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User-Centred Design of a Task-Oriented Upper-Limb Assessment System for Stroke

by

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A thesis submitted in partial fulfilment of the requirements for the
degree of
Doctor of Philosophy in Engineering

WMG, University of Warwick

May 2015

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Acknowledgements

I would firstly like to thank all the supervisors involved in this work.

Professor Gillian Hundt's sheer drive and determination, constant advice, support and general care has been invaluable throughout. She was always there supporting when times were tough towards the end, and I am genuinely grateful for this.

I am also highly grateful to Professor Theodoros Arvanitis, who stepped into this work towards the latter half, without any hesitation. Without his guidance, knowledge and constant support, this work would not have turned into what it is, and I am extremely thankful for that.

I would also like to thank Professor Vinesh Raja, who steered the project from the beginning. Without Vinesh's ideas, trust and motivational talks, this work would not have been possible.

The combination of skills and experience from having three supervisors throughout has led to the rounded approach I have managed to adopt in this work, and I have learned so many lessons from each of them.

Perhaps more formally, I am grateful to the Engineering and Physical Sciences Research Council (EPSRC) and Economic and Social Research Council (ESRC) for providing me with the funding to conduct this research and I hope it moves on to have an impact in healthcare systems, helping the patients who are so in need of this support.

Thanks must also be given to everybody I have met in WMG and the University of Warwick who have allowed me to have such a great time, whether in work or socially.

I would also like to take time to thank my Mother and Father for their support throughout this PhD and for all their care up to this point. Without what they have put up with and been through, none of this could have been possible, and I shall always be grateful. I fully understand how much you have surrendered over the years to achieve this, both in your own individual ways. Mom, I love our constant chats, and always relish coming home to see and spend time with you. Dad, I'm always excited by my trips away to see you and am hoping that this shall continue and the amount of trips increase in the near future!

I also would like to thank Jo for her constant encouragement and kindness through the past few years; I truly believe she is the most caring individual I have ever met. She has changed my views of the world and I have no doubt that I would not have completed this without her. I grow more and more excited every day about our future together.

Another mention must be given to Jo's family for all the times they have supported me. I'm not sure they realise how welcome they have made me feel, and how they have turned Leamington into my second home!

I would like to mention my Nan and Grandad, who have put up with my ramblings for the last few years, yet have always been there to listen and fill me with confidence! Much of what they taught me as a child has led to this; I always wanted to be as intelligent as my Grandad and as caring as my Nan!

Mentions must also be given to my two sisters, Corrina and Siobhan, and also to Richard, who have always been there, without a moments doubt. I know I can always rely on them.

Finally, I would like to thank all the participants who were involved in this research, with particular thanks to the two NHS therapists who were involved in the structuring of this research, I cannot mention names at this point for ethical reasons, but without them this thesis would not have been possible.

Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree

The work presented (including data generated and data analysis) was carried out by the author except in the cases outlined below:

Thematic coding of interviews - Transcripts were also read by Professor Gillian Hundt (supervisor) in order to collaborate on themes to be used within the full analysis.

Parts of this thesis have been published by the author:

Golby, C., Raja, V., Hundt, G. (2013). Physiotherapists' and Occupational Therapists' Perceptions of the Assessment of Stroke Patients for Musculoskeletal Rehabilitation in the UK National Health Service, Journal of Health 5(9) pp.1478-1485.

Golby, C., Raja, V., Hundt, G., Badiyani, S. A Low Cost Activities of Daily Living Assessment System for the Continual Assessment of Stroke Patients, from Acute Rehabilitation through to Telerehabilitation. In: Successes and Failures in Telehealth, Brisbane, Australia 1-2 December 2011.

Abstract

During rehabilitation from Stroke, patients require assessment of their upper-limb motor control. Outcome measures can often be subjective and objective data is required to supplement therapist/patient opinion on progress. This can be performed through goniometry; however, goniometry can be time-consuming, have inaccuracies of $\pm 23^\circ$, and is therefore, often not used.

Motion tracking technology is a possible answer to this problem, but can also be costly, time-consuming and not suitable for the clinical environment. This thesis aims to provide an objective, digital intervention method for assessing range of motion to supplement current outcome measures which is suitable for the clinical environment. This was performed by creating a low-cost technology through a user-centred design approach.

Requirements elicitation demonstrated that a motivational, portable, cost-effective, non-invasive, time saving system for assessing functional activities was needed. Therefore, a system which utilised a Microsoft Kinect and EZ430 chronos wrist watch to track patient's movements during and/or outside of therapy sessions was created. Measurements can be taken in a matter of minutes and provide a high quantity of objective data regarding patient movement.

The system was verified, using healthy volunteers, by showing similar error rates in the system across 3 weeks in 10 able-bodied individuals, with error rates produced by a physiotherapist using goniometry. The system was also validated in the clinical setting with 6 stroke patients, over 15 weeks, as selected by 6 occupational therapists and 3 physiotherapists in 2 NHS stroke wards.

The approach which has been created in this thesis is objective, repeatable, low-cost, portable, and non-invasive; allowing it to be the first tool for the objective assessment of upper-limb ROM which is efficiently designed and suitable for everyday use in stroke rehabilitation.

List of Abbreviations

Abbreviation	Definition
ADL	Activities of Daily Living
API	Application Programming Interface
BCI	Brain Computer Interface
CAHAI	Chedoke Arm and Hand Activity Inventory 7 point score
CE	Conformité Européenne
CG	Christopher Golby
CI	Confidence Interval
EEG	Electroencephalography
EMG	Electromyography
EVREST	Effectiveness of Virtual Reality Exercises in Stroke Rehabilitation
FAAST	Flexible Action and Articulated Skeleton Toolkit
FIM-FAM	Functional Independence Measure and Functional Assessment Measure
GH	Gillian Hundt
GP	General Practitioner
HMD	Head Mounted Display
ICI	Inferential Confidence Interval
IISU	the Interface IS yoU
IREX	Interactive Rehabilitation and Exercise System
M	Mean
MIT-Manus	Massachusetts Institute of Technology Manus
NIHSS	National Institutes of Health Stroke Scale
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRES	National Research Ethics Service
OPEN NI	Open Natural Interfaces
PC	Personal Computer
REC	Research Ethics Committee
RF	Radio Frequency
ROM	Range Of Motion
SD	Standard Deviation
SDK	Software Development Kit
T-TOAT	Technology-supported Task-Oriented Arm Training
Ubi-Rehab	Ubiquitous Rehabilitation System
UK	United Kingdom
URL	Uniform Resource Locator

Chapter 1: Introduction

This chapter will provide an introduction and overview of this thesis. A description of the background to the thesis shall be given, placing it in context and assessing the need for it. The specific aim, objectives and associated research questions shall then be discussed, before a summary is given of the contribution to knowledge provided by this thesis. Finally, an overview of the structure of the main body of the thesis shall be presented.

1.1 - Context and Motivation

The World Health Organization defines stroke as:

“An acute neurologic dysfunction of vascular origin with sudden (within seconds) or at least rapid (within hours) occurrence of symptoms and signs corresponding to the involvement of focal areas in the brain.” (World Health Organization Task Force, 1989, p.1412).

In the ‘Atlas of Heart Disease and Stroke’ also published by the World Health Organization, stroke is defined as follows:

“Strokes are caused by disruption of the blood supply to the brain. This may result from either blockage (ischaemic stroke) or rupture of a blood vessel (haemorrhagic stroke).” (Mackay and Mensah, 2004, p.19).

On average, fifteen million people worldwide suffer from a stroke every year. Five million of these strokes will result in fatality, and another five million will result in permanent disability (Mackay and Mensah, 2004).

Owing to the increase in risk factors for stroke, such as hypertension, ageing, diabetes and obesity, there is an ever increasing incidence of stroke worldwide (Feigin, 2005, World Health Organization, 2011).

In the United Kingdom, there are around 152,000 cases of Stroke each year, and there are currently 1.1 million individuals living in the United Kingdom who have survived a stroke (Townsend et al., 2012), with more than half of all survivors left dependent on others (Adamson, Beswick and Ebrahim. 2004). The National Audit Office's 2010 report, entitled 'Progress in Improving Stroke Care' states:

“There are approximately 110,000 strokes and 20,000 TIAs (Transient Ischaemic Attack) per year in England alone. Around 300,000 people are living with moderate to severe disabilities as a result of stroke. We estimate that, in 2008-09, the direct care cost of stroke was at least £3 billion annually, within a wider economic cost of about £8 billion. Without preventative action, there is likely to be an increase in strokes as the population ages” (National Audit Office, 2010, p.4).

Stroke results in a 'neurological lesion' in the brain, causing symptoms such as Hemiplegia (paralysis of one side of the body), Hemiparesis (loss of strength in the arm and leg) and Dysphasia (speech problems) (Anderson, 1992). Patients who experience a stroke may need to undergo rehabilitation. Rehabilitation allows new neural pathways to be formed away from the lesion caused by the stroke (Teasell, 2008), allowing a patient to regain these neural functions which had been lost.

The United Kingdom (UK) National Health Service (NHS) provides rehabilitation to help patients establish new neural pathways, in order to regain motor skills and improve their quality of life (NICE, 2008).

During this time stroke patients will be seen by a variety of professionals, including nurses; physiotherapists; occupational therapists; speech and language therapists; and dieticians. Rehabilitation is split according to each area covered by these professionals, and patients should receive a minimum of 45 minutes rehabilitative care daily (Intercollegiate Stroke Working Party, 2012). These shall focus specifically on occupational therapy and physiotherapy.

Occupational therapists carrying out stroke rehabilitation aim to help with task-specific aspects of the patient's life. The occupational therapist decides, after collaborating with the patient, what the best form of treatment is and this will include help with both mental and emotional issues, such as anxiety and depression, cognitive impairment, attention and concentration and memory, as well as physical functioning, such as splinting and stretching, task specific training, and Activities of Daily Living (ADL) (Intercollegiate Stroke Working Party, 2012).

Occupational therapists ensure patients and carers have support structures in place when they leave hospital, and, at regular intervals thereafter. Patients and carers should see the occupational therapist at least every six months, for a formal interview.

Physiotherapists in the NHS aim to support stroke patients by setting long and short term goals. The patient is usually encouraged to stay as mobile as possible and to achieve moderate physical activity levels by themselves. Physiotherapists decide

which treatments are most suitable for the patient and these may include fitness training, arm re-education, functional electrical stimulation, mental practice, positioning, robotic assisted movement therapy, splinting and stretching, strength training and task specific training (Intercollegiate Stroke Working Party, 2012).

After discharge from attending outpatient physiotherapy, patients are encouraged to remain active and, as with occupational therapy, have formal reviews, at least every six months.

Rehabilitation for stroke is an essential part of the stroke care pathway, however, there are issues with this process. The time that staff members have ‘face-to-face’ with patients is important as evidence suggests that more intensive rehabilitation produces a better functional outcome (Kwakkel et al., 2004). Tyson and Turner (1999) argued that the most frequently cited reason for deficiencies in care was the lack of time that support staff members spent with patients. Patients can spend a lot of their rehabilitation time in bed or in a hospital room, being inactive (De Wit et al., 2005, 2007). The NHS have addressed this issue by releasing National Clinical Guidelines stating that a minimum of 45 minutes per day should be spent with a patient (Intercollegiate Stroke Working Party, 2012). However, there is still evidence that this guideline is not being followed. Rudd et al. (2009) state that 75% of patients receive less than an hour of treatment a day and 25% of patients received less than half an hour a day of treatment.

Rudd et al. (2009) suggest that the NHS currently struggles with providing enough time for rehabilitation, due to the limited number of staff available. There are on average 1.3 occupational therapists and 1.7 physiotherapists to every 10 beds in the

NHS. By asking staff what would be required to achieve a high level of care, Rudd et al. calculated that an additional 1 occupational therapist and 1.3 physiotherapists per 10 beds were needed.

However, extra staff may be currently unachievable, due to rising costs in this area. The National Audit Office evaluated current stroke care costs in the U.K. and stated that the main burden of stroke was in the cost of rehabilitation and life after stroke. There has now been an allocation of £30 million to support care at the post-hospital stage (National Audit Office, 2010). There are currently issues with how productive the NHS can be with the resources it has at its disposal in this area, particularly when taking into account the increasing prevalence and risk factors of stroke and the increasing amount of individuals who live with a long term disability as a result of stroke, each of which long term rehabilitation.

1.2 - The Need

The NHS has an aim to provide a minimum of 45 minutes rehabilitation per stroke patient, per day (Intercollegiate Stroke Working Party, 2012). However, it has been noted that this may be difficult, as the prevalence of stroke and risk factors increase, and the current system has limited resources available, in particular medical staff, to provide the rehabilitation services to meet targets (Rudd et al., 2009).

There has been an increased amount of funding added to the system, in order to provide rehabilitation to stroke patients (National Audit Office, 2010); however, staff shortages are still a problem, and increased funding may not necessarily improve this. In addition, as the prevalence of stroke increases, it may be an unsustainable

method to simply keep adding more staff to the system, using the current methodologies. Therefore, an argument can be put forwards that a change to the current methodologies may be required, by finding an approach which allows current medical staff to optimise their processes, and create more time for rehabilitation. One method for achieving this, may be through the use of technology.

One particular area which could be used to optimise rehabilitation, and has been suggested in the literature, is motion tracking technology, particularly for assessing motor control in the upper-limb. However, such motion tracking systems can be characterised as being technologically driven, not suited to the clinical environment, costly and difficult to use. While valuable lessons may be learned from current technologies which have been developed (inside and outside the field of motion tracking), a solution is required which is developed using a clinical perspective to accompany current outcome measures, which is therefore suited to the clinical environment. This will be discussed in more detail in Chapter 2: Literature Review.

1.3 - Aim of the Thesis

This aim of this research was to create a clinically driven digital intervention and associated tool which could assist in the functional assessment of upper-limb motor control in stroke patients using motion tracking technology.

In order to create a clinically driven technology, a user-centred design approach was followed. A user-centred design approach aims to put the user at the centre of any product designed, constantly referring to them for opinion throughout the design process. Martin et al. (2012) discuss how a current problem area in medical device

development is the lack of research conducted in the early design stages, and how users are often not spoken to until technology driven design briefs have already been created; yet it can cost up to ten times as much to alter a system after the design stage to suit users' needs (Johnson et al., 2005). User-centred design allows the users of the system to be involved in the design process, and subsequently observed in their natural environment, developing a rich data source not available through other data collection methods (Sharp et al., 2002). Sharp et al. suggest five points, which would allow therapists to be involved in the design process, allowing the tool to be clinically driven:

1. Users' tasks and goals are the driving force behind the development.
2. Users' behaviour and context of use are studied and the system is designed to support them.
3. Users' characteristics are captured and designed for.
4. Users' are consulted throughout development from earliest phases to the latest and their input is seriously taken into account.
5. All design decisions are taken within the context of the users, their work, and their environment.

This research placed the user at the centre of the design process, following the above points through the use of observational studies (Johnson et al., 2005) and semi-structured interviews with users (Martin et al., 2012).

This was performed by initially gathering user requirements through a requirements elicitation approach. This was followed by a process to produce a rapidly developed

prototype. Designing a prototype allows for a trial of different design types, and for the possibility to identify certain issues and solutions (Sommerville, 2011).

This tool was then evaluated by therapists to help derive user needs for a complete system. This evaluation was performed through a rigorous verification and validation process using the system. The process of evaluating a prototype can allow users to see how the tool may support them, identify strengths and weaknesses and be able to suggest ideas for improvements and additional needs (Sommerville, 2011). This resulted in a set of requirements and user needs for future versions of a more complete system in a potential subsequent development stage.

1.4 - Research Question

In line with the aforementioned aim for this research, the main research question in this thesis was as follows:

What clinically-driven method (technology) can supplement current outcome measures by providing an objective assessment of upper-limb motor control in stroke patients?

1.5 - Specific Objectives

In order to answer the research question and achieve the thesis' aim, specific objectives were set as secondary research questions. These were as follows:

- *What are the current concerns of Occupational Therapists and Physiotherapists in the NHS with the assessment of Upper-Limb motor*

control assessment and how do these therapists feel they can they be alleviated through the use of technology?

- *What initial prototype can be developed to assist therapists in the assessment of upper-limb motor control in stroke patients, based on current issues identified in the literature and the outcomes of the previous question?*
- *How does such a device perform at this initial prototype stage, in healthy volunteers, and in the clinical setting?*
- *What further system refinements and user needs can be derived from the verification and validation of the developed prototype?*

1.6 - Organisation of the Thesis

Initially, to put this work in context, a literature review was conducted (chapter 2); this involved reviewing the current-state-of-the art and detailing the current problem areas in motor control assessment of the upper-limb for stroke patients in the NHS. This review included a critical discussion of how motion tracking technology has been used to address the issues in this area, and where research currently stands. Finally, a review of alternative technologies to motion tracking is presented, from which lessons may be learned.

A methodology for the thesis then needed to be derived and this is presented in chapter 3. This chapter details the three major stages in this research: requirements elicitation, system development and system evaluation.

In order to establish initial requirements, a requirements elicitation study was conducted. Occupational therapists' and Physiotherapists' perspectives of motor

control assessment in stroke rehabilitation were sought and this is presented in chapter 4. This process utilised semi-structured interviews and non-participant researcher-based observation within the clinical setting.

Following this stage of the work, design and implementation of the prototype was undertaken which is shown in chapter 5. Critically derived elements from the literature review of this thesis were intertwined with the initial requirements drawn from the elicitation exercise to create this.

Chapter 6 presents an overview of the evaluation of the system. This details results from the verification and validation steps followed, as part of this process.

The verification stage involved comparing any error rates made by the system, with any errors made by a chartered Physiotherapist when measuring Range of Motion (ROM). This was performed by comparing measurements taken by the therapist / system across a three week period, in 10 participants, and comparing any discrepancies between weeks.

The validation stage involved a feasibility study, which involved trialling the prototype system in two clinical settings. The system was evaluated through a user-centred design trial, in which the system was placed in the users 'natural' clinical environment for up to 15 weeks, with therapists using the system to assess selected stroke patients over time. Semi-structured interviews were conducted at the end of this stage to evaluate use of the system from the perspective of the user.

Chapter 7 includes a discussion of the thesis as a whole, including both a critical account of the issues raised during the design stage (requirements elicitation), the

system developed as part of the thesis' proposed solution in motor control assessment of the upper-limb for stroke patients, and the evaluation (verification and validation). This discussion is followed by a summary of ideas for future system developments, based on the advantages of the proposed solution and by taking care of any current limitations observed during the evaluation of the work.

Chapter 8 provides a conclusion for the thesis, details of the contribution to knowledge and ideas for further research.

Chapter 2: Literature Review

This chapter discusses the current state-of-the-art for upper-limb motor control assessment for stroke patients in the NHS through the use of motion tracking technology. The chapter begins by reviewing the literature which describes the current problems with upper-limb motor control assessment for stroke patients in the NHS. This is followed by a review which describes how this is currently being addressed through the use of motion tracking technology, what stage this is at, and what the current problems associated with using motion tracking technology to assess upper-limb motor control in stroke patients are. This latter stage also contains a discussion of the specific motion tracking tool used in this research, the Microsoft Kinect (with a justification for this) specifically for this purpose. Finally, a review of other technologies which have been utilised in this field is also presented; this is to derive any lessons which can be learned from deploying different technologies in similar circumstances.

2.1 - Upper-Limb Motor Control Assessment of Stroke Patients in the NHS

Part of stroke therapy is the rehabilitation of the upper-limb. 50-75% of stroke patients suffer from a neurological problem in which they lose motor control in the upper-limb, and suffer from reduced ROM (Olsen, 1990). This is an important issue, as this functionality is needed for most ADL and this in turn can affect the patient's quality of life. Most ADL require some sort of upper-limb functionality; even

predominantly lower-limb based tasks such as walking require upper-limb control (Patten et al., 2006).

Upper-limb function can improve over time, as patients demonstrate neuroplasticity (Young and Tolentino, 2011). However, faster improvements have been shown through regular therapy and exercise aimed at increasing ROM. Evidence shows that task-oriented, high repetition therapy is most successful in the re-learning of motor skills (Jones et al., 2011).

Even though this is such a major aspect of stroke rehabilitation, previous reports have shown that up to 50% of stroke survivors suffer from upper-limb impairment 6 months after their first stroke encounter, despite high investment of resources in this area from the NHS (Kwakkel et al., 2004). The amount of time required to provide such high intensity upper-limb rehabilitation is difficult in the current NHS care pathway (an interactive tool demonstrating the National Institute for Health and Care Excellence (NICE) care pathway can be found online (NICE, 2014)), as it is so resource intensive already.

An important part of any rehabilitation process, and the particular focus of this thesis, is the assessment of the individual throughout therapy. This is key for goal setting, motivation of the patients and feedback to the therapists.

Assessment in this field needs to evaluate the control and coordination of the upper-limb, including the ability to conduct ADL and the biomechanical parameters involved in motor skills. However, National Clinical Guidelines for Stroke (linked to the care pathway (NICE, 2014)) do not provide methodologies specifically for the assessment of the upper-limb through the use of technology. The only advice given

on rehabilitative assessment of the upper-limb, which could potentially be linked to technology, is instructions on the use of outcome measures:

“Measurement of function is central to rehabilitation. Many valid tools exist, and although these guidelines do not specify which ones should be used, some suggestions are made in the appropriate parts of the document... It is important staff are trained in whichever scales are chosen to ensure consistency of their use within the team and an understanding of their limitations and purposes. This section only considers general principles” (Intercollegiate Stroke Working Party, 2012, p.30).

In current practice, occupational therapists and physiotherapists provide feedback to patients through verbal communication of progress, or outcome measures. However, non-formalised feedback has the potential to contain a degree of subjective and/or inaccurate analysis (Talvitie, 2000). Therefore, therapists often use set outcome measures to assess rehabilitative progress, which have been evaluated in the literature (reliability, responsiveness, validity, etc.) (Quinn et al., 2009; National Stroke Association, 2006). Outcome measures come in a number of forms for assessing different areas. Scales that are particularly applicable to this research evaluate ROM in the upper-limb and the patient’s ability to conduct ADL. Some examples of these types of outcome measures include the Barthel Index, National Institute of Health Stroke Scale (NIHSS), Rankin Scale, Glasgow Outcomes Scale, Scandinavian Stroke Scale, The Timed Walk and the Frenchay Activities Index (Quinn et al., 2009). A more thorough description of these outcome measures can be found in Appenix H

These outcome measures allow for a robust and standardised way of assessing upper-limb motor control. However, as described above, the National Clinical Guidelines for Stroke do not recommend any particular one for use in the NHS. There are a large amount of these outcome measures and this can make it difficult to maintain a structured care pathway. For example, there are over 200 ADL scales and research has previously shown that some of these can potentially produce qualitative and ambiguous data (Shah et al., 1989), with refinement sometimes needed to detect clinically important differences (Gompertz et al., 1993).

Duncan et al. (2000) stated that there was no consistency in the selection of outcome measures, or the timing of assessments. The National Audit Office (2010, p.8) have stated that it is “difficult to assess the cost-effectiveness of long term care provision because of a lack of outcome measures”. Despite developments over the last decade, stroke patients are still not adequately assessed for rehabilitative purposes (Skinner and Turner-Stokes, 2006).

One pertinent type of outcome measure, which currently provides quantitative data, is that of goniometry. Goniometry allows for the assessment of ROM, and can be used to assess the upper-limb. In this type of assessment, a goniometer, as shown in Figure 2-1, can be used to measure minimum and maximum ROM, manually, by a therapist. However, although goniometry allows for a more objective measure of upper-limb functionality, it can be time consuming and evidence has shown that goniometry displays inaccuracy rates, shown to be anywhere from ± 5 degrees up to 14-23 degrees (Clapper and Wolf, 1988, Garcia-Elias et al., 1989, Hayes et al., 2001).



Figure 2-1: A Goniometer

The use of technology has been suggested as a way forward, and evidence for this area shows improvement in outcomes. Research has shown that motion tracking could potentially provide quantitative and objective assessment data. It has been recommended that ways of providing highly technical biomechanical data to therapists/patients, in a usable manner, could assist in motor skill re-learning.

There is a focus on cost saving, alongside improving care, within the NHS and a way to achieve this could be through creating “more with the same, not more of the same” (Appleby et al., 2010, p.1). It is possible that physiotherapy and occupational therapy services could be streamlined through the automation and increased quantification of rehabilitative assessment of the upper-limb in stroke patients, which can sit alongside current outcome measures, to create a more holistic approach. If an occupational therapist and/or physiotherapist can be presented with biomechanical

data at first contact with a patient and, at each session thereafter, therapy could be optimised and patients could receive more direct therapy time. One way to achieve this would be to utilise motion tracking technologies to provide these biomechanical data.

2.2 - Motion Tracking as an Assessment Tool for Upper-Limb Motor Control.

A method for assessing motor control in the upper-limb is through the use of motion tracking technology. Motion tracking allows motion patterns and estimations of body poses to be devised through computer analysis (Alexander et al., 2010). This can be used to evaluate the movement of the upper-limb by evaluating aspects, such as speed and smoothness of movement. Assessment may be performed by breaking down the components of motor control or through using the technology to calculate existing outcome measures. Motion may be detected through the placement of markers on the individual and the recording of the movement of these markers; or through special markerless motion tracking cameras, which can identify a human shape and track various aspects of its movement. These two types of tracking and their use within upper-limb motor control assessment in stroke patients shall be discussed in the following sections of this thesis.

2.2.1 - Examples of Marker-based Motion Tracking Systems

One method for performing motion capture is through the placement of markers on the patient. An example of this, when used in stroke upper-limb motor control assessment, is demonstrated by Timmermans et al. (2010). Timmermans et al.

utilised a Philips Research Stroke Rehabilitation Exerciser (a full rehabilitative suite with a patient and therapist station), shown in Figure 2-2. The Philips Research Stroke Rehabilitation Exerciser uses “wireless inertial sensors for measuring joint kinematics, an active exercise board which is capable of interaction with real-world interactive objects and a Personal Computer (PC) with touch screen via which exercises are offered and feedback on performance is provided” (Timmermans et al., 2010, p.115).

Figure 2-2: Using the Philips Research Stroke Rehabilitation Exerciser for ADL. These include: A: Sensor placement and garments. B: Example of drinking from a cup. C and D: Examples of eating with knife and fork.



(Timmermans et al., 2010)

Timmermans et al. used a method they described as the ‘Technology-supported task-oriented arm training’ (T-TOAT). This method involves the breaking down of ADL into sub-categories. For example, drinking from a cup may be broken down into reach out to cup; grasp cup; lift cup; bring cup to mouth; empty cup into mouth; place cup on table and release cup. Timmermans et al. state that the reason for this categorisation is that “exercise programs can be implemented in technology-supported training” (Timmermans et al., 2010, p.117). The system is also adaptable and is based on exercise physiology and motor learning. The system and software were tested with nine participants. The participants demonstrated improvements after eight weeks on the Fugl–Meyer, Action Research Arm Test, and Motor Activity Log. A lot can be taken from this paper and applied to this research, particularly the breaking down of tasks into sub-categories and the adaptability of the system. However, the low numbers of participants in the research by Timmermans et al. means that large scale conclusions cannot be drawn. Also, participants may have improved on the tests specified without the system present.

Another example of a marker based research system which has been used to evaluate the upper-limb, is the ‘Computer Assisted Rehabilitation Environment’ (CAREN) (Subramanian, 2007). This system includes a Head Mounted Display (HMD), a CyberGlove haptic device and an OptoTrak motion tracking system. The user is able to work in a 3-dimensional virtual reality environment and conduct goal-directed upper-limb exercises for the improvement of upper-limb motor function. This is performed by asking the patient to move their arm towards set targets in the environment, with the movement tracked through the marker based system. To test the system, a comparison was made to targets in a physical environment established

at the same distance as the ones in the virtual environment. The tests were performed with 15 stroke patients and 8 age-matched non-disabled individuals. Results showed good correlation with the non-disabled individuals showing a range of 257–356 mm in the physical environment and 275–370 mm in the virtual environment and stroke patients showing a range of 263–363mm in the physical environment and 275–379 mm in the virtual environment.

Another marker based system that can be potentially utilised in stroke rehabilitation and upper-limb assessment is the Vicon motion capture system, a marker based commercial motion tracking system (Hingtgen et al., 2006). Hingtgen et al. used a Vicon workstation to evaluate upper-limb activity using a kinematic model, developed specifically for this research. This is an important aspect of any motion tracking system, as the initial data must be turned into clinically relevant data, and kinematic analysis must be performed in order to achieve this. Hintgen et al. tested 8 adults who had suffered a stroke and analysed the accuracy of the system. They were able to successfully quantify the movement and demonstrate greater velocity in unaffected arms of the patient when compared to the affected arm.

One popular use of a motion tracking system is demonstrated by Nintendo's Wii™. The Wii is a low cost, commercially available gaming system (Deutsch et al., 2008) and could potentially be used in stroke rehabilitation and upper-limb assessment. The 'WiiMote' (The Wii's remote control) can be utilised as a handheld pointing device and although its efficacy is unproven within a rehabilitation setting, studies have demonstrated promising results.

Mouawad et al. (2011) carried out an experiment using the Wii as a rehabilitation tool. In this experiment seven patients utilised the Wii over a two week period. The authors claim that clinically relevant improvements were made with mean performance time decreased from 3.2 to 2.8 seconds and Fugl-Meyer score increases from 42.3 to 47.3, however, the small cohort warrants further trials to validate the results fully.

Celinder and Peoples (2012) also utilised the Wii in a similar manner. Nine stroke patients used Wii Sports as a supplement to traditional therapy. Qualitative analysis was drawn from this in the form of semi-structured interviews and field notes. The results showed that use of the Wii helped increase variety and engagement, whilst helping to overcome specific obstacles and challenges. These reported results provide evidence for the additional benefits of using such tools in stroke rehabilitation and assessment.

However, it should be noted that the use of the Wii as a tool for stroke rehabilitation and assessment has some disadvantages. Due to the nature of the device, only hand positions in space may be measured and not individual joint movements, limiting the amount of assessment which can be performed.

There is currently a limited evidence base for the use of the Nintendo Wii within stroke upper-limb assessment. Saposnik et al. (2010a), in their initial protocol, have investigated the 'Effectiveness of Virtual Reality Exercises in Stroke Rehabilitation' (EVREST). The importance of this research is identified in their claim that despite advancement in this area, this is the first clinical trial that used the Wii for stroke rehabilitation. In the experiment 21 patients were randomised to either a regular

therapy group or a group which utilised the Wii in therapy. Results produced from this study (Saposnik, 2010b) showed that patients in the Wii therapy group demonstrated an improvement in mean motor function of 7 seconds (Wolf Motor Function Test, 7.4 seconds; 95% CI (Confidence Interval), -14.5, -0.2) over patients in standard rehabilitation.

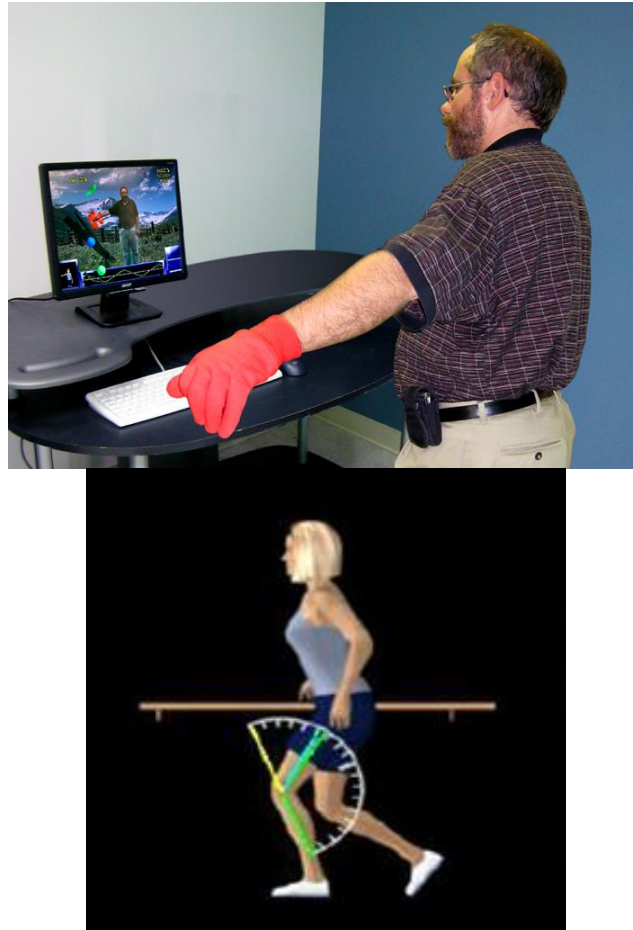
Overall, marker-based motion tracking systems may be used for the assessment of upper-limb, and the low-cost and portable nature of commercial devices such as the Wii could provide a method for achieving this. However, limitations in terms of evidence base, limited feedback (e.g. the Wii only returning the positions of the controllers and nothing else) and time-consumption when setting up equipment (i.e. placing the markers on an individual) provide limitations for this area when using the technology in the clinical environment.

2.2.2 - Examples of Markerless Motion Tracking Systems

An alternative method for the motion tracking of the upper-limb is through markerless tracking systems, which take away the need for markers to be placed on a patient. Markerless tracking employs video capture techniques in order to achieve its goal, allowing real time feedback without head mounted displays, gloves or markers (Weiss et al., 2004).

These systems are being adopted and becoming available commercially, for example, a company called 'Gesturetek' have released a system specifically aimed at the rehabilitation sector which could be used for the assessment of upper-limb motor control; this can be seen in Figure 2-3.

Figure 2-3: Interactive Rehabilitation and Exercise System (IREX)

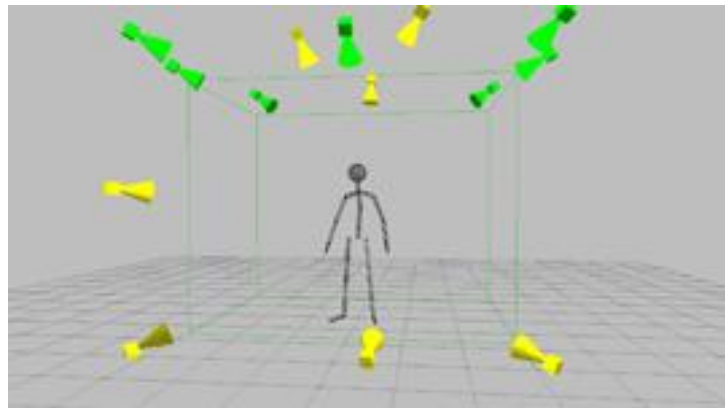


(Source: GestureTek, 2007)

Figure 2-4 shows another commercially available markerless motion tracking system, the Biostage platform from Organic Motion. This is a multi-camera markerless motion tracking system, with cameras set-up around an individual to create a 3 dimensional representation and record motion.

A further commercial system is the 'EyeToy' for the Sony PlayStation II (Huber et al., 2008). The EyeToy is an off-the-shelf low cost gaming application, and represents one of the first large scale commercial attempts to employ a markerless motion tracking system.

Figure 2-4: Biostage Platform from Organic Motion



(Source: Organic Motion, 2012)

Another system to be developed, which is low-cost, portable, and could be suitable for the clinical environment, is the Microsoft Kinect system. This is a one-camera system originally designed for use with Microsoft's XBOX 360 console, and could be applicable to stroke rehabilitation (Chang et al., 2012). Due to these attributes, the Microsoft Kinect has been selected for use in this research. The reasoning behind this, including further details of this system, will be discussed in more depth in section 2.3 - The Use of the Microsoft Kinect as a Tool for Assessing Upper-Limb Motion.

These systems could potentially be used for the assessment of upper-limb motor control in stroke patients. Allin et al. (2010) actually created a specific algorithm for tracking the arm of stroke patients using multiple cameras in markerless systems, such as the biostage platform. The system divides the arm into three segments (upper-arm, lower-arm and hand). It has been evaluated using two methods; the first of these was to compare the system to the commercially available marker based tracking system Vicon (Vicon, 2012); the second of these was to evaluate the system with seven stroke patients using the upper extremity section of the Fugl–Meyer Score. The system demonstrated positive results, confirming that the “average absolute discrepancies between 15 infrared markers measured by a VICON and 15 corresponding virtual markers measured with a parts-based tracker to be 80 mm, with a standard deviation of 5 mm” (Allin et al., 2010, p.8).

Various devices now exist, and are commercially available. However, as previously described in this thesis, research must now be performed to identify how to make these systems suitable for the clinical environment. This research will particularly focus on the Microsoft Kinect technology and how it can be used within the clinical environment, and a discussion of this will take place later in this chapter.

