleration of body movement was determined and from this the overall amount of mobile activity that a patient undertook was calculated. Authors used this to compare recovery from laparoscopic versus open surgery, finding that patients in the laparoscopic group demonstrated a quicker return to normal levels of mobility that their open counterparts. Limitations of the sensor used included its relatively large size, the fact that it had to be worn on the ankle which could move even when the patient was sitting, and the fact that it did not have the ability to wirelessly relay this information onto the study organisers. This meant that all the data was collected and analysed retrospectively and therefore could not form part of a real-time pervasive monitoring system.

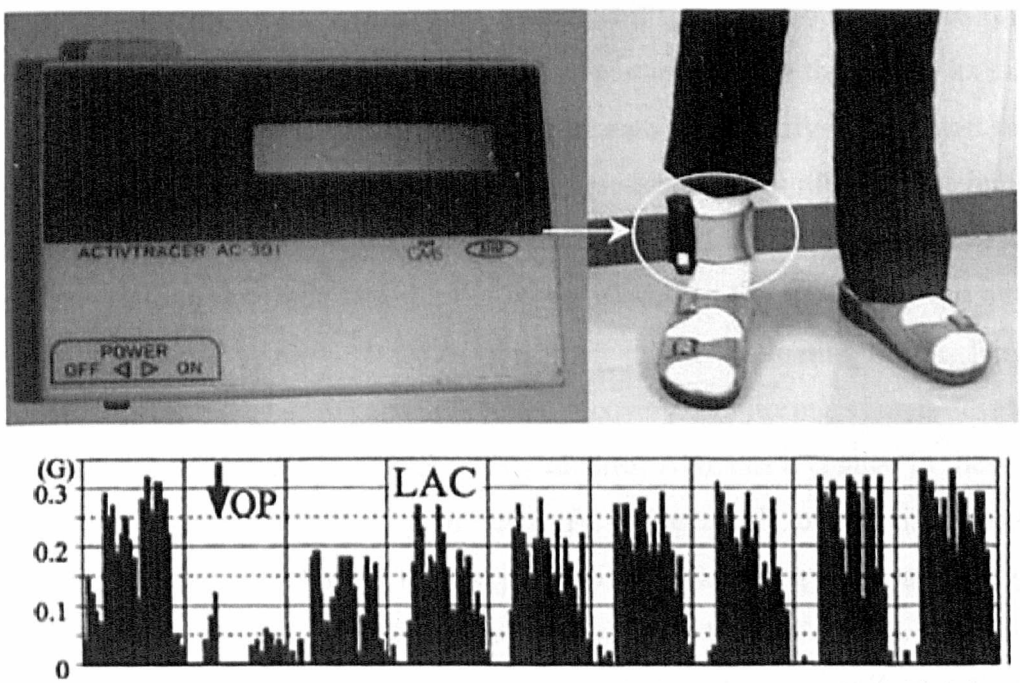


Figure 3.3: *The post-operative 'Active Tracer (AC-301)' accelerometer motion tracking system as proposed by Inoue et al. (Surgical Endoscopy 2003).*

Basse et al (2005) used a wrist-worn 'Actigraph' device to measure physical activity as part of a functional recovery program following laparoscopic and open colonic surgery [100], with the same limitations applying to this technology. These studies raise the possibility of using biomechanical markers of mobility to infer the functional recovery of a patient. Should this be possible, such as measure would be an invaluable part of a pervasive post-operative home recovery monitoring system.

The evaluation of a patient's return to normal Activities of Daily Living (ADLs) begins in the hospital setting when physiotherapists and occupational therapists evaluate their ability to walking around the ward, climb stairs without assistance, wash independently, and prepare meals. Prior to discharge a patient has to demonstrate the ability to transfer independently (move in and out of a chair or bed), feed independently (through a receptacle, such as a cup or plate), toilet themselves (getting to and from the toilet, getting on and off the toilet, and performing associated personal hygiene), dress themselves (put on and take off all items of clothing and any needed braces, fasteners or artificial limbs), and finally bathe (washing oneself in a bath tub or shower, or by sponge bath) [147]. Once a patient has satisfied these requirements, they are discharged home and followed up in an outpatient setting. Whilst a number of scales of activities of daily living have been developed, two are of particular note. The 'Barthel ADL Index' (BI) contains 10 items relating to self-care and mobility that are assessed at any given time [148]. Used mainly by physio- and occupational therapists, it does not measure any one movement in isolation, but the ability to carry out activities (the output of a number of movements). Whilst the BI is easy to administer over the phone, its limitations lie in its ability to be sensitive enough to reflect change particularly in the short term. The 'Extended activities of daily living' (EADL) scale assesses the activities that are important in the rehabilitation of stroke patients in the community [149]. It includes the assessment of activities that relate to domestic tasks in the home as well as those taking place outside the home environment. Although these scales have their role in evaluating ADLs, they rely of patient recall and compliance. A pervasive home recovery monitoring system developed for this purpose would be expected to continuously monitor ADLs as a change in these may the first sign that a patient displays of poor recovery. An example of this is a patient who develops a chest infection. Whilst in the early stages their physiology (HR and SpO_2) at rest may be only slightly affected, a loss of appetite and reduced level of activity may be the first sign of a problem. This would prompt closer review by a healthcare professional and would result in earlier administration of antibiotics. The impact this has on healthcare provision is

not only financial, but also on the quality of life for the patient. Another scenario where activity may be affected following surgery is in the case of post-operative pain, which a reduction in the desire to move can occur due to discomfort. Administering analgesia in this case would be the required intervention.

Activities of daily living and mobility are components of functional recovery that represent the global wellbeing of the patient. They may be one of the earliest signs of poor recovery and therefore have the potential to form the core of a pervasive post-operative recovery monitoring system. The identification of biomechanical parameters that could be measured using a pervasive monitoring system in the home environment, and in turn used to determine both activity and impaired mobility is the focus of the next section of this chapter. These surrogate markers of recovery must be monitored objectively, continuously, and pervasively with high levels of patient compliance.

3.4 Biomechanical Parameters for Measuring Functional Recovery

Human movement is a complex process involving several elements of the locomotor system. Bones, muscles, and joints, all interact with each other and are organised into head, upper limb, lower limb, and truncal units, for its function as shown in Figure 3.4. Whilst these units themselves comprise of a large number of components that interact with each other, it is important to consider the role that they play in daily life. The primary function of the *upper limb* through its shoulder girdle, forearm, wrist and hand, is providing the ability to hold and push objects, sensory input through 'feel', and communication. The *lower limb* enables locomotion, and supports body weight during standing, lifting, and pushing. It comprises of the pelvic girdle, femur, knee, tibiofibial, ankle, and foot components. The *trunk* comprises of the vertebral column running from the skull to the pelvis, thoracic cage, and abdominal wall. It plays an important role in protecting vital organs, enabling respiration, and stabilising the body by absorbing and dissipating stress during movements. It is important to note, that the head in its attachment to the cervical spine and alignment with the trunk, is a relatively stable part of the body during normal activities and locomotion.

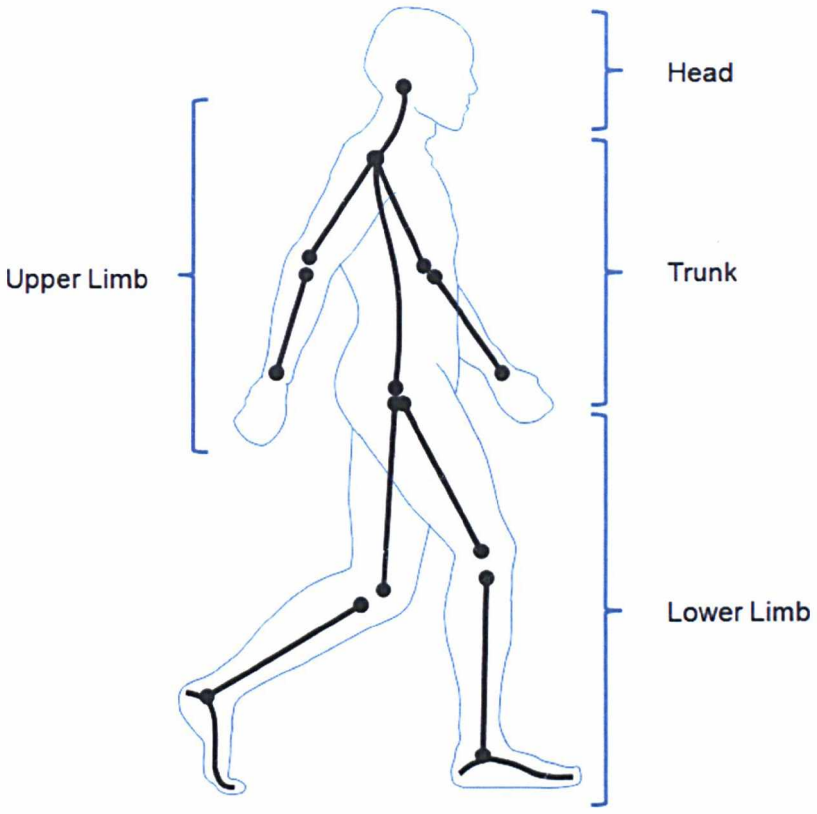


Figure 3.4 *The human body's functional locomotor units shown diagrammatically with the subject in a natural position during walking.*

Functional activities are complex and require a close coordination of a number of muscles, and musculoskeletal systems. When drinking from a glass for example, the biceps brachii muscle is used to raise the glass to the lips, whilst muscles of the hand hold the glass and the muscles of the neck move to approximate the lips to the correct drinking position, and muscles of the trunk and lower limb stabilise the body. Another place where multiple muscles may be involved is when an activity requires the generation of force over a wide range of movement. Figure 3.5 demonstrates how the gluteus maximus and hamstring muscles achieve this during flexion of the hip for a stepping motion to occur. In order to be able to use ADLs such as walking, sitting, standing, and lying down as measure of functional recovery, a means of objectively quantifying and classifying these must be identified. The same applies for the assessment of normal and impaired gait as a measure of mobility during functional recovery from surgery.

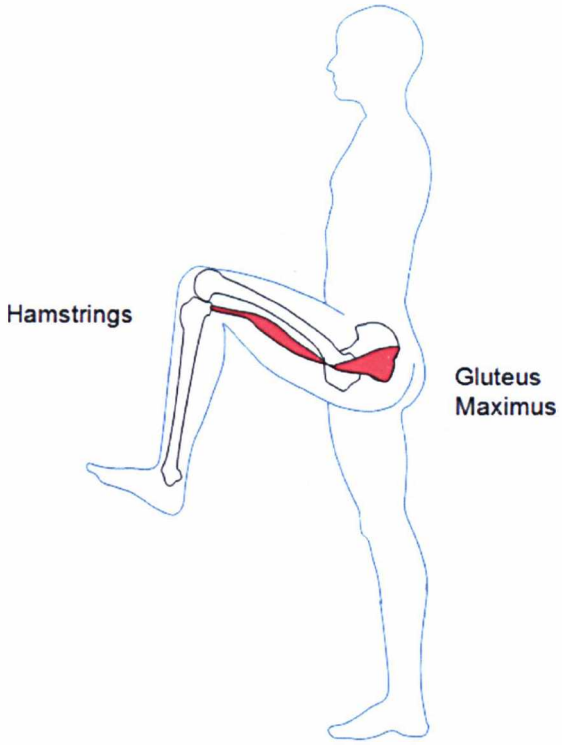


Figure 3.5 *During a stepping movement, the hip is flexed through a combination of hamstrings and gluteus maximus muscle. Initially the strength of movement is provided by the hamstrings, however towards the end the gluteus takes over.*

Biomechanical analysis of motion through *kinematics* (the description of motion) is able to provide a means of studying complex types of human motion and breaking this down into key components such as linear motion (translation), angular motion (rotation), displacement (shortest distance between two points), velocity (the rate of change of position), and acceleration (the rate of change of velocity) [150]. Kinematics involves studying motion from a spatiotemporal perspective without reference to the forces involved causing this motion [151]. In order to study complex movements such as those comprising ADLs, a *Cartesian* coordinate system that is able to describe any movement in three planes has been developed [152]. Figure 3.6 displays this with the x coordinate representing anterior-posterior movement, the y coordinate representing medial-lateral movement, and the z coordinate representing superior-inferior movement.

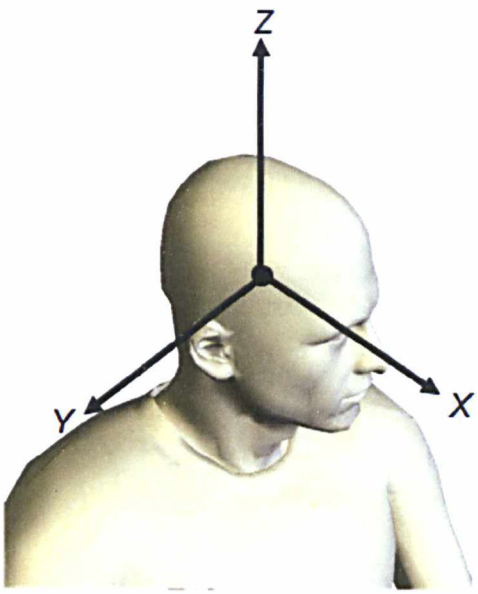


Figure 3.6 *The Cartesian coordinate system demonstrating movement of the head in x, y, and z directions.*

To describe complex activities, the movement and position of any part of the body may be defined using a set of standardised terms with the body in a reference position. Known as the 'anatomical position', this involves the body being erect with head facing forward, arms at the side, palms facing forward, and legs together with feet facing forward [151]. Figure 3.7 displays the terms used to describe position or direction relative to this anatomical position. *Medial* refers to a position or movement towards the midline, *lateral* refers to a position or movement away from the midline, *proximal* refers to a position closer to any given reference point, whilst *distal* refers to a position away from that reference point. *Superior* is used to describe a point closer to the top of the head, and *inferior* is used to describe a point closer to the feet. *Anterior* describes a location closer to the front of the body whilst *posterior* describes a location closer to the back. Finally *ipsilateral* describes an activity or location on the same side as a reference point, whereas *contralateral* describes this as being on the opposite side to that reference point.

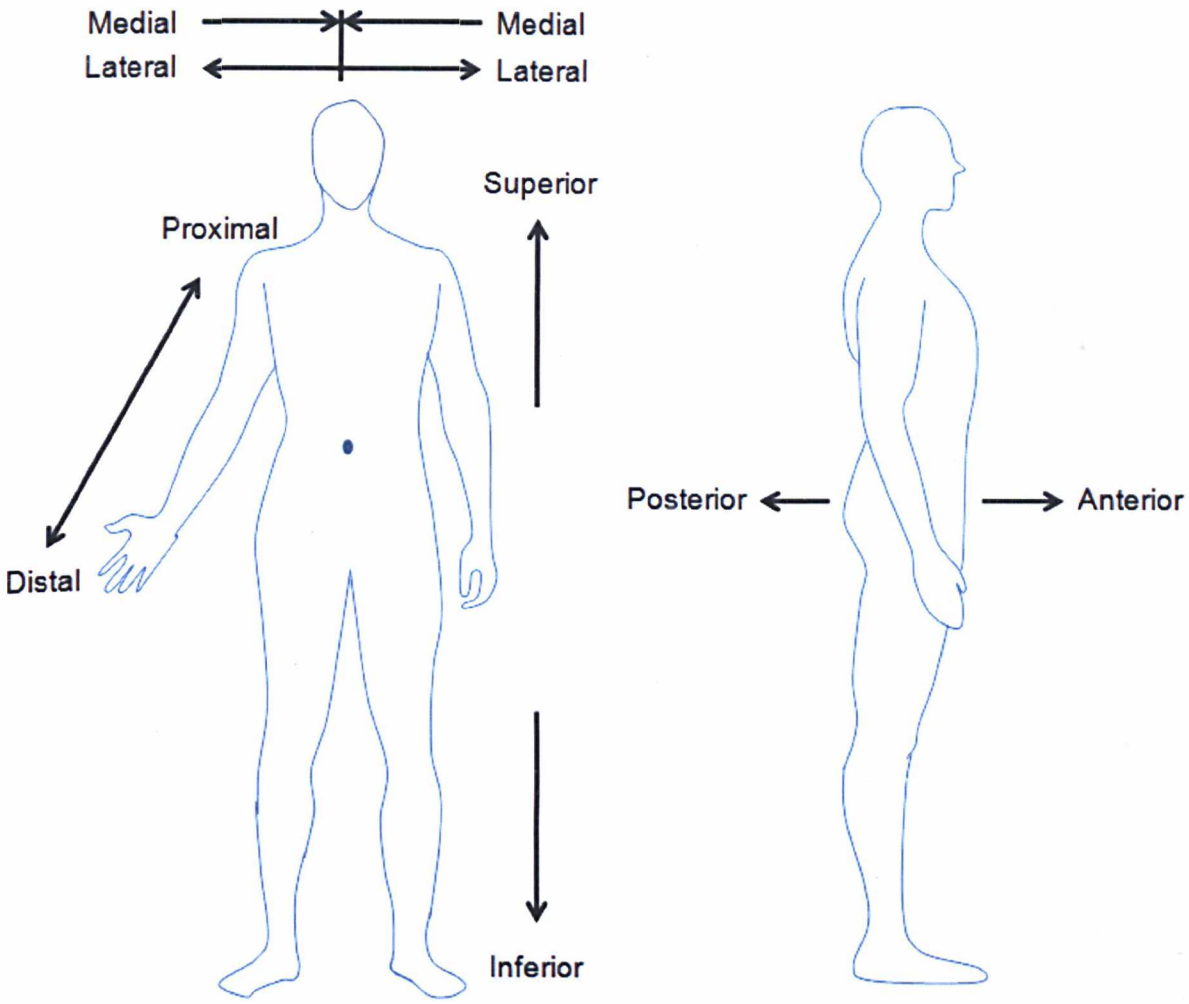


Figure 3.7 *Anatomical terms used to describe relative position.*

Five basic movements may occur in varying combinations in the body's joints: *Flexion* of a joint is a bending movement where the relative angle of a joint between two adjacent segments decreases, whereas *extension* is a straightening movement of a joint where this angle increases. *Abduction* is a movement away from the midline whereas *adduction* is a movement towards the midline. Finally *rotation* can be either internal or external. Figure 3.8 displays these terms with accompanying examples of basic movements. Whilst a number of other specialised types of movement occur at various joints, these can be considered in turn when describing that movement.

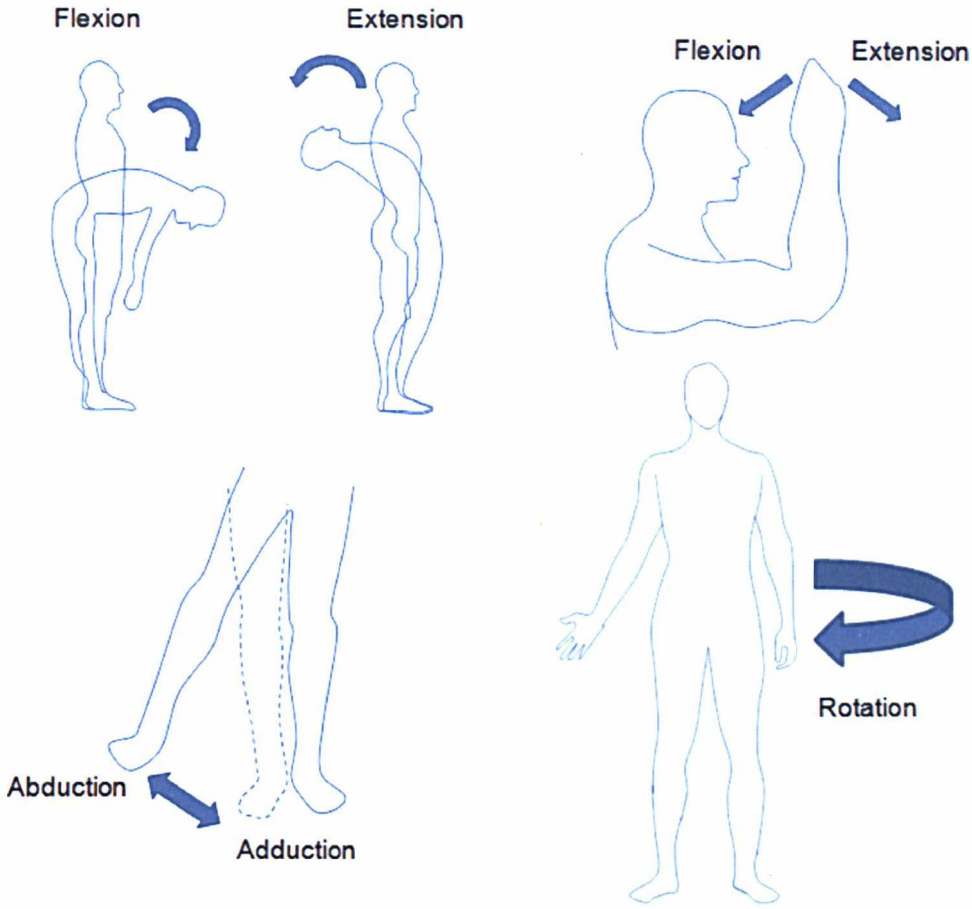


Figure 3.8 *Anatomical terms used to describe basic movements of the human body.*

A number of tools are available in the biomechanical assessment of movement including observational analysis systems (describing a movement based on a pre-determined framework) [153], mechanical video analysis systems (using film qualitatively and quantitatively) [154], and the use of visual tracking systems such as three-dimensional optical motion trackers [155]. Joint range can also be measured using goniometers which may be hand-held, Electronic or Optoelectronic [156]. The forces generated by muscles can be determined using force plates, or the pressure generated detected using pressure plates on in-shoe devices particularly when detecting the distribution of force or pressure during walking [157, 158]. Electromyography (EMG) can be used to detect phasic muscle activity during complex movements [159]. Accelerometers have been attached to limbs to measure acceleration during gait and activity analysis by attaching them to the limbs, and gyroscopes have been used to measure angular velocity and acceleration during gait analysis [160]. The challenges with these sensors is achieving strong fixation to the body in order to obtain accurate data.

The use of biomechanical markers to determine and quantify activities of daily living and mobility in the home setting may form the basis for a pervasive post-operative monitoring system to measure functional recovery. In essence these would act as surrogate markers for functional recovery following surgery. In order to capture this information, a wireless BSN platform and wearable pervasive device comprised of the appropriate sensor types is required. The next two sections of this chapter focus on these aspects and describe them in more detail.

3.5 Sensor Node Design for Pervasive Functional Recovery Monitoring

In order to develop a system that is truly pervasive and ubiquitous in its measurement of post-operative functional recovery in the home environment, a specialised BSN architecture and sensor node design is required. This section describes the Imperial College BSN sensor node, its architecture, operating system, wireless communication, and power management components that form the basis for the pervasive home recovery monitoring system developed in this thesis [11]. It also goes on to describe the sensor types that were chosen as part of this system to objectively measure parameters of functional recovery with accompanying changes in physiology occurring in the post-operative period. Finally an ear-worn activity recognition (e-AR) sensor encapsulating all these components is presented as the wearable BSN device used to monitor post-operative recovery in the next five experimental chapters in the thesis.

3.5.1 System overview

The fundamental component of the Imperial College BSN architecture is the '*BSN node*', which allows multiple body-worn sensors to be wirelessly connected to each other and to a local processing unit (LPU) that can send information at the required intervals to a centralised patient database via a wireless local area network (WLAN) or mobile phone network. Figure 3.9 is a diagrammatic representation of this BSN system in which three BSN node-sensor complexes are depicted as collecting data on a patient. To illustrate how this system may work, let's assume that the wrist-worn sensor measures heart rate, the ear-worn sensor is a pulse oximeter measuring oxygen saturation, and the chest-worn sensor records continuous electrocardiography (ECG). In the event that a patient experiences a tachycardia (heart rate >100 beats per minute), the wrist-worn BSN node may communicate with the ear-worn and chest-worn nodes to activate their sensors and start collecting and processing data. This data would be sent to the LPU which would process it further before sending it on to a central

patient monitoring server. An alarm could be triggered here resulting in a clinician being alerted and able to monitor the patient's progress on a workstation and take action as necessary. Such a system would not only allow the capture of this type of episodic event, but would also allow it to be closely studied in real-time so that action could be taken to treat the cause sooner. The ability to monitor the patient in this way is missing in the vast majority of existing home monitoring systems.

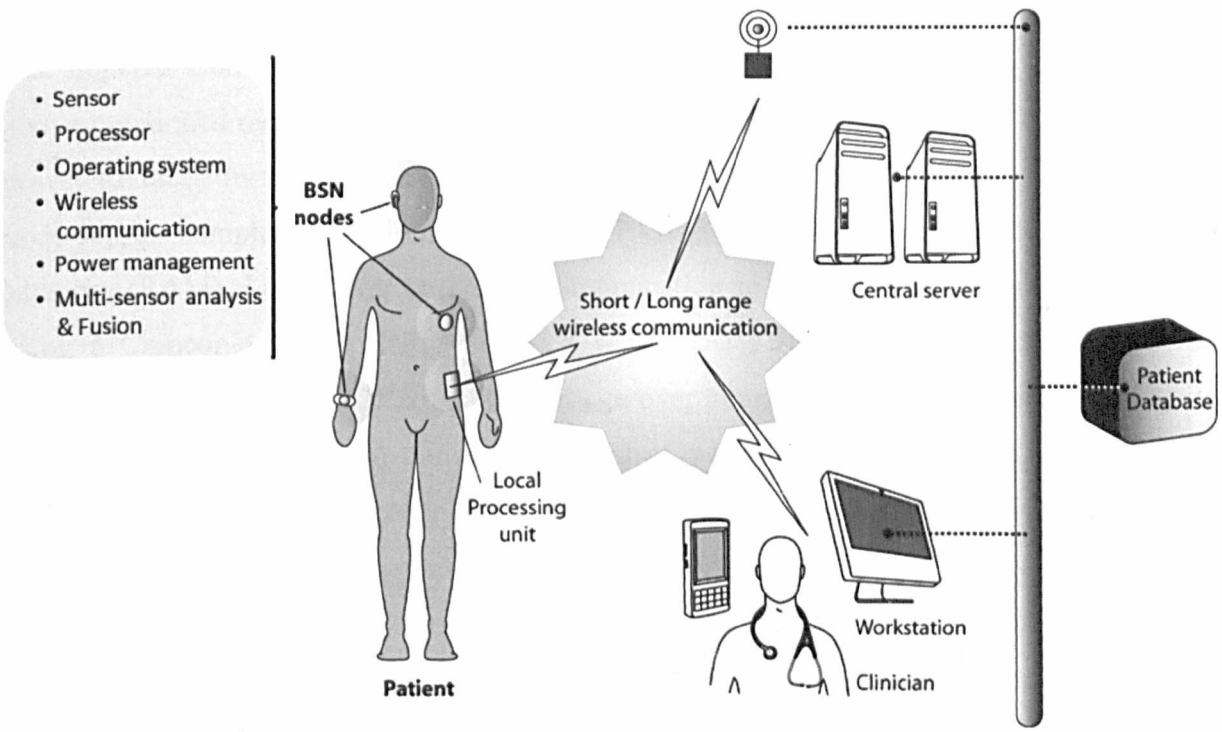


Figure 3.9 *A diagrammatic representation of the BSN system worn by the patient and connected wirelessly to central servers where this information can be accessed by the clinician.*

3.5.2 Key features

In order to be integrated into a wearable device, the Imperial College BSN node needs to fulfil the following requirements:

- Low power consumption, thereby reducing the size of battery required and also the frequency with which it needs to be recharged. This entails not only a low power processor, but also an energy efficient operating system and wireless communication.

- Compact and lightweight design, thereby reducing the overall size of the wearable device that is ultimately meant to be pervasive and hence almost forgotten by the patient as they carry out their normal activities.

- Flexible sensor interface allowing the node to be combined with a number of sensor types, thereby providing a versatile environment for developing wireless sensing applications.

- Sufficient memory for storage of sensor data and to perform 'on node' processing, thereby reducing the quantity of sensor data transmitted, and also the energy cost of transmitting this data wirelessly.

The Imperial College BSN node has the following key attributes that allow it to fulfil the above-mentioned requirements: It comprises of a Texas Instruments MSP430 16-bit ultra low power Reduced Instruction Set Computer (RISC) processor that acts as the 'brains' of the node-sensor complex, containing 60KB+256B flash memory, 2KB of Random Access Memory (RAM). Low power wireless communication to link the sensor nodes is provided using a Chipcon CC2420 (IEEE 802.15.4 compliant) 2.4GHz wireless radio transceiver, which has a throughput of 250kbps and a range over 50m. Typical BSN applications require relatively short-range (2-3m) transmission, and as a result a dipole antenna is suitable for most BSN applications. The operating system used to manage the network and its resources in TinyOS, a small, open source and energy efficient sensor board operating system developed at UC Berkeley. TinyOS manages both the hardware and the wireless network, taking sensor measurements, making routing decisions, and controlling power dissipation. As a result of this, the BSN node requires 0.01mA in active mode and 1.3mA when performing computation intensive calculations. Figure 3.10 shows the compact and lightweight design of the BSN node on a circuit board.

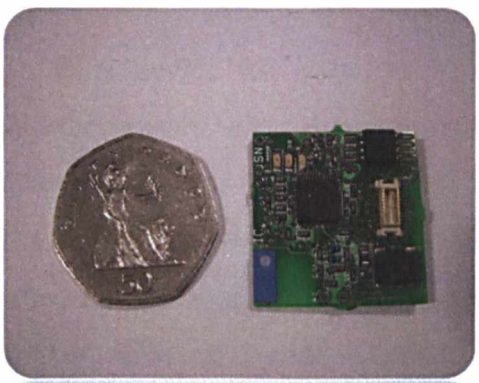


Figure 3.10 *The Imperial college BSN node comprising of the above-mentioned components on a circuit board (right) compared in size to a fifty pence coin (left).*

3.5.3 Sensor selection

As discussed in the previous section, the BSN node has been designed so that it may be combined with a number of different sensor types. Figure 3.11 below shows the node connected to a 3-lead ECG sensor worn on the anterior chest wall, a trunk accelerometer worn as a strap around the chest, and a finger-worn pulse oximeter. Whilst each of these sensors offers important clinical information that may be of use in the post-operative period, when designing a pervasive home monitoring device it is important to choose sensors that measure parameters relevant to the type of recovery being monitored, are small and therefore lightweight, have low power consumption, and are placed at a site which is unobtrusive to normal daily activities. The device containing the BSN node-sensor complex also has to be easy to wear, and should have a battery life that allows it to be worn for significant periods of time. For this purpose, it is desirable to have a single device encapsulating the BSN node and multiple sensor types, as it is likely that multiple devices will be accompanied by a poor patient compliance.

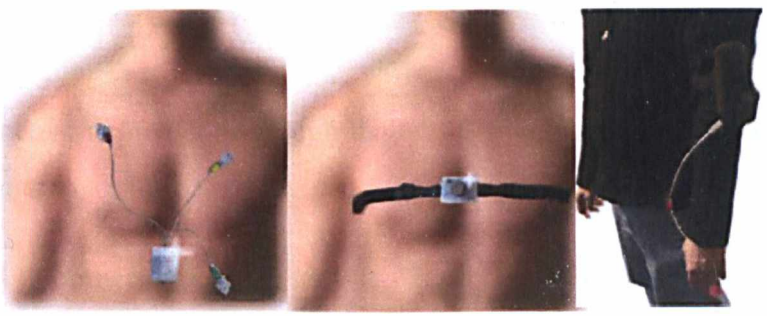


Figure 3.11 *Common sensors that may be used with a BSN, namely 3-lead ECG (left), trunk accelerometers (centre), and finger-worn pulse oximeters (right).*

In the case of developing a BSN device for post-operative home functional recovery monitoring, it is important that the sensors selected can measure biomechanical parameters that can be related to ADLs and mobility. It is also important to select sensors that offer some physiological information that is relevant to the types of activity being monitored. Two sensors that have been identified for this role during the research undertaken for this thesis are *accelerometers* to measure biomechanical aspects of measures of functional recovery, and the *pulse oximeters* to monitor the patient's HR and SpO_2 during this activity. Both these sensor types are considered in turn and described in more detail in the following two sections.

3.5.4 Using accelerometers to monitor functional recovery

Accelerometers are electromechanical devices that measure applied acceleration forces along an axis. Whilst there are a number of different mechanisms by which this acceleration is measured, accelerometers can be classified as either requiring an external power supply or not, and either responding to static accelerations or not. Modern accelerometers are mostly micro electro-mechanical systems (MEMS) devices, comprising of a cantilever beam with a proof mass (also known as seismic mass). Mathie et al (2004) have identified a number of features of accelerometers that are desirable in the monitoring of human movement [161]:

- They respond to both the frequency and intensity of movement, and as a result are superior to actometers or pedometers, which are attenuated by impact or tilt.
- They can be used to measure tilt as well as body movement, making them superior to motion sensors that are unable to measure static characteristics.
- Advancements in MEMS technology mean that accelerometers can be miniaturised and manufactured at very low cost.
- Accelerometers demonstrate a high degree of reliability in their measurements, with little variation over time.
- Compared to other types of sensors, accelerometers have relatively low power consumption.

The above-mentioned characteristics make accelerometers suitable components for small and lightweight wearable devices that may be considered pervasive would not impair activities of daily living. As a wearable sensor, the accelerometer has been used extensively in the evaluation of gait. Kavanah et al (2006) studied the reliability of a wearable gait analysis system comprising of accelerometers worn on the head, over the spine, and on the ankle [162]. Whilst the accelerometers were battery powered and attached to each other through wires, these were connected through a processor box which transmitted the data to a receiver via a blue-tooth module as shown below in Figure 3.12. Authors reported a high degree of waveform repeatability in their results, suggesting that such a system may be used in the analysis of gait over a short period of time. It is however difficult to see how such a system may be practically used to monitor the activity of post-operative patients over a period of days.

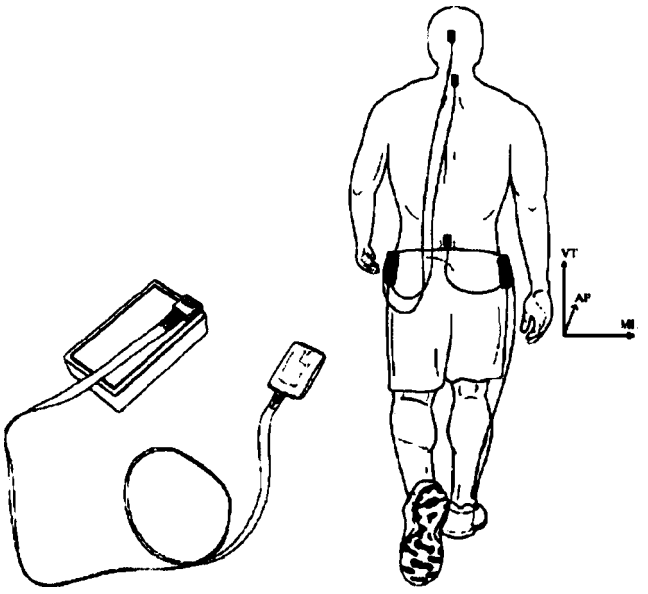


Figure 3.12 *The sensor system described by Kavanah et al (2006) which consisted of three triaxial accelerometers, each connected to a processor box worn on the subject's waist. The accelerometers were fixed to the head, C7 spinous process, L3 spinous process, and the lateral malleolus of the ankle.*

Accelerometer based systems have also been used to evaluate changes in gait that occur in patients with neurodegenerative disorders such as Parkinson's and Alzheimer's disease. In these populations, such sensors have been proposed to monitor the decline in motor function that takes place over time. An example of this is WAMAS, a 'Wearable Accelerometer Motion Analysis System' developed at Stanford University Medical School comprising of a system of accelerometers attached to the head, waist, and other parts of the body, connected to each other through a series of wires [163]. Limitations of this system that would preclude it from monitoring post-operative patients include its size and energy requirements.

Finally, wearable accelerometer systems have been used to monitor the activity and gait of vulnerable patient groups such as the elderly, patients recovering from stroke, and those with conditions such as chronic obstructive pulmonary disease (COPD). Menz et al (2003) used the output from accelerometers strapped to a head-worn helmet and on a belt at the level of the sacrum in elderly subjects between the ages of 75 to 93 years, to determine their stability under challenging conditions. Whilst this is of interest as a research tool, there are likely to be some challenges that would need to be overcome should this technology be of use in the real home setting [164]. Hauber et al. (2004) used an ankle-worn 'Step-watch Activity Monitor' (SAM) comprising of an accelerometer linked to a microprocessor and a hip mounted accelerometer to determine the stride counts and calorific expenditure of patients recovering

from stroke during the day whilst at home [165]. Boissy et al (2007) have described the use of accelerometers, gyroscopes, and load cells, to evaluate the correct use of mobility assist devices such as canes by stroke patients [166]. Okeefe et al (2007) have described the use of hip-worn gyroscopes and accelerometers which monitor the periodic vertical rotation of the pelvis during the walking cycle, and using this information as a predictor of gait events. Finally, Casaburi (2007) describes the use of a number of accelerometer based systems to monitor activities of daily living and energy expenditure in patients with COPD [167], and Sherill et al (2005) have described techniques to classify the motor activities of COPD patients undergoing pulmonary rehabilitation from wearable accelerometer sensor data [168].

As sensors, accelerometers offer the potential to evaluate post-operative activity and to assess mobility in the unsupervised home environment. As previously mentioned, these parameters are an important part of post-operative functional recovery that are currently very difficult to measure objectively.

3.5.5 Using pulse oximeters to monitor activity-related physiology

Pulse oximeters are sensors that measure the differing absorption spectra of oxyhaemoglobin and deoxyhaemoglobin in an arterial pulse signal [169], and use it to calculate oxygen saturation (SpO_2) and heart rate (HR). Both oxyhaemoglobin and deoxyhaemoglobin absorb light over a range of wavelengths, but their absorption spectral peak is at 660 nm (red light) and 940 nm (infrared) respectively. Pulse oximeters consist of two light-emitting diodes (LEDs) which emit light at these frequencies. A photoreceptor placed on the opposite side to the LEDs records the transmitted light and generates the sensor signal output. The tissue to be measured, for example the finger, is placed between the LEDs and photoreceptor and a signal processor is used to compare the ratio of absorption of the two spectra against a stored set of reference values where both the absorption spectra ratios and direct arterial oxygen content are known.

When interpreting results from pulse oximetry, it is important to consider the relationship between SpO_2 and partial pressure of oxygen in blood (pO_2), which is determined by the affinity of haemoglobin (Hb) to oxygen (how readily it acquires and releases oxygen molecules). This relationship is best described in the sigmoidal 'haemoglobin-oxygen dissociation curve shown below in Figure 3.13, that occurs as a result of the increasing affinity of Hb to oxygen molecules as it binds them. The curve describes the relation between

the pO_2 (x axis) and SpO_2 (y axis), and shows that as Hb reaches its limit of binding 4 oxygen molecules, very little additional binding occurs and the curve levels out. At this point the haemoglobin becomes saturated with oxygen, giving the curve its sigmoidal shape. It is important to note that as the SpO_2 value drops below 90% (which should always be considered abnormal), a relatively small fall is SpO_2 results in a large fall in pO_2. Normal values of SpO_2 in healthy individuals would be expected to be between 95 and 100%.

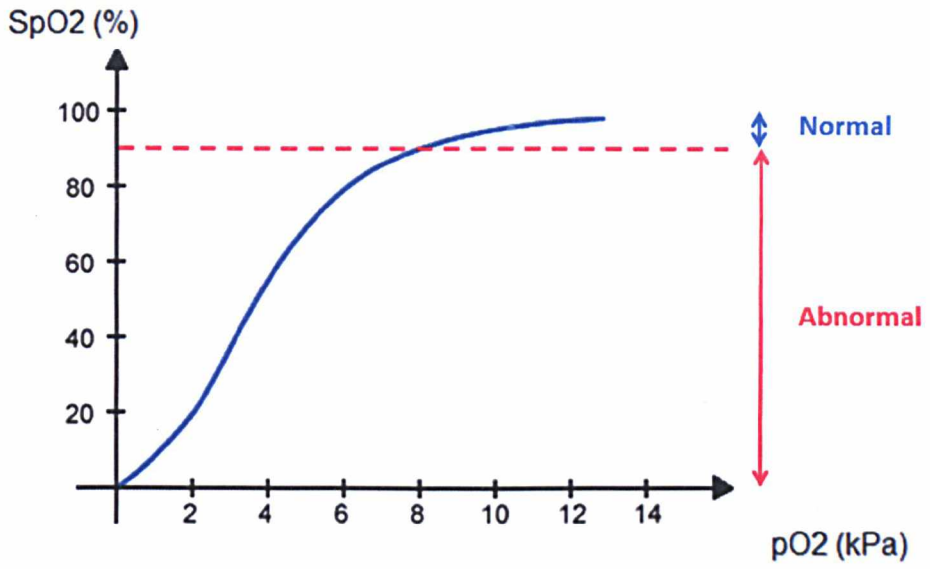


Figure 3.13 The sigmoidal haemoglobin-oxygen dissociation curve. It can be seen that there is little variation in the pO_2 between SpO_2 values of 90-100% (above the dotted line). Below this a small drop in SpO_2 results in a large drop in pO_2.

Pulse oximetry has now become a widespread, non-invasive and reliable method of determining information about patients' blood oxygen levels, and is a part of most acute hospital patient monitoring systems [170, 171]. SpO_2 is an important parameter to measure in the post-operative patient group because a fall in its value may be the earliest manifestation of complications such as lung collapse, infection, wound pain, or pulmonary embolism. A 2003 Cochrane systematic review of 21,773 patients being monitored in the peri-operative period, has shown that pulse oximetry is able to accurately detect hypoxia and its related events in this patient group [172]. As a result of this and other similar evidence, the use of this sensor to monitor patients during the peri-operative period has become part of mainstream clinical practice in hospitals across the world. The ability of pulse oximeters to measure HR is also important in the post-operative patient group, as a rise in resting HR to a value greater than 100 beats per minute (a tachycardia) may be the first manifestation of

cardiac, respiratory, or infective complications that if identified and treated early, could prevent morbidity and mortality [173]. In the home setting, pulse oximetry has been used to monitor night-time HR and SpO_2 of patients who are suspected of having obstructive sleep apnoea, and is an important part of diagnosing the condition [174]. To date however, the use of pulse oximetry to continuously monitor post-operative patients at home has not been routinely possible because of infrastructure required to setup such a system.

In order to develop a system that uses ambulatory pulse oximetry to monitor patients at home, it is important to consider the limitations of this type of sensor. First, factors that negatively affect the absorbance characteristics of pulse oximetry or alter its signal-to-noise ratio can result in inaccurate readings. These include *skin pigmentation* (darker skin colour), the presence of *nail polish* or dirty nails, *jaundice*, and the presence of *dyshaemoglobins* in the bloodstream (carboxyhaemoglobin and methaemoglobin) [175]. In absolute terms, these have all been shown to result in over-estimation of oxygen saturation and hence a 'falsely favourable' reading [176]. Second, factors that result in a low signal-to-noise ratio have also been shown to increase pulse oximeter inaccuracy through either high background noise or low pulsatile signal. High background noise may be cause by *bright ambient light* [177], or the presence of *motion artefact* [175]. The latter is a common problem, and has been shown to result in reduced accuracy, loss of signal, false desaturation alarms, and missed hypoxic events in patients [178]. Low pulsatile signal most frequently occurs with finger-worn sensors, and is cause by *low tissue perfusion* resulting in poor blood supply to the peripheries [175]. Strategies that have been developed by a number of pulse oximeter manufacturers to overcome this include not only improved sensor design, but also improved signal processing algorithms and signal extraction techniques [179]. Finally, *finger size* has been shown to be associated with pulse oximeter bias, making the case against sensor placement on this site, especially in the ambulatory setting [176]. As a result of these limitations, pulse oximetry is unlikely to provide accurate information on post-operative physiological recovery on its own. The ability to determine resting HR and SpO_2 during periods where movement artefact is absent however, would allow the determination of patients' physiology during the functional recovery. Combined therefore, an accelerometer and pulse oximeter sensor would complement each other as part of a pervasive monitoring system for functional recovery.

3.6 The ear-worn activity recognition (e-AR) sensor

The ear-worn activity recognition (e-AR) sensor is a wearable BSN device that encapsulates many of the features required for pervasive home monitoring of functional recovery. The device comprises of an Imperial College BSN node, its battery power supply, a three-dimensional accelerometer, and a pulse oximeter all of which are enclosed within a casing that is designed to be worn on the outer ear [180]. Figure 3.14 shows the e-AR sensor casing that houses all its individual components. The device also has an 'earlobe clip' that houses the pulse oximeter's LEDs and photoreceptors that are used to detect an arteriole pulse in the earlobe thereby calculating HR and SpO_2.

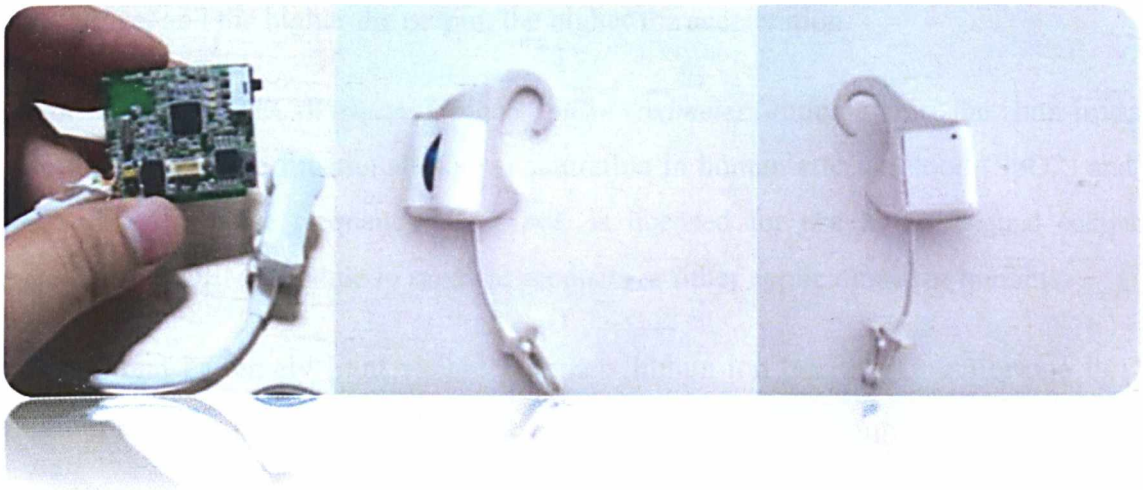


Figure 3.14 *The e-AR sensor comprising of a BSN node connected to an ADXL330 accelerometer, ChipOx© pulse oximeter with ear clip and power supply (left). The device casing itself that is designed to be worn on the outer ear (middle and right).*

3.6.1 Key Components

Embedded within the e-AR sensor are the following key components:

- *Analog Devices ADXL330 3-axis MEMS accelerometer* which records movement relative to the X, Y, and Z Cartesian axes previously described. The ADXL330 is a small, thin, low power, complete 3-axis accelerometer with signal conditioned voltage outputs, all on a single monolithic IC. The product measures acceleration with a minimum full-scale range of ±3 g. It can measure the static acceleration of gravity in tilt-sensing applications, as well as dynamic acceleration resulting from motion, shock, or vibration. Bandwidths can be selected to suit the application, with a range of 0.5 Hz to 1600 Hz for X and Y axes,

and a range of 0.5 Hz to 550 Hz for the Z axis. The ADXL330 is available in a small, low profile, 4 mm × 4 mm × 1.45 mm, 16-lead, plastic lead frame chip scale package (LFCSP_LQ). The ADXL330 contains a polysilicon surface micromachined sensor and signal conditioning circuitry to implement an open-loop acceleration measurement architecture. The sensor has a polysilicon surface micromachined structure built on top of a silicon wafer. Polysilicon springs suspend the structure over the surface of the wafer and provide a resistance against acceleration forces. Deflection of the structure is measured using a differential capacitor that consists of independent fixed plates and plates attached to the moving mass. Analogue to Digital Conversion (ADC) of this data results in *x*, *y*, and *z* axis accelerometer channel outputs ranging from 0-4096, representing 0-3V. The higher the voltage, and the higher the output, the higher the acceleration.

- *ChipOx® (ENVITEC-Wismar GmbH) pulse oximeter* module for the non-invasive determination of the functional oxygen saturation in human arterial blood (SpO2) and for measuring the pulse frequency. ChipOx® is licensed for use as an original equipment manufacturer (OEM) module in medical products or other applications for humans.

- A small and extremely light weight polymer lithium-ion battery (Unionfortune 041528 Lithium-polymer battery).

Figure 3.15 below shows the BSN node, pulse oximeter module, and battery power supply housed within the e-AR sensor casing.

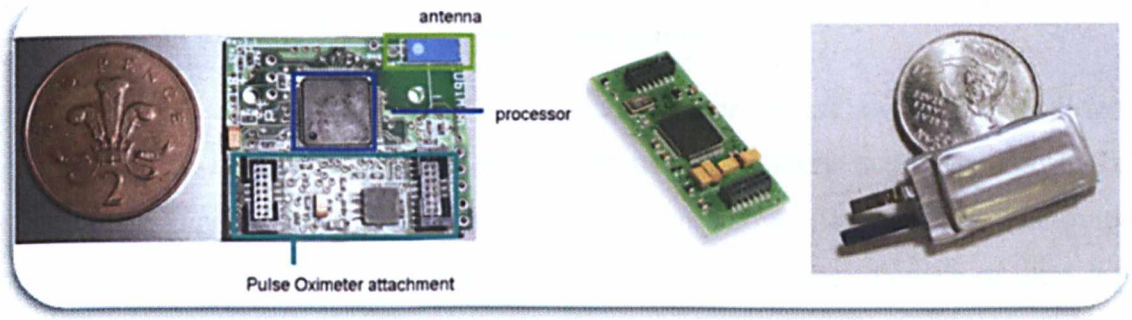


Figure 3.15 *e-AR sensor components: the BSN node on a circuit board (left), MCC ChipOx® pulse oximeter module (centre), and light weight polymer lithium-ion battery (right).*

Features that have been incorporated in the e-AR sensor's design to make it suitable for pervasive home monitoring include a small size, lightweight design, and use of the ear as the site of sensor placement because this leaves the hands, arms, and legs unimpeded for the

patient to carry out their normal daily activities. In addition to this, the ear is likely to be an acceptable site for sensor placement because of the widespread use of a number of other ear-worn devices in daily life including mobile phone wireless (Bluetooth) headsets and hearing aids. Figure 3.16 below shows the e-AR sensor being worn by a volunteer subject. It can be seen that the majority of support to the device is provided by the ear cartilage, although a pulse oximeter probe is then clipped to the earlobe to maintain apposition between the earlobe capillary bed and the sensor. The device is completely supported without the need for any adhesives and is aimed to be easy to wear and independent from the limbs. Both these factors are aimed at minimising the disruption to daily life caused by the sensor and maximise compliance in patients recovering from surgery at home.



Figure 3.16 *Wearing the ear-worn activity recognition sensor by hooking it around the base of the ear cartilage and clipping the pulse oximeter sensor on the earlobe.*

3.6.2 The head as a site for accelerometer placement

The arrangement of the three-axis MEMS accelerometer on the e-AR sensor allows the determination of head displacement three dimensions, namely x (anterior/posterior), y (medial/lateral), and z (superior/inferior) axes in shown below in Figure 3.17. The output of the accelerometer reflects its orientation which is controlled by the subject's posture, type of activity being performed, and its intensity [84]. Whilst a uni-axial accelerometer records accelerations in a single direction, a triaxial accelerometer acts along three orthogonal axes and so can provide a picture of acceleration in three dimensions. At rest, the output of accelerometer is determined by its orientation relative to the gravitational vector. As a result, provided that the orientation of the accelerometer relative to the subject is known, the e-AR sensor can be used to determine the orientation of the subject. This is very important for

determining static activities such as lying down and sitting in the home environment. A disadvantage of accelerometers however, is that they are sensitive to movement artefact particularly as they move relative to the skin and parts of the body.

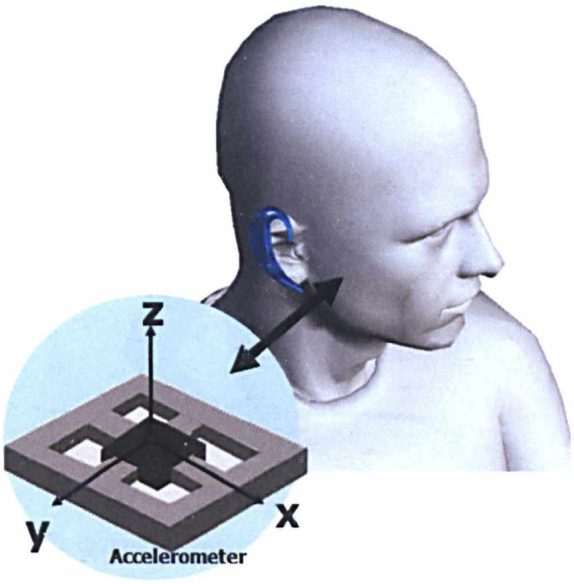


Figure 3.17 *The X, Y, and Z accelerometer axes in the e-AR sensor.*

The head is a good site for accelerometer placement when trying to determine the amount or type of activity that a subject is performing because as a whole, its position corresponds well to the position of the body. A good illustration of this is that when a patient is lying down, sitting still, or resting, the head remains relatively static and in alignment with the rest of the body, whereas the arms and legs may still move independently from it. This has been supported in a paper by Kavanah et al. (2005) who found accelerations of the head to be more tightly controlled compared to accelerations of the lower trunk during activity [181]. As a result, when designing a single BSN device to determine overall body position and activity, placing an accelerometer on the head was thought to be most likely to discriminate between types of activity compared to placing it on the limbs.

3.6.3 The ear-lobe as a site for pulse oximeter placement

A number of different sites have been proposed for pulse oximeter sensor placement, with the most popular sites in clinical practice being the earlobe [182], forehead [183], and finger [184]. All these sites have a rich capillary blood supply that helps in accurately determining oxygen saturation with pulse oximetry. Figure 3.18 shows some potential sites for sensor placement that have been used with varying success.

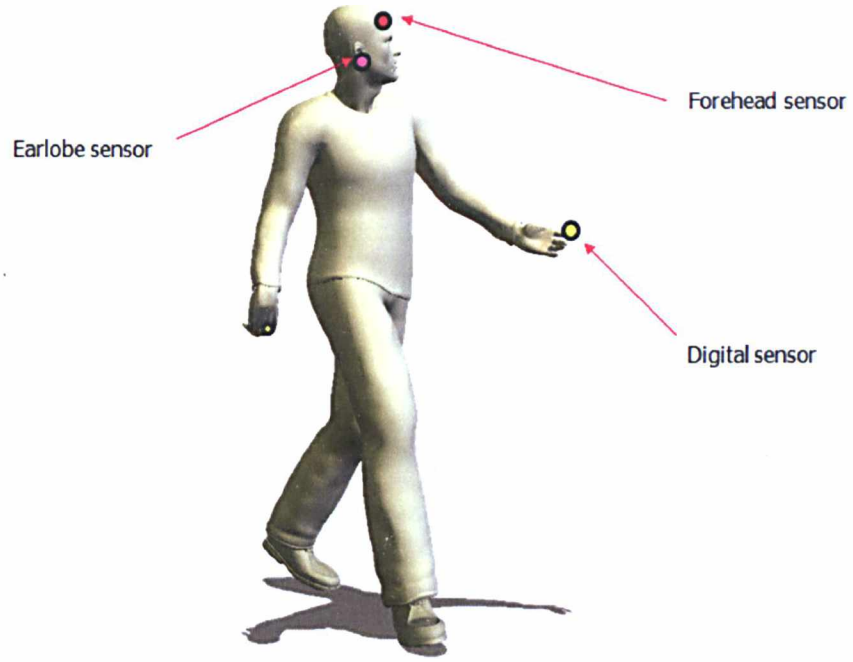


Figure 3.18 *Common sites for pulse oximeter sensor placement in clinical practice.*

In the case of ambulatory (wireless) pulse oximetry, there are limitations to some of these sites. The finger for example, is not a site where wearing a sensor is practical during daily life, mainly because it prevents adequate use of the hand. To that extent, the forehead is a better site for sensor placement, but requires the use of adhesives and is not cosmetically acceptable for patients to use outside the hospital. The ear is therefore the most acceptable location for sensor placement because it frees up the use of the hands and also an appendage onto which a sensor can be attached without the need for adhesives. It is also a relatively stable part of the body, unlike the limbs which move even when at rest. Finally the skin at the ear is often less pigmented and thinner, making the measurement of pulse oximetry more accurate.

3.6.4 Regulatory approval

In order to undertake the experiments outlined in this thesis testing the ability of the e-AR sensor to monitor functional post-operative home recovery following surgery, regulatory approval for the use of the device in volunteers and patients had to be obtained from the Medicines and Healthcare products regulatory agency (MHRA). This approval for the e-AR sensor was granted for the protocols outlined in the experimental chapters of this thesis. The e-AR sensor is categorised by the MHRA as a Class I device (CI/2007/0043) for human use.

During the course of the experiments there were no adverse incidents that required notification to the relevant authority.

3.7 Conclusions

This chapter has described the technological, clinical, and socioeconomic trends in modern surgical practice that have led to earlier discharge from hospital following an operation, and highlighted the need for pervasive post-operative recovery monitoring in this setting. The different types of recovery that a patient may experience have been classified into biological, physiological, functional, and psychological categories, with means of monitoring these explored. Functional recovery has been identified as a good global indicator of a patient's progress, and in particular activities of daily living and mobility as measures of functional recovery that could be monitored objectively and pervasively in the home environment. Current systems for monitoring ADLs and mobility including questionnaires, indices, and podometers have been reviewed and their limitations precluding them from forming part of a pervasive monitoring system outlined. Identifying biomechanical markers of activities of daily living and impaired mobility, and the sensor types that may be used to objectively measure these is vital if post-operative functional recovery is to be measured pervasively in the patient's home.

Miniaturised sensors, accelerometers are well suited to the measurement of biomechanical markers pervasively as they are relatively accurate, and consume little energy. Pulse oximetry has also been suggested as a means of measuring activity-dependent heart rate and oxygen saturation, giving an indication of the patients' resting physiology. A sensor node design and a wireless BSN are proposed as the platform for capturing this information and an ear-worn activity recognition device described as the wearable sensor that may be used by the patient at home during their post-operative recovery period. Understanding the biomechanical parameters that need to be measured and testing the ability of the e-AR sensor to capture these before they are analysed and converted by appropriate frameworks into surrogate biomarkers of functional recovery are the focus of the experimental chapters of this thesis.

4 Home Activity Monitoring

4.1 Introduction

A patient's return to their normal activities of daily living (ADLs) is one of the best global indicators of functional recovery following surgery, yet as mentioned in Chapter 3, the objective measurement of this parameter in the home environment remains a real challenge. Amongst the number of activities that a patient may undertake in their homes, there are some ADLs that they must be able to undertake effectively in order to be considered independent [150]. Assessing a patient's ability to undertake these activities is therefore an extremely important part of valuating a patient's post-operative recovery:

- Going from *sitting-to-standing (STS)* position is a key requirement for a patient to be mobile, and is predominantly a lower limb activity. Use of the upper limb during STS is helpful and can reduce the force required from the extensors of the hip and knee during STS by up to 50% [185]. It has been shown by Mak et al (2003) that the energy requirement for STS are greater than that needed for walking because the relevant muscles have to raise the body vertically through a distance of about a metre [186]. The use of accelerometers has been shown by Jansson et al (2008) to provide valid and accurate data on STS movement, its duration, and the body's posture during the activity [187].

- *Locomotion* in the form of *walking* and *running* involves rhythmic, reciprocal and repetition movements of the limbs, cervical, and lumbar spines, and is important for both physical independence and exercise. It also directly prevents complications of stasis such as deep venous thrombosis (DVT). The term 'gait' is used to describe the manner in which walking takes place considering both the kinetics and kinematics of the activity.

- *Use of the upper limbs* in terms of reaching and grasping is important in ADLs involving self care and feeding. In addition to this the upper limb undertakes a series of complex coordinated movements during activities such as brushing your hair or teeth.

- *Lying down* is an ADL that most patients spend a substantial proportion of their day doing and may be face up, face down, or on their side. Going from *lying to standing (LTS)* is an important aspect of a patient's recovery as an inability to do this because of discomfort or lethargy will result in the patient spending a substantial portion of their day in bed.

The only way that ADLs can currently be quantified is through the use of home assessments and questionnaires, both of which are labour-intensive and rely heavily on patient recall [188]. In order to be able to pervasively and objectively measure ADLs in the patient's home, a series of biomechanical markers that are specific to these activities must be identified, and a system to measure and interpret these developed. Such a pervasive post-operative ADL monitoring system would be required to measure the following parameters:

- First, the system must be able to determine the type of activity the patient is undertaking. This may for example include detecting that they are getting out of bed, walking downstairs, preparing and eating meals, and mobilising around their home. Whilst in isolation these may seem to be trivial activities, putting together the amount of such activity that a patient undertakes over their day would give an invaluable picture of their overall function after surgery.

- Second, the system must be able to numerically quantify a patient's home activity so that one time period in their post-operative recovery may be compared to the next. Over the course of a week for example, a patient's daily activity could in this way be compared from one day to the next, and plotted on a graph. This 'functional recovery curve' could be an invaluable patient monitoring tool and would help healthcare professionals caring for patients in the community to target their resources to those needing them the most.

- Finally, the system must be able to identify abnormal periods of inactivity, triggering an intervention such as a home visit or telephone call to further assess the patient. For example finding that a patient is spending all their day in bed and not walking around, strongly suggests a problem in their recovery which could be either physical (e.g. wound pain), psychological (e.g. depression), due to a post-operative complication (e.g. pneumonia). A pervasive monitoring system that detected this and triggered a home visit by a district nurse would begin the process of identifying the cause much

earlier than otherwise possible. In the case of wound pain due to inadequate analgesia, the administration of more pain relief could quickly result in the patient mobilising again, and would prevent further complications.

ADLs are all composed of key biomechanical components that occur in patterns and combinations than may be used to recognise and hence quantify them. For example, human motion during any activity can be *linear* (where all the particles of the body describe equal or parallel paths) or *angular* (also known as rotation). In actual fact, human movement during ADLs involves a combination of the two, with walking serving as a good example of this. During walking, rotational movement occurs across the ankle and then the hip, whilst the trunk moves in a linear manner. The forces generated by muscles can also vary with different activities, as can the muscle groups that are active at any given point during human movement. The pressures, stresses, and strains experiences by the bones, ligaments, muscle tendons, and joint cartilages also change during these activities. In using a head-worn three-axis accelerometer, the e-AR sensor determines the acceleration in the Cartesian x, y, and z direction at any given point during an activity as demonstrated below in Figure 4.1.

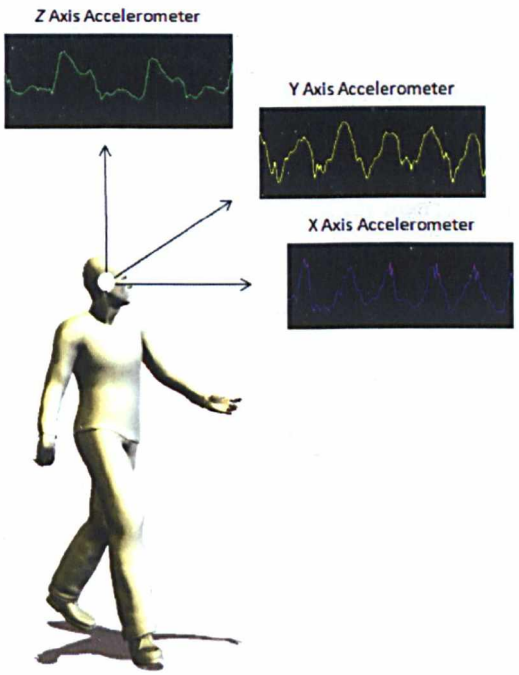


Figure 4.1 *Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk.*

These three biomechanical outputs from the e-AR sensor measured during the course of a patient's day may be used to determine the activities that a subject is performing over a given time period. This chapter tests the hypothesis that: '*The e-AR sensor can be used to measure*

the changes in head acceleration that occur with varying postures and movements during key ADLs. This biomechanical information can then be analysed using an activity classification framework and used as the basis for inferring the ADLs being performed. In this way the biomechanical information captured by the e-AR sensor can be used to objectively quantify functional recovery.'

An experiment comprising of 5 key ADLs was undertaken to determine the biomechanical changes that occur during these activities and correlate them to the accelerometer outputs from the e-AR sensor. An activity classification framework was then used to analyse these biomarkers and tested on a larger dataset of thirty-four activities undertaken in a simulated home environment. In this way, the ability of the e-AR sensor to correctly classify home ADLs was evaluated.

4.2 Materials and Methods

4.2.1 Overview

All participants that that took part in these studies were normal healthy volunteers that were directly approached for recruitment. A pilot study of 8 subjects performing 5 key ADLs that form an important part of any purposeful home activity was undertaken, and used to evaluate the biomechanical components of these activities that could be detected by the e-AR sensor. These biomechanical markers were then used to test an activity classification framework that could determine the activity class that a subject was performing at the time. An activity index that converted these biomechanical markers into a numerical value signifying the intensity of activity being performed was also tested. Having developed an objective ADL classification system, the e-AR sensor and framework were then tested in a larger simulated home environment. A total of 22 volunteers were asked to undertake scenario of 34 ADLs whilst wearing the e-AR sensor.

4.2.2 Pilot study

The pilot test circuit was set up in the Wolfson Laboratory at the Department of Computing (Imperial College London) where healthy subjects (N=8) were asked to undertake 5 ADLs whilst wearing the e-AR sensor namely:

- Moving from sitting to standing (STS)

- Moving from lying to standing (LTS)
- Locomotion: walking at a speed of 2km/h on a treadmill
- Locomotion: walking at a speed of 5km/h on a treadmill
- Locomotion: Running at a speed of 8km/h on a treadmill

Each activity lasted a minute and the transition from one activity to the next was marked as a time-point by the study coordinator. The total time taken to undertake these five activities was therefore approximately 5 minutes per subject.

4.2.3 Simulated home environment

A multi-room simulated home environment was set up in two rooms connected by a corridor at the Institute of Biomedical Engineering at Imperial College London. The first room comprised of a combined living and dining room containing a sofa, plasma screen television, and dining table. The second room comprised of a bedroom area containing a double bed and bedside table; a kitchen area containing a sink, a food preparation surface and a stool; and a bathroom area containing a sink. Subjects (N=22) were asked to undertake a scenario of thirty-four activities in this circuit whilst wearing an e-AR sensor. This aimed to be as realistic as possible to the home environment and contained activities that a recovering patient would be expected to perform there. The activities comprising this scenario and the order in which they were undertaken are shown below in Table 4.1. To ensure that subjects took part in all the relevant activities, they were prompted from one to the next by a study coordinator, with the transition points numerically marked for later data analysis. Figure 4.2 shows the detailed floor plan for this simulated home environment, with the order of the activities performed in each room numerically marked.

4.2.4 Data Collection

The e-AR sensor and the BSN platform used in this study have already been described in detail in Chapter 3. Accelerometer data representing x (forward-backward), y (side-to-side), and z axis (up-down) displacements of the e-AR sensor was collected in volunteers undertaking the experiments, and was wirelessly transmitted through the Imperial College BSN platform to a portable handheld personal computer. The accelerometer in the e-AR sensor had a sampling frequency of 50Hz (1 sample every 20ms) and the pulse oximeter had a sampling frequency of 1 Hz (1 sample per second). This data was automatically placed into a comma separated value (.csv) file which is compatible with Microsoft™ Excel software.

Participants were video-taped and visually monitored as they undertook these studies, with the transition from one activity to the next marked on the accelerometer data collected. This observed validation therefore provided us with 'ground truth' as to what activities were being performed against which to compare the activity classification framework.

Activity No.	Verbal Instruction	Task
1	*Enter the room and switch on television*	Walking
2	*Sit Down on the sofa*	Sitting down
3	*Stand up, change channel and then sit down*	Standing & sitting
4	*Lie down and watch TV*	Lying down
5	*Get up and turn the TV off*	Standing up
6	*Walk to the kitchen*	Walking
7	*Prepare a tray with a glass of water and a banana*	Food preparation
8	*Walk to the dining room table with the tray*	Walking
9	*Sit down, placing your tray in front of you*	Sitting down
10	*Eat the banana*	Eating
11	*Drink the glass of water*	Drinking
12	*Read the paper provided*	Reading
13	*Stand up with your tray and walk to kitchen*	Standing & walking
14	*Throw rubbish in dustbin and wash up dishes.*	Washing up
15	*Using the sink brush your teeth*	Brushing teeth
16	*Walk towards the bed and stand by the side of the bed*	Walking
17	*Take your shoes off*	Taking off shoes
18	*Get into bed and lie down*	Lying down
19	*Wake up, get up and stand by the side of the bed*	Standing up
20	*Put your shoes on.*	Putting on Shoes
21	*Move towards the blinds and open them*	Opening Blinds
22	*Move to kitchen.*	Walking
23	*Prepare a cup of tea/coffee and take a biscuit.*	Food Preparation
24	*Sit down on the stool by the kitchen area*	Sitting down
25	*Eat Biscuit*	Eating
26	*Drink tea / coffee*	Drinking
27	*Stand up and walk towards the door.*	Standing & walking
28	*Open the door, and walk down the corridor*	Walking
29	*Stop at the end of corridor*	Walking
30	*Go to the bottom of the stairs*	Waiting
31	*Climb to the top of stairs turn around and stop*	Ascending stairs
32	*Come down the stairs turn around and stop*	Descending stairs
33	*Climb to the top of stairs turn around and stop*	Ascending stairs
34	*Come down the stairs and stop*	Descending stairs
35	End	End

Table 4.1 *List of activities performed in the simulated home with command and task description.*

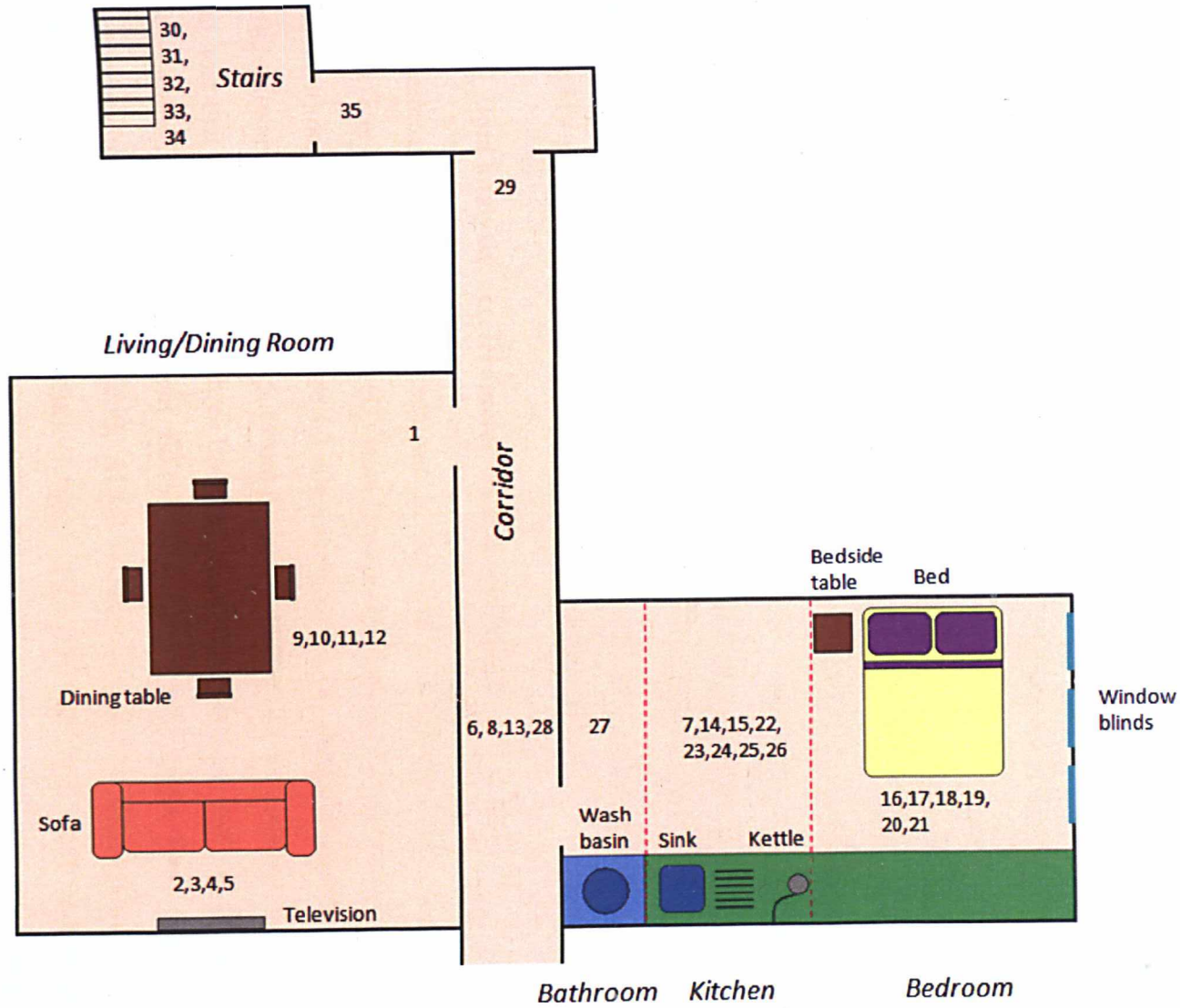


Figure 4.2 *Floor plan of simulated home environment, with activities performed in each room labelled numerically as in table 4.1*

4.2.5 Ethical approval and Informed consent

Ethical approval for these studies was obtained from the Local Research and Ethics Committee (LREC) at St. Mary's Hospital, London, UK. As part of this approval process informed written consent had to be gained from all subjects, who were also given an information sheet regarding the study. As already mentioned, MHRA approval for the use of the e-AR sensor in this study protocol had been obtained.

