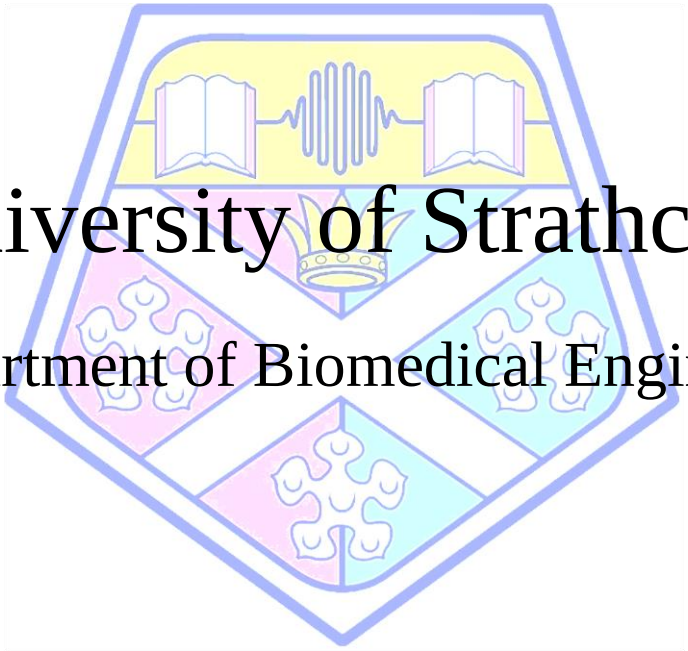

University of Strathclyde

Department of Biomedical Engineering

Tele-rehabilitation platform

A total knee arthroplasty prototype study

By

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A thesis presented in fulfilment for the requirements of the degree of PhD

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Abstract

Long term conditions are the biggest challenge facing the NHS and a reablement paradigm shift is pursued as a solution. Rehabilitation services are to deliver this new way of doing things that focusses on prevention and restoration of lost function to keep care from becoming unaffordable. Unfortunately the rehabilitation services are already overburdened and cannot deliver sufficient rehabilitation to people with long term conditions. This insufficiency increases cost of care as it is part of a re-admission cycle. Breaking this cycle and also driving the paradigm shift would require a greatly increased amount of rehabilitation to be delivered.

This could be accomplished by the use of tele-rehabilitation (TR), the use of ICT to deliver the service of rehabilitation by distance. This would save resources wasted on travelling, but TR can also provide functions such as biofeedback, that enables patients to do exercises unsupervised, greatly increasing the amount of exercise they could do. For TR to be used in practice, a TR platform that can be used at a large scale is required. This technology had so far not been developed so the aim of this work was to develop a prototype and test if it meets all requirements for use at a large scale.

For this prototype post total knee arthroplasty rehabilitation was chosen, although the platform has generic value thanks to its modularity and flexibility. Additional required properties and functions were uncovered, a development model chosen, a design method chosen and several versions of hardware and software developed as part of this iterative design method. Clinicians were interviewed, a new type of electro-goniometer was developed and its performance tested, and a usability study performed to confirm that the platform is easy to use for patients. It was found that the platform meets all demands and that it is therefore currently technologically possible to implement TR into practice. However, there are many more barriers before a TR service can be set up.

Acknowledgements

From the moment my family and friends sped me on my way, this PhD project has been a wonderful adventure. Along the road to completion I have been fortunate, and met many kind friends here in Scotland. Now that the project has come to an end, I feel grateful to have been given the opportunity to undertake it. There have been many people who have selflessly helped me along in the last few years; friends, software developers, nursing staff, physiotherapists, arthroplasty practitioners, university administrative staff, janitors, lecturers, fellow students, university technicians and many more. A few people's contributions to the adventure I would like to separately acknowledge;

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Andy, who as my second supervisor always had time for a friendly chat and provided me with valuable advice and feedback.

The patients who were brave enough to try to use the technology I made without any training. As a group your contribution is instrumental in developing the healthcare technology of tomorrow.

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The University of Strathclyde and the Scottish government for generously providing me with a stipend.

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Becky, for keeping me sane whilst I faced the Vogons. For sharing the good and the bad, and everything in between.

To all of you a sincere thank you, I would not have gotten far without you!

Declaration

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

Signed:

Date:

Published work

1. Performance of a new type of electro goniometer for use in a homely setting
Gerards, T., Rowe, P.J., Kerr, A. 09 Nov 2016 *VVBN PhD day* Maastricht
Research output: Conference › Oral presentation

2. A prototype Tele-Rehabilitation platform that is easy to use, low cost, robust, and mobile
Gerards, T., Rowe, P.J., Kerr, A. 26 Okt 2016 *RI world congress* Edinburgh
Research output: Conference › Oral presentation

3. Chain Linked Electro Goniometer: robust, low cost, easy to use sagittal plane knee kinematics.

Gerards, T., & Rowe, P.J. (2017) In: *Journal of Biomechanics*
Research output: Contribution to Journal › Article (Submitted)

Abbreviations

TH	tele health
TM	tele medicine
ICT	information and communication technology
TR	tele rehabilitation
AHP	allied health professional
CR	conventional rehabilitation
RTVC	real time video communication
AC	articular cartilage
QOL	quality of life
ADL	activities of daily living
DOF	degrees of freedom
RA	rheumatoid arthritis
OA	osteo arthritis
NSAID	nonsteroidal anti-inflammatory drug
PCL	posterior cruciate ligament
ACL	anterior cruciate ligament
OKS	Oxford knee score
WOMAC	Western Ontario and McMaster Universities Arthritis Index
6MW	6 minute walking test
TUG	timed up and go test
SCT	stair climbing test
5x STS	5 times sit to stand test
PEG	potentiometric electro goniometer
FEG	flexible electro goniometer
FOEG	fibre optic electro goniometers
IMU	inertial measuring unit
MARG	magnetic, angular rate, and gravitational sensor unit
CLEG	chain linked electro goniometer
FDM	fused deposition modelling
PLA	poly lactic acid
3D	three dimensional
RGB	red-green-blue
OS	Operating system
PC	Personal computer
USB	universal serial bus
IDE	integrated development environment
STA	soft tissue artefacts
HP	health professional
ARI	Activity recognition index
MCRD	Minimal clinically relevant difference

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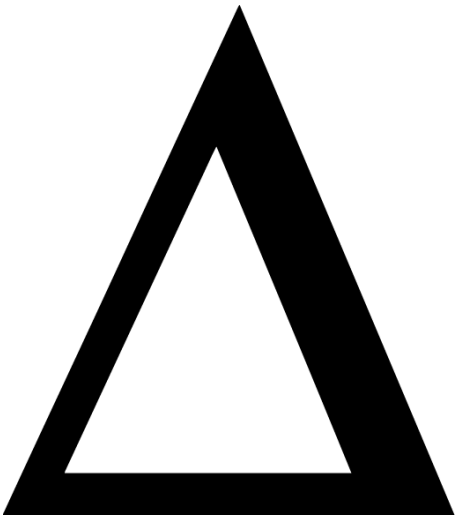
Chapter 1

Introduction



1.1. Introduction

"Change is the only constant" is a phrase coined by the Greek philosopher Heraclitus around 500 BC. The idea that change is ever present still holds true today. In some areas change presents problems, in other areas however it might present us with the solution to these problems. Scotland's demographics are changing, and with it the demands the healthcare system has to meet. Exploring how these demands are changing is important if they are to be addressed.

An increase in chronic conditions due to ageing is expected, which if not checked would lead to an unsustainable increase in cost. Fortunately, technology changes as well. The advent of affordable, portable, computing coupled to the internet means that the way physiotherapy is delivered can be changed, possibly providing the solution for these problematic demographic changes.

This chapter examines the nature of the ageing population, and the consequences this is predicted to have for demands on the Scottish health care system. After this, the proposed measures to meet the demand are reviewed, revealing rehabilitation services to become increasingly important. The subsequent section however uncovers that there is a shortage of these services, which then leads to the aim of this work; developing a scalable tele-rehabilitation platform.

In the past the desire for fast, long distance communication sparked many inventions, the first electrical one being the telegraph. The idea for a telegraph was first proposed in 1753 in *Scots' Magazine* by an anonymous author known only as C.M. from Renfrew, Scotland. Subsequently many scientists and inventors the world over began constructing electrical telegraph systems (Fahie 1884), far too many to be listed here. Suffice it to say the American Samuel Morse is generally recognised as "father" of the telegraph due to the commercial success of his version, which he demonstrated in 1838. In the years following this demonstration, a network of telegraph lines was constructed, enabling high speed communication between continents for the first time in history. Using this network, a doctor in 1917 in Australia used a telegraph to overcome a 2000

mile distance, and guide a postmaster in performing an operation. The patient, a stockman called Jimmy Darcy, was suffering from a life threatening ruptured bladder. Using whisky, a penknife and the doctor's remote guidance, the postman successfully operated on the bladder and the patient's life was saved (Jervis 2013). A good example of just how valuable information and communication technology can be in order to overcome distance in a medical context.

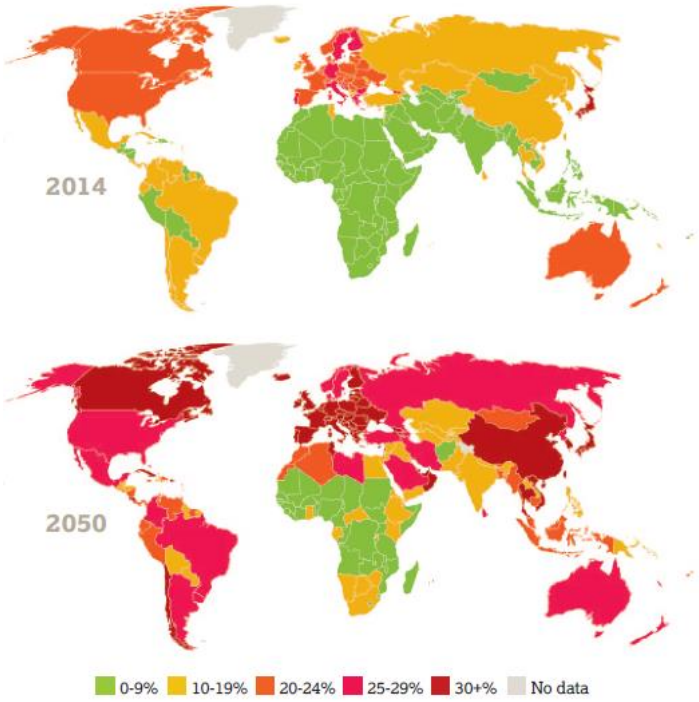
Inspired by the telegraph of the 1840's, scientists soon began exploring the concept of transmitting sound through a wire. The Scottish born Alexander Graham Bell was among these scientists, trying to transmit the human voice over an electric wire for many years. With the assistance of Thomas A. Watson he eventually succeeded in doing this; in 1876 Bell made the first ever telephone call. As with the telegraph before it, a network of telephone lines was constructed, connecting any telephone in the world to any other. This enabled any two people in the world in possession of a telephone to communicate with one another directly, without having to go to a telegrapher's office. The medical application of the telephone was recognised quickly. Since the 1880's the telephone has been used by physicians in order to prevent long waiting and unnecessary travel (Scalvini et al. 2004).

Because only acoustic signals could be sent through the telephone network, it would seem unlikely that it would be used to connect digital computers, emerging in the latter half of the 20th century. However, this is exactly what happened. By using modems that convert digital signals into sound, and back again, data could be sent through the telephone network. Using these modems, the consumer use of the internet became popular at the end of the 20th century, producing a leap in information and communication technology. Now, at the beginning of the 21st century, internet connections have become a lot faster and we can transmit vast amounts of data, ranging from text to photographs, sound and video, across the globe. Moreover, the recent advent of mobile internet-connected devices such as smartphones means this information exchange is no longer bound to temporal or geographical restrictions. No more telegraphers' opening hours, or sitting at a computer station. Communication is now possible anytime, anywhere. The effects this has had on our lives are profound.

Using mobile internet, shopping can be done from anywhere, as can learning, and chatting with friends. In a medical context, the internet might also be used to enable a change in the delivery of physiotherapy. In 1959, satellite based communication technology was used to provide the clinical service of rehabilitation over distance (Rao et al. 2012), the first application of what is now known as tele-rehabilitation (TR). However, satellite based ICT is expensive, a factor that undoubtedly contributed to the lack of any large scale uptake of the initiative. Using the more cost effective internet might enable TR on a large scale.

1.2. Ageing population predicted

Population ageing is defined as an increase in the mean or median chronological age of a population (Lutz et al. 2008). As can be seen from figure1.1, ageing is predicted to happen on a global scale. All countries in Europe are experiencing an ageing population (WHO 2009), and Scotland is no exception. The average life expectancy in Scotland continues to increase, as it has done since at least 1861 (Registrar general 2012). Combined with several other factors such as reduced child birth, this is currently leading to an older population all over Scotland (National records of Scotland 2013). It is predicted to be greatest in the rural areas of Scotland such as the Highlands and the Isles (Scottish government 2008) as young people leave to look for work elsewhere. One of the implications of this ageing population is a larger proportion of older people, and a decrease in the old age support ratio. This ratio indicates the number of working age people per pensionable aged person and is predicted to decline from 3.18 in 2012, to 2.68 in 2037 (National records of Scotland 2013). It becomes clear why this old age support ratio decreases, when the population is divided into age classes and presented graphically as in figure 1.2. From this figure it can be seen that compared to 2012, the number of older adults (aged 65 or over) will increase substantially, and that they will have to be supported by a decreasing number of younger people come 2037.



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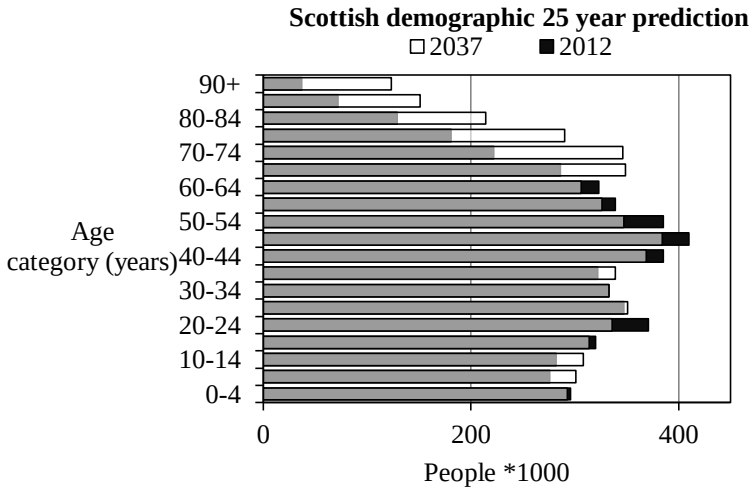

Figure1.2. Current and predicted demographics of the Scottish population, Predicted data is laid over existing data in semi translucent white. Data adapted from National records of Scotland 2013.

Although chronological age is used here to define an ageing population, ageing itself can be defined as the accumulation of biological, psychological and sociological changes in a person over time (Caprani et al. 2012, Rogers et al. 2006, Taveira and Choi 2009). These changes are not usually positive as they often lead to decreased physical functioning, prevent people from being able to work, have to rely on caregivers, and eventually die. Because of this, an ageing population will have an adverse effect on healthcare systems.

1.3. Increase in long term conditions, increase in cost of care

Whether or not the predicted ageing will lead to increases in illness and disability and thus higher care expenditure is crucial for developed countries. There are three possible scenarios. The first is compression of morbidity; here acute illness and disability strike later in life and then lead to death relatively quickly (World Health Organization 2009). This allows people to live longer but would not necessarily increase health care cost. Conversely, the second scenario assumes expansion of morbidity; people survive serious illness where in the past they would have died (World Health Organization 2009). They then live longer with the consequences of that illness, increasing cost. The third is an equilibrium where the proportion of life spent in ill health remains the same and the cost would remain more or less the same as well. Which scenario will prevail, and what the consequences on acute care will be, is still uncertain. What is likely however is that as people live longer, there will be an increase in long term conditions, leading to an increase in expenditure on long term care (World Health Organization 2009).

Examples of long term conditions requiring such long term care include diabetes, stroke, arthritis, dementia, depression, lower back pain, chronic obstructive pulmonary disease, and chronic heart disease. These conditions last for more than one year and limit what a person can do. Managing them is seen as the biggest challenge facing health systems worldwide with 60% of all deaths attributable to them (Audit Scotland 2007).

In the UK, they account for 80% of all GP visits and more than 60% of hospital bed days. Recently the Scottish Public Health Observatory examined the burden caused by various diseases in Scotland. The conditions causing the greatest loss of healthy life were found to be heart diseases, low back and neck pain, and depression (the Scottish Public Health Observatory 2017). In Scotland it is estimated that one in five people has at least one long term condition, and prevalence increases with age (Audit Scotland 2007). Thus, as the number of older people in Scotland increases, it is expected that a growing number of people will suffer from a long term condition which augurs badly for the cost of care (Scottish Government 2016). In addition to this there are growing pressures in other areas; increased spending on drugs, increased staff costs, and in-flexibility in financial planning that prevents spending to save. Further complicating financial planning is the fact that healthcare needs are not static and will continue to increase as Scotland's population ages. (Audit Scotland 2017).

Using the current modes of care delivery, and assuming demand increases in line with the increasing number of older people, ageing would result in a cost increase for health and social care for older people from 4.5 billion pounds in 2007/2008 to nearly 8 billion pounds in 2031 (Scottish government 2011) Unfortunately NHS budgets are already under pressure (Scottish government 2011) (Christie 2011). In 2008/09 the NHS budget accounted for 38% of the overall Scottish Government budget. In 2016/17 this has risen to 43% of the overall budget at £12.9 billion, making it the single largest area of Government expenditure (Audit Scotland 2017).

A further cost increase is not sustainable, especially when considering the concurrent decrease in the working age population, which means both the number of people to provide care, as well as health system income will decrease (World Health Organization 2009).

1.4. The reablement paradigm shift

Clearly there is a need to explore how the cost of care could be kept under control in the future, and there is general consensus in Scotland that healthcare cannot continue to be delivered in the same way (Audit Scotland 2017). Improving the efficiency of care delivery and preventing disease in old age, especially long term conditions, will become increasingly important to achieve this. It is the damage that accumulates over a lifetime that makes people age physiologically. Having lifestyle factors that delay this are instrumental to successful ageing, as described by Rowe and Kahn as early as 1987 (Rowe & Kahn 1987). In order to maintain health and thereby independence it is important to have a lifestyle that reduces the amount of damage accumulating, for instance by having a balanced diet, not smoking or drinking alcohol excessively, and being physically active. The latter sometimes being called: "the best preventive medicine for old age" (Oxley 2009). If however a person for some reason does have limited physical function, difficulties can be reduced with rehabilitation (WHO 2011), thus enabling people to get back to the best preventive medicine; a physically active lifestyle. Improving people's health is a main part of the Scottish Government's vision of health and social care in the future, as a healthier population is likely to reduce the future burden due to fewer people developing conditions stemming from unhealthy lifestyles (Audit Scotland 2017).

Services focussed on prevention, maintenance of independence and reablement have been shown to produce comparable results when compared to traditional care, but at reduced cost (Panagioti et al. 2014) (Taylor et al. 2014). The Scottish government regards them as a specific outcome to be achieved by 2021, as set out in the Scottish government document "reshaping care for older people, a programme for change 2011-2021" (Scottish government 2011), and more recently in the Health and social care delivery plan (Scottish government 2016) and Active and independent living programme (Scottish Government 2017). The National Health Service too, acknowledges the importance of preventing disease and restoring lost function in old age in order to keep care from becoming unaffordable. They therefore promote a care delivery paradigm shift toward a reabling, person centred approach. Shifting dependency away from healthcare

professionals, towards reablement, or assisted self-management, in order to meet the vision of allowing older people to live full and positive lives at home or in a home setting (Scottish government 2011) (Christie 2011) (Scottish government 2012) (NHS Scotland 2013). Recently this person centred health care delivery paradigm focussing among others on personal responsibility and decision making has been introduced for the NHS a whole, dubbed 'realistic medicine' (Audit Scotland 2017).

Expected to become central in driving this care delivery paradigm shift are the rehabilitation services. They are provided by Allied Health Professionals (AHPs); physiotherapists, occupational therapists, speech and language therapists, arts therapists, dieticians, orthoptists, podiatrists, prosthetists and orthotists (Scottish government 2012). In 2010 there were approximately 12.000 (NHS 2011) AHPs providing services to the over 5 million (National Records of Scotland 2012) people of Scotland. These AHPs are expected to become central in reablement as they aim to support independent living in an increasingly ageing population (Hill 2010a). Also, they are in the position, and have the knowledge to encourage a healthy lifestyle, thus contributing to the prevention of disease through a holistic approach, as pursued by the Scottish Government (Scottish Government 2016). Additionally, as set out in the national delivery plan for the Allied Health Professions in Scotland 2012-2015, they can make a vital contribution to faster diagnostics and earlier interventions, so reducing unnecessary and expensive admissions to hospitals. AHPs are therefore to be the "agents of change" at the front of the paradigm shift towards reablement (Scottish government 2012). Reablement is also what patients themselves desire, as it allows them to remain independent (Scottish government 2011).

1.5. Current mode of rehabilitation delivery unsustainable

As set out in the above, AHPs could transform healthcare, effectively reducing the cost while at the same time increasing quality. However, being the agents of change driving the reablement paradigm shift would increase the rehabilitation services' workload if current practice is continued. Further, patients already receive insufficient rehabilitation which has been expressed by patients as a tendency for people with long

term conditions to receive less rehabilitation than they perceived they needed (Hill 2010b p16). Moreover it was mentioned in a 2008 Cochrane review on rehabilitation environments that the current insufficiency in rehabilitation is an integral part in the 'vicious circle' model, describing "the inter-relationship between pressure on hospital beds, increased use of expensive residential and nursing home care, less finance available for preventative services and, ultimately, more frequent re-admission to hospital" (Ward 2008).

There is general consensus in Scotland that healthcare cannot continue to be delivered in the same way (Audit Scotland 2017), and the above shows that neither can rehabilitation. Improving the Scottish people's health to reduce future burden, as is the Scottish Government's vision of health and social care in the future (Audit Scotland 2017), will rely on the AHPs to continue to get people back to being physically active after an operation or disease, which is the best preventive medicine. In addition to this it will rely on the AHPs supporting independent living, encouraging healthy lifestyles, enabling faster diagnosis and earlier intervention. Within the current policies of early discharge, that means their services need to be delivered in the community; at home or in a hub.

If the AHPs are to be the agents of change driving the paradigm shift, they will need the right tools for the job. Better measurement, data collection and the use of ICT (known as e-health or tele-health) will be required to support AHPs (Scottish government 2012) and improve access to their services (Scottish Government 2017). To enable the reablement paradigm shift, rehabilitation needs to be delivered more efficiently.

1.6. Tele-Rehabilitation

E-health, or tele-health (TH), is defined as "the interaction of an individual with or through an electronic device or communication technology to assess or transmit health information or to provide or receive guidance or support on a health related issue" (Whitten 2001). This may sound like a very modern concept, but as explained in the

introduction it dates back at least as far in time as the telegraph. Then, as now, it allows the remote exchange of data between patient and care professional (Sanders et al. 2012).

Although the distinction between the two is not always made, (e.g. Sanders et al. 2012) tele-medicine (TM) can be considered a sub category of tele-health (TH). It entails the provision of clinical services at distance using information and communication technology (ICT) (Scalvini et al. 2004). An example would be performing a dermatological diagnosis remotely. In certain long term conditions, TM was found to lead to reductions in hospital admissions, hospital length of stay and emergency department visits (Bashur et al. 2014).