2.2.3 - Data Processing when Analysing Upper-Limb Motion

A difficult area which affects all motion tracking systems, and has to be taken into account for assessing upper-limb motion control, is the way in which data is processed in order to review the tracked motions. This processing requires human body models, such as a 3-dimensional skeleton, a volumetric model (Tao and Hu,

2003) or other various kinds of kinematic models (Cheung et al., 2005). There are a range of algorithms that have been used in order to achieve this processing, that estimate human motion (Mündermann et al., 2006).

2.2.4 - Advantages and Disadvantages of Motion Tracking in Upper-Limb Motor Control Assessment

When using marker based systems, there is a requirement for special cameras and equipment (Tao and Hu, 2003). The markers that are placed on a suit or on the skin restrict movement causing problems with realism (Zheng et al., 2005). There are also problems with the accuracy of readings as soft tissue can move causing noisy data, the marker itself can ‘wobble’ or actually move, and, creating standardised spots to place the marker on the body is a problem due to diminishing accuracy levels (Zhou and Hu, 2008). Marker based systems also take sections of limbs as solid entities and employ estimation algorithms in order to achieve motion playback, causing problems with accuracy (Mündermann et al., 2006). In line with these problems, many marker based systems are too expensive for the clinical environment and simply not designed for it, making this technology unsuitable for this purpose. A tool, such as the Wii, may alleviate some of these issues as it provides off-the-shelf, affordable availability, which could be suited to the clinical environment. Some promising studies have been shown in this area; however, there are certain limitations to what the Wii may show, as it effectively only demonstrates the position of 2 markers (the controllers) in space and provides no analysis of movement in the body, so there is no way to assess whether the patient is conducting the correct movement or

performing compensatory movements. The Wii may be suited to the rehabilitation environment, when utilised for basic exercise and motivational activities. However, it does not currently provide enough data to analyse the upper-limb successfully and is therefore currently outside of the scope of this research.

Markerless motion tracking may be able to relieve some of the problems set out above, but this may come with a trade-off in terms of accuracy levels. Also, markerless based motion tracking still has problems with depth, occlusion, appearance deformation, kinematics issues (Tao and Hu, 2003), line of sight and the true animation of human motion (Zhou and Hu, 2008). Again, markerless motion tracking systems may be expensive and unsuitable to the clinical environment.

However, a recent progression in terms of technology, has been in the development of commercially available off-the-shelf devices, which allow for markerless motion tracking. If it can be shown that these systems are capable of providing a high enough accuracy level to be suited to the clinical environment, whilst still meeting needs such as portability and cost, then they may be utilisable within a rehabilitation setting. As previously stated, this research shall use the Microsoft Kinect technology to learn whether such a system can be created which is adapted to the clinical environment, deriving needs through a user-centred design approach.

2.3 - The Use of the Microsoft Kinect as a Tool for Assessing Upper-Limb

Motion.

A technology that has recently been developed is a markerless commercial motion tracking system, the Microsoft Kinect (see Figure 2-5). It is a single-camera system

originally designed for use with the Microsoft Xbox 360 console and can be used to track up to 20 joints in the ‘skeleton’ of the player, which it displays on screen. The Microsoft Kinect is available at a low price (below GBP£200), making it affordable in the clinical environment.

Figure 2-5: Microsoft Kinect



Chang et al. (2012) state that the Microsoft Kinect could be a valuable tool for stroke rehabilitation and shows high promise for clinical settings and in remote environments.

A system has actually already been developed which could be used for rehabilitative purposes with the Microsoft Kinect, which could allow for upper-limb assessment. The system allows for programs to be developed using the Microsoft Kinect at a quicker rate through the use of a user interface and is called the ‘Flexible Action and Articulated Skeleton Toolkit’ (FAAST) which allows for rapid game development (Suma et al., 2011). The authors explain the system as follows:

“FAAST considers two broad categories of information from the sensor: actions and articulated skeletons. Articulated skeletons consist of the positions and orientations for each joint in a human figure, and are useful for virtual reality and video game applications in allowing direct body-based control of a virtual avatar. FAAST retrieves these skeleton joints from the OpenNI drivers and transmits them to the end-user application” (Suma et al., 2011, p.245).

Suma et al. state that they developed their own methodology for streaming skeletal data at each joint as a six-degree-of-freedom tracker. This could be a useful toolkit within this research and could allow for rapid product development. The only issue, at this current point in time, is that end users are asked to initially stand in a calibration pose with their arms held in the air, a position that most stroke patients would find difficult to achieve.

Current upper-limb rehabilitative assessment games have already been developed for research purposes and include tasks such as ‘reaching for objects’ and ‘cognitive challenges’ (Lange et al., 2011). 20 participants were recruited into this study (10 of which had suffered a stroke), alongside 10 clinicians. A game was developed which was goal-directed; it involved collecting gems, while driving through a mine and placing them in a cart. The distance and angle of the gems was altered according to the patient. This paper demonstrated the use of usability testing to gain initial feedback on the system. Participants asked for more instructions when using the game; better visual effects were identified as a need, as users struggled to see the gems and 3 participants stated that they would like more of a ‘story’ within the game. These are important aspects, as any rehabilitation/assessment tool developed

must provide ample instructions as cognitive issues can be a problem within this patient group. However, most of the patients stated that they found the system highly motivating and challenging, complying with the principles of goal-driven tasks and therapy. Any assessment tool could eventually be placed within a full rehabilitative system. This could potentially involve the use of gamification to improve motivation and help alleviate time pressures on clinical staff.

A study, which has been performed to demonstrate the effectiveness of the Kinect within rehabilitation, utilises a methodology that could be used for upper-limb motor control assessment (Chang et al., 2011). Chang et al. developed a 'KineRehab' system which was used by the participants whilst in wheelchairs. The participants were asked to carry out certain movements and these were assessed using gesture recognition. The participants were assessed using an ABAB system. The authors describe this as four stages of an experiment, with A demonstrating a non-intervention stage, followed by phase B in which an intervention phase is introduced, followed by another repetition of each of these phases. It was stated that the amount of movements, which were correct, were higher at B than at A. However, more research is needed with more than the two utilised participants to prove this result. A point, raised in this paper, is with regards to the motivational factor that the Microsoft Kinect can provide, and how mundane tasks can be made increasingly more interesting. However, this is performed with a group of students, and further validation with patients would be required to prove this.

It was also stated that the therapist using the system believed it provided excellent feedback and patients would benefit from it by increasing their motivation.

Although, this would require further validation as the therapist had been involved in the research and their opinion is open to bias.

Clark et al. (2012) state how useful the Microsoft Kinect could potentially be as a tool for stroke rehabilitation, describing how the reference points provided by the system are comparable to that of a standard commercial motion tracking system at a much lower cost.

Table 2-1 shows the results of a number of functionality tests performed on the Microsoft Kinect (Livingston et al. (2012) provide more details of these tests in their paper ‘Performance measurements for the Microsoft Kinect skeleton’).

Table 2-1: Kinect Specifications

Measurement Type	Measurement
Range	1.2–3.5m
Noise	1.3mm at 1.2m (standard deviation 0.75mm) 6.9mm at 3.4m (standard deviation 5.6mm)
Accuracy	5.6mm with a standard deviation of 8.1mm
Latency	one skeleton: mean 146ms (maximum 243ms) two skeletons: mean 234ms (maximum 386ms)
Resolution	lateral resolution of 3mm (0.086°)

(Source: Livingston et al., 2012)

Leyvand et al (2011) discuss how the optimum measurement range for the Microsoft Kinect is 1-3 metres, with accuracy improving as the user moves closer to the 1m range. As the user will predominantly be in the same gross body position during assessment, the system will prompt the user to stand at a distance of between 1-2 metres from the Kinect camera, eliminating difficulties with detection range.

The accuracy of the Kinect is currently to within 5.6mm, as stated by Livingston et al. (2012). A stroke patient, when using the system, may often make movements which require a large ROM (above 65° at any one joint), making a 5.6mm inaccuracy level of low significance. Fernandez-Baena et al. (2012) specify a mean inaccuracy level, when measuring ROM on the Kinect, of 8.63 degrees.

To place this data in perspective, various authors have released papers stating that the current method for measuring ROM, namely goniometry, also displays inaccuracy rates, shown to be anywhere from ± 5 degrees up to 14-23 degrees of inaccuracy (Clapper and Wolf, 1988, Garcia-Elias et al., 1989, Hayes et al., 2001), demonstrating a similar and possibly greater inaccuracy level to that of the Microsoft Kinect. However, there are other additional issues with goniometry. Goniometry has been shown to have a low inter-rater reliability ($R=.53$ (Petherick et al., 1988)), whilst the Kinect is automated and eliminates the need for different testers. The Kinect is also capable of taking a high amount of measurements (up to 30 Frames Per Second of every joint) (Microsoft, 2012a), which is also without a therapist present, in comparison to the time it takes a therapist to measure each individual

joints ROM (for which a separate maximum and minimum position must be measured).

Researchers have also utilised the Microsoft Kinect in collaboration with other sensors to create greater accuracy rates. Bó et al. (2011) state that the potential when combining the Microsoft Kinect with other systems (e.g., accelerometers) is encouraging.

Stroke patients predominately suffer from reduced movement rates (speed and smoothness) (Rohrer et al., 2002). These reduced movement rates should limit the effects of noise and latency in line with a speed-accuracy trade off. The inaccuracy rate of only 5.6mm in large ROM activities demonstrates that noise and latency do not cause an underlying issue when used for this purpose.

It must be taken into account that the Microsoft Kinect has a limit on the types of movement it is capable of tracking. The Kinect is capable of measuring large movements such as flexion/extension at the elbow and abduction/adduction at the shoulder. However, it is not capable of detecting smaller movements, such as the pronation/supination movement at the wrist joint that is essential to most ADL. This may be solved through combination with other sensors if required.

In summary, initial studies have shown that the Microsoft Kinect may be suitable to the assessment of the upper-limb in stroke rehabilitation, due to -its low-cost nature and off-the-shelf availability. Initial studies also show that accuracy levels should be high enough for use in the assessment of the upper-limb. However, research is now required in how to best utilise the device for this purpose. Systems must be developed, which are clinically-driven and tested from an early stage according to

user-centred design principles, and deployed in a manner that proves a high enough accuracy level when utilised in the clinical setting.

2.4 - Alternative Technologies used in Stroke Patient Upper-Limb Motion

Assessment (from which lessons may be learned).

This section discusses alternative technologies, which have previously been used in the assessment of stroke patient motor control. This is done in order to create a holistic view of the field and derive lessons, which may be learned from other areas.

2.4.1 - Virtual Reality

Virtual Reality is a technology applicable to the area of the upper-limb during stroke rehabilitation, as it can motivate the user to interact with a system in a setting other than the real world. This could create a more meaningful, task-oriented assessment environment.

There is evidence that virtual reality within upper-limb stroke rehabilitation can be effective and used for assessment purposes. Pridmore et al. (2007) describe experiments in which virtual reality was used to make hot drinks, allowing for the evaluation of cognitive functionality in the upper-limb. Pridmore et al. suggest improvement in patient activity, however, limited results were described when used in a clinical setting, as only 9% of patients were able to use the system. It is an important aspect in the development of a clinical system, that it must be tested at an early stage in the clinical environment, as some of these technologies are not

originally designed for this setting. The idea of ‘immersing’ a user to drive motivation may also be a factor in the success of a system.

In a Cochrane review (Laver et al. 2012), a summary of research in virtual reality for stroke rehabilitation was provided. The review described virtual reality as a promising field, particularly within rehabilitation; however, studies were too small and too few to draw any large scale conclusions. Laver et al. stated that side effects produced through the use of virtual reality (e.g., headaches and motion sickness) were not reported within any of the studies. It was therefore concluded that this was a safe technology to utilise in stroke rehabilitation. However, this information was only based on small studies and could be contradicted in a future large study. Laver et al. discussed the need for future research, which is also applicable to other virtual reality devices in this area. They concluded that “more randomized controlled trials are required. Furthermore, research is required to determine which types of virtual reality programs are most effective; which type of patient is most likely to benefit; at what point in their rehabilitation it should be used; and how acceptable the approach may be to stroke survivors” (Laver et al., 2012, pp.20-21).

2.4.2 - Augmented Reality

Augmented reality is a method of combining computer generated data with data from the real world (Leventhal, 2009). Silva et al. (2003) describe augmented reality as a view of the real world with computer graphics placed over it. Augmented reality is similar to virtual reality, with the difference of overlaying graphics on top of the real

world and mixing the two (augmented reality is sometimes referred to as mixed reality), as opposed to the immersion used in virtual reality.

Therefore, augmented reality has similar benefits to that of virtual reality; however, augmented reality could potentially offer something more. Kozak et al. (1993) question how easily skills learned in virtual reality could be transferred to the real world and Lindén et al. (2000) stated that things that do not appear in the real world should not appear in a rehabilitative technology, as it can do in virtual reality programs. As augmented reality utilises the real world with objects added to it, this can create a more meaningful rehabilitation environment and allow for more life-like assessment activities.

For example, Choi (2011) used motion tracking data from an ‘eGlove’, called the Novel Ubiquitous Rehabilitation System (Ubi-REHAB), in combination with an android device to create an augmented reality rehabilitative system for stroke patients. The e-glove sends feedback via Bluetooth to a mobile phone, where a 3D reconstruction of the hand is shown in a scene in which objects can be interacted with. This system could be useful for assessing motor control in the hand; however, the device is yet to be substantiated in a healthcare setting.

Al-Issa et al. (2012), in their report entitled ‘Augmented reality applications in rehabilitation to improve physical outcomes’, described the state of augmented reality research as follows:

“The existing evidence on the effectiveness of augmented reality applications in rehabilitation within a physical context is limited and the technology appears not yet at the stage for general practical use. However, the encouraging results indicated that

further research in this area should be undertaken and more patient-based studies conducted” (Al-Issa et al., 2012, p.26), aligning it to virtual reality with limited clinical based studies at the early stage of development.

2.4.3 - Robotics

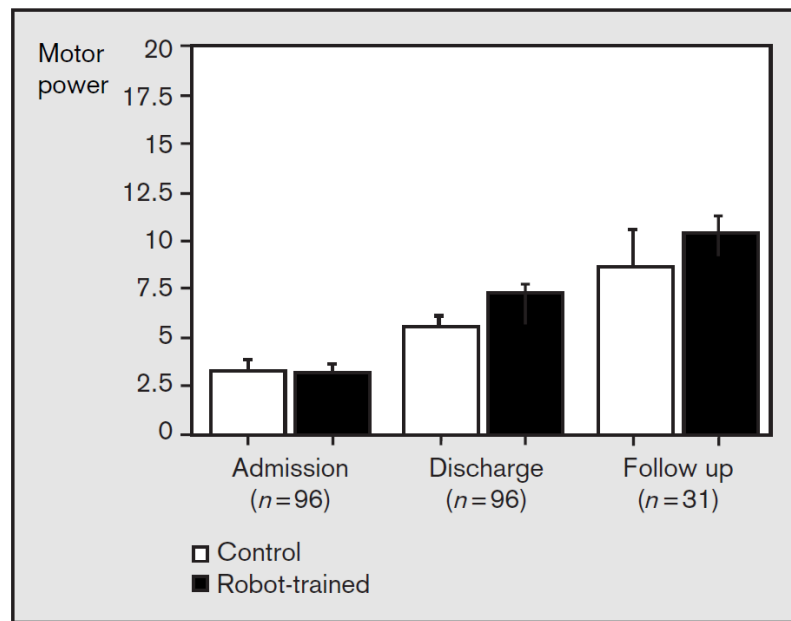
Robotics could be another method for providing assistance to therapists in stroke rehabilitation. Riener et al. (2005) and Volpe et al. (2001) claim that sensorimotor outcomes in patients that have suffered from a stroke can be improved through the use of robotics, with the ability to increase the productivity and quality of care provided. These improvements are a result of increased therapy time through the use of automated sessions and increased repetition coupled with increased efficiency, whereby the therapist is allowed to concentrate on other aspects of the patient’s recovery. These are principles that can be applied to any rehabilitative, motor control assessment system.

Repetitive, increased activity through robotics has allowed for demonstrable improvements in stroke patients. For example, a major work in the area is the Massachusetts Institute of Technology Manus (MIT-Manus) (Hogan et al., 1995) which has been tested on 96 patients and demonstrates an improvement in outcomes as shown in Figure 2-6.

Functional tasks have also been assessed using robotics. Abdullah et al. (2011) developed a robotic device, which allowed patients to carry out ADL whilst having movement assisted by a robot that used force feedback. The system was able to move through 5 degrees-of-freedom and had a memory of correct movements for

ADL, assisting the patient in performing these. This could allow for testing of passive range of motion in stroke patients and focus on task-oriented training and assessment. Twenty patients used the system, randomly assigned to a robotic or non-robotic therapy group (with 1 withdrawal). When tested using a Chedoke Arm and Hand Activity Inventory 7 point score (CAHAI-7), 11 patients assigned to the non-robotic group improved by 30%, whereas the 8 patients in the robotic group improved by 62%.

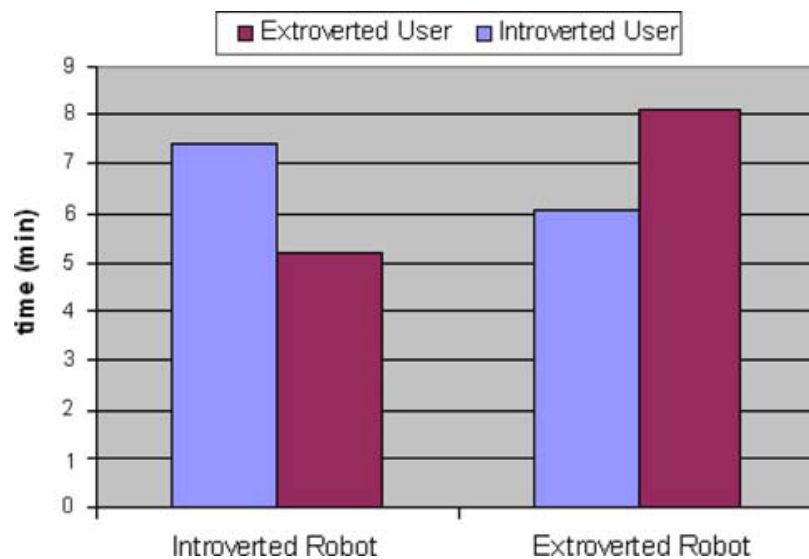
Figure 2-6: Mean \pm standard error Motor Power Scores (max 20) for patients using the MIT-Manus



(Hogan et al., 1995)

Alamri et al. (2008) defined 5 common exercises (which were task-oriented) for testing. They attempted to quantify motor control assessment, and develop a clinical decision support system. In order to achieve this task, they utilised three pieces of haptic equipment (namely the cyberglove, cybergrasp and cyberforce armature). The system has been tested with healthy volunteers and showed expected range and speed statistics. The authors state that in future work they aim to gather baseline data with 50 participants in order to eventually compare with stroke patients.

Figure 2-7: Comparison of feedback type individuals using a comparative feedback robot. The Y column shows time spent performing rehabilitation.



Robotic system can allow for additional feedback to a patient. Tapus et al. (2008) studied human-robot interaction and developed a robot that spoke to the patient in a certain manner, dependent on whether they possess an introverted or extroverted personality type. Results showed a connection when pairing introverted users with the introverted robot and vice versa. A summary of this is shown in **Figure 2-7**.

Feedback, and how this is presented must be analysed when creating an assessment system, to be in a suitable format for the end-user.

2.4.4 - Haptic Technologies

Haptic technology allows for a sense of ‘touch’ to be felt by a user, when utilising a system (Laycock and Day, 2003). These are predominantly in the form of objects which provide ‘force feedback’ and create a sense of touch. When assessing patients for upper-limb motor control, this sense of touch can allow for a more realistic interaction with a computer system and allow for more accurate assessment.

For example, in the EU-funded project GENTLE/s (Coote et al., 2003), a haptic master device has been used in research which evaluated subjects’ upper-limb motor control assessment. In this research, patients were asked to perform three activities, namely a reach-touch test (reaching and touching separate targets), a cup placement test and a test which asked the participant to ‘catch’ falling virtual objects (Adamovich et al., 2009).

Figure 2-8: SensAble Phantom Omni



(Source: Streng, 2009)

An example of an off-the-shelf product used in stroke rehabilitation research is the Phantom Omni (shown in Figure 2-8). Lövquist and Dreifaldt, (2006) describe how a serious game was designed, called the labyrinth, which acted as a maze for the user to pass through. The users moved through the labyrinth using the omni. The system was tested on three stroke patients. Observation and interviews were conducted with these patients and promising results were demonstrated, with patients agreeing that this system was highly motivational. Psychological models of goal setting were also used in this paper, looking at reward systems, difficulty, multimodal feedback, environment design, intuitive tasks and new possibilities.

Another haptic technology is that developed at Rutgers University, namely the Rutgers master II. This device was tested with three participants; demonstrating mixed but encouraging results and further studies are required to warrant the validity of such a system (Burdea et al., 2010). Burdea et al. state that the acceptance of the technology and the willingness of the patients to use it were high; demonstrating a desire by stroke patients for such a technology to be used.

Haptic technology could allow for the assessment of function through the testing of passive movement and to provide a more realistic environment, which allows for a sense of touch, in which patients are assessed. However, better programs designed directly for stroke patients that have a sound evidence-base in the clinical environment must be developed before this is achievable.

2.4.5 - Brain-Computer Interfacing

A novel technology that has moved to the forefront of Stroke rehabilitation research is that of 'Brain Computer Interfacing (BCI)'. It is described by Vallabhaneni et al. (2005) as a communication mechanism using neural activity of the brain.

A study based in the Agency for Science, Technology and Research has recently used BCI to assist stroke patients in building new neural pathways for communications with the upper-limb (Ang et al., 2009). The system combined a MIT-Manus haptic device and an Electroencephalography (EEG) cap. Significant improvement was shown by an experimental group (n=18) after using the equipment for a 4 week period. However, further tests are required to validate this as it is still in the prototype phase.

The annual BCI research awards (g.tec medical engineering GmbH Austria, 2012) demonstrate some of the latest research within the field of BCI. Certain projects submitted for this competition discuss how a system can utilise neural activity to support motor function rehabilitation. A 2012 award nominee presented the idea of the brain-body-robot interface (B²RI), discussing how they wish to integrate brain activity and bio signals (e.g., changes in blood pressure) directly into physical therapy (Zimmermann et al., 2011). The authors state that when passive movement therapy is currently conducted, the brain is not utilised and this system provides a way of reading brain activity and using this for rehabilitative purposes. However, testing has only been performed with 7 volunteers and requires clinical substantiation.

Another tool that has been used in an attempt to quantify motor control in stroke patients is the analysis of movement synergy. Kung et al. (2010) describe how they measured these synergies using kinematic, kinetic, and EMG (Electromyography) signals to develop biomechanical and electrophysiological indices. They compared twelve stroke patients with able-bodied individuals (individuals who had not suffered a stroke before) and demonstrated differences in movement synergy. The important issue raised by this paper, and in particular for this research, is that if individual movements are to be broken down into sub-categories for quantification, it must be remembered that the synergy of these movements, between different parts of the body, are still an important part of neurological rehabilitation and must not be overlooked.

BCI is an area that could become utilised within the field of stroke rehabilitation and assessment in the future, with certain lessons which can be drawn. However, the technology is still in its infancy and is not yet suitable for the clinical environment.

2.5 - Summary

This chapter reviews the literature based around the use of technology in the assessment of the upper-limb in stroke patients.

The initial section of this chapter presents a review of the associated problems with upper-limb assessment in the NHS. It portrays how currently occupational therapists and physiotherapists have methods for obtaining data in a verified manner. However, there is often a trade-off between resources required and amount of data which can be derived. With resources becoming gradually strained in the NHS, it is believed

that new technologies could be used to supplement current outcome measures, providing a methodology to gather data which would otherwise require a high amount of resources to obtain.

The next section of this literature review identifies the motion tracking technologies which have been used to address this. An array of motion tracking technologies used in research and commercially are described. This technology could help to automate tasks, but is often costly and not suitable in the clinical environment. New gaming technologies such as the Wii and the Microsoft Kinect may provide adequate solutions to this with their portable and off-the-shelf availability. However, research is now required to evaluate how these systems can be adapted to the clinical environment, and exactly the best format they can be used in to evaluate upper-limb motor control in the most efficient and accurate manner.

The additional technology groups presented in this review provided some additional lessons which must be taken into account when developing upper-limb assessment technology. For example, it is useful to provide motivation and feedback which can be given to the patient through quantitative objective measures, with in-depth details and a breakdown of biomechanical data in an understandable format. Assistance from devices can also be given to patients to help 'drive' them in assessment tasks (e.g., haptics). These assessments can be task-oriented; functional and life-like; safe and varied; with more adaptability than what is currently available. The technologies also provide time-saving options, allowing for the optimisation of therapist time, and possible automation of assessment activities.

However, most systems currently exist in the pilot stage and have little clinical evaluation, particularly at an early stage of development, and are often performed with low participant numbers and short time scales. This can present a difficulty in user acceptance of any technology with therapists and patients. Finally, any system must be evaluated for cost, portability and accuracy, areas which are all important for clinically based technology, and trade-offs between these areas require research in order to evaluate which is the optimum technology and associated approach.

Chapter 3: Methods

The assessment of Upper-limb motor control for stroke patients within the NHS is currently performed through a set of validated outcome measures. The literature review in this thesis identified areas in which motion tracking technology (amongst others) has been utilised to help improve these outcome measures, by adding additional quantitative measurements. However, as discussed, technology developed in this field can lack clinical input at an early stage of the design, particularly when it comes to placing users at the centre of this process.

This research aimed to develop a system through a user-centred prototype design approach, which incorporates therapists throughout the entire design and development procedure, to produce a clinically driven system. To achieve this, four stages are used, including initial requirements gathering as part of requirements elicitation, design and development of the prototype, verification to see if the ‘product has been built right’, and validation, to see if the ‘right product has been built’ (Sommerville, 2011). This chapter will present the methodologies used to produce these four stages.

3.1 - Requirements Elicitation

The aim of this part of the research was to elicit the needs of occupational therapists and physiotherapists in the NHS, when assessing motor control of stroke patients. This was an important part of the user-centred design process, as it was imperative to

derive exactly what it was that the therapists wanted from such a system. Noyes and Baber (1999) discuss how an issue in the design process is eliciting from users exactly what it is they do and what they need. They describe requirements elicitation as the critical first step to design knowledge-based systems.

3.1.1 - Elicitation Study Design

The study was performed by conducting non-participant observation of therapy sessions with therapists and stroke patients, followed by semi-structured interviews with therapists. This data collection provided an understanding of current practice, and of the views of therapists regarding strengths and weaknesses of existing assessment methods and how therapists thought that technology could help in this area.

Initially, non-participant observation was conducted. This is described by Bryman (2012) as a method whereby a researcher observes a social setting but involves themselves as little as possible. This type of observation provides additional data to that which will be gathered by interviews (see below). Noyes and Baber (1999) state that this is valuable when designing systems, as it can indicate what people do in reality. Noyes and Baber state that this is in contrast to methods, such as questionnaires and interviews, as people are not responding to what the experimenter wants, and therefore not altering answers in order to portray what they are meant to do at work, presenting bias in questions. Non-participant observation also allows for the observation of the user in their natural environment, as when taken out of this (e.g., into a usability lab), behaviour may change.

Non-participant observation was followed by semi-structured interviews, with therapists, which were undertaken at two NHS stroke units. Interviews were used as a way to elicit the needs of the therapists (Holloway and Wheeler, 2013). They include open ended questions (these can be seen in Appendix I), with general structure being driven by the interviewer. This allowed for some structure to remain in the study, whilst allowing the interviewee to discuss needs of the end-user which the researcher may not have been aware of, and hence may have missed from a more structured topic guide. Therefore, semi-structured interviews allowed the researcher to derive a resource rich set of data from which the requirements could be derived, whilst also avoiding issues such as poor response rates which can be associated with methods such as questionnaires (Noyes and Baber, 1999).

3.1.2 - Recruitment

Two Research and Development departments within the NHS were asked to circulate emails to occupational therapists and physiotherapists, asking whether they would like to be involved in a non-participant observation study and/or an interview regarding the current methods of rehabilitative assessment for stroke patients in the NHS. Occupational therapists and physiotherapists were then able to volunteer for the study by contacting the researcher by email or phone.

Chartered occupational therapists and physiotherapists were then selected, based on the following inclusion/exclusion criteria:

Inclusion Criteria: All occupational therapists/physiotherapists must be chartered and work within the NHS in the field of stroke rehabilitation.

Exclusion Criteria: All occupational therapists/physiotherapists must have more than one year experience in practice.

3.1.3 - Sample

10 full interviews were conducted. 12 participants were recruited in total, so 2 pilot interviews could be conducted. Pilot interviews can increase the interviewer's confidence in the scenario (Holloway and Wheeler, 2013) and allow for refinement of the structure of the interview, so the structure can be edited at the start, so the correct aspects can be elicited.

In addition to this, two therapists were also recruited for non-participant observation. One therapist agreed for a single therapy session to be observed, whilst another agreed to two therapy sessions.

3.1.4 - Protocol

For non-participant observation, the researcher introduced himself to the therapist and patient at the beginning of the relevant therapy session, took consent (see 0), and then observed; interacting as little as possible within the session. Field notes were taken by the researcher.

For semi-structured interviews, pilot interviews were initially conducted through the use of a topic guide, and when these were complete, relevant adjustments were made. The main interviews involved the use of the updated interview topic guide in which the interviewer could ask additional questions in order to elicit supplementary responses (Bryman, 2012). These interviews used the topic guide shown in Appendix I.

3.1.5 - Analysis

The main outcome of the non-participant observations, were the field notes taken by the researcher. The aim of the field notes is to provide rounded qualitative data with descriptions of the different steps taken to complete tasks (Noyes and Baber, 1999), in this case, the separate tasks undertaken by the therapists during the session. These notes will portray the overall events which occur (e.g., measurement of ROM), and the steps taken to produce these. These observations are detailed in this thesis as shown in section 4.1 - Findings from Non-Participant Observation.

The semi-structured interviews were recorded, transcribed and qualitative thematic analysis was undertaken. Thematic analysis was used with the aim to identify ‘what’ is described in the interview, as opposed to ‘how’ (Holloway and Wheeler, 2013). This is to break the story down into themes that are common across all of the interviews, in order to describe ‘what’ it is that the therapists are saying.

In order to achieve this, transcripts were read independently by the researcher and one of the supervisors, Professor Gillian Hundt (GH). To identify emergent themes, the researcher Christopher Golby (CG) and GH compared the themes they had identified across the interview, in relation to ‘what’ the therapists were attempting to say. A template based on the agreed themes from these interviews was used to create a summary of each theme, including the relevant quotes from the interviews which portray the themes. These themes and the subsequent summaries are presented in section 4.2 - Findings from Semi-Structured Interviews.

3.1.6 - Ethics

Ethics permission was requested from the UK National Research Ethics Service (NRES) through the ‘Birmingham East, North and Solihull Research Ethics Committee’ (REC). The reference number is 10/H1206/90 and the confirmation letter for this can be seen in 0. The study was further approved by local NHS trusts who granted access to hospitals for the purposes of the study. The study adheres to ethical principles as set out by the REC and local NHS trusts.

The therapists only contacted the researchers when they wished to be involved in the study and participation was entirely voluntary. Information sheets were provided to the therapists at least 24 hours before interview or observation. They were also asked to sign an informed consent sheet before taking part in the study, as shown in 0. All participants signed a consent form, granting permission to be recorded. Participants were also informed that any information collected would be kept strictly confidential and anonymous. Each participant was assigned an identification number, which at no point was linked to their personal data. Transcripts were created from the recordings, which remained anonymous, and recordings were deleted at this point. No details of therapists or patients were placed in the non-participant observation notes.

3.2 - System Design and Implementation Methodology

After gathering user needs in this research, a prototype system which was derived from these needs was created to help evaluate this area further. This section introduces this process and the methodology for system implementation.

3.2.1 - Defining of Requirements

In order to create the system, a set of user requirements were defined, which describe functional requirements (i.e. specifically what the system should do, in terms of functions) and non-functional requirements (i.e. characteristics of the system as a whole) (Sommerville, 2011, p.85). Sommerville states that these are a structured set of points that describe the system by its external behaviours.

These are a set of points used for system design, and are a direct summary in point form of the user needs which are elicited in Chapter 4: Requirements Elicitation.

3.2.2 - Design and Development of System

The next process, which was carried out in this research, was to turn the user requirements into a working prototype.

It was important that a prototype system, which is used to gather these details could be created quickly enough, yet with the robustness to be deployed within a healthcare setting. In order to achieve this, and in line with the aims of developing a prototype, it was decided that a rapid, iterative development approach (Sommerville, 2011) was adopted in which a system could be developed against the user needs derived from the requirements elicitation, resulting in a rapid prototype.

This process involved taking off-the-shelf technologies with pre-defined Software Development Kits (SDK) and Application Programming Interfaces (API). In order to align with the rapid, iterative development approach, it was decided that any hardware would use the same programming language for speed of use.

The process also involved using software libraries, which were already in use for the proposed technology. The main development tasks involved adapting the code to suit the user needs.

Chapter 5 describes the design decisions which were made, based around the user needs developed through the requirements elicitation. An overview of the system is given, followed by a more detailed look into each of the sections of the system.

3.2.3 - Review of the Prototypes Technical Limitations

An issue in testing prototypes is that they are not fully finished systems, and will contain certain limitations (Sommerville, 2011). After the description of the system design and development, any particular technical limitations of the system that were discovered during the development process are also discussed.

3.3 - System Verification

Before the system could be deployed in a healthcare setting, a verification stage was required. This allowed for testing of the internal and technical workings of the prototype. Therefore, the system was verified with able-bodied individuals (i.e. individuals who had not suffered a stroke), outside of the healthcare setting, comparing the prototype's results with the assessment results provided by a chartered physiotherapist.

3.3.1 - Verification Study Design

To verify the system, a study was designed, in which able-bodied individuals used the system. This is to see whether the prototype met its requirements, by checking the internal functions work as well as they were planned, and in this case, checking whether the system measures upper-limb ROM accurately (Sommerville, 2011).

Therefore, verification was performed by comparing manual goniometric measurements taken by a Physiotherapist with measurements taken version of the system which measured ADL. These measurements were taken over a three week period and the rate of error compared between the therapist, and the system.

3.3.2 - Recruitment

The study population was initially selected from within the University of Warwick, UK, via the use of email contact to advertise the study. This email was sent to several departments. However, a snowball sampling method (Bryman, 2012) was used, whereby the study could be recommended to participants from outside of the University.

3.3.3 - Sample

The study had 10 able-bodied individuals to use the ADL version of the prototype, over a 3 week period. A chartered physiotherapist also took, the same measurements the system takes, with a goniometer, during the same session.

The population was a non-probability sample (Bryman, 2012). Exclusion criteria meant that all participants selected for the study, as detailed in an initial email, stated that they had no knowledge of any kind of injury or illness, whereby the ROM in their upper-limbs would be affected and could fluctuate over a course of three weeks. Participants were also asked this at the beginning of each intervention.

3.3.4 - Protocol

The protocol for testing began by asking participants to carry out a set of ADL that required a large ROM, as prompted by the system. These were as follows:

- Combing of the hair (particularly the back of the head).
- Pouring water from a pitcher into a cup.
- Picking up a telephone from a stand and holding it to the ear for 5 seconds.

Participants ROM was also taken by a chartered Physiotherapist separately, in the same session. Participants were asked to return twice after the initial test at weekly intervals. At this point the test was repeated. This was in order to plot ROM over time. Half of the participants had their ROM taken by the physiotherapist first at each session, followed by the system, and vice-versa.

3.3.5 - Analysis

The analysis in this study aimed to verify the prototype with 10 participants. In order to achieve this, the error made by manual goniometry as taken by the Physiotherapist and the system were compared.

Measurements were taken using the Kinect camera (ROM at the shoulder and elbow in both arms, resulting in 4 measurements, taken from 10 participants). An additional movement at the wrist was taken by the watch used in the system, resulting in an additional 10 measurements being taken (1 per patient).

To evaluate this, a standard deviation, taken by calculating the difference in measurement from each week, was used to compare ROM taken by the chartered Physiotherapist, and ROM as calculated by the system. In order to achieve this, a paired sample, two tailed t-test was used to evaluate whether statistical difference did or did not exist. This resulted in a total of 50 measurements.