4.2.6 Participant Questionnaires

The 22 participants who took part in the scenario-based normal activity circuit were asked to complete a 3-5 point Likert scale pre-study questionnaire that was adapted from the Computer Anxiety Rating Scale (CARS-C), the Computer Thoughts Survey Scale (CTS-C), and the General Attitude Towards Computer Scale (GATC-C) [189]. This questionnaire contained seven components and was designed to evaluate the perceptions of the participants to the use of pervasive home monitoring technologies. The composition of this questionnaire and its results are shown in Appendix A. After completing the circuit, the same participants were asked to complete a four-question post-study questionnaire designed to capture participant's feedback regarding the e-AR device and its comfort. The composition of this post-study questionnaire and its results are shown in Appendix B.

4.2.7 Data analysis: accelerometer trace morphology

Accelerometer outputs were visualised in real-time and retrospectively using BSN Signal Editor Version 1.1 software (©Visual Image Processing-VIP Group, Imperial College London) on the tablet PC. Figure 4.3 is a screenshot of the graphical user interface (GUI) for this software displaying the output from the accelerometer on the e-AR sensor. It is important to note that in this figure, the three traces seen represent the x, y, and z displacements of the accelerometer. The BSN Signal Editor colour-codes and labels these traces as ADC0 (representing z axis displacement), ADC2 (representing y axis displacement), and ADC3 (representing x axis displacement). Subjects were observed by a study coordinator as they went performed the activities in the pilot study and scenario-based home activity trial. The transition point from one activity to the next was clearly 'marked' by the coordinator using a utility incorporated into the BSN Signal Editor (©VIP Group, Imperial College London) software. This ability to mark the data was very important as it later served as a means of validating the results of the activity classification techniques described later on in this

chapter. Marking the data also meant that the accelerometer output for particular activities could be extracted and analysed separately.

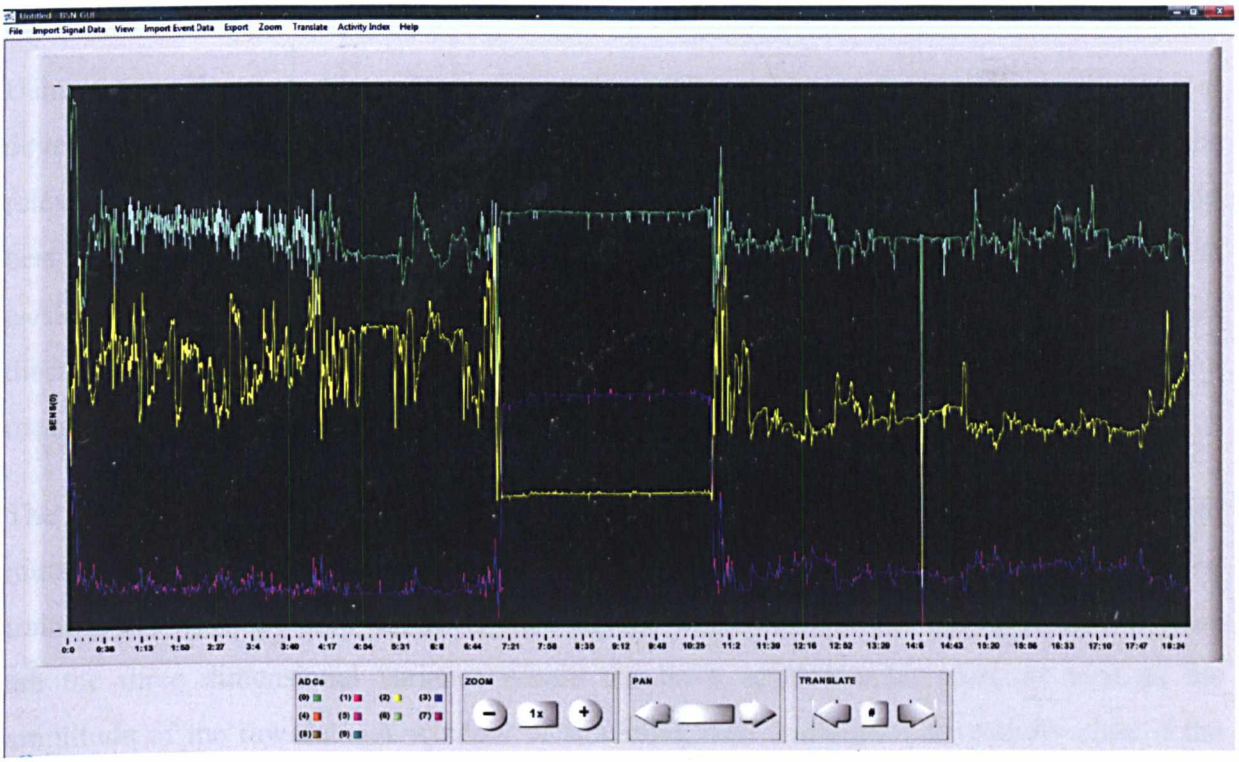


Figure 4.3 *BSN Signal Editor Version 1.1 graphical user interface (GUI) used in this study demonstrating accelerometer outputs from Z (ADC0-top trace), Y (ADC2-middle trace) , and X (ADC3-bottom trace) axes.*

4.2.8 Data analysis: Activity classification and Index

In order to be able to classify the activity that a subject was undertaking at a particular time in the pilot study, a Matlab© (Mathworks Inc.) environment based software program developed by Lo et al (2007) [190] was used for data analysis. It has previously been shown that when analysing this type of data, it is important to select relevant features as this can vastly improve the accuracy of activity classification [191] when compared to studies where activity recognition was based on empirical feature selection techniques [192-195]. Given the real-time constraint for feature extraction in the home setting, a number of features of the accelerometer data have been evaluated and include:

- Signal energy
- Signal RMS (root mean square) value
- Average distance between consecutive peaks
- Troughs

- Zero-crossing
- Number of zero-crossing
- Variance across the 3 axes

Using the accelerometer data obtained from the e-AR sensor described in this study, Lo et al developed a Bayesian Framework for Feature Selection (BFFS) technique to rank the relevance of features to different activity classes in order to determine the feature that would best used to differentiate activities for this system. The results of the BFFS as applied to the e-AR sensor accelerometer data showed that 'variance' was the feature that provided the best discrimination among all activity classes. Authors also found that variance provided a good measure of the level of activity of the subject.

The software program developed by Lo et al [190] uses a Bayesian classifier with multivariate Gaussians to model activity classes, presenting an efficient way for off-line training and a fast method to classify and stream real-time data. The inputs to the classifier are the three dimensional variance across the three accelerometer axes, as well as the amplitude of the raw data. A window of streaming data is assigned an activity class if the probability of belonging to this class was more than the probability of belonging to all other classes. The activity classes are assumed to have equal prior probabilities. To enhance the accuracy of the classification, the signal amplitude is used to identify static activities (such as lying down or sleeping), and the classifier is used to determine other dynamic activities (such as running and walking). Finally for the purposes of objective classification, the software allows activities to be groups into four groups, namely 'very low' (Class 0), 'low' (Class 1), 'medium' (Class 2), and 'high' (Class 3) level activities. Appendix C is a technical paper that further describes the classifier developed by Lo et al. The overall intensity the activity being undertaken was determined using an 'Activity Index' calculated from the averaged variance across the 3 accelerometer outputs. The value of the activity index ranged from 0-15 with a greater value signifying a greater amount of movement and hence a more active type of activity.

4.3 Results

4.3.1 Pilot study: biomechanical evaluation of ADLs

Data was successfully collected using the e-AR sensor from all eight subjects taking part in the pilot study. Each of the five ADLs were carefully observed in these subjects using video analysis and related to the corresponding x, y, and z axis accelerometer traces visualised using the BSN Signal Editor. In this way, the biomechanical data obtained from the e-AR sensor was validated against the visualised ground truth data. The results for each of these ADLs are presented in turn below:

4.3.1.1 Sitting to Standing (STS)

The biomechanics of STS were broadly divided into *seated* and *stance phases* as has been previously described [150]. During the seated phase subjects were seen to move their trunk forward and limbs out of the way, thereby moving their centre of gravity forward until it was almost over the feet. During the stance phase the lower limbs were seen to begin to take the weight of the body as the centre of gravity was shifted forwards and upwards until it was in front of the ankle joint. The limbs were then extended until the erect posture of standing was achieved. The seated and stance phases observed during this phase of the study are illustrated below in Figure 4.4:

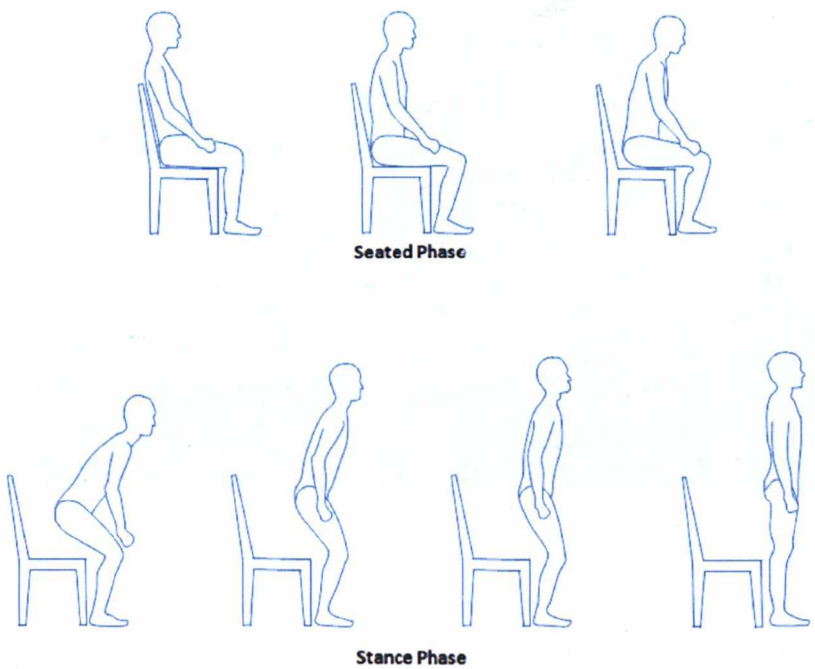


Figure 4.4 *The seated (above) and stance (below) phases of the STS activity*

The accelerometer output from the e-AR sensor and accompanying image of a subject as they go from seated to stance phases of STS is shown below in Figure 4.5. The purple trace represents *x* axis displacement (forward-backward), the green coloured trace represents *z* axis displacement (up-down), and the yellow trace represents *y* axis displacement (side-side) of the sensor. As the body goes from a seated to a standing position, the variance in the accelerometer trace increases with high amplitude 'spikes' representing point where the sudden changes in sensor direction take place.

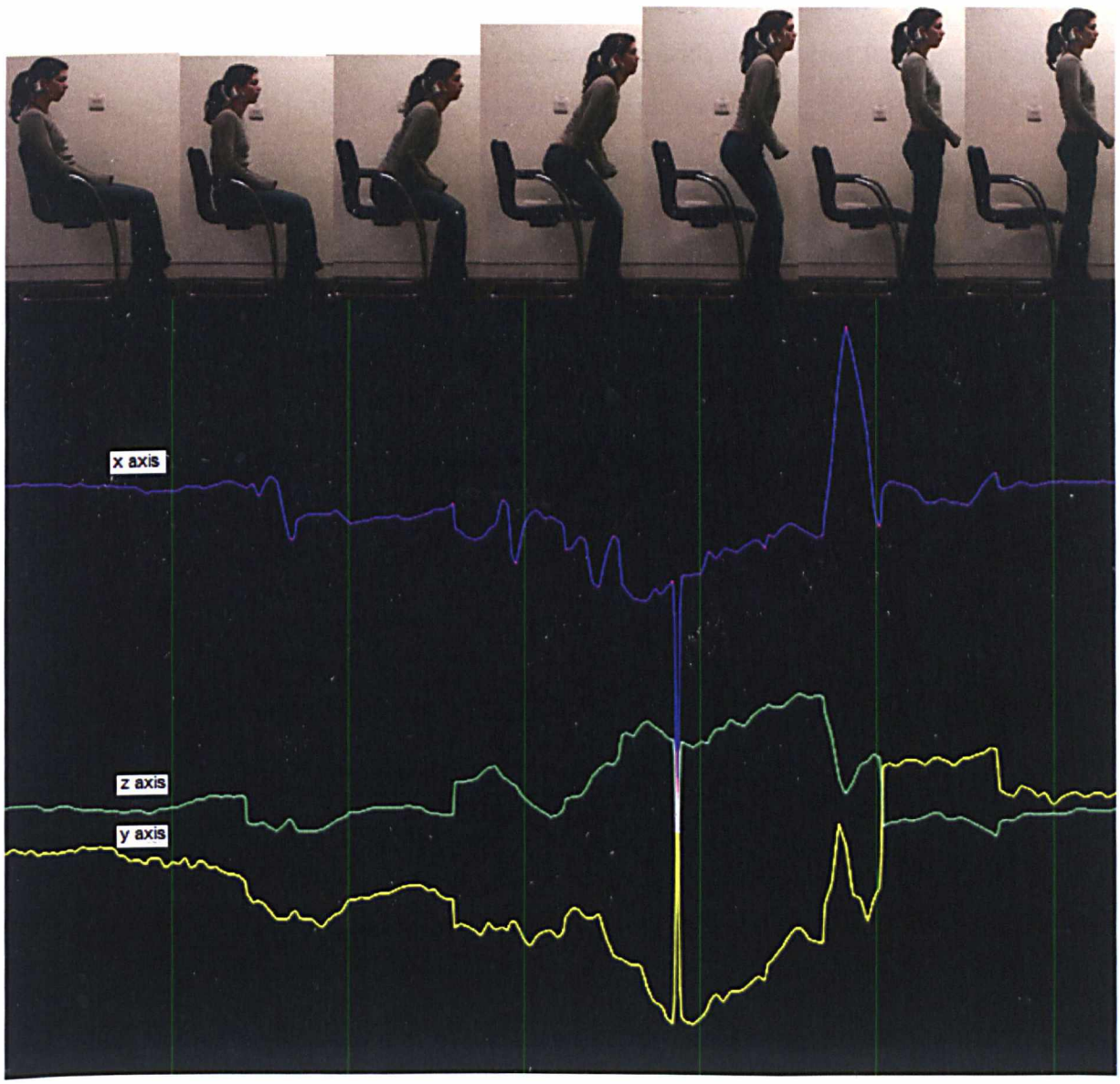


Figure 4.5 *Accelerometer traces showing the transition from sitting to standing positions. The purple trace represents x axis displacement (forward-backward), the green coloured trace represents z axis displacement (up-down), and the yellow trace represents y axis displacement (side-side) of the e-AR sensor.*

The following observations can be made about the movements that take place during STS and the corresponding outputs from the e-AR sensor:

1. When the subject is seated, the variance in accelerometer trace is almost negligible, and the final orientation of the e-AR sensor directly corresponds to the subject's head position. It should be noted that the small variations in accelerometer trace when the subject is at rest are thought to be due to signal noise.

2. As the seated phase begins, the accelerometer output shows how the body is positioned in anticipation of the stance phase with the subject leaning forward. The vertebral column and especially the cervical spine are flexed to carry the head forward and bring the centre of gravity in front of the ankles. The momentum generated during this phase helps the muscles of the leg achieve an upright position.

3. By the start of the stance phase the centre of gravity is seen to be slightly anterior to the ankles. The hip flexors then contract to continue further anterior movement and the anterior abdominal muscles ensure that the trunk follows this movement. There is very little movement seen in the spine during this phase. The forward transfer of weight now occurs with quadriceps and hip extensors ensuring the body's 'lift-off' from the chair. There is passive dorsiflexion of the ankles at this stage. During this phase the movement of the trunk is mainly horizontal.

4. Once the subject's centre of gravity is anterior to the feet, horizontal movement is replaced by vertical movement and the trunk, hips, and knees are extended as the ankle is plantar-flexed.

The converse activity to this is shown in Figure 4.6 where the subject goes from standing to seated with accompanying accelerometer outputs shown. It is important to note that whilst STS is an activity that results in high variance of the accelerometer output, the act of sitting itself is a relatively low variance activity.

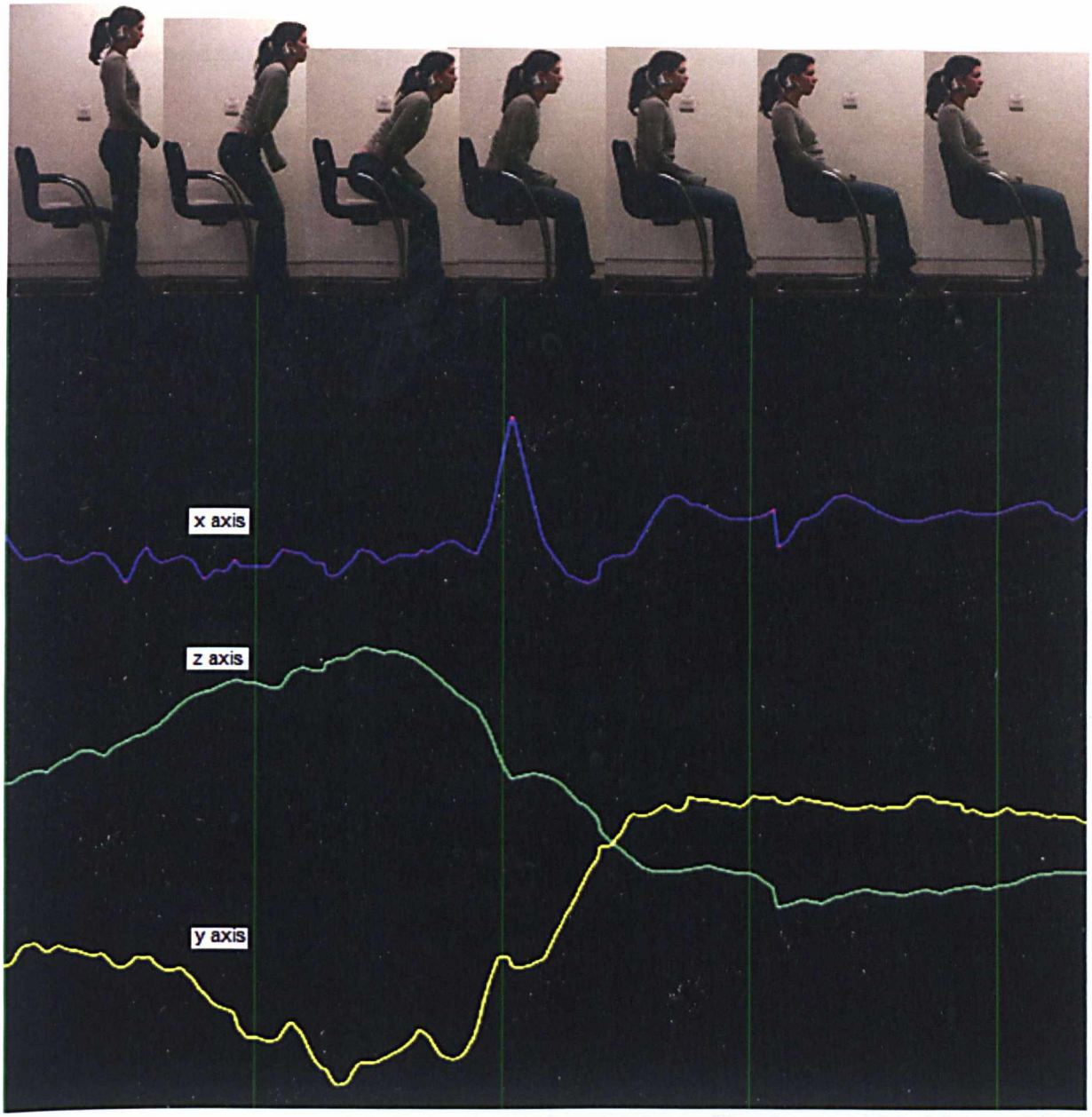


Figure 4.6 *Accelerometer traces showing the transition from standing to sitting down and reading. The purple trace represents x axis displacement (forward-backward), the green coloured trace represents z axis displacement (up-down), and the yellow trace represents y axis displacement (side-side) of the e-AR sensor.*

4.3.1.2 Lying to Standing (LTS)

During the LTS activity, subjects were seen to transition from a position of lying on their back, to one where they were standing up. The biomechanics of the LTS activity were broadly divided into *sit-up*, where flexion of the cervical and lumbar spine along with assistance from the upper limb resulted in the subject sitting up, and *sitting to standing (STS)* phases. The process of sitting up involves a combined flexion of both the pelvis and trunk. Initially, flexion of the lumbar spine takes place, followed by anterior tilt of the pelvis due to hip flexion. This is illustrated below in Figure 4.7.

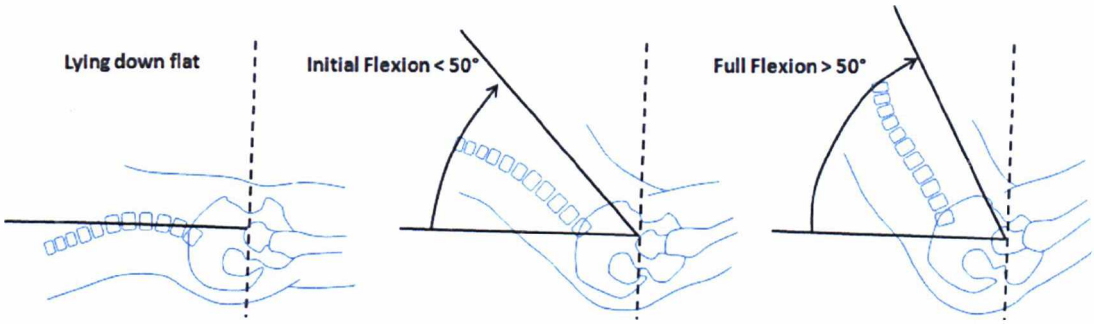


Figure 4.7 *Combined movements of the pelvis and trunk during the 'sit up' phase of the LTS activity. Initial flexion at the lumbar spine is followed by full flexion at the hip.*

The accelerometer output from the e-AR sensor and accompanying image of a subject as they go from seated to stance phases of STS is shown below in Figure 4.8. Once again, as the body goes from a lying to a standing position, the variance in the accelerometer trace increases with high amplitude 'spikes' representing point where the sudden changes in sensor direction take place.

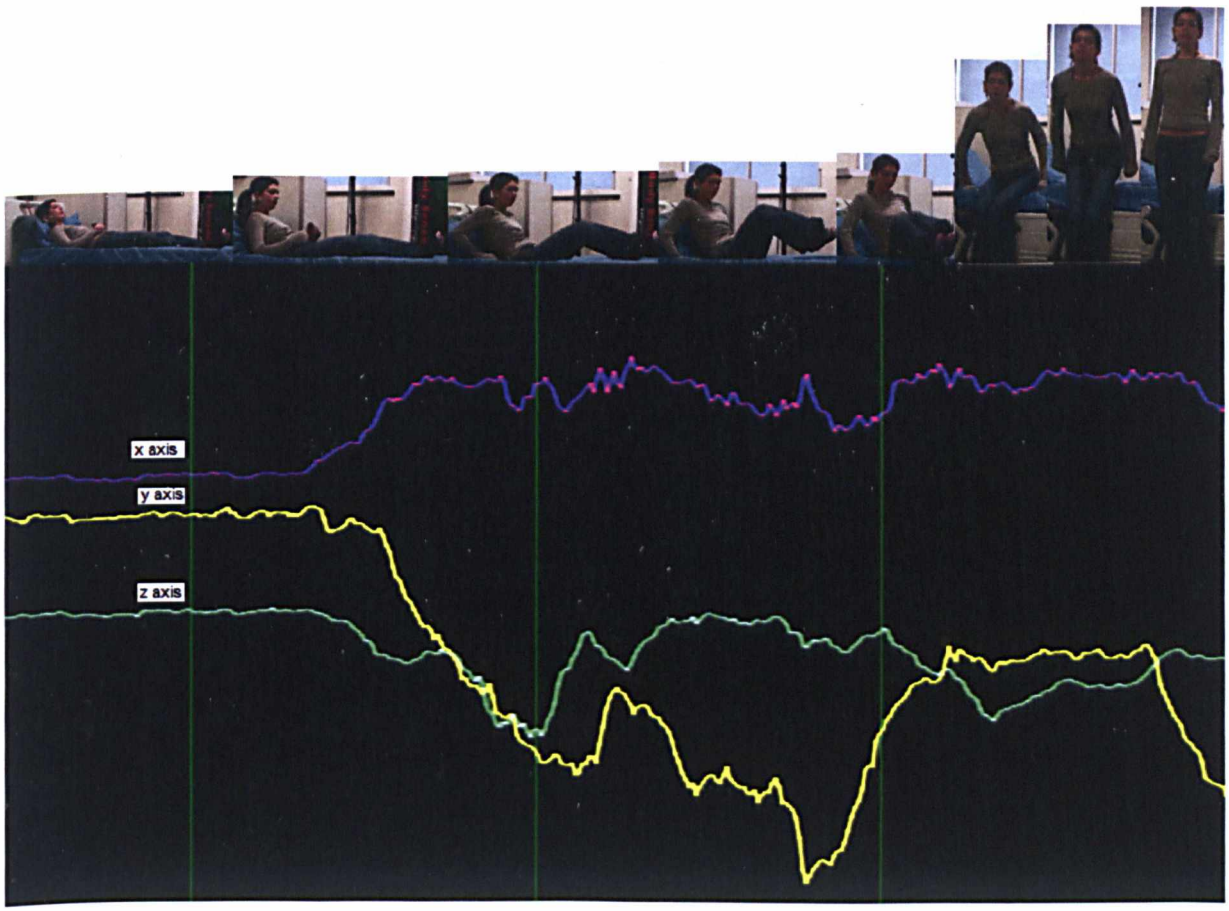


Figure 4.8 *Accelerometer traces showing the transition from lying down to standing. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement of the e-AR sensor.*

The following observations can be made about the movements that take place during LTS and the corresponding outputs from the e-AR sensor:

1. When the subject was lying down, the variance in accelerometer signal was almost negligible, and the final orientation of the e-AR sensor directly corresponded to the subject's head position. The orientation of the accelerometers was very different with lying down compared to seated positions.

2. Flexion of the trunk was seen to be free in the cervical and lumbar regions but limited in the thoracic regions. The majority of this flexion took place due to the anterior abdominal muscles, with some contribution from psoas major, minor, and quadrates lumborum.

3. The momentum generated by these muscles along with assistance from the upper limb was seen to bring the head into an upright position in line with the hips. This was seen as a major change in acceleration of the head and orientation change of the accelerometers themselves. The subject was then seen to go from a seated to standing position as seen in the STS activity.

The converse activity of going from a standing to a lying down position with accompanying accelerometer outputs is shown in Figure 4.9. Once again it is important to note that whilst LTS is an activity that results in significant variance in accelerometer output, the act of lying down itself is a relatively low variance activity.

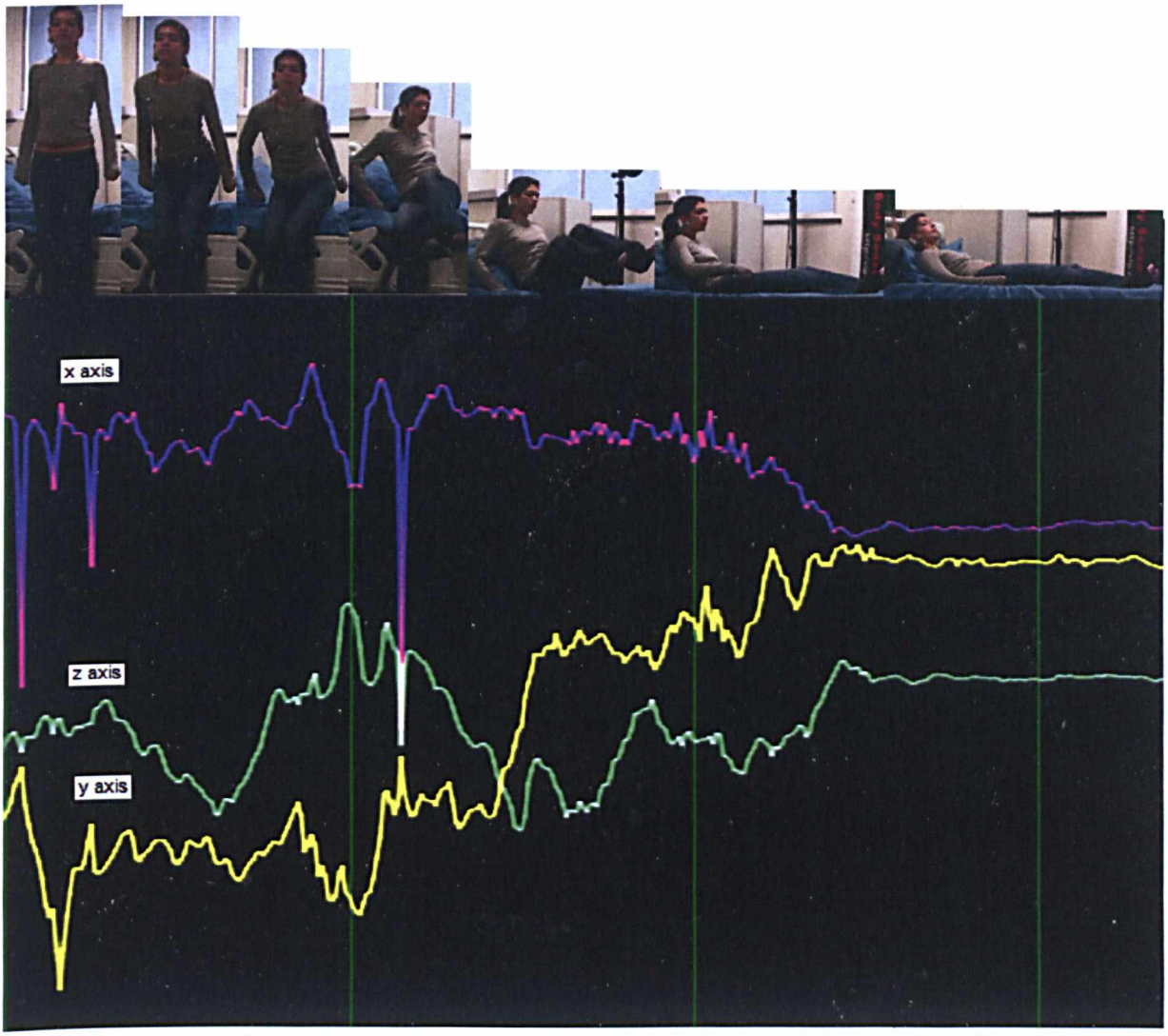


Figure 4.9 *Accelerometer traces showing the transition from standing to lying down. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement of the e-AR sensor.*

4.3.1.3 Locomotion: Walking

The gait cycle of subjects walking at 2km/h and 5km/h was observed and described using a commonly used international terminology for normal gait [150, 151]. Here the *swing phase* is described as the period of time when the limb being considered is not in contact with the ground and the *stance* phase is described as the period when that limb is in contact with the floor. The period of time when both limbs are in contact with the floor is called the *double stance phase*. Figure 4.10 below diagrammatically shows the stages of the gait cycle observed in subjects during this study.

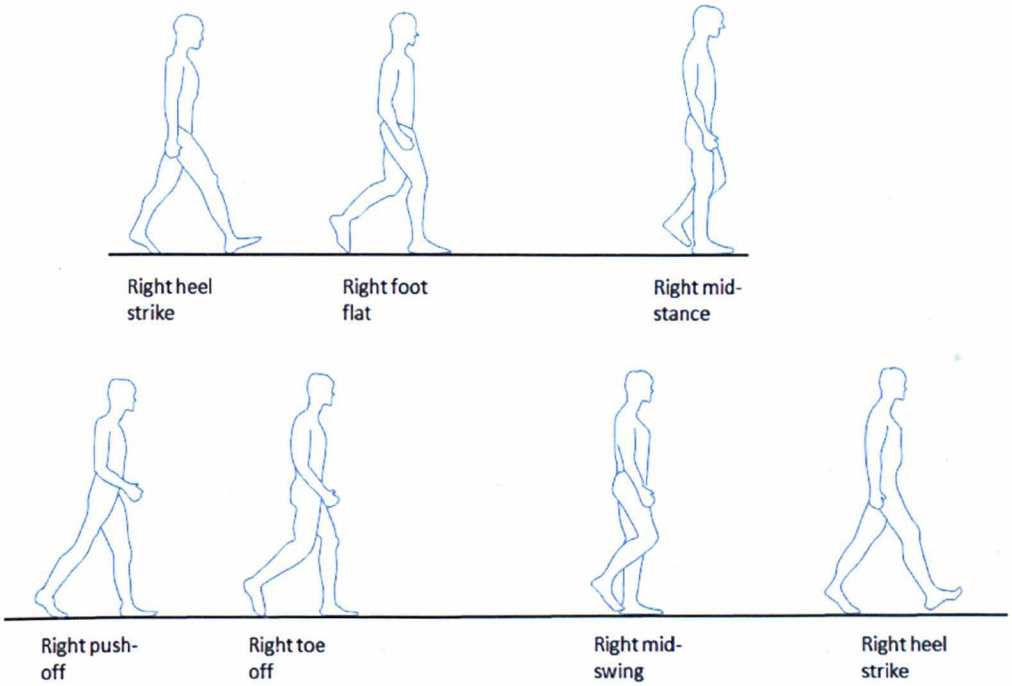


Figure 4.10 *Stages of the gait cycle observed in subjects as they walked with conventionally used terminology marked at the appropriate points.*

The accelerometer traces for a subject walking on a treadmill at a speed of 5 km/h for 40 steps are shown in Figure 4.11 below. A single gait cycle accelerometer trace is shown in Figure 4.12 with the corresponding image of the subject as they undertake this.

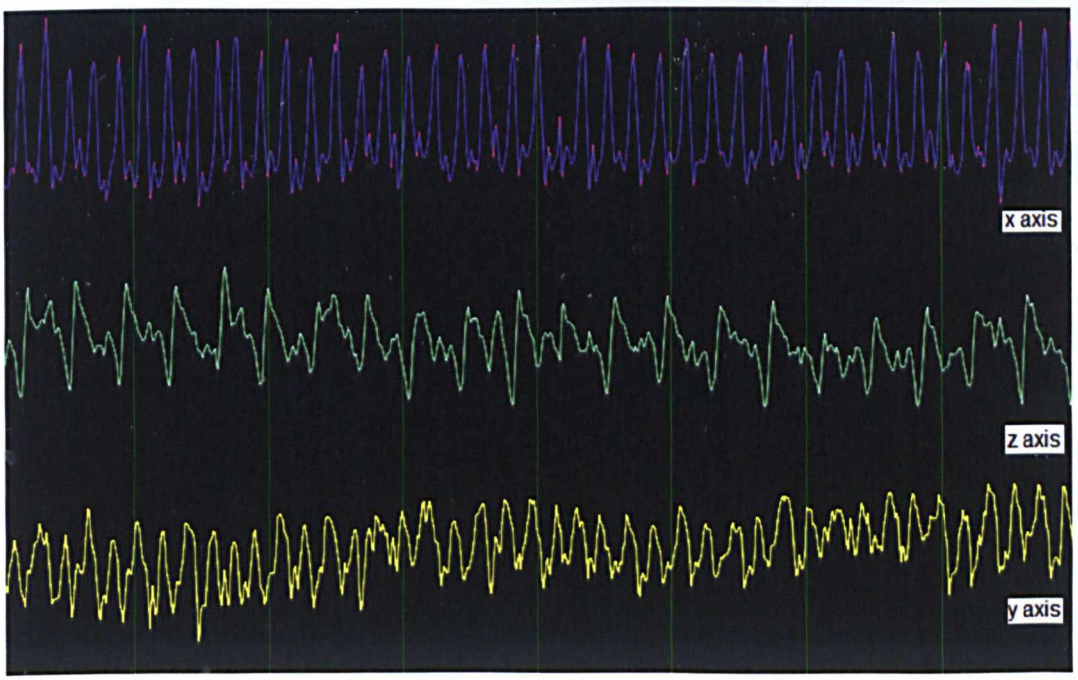


Figure 4.11 *Accelerometer traces for walking on a treadmill at 5km/h whilst wearing the e-AR sensor. The trace shows the accelerometer trace over 40 steps with the purple trace representing x axis displacement, the green coloured trace representing z axis displacement, and the yellow trace representing y axis displacement.*

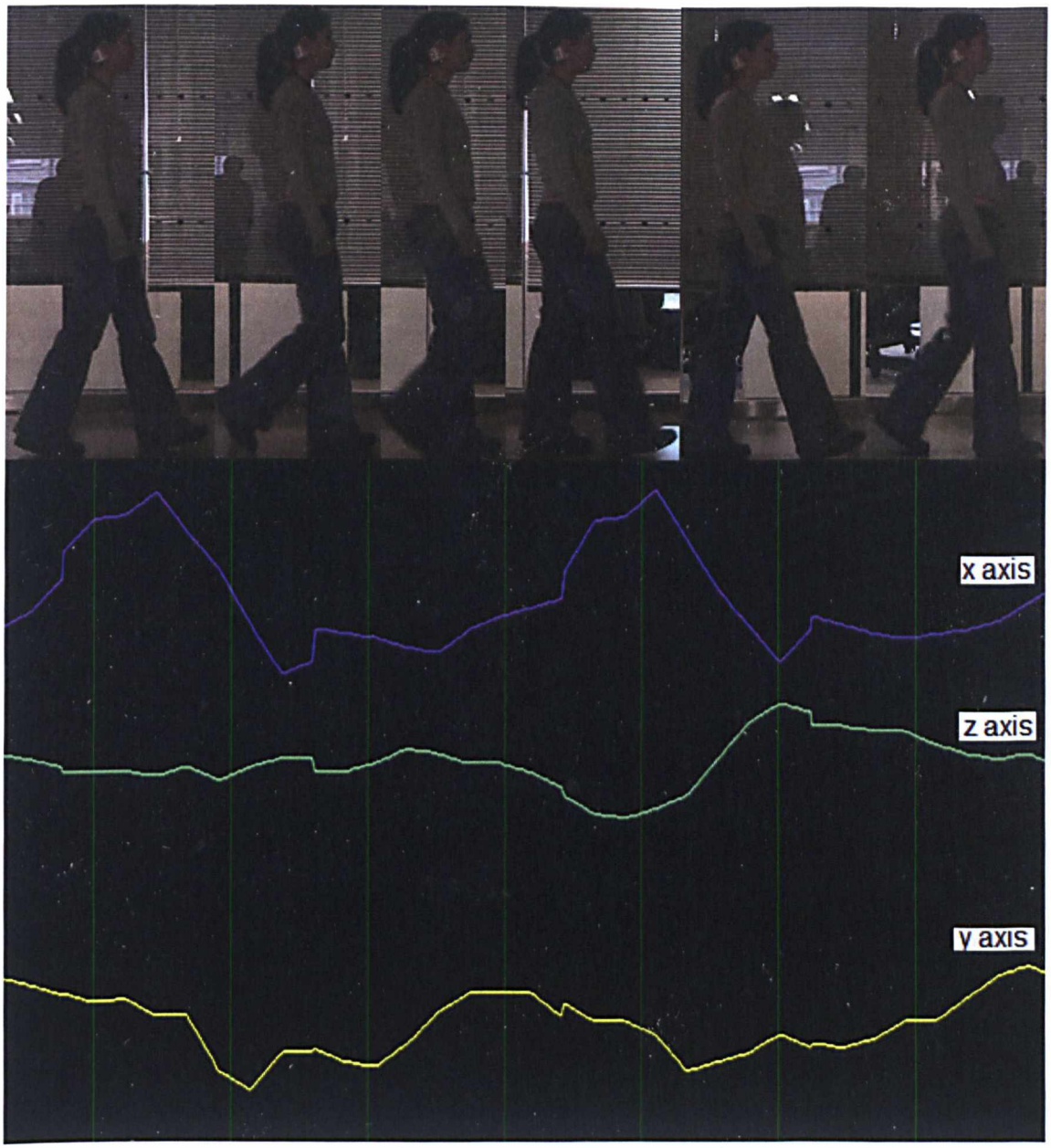


Figure 4.12 *The accelerometer trace for a single gait cycle with corresponding images of the subject as they undertake this. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement.*

The following observations made from these:

1. Right heel strike was seen to occur at a point when the left foot was also touching the ground with the subject in a stable double stance phase. Here the hip joint was partially flexed with gluteus maximus and hamstrings contracting to begin extending the hip. In this position the quadriceps help control the degree of flexion of the knee and dorsiflexors of the foot ensure a neutral position as the heel hits the ground.

2. Right foot flat resulted in the whole of the weight of the body being rapidly loaded onto the right limb. Here the hip was extended and knee flexed to cushion heel-strike and maintain a close centre of gravity. Controlled plantar flexion occurred at the ankle to prevent the foot from slapping down on the floor.

3. During 'right mid stance' the left limb was seen to be in the swing phase with momentum carrying the body forward. Hip extension continued as a result of the body's forward momentum.

4. Right push off resulted in propulsion of the body forward and involved the heel lifting off the ground.

5. Right toe off occurred after plantar flexion of the forefoot against the floor, and eventually lifted the right toe off the ground.

6. The right leg now accelerated and was swung forward with knee and hip flexing until it reached a point in front of the left limb which was in the stance position. At this point it decelerated in preparation for the heel-strike.

The traces for walking at 2.5km/h and 5km/h are shown side-by-side below in Figure 4.13 below. Here it can be seen that walking at a faster speed resulted in higher amplitude of accelerometer trace in each of the axes, though the patterns themselves were similar. This is because during brisk walking the gait pattern became exaggerated due to the pelvis tilting away more from the straight support limb thereby requiring a greater level of activity from the limb abductors. There was also increased flexion of the hip and more rapid extension to propel the body further more rapidly. From these traces there appeared to be a clearly identified and repeatable displacement in output across the three axes each time a subject took a step with peaks and troughs occurring at regular intervals. These are likely to occur as a result of vibrations transmitted through the body as well as changes in posture such as sway that occurs with a normal gait. These patterns were found in all 8 subjects although in some subjects the three-axis accelerometer patterns obtained were more reproducible than in others.

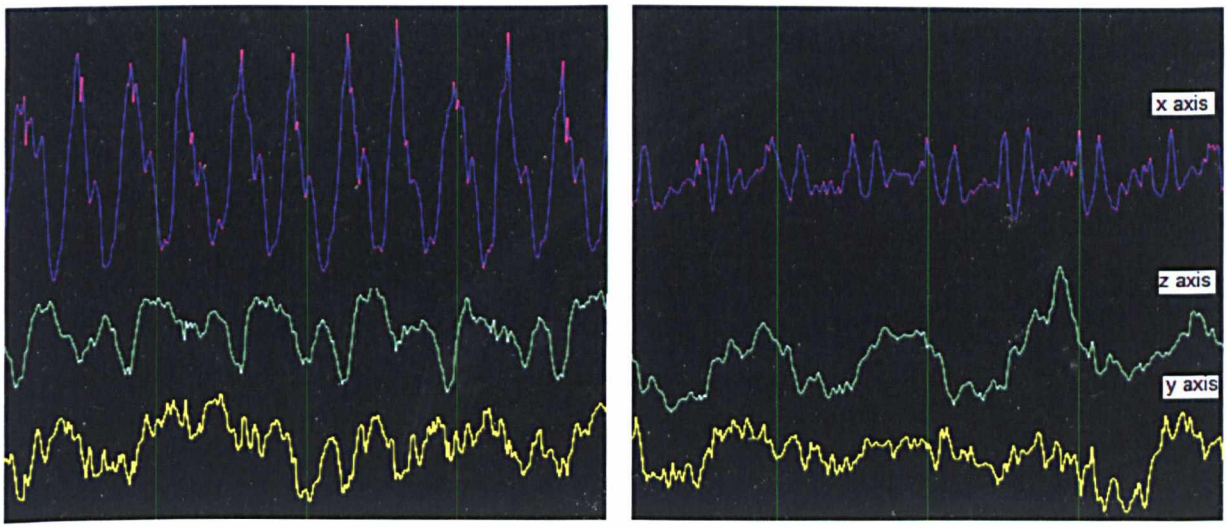


Figure 4.13 *The accelerometer traces for a subject walking at 5km/h (left) and 2.5 km/h (right) with marked change in amplitude of accelerometer trace visible. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement.*

4.3.1.4 Locomotion: Running

The biomechanics of running were also described as *stance* and the *swing* phases although it is important to note that unlike walking, running does not have a double-stance phase. Instead there is a period where there is no foot contact with the ground at all. In running the stance phase consists of foot-strike, mid-stance, and toe-off (Figure 4.14), and the swing phase consists of follow through, hip flexion and leg descent (Figure 4.15).

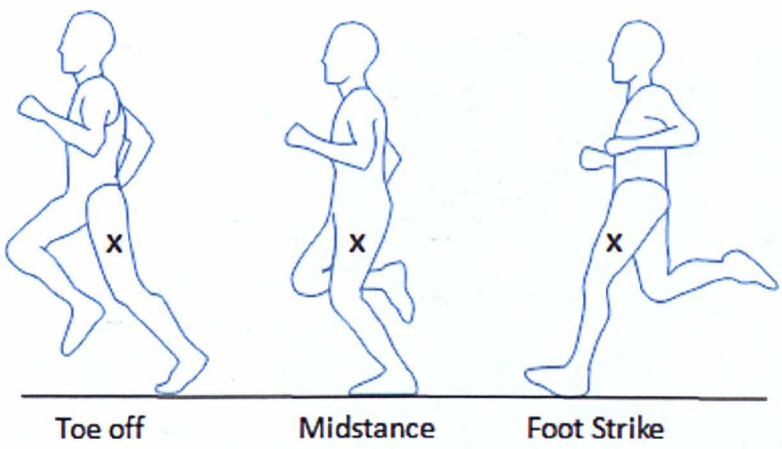


Figure 4.14 *Stance phase of the gait cycle observed in subjects as they were running. This phase is described by the limb marked X.*

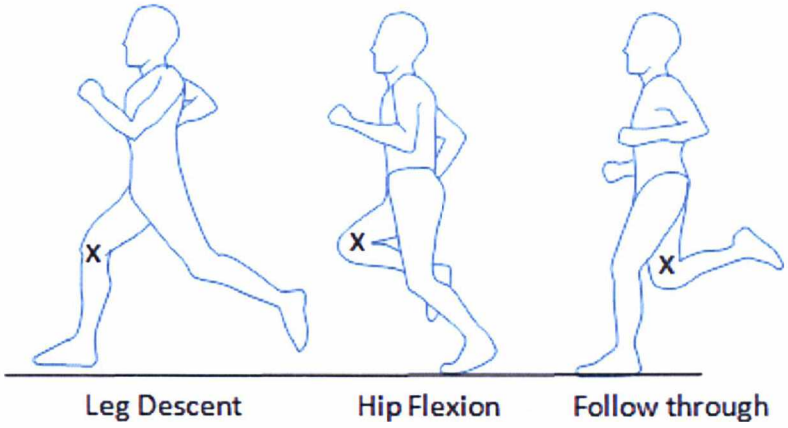


Figure 4.15 *Swing phase of the gait cycle observed in subjects as they were running. This phase is described by the limb marked X.*

The three axis accelerometer outputs from the e-AR sensor as a subject runs on the treadmill are shown below in Figure 4.16. The 'foot strike' of each limb resulted in a sudden change in acceleration in all three directions represented by a 'peak' in accelerometer signal. It can be seen that both the amplitude and frequency of the peaks and troughs is greater in the case of running. Once again there is a very repeatable pattern representing the vibrations transmitted through the body as a subject's heel strikes the ground and sway, but also as a result of head movements that occur during this activity. As compared to walking, running involves a greater degree of almost all types of motion across the hip joint apart from hyper-extension. These findings were repeatable across all eight subjects in the pilot study.

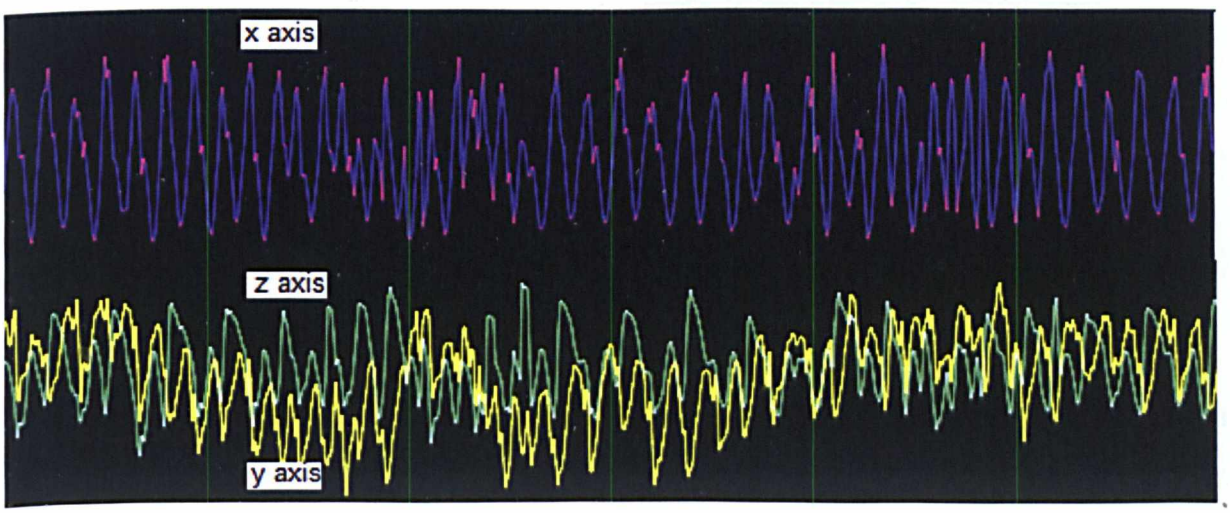


Figure 4.16 *Accelerometer traces for running on a treadmill at 8km/h whilst wearing the e-AR sensor. The purple trace represents x axis displacement, the green coloured trace represents z axis displacement, and the yellow trace represents y axis displacement.*

4.3.2 Activity classifier and index

4.3.2.1 Activity classification

Having evaluated the performance of the e-AR sensor's three-axis accelerometer in detecting biomechanical parameters that represent changes in body posture over the five activities in the pilot study, the ability of the activity classification software to use this data to correctly classify the same five activities was then tested. In this way, raw biomechanical parameters were converted into a quantitative measure of the activity a subject was performing. For data visualisation, a moving window of 4 seconds in size was used to extract variance features from the signal output of the three accelerometers. This window was moved every 2 seconds along the dataset. The accuracy of the classifier in correctly labelling each activity when compared to ground truth (visually marked) data is shown in Table 4.2 below. It can be seen from this table, that the accuracy of the classifier in general was high, with an average of 87% correct classification across 8 subjects undertaking the 5 activities. From this it is evident that by choosing the ear as a site of accelerometer placement, problems with sensor calibration and subject dependency may be naturally eliminated, and that the classifier may identify activities of different subjects accurately despite their differences in size, shape, and gait.

Subjects \ Activities	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Reading	87.5	93.8	80.0	84.6	100.0	91.7	80.0	100.0
Walking slowly	100.0	91.7	100.0	80.0	93.3	100.0	100.0	90.9
Lying down	80.0	91.7	62.5	100.0	0	100.0	33.3	87.5
Walking	100.0	95.0	77.8	100.0	80.0	72.7	100.0	66.7
Running	100.0	93.8	100.0	100.0	83.3	100.0	84.6	100.0

Table 4.2 Activity classification results from the pilot study.

Using this classification software, when a relatively low level activity such as reading is compared to higher level activities such as walking and running, the results for activity classification with variance across 3 accelerometer axes as the feature are shown in Figure 4.17. This graph demonstrates that the variance of accelerometer outputs across three axes for these activities clusters separately. As a feature therefore, variance seems to be able to discriminate in this case between the activities of reading, walking, and running.

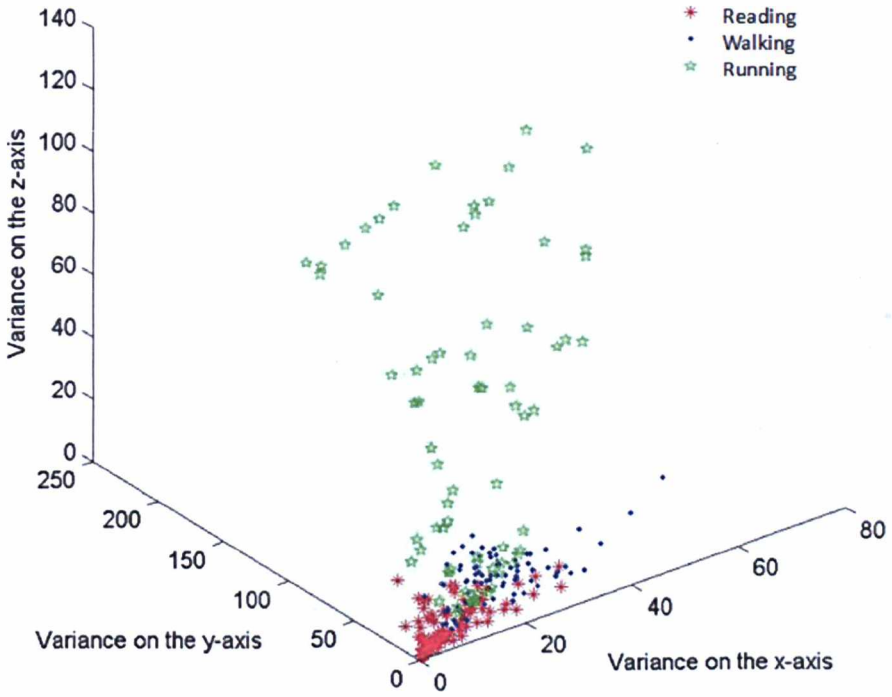


Figure 4.17 *Clustering and classification of reading, walking and running for all subjects whilst wearing the e-AR sensor during the pilot study. This classification system was based on the signal variance across 3 accelerometer axes.*

The activity classifier was also used to group the five ADLs undertaken in the pilot study into one of four classes, namely 'very low' (Class 0), 'low' (Class 1), 'medium' (Class 2), and 'high' (Class 3) levels. It should be noted that reading and lying down were identified as Class 0 activities, walking at 2km/h was identified as a Class 2 activity, and walking at 5km/h and running were identified as Class 3 activities. None of the five ADLs in the pilot study were classified as a Class 1 activity. Figure 4.18 shows the clustering and correct classification of these activities across all eight subjects. Furthermore it should be noted that the clustering and distributions of the plots in both figures 4.15 and 4.16 are consistent.

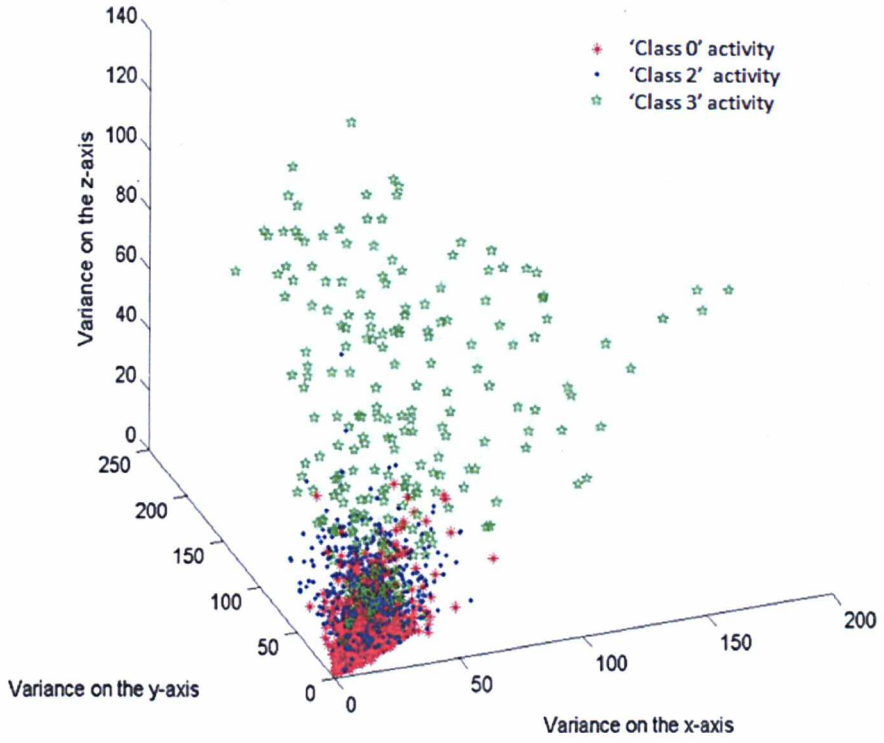


Figure 4.18 *Clustering and correct classification of these activities into 'Class 0', 'Class 2', and 'Class 3' activities during the pilot study.*

4.3.2.2 Activity index

Having demonstrated the ability of the activity classification system in determining the type of activity that a subject was performing whilst wearing the e-AR sensor during the pilot study, the activity index was also calculated for each of the five activities undertaken. Figure 4.19 is a graph showing a raw accelerometer trace, activity classification, and activity index for one subject as they undertook the pilot study. From this it should be noted that as expected, activities with a high index resulting from more variance in the accelerometer signal were also classified as higher level activities (Class 2 or 3). Importantly, as a subject transitioned from one low level activity to another, 'peaks' in both the activity index classifier were noted. These were due to movements such as STS or LTS which occurred as a patient goes from one low level activity (sitting) to another one (standing). The transition itself however, was correctly noted as a high level activity. In the case of lying down for example, a period of low variance then ensued as a resting position was achieved.

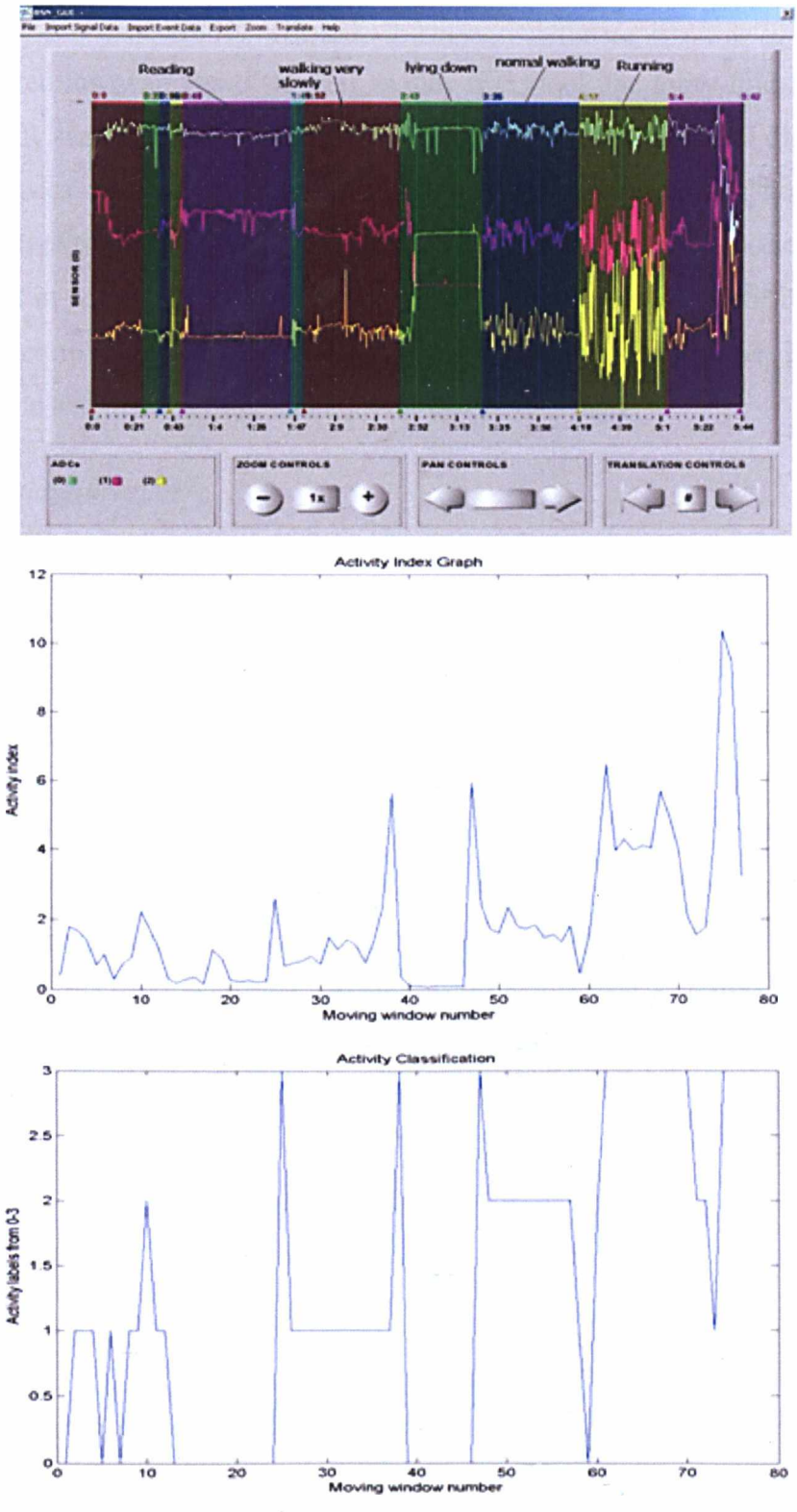


Figure 4.19 *(a) Graph showing the raw accelerometer data from a subject in the 5-activity pilot study. (b) The activity index for the above subject showing the levels of variance as an activity is undertaken. (c) Results of the classifier on the accelerometer data.*

4.3.3 Simulated home activities circuit

Data was collected for twenty-two subjects as they undertook the thirty-four activities whilst wearing the e-AR sensor in the simulated home environment. Figure 4.20 displays the three accelerometer traces obtained from the e-AR sensor across the entire simulated home activity circuit, with each of the 35 activity points marked. From the quantity of accelerometer data, it can be seen that in such an environment, the raw accelerometer data is difficult to interpret visually. In order to classify the activities that were undertaken by the 22 subjects and quantify them, the activity classifier and activity index were used.

4.3.3.1 Activity classification

The activity classification system based on the variance across the three accelerometer axes occurring during each of the thirty-four activities was used on this dataset. Once again, for data visualisation, a moving window of 4 seconds in size was used to extract variance features from the signal output of the three accelerometers. This window was moved every 2 seconds along the dataset. Figure 4.21, shows the variance across 3 axes for the different activity types, for one subject undertaking the activity circuit. It should be noted that marker '35' signifies the end of the study and is not a distinct activity type. From this figure it can be seen that firstly, there does appear to be some clustering of the activities into groups, and secondly that as in the pilot study the variance data for different activities is scattered apart from each other which again depicts the relevance of the variance feature.

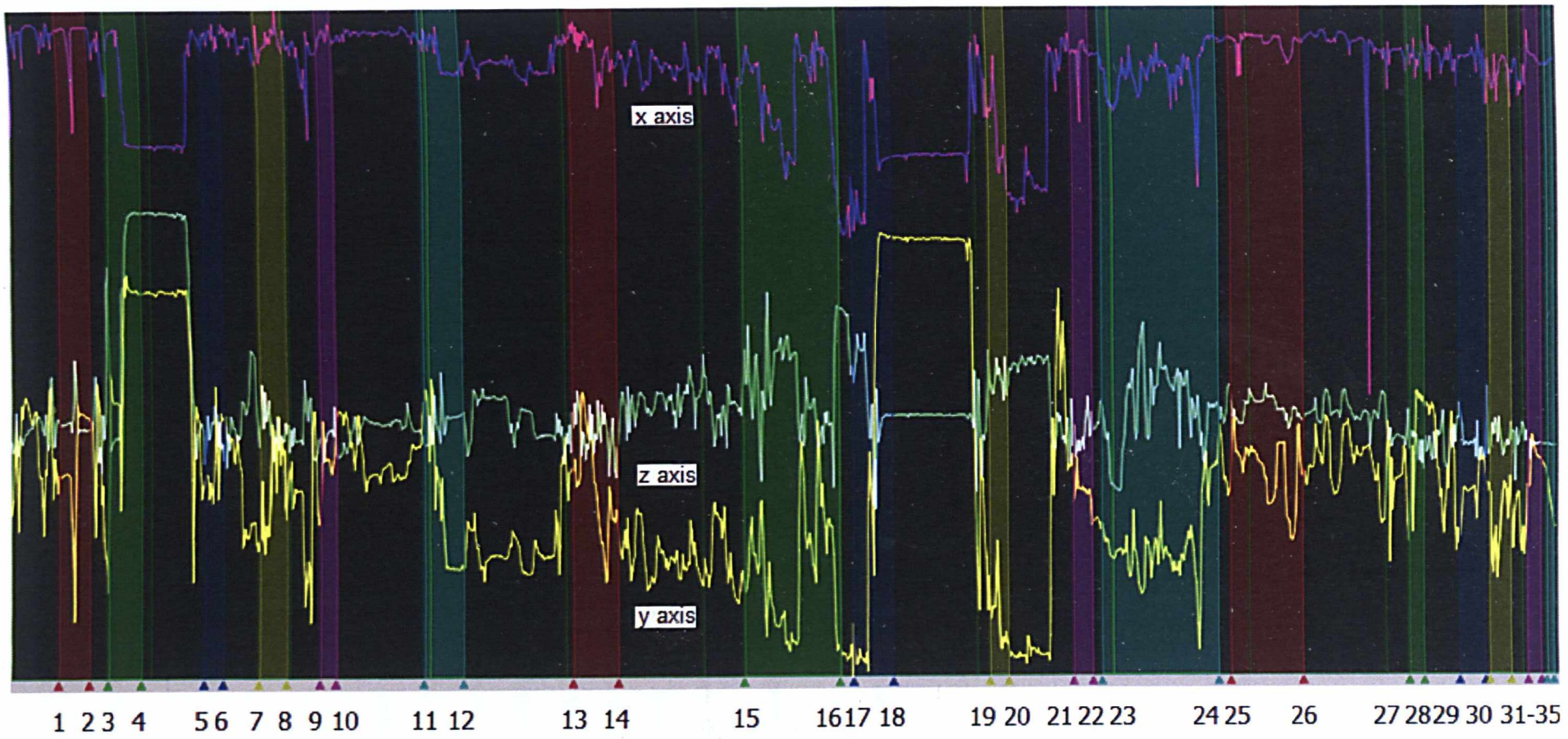


Figure 4.20 *Accelerometer traces for one of the subjects undertaking the 34 activity simulated home trial. The activities are labelled from 1-34 at the bottom of the diagram a marked by the study coordinator during the trial. It should be noted that marker 35 signifies the end of the study and is not a distinct activity.*

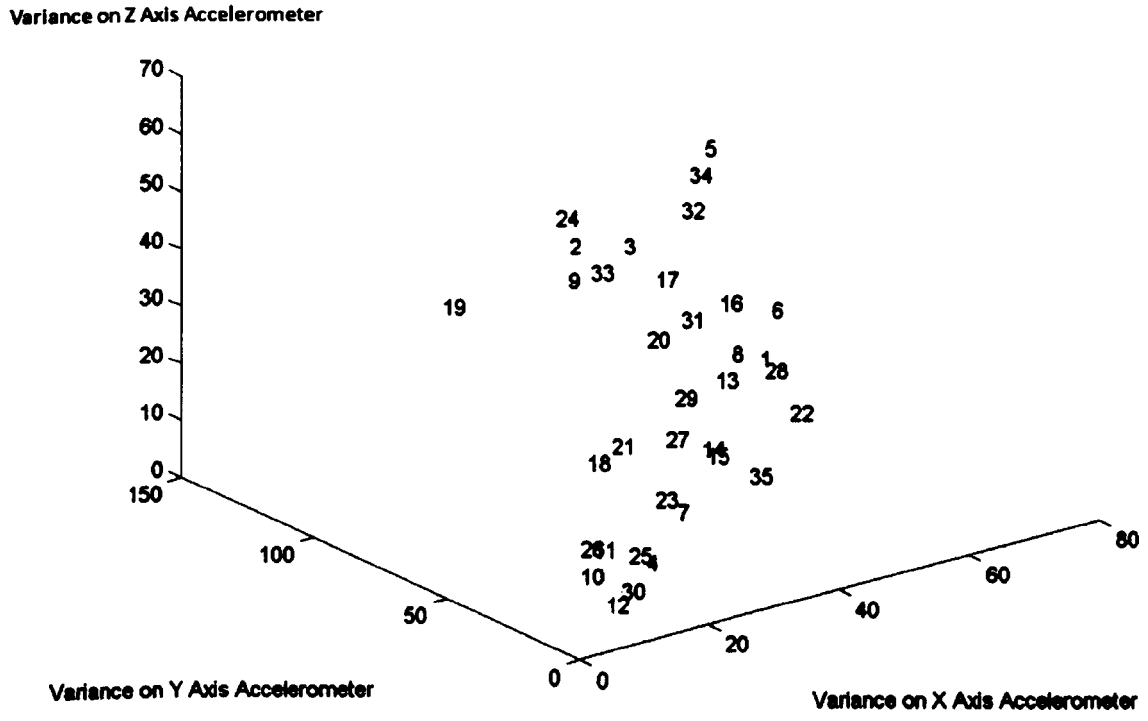


Figure 4.21 *Average variances for each activity for one participant in the scenario-based activity circuit*

For all subjects taking part in the study, Figure 4.22 shows the clustering and correct classification of the activities being undertaken into 'low' (Class 0), 'very low' (Class 1), 'medium' (Class2) and 'high' levels (Class 3) using the activity classifier software developed for this study. Table 4.3 lists the activities that were classed by this program into the various groups, with findings supporting those of the pilot study. They also support the findings from analysis of the accelerometer outputs which showed that variance was greatest with activities such as standing up from lying down, and ascending stairs, and lowest when lying down or sitting. Finally, the activity classification (Classes 0-3) for one subject undertaking the entire simulated activities circuit is shown in Figure 4.23.