Tele-rehabilitation (TR) in turn is a sub category of TM, and is defined as the use of ICT to deliver the clinical service of rehabilitation over distance (Cooper et al. 2001) (Russell 2007) (Brennan et al. 2010) (Hill 2010a). This reduces the need to travel for delivering the service of "rehabilitation", which is not defined. In this text the same definition as in the aforementioned Cochrane review on rehabilitation environments (Ward et al. 2008) will be used; "A process aiming to restore personal autonomy in those aspects of daily living considered most relevant by patients or service users, and their family carers". How these different "Tele" categories relate to each other is here based on the fact that medicine can be considered a subdomain of health, and rehabilitation a subdomain of medicine, and presented graphically in figure 1.3.

Like tele-health, TR too, is not new. It was first documented in 1959 (Rao et al. 2012), and by employing TR in clinical practice, the delivery of rehabilitation could become more efficient. TR could reduce travel and support AHPs by providing them with the tools they need; apart from being a form of e-health it could also provide better measurement and data collection, in line with the demands of the reablement policy. This would enable an increase in community rehabilitation, and enable AHPs to become the agents of change toward a more holistic approach to public health.

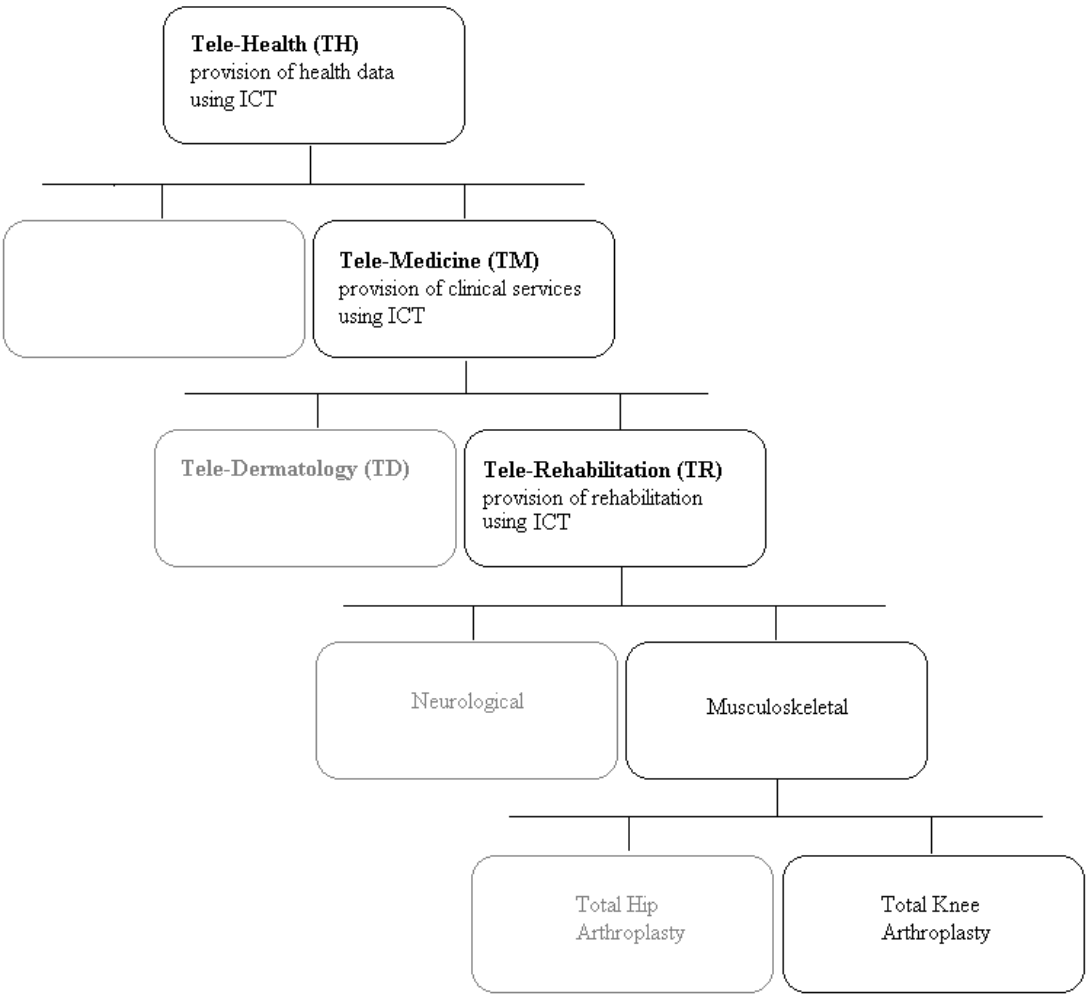

Figure1.3. Taxonomy of TR as a subcategory of TM and TH.

Unfortunately, as will become clear in the next chapter, TR is currently not routinely used in practice as there is insufficient evidence demonstrating clinical- and cost-effectiveness, both of which require large scale studies. Further, the TR technology that has been developed until now is not suited for use at a large scale, precluding these studies from being performed.

1.7. Aim

As set out above, there is an undeniable need for tools that enable AHPs to take advantage of the recent developments in information and communications technology and make delivery of rehabilitation more efficient, and allow AHPs to support independent living and encourage healthy lifestyles, working toward a more holistic approach to public health.

Currently there is a paucity of such tools that can be scaled up, hence limiting the evidence regarding TR to small scale studies and hindering its progression toward use in clinical practice. The aim of this work therefore was to develop a prototype of a scalable TR platform that provides better measurement, data collection and e-health, and test it to confirm its feasibility.

Chapter 2

Tele-Rehabilitation

2.1. Introduction

TR was defined as: the use of ICT to deliver a clinical service aiming to restore personal autonomy in those aspects of daily living considered most relevant by patients or service users, and their family carers. If implemented into clinical practice it holds the promise to enable intensive rehabilitation within current financial constraints, but it has many more advantages. There are however several milestones that have to be reached before a TR initiative can be implemented, with specific barriers for each one. Unfortunately, the milestone of large scale studies is rarely reached, limiting evidence and holding the field back. To remedy this, a TR platform with a unique blend of functions and properties will be needed.

An archetypal TR system could be imagined as two devices using a form of ICT to overcome distance between them, one used by an AHP, the other by a patient. Both devices would have means for input (e.g. a mouse for navigating menus, or patient measurements such as weight and blood pressure) and output (e.g. a monitor), enabling user interaction (figure 2.1). Using such a system, the patient would be able to measure their own relevant health measures and communicate them to their AHP. The AHP would then take appropriate actions based on the information received, all without the need to travel. Because of the physical or "hands on" nature of some rehabilitation treatment techniques, it is reported that TR is not always considered suitable (Hill 2010b). Still, there are many possible uses of TR, and depending on the functionalities of the technology used, many possible advantages over conventional rehabilitation (CR).

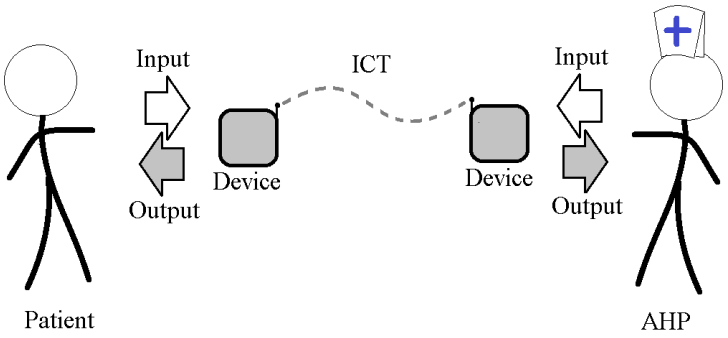

Figure 2.1. An archetypal TR platform.

This chapter will first review the advantages of TR, before addressing the evidence gap in the field. Once it is clear what the gap is, the focus shifts to a development model which will be necessary in order to cope with the multitude of barriers a TR platform would face on its way toward implementation. This will generate the functions and the properties required in order to maximise scalability, after which some previous initiatives in TR are compared to these functions and properties.

2.2 Advantages of Tele-Rehabilitation

As a form of e-health, TR in general has many advantages over CR. A major one being that it improves access to the service (Hill 2010b), especially in remote rural areas where traveling is more challenging (Russell 2010), coincidentally these are the areas in Scotland where ageing is expected to be most profound. TR also seems a viable method for teaching home based self-management (Faett et al. 2013), as strived for in the reablement paradigm shift.

TR would enable the acquisition of more data, more objectively. Aiding research, as well as shortening assessment intervals, leading to faster adjustment of therapy plans (Hill 2010b). As well as possibly improving treatment and improving access to it, TR is believed to also reduce the cost thereof (Dijkers et al. 1991)(Tousignant et al. 2015). The alternate view has been expressed that TR might increase total expenditure, as improved access might lead to an increased demand for rehabilitation services (Hill 2010b). However, if the cycle brought on by a current shortage of rehabilitation services (section 1.5) is a reality, this would seem like a problem that should be aspired to.

There are several other advantages TR can offer. Patient adherence to the exercise program for instance could be improved (Balaam et al. 2011). An advantage that could be amplified by using exercise games which are games that use a certain exercise as input, and base scoring on performance of said exercise. These games can

serve as a key motivational tool (Giggins et al. 2013) (Parmanto & Saptono 2009) although there is little evidence of clinical effectiveness as yet (Harms, 2012).

In long term conditions, patients want more information about their condition (audit Scotland 2007). It was shown that access to internet health information improves the way patients take care of themselves, and helps them to manage their illnesses. Unfortunately, some patients don't have access to the internet or are not able to understand the information (Leisey & Shipman 2007). TR could provide another advantage here, by providing patients with a central information point which can cater to their needs, and provide access to the information in a way that promotes understanding. Next to information, the need for social support was found to be a major issue in certain long term conditions (Taylor et al. 2014) which could be provided using a social network on a TR platform.

Further, TR could enable intensive long term rehabilitation if it is used to provide biofeedback. This has the potential to encourage correct performance of exercises without supervision (Ayoade and Baillie 2014). This is arguably where TR has the biggest advantage, as it would enable a drastic increase in rehabilitation, thereby breaking the hospital bed pressure cycle.

Unfortunately, despite its many advantages, TR implementation is not as yet widespread in Scotland (Hill 2010b), a phenomenon that occurs regularly in TM with over 75% of all initiatives failing to be implemented into daily practice (Broens et al. 2007). Recently Home and Mobile Health Monitoring has seen significant growth in Scotland as simple and low cost technology has led to higher engagement (Scottish Centre for Telehealth and Telecare 2017). This monitoring is a form of TH and shares the same motivation as TR; changing demographics and the economic environment. The functions Home and Mobile Health Monitoring provides are identical to some functions of TR; to acquire relevant health information, keep a record of it and relay it to health professionals (Scottish Centre for Telehealth and Telecare 2017). Therefore it could be argued to be a sub category of TR, where TR also uses this information to enable biofeedback and exercise games which enables added advantages. Like TR,

implementation is not widespread in Scotland, with candidate scale-up services as yet only emerging (Scottish Centre for Telehealth and Telecare 2017).

2.3. Evidence gap in the field of TR

A 2000 Cochrane review on TM showed a trend in results; the technology used in various trials was well accepted by users and produced comparable, perhaps better, results than face to face service delivery. However, studies were almost without exception lacking cost effectiveness evidence, and were small scale (Currell et al. 2000). Since then, the number of papers on TM has increased dramatically, and a recent review involving 141 RCTs in chronic disease management, involving a total of 37,695 patients, confirms the trends of good acceptance and clinical effectiveness of TM. It also confirms the lack of cost effectiveness evidence, and the limitations due to the short term (median duration 6 months) of the studies performed (Wootton et al. 2012). Suggesting a need for long term, large scale studies including cost effectiveness in the field of TM.

TR being a subcategory of TM (see figure 4), many TR initiatives struggle with the same problems. A review of 28 TR articles involving a total of 1055 participants confirmed the trend of good acceptance and clinical effectiveness seen in TM, as well as the need for cost effectiveness evidence (Kairy et al. 2009). Although "there is strong emerging evidence that TR can provide patients with the same clinical outcomes as traditionally delivered rehabilitation programs in specific populations and that patients are highly satisfied with treatment being delivered remotely" (Hill 2010b), the evidence is *emerging*, with a lack of cost effectiveness data (Hill 2010b). To the best of the author's knowledge the first study reporting the cost effectiveness of TR was not performed until very recently (Tousignant et al. 2015). In the case of home and mobile health monitoring large scale research involving a total of 10,000 participants has been performed and here cost effectiveness was found as the cost per patient was reduced (Scottish Centre for Telehealth and Telecare 2017). However, monitoring lacks some of the functions of TR such as biofeedback believed to be most beneficial. Recently more

small scale TR cost effectiveness research has been performed with positive results (Fusco and Turchetti 2016, Frederix et al. 2016, Frederix et al. 2017, Pastora-Bernal et al. 2017), although other studies have found negative results (Kidholm et al. 2016).

Thus, at this point there seems to be sufficient evidence on acceptance and clinical effectiveness of TR to warrant further research. Especially large scale, long term, studies would be valuable to strengthen evidence of acceptance and clinical effectiveness, as well as the cost benefits of TR. Once proven, the cost benefits are believed to become one of the most influential factors in the expansion of TR (Hill 2010b). However, there are many barriers to be overcome before an initiative is ready to be scaled up, able to perform cost effectiveness research.

2.4. TR development model

In TM a layered implementation model has been proposed in order to improve the chances of scaling up the technology, as well as coping with inherent multidisciplinary problems (Broens et al. 2007). In this layered model, focus shifts from the technological barriers in the prototyping phase, through acceptance barriers in the small scale pilot phase, to financial barriers in the large scale pilot phase, and organisational, policy & legislation ones in the final phases of the operational product. It was noted by the authors however that although the focus shifts during development, all barriers should be kept in mind from the start.

For the subcategory of TR, the known barriers in TR as well as those in both TH and TM believed to be relevant are organised using the phases suggested by Broens et al. There are four phases, with milestones that can be achieved after the barriers of that phase have been overcome. Once a milestone has been reached the next phase can be initiated, see figure 2.2.

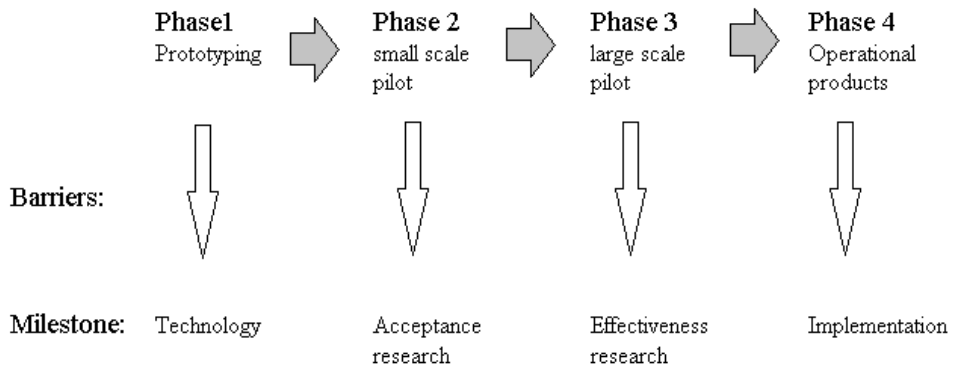

Figure2.2. The four phases in TR development based on the TM development model proposed by Broens et al. 2007.

The focus of the current project is reaching the phase 1 milestone; technology developed. However, all barriers will be mapped and taken into consideration here. Due to the sheer number of barriers that have been reported by previous initiatives, the barriers have been grouped together into categories where necessary. These categories are then assigned to the different phases leading to a "map" of which barriers should be focussed on overcoming in which phase, and more importantly; how.

2.4.1. Phase 1, developing technology

The first collection of barriers consists of the categories *hands on approach* & *psychological*, the solution for these constitutes choosing a suitable form of rehabilitation. As briefly touched upon at the start of this chapter, not all areas of rehabilitation are suitable to be delivered through TR due to their "hands on" nature (Hill 2010b) (Mikolajewska & Mikolajewski 2014)(Cherney & van Vuuren, 2012). This precludes any techniques relying on physical manipulation from being delivered. TR could still be of value in these areas as it allows the provision of information and remote monitoring, but physical, face to face, contact would remain necessary unlike areas of rehabilitation where these physical manipulation techniques are absent, for instance COPD, heart failure, or diabetes.

The *European Momentum for Mainstreaming Telemedicine Deployment in Daily Practice* published a list of 18 critical success factors in order to mainstream TM. Their first factor is "ensure cultural readiness" and the third one "identify a compelling need" (Momentum 2014). These factors are part of the second category of barriers: *psychological* ones. A study by Sanders et al. published in 2012, was able to uncover some psychological barriers by interviewing a group whose points of view are not routinely found in TH studies; patients who refused to take part. 9214 people were approached to participate in the Whole System Demonstrator TH trial, taking place across the south of England. 36.7% of these people declined to take part in the study, in line with the typically high refusal rate seen in home based TM trials (Sanders et al. 2012). Of the people who refused, 61 were approached to explain their choice, 22 of these agreed to be interviewed. An interesting barrier to patient acceptance found in this group stems from the high appreciation patients have for existing services. TH services were expected to disrupt the highly valued existing service, which is why many people declined. Another barrier was found in the technology being perceived as a threat to identity, making patients feel sicker than before. Some technology can be perceived as a threat to independence as well, for instance oxygen therapy machines were perceived as something patients over time might become dependent on (Sanders et al. 2012). Apart from being perceived as a threat by patients, some clinicians too might feel aversion from the new technology as they may feel their expertise is under threat (Hill2010b).

Ranging from physical manipulation to being perceived as a threat, the first collection of barriers already shows the potential to deter the uptake by patients, prohibiting large scale studies if an initiative fails to overcome them. One way to overcome this collection of barriers might be "starting where they are not". This means, choosing an area of rehabilitation where there currently are no, or minimal, existing services that would be threatened by the new TR initiative. In order to overcome the *hands on approach* category of barriers, an area of rehabilitation should be chosen that can be delivered without physical manipulation. Additionally, this area would also have to have a compelling need and cultural readiness to help overcome the *psychological* category of barriers.

The area of rehabilitation chosen for the prototype TR platform in this thesis is post total knee arthroplasty (TKA) rehabilitation, as it satisfies these conditions. It is a form of rehabilitation that does not require physical manipulation, and as will be shown in the next chapter, it is an area of rehabilitation with a compelling need. Cultural readiness for this type of rehabilitation to be delivered through TR has been demonstrated by the success of previous initiatives (Russell et al. 2004, Tousignant et al. 2009). Also, the current service in the acute phase of recovery is minimal, even absent in the sub-acute phase so there is a minimal existing service that would be threatened. Because of the nature of TKA, the threats to identity and independence are negated. TKA is not a milestone signifying the worsening of a condition, but a possible cure. These factors make post TKA rehabilitation an ideal candidate for a prototype study.

The aversion therapists may have to the technology due to their expertise being threatened, sometimes called professional possessiveness, can be addressed by the design of the platform; emphasizing the fact that it is merely a tool for the therapist and is not aiming to replace them. The patients interviewed by Sanders et al. (2012) also revealed aversion to technology as a barrier to patient acceptance. Patients held the view that special skills would be required to operate the technology involved, though this was often based on misunderstandings. These barriers have some overlap with the *psychological* category from the previous section, but are here put into the *usability* category of barriers.

Apart from aversion to technology, there are some other considerable barriers in this category. Usability was recognised as a critical aspect of the technology involved in TM, Momentum's success factor no. 15 being "ensure that the technology is user-friendly", user-friendly meaning usable (Momentum 2014). Any technology used should be usable for everyone involved, in this case including a heterogonous group of patients. For instance, consideration should be given to patient's possible deficits in the areas of cognitive-, gross or fine motor-, visual- and language-skills (Brennan and Barker 2008). A literature review of 45 TM initiatives on the determinants of successful

implementations confirms usability to be "a major factor in success". Additionally the authors noted that patients should be comfortable wearing any new monitoring technology (Broens et al. 2007). As in TM, in TR too usability was uncovered as one of the required characteristics for success (Saptono et al. 2009). So the platform design will have to ensure the property of usability, for both patients and therapists.

An additional category of barriers that would have to be overcome by the platform design is *quality*. If a TR platform is to be accepted by users, it needs to be of high quality and robust. If devices placed in a home setting are too fragile they would soon fail as this environment can be very unpredictable. For example children and pets could prove to be a challenge for all but the most robust devices. Or, as put more eloquently by Brennan and Barker (2008): "devices placed in the home must be simple to operate, reliable and have a high level of fault tolerance". Minor technical problems such as drained batteries, troublesome wireless data connections, and cable breakages were found to be a major barrier for the implementation of TM systems (Broens et al. 2007), so care should be taken to prevent them.

Because TR has such a broad scope, it has been noted that no single generic platform could meet the needs of all applications. Rather, a platform should have *Flexibility* (Brennan and Barker 2008). For instance by offering both synchronous (real time) and asynchronous services, and meeting participants' expectations of solutions that work anywhere and everywhere, across a range of devices (Cherney & van Vuuren 2012). This indicates that mobility is a form of flexibility that an ideal TR platform should have. Furthermore, having *flexibility* would aid the interoperability of the platform, enabling adoption by other AHP services. The skills occupational therapists (OTs) for instance possess are key to preventive services, and it has been noted that they should be involved in reablement programmes (College of Occupational Therapists 2010), illustrating the importance of interoperability. A flexible platform would enable their inclusion in the treatment, as well as that of physiotherapy, nutritionists etcetera, thereby improving generic value.

The above barriers are believed to be surmountable by the platform design. The platform should have good *usability*, be as user friendly as possible in order to enable its use by as many patients and their care workers as possible. This means Human factors considerations, especially in older adults, will have to be taken into account. The platform should be of high *quality*, minimising the chance of technical problems, and it should also be *flexible*, allowing for changes to both software and hardware used. Choosing a suitable area of rehabilitation, as well as having an adequate design is believed to overcome the phase 1 barriers. However, as stated earlier it is recommended to consider at this early stage all the different phases of development, and keep all barriers in mind at all times (Broens et al. 2007), hence the barriers of the next phases will be considered as well.

2.4.2. Phase 2, gaining user acceptance

The barriers in this phase comprise the categories *training* and *tech-support*. Although an adequate design will ensure that the platform is usable and the occurrence of technical problems is minimised, this is not enough to guarantee user acceptance.

Without *training*, users will be unfamiliar with any new system, regardless of how usable, or user-friendly, it may be. This unfamiliarity may lead to frustration and consequently abandonment of use. Therefore, training is important (Brennan and Barker 2008) (Rogers et al. 2006) not just for patients, but for everyone involved (Broens et al. 2007). Also, patients should be given a chance to express expectations and concerns regarding the TR platform prior to installation (Sanders et al. 2012), for which the training period would be very suitable. *Tech-support* is needed because without it, problems during the use of the system lead to de-motivation and a high probability of abandoning the system. This makes tech-support a major issue for the acceptance of a TR platform (Broens et al. 2007). In order to overcome these barriers, it is clear that the services of *training* and *tech-support* will have to be provided.

After a TR platform successfully completed its first milestone by delivering functional technology, and provides the services of *training* and *tech-support* described above, the barriers of phase 2 would theoretically have been overcome and the user acceptance would be largely determined. Thus, an initiative would be ready for its second milestone; acceptance research.

2.4.3. Phase 3, scaling up

In TM scaling potential is mentioned as Momentum's success factor number 18 (2014). It has been mentioned as one of five required characteristics for success, next to openness and cost effectiveness (Saptono et al. 2009), and it was found to be the major factor holding the field of TR back. The barriers in this third phase are important for the platform design, and they are here argued to be able to be overcome by taking advantage of the "Open Source" paradigm. As a product development model, Open Source provides universal access to a product's blueprints, and universal redistribution of that blueprint. From a consumer point of view, it leads to products that are cost effective and readily available. For research, this would enable the milestone of long term, large scale trials, able to strengthen both acceptance and clinical effectiveness evidence as well as providing strong evidence on cost effectiveness.