The intention of the tests was to distinguish if the new tool was 'not inferior' to manual methods, by proving statistical equivalency. Initially, a paired samples two tailed t-test (Howitt and Cramer, 2005) was conducted to evaluate whether or not any statistically significant difference could be identified in the 50 measurements. However, if no difference was identified, this simply proves that there is no difference, but not that the measurement types are statistically equivalent. Therefore, a test developed by Tryon (2001) and later improved by Tryon and Lewis (2008), using inferential confidence intervals was utilised in order to assess statistical equivalency.

3.3.6 - Ethics

This study adhered to strict ethical guidelines as established by the University of Warwick and were scrutinised as part of the PhD upgrade procedure in the School of Health and Social Studies. Participants were asked to sign an informed consent sheet

upon agreeing to participation as shown in Appendix B. They were presented with an overview of the experiment at this stage. Participants were also debriefed after the study.

3.3.7 - Hypothesis

The prototype should produce ROM measurements that are statistically equivalent to, or more accurate, than manual goniometry taken by a physiotherapist. It was expected that the automated assessment should be completed in a significantly shorter time than manual goniometry. As the participants are able-bodied, it was expected that the measured ROM repeated over the experimental period would not fluctuate significantly, assuming none of the participants attain an injury or condition that affects their upper-limb function within that period.

3.4 - System Validation with Stroke Patients

Validation is an intrinsic part of prototype evaluation, assessing whether the system meets the users' needs; going beyond checking it against specifications, but demonstrating that it does what the user wants and expects it to do. It is important, as it involves seeing how the tool may support the user, identifying strengths and weaknesses and putting the user in a position to suggest ideas for improvements and additional needs and requirements (Sommerville, 2011). This was performed by placing the prototype in a formal healthcare setting, with therapists and stroke patients, for up to 15 weeks.

3.4.1 - Validation Study Design

The aim of this part of the study was to validate the device developed with therapists and stroke patients. This involved trialling the device for 15 weeks within the UK NHS, at two Midlands based hospitals, with chartered Occupational therapists and physiotherapists, who would in turn select suitable patients. Each hospital used a different version of the system (measuring ADL, or in-therapy).

The therapists were asked to use the system with these patients for the time period established. The researcher would not be present for all uses of the system, but returned once every 2-3 weeks in order to evaluate issues with the system, and take field notes regarding user comments and suggestions. It was the therapists' decision as to how long each patient used the system for (this was due to ethical considerations when using a prototype system).

3.4.2 - Recruitment

The researcher began recruitment for this experiment by contacting lead occupational therapists and physiotherapists within two separate NHS trusts. These occupational therapists and physiotherapists were asked to circulate emails which asked for participants to partake in the study.

In addition to this, occupational therapists and physiotherapists that were interviewed in the requirements elicitation phase of this research were again contacted to ascertain whether they wished to be involved in an evaluation study for the technology.

Therapists received email contact through one of these sources, and the researcher awaited a response before further contact was made. Once therapists were recruited, they were invited to an 'open day' at the University of Warwick, where they were given an introduction to the device and presented with more details regarding the study.

The occupational therapists and physiotherapists taking part in this study were asked to select patients for participation, according to the following inclusion/exclusion criteria:

Inclusion Criteria:

All occupational therapists/physiotherapists must be chartered and work within the NHS in the field of stroke rehabilitation. They must have their own patient cohort and be able to select patients for the trial.

Occupational therapists/physiotherapists shall select patients whom they feel are capable of completing the study. All patients selected must have suffered a Unilateral Stroke prior to the commencement of the study. Patients must be able to stand, in order to use the prototype effectively. Patients must be English speaking. Any patients selected must be capable of using the technology to a reasonable standard without assistance (final decisions regarding this matter will be determined by the relevant therapist).

Exclusion Criteria:

All occupational therapists/physiotherapists must have more than one year experience in practice.

Patients involved in this study must have no pacemaker or other implanted metallic device. They must also have no progressive neurological disorder such as Alzheimer's or no terminal life expectancy condition such as renal failure or end stage AIDS. Patients must not have suffered from a stroke associated with illicit drugs.

The therapist, at this point, decided if they felt the patient was capable of completing the study and the length of time for which they felt the patient could be involved.

3.4.3 - Sample

This section of the research used 3 physiotherapists and 6 occupational therapists. 5 stroke patients were selected for this trial by these therapists.

3.4.4 - Protocol

The evaluation of the system took 15 weeks (12 weeks at 1 hospital, and 15 weeks at another). Each hospital had a different version of the system (measuring ADL, or in-therapy).

The system was setup in two separate NHS hospitals. The researcher was present in the initial week of testing at both hospitals. At this point, the researcher was able to answer questions regarding the initial setup and design of the system. The researcher left the physiotherapist/occupational therapist with the device after this initial stage, but was always available via phone or email, in case of any issues. The researcher also returned every 2-3 weeks during the course of the research in order to observe

how the system was being used. At this point the researcher took field notes regarding general opinions and concerns about the system, as well as adding ideas generated by therapists/patients.

At the end of system testing the therapists were asked to give their views of the device in its current form, through a short, semi-structured interview. These interviews were used to explore how effective the system was during its time in the hospital, and what ideas the therapists had for improvement of the system. The interviews also queried whether the therapist, through the use of the prototype system, had developed any ideas for the enhancement of current assessment methods for stroke upper-limb motor control assessment. The topic guide used during the interviews is shown in Appendix K.

It must be noted that minor changes had to be made to the original research design. However, these changes are accounted for in these methods and the latest version is shown here. Any changes which were made are detailed in Appendix E.

3.4.5 - Analysis

In order to validate the system, field notes were taken by the researcher throughout the evaluation period.

At the end of the evaluation period, semi-structured interviews were conducted to evaluate the views of therapists with regards to how the system performed; how they felt upper-limb assessment systems for stroke patients can be added to the current

NHS Structure, and, if they had any further ideas for additional components and technologies which would be useful in future versions of such a system.

The analysis of the interviews from this study (performed after each section of testing) was performed through coding of emergent themes (as previously discussed in 3.1.5 - Analysis). The interviews were recorded, transcribed, and, qualitative thematic analysis used to evaluate them. A thematic template was created for this purpose which is presented in Chapter 6: System Evaluation.

3.4.6 - Ethics

This study was reviewed by the UK NRES, part of the NHS. The Nottingham 2 REC reviewed the study and granted it favourable ethical approval. The confirmation letter for this can be seen in Appendix C, with approval number 12/EM/0077. The study was further approved by local NHS trusts who granted access to hospitals for the purposes of the study. The study adheres to strict ethical principles as set out by the REC and local NHS trusts.

Informed consent for the assessment phase of this study was sought through an information sheet (sent at least 24 hours before the trial commenced) and a consent form (signed prior to commencement) as shown in Appendix C, following NHS guidelines. All participants were informed that participation was voluntary and all information would be kept confidential and anonymous. All interviews with therapists were semi-structured, using a topic guide.

If a patient was unable to provide written consent, verbal assent was taken as an audio recording. This would be performed by stating the title of the research, patient identification number and date, then reading each section on the informed consent sheet and asking the participant to say yes if they agree, before asking the participant to state the following: 'I give my full consent to take part in this research'. At no point were any of the patients' personal data recorded. During this study, all participants were given identification numbers to preserve anonymity.

A copy of each of the participant's signatures were kept on an informed consent sheet. However, these were kept separate from any recordings, field notes and transcripts, so the participants could not be identified. Informed consent sheets contained only a participant identification number which could not be linked to personal data. These are stored in secure storage at the University of Warwick for 10 years after the study completion date, in compliance with the University of Warwick's research data management policy.

The email addresses and telephone numbers of occupational therapists and physiotherapists are the only personal details, which were kept during the course of the study. This was in order to make contact regarding meeting times. These details were not linked to any data taken from the study and were deleted after its completion.

When recording, participants were referred to by number and any names or details mentioned within the recording were eliminated from the final transcripts. All recording data was deleted after the transcript was created.

Any information, taken regarding patient assessment, had only an identification number and records of performance (numbers detailing the ROM at three separate joints), and therefore could not be linked to an individual. The system automatically generated this number, and the therapist was asked to keep a record of this for future therapy sessions. The research team also kept a record of this number. However, this was kept on a separate computer to any assessment data, in a secure location at the University of Warwick. Only the research team had access to this identification number (as a backup in case of loss), which always remained at the University and was deleted at the end of the study.

During the study, any data that was collected was again kept in either a password protected computer (which only the researcher had access to) or a locked cabinet, both within a secure location at the University of Warwick.

3.5 - Summary

This chapter outlines the key methods which will be used in this research. This is split into 4 components, namely requirements elicitation, system development, verification and validation.

The requirements elicitation exercise involved the non-participant observation of 3 NHS physiotherapists / occupational therapists in a stroke rehabilitation session. This was followed by semi-structured interviewing of 10 physiotherapists / occupational therapists regarding their views surrounding the assessment of upper-limb motor control in the NHS, how it is currently performed and how it could potentially be improved upon.

A rapid prototype system was then developed, based on the requirements elicitation. The system was capable of assessing the upper-limb motor control in stroke patients. The system then underwent evaluation in two stages, verification and validation. To verify the system, a study was conducted in which 10 participants used the system over a 3 week period, using the ADL version of the system. At the same time, a chartered Physiotherapist took ROM measurements of the 3 movements assessed by the system (abduction/adduction at the shoulder, extension/flexion at the elbow and pronation/supination at the wrist). Error was then calculated across the 3 weeks by the Physiotherapist and the system, and compared statistically using an equivalency test.

Finally, a clinical validation of the system was conducted. This involved deploying the system for 15 weeks in 2 NHS stroke wards. 9 physiotherapists / occupational therapists were selected to use the system. Therapists used the system with 5 stroke patients for this time period, assessing the patient at least every 3 weeks. At the end of this time period, all therapists underwent a semi-structured interview, in which advantages / disadvantages of the system were discussed, alongside a discussion surrounding ideas which have arisen as a result of using the technology.

Chapter 4: Requirements Elicitation

This chapter presents the results of the requirements elicitation phase of this research. The aim of this was to generate initial therapist opinion about what was felt to be problematic in the field, how the therapists believed this could be corrected, and how this could be improved through the use of technology. This was performed through a set of interviews and non-participant observation. Details of the methods used can be found in Chapter 3: Methods. The chapter includes a presentation of the qualitative results and a critical discussion regarding these results.

4.1 - Findings from Non-Participant Observation

Three non-participant observation sessions were conducted, with three separate patients. Two sessions were with an occupational therapist and one was with a physiotherapist.

4.1.1 - Non-Participant Observation of Occupational Therapist with Patient 1

Patient one had suffered a stroke in December 2009 and was observed in March 2011. They had made an exceptional recovery. The patient described how they had been unable to even walk at first, but now their upper and lower limbs were all highly functional, albeit some minor motor control problems due to the stroke. The only factors which had stopped the patient making a fully-fledged recovery were, in fact, problems prior to the stroke; an injured shoulder which affected ROM; a

previously broken finger which also affected ROM; and finally balance difficulties which were heightened by the stroke.

The therapist detailed before the session that this was not an initial assessment, and as this had been performed previously, there would not be a great amount of assessment taking place. However, once arriving in the session, it became very clear that the therapist was constantly assessing the patient during every movement and between each exercise. It should be noted how integrated assessment is within rehabilitation and it is not always conducted as a separate process.

The patient began the session supine. Whilst in this position, the therapist began to evaluate their ROM. The therapist was mainly focussed on the abduction/adduction of the left shoulder joint and the extension/flexion of the elbow joint. Supination and pronation were constantly happening during this time, however, the patient was not aware of this (the therapist later explained that they pay particular attention to this supination/pronation at the elbow joint as this is a highly problematic yet very common problem in individuals with stroke).

It became very clear, as the session continued, that the therapist was constantly checking the individual's ROM in various joints. What was particularly striking was how ad-hoc this procedure was. The therapist checked the patient's ROM and then decided whether the patient had progressed. Rarely would the therapist write or check notes to see the patient's progress. Even when notes were taken it became clear that the procedure was ad-hoc.

Throughout the session, during all activities and assessments, the therapist would be constantly supporting various body parts of the patient (e.g., supporting the elbow

joint whilst checking flexion, extension and deviation of the wrist joint). This was due to the patient being unable to hold their limbs in certain positions, which would allow the therapist to assess other joints. This was particularly apparent when the patient was asked to hold their arm in the air, where it simply dropped down at a slow speed, with the patient completely unaware of the problem.

A task was then conducted in which the therapist held their arm high in the air and asked the patient to touch it ten times. The patient was able to do this but they were clearly having difficulties. What was quite noticeable at this point was the change in the patient's behaviour as they seemingly became emotionally agitated at the fact that they struggled to carry out the task. Motivation from the therapist was a factor at this point as the patient may have lost the determination to continue.

The next test, which was conducted, was a sensitivity assessment. The patient was asked to rate their sense of feeling on a scale of one to ten when the therapist touched firstly the front of their hand, and latterly the back of their hand. The patient commented at this moment that they had much more feeling on the palm of their hand than on the back. They also commented that they were unable to place their hand in hot water. A test of sensitivity then continued whereby the patient was asked to close their eyes whilst the therapist touched the end of the patient's fingers with a pen. The patient was then asked to state which digit had been touched. This sense of touch is integrated into therapy and should not be forgotten about when designing rehabilitation systems.

The therapist then moved on to testing the patient's grip. The patient spoke about how they experienced pain whilst grasping objects and this prevented them from

practising this. At this point the patient also mentioned that their vision was poor and they had recently had a fall because they were unable to see a chair clearly and attempted to sit down too far in front of it. The therapist now carried out a grip test, asking the patient to grasp and release a cup ten times. Whilst they were performing this exercise, they were asked to keep their elbow firmly on the table in order to support it (as done previously by the therapist). Grip tests were affected by mild spasticity in the hand. Another problem which occurred was the patient moving their shoulder forwards in order to 'propel' their arm forwards to avoid using muscle groups. The therapist stated later that this is a very common compensatory movement in stroke patients. Any system that is developed could evaluate compensatory movements.

The patient commented that they receive a lot of motivation from their caregiver and the therapist later commented that there is a far greater improvement in patients who have a caregiver. The therapist was providing constant 'hints' to the patient throughout the session (e.g., put weight on your left leg, keep your back straight). The patient did state that they required constant 'hints' as they struggled to concentrate on two things at once. This idea of motivation and feedback is something that must be incorporated within rehabilitation.

4.1.2 - Non-Participant Observation of Occupational Therapist with Patient 2

Patient 2 arrived for their therapy session in discomfort due to experiencing back pain, which the therapist believed to be not directly related to the stroke. This patient also appeared to have made a good recovery from stroke, although it was difficult to

ascertain a detailed level of information due to cognitive difficulties of the patient coupled with stress from the pain in their back.

The first point that the therapist commented on was the patient's ROM (an apparent improvement of around 40 degrees abduction, with extension at the elbow up to around 80 degrees). The therapist stated that this was a "massive improvement". However this was from the therapist's memory.

The occupational therapist now proceeded to conduct a task whereby they placed their hand in the air and asked the patient to touch their hand ten times. The patient carried out this task efficiently, although appeared to be in a lot of discomfort with back pain.

The therapist then asked the patient to pour some water into a cup. The patient completed this but again with back pain. However, it was noticeable that some movements were not correct when pouring the water (e.g., pronation of the forearm). Their elbow was supported by the therapist during pouring of the water.

The therapist then asked the patient to carry out some simple tasks involving folding and rolling a towel. The patient completed this but with some incorrect movements. The therapist was constantly telling the patient minor details that they needed to correct. They were asked to continue this at home, as well as practising picking up and releasing various sized objects. The idea of constant motivation is something that should be provided in rehabilitation.

The therapist now proceeded with strength tests involving a dynamometer and a pinch gauge. This was the first point at which quantitative data was taken and compared with previous sessions.

The therapist completed the session by asking the patient to close their eyes, whilst the therapist touched each of the patient's fingers with a pen, and asked the patient to state which digit had been touched. The patient struggled with this and the therapist stated that it was something that would need to be addressed at a later point.

This session was eventually ended prematurely due to the patient's back problems (which were not directly linked to the stroke) with the therapist recommending that the patient seek the advice of a GP (General Practitioner). Any system developed must take into account that problems such as this can be prevalent amongst stroke patients due to their condition, and must be able to account for this.

4.1.3 - Non-Participant Observation of Physiotherapist with Patient 3

This observation was a small part of an initial assessment session with a new patient that had just began treatment at the rehabilitation hospital. The session was short due to the patient having speech and hearing impairments (no speech or hearing) before their stroke. As stated by the therapist, a sign language expert was due to arrive at the hospital to assist the patient in their rehabilitation; but as this had not yet happened only minimal assessment was performed. There were two physiotherapists present for this session (one therapist was an assistant to the second therapist, and had entered the room purely to assist with certain tasks).

The session began by asking the patient to move their feet. First of all, plantar and dorsi flexion at the ankle were assessed, however, problems were already arising in communicating to the patient how to move. The patient managed to conduct this task, however, even though the patient was able to flex their right foot, it was still a slow movement and was inhibited by the stroke. Communication is something that is important in rehabilitation systems. Speech and language issues can appear amongst stroke patients, and systems must be able to cope with this.

The physiotherapist then checked the patient's flexion and extension at their knee joint. This was the first instance at which resistance was used, pushing lightly on the patient's ankle to see if they could still extend their leg. The patient struggled to completely extend their leg and needed some help with completing this task. It must be noted that assessment systems which are developed must take into account the differentiation between active and passive movement.

The patient was then asked to perform knee raises. Again resistance was applied but the patient managed to complete this exercise.

The physiotherapist then proceeded to assess the patient's upper-limbs. First of all, flexion and extension at the shoulder joint were tested. The patient was asked to fully flex their arm at the shoulder and place their hand behind their back. The patient was unable to achieve this without assistance and actually experienced pain around their right scapula, so the Physiotherapist ceased this task. Any system developed must allow the patient to stop if they are feeling any form of pain or discomfort.

The patient was then asked to extend the fingers on their right hand. The patient kept ‘flicking’ their right hand, becoming increasingly agitated at their inability to control their fingers. The physiotherapist moved on to another test promptly.

The patient was then asked to flex their arm at the elbow joint. The patient needed assistance in performing this task with their right arm. At this time, the physiotherapist also checked for abduction at the shoulder, however, with pain still present, this task was ceased.

Both physiotherapists then proceeded to help the patient stand (the patient had originally been in a wheelchair). The patient seemed to struggle with this and it seemed to take a lot of effort by the physiotherapists. The development of any technology that requires calibration will have to take into account the fact that patients may be unable to stand. The patient also required a support strap placed around their back. The physiotherapists used this strap to support the patient while standing. One physiotherapist began checking for hyperextension at the knee joint whilst the patient was standing, something that can happen to a stroke patient and must be observed by the therapist.

The physiotherapists then moved the patient to the bed in the room where they sat him down so they could perform further assessment. A length of time was now used where the patient was trying to tell the physiotherapists something, hindered by speech difficulties. The patient used a board with letters on to try to spell out what they wanted to say. They also tried writing sentences down on a piece of paper. These speech and hearing difficulties were present before the stroke, but with patients potentially suffering these problems as a result of stroke, any technology

that is developed must take this into account. The patient appeared anxious during this period and the Physiotherapist constantly gave motivational support and this appeared to be an important part of rehabilitation. The patient managed to state that they used to walk and drive and that they have only been walking a small amount since the stroke. The physiotherapist then told the patient that they would set goals that targeted allowing the patient to walk again. Rehabilitation technologies could potentially incorporate this idea, helping to set goals with the patient and therapist, and recording progress against them.

The patient was then asked to move to supine position. They were asked to plantar flex their feet and flex their knees whilst carrying out extension at the hip joint. The patient's right knee was not stable during this task (as a result of the stroke) and they were asked to concentrate on keeping their knee straight. The patient was then stood up again and the physiotherapists helped the patient walk out of the room. The patient seemed very confident in performing this activity. It was decided that the therapy session would cease here.

4.1.4 - Summary of Findings from Non-Participant Observation

Non-Participant observation was essential in understanding the context and setting in which the system would be used. These observations allowed a set of system requirements to be generated as follows:

- Quantitative objective feedback is needed, which can be performed at set intervals.

- It would be advantageous to have a breakdown analysis of movement at different joints; however, it is still important to be able to compare them for synergy purposes.
- The patient may be unaware that they are not moving as they intended (e.g., their arm drops when a therapist asks them to keep it raised, without their knowledge). Therefore, the system needs to focus the patient on a set task, whilst it analyses the movements and provides a breakdown of these.
- There should be motivational feedback provided to the patient.
- The system should be adaptable to provide tasks adaptable to the patient's capabilities.
- There must be quantitative feedback presented over time, so there is data to compare current motor control capabilities against.
- Feedback should be presented to the user in various forms (e.g., visual, auditory)
- The system should differentiate between active and passive movement.
- Any assessments should not be overly time-consuming due to potential cognitive issues in stroke patients.

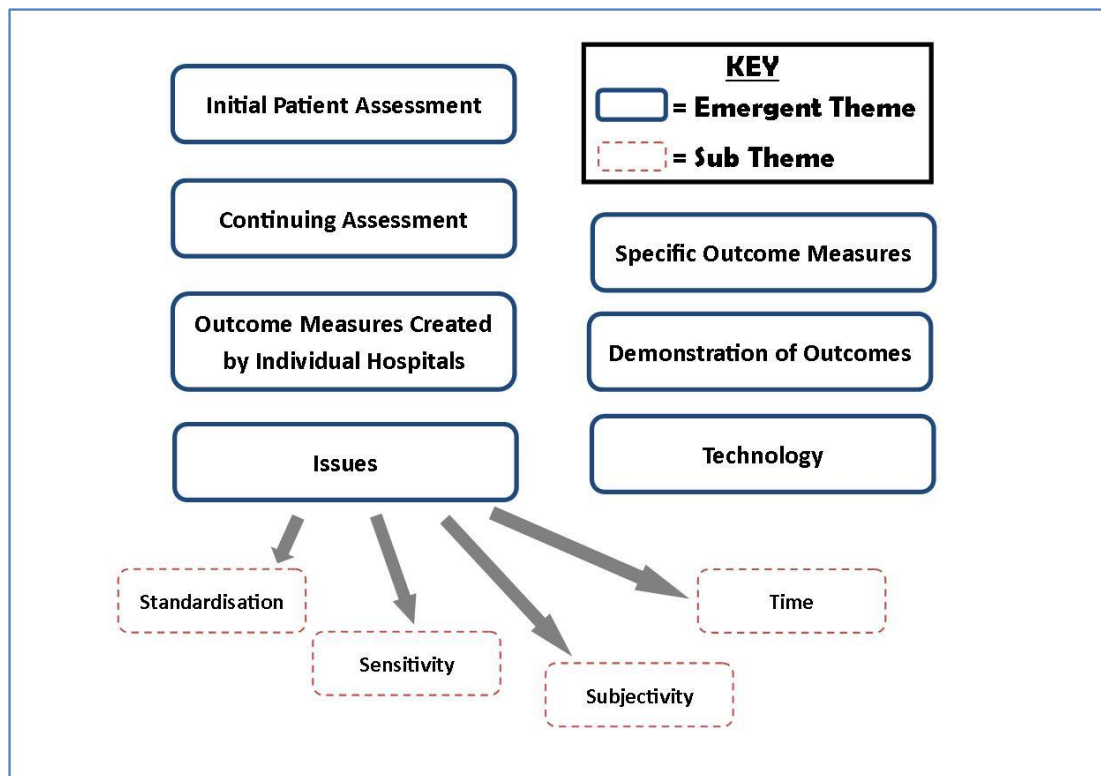
4.2 - Findings from Semi-Structured Interviews

Certain changes were made after the two pilot interviews. Additional prompts were added, asking about the strengths and weaknesses of assessment methods. A prompt was also added in question 6 to ask for differentiation between stroke care at 6 months and 1 year. Finally, in question 7, a prompt was added to ask the therapists

about the comparison of the UK to other countries in terms of long term rehabilitation at the post 6 month stage. The results of these pilot interviews were not included in the study sample.

Thematic coding, as previously described, led to the creation of seven emergent themes shown in Figure 4-1. The theme ‘issues’ had four sub-themes.

Figure 4-1: Template of Emergent themes and sub-themes used to analyse interviews



Each theme and sub-theme is described in the sections below.

Ten participants (5 physiotherapists and 5 occupational therapists) were interviewed and these are referred to as PT1-5 and OT1-5 below.

4.2.1 - Initial Patient Assessment

Therapists who were interviewed during this study spoke of an initial formal assessment which they conducted when they first met stroke patients, which was usually standardised. 8 out of the 10 therapists that were interviewed commented on this: *“I do my initial assessment right at the beginning”* (PT4).

“So initially when the patient comes in they would have a full assessment” (OT1).

“They will all be assessed initially” (OT4).

OT3 also added that this was performed by a *“qualified member of staff”*.

Some therapists said that they used pre-made outcome measures: *“Using the Berg Balance when I first see them”* (PT3).

“We start when they first come in; we have an initial interview which is a standardised assessment..... What we do is baseline assessments where we look at washing and dressing. We usually do that when they first come in” (OT2).

The time at which the initial assessment is completed is considered crucial within rehabilitation, and the National Clinical Guideline for Stroke state that staff must *“ensure patients are seen by at least one member of the specialist rehabilitation team within 24 hours for assessment”* (Intercollegiate Stroke Working Party, 2012, p.15).

Two therapists referred to this: *“In terms of assessments, the earlier the better; we aim to assess people within 24 hours”* (OT5).

“We assess patients when they first come onto the Ward. We assess them the first day that we meet them” (OT4).

4.2.2 - Continuing Assessment

8 out of 10 therapists reported that they did not use standardised outcome measures at set periods. One therapist mentioned how important regular assessment is: *“You obviously need to continue to assess along the way”* (OT3).

However, there appeared to be a lack of standard practice with regards to the timing of interventions and the differentiation between formal and standardised assessments and on-going assessments. Some therapists spoke of how they use ad-hoc assessment every time they see a patient: *“Realistically, every time I see a patient I reassess”* (PT3).

“I do a brief assessment of tone every time I actually see a patient” (OT1);

“Every time you treat a patient you are re-assessing” (PT2).

“They are assessed every time we see them. Each patient we see we would do a mini assessment” (OT4).

“With upper-limb treatment I actually do an assessment of their tone before I start a session ... so I’ve got a starting point and an end point” (OT1).

Other therapists described set times for assessment, but these varied greatly: *“they [patients] are not reviewed on a regular basis”* (PT1).

This was a recurring response (mentioned unprompted on eleven separate occasions), with therapists stating:

“There is no timeframe where patients need to be assessed after X amount of time, it is just an individual clinicians decision to decide” (OT5).

“We assess them almost every single day” (PT2);

“On a Stroke Unit [disability] is measured weekly” (PT1).

“[Assessment happens] most days in inpatient, so we will be reassessing everyday” (OT5).

“I guess the assessment process is on-going, so it isn’t just ‘assess’ and then ‘rehab’, it is ‘assess’ then intervention, then ‘re-assess’” (PT5).

This can make continuing formal assessments difficult.

Therapists were clear that what is assessed changes from session to session, and patient to patient: *“I may reassess everything in a couple of weeks or I may not reassess anything until discharge”* (PT4).

However, this may be down to a patient’s capabilities:

“Sometimes you can do the assessment in one go, if they are able to, otherwise, the assessment can take 2-3 days” (PT2).

“It can be quite tiring and if you have a patient that fatigues quite quickly that might be all you do in that session that day with them” (PT1).

Some therapists also discussed the differing types of assessment they carry out on a continual basis:

“We’ll look at range of movement, muscle strength, proprioception, we’re also looking to see their ability to follow spoken word and gestures, whether they are attending to their affected side, whether they have any compensatory movements” (PT4).

“We will be looking at the range of movement; the power; the sensation and the proprioception; with regards to what is their head movement like; can they turn both ways; the arm movements; are there any tonal deficits; do they have a very low floppy arm or is there a spasticity within it that is limiting the movement?” (PT2).

“Assessment would include discussions with the patient as to what their goals are and what they want to be working towards” (PT5).

“Getting them to see how much they can do independently and how much minimum assistance they need” (PT2).

One therapist spoke of the lack of well-timed, standardised assessments, revealing how there is a lack of decision support tools and was aware that continual assessment needed to happen, however, that there were resourcing issues that prevented this:

“Sometimes it’s wonderful to watch all these people go through these things, but then you just don’t have anything to say well, this is what we’ve done. You’ve seen it, but there isn’t anything formal that is there..... I think that the assessment needs to happen continuously...whether the resources are there to support that is an entirely different issue (OT1)”.

Another therapist added to this: *“We’d want to see them [patients] everyday, but we don’t always have that luxury. We try to”* (OT2).

4.2.3 - Outcome Measures created by Individual Hospitals

In close contrast with initial patient assessment, some therapists described outcome measures that had been created within their own hospital, and only existed in that hospital: *“We in our hospital have a set form we use for occupational therapy and physiotherapy”* (OT4).

“We just use our own assessment form” (OT4).

“We have our own paperwork for upper-limb, washing and dressing (OT2)”.

“We have our assessment paperwork where we look at things like active range of movement and muscle power and function, how well can they walk, can they stand, what is their balance like?” (PT5).

Therapists discussed these hospital specific outcomes by pointing out their limitations.

“The way we get round that here, is on our assessment form, we have a description of what each grade is so only those grades are used. So, whilst it’s not an ideal score, it’s the only one we’ve got in the absence of expensive equipment which we don’t have access to” (PT1).

“We have our own stroke outreach assessment sheet, which does, I must admit contain a lot of general questions.” (PT3).

4.2.4 - Issues

4.2.4.1 - Time Constraints

Eight interviewees described how time constraints affected their ability to perform adequate assessment using assessment scales, particularly with protracted outcome measures: “*Something that stops us using them a lot is the time factor*” (OT4).

“Things that you need to consider is how long the tests are and how much time it takes to administer a test” (OT1).

“The scales are quite lengthy and they don’t always assess exactly what you want” (PT4).

“A lot of them [outcome measures] are quite time-consuming” (OT3).

“They can be time-consuming, so we would try to look for quite a quick scale” (OT5).

One therapist stated that it wasn’t just the timing of the outcome measures but also issues with resources and availability of staff: *“I’d say time constraints [are a weakness], with the proportion of patients to staff...you don’t have the time to spend with one [patient] that you might like to, so you tend to spend that time treating rather than reassessing”* (PT4).

“We wouldn’t have time to treat patients and use the scales” (OT4).”

It appeared that therapists knew the importance of outcome measures but had to balance the time involved in assessment with the need to treat:

“If we did review them [after an extensive period of time] and pick up problems, we wouldn’t have the capacity to provide them with therapy again” (PT1).

One therapist pinpointed another problem with paperwork:

“When you’ve been given extra paperwork that you have to fill in and government standards where they are telling us to do that daily we wonder whether we have any time left for therapy...we need to fill in paper work and sometimes we possibly don’t do the OT assessment that we need to. General assessments, kind of slip away, and then you have to make another visit which can have a knock-on effect on your time with that individual” (OT3).

Four therapists also spoke about the difficulty of carrying out long term assessments of stroke patients for rehabilitation, stating how the longevity of stroke rehabilitation and follow up is an issue:

“A lot of our patients come back in to see the doctor at six months but do not get an opportunity to see the therapists” (PT4).

“We don’t really get involved with post one year stroke” (OT4).

“As you get further down the line there are more time limits in the NHS. It is a problem to keep people on for a long period of time” (PT5)

One therapist spoke about how they simply struggle to carry out extensive outcome measures and the lack of confidence that they now have in them:

“We’ve tried doing them [outcome measures] as a team, we’ve tried doing them by ourselves and we just can’t get to do them regularly” (OT4).

4.2.4.2 - Subjectivity

A re-occurring theme was the therapists' belief that there can be subjectivity in outcome measures. Therapists described how outcome measures are “...*quite subjective really, and the patient score isn't always correct*” (OT2), and that they “*are quite open to interpretation*” (PT1). This theme was mentioned on 21 separate occasions during the interviews, for example: “*A lot of them [outcome measures] can be quite subjective*” (OT4).

“*A lot of things we use are subjective, rather than objective*” (OT3).

Therapists also discussed the subjectivity of specific outcome measures: “*There are bits of the FIM-FAM scale that talk about whether the patient can contribute more or less than 25% of the activity and that is a subjective interpretation*” (PT3).

“*Sometimes, with the goniometer, you have to ask how accurate is it? Especially if it is only one person using it*” (PT3).

Multiple therapists also discussed inter-rater reliability of outcome measures: “*I don't know what the inter-rater reliability is like on all of them. It can be quite subjective*” (PT1).

“*You use two different people, and they will give you two different answers*” (OT4).

“*What someone's 4/5 might be, somebody else might think is a 3/5*” (OT5).

“*I think a lot of it does depend on the skills and the experience of the assessor. A lot of it is quite subjective*” (PT3).

“There is quite a big jump between some of the grades in the scale...it’s very difficult for the next person coming along to know what is the difference between a 4+ or a 5” (PT1).

“It is subjective; somebody testing on the same day with the same patient can come out with a different outcome.... [Outcome measures don’t] take into account different peoples’ experiences ... if I put my hands on a [patient in a] certain way, and somebody else doesn’t, then their assessment can be completely different depending on their experience” (OT4).

One therapist stated that due to these inconsistencies: *“People do not necessarily use them [outcome measures] appropriately. The guidance information on how you carry them out is not always clear” (PT1)*, whilst another professional added how this has a knock on effect: *“Junior therapists, I would actually say they struggle with knowing what to do (OT1)”*.

4.2.4.3 - Standardisation

Another emergent theme in these interviews was the therapists’ concerns surrounding a lack of standardisation based on which outcome measures to use at which point when assessing patients: *“There isn’t a consistent service out there” (PT2).*

“I imagine everywhere assesses slightly differently” (OT5).

“I think often patients are not being viewed as they should. There isn’t a service” (PT1).

“They [patients] are being reassessed, but not in a more formal structure that is being fed back” (PT4).

Therapists described differences in outcome measures between hospitals: *“Some places are not as good at using standardised outcome measures as others” (PT1);*

“That’s just what we use in our hospital [outcome measures], and it will definitely be different to what everybody uses in every other hospital” (OT4).

“I think because it is not a uniform approach, some centres have got better facilities” (PT2).

It was also described that there was a difference between assessments in departments: *“Different departments tend to be towards one side or the other, and that can cause discrepancies between the units” (PT1).*

“It is not standardised [outcome measures] across this hospital site at all” (PT1).

“There’s probably a lack of training at the university level” (OT1).

“We use a range of outcome measures, but we wouldn’t necessarily use the same ones with each person” (PT5).

“We pick and choose which ones [outcome measures] we use with each patient, rather than using the same for everybody” (PT4).

There seems to be agreement that outcome measures can be interpreted subjectively.

Some therapists spoke about the long term assessment of stroke patients for rehabilitation (generally around post six months), mentioning an even larger gulf in standardisation:

“There are so many interventions that can be given. It is a shame that if it’s left for six months and they come in and they have an issue that can’t be addressed so easily - it’s bad news” (PT3).

“Potentially a year down the line they [patients] could improve but they won’t be getting the service” (OT2).

“You often don’t see them [patients] at six months or yearly and they are just told to go back to their GP if there’s any problems” (PT1).

“I personally think long-term monitoring is vital for these patients. At the minute, I think, with all the cuts and added pressures this is something that may be lost” (PT3).

Another problem area was that of regulation between specialties:

“We probably need to have a little bit more standardisation inter-disciplinary wise” (OT1).

“I think often patients are not seen by a multidisciplinary team” (PT1).

One therapist, when talking about results of outcome measures stated: *“I am not actually sure that anybody does anything with the data”* (OT3), whilst another said:

“We are not meeting the standards set out in the stroke strategy” (PT1).

4.2.4.4 - Sensitivity

Three of the therapists that were interviewed described how outcome measures *“don’t always pick up all of the problems the patient may have”* (PT5), with one

stating: *“Improvement in our patients is often quite a small thing to measure and we can see that they have made some improvements but it doesn’t show on the scale. They are not sensitive enough for them”* (OT4).

Two therapists in particular moved on to criticise the various outcome measures available: *“You can make small changes, such as gait, but on a formal assessment this may not show”* (PT5).

“Somebody can score the same on the scale for standing as the last month, but actually their standing has improved massively in terms of alignment and in how they feel about themselves and where we put our hands, but the scale doesn’t show it..... A lot of them have ceiling and floor effects” (PT4).