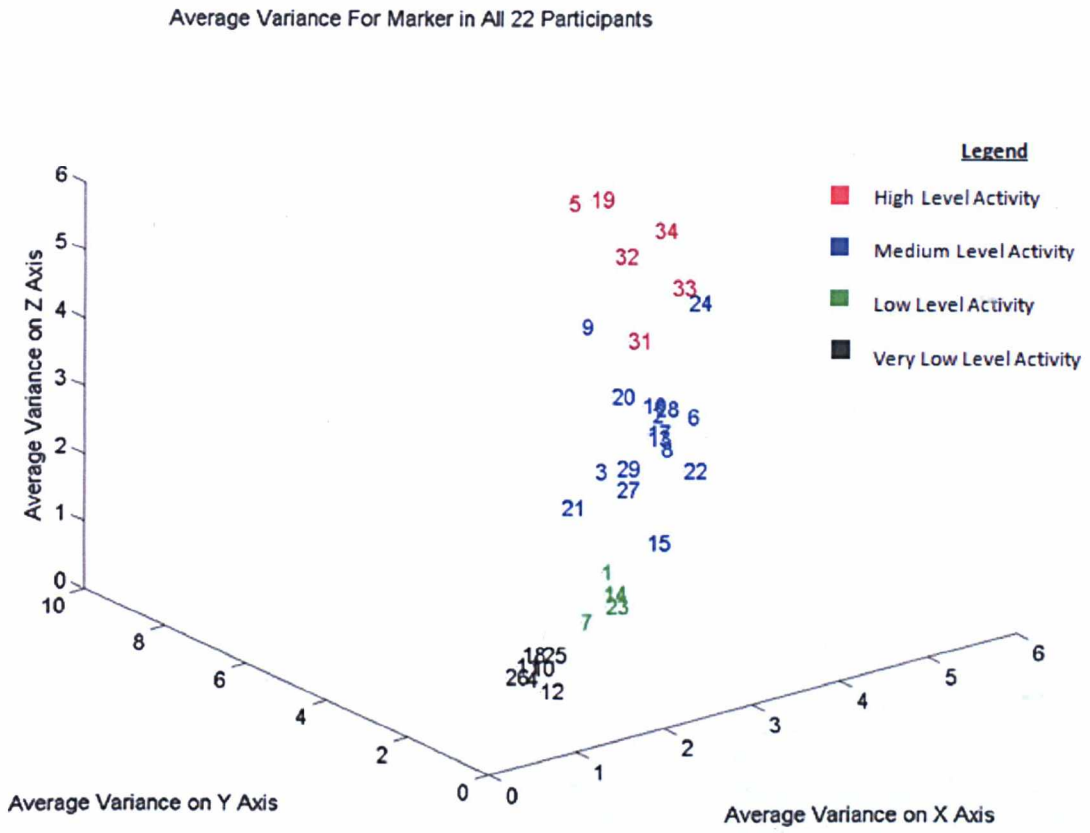


Figure 4.22 *Clustering and correct classification of these activities into 'very low', 'low', 'medium' and 'high' levels during scenario-based activity circuit across all subjects.*

Activity Level	Description	Activity Number in this Group
High	Standing up from lying down. Stair ascending and descending	5,19,31,32,33,34
Medium	Sitting down, standing up from sitting down, walking, Brushing Teeth, Shoes Off,	2,3,6,8,9,13,15,16,17,20,21,22,24,27,28,29
Low	Food preparation, Switching on TV,	1,7,14, 23
Very Low	Lying Down, Sleeping, Eating, Drinking, Reading	4,10,11,12,18,25,26

Table 4.3 – *The activities classified as 'very low', 'low', 'medium', and 'high' levels using the activity classification software.*

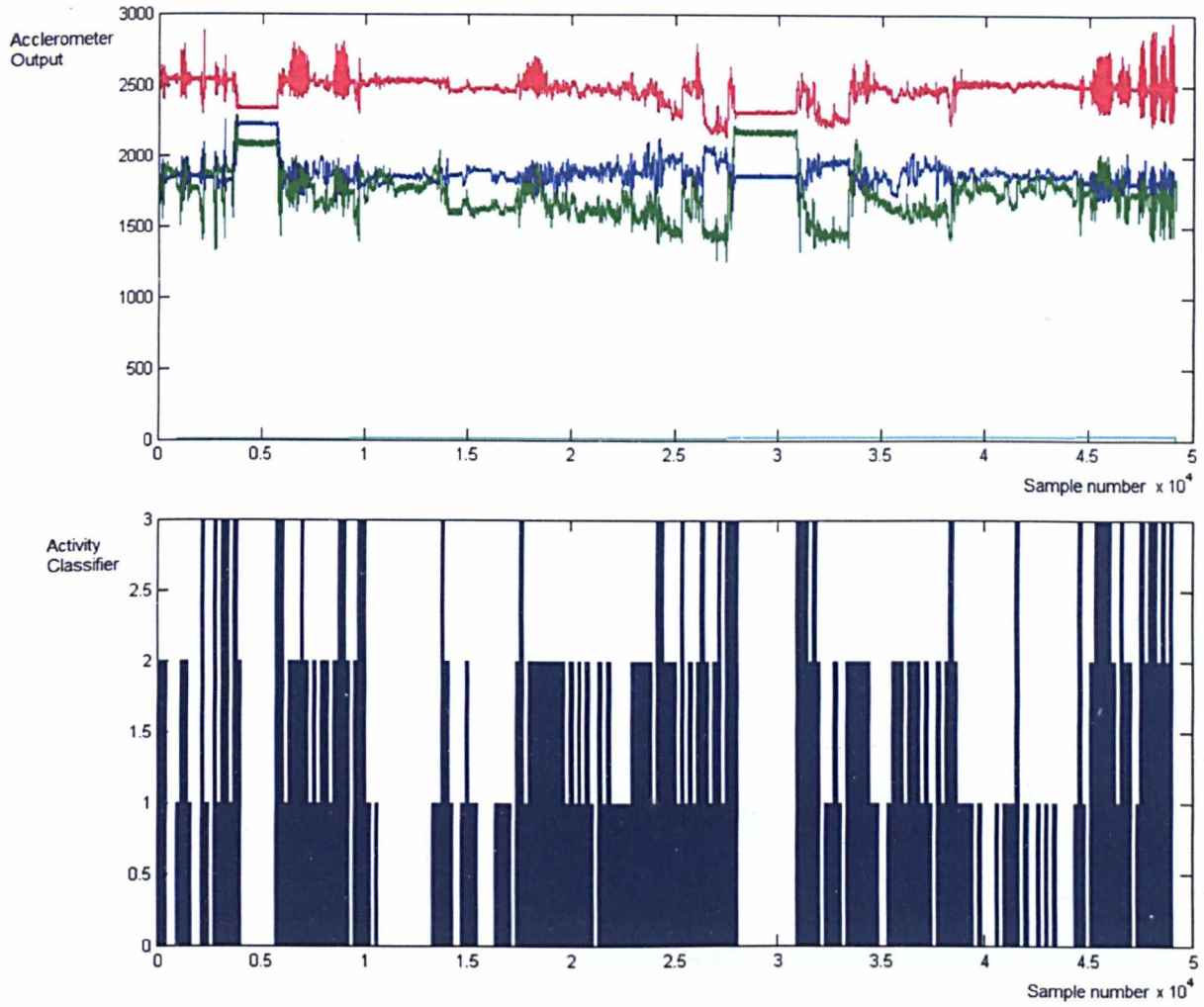


Figure 4.23 *Accelerometer trace for one participant in the scenario-based simulated home circuit (above), with associated activity classification results from 0-3.*

4.3.3.2 Activity index

The activity index for one subject as they undertook the scenario-based simulated home activity circuit along with the corresponding accelerometer traces is shown in figure 4.24. The mean activity index with standard deviations for all twenty-two subjects undertaking each of the thirty-four activities in the trial is displayed in Figure 4.25. It can be seen from this graph that activities such as climbing up and down stairs, and standing up resulted in accelerometer signals with the highest mean variance, whilst activities such as drinking and lying down had the lowest mean variance. As before the activity index corresponds well to the activity classification system, with a higher activity class correlating with a higher mean activity index.

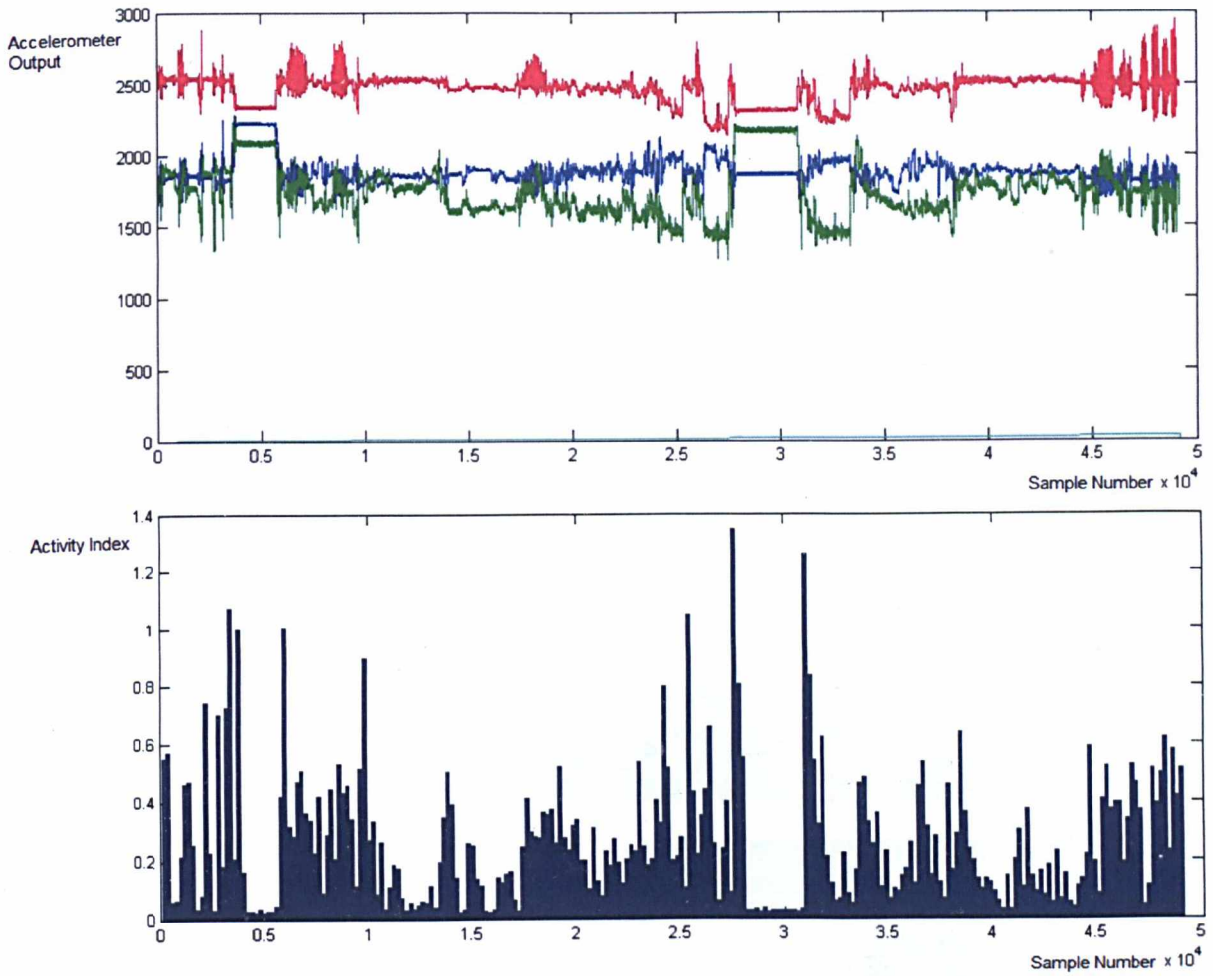


Figure 4.24 *Accelerometer trace for one participant in the scenario-based simulated home activity circuit (above), with associated activity index results.*

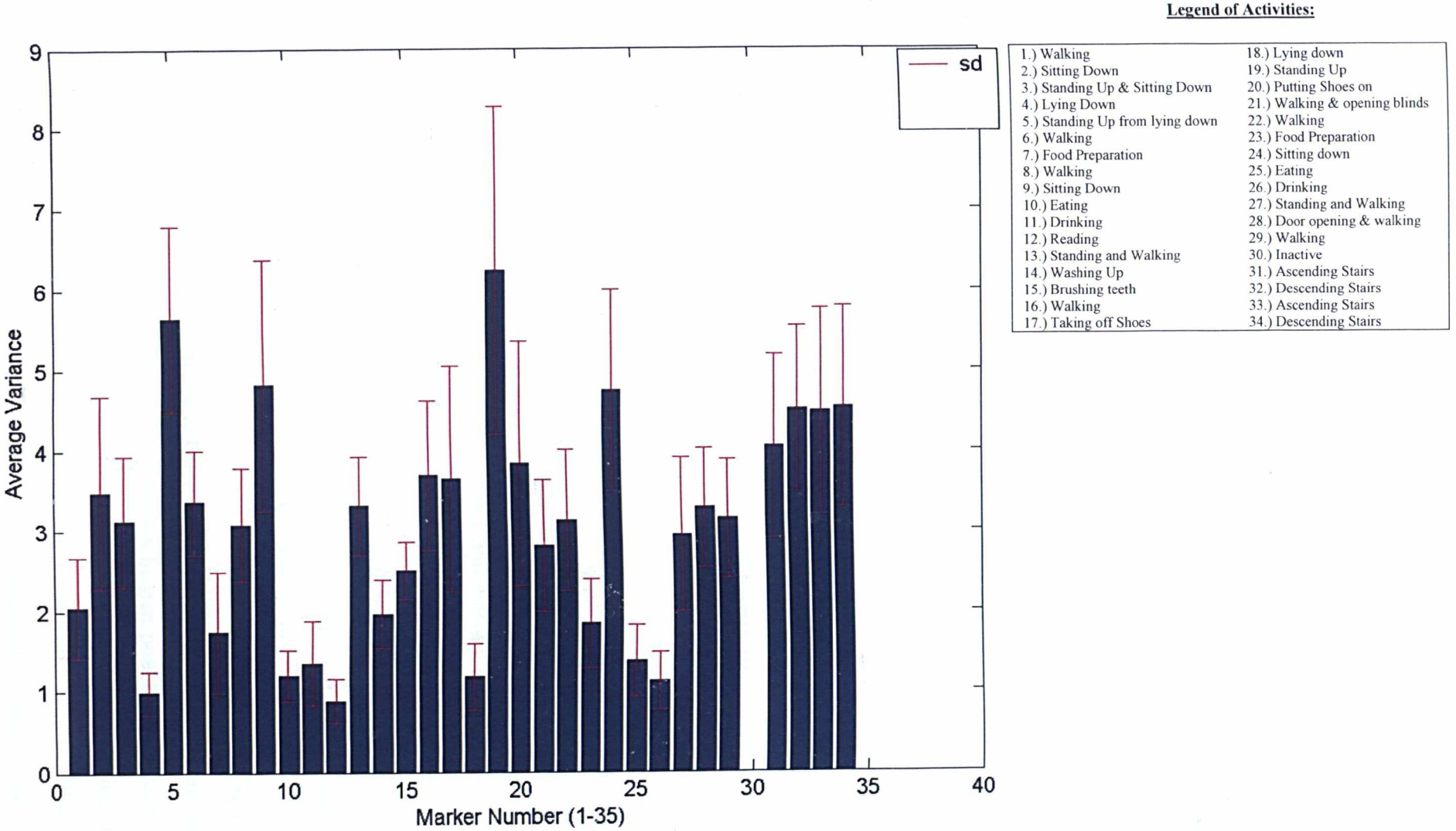


Figure 4.25 *The mean variance for each activity for all 22 Participants in the circuit. Error bars represent standard deviation. Legend shows activity description.*

4.4 *Discussion*

In this chapter we have described the need and outlined the role for a BSN device to objectively monitor home activity as a measure of functional recovery in patients who have recently undergone surgery. The e-AR sensor was used to collect biomechanical markers of key ADLs using its three-axis accelerometer. Analysis of this raw biomechanical data demonstrated that ADLs such as STS, LTS, and locomotion (walking and running) could all be differentiated from each other using ear-worn accelerometry as they result in not only distinctly different types of movement at the head, but also varying intensities of this movement. The accelerometer outputs obtained from the e-AR sensor displayed characteristic patterns and features that were specific to certain activities, with variance in accelerometer signal correlating well with the intensity of activity. An activity classification framework was then used to convert this raw biomechanical accelerometer data in activity classes of 'very low' (Class 0), 'low' (Class 1), 'medium' (Class 2), or 'high' (Class 3) levels using a specially designed Bayesian classifier based software program utilising multivariate Gaussians to model activity classes. This classifier was shown to have a mean correct classification rate of 87% across five key ADLs, with higher rates seen for activities such as walking and running. Finally, a real-time 'activity index' calculated from the averaged variance across the 3 accelerometer outputs was tested and showed good correlation with the activity classification system. The value of this activity index ranged from 0-15 with a greater value signifying a greater amount of movement and hence a more active type of activity. In a simulated home environment of 34 activities, this system was shown to convert a substantial amount of raw biomechanical accelerometer data into activity classes that could be used to interpret the course of a subject through that circuit. It is hoped that such activity index data will provide objectivity in a monitoring environment that is currently highly subjective.

When interpreting the findings of this chapter, it is important to consider a number of limitations. First, we should mention device fixation to the ear, which is very important because of both movement artifact and change in orientation of the e-AR sensor as patients mobilize. Because of variation in patient size and shape, it is important to have a range of different devices to fit the ears of a heterogeneous human population, which would in turn increase the accuracy of the system. Another way of ensuring good device fixation would involve the use of external fixation such as through a headband, although this has important implications for device acceptability. Second, the amount of time that subjects were

monitored in the simulated home environment was small compared to what would be expected of the system over the course of a day. Power supply and battery life are likely to be important determinants of this, and the main way of increasing the amount of time the e-AR sensor can be used may be to reduce energy consumption. Third, this study was carried out in a simulated home environment where availability of wireless network was good. In the real home, this is likely to be much more heterogeneous. Finally, patient compliance for such a device is likely to be much lower in the real home setting where they are completely unsupervised compared the simulated environment where they are wearing the e-AR sensor for a short time as part of a study.

The finding that variance across the three accelerometer axes was the feature that resulted in the greatest discrimination between activities is not surprising. Looking at the three axis accelerometer traces, it can be seen that whilst features such as signal energy, root mean square value, average distance between consecutive peaks, troughs, zero-crossing, and number of zero-crossings may all be important in discriminating certain activities, the variance in the three axes was markedly different depending on the type of activity being performed. Examples of this are the 3-axis accelerometer patterns for walking (Figure 4.7) and lying down (Figure 4.8), which were characteristic in their morphology and showed both inter- and intra-subject reproducibility. Whereas the accelerometer patterns for walking showed a characteristic morphology with high average variance, the opposite was true for lying down, where the outputs from the accelerometers showed low variance, but had a characteristic accelerometer orientation. In simple terms therefore, high variance would be expected with a more mobile type of activity. This is of great practical importance because knowing how much of the day a patient is lying down and therefore resting, is an important part of post-operative recovery to consider. When all subjects were considered, mean variance for each activity however found to have a large standard deviation. This may represent variation in the way different subjects perform the same activities, which would be entirely expected.

In developing a measure of activity classification that assigns a numerical value (from 0 to 3) corresponding to the level and type of activity that a subject is undertaking in their home environment, we aimed to provide objectivity in home post-operative recovery monitoring. Whilst raw accelerometer signals may allow us to distinguish activities, they would not themselves be able to provide objective quantification of activities without the development

of further activity classification and quantification techniques. Also, the quantity of data that would be produced even in one day would be too large to go through manually, and the unsupervised nature of the home environment would make interpretation impossible. The software used in this study utilised feature selection techniques and a multivariate Bayes classifier to accurately classify these activities into very low (0), low (1), medium (2), and high (3) levels, allowing us to discriminate between activity types. The ability to mark the data in real-time provided us with the ground truth information that we needed to develop the system and also allowed us to determine its accuracy. It is important to note that the transition from one activity to the next resulted in transitional 'spike' patterns in activity classification. These could themselves be used as markers when analyzing unsupervised data. Finally, it is important to consider the advantages of an 'on node' activity classification technique when developing a practical means of pervasive home activity monitoring. The ability of the node to perform this level of processing on site and prior to data transmission to a server, is likely to result is a more efficient, less power-consuming, and more reliable mode of data transmission from the BSN. It also removes the need to send large amounts of data continuously to a central server for further processing and evaluation. This is a key attribute of BSNs, and sets them apart from other wireless patient monitoring systems.

The activity index (0-15) allows the objective determination of the intensity of activity being performed in real-time. The motivation in developing these types of objective activity classification and quantification tools is the need to accurately monitor how patients recover at home following discharge after major surgery. Ultimately this system aims to provide an indication of whether patients are making an uncomplicated return to their normal daily activities of living. An example of where this type of information may be relevant is in patients who live alone at home and who to date have shown a good recovery towards normal activities, particularly during the day. If this level of activity starts to fall, and the patient is noted to be spending more and more of their day performing very low level activities, this may signify deterioration in their condition or an inability to cope. The consequence of this is that the patient may be spending most of their day in bed, and not getting enough nutrition and fluid to fuel their body's recovery. An early visit from a district nurse or a general practitioner would in this instance result in an intervention that would be aimed at either providing them with more support, treating their worsening clinical condition, or making a decision to re-admit the patient before a marked deterioration in their condition took place. It is easy to see how this may be particularly important in vulnerable groups such as those with

chronic disease and the elderly. The latter is a particularly important group to consider because of an increasing demographic towards a more elderly population who are arrive back at home after surgery earlier than ever before, and live alone. For these patients, pervasive BSNs have the potential to provide a more secure patient discharge to the home environment. To do this however, BSNs have to become an integrated part of the existing medical infrastructure.

5 Detecting Impairments in Mobility

5.1 Introduction

The importance of measuring functional post-operative home recovery in terms of ADLs undertaken by a patient during the course of their day has already been demonstrated. The ability of a patient to mobilise normally for locomotion is another key part of this functional recovery that if monitored could give good indication of a patient's progress. The types of mobility impairment that patients may experience following abdominal surgery can broadly be divided into truncal and limb immobility types, and are considered in turn below. Once again, in order to detect and monitor mobility impairment, biomechanical markers th at distinguish 'normal' from 'impaired' need to be identified and analysed to convert them into surrogate markers of functional post-operative recovery.

5.1.1 Truncal mobility impairment following abdominal surgery

This type of mobility impairment occurs directly as a result of abdominal surgery and involves increased abdominal rigidity secondary to muscle spasm and pain occurring directly as a result of skin, soft tissue, and muscle-splitting wounds that are made during abdominal incisions [196, 197]. Figure 5.1 shows the anatomy of the anterior abdominal wall which is richly innervated and comprises mainly of rectus abdominis, external oblique, transverses abdominis, and internal oblique muscles which are oriented as shown. When making incisions to gain access to the abdominal cavity, the site of the incision determines the muscles being split. For example, a skin incision through the midline of the abdomen involves cutting through the linea alba which represents the fusion of the entire anterior abdominal wall muscles in the midline. This increase in abdominal wall rigidity that results from such an incision leads to reduced chest expansion due to limited diaphragmatic movement, and a reduced speed and agility of movement due to pain, affecting common activities of daily living such as walking and standing [198]. Laparoscopic skin incisions are smaller but can still be very painful as they involve splitting the abdominal cavity. The muscle layers of the anterior abdominal wall that may be disrupted by abdominal incisions are shown in Figure 5.1.

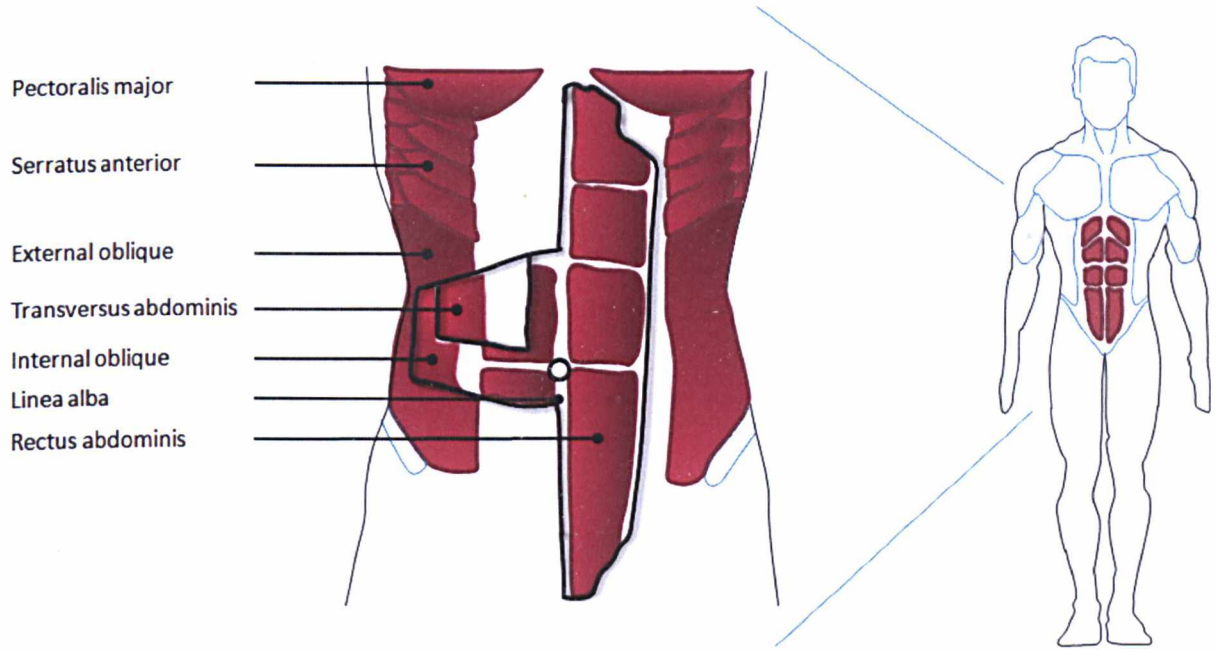


Figure 5.1 *Muscle layers of the anterior abdominal wall affected by surgical incisions.*

5.1.2 Lower limb mobility impairment following abdominal surgery

Impaired locomotion due to limb mobility impairment can occur either directly as a result of abdominal wound pain being exacerbated by movement of the legs, or due to swelling and stiffness of the limb from complications such as a deep vein thrombosis (DVT) [199]. In the case of DVT, a blood clot forms in the deep veins of the legs following the period of immobilisation that surrounds surgical procedures. During normal walking, lower limb muscles such as the gastrocnemius are exercised and contribute to the pumping of blood from the peripheries to the central venous system, ultimately leading back to the heart. Disuse of this 'muscle pump' due to immobility following surgery results in venous stasis in the deep veins of the lower limb, predisposing the patient to the formation of a blood clot (thrombus) within them. This can result in swelling, pain, and stiffness of the limb, and may lead to a life-threatening condition known as a pulmonary embolism. Here, a fragment of thrombus may break off and become free-flowing within the blood stream, where it travels through the heart and ultimately to the lungs, where it can become lodged in blood vessels. It is a life threatening emergency which results in difficulty breathing and ultimately death [200]. Figure 5.2 below shows of a DVT on leg size, resulting in pain and stiffness. Hospital prevention of this condition involves early mobilisation, and injection of low molecular weight heparin to reduce the coagulability of blood, and the wearing of thrombo-embolic

deterrent stockings that reduce the static volume of blood in the legs [201]. Despite this however patients recovering at home remain vulnerable to this complication for which they are currently not monitored.

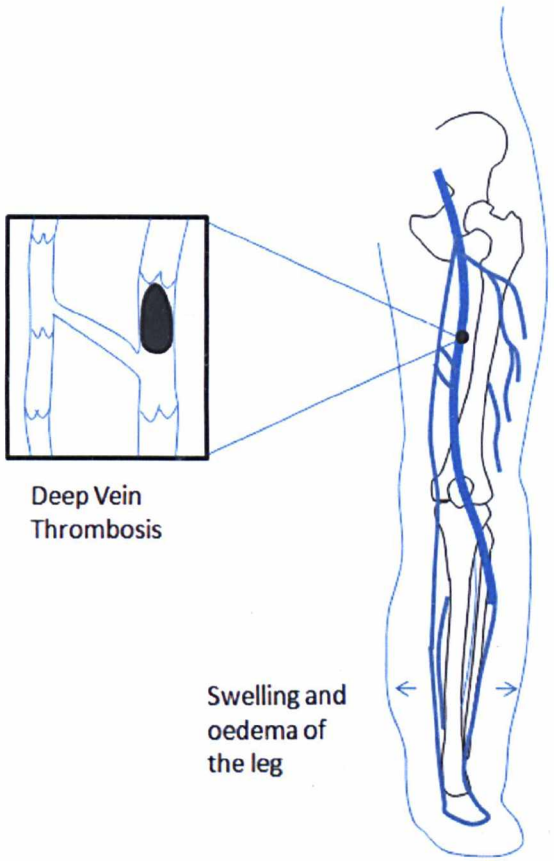


Figure 5.2 *Thrombosis of the deep veins (left) results in swelling of the leg, causing pain and immobility. Ultimately a fragment of the clot may dislodge and become free-flowing within the blood stream, becoming an embolus.*

Both truncal and limb mobility impairment can result in an abnormal patient gait, which during the course of a hospital admission can be observed and subjectively monitored. For example, a patient who is limping and complaining of limb pain would be examined and any tenderness or swelling would lead to further investigations such as ultrasound scanning to look for a DVT. In the case of truncal immobility, a patient who was unable to mobilise due to abdominal or would pain would have their abdomen and surgical incisions examined to look for complications such as infection and impaired would healing. The clinician would also ensure adequate analgesia (pain relief) was provided so that the patient could subsequently mobilise adequately. Once the patient left the hospital and entered their home environment however, monitoring them in this way would become impossible. Detecting changes in a patient's gait that occur due to impaired mobility following surgery may

therefore represent a single best means of pervasively monitoring their functional recovery, wound pain, and risk of developing a DVT.

5.1.3 Changes in gait following surgery

The biomechanical aspects of normal gait have been previously discussed in Chapter 4. From this, it should be noted that although there is some variability between people in the extents to which muscles are used, there is a 'normal' gait pattern which is clearly identifiable. The aspects of a normal gait that may be affected by surgery include: The ability of each leg to support the entire weight of the body without collapsing, maintaining balance on the stance leg, the ability of the swinging leg to move to a position where it can take on a supporting role, and the availability of sufficient power so that limb movements and advancement of the trunk can take place. Although these aspects are all easily fulfilled in normal walking, the presence of an abdominal wound or a complication involving the lower limb such as a DVT may limit movements due to pain or stiffness. They may also result in an increased energy consumption required to achieve the same movement thereby resulting in early tiring. A number of aspects of gait may be affected following abdominal surgery including lateral trunk bending (which normally reduces the force required by abductors of the hip), anterior trunk bending (putting more pressure on extensors of the knee), posterior trunk bending (putting more force on hip extensors), inefficient push-off or abnormal walking base [202].

5.1.4 Measuring changes in gait following surgery

Walking is a complex activity comprising of a number of different components that has previously been discussed and evaluated using the e-AR sensor in Chapter 4. The study of human gait and its role in injury rehabilitation, improving athletic performance, and the design of prosthetic limbs has in the past been an active area of research, with a number of systems proposed for observing gait irregularities. All proposed systems for gait quantification ultimately rely on having features that can quantify human gait, with most existing systems relying on video image sequences to capture the required information. Used in conjunction with biomechanical models, these features can allow quantitative analysis of many specific gait characteristics such as joint moments and powers (kinetic analysis), joint angles, angular velocities, and angular accelerations (kinematic analysis) [203]. In these systems, optical markers are placed near anatomical landmarks of the body and features related to gait are extracted from video sequences. Parametric models have been used extensively to describe a set of image observations. An example is 3-D modelling of moving

people which can be achieved by using volumetric bodies based on elliptical cylinders [204]] or tapered super quadrics. Alternatively, 2-D models that represent the projection of 3-D data to an imaging plane can be used (2D/3D contour modelling for example [205]).

In general, methods that consider the use of kinematic constraints can handle more complex motions and occlusions. These constraints are used to improve tracking as well as preventing model violations of the derived 3-D structures. For example, Dockstader et al. [206] used soft constraints in a hierarchical structural model of the human body to analyse video sequences captured in a home environment. Reviews on human motion analysis based on video, including summaries of modelling, tracking and recognition, are provided by Dariush [207] and Aggrawal et al. [208].

An alternative to vision based gait analysis is the use of body worn sensors to obtain motion data from patients. The variables that can be measured during gait analysis depend on the technique selected. The most commonly measured variables include initial contact (IC) that defines the beginning of a complete gait cycle and thus cycle duration and frequency, and terminal contact (TC) that marks the start of the swing phase. Gyroscopes, which measure angular velocity, and accelerometers which measure linear acceleration, have been used as a wearable option to measure these variables [209]. Coleman et al. [210], Aminian et al. [209] and Selles et al. [211] provide methods of measuring both TC and IC timing information. On the other hand, Yoshida et al. [212] use an accelerometer attached to the patient's waist and observe frequency peaks in the anterior plane to detect leg injury. What is important to remember however, is that an injury or wound resulting in gait impairment causes changes not only to the temporal, but also to the frequency domains and that this variation is not normally limited to just one direction of motion. In the case of a patient who has an impaired gait due to an abdominal surgical wound or the development of a DVT, their motion can show signs of swaying to maintain equilibrium, as well as a change in the distribution of the forces when the patient's foot touches the floor.

5.1.5 Using head-worn accelerometers to evaluate gait changes

Head-worn accelerometers have in the past been used to study the movement of the head compared to the rest of the trunk, and also to study changes in gait that may arise due to certain disease states, or even the normal aging process. As a subject mobilises, the head remains relatively stable when compared to the trunk, and therefore the direction of its

movement during activities such as walking is more representative of the body's movement as a whole. A study by Kavanagh et al (2005) used tri-axial accelerometers attached to the head and trunk of normal volunteer subjects to collect data whilst they were walking, and showed that accelerations detected at the head were not only more regular than those at the trunk in each direction, but also associated with a greater degree of coupling between directions [181]. Authors concluded therefore that during walking, accelerations of the head are significantly attenuated and more tightly controlled when compared to accelerations of the lower trunk, making the head a very useful site for quantifying body motion for this activity.

Despite being a relatively stable part of the body during motion, the head moves proportionately more with increasing activity (for example climbing stairs versus walking on a flat level) [213], which is important to consider when evaluating gait. It does however move less than the limbs due to the stabilising effect conferred by the trunk and neck, making it an attractive site for sensor placement [214, 215]. The trunk does play a critical role in maintaining head stability by regulating gait-related oscillations in all directions, and the neck confers additional control thereby enhancing head stability during walking [216].

Head acceleration during walking has also been studied in the elderly patient group, with results suggesting that this site for sensor placement is able to detect changes in mobility with that occur with increasing age [217]. A study by Kavanagh et al (2004) showed significantly different patterns of head and trunk motion in the direction of travel in elderly as compared to young people [218], whilst a study looking at gait initiation by Laudani et al (2006) showed that the transition from standing to walking was performed with more variability in older as compared to younger women [219]. Finally, in a study using head-worn accelerometry to look at gait patterns in diabetic patients, Petrovski et al (2005) found that compared to the control group, diabetic patients had a significantly higher coefficient of variation of acceleration for either flexion-extension or lateral movement of the head [220]. These findings all suggest that as a site for wearable accelerometer placement, the head offers the prospect of detecting impairments in mobility and gait that occur in the post-operative patient group recovering from surgery at home.

The experiments outlined in this chapter aim to test the hypothesis that '*the e-AR sensor can be used to collect raw biomechanical data to detect impairments in human gait due to truncal and limb immobility. These parameters can then be converted using a spatiotemporal*

analysis framework into surrogate markers of normal and impaired mobility'. In order to achieve this, truncal and limb immobility was simulated using bracing systems and subjects asked to mobilise in a simulated home environment whilst wearing the e-AR sensor to collect raw biomechanical data. A multi-resolution spatiotemporal framework software was used to analyse the e-AR sensor's accelerometer data which instead of using fixed measures (such as gait cycle) that generally do not take into account of 3-D motion, used multi-resolution wavelet features across all directions of motion. This technique used automatic margin-based feature selection to select the frequency bands of the wavelet transform that provide discrimination between classes of motion, and Independent Component Analysis (ICA) as a means of source separation for 3-D acceleration [221].

5.2 Materials and Methods

5.2.1 Overview

Two comparative datasets of normal versus impaired mobility were acquired for this study. In the first dataset *lower limb mobility* was impaired using a knee brace system (simulating a DVT). In the second dataset *truncal mobility* was impaired using an abdominal brace system (simulating the post-operative abdomen). The data from these two datasets was used to determine the ability of the system (e-AR sensor and the multi-resolution spatio-temporal framework) to determine the changes in gait that accompany the types of mobility impairment following abdominal surgery and lower limb DVT.

5.2.2 Simulating impaired lower limb mobility

Mildly impaired lower limb mobility resulting from leg swelling and stiffness (such as that following a DVT) was simulated by asking participants to wear an elasticated knee support bandage (Tubigrip), thereby simulating immobility from an early DVT. *Moderately impaired lower limb mobility* was simulated using a knee brace (McDavid 425 Ligament Knee Support), thereby simulating immobility from established DVT. Figure 5.3 shows a subject walking on a treadmill whilst wearing the brace.

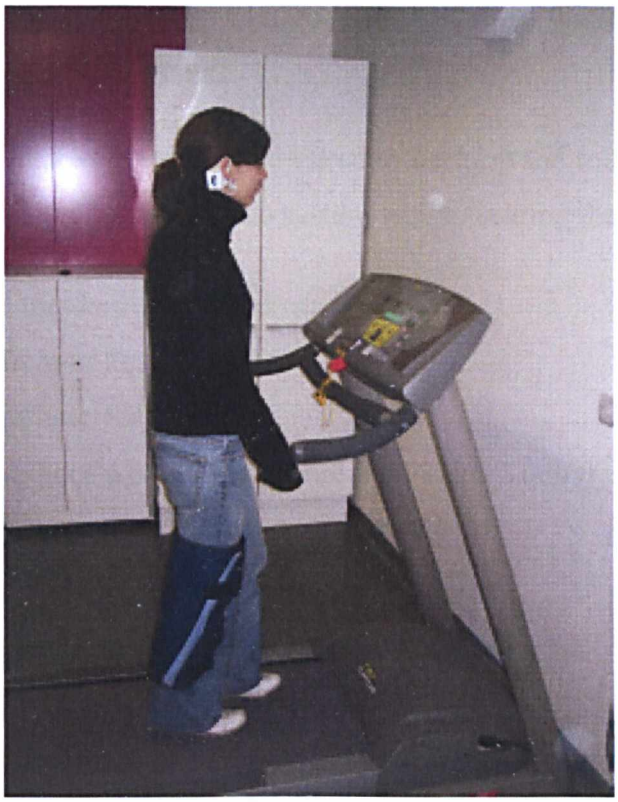


Figure 5.3 *The subject is wearing a knee brace whilst walking on the treadmill.*

10 normal volunteers took part in this arm of the study. Accelerometer data was collected using the e-AR sensor whilst the subjects performed the following activities:

- Walking on a treadmill without any brace
- Walking on a treadmill with mild lower limb impairment (Tubigrip)
- Walking on a treadmill with moderate lower limb impairment (McDavid Ligament Knee Brace)

Subjects were always asked to wear the tubigrip or brace on their right leg, and walked on a treadmill using a fixed walking speed of 2.5 Km/h for a total of 3 minutes.

5.2.3 Simulating impaired truncal mobility

The type of truncal immobility experienced by patients who have undergone abdominal surgery (both laparoscopic and open) was determined via a questionnaire as outlined in Appendix D. The results from this questionnaire showed that an abdominal wound restricted overall activity and walking by reducing *pelvic tilt*, *lateral flexion*, and *spinal rotation*. Finally, it was noted that *abdominal tightness* also impaired patients' mobility. With this in mind, a truncal immobility brace system was derived consisting of a spinal brace

(Orthomerica Air Back™ Spinal Support System) with additional thigh strapping. Figure 5.4 shows the truncal immobility brace system.

A total of twenty-two normal volunteers were asked to perform the following activities both with and without the truncal immobility brace system whilst wearing the e-AR sensor:

- Walking on a treadmill at a speed of:
  - 1.5 km/hour for 2 minutes
  - 3.5 km/hour for 2 minutes
  - 3.5 km/hour with 30 centimetre incline for 2 minutes
- Walking down a corridor (50 metres)
- Walking up a flight of stairs (9 steps).
- Walking down a flight of stairs (9 steps).

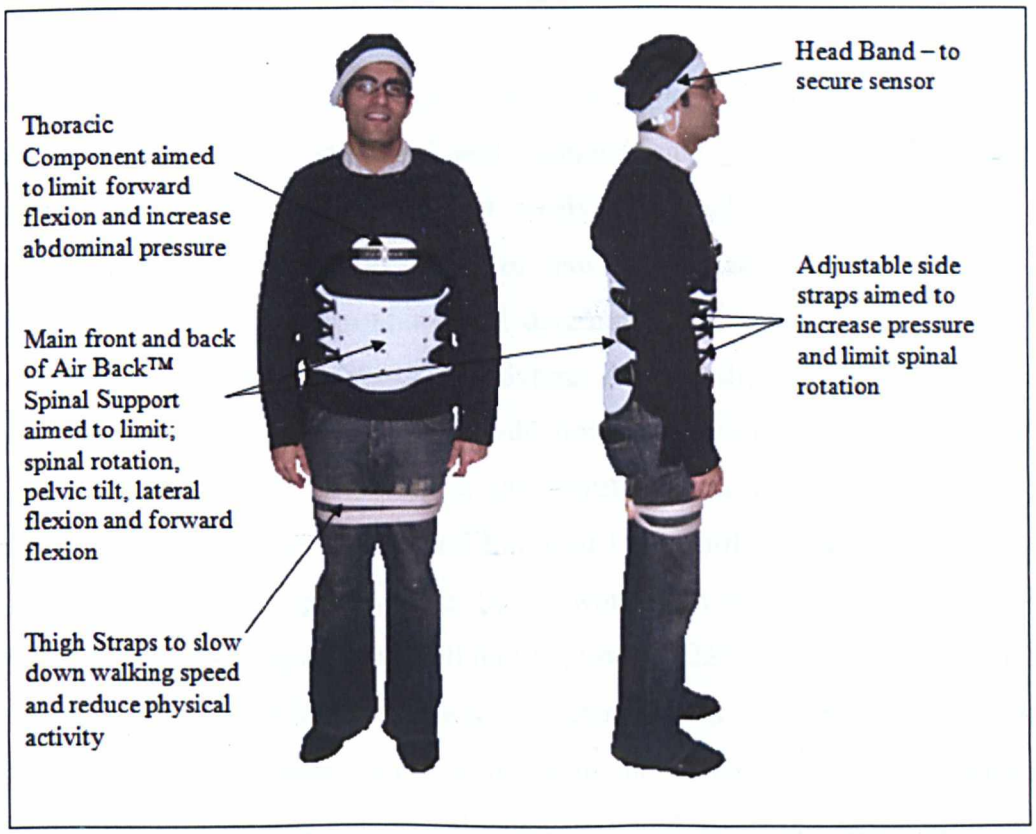


Figure 5.4 *Subject shown wearing a truncal immobility brace system, with the components labelled. Please note that the subject in this figure was asked to wear a headband to secure the e-AR sensor.*

5.2.4 Data Collection

The e-AR sensor used in this study have already been described in detail in Chapter 3. Accelerometer data representing *x* (forward-backward), *y* (side-to-side), and *z* axis (up-down) displacements of the e-AR sensor was collected in volunteers undertaking the experiments, and was wirelessly transmitted through the Imperial College BSN platform to a portable handheld personal computer. The accelerometer in the e-AR sensor had a sampling frequency of 50Hz (1 sample every 20ms) and the pulse oximeter had a sampling frequency of 1 Hz (1 sample per second). This data was automatically placed into a comma separated value (.csv) file which is compatible with Microsoft™ Excel software.

5.2.5 Mobility impairment detection

In order to analyse the accelerometer data, a specifically designed 'Mobility Impairment Detection' software program developed by Atallah et al [222] was utilised. This used the following techniques to detect changes in gait with and without truncal or limb mobility impairment:

1. Blind Source Separation using Independent Component Analysis (ICA) - Independent component analysis is a statistical and computational technique that is used to decompose complex data such as that received through each of the three axis accelerometer signals from the e-AR sensor, into its component parts. It is a means of performing blind source separation, and determines the source or original signal without making assumptions about the mixture. As a result, only the desired signals are extracted. Apart from the source signals, noise can also be assumed to be part of the sources. The first step is to remove any correlations in the data (i.e. 'whiten' the data thereby uncorrelating the signals) followed by an orthogonal transformation of the whitened signals to separate them. In this work, ICA was implemented for blind source separation as suggested by Bell and Sejnowski [223]. It was an important first step in analysing the e-AR sensor's accelerometer data, as each one of the *x*, *y*, and *z* axis signals contained some information about the underlying motion. Instead of analyzing the signals directly, signal analysis could be made more efficient by analyzing the resulting source signals that summarize the underlying motion. To further illustrate the use of ICA in analysing accelerometer data from the e-AR sensor, Figure 5.5 below shows two ICA components derived from a single axis accelerometer trace for a subject walking as described by Lo et al [224]. The first

component clearly indicates the running pace of the subject, whereas the second component appears to capture the high frequency component of the body movements. By extracting the significant feature (i.e. the first ICA component) from the sensor signal, better classification can therefore be achieved.

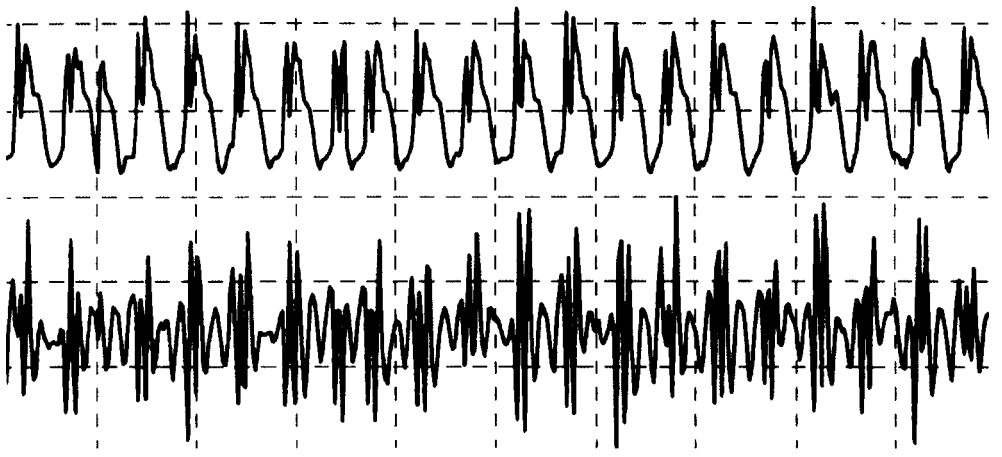


Figure 5.5 *The recovered ICA components of an accelerometer trace from a subject when walking. The upper component indicates the running pace, whilst the lower component represents high frequency components.*

2. Multi-resolution wavelet analysis – As described by Fourier theory, a signal can be described as a sum of a series of sines of cosines, also known as a Fourier expansion [225]. A disadvantage of a Fourier expansion however, is that it has only a frequency resolution and not a time resolution. As a result, whilst all the frequencies in a signal can be determined, knowing when they are present is not possible. The wavelet transform or wavelet analysis overcomes this problem, allowing the observation of the multi-resolution properties of the acceleration signals across both time and frequency [226]. The wavelet transform uses a fully scalable modulated window that is shifted along the signal and for every position the spectrum is calculated. The process is repeated a number of times with a window for every new cycle, resulting in a collection of time-frequency representations of the signal, all with different resolutions. Because this is a collection of representations, it is called 'multiresolution analysis'.

   The Discrete Wavelet Transform (DWT) was selected as it can provide a compact representation of a signal in time and frequency that can be computed efficiently. Discrete wavelets can only be scaled and translated in discrete steps and are not

continuously scalable and translatable. When they are used to transform a continuous signal the result is a series of wavelet coefficients, or 'wavelet series decomposition'. DWT analysis can be performed using a fast, pyramidal algorithm related to multirate filterbanks. This is achieved by filtering of the signal using a high pass filter to obtain the signal details, and a low pass filter to obtain the approximation coefficients. This is followed by sub-sampling, and the sub-sampled signal is passed through both filters again to obtain the DWT coefficients at several scales, as shown in Figure 5.6. For our experiment, the DWT coefficients were calculated for 3 axis accelerometer data (as shown in Figure 5.7) using the 4 coefficient Daubechies wavelet family. Finally figure 5.8 is another representation of the shows DWT coefficients for the ICA component of the accelerometer signal representing the walking pace. In this study, wavelet coefficients were calculated across the 5 scales using a moving window.

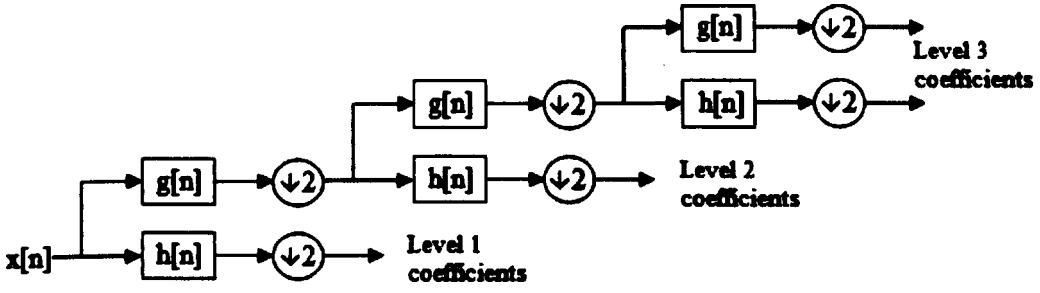


Figure 5.6 *Stages of a wavelet filter composed of high pass and low pass filters at each stage.*

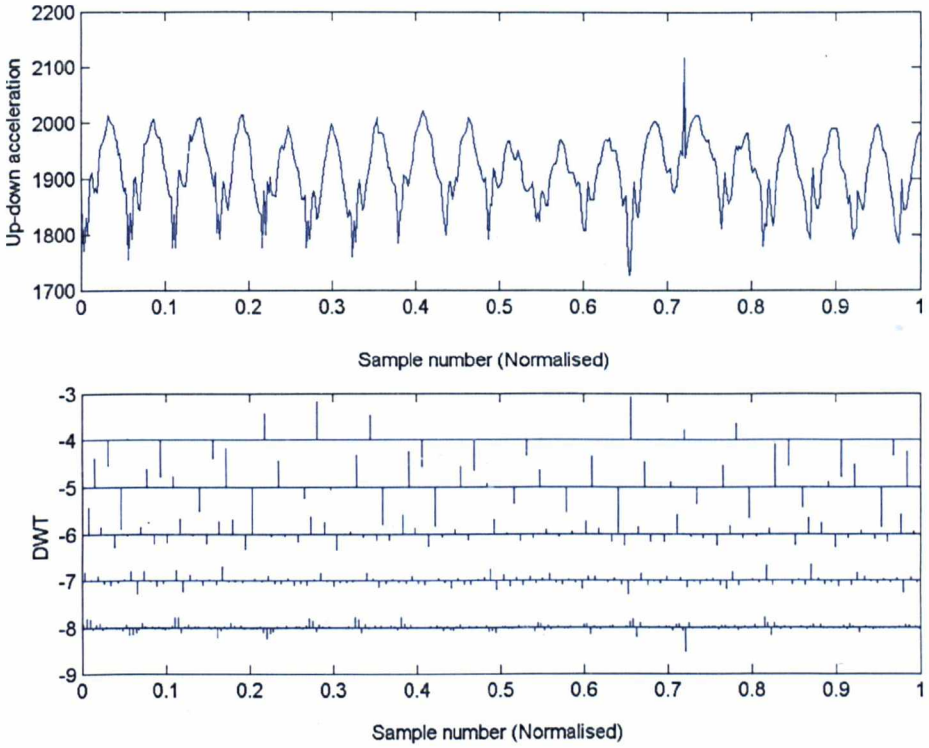


Figure 5.7 *An example multi-resolution DWT of an acceleration signal.*

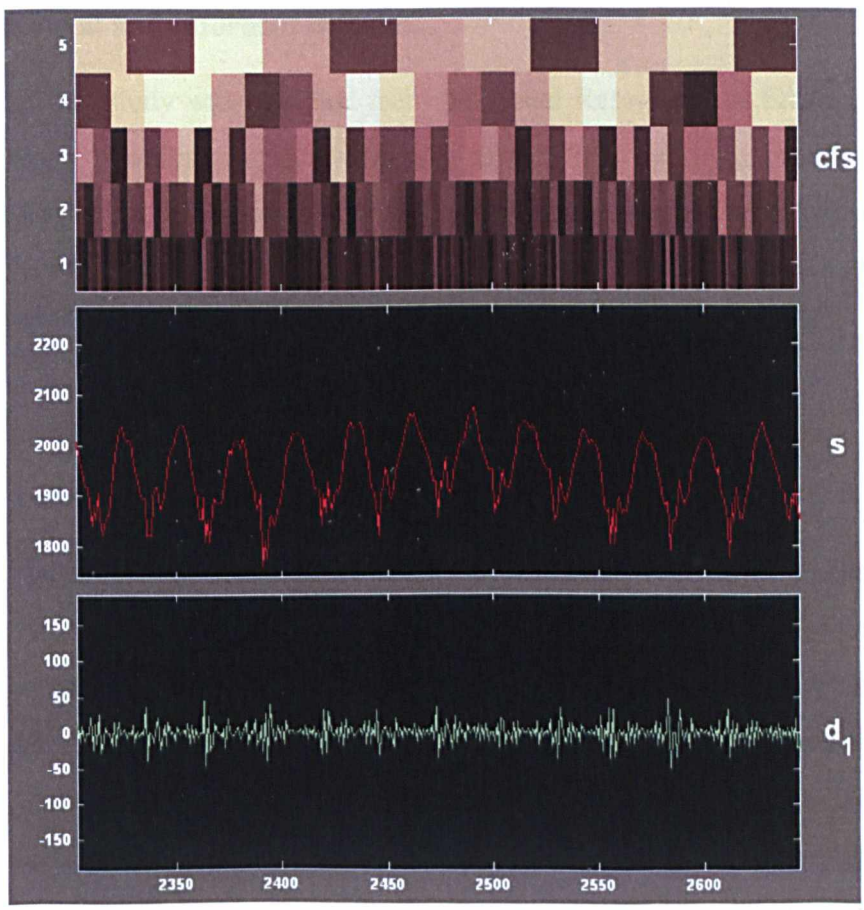


Figure 5.8 *The DWT coefficients (above) for the ICA component of the accelerometer trace representing the walking pace (middle), with the high frequency component separated (below).*

3. Margin-based feature selection - Due to the fact that a large feature space was generated from the DWT, supervised feature selection was used in order to select the most useful features. These are features that would provide optimal clustering between impaired and unimpaired activity. In this work, the Iterative Search Margin Based algorithm (Simba) proposed by Gilad-Bachrach et al. [221] was used. A margin is a geometric measure for evaluating the confidence of a classifier when making a decision. An evaluation function was used to assign a score to a set of features according to the margin they introduce.

4. K Nearest Neighbour (KNN) Algorithm for Classification – This supervised learning algorithm is a simple classifier that can deal with non-linear class boundaries, and was used to separate classes of normal versus impaired mobility [227]. K-fold cross validation was used to observe rates of correct classification.

Appendix E is a technical paper by Atallah et al [222] providing more detail on the mobility impairment detection techniques used in this study.

5.2.6 Ethical approval and informed consent

Ethical approval for this study was obtained from the Local Research and Ethics Committee (LREC) at St. Mary's Hospital, London, UK. As part of this approval process informed written consent had to be gained from all subjects, who were also given an information sheet regarding the study. MHRA approval for the use of the e-AR sensor in this study protocol had been obtained.

5.3 Results

5.3.1 Detecting lower limb mobility impairment

The accelerometer outputs from the e-AR sensor for one subject walking with normal versus with moderate lower limb impairment (McDavid ligament knee brace) are shown below in Figure 5.9. Visual inspection of this raw biomechanical data shows that with normal walking, accelerometer traces are more repeatable, regular, and compact when compared to impaired mobility. This is true for all three accelerometer axes. The number of steps taken over a period of time (cadence) was also seen to be reduced with impaired lower limb mobility.

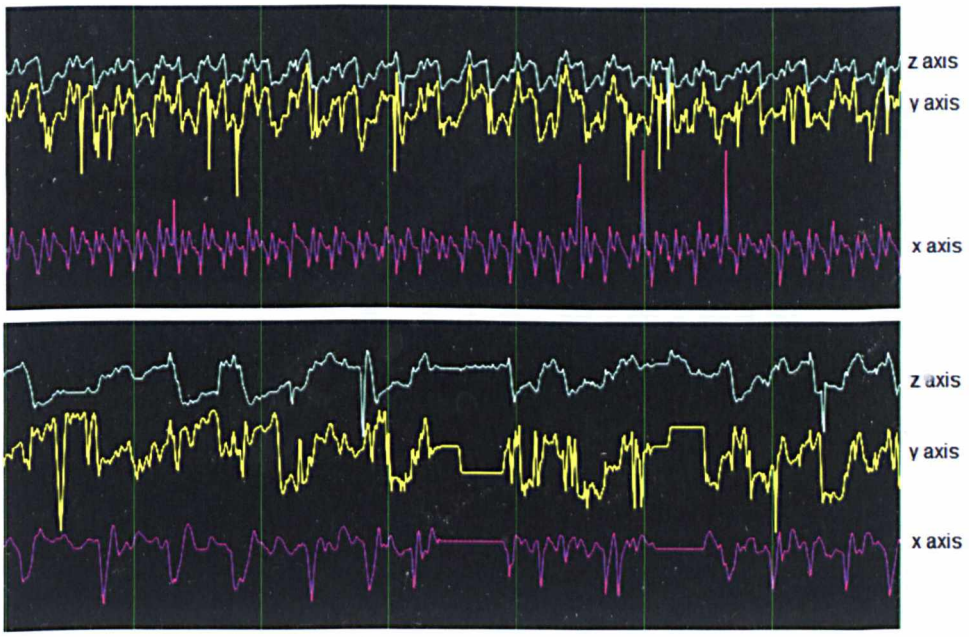


Figure 5.9 *Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally (above) versus with moderate lower limb mobility impairment (below).*

Each accelerometer signal was filtered using the DWT and the features were calculated per moving window. The analysis was performed for all 10 subjects separately in order to be able to detect and quantify differences between normal and degrees of impaired walking per subject. Another reason for performing the analysis on subjects individually was that because different people had different walking patterns, it is was much less accurate to compare normal versus impaired walking by combining data for all subjects. Although three classes of data were collected, namely normal walking, walking with mild lower limb involvement (tubigrip) and walking with moderate lower limb impairment (knee brace), the mild lower limb impairment class seemed to completely merge with the normal walking class. The main reason for that was that the leg-tubing did not alter the subjects' gait sufficiently when walking, and as a result most subjects walked normally even when wearing it. As a result, for the purposes of this study the two groups were combined and compared to the moderate lower limb impairment group.

The results of using DWT for feature extraction using 5-fold cross validation with the KNN classifier with K-value fixed to 5 per subject (numbered from 1 to 10) are shown in Figure 5.10. Each bar in the figure shows the percentage of correct classification. The colours show the number of features selected by Simba varying from 1 (blue) to all features (red) for each patient. When ICA was used for source separation before the feature extraction step, correct classification rates were improved as shown below in Figure 5.11.

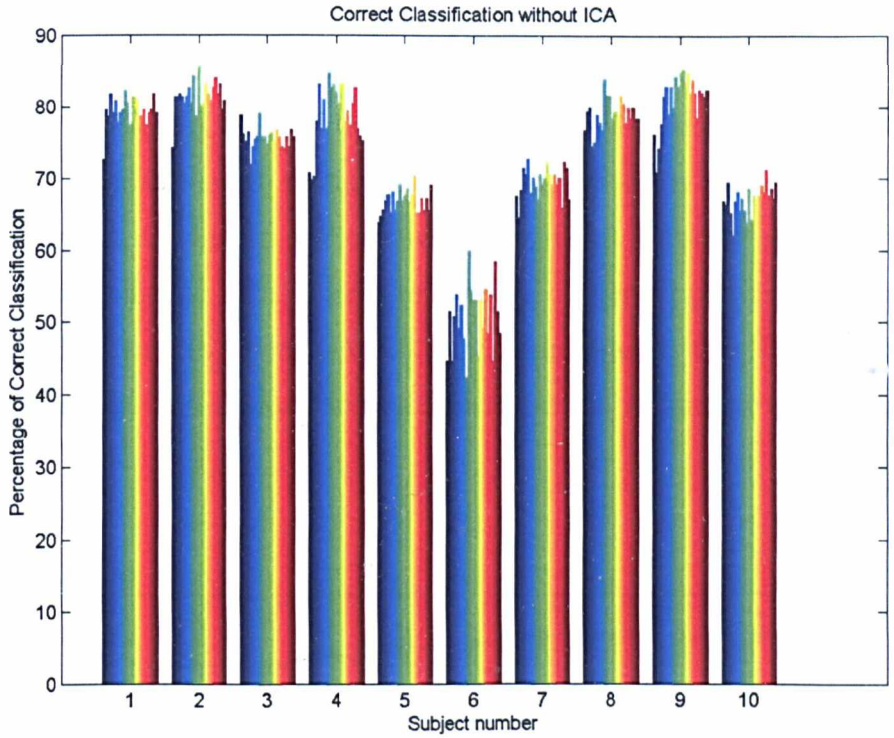


Figure 5.10 *Results of using a KNN 5-fold cross validation on 10 subjects using DWT. Colours represent the number of features selected by Simba varying from 1 (blue) to all features (red). Percentage correct classification of normal versus moderately impaired lower limb mobility is shown.*

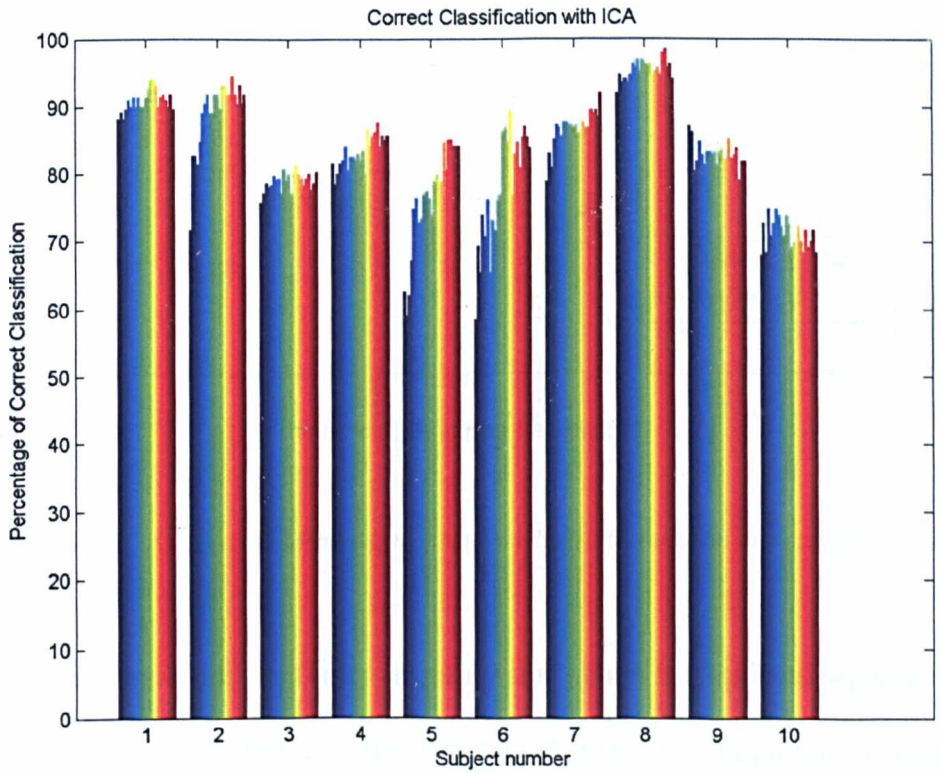


Figure 5.11 *Results of using a KNN 5-fold cross validation on 10 subjects using DWT when ICA was used for source separation before the feature extraction step. Colours represent the number of features selected by Simba varying from 1 (blue) to all features (red). Percentage correct classification of normal versus moderately impaired lower limb mobility is shown.*

It is evident from this that performing ICA on the accelerometer signals before the wavelet analysis stage led to a large improvement in the results, reaching 15% in some cases. This is better illustrated in Figure 5.12, which is a graph showing how the percentage correct classification of normal versus moderately impaired mobility changed with increasing number of features used, when all subjects were considered. It can be seen that the 'plateau' of best results was achieved with 11 features averaged over all participants when ICA was not used, and with 5 features when ICA was used. This suggests that filtering redundant and irrelevant features provided a more accurate classification and improved the results of the system.

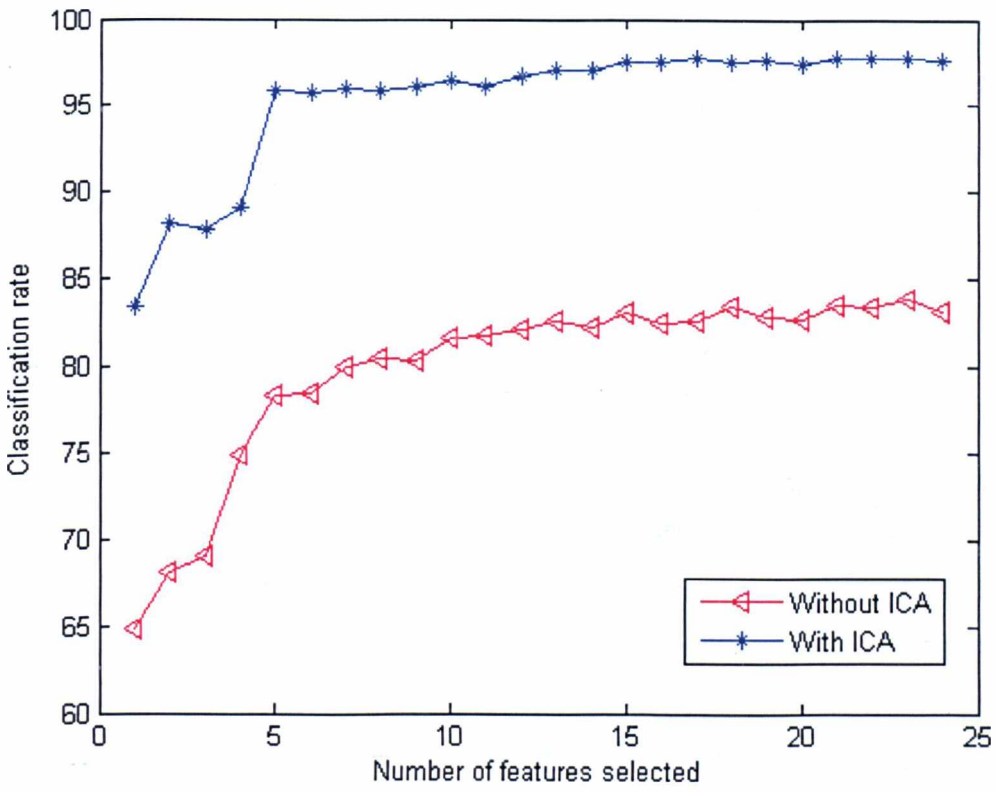


Figure 5.12 *The impact of ICA and increasing number of selected features on correct data classification rates for impaired lower limb mobility.*

5.3.2 Detecting lower limb mobility impairment: achieving optimal separation

In order to optimise the system described in this chapter, it is important to understand the effect of increasing the number of features used on the correct classification of normal versus impaired lower limb mobility. Table 5.1 summarizes the results of using a 5-fold cross validation KNN classifier with different numbers of features selected on the dataset. The

columns show several values for the parameter K (number of nearest neighbours considered). It is evident from this table that that even with a low number of features, the methods described in this chapter showed good separation (around 90%) between the two classes, namely normal walking and moderately impaired walking.

Number of features\K	K=5	K=10	K=20	K=25
1 (Feature)	87.8	86.3	88.3	88.3
2	87.3	88.8	87.8	86.8
3	90.2	89.3	88.3	87.3
4	87.8	88.3	88.3	87.8
5	91.2	90.7	89.8	89.7
6	90.2	90.7	87.3	88.8
7	91.2	91.2	89.8	89.3

Table 5.1: *The results of using KNN with 5-fold cross validation on the normal versus impaired lower limb mobility dataset.*

5.3.3 Detecting impaired truncal mobility

As before, each accelerometer signal was filtered by using the DWT and the features were calculated per moving window. Data analysis was performed for all 22 subjects separately in order to be able to detect and quantify differences between normal and impaired truncal mobility. Two classes of data were identified namely normal walking and walking with truncal mobility impairment (wearing the abdominal brace system). Activities performed included walking down a corridor, walking up and down stairs, and walking on a treadmill at varying speeds. The results of using DWT for feature extraction using 5-fold cross validation with the KNN (K nearest neighbour) classifier with K-value fixed to 5 per subject, with and without the use of ICA are presented below. It is important to note that for some activities the number of subjects were smaller because of data loss from the sensor.

5.3.3.1 Walking on a treadmill

The e-AR sensor accelerometer outputs for a subject walking on a treadmill at 3.5 km/h with normal versus impaired truncal mobility are shown below in Figure 5.13. In this case, the accelerometer traces for all three axes appear very similar however looking at the z-axis (up/down) accelerometer, the amplitude of the oscillations in this trace are reduced with the truncal immobility brace.