The first category of barriers on the way to large scale trials is *financing*. The cost of establishing a TR service, including costs of training, may be a major barrier to its implementation (Hill 2010b). When large numbers of platforms are required, the cost of the devices used, as well as any costs of licensing and distributing many copies of software, can have a considerable impact on the total cost and should be kept to a minimum. Moreover, keeping cost to a minimum will improve on cost effectiveness of the TR service as well. To this end the use of low cost open source components has been suggested (Saptono et al. 2009). Cost effectiveness arguably is the most important aspect of a TR platform, as financial pressures are the motivation for developing it. Although possible increases in rehabilitation duration and intensity, and any long term preventive effects stemming from this should not be ignored, on the short term a TR platform

should be cost effective too. The resources saved from reduced travelling should not be exceeded by the cost of the technology involved.

To overcome the *diffusion* category of barriers, the technology should again strive to have generic value (Broens et al 2007). Moreover, an initiative needs to build familiarity and enthusiasm among interested parties. Leading champions motivated and willing to experiment with new TM technology are essential in this (Broens et al. 2007), "ensure leadership through a champion" being listed as Momentum's success factor number two (Momentum 2014).

The categories of *financing* and *diffusion* can be influenced to a considerable amount by choosing open source components and software. Regarding *financing*, the use of low cost open source components and software would keep costs down and provide a network for distribution, aiding scalability. *Diffusion* stands to gain as well, as large open source software initiatives would provide better accessibility for interested parties than proprietary versions. Moreover, rather than limiting the platform to the use of open source components and software, it should be itself open source. Open source has been used successfully for software before; the currently largest mobile operating system, Android, for instance is open source. Recently, the same principles have been applied to hardware. Made possible by new digital manufacturing technologies such as 3D printing, free and open source hardware has the potential to maximise return on public investments, especially in technologies associated with science, medicine and education (Pearce 2015). Developing a TR platform requires public investments, and the potential return on these investments as cost savings for the health system is only achieved if it is implemented into clinical practice. By making the TR initiative open source, it would be available to anyone interested, and a collective effort to further develop it would be possible. This would allow various research groups to test aspects of the platform and, having access to designs and source code, they could make improvements, or adapt some aspects to make the platform suitable for different areas of rehabilitation. Once tested and approved, such adaptations could then be added to the open source TR initiative itself, increasing the possibilities of the initiative as a whole. This would be a

major advantage in terms of scalability, thus the chances of implementation, and return on the investment, would increase. Also, being open would allow for easier duplication of studies, which was shown necessary to strengthen evidence in research (Ioannidis 2014).

2.4.4. Phase 4, implementation

After filling the gap in the evidence base for TR including large scale clinical- and cost- effectiveness evidence, progression into the fourth phase with its milestone of implementation would be possible. Although implementation is far beyond the scope of the current work, the fourth phase barriers will be briefly addressed because, as mentioned before, all barriers should be taken into account when starting a new initiative.

Failure to comply with *legislation and organisation* issues such as data security and patient privacy hinders implementation of TR services into the clinical setting (Cherney and van Vuuren 2012). Also, implementation means the TR platform would have to fit into an organisations daily work practice, which means that the involvement of care professionals in the design process is crucial (Broens et al. 2007). Patient privacy is considered especially important (Brennan and Barker 2008) (Hill2010b p33): which means commercial real time video conferencing (RTVC), or voice over internet protocol VoIP may not be suitable for implementation into practice (Audit Scotland 2007), and care should be taken when handling patient data. If a system is to be implemented into clinical practice it needs to employ communication standards that are safe.

Cooperating with care professionals, as well as manufacturers of patient records software at an early stage should improve the chances of the TR technology reaching the phase 4 milestone of implementation. However, the focus would shift to cooperation only toward the end of the development process, for now the focus is on delivering functional technology.

2.5. Platform functions and properties

The prototypal TR platform being developed here must have a specific set of functions and properties if it is to be scalable and improve on its chances of being implemented. These are based on the advantages and barriers of TR described in the previous sections.

2.5.1 Functions

Certain functions that a TR platform can provide yield advantages over CR and so should be built in. One such advantage is that TR can improve access to the service by negating the need for travel. To provide this advantage, the platform should enable communication between the therapist and patient. Some examples of how to enable this communication would be telephone calls, or real time video conferencing (RTVC). Both used with success in previous initiatives (Odole et al. 2014, Russell et al. 2004). Apart from the personal communication between patient and therapist, health data has to be communicated too, so the ICT used for the communication should be able to handle health data as well.

In order to acquire this health data, patients have to be provided with an instrument, a way to measure their relevant outcome measures. As is done for instance for diabetes patients who measure their own blood sugar levels. After these outcome measures are communicated to the therapist, they would then have to be stored. Considering the paperless NHS target, this storing would have to be done electronically in an electronic patient file. Together, these functions of communication, data acquisition and storage, would fulfil the reablement policies' demand for a way to provide e-health, better measurement and data collection to AHPs. There are however additional functions that could increase the platforms effectiveness.

As touched upon in chapter 1, providing patients with relevant information (Leisey and Shipman 2007), as well as social support (Taylor et al. 2014) has the potential to improve clinical outcomes. Exercise games might be valuable as well, as

such games have the potential to increase exercise motivation and consequently the amount of therapy a patient adheres to. Because adherence "has been identified as an antecedent to successful patient outcomes, especially those with musculoskeletal disorders" (Picha and Howell 2018) this is believed to lead to better outcomes. The last additional function; biofeedback, is an important one as it encourages correct execution of exercises. By providing feedback on performance of an exercise, patients are enabled to do a therapy session without therapist supervision (asynchronously) which would enable the length and frequency of sessions to not be limited by the therapists' availability.

2.5.2. Properties

As mentioned previously there are numerous barriers that a TR initiative is expected to encounter along its way toward implementation. To overcome them, a platform would have to provide its functions with certain properties.

The *hands on approach* and *psychological* groups of barriers can be overcome by the solution *choice*; choosing an area of rehabilitation where physical manipulation is not required, and where there is cultural readiness and a current paucity of service. For this prototype study post TKA rehabilitation was chosen. In the next chapter it will be shown how this area of rehabilitation meets these demands.

The solution *design* will be the subject of chapter 4 and will ensure that the barriers in the groups *usability, quality* and *flexibility* are overcome.

The categories of barriers addressed in the small pilot phase of this thesis are *tech-support* and *training.* Because they are crucial in the adoption of any new technology, they will have to be provided once the platform moves on to phase 2. However, the design of the platform is expected to have a substantial impact on the requirements for these *services*, that from a cost perspective are best kept to a minimum.

Large scale, long term clinical- and cost-effectiveness research is the milestone for the third phase. But given the importance of cost effectiveness, not only for implementation and long term usability for the self-management of LTCs, but also for

large scale research, the ability to deliver long term, cost effective services through the platform should be a property it possesses from the start.

There are two categories of barriers in the third phase; *financing* and *diffusion*. Each posing different requirements on the platform, but both believed surmountable with one solution. As explained before, open source is a relatively recent way of approaching products. By making designs and source code publically available, products stimulate competition, and any obvious design flaws would be quickly discovered. As a result, the consumer is ensured of a quality, fairly priced product. Using open source components would ensure the TR platform of quality, affordable parts, aiding in overcoming the financing barriers in this phase, as well as the quality barriers of phase 1. By becoming open source itself, the diffusion barriers could be overcome and the milestone of large scale research reached,

The fourth and final milestone is implementation of the TR platform into practice. Before implementation is reached however, there are more barriers to be addressed. *Legislation and organisation* was found to be a category, which is expected to be overcome by collaborating with the appropriate parties at the appropriate time. For the first phase of the platform, collaboration was sought with physiotherapists, as well as a manufacturer of electronic patient files, but in later stages collaboration with legal professionals is likely to become necessary.

The next chapter will explore the literature related to TKA, the area of rehabilitation chosen for the platform and the aspects of it that are relevant for the development of the platform.

Chapter 3

Total knee arthroplasty

3.1 Introduction

Knee arthritis is a long term condition that can be "cured" by replacing the diseased joint; a total knee arthroplasty (TKA). As will become clear from the following, the knee enables many activities that would otherwise be difficult. It is a mechanically complex joint with some remarkable properties. Years of research and development in joint replacements have led to knee prostheses that conform to the complex mechanics of the natural knee. These are used to replace the diseased knee, improving quality of life and function. Following this operation, there currently is only a very limited amount of rehabilitation. If patients are to regain a sufficient level of knee function following a TKA however, intensive rehabilitation is crucial. TR could enable this, indicating the need for TR in post TKA rehabilitation.

This chapter will first review the anatomy, function and mechanics of the knee, before addressing arthritis. Once it is clear what an impact arthritis can have on health and well-being, the focus shifts to TKA and the relevant outcome measures that a TR platform should be able to acquire. The chapter finishes by reviewing some knee TR initiatives and stating the research aim.

3.2. The knee joint

The knee joins the upper and lower leg together in a way that allows a principal movement known as knee flexion. It belongs to the category of diarthrodial, or synovial joints, which means that the joint's articulating surfaces are covered in cartilage and contain a lubricating fluid called synovial fluid (Ellis 2002). But there are many more aspects to the knee's anatomy and functions that are important to consider in the development of the TR platform.

3.2.1 Anatomy

The three bones that make up the knee joint are the femur, tibia and patella. There are medial and lateral articulations between femur and tibia, forming the proper knee joint responsible for functional weight bearing. The other articulation is between femur and patella and is considered the joint of the extensor muscles (Evans 1986). In this joint, the patella acts as a pulley, transmitting extensor muscle forces to the tibia as it slides in the trochlear groove of the femur. All these articular surfaces are covered with a hyaline cartilage that functions as the joints' lubricating surface known as articular cartilage (AC). Aided by the synovial fluid in the joint, this leads to a remarkably small amount of friction. With a friction coefficient of just 0.0025 to 0.005 (Mow et al. 1990), it has roughly ten times less friction than a steel skate on ice has; the steel on ice friction coefficient being 0.03. Next to reducing friction, the AC also distributes joint forces and transmits them to the underlying bone (Mow et al. 1990). This underlying, or subchondral, bone is very thin and is supported by thin beam like bone structures called trabeculae. Being only around 0.2mm thick (Walker and Helewa 1996), the trabeculae make up a sponge like structure that is able to deform under load, thereby absorbing mechanical energy and protecting the AC from excessive impact loads (Mow et al. 1990). To get an idea of what this sponge-like structure looks like, a photograph of an end piece of tibia is displayed in figure 3.1. If you have the opportunity, this sample can be admired in real life at the Hunterian museum in Glasgow.

Figure 3.1. A sample of tibia with trabeculae, on display at the Hunterian museum in Glasgow.

Another structure that protects the AC from impact loads is formed by fibrous cartilage called the menisci. These semilunar bands improve congruence between femur and tibia and act as a shock absorber. Also between femur and tibia are the collateral and cruciate ligaments, somewhat flexible bands joining the two bones together, providing stability, guiding movement and providing proprioception (Mow et al. 1990). Surrounding the tibia-femoral articulations, is the joint capsule with the patella effectively a part thereof (Kahle et al. 1986). Figure 3.2 illustrates this schematically, for a more detailed overview of the knee anatomy, please refer to an atlas of anatomy.

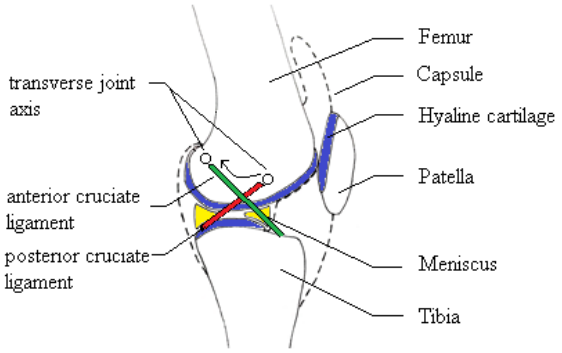

Figure3.2. Schematic sagittal cross section of the medial part of the right knee. Note the moving of the transverse joint axis to posterior as the knee flexes.

3.2.2. Function and mechanics

The knee allows for movement of the tibia relative to the femur; it affords degrees of freedom (DOF). The main DOF is a rotational movement in the sagittal plane; knee flexion or –extension (Ellis 2002). Although it should be stated that the knee is but a part in the chain of all the joints of the lower limb, it is crucial for lower limb function. And it is easily understood how a lack of knee function has a detrimental effect on quality of life (QOL). Many activities of daily living (ADL) would become difficult if not impossible without proper knee function. To illustrate this point, one need only imagine putting on a shoe, or getting out of a chair, without being able to bend your knee.

Knee flexion is quantified by the angle between the shafts of tibia and femur. Their orientation can be determined by imagining lines between trochanter major and lateral epicondyle of the femur of the thigh, and fibular notch and lateral malleolus of the lower leg (Edwards et al. 2004). When in the anatomical position, these lines are parallel to one another (the angle between them is 180 degrees) and, following the neutral zero method first described by Silver in 1923 and later by Cave and Roberts in 1936 (Norkin & Whyte 2003) (Green & Heckman 1994), the knee angle is defined as zero. Extending the knee beyond this point leads to negative flexion angles called hyperextension, with around 5 degrees of hyperextension being considered normal (Evans 1986) (Kahle et al. 1986). Knee flexion on the other hand has a considerable larger normal range of 135 to 150 degrees (Norkin & Whyte 2003) (Greene & Heckman 1994) (Clarkson 2013).

Knee movements are generally caused by the voluntary muscles of the joint, however there also is a so called conjunct movement in the knee joint, which means the movement is automatic and inevitable. As the knee is extended, there is an automatic exo-rotation of the tibia. This means that the knee flexion and extension movement is not a simple hinge movement, but is accompanied by a swivel (Evans 1986). Known as the "screwhome" mechanism this exo-rotation of the tibia locks the knee, preventing it from rotating when in extension. When walking for instance, the amount of exorotation of the tibia during the stance phase is generally accepted to be 11 degrees (Benoit et al. 2007), while between 4 degrees of abduction (valgus), and 2 degrees of adduction (varus) occur in the frontal plane (p88 Perry & Burnfield 2010). This shows that the knee is not a simple hinge joint; rotations in the coronal and frontal plane occur as well, albeit with much smaller excursions than knee flexion in the sagittal plane.

There is another significant deviation from a simple hinge movement in the knee joint; flexion is polycentric. The spiral like shape of the femoral condyles combined with the rolling and sliding motion of these condyles on the tibia, causes the transverse axis around which the knee flexes to move as flexion progresses (Evans 1986). The axis moves from the point where the posterior cruciate ligament attaches to the femur when the knee is in extension, through the curved trajectory where the cruciate ligaments cross

each other as the knee is flexed, until the point where the anterior cruciate ligament attaches to the femur at around 135 degrees of knee flexion, see figure 3.2. The trajectory of the axis of rotation is thus determined by the geometry of the cruciate ligaments that form a four bar linkage (Mow et al. 1990).

This means that apart from the three rotational DOF (flexion/extension, rotation of the tibia, and varus/valgus), the knee also allows the tibia two translational DOF relative to the femur, one anterior/posterior, and one distal/proximal. This makes for a total of five DOF. However it should be noted that the missing DOF; medial/lateral translation does occur to some extent, as the stabilising structures are somewhat flexible and so do not limit these movements to zero. As will become clear in section 4.3 the many DOF of the knee are important in the development of instruments that can accurately measure knee kinematics (Tesio et al. 1995).

There are many factors contributing to the stability of the knee; the articular surfaces, the knee muscles, the joint capsule, and additional bands and ligaments. Although the posterior cruciate ligament (PCL) is sometimes called the fundamental stabiliser of the knee (Evans 1986), it is significantly assisted by the collateral ligaments, that provide mainly varus/valgus stability. In anterior-posterior direction, both the cruciate ligaments are responsible for providing stability, the PCL prevents posterior subluxation of the tibia while the anterior crucuiate ligament (ACL) does the same in the anterior direction. Apart from this, the anterior cruciate also limits endo-rotation of the tibia, while exo-rotation is limited by the collateral ligaments. The ligaments are very important for joint stability, and if they are sectioned, the joint becomes unstable (Gollehon et al. 1987).

However it has been noted that when large amounts of force are involved, the cruciate ligaments assume a sensory rather than just a stabilising role as they would otherwise simply tear. Instead of restricting motion themselves, they provide proprioceptive information that is used to control the knee muscles that then stabilise the joint (Mow et al. 1990), illustrating the musculature's importance for joint stability. The knee musculature is so effective in stabilising the knee that it can even be used to

compensate for an unstable joint, provided its power is sufficient. However, this seems ineffective in compensating for rotational instability (Evans 1986). Unfortunately knee muscles, as well as other parts of the knee, can be adversely affected by certain knee disorders.

3.3. Arthritis

Arthritis is the most common source of disability (Albert 2004) and 99% of knee arthroplasties (TKA) performed in Scotland every year are due to arthritis (Information Services Division Scotland 2014). Apart from traumatic conditions, it is the oldest and most widespread condition in paleopathology. It is actually older than humankind; evidence of arthritis has been found in dinosaur skeletons. In humans it has been observed since the Neanderthals and later in Egyptian societies (Walker & Helewa 1996), but it was not until around 400BC that it was given the name arthritis by the Greek physician Hippocrates (Mow et al. 1990). Currently over 100 different types of arthritis are recognised, all characterised by the degenerative processes of the AC (Walker & Helewa 1996).

Degeneration of the AC may have many causes, one example would be an auto-immune disease. This condition is called rheumatoid arthritis (RA) and can cause inflammations in the knee joint, making it painfully swollen and deteriorating the AC. This makes weight bearing painful which can lead to disuse of the joint.

Another form of arthritis is osteo-arthritis (OA). In the year 2000, OA in general was reported to be the 8th leading cause of non-fatal health burden in the world (Woolf and Pfleger 2003). By 2030, it is predicted that the prevalence of OA will have risen from 20% to 30% in the over 60 year olds (Croft 2005), indicating OA is a serious problem, expected to get worse. In the knee OA can begin during athletic activities or when the menisci are damaged beyond repair and have to be removed. Not having a meniscus increases the chance of damaging the articular cartilage due to a lack of load distribution; a load is concentrated on too small an area of AC which leads to overload (Helfet 1982). Obesity may be a cause, as OA occurs more often in the markedly

overweight; the Ponderal index (calculated as body mass in kilograms, divided by height in metres to the power of three) has been shown to correlate with knee OA (Helfet 1982). However, although obesity correlates positively with the presence of OA, a clear cause and effect relationship between the two has not yet been identified (Walker & Helewa 1996). Whatever the underlying cause, be it idiopathic obesity or over-zealous athletic activity leading to OA damage, the result is degeneration of the AC.

Early in the course of knee OA, the deteriorating AC will leave the knee painful after sustained use. As the degeneration progresses, any active or passive movement may be painful, so patients often avoid movement. The same is seen in the early stages of knee RA, where pain may be experienced due to swelling of the joint. Later the swelling of the joint may lead to cysts, the treatment for which consists of avoiding weight bearing (Walker & Helewa 1996). Thus arthritis in the knee in general seems to have a tendency to lead to reduced use of the joint in order to reduce pain. When initiating gait for instance, unilateral knee arthritis patients shorten the monopodal phase of the affected leg and reduce the motion of the knee, likely in an effort to reduce pain (Viton et al. 2000). This reduced use of the knee can lead to a rapid deterioration of the biochemical and mechanical properties of not only the AC, but also ligaments, tendons, muscles, and bones.

As a result of disuse, the AC becomes more susceptible to further damage as it decreases in thickness and the cells inside it are at risk of necrosis (Walker & Helewa 1996). The ligaments deteriorate due to disuse and lose strength rapidly. After 6-9 weeks of disuse they are only half as strong and stiff as they were. Recovery on the other hand is not as rapid and may take months (Walker & Helewa 1996). The muscles spanning the joint are markedly affected by the disuse. They too adapt to the circumstances they find themselves in, and the lack of use causes them to waste away. Given the stabilising influence that the muscles surrounding the knee have, it has been hypothesized that this leads to a vicious circle. From pain related disuse, to muscle weakness, to instability of the joint, back to more pain and disability (Dekker et al. 1992). Bone, like muscle, is an adaptive tissue. It is constantly being remodelled as osteoclasts break it down, and

osteoblasts rebuild it. The governing factor in this process, determining whether the bone will become stronger, weaker, or maintain its strength is generally accepted to be the strain on the bone, as postulated in Wolff's law and more recently in Frost's "mechanostat" hypothesis (Frost 2004) .If the strain is below the lower limit, as can happen due to arthritis, the bone will become weaker.

Combined, these adverse consequences of arthritis have a massive impact on the patients' physical functioning and QOL. The ability to work, enjoy leisure activities, and perform ADL can be seriously compromised. It is not surprising then, that depression occurs in around 20% of arthritis patients, on par with that in other chronic diseases such as pulmonary or cardiovascular diseases. This is bad enough in itself, but being depressed may worsen matters further by exacerbating the arthritic pain and disability (Walker & Helewa 1996) (Dekker et al 1992). Physical activity has been shown to have positive effects on depressive symptoms (Pinto Pereira et al. 2014) but not being able to be physically active due to arthritis precludes this as a form of treatment. Other benefits of being physically active include a reduced risk of cancer (European code against cancer 2018), hinting at the potential chain of effects knee arthritis can set off. No aerobic exercise from time to time also means the cardiovascular system will decondition faster, increasing the chances of suffering from additional long term conditions such as a stroke or heart attack (Berendsen et al. 2011). Because of the lack of physical activity, the risk of contracting type 2 diabetes (Hu et al. 2001)(Sigal et al. 2006) is increased, and because of the muscular wasting the chance of experiencing a fall is increased as well (Todd and Skelton 2004). Making falling a double jeopardy is the fact that the bones of the arthritis patient are more likely to be osteoporotic as a result of inactivity (Walker & Helewa 1996), so the probability of fractures if a patient should fall increases, as well as the probability of a fall.

In conclusion, it is clear arthritis is a condition that can have a more profound influence on quality of life and healthy ageing than it would appear to have at first sight. Progressive arthritis has the potential to usher in a chain reaction of health degrading changes, which severely restrict a patient's ability to be physically active, and hence

accelerate physical aging. Luckily not all patients suffer from progressive arthritis and the majority can be managed with nonsurgical approaches (Walker & Helewa 1996).

3.4 OA treatment

Physical exercise and losing weight are lifestyle measures that are recommended to help relieve symptoms, however nonsteroidal anti-inflammatory drugs (NSAIDs) are the mainstay of nonsurgical OA treatment (Altman 2010)(Schnitzer 1993). These drugs alleviate pain and reduce inflammation, but can have adverse cardiovascular, gastrointestinal and renal side effects. Therefore they are preferably used topically which is considered a safe and effective pharmacological OA treatment (Altman 2010). Alternative treatments to stop the AC from degrading are being investigated however (Fakhari and Berkland 2013)(Castaneda et al. 2012), as lifestyle measures and pain management alone do not always stop the progression of arthritis. For some patients arthritis continues to progress until the joint has been damaged so extensively that a total knee joint replacement, also called total knee arthroplasty (TKA), is necessary (Walker & Helewa 1996) (Helfet 1982).