“I think the difficulty with some of them, such as the berg balance, is an assessment of balance and somebody could potentially score really well on that but when you see them in function they still have balance difficulty” (PT5).

Other concerns that were raised about scales related to cognition and communication issues, which made it difficult to administer outcome measures. One therapist felt that *“all [outcome measures] have got some kind of flaw to them”* (PT1).

4.2.5 - Specific Outcome Measures

Sixteen separate outcome measures were spoken about during the course of the interviews. Each test described had been used by a therapist within the hospital they were employed by. Table 4-1, illustrates the number of different outcome measures and how many times they were mentioned during interviews.

Table 4-1 demonstrates outcome measures used across the two NHS hospital sites, illustrating the variability of outcome measures within departments and between the therapists themselves.

Table 4-1: Different outcome measures and times mentioned

Outcome Measure	Times Mentioned
Rivermead Mobility Index	6
Oxford Scale	8
Berg Balance Scale	9
Range of Movement/Goniometry	8
10m Walk	5
Ashworth Scale	6
Therapy Outcome Measures (TOMS)	4
Barthel Index	6
Functional Independence Measure and Functional Assessment Measure (FIM-FAM)	3
Dynamic gait Index	3
Get up and Go	2
Other Outcome Measures*	5
Total	65

***Other outcome measures are tests which were only mentioned once during the interviews**

Some therapists did make comments regarding the appropriateness of some of these scales: “Muscle strength, we use the Oxford scale, which can be slightly difficult if someone has abnormal tone” (PT3).

“We might take bits from the Berg, like a supported stand, or a functional reach, or a 360 turn, or a 180 turn depending on what level they are on” (PT4).

“I know my colleagues are quite into the Ashworth scale” (PT3).

4.2.6 - Demonstration of outcomes to show progress in rehabilitation

A theme that emerged from the interviews was that it would be desirable to have a method of demonstrating assessment outcomes to patients, staff and families: *“so someone can see where they are [current rehabilitative progress]” (PT3).*

“[It would be useful to have] data we can actually look at from when they first came to us and on discharge” (OT3).

One therapist stated: *“I think it would probably be helpful for both therapist and patient if there was a way of collating all of the measures that are used in a way that ... can be turned into graphs, something quite visual” (PT1),*

Some therapists reported that they tried to collate data visually for patients and their families.

“I try to go by what I feel displays my patient’s progress best to them and other people” (PT4).

“If the patient’s family wants to see that they are getting better you could show them using an objective scale” (OT4).

Therapists discussed a lack of methods for representing the progress of patients: *“Possibly having some kind of visual aid might help the therapist” (PT1).*

One professional claimed that some kind of visual feedback tool would be useful: *“It’s a really good way of assessing people as you can go back and look at it and it is a lot easier to compare”* (PT5).

One therapist also suggested that: *“you could use that kind of information [visual assessment data] to give to commissioners, for instance”* (PT1).

4.2.7 - Technology

One of the topics for discussion in the interviews was whether and how technology could support upper-limb motor control assessment. A variety of technological approaches and ideas were spoken about and discussed during the interviews. A mixed knowledge of current technologies was spoken about, with the therapists generally demonstrating some knowledge of technologies already in use in healthcare systems. A list of the technologies which were discussed can be found in Table 4-2.

Therapists commented further on some of these technologies, stating their opinions on how useful technology could be:

“I think EMG would be a good tool to use” (PT2).

“Muscle stimulation ... is really useful” (PT3).

“We found that the odd few that we videoed really helped gait assessment in stroke” (PT4).

“On a treadmill you could at least see how many steps you did a minute or your resistance or how fast you could walk” (OT4).

“Maybe video, so we can look at speed, so you don’t have to hold a stopwatch and count steps, all at the same time” (PT4).

Table 4-2: Technologies mentioned by Therapists in the Interviews

Technology Mentioned	Therapists
Functional Electrical Stimulation	PT3, PT2
Biometrics	OT1
Video (Gait Analysis)	PT4
Force Plates	PT4
EMG	PT2
Marker Based Motion Tracking	PT2
X-Rays	PT2
Treadmill (Gait Analysis Tools)	OT4
Magnetic resonance imaging (MRI) Scans	PT2

Even though certain technologies were specifically named, therapists also often spoke about processes that involved some sort of technological assistance that was already in use in the stroke rehabilitation environment: *“The occupational therapists use programs for upper-limb where you can assess grip strength and various bits and pieces”* (PT5).

“We have got a couple of systems we use for visual cues and things. We do try and e-mail things” (OT2).

“That’s the only thing we are doing here, introducing technology so none of our assessment forms will be paperwork” (OT5).

As well as therapists conversing about technologies that are already in existence, new ideas for technologies and their uses emerged: *“We could [use technology to] identify, for instance, if the patient’s fatigue is worse at the end of the day, and, this is the task that they find difficult, so we could focus on that”* (PT2).

“I suppose some balance things would be quite useful” (PT4).

“When you go to the cinema, you see people in body markers. It would be nice to have those body markers to have an idea of what peoples’ activity is like over several hours” (PT2).

“In terms of arm function, is there a standardised quick assessment where you could measure range of motion ... that is quick and portable...computer packages could be useful, if there is something you could get your patient to do; function, reaction time, or something to do with the cognitive side. I’m just thinking about driving, a lot of patients want to get back behind the wheel” (OT3).

“An electronic note taker would be good” (OT2).

“I think there is probably more room for tools such as accurate goniometry” (PT4).

The idea of assessment of patients using remote monitoring was also discussed:

“Thinking about being in an office and being able to see somebody in their home would be great” (PT3).

“[Assessment through] exercise programs ... using the computer or television” (OT1).

“Maybe if there was something you can leave with the patient, to help them practise movement” (PT4).

“Probably making use of the computer, or a television, you know to help them with their home programs” (OT1).

OT2 mentioned a process which could be adapted for assessment: *“If you could type in your measurements and heights when you are out on the home visits then it wouldn't take so long to do the report”.*

Some therapists, however, still showed distrust when addressing the adoption of technology. They showed concern about it being expensive or the cognitive barriers for the patients.

“I think hands-on assessments are a better idea, then using technology to do that for you” (OT2).

“Money is an issue; we can't even get the money to buy new uniforms” (OT4).

“Because of cognitive difficulties, some patients don't grasp the technology” (PT4).

Some therapists felt that there is a shift in attitudes towards technology and user acceptance: *“I think a lot of patients; even the elderly patients ... are computer literate and have a computer in the house”* (PT3).

“You’re getting ... younger patients with technology knowledge” (OT2).

There was an acceptance of the use of technologies for supporting post stroke rehabilitation assessment from therapists themselves, with one therapist in particular mentioning: *“I think it [technology] could be used in terms of outcome measures”* (OT1). This therapist also stated that a tool that *“anybody can go and use”* which accurately assesses an individual would be useful. This was mentioned again when a Physiotherapist stated that patients *“quite like having a number”* (PT1) which describes their rehabilitative progress.

OT4 actually spoke about this in more detail: *“From a patient’s point of view, people like things, electronic things, gadgets, you know. This machine is going to measure me and make things better, they would like that”*.

4.2.8 - Coping with Stroke

All interviewees raised the issue of the effects that stroke has on individuals, and this is something that must be taken into account when developing any new form of upper-limb assessment tool.

Assessment should aim to be as functional as possible and take into account a range of areas: *“I think [assessment is needed for] independent living at home. Especially for people who have cognitive difficulties”* (OT1).

“We’ll do our home visit, where we go with the patient, probably for about an hour or so, and it’s really looking at them in their own home and seeing how well they can get on...We look at the upper-limb to see if there’s any movement and obviously try and increase movement” (OT2).

“Looking at sitting balance, standing balance, and the ability to do a transfer within the bed” (PT2).

“[I look at] how they move, their sitting balance, their standing balance, what the quality of movement is, if they can and whether they will be walking” (PT1).

“If the patient wants to go down that route, then more upper-limb tasks [are utilised]” (PT4).

“It [rehabilitative assessment] is very much geared towards looking at the range of movement and power there is in the upper-limb” (PT2).

It was also asserted that inter-professional working is essential to the assessment of stroke patients for rehabilitation:

“If it is more of a muscle or balance issue it gets referred to me. If it is more, sort of, transferring or moving from place to place they tend to go to the occupational therapists initially...so as a physiotherapist I mainly looking at that person’s ability to move ... I work very closely with my colleagues occupational therapists, speech therapists, neurophysiologists and nurses in order to gain the full picture” (PT3).

Therapists described how the timing of rehabilitative interventions can also affect progress and this must be taken into account during assessments: *“Certainly after six*

weeks of someone having had stroke you really know whether the patient has made improvements” (OT3).

It was noted that assessment for strokes will always be difficult as *“Their [the patient] recovery can be so different from one to another” (OT2).*

PT3 stated that therapists will *“try to get the patient to make the most of what they have got”*, while PT2 mentioned that: *“the stroke can affect them visually or cognitively”*.

4.2.9 - Summary of Findings from Semi-Structured Interviews

These interviews identified issues with time, subjectivity, standardisation and sensitivity in stroke patient assessment for upper-limb motor control. There was a confirmation that therapists believed technology could assist in this area if it utilised the following:

- Continuing formal assessment in a quantified manner. This would allow the therapist to perform assessment at set time intervals.
- Provide evidence that can be used in conjunction with current outcome measures.
- Technology should alleviate time required by the therapist.
- Feedback should be available to patients and therapists in an understandable manner. Feedback to therapists must be more detailed.
- Therapists stressed how assessments are relevant if they are functional.
- Technology must be portable enough to move around a clinical environment.

4.3 - Discussion of findings from Requirements Elicitation

The results presented showed issues within stroke patient motor control assessment. It was felt that this is a much needed activity, which is currently being performed, however, it was felt that these underlying issues could be improved upon to help progression of this field and alleviate certain pressures placed on the interviewed NHS staff.

There was a general consensus that a patient should and did receive an initial assessment when they arrived in a rehabilitative setting. Continuous assessment was also being done on an on-going basis, but not necessarily in a standardised way in terms of outcome measures and timing owing to the tension between treatment and assessment. Time was stated as being a limitation, with several therapists describing how pressures on resources meant they simply did not have enough time to conduct certain outcome measures and still have time to provide therapy. In addition to this, the large amount of paperwork that therapists are required to fill out further limits their assessment options. It became apparent throughout the interviews that faster methods of assessment are required, whether this is through new outcome measures being derived in their current format, or through a new approach.

A further limitation of current outcome measures is that of subjectivity. It was described by therapists, that they believed there is limited objectivity in some scales. It was felt that although the measures could identify progression to a certain level, a degree of subjectivity could lead to an under or over representation of the patients rehabilitative progress. This was mentioned repeatedly throughout the interviews,

and therapists described having to carry out their own assessments when they see a patient that has already been seen by another therapist. In addition to this described lack of objectivity, some therapists felt that current outcome measures could lack sensitivity to pick up changes made by the patient.

Some therapists described a viewpoint on a lack of standardisation regarding when and how to assess motor control in the NHS. It was believed that the way patients are assessed changes from therapist to therapist. A total of 16 different outcome measures were spoken about during the interviews, with each therapist explaining how they used a set of outcome measures which were different from other therapists. Rudd et al. (2001) claim that variations in stroke care across the country that cannot be explained by clinical factors may represent different local health care policies.

Another aspect identified in this research was that of hospitals creating their own assessment criteria. This is predominantly performed for the initial assessment of patients and could be linked with a lack of direct instruction in the 'National Clinical Guidelines for Stroke' (Intercollegiate Stroke Working Party, 2012) surrounding which outcome measures to use. Therapists portrayed how they used their own departmental assessment forms in order to overcome issues in current outcome measures. However, they were still aware that there were limitations to this method of assessment and some discontent with the current structure was apparent. The combination of all of these problems added to confusion over how continuing assessment should be carried out.

The interviewees also mentioned, but gave no explanations of why they felt they were short of time when working with patients. The time that staff members have

‘face-to-face’ with patients is a major factor in rehabilitation. This is particularly important as evidence suggests that more intensive rehabilitation produces a better functional outcome (Kwakkel et al., 2004). Tyson and Turner (1999) have argued that the most frequently cited reason for deficiencies in care is the lack of time that support staff spend with patients. Patients can spend a lot of their rehabilitation time in bed or in a hospital room, being inactive (De Wit et al., 2005, 2007). The NHS have attempted to address this issue by releasing National Clinical Guidelines, stating that a minimum of 45 minutes per day should be spent with a patient (Intercollegiate Stroke Working Party, 2012). However, there are still views that this guideline is still not being followed. Rudd et al. (2009) stated that 75% of patients receive less than an hour of treatment a day and 25% of patients received less than half an hour a day of treatment. It would seem reasonable to posit that increased staffing levels would resolve some of the issues described in these interviews, but with the current focus within the NHS on lean management and efficiency, the cost of additional staffing means this is unlikely.

There is a potential for the introduction of technology to create objective and expeditious outcome measures and address the issues of lack of staff due to costing concerns. It became apparent in the interviews that the therapists believed that end user acceptance will always be an issue with regards to technology, particularly within healthcare; however, attitudes are shifting and people are becoming more receptive. As more healthcare technology is adopted within the NHS, users become more receptive to novel methodologies of healthcare through technology and the interviewed therapists mentioned how technology could be used for assessment purposes. One therapist directly spoke of measuring motor control deficiencies in the

upper-limb. Therapists also spoke of how computer packages were able to evaluate joint movement.

In particular, an area for concern within this field is the current lack of ability to demonstrate simple outcomes to patients and healthcare commissioners without having to take full gait analysis and manual goniometry (which can potentially strain resources). Therapists mentioned that they would welcome a technology that is simple to use and effective which allows them to demonstrate therapeutic outcomes.

However, if any healthcare technology is to be adopted for this purpose, it must overcome some initial issues. A large area for concern is that of the varying requirements of stroke patients. Stroke patients are affected in different ways physically and cognitively and any system that is developed must be adaptable to this. Results must be useful and interpretable by a multi-disciplinary team.

Technologies must also demonstrate cost effectiveness, as there is no reason for the development of a tool if it detracts from other resources. They must also be accepted by the end user, whether that is the therapist or the patient.

4.4 - Summary

In recent times there has been a move to increase the standardisation of care across the NHS. With budget cuts now being enforced, the NHS is streamlining systems and asks for “More with the same, not more of the same” (Appleby et al., 2010, p.1).

It has previously been identified in this thesis that there are issues associated with upper-limb motor control assessment in stroke patient rehabilitation. The problems

identified align with issues shown in this chapter, including time constraints, subjectivity of assessment, standardisation and sensitivity.

The interviews showed that outcome measures are currently not being used in a standardised way within the NHS hospitals at which these therapists were based and staff struggled to establish objective feedback methods.

Therapists will assess a patient once they arrive in a rehabilitative setting, and will sometimes assess on discharge; however, it is apparent that continuing formalised assessment is not being implemented effectively due to varying pressures on the therapists (often based around time and cost of treatment). This means that limited feedback, and a particular lack of quantitative feedback, can be provided to the patient, their families, healthcare commissioners or indeed the therapists themselves.

Technology could be a method for providing these quantifiable results which can help to alleviate some of the strain on resources. In particular, therapists identified that numerical data regarding ROM would be of particular use.

Chapter 5: System Implementation

This chapter presents an overview of the system which was developed for the evaluation of upper-limb motion in stroke patients. An initial summary of the requirements for the system is presented as derived through the literature search and requirements elicitation exercise. An overview of the system, based on these requirements is then presented, followed by a summary of what the known technical limitations of the system were at the end of the rapid prototype development.

5.1 - A Critical Summary of the Issues from Requirements Elicitation.

The literature search and requirements elicitation exercise allowed for conclusions to be drawn on the opinion of physiotherapists and occupational therapists within the participating NHS hospital Stroke wards, with regards to current issues which they face in the assessment of the upper-limb motor control in stroke patients. These are as follows:

- **Subjectivity** – Therapists spoke in the requirements elicitation of a level of subjectivity in outcome measures which they use. They spoke of the desire to be able to add some form of quantitative assessment to support the current measures available.
- **Standardisation** – Due to subjectivity in certain aspects of outcome measures, as described above, and the variation in outcome measures which can be used (as detailed in the literature search, with limited advice on outcome measures

recommended by the NHS), therapists often spoke of a desire to have quantitative results which could be continually used. This could potentially improve standardisation in the wards.

- Continual Assessment – Some therapists’ spoke of how continual assessment can be difficult in the current environment and therapists may repeat tests, especially when moving the patient from one therapist to the next. The addition of a quantitative element to current measures may provide a method to help with continual measurements when moving patients between therapists.
- Functional – Therapists (particularly the occupational therapists) spoke of the desire to be able to assess individuals quantitatively during functional tasks, in order to create transferable skills which are applicable to real life situations. This was also apparent in the literature search.
- Time and Cost – It was identified that time is of the utmost importance in the clinical environment, and any tool which is capable of saving time and costs is of use within the NHS.
- A limit in current tools to assist in providing quantitative motivational feedback – The idea of providing quantitative measurement of movement, particularly functional movement, is of importance to therapists due to the ability to provide some sort of additional feedback to patients.
- Limited Clinically Driven technology (clinically based user-centred design at the early stages of development) – The literature reveals that tools currently in research and surrounding upper-limb assessment of stroke patients can

have limited evaluation in a clinical environment at the early stages of development.

- Motivation – The current lack of quantitative assessment methods can mean that it is difficult to present rehabilitative to progress, as discussed in the requirements elicitation. Motivation is a key aspect in rehabilitation and any tool which can help with quantitative goal setting would be advantageous.

5.2 - The derived Requirements of the System.

Through the issues identified in the literature search, and in the NHS settings described in the requirements elicitation exercise, a set of user requirements were established. These system requirements are identified below:

- Assess the Upper-Limb in line with the scope of the project (this may be advanced at a later stage, however, a focus is provided in this area due to the current evidence-base on upper-limb assessment shown in the literature review). The system should provide a breakdown of individual movements, and be able to differentiate between active and passive movement.
- A method for providing quantified measurement which can be used in conjunction with current outcome measures to create an increased holistic assessment approach. However, these should have adaptable difficulty levels, for different individuals.
- A tool which could potentially allow for an increase in therapist efficiency by minimising interaction time needed by the therapist when using the system, whilst alleviating time required for assessments of patients.

- Low cost and affordable system.
- Evaluated in the clinical environment at an early stage, with further developments driven by this, in order to be end user-accepted and driven.
- Portable and usable in the clinical environment.
- Task-oriented and functional to create translational skills, with all feedback being given in multiple formats (e.g. visual, auditory).
- Motivational, with ample feedback to the patient and the therapist, in terms which are understandable to both.
- Easy to use
- Safe.

5.3 - Framework of System.

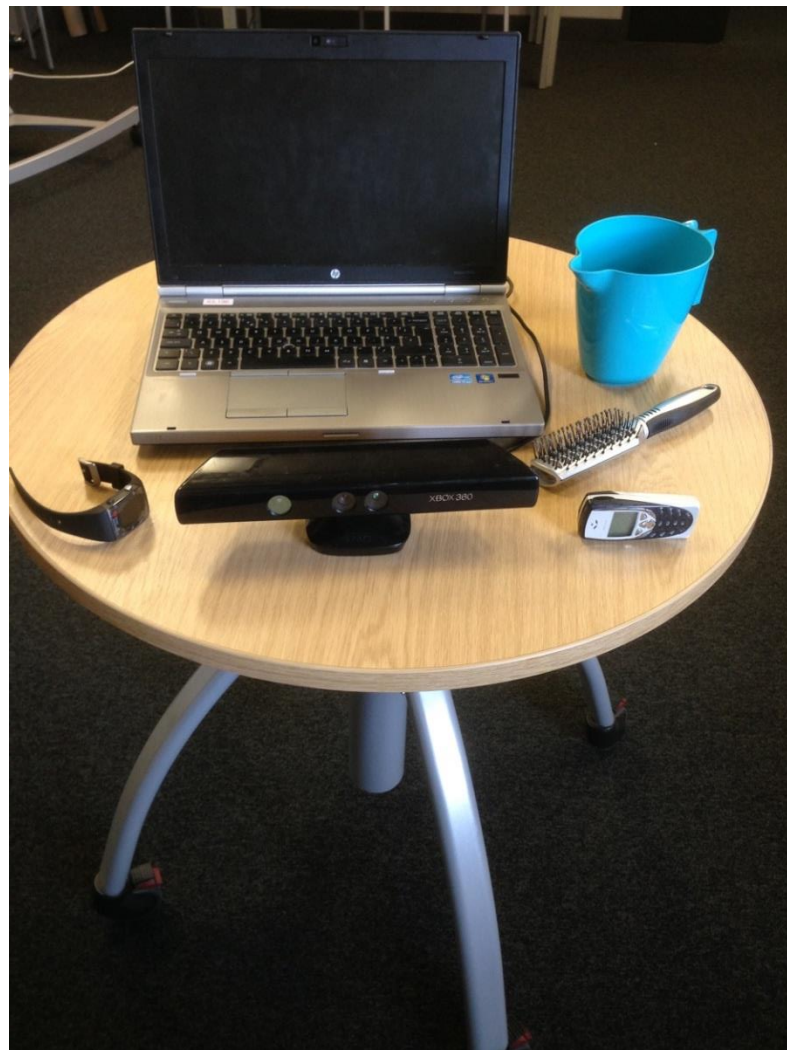
Based on the requirements identified, a system was developed. The system was to be developed as a rapid prototype with the knowledge that it would be placed in a clinical environment for evaluation before it was developed further.

5.3.1 - Overview of the Developed System and its Aims

For this research, a markerless motion tracking system was developed which aimed to assess the upper-limb motor control of patients who had suffered a stroke. The aim of the system was to provide quantitative measurements of ROM during functional activities. The data which are collected could be used in conjunction with other outcome measures currently in existence, to create a rounded assessment of the

individual whilst providing structured feedback to patient and therapist about current therapeutic progress.

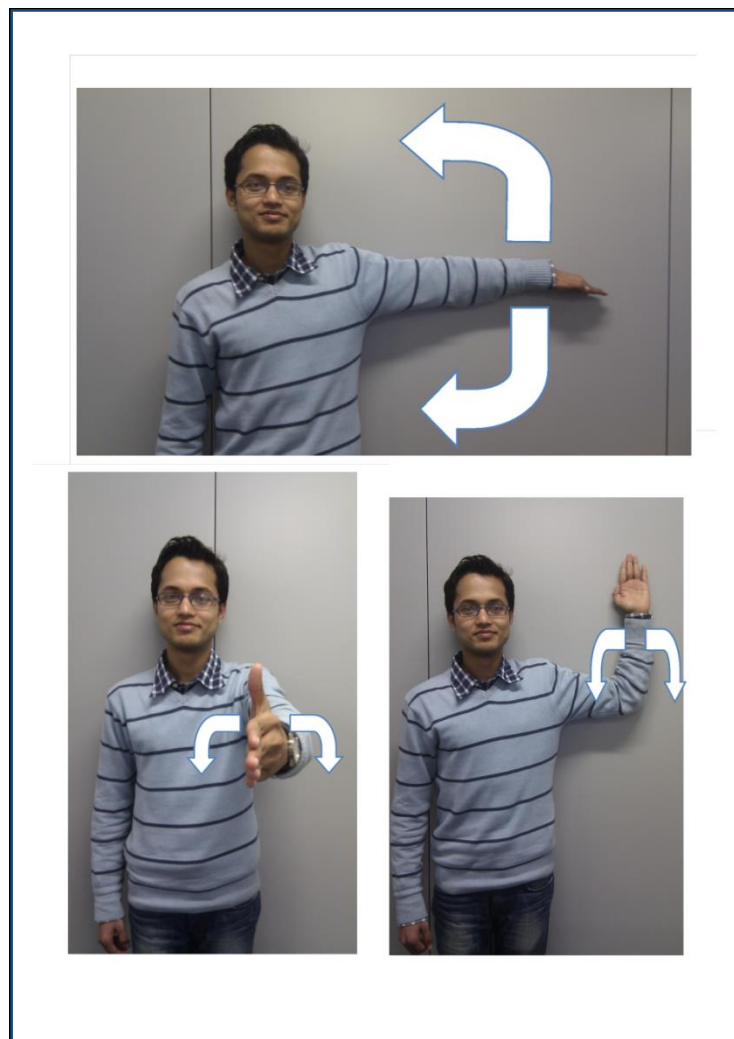
Figure 5-1: The Prototype System Provided to the NHS (including laptop, Kinect, EZ430 chronos watch and ADL objects on portable table)



The overall system which was developed consisted of a standard laptop, a Microsoft Kinect markerless motion tracking camera, and EZ430 chronos watch, which the

patient wore on the wrist. The laptop and devices were placed on a portable table which could be easily moved around the clinical environment, and stored, as the table was on wheels. A picture of the system is shown in Figure 5-1.

Figure 5-2: Movements (Top: Abduction/Adduction, Bottom Left: Pronation/Supination, Bottom Right: Flexion/Extension)



The system allows a patient to be placed in front of it, whilst they carry out functional activities. There is no calibration stage and no markers to be placed on the patient. After completing functional activities, the system presents a breakdown of ROM during the activity, in the upper-limb, by joint, in graphical format to the therapist.

At the time of development, in order to achieve the system requirements, it was unclear whether it was best to measure functional activities during a therapy session itself, or whether it was best for a patient to be prompted to carry out set ADL with ROM to be measured at this point (without the therapist involved). Therefore, the initial system had 2 types of assessment which could be used, a version with the therapist present (in-therapy version), and without (ADL version). Although both versions collected data in a different manner, both displayed results in the same format. The data collection aspects and single results section are discussed in this chapter.

The system which was developed was initially set to detect 3 movements in the upper-limb (although this is extensible). This was to conform to the rapid prototype development methodology, as three specific movements could be scrutinised in an adequate manner. These are shown in Figure 5-2 and are abduction/adduction at the shoulder, extension/flexion at the elbow and pronation/supination at the wrist. See Appenix I for a more in depth description of these movements.

In order to perform the main part of the upper-limb tracking, a Microsoft Kinect camera was used. This device was chosen due to its low-cost nature; off-the-shelf availability (with CE (Conformité Européenne) marking); portability; and easy to use

application programming interface. The sensor allows for markerless motion tracking of a human, providing the coordinates of up to 20 joints; these are shown in Figure 5-3. The system is currently priced at under GBP£200. More information about the Microsoft Kinect, including its technical specifications, can be found in 2.3 - The Use of the Microsoft Kinect as a Tool for Assessing Upper-Limb Motion.

Figure 5-3: Microsoft Kinect and the Joints it Tracks



(Source: MSDN, 2012)

An issue, which was encountered during development, was the Kinect's inability to assess rotational movements such as pronation/supination at the wrist joint accurately enough. It was decided that the optimum way to alleviate this issue was with an additional sensor. It was decided that a Texas Instruments EZ430 chronos watch (Texas Instruments, 2012) (see Figure 5-4) was best suited, due to its similarity to the Kinect in being off-the-shelf and low cost, but also due to its extensibility to other healthcare monitoring purposes such as detection of heart rate which could potentially be used in future applications.

Figure 5-4: EZ430 Chronos Watch



The EZ430 watch contains an accelerometer which measures its current rotation in the X, Y and Z axis by calculating the acceleration caused by gravity, which could allow for detection of the rotation of the wrist (Luczak et al., 2006).

The Microsoft Kinect and the EZ430 chronos watch were able to connect to a standard laptop, which was used to calculate and store the measurements. Another

reason for the selection of these two devices is that both could be programmed using Visual Studio and the C# coding language (utilising standard code libraries, and libraries designed to integrate the systems). Therefore, a program with a set user interface was created using these tools. All data taken using the system was stored in a MySQL database (MySQL, 2012).

The next part of this chapter shall describe the system processes and user interface in detail. This will include the data collection aspects of each version of the system (in-therapy session and ADL), and will also detail the results which are presented to the therapist (which is the same in each of the 2 versions).

5.3.2 - The In-Therapy (data collection) Version of the System.

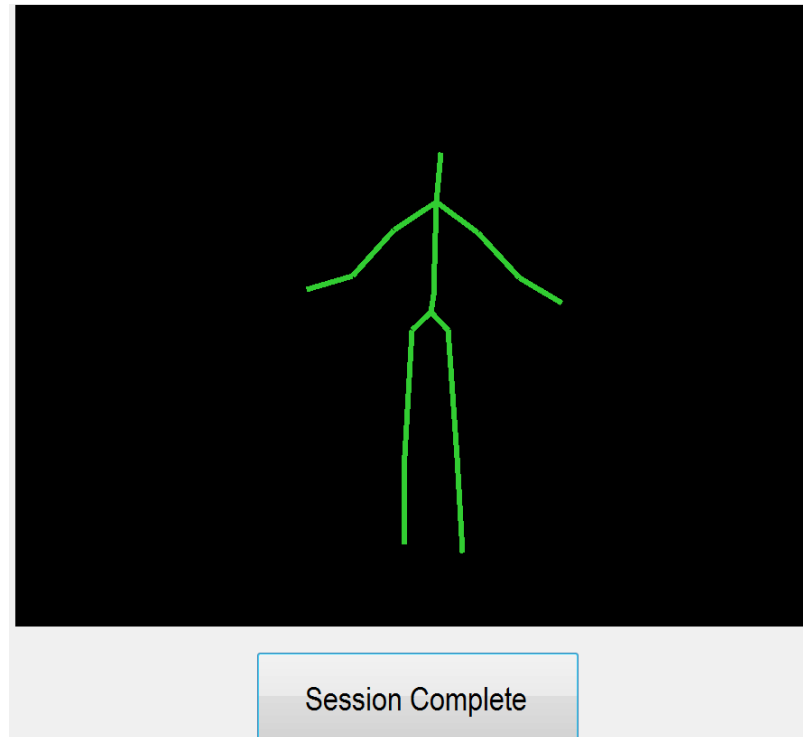
The first stage in development was to produce a version of the system for the tracking of the patient whilst the therapist was present. This version of the system was to be placed in the background of a therapy session and detect upper-limb motion data from the patient (based on the three movements described earlier in this chapter). The therapist could start the system by simply double-clicking a desktop icon.

Figure 5-5: System Login Screen



The first step the user encountered when using the system was a login screen asking for a patient identification number, as shown in Figure 5-5. If the patient did not have an id number then a button for a new patient could be clicked and the system would generate a unique six digit code. The user could then enter this code each time they used the system and their data was stored.

Figure 5-6: Skeletal Representation on-screen



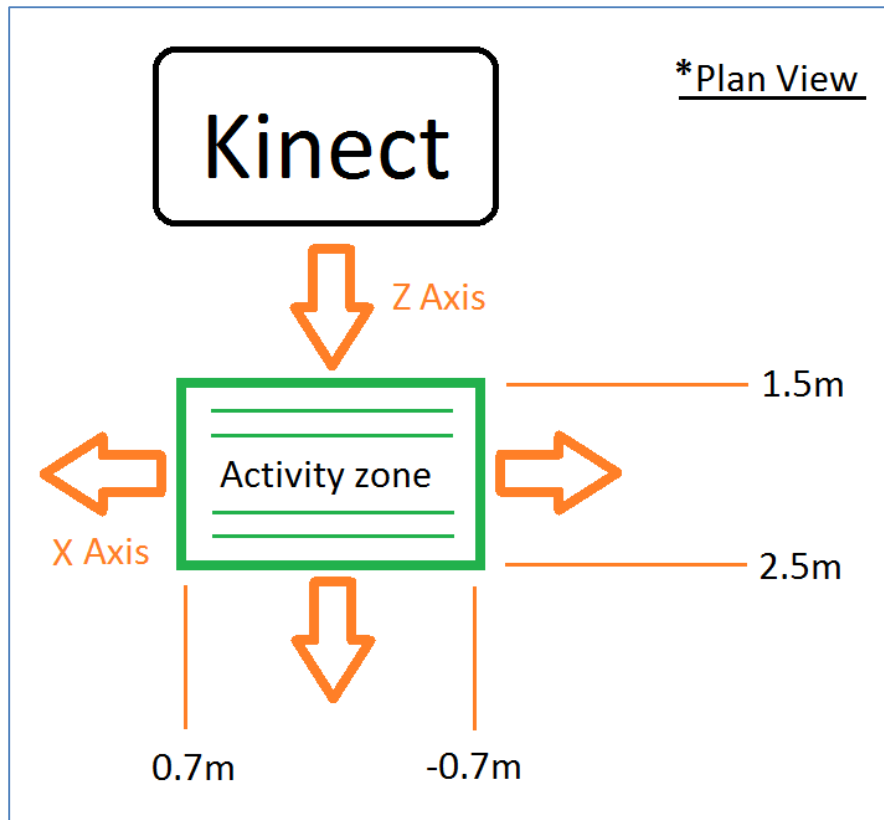
The reason for the login screen is for security purposes. This was a problem which had to be overcome as patient data has to be securely protected and this data would not be on a hospital based machine (the machine could not be connected to the hospital network for security and ethical reasons). Therefore, the system involved no personal data, and any movement data which was stored utilised the six digit unique identification number. This was linked to the patient's ROM data (during use, therapists are asked to keep a copy of the identification number with the patients records). ROM data is always matched up with a session identification number, so each session contained a date and a unique identification number, but nothing which could identify the patient from the data on the system alone.

After logging in, the therapist was guided to the main section of the system. A problem to overcome was getting the patient to stay in an area where they could be

effectively tracked by the Kinect. Therefore, after the therapist logged in, they were presented with a screen where they could see the patient being tracked as shown in Figure 5-6. The therapist was asked to only place the patient in view at this point, and if two people were detected, an error would appear, prompting the user to only have the patient in view. The system also prompted if the patient was outside of a required 'Activity Zone' for the system to measure movements correctly. This was 1.5 – 2.5 metres on the z axis, and 0.7 to -0.7 metres on the x axis; with the Kinect device acting as the origin, as shown in Figure 5-7. The position of the patient was continually tracked throughout therapy (with prompting of a positional change being made if necessary. This had to be coded into the system as this version of the Kinect SDK was not able to perform this task.

The system also detected the patient's centre shoulder position on the Y axis when the program first loaded. The Microsoft Kinect contains a small motor, which allows the camera to pivot up and down. This was controlled and the angle of the camera set according to the position of the patient, with the camera being moved to point in-between the patient's shoulders (a point derived as one of the 20 joint positions tracked by the Kinect device). The reason this position is chosen as the centre point, and not the waist, is to allow enough room for the patient to fully abduct their arms at the shoulder joint. The table on which the system was placed, could also have its height adjusted, if further modifications were needed.

Figure 5-7: 'Activity Zone', showing the area in which the patient must stand, as measured by the system.



Once the system had detected the patient in the correct position and adjusted its elevation using the motor, the system would begin to track the patient.

The system remembered the X, Y and Z co-ordinates, taken from the Kinect, of the patient's joints. Data was also taken from the watch, by calculating the coordinates of the accelerometer data. All these coordinates were taken and combined in order to calculate Abduction/Adduction at the shoulder, Pronation/Supination at the wrist, and Flexion/Extension at the elbow. During each frame which was fed back from the Kinect device (up to 30 frames per second), the current angles of each joint in the movements described above were recorded and stored.

In order to calculate Abduction/Adduction, coordinates from the hip centre; shoulder; and elbow, as taken from the Kinect system, were used to calculate an angle, utilising inbuilt functionality within a standard code library. For the elbow joint, the shoulder; elbow; and wrist joint coordinates were used in the same process.

However, for the pronation/supination movement, the current rotation of the EZ430 chronos watch was calculated, using a function which could be utilised through the watches corresponding code library. The code library, for each axis, outputs the data as one of four 90° segments, and the current angle in that segment, giving a 360° representation of its current angle of rotation in each axis. A function was written to translate this data into -180° to 180° in one axis, which portrayed pronation/supination at the wrist joint, with this angle being recorded each time a frame was returned from the Kinect, to ensure consistency in the system.

As this version of the system was to be used during therapy, an issue which needed to be overcome was the system's ability to detect when the therapist entered the camera's view and when the therapist's hand came into close range of the patient. This would allow the system to differentiate between passive and active movement. The system can calculate joint positions, but not the outline of the arm itself (within an accurate degree for this device). Therefore, it calculates which is larger, the halfway point between the patient's wrist and elbow, or the halfway point between the elbow and shoulder. If the therapist's hand is moved within this distance of the patient's wrist, elbow or shoulder (with the distance used as a radius) then the system will register this and stop collecting data. To make the therapist and patient aware of this, if the therapist entered the system, their skeleton according to the Kinect would

be displayed on the screen in blue, whilst displaying ‘Therapist Detected’ on the top right of the screen. The screen would also display a label, stating whether active or passive movement was being recorded (i.e. whether the system was, or was not currently recording movement).