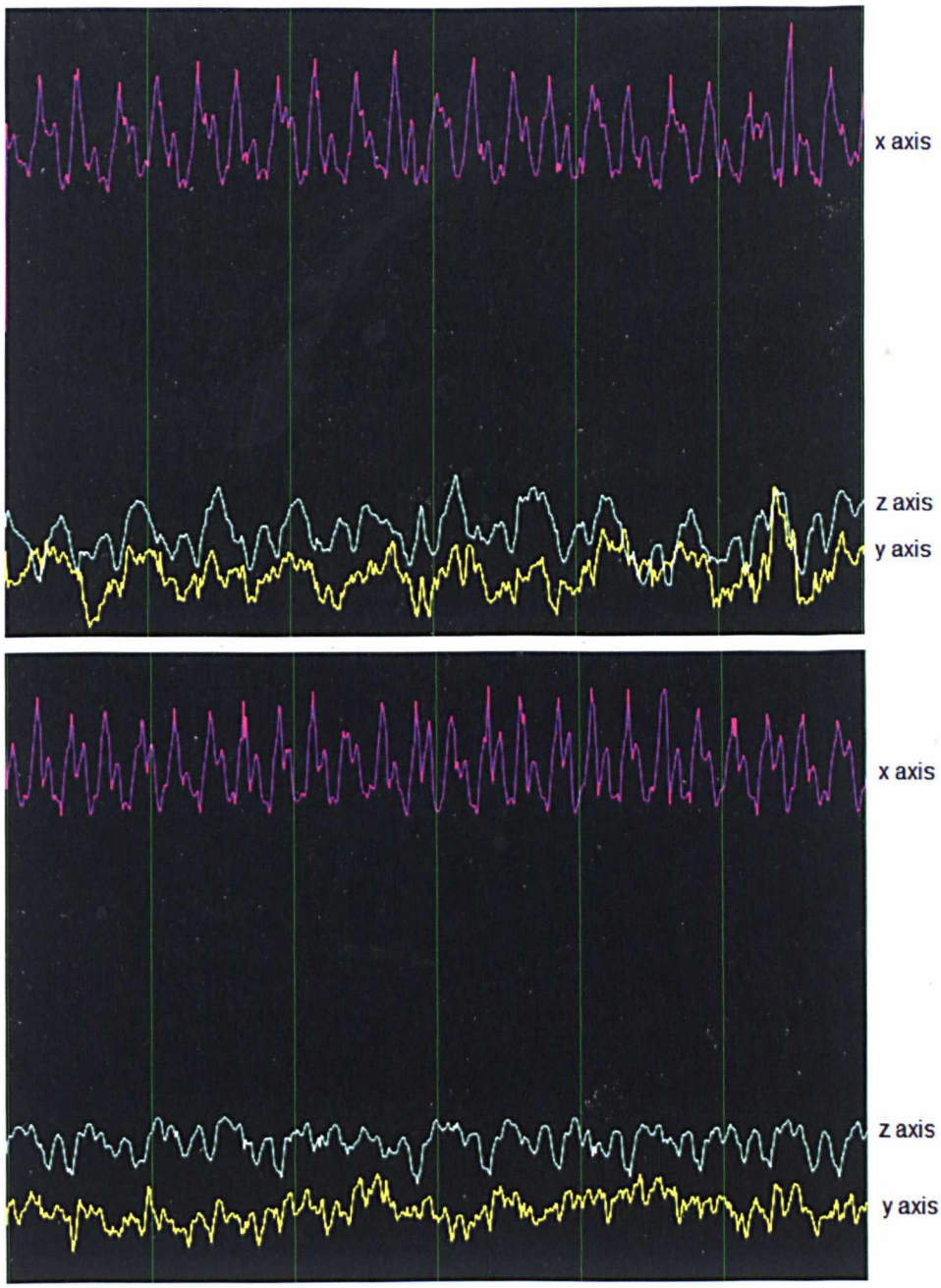


Figure 5.13 *Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally (above) versus with truncal mobility impairment (below). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.*

Analysis of this biomechanical data for normal versus impaired truncal mobility in 22 subjects using the mobility impairment detection framework was performed, with results shown in Figure 5.14. This shows how the percentage correct classification of normal versus impaired walking changed with increasing number of features used, and increasing walking speeds and an incline. What is evident is that using the techniques mentioned in this chapter, the e-AR sensor was able to detect differences between normal and impaired walking over the 1.5-3.5 km/h range of walking speeds, and with an incline. As before, performing ICA on

the accelerometer signals before the wavelet analysis stage led to a large improvement in the results. It can be seen that the 'plateau' of maximum correct classification results were achieved with 14 features averaged over all participants when ICA was not used and with 5 features when ICA was used.

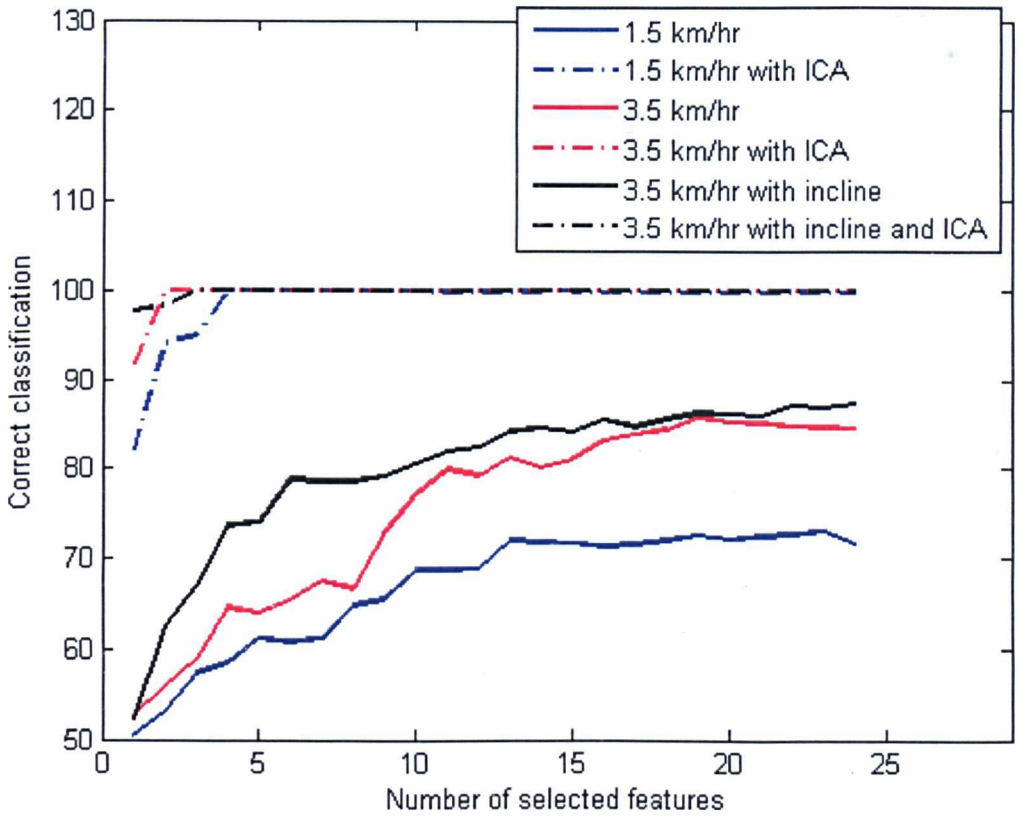


Figure 5.14 *The impact of ICA and increasing number of selected features on correct data classification rates when the e-AR sensor was used to detect normal versus impaired truncal mobility when walking on treadmill at varying speeds and incline.*

5.3.3.2 Walking along a corridor

The accelerometer outputs from the e-AR sensor for one subject walking along a corridor with normal versus with impaired truncal mobility are shown below in Figure 5.15. Visual inspection of this data shows very little difference between the two sets of accelerometer traces apart from an increased irregularity of the x axis (forward-backward) trace with impaired truncal mobility.

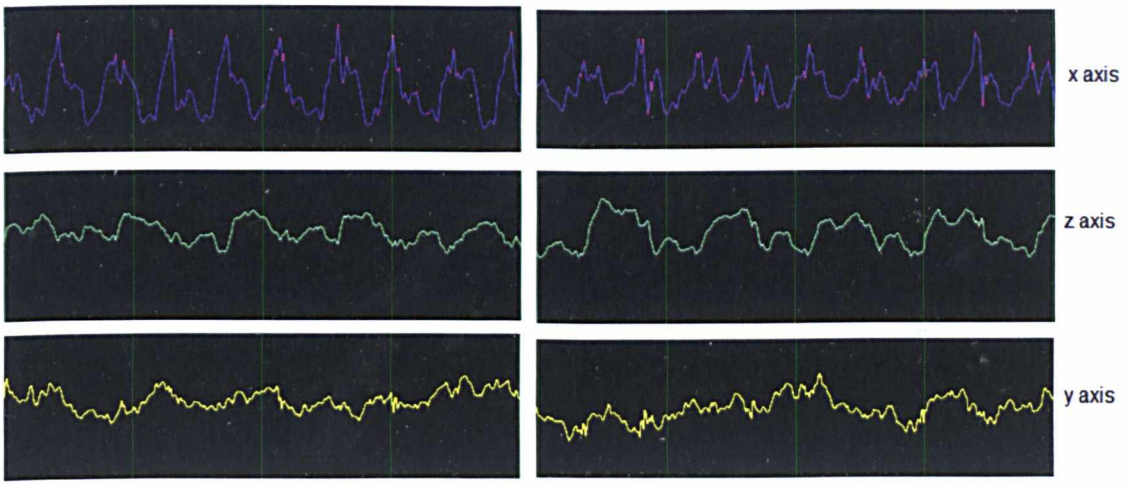


Figure 5.15 *Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally across a corridor (left) versus with truncal mobility impairment (right). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.*

The results for detection of normal versus impaired truncal mobility using the analysis framework for the 22 subjects studied is shown in Figure 5.16, which shows how the percentage correct classification of normal versus impaired walking changed with increasing number of features used.

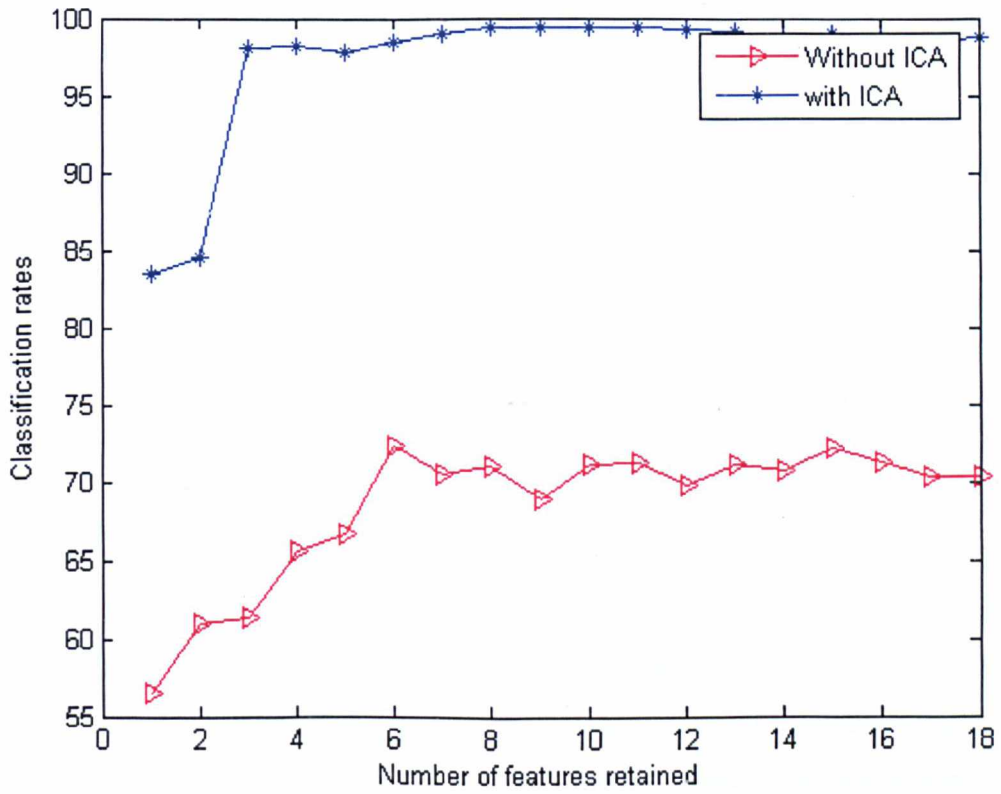


Figure 5.16 *The impact of ICA and increasing number of selected features on correct data classification rates when the e-AR sensor was used to detect normal versus impaired truncal mobility walking along a corridor.*

The margin-based feature selection, wavelet transform, and ICA techniques used were able to detect differences between normal and impaired walking with the e-AR sensor, with ICA leading to a large improvement in the correct classification rates between classes. The 'plateau' of maximum correct classification of results was achieved with 6 features averaged over all participants when ICA was not used and with 3 features when ICA was used.

5.3.3.3 Walking up stairs

Walking up stairs (stair ascent) was described in the same terms as walking as it involves a stance, swing, and double support phases as shown diagrammatically below in Figure 5.17.

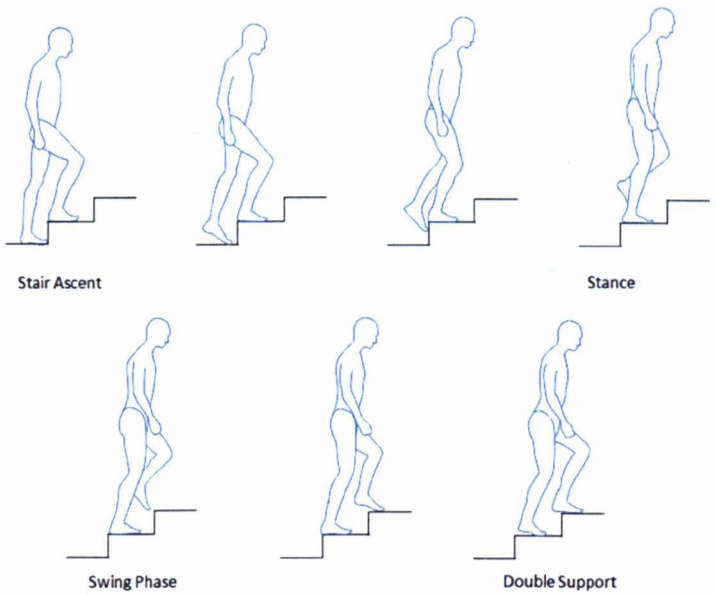


Figure 5.17 *The normal pattern of stair climbing*

The following aspects are of particular note:

- As an activity, stair climbing is more strenuous than walking, placing considerably higher forces on the joints of the lower limb, and requiring balance.

- The beginning of the stance phase of stair ascent starts involves contact between the middle and anterior third of the foot on the step, followed by the remainder of the foot. The hip and knee extensors then contract to extend the lead limb and raise the body up and over the step. At the point where the entire body weight is being supported on a single limb, the abductors of the hip prevent the pelvis from dropping. Gastrocnemius and Soleus contract to produce plantar flexion and accelerate the body upwards and forwards.

- During the swing phase on stair ascent, flexion of the hip, knee and ankle joints (dorsiflexion) is required to achieve intermediate step clearance and to prevent the foot from catching on the top step.

The accelerometer outputs from the e-AR sensor for one subject walking up a flight of stairs with normal versus with impaired truncal mobility are shown below in Figure 5.18. Visual inspection of this data shows irregularity of the all three accelerometer traces with impaired truncal mobility.

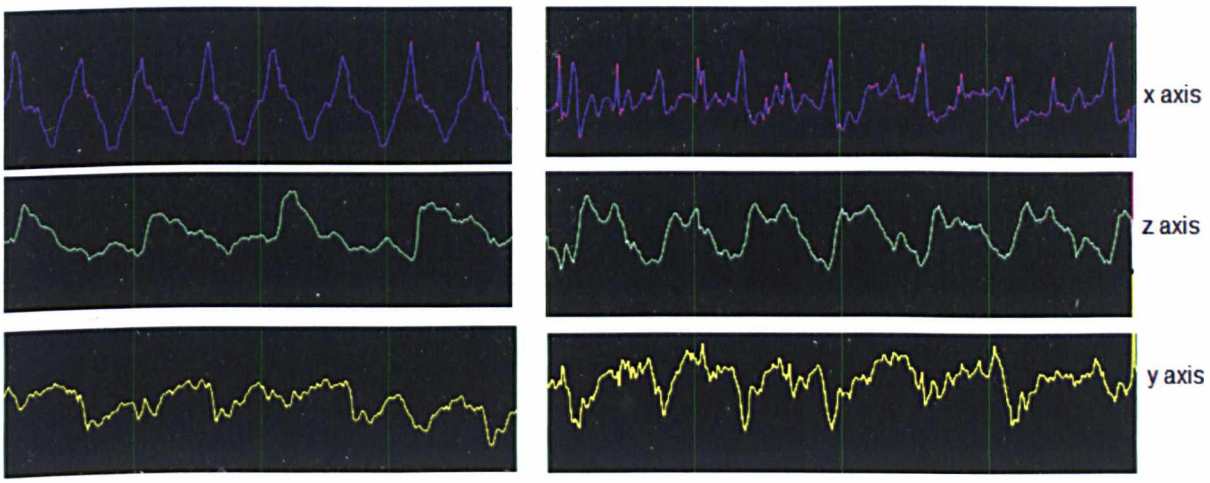


Figure 5.18 *Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally up a flight of stairs (left) versus with truncal mobility impairment (right). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.*

Data for 17 of the 22 subjects walking up stairs was obtained. The wireless transmission of 5 of the subjects' data was lost during this activity in wireless transfer between the sensor and the tablet computer. The results of using DWT for feature extraction using 5-fold cross validation with the KNN classifier (K-value fixed to 5) when all subjects were considered are shown in Figure 5.19. These results demonstrate that performing ICA on the accelerometer signals before the wavelet analysis stage led to an increase in the correct classification rates between normal and impaired truncal mobility whilst climbing stairs. A 'plateau' of maximum correct classification was achieved with 12 features averaged over all participants when ICA was not used (75%), and with 4 features when ICA was used (95%).

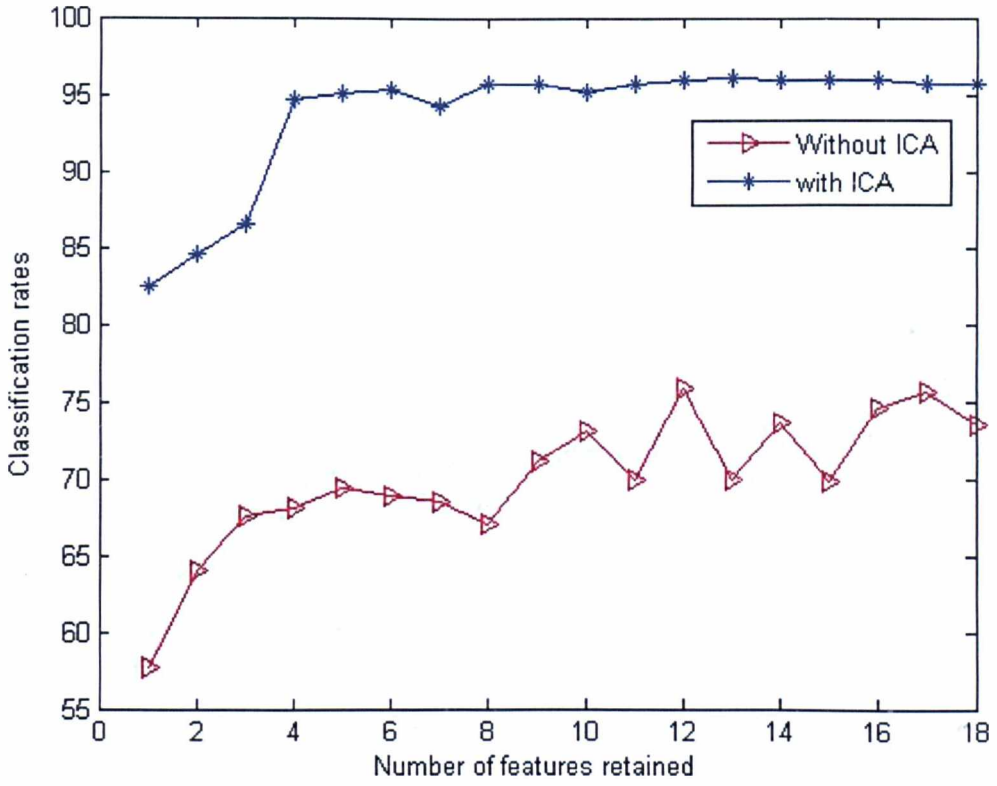


Figure 5.19 *The impact of ICA and increasing number of selected features on correct data classification rates for impaired truncal mobility in all subjects when walking up stairs.*

5.3.3.4 Walking down stairs

Stair descent also involves stance, swing and double contact phases and is described as in Figure 5.20 below.

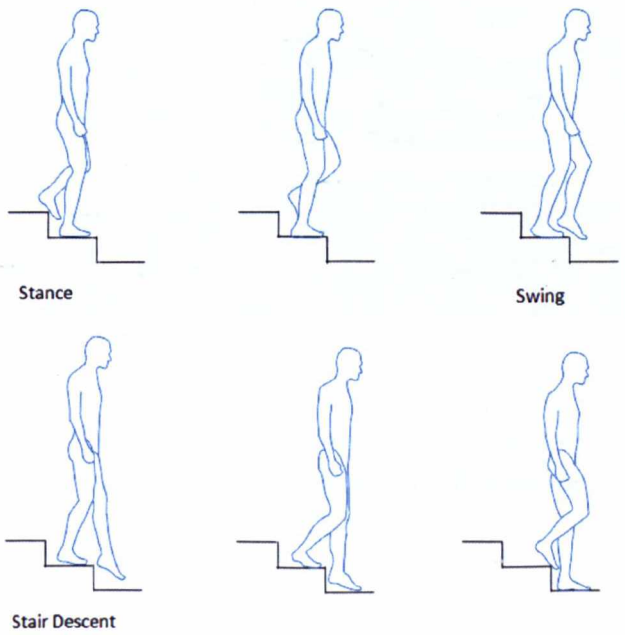


Figure 5.20 *The normal pattern of stair descent*

The following points are of note about this activity:

- The stance phase of stair descent beings with weight acceptance, during which the anterior and lateral border of the foot make contact with the lower step. At this point the hip and knee joints are in flexion. The quadriceps then contract to extend the knee and move the centre of gravity in front of the stance limb. Lowering the body onto the next step involves controlled hip and knee flexion as well as ankle dorsiflexion.

- The swing phase of stair descent involves flexion of the hip and knee to lift the limb off the top step, and swinging it forwards and downwards clear the intermediate step until it is ready to take the weight of the limb and start the next cycle. The limb then extends in readiness for foot placement and plantar flexion of the ankle takes place in readiness to take the weight on the lateral border on the foot.

The accelerometer outputs from the e-AR sensor for one subject down a flight of stairs with normal versus with impaired truncal mobility are shown below in Figure 5.21. Visual inspection of this data shows irregularity of the all three accelerometer traces with impaired truncal mobility.

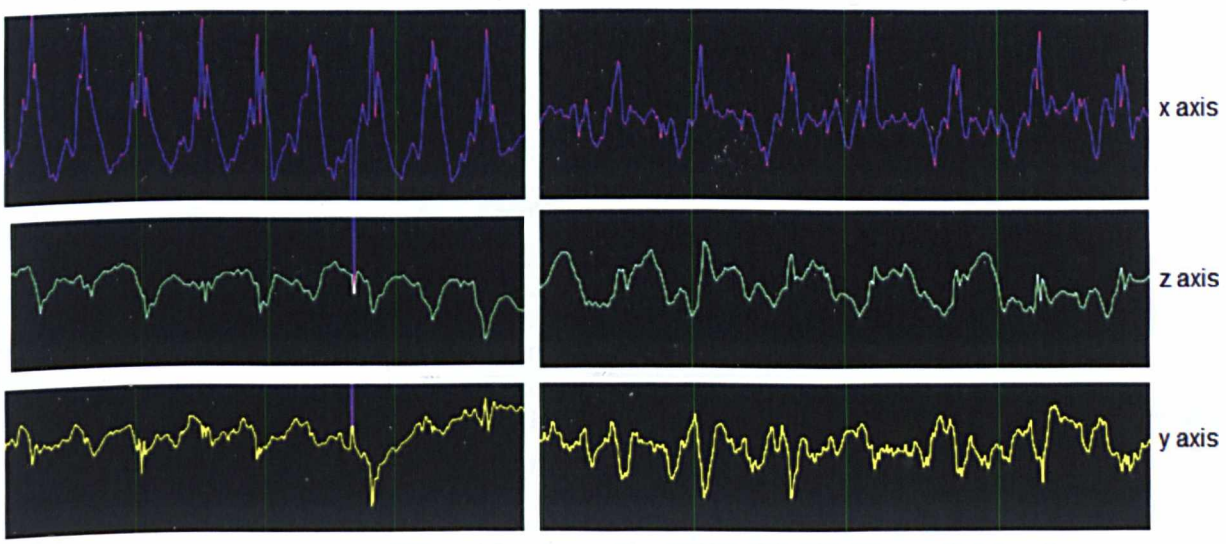


Figure 5.21 *Three-axis accelerometer outputs from the e-AR sensor for a subject as they walk normally down a flight of stairs (left) versus with truncal mobility impairment (right). The purple trace represents x axis, the green trace represents z axis, and the yellow trace represents y axis displacements.*

Data for 17 of the 22 subjects walking down stairs was obtained. The wireless transmission of 5 of the subjects' data was lost during this activity in wireless transfer between the sensor and the tablet computer. The results of using DWT for feature extraction using 5-fold cross validation with the KNN classifier (K-value fixed to 5) when all subjects were considered are shown in Figure 5.22. These results demonstrate that performing ICA on the accelerometer signals before the wavelet analysis stage led to an increase in the correct classification rates between normal and impaired truncal mobility whilst climbing stairs. A 'plateau' of maximum correct classification was achieved with 17 features averaged over all participants when ICA was not used (67%), and with 7 features when ICA was used (95%).

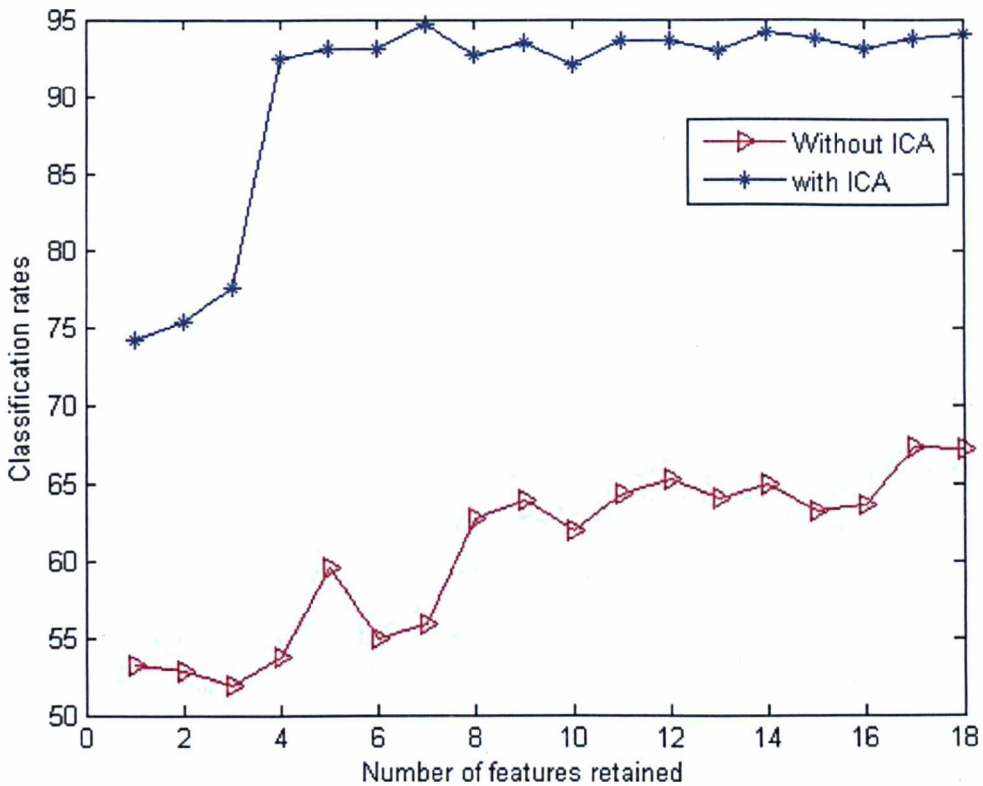


Figure 5.22 *The impact of ICA and increasing number of selected features on correct data classification rates for impaired truncal mobility when walking down stairs.*

5.3.4 Detecting truncal mobility impairment: achieving optimal separation

In order to optimise the system described in this chapter, it is important to understand the effect of increasing the number of features used on the correct classification of normal versus impaired truncal mobility when walking. Table 5.2 summarizes the results of using a 5-fold cross validation KNN classifier with different numbers of features selected on the dataset obtained for subjects walking along a corridor. The columns show several values for the parameter K (number of nearest neighbours considered).

Number of features\K	K=5	K=10	K=20	K=25
1 (Feature)	81.7	83.4	84.1	82.6
2	84.7	85.1	85.6	85.5
3	98.5	98.2	98.1	98.1
4	98.6	98.5	98.1	98.2
5	98.2	97.9	97.8	97.9
6	98.9	98.7	98.3	98.4
7	98.9	98.8	98.4	98.4

Table 5.2 *The results of using KNN with 5-fold cross validation on the subjects walking along a corridor with and without impaired truncal mobility.*

It is evident from this table that that even with a low number of features, the methods described in this chapter showed good separation (around 98%) between the two classes, namely normal walking and moderately impaired walking. In addition to this, increasing the value of K above 5 when 3 or more features were used did not significantly improve results.

5.4 Discussion

This chapter has investigated a framework for multi-resolution gait analysis used to convert raw biomechanical accelerometer data obtained from the e-AR sensor into markers of normal and impaired mobility. Instead of defining pre-fixed parameters that could distinguish impaired from normal mobility, an automatic feature selection method was used, with Discrete Wavelet Transform utilised for feature extraction, and the Iterative Search Margin Based algorithm used for feature selection. Models of truncal and limb mobility impairment were tested, both of which have relevance to patients who have undergone abdominal surgery and are recovering at home. The results of this study suggest a good separation between classes in both models of mobility impairment, and suggest that the features obtained could be used to observe post-operative recovery in a patient's mobility following abdominal surgery. Considering each of the two mobility impairment models however, the following should be noted:

- In the case of the impaired lower limb mobility model designed to simulate a lower limb DVT, although the initial experimental design resulted in three classes of data collection namely normal walking, walking with mild lower limb involvement (tubigrip) and walking with moderate lower limb impairment (knee brace), the mild

lower limb impairment class completely merged with the normal walking class. This suggests that in the case of DVT, this complication would not be able to be detected by this system until it was significant enough to cause mobility impairment. Further work is required to increase the sensitivity of the framework and test it on patients who have developed real DVT of the lower leg. An extension of the work carried out in this study could include a study of the relationship between the time-frequency features extracted and those used traditionally by gait-analysis labs (such as initial and terminal contacts), as well as validating results with vision based techniques. Finally it would also be interesting to observe these features for patients walking normally as opposed to on a treadmill, to see the impact of pace and the swaying motion on results.

- The truncal immobility brace was designed from feedback obtained from real patients who had experienced abdominal wounds in order to make it as realistic as possible to the impairment they faced in the post-operative period. Despite not directly impairing the lower limbs, it was often obvious from observation of volunteers taking part in the study, that their mobility appeared different when the subjects were wearing the brace compared to when they were not. This highlights the importance of the trunk in stabilising the body during activities such as walking. The impact that an abdominal wound can have on mobility should therefore not be underestimated, as the restriction of movement through pain is significant. Whilst this has previously been very difficult to quantify, the use of objective mobility impairment detection techniques such as that developed in this study should help to do this. The findings that this impairment was detectable during walking on both a treadmill and stairs as well as when walking up and down stairs was very encouraging especially as these activities will be regularly performed by patients recovering in their home environments.

- For both models of mobility impairment, it was evident that performing ICA on the accelerometer signals before the wavelet analysis stage led to a significant improvement in the percentage correct classification rates of normal versus impaired mobility. These results demonstrated the importance of filtering redundant and irrelevant features from the accelerometer data and thereby providing a more accurate classification of mobility type. It was also evident from the results that even with a low number of features, the methods described in this chapter showed good separation

between normal and impaired classes. Increasing the number of these features did not have a linear correlation with increase in correct classification rates, therefore for each application a decision needs to be made as to the number of features required for optimum separation. It is important to note however that the mobility impairment techniques used in this chapter require the identification of periods of walking or climbing stairs during the patient's day. In order for such a technique to be used in the real home environment, the vast amount of accelerometer data collected during a patient's day will need to be mined and these period of mobility extracted for impairment analysis.

Whilst the detailed analysis of gait was not the subject of this study, the finding that this type of information could be extracted from the e-AR sensor suggests an application for this BSN technology in areas such as sports medicine, neurology, orthopaedics, and physiotherapy, where continuous and pervasive gait analysis may be of great benefit in monitoring disease processes, providing objective measures of recovery, and ultimately measuring the impact of an intervention on final outcome. An example of a specific area that may benefit is in patients undergoing knee-replacement surgery, where manufacturers have already started to consider including accelerometers in their prostheses to try and measure limb mobility in an objective manner [228].

Clinical applications for the e-AR sensor as a device to monitor recovery following abdominal surgery may include the quantification on mobility impairment and the return of this parameter to normal over time. This would be an important way of safely monitoring the functional recovery of patients at home along with the activity classification techniques described in Chapter 4. In addition to this, these objective measures of recovery also have implications for research where the impact of a minimally invasive procedure is being compared to that of a conventional one. Here, objective measures of activity and mobility impairment would be an invaluable tool when determining the impact of an intervention on the life of a patient.

6 Monitoring Functional Post-Operative Recovery in the Real Home

6.1 Introduction

The ability of the e-AR sensor and its three-axis accelerometer to capture biomechanical parameters as indirect measures of activity and mobility impairment, and the use of software frameworks to convert these into surrogate markers of functional recovery has already been demonstrated in the simulated home environment experiments conducted in the previous two chapters of this thesis. However, these experiments took place in a highly supervised setting where observation was used to mark the data and the ability of both activity and mobility impairment classification systems to correctly classify these biomarkers was evaluated. In order for this system to be used in the real home, it needs to be evaluated in an unsupervised setting. This, along with the heterogeneity of a patient's home environment brings with it a set of new of challenges in experimental design. Ultimately it is in this manner that a pervasive wireless technology will need to function if it is to be successful in the real home, replacing existing labour-intensive and costly means of post-operative home recovery monitoring.

6.1.1 Challenges of continuous home activity monitoring

There are a number of significant differences that exist between the simulated and real home environments that must each be considered in turn when evaluating the e-AR sensor's ability to pervasively monitor functional home recovery:

1. In a real home, visual observation is no longer an appropriate means of monitoring a patient's transition from one ADL to the next, firstly because it is labour-intensive, but secondly because it represents an invasion of privacy. Instead the activity classification system and mobility impairment framework's ability to correctly classify accelerometer data have to be relied upon and may only be validated against the subject's general account of what they were doing over a time period. Ultimately this is equivalent to how the e-AR sensor will be used by real post-operative patients.

2. The types of activities that a patient undertakes spontaneously in their real home are likely to be more complex and heterogeneous than in the simulated home or lab setting. One example of this is that a subject may be reclining in a chair whilst on the phone and eating. In this case determining the exact activity being undertaken (activity classification) is more difficult and thus less valid than the intensity of activity being performed (activity index). Ultimately both measures may play a role in determining functional post-operative recovery as part of this pervasive monitoring system.

3. Periods of mobility may in themselves be shorter in the real home and interspersed with ADLs such as cooking and cleaning, making them more difficult to detect and interpret. An example of this is that the subject may only have to walk a few steps from their sofa to their dining table to sit down and eat. This has a particular implication for mobility impairment detection, as a smaller accelerometer dataset during walking makes the sample size smaller and hence the determination of impairment much more challenging.

4. In a real home, variability between subjects becomes more important as one individual may have one set of habits and activities as compared to another. In the simulated environment experiments undertaken so far in this thesis, this was not so much a factor, as subjects were asked to take part in a scenario of activities. As a result, in the real home 'intra-' subject variability will be more apparent.

5. People's homes vary in their size, layout, and composition. This has important implications for not only the activities that they are able to perform, but also poses a challenge for wireless data collection due to need for a good wireless connection throughout the environment. Additional factors such as small children and pets are hazards that also pose a challenge.

Although number of pervasive patient monitoring systems have already been described earlier in this thesis, it is important to highlight the systems currently available for home activity monitoring, and how they overcome the challenges mentioned above. Broadly speaking these are divided into *wearable activity sensing systems* (through attachable body sensors or clothing-embedded sensors), *ambient activity sensing systems* (through

environmental sensors), or *sensor fusion activity sensing systems* (combination of both wearable and ambient sensors).

6.1.2 Wearable activity sensing systems

Obermiller et al (2008) describe a wearable 'pervasive at home sleep monitoring system' (PATHOS), that uses a network of wireless sensors and motes to communicate with each other using the Zigbee protocol [229]. These include nasal thermistors that measure the patient's breathing, a microphone near the base of the subject's neck to record sound such as snoring, a pulse oximeter worn on the subject's finger to detect periods of hypoxia whilst they sleep, accelerometers worn on the arm and leg to measure movement, and a thermometer to measure the subject's temperature. Authors acknowledge that whilst such a large number of sensors may be used to monitor night-time sleep patterns, their system is too cumbersome to be worn and maintained during the day. This is a challenge that the e-AR sensor aims to overcome with its size, ease of use, and location.

Parkka et al (2006) and Ermes et al (2008) describe the importance of an 'activity diary' that can offer subjects behavioural feedback in their homes so that they may modify their lifestyle for long-term health [230, 231]. They also see the need for such activity diary information to be utilized by context-aware services and devices that offer adapted information based on the user's activity type. The authors describe a system requiring the placement of multiple wearable sensors including accelerometers in varying locations, and the use of a custom decision tree, automatically generated decision tree, and artificial neural network based technique to classify activities. Whilst their system was clearly not suited for continuous pervasive monitoring, their study highlights the importance of the strategy that the e-AR sensor is using in aiming to provide continuous activity monitoring through a single wearable device.

Finally groups such as Mathie et al (2004), have argued the case that wearable accelerometers can as sensors provide a low-cost objective means of measuring functional ability of people in the home environment [161]. Applications for home activity monitoring that these groups have identified include the clinical assessment of gait, monitoring for adverse events such as falls, and monitoring key movements to allow longitudinal tracking of activities. The e-AR sensor aims to provide this information to monitor a post-operative patient group in their home as they recover from surgery.

6.1.3 Ambient activity sensing systems

A number of ambient sensor systems have been described for assisted living in groups such as the elderly and handicapped patients. Logan et al (2006) describe the use of over 300 ambient sensors in MIT's 'PlaceLab', a residential condominium in Massachusetts which has been designed to be an observational facility for the scientific study of people in home environments [232]. These sensors range from switch sensors on lights, cupboards, electrical appliances, and faucets, to wireless sensors attached to objects in the apartment. Environmental sensors types include temperature probes, pressure sensors, cameras, microphones, water usage detectors, PIR (passive infrared) and RFID sensors. The data from all of these sensors is relayed to a central processing and storage facility in the apartment, from which it can be captured and later analysed for ADLs. Other similar environments include Georgia Tech's 'Aware Home'2 [233] and the Welfare Techno house in Japan [234]. Whilst this level of equipment is suited for research purposes, it is not practical for the real home. The e-AR sensor's ADL and mobility impairment systems aim to provide this information through wearable sensors alone, which is practical if this technology is to be deployed for wide scale use.

6.1.4 Wearable and ambient sensor fusion

The fusion of data from wearable and ambient sensors is attractive for several reasons. First, many of these environments use a heterogeneous set of sensors with varying power requirements (those with a high power requirement may not be suited to wireless data transfer). Second, the use of sensor fusion combines the strengths of both ambient and wearable sensors, thereby providing a potentially better view of a person's activity profile during ADL monitoring. Finally, sensor fusion can address the problem of absent or incorrect data which is a problem that commonly plagues the real home scenario. Whilst the role of the e-AR sensor as a sensor fusion device is currently being investigated by Pansiot et al (2007) with promising results, it is not the focus of this thesis [47].

The experiments outlined in this chapter aim to test the hypothesis that: '*The e-AR sensor and its biomechanical data analysis frameworks can be used to quantify the intensity and type of activity being performed by a subject in their normal home, and detect any impairment in their mobility in this completely unsupervised environment*'. Accelerometer data was collected using the e-AR sensor, worn by healthy volunteers in their own homes. In order to simulate mobility impairment, subjects were asked to take part in three separate legs of the

study where they were either wearing an abdominal bracing system (simulating impaired truncal mobility), an abdominal and knee bracing system (simulating impaired truncal and lower limb mobility), or no bracing system at all (normal mobility). The activity classification framework and index, mobility impairment detection framework, and accelerometer trace morphology assessment tools developed to date were then used to analyse this data and results compared to a diary kept by the subject.

6.2 Methods

6.2.1 Overview

Nine healthy volunteers were asked to wear the e-AR sensor in their own homes on three separate occasions, during which time accelerometer data was collected using the Imperial College wireless BSN platform. On the first occasion, subjects went about their activities in a completely unimpaired fashion, on the second occasion they were asked to wear a bracing system to impair their truncal mobility, and on the third occasion they were asked to wear bracing to impair both truncal and limb mobility. In this way, 27 datasets for home functional activity each lasting 30 minutes were obtained for analysis in this study. As this was completely unsupervised data, subjects were asked to keep a diary card of their actions and document the times when they transitioned from one area of their home to the next.

6.2.2 Mobility Impairment

The limb (McDavid 425 Ligament Knee Support) and truncal (Orthomerica Air Back™ Spinal Support System) mobility impairment braces used in this study have already been outlined in the experiments in Chapter 5 of this thesis and are shown in figures 5.3 and 5.4 respectively. These braces were chosen to simulate mobility impairment following abdominal surgery and DVT of the leg. All subjects were shown how to correctly apply and remove these bracing systems on several occasions so that they could do this themselves in their homes. The actions they performed at home when wearing them were left to their own discretion. In this way a 'normal mobility' (no brace), 'mildly impaired mobility' (truncal brace), and 'moderately impaired mobility' (truncal and limb brace) dataset was collected for each subject as outlined in Figure 6.1.

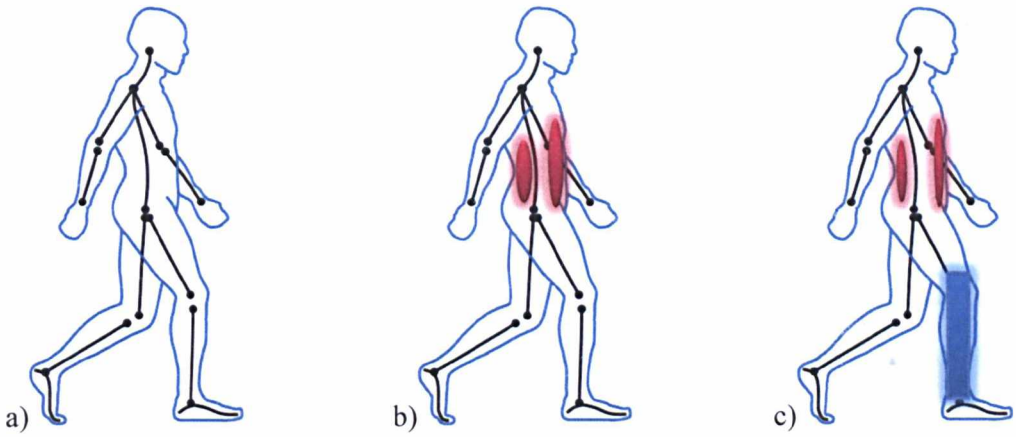


Figure 6.1 *The three types of immobility simulated in the home environment during this study namely no impairment (a), impaired truncal mobility through a spinal brace (b), and impaired truncal and limb mobility through a spinal and limb brace (c).*

6.2.3 Data Collection

The e-AR sensor used in this study have been described in Chapter 3. Accelerometer data representing *x* (forward-backward), *y* (side-to-side), and *z* axis (up-down) displacements of the e-AR sensor was collected in volunteers undertaking the experiments, and was wirelessly transmitted through the BSN platform to a portable handheld personal computer. The accelerometer in the e-AR sensor had a sampling frequency of 50Hz (1 sample every 20ms) and the pulse oximeter had a sampling frequency of 1 Hz (1 sample per second). This data was automatically placed into a comma separated value (.csv) file which is compatible with Microsoft Excel software.

Subjects were also given a paper diary card in which they were asked to manually enter a description of what they were doing and the time they spent doing this. They were particularly asked to document the time points where they transitioned from one activity type to the next or if they moved from one area to the next. The manner in which they documented this was left to the subjects' discretion. Once collected, this data was inputted and stored on a Microsoft™ Excel spreadsheet format.

6.2.4 Ethical Approval and Informed Consent

Ethical approval for this study was obtained from the Local Research and Ethics Committee (LREC) at St. Mary's Hospital, London, UK. As part of this approval process informed written consent had to be gained from all subjects, who were also given an information sheet

regarding the study. MHRA approval for the use of the e-AR sensor in this study protocol had been obtained.

6.2.5 Data Analysis

Accelerometer outputs were visualised retrospectively using BSN Signal Editor Version 1.1 software (© VIP Group, Imperial College London) as shown in figure 4.3. This software also allowed the insertion of markers that annotated where subjects had diary carded their activities. I this way, morphology analysis of the accelerometer traces could be performed in the presence of some contextual information.

In order to be able to classify the activity that a subject was undertaking at a particular time in their home, a Matlab© (Mathworks Inc.) environment based software program developed by Lo et al (2007) [190] was used for data analysis. This uses a Bayesian classifier with multivariate Gaussians to model activity classes. The inputs to the classifier are the three dimensional variance across the three accelerometer axes, as well as the amplitude of the raw data. A window of streaming data is assigned an activity class if the probability of belonging to this class was more than the probability of belonging to all other classes. The activity classes are assumed to have equal prior probabilities. For the purposes of objective classification, the software allows activities to be groups into four groups, namely 'very low' (Class 0), 'low' (Class 1), 'medium' (Class 2), and 'high' (Class 3) level activities.

The overall intensity of the activity being undertaken was determined using an 'Activity Index' calculated from the averaged variance across the 3 accelerometer outputs. The value of the activity index ranged from 0-25 with a greater value signifying a greater amount of movement and hence a 'more active' type of activity. In order to test the ability of this activity index to correctly predict the intensity of activity being undertaken by a subject, a binary logistic regression model was used. Information from the diary card was divided into one of two categories:

- Low level activities – These included lying down (sleeping, resting) or sitting (including reading, eating, watching television) activities.
- High level activities – These involved moving whilst standing (including walking, cleaning, and cooking).

The mean activity index (+/- standard deviations) for periods during which subjects marked their diary cards as undertaking low and high level activities were calculated, and a logistic regression analysis performed between the diary carded activity level (dependent variable) and the activity index (independent variable). Data analysis was performed by using SPSS version 16 for Windows.

In order to detect mobility impairment in the home, the BSN Signal Editor Version 1.1 software (© VIP Group, Imperial College London) was used to identify and separate periods of walking. A multi-resolution spatiotemporal framework software was then used to analyse the e-AR sensor's accelerometer data which instead of using fixed measures (such as gait cycle) that generally do not take into account of 3-D motion, used multi-resolution wavelet features across all directions of motion. This technique used automatic margin-based feature selection to select the frequency bands of the wavelet transform that provide discrimination between classes of motion, and Independent Component Analysis (ICA) as a means of source separation for 3-D acceleration [221].

6.3 Results

In total 27 datasets for home functional activity each lasting 30 minutes were collected, amounting to a total of 810 minutes of unsupervised home monitoring using the e-AR senor. Results for unsupervised home activity classification, activity index sensitivity, and mobility impairment detection are presented in turn below. All data analysis was performed retrospectively.

6.3.1 Unsupervised home ADL classification

The accelerometer traces and accompanying results of ADL classification for subjects 1, 4, and 7 during one leg of this study are shown graphically below in Figures 6.2, 6.3, and 6.4 respectively. Each graph represents an approximately 30 minute long time period of home activity, and has their diary card information annotated alongside the accelerometer trace. These three samples were selected because they each illustrate important aspects of pervasive home activity monitoring, covered in more detail below:

Subject 1

During this period, this subject spent their time tidying up around the living room (1), sitting down and talking on the phone (2), tidying up their bedroom (3), working in front of a computer whilst seated (4), and finally getting up to eat a packet of crisps (5). In figure 6.2 below, it can be seen that during periods 1, 3, and 5, the classifier showed more sustained periods of class 3 activities. During the periods 2 and 4, the classifier consistently showed class 1 or 2 activities. There were however 'spikes' of class 3 activities seen during these time periods, corresponding to variance in the accelerometer signal likely to be due to either changes in head position (such as looking over their shoulder), physical contact with the e-AR sensor, or signal noise.

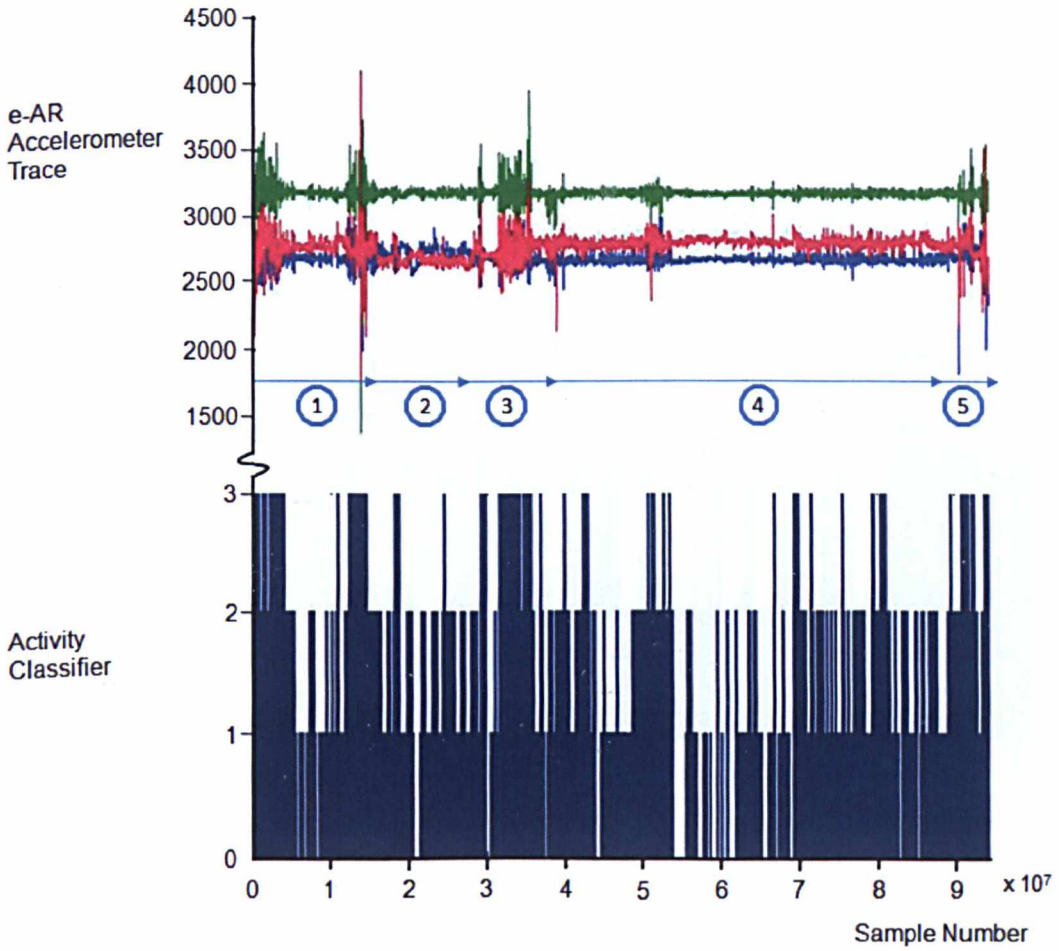


Figure 6.2 *The accelerometer trace (above) and accompanying activity classifier (below) for subject 1 in their home environment. A timeline (middle) indicating the events in the diary card of this subjects is included and labelled as follows: 1=Walking around the living room tidying up; 2=Sitting down and talking on the phone; 3=Tidying up the bedroom; 4=Sitting and working in front of a computer; 5=Getting up and eating a packet of crisps.*

Subject 4

This subject spent their time making food in the kitchen (1), sitting and eating whilst watching television (2), and washing up their dishes (3). Figure 6.3 below clearly shows that during diary periods 1 and 3 the accelerometer trace shows greater variance and the classifier consistently shows class 3 activities taking place. This is in contrast to period 2, where because the subject was sitting and eating, the classifier consistently showed level 1 activities with some intermittent and short-lasting peaks of class 2 and 3.

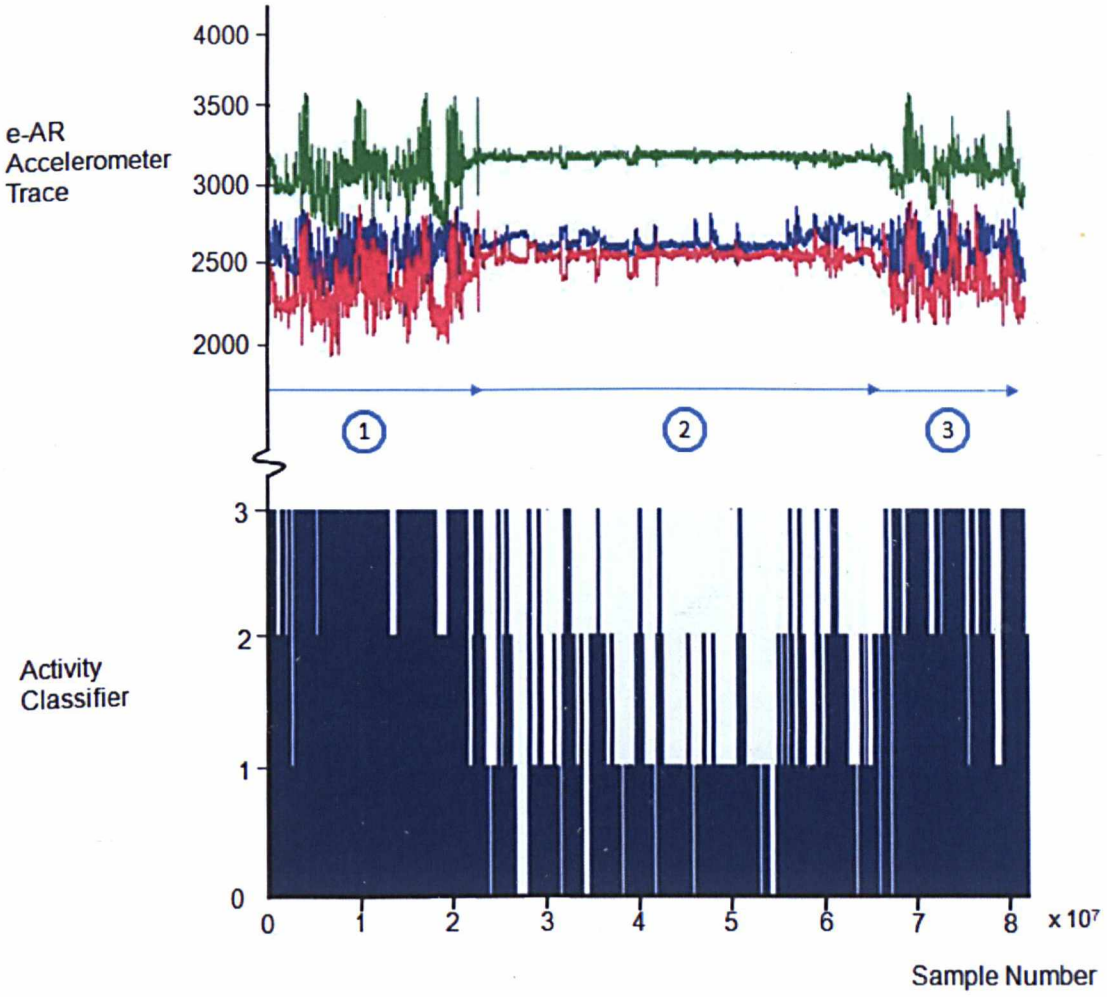


Figure 6.3 *The accelerometer trace (above) and accompanying activity classifier (below) for subject 4 whilst at home for one leg of this study. The timeline (middle) is labelled as follows: 1=Making food in the kitchen; 2=Sitting, eating and watching television; 3=Washing up the dishes.*

Subject 7

This spent their time tidying up (1), cooking dinner (2), and sitting and eating (3). Figure 6.3 below clearly shows that during diary periods 1 and 2 the accelerometer trace has a very high degree of variance and the classifier consistently shows class 3 activities when compared to period 3 where level 0, 1, and 2 activities were also seen. It is important to note that during higher class activities it was difficult to see the transition from one diary card event to the next.

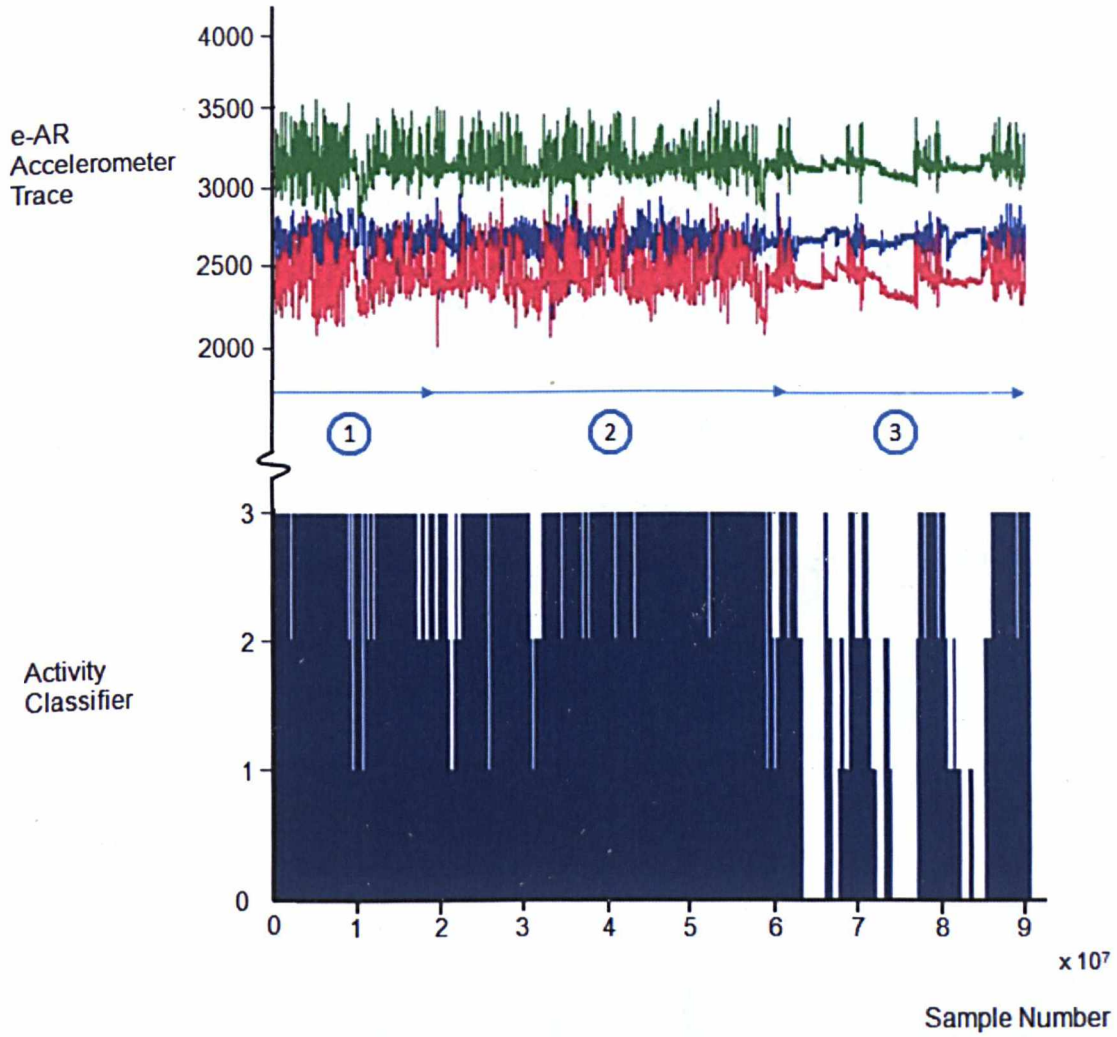


Figure 6.4 *The accelerometer trace (above) and accompanying activity classifier (below) for subject 7 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card as follows: 1=Tidying up and organising bags; 2=Cooking dinner; 3=Sitting and eating dinner.*

6.3.2 Unsupervised home activity index

The results for activity index of the same three subjects are shown below in figures 6.5-6.7 below. Again this has been plotted on a graph together with the accelerometer trace for each subject and the diary card information.

Subject 1

In Figure 6.5 it can be seen that peaks in activity index correspond well to diary card periods 1, 3, and 5 during which the subject was undertaking higher level activities. There was however a rise in index with a prolonged peak in diary card period 4, which may be due an event that the subject did not record.

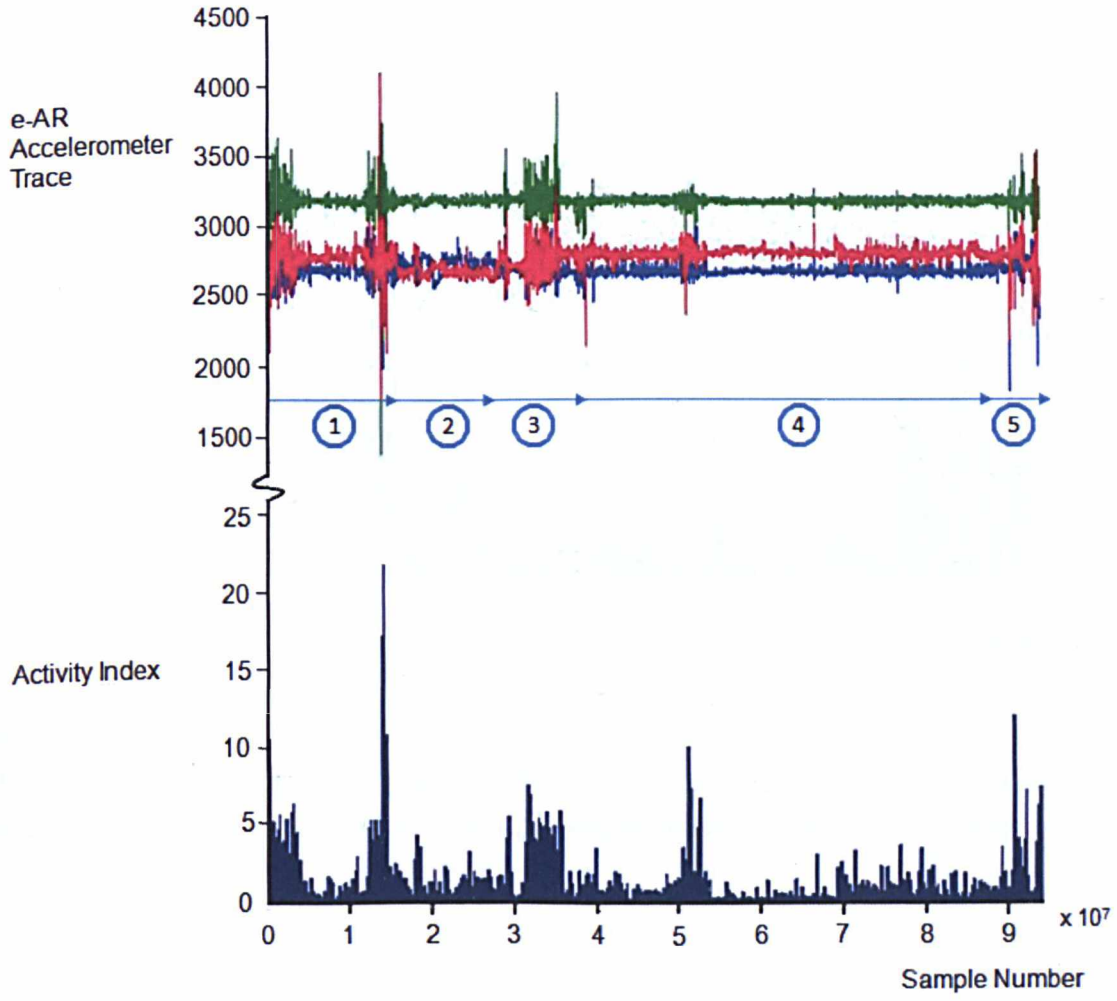


Figure 6.5 *The accelerometer trace (above) and accompanying activity index (below) for subject 1 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card kept by the subject as follows: 1=Walking around the living room tidying up; 2=Sitting down and talking on the phone; 3=Tidying up the bedroom; 4=Sitting and working in front of a computer; 5=Getting up and eating a packet of crisps.*

Subject 4

Figure 6.6 shows the periods where the subject was cooking dinner and washing up (diary periods 1 and 3) were clearly associated with higher activity index measurements when compared to eating dinner (diary period 2).

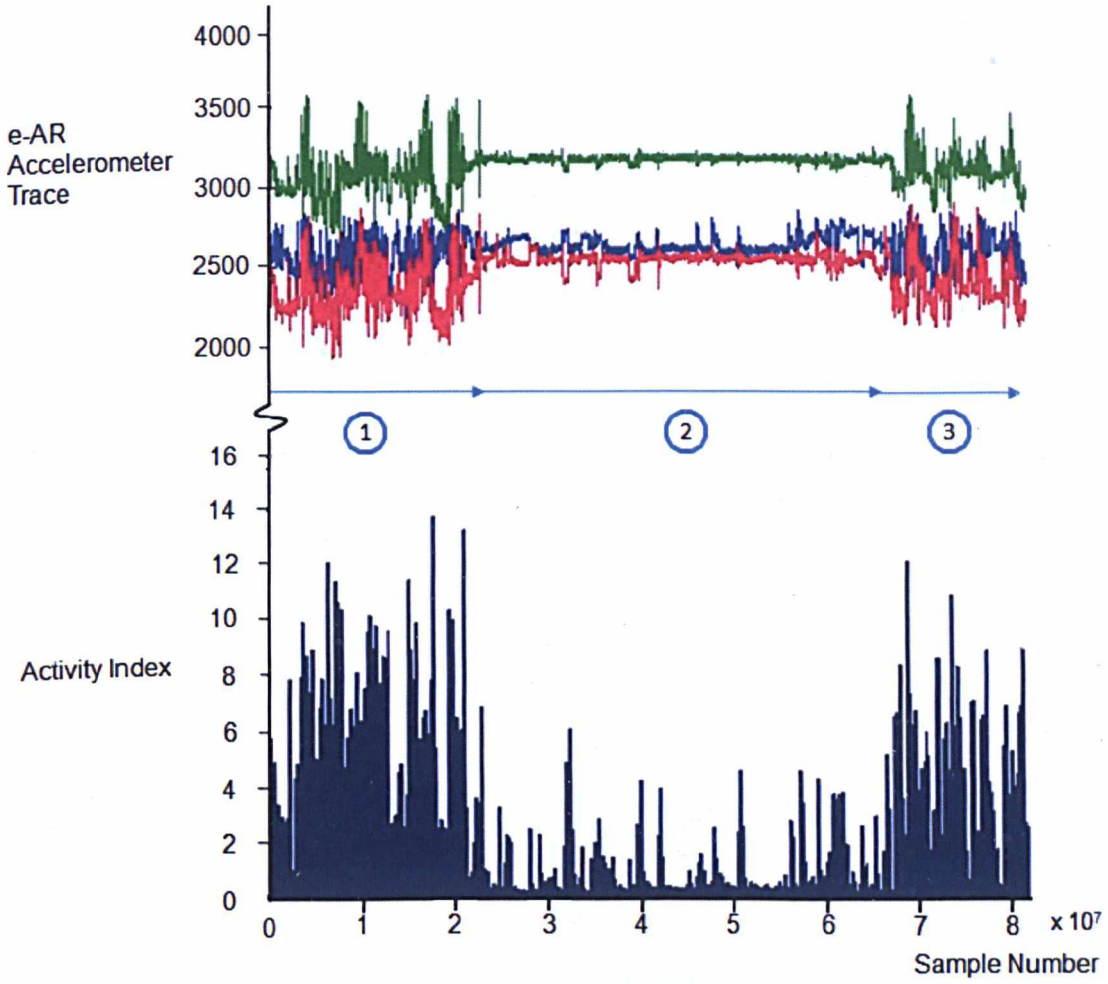


Figure 6.6 *The accelerometer trace (above) and accompanying activity index (below) for subject 4 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card kept by the subject as follows: 1=Making food in the kitchen; 2=Sitting, eating and watching television; 3=Washing up the dishes.*

Subject 7

Figure 6.7 shows that the periods where this subject was tidying up and cooking dinner (diary periods 1 and 2) were clearly associated with higher activity index measurements when compared to eating dinner (diary period 3). What is interesting in this trace however is that there appear to be three periods of high activity in diary card period 3 where the subject is more active, which was harder to see when looking at results from activity classification. Indeed these may be due to event such as getting up in the middle of their meal, which is something that the subject did not record in their diary card.