3.5. Total Knee Arthroplasty

Since at least 1860, when the French physician Verneuil proposed the interposition of soft tissue between bone ends, the search has been on for a way to reduce pain, improve QOL and restore function of the arthritic knee. Since the early 1900's all sorts of materials, from pig's bladders to nylon, were used in these interposition arthroplasties, operations that were thought to allow the AC to regenerate after the diseased AC had been removed. Regardless of the material used however, results were never good (Shiers 1954). A total knee arthroplasty (TKA) in which all of the weight bearing surfaces of the knee joint are replaced by a prosthesis, is the current standard. The goal of TKA is still the same as the one Verneuil had; to alleviate pain, improve function, and improve QOL (Moffet et al. 2004), thereby curing the long term condition of knee arthritis. In recent years, the number of TKAs performed in Scotland

has more than doubled; from 3592 in 2001 to 7632 in 2013, at which point the average age of the recipients was 68.2 years. 96% of these TKAs are due to OA, with RA responsible for 1% and other arthritic conditions for 2%. Leaving just 1% of TKAs performed to remedy non arthritic conditions (Information Services Division Scotland 2014). As would be expected due to the predicted increase in OA prevalence, the increasing number of TKAs is an international trend, and is expected to increase even further due to population ageing (Singh 2011) (de Pina 2011).

3.5.1. Prosthesis type

The prostheses that are being used in TKA are the result of years of research and development. Their evolution up to the early 1980's has been described extensively in chapter 16 of Arthur J Helfet's book on knee disorders (Helfet 1982). It describes how the first designs stem from the 1940's and used metallic replacement surfaces for tibia and femur, but their application was limited and they produced variable results. In the 1950's hinge type prostheses were introduced, but they required large sections of bone to be removed whilst still producing variable results. Loosening due to torsion was common for these prostheses (Wright and Chitnavis 2011). Then in the late 1960's, inspired by developments in total hip joint replacements using polyethylene acrylic bone cement, Gunston and Charnley devised a cemented knee prosthesis that allowed for a more natural polycentric movement. This was a considerable improvement over what had thus far been available, but this generation of prostheses still had problems; loosening and patello-femoral pain were prevalent. Also, maximum flexion for these prostheses was limited to between 90 and 105 degrees (Chiu et al. 2002). Since the 1970's, a central peg on the tibial plateau was added to the prostheses in order to increase stability, as well as a patellar flange to counter patellar pain. Ongoing advances have led to a cut-out to retain the PCL, as the PCL sacrificing prostheses had a problem with posterior subluxation of the tibia. These PCL retaining prostheses also improved maximum flexion to an average of 107° (Chiu et al 2002). The subluxation can be prevented without retaining the PCL however, by using posteriorly stabilised prostheses. These typically use a tibial post and femoral cam, but many other designs are possible.

Although stabilised prostheses involve greater bone loss, they seem to have even better flexion than the PCL retaining ones (Thomsen et al. 2013)(Wright and Chitnavis 2011)(Chiu et al. 2002). A study compared the average maximum flexion in weight bearing mode for 20 patients with a PCL retaining prosthesis, to that of 20 patients using a stabilised prosthesis and found an increased range of motion from 103° for PCL retaining, to 113° for the stabilised variety (Dennis et al. 1998).

Improvements in the design of these posteriorly stabilised prostheses enable even higher maximum flexion angles. A prosthesis developed at Kyoto University for instance, enabled an average maximum flexion angle of 120° (Akagi et al. 1997). Most recently, mobile bearing prostheses were developed that have the potential for rotational self-alignment of the tibia relative to the femur. However, they have not been shown to have an advantage over fixed bearing ones, while they do have greater potential for dislocation (KAT group 2009) (Wright and Chitnavis 2011). Among the many prostheses that are available, there are also cement-less varieties. Most TKA's are currently cemented, which is effective and produces results comparable to that of the more expensive cement-less ones. Modern prostheses last 13 to 15 years in 90% of the cases (KAT group 2009), after that a revision would be needed. Considering the loss of bone due to cement removal during such a revision, cement-less prostheses do have favourable features for younger patients (Wright and Chitnavis 2011).

There are many different versions of prostheses, each with their own suggested advantages and disadvantages. It seems that whether or not the patella is resurfaced does not matter, whether or not a PCL substituting design is used might be another matter. Substituting the PCL could be preferable if the ligaments are deteriorated due to the arthritis related disuse. Rather than a mobile bearing, a fixed bearing prosthesis seems to be the better choice, as there appear to be no benefits to the mobile bearing, but it is more prone to dislocation. However, picking one prosthesis that is superior to all others is very difficult. Even when a typical arthritis patient is considered to decide on certain features, the decision remains a challenge as studies into prostheses are often small and short term (Wright and Chitnavis 2011). Joint registries could potentially serve as a

source of data for large scale research, but these registries do not currently include any quantitative outcome measures and therefore currently are of little value in assessing which prosthesis, surgical technique or therapy is superior. This could be remedied by using a suitable TR platform at scale that links to one of these registries, thereby providing the desired data.

3.5.2. Cost effectiveness of TKA

Cost effectiveness is becoming an ever more important aspect of healthcare, as the NHS is facing financial constraints. Resource allocation cannot be based solely on clinical outcome but must involve economic aspects as well. Burden of disease is generally measured as disability-adjusted life year (DALY), and arthritis in Scotland has a DALY of 33,800 compared to the disease with the highest burden at 100,400 DALY for ischaemic heart disease (Information Services Division Scotland 2017), indicating it is a substantial burden. The measure generally used to simultaneously consider cost and clinical outcome is cost per quality-adjusted life years (QALY). It is calculated as the product of quality of life (QOL) scored from zero to one, and remaining life expectancy. For example; an intervention is performed at a point in life where the patient has a remaining life expectancy of ten years, and improves QOL from 0.5 to 0.75 The added QALY would be 10 x 0.25 = 2.5. If this intervention would cost £10.000,- the cost per QALY would be £4000,-, well below the National Institute for Clinical Excellence (NICE) threshold.

NICE was established in 1999 in order to provide national-level guidance on the effectiveness and cost effectiveness of new health technologies in the NHS. It is often claimed NICE maintains a cost effectiveness threshold of £20.000 to £30.000 per QALY (Devlin & Parkin 2004), but uncertainty about the cost effectiveness as well as the burden of the disease also play a role in whether or not a new technology will be accepted. Because of this, some technologies well above the aforementioned threshold have been accepted in the past, for instance the weight management drug Orlistat at

£46.000 per QALY. However, the chances of rejection increase as cost effectiveness decreases (Devlin & Parkin 2004).

Recently the cost effectiveness of TKA has come under scrutiny. A study including 323 Scottish patients found an average gain of 4.0 QALY measured using patient reported measures on quality of life (EQ-5D) following a TKA. Costing £8404, the authors concluded that at £2101 per QALY, TKA is extremely effective both clinically as well as in terms of cost-effectiveness (Jenkins et al. 2013). This finding is in line with that of a study involving 65 German TKA patients that also reported their QOL before and after TKA using the EQ-5D resulting in an added 2.93 QALY (Krummenauer et al. 2009). However, cost effectiveness is only assessed using patient reported improvements in QOL which is undoubtedly a critical aspect, but does not provide a complete view as it lacks information about physical function.

3.6. Outcome measures after TKA

Several outcome measures are used to assess how far the TKA meets its goals of alleviating pain and improving QOL and function. With function, or the ability to use the prosthetic joint in ADL, now considered the most important one (Miner et al. 2003). The different measures used to assess knee function, pain and QOL can be divided into three categories; patient reported (i.e. questionnaires), performance based (e.g. 6 minute walking test) and quantitative (e.g. knee angles), each with their own advantages and disadvantages.

3.6.1 Patient reported measures

Numerous questionnaires that provide patient reported measures on knee problems are available (Howe et al. 2012). Some examples are the Western Ontario and McMaster Universities Arthritis Index (WOMAC) or the Oxford Knee Score (OKS). These patient reported measures have an advantage because they are cheap and don't necessarily require patients to visit the clinic (Mizner et al. 2010). The disadvantage is that they fail in providing an objective measure of physical function, as they are

significantly influenced by the pain a patient experiences (Stratford et al. 2006). However, patient reported measures do provide useful information regarding the patients' QOL and their perception of function (Meier et al. 2008) (Mizner et al. 2010) (Stratford et al. 2006) which is why they are routinely used. The EQ5D for instance is used in the aforementioned QOL related cost-effectiveness calculations (Jenkins et al. 2013) (Krummenauer et al. 2009).

To measure perceived function in TKA patients, the OKS arguably is the best suited, as it was developed specifically to measure outcomes of knee replacement surgery rather than general knee problems. Moreover, it has consistently been shown to perform at least as well as other thoroughly assessed alternatives such as the SF 36 or WOMAC (Dunbar et al. 2001)(Liow et al. 2003) (Garrat et al. 2004)(Davies 2002), while it consists of only 12 multiple choice questions compared to the 36 of SF36 and 24 of WOMAC.

Thus the OKS appears to be a good choice for patient reported outcome measure (Davies 2002). Although it has been noted that the OKS is not ideal (Whitehouse et al. 2005), its use is encouraged but should ideally be complemented with a more generic questionnaire (Dawson et al. 2006) for which the EQ-5D could be used. The EQ5D could then also provide information about QOL.

3.6.2 Performance based measures

Examples of performance based measures are: the 6 Minute Walking test (6MW), the Timed Up and Go test (TUG) and the Stair Climbing Test (SCT) (Steffen et al. 2002) (Rejeski et al. 1995) (Stratford et al. 2006). Of these, the 6MW is the favoured measure because of its strong responsiveness to change in TKA patients (Mizner et al. 2010). The advantage of performance based measures over patient reported ones is that they can provide a more objective measure of physical function (Mizner et al. 2010). The five times sit to stand test for instance is a measure of functional lower limb muscle strength after TKA (Piva et al. 2011). Disadvantages are that performance based measures traditionally require the patient to visit the clinic, or a healthcare worker to visit the patient. They also tend to be more of a fitness test, rather than relate to the

ability to perform ADL (Senden et al. 2011). More importantly, on their own they cannot be used to deduce what the cause of any reduced performance could be and therefore have limited value in guiding therapy efforts or choice of prosthesis.

3.6.3 Quantitative measures

Quantitative measures relevant to TKA are for example knee joint girth, kinematics, and strength. Knee girth can be used to assess swelling of the joint, indicating possible complications, but the latter two are more interesting from a physical function perspective.

A measure of the knee's function are the knee angles, or knee kinematics when recorded with respect to time. These should be measured during active weight bearing tasks as measurements of knee range of motion in a supine position have not shown to correlate well with physical function (Chiu et al. 2002) (Dennis et al. 1998). Weight bearing kinematics can be used to detect pathological knee conditions (Piriprayasarth and Morris 2007) and give insight into the efficacy of rehabilitation programs and surgical procedures such as TKA. The most common types of knee dysfunction occur in the sagittal plane; for instance limited knee flexion and knee hyperextension (p213 Perry & Burnfield 2010). The maximum knee extension angle can uncover a pathological gait called flexed knee gait (Okita et al. 2013). How maximum flexion relates to physical function becomes clear when contemplating the average amount seen during ADL. In healthy subjects, depending on age, a maximum of roughly 50° to 60° knee flexion is reached during the swing phase of walking (Paroczai et al. 2006). In order to descend and ascend stairs the knee flexes more, to a maximum of 97° and 99° respectively. Getting out of a standard height chair shows a similar value, with an average of 99°. A slightly higher value of 104° is needed to rise from a low chair, while getting out of a bath tops the range at 138° (Rowe et al. 2000). This shows that bathing is a demanding ADL, so it may not be surprising that bathing is the most prevalent ADL disability in an elderly population (Albert 2004). The above shows that, in healthy subjects, maximum flexion angle is related to function. To be able to execute the majority of ADL with

kinematics comparable to those of healthy subjects, the required flexion angle after TKA is generally agreed to be at least 110° (Devers et al. 2011) (Rowe et al. 2000) (Meier et al. 2008). Angles beyond 110° do lead to increased functionality (Devers et al. 2011), as patients with around 130° achieve the best functional results (Ritter et al. 2008), but this does not further improve patient satisfaction (Thomsen et al. 2013). A finding confirmed by a study where an improved prosthesis design increased maximum flexion angle to 120 degrees, but failed to improve the ADL score (Akagi et al. 1997).

A conclusive minimal clinically relevant difference (MCRD) for knee angles could not be found in the literature, although 5 degrees or more has been suggested (Rudisile 2011). Other authors, (Bruun-Olsen et al. 2009), suggested 15°. Here we will use the larger one of these two reported values; 15°. With differences of 30° or more in maximum knee flexion between ADL such as walking, rising from a chair, and getting out of a bath, 15° would be more than sensitive enough to determine ability when performing these ADL.

A lack of quadriceps strength is to be expected due to arthritic related disuse, and has been shown to have a strong correlation with knee function. Quadriceps strength is considered a critical factor in knee health (Meier et al. 2008) and is generally assessed by measuring knee extension torque, with isokinetic measurements being the golden standard (Toonstra & Mattacola 2013). A lack of extension torque has been shown to be one of the main impairments before and after TKA and has been related to limb avoidance loading patterns (Mizner et al. 2010) and reduced performance on a stair climbing or walking test, consistent with that seen in chronic quadriceps muscle weakness patients (Meier et al. 2008). Like the knee angles, consecutive knee torque assessments can be used to quantify treatment efficacy (Stark 2011). Given the stabilising influence knee musculature has, it would be a valuable outcome measure. Predicting function from torque measurements however, or even assessing whether it is in a poor, fair or good range for a certain patient, is not as straightforward as it is for knee angles. Some authors have related the knee extension torque to age and sex matched normative values, but this is still very subjective (Davies 2002). It therefore

seems more straightforward to use a performance based measure such as the five times sit to stand (5xSTS) mentioned in the previous section, shown to have an adequate correlation with quadriceps strength (r=0.44) in TKA patients (Piva et al. 2011).

3.6.4. A short battery of combined outcome measures

The goal of a TKA assessment is to measure to what extent the procedure meets its goal of alleviating pain, improving QOL, and improving function. In order to measure function, patient reported measures are not suited. However they can provide valuable information about perceived function, pain and QOL and should therefore be part of the assessment. Concerning function, performance based measures as well as quantitative measures can be used. (Stratford et al. 2006). To provide a complete assessment outcome measures should be combined into a short battery. Both patient reported, as well as objective outcome measures should be included (Toonstra & Mattacola 2013). As explained above, the OKS complemented with the EQ-5D, maximum knee extension and flexion angle and the activity during which they were achieved, and 5xSTS performance as an indirect measure of quadriceps strength should ideally be part of a TKA assessment.

3.7 Rehabilitation after TKA

The routine in the UK is for TKA patients to undergo a period of in-patient physical rehabilitation starting as soon as 24 hours after the operation. (Wilmore & Kehlet 2001) The duration of this period has halved since 2001, from 10 to just under 5 days (Scottish Arthroplasty project 2017). After this, patients are expected to perform most, if not all, of their remaining rehabilitation without therapist support using a home based program. It is recommended by the NHS that patients do these home based exercises for at least three months. Typical exercises are supine and sitting knee bending. as it is important to fully straighten the knee, supine and sitting knee stretches are done as well. To strengthen the quadriceps, supine and sitting leg rises are

recommended, for the hamstrings standing and supine knee flexions. Also, as strength improves, sit-to-stand and step-up exercises are to be performed (http://www.nhslothian.scot.nhs.uk/Services/A-Z/Orthopaedics/KneeConditions/TotalKneeReplacementPatientsGuide.pdf accessed 12-06-2016)

The aim of this post TKA rehabilitation is to optimise functional recovery (Naylor et al., 2011), no easy task considering the extensive damage that may have resulted from the arthritis related disuse described in section 3.3 and the fact that patients' physical function typically worsens following a TKA surgery. Mizner and colleagues (Mizner et al. 2010) performed a study involving 100 unilateral TKA patients, and showed that compared to before the TKA, at 1 month post-operation, knee motion was reduced by 25% and quadriceps muscle strength was reduced by 50%. In the long term, patients with good pre-operative knee flexion actually lose some of it. Yet their post-TKA flexion range is still better than that of patients who had a poor preoperative range, who conversely tend to increase their range after TKA. Thus both groups of patients tend to converge toward a middle value for maximal post-operative knee flexion. (Mizner et al. 2010) (Rowe et al. 2005). Based on findings from over 1700 operations performed between 1980 and 2000, an average of 100°-115° of maximal post-operative knee flexion was found (Chiu et al. 2002). However, performance based outcome measures show only modest improvements following TKA and substantial functional deficits persist compared to healthy controls. This is believed to be caused by continuing Quadriceps weakness. Muscle impairments and functional limitations following a TKA can be reversed by means of physiotherapy however (Meier et al 2008).

Intensive physiotherapy has been found to be a critical factor for improving post-operation ROM (Lizaur et al. 1997) (Chiu et al. 2002), with improvements occurring up to one year post-operation (Lizaur et al. 1997). To achieve the best functional recovery however, rehabilitation should focus not only on alleviating pain and improving ROM, but also on improving quadriceps strength (Meier et al. 2008). The view has been

expressed that in order to improve recovery, intensive rehabilitation is needed not only in the acute phase, but also in the sub-acute phase (2-4 months post-op) (Moffet 2004). On an even longer term, improvements have been shown to continue for years. Small improvements in pain, physical function and health related QOL were found up to two years after surgery (KAT group 2009). Even in the period between 18-24 months and seven years post-surgery, improvements in knee function were found in a sample of 19 TKA patients (Linden et al. 2006). This shows the need for intensive, long term rehabilitation in order to get the most from a TKA. Even the evaluation of TKA takes longer than the current period of rehabilitation, as the measures of physical function that are used take at least 6 months after a TKA to stabilise (Mizner et al. 2010). However, after about five days of inpatient rehabilitation, patients are currently left to their own devices.

The above literature indicates that this is an area of rehabilitation with a compelling need and where existing services are minimal. As set out in the introduction, TR is needed as an enabler of long term intensive rehabilitation in TKA in times of financial constraint. A platform with the functions and properties outlined in chapter 2 that agrees with the mechanics of the knee, enables the exercises needed for rehabilitation and reablement, and provides the outcome measures that should be used to assess TKA is needed for this. Some post TKA TR initiatives will be reviewed, and compared against this ideal image presented in the above.

3.8. Previous knee TR Initiatives

In chapter 2 a checklist or "map" for what an ideal TR platform should look like was presented. However, in telemedicine "the map is not the territory" (Thorpe 2015, personal communication) meaning that in practical situations, sometimes a deviation from this map will be necessary, as the first reviewed initiative will illustrate.

A Nigerian study compared 25 CR to 25 TR knee OA patients (mean age 55.5 +/- 7.55 years) for 6 weeks (Odole et al. 2014). They employed mobile telephony "using

uniform statements contained in structured telephone monitoring" to monitor and coach knee OA patients performing their home exercise programmes. Telephony was chosen as the form of ICT because of the lack of availability and high cost of internet services in Nigeria. The initiative is reviewed here because of the low cost, simple approach.

Because of this approach, the functions of this TR platform were limited to communication and outcome measurement. These functions were not optimal. The patient reported outcome measures fail to provide objective information, and the lack of RTVC reduces communication (Rao et al 2012). A meta-review on supporting self-management showed communication between patient and care professional to be critical (Taylor et al. 2004). On the other hand, because "off the shelf" mobile telephones were used, the system was usable, of high quality and flexible. The services of training and tech support would already be provided by the telephone provider, meaning that the first and second phase properties of this platform were satisfied. Furthermore, at first glance it would seem this platform could also satisfy the properties of financing demanded for phase 3 as mobile phones are not expensive, and patients may well own one already. Legislation and organisation of phase 4 are believed surmountable as telephony is already used in health care organisations. This means that this initiative may well be suited for large scale research and eventually reach implementation.

Despite the limited functionality, the authors found comparable improvements in QOL among both CR and TR groups. Measured using the WHO QoL bref scores improved from a mean of 51.48 and 53.72 for control and experimental group respectively, to 71.16 and 69.28 over the six week period. Thus, their results show that outcomes for the two groups are comparable, and that this simple platform can be used to provide TR, successfully overcoming geographical distance. The authors infer that this mode of TR "would undoubtedly reduce clinic visits, clinic waiting time, and cost incurred on transportation to the clinic". However, these benefits were not quantified, and any cost savings for the health care system were not addressed. Moreover, despite the advantages concerning training and tech support, using telephony as ICT limits the potential advantages of TR, and fails to meet the demand of better measurement set out in the reablement policy.

The second study was performed in Australia and used a different form of ICT; the internet. The ubiquity of which in Australia means RTVC is more affordable and widely available. In 2003, Russell et al. developed a TR platform for home based post TKA rehabilitation using the internet. This platform consisted of a laptop, webcam, microphone, and bespoke software that enabled both RTVC and measurement of the patient's knee angle by the AHP. Thereby it enabled high quality communication and outcome measurement functions. However, using this platform, knee angles can only be measured while the therapist is in session with a patient known as synchronous service. This precludes the functions of biofeedback or exercise games and the advantages that come with them. Despite this, clinical results were satisfactory; after comparing TR delivered through the platform with CR for six weeks in a RCT involving a total of 21 patients, the authors concluded that the platform was well accepted by patients, and clinical outcomes were at least as good for TR as for CR. One year later, the platform was used to examine the experience of clinical physiotherapists, as well as that of 31 patients (Russell et al. 2004). High levels of satisfaction were reported by the participants (mean responses > 7 on a 10 cm visual analogue scale) and it was concluded the platform integrated well into clinical practice and was found to be safe, effective and easy to use, demonstrating the efficacy of the internet as ICT in TR.

As in Australia, the internet is ubiquitous in Canada, and it was used as ICT when Tousignant et al. (2009) performed their pilot study of in-home post TKA TR there. The platform developed for this study consisted of Tandberg 500MXP teleconferencing units coupled to a 20 inch LCD TV. Only the function of communication was provided with this platform, meaning rehabilitation can only be provided through it synchronously. No outcomes were measured; this means that again the functions of biofeedback and exercise games cannot be provided through this platform. Moreover, this means there are no quantitative outcome measures with which to assess the progress of the rehabilitation process. Despite this, patients (n=4), as well as the clinician involved reported very high satisfaction with the platform after 8 weeks

of use. Scored on a Likert scale and expressed as a percentage, patients indicated a mean satisfaction of 94.7% with the TR platform, clinician satisfaction scored high at 76.6%.

Having demonstrated user acceptance (phase 2 milestone), the authors went on to demonstrate cost effectiveness of their platform a few years later (Tousignant et al. 2015), making theirs the first TKA TR platform with proven cost effectiveness. This time employing a Tandberg 550MXP in a study involving 197 participants, the authors concluded that TR delivered through their system yielded an 18% reduction in cost to the health care system, however they noted that costs saved on traveling were counterbalanced to some extent by the cost of the technology. In their cost effectiveness calculations, the authors assumed that the system would be used for 16 sessions per patient, and an average of 100km of traveling would be saved per session. At 0.40 Can$/km, that means that 16 X 100km X 0.40 Can$/km= 640Can$, or roughly 320GBP would be saved on travelling over the course of the rehabilitation (16 sessions). The technology used here (Tandberg 550 MXP), is expensive at roughly $5000,-, or GBP3200,- per unit. The authors accounted for this rather high cost by assuming the platform could be used for many patients over a long period of time; providing 17 hours of rehabilitation per week for three years. This means that it could not be used to provide long term intensive rehabilitation for just one patient without exceeding the budget. Moreover, physiotherapists interviewed on behalf of this prototype study at the University of Strathclyde, Glasgow, expressed the concern that once you place a platform in a patients' home there is a chance you will not get it back due to the high levels of deprivation that plague some parts of the City of Glasgow. (personal communication East Glasgow Rehabilitation Service). Both the lack of long term potential and the risk of not getting the equipment back, make the expensive equipment less than ideal, instead a TR platform that can be used for long term rehabilitation, where a system would be given to a patient for life, would be preferable.