When the therapist felt they had completed the session, they could finish it by clicking the ‘Session Complete’ button. At this point they will be presented with the results section, as described in 5.3.4 - Presentation of Assessment Results in the User-Interface.

5.3.3 - The ADL (data collection) Version of the System.

A second version of the system was also created, which allowed the patients to carry out ADL while being assessed without the therapist having to be present.

There were some differences that had to be incorporated into the version of the software in which the therapist was not present. In particular, the system needed to be as automated as possible as it was to be primarily used by the patient. The amount of clicks required was reduced to an absolute minimum in order to improve usability. Initial screens were also automated with timers (to allow patients time to adjust to what was happening with the system).

Figure 5-8: Objects used in ADL section of the system



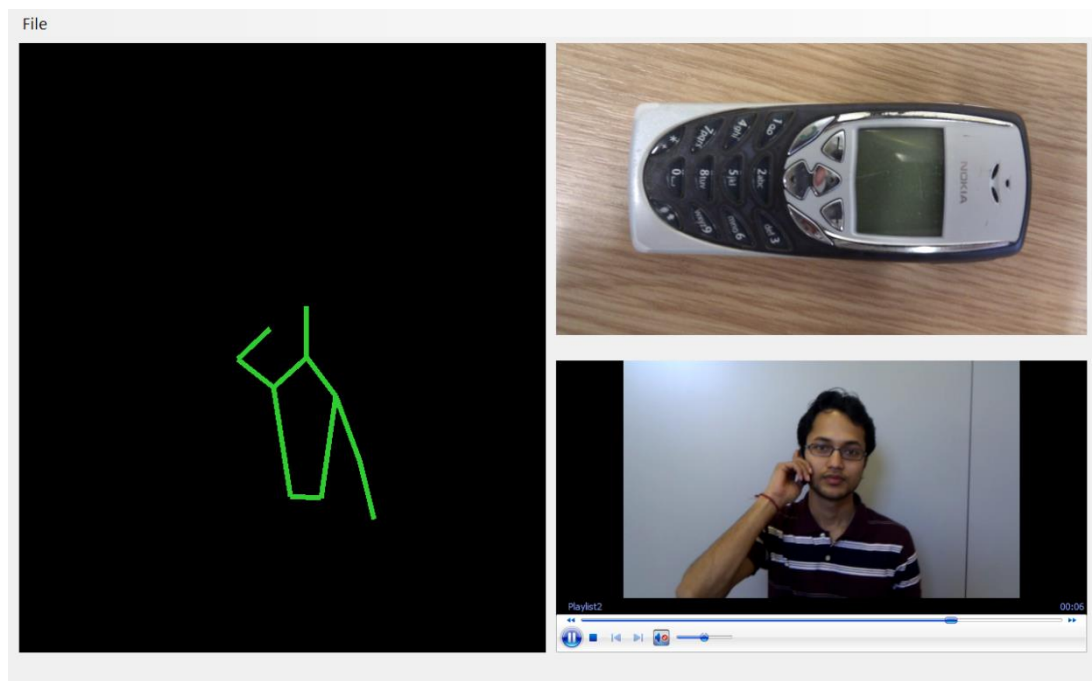
This version of the system allowed for the testing of ADL by asking the patient to carry out 3 activities. The reason for the selection of these activities is that in the book ‘Measurement of Joint Motion (Norkin and White, 2003)’, which shows required ROM for ADL tasks, these three tasks were shown as producing large ROM for each of the three movements being tested in this system. The three ADL selected were pouring water from a pitcher to a jug, answering a telephone and combing the back of the hair. Each task required the user to carry these tasks out with one of the objects shown in Figure 5-8. If the user was unable to pick up the object due to their stroke, they were asked to practice the activities initially without the objects, with recordings still being taken, with this being noted by a therapist. Detection of hand movement is something which may be added at a later stage.

The system followed the same process as the in-therapy version of the system, initially asking the user to login, and then following initial patient placement in the

‘activity zone’ (as previously shown in Figure 5-7), and change of elevation of the Kinect using the system motor in correspondence to the shoulder centre position.

However, a different interface was used during actual data collection. Figure 5-9 demonstrates the screen that was displayed.

Figure 5-9: User Interface during Patient-Led Task Stage

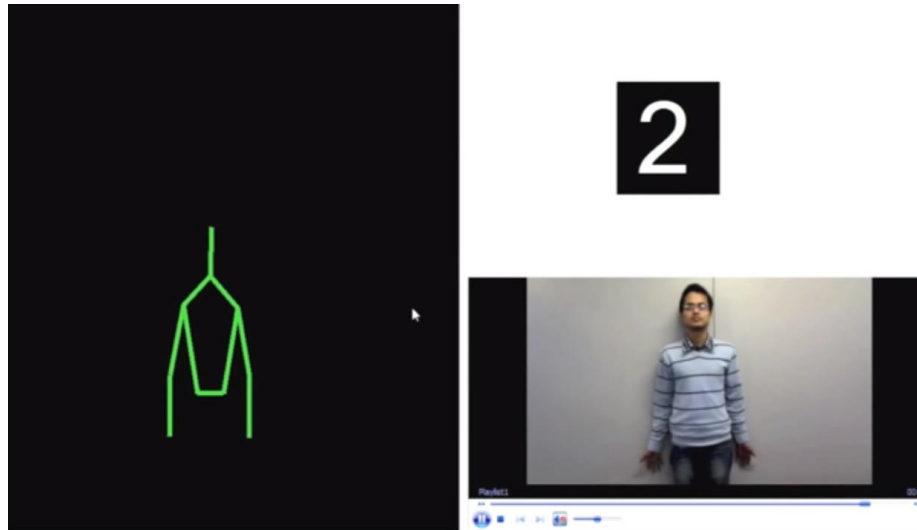


A known issue when designing systems for stroke patients is the variability of the patient’s symptoms including cognitive difficulties (Wilson, 1997). Therefore, it was decided that the system needed to provide as many visual and auditory cues in the interface as possible. To the left of the screen is the patients ‘skeleton’, allowing the user to know the system has detected them and that they are in adequate space. To the right of the screen is a picture of the specific ADL object they were required to use at that time, accompanied by a video demonstrating the way in which to use it.

This was also accompanied by sound instructing the patient as to what task they needed to perform, with clear instructions (e.g., “Please pick up the comb and comb the back of your hair; please make sure you are combing the back of your hair”) of how to accomplish this.

The system would monitor whether the patient had completed the task. It was known from ‘Measurement of Joint Motion (Norkin and White, 2003)’ that each of the ADL had a minimum ROM required to complete the task. The system would monitor if these ROM had been performed (from picking up the object, to pacing it back down). The system would also time out after one minute, in case the patient was unable to complete the task. Once each task was completed, the patient was asked to place the object down and place their hands by their side (the system also gave visual and auditory feedback for this), this would provide a standardised starting position from which ADL ROM could be measured against for task completion. During this transitional phase, a counter ticked down from ten seconds, before the next task began, as shown in Figure 5-10. This also allowed for patients with movement difficulties to transition easily between tasks, and to allow for a steady results output, with a clear transition between tasks.

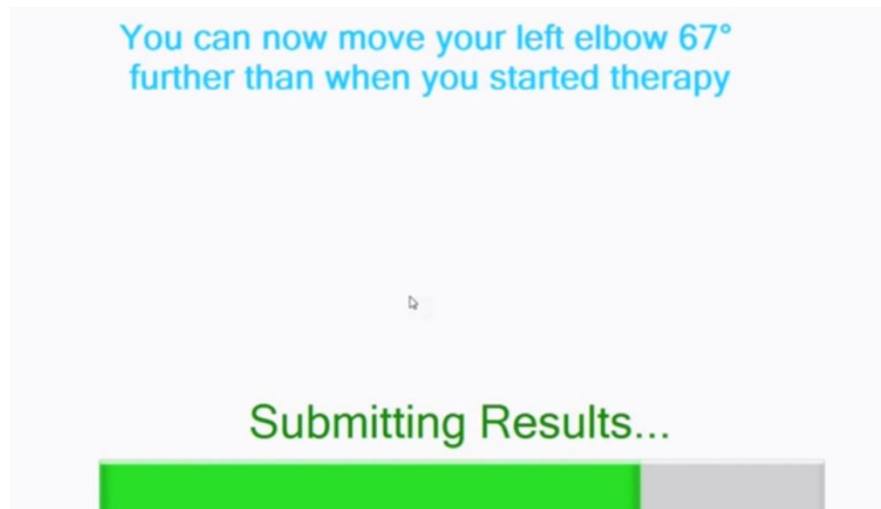
Figure 5-10: System reset screen, as displayed between ADL.



After completing the 3 ADL, the system would automatically switch to a new screen which provided details regarding patient progress since first use of the system. The system would calculate if there had been improvements in ROM since previous sessions at any joint measured and present this to the user. Only positive results would be shown (in order to avoid negative feedback), as shown in Figure 5-11.

The results screen was displayed for 1 minute (displaying 'Submitting Results' if no positive improvement had been detected). Once this had been completed, the system automatically timed out and completed the session, at which point the therapist would take over. The results section would be displayed at this point, which is discussed in the next section of this chapter.

Figure 5-11: Basic feedback as provided to the patient when they are using the ADL version of the system



5.3.4 - Presentation of Assessment Results in the User-Interface

The final stages of this system involved the presentation of results to the therapist. This was performed through a set of graphs. The results screen would appear after the therapist had clicked complete session in the initial version of the system, or if the ADL tasks had been completed by the patient.

A set of graphs were presented to the therapist on this results screen. Initially, these graphs were able to show movement during the assessment for each of the three ROM being assessed (pronation/supination at the wrist, abduction/adduction at the shoulder and flexion/extension at the elbow), in both the right and left arm. Each graph represented one of the joints. The therapist was only required to click one button to access each of these graphs. The interface for this and an example output for detected flexion/extension at the elbow can be seen in Figure 5-12.

Figure 5-12: User Interface during Results Presentation –

Red line represents the right arm and blue represents the left arm.



In the ADL version of the system, yellow lines marked the end of each of the ADL which were conducted.

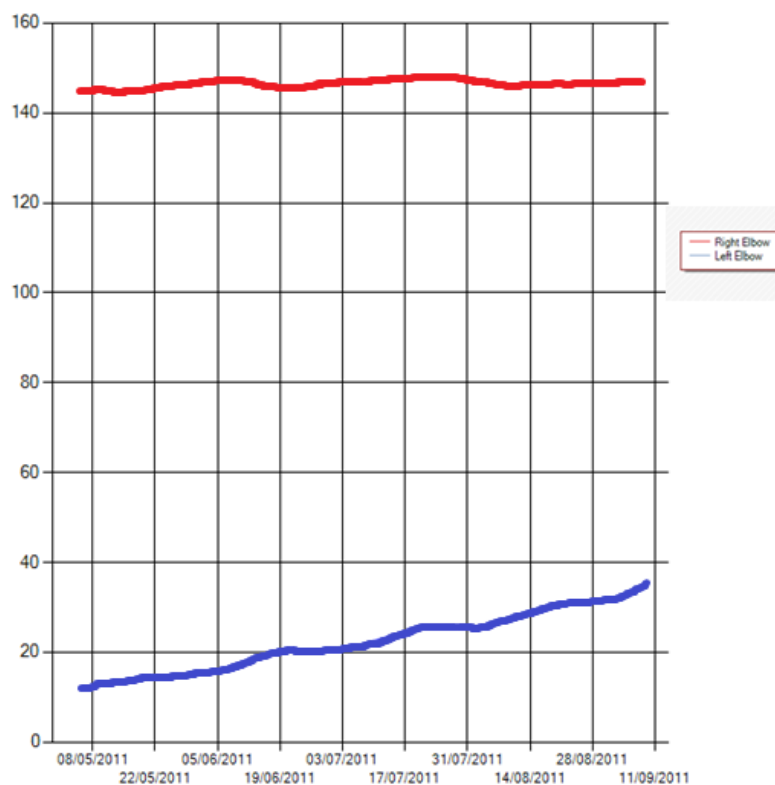
In order to produce these graphs, the data was initially smoothed of any anomalies to eliminate noise. This was performed using a moving average smoothing algorithm:

$$X_n = \frac{X_1 + \dots + X_i}{i}$$

This algorithm was selected due to its use in other studies using the Microsoft Kinect (Stone and Skubic, 2011, Kristensson et al., 2012, Kepski et al., 2012). A moving average using a queuing system with a value of $i=4$ was utilised in this software.

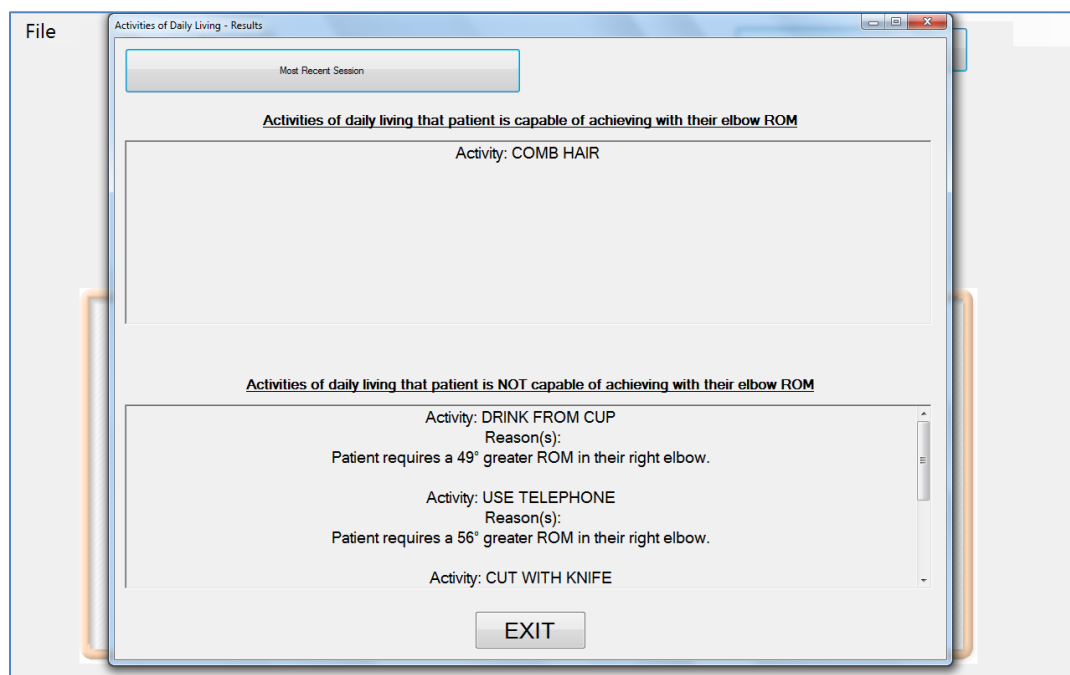
The data was also looped through, and, the maximum and minimum range during the session at each measured joint was used to calculate total ROM throughout that session, which is also displayed above the graph. This is stored in the database along with the date it was recorded.

Figure 5-13: Elbow ROM Assessment Data over Time –
Note: Red line represents the right arm and blue represents the left arm.



In addition to movement during the current session, the therapist was also able to access ‘ROM over time’, which presented the maximum/minimum ROM data previously stored, and from the current session in order to evaluate patient progress over time. An example of this is shown in Figure 5-13.

Figure 5-14: ADL Activity Breakdown



Finally, the system was able to output which ADL could be achieved with the demonstrated ROM. It was also able to provide a breakdown of which joints were causing problems with a specific ADL. To provide this, the user was presented with a screen as shown in Figure 5-14, which shows which ADL they are capable of achieving based on ROM demonstrated in the current session and ROM demonstrated over time. The user was also presented with a breakdown of why they are unable to achieve a certain activity (e.g., lack of elbow ROM), if they had not demonstrated the required ROM. The minimum ROM for each ADL was derived from 'Measurement of Joint Motion' (Norkin and White, 2003). This screen also presented additional ADL which were not tested, but data was available for.

5.3.5 - Video of the User Interface

An overview of the user interface in the non-therapist ADL mode can be found in video form online. To view this video access the Uniform Resource Locator (URL) presented in Appendix L.

5.4 - Technical Limitations

As the methodology required creation of a rapid prototype, there would always be certain technical limitations within the system.

The first of these issues is the difficulty the system currently has with tracking seated users. The Kinect SDK (Microsoft, 2012b) currently has two available options for tracking: full body tracking and upper body tracking. It would be advantageous to use the upper body tracking algorithms (this would help in areas such as detecting patients in wheelchairs). However, this method does not allow for the hip joint to be tracked, and therefore abduction/adduction at the elbow joint and at lower joints cannot be calculated. Also, when a patient is seated, accuracy of the system can decrease because the patient's legs are not visible. If Microsoft, in a future release of the Kinect SDK, allow for the hip joint to be tracked, this issue may be solved.

Another issue is the accuracy of the system, especially when certain joints become occluded from view. The accuracy level of the system can still improve and with the constantly evolving state of the Microsoft Kinect and the Kinect SDK, this should occur over time, improving the efficacy of the system. An evaluation of this is demonstrated in 6.1 - System Verification.

A further issue with this system in its current state is its capabilities for the tracking of the therapist. Currently, the system is able to accurately record the patient. If a therapist initially walks into view of the camera then the system records them and measures how close their hands are to the patient at all times. A problem can occur if the therapist walks into the screen at a certain angle, particularly when the patient is close to the Kinect, and the system may not always detect the therapist accurately, due to the therapist's full body not being in view of the camera. In the current version of the system, therapists are asked to check whether or not the system has detected them before they continue therapy.

In line with this problem, another known issue exists with the tracking algorithms for the therapist. An issue can occur when the therapist walks in front of the patient during a therapy session. The system may interpret this as the patient moving forwards and will begin to assess the therapist instead of the patient. Currently therapists are asked not to walk in front of the patient, and to move behind them, although, this would not be feasible for future systems and would require correction.

Another current flaw in the system is that the Kinect only allows for the tracking of two individuals, so passive motion can only be recorded whilst one therapist is in view and not multiple. However, it is expected that Microsoft will release functionality for this in the future, and hence this is not regarded as a priority issue.

There was a smoothing algorithm used when presenting results data, in order to eliminate noise. A negative side to the use of this algorithm is the faster the movement (and therefore the further apart the points are on the axis), the more smoothing that will occur, and can therefore misrepresent the movements through

limiting the ROM demonstrated. However, as previously mentioned, stroke patients predominately suffer from reduced movement rates (Rohrer et al., 2002) and therefore, it is believed that this should not be a key issue.

Tracking algorithms for the Kinect are constantly improving and this should not be an issue in later systems. Furthermore, additional research and development could be performed in order to improve the efficiency of this section of the system and produce additional tracking algorithms.

This system was designed as a rapid prototype. Therefore, it must be noted that the author is aware of some immediate changes that could be performed on the system to enhance it further.

The initial change that would need to be applied would be the extension of the ROM measurements. At the moment, only three ROM's are measured (previously shown in Figure 5-2). This was due to the fact that the system's efficacy could be proven with just these three movements. However, in limiting the amount of movements, processing times could be decreased until more efficient programming archetypes are released.

Another natural progression in this system would be the further development of the ADL. At the moment three ADL are selected. This is due to the fact that these were the ADL detailed in the book 'Measurement of Joint Motion' (Norkin and White, 2003) most suited to the system. In order for the system to work effectively and there to be fewer issues with end user acceptance, a range of ADL would need to be incorporated. A separate study using a high performance motion tracking system (possibly a marker based system such as the Vicon MX (Vicon, 2012)) could be used

to assess which ROM are required for certain activities and include these within the finished system.

5.5 - Summary.

This chapter demonstrates the development of the system which can be used to assess functional activities in stroke patients, and in turn, help to evaluate motor control in the upper-limb. This system was developed as a rapid prototype and has been designed in order to be deployed in a hospital environment.

The system has two versions, one which tracks the patient's movement during a therapy session, and one which tracks the patient's movements whilst conducting ADL. The system is currently capable of tracking three motions, namely pronation/supination at the wrist, abduction/adduction at the shoulder and flexion/extension at the elbow. The movement which is conducted is presented to the therapist through a set of graphs. Three graphs are shown which detail the movements described. This is accompanied by graphs which detail maximum ROM at each joint over a period of time, therefore showing patient progress. Finally, the system provides data on which ADL can currently be completed based on demonstrated ROM, providing data on what increase in ROM is required to complete the ADL.

The next chapter in this thesis shall discuss the evaluation stages of the system, including verification and validation.

Chapter 6: System Evaluation

As described in the methods chapter of this thesis, the prototype which was developed required evaluation. This was initially through a verification stage, testing that the systems measurements compared well with that of a chartered physiotherapist. This was followed by a validation, in which the system was deployed in 2 healthcare settings, and was designed to elicit the views of therapists with regards to advantages/disadvantages of the system, and views for future versions of the system, including additional components. This chapter presents the results of this evaluation.

6.1 - System Verification

Ten participants completed testing in at least two of the three weeks, with six participants partaking in all three weeks of the experiment.

A comparison was made between the manual measurements taken by the chartered Physiotherapist, and these were compared with data from the system. 40 measurements were taken using the Kinect camera (ROM at the shoulder and elbow in both arms, resulting in 4 measurements, taken from 10 participants). This set of measurements is referred to here as the Kinect-only measurements.

An additional movement taken at the wrist by the watch was also taken, resulting in an additional 10 measurements being taken (1 per patient) and taking the total up to

50 measurements. This set of data shall be referred to as Kinect-and-watch measurements.

To evaluate this, a standard deviation, taken by calculating the difference in ROM between weeks for each participant, as measured by the chartered Physiotherapist, and then the system. In order to achieve this, a paired sample, two tailed t test was used to evaluate whether statistical difference did or did not exist.

An analysis was established using the Kinect-only measurements in which the null hypothesis stated that there was no statistical difference and the alternative hypothesis stated that there was a statistically significant difference.

The data which was collected can be summarised as the following for the Kinect-only measurement groups:

- Group 1 (Physiotherapist measurements): $M=1.852$, $SD=2.367$, $n=40$.
- Group 2 (measurements by system): $M=2.824$, $SD=2.463$, $n=40$.

This test demonstrated no statistical difference and the null hypothesis was maintained with the following data:

- Paired $t(39) = 1.658$, $p = 0.105$.

The Kinect-and-watch measurement group in the test is summarised as follows:

- Group 1 (Physiotherapist measurements (elbow and shoulder only)): $M=1.757$, $SD=2.095$, $n=50$.

- Group 2 (measurements by system): M=2.321, SD=2.571, n=50.

Again, no statistical difference was found with the result:

- Paired t(49) = 1.229, p = 0.224.

A summary of all t-tests is shown in Table 6-1.

	Physiotherapist Error	System	Physiotherapist Error	System (Kinect and Watch)
Measurement Type	Shoulder and Elbow Only	Shoulder and Elbow Only	Shoulder, Elbow and Wrist	Shoulder, Elbow and Wrist
n	40	40	50	50
Mean	1.852	2.824	1.757	2.321
Standard Deviation	2.367	2.463	2.095	2.571
Paired t	1.658, p = 0.105		1.229, p = 0.224	

Table 6-1: Summary of t-tests.

These results mean that no statistical difference can be implied, and both null hypotheses are kept.

The data was also tested for statistical equivalency (Tryon, 2001). In order to perform this test a delta value was decided upon; this is a value which is classed as the minimum difference between the means which is inconsequential. It was decided that error rates in goniometry have been reported to range from ± 5 degrees up to 14-23 degrees of inaccuracy (Clapper and Wolf, 1988, Garcia-Elias et al., 1989, Hayes et al., 2001). Therefore, it was decided that over a three week testing period a ROM

measurement taken by the Physiotherapist could be in error by 5 degrees in one of the weeks and therefore standard deviation across the three weeks would be 2.35702, creating a delta value.

From the summary of data described above (mean and standard deviations) we can derive the following Inferential Confidence Interval's (ICI) in the Kinect-only measurement category:

- ICI1: 2.379-3.372
- ICI2: 1.324-2.275

It is proved that there is no statistical difference as the ICI's overlap, and statistical equivalency occurs as the total range (maximum probable mean difference estimate):

- $3.372 - 1.324 = 2.048 < \text{delta} = 2.35702$.

When testing in the same manner with the Kinect-and-watch measurement group, the following ICI's were found:

- ICI1: 2.138-2.788
- ICI2: 1.376-1.853

The confidence intervals therefore overlap and the maximum probable mean difference estimate is $1.411 < \text{delta} = 2.35702$ and therefore proves statistical equivalence.

6.2 - System Validation

Overall, 9 therapists participated in system testing, consisting of 6 occupational therapists and 3 physiotherapists.

6.2.1 - Field Notes

The researcher took field notes, in order to gain a view on use of the system and how improvements could be made to the system, and to gather ideas for improvements in this field. These were as follows:

“When the therapists in the hospital were initially shown the system, they became very enthusiastic. It must be noted that this may have been down to the ability to see their ‘skeleton’ on screen. A few therapists did ask a lot of questions about how the system could be used, particularly to provide feedback to the patients without adding any additional workload to their current roles.”

“On returning to the hospital, one therapist mentioned that due to the issues with moving around during therapy, and the system not being able to detect the differences between therapist and patient accurately enough, they had started using the system at the start of therapy. They mentioned that they were using it as a type of outcome measure, and this was useful, due to the fact that it was much quicker and more reliable than current methods. However, they did move on to mention that the system would be enhanced if it was capable of being placed in the background during therapy and still working accurately as this would ‘save so much time’.”

“When the system was first placed in the hospital a number of difficulties occurred. The first of these was that the camera was placed on a ward pathway, with numerous individuals walking past throughout therapy. This required a lot of processing by the computer and made it slow and less accurate.

The other issue that arose was that of the motions the therapist asked the patient to perform. The therapist was actually asking the patient to perform flexion/extension at the shoulder joint, instead of flexion/extension at the elbow and abduction/adduction at the shoulder (although, in later systems more movements would be capable of being measured so this would not be an issue).”

“One therapist demonstrated the use of the system to the researcher with a patient present. The therapist mentioned that the patient was very ‘tech savvy’ and so they enjoyed using it. The patient agreed with this, speaking about the technologies they owned. This patient moved on to speak about how it was very useful that they were provided with feedback, in particular quantitative feedback that they would not usually have access to. At a later date, another patient also mentioned how this was useful for the same reasons.”

“One therapist asked for a slight manipulation to the software which was performed for them. This was to have a separate access point in the software which was capable of presenting the results of assessments without having to assess the patient first. Another alteration which was requested was for dates of assessments to appear on the graph as data labels (as opposed to simply being on an axis).”

“An issue that occurred during the course of the experiment was that the battery in the watch ran out of power. The problem with this, was that the watch contained enough power to maintain timing functionality, but too little to preserve the operation of the accelerometer. This meant that the watch still looked as if it were working, and the therapist believed that the system had ‘broken’ and stopped working when pronation/supination was not recording. If this system was to be developed further, a structure would have to be put into place, whereby an alert is presented to the end user when power is low.”

“The system can experience some difficulties in registering a person when they are sat on a chair which has ‘arms’, and in particular, wheelchairs. The system cannot differentiate between the patient’s arms and the chairs and this can therefore lead to inaccurate readings. This issue was avoided in the hospital setting by having patients use chairs which did not have arms. However, this could present issues when working with more acute stroke patients as they may not be able to balance in chairs without arms. This issue may be solved in the future as tracking algorithms improve. It was later mentioned by a different therapist that the system had some issues in initially tracking the patients’ arms until they ‘moved them around’. This caused some confusion, but was usually easy to rectify.”

“The therapists had some initial issues whilst getting used to the system and its tracking of passive movements. The therapists usually entered the camera view too

early and therefore, the system began to track the therapist and not the patient. This was solved after explanation by the researcher. However, it must be noted that more thorough training must be provided in use of the system if it is to function in a healthcare setting.”

“An aspect that occurred during the research, which was not originally intended, was the ability of the system to detect movement synergies. When viewing a patient interacting with the system, the patient was fully capable of producing full abduction at the shoulder joint and full flexion at the elbow. However, when conducting patient-led exercises, they were unable to complete them. As a result of this, the Occupational Therapist present decided to investigate further, discovering that when the patient abducted their arm, it was fully extended at the elbow, providing balance support. However, when the elbow was flexed during the tasks, the patient had problems with trunk control and was unable to fully support themselves. Although the therapist had previously noticed issues with trunk control, they had not realised how much it had affected ADL until this juncture.”

“One Physiotherapist commented that they would prefer to be presented with some ‘normal’ data regarding the ADL movements, i.e. they would like to see a minimum/maximum ROM line at each point of an ADL to see if the patients movement fitted in that scope, and if not, at which point of the movement it would deviate. The therapist and the patient may then be able to know how close the patient is to a ‘normal’ movement.”

“Some therapists mentioned that the system has difficulty tracking patients in certain lighting conditions, however, this is a known issue and is something that Microsoft are working to improve.”

A discussion of these field notes is presented in Chapter 7: Discussion.

6.2.2 - Post Assessment Interviews

The 9 therapists who participated in the study were involved in an interview after trialling the device. Their views have been thematically coded and are presented below.

6.2.2.1 - Technical Issues

During the validation of the system, the therapists described certain technical issues, which they felt were resolvable and would need to be improved in future versions of the system.

Some therapists spoke of issues with lighting in the room affecting the system functionality, whether this was artificial or natural:

“It didn't work properly when we had the window blinds open” (PT2).

“We had the curtains drawn off to make sure there were no ‘distractors’ for the device” (OT2).

“There were difficulties with lighting” (OT4).

“[We had issues and] I think it might have been the lighting that we have in the gym” (PT1).

“We found that when we turned the lights off, it seemed to pick people up better” (OT5).

Two therapists spoke of difficulties the system had in detecting certain movements, particularly when initially setting up the device:

“Sometimes it can be off-putting and it can be frustrating if the movements are not being picked up” (OT5).

“It did pick up the movements, but it did struggle sometimes....sometimes it didn't pick up what we were doing in the gym” (PT1).

“There were some issues with picking the person [patient] up, sometimes if you are a bit too close” (PT3).

“I think he [the patient] was improving more than the system was telling him sometimes” (OT6).

One therapist spoke of how this may have been down to issues with not knowing where to place the system:

“Sometimes we had difficulty trying to place the system, putting a table in front of someone caused errors. We tried moving the table to the side, but then the system would ‘see’ both individuals and cause errors. We would then have to switch the machine off and start again” (OT4).

Two therapists also spoke of difficulties when they were first loading the system, stating that there were difficulties in detecting the arms of a patient:

“Sometimes it was not detecting the hands by the side at the start of the program” (PT1).

“Sometimes it had difficulty picking up the signal for the arms” (OT6).

This was a problem that was particularly noticeable when patients used the system whilst seated:

“When patients are sitting down it is not picking up their movements... We often had to make the patients stand up” (OT1).

“He [the patient] didn’t have very good sitting balance so we struggled sometimes with him...we struggled with him as he couldn’t sit on his own...sometimes patients haven’t got the sitting balance that’s required” (OT6).

“Most of the patients that we tend to see have to be seated, so the arms of the chairs can get in the way” (OT4).

“In use there have been some issues, for example when people are sitting in chairs, sometimes it is picking up the arms of the chair rather than the person” (OT2).

In addition to initial issues of patient detection, there were also difficulties with other people moving in front of the system. Although therapists were asked not to enter the view of the camera at certain times, this became difficult as patients required so much support:

“It is picking up the therapist” (OT1)

“It cannot discriminate between the patient and other people” (OT2)

Two therapists discussed how these difficulties could be problematic in a finished system:

“The slight technical issues: the lights, the sensitivity, the distance....If it is going to be stop-start, stop-start, then it may be difficult to use” (OT4).

“It does need more work on not being so sensitive to the conditions such as the lights and the number of people on screen” (PT2).

One therapist also mentioned a problem with the watch:

“I think we had a problem where the watch battery stopped working” (PT3).

6.2.2.2 - Advantages of the System

All therapists during the interviews spoke of the advantages of having such a system, and the potential that it showed. Some therapists stated how they believed it would save time:

“[The system could] potentially be quite timesaving and accurate....sometimes when you are using a goniometer it can be a two-person job and hopefully this will help that” (PT1).

“It is quick....you don’t have to take time out of your therapy time....with other outcome measures they can take up part of your therapy session whereas this is quite quick, simple to use, and you can incorporate it as part of a functional activity so you can do the two in one” (OT6).

“I wouldn’t be able to get a goniometer out at every therapy session because we don’t have enough time, so if you have a system that measures ROM more rapidly, or in a more correct manner, more specific, then I think that’s one advantage, because you’re more likely to do that then. At the moment we just sort of eyeball the movement, rather than using something that is specifically objective.” (PT3).

The therapists also spoke of the ease of use of such a system:

“The instructions were clear to follow....When we have done it [used the system] with patients here, they’ve been able to follow the instructions quite easily....it was quite simple movements, so that was good, and it was functional” (PT1).

“I found it quite easy to use” (OT5).

“The best part of the system is the ease-of-use. It’s quite easy to pick up. How easy it was to set up, and review, and explain was really good” (OT4).

“In terms of the actual setup, it is simple to use....you just go through the movements with the patient and it picks them up” (OT2).

In line with the ease of use of the system that was described, the therapists believed that user acceptance by healthcare staff, caregivers and therapists would not be an issue:

“I think generally they [patients] probably wouldn’t reject the technology because it is unobtrusive” (OT5).

“Even with older people I don’t think it was a scary thing, they just stood in front of it and it worked” (PT1).

“I like the fact that it uses existing technology, such as the Kinect, which is something that already appears in people's homes and people already use on a day-to-day basis” (OT5).

“It was quite straightforward to use and explain to the patients” (OT6).

“Generally, I felt it was fairly easy to set up...obviously once you've used it a few times it gets even quicker” (PT3).

One therapist also stated that the change in generation would make the introduction of such technologies easier:

“Younger patients are coming through who are more used to technology” (PT1).

A particularly promising aspect of the system was the belief of the therapists in the feedback aspect. A lot of therapists spoke of this as a useful addition to stroke rehabilitation:

“I think it's good for them to be able to look at the progress objectively and be able to see changes... “I think it's good that you can track progress and you can have an objective measure of movement, particularly in occupational therapy” (OT5).

“There are advantages, because it would give you immediate measurements that are accurate, and obviously you can show it to patients and show them their progress...They [the patient] can see their progress written down and get feedback” (PT1).

“The advantage, I believe, is that you can see some small changes that the therapist or I, may not spot, or be able to see....It is good for picking up little movements and

helping to see if there are improvements. It is also a good way to show patients if there is no change, post-rehab, because sometimes they struggle to see this, or they say they feel they are improving and they are really probably not...it is good for looking at the arm in isolation” (OT3).

“It was quite good feedback for him [the patient] ...it is quite immediate feedback for the therapist and the patient” (OT6).

In addition to this, therapists spoke of the motivation that this feedback can give the patient:

“They can see their progress and it's motivating....I suppose it is only like anything you are doing yourself, if there is somebody there saying ‘come on’, like any exercise programme” (PT1).

“Sometimes improvements can be very small, and slow, and they [the patients] don't feel they're making any progress, and it's good if a graph shows them how they are getting on” (OT5).

“If it is a way of encouraging patients; that can only be a good thing” (OT3).

“I think it will give them the ownership of their rehabilitation” (OT4).

“It was a good outcome measure that he [the patient] could get involved with and understand fully” (OT6).

This motivation and feedback was further spoken of, in terms of allowing the patient to continue rehabilitation by themselves:

“I think it is good because it makes the patients become a bit more independent and they can take a bit more responsibility of their condition...I guess it makes the patients more independent if they are able to have their rehabilitation programme on a computer and they want to do it” (PT2).

Therapists like the fact that the system was functional and repetitive, and saw promise in this way of functioning:

“The functional aspect of it, I think will be useful....I would predict that the functional bit of it would provide a better outcome” (OT2).

“In terms of the repetition of it, it is good to have the functional aspect” (PT1).

“I did like the fact that it was quite functional and for OT’s that is very important” (OT5).

“I like the functional aspect, that they may be reaching for a telephone and it is giving people a distraction so they are not scrutinising their own movements as much....I think it would give a bit of purpose to the activity” (OT3).