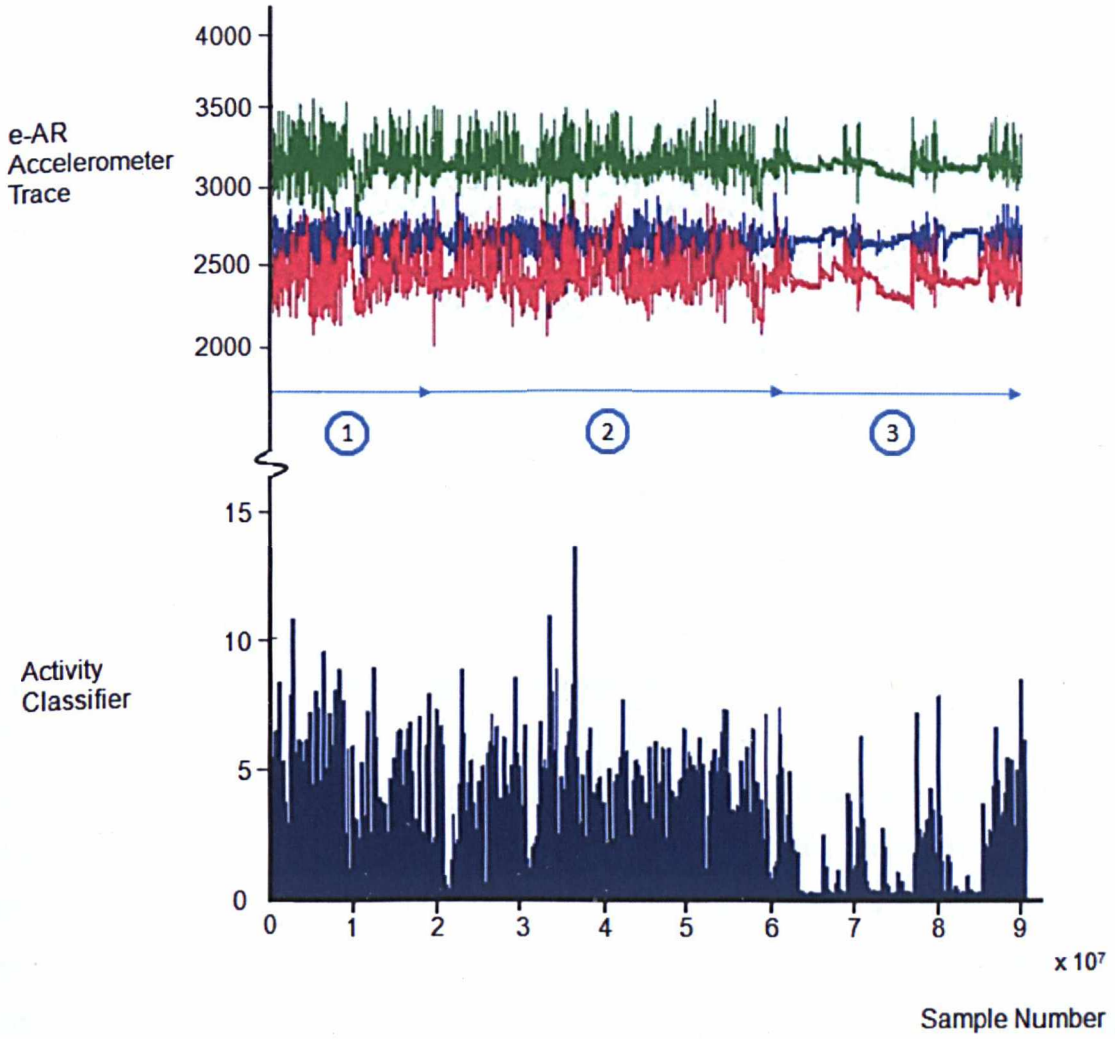


Figure 6.7 *The accelerometer trace (above) and accompanying activity index (below) for subject 7 whilst at home for one leg of this study. A timeline (middle) indicates the events in the diary card kept by the subject as follows: 1=Tidying up and organising bags; 2=Cooking dinner; 3=Sitting and eating dinner.*

6.3.3 Logistic regression of diary card activity versus activity index data

The 27 diary cards contained a total of 114 activity time periods of which 58 corresponded to low level activity and 56 corresponded to high level activity. Figure 6.8 below shows the mean activity index for the 58 'low' level diary card activity periods, and the 56 'high' level diary card activity periods recorded by subjects during this study.

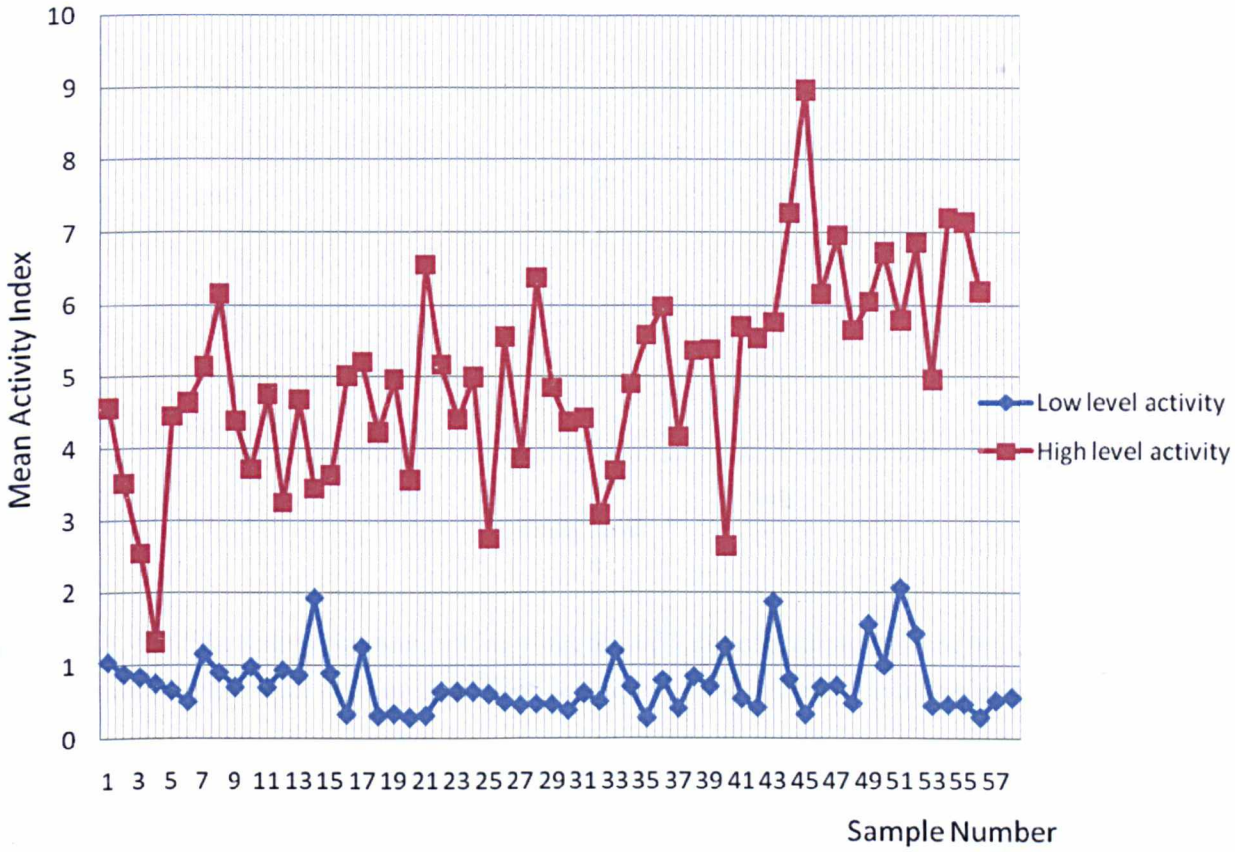


Figure 6.8 *The mean activity index during periods of high and low level activities recorded by subjects in this study.*

The order of magnitude of the difference in activity index between periods of low versus high diary carded home activity is shown below in Figure 6.9. Here, the mean activity index and two standard deviations for each subject when undertaking low and high level diary card activities can be seen. Results from the logistic regression analysis of this data showed that the activity index was significantly greater for high level activities ($p=0.003$) and was strongly predictive of the level of activity the subjects were undertaking in their home, with a high odds ratio of 55.2 (95% CI = 4.044 to 754.082).

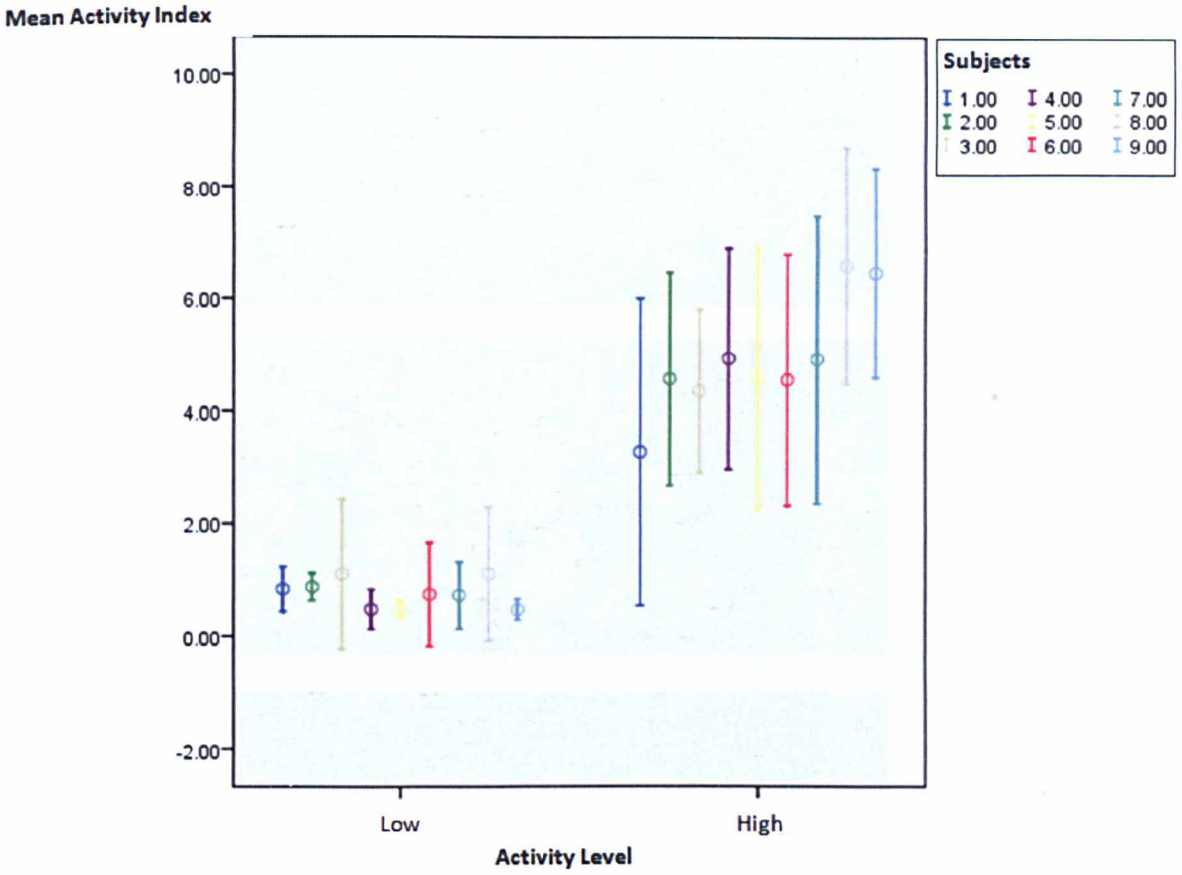


Figure 6.9 *A graph showing the mean activity index for the 9 subjects during low and high level activities in their own unsupervised home environments. Error bars represent two standard deviations of this mean.*

6.3.4 Unsupervised home mobility impairment detection

The accelerometer data from each of the three legs of the study was visualised using the BSN Signal Editor Version 1.1 software (© VIP Group, Imperial College London), and traces that clearly represented walking were identified. Figure 6.10 shows the walking traces over the three study legs for subject 2. This demonstrates that the morphology of the 'normal' and 'mildly impaired' mobility walking traces were similar, but that those seen with 'moderately impaired' mobility were notably different. The irregularity of the spacing between peaks (representing the gait cycle) and their amplitude (representing the force with which heel strike occurs) was notable. The fact that this occurred in all three accelerometer traces also suggests an element of increased sway in the subject's walking.

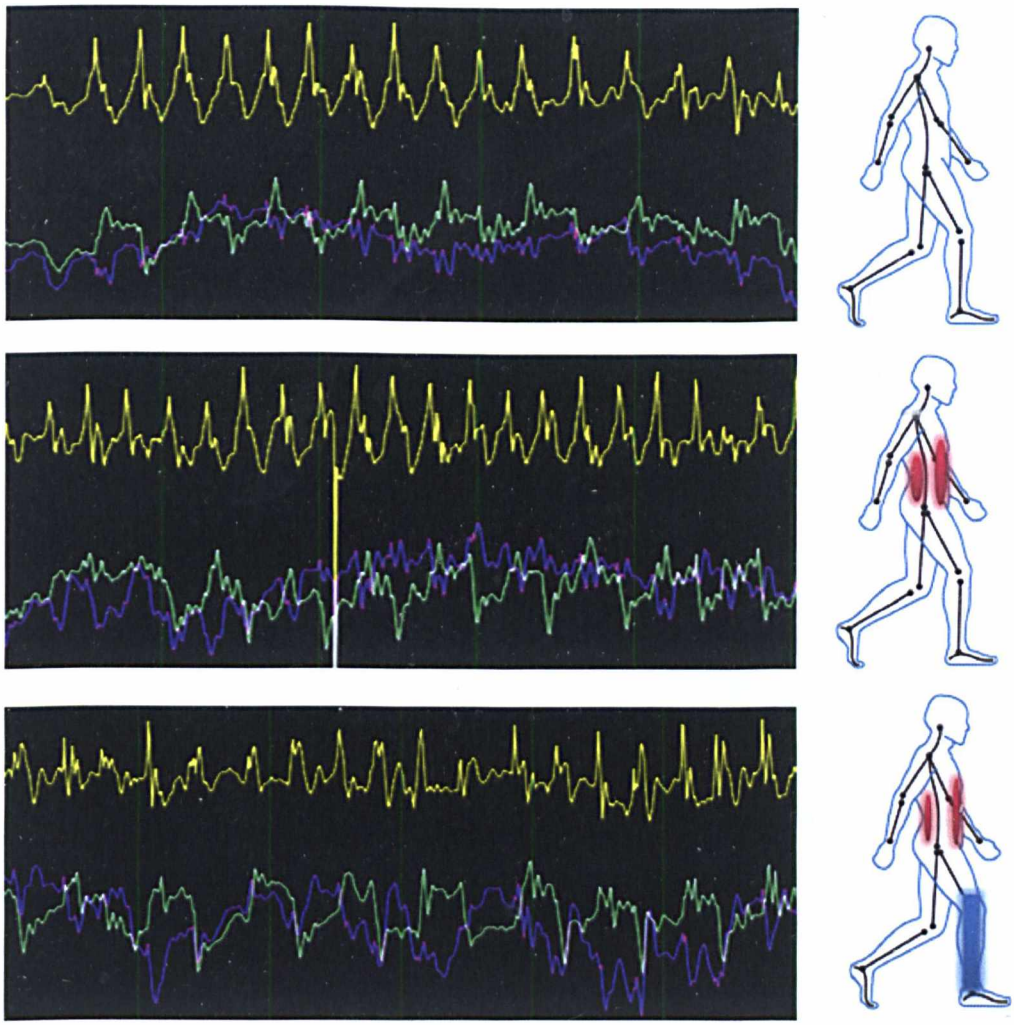


Figure 6.10 *The accelerometer traces for unsupervised walking in the home environment for subject 2 with 'normal mobility' (top), 'mildly impaired mobility' (middle), and 'moderately impaired mobility (bottom).*

The 'Mobility impairment detection' software was used to filter each accelerometer signal using DWT (wavelet window=256 samples), ICA, and then feature selection. This analysis was performed for 3 walking datasets per subject and for all 9 subjects. The results for normal walking compared to the two types of mobility impairment were as follows:

Combining the data for all 9 subjects taking part in this study, Figure 6.11 demonstrates the clustering and correct classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment. It can be seen from this figure that whilst the two types of mobility impairment clustered closely together, normal walking was seen to cluster in a distinctly separate manner.

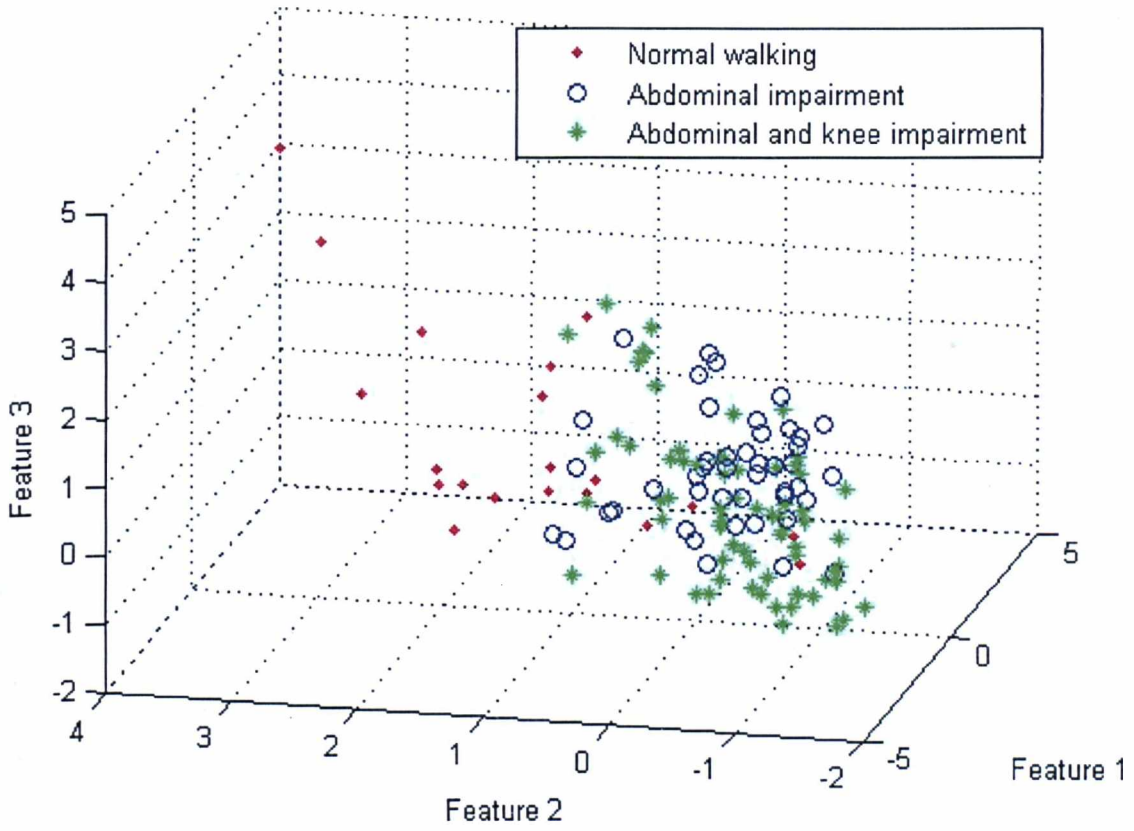


Figure 6.11 *Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for all 9 subjects when wearing the e-AR sensor in their unsupervised home environment.*

When analysing the subjects' data individually, it was seen that in many cases the three classes could be clearly separated, with normal walking clearly mapped in between the two types of mobility impairment. This is shown in the cases of subjects 4, and 5 in figures 6.12 and 6.13 respectively. Morphology analysis of the accelerometer traces for these subjects showed that whilst the abdominal brace did slightly affect the homogeneity of data when compared to normal, it was the abdominal and knee brace that had the highest impact. This is entirely expected as wearing two braces simulates the greatest degree of mobility impairment.

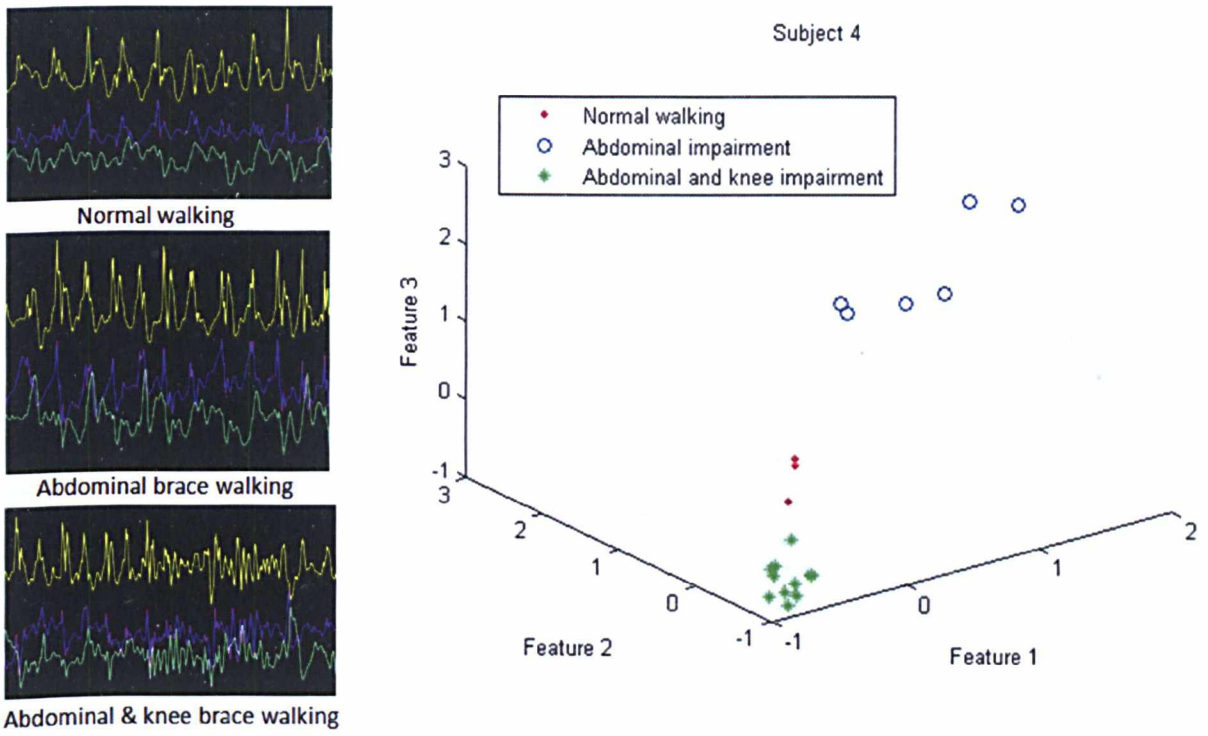


Figure 6.12 *Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject 4 whilst wearing the e-AR sensor in the unsupervised home. Accelerometer traces are shown on the left. Normal walking is seen to cluster between the two types of impairment.*

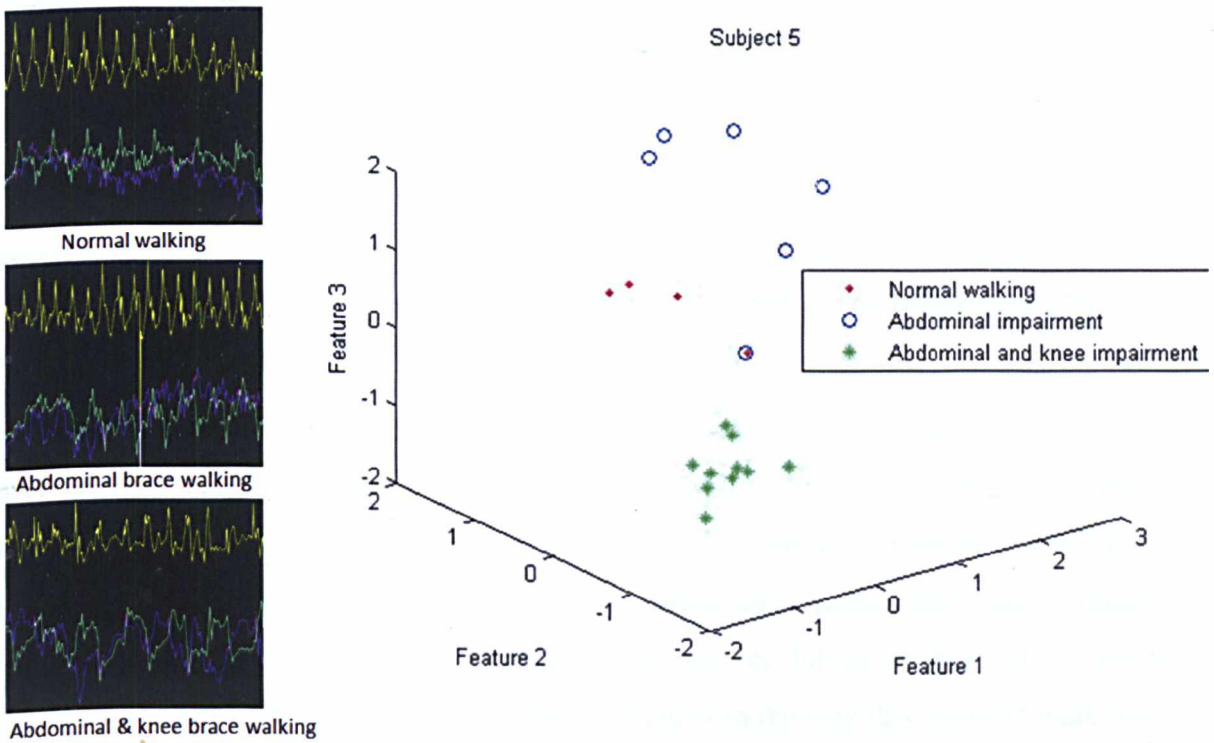


Figure 6.13 *Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject 5 whilst wearing the e-AR sensor in the unsupervised home. Accelerometer traces are shown on the left. Normal walking is seen to cluster between the two types of impairment.*

There were however, some interesting findings in two subjects: First, the mobility impairment classification results for subject 7 showed that whilst the three mobility classes did clearly separate, the pattern of this separation was different, with normal walking clustering in a different area to what was expected (Figure 6.14). Morphology analysis of the accelerometer traces for this subject shown to the left of the figure revealed a marked reduction in variance when wearing the abdominal brace alone as compared to the abdominal and knee brace. This was unique to subject 7 when compared to the others.

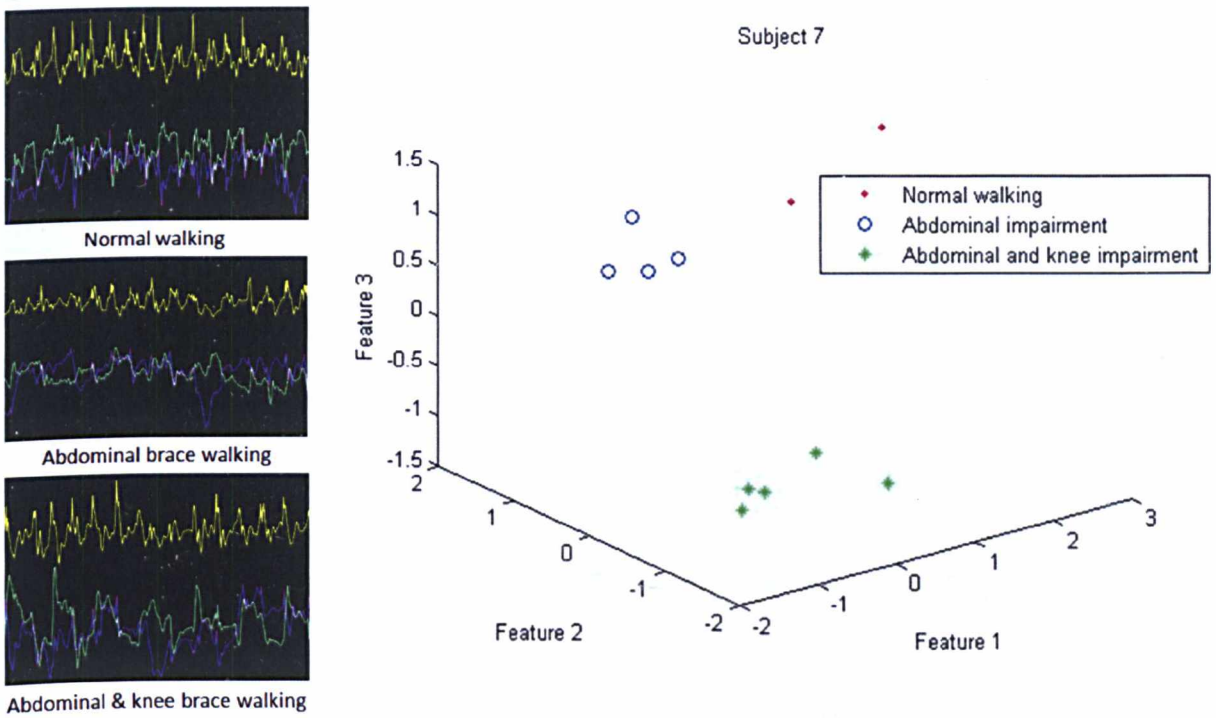


Figure 6.14 *Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject7 whilst wearing the eAR sensor in the unsupervised home environment. Accelerometer traces are shown on the left.*

Second, the mobility impairment detection results for subject 8 showed no clear separation between the three classes, with normal and impaired walking merging instead of clustering into distinct entities (Figure 6.15). Morphology analysis of the accelerometer traces for this subject revealed that whilst the abdominal brace created some heterogeneity and variance in the pattern, the abdominal and knee bracing system together did not do this to the extent that would be expected. This suggests important differences in the way that subjects walk that make comparison between subjects (inter-subject) challenging.

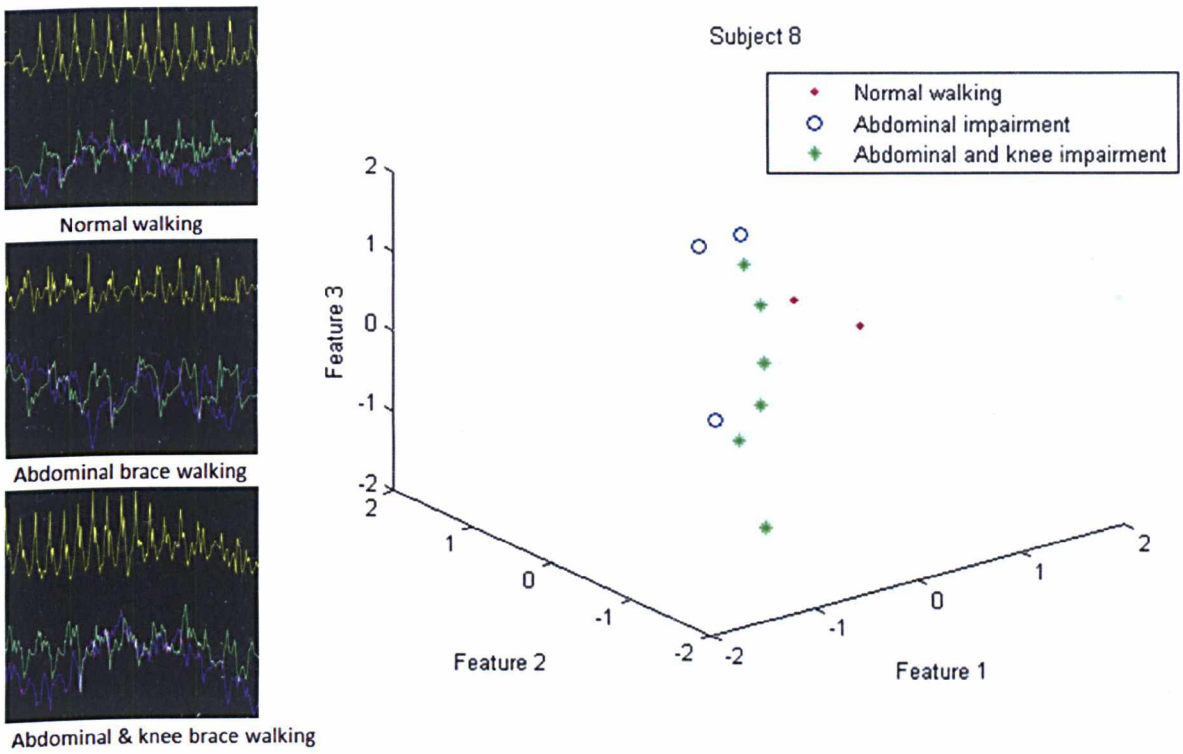


Figure 6.15 *Classification of normal walking, walking with abdominal impairment, and walking with abdominal and knee impairment for subject 8 whilst wearing the eAR sensor in the unsupervised home environment. Accelerometer traces are shown on the left. Clustering does not occur in this case.*

6.4 Discussion

This study has shown that the e-AR sensor and its biomechanical data analysis framework can be used to objectively monitor functional recovery in the real home both in terms of both the type and intensity of activity being performed. It has also been demonstrated that impairment in mobility may be detected in a completely unsupervised manner, although inter-subject variations make this more challenging.

For each subject, the activity classifier (levels 0-3) acted as a 'digital diary' of their ADLs that corresponded well with the diary cards they kept. These activity classification results show how the home activities of subjects over long time periods may be determined. Limitations of the classifier highlighted by this study were that accelerometer 'spikes' during otherwise low level activities made the data more heterogeneous and 'noisy'. This in turn made the boundaries between one activity type and the next less distinct. The affect of these accelerometer spikes on the classifier are an important factor to consider when monitoring a continuous parameter that is dependent on motion. This is because no activity is completely homogenous and also because in the case of the e-AR sensor, a sudden movement in the head may confuse the classifier. Also, variations in the shapes and sizes of subjects' ears mean that the e-AR sensor may be slipping off the ear at times. Despite this, the activity classifier has the potential to play an important role in helping to provide information on the context in which the patient is at any one time, something that is very difficult to determine in the unsupervised home. This contextual information is particularly pertinent to home vital signs monitoring where without knowing the context in which the patient is, it is impossible to interpret vital signs data. An example is in the case of sensing heart rate with the patient at home. In order to determine whether a high heart rate (above 100 beats per minute) is due to a disease process or normal, one has to know whether the subject is exercising or not and whether this increase in heart rate is a normal physiological response.

This study has demonstrated how the activity index (ranging from 0-25) may be used to quantify the intensity of home activity being performed. Derived from the mean variance of the three accelerometer axes, this measure showed its ability to correctly predict home activity levels as demonstrated by the highly positive odds ratio of 55.2 ($p=0.03$) when comparing it to diary cards the subjects had kept. In a similar manner to the classifier, the activity index also was affected by spikes of increased accelerometer output variance, as demonstrated by the large standard deviations in readings during both high and low level

diary card activities. Despite this however, it was a strong indicator of the intensity of activity.

Periods of walking were able to be clearly identified and manually extracted in this unsupervised dataset for the purposes of mobility impairment detection analysis. The results for this mobility impairment detection showed a clear differentiation between normal and impaired mobility between subjects. There were however some important limitations of this system that should be noted before it is used in patients. First, the periods of walking that a subject undertakes at home are much shorter and interspersed between other heterogeneous activities when compared to the simulated home experiments previously undertaken in this thesis. An example of this is that whilst in the simulated environment subjects were asked to walk for 3 minutes (several hundred steps), in the real home a subject walks for much shorter periods (5-10 steps at a time). This means that the mobility impairment detection system has a much shorter dataset to interpret and is therefore going to be less reliable. Second, as seen in the data for subjects 7 and 8, there is significant inter-subject variability in the way that people walk normally and with impairment. This makes it difficult to generalise the effect that mobility impairment has on real patients recovering at home from surgery. Instead, the results of this study suggest that intra-subject variability is what this system should be looking out for and that in order to do this, the normal mobility of a subject must be known first. This means that in using this system for post-operative recovery monitoring, patients should be asked to first wear the e-AR sensor for a pre-operative time period so their normal mobility can be determined. Finally, although manual extraction of walking data was possible in this study, when looking at datasets that last days there needs to be an automated means of extracting this information.

There are some important implications that the findings of this study have on the use of the e-AR sensor as a continuous post-operative home recovery monitoring device that should be considered before deployment in patients: First, the relatively simple variance calculations required to derive the activity index make this a parameter that is suitable for 'on BSN node' calculation, thereby significantly reducing the amount of energy required to wirelessly transit this data. This is very important for a technology that needs to be worn over a week, meaning that instead of being replaced every few hours, the battery could be replaced every few days. Second, the fixation of the device to the patient's ear is important as any drift or slipping of the sensor on the patient's makes it prone to erroneous spikes in accelerometer trace. As a

result, for the purposes of patient use, either a range of shapes and sizes of the device are needed, or a mode of fixation such as a headband may be of use. Finally, patient compliance with wearing the device continuously is the one factor that is of paramount importance if the e-AR sensor is going to be able to be used to monitor patients in the post-operative period. Without it, the device and its activity classification, index, and mobility frameworks cannot function.

7 Home Vital Signs Monitoring in the Context of Activity

7.1 Introduction

The return of resting vital signs to normal limits is usually a pre-requisite to a patient being discharged home from hospital following surgery. There remains however, a role for continuing to measure certain vital signs such as heart rate (HR) and oxygen saturation (SpO_2) during the early post-operative period, as commonly seen complications such as chest infections, poor chest expansion due to wound pain, pulmonary embolus, dehydration, myocardial infarction, and wound infection can all result in an early change to one or both parameters. As in the hospital setting, monitoring SpO_2 and HR in the home environment during the early post-operative period would allow the detection of trends suggesting that a patient either has developed, or is at high risk of developing one of these complications. Early identification and intervention in these cases could at best prevent the complication altogether, or at the very least minimise its resulting morbidity.

The practice of continuous vital signs measurement is currently limited mainly to the hospital environment primarily because of the large amount of infrastructure required and its high setup cost. Apart from the monitoring equipment itself, trained staff is required to visit the patient at regular intervals, take the measurements, record them, and interpret their results. Pervasive wearable BSN technologies provide a means to acquire this data automatically without labour-intensive infrastructure, after which trend analysis can be performed. The e-AR sensor comprising of a pulse oximeter, 3-D accelerometer, and BSN node, together with its data analysis frameworks offers a means of recording home HR and SpO_2 continuously and in light of information on the context in which these measurements are being taken.

7.1.1 Normal and abnormal variations in HR and SpO_2

In devising a strategy for pervasive home vital signs monitoring, it is important to differentiate the normal physiological changes that occur in HR and SpO_2 with exercise and rest, from those that are due to underlying pathologies. The physiological response to an

episode of acute aerobic exercise such as climbing stairs, aims to meet the increased energy demands of movement and remove metabolic by-products brought about by this physical stress. The delivery of oxygen to the working skeletal muscle needs to increase so that more aerobic energy production can occur. In addition, higher levels of carbon dioxide produced by increased metabolism need to be removed. Whilst there is some variation in the size of this response in individuals with varying age, gender, genetics, fitness level, and those with cardiovascular and/or pulmonary disease, the nature of the response is universal. At rest, an apparently healthy subject's cardiac output (CO), a product of their heart rate (HR) and stroke volume (SV), is approximately 5 L/min. During moderate exercise, both HR and SV increase, resulting in an increase in CO to approximately 20 to 25 L/min. [235]. An accompanying increase in respiratory rate and lung tidal volumes results in an increase in an increased oxygen intake and carbon dioxide removal. As a result, SpO_2 remains near 100% with exercise in normal subjects. An SpO_2 reading of less than 90% in an otherwise health subject during exercise periods is therefore likely to be due to motion artefact and ambient light. The normal human physiological response to exercise is summarised below in Figure 7.1.

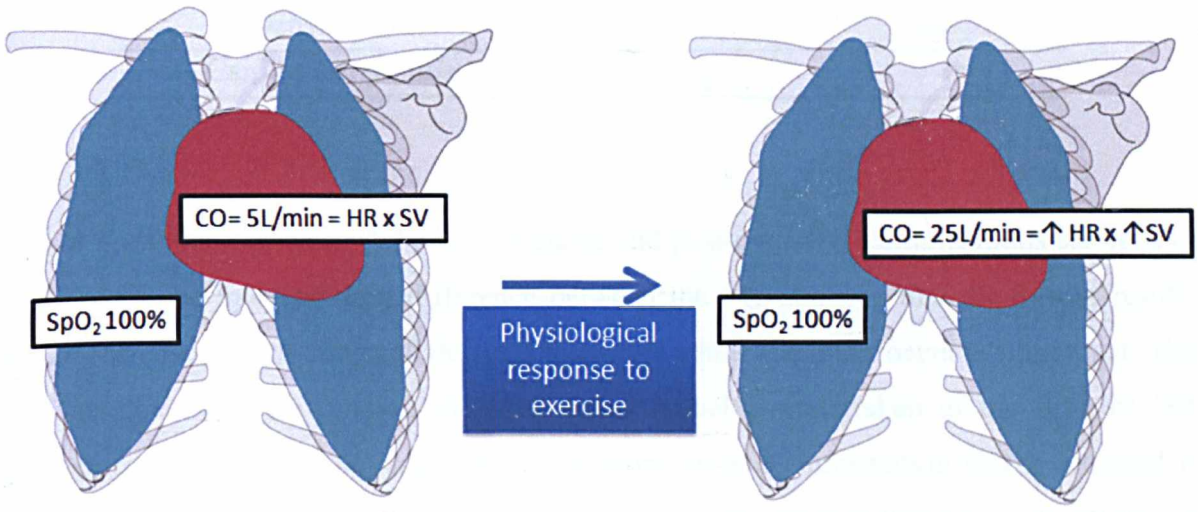


Figure 7.1 *Normal physiological response to exercise and its impact on HR and SpO_2. CO=Cardiac output, SV=Stroke volume.*

Pathological disease states such as post-operative infection can lead to increased physical stress, thereby necessitating an in increase in cardiac output and rise in HR at rest. In similar way, dehydration results in a compensatory rise in HR even at rest. Conditions that affect the ability of the lungs to oxygenate blood such as post-operative chest infection and pulmonary embolus on the other hand, can result in a reduction in SpO_2 as well as a compensatory rise HR. Finally post-operative wound pain that can occur either because of poor analgesia but also as a result of wound-related complications, has been shown to stimulate an autonomic response that results in a rise in HR. Whilst the magnitude of this response varies between subjects, its repeatability in normal subjects has previously been demonstrated [236]. The impact of these common complications on HR and SpO_2 is shown below in Table 7.1.

Table 7.1 *The effect of common post-operative complications during the early home recovery period on HR and SpO_2 measurements.*

Post-operative complication	Impact on HR	Impact on SpO_2
Wound infection	↑	↔
Chest infection	↑	↓
Pulmonary Embolus	↑	↓
Deep vein thrombosis	↔	↔
Wound Pain	↑	↔ or ↓
Dehydration	↑	↔
Cardiac arrhythmia	↑ or ↓	↔

It can be seen therefore that whilst both exercise and post-operative complications can lead to a rise in HR, the most obvious difference between the two states is that the former results from an increased energy demand due to movement, whilst the latter occurs even at rest. The ability to determine the amount of activity that is being undertaken at the time of HR measurement is therefore the single most important piece of information that is required if this parameter is to be monitored in the home environment. Factors that adversely affect the performance of pulse oximeters in accurately measuring HR and SpO_2 such as movement artefact, skin pigmentation, temperature, and ambient light have already been discussed earlier on in this thesis. Whilst there is little that can be done about a patient's skin pigmentation or temperature, the effect of movement artefact and ambient light can be minimised by a combination of good fixation of the sensor to the skin and choosing a time when the subject is relatively static to measure their oxygen saturation.

7.1.2 Context awareness in home vital signs monitoring

Context is defined as *"the circumstances relevant to an event or fact"* [237]. Knowing the context in which a patient's HR and SpO_2 readings are taken in the home, is a vital piece of information, without which it is impossible to distinguish between normal and abnormal states. As mentioned above, an elevated HR could signify that a patient was acutely unwell, but may also mean that they are performing an activity such as stair climbing. Similarly, a low SpO_2 reading (below 90%) may signify that the subject is hypoxic due to a chest infection, but may also be due to motion artefact from an activity such as cleaning the kitchen floor. In simple terms, in order to determine whether a person's HR and SpO_2 are abnormal, we need to know what they are doing at the time when the measurement is taken. Pervasive home vital signs monitoring systems therefore need to be 'context aware'.

A number of pervasive strategies have been devised to provide context information of subjects' location in their home. Kelly et al describe the use of radiofrequency (RF) signal tracking to determine a subject's location within their home using wearable wireless sensors [238]. Tapia et al used seventy wireless environmental state change sensors that were installed within a subject's home to detect location and therefore used to infer activities such as toileting, bathing and grooming [239]. Accelerometers and gyroscopes have also been used by several groups to provide information on context, in particular to measure movement and posture. Van Laerhoven et al. [240] used the outputs of 30 wearable accelerometers to train a neural network to recognise particular postures and movements. Kern et al. [241] used seven, triaxial accelerometers over the whole body to measure posture and movement to annotate meetings, and Lee et al [242] used a single bi-axial accelerometer, located in the user's trouser pocket to measure the forward and upward acceleration of the user's thigh, and a separate gyroscope to measure thigh angle to recognise and classify sitting, standing and walking. Finally Knight et al used a single bi-axial accelerometer attached to the lateral side of the right leg with the x-axis running parallel to the longitudinal axis and the y-axis running parallel to the sagittal axis, to provide this context information [243].

The experiments undertaken so far in this thesis have focussed on the use of the e-AR sensor to monitor functional recovery through objective measurement of ADLs via an 'activity classifier and index', and mobility impairment via an 'impairment detection framework'. This chapter aims to examine the ability of the e-AR sensor to provide context-aware home HR and SpO_2 monitoring through its pulse oximeter and activity index framework. It aims to test

the hypothesis that: '*The e-AR sensor and its activity index framework can be used to identify variations in HR and SpO_2 that occur with both exercise and home ADLs of varying intensity in light of context information, separating these from motion artefact*'.

7.2 Methods

7.2.1 Overview

This study involved subjects wearing the e-AR sensor in three scenarios namely a varying speed treadmill circuit and a simulated home ADL circuit set up at the Institute of Biomedical Engineering (22 subjects), and the real home environment (9 subjects). The ability of the e-AR sensor to provide context-aware HR and SpO_2 readings in these environments was evaluated by determining whether the sensor was able to detect the normal physiological response to aerobic exercise and activities, and differentiate these from erroneous readings due to motion artefact. All subjects in this study were healthy volunteers, and so this study was not designed to determine the ability of the e-AR sensor to detect pathological changes in HR and SpO_2.

7.2.2 Ethical approval and Informed consent

Ethical approval for this study was obtained from the Local Research and Ethics Committee (LREC) at St. Mary's Hospital, London, UK. As part of this approval process informed written consent had to be gained from all subjects, who were also given an information sheet regarding the study.

7.2.3 Regulatory approval

Regulatory approval for the use of the e-AR sensor in these subjects was obtained from the Medicines and Healthcare products regulatory agency (MHRA) as a Class I device (CI/2007/0043). During the course of the study there were no adverse incidents that required notification to the MHRA.

7.2.4 Data collection

The ear-worn activity recognition (e-AR) sensor [180] designed for this study was, as previously described, worn by subjects on the outer ear with a clip attaching the pulse oximeter to the earlobe. It is important to note that the e-AR sensor contains an MCC ChipOx® pulse oximeter module that allows non-invasive arterial oxygen saturation

measurement (SpO2) and heart rate (HR). ChipOx® is licensed for use as an OEM module in medical products or other applications for humans. The e-AR also contains an Analog Devices ADXL330 3-axis MEMS accelerometer which records movement relative to the X, Y, and Z Cartesian axes. In this way, the pulse oximeter was used to measure the subjects' SpO_2 and HR, whilst data on body movement was collected by the accelerometer. The output from the pulse oximeter was collected on e-AR sensor's BSN node and wirelessly transmitted to a tablet personal computer for further analysis. The accelerometer had a sampling frequency of 50Hz (1 sample every 20ms) and the pulse oximeter had a sampling frequency of 1 Hz (1 sample per second). The 'Activity Index' was calculated for this data from the averaged variance across the 3 accelerometer outputs as described in Chapter 4. The value of the activity index ranged from 0-25 with a greater value signifying a greater amount of movement and hence a more 'energetic' type of activity.

7.2.5 Scenarios

Normal healthy volunteers were recruited to take part in the three scenarios of this study as follows:

7.2.5.1 Varying walking speed treadmill circuit:

A total of 22 subjects were asked to walk on a treadmill whilst wearing the e-AR sensor at a speed of 1.5km/hr for three minutes, followed by 3.5km/hr for three minutes, and finally 3.5km/hr with an incline of one metre for three minutes. This treadmill circuit of incrementally increasing aerobic exercise intensity was designed to test the e-AR sensor's ability to detect a change in HR through a normal physiological response to aerobic exercise. Subjects took part in this circuit on two occasions, amounting to 44 datasets of continuous HR, SpO_2, and accelerometer data.

7.2.5.2 Scenario-based normal ADLs circuit:

A total of 22 subjects took part in a simulated home ADL circuit of 34 activities (previously described in Chapter 4) on two occasions whilst wearing the e-AR sensor. In this way a total of 44 samples of continuous HR and SpO_2 data were collected alongside accelerometer data for home activities. The activities of interest for this study included sitting, eating, sleeping, walking, and climbing stairs amongst others. In this circuit, subjects were prompted to transition from one ADL to the next by a study coordinator and this transition clearly marked. This scenario-based ADL circuit was designed to test the ability of the e-AR sensor to detect

changes in HR and SpO2 that occur with activities of varying energetic intensity. In normal volunteers whilst HR would be expected to increase with higher level activities, any drop in SpO_2 below 90% was likely due to movement artefact.

7.2.5.3 Real Home Environment

A total of 9 healthy volunteers were asked to wear the e-AR sensor in their own homes on three separate occasions, during which time continuous HR and SpO_2 data was collected alongside accelerometer data using the Imperial College wireless BSN platform. In this way, 27 home activity datasets each lasting 30 minutes were obtained for analysis in this study. Subjects were asked to keep a diary card of their actions and document both times of rest and activity in their homes. This study was designed to test the ability of the e-AR sensor to detect differences in HR and SpO_2 between rest and activity periods. Unlike the simulated home ADL circuit where subjects' activities were relatively homogenous, in the unsupervised home environment subjects performed a completely heterogeneous set of activities. As before, whilst normal volunteers' HR would be expected to increase with intensity of diary-carded activity when compared to rest periods, any drop in SpO_2 below 90% is likely to be due to movement artefact.

7.2.6 Data Analysis

7.2.6.1 Varying walking speed treadmill circuit (22 subjects, 44 samples)

For each subject the mean and standard deviations of HR values collected by the e-AR sensor were calculated at the three treadmill walking intensities, namely 1.5km/h, 3.5km/h, and 3.5km/h with incline. A one sample Kolmogorov-Smirnov test was used to determine the parametric nature of this data. A One-Way Analysis of Variance (ANOVA) test was then used to test the equality of these three mean HR measurements. The null hypothesis was that the three mean HR values during the three different treadmill walking intensities in this circuit were equal. Data analysis was performed by using SPSS version 16 for Windows. It should be noted that as all subjects were healthy volunteers, the SpO_2 measurements between these three groups were not expected to change with increasing treadmill intensity and so were not compared.

7.2.6.2 Scenario-based normal ADLs circuit (22 subjects, 44 samples)

The mean HR at the end of periods of sitting, sitting and eating, lying down and sleeping, walking, and climbing stairs was calculated for each subject dataset. A one sample Kolmogorov-Smirnov test was used to determine the parametric nature of this data. A One-

Way Analysis of Variance (ANOVA) test was used to test the equality of these five mean HR measurements. The null hypothesis was that the mean HR values at the end of each of these five activities were equal. Data analysis was performed by using SPSS version 16 for Windows. In addition to this, periods where SpO_2 readings for subjects were found to be less that 90% were identified and the mean activity index during these periods calculated. As previously mentioned, an SpO_2 of less than 90% in a healthy subject was assumed to be due to movement artefact, ambient light, or sensor error. This data was used to determine the activity index above which the e-AR's SpO_2 measurements should be considered inaccurate.

7.2.6.3 Real Home Environment (9 subjects, 27 samples)

The mean HR after a period of low level activity (corresponding to periods diary carded as sitting or lying down) and high level activity (corresponding to periods diary carded as performing an activity involving standing) was calculated. A one sample Kolmogorov-Smirnov test was used to determine the non-parametric nature of this data. A Spearman's Rank Correlation Coefficient Test was used to determine if there was a significant correlation between the mean HR and the type of diary carded activity being performed by subjects in their homes. Data analysis was performed by using SPSS version 16 for Windows. Once again periods where SpO_2 readings for subjects were found to be less that 90% were identified and the mean activity index during these periods calculated to determine the activity index above which the e-AR's SpO_2 measurements should be considered inaccurate in the real home.

7.3 Results

7.3.1 Increasing walking intensity treadmill circuit

The HR, SpO_2, and a single axis accelerometer trace from the e-AR sensor as subject 2 undertook the treadmill circuit is shown below in Figure 7.2. It can be seen from this that as the subject's intensity of treadmill activity increased, their HR rose but SpO_2 remained the same. The accelerometer signal provides some context information, demonstrating an increase in amplitude and variance with increasing walking intensity.

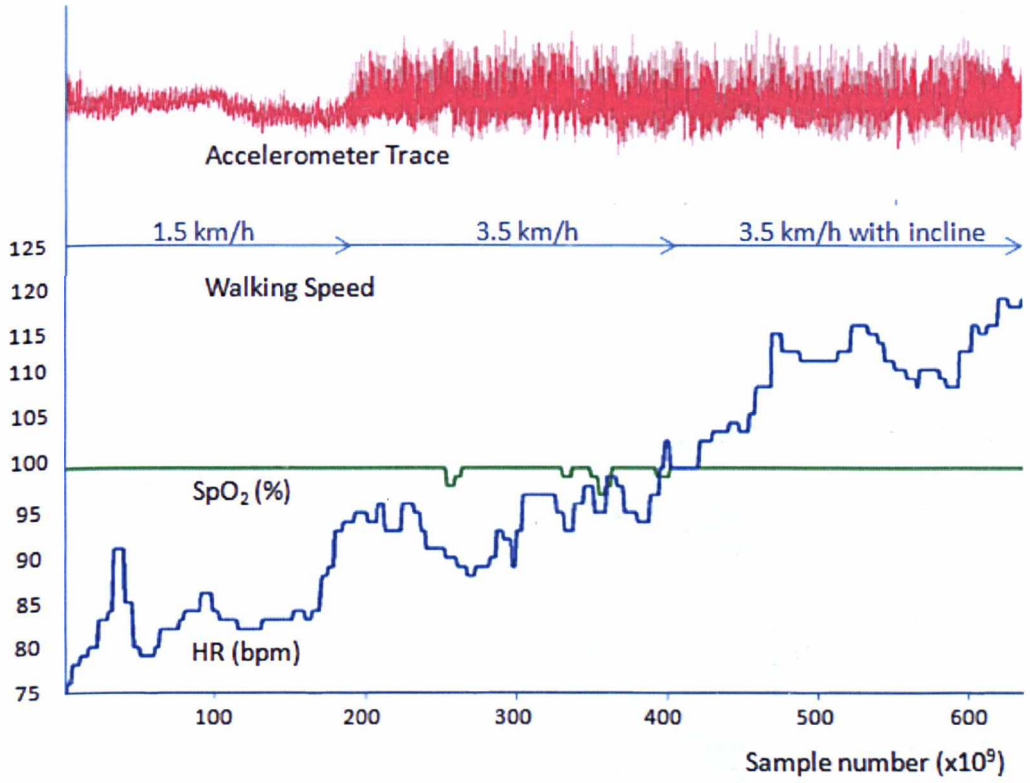


Figure 7.2 *The HR, SpO_2, and X-Y axis accelerometer outputs for a subject as they undertook the treadmill circuit. The walking speeds are also labelled on this graph.*

The mean HR values for each of the 44 samples across the three treadmill intensities are shown in Figure 7.3. It can be seen from this that for most subjects the e-AR sensor was able to detect a rise in HR as the speed and intensity of the treadmill walking was increased. In all subjects, peak HR values were seen with walking at 3.5km/h with an incline. The magnitude of this response did however vary from subject to subject. For example, whilst sample 32 shows a marked rise in HR with increasing treadmill intensity, this is much less obvious in the case of sample 14.

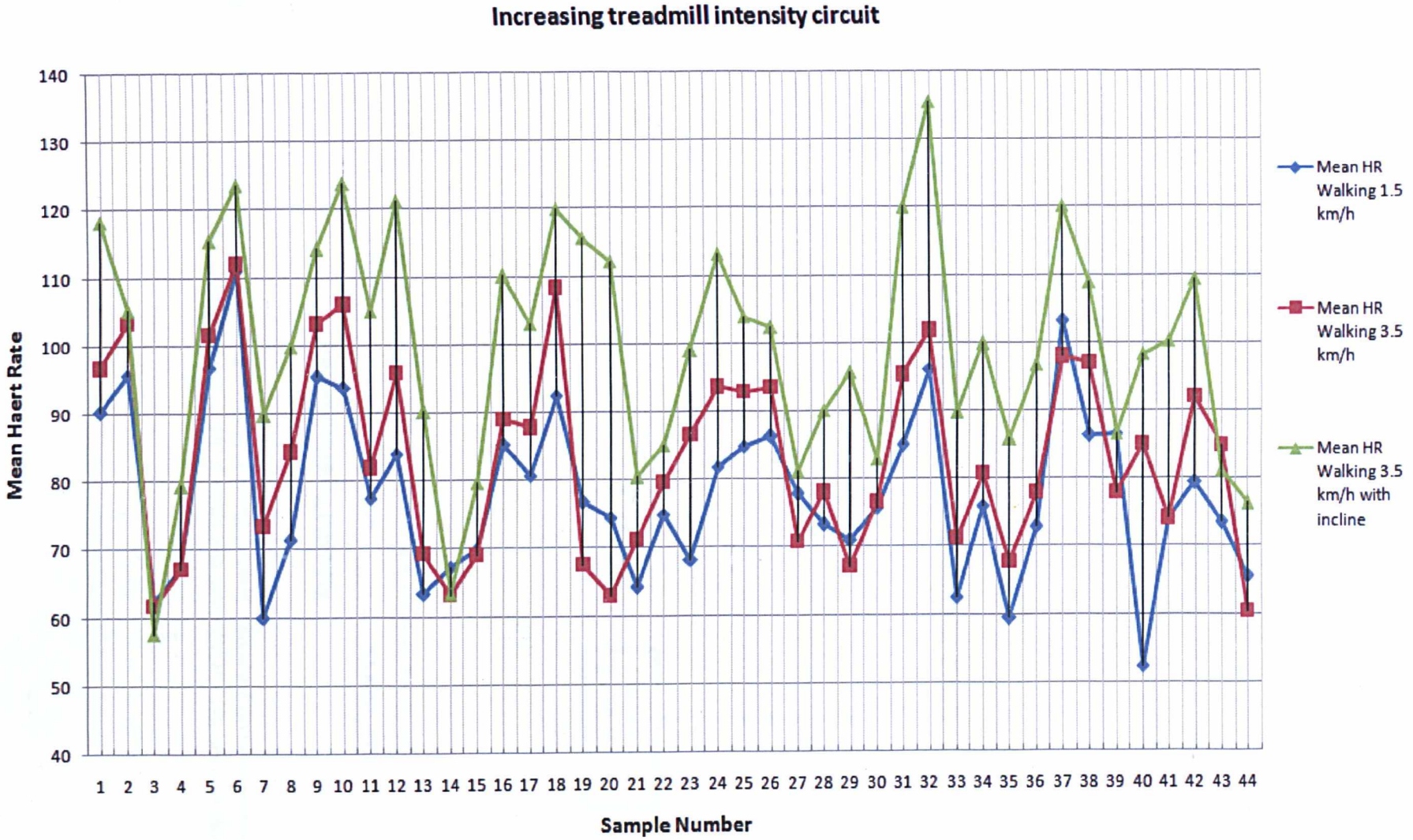


Figure 7.3 *Mean HR (bpm) collected using the e-AR sensor with increasing treadmill walking intensity for each of the 44 volunteer samples.*

Analysis of the 44 data samples showed that the mean HR for walking at 1.5 km/h was 78.38 beats per minute (bpm) (SD=4.27), rising to 83.66 bpm (SD=4.31) with walking at 3.5km/h, and 99.83 bpm (SD=4.13) when walking at 3.5km/h with an incline. These results are shown below in Figure 7.4, along with the one-way ANOVA test results for this dataset. This found a statistically significant difference between walking at 1.5km/h and walking at 3.5km/h with incline (p=<0.05), as well as between walking at 3.5km/h and walking at 3.5km/h with incline (p=<0.05). Although a rise in HR was seen when walking at 3.5km/h as compared to 1.5 km/h, this was not found to be statistically significant (p=0.294).

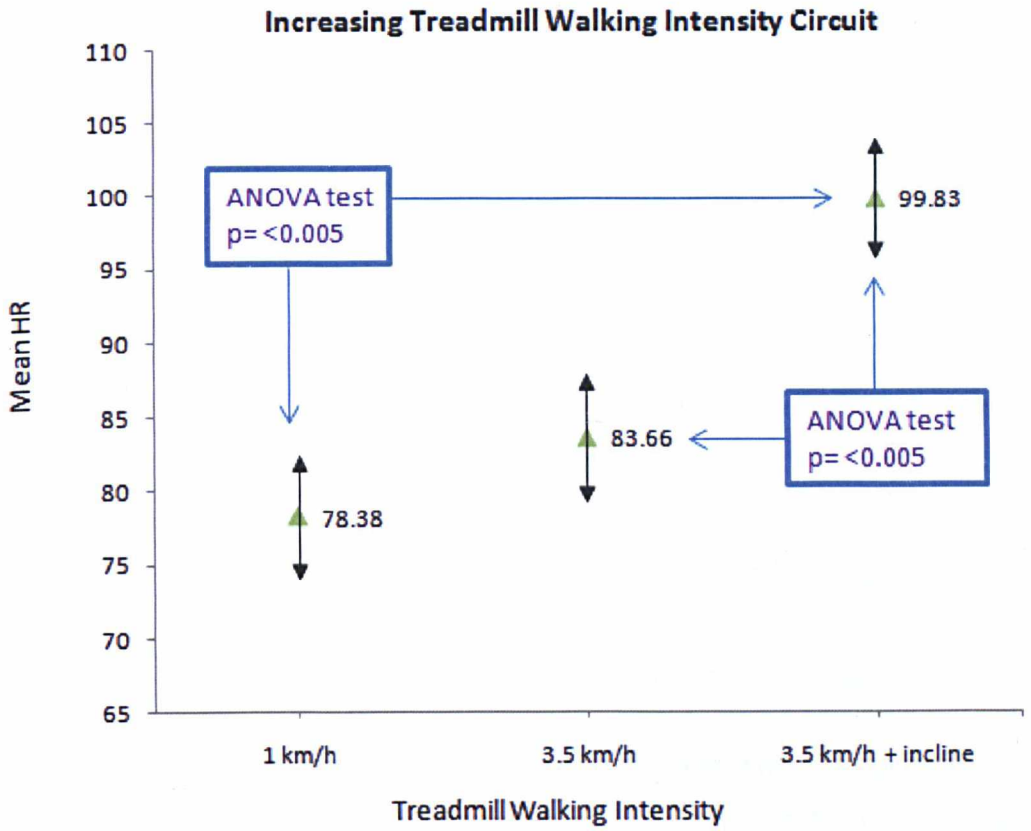


Figure 7.4 *Mean HR (bpm) with increasing treadmill walking intensity (standard deviations shown as arrows either side of the mean). Statistically significant results from the one-away ANOVA test are also shown.*

7.3.2 Scenario-based normal ADLs circuit

The HR and SpO_2 readings for subject 12 undertaking the scenario-based ADL circuit are shown below in Figure 7.5. This highlights the variation in HR and SpO_2 that was seen with subjects as they undertook the circuit. There were also periods where sudden drops in HR and SpO_2 were seen, likely as a result of movement artefact. Overall however, the e-AR sensor was able to determine a subjects' variation in HR and SpO_2 throughout the ADL circuit.

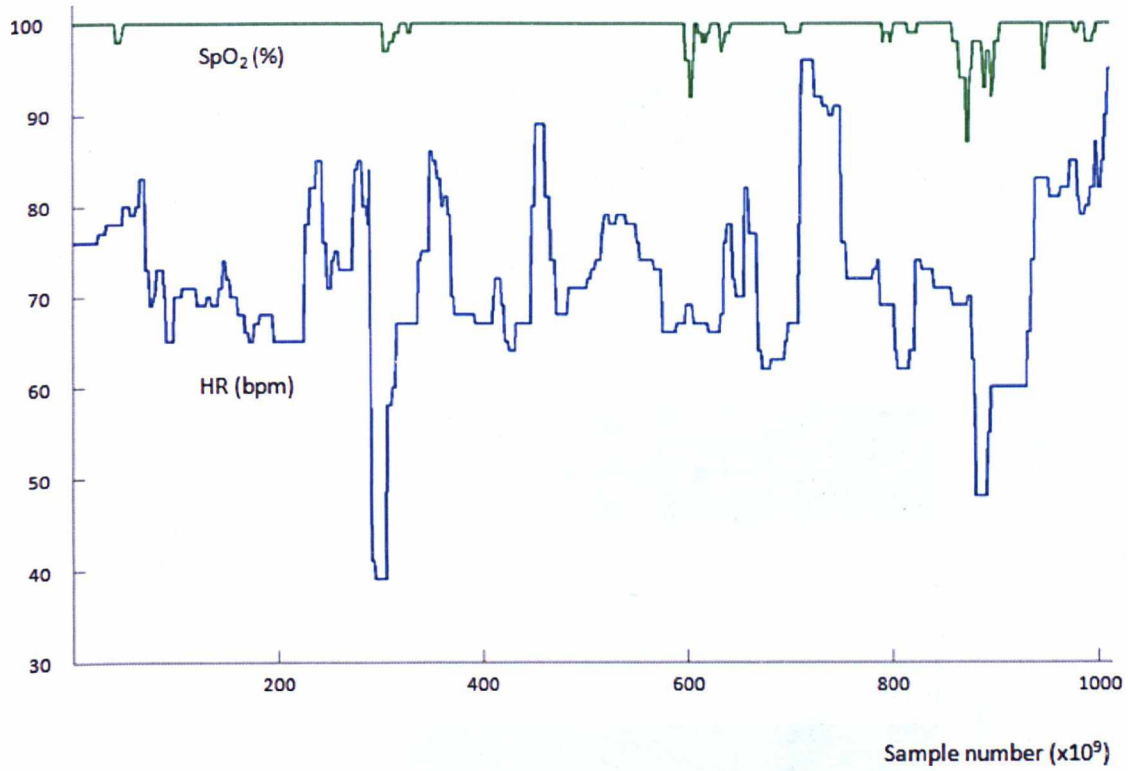


Figure 7.5 *The HR and SpO_2 data for a subject 12 as they undertook the scenario-based home ADL circuit.*

When the data for all 44 samples was analysed, the mean HR after periods of sitting was 72.34 bpm (SD=11.57), sitting and eating was 73.45 bpm (SD=11.61), lying down and sleeping was 68.57 bpm (SD=9.58), walking was 83.50 bpm (SD=12.18), and climbing stairs was 90.17 bpm (SD=16.20). The one-way ANOVA test results showed that the difference in mean HR values during periods of sitting, sitting and eating, and lying down were statistically significant when compared to the HR after periods of walking and climbing steps. Figure 7.6 summarises these findings, with associated p-values. It is important to note that whilst the lowest HR value was seen during lying down, this was not statistically significantly different to the periods of sitting (p=0.231) and eating (p=0.077).

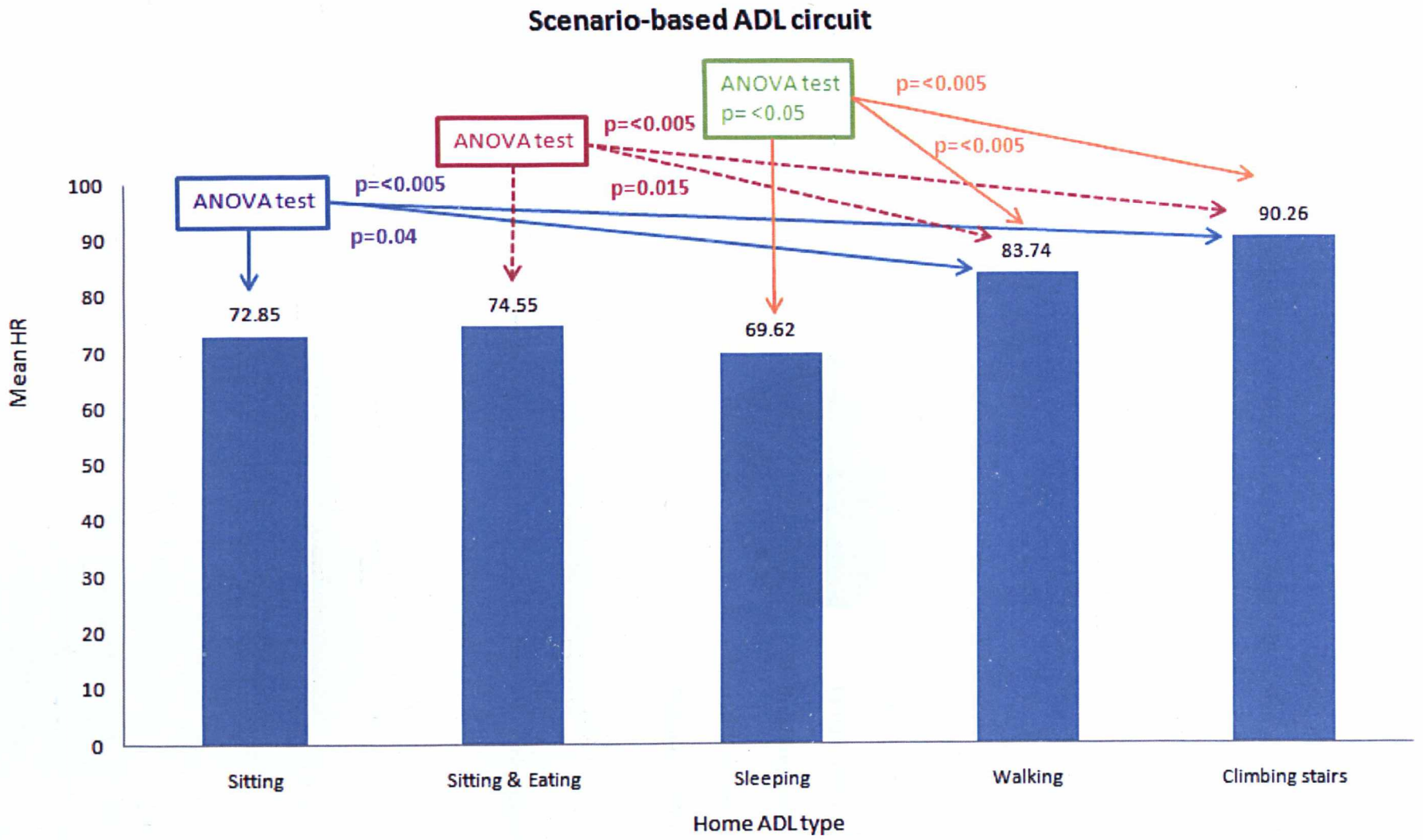


Figure 7.6 *Mean HR (bpm) collected using the e-AR sensor after 5 activities in the scenario-based ADL circuit. Results of the one-way ANOVA test are shown, showing statistically significant differences between the activities of sitting, eating, and sleeping when compared to walking and climbing stairs. Associate p values are shown.*

As they undertook the scenario-based home ADL circuit, the e-AR showed subjects' SpO_2 to be near 100% during 1254 out of 1496 (84%) of the activities. An SpO_2 of less than 90% was found during 242 out of 1496 (16%) activities undertaken by the subjects. Further analysis showed that an SpO_2 of less that 90% was seen most frequently during walking (48%), followed by times when subjects were eating and drinking (24%). Other activities resulting in a low SpO_2 included brushing teeth (9%), and putting on or removing shoes (8%). Finally, low SpO_2 readings were seen to occur least frequently during the activities of sitting (4%) and lying down (7%). Figure 7.7 is a pie chart outlining these results.