A recent Scottish initiative addressed the issue of not offering the asynchronous services that limited the advantages of the previous initiatives (Ayoade 2014). Like the previous Australian and Canadian initiatives, the internet was chosen as ICT and RTVC

was enabled by using a laptop centred platform. Coupled to inertial measuring units (IMUs) this allowed measurement of the quantitative outcome measure; knee angles. These were used to enable the visualisation of exercises. This biofeedback encouraged correct performance of exercises as well as enabling tracking of progress, and improving dialogue between patient and therapist. A considerable advantage especially when considering the importance of communication between patient and care professional. However, here too not all the potential advantages of TR were exploited, as no games, information or social support were provided. Moreover, IMUs are not the optimal outcome measurement device, as will be shown in chapter 4, and the laptop centred platform is not ideal both from a usability as well as a cost effectiveness point of view. Nonetheless, the platform was able to reach the second milestone of an acceptance study. A six week RCT involving 16 patients demonstrated this platform to be well accepted and effective in providing home-based TR. The experimental group consisting of 9 patients scored a user interface satisfaction questionnaire in a range of 6 to 9 out of 9, with a median score above 8. Although the lack of mobility of the platform meant one of the participants in the experimental group did not accept it, instead preferred the exercise booklet over the platform. Effectiveness was shown as participants in the experimental (TR) group achieved comparable improvements in the Oxford Knee Score questionnaire (OKS), knee flexion, and extension as the control group. OKS scores improved by a median of 152% and 127% for the experimental vs. control groups respectively. Over the six weeks the study lasted, the experimental group improved knee extension from a median of 14° to 6°, the control group from 8° to 7°. Concerning knee flexion, the experimental group showed improvements from a median of 69° to 96°, the control from 81° 105°. However the phased implementation model suggested by Broens et al. (described in section 2.4) was not adhered to, and consequently the authors noted they experienced multidisciplinary problems. Moreover, together with the IMUs, the total cost of the system is estimated to be around 600GBP,- Cost effectiveness data is, at this point, only available from the Canadian study by Tousignant et al. therefore, only this data can be used to guide what the cost of a TR platform can be before the cost of

the technology offsets the savings on travelling. At 320GBP of travelling costs that could be saved, this is well below the Ayoade et al. platform.

The studies described above all show that the TR technology used led to high rates of acceptance, and at least as good as clinical results compared to CR. Also, the more of the aforementioned functions a TR platform provides, the more advantages over CR it is believed to deliver, which is why the internet is the preferred form of ICT if it is available. However, a platform able to deliver all functions believed to be advantageous has not been developed so far. Furthermore, none of the initiatives were explicitly designed with the phased implementation model and barriers described in section 2.4 in mind. Consequently none of the internet based platforms are believed to meet the strict cost effectiveness demands, severely limiting their scaling potential. This inability of platforms to scale up is undoubtedly the reason for the current evidence gap of large scale studies.

3.9. Research aim

The aim of this work was to develop a prototype TR platform that maximises the scaling potential and to demonstrate its feasibility. The prototype should unite the ideal of functions and properties, and should eventually be able to be used to perform large scale studies. If results of these large scale studies were favourable, it might then be used by AHPs and increase their effectiveness and the quality of their service provision, so supporting the reablement paradigm shift.

In order to reap these benefits, the platform would have to be implemented into clinical practice and hence go through all four phases of development. This unfortunately is beyond the timescale of this work. The scope will therefore be limited to phase1; development. In this first phase the platform will be developed and validated, the main research question is;

Can a TR platform with all functions believed beneficial be developed, with all properties required to maximise scalability?

To answer the research question, the project will implement the following research objectives:

1- *Develop the platform to have sufficient usability*

If it is to be used in practice, the platform needs to be deemed easy to use by the majority of TKA patients. Human factors especially in older adults need to be taken into account and suitable input devices, software and devices will have to be selected or developed. Sufficient usability is here defined as the majority of participants indicating that they found the platform easy to use.

2- *Develop the platform to have sufficient quality*

The platform has to be robust and have a high level of fault tolerance. Minor technical problems such as drained batteries need to be prevented. To this end devices and software will be selected or developed to prevent such issues wherever possible. Sufficient quality is defined as no problems occurring for the majority of participants.

3- *Develop the platform to have sufficient flexibility,*

The platform should be mobile, offer both synchronous and asynchronous service and allow for interoperability. Software will be developed in a modular fashion and production techniques for devices will be selected to guarantee flexibility.

4- *Develop the platform to require minimal training*

Unfamiliarity with a new technology necessitates training, therefore the platform should use technology that is familiar to a general public wherever possible and offer an intuitive interface. To investigate whether this objective is achieved participants will be asked to use the platform without any prior training. If despite this the majority of participants don't indicate that training would have been necessary to use the platform this objective is satisfied.

5- *Develop the platform to require minimal tech support*

In addition to using familiar technology, using off the shelf products where possible will mean that technical support is provided by the manufacturer and therefore would not have to be a part of the TR platform. For any components that are not off the shelf, the development will take this into account and robust solutions will be striven for. This objective is achieved if the majority of participants do not require tech-support.

6- *Develop the platform to have a l*ow *cost (<320GBP),*

In order to offset typical travelling cost, this price point must not be exceeded. Additionally, any reduction in cost of the platform would contribute to increasing cost effectiveness so as low a cost as possible should be striven for. To this end cost effective production methods, devices and software will need to be identified.

7- *Develop the platform to provide e-health*

E-health in the form of long distance communication is a function the platform should provide, with RTVC being the preferred mode. Therefore, the platform has to be able to provide RTVC and suitable communication protocols will need to be found.

8- *Develop the platform to provide better measurement*

Outcomes have to be measured not only to assess function, but also to enable the asynchronous functions such as biofeedback and exercise games. An outcome measurement device is needed that can accurately do this in a home setting, whilst being able to be produced in a flexible and low cost manner.

9- *Develop the platform to provide data collection*

In order to keep track of progress, measured outcomes need to be collected, communicated and stored in an EPF. The platform has to enable this which means that again a suitable communication protocol needs to be identified.

10- *Develop the platform to provide exercise games*

As a key motivational tool, exercise games can improve adherence to exercise leading to better outcomes, the platform should provide this function in a low cost, flexible and easy to use way.

11- *Develop the platform to provide info*

Information can lead to better outcomes as well, which would increase clinical effectiveness. Therefore this function too should be provided, and for this function too, a suitable communication protocol found.

12- *Develop the platform to provide biofeedback*

Allowing unsupervised, correct execution of exercises, this function is central to asynchronous functioning of the platform and has to be enabled by the platform. Like some other functions this will rely on communication between the patient outcome measuring device and interactive patient device for which a suitable communication protocol needs to be selected.

The design of the platform to satisfy these research objectives is the subject of chapter 4.

Chapter 4

Platform design

4.1 Introduction

The previous chapters showed that there is a need for a post TKA TR platform that has functions and properties never united in one platform before. Cost effectiveness was found to be especially important. To unite these functions and properties successfully is a challenge, which is why a proper design is important. In this chapter, a user centred design is used in combination with the double diamond design method that splits the design work up into different stages. This resulted in a new kind of electro-goniometer, existing patient and therapist devices being chosen, and a mixture of custom made and existing software to complete the platform.

The design methods and requirements gathering will be addressed first, then follow the chosen method for a goniometer, patient device, therapist device, and software, together making up the platform. For the patient and therapist device, as well as most of the software, existing "off the shelf" solutions could be found. For the goniometer, biofeedback application and portal application these could not be found and hence were constructed.

4.2. Design methods and requirements gathering

It was shown that the functions of communication, outcome measurements, electronic patient file, relevant information, social support, games, and biofeedback are expected to produce the biggest advantages over CR. See figure 4.1 for a schematic overview of these functions. In order to maximise scalability, a platform would have to provide these functions with the properties stemming from the solutions choice, design, and services, as well as open source and collaboration. These properties translate to requirements, and will guide the design. But there are more factors that need to be taken into account: involving patients and professionals in the design process is crucial (Broens et al. 2007)(Saptono et al. 2009) (Momentum 2014). This was recognised by Ayoade who performed a requirements gathering exercise involving patients and professionals for his post TKA TR platform (Ayoade 2014). The findings of Ayoade in

terms of user generated requirements will be used to inform the design, after the design methods have been addressed.

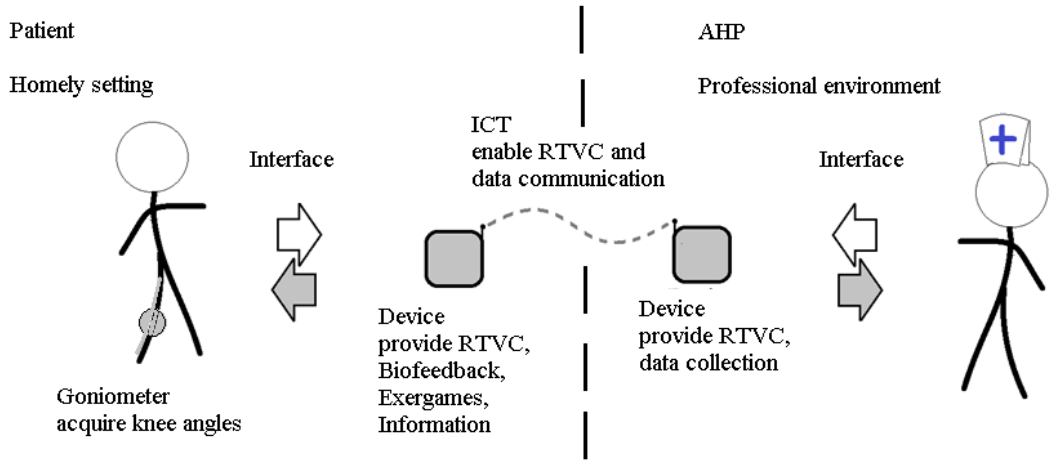

Figure 4.1. A schematic overview of an ideal post TKA TR platform.

4.2.1 Design method

The history of design methods was described by the British Design Council (British Design Council 2007); they have their origins in crafts and sprung from a desire to define not just products, but also the way in which they are produced. Theories about design methods were first formulated in the early 20th century by Bauhaus, and in the 1960's Bruce Archer published a first model of the design process. This model involved phases of analysis, evaluation and synthesis and was aimed to reduce the toll that sometimes overwhelming design considerations were having on the creative process. The limitation of this linear model, varieties of which were still in use in the early 1990's, was that it suggested that a problem could be solved in one go, hence iterative models that allowed time to test and evaluate ideas were developed.

One such iterative model was developed by Stuart Pugh and consisted of an iterative cycle starting with a needs assessment and ending with implementation. This cycle was then completed at least once for various steps of the design process such as concept design, manufacture, and finally sales. Models such as these proved very helpful with more complex problems, such as in engineering. As the design process was developed and formalised, the importance of user participation also started to be recognised.

Presently the level of complexity that occurs within the design process is accentuated by factors such as technology, sustainability, legislation etcetera and the borders of design start to blur. The design process of today is adapted to meet changing demands and is less scientific than it once was. Because change is occurring at such a rapid pace there may never be an ideal design method, and flexibility has become more important. The general consensus is that there is no one best practice, there are however some commonalities across methods used that typically consist of four or five distinct phases.

The design method chosen for this work is called “double diamond” and consists of four phases, with each phase consisting of a series of iterative loops that allows for exploration and testing of ideas. This method was developed by the British Design Council in 2005 as a simple graphical way of describing the design process. It divides the design work up into diverging and converging stages that are completed consecutively; *Discover*, *Define*, *Develop* and *Deliver*. Although the shape is generic it is morphed depending on the project’s characteristics such as the type of product, or whether it is a completely new product or a further development of an already existing one. The first half of the method consists of the discover and define stages, and aims to clarify the needs to be addressed. In the discover stage, possibilities are kept as broad as possible whereas during the define stage they get narrowed and focussed. Then, the second half entails solutions; the develop stage again involves broadening, exploring various solutions, while the deliver stage focusses on the most suitable one, thus producing the double diamond shape depicted in figure 4.2.

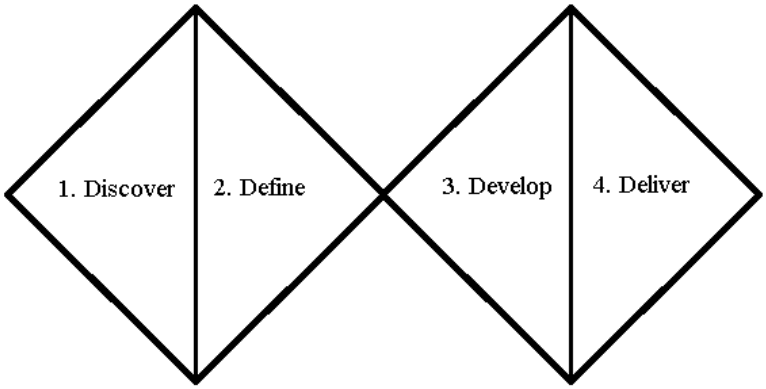

Figure 4.2. The double diamond design method

After this method has been followed for the present work, a prototype of a TR platform with all functions believed beneficial whilst having all the desired properties to maximise scalability will have been produced. It should be noted however that a prototype is not a finished product, it is meant to be replicated or learned from, and as the platform is moved through the development model depicted in figure 2.2 it will require re design using the lessons learned from the prototype developed in this first phase as input in order to arrive at the final product after the fourth development phase has been completed.

4.2.2 Requirements

As explained before, the requirements for the TR platform stem from the properties it should have in order to overcome the barriers of *usability*, *quality* and *flexibility* in phase1, whilst taking the barriers of the additional phases, *scaling, diffusion, standardisation, legislation and organisation*, into account. In an effort to involve patients and professionals in the design process, Ayoade interviewed physiotherapists regarding the functions and requirements a TR platform should have. This confirmed the functions of encouraging correct performance (biofeedback), motivating (provide exercise games and information), tracking progress (electronic patient file), and enhancing communication. The requirements the physiotherapists had

were that the system must be accurate, knee angles should be determined with an accuracy of within 5 degrees. Also, the system should be easy to use (i.e. have usability) because patients are mostly older adults. Ayoade was also able to confirm the functions of biofeedback, motivating, tracking progress, and communication as being desired after interviewing a group of older adults. Like the therapists, patients too were concerned with the usability of the technology involved. Thus the user involved design performed by Ayoade 2014 confirms the functions, and some of the properties stemming from the literature review performed in chapter 2. Hence the functions and properties of chapter 2 will be used as the requirements guiding the design.

4.2.3. User profiles

In accordance with user centred design practices, a user profile is used to guide the design. The therapists that will use the platform are all professionals, and of a working age. They are assumed to have experience using computers and the internet for activities such as e-mailing. But the design should emphasize that it is merely a tool for the therapist and is not aiming to replace them in order to reduce professional possessiveness. Patients as users of the platform are harder to describe as they make up a very heterogeneous group. The average age of a TKA patient was found to be 68.2 years in chapter 3, but there is of course a range of ages; some patients will be substantially younger than the average whereas others may be older. Their background may also differ widely; where some may have excellent computer skills, others may get anxious at the thought of using one. Because of this, taking human factors into consideration is especially relevant for the patient user group, and the technology should aim to accommodate even those patients without computer experience who might be suffering from various conditions accompanying old age.

According to the office for national statistics (Office for national statistics 2017) in the UK in 2017, almost all adults (99%) aged 16-34 used the internet. For the 65-74 year olds internet usage has gone up from 52% in 2011 to 78% in 2017, a trend that is also seen in the over 75's who increased their internet usage from 20% in 2011 to 41%

in 2017. Despite this however, the over 75's still show the lowest internet use of all adults and care should be taken when designing a platform that needs to be usable for age groups where never having used the internet before is common.

. In general older people have a positive attitude towards technology and will use it if there is need for it (Fisk et al. 2009). But technology that poorly matches the capabilities and limitations of older adults may cause anxiety which reduces their interest in using it (Charness and Boot 2009). An example of this for instance are error messages, as older adults appear to experience stronger negative emotions than younger users when faced with them (Rogers et al. 2006). Therefore, the design of the platform should minimise factors such as errors that could cause anxiety.

Cognitive changes are known to occur with aging. In one study fluid intelligence was found to be the strongest predictor of technology usage (Czaja et al. 2006). As people age their ability to solve abstract problems, called fluid intelligence, tends to decrease while their experience in solving concrete problems, called crystallised intelligence, increases up to a certain point (Kaufman and Horn 1996). This means that with increasing age, it becomes increasingly difficult to solve problems never encountered before, as found when trying to use a new technology. Aging also leads to a reduction in other cognitive resources; working memory, and information processing speed decline (Kester et al. 2002), as do attention skills (Caprani et al. 2012) (Charness and Boot 2009), and the ability to inhibit irrelevant information (Rogers et al. 2006), impairing the ability to perform cognitive demanding tasks. Therefore, in order to reduce the load on working memory and selective attention, there should be no distractions in the technology developed. In the case of an interface, unnecessary graphics or animations should be avoided as they burden the attention skills (Caprani et al. 2012) (Rogers et al. 2006).

Vision and hearing are arguably the most important senses in interacting with technology (Scialfa et al. 2004). Unfortunately, they too decline as a result of aging. About 50% of men and 30% of women over the age of 65 suffer from hearing loss (Fisk et al. 2009). The perception of high pitched sound, including critical speech components, is reduced (Rogers et al. 2006)(Charness and Boot 2009). Sounds with a relatively low

frequency and adjustable volume are therefore preferred over fixed volumes at high frequencies. Aging leads to reduced visual acuity, colour discrimination and contrast sensitivity whilst sensitivity to glare increases (Schieber and Kline 1994) (Schieber and Baldwin 1996). The reduced acuity is caused by a stiffening of the eye lens, this can be compensated for by increasing font size; reading performance regarding printing on paper was found to be improved when font size was increased from 12 to 14pt (Vanderplas and Vanderplas 1980). A yellowing of the eye lens leads to declined contrast sensitivity in older adults as well as causing difficulties discerning shades of blue (Rogers et al. 2006). Moreover, older adults have difficulties recognising the fine detail, found for instance in icons and the mouse pointer used in many graphical user interfaces (Taveira and Choi 2009). Therefore designs for the elderly should provide appropriately sized text and pointers, and use high contrast colours (Fisk et al. 2009). Another aspect making the use of devices such as a mouse more difficult for older adults is the fact that they may suffer from motor skill declines. Older adults have an increased incidence of arthritis and tremor (Taveira and Choi 2009), tend to move slower (Caprani et al. 2012), have declined force control, and reduced fine motor coordination (Rogers et al. 2006).

By no means is it the intention of the above to present a generalised stereotype of older adults, and many of the senior members of society may never suffer from any of the above (Rogers et al. 2006). However, the changes in cognition, motor skills, visual, and hearing described above are known to occur with ageing, and will have to be taken into account when designing the technology for the TR platform. By doing so it would be accessible for as many people as possible in the heterogeneous group represented by post TKA patients.

4.3 Goniometer

“The development of reliable assessment tools for use in TR in the first instance will allow rehabilitation research to expand and investigate areas not currently able to be researched thoroughly. Many of the barriers to the implementation of TR services could

be overcome by the scientific collection of outcome data for this method of service delivery" (Hill2010b p34). This quote of Anne Hill indicates the importance of reliable assessment tools, and this section describes the development of such an assessment tool for post TKA TR.

4.3.1 Discover

A crucial aspect of a post TKA TR platform is acquisition of knee angles. Clinicians usually use static measurement tools such as hand held goniometers (Edwards et al. 2004). However, these measurements are generally in a non-weight bearing mode, which is not shown to adequately reflect the angles seen during functional activities (Rowe 2001) (Viton et al. 2000). In order to measure knee angles during functional, weight bearing activities, dynamic measurements are necessary. Moreover, these dynamic measurements should be real time for the purposes of biofeedback. To enable such measurements in a home setting, an instrument would have to have the properties mentioned for the platform as a whole; 1: be affordable, 2: be usable 3: be robust, 4: be flexible 5: require minimal training and tech support. Because it is an assessment tool, it should also; 6: have an adequate measurement range, 7: be valid, 8: be reliable, 9: be portable, 10: have long term usability, 11: be sensitive enough to detect the MCRD.

These properties are further defined as;

1: Because the measuring instrument is a part of the total platform, the maximal allowed cost of it depends on the other parts used. However, affordable in the context of a TR platform means that the complete platform may cost 320 pounds or less, as explained in section 3.8, this is the amount saved on travelling (tousignant et al. 2015). Any reduction in this price would lead to improvements of the TR platform's cost effectiveness, shown to be important in driving TR forward. Therefore, the cheaper the instrument, the better, and an initial price goal of below 100 pounds was set.

2: Usability for the instrument means reductions in motor skills described in section 4.1.3 will be taken into account; any buttons will be large. In a more general sense, the less steps needed to operate the goniometer, the better. So a minimum number of steps needed to operate will be striven for.

3: Robustness will ensure that the goniometer can be used in a home setting; where it may be dropped, and kids or pets might play with it. The goal therefore is to have an instrument capable of surviving daily use and a 1m fall onto concrete.

4: In order to offer flexibility, the goniometer will be made in a modular fashion, able to adapt to varying body sizes and capable of measuring other joints. The data communication will enable the goniometer to connect to a multitude of devices.

5: Minimal training and tech support has some overlap with usability, as the easier to use, the less training will be needed. The need for technical support can be curtailed by using quality parts and a robust construction.

6: As described in section 3.4.3, 0-110° of knee flexion is what should be aimed for in rehabilitation following TKA, and the goniometer should have a range of this magnitude at the very least. Some ADL show greater flexion values however, for instance getting out of a bath at 138°. Therefore, in the ideal case, an instrument would have a measuring range equal the normal physiological range, found to be 150° of flexion and 5° of hyperextension in section 3.1.2.

7: An accuracy of within 5° was found to be what physiotherapists desire in the requirements section above (4.2.2), and will therefore be the validity goal here, operationalised as an average error of below 5° when assessing flexion angle during squatting. The current instrument used in post TKA assessment; hand held universal goniometers (UG) offer a comparable validity; a study investigating the validity of UG against X ray measurements after TKA showed an error of about five degrees (Edwards

et al. 2004). Results confirmed by a different study comparing UG measurements against X-ray measurements (the gold standard for static knee angle measurement) that showed UG measurements of maximal knee flexion angle to overestimate the true value by an average of 4.03° (Lavernia et al 2008).

8: reliability too should be as good as, or better than, hand held UGs. A study investigating UG reliability found a high intratester ICC of 0.997 for flexion, and 0.972 to 0.985 for extension (Brosseau et al. 2001) However, the ICC is an inadequate measure of reliability, and the standard error of measurement (SEM) should be used instead (Weir 2005). The SEM for UGs was found to be up to 2.66° over a knee flexion range of 10° to 90°, when measurements were performed by the same tester (Milanese et al. 2014). A slightly higher value of SEM for knee flexion was found in a different study, at 3.41° (Mehta et al. 2017), and another study found a SEM of up to 4.65° for the UG when measuring knee flexion (dos Santos et al. 2012).

9: Portability means the instrument, and in fact the entire platform, should be light and compact enough to be carried around easily. Initial goals of a weight below 500g and dimensions below 300mm x 200mm x 100mm are set for the goniometer.

10: Long term usability means that the instrument must remain stable for the longest duration it might be used for in practice. Given that the instrument will be used as an input device for gaming, the initial goal is set at one hour.

11: Sensitivity should be adequate to detect the MCRD of 15°.

The current gold standard for dynamic measurements is stereo fluoroscopy, a technique that uses a series of X-rays. Most used however is stereo photogrammetry (Robertson et al. 2014 p12) because of its non-invasiveness. A stereo-photogrammetry system consist of several cameras that track markers placed on anatomical landmarks,

and by now are a common sight in gait labs. Unfortunately, dynamic knee joint measurements are rarely performed outside of a lab due to the limitations of the devices currently available (Piriprayasart and Morris 2007). Both the fluoroscopy and photogrammetry methods described above are large, stationary, expensive systems and require trained operators. This makes them unsuitable to be used in routine clinical practice, or a home setting (Schmitz et al 2014). For this, a more portable, affordable, and more usable device would be required.