In addition to the above advantages PT1 spoke of the cost of the system being a positive aspect:

“I actually think the cost would be a good aspect of the system...It is a lot cheaper than I thought it would be” (PT1).

Overall, the therapists saw a lot of positives in the device, and saw it as a good addition to stroke rehabilitation:

“This system is portable and easy to use in an everyday setting, particularly in the community, it has the ability to add on to it; it is functional; it is cost-effective; so I think it is a realistic system” (OT5).

“It would be interesting to see a new version of the system” (OT3).

“I think that it could be advantageous if it was just a little bit corrected” (OT1).

“I definitely do not think it would be a negative thing for patients” (PT1).

“Yes, it was quite exciting....and obviously I am aware that these are small problems, and with the development of such a system, this is only going to get better....I think when the system is fully developed it will be a great system” (OT4).

“There were some negatives to it, but as the bigger picture stands, there's lots of good positives from our perspective and from the patientseverybody that we did this with was interested in the research and was interested to note that this was the future” (OT2).

6.2.2.3 - Telerehabilitation (Rehabilitation from a Remote Location)

An area which could be a further advancement to this research is the idea of eventually using such a system in telerehabilitative setting. Therapists referred to this in the interviews:

“Obviously in the future, you could use it in patients’ homes for either rehab or as an assessment tool and you are not going to have to go out to be with them face-to-face but could do it over the internet” (PT1).

“There is a lot of potential for it to be used at home and in the community....I can see applications in terms of remote healthcare and helping unqualified staff with rehabilitation” (OT5).

“It has got good potential to be used for home treatment and self-management for people” (OT2).

“Using ‘telerehab’ they can see their improvements quite quickly...it encourages them to do more ‘rehab’ at home” (OT6).

“As far as having it in their own home, it can only be beneficial, that’s where things are heading towards....I’m a big fan of getting the patient to do as much as they can” (PT3).

“Twice a week is the maximum time we can treat a patient for, so I can potentially get a patient to do a lot more using a set programme” (OT3).

“I think it would need more development to be used in the community, but I do think it is something that could be used” (PT2).

6.2.2.4 - Suggested Developments to the Current System

Therapists spoke during the interviews of improvements they would like to see in the system to improve functionality. One Occupational Therapist described how additional components could improve the system:

“I think for it to be useful, maybe it needs to do a bit more. It seems odd to set it up and only do three movements....I think there should be more of a rehabilitation

programme...It would be nice if there were a wider variety of activities to use....I found it quite quick though and I was expecting it to be a bit more in-depth” (OT5).

In addition to this, a Physiotherapist stated that they would want to see a method for collecting maximal ROM and not just functional:

“If there could be some way of measuring full [maximal] range of motion it would be very useful” (PT1).

A lot of therapists spoke of their desire to have such a system implemented as an outcome measure:

“It [the device] can act as a score or outcome...it would be a good outcome measure” (OT1).

“We haven't got good outcome measures, probably here. It is difficult to take outcome measures without it being different from therapist to therapist, and this would help with that aspect....It [the system] is probably something that I would like to do at the end of each session, for like a five-minute follow up” (OT3).

“For OT's it is useful for us to have a separate objective measure as to what sort of movements are happening” (OT5).

“We ended up using it at the start and asking the patient to do the movements....it gives you a very accurate way of presenting peoples range of motion....it can be a good use of an outcome measure for looking for improvement or deterioration” (OT2).

“It is quite a good outcome measure...it is good for us and the hospital to see people’s improvements” (OT6).

“We tended to use it at the start of a session as an outcome measure...I think having the ADL’s was a useful way of trying to work out what movements people need....half the time for us it is an educated guess rather than knowing that a person can do something....often it’s trial and error” (PT3).

One therapist spoke of their desire to have the system assess quality of movement in addition to just range:

“I do not know whether the system detects the quality of movement; if there are trunk problems and things like that. I think if I was setting up patients to use it, I would like to know whether there is something going on in the trunk that I am unable to see” (OT3).

Two therapists spoke of their desire for the system to give additional feedback to what the system is currently capable of presenting:

“I think if you could look at shoulder flexion and abduction then obviously that would be a benefit and would make it much easier to use” (PT3).

“If they do the functional activities and the machine tells them what they can and can't do, then that is more useful information....I think more feedback to the patient using it” (OT2).

OT2 also stated that they would prefer to see more interactive elements to the system:

“Something on the screen that they can tap such as playing a game of cards” (OT2).

One therapist spoke of how ‘Gait Analysis’ with the system could be useful:

“Analysing gait would be useful” (PT3).

6.2.2.5 - Further Training and Support

There were some comments during the interviews with regards to training and support when using the system. Two therapists commented on how they would prefer to have some formal initial training, particularly in teaching them about what errors can occur in the system:

“More training would have helped. So we can know what is going wrong with it...I suppose, if it is not working, we would like to know what the most common things that stop it working are, for example, lighting levels; standing the correct distance from it” (PT1).

“It would be good to know what it ignores” (OT4).

OT4 also spoke of how additional support during use would also be beneficial:

“Maybe some additional support could have been useful” (OT4).

OT6 also spoke of the support structure:

“I think as long as there is somebody on hand like yourself [the researcher] that you could ring if there was a problem...I think if we were left with it there may have been a few more ‘teething’ problems...I know you [the researcher] used to come in quite a bit and I think we needed that, but that was sufficient” (OT6).

Some felt that if more training was given, perhaps user acceptance of the system would increase but others did not agree.

“I think so, if I was more comfortable using it, with a bit more training” (OT1).

“I don't think so, I think as it stands it was quite simple to use” (OT2).

“I felt everybody who used it fully understood what it was about and how to use it” (OT6).

6.2.2.6 - Disadvantages of the Current/Future System

Some therapists did discuss disadvantages to using such a system with the NHS.

Some therapists stated that with the system in its current format, they felt a therapist or caregiver would still need to be with the patient at all times:

“We [therapists] would just have to keep an eye on them so we knew what they were doing” (PT1).

“I do see it as a support tool; so you do still need a therapist there working with the patient” (OT4).

“It is not very often that the patient can actually do much treatment by themselves, because they need a pair of eyes on them....they are quite a hard group to set up with self-management” (OT2).

“We [therapists] thought that if some of the patients were to use it, they would need help and assistance for some of the tasksI think it would need to be closely monitored” (PT2).

“I'm not sure how much assistance you can give to a patient whilst the system is testing, because we often give the patient a little bit of gravity support” (OT3).

Some therapists believed this support would be needed due to cognitive problems in stroke patients:

“Some patients would not be able to do it because they just need that one-to-one therapy and can be anxious or have cognitive problems....some patients with stroke have cognitive problems or language problems, so they would have issues following instructions” (PT1).

“[It is good] if they [the patient] have the understanding” (OT6).

“I think a lot of the population we deal with are very cognitively unable” (OT5).

“The majority of patients, even if they have low-level cognitive problems, they would struggle with setting up or following the instructions.... people would need help if they had cognitive problems...sometimes, you would also have to repeat instructions to the patient” (OT4).

Another issue with not having a therapist present would be compensatory movements that the patient is likely to develop, particularly as this can lead to issues with user acceptance amongst therapists:

“I'm not sure about, with compensation movements, and things like that... whether the patient would gain compensation movements; that would be the concern that we would have” (OT3).

“I don’t know if it picks up compensation movements, as this particularly happens in Stroke” (PT3).

“They may be doing arm exercises but their sitting balance is off and they don't know that” (OT2).

One therapist also mentioned issues with the cost of running such a service:

“I think in terms of getting the equipment in and installing it, well I suppose it depends on how often it's going to be used as to whether it is cost-effective” (OT5).

Three therapists also spoke of the initial time that would be needed to establish the system:

“It is time-consuming, initially” (OT1).

“I think it was a bit time consuming at first, but if we used it a lot then it would improve” (PT3).

“So at the moment, with the setup, it has been a little bit more time-consuming, you know, it'll be better if you could set them up, go away, and come back to them” (OT4).

One Occupational Therapist also spoke of issues with complex movements, and their lack of trust in the system in detecting these movements:

“They may be managing to move their arm, but there may be other stuff that the system cannot see is going on elsewhere” (OT3).

A discussion of these interviews is presented in Chapter 7: Discussion. The discussion examines the technical difficulties discovered, how these can be corrected

and whether they are truly detrimental to the system. The therapists' views of the system are also taken into account with a discussion of advantages and disadvantages of the system. Finally, ideas from therapists which are derived through use of the system are discussed and detailed as potential future user requirements.

6.3 - Summary

This chapter presents the main results from the evaluation of the prototype designed as part of this research (in-depth discussion of these points shall occur in Chapter 7: Discussion, where the system and evaluation are discussed as a whole).

The evaluation is split in to two phases. Initially, verification was conducted, in which the systems performance, in terms of measuring ROM, was compared with that of a Physiotherapist. The user, upon interaction with the system, conducts three ADL which require a large ROM. This ROM is compared with that taken by a Physiotherapist, manually, with a goniometer. Error rates of the system and the physiotherapist were calculated and compared. Results were shown to be statistically equivalent.

The second stage of this evaluation was to perform a validation study. This involved deploying the system at two NHS sites for a 15 week time period. 9 therapists partook in the study, with each site using a different version of the system (in-therapy version, and ADL version).

Field notes were taken throughout and semi-structured interviews were conducted at the end with all 9 therapists. Field notes and interviews identified certain technical issues (e.g., lighting, system placement and passive movement detection), system

advantages (e.g., timing, ease of use, feedback and motivation, improvements ('normal' ADL data, increased amount of movements and gamification), use for remote rehabilitation (telerehabilitation), initial training and disadvantages (cognitive and language difficulties, compensatory movements, initial time to establish a service).

The next chapter discusses these results in depth, and provides an analysis of where the system currently stands, what is needed to improve it, and how future systems could be developed, based on ideas derived from this research.

Chapter 7: Discussion

This chapter provides a discussion of this thesis as a whole. This will include a discussion of the design stage of the system (requirements elicitation), system implementation, and the evaluation of the system (verification and validation). This chapter also describes how the current system would need to be adapted based on user needs, followed by a summary of ideas for future system developments, based on the system validation.

7.1 - Discussion of the Designed System (Requirements Elicitation and System Implementation)

In this research a prototype was developed to assess ROM in stroke patients. The system comprises of a Microsoft Kinect motion tracking camera; an EZ430 Texas Instruments chronos watch; a laptop and a bespoke piece of software.

Requirements elicitation was conducted through a set of semi-structured interviews which were conducted with 10 therapists (5 physiotherapists and 5 occupational therapists), and non-participant observation which was conducted with 2 of these therapists (1 physiotherapist and 1 occupational therapist) and 3 stroke patients. The system was derived from this requirements elicitation, which meant the system needed to measure functional tasks using the upper-limb in a quantified manner, which was time and cost effective, while remaining portable and suited to the clinical environment.

The prototype, which was developed, had two software versions. The initial version allowed the tool to be placed in the background during a physiotherapy or occupational therapy session and measure the patient's ROM throughout the session, with minimal interaction from the therapist. Feedback was then presented to the therapist for further analysis.

The alternative version of the system asked the patient to carry out three ADL while facing the system, before presenting feedback to the patient. The therapist is then able to access more detailed feedback once the session is complete.

The intention of the prototype is to be placed alongside current outcome measures which are currently available in order to compliment these by providing additional quantitative feedback regarding motor control in the upper-limb. The tool may be able to act as a decision support system; to provide motivational feedback to the patient via the presentation of their progress or to allow therapists to have additional quantified data which can show progress of their patients.

It must be noted that there are some limitations to what the system is currently capable of doing, and it must therefore be used in combination with other outcome measures. In particular, the system is not able to detect strength and power of movements; touch and sensation; proprioception; compensatory movements; tone and any movements outside of the upper-limb. Although some of these points have potential to be added to the system (e.g., compensatory movements and non-upper-limb movements), therapists using the system must be made aware of the pros and cons of such a system through adequate training methods.

The limitations of the system do not only involve aspects the system cannot track. The system also has some additional limitations in terms of the initial learning curve that is required for therapists and patients using the system, particularly as training may be required. Therapists must also be aware of the accuracy limitations of the system, due to its low-cost nature. Although this accuracy level is likely to improve over time, therapists must always be aware of what the system can and cannot do.

7.2 - Comparison of the Implemented System against the System Requirements

This section compares the overall outcomes of the system against the initial specifications, which were established in the implementation section of this thesis. The following points are the actual specifications, followed by a discussion as to how these were approached:

Assess the Upper-Limb in line with the scope of the project (this may be advanced at a later stage, however, a focus is provided in this area due to the current evidence-base on upper-limb assessment shown in the literature review). The system should provide a breakdown of individual movements, and be able to differentiate between active and passive movement.

The system allowed for the evaluation of ROM in the upper-limb, using a Microsoft Kinect motion tracking camera, a Texas Instruments EZ430 chronos watch and bespoke software deployed on a laptop. The ROM which were assessed were

pronation/supination at the wrist joint, flexion/extension at the elbow joint and abduction/adduction at the shoulder joint.

A method for providing quantified measurement which can be used in conjunction with current outcome measures to create an increased holistic assessment approach. However, these should have adaptable difficulty levels, for different individuals.

The in therapy version of the system allowed for the quantified assessment of ROM to be carried out in therapy sessions. However, initial difficulties did arise with this version of the system, which shall be discussed later in this chapter.

However, the ADL version of the system was created which allowed for the monitoring of ROM whilst the patients conducted three ADL; namely, picking up a telephone, pouring water from a jug into a cup and combing the back of their hair.

As the patients were being assessed, they were only shown improvements against their own previous outcomes. This allowed the system to be adaptable to different individuals.

A tool which could potentially allow for an increase in therapist efficiency by minimising interaction time needed by the therapist when using the system, whilst alleviating time required for assessments of patients.

The system allowed for the assessment of upper-limb motor control in stroke patients using a system which could either be placed in the background during therapy, or as an ADL assessment system. There is potential that this could be time-saving to therapists as data can be drawn without the therapist having to conduct an assessment themselves; however, even though the system was designed with this element in mind, the full implications of this are to be fully substantiated and is in scope for further work.

Low cost and affordable system.

The system was created with costs in mind. It was developed using a Microsoft Kinect (less than £150), an EZ430 Texas Instruments Chronos Watch (less than £50), custom software and a regular laptop.

Evaluated in the clinical environment at an early stage, with further developments driven by this, in order to be End user-accepted and driven.

The system which was developed was designed based on a requirements elicitation exercise which involved semi-structured interviews with occupational therapists and physiotherapists in the NHS. The system was created as a prototype which was deployed in the NHS at an early stage (in 2 NHS sites for 12/15 weeks respectively), resulting in user requirements and technical considerations within a healthcare environment, in order to be a clinically driven technology.

Portable and Usable in the Clinical Environment.

As the system was created using a laptop and off-the-shelf portable hardware, this specification was met. To allow increased portability of the system, therapists who used the system were also offered a mobile table.

The purpose of this system is to monitor ROM during functional activities either during therapy or via the conducting of ADL. This was to allow the assessments to be as translational to the real world as possible. Although, quantitative data is not available with regards to how translational the activities were, as this would have been outside the scope of this project, this is a suitable task for future research.

Motivational, with ample feedback to the patient and the therapist, in terms which are understandable to both.

The system was able to provide initial feedback to the patient when they were using the system. The patient was presented with basic feedback, showing them how much they had improved (e.g., 20° more movement at the elbow joint since their first session).

The system also provided quantified feedback to the therapist in a graphical representation, in which the patient's movement at each joint could be seen during the current session, and in the form of ROM over time.

Easy to use.

The system was designed to be as usable as possible, with minimal inputs required from the therapist/patient and maximum feedback being presented during usage. The validity study in this research provided feedback on the ease-of-use of the system, with therapists commenting, unprompted, on its ease of use.

Safe.

The system was always required to follow relevant safety principles. In order to achieve this, full NHS ethics was acquired before any system testing could be conducted. The system was also constructed from off-the-shelf CE marked products which guaranteed a certain level of quality assurance.

7.3 - Discussion of System Verification

The system verification study aimed to evaluate whether the system developed for this research was not inferior to the current method for assessing ROM in terms of accuracy. This was performed through a testing process in which ROM was evaluated in 10 healthy volunteers over a 3 week period by a chartered Physiotherapist, and through ADL functionality tests taken by the system.

The study showed that the physiotherapist, when taking ROM measurements showed a mean error of 1.757 with a standard deviation of 2.095. The measurements taken by the system actually showed a larger mean (2.321) and standard deviation (2.571)

then the therapist. However, when these figures were compared using a paired samples t-test, the difference was shown to insignificant.

A further test was also deployed to establish whether the figures were actually equivalent (as the t-test would only prove that there was no difference, and not equivalency). When using the equivalency test, it was decided that an error rate of $\pm 5^\circ$ would be used as the comparison value, due to this being the minimum rate of error displayed in the journal articles reviewed, which evaluated goniometry. When using this error rate, the results taken by the therapist were shown to be statistically equivalent.

The results show that the device can operate at the same level of error as the chartered physiotherapist. However, through use of the system, other issues may be alleviated, such as inter-rater reliability in goniometry and time taken to complete goniometry with therapists present as multiple measurements can be taken from the system. The system also has scope to extend to other areas such as gamification and could help improve feedback and motivation.

However, there exist some limitations in this study. The first of these was that the physiotherapist, when taking measurements, always rounded to the nearest five degrees, which could potentially have some effect on results. Secondly, not all participants completed three weeks of testing; further tests must be conducted over an extended time frame. In addition to this, only 10 participants were used and 1 physiotherapist (due to timing and cost constraints), and this may limit the extent of these results.

It must be noted that the experiments in this study were conducted utilising algorithms from an SDK which has recently been improved in terms of accuracy, and over time, error margins are likely to decrease even further in this area. Further tests should be performed utilising a more up-to-date SDK.

7.4 - Discussion of System Validation

The system validation study was able to identify the current advantages and disadvantages to using the prototype within a healthcare setting. The system was deployed in a hospital setting for 15 weeks with 9 therapists; field notes were created during this time. This was followed by semi-structured interviews with all therapists who had used the prototype. The system was deployed in 2 hospitals, with each using a different version of the system (ADL version or in-therapy version).

7.4.1 - Advantages of the System

Therapists initially seemed motivated by the system, due to the belief that this tool could provide time saving capabilities. In particular, there was a belief that if used at the start of sessions (using the ADL version of the prototype), it could be used as a quantitative outcome measure and save time having to assess the patient; especially as it was also possible to have the patient performing the activities while the therapist was preparing other items for the session. In using the system as an outcome measure, one therapist identified how this may alleviate problems with inter-rater reliability in certain outcome measures, as a quantitative measure can be presented when moving the patient between therapists.

One therapist mentioned that when using traditional goniometry, it would either require 2 therapists to be present, or therapists would have to “eyeball” ROM, creating inaccuracies. Therefore, the system may be capable of spotting smaller changes than what would currently be available, particularly as it may be able to isolate individual movements.

Therapists did mention that having the system in the background during therapy sessions would be highly useful, but seemed to be impractical due to constraints that were placed on the session (e.g., the patient having to face the camera at all times with the therapist not moving in front of them). It appeared at this point that the ADL version of the system may be more suitable for the purposes of motor control assessment in the upper-limb.

The therapists appeared enthused by the feedback they could give to the patients, and even suggested that the system should give more basic feedback to the patient regarding their progress, which could help improve motivation, ownership of rehabilitation and self-management. It may also help, through reporting progress, to give more purpose to the rehabilitation. This is something that will require further investigation.

The therapists were also interested in the usability of the system. It was expressed that the ease-of-use of the system led to increased interest; although, some therapists did express concerns with difficulties in its initial set-up. The therapists spoke of how the usability of the system made user acceptance high as the system was “unobtrusive”, but improvements were needed in terms of patient detection and avoidance of technical issues. It was also discussed, in the interviews, that younger

patients may be particularly interested in such a system, particularly as it uses existing technology which some individuals may be familiar with. This may be in the form of additional training for the therapists involved, or modifications to the system in order to alleviate any technical difficulties.

Therapists, during validation and in the interviews, expressed this idea of motivation to the patients. The idea of providing quantitative data to the patients, in a format that could be easily understood was advantageous. One therapist actually mentioned that ‘tech-savvy’ patients became interested in the prototype and asked for further information.

The therapists involved in the study also expressed how much they liked the testing of functional ROM. It was spoken about that this is currently difficult to assess and the ability to transfer the assessment to a ‘real-life’ situation was advantageous.

An idea spoken about during the validation was the idea of using the system for telerehabilitation. It was believed that the low-cost and portable nature of the system made it highly applicable to this scenario. With the ADL version of the system proving the most advantageous, this version of the system could potentially be used in the clinical and remote environment to improve motivation and increase the amount of time in which patients conduct rehabilitation outside of hospital. The use of the system in the home environment is something that could be investigated further to test this hypothesis.

7.4.2 - Technical Issues

A range of technical issues (a summary of these are shown in Table 7-1) were identified during the system evaluation.

One problem which was identified was with lighting, particularly when using the system in direct sunlight. This is a known issue with the system and Microsoft give guidance to lighting when selling Kinect devices (Microsoft, 2013). As this is a known issue it is something that therapists would have to be trained in when delivering a future version of the system.

Table 7-1: Summary of Main Technical Issues

Technical Issues
Lighting.
Multiple Person Detection in Busy Areas.
Detection of Therapist and Passive Movement not Accurate Enough in Practice.
Initial Detection of Patient (particularly the arms).
Sitting (particularly with patients in wheelchairs).
Low Power in Watch Stopping Accelerometer Working.

Another issue which occurred during validation, was that the system was placed on a busy hospital pathway, which made it difficult for the system to detect the patient accurately, as it was often detecting multiple individuals, and finding it difficult to determine which one was the patient.

In another incident, the battery in the EZ430 chronos watch was low on power; this created a scenario in which the clock still worked, but the accelerometer would not function properly, this again could have potentially been avoided with more advanced training.

In addition to these issues, therapists stated that a lot of issues occurred when first ‘setting up’ the equipment. One particular issue which occurred during set-up was the detection of the patients’ arms, if the arms stayed still when the system was performing its initial detection of the patient. This was particularly noticeable in patients who required a wheelchair, as the system was sometimes unable to differentiate between the wheelchair’s arms, and the patients. When initially starting the system, the patient would often have to move their arms around slightly before detection occurred. This is an issue that would have to be overcome in future versions of the system. In addition, there were often problems when the therapist entered the field of view. This only happened in the in-therapy version of the system, when the view was obscured by the patient and the system could not see the therapist accurately, causing problems with therapist detection, and in particular, detection of passive movement. This seems to be another justification for the use of the ADL version of the system, as the in-therapy version seemed to be a difficult set-up to use.

Some of the issues identified here could potentially be corrected using newer versions of the Kinect SDK, which may have more robust tracking algorithms. In addition to issues corrected by newer versions of the Kinect for Windows SDK, therapist complained about the ability of the system to detect people when they are seated; particularly people in wheelchairs. The new version of the SDK contains an

enhanced 'seated' mode which will allow the system to overcome this issue (Microsoft, 2012b). The newer SDK's may also help with any issues with tracking. Accuracy is consistently improving with time, especially initial detection of the individual. With processes such as seated mode, near mode and a 'sticky player' mode in which algorithms are used to keep tracking one individual, this tracking should become a much more stable process.

7.4.3 - Overall Disadvantages of the System

The system also displayed some disadvantages, which were not due to technical limitations.

Some therapists forgot which movements the system measured while conducting therapy and were then unsure how to use the system; with one therapist querying how complex the movements could be whilst using the system. However, this may improve if, in later versions of the system, only ADL tasks are assessed, as this was only a problem in the in-therapy version.

One therapist also discussed issues with some patients not being able to understand the system, due to cognitive and language difficulties. A certain level of cognitive function would be needed to use the ADL version of the system which requires following a set of instructions. Although the system utilises feedback in different formats (e.g. visual, auditory), some individuals may still not be able to understand this, and this will remain as a disadvantage of the system.

Another point discussed during the interviews were concerns around costs of the system. Therapists often believed that the low cost of the system itself was advantageous, however, discussions were raised around the cost of implementing such a system as this would involve initial set-up costs, support structures and training. This initial set-up may also take a period of time, and some therapists expressed a concern over this. This is something which would require further investigation and would require a full economic evaluation.

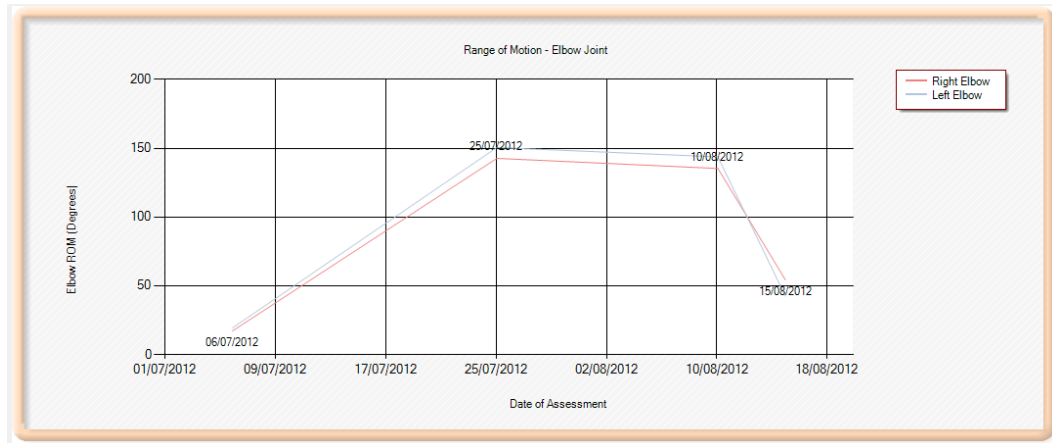
A therapist also mentioned how the system may encourage patients to develop compensatory movements. It may be possible that future versions of the system could detect compensatory movements by monitoring more joints. However, the therapist must always be encouraged to monitor the patient for any compensatory movements they are attempting whilst using the system.

It was previously spoken about in this chapter that therapists should have adequate training before using the system, and this is something therapists requested in the final interviews, with this currently being a disadvantage of the prototype in its current state. This training should include information regarding what the system can and cannot do. In particular, this should focus on the accuracy levels of the system, so the therapist is aware of what the system can identify in the patient.

7.4.4 - Issues in Collected Results

This system allowed for the evaluation of patients' ROM at specific joints over time. 5 Stroke patients participated and they are referred to as PAT1 – PAT5.

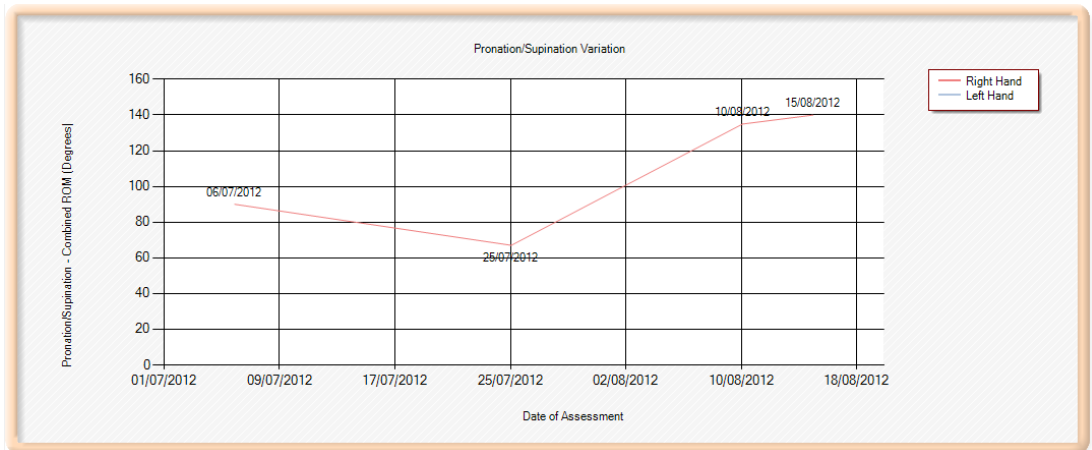
Figure 7-1: Elbow ROM over Time as Measured by the System in PAT2



The most noticeable factor in the experiments was the variation in ROM between tests. This ROM could often increase and decrease quite rapidly as shown in Figure 7-1. This variation could be caused by the stroke suffered by the patient. However, there is also the problem that some measurements may vary due to the technical difficulties described by certain therapists, as there is currently no method for deleting sessions when errors occur.

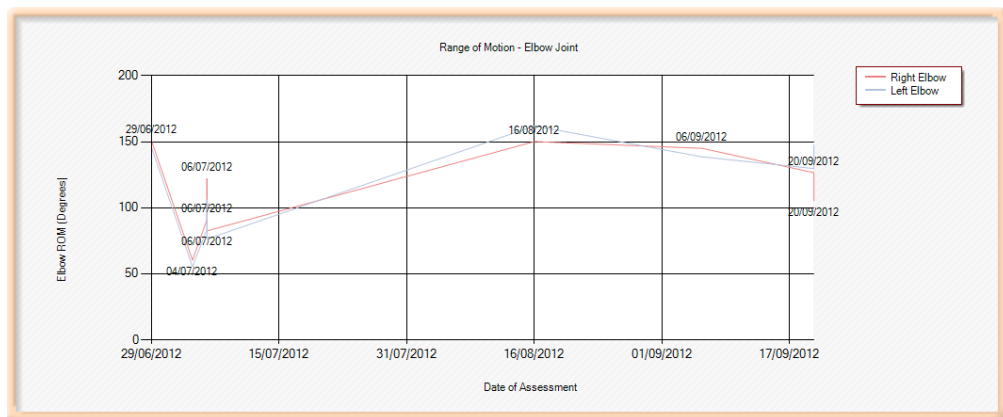
Although these problems did exist, and there was limited time to gather data due to certain issues, some patients did begin to see changes in their ROM, as represented by the system. Figure 7-2 demonstrates a steady improvement by one patient, over a period of time.

Figure 7-2: Pronation/Supination ROM over Time as Measured by the System in PAT2



An issue which occurred during testing, due to the technical difficulties were the clustering of data points around a certain date as shown in Figure 7-3. This figure shows multiple tests conducted on 6th July 2012, in which technical issues occurred and multiple tests were performed. This resulted in a misrepresentation of the patient’s progress in graphical format. This was again due to not being able to delete sessions with errors.

Figure 7-3: Elbow ROM over Time as Measured by the System in PAT4



All graphs depicting patient ROM over time at each joint are shown in Appendix D.

7.5 - Generated Requirements for a New Version of the Current Prototype

Based on current positives and issues regarding the prototype, and a comparison with initial requirements; it is now possible to generate future requirements for the prototype system developed.

An issue that occurred during testing was the cluster of multiple tests which occurred on one day. This was due to the therapist either experiencing difficulties with the system, or having to pause a therapy session due to an event in their environment; this meant that the therapist would re-start the session, with no way to delete the previous one, causing a cluster of tests on one day. A component which would be possible to add to the system to control this is the ability to pause the system during assessment, and the ability to delete certain sessions, if it is felt that a problem occurred.

The therapists who were interviewed spoke of the time saving capabilities of the device, and the motivation and feedback that it gave to the patients. However, there was a general feeling amongst therapists that this was much more noticeable in the version of the system in which the therapist was not present. Although therapists mentioned that the assessment system would be useful if it were capable of being placed in the background, the difficulties in carrying out therapy in a manner which allowed the system to work were not feasible (e.g., having to face the camera, detecting active/passive movement effectively). Therapists did mention that they felt the system was effective when used at the start of a therapy session to measure ADL

progress. Therefore, it is recommended that only the ADL version of the system be carried forwards.

A further change that could be made to the system involves the recording of passive movement data. At this point in time the system stops recording data if it is determined that the therapist's hand is within a set distance of the patient. It would be useful to display this data on a separate graph. Algorithms may even be calculated to determine current ROM against potential ROM as discovered through passive ROM. However, further research is required to address this.

Therapists often spoke of how the system would be more useful if it was to provide increased feedback to the patients in a new format, with more detail and not mainly to the therapist.

Another adaptation to the current system could be the recording of all motions from all sessions. Currently the system displays all movements in the current session and total ROM in previous sessions. It would be useful to include all movements from all sessions at some point in the database for reference purposes. This could be utilised for further points such as kinematic analysis.

In addition to technical adaptations, there is additional information which staff asked for. Initially, therapists would like to know what the cost implications are for using such a system; a full economic evaluation would have to be performed in order to achieve this.

Therapists would also like to know about the safety implications of using such a system and this must be scoped. This could also be included in more formalised and extended training sessions to inform therapists in how to use the system.

Further investigation is also required into how well patients with cognitive problems, potentially as a result of stroke, are able to use the system, and how much these cognitive problems affect their interaction with it.

An area which was spoken about during the interviews was the initial set-up of the system. Problems were identified with how the system 'identified' the patient. The system would often detect people other than the patient, or not be able to detect the patient at all. This required further investigation, and it is suggested that an improved therapy set up section is implemented, alongside further training with regards to how to use this section. The section may include prompts regarding clutter in the environment, lighting conditions and the detection of multiple persons.

In addition to the detection of individuals, new versions of the system must make use of detecting participants in 'near' mode. This is something implemented in the newer Kinect SDK and may help to alleviate initial detection issues. Another aspect of the newer SDK which may help, is the detection of individuals in seated mode. Further research is required to evaluate the advantages of this.

Therapists in the system validation stage declared how they like the fact that the system evaluated patients using functional assessment. However, there were suggestions made that the system could evaluate a larger amount of ADL. This may help increase the evaluation the system can perform, and its motivational factor due to increased variation and is something that requires further analysis.

An issue identified during testing was that the system would only show results after an assessment. This meant that the therapist could not talk about results with the patient, unless a session was conducted beforehand. This is an adaptation to the system which must be performed.

A final adaptation which must be made to the system is feedback to the therapist when the EZ430 chronos watch has too little power to use the accelerometer data. The watch at this point still has enough power to use the display and could be programmed to raise this error to the therapist.

7.6 - Generated User Needs for Future Systems and Components

An important aspect of this research was to generate potential future research and development projects, which are based on therapist suggestions made during the semi-structured interviews, with an aim to create clinically driven technology. This section examines these derived research challenges by discussing questions left open from the final interviews in the validation stage.

An initial item spoken about was a query to supply data surrounding ‘correct movement patterns’ when performing ADL. Although there is no ‘correct’ manner in which an ADL should be performed, it may be possible to perform further research into maximum and minimum ROM experienced on able-bodied individuals, to provide some guidelines when patients are performing ADL. This could be performed in addition to testing for maximal ROM as described previously; therefore, if variability was to occur (as demonstrated in the quantitative results) then therapists may be able to further break down and analyse what is occurring and

causing these problems. This may be derived through research (possibly with the use of gold standard motion capture technology) to ascertain a general minimum and maximum trend line which able-bodied individuals follow when conducting a specific ADL.

Another point mentioned by therapists was a more integrated method to check for compensatory movements. This may be possible to intrinsically link with a 'normal' ADL movement system, helping to identify compensatory movements. This area may also be developed further, to improve the checking of ADL through detecting correct movement synergies, for example, the elbow and shoulder joint can work in tandem when carrying out ADL such as picking items up and over-compensation at one joint may be analysed and compared with a lower amount of movement at another.

The therapists that were interviewed often discussed the idea of adding additional components and modules to the system. The idea of having separate sections for physiotherapists and occupational therapists may be of importance, particularly as physiotherapists can have interest in detecting maximum ROM as opposed to functional.

The idea of adding 'more' to the system in terms of routines and even games was also of value. This research was intended to provide a prototype; the therapists saw the opportunity for further improvements through the addition of these components.

Therapists also spoke of the potential of using such a tool in a remote environment. Therapists believed that the low cost and portable nature of the device would allow for this. More research into using the system for telerehabilitation is required. One

therapist spoke about suggestions for corrections to movements which could be delivered across the internet.

A therapist in the interviews also suggested the idea of testing movement quality. This may involve the additional use of speed and stableness of the movement. Algorithms would have to be implemented to detect this.

One therapist also suggested that it would be useful if the system could perform gait analyses, in order to improve what the system offered. However, further investigation as to whether this is possible is needed, and whether the Kinect camera is capable of performing this.

7.7 - Limitations of this Research

This thesis is able to suggest a new system for the assessment of upper-limb motor control in stroke patients, which is clinically driven and evaluated. However, there are certain limitations to this research which must be noted.

The research only contains a limited number of participants throughout all parts, due to timing and cost constraints. Semi-structured interviews in the requirements elicitation and validation sections used suitable sample sizes to avoid data saturation, however, they can only be deemed to reflect the views of therapists within the hospitals analysed.