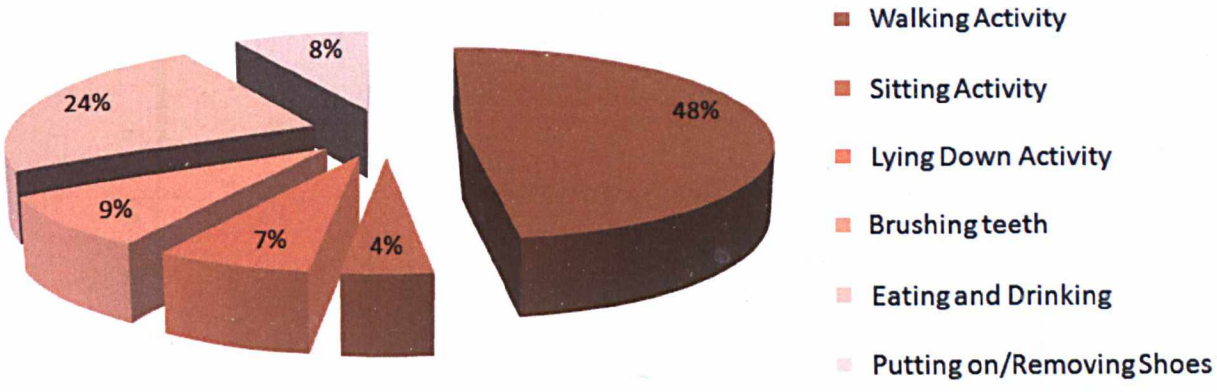


Figure 7.7 *A pie chart showing the activities involving an SpO_2 reading below 90% during the scenario-based ADL circuit.*

7.3.3 Real Home Environment

The HR, SpO_2, and activity index result for subject 16 as they spent time in their own home environment is shown below in Figure 7.8. From this it can be see that periods of increased activity index were associated with peaks in HR and troughs in SpO_2 values below 90%.

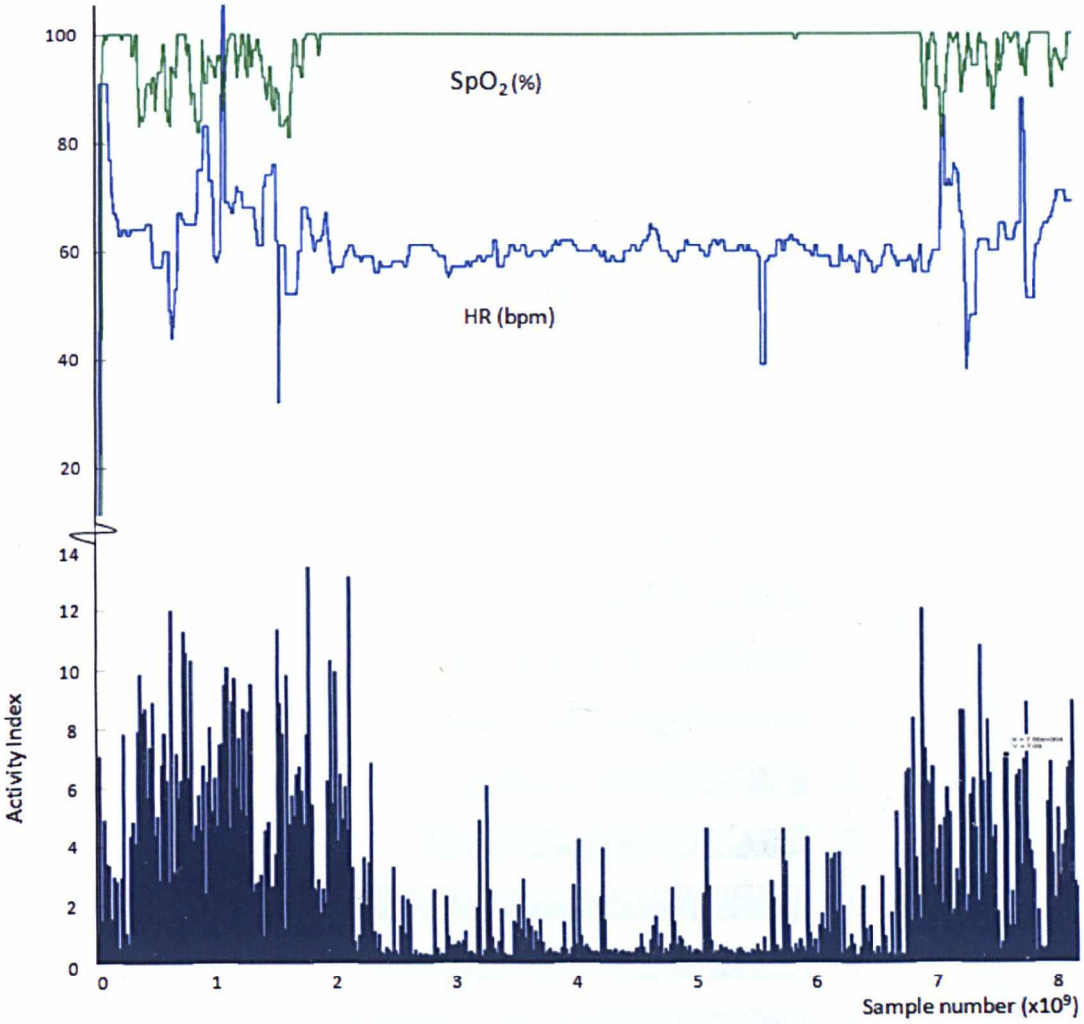


Figure 7.8 *The HR, SpO_2, and activity index for a subject undertaking unsupervised activities in their own home environment.*

Results from analysis of all 27 samples are shown below in Figure 7.9. The mean HR after periods diary carded by subjects as low level activity (e.g. sitting, sleeping, or watching television) was 66.15 bpm (SD=11.99) and after periods diary carded as high level activity (e.g. cooking, cleaning, or walking) was 76.90 bpm (SD=16.03). Spearman's Rank Correlation Coefficient Test showed a statistically significant correlation between increasing level of home activity and HR (Correlation Coefficient=0.780, p=<0.005).

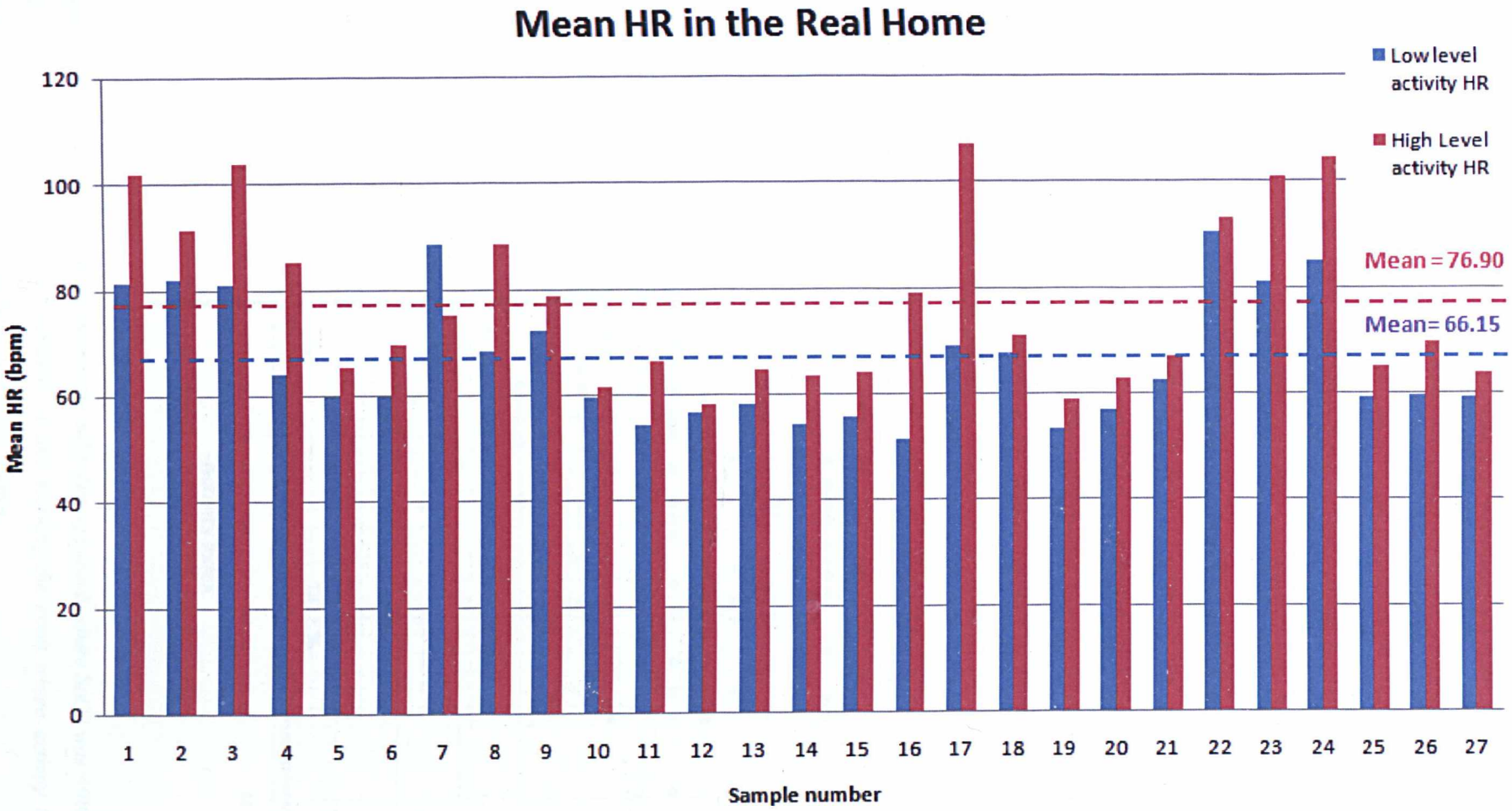


Figure 7.9 *Mean HR for each of the 27 samples during home activity circuit for low and high level activities. Overall means for high and low level activities are also shown.*

The Activity Index during periods where the SpO_2 values were found to be less than 90% in the home environment was calculated and is illustrated below in Figure 7.10, along with the corresponding SpO_2 values. It can be seen that in 90.5% of cases where subjects were found to have an SpO_2 value of less than 90%, they were performing an activity with an index value of greater than 5. Conversely only 10.5% of SpO_2 values less that 90% were seen to occur with an activity index value of less than 5. Whilst this is expected when it is considered that increased activity results in the potential for increased motion artefact in pulse oximetry resulting in falsely low SpO_2 readings, these findings highlight the importance of determining resting values when looking for pathological disease states. At rest therefore, the subject's physiology could be more accurately evaluated and differentiated from artefact. This finding highlights the e-AR sensor's ability to determine the context in which a physiology measurement is taken, thereby allowing the determination of resting HR and SpO_2 in post-operative patients recovering at home.

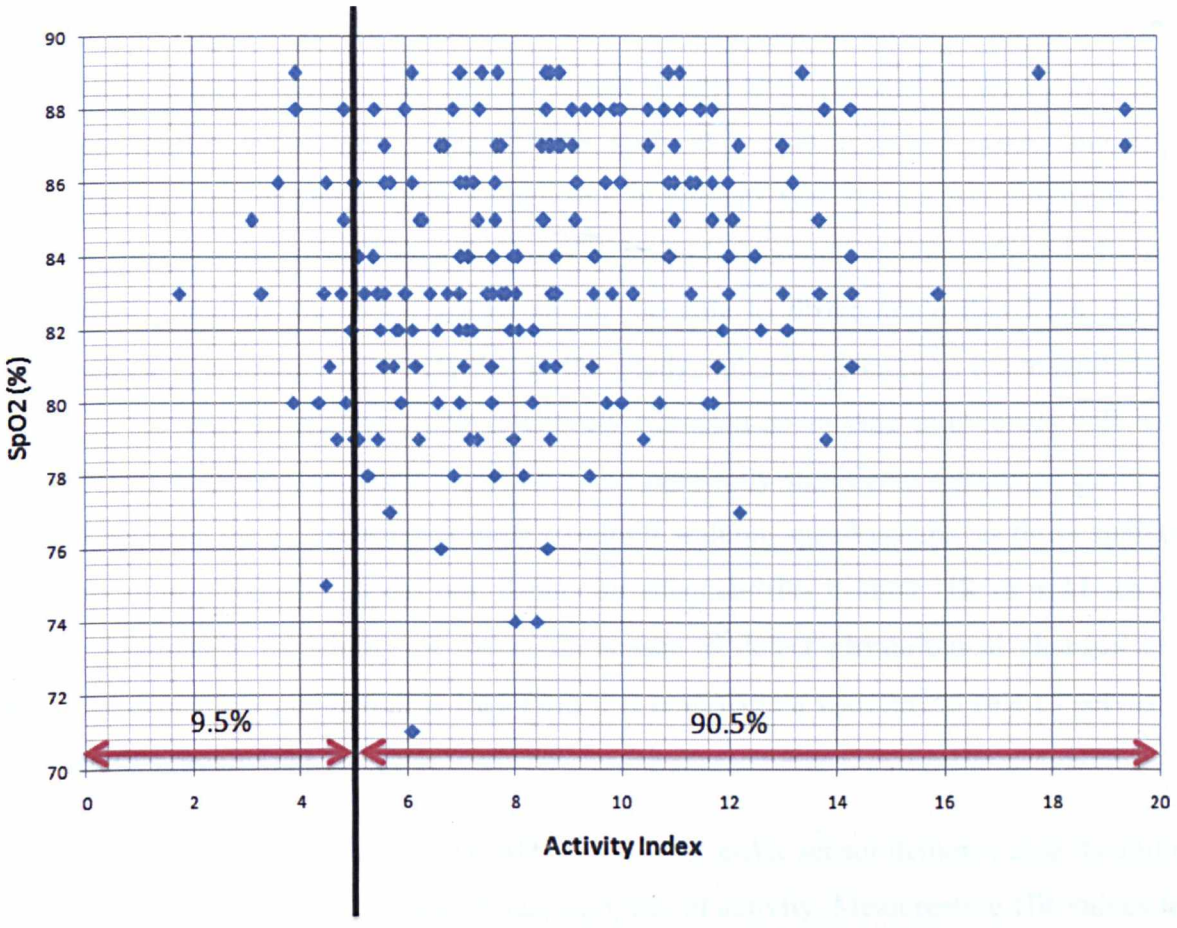


Figure 7.10 *A scatter plot showing the activity index during periods where SpO2 was <90% according to the e-AR sensor for the 27 home ADL datasets. A line marking the point where activity index was 5 and the proportion of readings above and below this is also shown.*

7.4 Discussion

The results of this study have demonstrated that the ambulatory e-AR sensor can be used to identify variations in HR and SpO_2 that occur with both exercise and home ADLs of varying intensity. Its activity index framework can be used to provide invaluable context information without which a pathological change in these parameters could not be differentiated from that due to normal exercise or motion artefact. Each of the three legs of this study demonstrate a slightly different aspect of the e-AR sensor's ability to monitoring ambulatory context-aware physiology, and so are considered in turn below.

The findings from the increasing treadmill walking intensity circuit show that e-AR sensor was able to detect statistically significant increases in HR from 83.66 bpm when walking at 3km/h to 99.83 bpm when walking at 3km/h with an incline, an increase in HR of 16 bpm. When it is considered that the resting human HR is usually 70-80bpm, and a tachycardia (pathologically high HR due to a disease process) is >100 bpm, it can be seen that the order of magnitude of this difference (20-30bpm) should be able to be detected by the e-AR sensor. Such tachycardias occur with complications such as would infection, chest infection, pulmonary embolus, or dehydration. Conversely in patients who have a pathologically low heart rate (bradycardia) of <50 bpm due usually to cardiac complications such as ischaemic heart disease (angina), the e-AR sensor should be able to differentiate this from normal resting values. It is important to note that in this study, subjects differed in the magnitude of HR rise in response to exercise. This is entirely expected as varying individuals will have varying levels of fitness, and may explain why a statistically significant difference could not be found between the 1.5km/h and 3 km/h treadmill walking speed groups, as those subjects who were more physically fit did not display an adequate rise in their HR to mild aerobic exercise. Ultimately the ability of the e-AR sensor to detect physiological changes in a heterogeneous patient population is important if it is to have a widespread role in pervasive post-operative monitoring.

In the supervised scenario-based home ADL circuit, the e-AR sensor demonstrated its ability to detect changes in HR occurring with varying types of activity. Mean resting HR values for the activities of sitting (72.34 bpm), sitting and eating (73.45 bpm), and lying down and

sleeping (68.57 bpm) were not statistically significantly different from each other. They were however significantly lower to HR values after walking (83.50 bpm) and climbing stairs (90.17 bpm). The ability of the e-AR sensor to detect this is important because in the home environment, it is unlikely that a subject will undertake prolonged levels of aerobic activity (as in walking on a treadmill), but will undertake ADLs of varying intensity as part of their normal daily routine. The results from the real home environment also supported these findings as the e-AR sensor was able to determine a statistically significant difference in HR between the low (66.15 bpm) and high (76.90 bpm) level activity groups in an unsupervised dataset. The ability of the e-AR sensor to detect changes in HR with varying activity has an important implication on its use to detect pathological disease states. First, a significant rise in HR during low level activities and in particular sleeping (resting HR), is likely to be the most sensitive means of detecting the physiological effect of a post-operative complication in the home environment. This is because a rise in HR is one of the body's first responses to many of the complications mentioned in table 7.1. It is therefore important that the context information provided by the e-AR sensor verifies that the subject is indeed resting when the measurement is taken. Second, the magnitude of the rise in HR from resting to active state (exertional tachycardia) may also be a sensitive indicator of a patient's physiological state. For example a patient who has a post-operative pneumonia may have a higher HR with walking that they did pre-operatively. In both cases, in order to use the e-AR sensor in this environment, a 'pre-operative baseline' must be established against which to compare post-operative values. This could for example take place as part of a patient's pre-operative assessment to surgery, where they wear the sensor for a period of time before their operation in their home environment as the data collected forms part of their baseline parameters.

In this study the e-AR sensor was used to monitor subjects' ambulatory SpO_2 in both the scenario-based home ADL circuit and the real home environment. Whilst it was not designed to detect pathological changes in this parameter, this study demonstrated the importance of taking into account the affect of motion artefact. In the scenario-based ADL circuit, motion artefact was responsive for SpO_2 reading of <90% in 16% of ADLs undertaken by subjects. It is not surprising that most of these episodes occurred during walking (48%) and least of them occurred during the activities of sitting (4%) and lying down (7%). Interestingly, a

disproportionate number of these events occurred during the activities of eating and drinking. Whilst during both these activities the subjects have to stop breathing to swallow, it is unlikely that this was the mechanism responsible. What is more probable is that the head tilt and change in head position during this activity resulted in motion artefact. The activity of 'tooth brushing' accounted for 9% of these low SpO_2 values, which is likely to be the result of vibrations and head-shaking during the brushing activity. In the real home environment, 90.5% of time that the SpO_2 was found to be <90%, the activity index was found to be greater than 5. These findings that resting SpO_2 with the e-AR sensor showing the subject to have an activity index of less than 5 in the home environment, is the most appropriate time to monitor this parameter, with the least likelihood of motion artefact clouding the results. Overall, the findings of this study suggest that times of rest or low level activity are the best opportunities to monitor both HR and SpO_2 in the real home environment.

It is at this point important to note a number of aspects of home pulse oximetry monitoring that need to be improved as this technology is deployed in the real home. First, improvements in sensor design, the development of noise reduction algorithms, and better data analysis techniques are all mechanisms that have been proposed to try and overcome the problem of motion artefact [175, 177]. The implementation of these solutions is very important to the use of this technology in the home setting, as the important role that this artefact plays in ambulatory physiology monitoring has been well demonstrated in this study.

Second, the pulse oximeter's energy consumption is a very important aspect to consider particularly when developing an ambulatory device that the patient would be expected to wear all day. In this study, the measurement of pulse oximetry was performed continuously for a maximum period of thirty minutes, primarily because the purpose of the three test circuits was to evaluate the ability of ambulatory pulse oximetry as provided by the e-AR sensor over a range of activities. In a patient's home however, it may be more beneficial to measure this at regular intervals, by programming the BSN node to switch the ChipOx® module on and off at regular intervals rather than keeping it on continuously. Another option for reducing power consumption would be to measure only HR continuously, with thresholds set so that an abnormally high or low reading would trigger the measurement of SpO_2.

Finally, the contribution of the ChipOx® module and its battery supply has a significant impact on the size of the device, making it larger and heavier and therefore less pervasive. This is turn also has an impact on the magnitude of motion artifact, because a larger device is prone to move around more on the ear than a smaller one. Miniaturisation of the device either through reducing power consumption via the mechanisms proposed above, or through integrating the pulse oximetry module further within the BSN node on a smaller chipboard, are likely to be the main mechanisms for this. This is a key aspect that must be considered when developing this technology further.

This study raises a very interesting possibility of using the e-AR sensor as a pre-operative tool to determine a subject's resting and peak HR, as well as their recovery times to normal with exercise. Currently this information is only available through direct questioning of the patient, asking them about symptoms such as dyspnoea (shortness of breath) and angina (chest pain) at rest or on exertion (the distance they walk before they get the symptom). Patients at risk of having underlying respiratory or cardiac pathologies are then further investigated with tests such as electrocardiography, X-ray, and echocardiography. The e-AR sensor and similar pervasive technologies would help to add objectivity to this pre-operative risk stratification through ambulatory context-aware physiology monitoring, a potentially important application for this technology. Pre-operative evaluation with the e-AR sensor would also provide a 'base-line' of activity and physiology data against which the subject's progress could be evaluated. Ambulatory pulse oximetry measurement has been shown to be effective in evaluating a patient's level of fitness for surgery in a study by Nokolic et al (2008) on 101 patients undergoing lung surgery (lobectomy) for benign and malignant conditions. Authors showed that the measurement of oxygen saturation and heart rate using pulse oximetry during stair climbing could be used to predict the risk of developing post-operative complications [244]. This is important because it suggests that monitoring the heart rate and oxygen saturation of a patient pre-operatively in their home environment, may be used to help determine their anaesthetic risk.

Finally, in order for pulse oximetry to be used to monitor patients' HR and SpO_2 at home, there needs to be a system that responds effectively to abnormal results. A study by Bowton et al (1991) evaluating the use of pulse oximetry in medical and surgical hospital wards

showed that despite 58% of patients reviewed having had at least one episode of desaturation in their SpO_2 to less than 85% during their hospital stay, this was documented in the nursing notes and bedside charts of only 33% of cases [245]. More importantly, it was found that this resulted in a change in respiratory therapy in only 26% of patients. These results suggest that even in the more supervised hospital setting where continuous pulse oximetry is possible, existing labour-intensive monitoring systems are too slow and inaccurate to be able to act in time. To this day, most hospitals even in developed countries still employ these manual chart-based monitoring systems. In the home setting, such systems carry little chance of making a difference to care, and therefore there is a need for a more dynamic way of monitoring pulse oximetry if it is to be used by patients in their home.

8 e-AR Sensor Patient Trial

8.1 Introduction

The preceding experimental chapters presented in this thesis have to date systematically developed and validated a system for monitoring parameters of functional and physiological post-operative recovery in the simulated home environment. The biomechanical components of mobility impairment and activities of daily living have been studied and converted into surrogate biomarkers that can be quantitatively measured using the e-AR device. This has resulted in the development of an activity index, activity classification system, and mobility impairment detection framework that are specifically tailored to the post-operative monitoring needs of patients recovering at home from major surgery. The ability of the sensor to provide context-aware physiology measurement with regards to both HR and SpO_2 has also been described. The use of the e-AR sensor and its frameworks to monitor post-operative home recovery in real patients who have undergone abdominal surgery is the next step in the validation of this system for clinical use.

Patient compliance and the e-AR sensor's power consumption are perhaps the two most important aspects that need to be taken into account before clinical use of this sensor. The following attributes of the device address these issues, preparing it for use in this environment: First, because it uses the ear as the site for sensor placement, the limbs are left free to allow the patient to take part in normal ADLs. This is also aimed at increasing patient compliance by incorporating the technology into their normal daily lives at home. Because the sensor does not use adhesives, it can be removed when bathing or showering for example, and worn again by the patient without the need for additional assistance. Second, the e-AR sensor minimises energy consumption through its low power wireless data transmission capabilities. The device is able to store data and transmit this at regular intervals to a base station within the home wirelessly. Because of the volume of data that needs to be transferred over the course of a day, any reduction in the power consumption of the BSN node during

wireless data transfer is likely to be important. Third, its BSN node can also reduce energy consumption by undertaking 'on-node' processing. This reduces the amount of information that needs to be transmitted wirelessly, ultimately prolonging battery life. The activity index in particular is a measure that can be determined through 'on node' processing, removing the need to wirelessly transmit data from three accelerometers, instead converting this into a single number that can be sent to the home station in the patient's home using less energy. Finally, because of the relatively high energy demands of continuous pulse oximetry monitoring, the BSN node within the e-AR sensor can be programmed to switch the pulse oximeter on and off at regular intervals rather than keeping it on continuously. Adjusting the frequency with which the pulse oximeter is switched on therefore represents perhaps one of the most efficient means by which the current energy consumption of the e-AR sensor can be controlled.

This chapter aims to use the e-AR sensor and its software frameworks to pervasively monitor functional and physiological post-operative recovery in real patients recovering from surgery in their own home environment. The experiments undertaken in this chapter demonstrate how the e-AR sensor and its frameworks address a number of significant issues that must be overcome if pervasive monitoring is to succeed in the patient's home. They highlight areas where pervasive monitoring offers invaluable information regarding a patient's recovery that would otherwise be almost impossible to ascertain even with existing labour-intensive monitoring systems. First, the e-AR sensor and its frameworks are used to pervasively monitor post-operative recovery in seven patients who have undergone inpatient abdominal surgical procedures. Here, unsupervised functional and physiological recovery data is collected with the subject in their own home environment. A pre-operative baseline in these parameters is determined, followed by up to 5 days of post-operative home recovery monitoring after discharge from hospital. This recovery data is analysed longitudinally, quantified, and presented for each patient, highlighting the important features of each case. Second, the e-AR sensor and its mobility impairment framework are tested in 10 patients before and after ambulatory (same-day discharge) surgery to determine its ability to detect post-operative changes in gait in the general surgical population.

8.2 Methods

This study involved the use of the e-AR sensor to monitor real patients in two settings. First, a post-operative home recovery study of 7 patients who underwent inpatient abdominal surgical procedures was undertaken. Measures of functional activity and physiological parameters were evaluated pre-operatively with these patients in their home environments, and this data was used as a baseline against which to compare their recovery within the first 10 days following home discharge. Second, the mobility impairment detection framework was tested in a supervised dataset of patients who had undergone ambulatory surgery with same day discharge. In these patients, pre- and post-operative walking was evaluated using the e-AR sensor and its mobility impairment frameworks. Further details of how these studies were undertaken are outlined in the section below.

8.2.1 Post-operative home recovery study

Patients undergoing general surgical procedures involving abdominal wall incisions were recruited for this study. In order to be included, the patients had to fulfil the following criteria:

1. The patients had to be scheduled for elective surgical procedures with a planned admission date. Patients undergoing emergency procedures were excluded from the trial because their pre-operative evaluation would not be indicative of their normal functional or physiological state.

2. The post-operative length of stay was less than one week. Patients with a post-operative stay longer than this were excluded because the functional and physiological parameters that the e-AR sensor is designed to measure may no longer be valid beyond this timeframe.

3. The patients all had to be adults above the age of 60. This target population was chosen because of their increased vulnerability during the post-operative period due to both age and co-morbidity. Children and young adults were therefore not included.

4. The patients had to reside within the West London area. This is because the logistics of arranging home visits for base station installation, sensor delivery, and data collection meant that the study coordinator had to visit their home on each of the data collection days.

During the post-operative home recovery study, patients who were selected and agreed to take part were visited at home, where they were given an opportunity to read a patient information sheet. They were then shown the e-AR sensor and given an opportunity to try it on, making sure that they were able to correctly wear and remove the device. Once informed consent was obtained, a base station laptop was installed in the patient's home, which was used to store and collect their data, in their home. The patients were asked to wear the sensor for four hours on a day in the week preceding their operation, and this data was collected from the base station later that day. Following surgery, the patients were visited in hospital where their consent to take part in the study over the post-operative period at home was confirmed. Once the patients were discharged home after surgery, they were visited daily at approximately the same time of the day, to wear the sensor for four hours at a time. They were asked not to wear the sensor when sleeping at night and to remove it when bathing or showering. Data was collected daily in this way from the sensor on up to five occasions within the first 10 days following surgery

8.2.2 Ambulatory surgery mobility impairment study

Patients undergoing ambulatory general surgical procedures involving either abdominal wall or peri-anal incisions were recruited for this study. In order to be included, the patients had to fulfil the following criteria:

1. The patients had to be scheduled for elective day surgical procedure with a planned discharge later on that day.

2. The patients all had to be adults above the age of 18, with children excluded from the study.

3. Patients had to be independently mobile without the use of any appliances such as a walking stick.

4. The planned surgical procedure had to have been carried out.

Patients were seen at the time of their presentation to the day surgery unit and given an opportunity to read a patient information sheet. They were then shown the e-AR sensor and given an opportunity to try it on, making sure that they were able to correctly wear and remove the device. Once informed consent was obtained, the patient was taken to a corridor of about 20 metres and asked to walk up and down it twice. Data was wirelessly collected from the e-AR sensor through a base station held by the study coordinator. Following surgery once the patients were ready for home discharge, they were asked to wear the sensor again and walk along the same corridor.

8.2.3 Outcome measures

The following outcome measures were collected or derived and recorded during the post-operative home recovery study:

1. *Patient Demographics* including age, sex, smoking status, co-existing medical conditions, number of people living at home, ability to self care, and exercise tolerance.

2. *Operative data* including type of procedure and post-operative complications.

3. *e-AR sensor raw data* including HR, SpO_2 and 3-axis accelerometer outputs.

4. *Mobility quantification data* including mean number of steps take per hour (determined from morphology analysis of the accelerometer traces) and mean activity index (AI) per hour.

5. *Context-aware physiology data* including the mean resting HR (at AI<5), peak HR at AI>5, and SpO_2 at rest (AI<5).

6. *Activity classification data* into levels 0-3

7. *Mobility impairment detection data* by classification of mobility as 'normal' or 'impaired'.

During the ambulatory surgery mobility impairment study the following outcome measures were collected or derived and recorded:

1. *Patient and operative demographics* including age and operative procedure.
2. *e-AR sensor* 3-axis accelerometer output raw data.
3. *Mobility impairment detection data* by classification of mobility as 'normal' or 'impaired'.

8.2.4 Ethical approval and Informed consent

Ethical approval for this study was obtained from the Local Research and Ethics Committee (LREC) at St. Mary's Hospital, London, UK. As part of this approval process informed written consent had to be gained from all subjects, who were also given an information sheet regarding the study. It is important to note that all data collected during this study was analysed retrospectively and therefore participation of patients in this study did not in any way change the way they were managed medically.

8.2.5 Regulatory approval

Regulatory approval for the use of the e-AR sensor in these subjects was obtained from the Medicines and Healthcare products regulatory agency (MHRA) as a Class I device (CI/2007/0043). During the course of the study there were no adverse incidents that required notification to the MHRA.

8.2.6 e-AR sensor data collection

The ear-worn activity recognition (e-AR) sensor [180] designed for this study was, as previously described, worn by subjects on the outer ear with a clip attaching the pulse oximeter to the earlobe. In cases where the patient's ear did not support the device adequately, a headband was also worn. The e-AR sensor has been previously described.

8.2.7 Data Analysis

The following measures of functional post-operative recovery were derived in this study:

1. *Activity Index* - In order to be able to classify the activity that a subject was undertaking at a particular time in the pilot study, a Matlab© (Mathworks Inc.) environment based software program developed by Lo et al (2007) [190] was used for data analysis. The software program developed uses a Bayesian classifier with multivariate Gaussians to model activity classes, presenting an efficient way for off-line training and a fast method to classify and stream real-time data. The inputs to the classifier are the three dimensional variance across the three accelerometer axes, as well as the amplitude of the raw data. A window of streaming data is assigned an activity class if the probability of belonging to this class was more than the probability of belonging to all other classes. The activity classes are assumed to have equal prior probabilities. To enhance the accuracy of the classification, the signal amplitude is used to identify static activities (such as lying down or sleeping), and the classifier is used to determine other dynamic activities (such as running and walking). Finally for the purposes of objective classification, the software allows activities to be groups into four groups, namely 'very low' (Class 0), 'low' (Class 1), 'medium' (Class 2), and 'high' (Class 3) level activities.

2. *Activity Index* - The overall intensity the activity being undertaken was determined using an 'Activity Index' calculated from the averaged variance across the 3 accelerometer outputs. The value of the activity index ranged from 0-15 with a greater value signifying a greater amount of movement and hence a more active type of activity.

3. *Mobility Impairment* - In order to detect mobility impairment in the home, the BSN Signal Editor Version 1.1 software (© VIP Group, Imperial College London) was used to identify and separate periods of walking. A multi-resolution spatiotemporal framework software was then used to analyse the e-AR sensor's accelerometer data which instead of using fixed measures (such as gait cycle) that generally do not take into account of 3-D motion, used multi-resolution wavelet features across all

directions of motion. This technique used automatic margin-based feature selection to select the frequency bands of the wavelet transform that provide discrimination between classes of motion, and Independent Component Analysis (ICA) as a means of source separation for 3-D acceleration [221].

8.3 Results

8.3.1 Post-operative home recovery

The 7 patients selected for this study, their demographics, and the operative procedures they underwent are shown below in Table 8.1.

Patient	Age/ Sex	Co-morbidity	Exercise Tolerance	Lives with	Operation	Post-op complication	Data Collected
1	79 (M)	IHD HT COPD ex-smoker	Limited (400 yards due to shortness of breath)	Son	Open right inguinal hernia repair	None	Pre: 1 day Post: 4 days
2	84 (M)	HT IDDM	Unlimited	Alone	Open left inguinal hernia repair	Seroma	Pre: 1 day Post: 5 days
3	80 (F)	HT Asthma NIDDM	Unlimited	Husband	Laparoscopic sigmoid colectomy	None	Pre: 1 day Post: 4 days
4	65 (M)	HT NIDDM	Unlimited	Alone	Open right inguinal hernia repair	Wound infection	Pre: 1 day Post: 4 days
5	64 (F)	HT NIDDM	Unlimited	Husband	Open cholecystectomy	Intra-abdominal collection (re-admitted to hospital)	Pre: 1 day Post: 3 days
6	74 (M)	IHD HT ex-smoker	Limited (50 yards due to chest pain)	Alone	Laparoscopic bilateral inguinal hernia repair	N/A	Pre: 1 day Operation postponed
7	62 (F)	IHD HT Asthma smoker	Limited (200 yards due to shortness of breath)	Alone	Revision of ileostomy	N/A	Pre: 1 day Withdrew post-op

Table 8.1 *Demographics for patients who were selected for the post-operative home recovery study. HT=hypertension, IHD=ischaemic heart disease, COPD=Chronic obstructive pulmonary disease, IDDM=Insulin-dependent diabetes mellitus, NIDDM=Non-insulin dependent diabetes mellitus.*

Pre- and post-operative home recovery data was successfully collected using the e-AR sensor for 5 patients. Patient 6 was excluded from the study because due to his extensive cardiac history the patient needed an echocardiogram prior to general anaesthesia. As a result, his operation was postponed for medical reasons beyond the timeframe for the study. Patient 7 withdrew from the study because she decided to spend her post-operative recovery period at her daughter's home outside of London, which was outside the catchment area for the study. The results from retrospective analysis of post-operative home recovery data for patients 1-5 during are presented below.

8.3.1.1 Patient 1

Patient 1 was a 79 year old male with a large right inguinal hernia, causing him localised right groin and testicular pain. Whilst he had lived with this hernia for over 5 years, an increase in the localised discomfort this was now causing him, combined with its impact on his mobility, had led him to see a surgeon for elective repair. He was an ex-smoker with a past medical history including ischaemic heart disease (IHD), hypertension (HT), and chronic obstructive pulmonary disease (COPD). He lived with his son on the fourth floor of a council block of apartments, was independently mobile, and self caring. The patient left his house only twice a week, largely due to his shortness of breath which limited his walking to about 400 yards at a time. He was responsible for all the cooking and cleaning of his house, with the aid of his son. The patient was approached to take part in the study at the time of his pre-operative assessment for surgery and gave his consent for the trial. He underwent an uncomplicated open right inguinal hernia repair with mesh and spent one night in hospital. Patient 1 wore the sensor for the same three hours of the day during one pre-operative day, and on days 1, 2, 4, and 6 following return home from surgery. Despite initially wearing the sensor at home on days 3 and 5, the subject later removed this preventing data collection on these days. On day 3 he had a visitor at his home around whom he did not wish to wear the sensor, and on day 5 he had to be out of his house for a hospital appointment. Figure 8.1 shows patient 1 wearing the sensor in their home.



Figure 8.1 *A picture of patient 1 wearing the e-AR sensor in their home with a close-up view (bottom right inset) of the patient's right ear.*

Figure 8.2 shows the context-aware physiology results for Patient 1 during the five days he wore the sensor at home. The mean resting heart rate (HR) at the end of periods were mean activity index was <5, was found to be consistently higher on post-operative days, rising from 40.4 (SD=6.1) beats per minute (bpm) pre-operatively to a peak of 60.6 bpm (SD=2.4) on post-operative home recovery day 4, before setting at 57.3 bpm (SD=3.8) on post-operative home recovery day 6. Whilst this may be as a result of the increased stress of surgery, the patient had pre-operatively been on a β-blocker medication (reducing his heart rate), which he was not administered on his first post-operative day, thereby accounting for the raised HR. Similiarly values for peak HR at the end of periods where mean activity index was >5 were both higher during the post-operative period, though highest on the first (91 bpm) and fourth (97) post-operative home recovery days. The resting SpO_2 readings for patient 1 remained constant at 100% during the study periods.

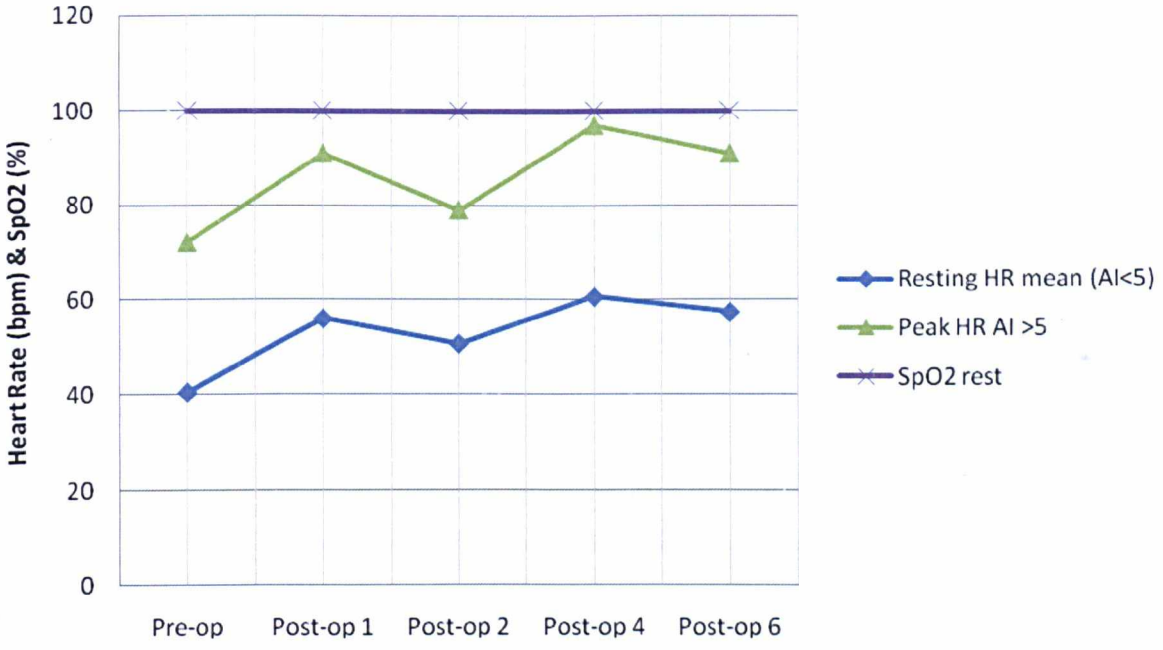


Figure 8.2 *A graph showing patient 1's mean resting heart rate (HR), peak HR at AI>5, and resting SpO_2 during the pre- and post-operative period.*

The mean number of steps taken per hour and mean activity index per hour for patient 1 are shown below in Figures 8.3 and 8.4. From these it can be seen that the patient's hourly step count was markedly reduced in the post-operative period, but was seen to return to by post-operative home recovery day 4. The activity index per hour took longer to recover, reaching pre-operative levels by day 6.

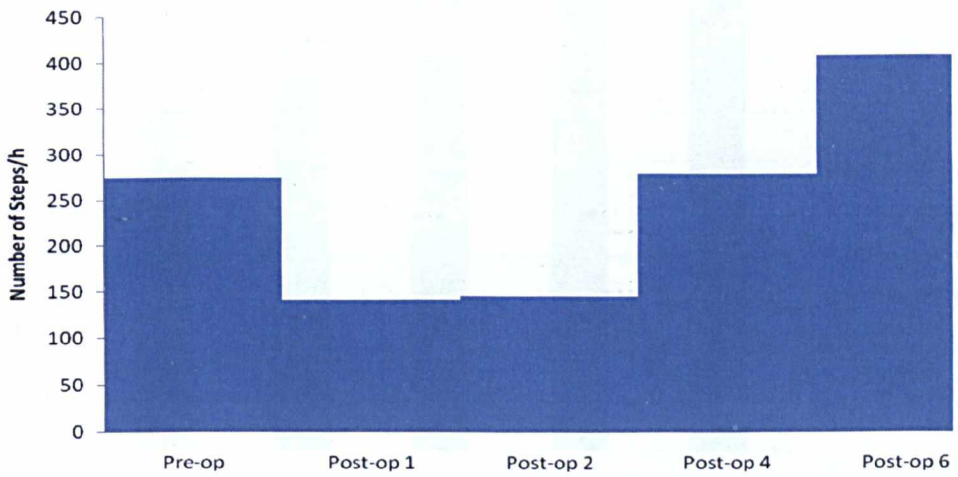


Figure 8.3 *A bar chart showing the mean number of steps per hour taken by patient 1 during pre- and post-operative periods at home.*

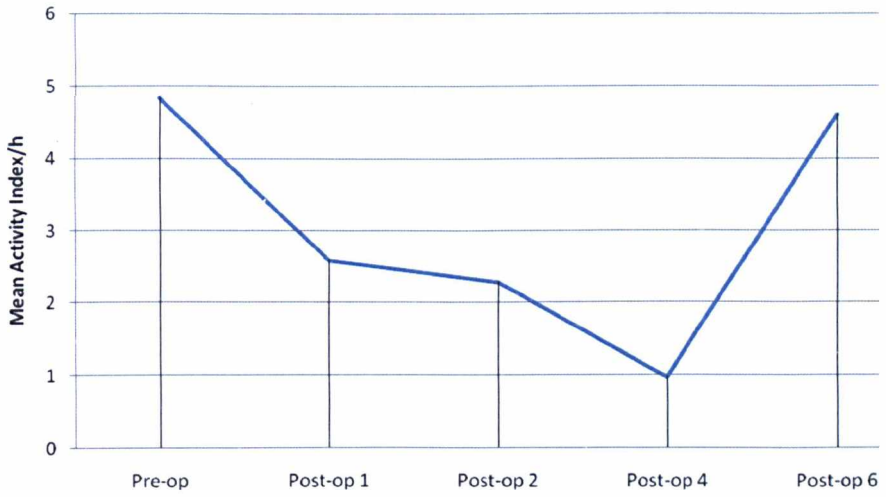


Figure 8.4 *A graph showing the mean activity index per hour for patient 1 during pre- and post-operative periods at home.*

The activity classification per hour profile for patient 1 is shown below in Figure 8.5. From this it can be seen that whilst pre-operatively the patient was seen to spend 53.8% of their time undertaking level 3 activities and 8.3% of their time on level 0 activities per hour, post-operatively this changed significantly with the subject spending over 70% of their time undertaking level 0 activities, increasing the amount of rest they obtained in the post-operative period. The activity classification per hour profile is seen to change daily following surgery and by post-operative home recovery day 6 the activity profile of the subject was seen to return almost back to its pre-operative level.

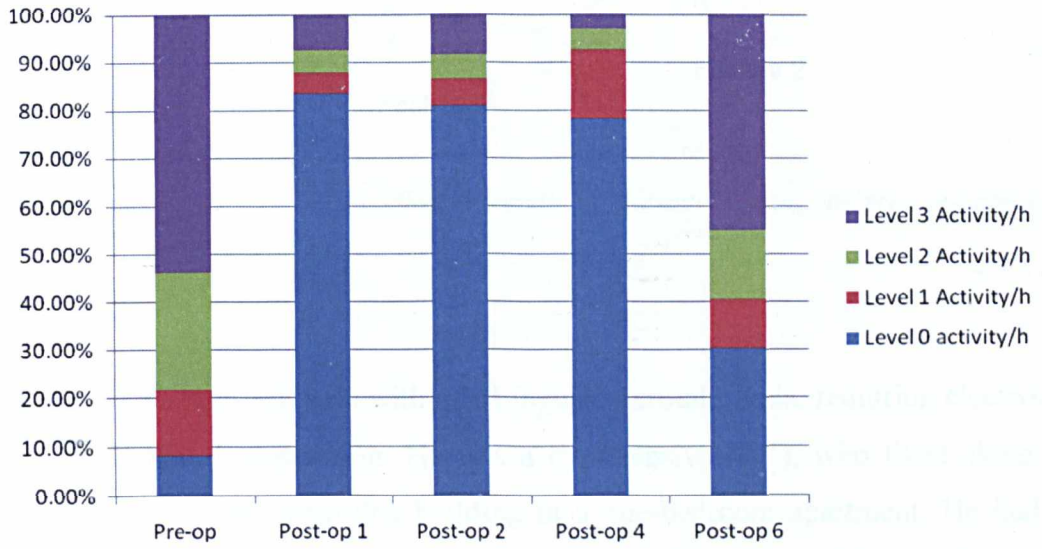


Figure 8.5 *The activity classification per hour profile for patient 1 during pre- and post-operative periods.*

The mobility impairment classification results for periods of walking during times when patient 1 was wearing the sensor are shown below in Figure 8.6. From this, a marked difference can be seen in the way that patient 1's walking clusters pre-operatively and on the first post-operative home recovery day. Following this, on each of the subsequent post-operative recovery days walking clusters onto distinct and separate areas. By post-operative home recovery day 6, this clustering is seen to be very close to that seen in the pre-operative period.

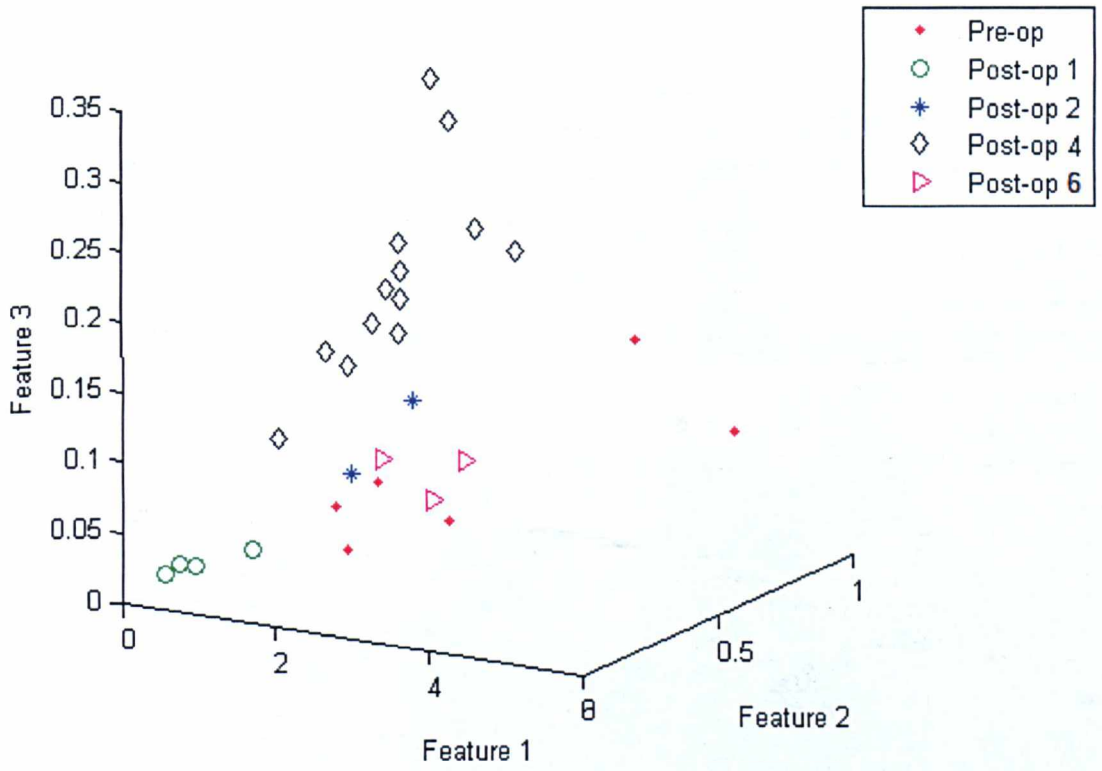


Figure 8.6 *The mobility impairment classification results for patient 1 during the pre- and post-operative periods.*

8.3.1.2 Patient 2

Patient 2 was an 82 year old male with a left inguino-scrotal hernia, requiring elective repair to prevent small bowel obstruction. He was a hypertensive (HT), who lived alone on the ground floor of a warden-controlled building in a one-bedroom apartment. He had carers coming to his home two days a week to help with cooking, shopping and cleaning. The

patient left his house daily to go to his local shops and buy a newspaper, and was in contact with his family by phone who visited him a few times a month. The patient was approached to take part in the study at the outpatient clinic stage when the decision to admit him for surgery had been made. He underwent an uncomplicated open right inguinal hernia repair with mesh and spent two nights in hospital because he required post-operative catheterisation as he developed urinary retention. Patient 2 wore the sensor for the same three hours of the day during one pre-operative day, and on days 1, 2, 3, 4 and 5 following return home from surgery. Figure 8.7 shows Patient 2 wearing the sensor in their home as he undertook a range of activities.



Figure 8.7 *A picture of patient 2 wearing the e-AR sensor whilst standing in his living-room. The insets show a close-up view of the patient's right ear (top left), she subject sitting and watching television (top middle), and the subject cooking in his kitchen (top right).*

Figure 8.8 shows the context-aware physiology results for patient 2 during the six days he wore the sensor at home. The mean resting heart rate (HR) at the end of periods where the mean activity index was <5, can be seen to be 66.2 bpm (SD=1.7) pre-operatively, and relatively stable between 54.6 and 60 bpm during the post-operative home recovery days. The peak HR at AI >5 for patient 2 was seen to rise dramatically from 70 bpm pre-operatively to 130 bpm on post-operative day 5. A sudden rise in HR such as this to a value above 120 bpm may represent an arrhythmia such as uncontrolled atrial fibrillation (AF), which is commonly seen in this patient population. In a patient such as this, AF results in a significantly increased risk of thrombo-embolic stroke. The resting SpO_2 readings for Patient 2 remained constant between 98-99% during the study periods.

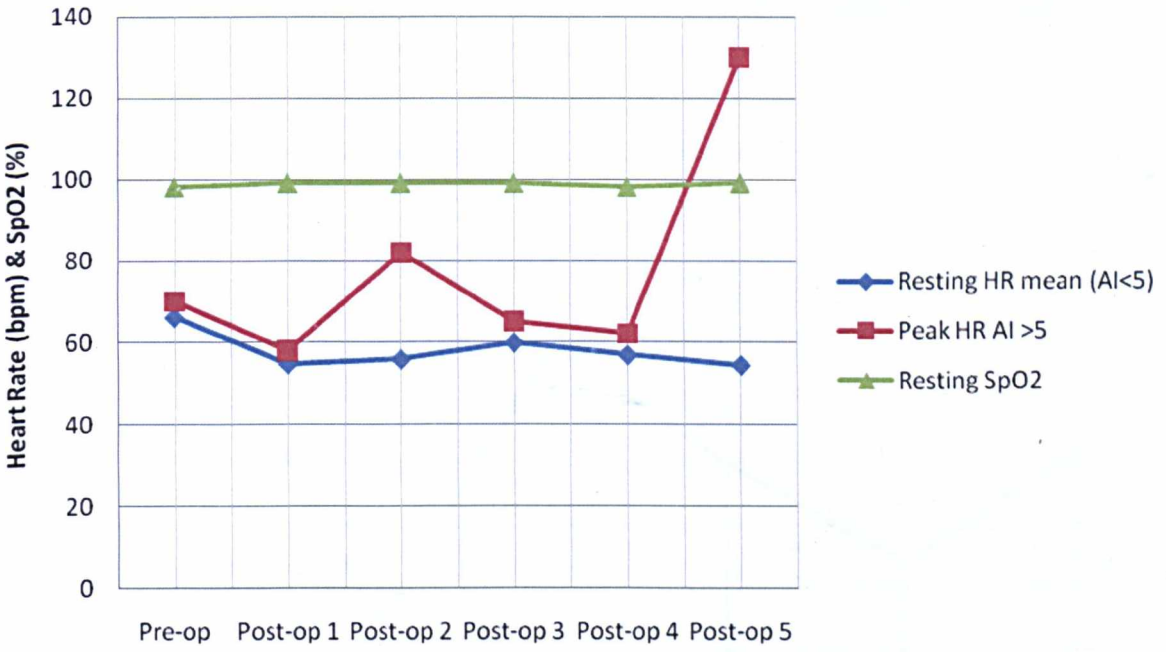


Figure 8.8 *A graph showing patient 2's mean resting heart rate (HR), peak HR at AI >5, and resting SpO_2 during the pre- and post-operative period.*

The mean number of steps taken per hour for patient 1 are shown below in Figures 8.9. From these it can be seen that the patient's hourly step count fell on post-operative day 1, rising steadily on days 2-4, before falling on day 5. The mean activity index per hour is shown in figure 8.10 and was markedly reduced on post-operative recovery day 1, rose steadily on days 1-2 before dropping suddenly on days 3-5. In the real clinical setting these findings would

suggest that the patient may be suffering a setback in their post-operative recovery between days 3-5 and suggests they may benefit from closer attention during this period.

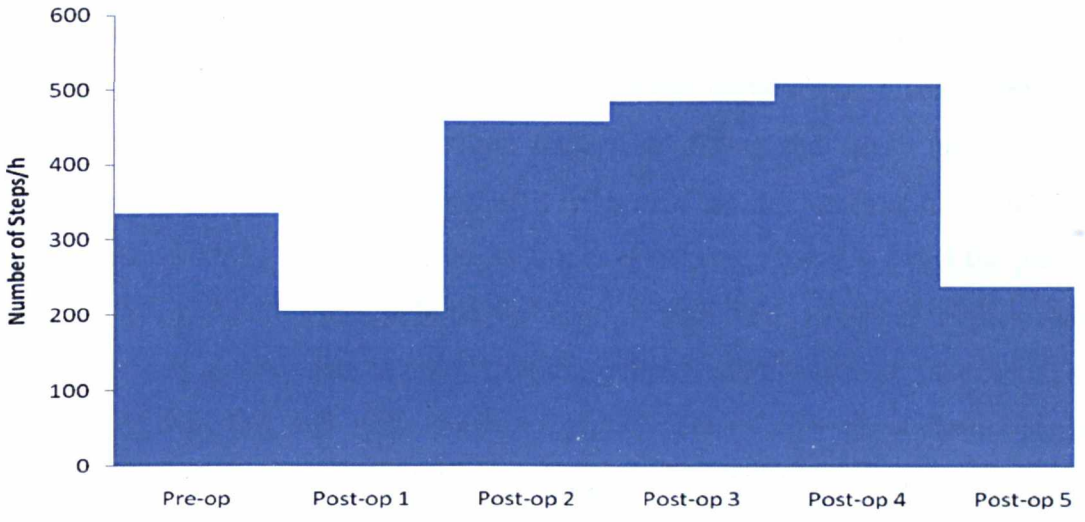


Figure 8.9 *A bar chart showing the mean number of steps per hour taken by patient 2 during pre- and post-operative periods at home.*



Figure 8.10 *A graph showing the mean activity index per hour for patient2 during pre- and post-operative periods at home.*

The activity classification per hour profile for patient 2 is shown below in Figure 8.11. From this it can be seen that whilst pre-operatively the patient was seen to spend 55.7% of their time undertaking level 0 activities and 40.1% of their time on level 1 activities per hour, post-operatively this changed significantly with the subject spending 94.5% of their time undertaking level 0 activities, and 4.7% of their time undertaking level 1 activity. The proportion of level 1 activity the patient undertook during the study periods gradually increased over post-operative home recovery days 2-5, and the amount of level 0 activity gradually reduced during this period. By post-operative home recovery day 5 the patient was spending 82.6% of their time undertaking level 1 activities, which is higher than pre-operative levels. It should also be noted that this subject undertook very little level 2 and 3 activity during both pre- and post-operative periods. Interestingly these results suggest an improvement in functional activity following surgery, which may be as a result of increased mobility following hernia repair, with the hernia no longer limiting movement.

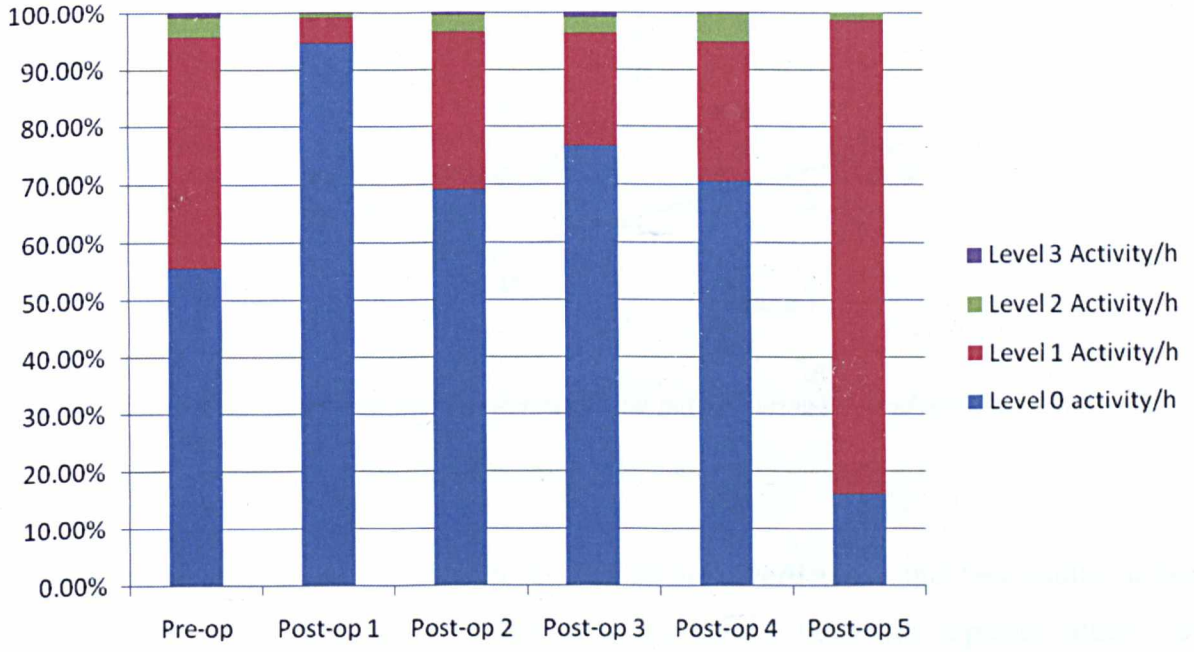


Figure 8.11 *The activity classification per hour profile for patient 2 during pre- and post-operative periods.*

The mobility impairment classification results for periods of walking during times when patient 2 was wearing the sensor are shown below in Figure 8.12. Clustering of this patient's walking data into distinct regions was not so clear during post-operative home recovery days 2-4, although it was noted that by post-operative home recovery day 5, the subject's walking was seen to cluster closer to pre-operative walking than at any other time during the post-operative period.

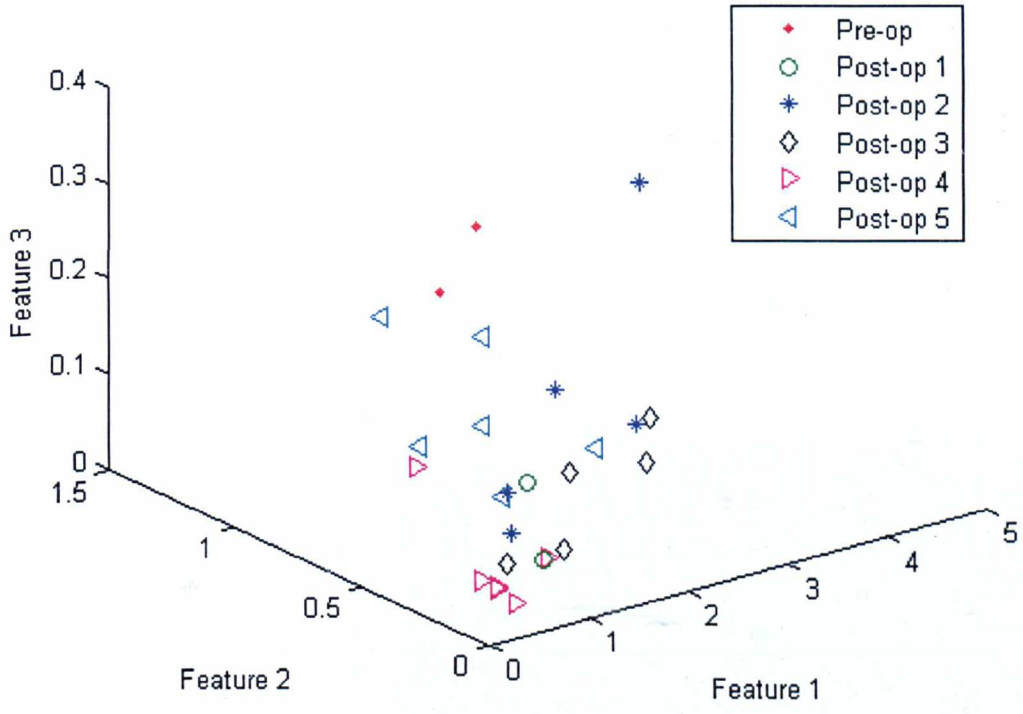


Figure 8.12 *The mobility impairment classification results for patient during pre- and post-operative periods.*

8.3.1.3 Patient 3

Patient 3 was an 80 year old female with severe sigmoid diverticulosis that had resulted in her being admitted to hospital several times over the past 3 years for repeated attacks of diverticulitis requiring treatment with intravenous antibiotics. The patient had opted for an elective sigmoid colectomy to resect her diseased sigmoid colon, and a primary anastomosis to restore her continuity. She was a hypertensive (HT), suffered from asthma and had non-insulin dependent diabetes mellitus (NIDDM). The patient was independently mobile, lived with her husband who suffered from severe Alzheimer's disease, and was his sole carer. She

left her house several times a day and was responsible for all the cooking and cleaning activities for her home. Patient 3 was approached to take part in the study prior to her pre-operative assessment for surgery and gave her consent to join the trial. She underwent a laparoscopic sigmoid colectomy and spent 6 days in hospital during which time she had a relatively uneventful recovery. During this time her husband was moved to a respite nursing home where he was cared for. Patient 3 wore the sensor for the same three hours of the day during one pre-operative day, and on days 1, 2, 8, and 9 following return home from surgery. The patient decided to not wear the sensor on post-operative home recovery days 3-7 because her husband was returning from his nursing home on these dates and she felt her participation in this trial by wearing the sensor and the associated home visits would unsettle him. As a result she agreed to wear the sensor on days 8 and 9 once he had been home for a few days alone with her and had settled into his home. Figure 8.13 shows patient 3 wearing the sensor on the pre-operative data collection day. It should be noted that this patient required additional fixation of the sensor with a headband as it otherwise kept slipping on her ear.

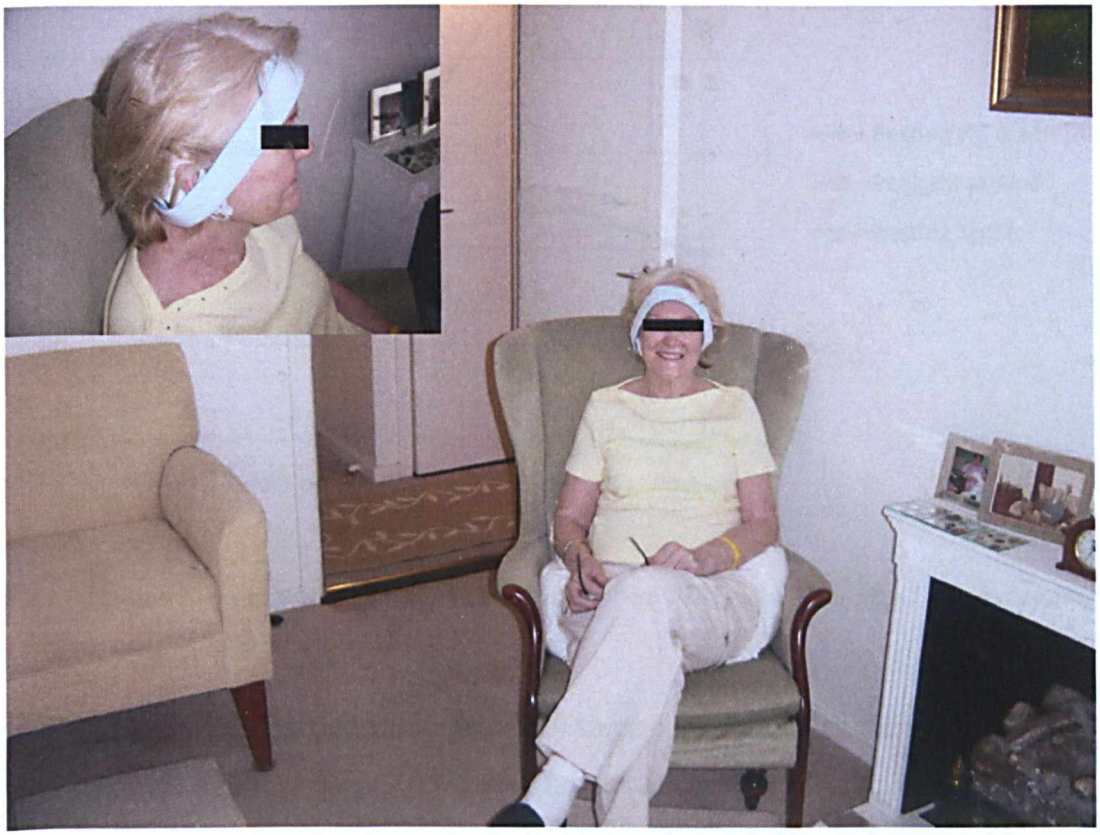


Figure 8.13 *A picture of patient 3 wearing the e-AR sensor in her home with a close-up view (top left) of the subject's ear.*

As seen in Figure 8.14, patient 3's resting HR rose from 57.5bpm (SD=5.14) pre-operatively to 67.5 bpm (SD=3.3) on post-operative home recovery day 1. This gradually fell over the post-operative period, reaching 59.5 bpm (SD=1.7) by post-operative day 9. Such a rise in HR followed by recovery to normal in the days following major abdominal surgery would be expected to take place as part of the normal physiological response to the trauma of surgery and wound healing. The peak HR at AI >5 for patient 3 rose dramatically from 70bpm pre-operatively to 97 bpm on post-operative day 8, and 83 bpm on post-operative day 9. This rise in exertional heart rate may again be a consequence of major surgery where the patient's functional reserve with regards to respiratory and cardiac systems may be reduced at a time when a great degree of wound healing is taking place. The resting SpO_2 readings for Patient 3 were relatively stable, remaining between 97-100% during the study periods.

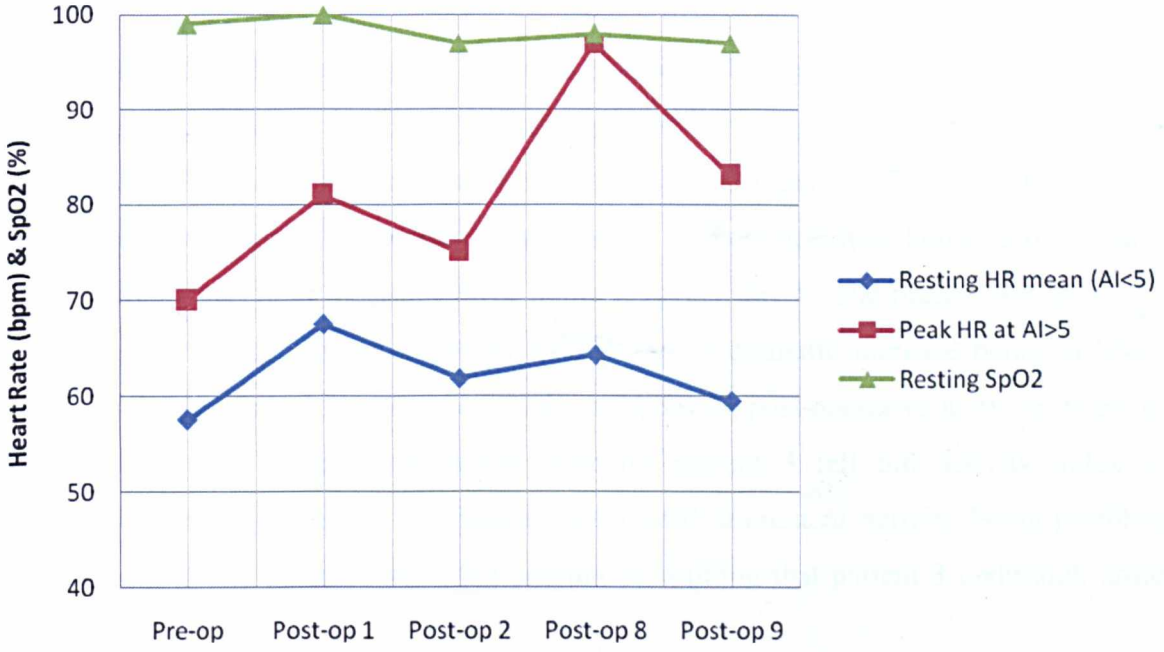


Figure 8.14 *A graph showing patient 3's mean resting heart rate (HR), peak HR with AI >5, and resting SpO_2 during the pre- and post-operative period.*

Patient 3's step count fell dramatically from 480 steps per hour during the pre-operative period to 130 steps per hour on post-operative home recovery day 1, rising to 290 steps per hour on day 8 and 230 steps per hour on day 9. This is shown below in Figure 8.15.