In the 1960's electronic goniometers were described (Tesio et al. 1995) that are usable, portable, robust and affordable. These devices were a milestone in goniometer development; for the first time, dynamic knee angle measurements outside of the gait lab were made possible. This type of goniometer was found to be well accepted by TKA patients (Kuiken et al. 2004), however validity of the measurements is limited due to the construction of the devices; these potentiometric electro goniometers (PEGs) consist of two arms and a low cost electronics component known as a potentiometer. This construction allows for just one degree of freedom (DOF); rotation along the potentiometer axis. However, as described in chapter 3, the knee is a multi-axis joint where the tibia not only rotates, but also translates in the sagittal plane with respect to the femur. Because of this, alignment problems with respect to the joint axis occur, resulting in measurements that some authors found tend to underestimate actual joint excursions as measured by UG when measuring angles exceeding 100° (Kuiken et al, 2004) although others found this underestimation to occur even at angles of only 90° (Tesio et al. 1995).

In an effort to add degrees of freedom to the otherwise solid PEG design, a parallelogram construction was later added that allows for translational movements (Robertson et al. 2014). However, the parallelogram construction does not allow for full freedom of movement. A translation in one direction will lead to a translation along an axis perpendicular to the original one, as the parallelogram forces a circular motion to occur. Thus, the translation is a conjunct movement. A measurement principle proposed by Tata et al. in 1978 employs two potentiometers linked together by a strip of plastic. Although this 3 bar linkage is different from the parallelogram principle, it has the same

properties in that it does not allow for full freedom of movement in the sagittal plane. Instead, translations again lead to a circular motion. Although this principle showed an agreement of within 4° of a television-computer analysis of human gait, only one stride was analysed. Moreover, no joint excursion beyond 90° was investigated, so the possible advantages of the added translational degree of freedom over traditional PEGs, albeit a conjunct movement, cannot be confirmed.

In order to allow for full freedom of movement (6 DOF), and thereby provide a more valid measurement, flexible electro goniometers (FEG) were devised in the late 1980's (Rowe et al. 1989). These strain gauge based devices were portable, and capable of following both the rotational and translational movements of the tibia, improving validity over the PEGs (Tesio et al. 1995). The invention of these devices enabled the same portable and out-of-lab dynamic measurements as the PEGs before them, but without the validity issues, thus marking another important point in goniometer development. Compared to PEGs however, the FEGs are more expensive. A price of 493 pounds was quoted for the Biometrics ltd SG150 (quote requested 2014), this is excluding the required amplifier. Moreover the devices are fragile. This is no problem in the hands of skilled clinicians, but they are not believed robust enough for unsupervised use in a home setting.

Almost indistinguishable in appearance, fibre optic electro goniometers (FOEG), share many of their properties with FEGs. FOEGs too, allow for full freedom of movement and seem to be as valid as FEGs (Mohamed et al. 2012). Another property FOEGs share with FEGs is a rather high price which makes them unsuitable for use in a TR platform.

A more affordable way of measuring whilst still allowing full freedom of movement is by using inertial measuring units (IMU), typically these have the form of little boxes containing accelerometers and gyroscopes thus enabling the determination of the spatial orientation of the box housing them. When containing magnetometers as well, these devices are called magnetic, angular rate, and gravitational sensor units

(MARG). To acquire knee kinematics, an IMU/MARG setup would consist of two boxes. One attached to the thigh, the other to the lower leg. After attaching the boxes to the leg, they have to be calibrated to a known knee angle. Then, although other approaches are possible (Tomaru et al. 2010), generally the gyroscope signals are integrated with respect to time to reveal a change in orientation. The accelerometer and, if used, magnetometers are used to correct for drift in the integrated gyroscope signal (Madgwick et al. 2010)(Ayoade et al. 2011). The accelerometers sense gravity and allow for a correction in pitch and roll. The magnetometers sense the earth magnetic field and do the same for yaw. Systems like these can achieve mean accuracies of around 5 degrees when attached to rigid objects during brief measurements in a laboratory setting (Ayoade et al 2011). However, using them in a home setting remains difficult due to the heterogeneity of the earth magnetic field in modern buildings. Furthermore, ferromagnetic objects in proximity of the sensors may cause interference; mobility devices such as walkers and wheelchairs are known to cause ferromagnetic interference, leading to errors of up to 35 degrees (Kendell & Lemaire 2009). For this reason research into ways to determine yaw without using magnetometers is ongoing (Cooper et al. 2009) (Seel et al. 2014). One way to do this is by using anatomical constraints; assuming the knee joint cannot rotate, and therefore there will be no yaw. Coupled to sophisticated signal processing in the form of Kalman filters, this magnetometer free approach produces errors of approximately 3 degrees RMS compared to stereo photogrammetry during walking and running (Cooper et al. 2009). However, the experiments Cooper et al. performed were relatively brief at 5 minutes and as the authors mentioned, the system can potentially become unstable as the filter used has an infinite impulse response, so long term stability remains uncertain.

More recently artificial neural networks have been used to process the signal of a magnetometer free system. Tested on one subject during walking, an RMS error of 3.8 degrees was achieved, compared to a FEG. But again the experiments were short, consisting of just 25 steps (Bennet et al. 2013). It seems therefore that although IMUs have good accuracy, their long term usability in a home setting remains questionable. Moreover, they are more expensive than PEGs, and the typical use of battery power and

wireless data connections is known to be a barrier to adoption in TR (see section 2.2.2). Furthermore, in a study into a TR system using MARGs, two out of nine participants unintentionally skipped the calibration at times (Ayoade 2014). Thus the required calibration after attaching them reduces usability; it represents an additional step in the process users would have to complete.

A different possibility of acquiring the knee kinematics has been used in the past to acquire for instance lumbar spinal kinematics (Rowe & White, 1996). Known as Isotrack (Polhemus), this system consists of a source and a sensor. The source emits alternating electromagnetic fields that are picked up by three orthogonally placed coils in the sensor, thus producing signals that can be used to determine the distance and orientation between source and sensor. However, this system costs GBP 2820,- (Polhemus Patriot) and is thus too expensive for home TR.

Another instrument that was considered is the Kinect; a compact device consisting of two cameras and an infrared projector that enables non-invasive user friendly 3D motion capture. Meeting the requirements of usability and portability, Kinect gets very close to meeting the price goal with a price of just below £130,- (http://www.xbox.com/en-GB/xbox-360/accessories/more accessed 19-09-2015). Recognising these favourable properties, Fernandez-Baena et al (2012) have successfully used Kinect for knee exercise-games, and compared its accuracy to stereo-photogrammetry (Fernandez-Baena et al. 2012). The authors presented a mean error of 6.78 to 8.98 degrees when flexing and extending the knee through a ROM of 89 to 115 degrees. These results do not meet the validity requirement. Moreover, they are a mean error occurring over the movement range. From the graphs the authors presented an error of up to 15 degrees can be estimated at the extremes of motion. Therefore, Kinect is not currently suited for use in a TR platform.

More recently the use of smartphone/tablet applications using the inbuilt camera of these devices have been investigated (Milanese et al. 2014) (Krause et al. 2015) Being

portable, cheap and easy to use they might be suitable. However, when used by patients achieving sufficient validity might be challenging, as subjects would have to ensure that their sagittal plane is perpendicular to the camera, which also means the screen would be in an uncomfortable position. These instruments therefore seem more suited to use by a clinician than by a patient.

Recently, a goniometer was described that is portable, low cost, easy to use, and has sufficient validity (Saggio et al. 2014). Based on a flexible sensor that changes electrical resistance when lengthened, this instrument housed in a knee brace produces a measure of knee angles with good validity and reliability. Compared to stereo-photogrammetry, the RMS error was below 1.28 degrees, and reliability was good with an ICC between 0.8 and 0.91. Based on the construction, the instrument also seems robust and hence would be suitable for use in a home setting. However, in the study protocol, positions were held for 6 seconds, necessitated by the slow response of the sensor used. There is a delay before the actual knee angle is indicated by the instrument, rendering it useless for the purpose of dynamic knee angle measurements, and therefore unsuitable for use in biofeedback and exercise-games both found important for TR.

4.3.2 Define

The discover stage shows that current ways of measuring knee kinematics are not optimal for use in a TR system. To enable long term dynamic knee angle measurements in a home setting, a measurement device would have to have the 11 properties of being affordable, usable, robust, flexible, require minimal training and tech support, as well as having an adequate measurement range, being valid, reliable, portable, having long term usability, and being sensitive enough to detect the MCRD. To the best of the authors knowledge to this date there is no device that combines all of these properties. Therefore the define stage will explore possible approaches that would combine these properties.

The first possibility that was explored was the use of webcams to acquire knee angles. Webcams are affordable, robust, portable, have no known long term use issues,

and are expected to have good usability. To enable software to easily recognise anatomical landmarks, coloured markers could be used. The distance between these markers in vertical and horizontal directions could then be used to calculate orientations of segments using a straightforward trigonometric approach. As for the smartphone applications, achieving sufficient validity might be challenging, as subjects would have to ensure that their sagittal plane is perpendicular to the camera. A problem that could be overcome by using two webcams in a stereo-photogrammetric approach. However, measurements would require a clear field of view, something that cannot be guaranteed in a home environment.

A different way of measuring knee angles would be using a flex sensor (SpectraSymbol FS L 0095 103 ST). Retailing at around 8 pounds (Sparkfun.com flexsensor 4.5" £8,34 accessed 20/09/2015), these sensors have the appearance of a thin strip, 6,35mm wide and about 110mm long, and change their electrical resistance when bent. Using them, a goniometer much like the FEG and FOEG could be made, that allows for freedom of movement in the sagittal plane and hence is not hindered by joint axis misalignment errors. Such a goniometer could be made at a low cost and may meet the required properties.

Also very affordable would be to use potentiometers. The traditional potentiometric goniometers performed well in all areas except validity, because of joint axis misalignment. It is believed that using potentiometers in a way that enables full freedom of movement in the sagittal plane would overcome these misalignment errors, and lead to a goniometer that is valid, like the FEGs, and also affordable, robust, easy to use and long term usable like the PEGs

At the end of this define stage the focus has narrowed as the first diamond ends. Only flex sensors and potentiometer approaches will enter the next design stage as they seem to have the best potential for meeting the required properties for use in home TR.

4.3.3. Develop

Define produced two candidates for this stage, where both flex sensors and chain linked potentiometers will be subjected to explorative testing.

Two 4,5” Spectra Symbol flex sensors were subjected to explorative testing in order to uncover their potential for use in a home TR goniometer. Results showed these flex sensors to be unsuitable for measuring knee joint angles in a TR context. The radius over which the sensor bends influences readings, but the primary objection is the time it takes the sensors to reach their final value, an estimated 30 seconds. This renders them useless for any dynamic measurements.

Chain linked potentiometers would allow a potentiometer based goniometer full freedom of movement in the sagittal plane. This setup would involve two potentiometers, one above the knee and one below, connected together in in a way that allows the distance between them to vary.

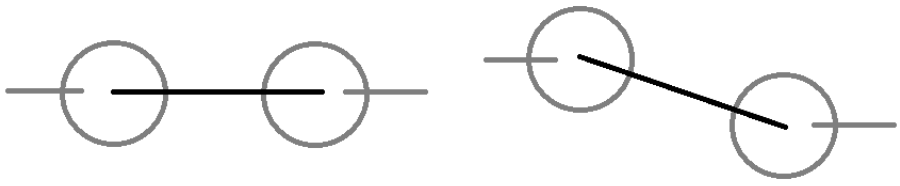

Figure 4.3. Diagram of the proposed chain linked potentiometer measurement principle, the black connection between the two potentiometers is telescopic.

From figure 4.3 it can be seen that the use of two potentiometers allows the two parts to move up or down, while still able to quantify the angle of the two parts relative to one another. Additionally, a telescopic connection between the two (the black line in the diagram), would allow the two parts to move closer to or further away from each other,

enabling full freedom of movement in the plane perpendicular to the potentiometer axes. This telescopic connection would have to be stiff around the potentiometer axes in order not to negatively influence precision of the goniometer. In the lengthwise direction it should move easily, and in any other direction, movement is allowed. A broad, flat chain was chosen as the telescopic connection because of its robustness and fluent movement, and because it can be bent along its longitudinal axis. In this way the 4 DOF afforded by the goniometer are: knee flexion/extension, proximal/distal translations, anterior/posterior translations and lateral/medial translations. Knee adduction/abduction would not be constrained when the knee is straight, but as the knee flexes the chain would rotate in the sagittal plane and the longitudinal axis of the chain would no longer be suitably aligned.

To enable adduction/abduction regardless of knee flexion, as well as long bone rotations of the knee, the chain linked potentiometers are attached to two thin, flexible strips, in turn attached to the leg using elastic straps. As the strips are flexible they would accommodate for adduction/abduction. The strip could also easily rotate with respect to the underlying bones of upper and lower leg, allowing for some rotation of the knee. This setup is believed to enable 6 DOF in the full physiological flexion range.

A proof of concept was made and two stainless steel strips were formed to attach the device to upper and lower leg. These strips were aligned along the lines between trochanter major and lateral epicondyle of the femur and fibular notch and lateral malleolus of the tibia, and were attached using hand sewn denim straps with velcro. Each strip holds one potentiometer, linked together by a plastic chain repurposed from a cheap wrist watch, see figure 4.4.

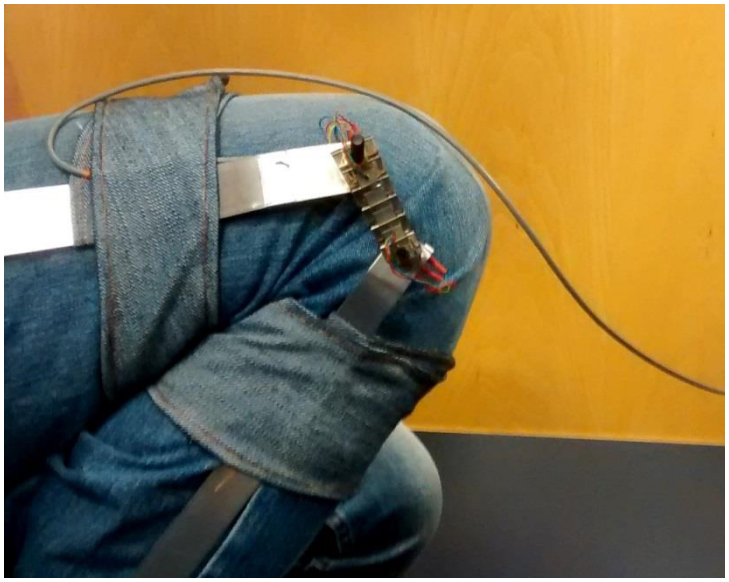

Figure 4.4. The setup allows for freedom of movement.

The two potentiometers were then powered (5V), and their signal was acquired using a microcontroller board (arduino duemilanove) with a 10 bit ADC, resulting in 1024 steps for the electrical range of the potentiometers (Piher 10k, linear) from +/- 120 degrees to -120 degrees. This yields a theoretical angular resolution of around 0.24 degrees per ADC step. Both potentiometers were fitted with a disc with 5 degree markings and calibrated in steps of 5 degrees.

The calibration showed that the potentiometers are not perfectly linear. In the lower leg potentiometer, the linearly predicted value deviated from the actual value by a maximal of +/- 7 degrees. In the thigh this was around 5 degrees. Because of the double potentiometer set up, the angles calculated from both potentiometers have to be summated, which would lead to a summation of the error. To improve on this without having to resort to expensive precision potentiometers, a two part polynomial calibration was used and programmed into the microcontroller that calculates the angles measured by the potentiometers. The angles were then summated and sent to a computer screen at a frequency of 1 Hz.

The goniometer was now positioned in various pre-set angles, while the lower leg part of the goniometer was moved into 20mm ventrally, dorsally or proximally to test whether the translations negatively affect results.

Results are presented in table1. During the 135 degree flexion with 20mm dorsal translation the thigh potentiometer was rotated to around 145 degrees, well out of its 120 degrees measurement range which is why there is no value reported here.

Table 4.1. Results of the proof of concept. No value at 135° due to one potentiometer moving out of range.

set angle °	Result normal °	Result ventral translation °	Result dorsal translation °	Result proximal translation °
-45	-40	-42	-42	-47
0	0	1	1	0
45	43	45	47	45
90	88	89	92	87
135	137	140	*	133

The results produced by the proof of concept device differed from the set angles by 5° or less and unlike the flex-sensors, the potentiometer based approach gives the result instantly. It has thereby shown the measurement principle to be feasible, but in its current setup with exposed wires, plastic potentiometers and a wrist watch chain it is fragile. Therefore a more robust prototype was developed.

Encouraged by the success of the proof of concept, a Prototypal chain linked electro goniometer (CLEG) was made, see figure 4.5. It consists of two Polypropylene arms (250mm long and 3mm thick) each holding a potentiometer and joined together by a broad chain roughly 60mm long. The arms are used to attach the CLEG to the upper and lower leg as before, this time using hand sewn nylon straps with Velcro. The arms are flexible by grace of the material used, which allows them to follow the shape of the

part of the leg they are attached to. The somewhat fragile plastic potentiometers were replaced with robust metal ones, attached to the polypropylene arms using little stainless steel brackets. See figures 4.6 and 4.7 for drawings of the arms and brackets. The fragile wristwatch chain was replaced by a plastic chain that was originally intended for use on a scale model tank, and in order to attach this chain to the potentiometers aluminium adapters were milled in the department machine shop. The loose wires from the first prototype were replaced by a robust cable that connects to the Arduino Uno microcontroller in a separate housing. After acquisition both potentiometer voltages are converted to an angle using a pre-determined two part polynomial calibration and then added up to produce the knee angle. Sample rates up to roughly 400Hz were attained using a small piece of circuitry (see figure 4.8) that acts as a clock and gives off pulses at selectable frequencies, however it was set at 100Hz for the first subject measurements.

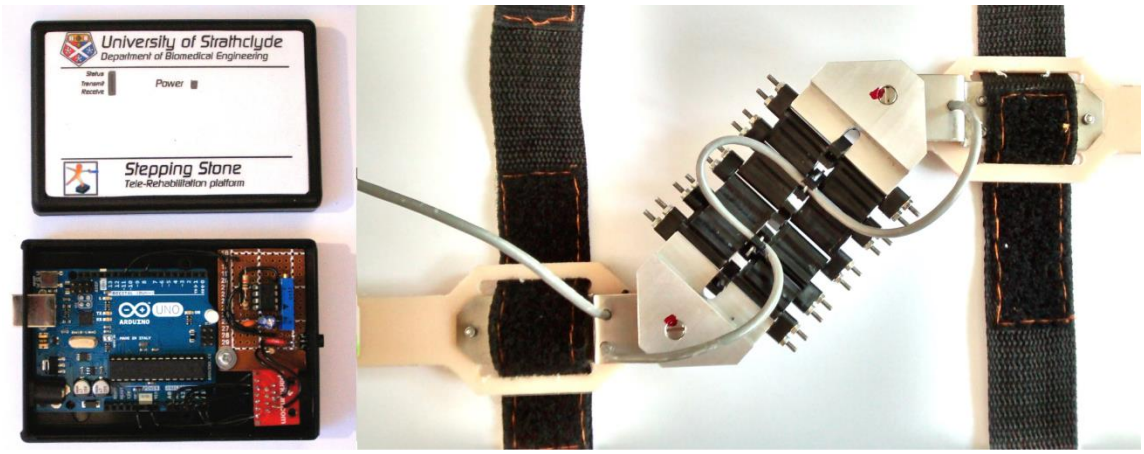

Figure 4.5 CLEG prototype1. On the left the housing with microcontroller and timing circuitry, on the right the chain and polypropylene arms.

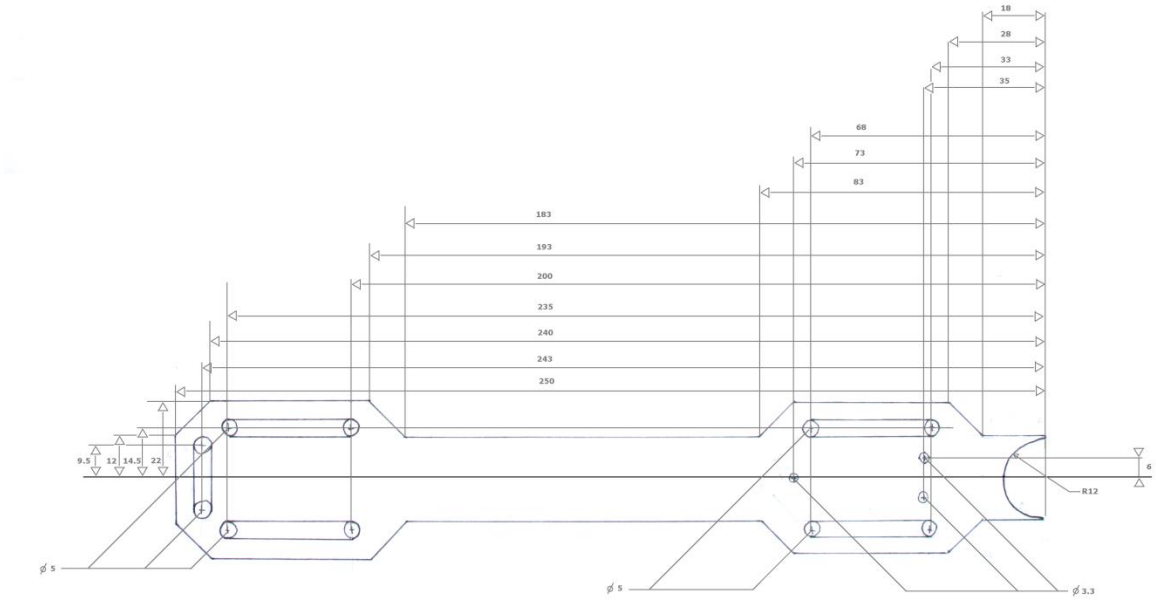

Figure 4.6. The polypropylene arms

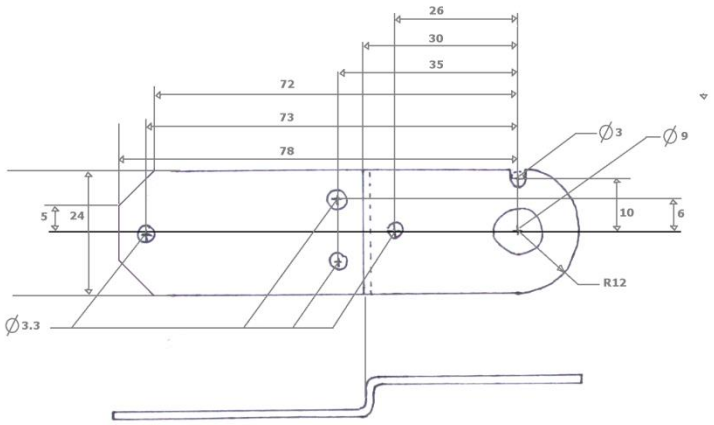

Figure 4.7. The stainless steel brackets

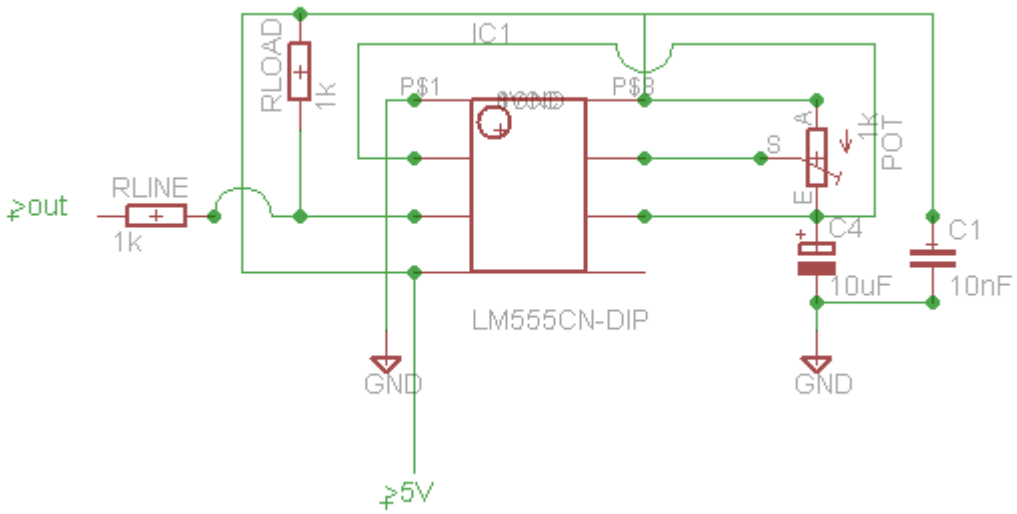

Figure 4.8 Schematic of the timer circuit

After attaching this CLEG to a universal goniometer, it was set at angles ranging from -140° to 140° in steps of 10°, see figure 4.9. The RMS error found between the CLEG readings and the angle set on the UG was 2.8°, however the biggest error was found at a set angle of -140° where the CLEG indicated -146°. This is not accurate enough and improvements will have to be made, nonetheless this first prototype was used for a subject measurement of treadmill walking, to assess agreement with stereo photogrammetry and get an insight into whether the measurement principle influences gait kinematics. On one test day, the researcher acting as subject (male, 28 years old, 1.85m tall, weighing 85kg) was measured concurrently with the CLEG and Vicon, both at 100Hz. After undressing, leaving only shorts, the CLEG was attached to the right leg and Vicon markers were placed according to the plug-in gait model. Data was captured with both CLEG and Vicon concurrently during level treadmill walking at 1.2m/s (condition W1), and after the CLEG had been removed by only Vicon during level treadmill walking at 1.2m/s (condition W2). After this the CLEG was re-attached and level treadmill walking at 1.2 m/s was again captured concurrently by CLEG and Vicon (condition W3).