In line with the above, limitations must be drawn on the verification stage of this research. Verification was performed in order to provide quantitative evaluation before the system entered the clinical setting. However, again due to timing and

costing constraints, this was only performed with a single chartered Physiotherapist and therefore, only limited conclusions may be reached.

In addition to the above limitations with the trials of the software, there are certain limitations with the device itself. The reader must be aware that the system is a prototype tool, developed using a rapid approach to allow for immediate clinical validation. Therefore, there are certain technical issues with the device as described, and, it must be taken into account that these issues may change when the device is expanded with further components, alongside additional issues which may occur.

The system which has been developed, also currently evaluated 3 movements (pronation/supination at the wrist, abduction/adduction at the shoulder and flexion/extension at the elbow). It is therefore unable to evaluate if the system will work as effectively if used with additional movements.

It must also be taken into account evidence which this study does not provide. It is portrayed throughout this thesis that the system aims to evaluate functional activities. While the system is developed around testing functional activities, it remains unclear how translational these skills are to a real world environment and further testing would be required to address this.

In addition to this, this thesis also speaks of the ability of the device to optimise therapist time. Again, although the system was developed with this in mind, it was not possible to evaluate how timesaving the device currently is and this requires further validation.

7.8 - Summary

This research resulted in an upper-limb motor control assessment device for stroke patients. The system is a prototype, with design based on requirements elicitation which stated that a system which provides motivational, quantified data regarding ROM in the upper-limb during functional activities; is low-cost, easy-to-use and suitable to the clinical environment would be fit for purpose. The system was developed against these requirements by using a Microsoft Kinect camera, an EZ430 chronos watch and a standard laptop to assess the patient during their therapy session (whilst placed in the background) and/or whilst carrying out three ADL.

In order to validate the system, and assess its comparison against the requirements, verification and validation steps were conducted. A verification which involved comparing the system to measurements conducted by a chartered Physiotherapist was conducted; these showed statistical equivalency. However, only limited evidence can be drawn from this, and further verification steps with more therapists must be conducted, which is currently outside of the scope of this project due to the main evaluation step being the clinical validation in line with the research questions.

Therefore, the next step in the process was a clinical validation, in which 9 occupational therapists / physiotherapists used the system in 2 NHS settings. Semi-structured interviews were conducted after use of the system, with therapists agreeing that the use of a functional assessment system which produced quantified data would be advantageous if used alongside current outcome measures. However, a range of technical issues were identified with the current prototype which included lighting, detection of patient and therapist, issues with seated patients and the space

required to use the system, and problems with low power for the accelerometer in the watch.

A number of changes which could be made to the system were also suggested. These included pausing sessions; storing of all ROM data including passive movement, increased feedback, an increased amount of ADL, increased staff training and solutions to technical issues. In addition to this, it became clear throughout the research that the in-therapy version of the system created too many issues due to positions the therapist had to be in, which made it unsuitable for use in the clinical environment. It became apparent that the use of the ADL version of the system is more feasible.

This research also allowed for the production of user needs for future versions of the system and extensions to it. These included detection of compensatory movements and synergy patterns; measurement of maximum ROM as well as functional; additional components to the user interface including the gamification of the device; the use of the system for remote rehabilitation; the analysis of gait and quality of movement.

Chapter 8: Conclusion

This chapter will discuss the conclusions of this work. This will begin by providing a brief summary of the research. This is followed by a conclusion, and details of further work.

8.1 - Summary

Initially, the literature showed that there is a need to measure ROM to demonstrate progression in patients' rehabilitation following a stroke. This is usually performed manually by way of goniometry; visually, or not at all. A digital system could provide a solution to this problem; but any system must be low-cost, portable and suited to the clinical environment; something current research systems do not provide.

The first study in this research was requirements elicitation, to further understand current problems in the field, according to therapists, and to allow their input in the design process. This involved the non-participant observation of 3 NHS physiotherapists / occupational therapists in a stroke rehabilitation session; followed by semi-structured interviewing of 10 physiotherapists / occupational therapists. The study identified an uncertainty amongst therapists on which outcome measure to use and problems with the measures themselves; including standardisation, sensitivity of scales, subjectivity of scales and the timing of them; issues with the continuity of assessments throughout therapy when the patient visits multiple therapists; and

problems demonstrating quantitative outcomes to patients, particularly for functional tasks.

In line with these results, a prototype system was developed which allowed for the quantified assessment of ROM when performing functional activities. It used a Microsoft Kinect, EZ430 chronos watch, and standard laptop to track motion of the upper-limb. The system had two versions, one which tracked the patient's movement at the upper-limb during a therapy session, and one which tracked the patient's movements whilst conducting ADL.

The system was then evaluated. This began with verification which was performed by trialling the system in ADL mode over a three week period with 10 participants; then comparing errors made to that of a chartered Physiotherapist who used a goniometer to measure the same movements over a 3 week period. The system showed equivalent error rates when compared to the chartered Physiotherapist.

The system was then validated in a healthcare setting, with 6 occupational therapists, 3 physiotherapists and 5 stroke patients. It was placed in 2 NHS stroke wards for 15 weeks, and culminated with semi-structured interviews conducted with the therapists.

Therapists spoke of how the use of quantitative data from functional activities could be combined well with current outcome measures. However, initial problems were identified with the current prototype, which included lighting; multiple person detection; accuracy; initial detection of patients; issues when patients were seated; and space required.

8.2 - Conclusions

Overall, this thesis aimed to provide a digital intervention method for turning the assessment of ROM in the upper-limb for stroke patients into a more objective process; this has been achieved by customising and adapting off-the-self gaming tools for the context of the intervention. The main conclusions of the thesis can be seen in chapters 5-7.

Chapter 5 demonstrates how an off-the-shelf gaming tool was adapted to provide quantitative measurement of upper-limb ROM. This is a method not utilised before in the stroke rehabilitation setting, and allows therapists to take ROM measurements in a time-effective manner, to supplement current outcome measures and add an objective process to the assessment.

Chapters 6 and 7 evaluate how effective the tool was at achieving the aim of this thesis. Initially, the verification, which demonstrated the accuracy of the system, showed that it was as effective as a physiotherapist in measuring ROM, and demonstrated good repeatability (the same as the physiotherapist). However, the ROM can be taken at a much faster speed, and without a therapist present. Therefore, the system has a certain error margin, however, this is consistent (and as consistent as goniometry) but with additional benefits such as time and the ability to evaluate ROM during functional activities.

The system was also validated within the NHS. It was shown that the system suffered from a number of technical difficulties in its current format. These would have to improve if a future version of the system were to be developed, and are

detailed in chapter 7. However, none of the technical difficulties invalidated the tool as a practical system.

It did become apparent, after evaluating technical difficulties, that an ADL version of the system is much more feasible, and it could be used during and/or after therapy.

The validation also allowed for the production of user needs for next prototype iteration and these are detailed in Chapter 7.

Overall, a digital, technology-enhanced method was developed for quantifying upper-limb assessment in the upper-limb for stroke patients. This is something not currently available in the NHS, as goniometry (which can be time-consuming and inaccurate) is not readily used and ROM measurements are often not taken or noted after visual observation.

Therefore, this thesis is able to present an associated integrated system which supplements current outcome measures, by providing an objective measure of upper-limb motor control during ADL. This is using a tool which is low-cost, non-invasive, portable and designed for the clinical environment; attributes which are not shown in other technologies which have been proposed in this sector.

8.3 - Contribution to Knowledge

This research demonstrates a new objective quantitative technology enhanced approach to the assessment of upper-limb functional activities in stroke patients.

Tracking of patient progress is an important aspect in stroke rehabilitation, and tracking of ROM provides a quantitative method for achieving this. However,

therapists often find this information difficult to ascertain. This is due to the fact that goniometry is the only current method of achieving this in the clinical setting, but this can be an inaccurate and time-consuming process, which is often not performed for these reasons. In fact, some therapist will often visually assess ROM improvements in patients, and this can be subjective.

This thesis presents a solution to these challenges by providing a digital intervention method for quantifying ROM in patients. This is delivered in the form of a novel motion tracking system. Other research systems have been identified to provide this, but lack the clinical relevance of the approach demonstrated here. This is because the system is clinically-driven, low-cost, portable, and non-invasive. In addition, the method provides a way of measuring ROM during functional activities, and in particular during ADL, providing information which is currently unavailable to physiotherapists/occupational therapists. The system sits alongside current outcome measures used in stroke rehabilitation and provides data to the therapist which is not currently available.

This research demonstrates that the method developed is objective and repeatable. The system has been developed with the intention of being utilised in a stroke rehabilitation environment. The system is as accurate as a therapist, and, although an error margin may exist, this has been shown to be consistent. The system is then able to provide additional benefits currently not available in the NHS, inclusive of time-saving capabilities and the optimisation of therapist time, alongside the testing of ROM during functional activities such as ADL. This thesis also demonstrates that the system provides this in a manner which can be utilised in a stroke

rehabilitation environment, something other research systems cannot offer at this point in time.

8.4 - Further Work

Overall, there was potential demonstrated by the system, but a range of modifications must now be made in order to produce the next iteration. The validation stage of this research was able to conclude a number of adaptations which could be made to the current system. These include a set of user requirements for the next iteration, and set of potential research areas.

In parallel with the derived improvements, modification of the current processes via technological updates and system advancements should be added to now continue system development. Initially, the user interface could be updated in order to increase appeal to the end user. Changes to the current SDK could also help to advance research through methods such as improved skeletal tracking capabilities. As the current SDK develops while Microsoft works upon this, this may consequently improve this system and further work may be performed with additional SDK's. Further investigation could also be performed into the use of alternative SDK's for these purposes such as the Open Natural Interface (OPEN NI) SDK (Open NI, 2013).

A further research area is in the evaluation of prediction algorithms using tools such as regression analysis and the extrapolation of data (Montgomery et al., 2012). This is something which was investigated during this research, but was deemed too far out of scope due to time and costing constraints. However, this could help provide

feedback to a patient and therapist with regards to predicted recovery times, particularly with a breakdown of each joint, or even certain synergies. This could also be used to inform the patient of the length of time that will be needed in order to conduct certain ADL.

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Appendices

Appendix A Ethics for Requirements Elicitation Study (Letter of Favourable Opinion, Information sheets and Informed Consent)



National Research Ethics Service
Birmingham, East, North and Solihull Research Ethics Committee
REC Offices
Prospect House
Fishing Line Road
Enfield
Redditch
B97 6EW

Telephone: 01527 582534
Facsimile: 01527 582540

13 December 2010

Mr Christopher Golby
PhD Student
International Digital Laboratory
WMG, University of Warwick
Coventry
CV4 7AL

Dear Mr Golby

Study Title: A Review of the Current Methods for Assessing, and Monitoring the Progress, of Patients Requiring Rehabilitation for Stroke.

REC reference number: 10/H1206/90

The Research Ethics Committee reviewed the above application at the meeting held on 08 December 2010. Thank you for attending to discuss the study.

Ethical opinion

Record of ethical issues discussed

- The committee said that A49-2 had been left blank as to whether or not the participant's GP was to be notified of their involvement. You confirmed that this should be 'no' as it was not necessary for this study.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and
Research Ethics Committees in England

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

Other conditions specified by the REC

- Remove the sentence 'You must be over 18 years of age' from the staff information sheets.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Investigator CV		23 August 2010
Protocol	1.2	10 November 2010
Supervisor's CV	1.0	07 September 2010
REC application	3.1	17 November 2010
Covering Letter		23 August 2010
Interview Schedules/Topic Guides	1.0	07 September 2010
Participant Information Sheet: Physiotherapists & Occupational Therapists - non-participant observation	2.0	25 October 2010
Participant Information Sheet: Patients - non-participant observation	2.0	25 October 2010
Participant Consent Form: Interviews	1.0	07 September 2010
Participant Consent Form: Assent - non-participant observation	1.0	07 September 2010
Participant Information Sheet: Interviews	2.0	25 October 2010
Participant Consent Form: Physiotherapists & Occupational Therapists - non-participant observation	1.0	07 September 2010
Participant Consent Form: Patients - non-participant observation	1.0	07 September 2010
Email to R&D Departments	1.0	07 September 2010
Contact List	1.0	07 September 2010
Unfavourable opinion letter		18 October 2010
Evidence of insurance or indemnity	Part 1	03 August 2010
Evidence of insurance or indemnity	Part 2	09 August 2010

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

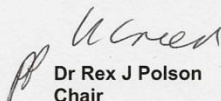
We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1206/90

Please quote this number on all correspondence

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

Yours sincerely


Dr Rex J Polson
Chair

Email: Karen.Green@westmidlands.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Peter Hedges, University of Warwick*

Ceri Jones, R&D, University Hospitals Coventry & Warwickshire

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The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and
Research Ethics Committees in England

Birmingham, East, North and Solihull Research Ethics Committee

Attendance at Committee meeting on 08 December 2010

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr S George	Consultant Psychiatrist	No	
Mrs Lynne Gray	Senior Biomedical Scientist	Yes	
Mrs Rosemary Harris	Solicitor (non-practising)	Yes	
Mrs Theresa Hyde	Retired Head Teacher	No	
Mrs Irene Linder	Assistant Manager, Local Authority	Yes	
Ms Veronica Morgan	Midwife	No	
Dr Richard Mupanemunda	Consultant Paediatrician	Yes	
Dr David O'Brien	GP	Yes	
Dr Rex J Polson	Consultant Physician	Yes	
Dr Timothy Priest	Consultant in Anaesthesia & Pain Management	Yes	
Mr Rajeshwar Singh	Chartered Engineer	No	
Ms Gill Tomlinson	Radiographer	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Jennifer Jinks	
Mrs Karen Green	Co-ordinator

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and
Research Ethics Committees in England

Participant Information Sheet – Interviews

(Version 2.0 25/10/10)

Project Title: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to contact the researchers on the attached contacts sheet if you have any more questions.

What is the study?

This study will focus on the ways in which physiotherapists and occupational therapists currently assess stroke patients for long term rehabilitation. This is to help with the eventual development of a new assessment tool for rehabilitation.

Why have I been contacted about this study?

In order to take part in this study you must be a physiotherapist or occupational therapist that has practised for more than one year in the NHS. You must also be over 18 years of age to take part in this study.

Do I have to take part?

Participation in this study is strictly voluntary. If you decide to participate in this study you will still have the right to withdraw from the study at any point you wish to, without reason and without your legal rights being affected.

What will happen during the study?

You will be asked to give your consent to participate in this study upon arrival. You shall then be given a copy of the consent form. The study will be a simple interview about current patient assessment methods for the long term rehabilitation of stroke patients and should last no more than one hour. Recordings of interviews will be taken.

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What will happen after the study?

Data collected during the interviews shall be transcribed and kept strictly confidential. You shall remain completely anonymous. The results shall be placed online at the following address:

<http://www2.warwick.ac.uk/study/csde/gsp/eportfolio/directory/pg/esrjai/>
(View Research Results and Publications in the left hand column).

This information may also be used towards the completion of a PhD thesis, which shall involve developing a technology / technologies to help in this field.

Will I be at any risk when participating in this study?

You shall be under no immediate risk when partaking in this study and you will not be identifiable in any of the data collected or reports produced.

What are the benefits of taking part in this study?

Although we cannot promise any immediate direct benefits to yourself, we do hope that this research will help to improve healthcare in this field, and many may benefit from it.

Can anything I say be linked back to me?

All data shall be kept in the strictest confidentiality; any transcripts created will have no identifying text. You shall be given an identification number so you remain anonymous. All data will be kept in compliance with the data protection act.

How is this project being funded?

This project is part of a PhD study that is being funded by two research councils (EPSRC and ESRC).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed by the Birmingham East, North and Solihull Research Ethics Committee.

Remember, find results at: <http://www2.warwick.ac.uk/study/csde/gsp/eportfolio/directory/pg/esrjai/>

Participant Information Sheet for Patients – Non-participant Observation (Version 2.0 25/10/10)

Project Title: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to contact the researchers on the attached contacts sheet if you have any more questions.

What is the study?

This study will focus on the ways in which physiotherapists and occupational therapists currently assess stroke patients for long term rehabilitation. This is to help with the eventual development of a new assessment tool for rehabilitation.

Why have I been contacted about this study?

We are looking to observe physiotherapists and occupational therapists assessing patients who have suffered from a stroke for rehabilitation.

Do I have to take part?

Participation in this study is strictly voluntary. If you decide to participate in this study you will still have the right to withdraw from the study at any point you wish to, without reason and without your legal rights being affected. Whether you decide to participate or not to participate, your normal treatment will not be affected in any manner.

What will happen during the study?

You will be asked to provide written consent to agree to take part in this study. If you are unable to provide this then verbal consent will be taken by your physiotherapist/occupational therapist; you will be asked to state the following: "I give my consent to take part in this study". You shall then be given a copy of the consent form. The study will be an observation of your treatment with no interference from the observer and no change to your normal treatment.

What will happen after the study?

Data collected during observation shall be kept strictly confidential and you shall remain anonymous. The results shall be placed online at the following address:

<http://www2.warwick.ac.uk/study/csde/gsp/eportfolio/directory/pg/esrjai/>
(View Research Results and Publications in the left hand column).

This information will be used towards the completion of a PhD thesis, which shall involve developing a technology / technologies to help in stroke rehabilitation.

Will I be at any risk when participating in this study?

You shall be under no immediate risk when partaking in this study and you will not be identifiable in any of the data collected or reports produced.

What are the benefits of taking part in this study?

Although we cannot promise any immediate direct benefits to yourself, we do hope that this research will help to improve healthcare in this field, and many may benefit from it.

Can anything I say be linked back to me?

All data shall be kept in the strictest confidentiality. All data will be kept in compliance with the data protection act.

How is this project being funded?

This project is part of a PhD study that is being funded by two research councils (The Engineering and Physical Sciences Research Council and The Economic and Social Research Council).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed by the Birmingham East, North and Solihull Research Ethics Committee.

Remember, find results at: <http://www2.warwick.ac.uk/study/csde/gsp/eportfolio/directory/pg/esrjai/>

Participant Information Sheet for Physiotherapists and Occupational Therapists – Non-participant Observation (Version 2.0 25/10/10)

Project Title: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to contact the researchers on the attached contacts sheet if you have any more questions.

What is the study?

This study will focus on the ways in which physiotherapists and occupational therapists currently assess stroke patients for long term rehabilitation. This is to help with the eventual development of a new assessment tool for rehabilitation.

Why have I been contacted about this study?

In order to take part in this study you must be a physiotherapist or occupational therapist that has practised for more than one year in the NHS. You must also be over 18 years of age to take part in this study.

Do I have to take part?

Participation in this study is strictly voluntary. If you decide to participate in this study you will still have the right to withdraw from the study at any point you wish to, without reason and without your legal rights being affected.

What will happen during the study?

You will be asked to give your consent to participate in this study upon arrival. You shall then be given a copy of the consent form. The study will be an observation of your day to day tasks, mainly observing the way in which you assess stroke patients for rehabilitation. This study will involve 10 separate observations, each 1 hour in length.

You will also be asked to provide patients that are being observed with information sheets before observation commences. Patients will then be asked to sign an informed consent sheet to indicate that they agree to take part in the study. If they are unable to do this then assent must be taken (verbal agreement by the patient), at which point you will be asked to sign a consent sheet to state that the patient has agreed to take part.

What will happen after the study?

Data collected during observation shall be kept strictly confidential. You shall remain completely anonymous. The results shall be placed online at the following address:

<http://www2.warwick.ac.uk/study/csde/gsp/eportfolio/directory/pg/esrjai/>
(View Research Results and Publications in the left hand column).

This information may also be used towards the completion of a PhD thesis, which shall involve developing a technology / technologies to help in this field.

Will I be at any risk when participating in this study?

You shall be under no immediate risk when partaking in this study and you will not be identifiable in any of the data collected or reports produced.

What are the benefits of taking part in this study?

Although we cannot promise any immediate direct benefits to yourself, we do hope that this research will help to improve healthcare in this field, and many may benefit from it.

Can anything I say be linked back to me?

All data shall be kept in the strictest confidentiality. You shall be given an identification number so you remain anonymous. All data will be kept in compliance with the data protection act.

How is this project being funded?

This project is part of a PhD study that is being funded by two research councils (The Engineering and Physical Sciences Research Council and The Economic and Social Research Council).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed by the Birmingham East, North and Solihull Research Ethics Committee.

Remember, find results at: <http://www2.warwick.ac.uk/study/csde/gsp/eportfolio/directory/pg/esrjai/>



Consent Form - Interviews (Version 1.0 07/09/10)

Patient Identification Number for this trial: _____

Title of Project: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

Name of Researcher: Christopher Golby

Please Initial box

1. I confirm that I have read and understand the information sheet dated 25/10/10 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
3. I understand that data collected during the study, may be looked at by individuals from WMG (The University of Warwick), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.
4. I agree to be recorded during this interview.
5. I agree to take part in the above study.

Participant Signature: _____ **Date:** _____

Researcher Signature: _____ **Date:** _____

When completed: 1 for participant; 1 for researcher site file.

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Consent Form for Physiotherapists and Occupational Therapists – Non-Participant Observation

(Version 1.0 07/09/10)

Patient Identification Number for this trial: _____

Title of Project: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

Name of Researcher: Christopher Golby

Please Initial box

1. I confirm that I have read and understand the information sheet dated 25/10/10 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
3. I understand that data collected during the study, may be looked at by individuals from WMG (The University of Warwick), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.
4. I agree to take part in the above study.

Participant Signature: _____ **Date:** _____

Researcher Signature: _____ **Date:** _____

When completed: 1 for participant; 1 for researcher site file.

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Consent Form for patients – Non-Participant Observation

(Version 1.0 07/09/10)

Patient Identification Number for this trial: _____

Title of Project: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

Name of Researcher: Christopher Golby

Please Initial box

1. I confirm that I have read and understand the information sheet dated 25/10/10 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
3. I understand that data collected during the study, may be looked at by individuals from WMG (The University of Warwick), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.
4. I agree to take part in the above study.

Participant Signature: _____ **Date:** _____

Researcher Signature: _____ **Date:** _____

When completed: 1 for participant; 1 for researcher site file.

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Assent Form for patients – Non-Participant Observation

(Version 1.0 07/09/10)

Patient Identification Number for this trial: _____

Title of Project: A Review of the Current Methods of Assessing, and Monitoring the Progress, of Patients Requiring Long Term Rehabilitation for Stroke.

Name of Researcher: Christopher Golby

Please Initial box

1. I confirm that the patient has read and understood the information sheet dated 25/10/10 (version 2.0) for the above study. They have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. The patient understands that their participation is voluntary and that they are free to withdraw at any time without giving any reason, without their legal rights being affected.

3. The patient understands that data collected during the study, may be looked at by individuals from WMG (The University of Warwick), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. They give permission for these individuals to have access to this data.

4. The patient agrees to take part in the above study and has provided verbal consent for this by stating the following: "I give my consent to take part in this study".

Therapists Signature: _____ **Date:** _____

Researcher Signature: _____ **Date:** _____

When completed: 1for Therapist; 1 for researcher site file.

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Appendix B Ethics for Able-Bodied Testing (Information sheets and Informed Consent)



Participant Consent Form (Version 1.0 15/05/12)

Title of Project: Automated Goniometry for the Assessment of Range of Motion in Patients with Musculoskeletal Weakness

Name of Researcher: Christopher Golby

Please Initial box

1. I agree to take part in the above study.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I understand that data collected during the study, may be looked at by individuals from WMG (The University of Warwick) or from regulatory authorities, where it is relevant to taking part in this research. I give permission for these individuals to have access to this data.

Participant Signature: _____ Date: _____

Researcher Signature: _____ Date: _____

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Appendix C Ethics for Full System Testing (Letter of Favourable Opinion, Information sheets and Informed Consent)

2012.04.03 further information favourable opinion re-issued to correct protocol date

NHS
Health Research Authority

NRES Committee East Midlands - Nottingham 2
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS
Telephone: 0115 8839428
Facsimile: 0115 9123300

23 March 2012

Mr Christopher Golby
International Digital Laboratory
WMG, University of Warwick
Coventry
CV4 7AL

Dear Mr Golby

Study title: A proof of concept study for a Novel Prototype System, for the continual assessment of stroke patients, from the inpatient/outpatient setting, through to Tele-Rehabilitation.

REC reference: 12/EM/0077

Thank you for your letter of 05 March 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

A Research Ethics Committee established by the Health Research Authority

2012.04.03 further information favourable opinion re-issued to correct protocol date

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

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

Document	Version	Date
Evidence of insurance or indemnity	Marsh	29 July 2011
Evidence of insurance or indemnity	Marsh	28 July 2012
Interview Schedules/Topic Guides	1.0 - Patient Stage 1	18 January 2012
Interview Schedules/Topic Guides	1.0 - Therapist Stage 1	18 January 2012
Interview Schedules/Topic Guides	1.0 - Patient Stage 2	18 January 2012
Interview Schedules/Topic Guides	1.0 - Therapist Stage 2	18 January 2012
Investigator CV	Christopher Golby	18 January 2012
Investigator CV	1.0 - Vinesh Raja	21 January 2012
Investigator CV	Gillian Hundt	
Other: Participant Assent Form	1.0	18 January 2012
Other: Email to Heads of Physiotherapy and Occupational Therapy Departments	1.0	18 January 2012
Other: Institute of Digital Healthcare Booklet		
Other: Contact List	2.0	05 March 2012
Participant Consent Form	2.0	05 March 2012
Participant Information Sheet: Patients	2.0	05 March 2012
Participant Information Sheet: Therapists	2.0	05 March 2012
Protocol	1.0	19 January 2012
REC application	87307/289364/1/378	18 November 2012
Response to Request for Further Information	Email	05 March 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for

2012.04.03 further information favourable opinion re-issued to correct protocol date

Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

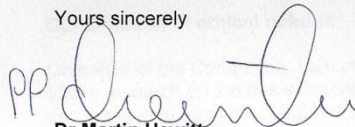
Further information is available at National Research Ethics Service website > After Review

12/EM/0077

Please quote this number on all correspondence

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

Yours sincerely

PP 

Dr Martin Hewitt
Chair

Email: heather.harrison@nottspct.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Sponsor - Dr Peter Hedges

Care organisation - Ceri Jones, University Hospitals Coventry and Warwickshire

Participant Information Sheet (Therapists)

(Version 2.0 05/03/12)

Project Title: A proof of concept study for a Novel Prototype System, for the continual assessment of stroke patients, from the inpatient/outpatient setting, through to Tele-Rehabilitation.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to contact the researchers on the attached contacts sheet if you have any more questions.

What is the study?

This study will focus on the ways in which physiotherapists and occupational therapists assess stroke patients for long term rehabilitation. You will be helping to trial a new type of assessment tool for stroke patients. This tool can be used during standard therapy sessions to assess range of motion, but can also be taken home after a session (however, this will be mimicked during this study with the patient remaining in another room in the hospital), allowing therapy to continue remotely.

Why have I been contacted about this study?

We are looking for physiotherapists and occupational therapists to use the device in their therapy sessions. The device will simply sit in the background during your session and record a patient's movement, whilst you continue standard therapy. You will also be asked if you feel after a certain amount of time, the patient could use the tool by themselves for around 10 minutes before or after your therapy session.

Do I have to take part?

Participation in this study is strictly voluntary. If you decide to participate in this study you will still have the right to withdraw from the study at any point you wish to, without reason and without your legal rights being affected.

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WARWICK

What will happen during the study?

You will be asked to provide written consent to agree to take part in this study. You will then be asked to nominate one or more patient(s) who you feel are capable of completing this study. This should be based on the following inclusion/exclusion criteria:

Physiotherapists/occupational therapists shall select patients whom they feel are capable of completing the study. All patients selected must have suffered a Unilateral Stroke prior to the commencement of the study. Patients must be English speaking. Patients involved in this study must have no pacemaker or other implanted metallic device. They must also have no progressive neurological disorder such as Alzheimer's or no terminal life expectancy condition such as renal failure or end-stage AIDS. Patients must not have suffered from a stroke associated with illicit drugs. Any patients selected must be capable of using the technology (final decisions regarding this matter will be determined by the relevant therapist).

The patient will also be presented with an information sheet and asked to provide consent. If they are unable to sign the form themselves, assent can be taken, whereby you will be allowed to sign to indicate that the patient is willing to participate.

The system will generate a unique identification number for each patient. You and the patient (or their caregiver) will be asked to take note of this identification number. This is so a record can be kept of patient assessment on the system throughout this study (This is in order to achieve patient anonymity).

You will then be given a piece of technology which assesses patients in two phases. In the first phase, a patient is placed in front of a system which includes a Microsoft (a multi-national corporation which develops computer products) product called Kinect® (a camera which allows for a person's movements to be tracked and analysed). The system has had bespoke software designed for the purposes of this study. You will be allowed to continue your rehabilitation session in your usual manner; however, 'Activities of Daily Living' objects that you use during your session will have orientation meters attached. An orientation sensor may also be placed on the patient's wrist. The rotation data taken from these will be used in combination with movement data that is collected by the Microsoft Kinect®. This data will be used to produce a graphical analysis of the patient's movement throughout the session.

The system will also store data from each therapy session. Using this data, you will be able to view a graph, which details the patient's progress over time. This graph can also be extended to provide you with an estimate of recovery time.

A researcher shall be present in the initial week of testing. At this point the researcher shall be on hand to demonstrate and answer any questions regarding the device. The device shall simply sit in the background and therapy can continue as normal (the only minor interventions that will need to be made is the starting and stopping of the device). The researcher will leave you with the device in later sessions, but will always be on hand via phone or email, in case of any issues.

If you agree that the patient is capable of continuing to use the technology, then the second phase of this study will be testing the device in a remote location (providing telerehabilitation). This will be performed through use of the same system in a remote location in the hospital. During this stage the patient will be in a room with what will need to be a trained member of staff to ensure the patient is safe (this task can be performed prior to, or after a therapy session). The device will instruct the patient to carry out a number of activities where they will be assessed. You will then be able to view this data, in the same methods described in phase 1, and compare the continuous data.

The researcher shall return, on average, every 3 weeks during the course of the research in order to observe how the system is being used. At the end of each phase of system testing you and the patient shall be asked to give your view of the device in its current form, through a short, semi-structured interview. This interview shall be recorded.

How long will this study last?

This study will last for a period of up to 15 weeks. However, total length will be decided by yourself, according to how long you feel the patient can participate in each section of the study for.

What will happen after the study?

Data collected during the study shall be kept strictly confidential and you shall remain anonymous. The results shall be placed online at the following address:

<http://www2.warwick.ac.uk/go/telerehab/>

(View Research Results and Publications in the left hand column).

This information will be used towards the completion of a PhD thesis, which shall involve developing a technology / technologies to help in stroke rehabilitation.

Will I be at any risk when participating in this study?

You shall be under no immediate risk when partaking in this study and you will not be identifiable in any of the data collected or reports produced.

What are the benefits of taking part in this study?

Although we cannot promise any immediate direct benefits to yourself or your patients, we do hope that this research will help to improve healthcare in this field, and many may benefit from it.

Can anything I say be linked back to me?

All data shall be kept in the strictest confidentiality. You will remain completely anonymous at all points during this study. All data will be kept in compliance with the data protection act.

How is this project being funded?

This project is part of a PhD study that is being funded by two research councils (The Engineering and Physical Sciences Research Council and The Economic and Social Research Council).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed by the Nottingham 2 Research Ethics Committee.

Remember, find results at: <http://www2.warwick.ac.uk/go/tele rehab/>

Participant Information Sheet (Patients)

(Version 2.0 05/03/12)

Project Title: A proof of concept study for a Novel Prototype System, for the continual assessment of stroke patients, from the inpatient/outpatient setting, through to Tele-Rehabilitation.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to contact the researchers on the attached contacts sheet if you have any more questions.

What is the study?

This study will focus on the ways in which physiotherapists and occupational therapists assess stroke patients for long term rehabilitation. You will be helping to trial a new type of assessment tool for stroke patients. This tool can be used during standard therapy sessions to assess range of motion, but can also be taken home by a patient after a session (however, this will be mimicked during this study and the device will remain in another room in the hospital), allowing therapy to continue after a hospital visit.

Why have I been contacted about this study?

We asked your physiotherapist and/or your occupational therapist to select a patient who they felt would be willing to trial the new technology and you were selected. Your physiotherapist and/or occupational therapist will use the device in their therapy sessions. The device will simply sit in the background during your session and record your movement, whilst you continue standard therapy. The system will be able to give you feedback as to how you are improving over time and shall hopefully assist in the improvement of your therapy. You may also be asked if you would like to continue using the system outside of your normal therapy (the system will guide you through everything you need to know and a member of staff will always be with you), in order to help with your rehabilitation.

Do I have to take part?

Participation in this study is strictly voluntary. If you decide to participate in this study you will still have the right to withdraw from the study at any point you wish to, without reason and without your legal rights being affected. Whether you decide to participate or not to participate, your normal treatment will not be affected in any manner.

What will happen during the study?

You will be asked to provide written consent to agree to take part in this study (your therapist can also take verbal consent if this is needed). Once you have agreed to take part you will be given an identification number; this is so you can participate in the study completely anonymously. You (or your caregiver) and your therapist will be asked to take note of this identification number so you can keep a record of your assessment throughout this study.

Your therapist will be given a piece of technology which will be used to assess your rehabilitation in two phases.

In the first phase, you will be placed in front of a system which includes a Microsoft (a multi-national corporation which develops computer products) Kinect® (a camera which allows for a person's movements to be tracked and analysed) camera. The system has custom software designed for the purposes of this study. You will be allowed to continue your rehabilitation session in your usual manner; however, 'Activities of Daily Living' objects that you use during your session will have orientation meters attached. An orientation sensor may also be placed on your wrist. Data taken from these will be used in combination with movement data that is collected by the Microsoft Kinect®. This data will be used to produce a graph of your movement throughout the session.

The system will anonymously store your data from each therapy session. Using this data, you will be able to view a graph, which details your progress over time.

A researcher shall be present in the initial week of testing. At this point the researcher shall be on hand to demonstrate and answer any questions regarding the device. The device shall simply sit in the background and therapy can continue as normal (the only minor interventions that will need to be made is the starting and stopping of the device

by the therapist). The researcher will leave the therapist with the device in later sessions, but will always be on hand via phone or email, in case of any issues.

If you are selected to continue to use the technology outside of therapy, then the second phase of this study will be testing the device in a remote location (providing telerehabilitation). This will be performed through use of the same system in a remote location in the hospital. During this stage you will be in a room with a trained member of staff to ensure your safety (this task can be performed prior to, or after a therapy session). The device will instruct you to carry out a number of simple daily activities, from which your movement will be assessed. You will then be able to view this data, in the same methods described in phase 1, and compare it with your therapy sessions.

The researcher shall return, on average, every 3 weeks during the course of the research in order to observe how the system is being used. At the end of each phase of system testing you shall be asked to give your view of the device in its current form, through a short, semi-structured interview. This interview shall be recorded.

How long will this study last?

This study will last for a period of up to 15 weeks. However, your therapist will decide on the total time that they feel they would like you to use the device for.

What will happen after the study?

Data collected during the study shall be kept strictly confidential and you shall remain anonymous. The results shall be placed online at the following address:

<http://www2.warwick.ac.uk/go/telerehab/>

(View Research Results and Publications in the left hand column).

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Although we cannot promise any immediate direct benefits to yourself, we do hope that this research will help to improve healthcare in this field, and many may benefit from it.

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Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed by the Nottingham 2 Research Ethics Committee.

Remember, find results at: <http://www2.warwick.ac.uk/go/telerehab/>

Participant Consent Form (Version 2.0 05/03/12)

Participant Identification Number for this trial: _____

Title of Project: A proof of concept study for a Novel Prototype System, for the continual assessment of stroke patients, from the inpatient/outpatient setting, through to Tele-Rehabilitation.

Name of Researcher: Christopher Golby

Please Initial box

1. I confirm that I/the participant have read and understood the information sheet dated 05/03/12 (version 2.0) for the above study.
I/the participant have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I/the participant understand(s) that my participation is voluntary and that I am/the participant is free to withdraw at any time without giving any reason, without legal rights being affected.
3. I/the participant understand(s) that data collected during the study, may be looked at by individuals from WMG (The University of Warwick), from regulatory authorities or from the NHS Trust, where it is relevant to taking part in this research. I/the participant give permission for these individuals to have access to this data.
4. I/the participant agree(s) to be recorded during any interviews which are taken.
5. I/the participant agree(s) to take part in the above study.