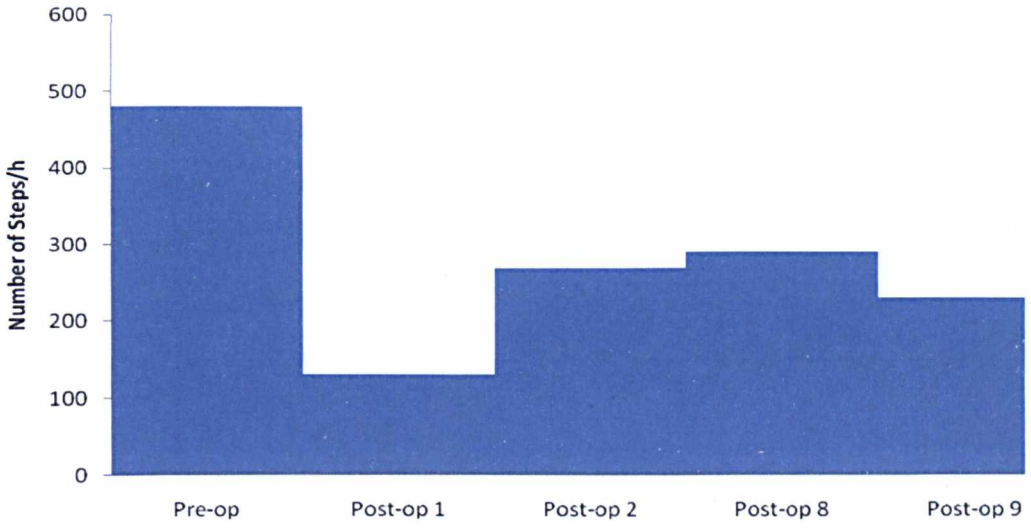


Figure 8.15 *A bar chart showing the mean number of steps per hour taken by patient 3 during pre- and post-operative periods at home.*

The mean activity index per hour of patient 3 rose steadily during the post-operative period from 1.2/h pre-operatively to 2.35/h by post-operative home recovery day 9 as shown below in Figure 8.16. The activity classification results shown in Figure 8.17 demonstrate a rise in level 0 activity from 60.9% pre-operatively to 64.9% on post-operative home recovery day 1, before falling to 62.1% on post-operative home recovery day 9. The patient was seen to be more active in the post-operative period with the most dramatic increase being in level 2 activity which rose from 4.9% pre-operatively to 34.3% on post-operative home recovery day 9. The finding that the step count per hour for patient 3 fell but activity index and classification rose suggests that the increase in overall amount of activity being performed was not solely due to an increase in the amount of walking that patient 3 undertook around their home.

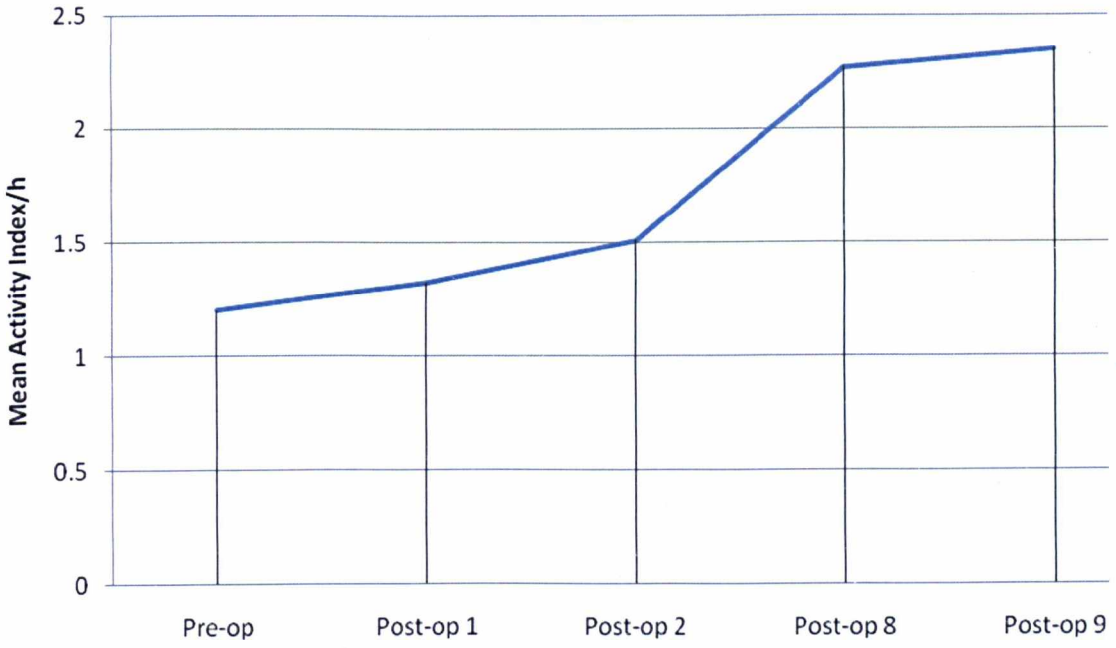


Figure 8.16 *A graph showing the mean activity index per hour for subject 3 during pre- and post-operative periods at home.*

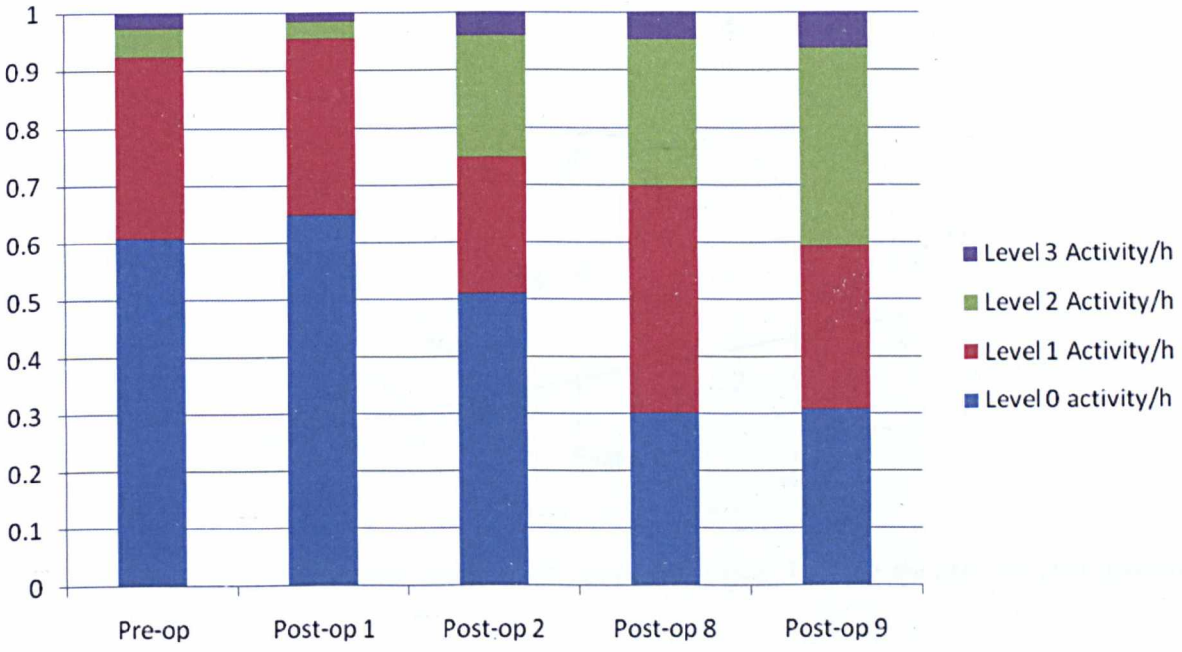


Figure 8.17 *The activity classification per hour profile for patient 3 during pre- and post-operative periods.*

The mobility impairment classification results for periods of walking during times when patient 3 was wearing the sensor are shown below in Figure 8.18. The furthest separation in clustering is seen between pre-operative walking and post-operative walking on home recovery days 1 an 2 suggesting that the mobility impairment on these days was most marked. By post-operative home recovery days 8 and 9, the clustering was still separate from the pre-operative period, but was seen to map closer to pre-operative levels than before. This suggests that mobility impairment was still present in this subject, though reduced.

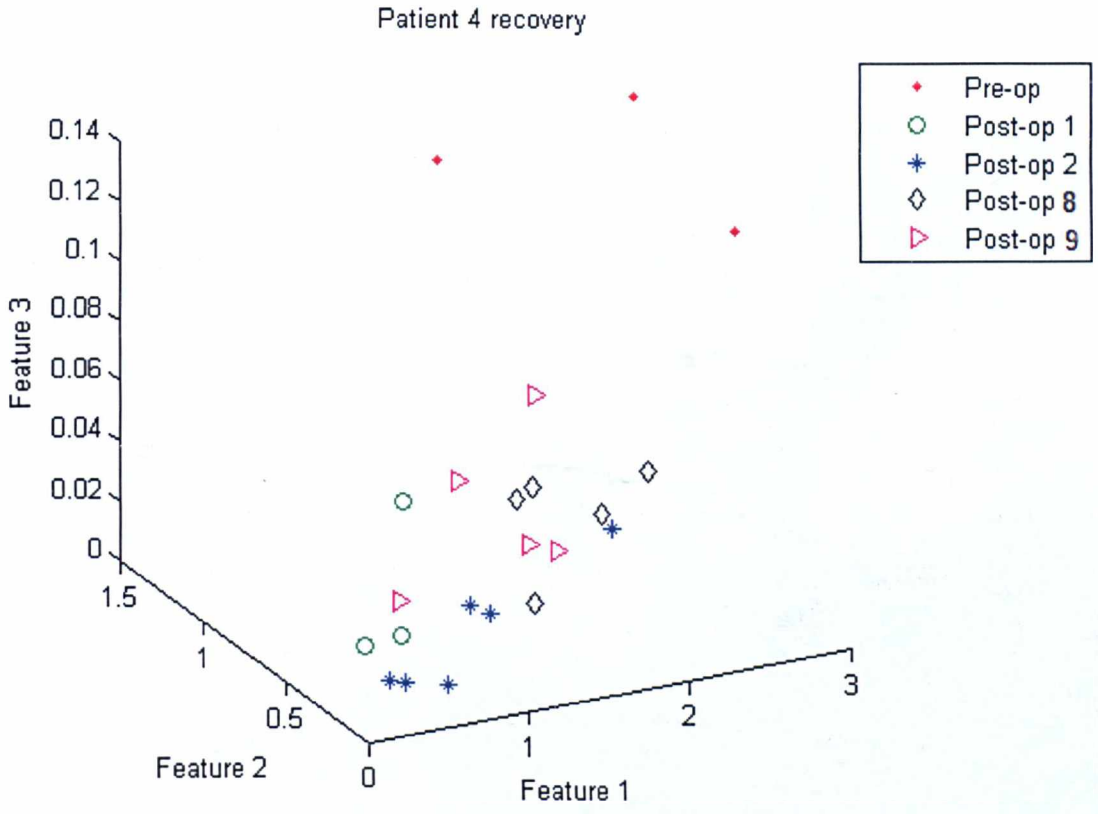


Figure 8.18 *The mobility impairment classification results for patient 3 during the pre- and post-operative periods.*

8.3.1.4 Patient 4

Patient 4 was a 65 year-old male who had presented with a right inguinal hernia that was irreducible, therefore requiring expedited elective surgical repair. The patient was

hypertensive but otherwise did not have any relevant past medical history. He lived alone on the ground floor of a council apartment building and was completely independent and self caring. His exercise tolerance was good and he left his house daily for several hours. Patient 4 was approached to take part in the study at the time of his first visit to the surgical outpatient department and gave his consent to join the trial. He underwent an open right inguinal hernia repair which resulted in him staying just one night in hospital. Patient 4 wore the sensor for the same three hours of the day during one pre-operative day, and on days 1, 2, 3, and 4 following return home from surgery. The patient presented to his General Practitioner 7 days following surgery with a wound infection resulting in groin pain, which required antibiotic treatment and local wound care. Figure 8.19 shows patient 4 wearing the sensor on pre-operative data collection day 1.

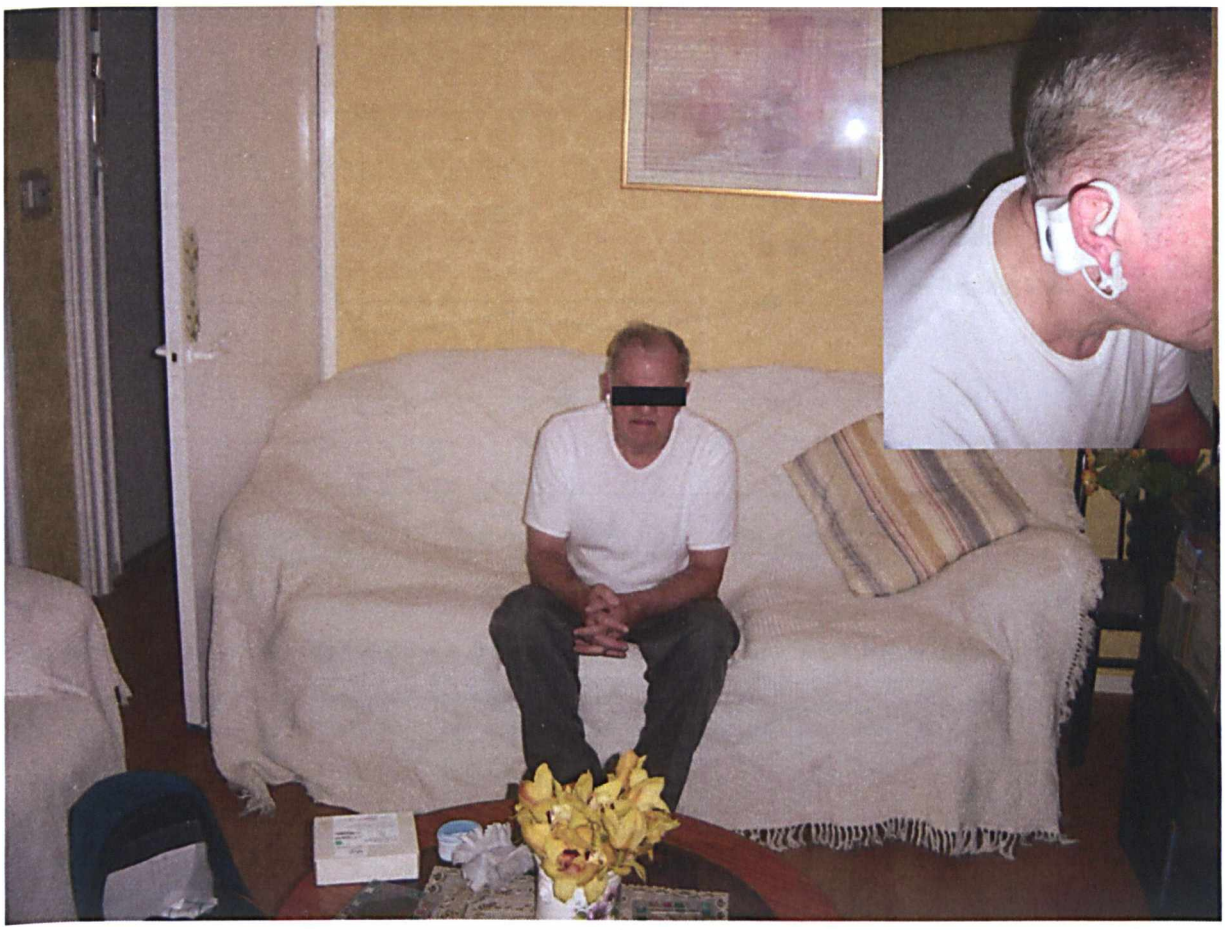


Figure 8.19 *A picture of patient 4 wearing the e-AR sensor in their home with a close-up view (top right inset) of the subject's ear.*

As seen below in Figure 8.20, the resting HR for this patient fell from 78.6 bpm (SD=1.6) pre-operatively, to 56.6 bpm (SD=2.6) on post-operative home recovery day 1, before rising to 60 bpm (SD=1.4) on post-operative home recovery day 4. The peak HR at AI>5 was seen to be 64 bpm pre-operatively and much higher at 80 bpm on post-operative home recovery day 1. By post-operative home recovery day 4 this had fallen to 75 bpm. This patient's resting SpO_2 remained between 99-100% throughout both pre-operative and post-operative home recovery periods. During the study period this patient's hourly step count (shown in Figure 8.21) remained relatively stable and infact rose on post-operative home recovery day 1 to 370 steps/h which was greater that the pre-operative period (320 steps/h).

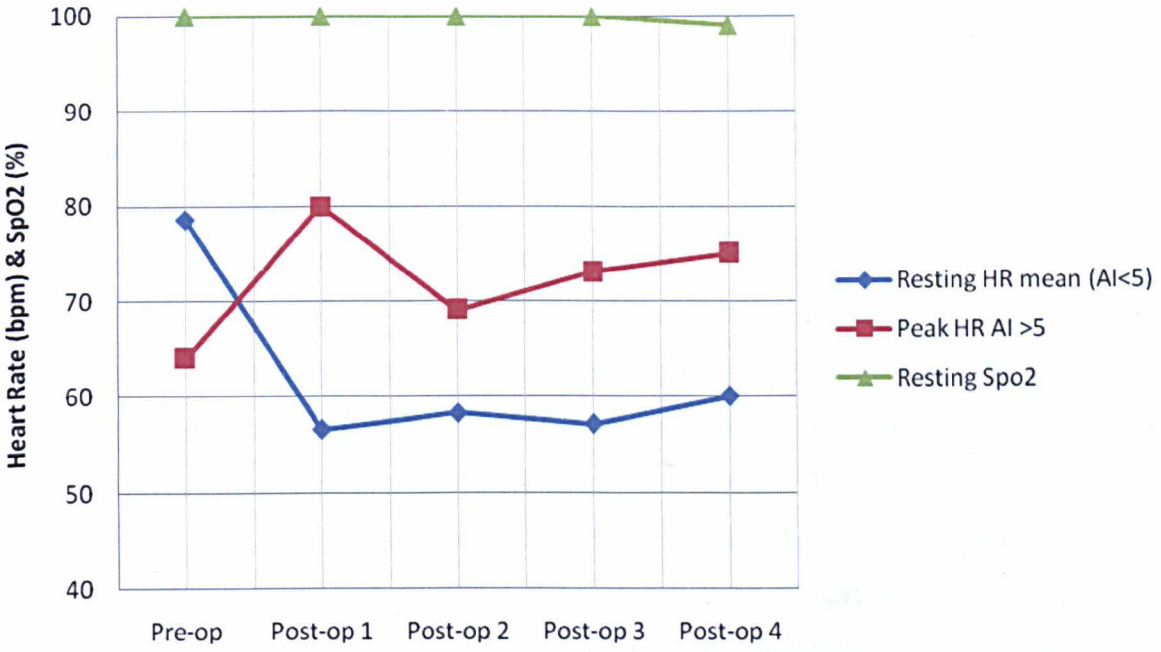


Figure 8.20 *A graph showing patient 4's mean resting heart rate (HR), peak HR at activity index (AI) >5, and resting SpO_2 during the pre- and post-operative period.*

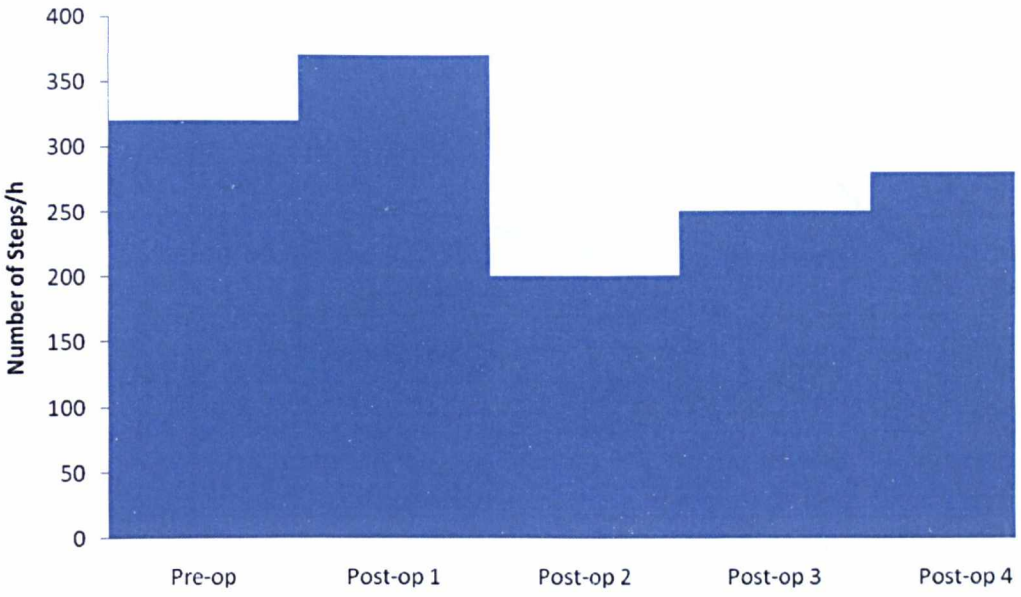


Figure 8.21 *A bar chart showing the mean number of steps per hour taken by patient 4 during pre- and post-operative periods at home.*

The mean activity index per hour and the activity classification results for patient 4 are shown below in Figures 8.22 and 8.23. From these it can be seen that the activity index fell during the first two post-operative home recovery days, and then on post-operative home recovery day 4. Similiarly the amount of level 0 activity undertaken by the patient rose from 10.3% pre-operatively, to 33.8% on post-operative home recovery day 1 and 56.4 on post-operative home recovery day 2. Also of note, the patient did not undertake any level 3 activity on post-operative home recovery day 2. Finally, whilst post-operative home recovery day 3 showed some increase in the overall amount of level 1-3 activity undertaken, this fell again on on post-operative home recovery day 4. This is important because this deterioration in his activity may have been as a result of increased pain from his wound infection for which he saw his doctor the next day.

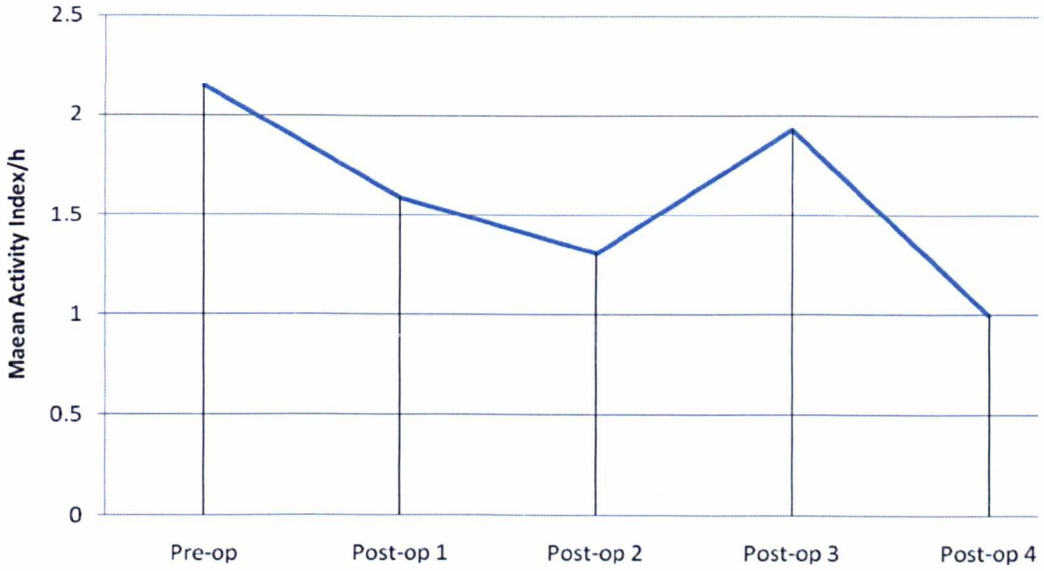


Figure 8.22 *A graph showing the mean activity index per hour for patient 4 during pre- and post-operative periods at home.*

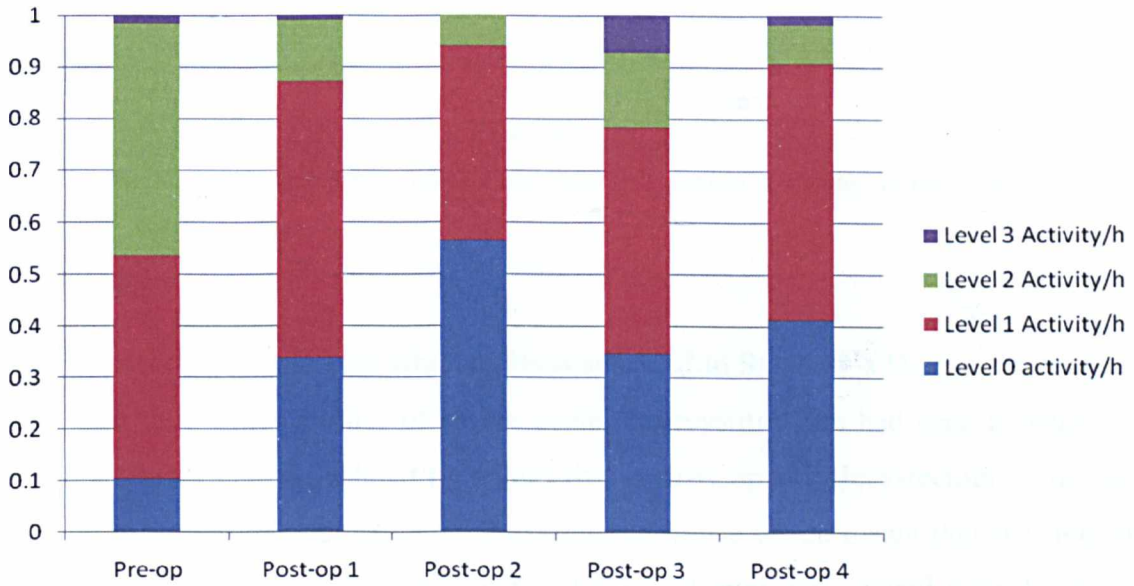


Figure 8.23 *The activity classification per hour profile for patient 4 during pre- and post-operative periods.*

The mobility impairment result for patient 4 shown below in Figure 8.24 below show that clustering was most obvious during pre-operative and post-operative home recovery days 4. As seen before, the areas where patient 4's walking mapped to on post-operative home recovery days 1 and 2 was furthest away from the pre-operative day. By post-operative home

recovery day 3 and 4, walking mapped closer to the pre-operative day suggesting a reduction in mobility impairment.

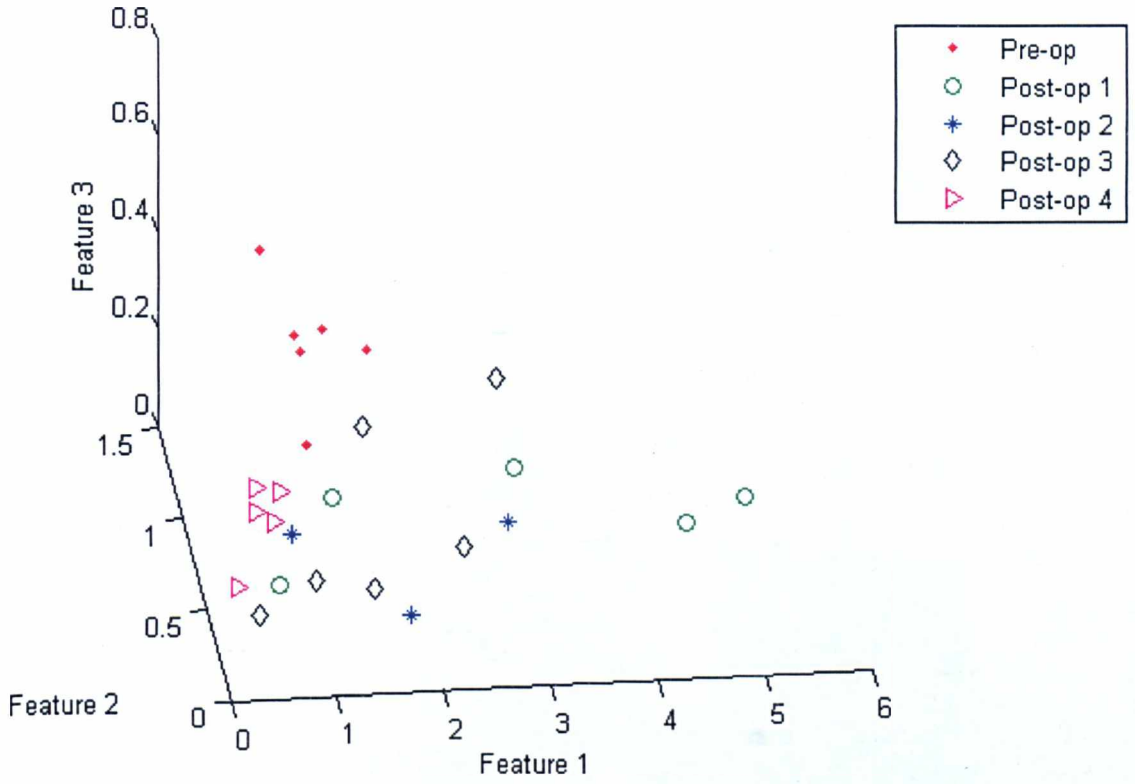


Figure 8.24 *The mobility impairment classification results for patient 4 during the pre- and post-operative periods.*

8.3.1.5 Patient 5

Patient 5 was a 64 year-old lady who had been admitted to St. Mary's Hospital several times over the past year with episodes of severe acute cholecystitis. She had been managed each time with antibiotics and scheduled for an elective laparoscopic cholecystectomy. The patient was a mild hypertensive, and had a good exercise tolerance which meant that she frequently left her home. She lived with her husband and had a cleaner who visited their house daily. The patient underwent a laparoscopic cholecystectomy that required conversion to an open procedure with a right sub-costal skin and abdominal wall incision. This was because of operative difficulties due to the degree of scarring around her gallbladder because of the previous attacks. She spent 6 days in hospital during which time she received a course of prophylactic intravenous antibiotics and was subsequently discharged home on oral antibiotics. The patient wore the e-AR sensor on one pre-operative day and during post-

operative home recovery days 1-3. She had to be re-admitted to hospital on post-operative home recovery day 4 because of fevers and was found to have a small intra-abdominal collection for which she required a further course of intravenous antibiotics. Figure 8.25 shows the patient wearing the sensor in her home.



Figure 8.25 *A picture of patient 5's living room. The inset (tops left) shows the patient wearing the e-AR sensor whilst resting in her bedroom, and a close-up view of her ear whilst wearing the sensor. The patient had to wear a headband with the sensor to prevent slippage on the ear during the day.*

This patient's mean resting HR rose from 73.9 bpm (SD=1) on post-operative home recovery day 1 to 86.9 bpm (SD=1.1) on post-operative home recovery day 2, remaining at 86.7 bpm (SD=2.39) on post-operative home recovery day 3 as seen in Figure 8.26. The peak HR at AI >5 rose dramatically on post-operative day 2 to 102 bpm. The worsening intra-abdmonial sepsis that ultimately led to this patient's hospital re-admission on day 4 may have contributed to this tachycardia along with the rise in resting HR. The patient's SpO_2 at rest

was 99% on all days except post-operative day 2, where it dropped to 95%. The proximity of the gallbladder and this patient's intra-abdominal collection to the diaphragm means that this fall in saturation may have been the result of localised lung collapse (basal atelectasis), which is often associated with this type of complication.

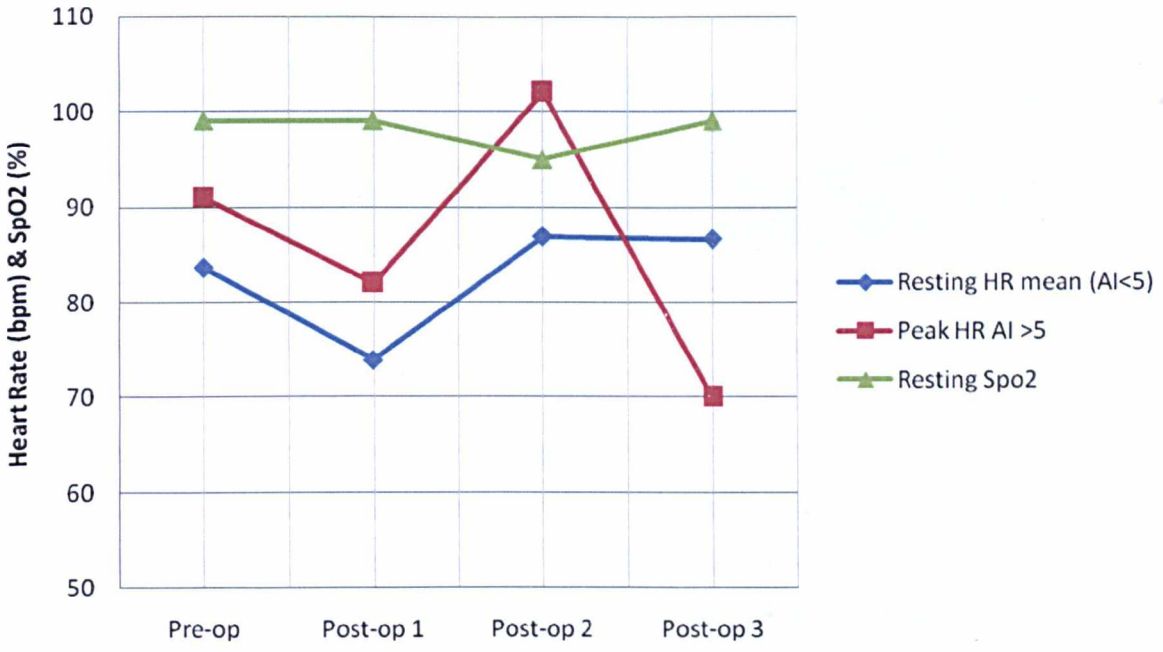


Figure 8.26 *A graph showing patient 's mean resting heart rate (HR), peak HR at AI >5, maximal HR with activity, and resting SpO_2 during the pre- and post-operative period.*

Patient 5's hourly step count fell from 480 steps/h pre-operatively to 220 steps/h on post-operative home recovery day1 and was lowest at 190 steps/h on post-operatove home recovery day 2. The step count was seen to rise to pre-operative levels by day 3. This is shown below in Figure 8.27.

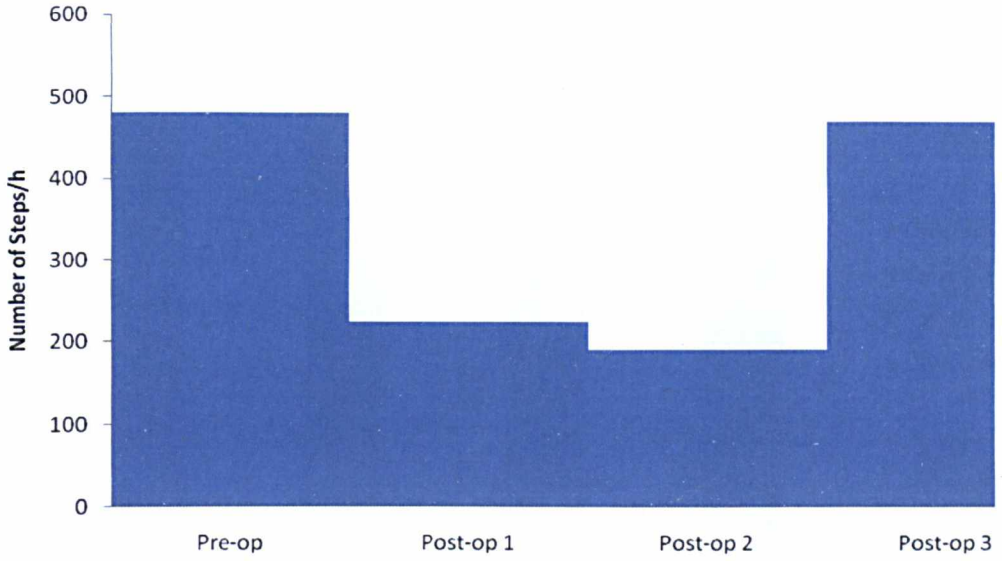


Figure 8.27 *A bar chart showing the mean number of steps per hour taken by patient 5 during pre- and post-operative periods at home.*

The mean activity index per hour fell postoperatively for patient 5 as shown below in Figure 8.28. When looking at the classes of activity that the patient undertook (figure 8.29), it can be seen that post-operatively the proportion of level 0 activity rose with level 2 and 3 activities falling when compared to the pre-operative period. This change was most marked on post-operative home recovery day 1 which is expected as the subject had only just been discharged from hospital.

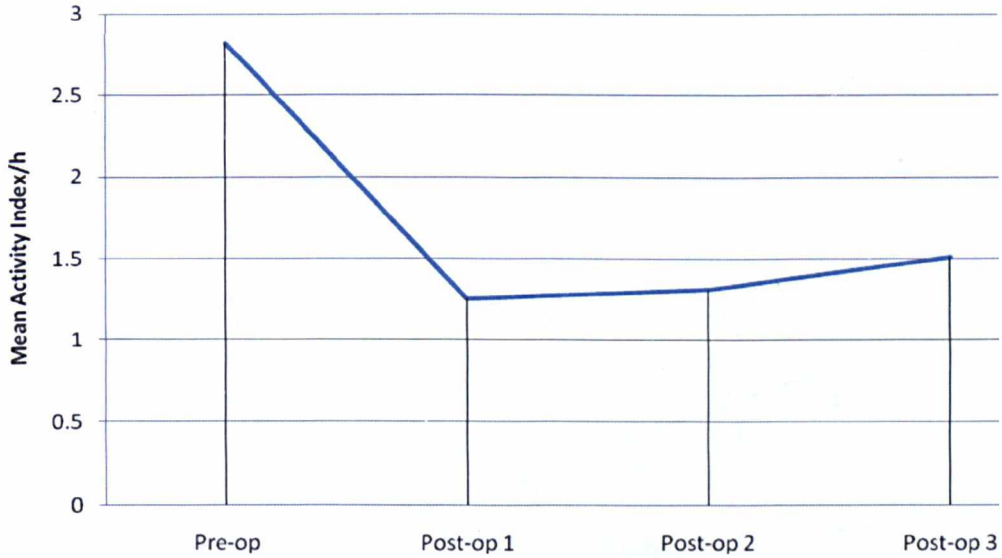


Figure 8.28 *A graph showing the mean activity index per hour for patient 5 during pre- and post-operative periods at home.*

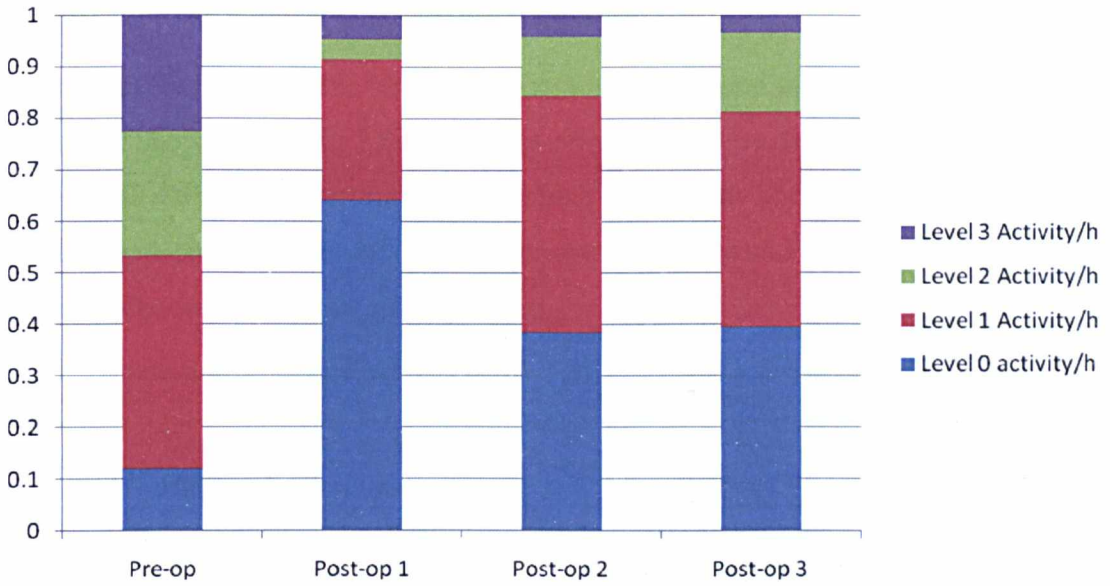


Figure 8.29 *The activity classification per hour profile for patient 5 during pre- and post-operative periods.*

The mobility impairment results for patient 5 are shown below in Figure 8.30. This shows that the mobility impairment in this subject did result in walking activity clustering into separate areas, but a pattern in this change is difficult to see.

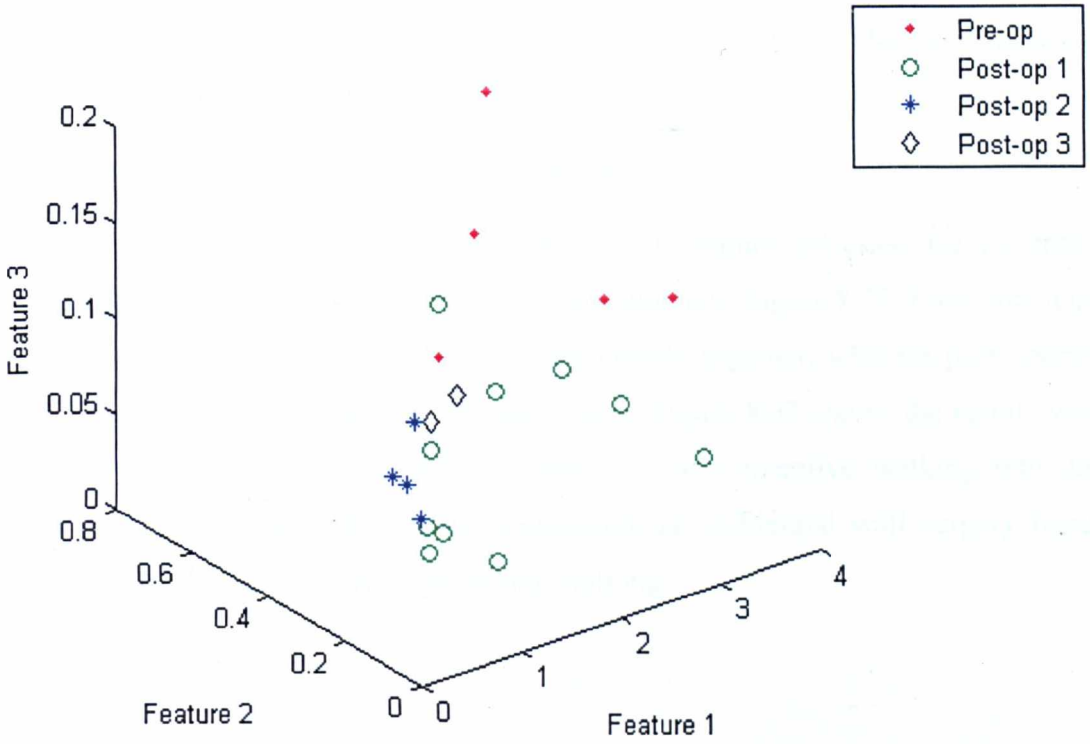


Figure 8.30 *The mobility impairment classification results for patient 5 during the pre- and post-operative periods.*

8.3.2 Post-operative mobility following ambulatory surgery

The 10 patients selected for this study, their demographics, and the operative procedures they underwent are shown below in Table 8.2. The procedures were divided into peri-anal surgery and abdominal wall surgery groups. All patients underwent uncomplicated procedures and were discharged on the same day as their operation. Pre- and Post-operative mobility data was successfully collected from all 10 patients.

Patient	Procedure	Group	Age
1	Haemorrhoidectomy	Peri-anal	27
2	Haemorrhoidectomy	Peri-anal	23
3	Open inguinal hernia repair	Abdominal wall	41
4	Open inguinal hernia repair	Abdominal wall	51
5	Peri-anal fistula surgery	Peri-anal	40
6	Peri-anal lesion excised	Peri-anal	56
7	Open para-umbilical hernia repair	Abdominal wall	30
8	Haemorrhoidectomy	Peri-anal	69
9	Open inguinal hernia repair	Abdominal wall	61
10	Open inguinal hernia repair	Abdominal wall	69

Table 8.2 *Demographics for the 10 patients selected for the post-operative mobility following ambulatory surgery study.*

8.3.2.1 Mobility following abdominal wall hernia surgery

The results from mobility impairment detection with feature selection for patients who underwent abdominal wall surgery without ICA are shown in Figure 8.31. From this it can be seen that pre-operative walking is seen to cluster closely together, whereas post-operatively this clustering is less apparent and in a separate area. Figure 8.32 shows the results with the use of ICA, which are shown to separate pre- and post-operative walking into distinct regions, either side of each other. This is expected, as abdominal wall surgery results in impaired mobility due to incisional pain during walking.

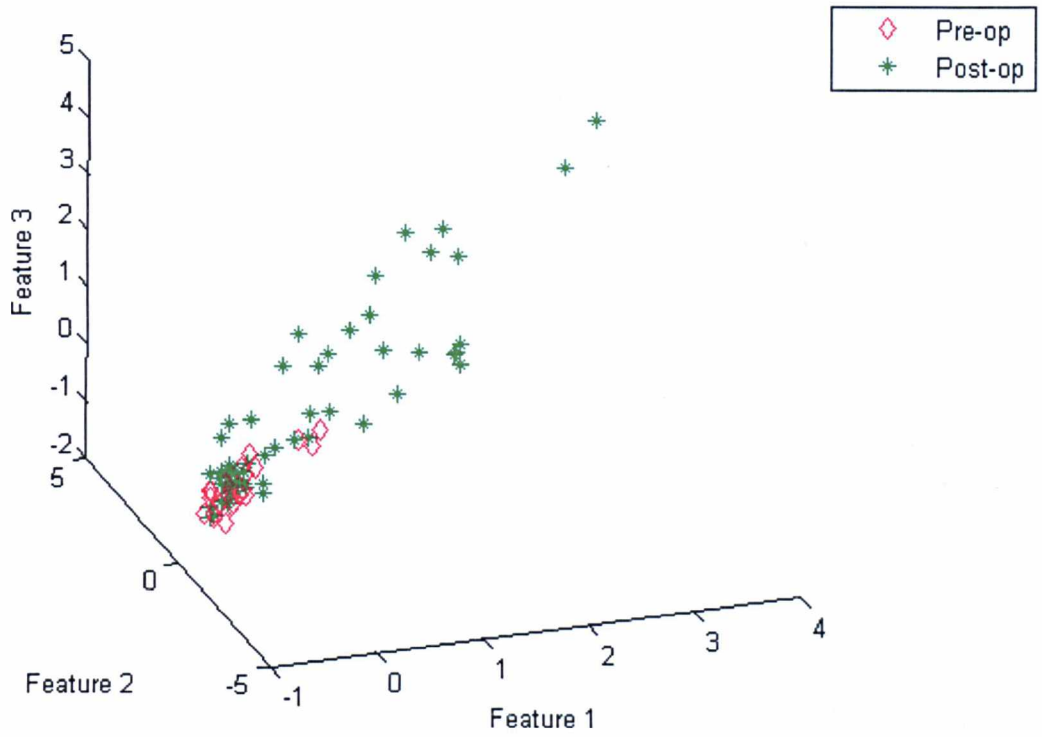


Figure 8.31 *Mobility impairment classification (without ICA) for pre- vs. post-op walking in 5 subjects who underwent abdominal wall surgery. Axes represent the most discriminant features selected by feature selection.*

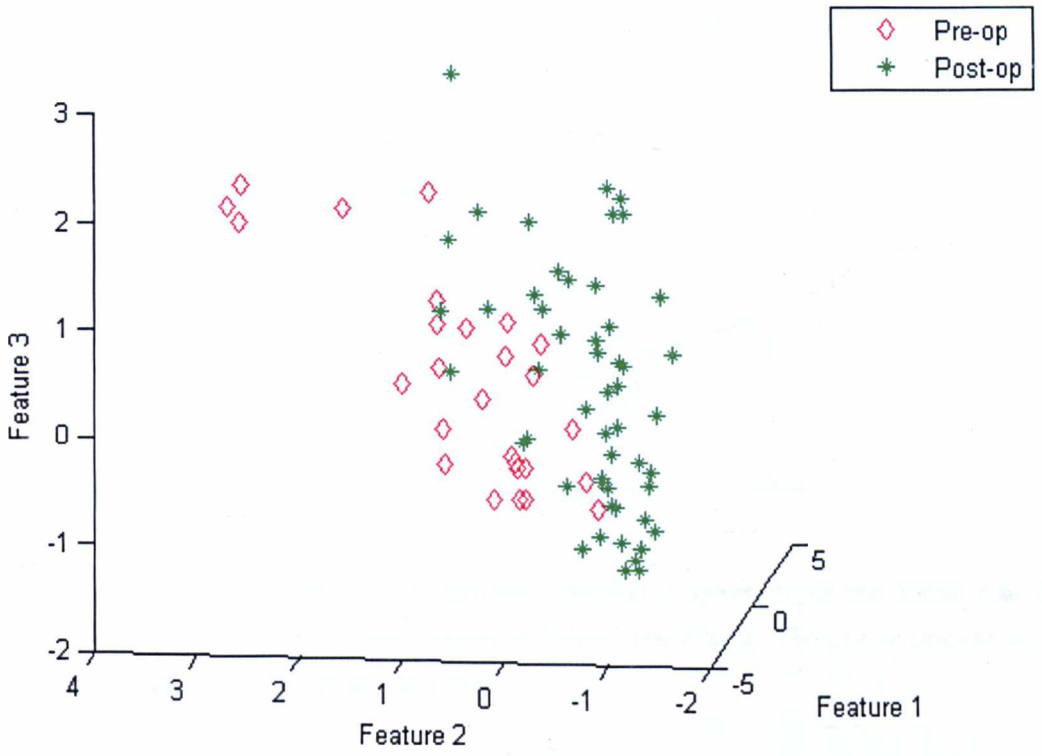


Figure 8.32 *Mobility impairment classification (with ICA) for pre- vs. post-op walking in 5 subjects who underwent abdominal wall surgery. Axes represent the most discriminant features selected by feature selection.*

8.3.2.2 Mobility following peri-anal surgery

The results from mobility impairment detection with feature selection for patients who underwent peri-anal surgery, without ICA are shown in Figure 8.33. Pre- and post-operative walking is seen to cluster separately into distinct and easily separable regions. Figure 8.34 shows the results with the use of ICA, which does not show this clustering so well. When compared to the abdominal surgery group, this suggests a difference in the post-operative mobilisation of patients undergoing peri-anal surgery. This is not unexpected as abdominal wall and peri-anal procedures would be expected to result in different types of pain exacerbated by different types of movement and would therefore result in different types of impairment.

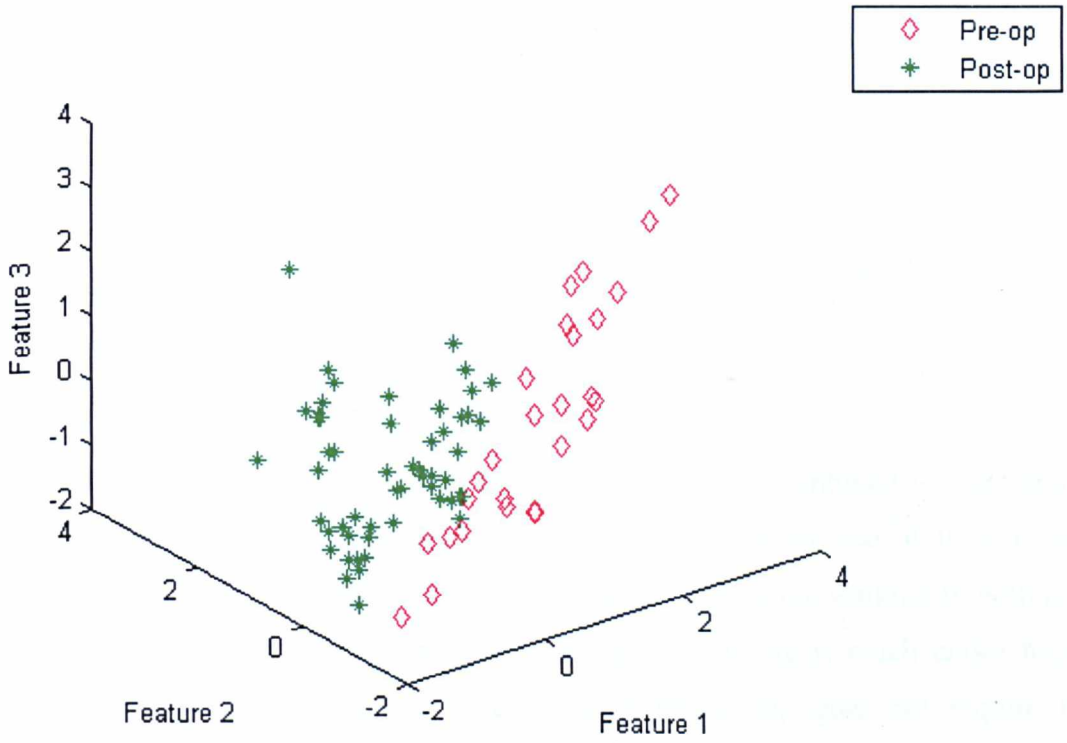


Figure 8.33 *Mobility impairment detection classification (without ICA) results for pre- versus post-operative walking in 5 subjects who underwent day surgery peri-anal procedures. The axes represent the 3 most discriminant features as selected by feature selection.*

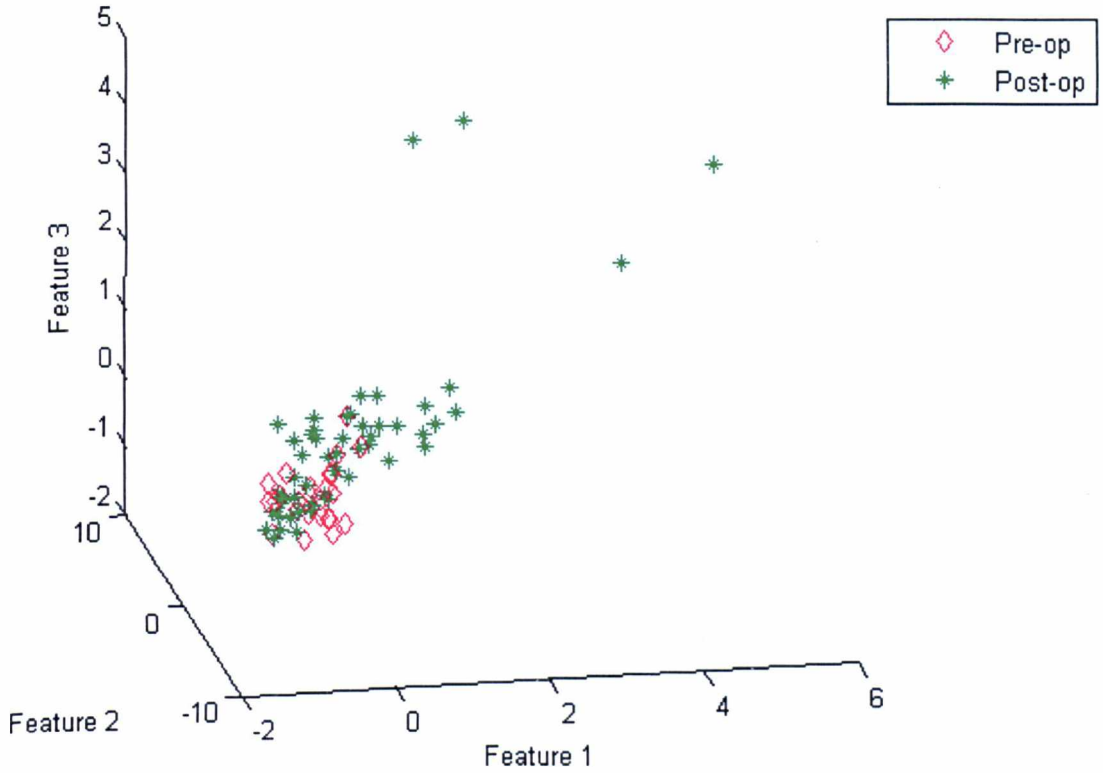


Figure 8.34 *Mobility impairment detection classification (with ICA) results for pre- versus post-operative walking in 5 subjects who underwent day surgery peri-anal procedures. The axes represent the 3 most discriminant features as selected by feature selection.*

8.3.2.3 Mobility for all patients combined

The mobility impairment detection results for all subjects combined without and with ICA are shown in Figure 8.34 and 8.35 respectively. Without the use of ICA, clustering into distinct and separate regions is seen for pre- and post-operative walking in both groups. This is much less obvious with the use of ICA, where clustering is much closer together. This suggests that mobility impairment detecting in this group does not require filtering of redundant features with ICA.

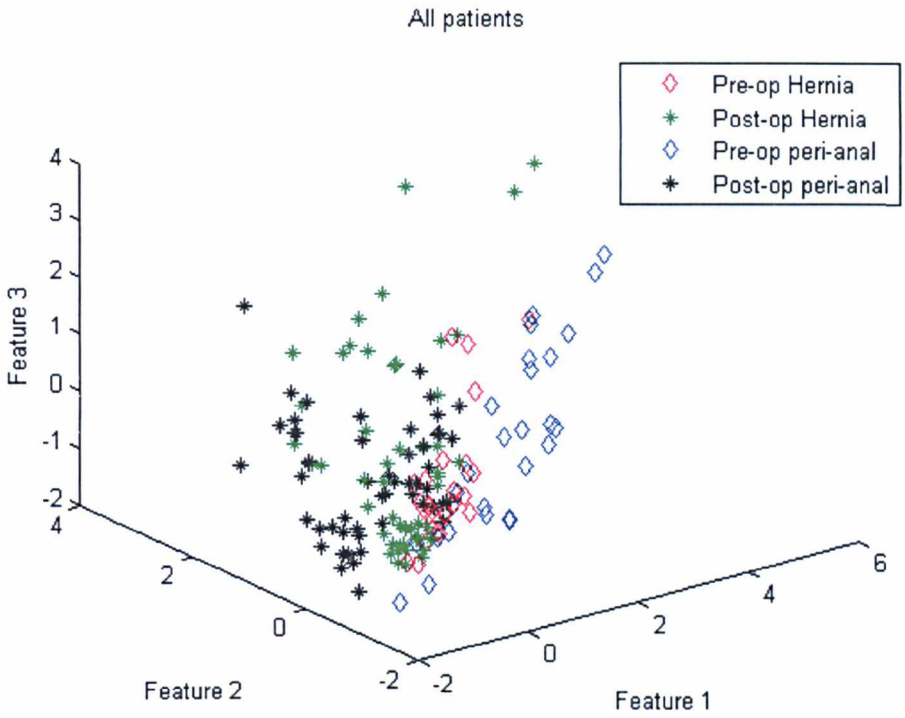


Figure 8.35 *Mobility impairment detection classification (without ICA) for pre- versus post-operative walking in all 10 subjects. The axes represent the 3 most discriminant features as selected by feature selection.*

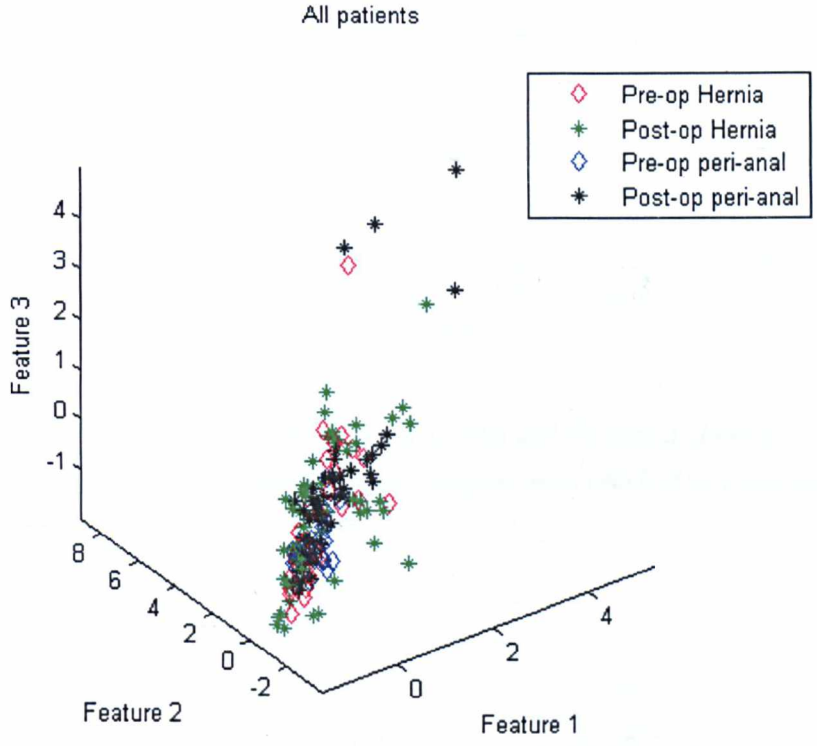


Figure 8.36 *Mobility impairment detection classification (with ICA) results for pre- versus post-operative walking in all 10 subjects. The axes represent the 3 most discriminant features as selected by feature selection.*

The correct classification rates for all subjects, abdominal wall patients alone, and peri-anal patients alone without ICA are shown below in Figure 8.37. Looking at this figure it should be noted that the best classification results were seen in the peri-anal surgery group, achieving over 95% correct classification with the use of 5 or more features. In the case of hernia patients, the classification was over 90% with the use of 7 features. When all patients were considered, classification was seen to be over 90% with 5 or more features.

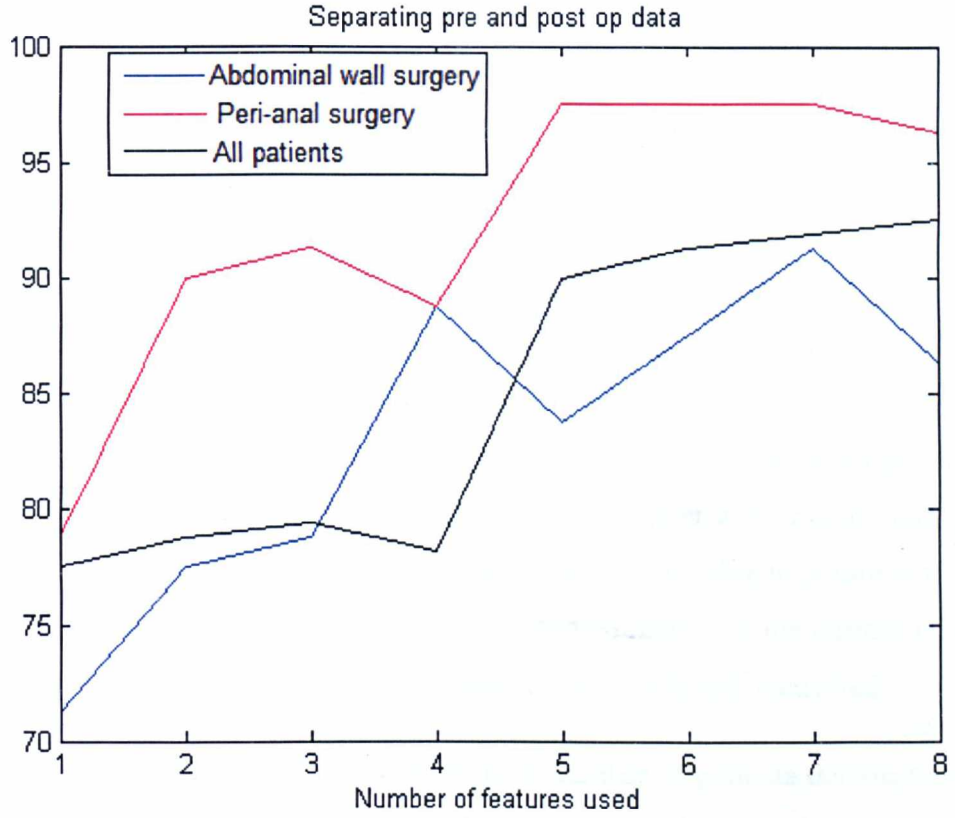


Figure 8.37 *The results for correct classification of mobility impairment and the impact of using an increasing number of features is shown for patient who had abdominal wall surgery, those who had peri-anal surgery, and both groups combined.*

8.4 Discussion

The results of the experiments conducted in this chapter have demonstrated the ability of the e-AR sensor and its frameworks to monitor functional and physiological post-operative home recovery. In the post-operative home recovery study, the sensor was successfully used to objectively quantify the outcomes of interest for 5 patients during their post-operative home recovery period. During this time the e-AR sensor quantified changes in patients' physiology in the context of their activities, without which this information would be otherwise impossible to interpret. Morphology analysis of the accelerometer traces allowed the determination of step count per hour, and the mean variance in the three traces allowed determination of activity index per hour. The activity classification framework allowed the patient's home recovery period to be characterised into levels of activity in a way that is currently impossible to quantify. Finally the mobility impairment framework demonstrated that whilst the heterogeneous data collected in the real home makes this analysis difficult, it is still possible to differentiate normal from impaired mobility. This was further demonstrated in the ambulatory surgery mobility impairment study where pre- and post-operative mobility could be correctly classified as normal versus impaired respectively. These findings represent a significant increase in the amount of information that we are able to obtain with a pervasive healthcare technology such as the e-AR sensor when compared to the current practice where very little of a patient's post-operative recovery can be objectively measured.

During the post-operative home recovery study, a number of patients demonstrated trends in physiological recovery that were expected, but would otherwise have been difficult to quantify. The resting HR at AI<5 of patients 1, 3, and 5 was seen to rise slightly in the post-operative period, which is a change that would be expected to occur secondary to the trauma of surgery and factors such as post-operative pain. A marked rise in resting HR such as in the case of patient 5 may have been due to the post-operative abdominal collection she suffered requiring early re-admission to hospital. In the case of patient 1, a sudden rise in peak HR at AI>5 to over 120 bpm may be been due to a cardiac event such as atrial fibrillation. Whilst physiological recovery is difficult to interpret in isolation, its evaluation is important as part of a multifaceted approach to monitoring post-operative recovery. It is important to note that a patient's medication may influence their HR, and therefore must be taken into account. This

is demonstrated in the case of patient 1 who was on a β-blocker medication that results in a reduced HR and an inability to raise this in response to trauma, infection, or stress. This makes interpretation of this data even more challenging. Conversely, omitting to take the medication may result in a rise in HR. Finally, SpO_2 at rest was a parameter that could easily be determined and may be of more use in patients with co-existing respiratory disease in whom a chest infection or atelectasis results in a rapid deterioration in SpO_2 because of their poor functional respiratory reserve.

With the exception of patient 4, a drop in post-operative hourly step count was seen on post-operative home recovery day 1 when compared to pre-operative baseline parameters. With the exception of patient 3, all subjects demonstrated a fall in mean activity index per hour on post-operative home recovery day 1. The time taken for these parameters to recover to normal levels varied from subject to subject. This is entirely expected, as factors such as wound healing and pain have their greatest impact on a patient's mobility in the early post-operative period. In the case of patient 4 who presented to his GP with a post-operative wound infection resulting in increased pain and requiring antibiotic treatment, the trend toward a fall in activity index per hour on between post-operative days 2-4 may have been an early indicator of this complication.

The activity classification results for the post-operative home recovery study showed how subjects' heterogeneous home activity datasets could be standardised and quantified into levels of activity. In all 5 patients, a rise in level 0 activity was seen to rise on post-operative home recovery day 1. This is significant because it shows how a patient is most vulnerable to complications secondary to immobility (such as DVT) at time of discharge following surgery. What is also interesting to note is the activity profile of patients at the end of post-operative home recovery monitoring as compared to that during the pre-operative assessment. Patients 2 and 3 for example demonstrated that they were more active at the end of post-operative monitoring in this trial, than before the operation. This may therefore, be a means of judging the success of their procedure.

The social implications of pervasive home monitoring were also demonstrated in this study and should not be underestimated. Patient 1 chose not to wear the e-AR sensor on a day when

he was being visited by a friend because he did not feel comfortable with the idea of looking 'different'. In the case of patient 3, the sensor was not worn on post-operative home recovery days 3-7 because the patient did not want her husband who suffers from Alzheimer's disease to become unsettled when he saw the sensor. Whilst miniaturisation of technology will go a long way to reduce any stigma attached to wearing sensors, ultimately these devices have to aim to be completely pervasive if they are to achieve maximal uptake. Another aspect that should be incorporated into the design of any such sensor is skin colour, as dark-skinned patient may not wish to wear a white sensor.

The classification of normal versus impaired mobility for patients in their home environments showed that in most cases, clustering of pre-operative mobility was seen to occur in distinctly separate regions to that for post-operative home recovery days 1 and 2. This can be explained by the fact that a patient's mobility is likely to be most impaired during the early as opposed to the later post-operative period. The results of the 10-patient ambulatory surgery mobility impairment study showed that even without ICA, mobility could be correctly classified as impaired in the post-operative period in over 95% of patients who had undergone peri-anal surgery, and over 90% of all patients, when 5 or more features were used.

It is important at this stage to mention several limitations of this study. Firstly, as described in the methods section, a base station laptop connected to a wireless network had to be installed in the patient's home and set up to directly capture data from the BSN earpiece. The wireless communication between this and the sensor was not at times as robust as in the simulated environment, resulting in some loss of data. We aim to address this in the next generation of BSN devices by using a more resilient error correction protocol and larger memory space to minimise packet loss. Secondly, the energy consumption of the BSN earpiece required a battery change every 8 hours. This was partly as a result of the energy consumption of the sensor, but also because of the processor and wireless data transfer. We aim to address these aspects by reducing the power consumption of the e-AR sensor but also by using more efficient batteries and considering novel energy scavenging techniques. Thirdly, the size of the e-AR device meant that although the sensor was easy to wear and stayed on the ear in most cases, some patients required the additional support of a headband. A reduction in weight of the device would help increase its acceptability and long-term wear. Advances in

key areas such as power supply miniaturization, increased battery duration, reduced energy consumption, and power scavenging will be essential to achieving this goal. Finally, the use of the device by patients for the same four hours of the day attempted to standardise the impact of timing of day on activity performed by patients. Addressing the limitations mentioned in this section will result in a device that can be worn for a 24-hour period and collect a full day's worth of data. This will be key to its widespread clinical adoption.

A limitation of the data analysis techniques used to determine activity index, activity classification, and mobility impairment detection for patients in this study was that they were relatively simplistic in their nature and the outcome measures they were trying to determine. The *activity index* (AI) was derived from the mean variance from the three accelerometer traces, but was used as a means of identifying periods when the subject was 'resting' versus 'active', something that was particularly important for context-aware physiology measurement. As previously shown, a high value for AI may be found place in the transition from one activity to the next, or in the case of sudden head movements even when the subject is at rest. Placement of the e-AR sensor on the head meant that this was less of a problem than if it was secured to a limb. The *activity classifier* did not separate the activities into individual components such as 'sitting', 'sleeping', 'walking', 'eating', each of which are important ADLs to determine in a recovering patient. None-the-less it gave a means of numerically quantifying and longitudinally following the amount of a certain type of activity that a subject was undertaking over their day. Finally, the *mobility impairment detection framework* simply differentiated impairment into 'normal' and 'impaired' as opposed to quantifying and identifying the type of impairment that took place (for example the amount of truncal versus lower limb impairment). Increased sophistication of the analysis frameworks used is likely to come with further trials using the e-AR sensor. It should be noted however, that the use of techniques requiring a high degree of data computation will limit their ability to be undertaken 'on node', something which is highly desirable for such a device. The computational power required to analyse results must also not compromise the time taken to analyse the data and the ability to see changes in real-time.