Whether the EG influences the variable it is trying to measure is answered by comparing maximal and minimal knee flexion angles for ten strides measured by Vicon, from W1, W2 and W3. W2 acts as the baseline, as there was no CLEG attached during this trial. The ten strides measured are the first ten after 30 seconds of starting the treadmill. In order to determine if the maximal and minimal knee angle differs when wearing the CLEG compared to the baseline, the three trials are compared using an ANOVA with a linear contrast between W1&W3 versus W2. Data was not tested for normality because when group sizes are equal the ANOVA is robust to violations of normality (Field 2009 p.360). Equality of variation was tested, and appropriate contrast results selected based on the outcome.

Levene's test for equality of variances showed no equality of variance ($p=0.007$ for MIN, $p=0.015$ for MAX), so the results not assuming equality of variance from the ANOVA linear contrast were selected. These results showed that both the minimal as well as the maximal knee angles) from W1 and W3, did not differ significantly from W2. ($p=0.434$ for MIN, $p=0.181$ for MAX)

Agreement with the standard is determined by comparing data from CLEG versus Vicon for the ten steps of **W1** and **W3.** The minimal difference needed to be considered real (MD) is calculated as 1.96*sqrt(2)*SEM, the SEM being the rms of the difference between EG and Vicon. If this MD is below the minimal clinically relevant difference the two devices could be used interchangeable in clinical practice (Bland and Altman 1999).

The SEM (rms) of the difference between CLEG and Vicon during the ten steps was 2.99° for W1 and for 3.68° for W3, see figure 4.10 for an impression of agreement between the two instruments. These SEM values can be likened to a standard deviation as they are both calculated as the rms. When multiplied by 1.96*sqrt(2) the SEM produces what is called the minimal difference needed to be considered real (MD). For W1 and W3 the MD has values of 8.29° and 10.20° respectively.

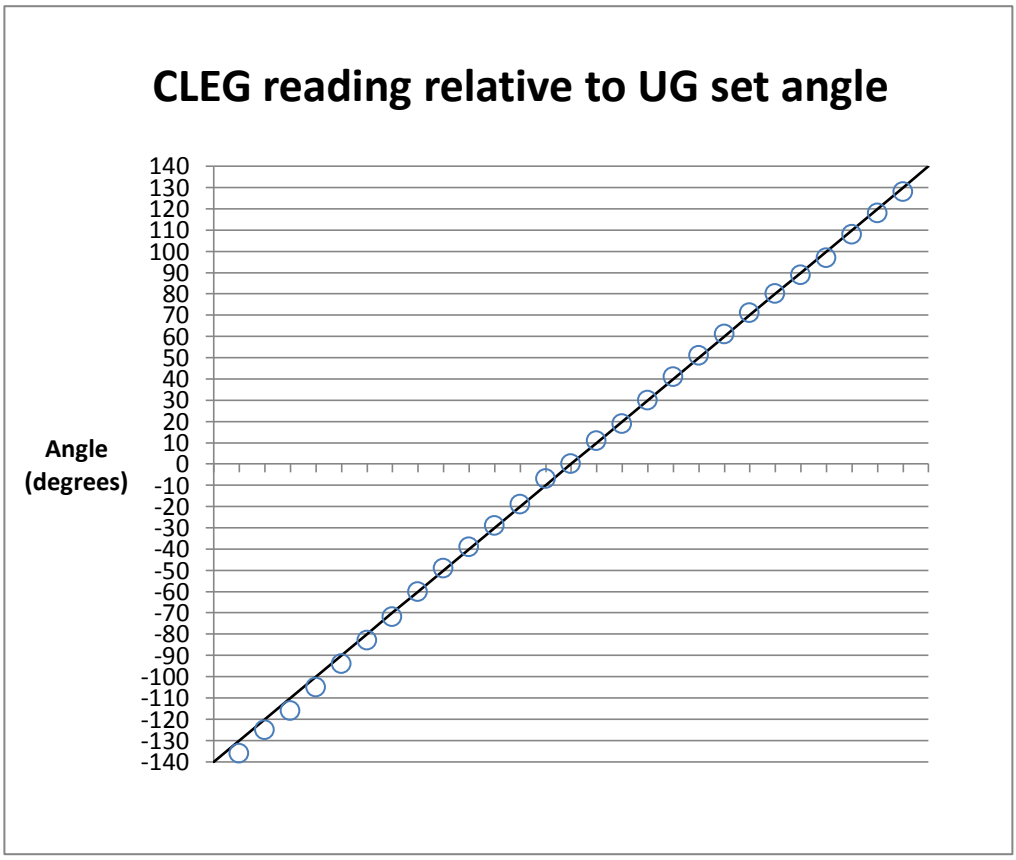

Figure 4.9. CLEG readings relative to the angles set on the UG. The black line is y=x.

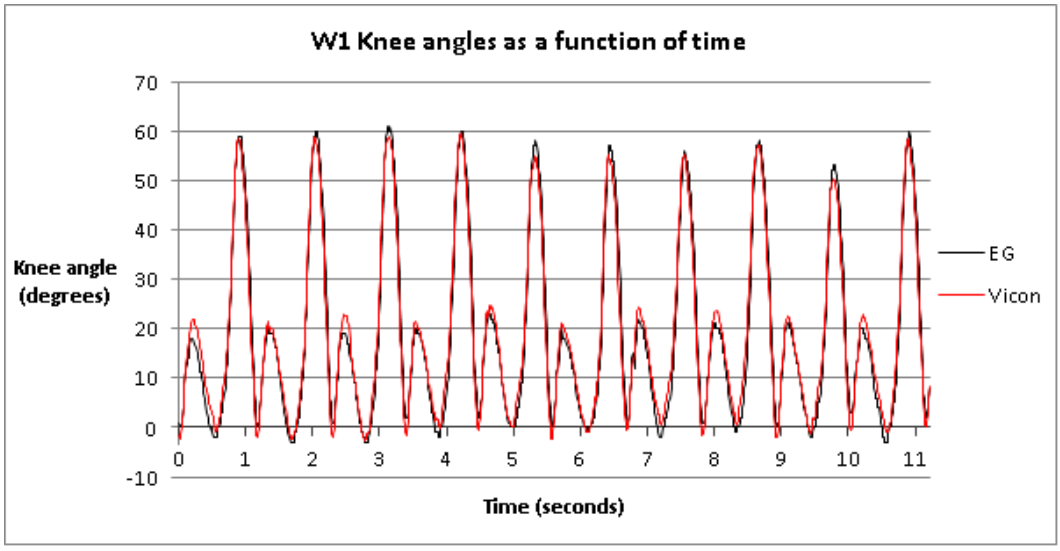

Figure 4.10 Vicon versus CLEG readings during level treadmill walking at 1.2m/s

When compared to set angles this first prototype had an rms error of 2.8°. The largest deviation from the set angle however was 6° which is more than can be tolerated in the light of the accuracy requirements. During the one subject measurements the CLEG was not found to influence treadmill walking kinematics, and the minimal difference needed to be considered real was found to be well within the minimal clinically relevant difference of 15°. Thus for this first prototype, results during a one subject method comparison against stereo-photogrammetry showed satisfying performance, with room for possible improvements. The lateral stiffness of the chain could be improved as this is suspected to be a contributing factor in the deviations from set angles, and the chain should not be allowed to flex inward. This was found to lead to the chain coming into contact with the subject's knee and possibly influence measurements. Also this version caused the piece of cable connecting the two potentiometers to flex considerably as a result of the potentiometer bodies, to which this cable was attached, being mounted on the parts that attach to the subjects leg. It would be preferable if the potentiometer bodies were attached to the chain so that knee flexion does not cause the cable to bend. The straps that were used were handmade which hinders scalability, as does the production technique involving hand milled parts. Also this first prototype has sharp edges where the screws are exposed at the edges of the chain, and the polypropylene strips couldn't easily be cut to size as the eyelets through which the straps run are a part of them, instead of being modular. For the second prototype these shortcomings will have to be remedied.

The second prototype was designed using a 3D CAD program and 3D printed using a stereo lithography technique, as 3D printing would aid scalability and flexibility. Its chain was designed to be stiff in a lateral direction, have recesses for the screws so there will be no sharp edges, and is only allowed to flex outward. Also, the ends of the chain now house the potentiometer bodies, instead of connecting to their stems to reduce cable flex. The microcontroller is attached to the thigh part of the CLEG for this version, and an accelerometer is added to enable the determination of the orientation in the sagittal plane of the thigh part of the CLEG, and thereby the thigh, using a simple trigonometric approach. The timer circuit was replaced by one of the digital output pins of the microcontroller which can be set to oscillate at 490Hz. After 5 of these oscillations have been detected the CLEG transmits its momentary readings, leading to a sampling frequency of 98Hz. Straps for this version were bought from

John Lewis's haberdashery department and the eyelets through which the straps run are attached to the polypropylene arms using a screw, making shortening of the arms to fit a person's leg easier. See figure 4.11 for an illustration of this second prototype.

Figure 4.11. The second prototype of the CLEG

A comparison with a universal goniometer (UG) was performed (see figure 4.12) over the range of -150 to 150 degrees, in increments of 5 degrees, leading to a RMS error between result and set angle of 1.65° and a largest deviation of 3°.

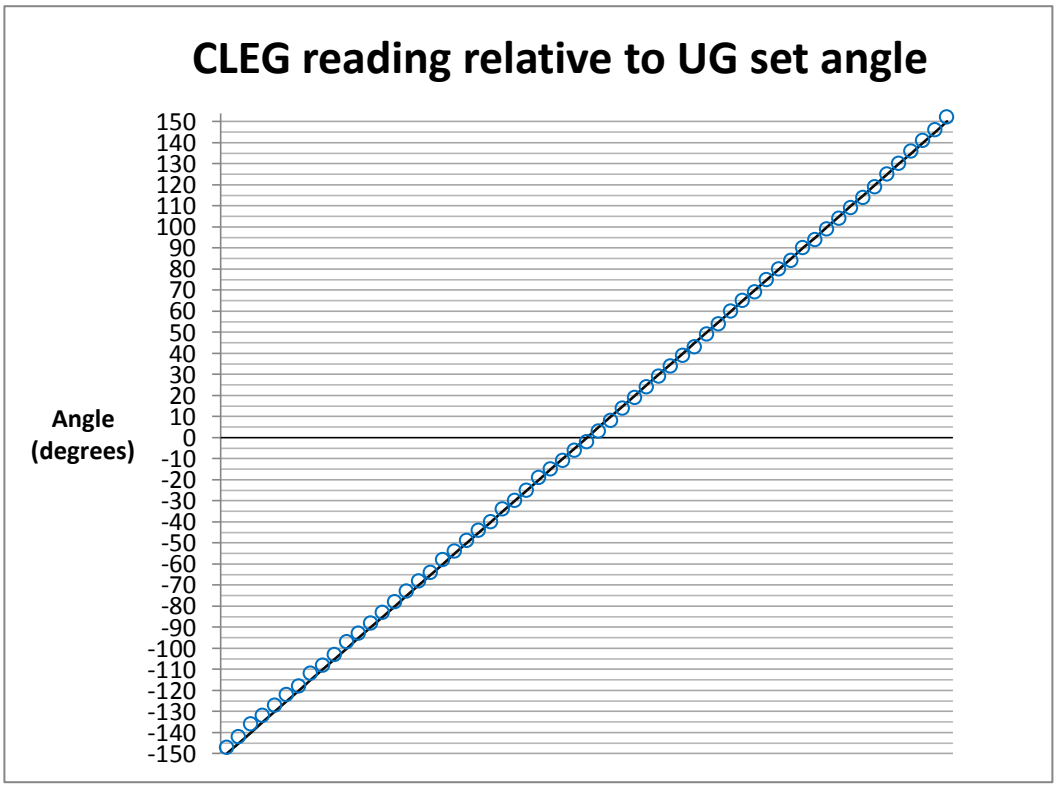

Figure 4.12. The second prototype's readings relative to set angles.

Following the UG comparison was a one subject method comparison against stereo-photogrammetry, again with the researcher acting as the subject (29 years old, 1.85m, 85kg) participating in the experiments described below. The subject was wearing tight fitting clothes and retro reflective markers were attached to anatomical landmarks in accordance with the lower limb plug in gait model, see figure 4.13. All activities were self-paced.

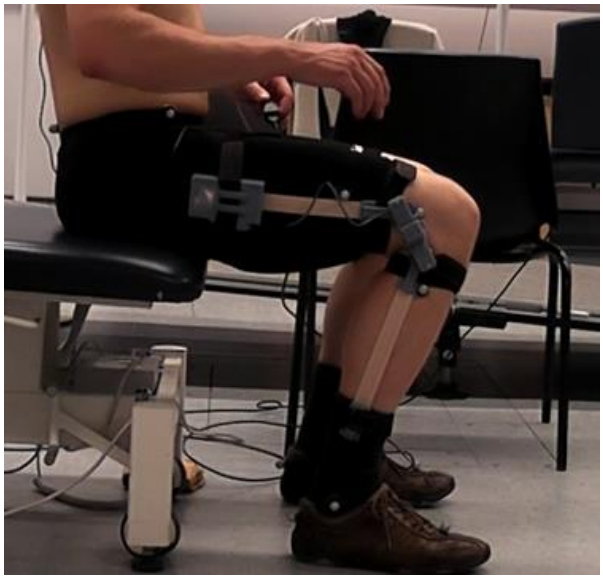

Figure 4.13. CLEG and reflective markers attached to the subject.

When used the CLEG must not influence knee kinematics. In order to confirm that the CLEG does not influence knee kinematics, the subjects knee kinematics were measured using stereo photogrammetry during level walking, both with, and without wearing the CLEG. The movement used to assess agreement with the widely used stereo photogrammetry is sit to stand.

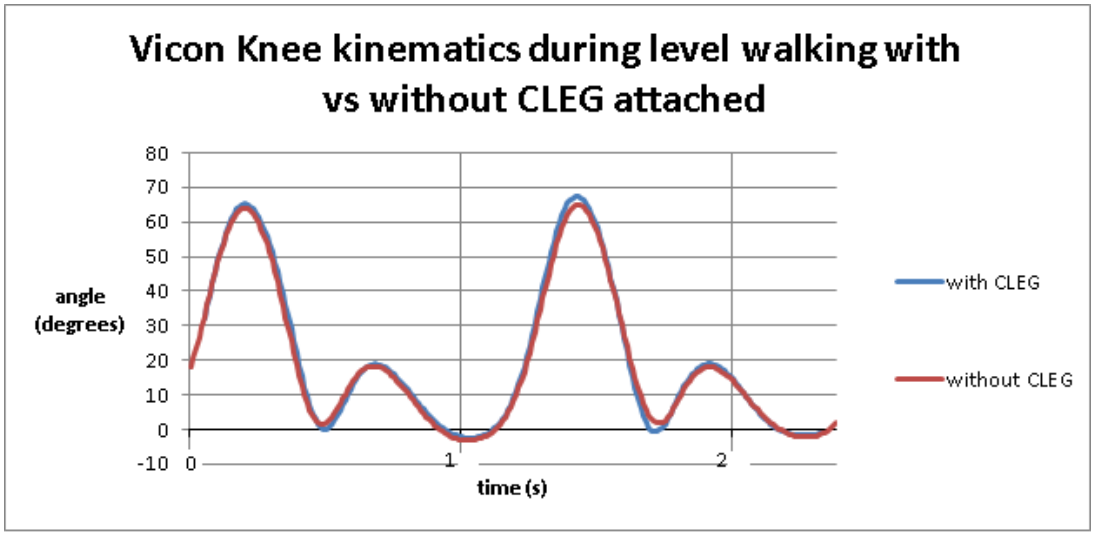

Figure 4.14. Vicon knee kinematics with and without CLEG attached.

The influence test showed near identical knee kinematics whether or not the CLEG was being worn with an RMS error of 3 degrees between the two conditions. Normal variation is known to be an SD of around 5 degrees over the full gait cycle (Perry & Burnfield 2010, Baker 2013). This means that, in a healthy subject, the CLEG does not influence gait kinematics and that it can be used safely.

During sit to stand movements, see figure 4.15, the ROMs determined by the CLEG exceeded those determined by Vicon by 3.1° to 5.8°, roughly 5%. However, it is known that because of soft tissue error in stereo photogrammetry, ROMs during sit to stand are normally underestimated by stereo photogrammetry (Stagni et al. 2005, Kuo et al. 2011) suggesting that the CLEG may be more valid than Vicon.

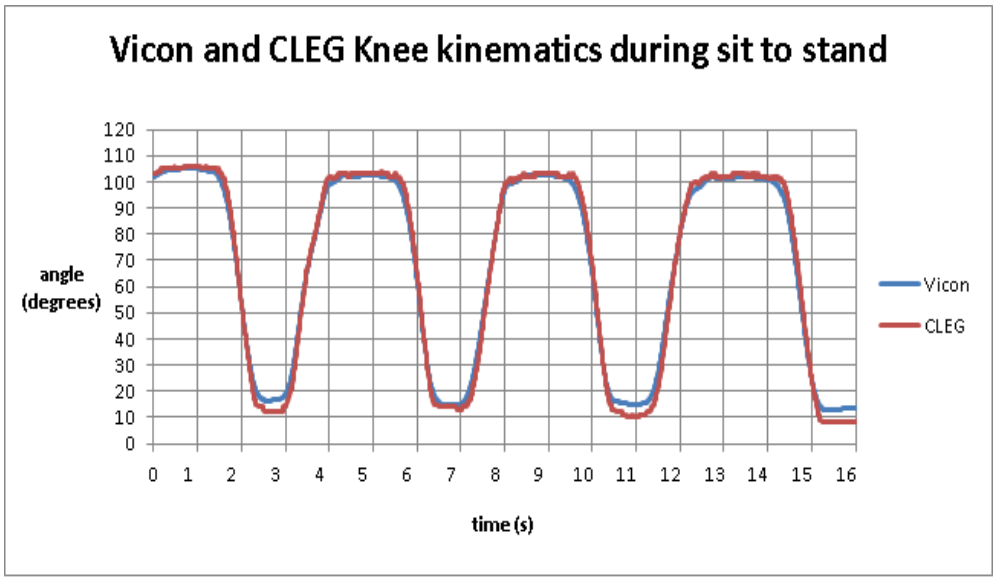

Figure 4.15. Knee kinematics during sit to stand as measured by vicon and CLEG.

Results show that the orientation angle calculated from a three directional accelerometer does not accurately reflect the thigh orientation during walking, see figure 4.16. However, during sit to stand the calculated angle, qualitatively, does agree with the thigh orientation, see figure 4.17.

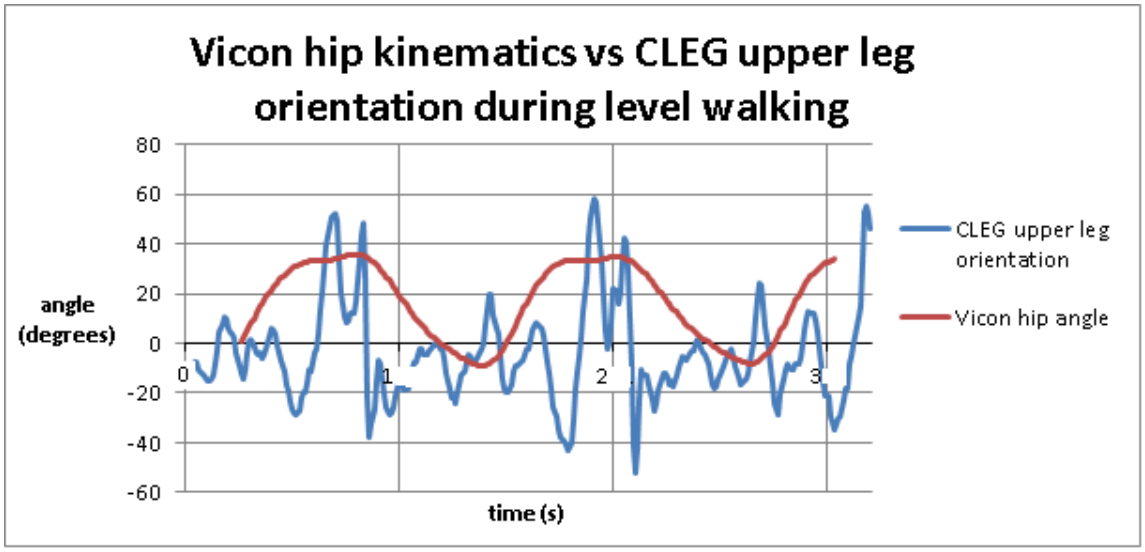

Figure 4.16. Walking thigh orientation

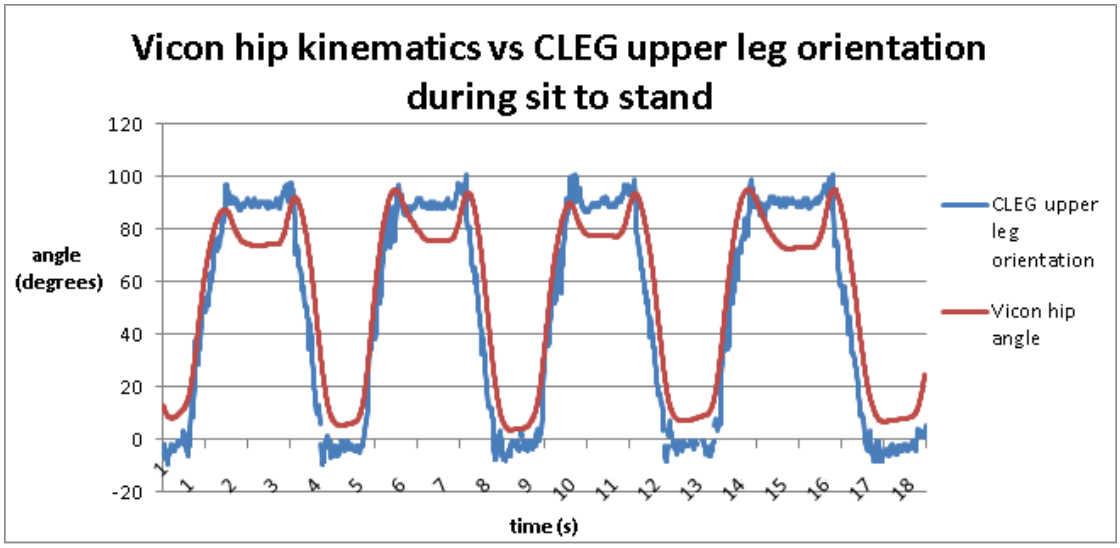

Figure4.17. Sit to stand thigh orientation

The above testing indicates that the design changes for this second prototype were effective; the rms error when compared to set angles has been reduced from 2.8° to 1.65°, and the largest deviation from the set angle halved from 6° to 3°. This is believed to be due to the improved lateral stiffness of the chain that also is unable to flex inwards

which was a shortcoming of the first prototype. The agreement with stereo photogrammetry was found to be within 3.1° to 5.8° when concurrently measuring sit to stand ROM. This is very nearly within the 5° accuracy required, and considering that stereo photogrammetry is known to underestimate true ROM, and the CLEG results exceed those of Vicon, it is possible that the CLEG results are more valid than the Vicon results. The change to a 3D printing manufacturing technique thereby seems to not just improve scalability and flexibility, but because of the ability to make otherwise very labour intensive parts such as a bespoke chain relatively quickly, improve performance of the CLEG. Unfortunately at the time of developing these prototypes the department of biomedical engineering did not have a 3D printer, and printing was outsourced to the department of design manufacture & engineering management, who could only offer the stereo lithography technique. This resulted in a cost for the printed parts in excess of GBP 200,-. This will have to be improved for the final prototype, as will performance of the accelerometer for determining thigh orientation.