Participant/Witness Signature: _____ Date: _____

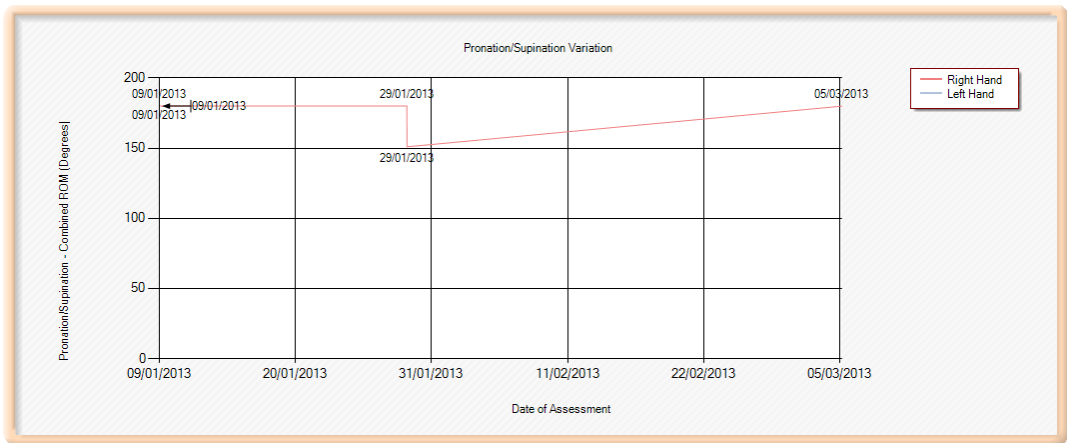
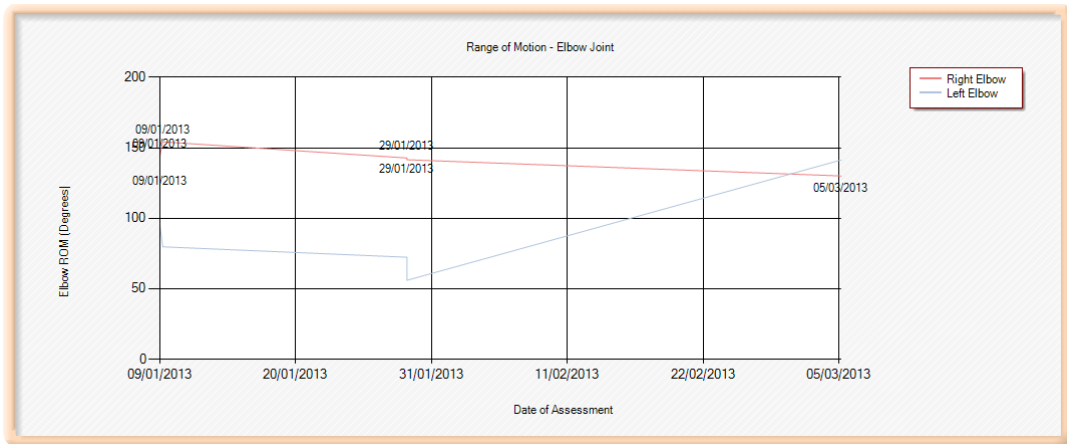
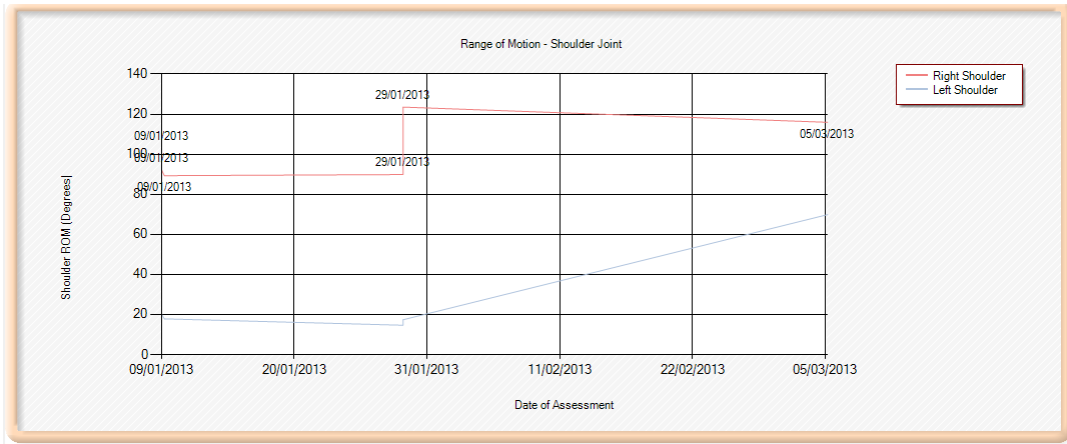
Researcher Signature: _____ Date: _____

When completed: 1 for participant; 1 for researcher site file.

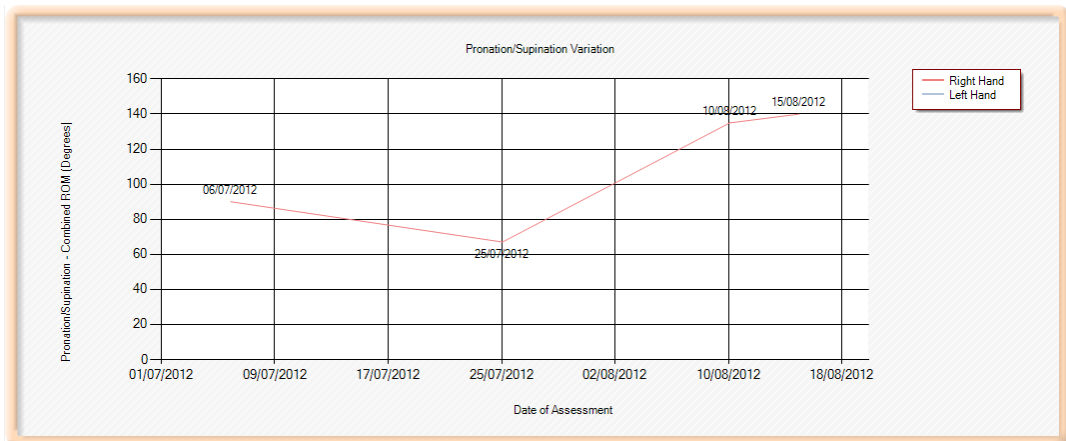
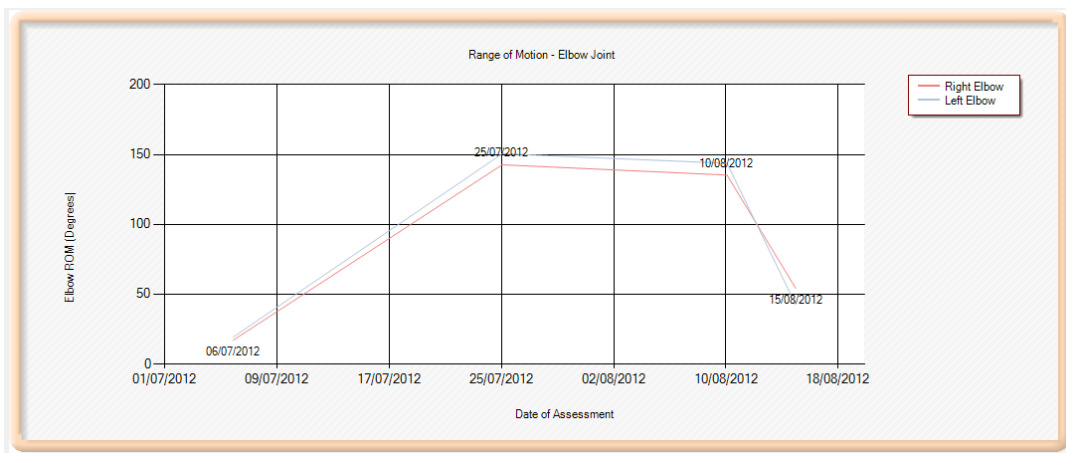
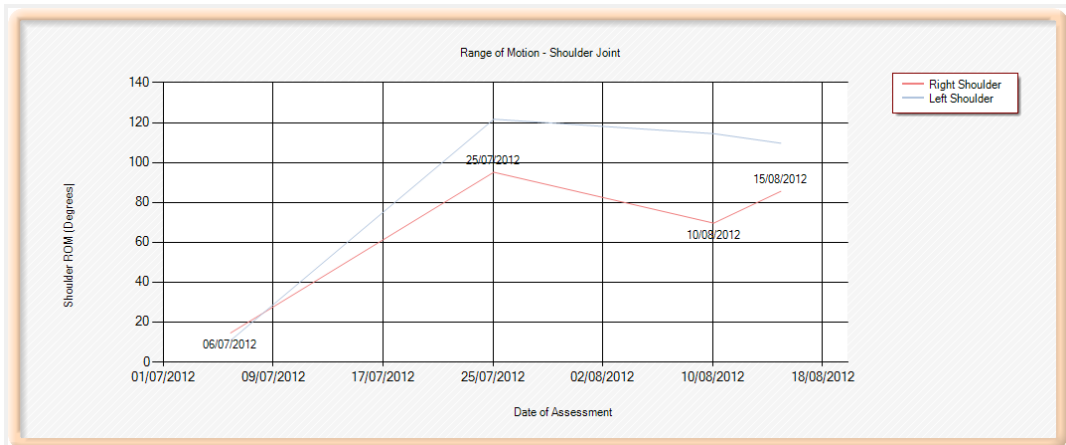
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Appendix D Results from Full System Testing

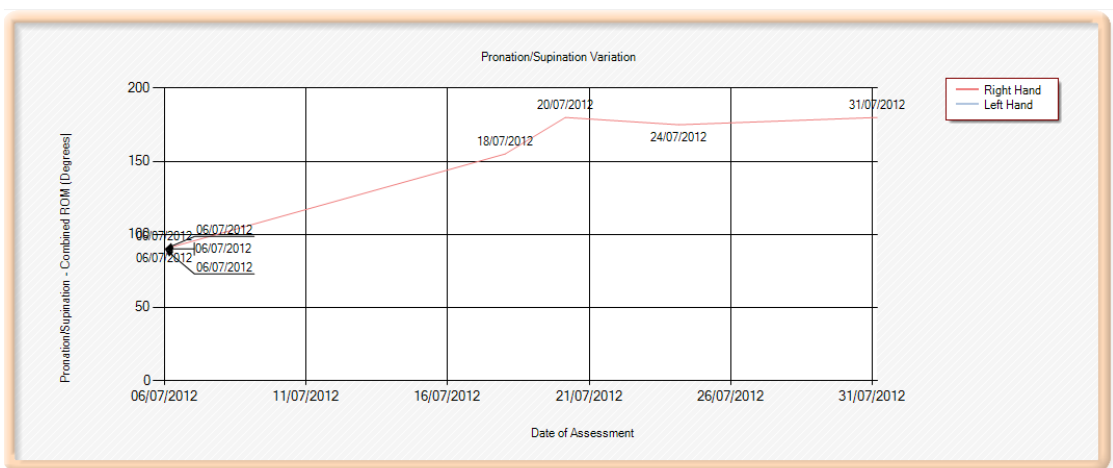
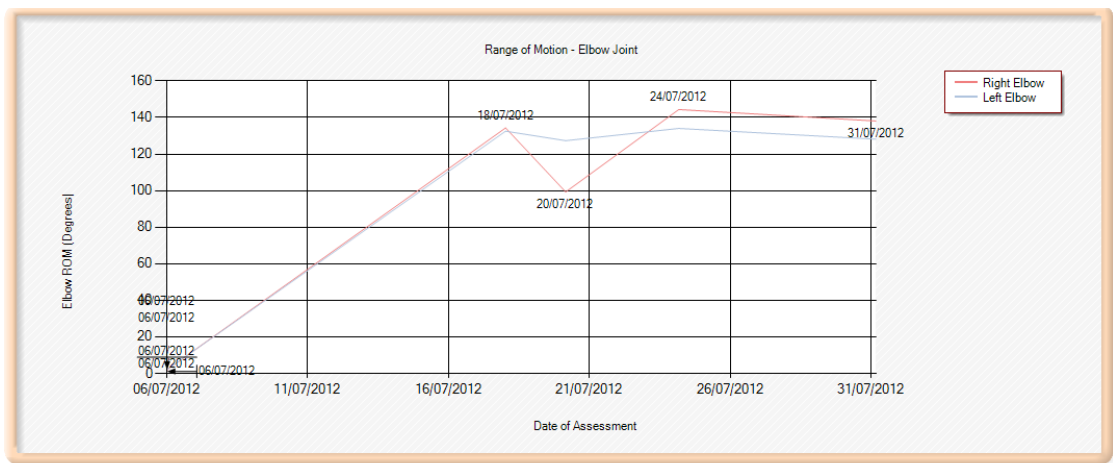
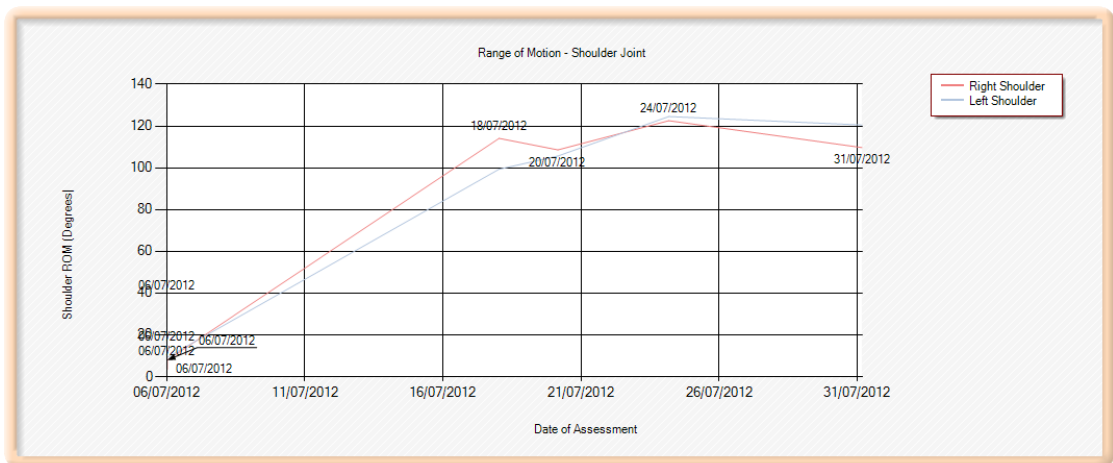
Patient 1:



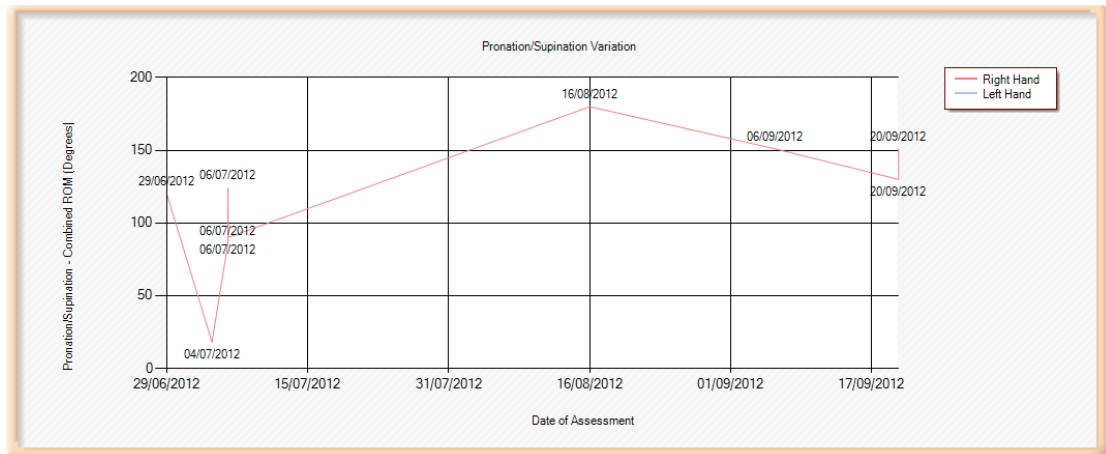
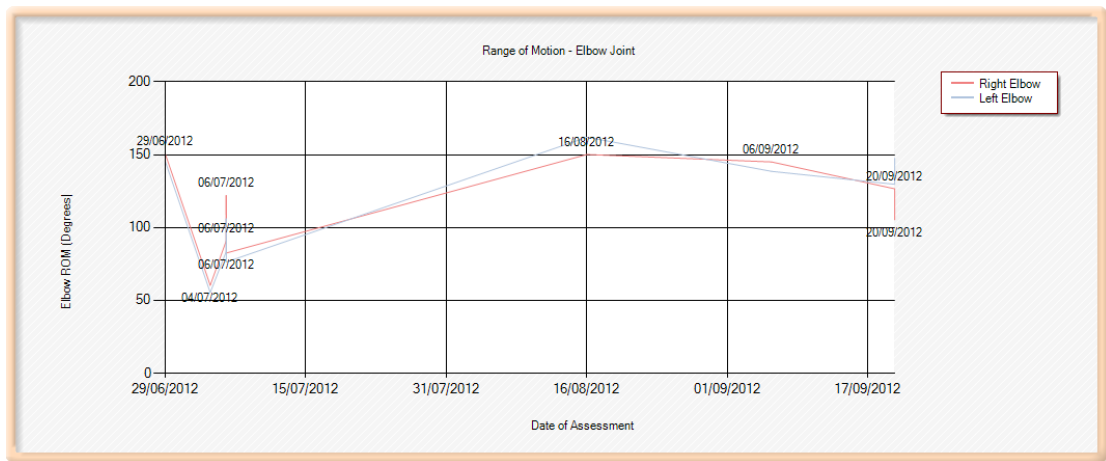
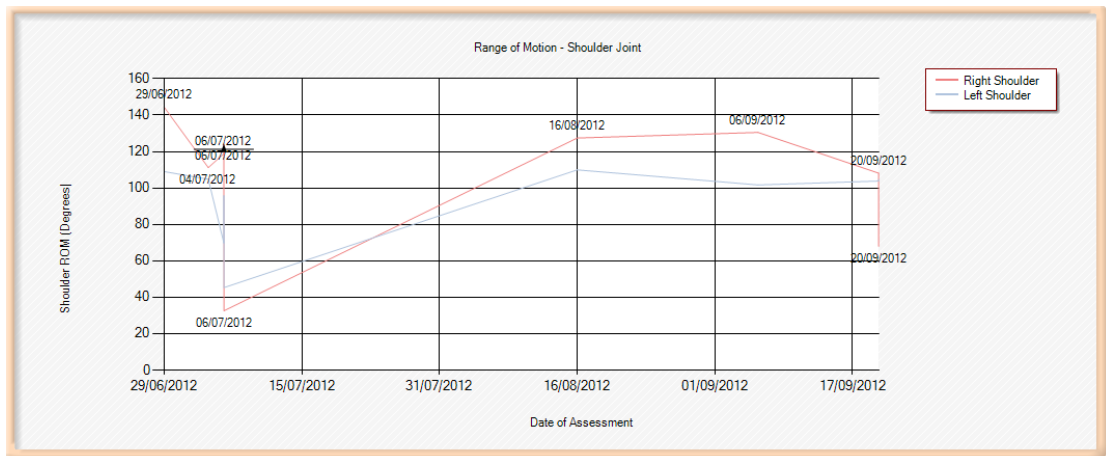
Patient 2:



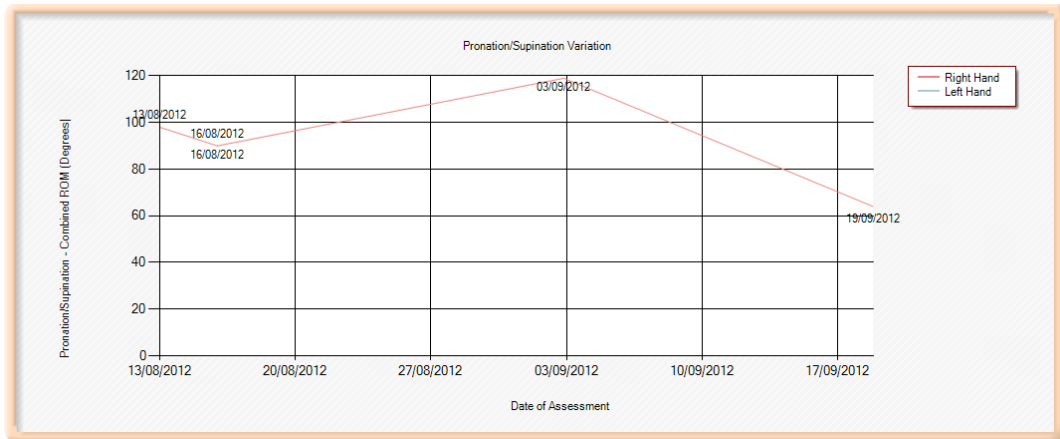
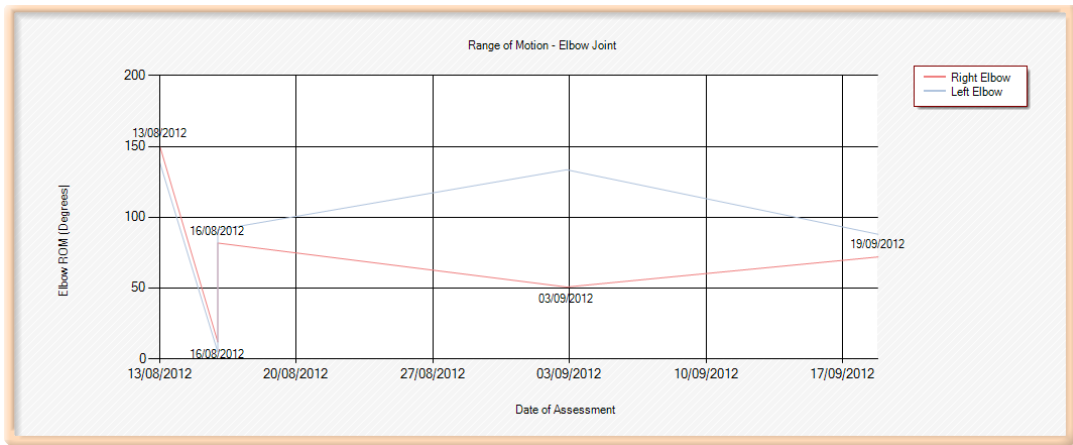
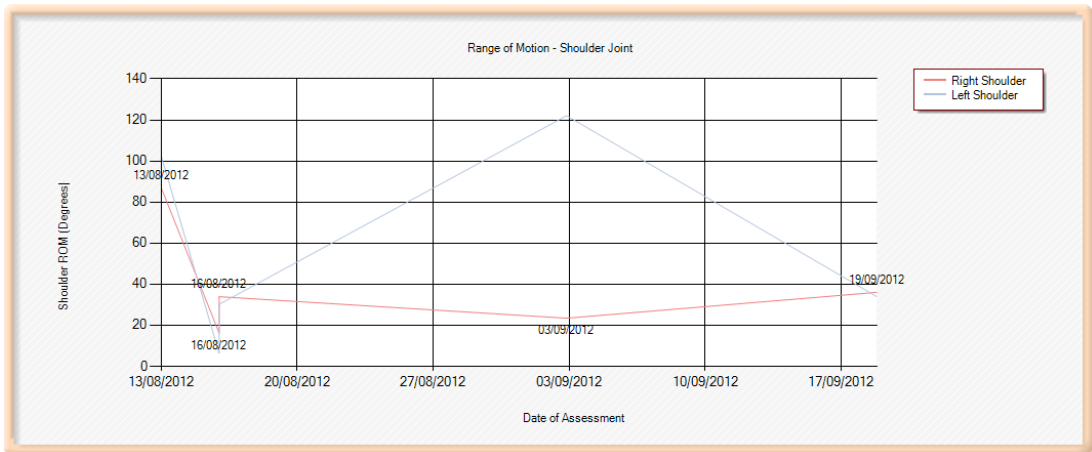
Patient 3:



Patient 4:



Patient 5:



Appendix E Alterations to Research Design in Clinical Setting

There were some modifications made to the initial research design. The system was intended for use in two hospital settings, for up to 15 weeks. One hospital performed this task, but was more focused on the ‘therapist present’ version of the system. This was mainly due to problems initially setting up the system, whereby it had been placed in areas which were not suitable for its effectiveness. These issues were resolved, but caused inevitable delay, and stopped the system being used for as long as was originally intended. It must be noted here, that if further research is conducted in this field, more formal user training must be provided prior to use with the system.

The second hospital was only able to use the system for a 12 week period, and was asked to focus more on the ‘ADL – Therapist not Present’ version of the system, in order to obtain an overall rounded view. Another issue did occur, in that the second hospital was closed at two separate points during the trial stage due to infection control issues. This hindered the data output from this site.

In addition to the issues described above, problems also occurred with two of the patients who were using the system, at which point interaction stopped. One patient suffered a fall and gained a shoulder injury; it became difficult to use the system due to pain in the shoulder and the therapists recommended that the patient cease use of the system at this stage due to on-going difficulties they were having, which were not related to the system. Another patient also deceased during the course of the experiments and so data collection from this patient was no longer possible.

Appendix F Psuedo Code

Pseudo Code to Detect Passive Movement

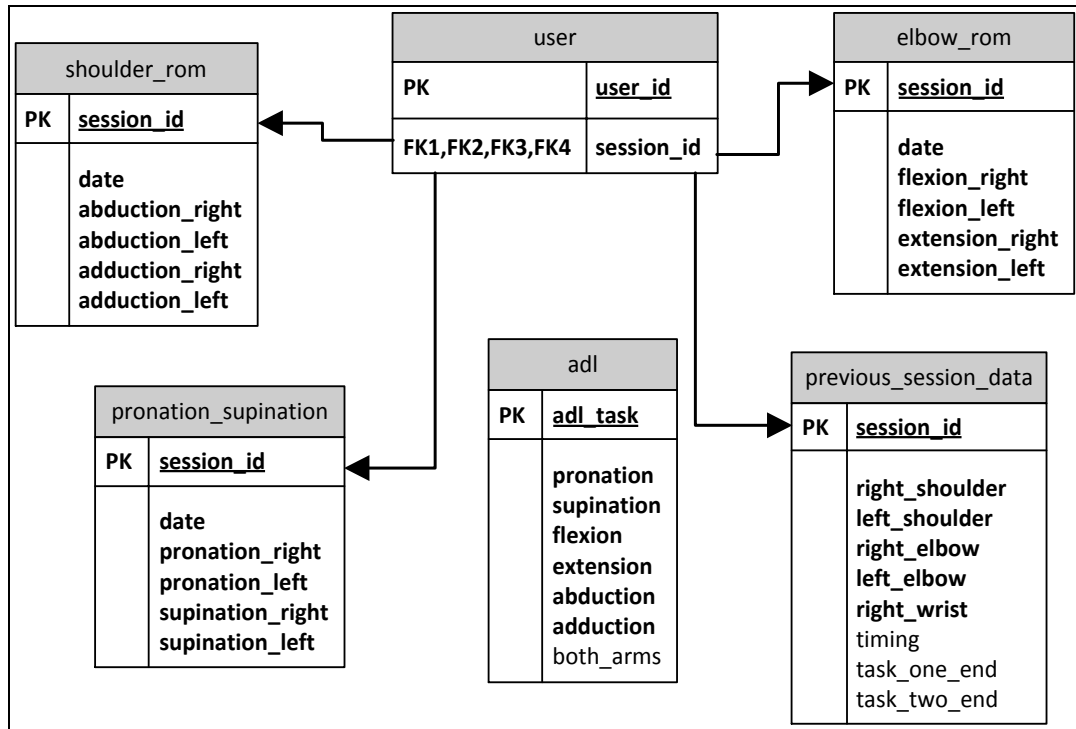
```
Boolean passiveMovement = false;
Void function PassiveMovementDetection
If patient's joints detected and therapist's joints detected
{
    If therapist's right hand is near patient's right hand or wrist or elbow or
    shoulder
        Set passiveMovement to true;
    If therapist's left hand is near patient's right hand or wrist or elbow or
    shoulder
        Set passiveMovement to true;
    If therapist's right hand is near patient's left hand or wrist or elbow or
    shoulder
        Set passiveMovement to true;
    If therapist's left hand is near patient's left hand or wrist or elbow or
    shoulder
        Set passiveMovement to true;
}
If passiveMovement = true
{
    Stop tracking patient's range of motion.
}
```

Pseudocode demonstrating the calculation of angles between joints

```
Double function GetRangeOfMotion(
    Double lowerJointCoordinates,
    Double middleJointCoordinates,
    Double upperJointCoordinates)
Double dot;
Vector3D = lowVector;
Vector3D = highVector;
If(all joints are tracked)
{
    lowVector = lowerJointCoordinates - middleJointCoordinates;
    highVector = higherJointCoordinates - middleJointCoordinates;
    dot = Vector3D.AngleBetween(highVector, lowVector);
    return dot;
}
```


Appendix G Database Structure

Entity Relationship Model for System Database



Appendix H Description of a Selection of Stroke Outcome Measures

This section demonstrates examples of outcome measures used in stroke rehabilitation in general (i.e. not specific to the upper-limb).

Barthel Index

Studies have previously suggested that the Barthel index is the most widely used and studied measure in stroke rehabilitation (Lyden and Lau, 1991). It is recognised as a good measure of functional ability (Gresham et al., 1980, Dombovy et al., 1986, Granger et al., 1979, Shah et al., 1989). The Barthel index is an ‘Activities of Daily Living’ (ADL) scale; objective ADL scales are used for assessing the patient’s ability to perform functional everyday tasks independently (Lyden and Lau, 1991).

The Barthel index is a simple and easily understandable measure of independence, scoring patients on their ability to take care of themselves. The Barthel index can be repeated to assess rehabilitation progress. The test examines patients in the following areas: feeding, bathing, grooming, dressing, bowels, bladder, toilet use, transfers (bed to chair and back), mobility (on level surfaces), and stairs (Barthel and Mahoney, 1965).

National Institute of Health Stroke Scale (NIHSS)

The NIHSS is a physical deficit scale based on neurological examination (Lyden and Lau, 1991). The NIHSS is a graded examination, which ranks 4 separate areas of rehabilitation. The NIHSS rates speech and language, cognition, visual field defects and motor and sensory impairments (Goldstein and Samsa, 1997).

Rankin Scale

The Rankin Scale can be described as a global ranking scale. In these scales the investigator renders a global ranking of each patient by assigning the patient to one of a limited number of broad classifications (Lyden and Lau, 1991). In the Rankin scale patients are placed in a category from I (no significant disability) to V (severe disability). The test is performed using previous activities performed and surveying requirements for assistance (Rankin, 1957). There has also been an update to the Rankin Scale named the Modified Rankin Scale, adding cognitive defects and language disorders (Van Swieten et al., 1988).

Functional Independence Measure (FIM)

The FIM index was created to be a more comprehensive and sensitive measure of disability than the Barthel index (Van der Putten et al., 1999). The FIM rates patients on a 7 point scale, from 1 (fully dependant) to 7 (independent with no aids). The scale is derived from 13 motor function tests and 5 cognitive function tests (Mackintosh, 2009).

Modified Motor Assessment Scale (MMAS)

The MMAS is a modified version of the motor assessment scale produced by Carr et al. (1985). The MMAS tests motor activity in the hemiplegic side of the body and assesses 8 areas of motor activity. These are movement from supine position to side lying; movement from supine position to sitting on the side of a bed; balanced sitting; movement from a sitting position to a standing position; walking; upper arm

function; hand movements and advanced activities. The latter three areas can be combined to form the combined arm score (Loewen and Anderson, 1990).

Glasgow Outcomes Scale

There are two versions of the Glasgow Outcome Scale; the five-point version and the eight-point version. It is a simplistic scale that shows categories of disability (usually used in for patients suffering from head injuries), for example, moderate disability; partial independence in activities of daily living and vegetative state (Wade, 1998).

Scandinavian Stroke Scale

This scale has been utilised in clinical trials and predicts neurological deterioration. The scale is a series of points regarding speech, facial palsy and gait, with points being scored for achieving the target within these categories (e.g. patient can walk five metres without aids, patient has no aphasia) (National Stroke Association, 2006).

Nottingham Extended Activities of Daily Living Scale

This is a scale which asks the patient how easily they are able to complete certain tasks (e.g. do you use the telephone, do you climb stairs). It asks the patient to rank themselves on a 4 point scale: not at all; with help; alone with difficulty and alone easily. The scale is useful for postal questionnaires (Wade, 1998).

The Timed Walk

Three different times have been investigated for walking tests, 2, 6 and 12 minutes. This test involves a therapist timing and watching a patient walking, looking at the speed that the person can walk at. This test has a ceiling effect once the individual reaches normal walking speed, although, there is potential to solve this by calculating running speed (Wade, 1998).

Frenchay Activities Index

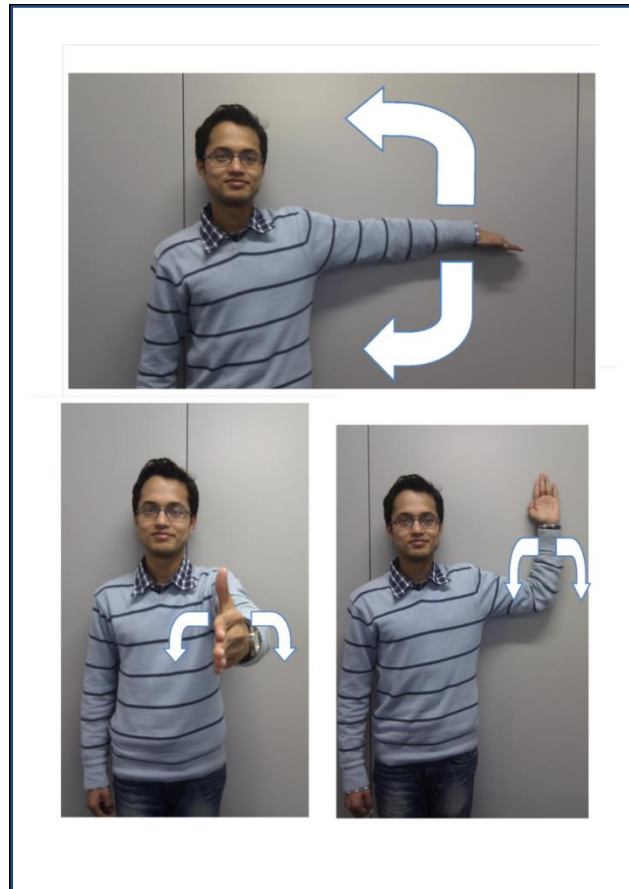
This is an easy to perform test that comes with guidelines. Activities which require patient initiative should be recorded, and the measure asks the patient how often they complete these activities. Activities used are ADL such as preparing meals, gardening, reading and shopping (Wade, 1998).

This section gives a general overview of outcome measures used in stroke. It can be seen that there is always an opinion of the therapist or patient utilised in the assessments, and therefore a certain degree of subjectivity and repeatability issues (items outlined in the requirements elicitation section of this thesis, chapter 4). For a thorough review of Upper-Limb Motor Control Assessment of Stroke Patients in the NHS, see section 2.1.

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Appendix I Description of Movements Assessed



Extension/flexion at the elbow (bottom right): This is the bending (flexion) and straightening (extension) of the arm at the elbow joint.

Pronation/supination at the wrist (bottom left): This is the rotation movement of the wrist joint.

Abduction/adduction at the shoulder (top): This is the raising (abduction) and lowering (adduction) of the arm, changing from being flat by an individual's side, to pointing upwards.

Appendix J Interview Topics for Requirements Elicitation

1. Experience of assessing stroke patients.
2. Frequency of assessment.
3. Strengths and weaknesses of stroke patient assessment for rehabilitation in the United Kingdom.
4. Scales used when assessing stroke patients.
5. Strengths and weaknesses of outcome measures.
6. Strengths and weaknesses of assessment, during **long** term rehabilitation of stroke patients in the United Kingdom (post 6 months).
7. Comparison of United Kingdom with other countries when dealing with assessment for stroke patients.
8. Possible Technologies for improvements.

Appendix K Interview Topics after Full System testing

1. Experiences of using the system (Best/worst aspect. Training).
2. Advantages and Disadvantages of the system.
3. The use of the system when the patient was by themselves (ADL Version).
4. Effects of the system on the patient's rehabilitation programme (Did it improve rehabilitation? Why/Why not? Time?)
5. Technological suggestions and adaptations.

Appendix L URL to Video of ‘System in Use’

<http://www.youtube.com/watch?v=cYNm0iNCYEY>