This chapter has highlighted some key applications for the use of the e-AR sensor and its BSN technology in the management of surgical patients: The first application is pervasive

functional and physiological post-operative recovery monitoring. This may lead to safer discharge from hospital at a time when a number of healthcare initiatives are driving the reduction in post-operative length of hospital stay. For this to take place there needs to be an infrastructure in place to respond to the vast amount of information that such pervasive home monitoring systems with generate. In the existing healthcare systems, BSN technologies may support focussed district or home nursing. Given access to patient recovery information through a BSN, a mobile district nurse could not only quantify this recovery for individual patients, but also prioritise patients into those who were and were not recovering well, representing a better distribution of limited resources. This intervention may in turn have an impact on reducing patient morbidity and ultimately hospital re-admission. The second application is the use of a BSN to pre-operatively assess the physiology and activity profile of patients prior to surgery. Visualisation and quantification of a patient's daily activity as has been demonstrated in this study, suggests the ability to identify those patients who are less active during their normal day and therefore potentially at higher risk of complications secondary to their stasis, such as deep vein thrombosis. Combined with physiology monitoring, this could prove a useful adjunct to operative risk stratification prior to elective surgery. Finally, the third application is the extension of BSN technologies into the hospital environment, although the complex regulatory environment combined with the volume of patients in close proximity makes monitoring in this setting a greater challenge.

9 Conclusions and Future Work

The experiments undertaken in this thesis have demonstrated the ability of a pervasive BSN device to objectively measure functional and physiological home recovery in the post-operative setting. This has been achieved through the identification of biomechanical parameters relating to functional recovery in terms of activities of daily living and mobility impairment, that have been objectively and continuously measured in the home environment through an ear-worn activity recognition (e-AR) device comprising of low power accelerometers, pulse oximeter, BSN node, wireless data transfer capability, and energy power source to collect this biomechanical raw data. A series of original hypotheses linking these biomechanical markers to outcomes to functional recovery have been tested through experiments conducted in the simulated and real home environments, and converted into surrogate markers of functional recovery through a series of frameworks. Finally this system and its data analysis frameworks have been used to monitor post-operative recovery in 15 patients who have undergone surgery.

This thesis has contributed towards the vision of a truly pervasive home healthcare monitoring system through the use of wireless BSNs. It has demonstrated the feasibility and importance of understanding the monitoring and healthcare needs of specific patients groups in whom deploying such a technology is desirable. In this way key markers of disease processes and a patient's recovery from these processes can be identified, and the challenges in quantifying these parameters overcome. In the case of measuring post-operative functional recovery, a parameter that is currently highly subjective and difficult to quantify, the experiments undertaken in this thesis have shown how surrogate biomechanical markers of motion can be turned into an objective indices and classifiers through a series of frameworks. Whilst in isolation such information is not so easy to interpret, the longitudinal analysis of this data helps to visualise trends in post-operative recovery. The experiments undertaken in this thesis have also highlighted the importance of obtaining context information when

interpreting physiological data using pervasive monitoring systems, an attribute which is vital for any BSN technology that is to be deployed in an unsupervised environment. It is important to note that whilst in the case of post-operative functional recovery monitoring the use of gross measures of movement and activity (variance) were appropriate, these did not provide detailed information on the qualitative aspects of movement that are important for monitoring some patient populations (for example stroke patients, or those which musculoskeletal injury). In monitoring post-operative activity, such a detailed assessment of quality of musculoskeletal movement was not required and so variance was a suitable feature to select.

As BSN devices are targeted to other patient groups with acute and chronic monitoring needs, the sensors for monitoring key aspects of their disease processes will need to be identified, and investigative processes such as those undertaken in this thesis will need to take place. The wireless BSN platforms for such systems are now are now in place, with the required technology becoming more and more accessible and affordable. As mentioned in Chapter 2 of this thesis, the monitoring and healthcare needs of an aging population with chronic medical conditions and acute exacerbations of these conditions represents a significant burden to current healthcare systems. A solution to their healthcare needs that will prevent or delay the need for hospital admission and allow a more personalised delivery of healthcare in their home environment is likely to be highly desirable to the patient and healthcare provider alike. Financial limitations that worldwide healthcare systems face, mean that reducing the cost of expensive hospitalisation has also become a strong motivator for adopting new, innovative technological solutions to patient care. Wireless BSNs for healthcare find themselves emerging at just the right time to have an impact. This thesis has taken a significant step towards such a healthcare system, though much work is still to be done if the vision of pervasive healthcare delivery is to be truly realised.

A number of limitations of current BSN technologies have been identified that must be overcome if this technology is to achieve widespread adoption including device miniaturisation, low power wireless data transmission, on-node data processing, achieving high patient compliance, data protection, system security, and finally the ability to respond to the vast amount of information that is provided in real-time. Having tested and validated the

e-AR sensor and its frameworks on healthy volunteers and real post-operative patients, the next step in this research is the use of this BSN device over larger surgical patient populations in three settings:

- The first setting is as part of a multicentre trial using the e-AR sensor to evaluate post-operative recovery in patients undergoing major surgery including gastro-intestinal, orthopaedic, and cardiothoracic procedures. Here, biomechanical data collected using the e-AR sensor and the resulting surrogate markers of functional recovery need to be validated for each specific patient group to create a database of reference tables representing a return to normal post-operative mobility and functional recovery in terms of ADLs. Having this data for patients who recover with and without complications will help determine normal ranges for objective post-operative recovery measurement against which future patients can be compared. In the case of patients undergoing orthopaedic surgery for example, measuring mobility impairment is going to be a key part of recovery monitoring as the weight-bearing limb heals and the patient returns to their normal gait. This is important in patient undergoing spinal surgery and those have joint replacements, where the functional impact of the intervention is often difficult to quantify. Biomechanical markers and data analysis frameworks that quantify and determine type of mobility impairment such as those developed in this thesis are particularly relevant to this group. In this case the mobility impairment framework may need to be further developed specifically for the orthopaedic patient.

- The second setting where the e-AR sensor may be used is in comparing new and existing surgical procedures and interventions to determine their clinical and cost-effectiveness. For example, whilst the impact of laparoscopic surgery on post-operative length of stay is well known when compared to open procedures, the real impact this has on the patient's return to normal function is almost impossible to assess objectively. In this group the e-AR sensor could provide a real and objective means of quantifying recovery following laparoscopy to truly understand the impact of this intervention. The same applies to a number of other types of minimally invasive procedures in cardiothoracic surgery (minimally invasive bypass versus

sternotomy for single vessel disease), urological surgery (conventional versus robotic prostatectomy), and orthopaedic surgery (hip resurfacing versus traditional hemi-arthroplasty) to name but a few. In this setting the e-AR sensor becomes an invaluable means of objectively determining the impact of one intervention versus another.

- The third setting is in the pre-operative assessment of patients prior to surgery. Here, the identification of those patients who have a low level of overall activity and poor daily ADL profile may form an important part of pre-operative risk stratification. Patients who are at high risk of post-operative complications secondary to poor mobility such as deep vein thrombosis would therefore be able to be targeted at home with physiotherapy. A clinical study comparing post-operative recovery in patients with poor pre-operative mobility and low activity profiles to those who were more active with this technology would be a unique opportunity to quantify this impact.

In addition to the proposed clinical studies mentioned above using the e-AR sensor, there are also a number of technical opportunities to develop new devices and frameworks for healthcare provision using BSNs. These will involve addressing a number of key features that would be desirable for such a technology to be deployed on a large scale:

- First, in order to truly capitalise on the full capabilities of a wireless BSN, multiple sensors must be deployed on the body, all wirelessly connected to each other. The combination of sensors will need to be tailored to the clinical need of the patient group being monitored, but these may involve implantable, wearable, and ambient sensor systems. Such a fusion of sensors would allow a much more comprehensive means of patient monitoring and would address the challenges of validating the contextual environment that a patient is in when determining whether they are displaying a normal or pathological physiological response (such as a rise in HR as a result of exercise as opposed to an infective process). In addition to this, wearable sensors may be linked to wearable or implantable therapy delivery systems, thereby closing the 'feedback loop'. Examples previously mentioned are insulin delivery in response to blood glucose in diabetics, and the delivery of electrical spinal stimulation in patients with musculoskeletal pain.

- Second, the data obtained from a wireless BSN needs to be able to be securely transmitted to locations where it can be further analysed and stored for further access. A certain amount of 'on node' processing is desirable as this will reduce the volume of such data, especially when a large number of patients are being monitored. Ultimately, frameworks that generate clinical alerts in response to the information obtained are going to be required if this technology is to be integrated into the healthcare infra-structure, closing the feedback loop. A key attribute that such systems must have however, is the ability to deliver real-time information. Whilst all the analysis undertaken in this thesis was retrospective for ethical reasons, real-time delivery of information on a patient's condition is important if it is to guide clinical decision making.

- Third, novel means of device fixation combined with sensor miniaturisation and improvements in aesthetic design are very important for patient perception, which will ultimately determine the degree of patient compliance the technology achieves. Technological and design solutions to these problems are imperative if BSN devices are ever to achieve wide scale adoption.

Pervasive BSN technologies such as the e-AR sensor have the potential to revolutionise healthcare through their ability to collect data continuously, and in any environment. This ubiquitous diagnostic ability will not only allow us to monitor our patients better, but will also help us learn about post-operative recovery and the impact that our interventions have on patients' lives in a way that is currently impossible. Clinical use will need to include an assimilation of these technologies into the healthcare systems such as the UK NHS, representing the next great challenge.

Appendix A: Pre-Study Questionnaire

Pre-Study Questionnaire: **Date:** _____

Time: _____

1. **Please circle your level of anxiety at this point for each of the following:**

   a. Wearing the vital signs body sensors over the next two hours

   Very much Much A fair amount A little Not at all

   b. Being monitored in a simulated home environment with the vital signs body sensors

   Very much Much A fair amount A little Not at all

   c. Having taken the sensors off, putting them back on again

   Very much Much A fair amount A little Not at all

2. **Imagine you were a patient who has returned home from abdominal surgery. Please give the most appropriate answer for the way you feel:**

   a. I would like to have my vitals signs monitored continuously at home.

   Agree completely Agree partly Do not agree at all

   b. I would like to have my vital signs measured four times a day.

   Agree completely Agree partly Do not agree at all

3. **Please circle the response that best describes your level of agreement**

   a. Wearing body sensors makes you feel more secure at home

   Strongly agree Agree Neutral Disagree Strongly disagree

   b. Wireless body sensors will lead to problems being picked up quicker.

   Strongly agree Agree Neutral Disagree Strongly disagree

Results

Question 1 evaluated the level of anxiety that subjects had towards wearing the e-AR sensor prior to commencing the study. The results for this are shown in Figure A1 and demonstrate that the majority of volunteer subjects were not anxious at all with the prospect of wearing the e-AR sensor.

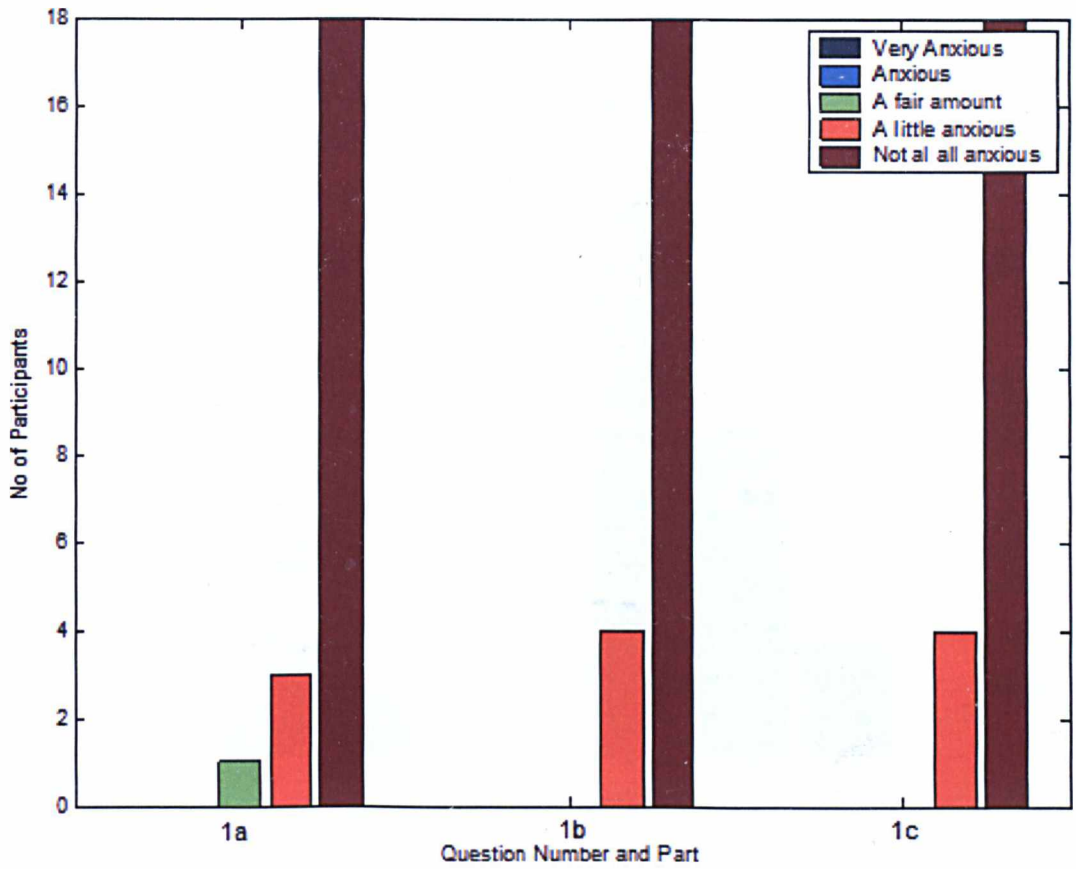


Figure A1 - *Question 1a* – *What is your level of anxiety for wearing the vital body sensors over the next 2 hours?* ***Question 1b*** – *What is your level of anxiety for being monitored in a simulated home environment?* ***Question 1c*** -- *What is your level of anxiety for taking the sensors off and putting them back on again?*

Question 2 captured the willingness of subjects to have home monitoring following surgery, as shown in Figure 5.6. This demonstrated that majority of subjects either completely agreed with the concept, or would partly agree and therefore be open to consider the idea of continuous monitoring. This sentiment was however much stronger with the suggestion that monitoring would take place only four times a day.

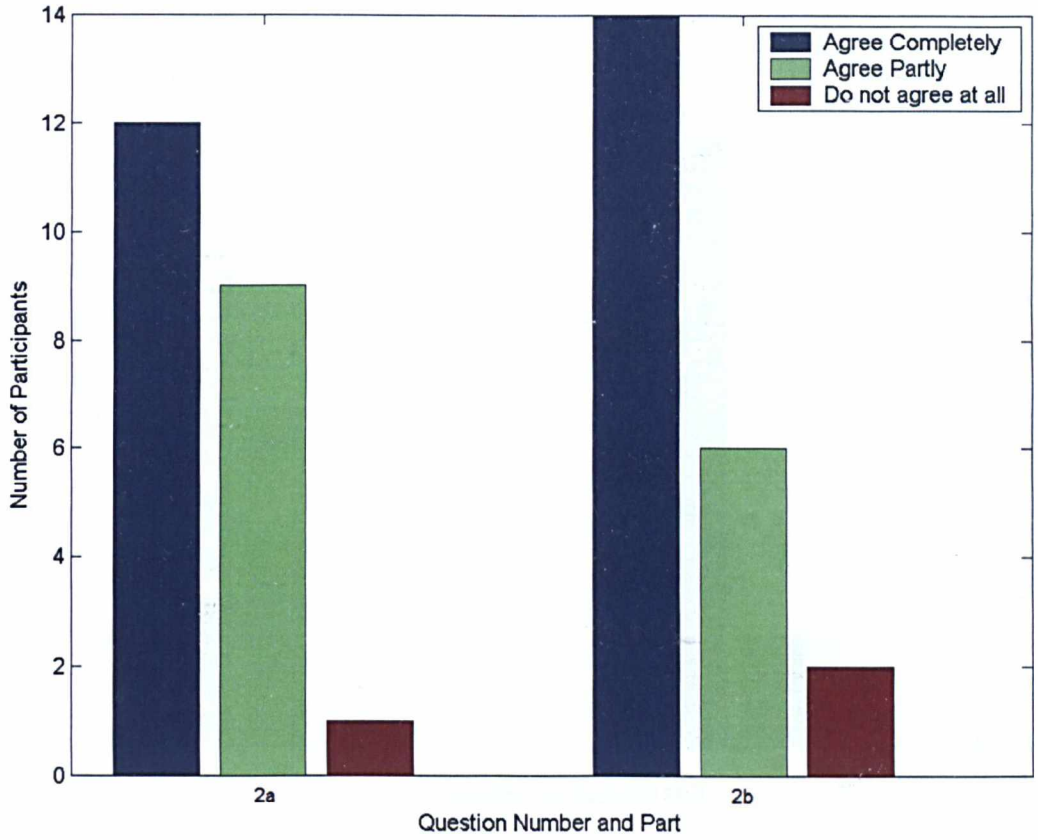


Figure A2 - *Question 2a* – *Imagine you were a postoperative patient would you like to have your vital signs monitored continuously at home?* ***Question 2b*** – *Imagine you were a postoperative patient would you like to have your vital signs measured 4 times a day?*

Question 3 evaluated subjects' perceptions of security with home monitoring, with results shown in Figure 5.7. Here subjects demonstrated a positive response to home monitoring resulting in a safer recovery, and also a perception that it would lead to earlier detection of complications.

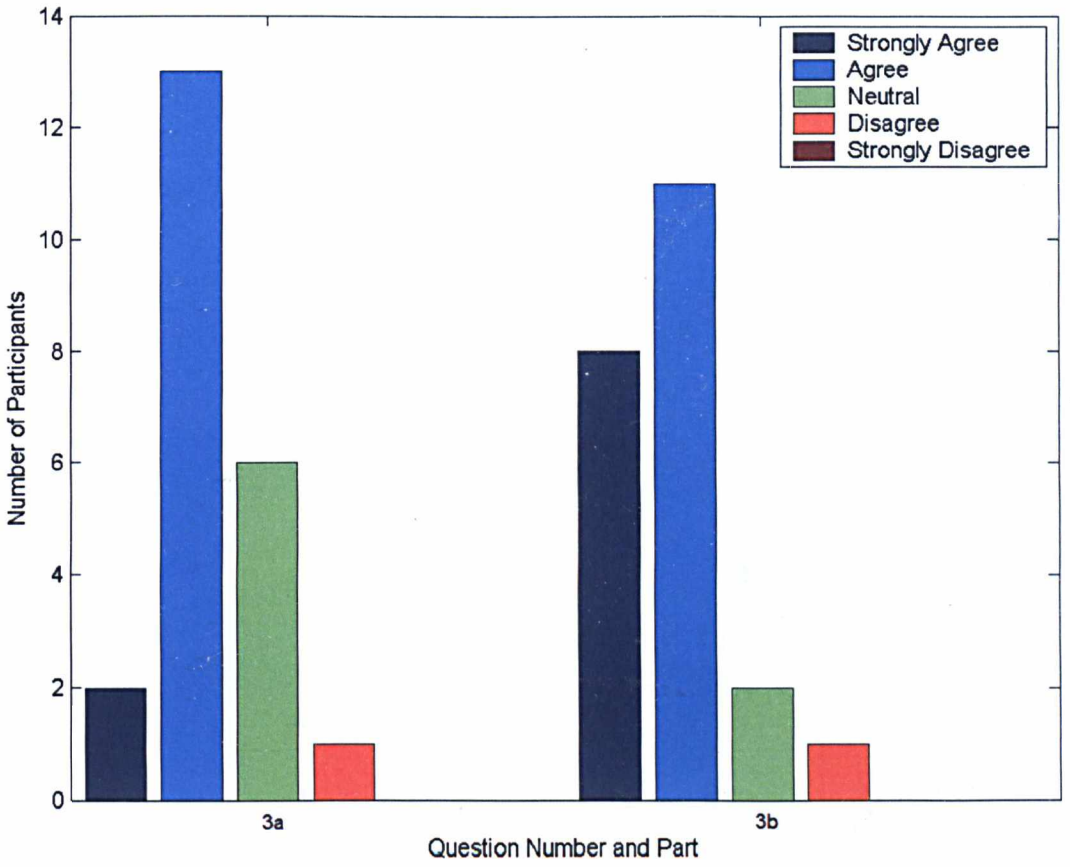


Figure A3 - *Question 3a* – *Does wearing body sensors make you feel more secure at home?* ***Question 3b*** – *Will wearing body sensors lead to problems being picked up quicker?*

Appendix B: Post-Study Questionnaire

Post-study Questionnaire: **Date:**_____

Time:_____

1. During this study you have been given the opportunity to use a wearable body sensor. Did you find this sensor comfortable?

   1-not at all 2 3 4 5-extremely

   If not please tell us why?_____

   _____

2. Did you think that wearing the sensor affect you activities in the scenario?

   1-not at all 2 3 4 5-extremely

   If so please tell us why?_____

   _____

3. Was the sensor easy to put on and take off? Yes / No

   If so please tell us why?_____

   _____

4. Did you find the ear clip sensor uncomfortable? Yes / No

   If so please tell us why?_____

   _____

Results

The results for e-AR sensor comfort are shown in Figure B1, with the majority of subjects finding the device comfortable to wear, although there was a notable proportion that did not find it comfortable at all (23%). As shown in Figure B2, the vast majority of subjects did not find that the e-AR sensor placement impaired their activities in the circuit. 95% of subjects found the device easy to wear and remove by themselves, and 88% did not find the ear-clip uncomfortable.

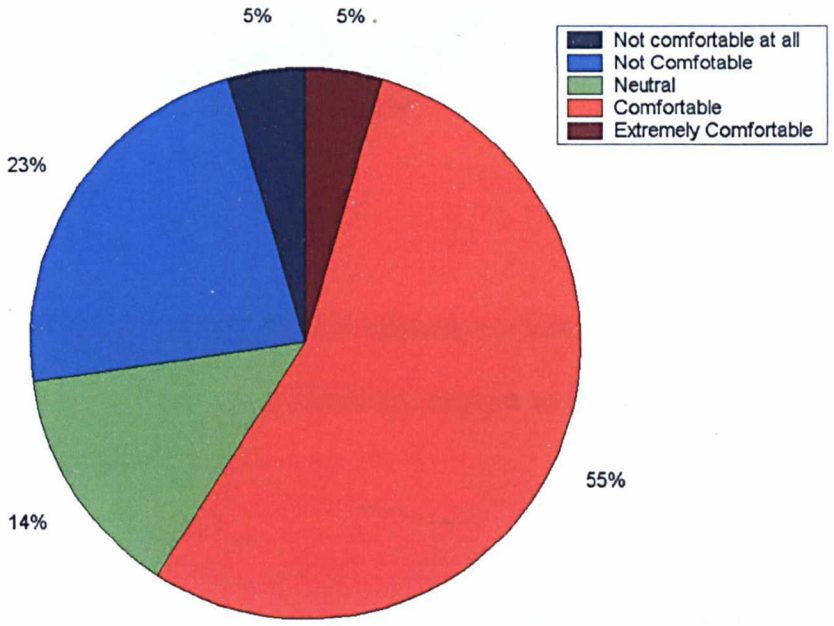


Figure B1 - *Question 1* – *During this study you have been given the opportunity to use a wearable body sensor. Did you find this sensor comfortable?*

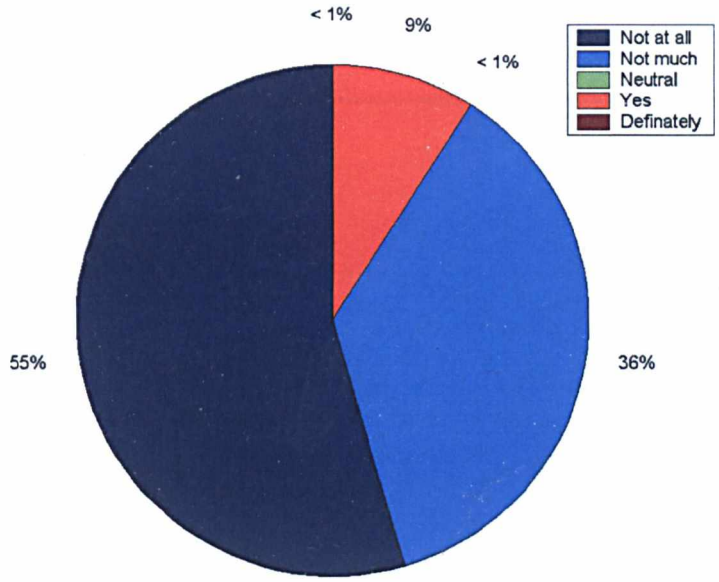


Figure B2 - Question 2 – Do you think that wearing the sensor affected your activities in the scenario?

Finally, the following are a range of comments made by subjects in the 'free text' spaces that were left in the post-study questionnaire:

"Bulky."
"Slips of ear."
"Easy to put on and take off because I'm used to putting earphone on and off Wobbly."
"It just clipped around the ear."
"Didn't notice it."
"I was slightly aware of it."
"Band around the head wasn't comfortable."
"Had to take care that it didn't fall off."
"Weight on the ear."
"It didn't fit my ear very well."
"Can't move ear dramatically."
"Simple to keep on, no wires."

Appendix C: Real-time Classifier

Real-Time Pervasive Monitoring for Postoperative Care

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Abstract—**Post surgical care is an important part of the surgical recovery process. With the introduction of minimally invasive surgery (MIS), the recovery time of patients has been shortened significantly. This has led to a shift of postoperative care from hospital to home environment. To prevent the occurrence of adverse events, the care of these patients is mainly relied on routine visits by home-care nurses. This type of episodic examination can only capture a snapshot of the overall recovery process, and many early signs of potential complication can go undetected. The development of Body Sensor Networks (BSNs) has enabled the use of miniaturised wireless sensors for continuous monitoring of postoperative patients. This paper examines the potential of processing-on-node algorithms for further reducing the wireless bandwidth, and therefore the overall power consumption of the sensors. The accuracy and robustness of the technique are demonstrated with lab experiments and a preliminary clinical case study.**

Keywords— **postoperative care, real-time analysis, Bayesian classifier, multivariate Gaussian model**

I. Introduction

Recent advances in Minimally Invasive Surgery (MIS) have greatly reduced patient trauma and improved post-surgical recovery. Unlike traditional open surgical approaches, MIS procedures are conducted through small body incisions with laparoscopic or robotic assisted instruments [1]. The significant patient benefits have propelled the general acceptance of MIS for a range of surgical procedures [2]. Currently, the rapid recovery process of MIS has led to a shift of postoperative care from hospital to home environment. For instance, the traditional postoperative stay in hospital after major gastrointestinal surgery has been between 5 to 10 days [3, 4], whereas for patients undergo laparoscopic cholecystectomy they may be discharged as early as 48 hours after the operation [5-8]. Although the MIS approach can significantly reduce the chances of post-operative reflux, life-threatening complications may still occur days after the operation. As an example, an early discharged patients was diagnosed with ureterovaginal fistula several weeks after the laparoscopic hysterectomy [9]. To prevent these adverse events, the care of early discharged patients has been relied mainly on homecare services with regular pre-scheduled visits [10]. These are usually conducted by specialists or nurses, and patients are monitored with further telephone contacts and postoperative examinations [11]. The drawback of this approach is that it is difficult to accurately quantify the recovery process which is a crucial element of the postoperative care.

Thus far, a range of techniques have been proposed to quantify the recovery process. They range from paper/electronic questionnaires [12] based methods to the use of activity sensors worn by the patient [13, 14]. The acquired data is then analysed retrospectively. Current research has also identified the need for continuous, real-time monitoring for MIS post-operative care and a pilot study has been conducted by Aziz *et al* by the use of Body Sensor Networks (BSNs) [15]. Through the use of an e-AR (Ear-worn Activity Recognition) sensor, it has been demonstrated that the mobility of the patient can be used as an indicator of the general well-being and recovery rate of the patient post MIS operation.

However, to monitor the patient continuously, the sensor data has to be transmitted to a local processing unit for data processing and trend analysis. The high power demand makes the miniaturisation of the device difficult, which can affect the general acceptance of the device by patients. The provision of processing on-node is therefore desirable both from the data reduction and user acceptance perspectives. In this way, the sensor data can be reduced at the node level to cut down radio transmission, and therefore the overall power consumption. This can also avoid the classification errors due to packet loss. The purpose of this paper is to provide a real-time BSN implementation framework that is suitable for post-surgical care. To enable real-time processing, relevant features are first identified using feature selection techniques, which is then followed by an efficient multivariate Bayes classifier for activity classification. Validation results based on lab-experiment are provided.

II. Real-time postoperative care

A. e-AR sensor

The e-AR sensor used for this study is based on the BSN platform that consists of a Texas Instrument MSP430 processor, a Chipcon CC2420 radio transceiver and an Atmel 512KB EEPROM [16, 17]. For capturing physiological parameters and general activities of the subject, a MCC ChipOX SpO_2 module and a 3-axis accelerometer (built by using two Analog Device ADXL202JE 2-axis accelerometers) are integrated into the device. Fig. 1 illustrates the overall design of the devices and how it is worn by the patient. Under this design, an ear-clip SpO_2 sensor is used to measure the oxygen saturation level and the heart rate of the patient. The accelerometer is embedded into the sensor for capturing the mobility and activity information of the user. Compared to other pervasive health monitoring devices, such as the ring sensor [18] and the EKG shirt [19], the e-AR sensor can capture a range of activities in addition to physiological indices. By positioning the sensor on the ear, the motion artefacts of the SpO_2 sensor can be reduced. This also avoids sensor placement and calibration problems encountered by other wearable systems [20, 21]. Although the e-AR sensor can provide both physiological parameters and activity information, this study will mainly focus on the use of motion information to infer the recovery progress of the patients.

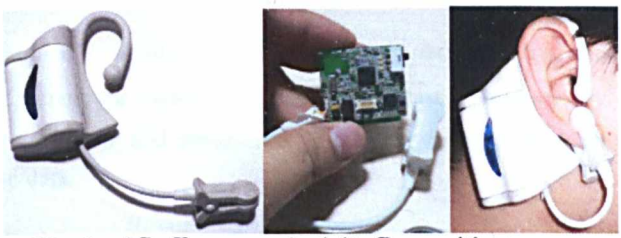


Fig. 1 e-AR (Ear-worn Activity Recognition) sensor

B. Feature selection

To quantify the mobility information and classify the activity of the subject, relevant features have to be identified. In general, selecting only relevant features can not only cut down the sensor channels but also improve the classification accuracy [22]. Most early studies for activity recognition are based on empirical feature selection techniques[23-26]. Recent studies have adopted more systematic feature selection techniques for enhancing the classification of activities [27-29]. Given the real-time constraint for feature extraction in this work, a number of features are identified:

- Signal energy
- Signal RMS (root mean square) value
- Average distance between consecutive peaks
- Troughs
- Zero-crossing
- Number of zero-crossing
- Variance across the 3 axes

The Bayesian Framework for Feature Selection (BFFS) was used to rank the relevance of features to different activity classes [30]. The result of the BFFS as applied to the e-AR sensor is shown on Fig. 2, where the expected AUC (Areas Under the ROC curve) is plotted against different features. It is apparent that the variance is the feature that provides the best discrimination among all activity classes. In addition, the variance provided a good measure on the level of activity ("activity index") of the subject.

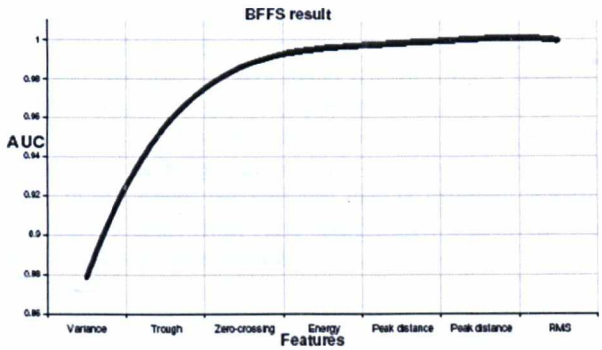


Fig. 2 BFFS results

C. Real-time classifier

Currently, most activity classification techniques are designed for retrospective analysis. For example, the hierarchical binary tree framework proposed by Mathie *et al.* for classifying daily activities requires extensive computation resources and real-time on-node processing is not feasible. The HMM (Hidden Markov Model) approach for physical activity classification proposed by Lester *et al.* was designed to provide off-line classification of activities [31]. Although there is provision of an embedded version of the algorithm for porting to a sensor node, the feasibility of porting the computation intensive HMM onto a sensor node is difficult.

Several methods have been proposed for real-time classification on the sensor node. For instance, DeVaul and Dunn

proposed a two layered model, which combines Gaussian mixture model with Markov models, for real-time motion classification [32]. However, only the feature extraction and Gaussian class-conditional posterior code was implemented on the 200MIPS StrongArm processor of the MIThril system. Carlos *et al.* proposed a very low complexity algorithm for ambulatory activity classification [26]. A decision-tree based technique was proposed to classify different activities, such as resting, lying, walking, running and going up/downstairs. Although it has been shown that the proposed technique can be implemented on a fixed-point Philips LPC2106 30MHz microcontroller, such 32-bit ARM processor is a relatively high power processor compare to microcontrollers in typical wireless sensors. In addition, decision tree is a computational intensive classifier as logic operations are expensive processes.

To enable real-time classification on a sensor node, a Multivariate Gaussian Bayes classifier is used for classifying different activities. The classifier is light-weighted in terms of computation but has an intrinsically efficient inferencing capabilities. As extensive memory is required for training the Bayes classifier, the training is conducted off-line where multivariate Gaussian density is used to model the different activity classes. Under this framework, the likelihood of multivariate feature vector x (variance across 3 axes) belong to class C_j is defined as:

$$P(x \mid C_j) = \frac{1}{(2\pi)^{\frac{n}{2}}\sqrt{|\Sigma_j|}} \exp\left[-\frac{1}{2}(x-\mu_j)^T \Sigma_j^{-1}(x-\mu_j)\right] \quad (1)$$

where n is the dimension of the feature vector, and μ_j and Σ_j denote the mean and covariance of class C_j respectively. The mean μ_j and covariance Σ_j are derived from the training data.

$$\mu_j = \frac{1}{N_j}\sum_{x \in C_j} x$$
$$\Sigma_j = \frac{1}{N_j}\sum_{x \in C_j} xx^T - \mu_j\mu_j^T \quad (2)$$

where N_j represents the number of features belong to class C_j.

According to the Bayes theorem, the posterior probability of activity class j given feature vector x is:

$$P(C_j \mid x) = \alpha P(x \mid C_j)P(C_j) \quad (3)$$

where α denotes the normalising constant and $P(C_j)$ represents the prior probably for class C_j. To minimise the bias towards more frequent activities, activity classes are assumed to have equal prior probabilities. The classification can be simplified as follows:

$$d_j(x) = -\frac{1}{2}\ln|\Sigma_j| - \frac{1}{2}\left[(x-\mu_j)^T \Sigma_j^{-1}(x-\mu_j)\right] \quad (4)$$

where x is belong to class C_j if $d_j(x) > d_i(x)$ for all $j \neq i$.

To enhance the accuracy of the classification, the signal amplitude is used to identify static activities (such as lying down or sleeping) and falls, and the classifier is used to determine other dynamic activities (such as running and walking).

III. Experiments

A. Lab-based experiment

A lab-based experiment was conducted to evaluate the proposed technique. The experiment involved 8 subjects who wore the e-AR sensor as they performed 5 different activities (reading, walking slowly, lying down, walking and running). To examine the performance of the classifier on the lab based data from the experiments, a moving window of size 4 seconds was used to extract the variance features over the three accelerometer signals. Fig. 3 shows the variances of the 3D accelerometer from the experiment. As an example, only three activities are shown on Fig. 3, which are reading, walking and running (physical activity). As shown in this graph, the variance data of different activities are scattered apart from each other which depicts the relevance of the variance feature.

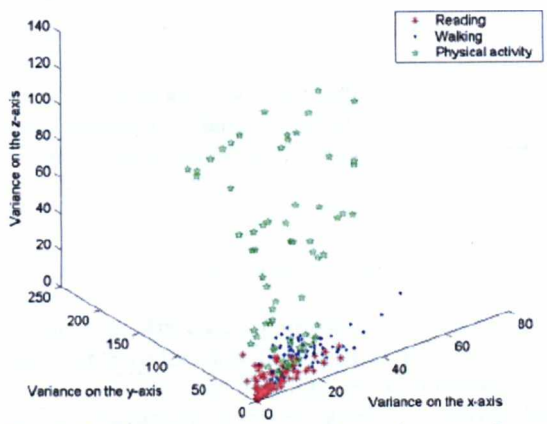


Fig. 3 Variance across 3 axes from the experiment

For activity classification, the activities are first grouped into four levels of activities, and the classifier is then applied to discriminate different activity levels. Table 1 shows the accuracy of the classifier in labelling each activity

against the corresponding activity level from the experiment.

Table 1 Activity classification results from the lab-based experiment

Subjects \ Activities	1	2	3	4	5	6	7	8
Reading	87.5	93.8	80.0	84.6	100.0	91.7	80.0	100.0
Walking slowly	100.0	91.7	100.0	80.0	93.3	100.0	100.0	90.9
Lying down	80.0	91.7	62.5	100.0	0	100.0	33.3	87.5
Walking	100.0	95.0	77.8	100.0	80.0	72.7	100.0	66.7
Running	100.0	93.8	100.0	100.0	83.3	100.0	84.6	100.0

It can be seen from Table 1 that the accuracy of the classifier is high in general, with an average accuracy of 87%. It is evident that by positioning the sensor on the ear, the sensor calibration and subject dependency problems are naturally eliminated, and the classifier can identify activities of different subjects accurately.

B. Patient trial

To validate the feasibility of using the e-AR sensor for postoperative care, a pilot study was conducted to evaluate the sensor and the proposed analysis technique. Five patients who were due to undergo various elective abdominal surgical procedures were approached and consented to participate in the trial. Before their operations, patient were shown how to wear the earpiece and a laptop computer with the wireless receiver was set up in the patient's home to collect and store the information captured.

A week before the operation, the patients were asked to wear the sensor for a day, and which will be used as a 'baseline' of their normal activity, where we could gauge their normal mobility level, daily activities, and body physiology. The patients were subsequently admitted for MIS operation and then discharged as per the hospital protocol. From this point onwards, patients were asked to wear the sensor for five days post-operatively. The only time they did not wear the sensor was when they had a shower or when they were sleeping at night. To minimise the disruption to the recovery of the patients, only routine telephone contacts were made by a clinician to check the status of the patients.

As an example, data for an 86-year old male who took part in the pilot study is presented. He had a large right inguinal hernia which was repaired with a mesh using an open approach. He required an overnight stay but was sent home promptly the next day. Fig. 4 shows the averaged activity index (every 4 minutes) for this subject for the pre-operative day and five post-operative days between the hours of 3pm and 7pm each day. This activity index was calculated using the techniques developed in the lab-based study as previously described. The figure shows some interesting trends in this patient's activity over the 6 days he wore the sensor. Preoperatively, there are clear high activity periods which do not occur during the first few days following surgery. This is most likely due to impaired mobility because of a healing groin wound and some scrotal oedema. What is also interesting is the trend showing recovery of the activity index towards pre-operative levels during the five days after surgery. These results suggest that recovery in terms of mobility can potentially be quantified and objectively measured, perhaps into a 'recovery curve' for each individual patient. The technology would therefore be useful not only in comparing different surgical interventions (laparoscopic versus open surgery) and their effects on the recovery curve, but also to monitor a patient's recovery in real-time and pick up poor recovery early. The latter would be a particularly useful adjunct to goal-directed recovery and home district nursing.

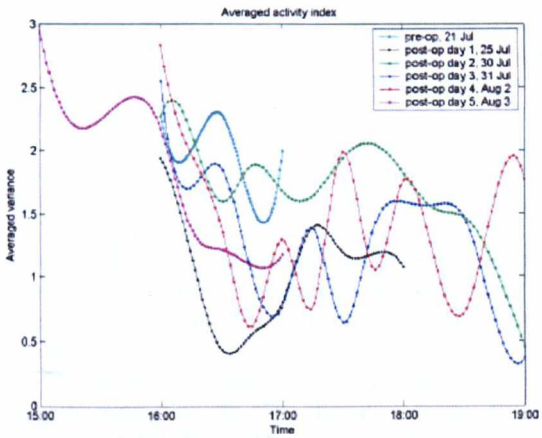


Fig. 4 The averaged activity index (every 12 minutes) of the patient for the pre-operative day and five post-operative days between the hours of 3pm and 7pm each day

IV. Conclusions

Advances in MIS have significantly shortened the hospital stay that permits early discharge of patients for home based postoperative care. The routine examinations used in the current homecare services involve extensive human interaction and cannot capture reliable transient events that may lead to critical events. A real-time analysis technique based on the e-AR sensor is proposed to objectively quantify the recovery curve of the patient in a non-intrusive manner. By relying on processing on-node, the amount of radio transmission, and therefore the overall power con-

sumption can be reduced significantly. This facilitates the further minimisation of the sensors to permit pervasive monitoring. To enable real-time processing on a miniaturised sensor node, the proposed technique processes only the relevant feature, and it identifies different activity using the efficient multivariate Bayes classifier. Although the proposed technique is relatively light-weighted, its accurate inferencing capability has been demonstrated from our lab-experiment. In addition, the feasibility of using the activity index for post-operative care has demonstrated the potential clinical value of the technique.

Acknowledgment

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Appendix D: Truncal Immobility Brace

In order to determine the types of immobility that patients who have undergone abdominal surgery face, a questionnaire study was conducted on 22 postoperative patients who had undergone either laparoscopic (keyhole) or open abdominal procedures. The impact the abdominal wound on mobility was determined using a 5-point Likert scale questionnaire comprised of eight statements as shown in table F1 below. Responses to each statement ranged from 'strongly agree' to 'strongly disagree'.

Statement Number	Feature	Full Statement Description
1	Wound Pain	My abdominal wound was painful after the operation.
2	Wound Pressure	The wound made me feel tight around my abdomen
3	Pelvic Tilt	I found it difficult to bend forwards especially to pick things up
4	Lateral Flexion	I found it difficult to bend from side to side especially when walking and in bed
5	Spinal Rotation	I found it difficult to turn around and look over my shoulder
6	Walking Activity	Walking was painful and slower than normal
7	Overall Activity	My overall physical activity was reduced
8	Respiratory Pain	I experienced pain on breathing in deeply

Table D1 *Truncal Immobility Patient Questionnaire Statements*

A summary of the results from the questionnaire study are shown in below in Figure F1. Whilst this shows that the most restricted features of an abdominal wound were overall activity, pelvic tilt, and walking activity, there were a significant number of patients who had difficulty with lateral flexion and spinal rotation. Using this information a bracing system was designed to reproduce the above mentioned mobility impairments in the subjects.

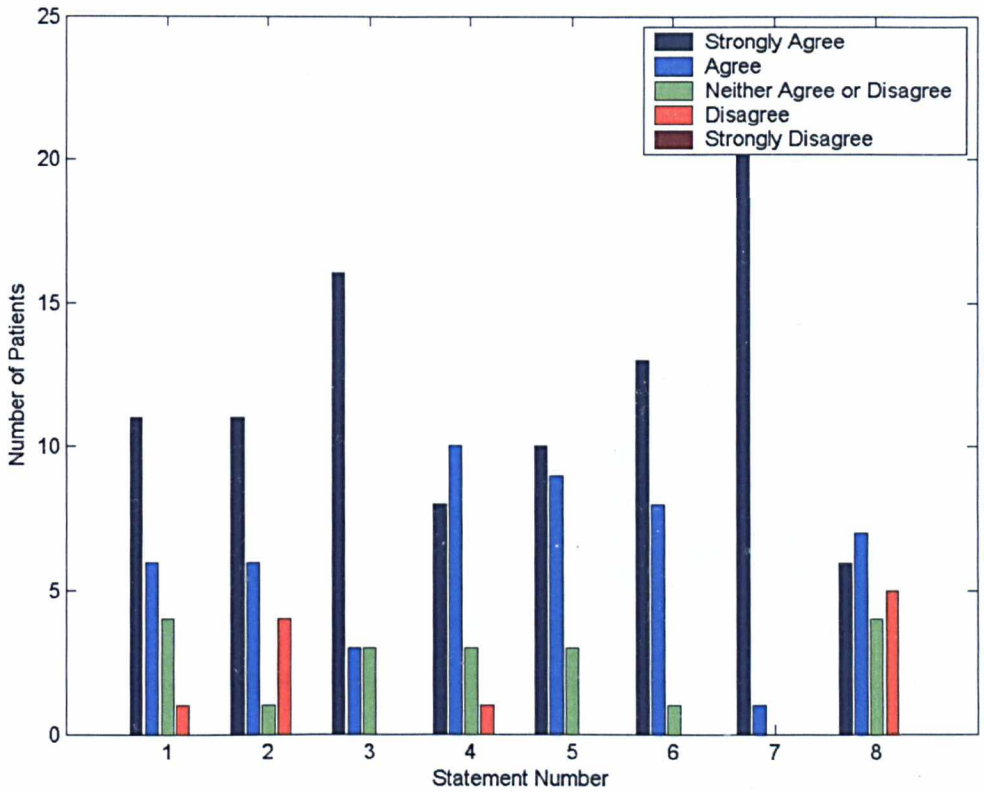


Figure D1 *Result from patient questionnaire survey*

The system that we designed was formed using Orthomerica's Air Back™ Spinal Support System. This spinal support was chosen as it limits spinal rotation, lateral flexion, forward flexion and pelvic tilt. In order simulate wound pressure, the abdominal brace was fastened tightly to put pressure on the abdomen. Finally to reduce walking and overall activity, we added an elastic fibre thigh strap made of to slow participants down while walking. The combination of the brace and thigh strap would simulate a reduction in overall activity. It was not our intention to simulate wound or respiratory pain.

Once the truncal immobility impairment brace system had been designed, it was objectively compared to actual truncal immobility due to abdominal wounds. This was done by undertaking the same eight-statement questionnaire on twenty-two subjects who were otherwise well, and the comparing results with those obtained from real patients. Figure F2 summarises these findings.

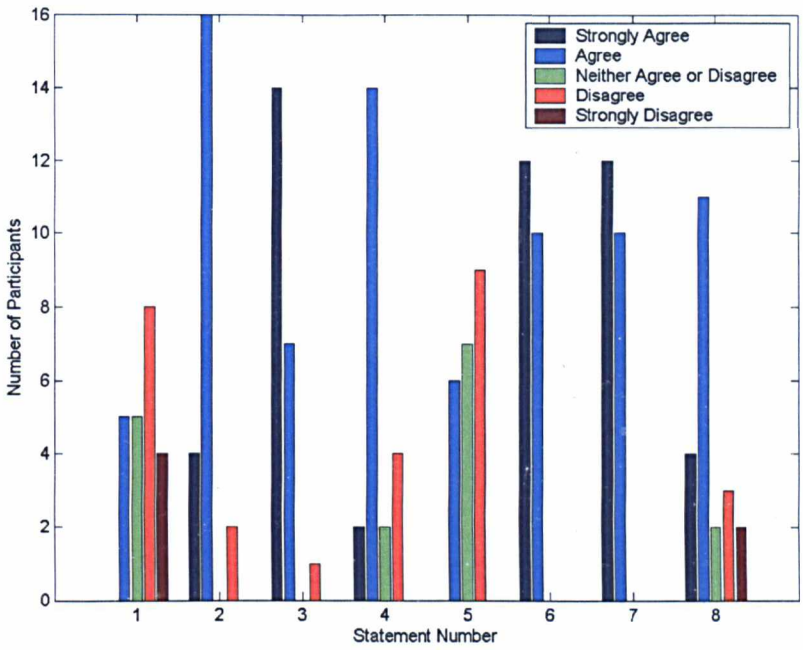


Figure D2 *Questionnaire results from the truncal mobility impairment brace.*

SPSS (*SPSS Inc.*) software was used to calculate statistical tests of significance. A Mann-Whitney test was used to see if the brace simulated an abdominal surgical wound and paired T-tests were used to compare measurements between the normal subjects and those with a simulated abdominal wound. A Mann-Whitney test was performed to compared results from the two groups (patients versus normal subjects wearing the brace), with results shown below in Table F2. A p value of less than 0.05 was deemed to be statistically significant.

Statement	Feature	P-value	Significant difference?
1	Wound Pain	0.000	Yes
2	Wound Pressure	0.258	No
3	Pelvic Tilt	0.678	No
4	Lateral Flexion	0.096	No
5	Spinal Rotation	0.000	Yes
6	Walking Activity	0.871	No
7	Overall Activity	0.002	Yes
8	Respiratory Pain	0.610	No

Table D2 *Summary of Mann-Whitney test*

Appendix E: Mobility Impairment

Detecting Walking Gait Impairment with an Ear-worn Sensor

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Abstract— **This paper investigates an ear worn sensor for the development of a gait analysis framework. Instead of explicitly defining gait features that indicate injury or impairment, an automatic method of feature extraction and selection is proposed. The proposed framework uses multi-resolution wavelet analysis and margin based feature selection. It was validated on three datasets; the first simulating a leg injury, the second simulating abdominal impairment that could result from surgery or injury and the third is a dataset collected from a patient during recovery from leg injury. The method shows a clear distinction of gait between injured and normal walking. It also illustrates the fact that using source separation before pattern classification can significantly improve the proposed gait analysis framework.**

Keywords: wearable sensors, gait, wavelet analysis.

I. INTRODUCTION

Features that can quantify human gait play a major role in the studies of injury rehabilitation, improving athletic performance, and the design of prosthetic limbs. Human gait has long been an active area of research, and many systems have been proposed for observing gait irregularities. Thus far, most of these systems are based on image information from video sequences. When used in conjunction with biomechanical models, these features can allow quantitative analysis of many specific gait characteristics such as joint moments and powers (kinetic analysis), joint angles, angular velocities, and angular accelerations (kinematic analysis) [1]. In these systems, optical markers are placed near anatomical landmarks of the body and features related to gait are extracted from video sequences. Parametric models have been used extensively to describe a set of image observations. An example is 3-D modelling of moving people which can be achieved by using volumetric bodies based on elliptical cylinders [2] or tapered super quadrics. Alternatively, 2-D models that represent the projection of 3-D data to an imaging plane can be used (2D/3D contour modelling for example [3]).

In general, methods that consider the use of kinematic constraints can handle more complex motions and occlusions. These constraints are used to improve tracking as well as preventing model violations of the derived 3-D structures. For example, Dockstader et al. [4] use soft constraints in a hierarchical structural model of the human body to analyse video sequences captured in a home environment. Reviews on human motion analysis based on video, including summaries of modelling, tracking and recognition, are provided by Dariush [5] and Aggrawal et al. [6].

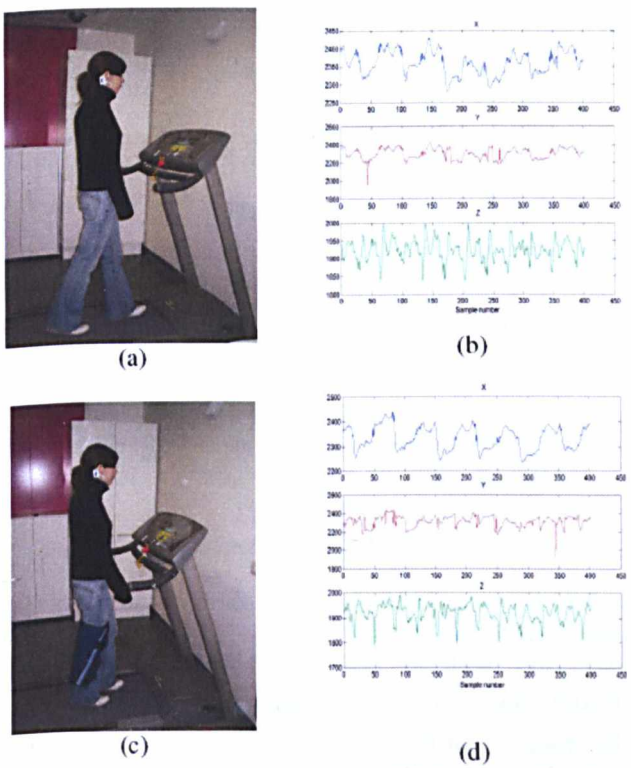
An alternative to vision based gait analysis is the use of body worn sensors to obtain motion data. The variables that can be measured during gait analysis depend on the technique selected. The most commonly measured variables include initial contact (IC) that defines the beginning of a complete gait cycle and thus cycle duration and frequency, and terminal contact (TC) that marks the start of the swing phase. Gyroscopes, which measure angular velocity, and accelerometers which measure linear acceleration, have been used as a wearable option to measure these variables [7] . Coleman et al. [8], Aminian et al. [7] and Selles et al. [9] provide methods of measuring both TC and IC timing information. On the other hand, Yoshida et al. [10] use an accelerometer attached to the patient's waist and observe frequency peaks in the anterior plane to detect leg injury. In reality, however, injury causes changes in both the temporal and frequency domains and this variation is not normally limited to one direction of motion. Due to leg injury, a patient's motion can show signs of swaying for maintaining equilibrium, as well as a change in the distribution of the forces when the patient's foot touches the floor. Injury in different parts of the body, resulting from abdominal surgery for example, could also affect gait and balance, especially when a patient needs to climb stairs, reach for objects or lie down.

II. USIND HEAD WORN ACCELERATION SENSORS

Head-worn accelerometers have in the past been used to study the movement of the head compared to the rest of the trunk, as well as gait changes due to disease and aging. As a subject mobilises, the head remains relatively stable when compared to the trunk, and therefore the direction of its movement during activities such as walking is more representative of the body's movement as a whole. A study by Kavanagh et al (2005) [11] used tri-axial accelerometers attached to the head and trunk of normal volunteer subjects to collect data whilst they were walking, and showed that accelerations detected at the head were not only more regular than those at the trunk in each direction, but also associated with a greater degree of coupling between directions [12]. Authors concluded therefore that during walking, accelerations of the head are significantly attenuated and

more tightly controlled when compared to accelerations of the lower trunk. Despite being a relatively stable part of the body during motion, the head moves proportionately more with increasing activity (for example climbing stairs versus walking on a flat level) [13], which is important to consider when evaluating gait. It does however move less than the limbs due to the stabilising effect conferred by the trunk and neck, making it an attractive site for sensor placement [14,15]. The trunk does play a critical role in maintaining head stability by regulating gait-related oscillations in all directions, and the neck confers additional control thereby enhancing head stability during walking [11].

The experiments outlined in this work are designed to observe changes in gait that occur following impaired truncal and limb immobility as detected by an ear-worn activity recognition sensor (e-AR sensor) [16]. The e-AR sensor has been used previously for observing post-operative recovery [16], activities of daily living and sports performance. A multi-resolution wavelet-based framework is proposed in this paper to analyse the e-AR sensor's accelerometer data in the 3 directions of motion. Automatic margin-based feature selection is used to select frequency bands of the wavelet transform that provide discrimination between classes of motion. Independent Component Analysis (ICA) is used as a means of source separation for 3-D acceleration.



(a) (b) (c) (d)

Figure 1. Walking with and without impairment (a) shows one of the participants in normal walking and (b) shows the accelerometer signals (forward backward X, right-left Y, and upward-downward Z) (c) shows a person wearing a knee brace to simulate impaired walking, and (d) shows the accelerometer signals acquired.

III. EXPERIMENTAL SETUP

Two comparative simulated datasets of normal versus impaired mobility were acquired for this study. In the first dataset *lower limb mobility* was impaired using a knee brace system. 10 subjects were asked to wear the e-AR sensor on the right ear then walk on a treadmill at 2.5 Km/h for 3 minutes. This was done without any braces, with mild lower limb impairment (Tubigrip) and with moderate lower limb impairment (McDavid Ligament Knee Brace). Fig. 1 shows a subject walking with and without the knee brace.

In the second dataset *truncal mobility* was impaired using an abdominal brace system (Orthomerica Air Back™ Spinal Support System). A total of twenty-two normal volunteers were asked to perform the following activities both with and without the abdominal brace system whilst wearing the e-AR sensor: Walking on a treadmill at the following speeds (1.5/2.5/3.5 km/h with a 30cm incline) for 2 minutes; walking down a corridor and up and down a flight of stairs.

A third dataset was obtained by recording data from a participant who had leg injury during the recovery period, and after full recovery. The participant was asked to walk quickly (around 4 km/h) on a treadmill while wearing the ear sensor.

IV. ANALYSIS METHODOLOGY

A. *Blind Source Separation Using ICA*

The main objective of source separation is to extract desired signals from a mixture of other signals. This is highly applicable to our study of gait as each one of the accelerometer signals collected in 3D contains some information about the underlying motion. Instead of analyzing the signals directly, signal analysis can be made more efficient by analyzing the resulting source signals that summarize the underlying motion.

In this work, ICA was implemented for blind source separation as suggested by Bell and Sejnowski [17] using the Infomax principle. Estimates of the original sources $u(t)$ can be obtained from the signals $x(t)$ by finding an un-mixing matrix W:

$$u(t) = W * x(t) \tag{1}$$

A stochastic gradient ascent is used to adapt the un-mixing filter weights:

$$\Delta W \propto [W^T]^{-1} + g(u(t))x(t)^T \tag{2}$$

where $g(.)$ is the sigmoid function that produces the higher order statistics needed to de-correlate the sources. Thus, an iterative algorithm is used until the un-mixing filter weights converge, resulting in estimates of the original sources.

B. *Multi-resolution Wavelet Anslysis*

In order to observe the multi-resolution properties of the acceleration signals across both time and frequency, the wavelet transform was used [18]. The DWT (Discrete Wavelet transform) was selected as it can provide a compact representation of a signal in time and frequency that can be computed efficiently (in $O(n)$ time). The DWT is defined by the following equation:

$$W(j,k) = \sum_j \sum_k x(k) 2^{-j/2} \psi(2^{-j} n - k) \qquad (3)$$

where $\psi(t)$ is a time function with finite energy and fast decay (j represents scale, and k time). DWT analysis can be performed using a fast, pyramidal algorithm related to multi-rate filter-banks. This is achieved by filtering of the signal using a high-pass filter ($h[n]$) to obtain the signal details, and a low pass filter ($g[n]$) to obtain the approximation coefficients. This is followed by sub-sampling, and the sub-sampled signal is passed through both filters again to obtain the DWT coefficients at several scales. For our experiment, the DWT coefficients were calculated for 3-D acceleration data (as shown in Fig. 2) using the 4 coefficient Daubechies wavelet family.

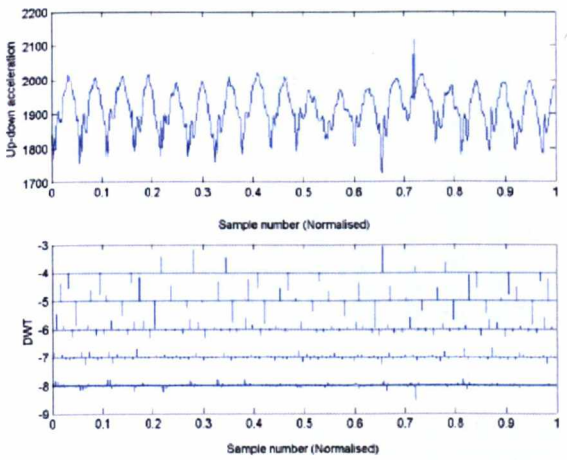


Figure 2. The multi-resolution DWT of an acceleration signal.

Wavelet coefficients were calculated across 4 scales using a moving window. Each window at timestamp i and scale j was summarized by using the mean $M_{(i,j)}$ and standard deviation $S_{(i,j)}$ of the wavelet coefficients. Thus 3 accelerometer signals result in a feature space of dimension $3 \times J$, where J is the total number of scales considered.

C. *Margin-based Feature Selection*

Due to the fact that a large feature space was generated from the DWT, supervised feature selection was used in order to select the most useful features. In this work, the Iterative Search Margin Based algorithm (Simba) proposed by Gilad-Bachrach *et al.* [19] was used. A margin is a geometric measure for evaluating the confidence of a classifier when making a decision. An evaluation function was used to assign a score to a set of features according to the margin they introduce. Let w be a weight vector over the feature set P, the margin of a point x can be written as:

$$\left\{ \begin{array}{l} \theta_P^x = \frac{1}{2}\left(\|x - nearmiss(x)\|_w - \|x - nearhit(x)\|_w \right) \\ \|z\|_w = \left(\sum_i w_i^2 z_i^2 \right)^{1/2} \end{array} \right\} \qquad (4)$$

where the margin is expressed as the difference between the weighted distance of a point to the nearest hit and nearest miss points. These distances denote the nearest point to x with the same and different labels, respectively. The Simba algorithm finds the weight vector that maximizes an evaluation function over the whole dataset and then uses a threshold to get the optimal feature set. Gradient ascent is used for maximisation. The computational complexity of Simba is $\Theta(TNm)$ where T is the number of iterations, N the number of features and m the size of the sample S.

V. RESULTS

A. *Lower Limb Impairment Results*

Each accelerometer signal was filtered using the DWT, and the features $M_{(i,j)}$ and $S_{(i,j)}$ were calculated per moving window (of size 2 sec). Although three classes of data were collected for the 10 subjects, namely normal walking, walking with mild lower limb involvement (tubigrip) and walking with moderate lower limb impairment (knee brace), the mild lower limb impairment class merged with the normal walking class. The main reason for that was that the leg-tubing did not alter the subjects' gait when walking, and most walked normally when wearing it. As a result, these two groups were combined and compared to the moderate lower limb impairment group.

The analysis was done for all 10 subjects separately to observe the differences between normal and irregular walking per subject. Fig. 3 shows the results of using 5-fold cross validation with the KNN classifier (k fixed to 5) per subject (numbered from 1 to 10). Each bar in the bar-graph shows the percentage of correct classification. The colour coding from blue to red is used to represent the number of features selected (from 1 to all, respectively). The graphs show that doing a source separation (ICA) on the accelerometer signals before the wavelet analysis stage leads to a large improvement in the results reaching 15% in

some cases. The maximum results are achieved for 11 features (averaged over all participants) for the data without ICA, and for 15 features for the data with ICA. Thus, feature selection can provide better results by filtering redundant and irrelevant features. Different values of k (for the KNN algorithm) were tested and (k=5) was chosen as the value that gave optimal results.

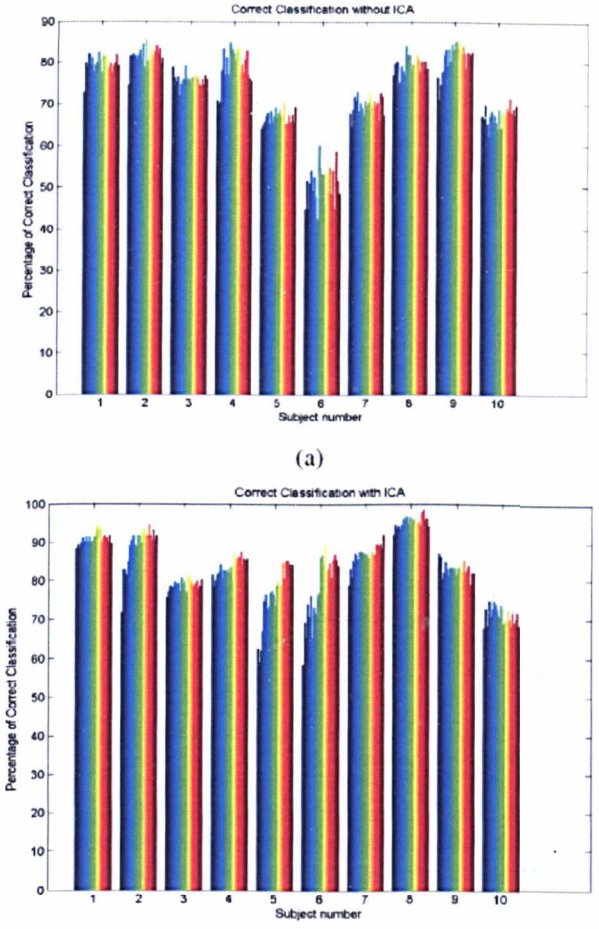


Figure 3. Lower limb impairment results (a) and (b) show the results of using a KNN 5-fold cross validation on 10 subjects. The colours show the number of features selected varying from 1 (blue) to all features (red). (b) shows the results after using ICA for source separation before the wavelet feature extraction step.

To investigate the performance of the method in separating impaired from normal data over all subjects, we combined all their data together and plotted classification rates with and without ICA with respect to changing the number of features, as shown in Fig. 4. The use of ICA increases classification rates, and maximum values are obtained for 10 features selected. The values of k in the KNN algorithm was used as k=10 as it showed the best results for the combined subject group.

B. *Truncal Impairment Results*

Fig. 5 shows the results on truncal impaired data. The same method and parameters explained in the previous section were applied to this dataset. 18 out of 22 subjects were used for analysis as parts of the data were missing for 4 subjects. Results shown are 5-fold cross validation classification using k=10 in the KNN algorithm. Fig. 5 (a) shows the results for walking on a treadmill at a fixed speed, which is not the case for Fig. 5 (b), where subjects were free to walk at their own pace in a corridor. Results show a drop but still show good rates of separating impaired from non-impaired walking. Similarly, impairment features in walking up and down stairs are picked up in Fig. 5 (d) and (e), showing an improvement (of more than 30%) with the use of ICA before feature selection.

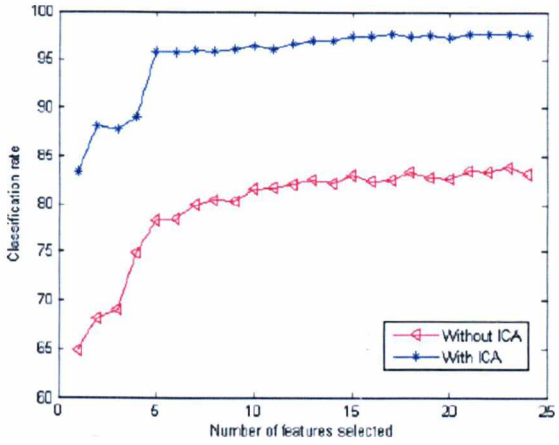


Figure 4. The impact of ICA on correct data classification rates for impaired lower limb mobility, shown for an increasing number of features.

C. *Patient-Impairment Data Results*

For patient impairment data, the three classes available were: normal walking, walking with injury and walking during recovery. The features selected as the most discriminant were the mean of the DWT of the second scale $M_{(i,2)}$ and the standard deviation of the DWT of the first scale $S_{(i,1)}$ (Fig. 6). The injured class shows more scattering as motion is likely to include more sway, and less similar steps. The transition between injured to normal walking is also shown.

VI. CONCLUSIONS

In this paper, we investigated a framework for multi-resolution gait analysis based an ear worn activity recognition sensor (e-AR). Instead of defining pre-fixed parameters that can distinguish injured from normal walking, an automatic feature selection method was proposed using the Discrete Wavelet Transform for feature

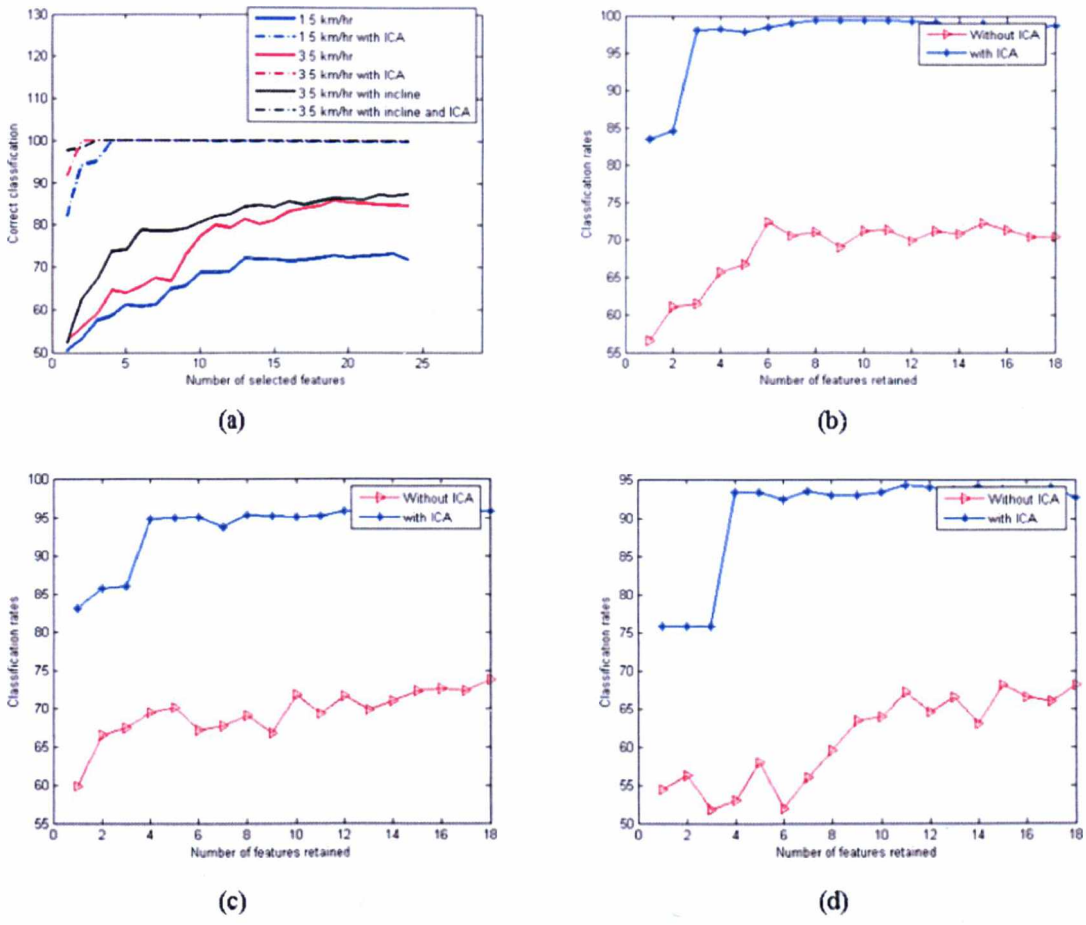


Figure 5. The impact of ICA on correct data classification rates for truncal impairment. (a) shows results for treadmill walking, (b) for normal walking in a corridor, (c) for walking up stairs and (d) for walking down stairs.

extraction, and the Iterative Search Margin Based algorithm for feature selection. The results on data collected from 2 datasets of impaired gait show a good separation between classes, especially with the use of ICA to perform source separation on the wavelet features before the feature selection stage. The method also performs well when different subjects with varying walking patterns and speeds are combined together. The observation of data from a patient with a leg injury shows a good separation between classes. It also shows that the features obtained can be observed to indicate recovery.

A further extension of this work could include the study of the relationship between the time-frequency features extracted and those used traditionally by gait-analysis labs (such as initial and terminal contacts), as well as validating results with vision based techniques. It would also be interesting to investigate the use of wearable sensors for observing the progress of some diseases that affect walking patterns, such as Parkinson's disease.

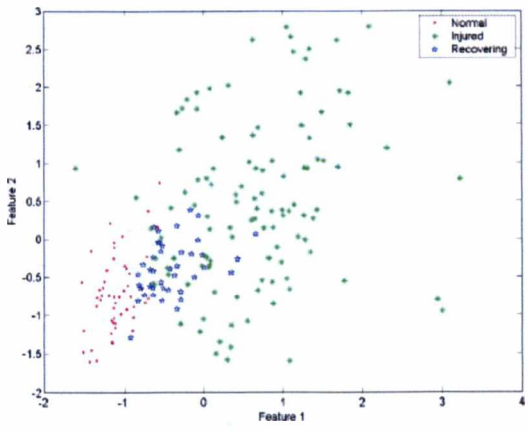


Figure 6. Scatter plot showing the mean of the DWT of the second scale and the standard deviation of the DWT of the first scale. Each dot represents a window in the original signal.

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