4.3.4. Deliver

Encouraged by the success of the previous prototypes, this measuring concept is believed to have the potential for meeting the demands set out in section 4.2.1. It is believed to be able to be made affordably due to the low cost components used, and be usable as it would only need to be strapped to the leg and powered on. It is believed to be robust because of the robustness of the components, and be flexible because it could be made to be modular and use a microcontroller that is recognised as a keyboard by other ICT devices which would enable it to be connected to a large variety of devices. Minimal training and tech support are believed to be required by grace of its straightforward operation, and it has an adequate measurement range as potentiometers can provide a large enough electrical range to allow for this. It is believed to be valid as the concept allows freedom of movement in the sagittal plane, be reliable as it would be possible to attach it to the leg in the same position by aligning it to anatomical

landmarks, be portable because of its small size and light weight, have long term usability because of the absolute values given by the potentiometers, and be sensitive enough to detect the MCRD because the goniometers could be calibrated precisely. The Chain Linked Electro-Goniometer (CLEG) was designed in 3D, using PTC Creo, with a chain that is forced to flex outward in order to prevent it from coming into contact with the knee. See figure 4.18.

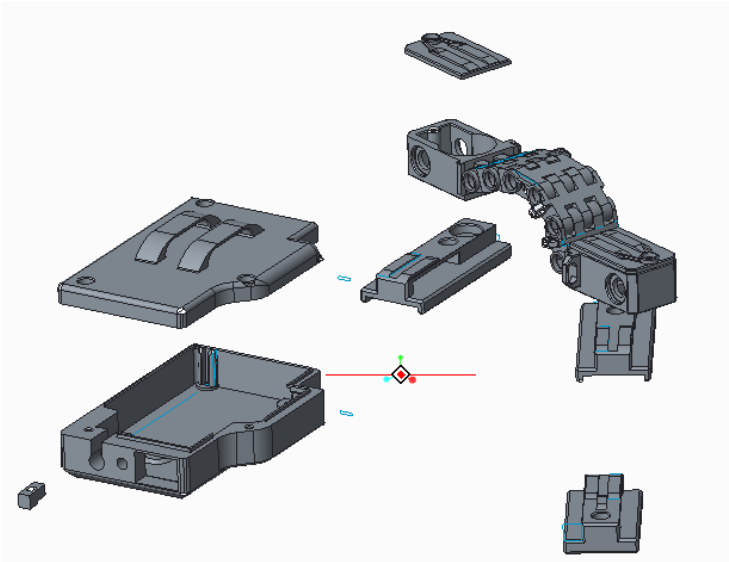

Figure 4.18. The Chain Linked Electro-Goniometer (CLEG) 3D design.

Also, care was taken to increase wearability of the CLEG by following the recommendations of Gemperle et al. (1998); the CLEG was kept lightweight (approximately 300g.) and with a profile running as close to the body as possible. The communications module housing the microcontroller was placed at the thigh, an area found suitable for wearable objects. Also, in order to meet the demands of usability, robustness and a minimal need for training and technical support; the CLEG was fitted with robust components and a large three position switch.

However, the stereo lithography 3D printing technique used for the previous prototype was expensive at over 200GBP per CLEG and would prevent the cost target of 100GBP being met. Therefore, the final version of the CLEG was produced using the more affordable fused deposition modelling (FDM) technique using poly lactic acid

(PLA). A 3D printer was acquired for the sole purpose of producing CLEG parts (the micro - www.m3d.com). At a price of 227GBP and an assumed lifespan of printing at least 10 CLEGs, the cost of the printer would work out to £22.70 per CLEG. Added to a parts cost of £70.59 (see table 2), the total cost per CLEG works out to £93.29, below the threshold of £100,-.

Table 2. Cost of parts per CLEG.

quantity	description	price/pc (GBP)	price subtotal (GBP)
1	roll pla	8.37	8.37
1	arduino leonardo	14.31	14.31
1	arduino proto shield	3.63	3.63
1	ADXL337 accelerometer	9.17	9.17
1	5mm RGB led	0.64	0.64
1	3 position switch	1.02	1.02
2	potentiometers	5.79	11.58
1	USB OTG cable	2.4	2.4
4	velcro stretch straps	3	12
4	rubber grommets	0.0294	0.1176
6	25mm M3 machine screw	0.024	0.144
2	16mm M3 machine screws	0.02	0.04
6	10mm M3 machine screws	0.017	0.102
1	6mm M3 machine screw	0.016	0.016
14	M3 locking nut	0.029	0.406
2	3mm polypropylene strip 25X280mm	3	6
0.5m	4 lead shielded wire 3mm diam.	1.16	0.58
4	resistors	0.015	0.06
		total (GBP):	70.59

There are limitations to FDM 3D printing. Because of the FDM technique that in essence lays down strands of molten plastic next to and on top of each other, see figure

4.19, the tensile strength of printed parts differs depending on the direction in which the strain is applied. In addition to this there are many problems that can occur; the part that is being printed may warp or lean over, it may develop a wobble along the Z axis, thin threads of molten plastic may ooze from the nozzle while it moves across the part, there may be too much, or not enough plastic being extruded and the layers may separate. Influencing these problems are many variables that need to be taken into account; the nozzle diameter and temperature, fan speed, layer height, wall thickness, infill density, offset height, filament colour and the environment. In addition to these variables there are several options that can be chosen; whether or not to print support material, whether to use model on model support, whether to use a raft or wave bonding, whether the print bed should be heated and to which temperature, and what build surface is being used.

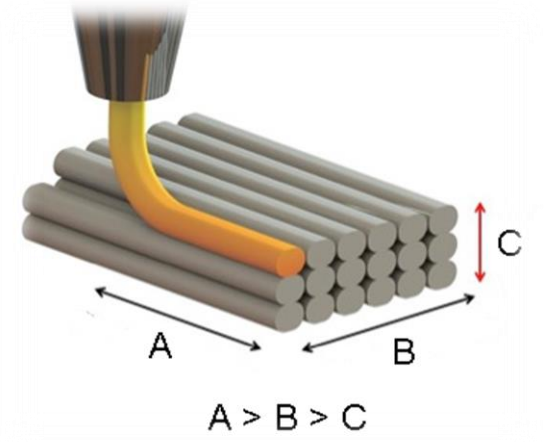

Figure 4.19. The FDM 3D printing technique

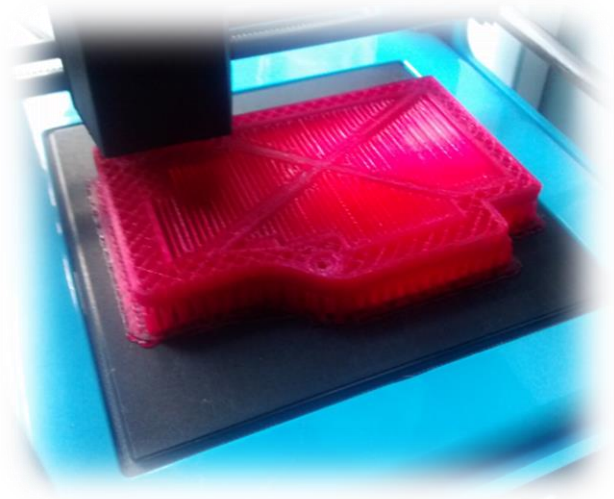

Figure 4.20 A lid being printed on the Micro.

To minimise problems occurring, parts should be designed so that their total height is a multiple of printer layer height, corners should be rounded and lengths should be minimised to reduce the chances of warping. Also they should be printed so that the direction in which they are expected to experience the greatest loads matches direction "A" in figure 4.19. The design of the second prototype was amended to agree with this as much as possible, and the little square protrusion on the underside of the lid that fills up the groove for the USB cable (seen in the lower left corner of figure 4.18) was no longer printed as a part of the lid as this dramatically increased printing time because of the extra layers that had to be printed. With all the variables and options in mind it can be understood that 3D FDM printing can be quite time consuming, and this was found to be the case for the CLEG parts that had to be printed. The box housing the microcontroller took 20 hours to print, and failed regularly due to warping, despite being designed with the above in mind.

Three CLEGs were printed using the FDM printer, see figure 4.20 to get an idea of what this printing looks like, and assembled. The microcontroller and "proto shield" circuit board holding an accelerometer and other electronic components were housed in the communication module together with the switch, red-green-blue (RGB) status led

and two cables; one 4 lead cable connected to the two potentiometers in the chain and the other a universal serial bus (USB) cable, see figure 4.21.

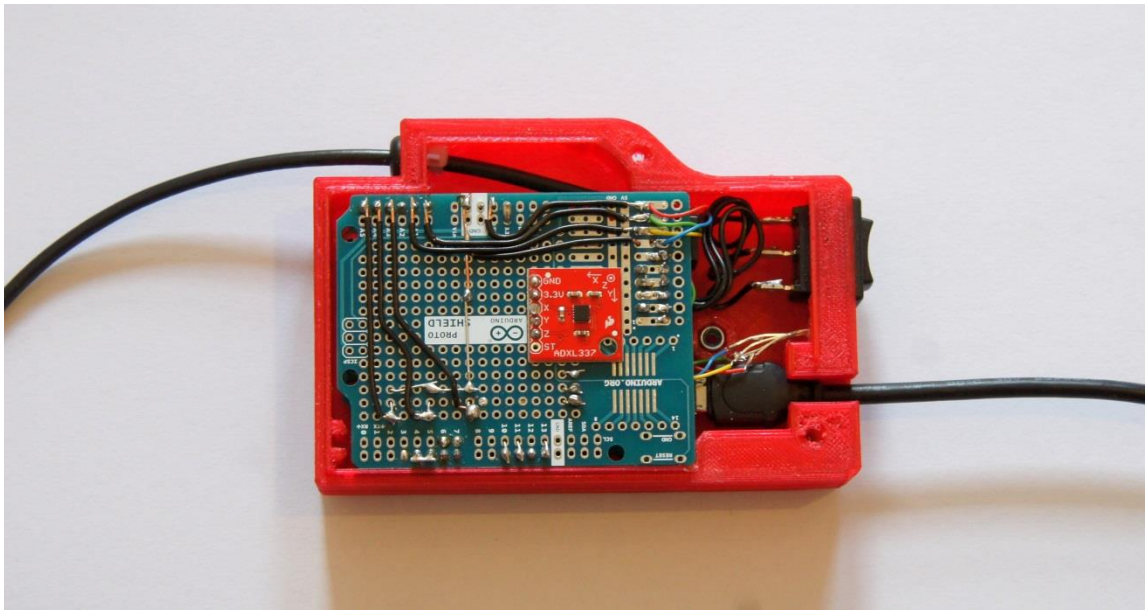

Figure 4.21. The electronics are housed in the communication module.

The accelerometer signals were analogously low pass filtered using one 4.7µF capacitor for each signal that together with the accelerometers' inbuilt resistors results in an Fc of 1Hz to improve results during activities where it would be exposed to higher frequencies such as walking, found to be a problem for the previous prototype. The X and Y signals were calibrated linearly using earth's gravitation and used to calculate the orientation of the communication module in the sagittal plane using a simple trigonometric approach. This will allow for the orientation of the thigh to be determined which will be needed for the biofeedback and activity monitoring functions.

The chain as seen in figure 4.22 was assembled, and potentiometers fitted into the boxes at the end of the chain. Rubber grommets and the cable coming from the communication module were installed and the potentiometers were then calibrated in the range between -150° and 150° using a custom calibration tool that was also 3D printed,

see figure 4.22. This tool consists of one part that is attached to the goniometer housing box at the end of the chain. This first part has a flexible wedge that clicks into place of the second part; a sprocket with teeth set 5° apart that attaches to the potentiometer axis. In this way the tool allows the potentiometer position to be set in 5° intervals accurately during calibration.

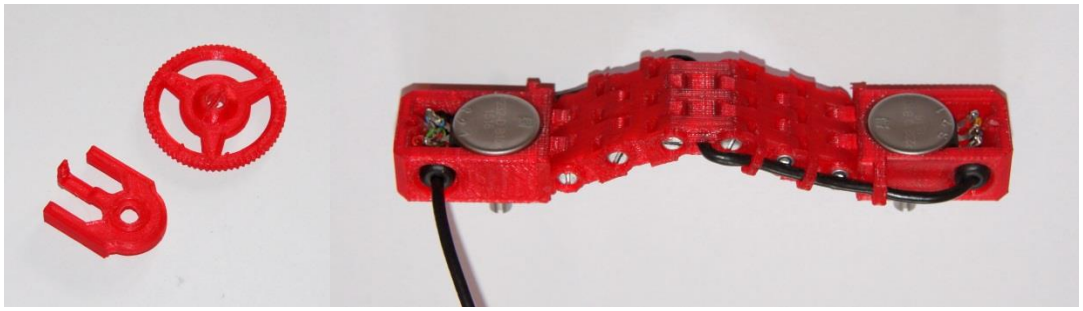

Figure 4.22. The calibration tool and the chain holding the two potentiometers.

Potentiometer readings were acquired using the CLEG's microcontroller and noted in MS excel, where two separate 2nd order regression lines were calculated. One for the positive half (0-150°) of potentiometer rotation, and one for the negative one. This was done separately for each potentiometer of each CLEG, and the results are used in the CLEG software. After calibration, adapters (see figure 4.23) were fitted to the potentiometer axes in order to attach them and their chain to two flexible polypropylene strips.

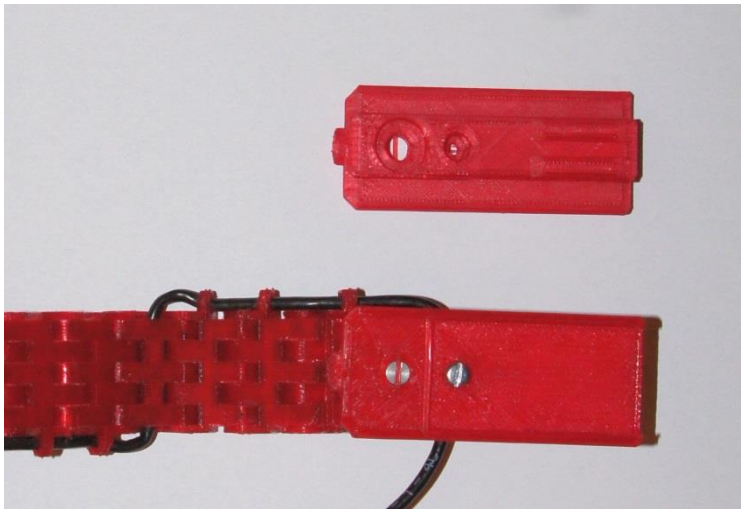

Figure 4.23 The adapters that connect the chain to the flexible strips.

The communication module was attached to an unused end of one strip, and a small adapter to the unused end of the other strip. Each adapter, as well as the communication module lid, has an eye through which flexible Velcro straps were run that then attached the whole CLEG to the leg, see figure 4.24.

Figure 4.24. The CLEG being strapped to the leg.

When set up this way the CLEG can measure knee kinematics and provide insight into thigh orientation. The CLEG will be tested on various aspects of performance when

measuring the knee in chapter 5. However it was made to be modular in an effort to improve on flexibility and create more generic value.

The communication module can be attached to a variety of body parts, and the chain can span a variety of joints. For instance, the communication module could be attached to a waistband and worn on the back, while one end of the chain could be attached laterally to the same waistband. The other end of the chain could be attached to a flexible strip strapped to the thigh, this way the CLEG could measure hip flexion and extension. Ankle kinematics could be measured as well, by attaching one end of the chain to a person's shoe and the other end to a flexible strip strapped to the lower leg. The communication module could be attached to this strip, providing some info regarding the lower leg orientation, or if a long enough cable is fitted, could be attached to the thigh or waistband as before.

Apart from the joints in the leg, the CLEG may also have some potential for acquiring kinematics of arm joints. If the flexible arms are shortened, the CLEG could be worn with the chain spanning the elbow, measuring elbow flexion and extension whilst the communication module would provide some information regarding upper arm orientation.

However, the CLEG was not tested in these alternative setups and future studies would be needed to confirm the CLEGs potential here. Other future work may include incorporating or developing different low cost and robust measuring devices such as heart rate monitors and respirometers that connect to the same communications module developed for the CLEG in an effort to expand the TR platform's scope.

4.4 Patient device

The goniometer described in the previous section had to be custom made, as the discover and define stage didn't uncover suitable alternatives. For the patient device, the define stage did identify a suitable device.

4.4.1 Discover

The patient device, as part of a TR platform, should be interactive; it needs to take inputs, and provide output to the user. It should also enable the main function of communication. This entails both the communication between patient and therapist, as well as data. This data needs to be communicated both from the CLEG toward the patient device, as well as between patient device and therapist device. As described in chapter 2, the ICT to be used for this is the internet, as it enables real time video communication (RTVC). The device should meet the requirements of chapter 2; usability, quality, flexibility, requiring minimal training and technical support, and low cost. The upper threshold for cost effectiveness for the entire TR platform was found to be £320,-. With £93.29 of this reserved for a CLEG, £206.71 is left for the patient device. Previous initiatives have for instance used a laptop computer, but generally this is beyond this price point. Moreover, laptops are known not to be optimal in terms of user acceptance among older adults. A more affordable, easier to use alternative is needed.

Input devices enable the communication from human to device, for instance by entering text, or by pointing a cursor on the screen and so navigating menus. They have a profound impact on ease of use and can be divided into either direct or indirect categories. A mouse for instance is indirect; it is moved across a desk in order to move the pointer on the screen, whereas a touchscreen is direct. Choosing the input device is a critical design issue (Rogers et al. 2006) and it is important to keep the needs and capabilities of prospective users in mind (Rogers et al. 2006) (Taveira and Choi 2009). The advantages and disadvantages of the various input devices when considered for use by older adults are discussed below.

Not having changed much from its 1868 design, the QWERTY keyboard is generally used to enter text rather than navigating menus, and is one of the most commonly used input devices today. Albeit at reduced speeds, older adults are able to use them without reductions in accuracy (Taveira and Choi 2009), although the extended

use of keyboard may be difficult due to the high prevalence of arthritis among older adults (Rogers et al. 2006).

With the advent of graphical user interfaces arose the need for a pointing input device to navigate the menus and windows. A need met by the mouse, which gained immense popularity and is now the most commonly used non-keyboard input device (Taveira and Choi 2009). It is an indirect pointing input device, meaning it relies on acquiring the necessary hand-eye coordination in order to use it effectively. Because of the decline in motor skills and coordination seen in the elderly (Ranganathan et al. 2001), using the mouse can be difficult.

For people with low strength and poor coordination, rolling a trackball can be easier than using a mouse. Studies comparing the mouse with a trackball showed that the trackball might be a better pointing input device for the elderly as the perceived exertion when using it was lower compared to the mouse, however other studies indicated the opposite (Taveira and Choi. 2009). Regardless of possible small differences between mouse and trackball, both are indirect pointing input devices. The trackball therefore shares the most important disadvantage with the mouse; the need to acquire new hand-eye coordination skills.

Although popular as input device for games, the joystick is not suitable for use by older adults. Apart from being very sensitive to tremor, it is inferior to a mouse in pointing tasks (Taveira and Choi 2009). It also shares the problem of the indirect pointing input devices addressed so far, in that it requires the acquisition of new hand-eye coordination skills.

Found on many modern laptops is the touchpad. Typically it has the approximate size of a credit card and responds to being touched with a finger. Because it is an indirect pointing input device, is of small size, and the required motor skills involved when tapping it, elderly users may experience difficulty in using it (Taveira and Choi 2009).

An indirect input device not commonly considered for navigating menus is the television style infrared remote control, which can be compared to the numerical keypad on a keyboard. Although it is indirect, like the keyboard it does not require the

acquisition of hand-eye coordination skills as it is not used to point, but to enter numbers. Using a remote control does however require a temporary shift of attention from the screen to the remote. Although the elderly tend to have difficulties dividing their attention (Caprani et al. 2012) (Charness et al. 2009), the remote control may be of value for use with the elderly. Rather than having to use their diminished liquid intelligence in order to learn how to use a new device, the remote control would enable the elderly to rely on their expanded crystalised intelligence stemming from their experience in operating television remote controls. Because of the familiarity they already have with the device, it may also be of help in reducing the anxiety towards computers.

A direct input device is found in the light pen. It is touched against a screen to manipulate the cursor, placing the cursor where the pen touched the screen. It can be seen as the predecessor of a stylus used on a touchscreen. The light pen has been found to out-perform the mouse, as it halves time needed to move to a target (Charness et al. 1995). Despite this, the mouse was found to be easier to use, and more acceptable by older adults (Taveira and Choi 2009).

Using one's voice to control a computer, although slower in selecting a target, is preferred by older adults over the light pen, but using this input technique extensively may lead to vocal fatigue (Taveira and Choi 2009). Furthermore the part of the brain responsible for recall and problem solving is also used for speech, causing people to have more difficulties thinking and speaking, than thinking and typing on a keyboard (Caprani et al. 2012). This makes voice recognition less than ideal as an input device.

By tracking the eyes, the location of the users gaze can be determined. Using this as input device would free the hands, and reduce the time required to move to a target (Taveira and Choi 2009). Older adults found this easier to use than a mouse (Caprani et al. 2012). However, eye tracking devices that could be used as input device are not currently available commercially.

Touch screens are a combination of input and output device. For the input part, modern capacitive screen technology means that even the lightest touch can be detected.

This touch can then be used to navigate menus, where visual feedback on touch location has been found to help reduce error rates (Weiman et al. 1985). Touch screens have been found better than other input devices, as long as no scrolling is involved (Rogers et al. 2006). They do not require the learning of new hand eye coordination, and are found appropriate for menu selection tasks, and particularly for tasks where training cannot be provided (Taveira and Choi 2009).

From the above, the television style remote control and the touchscreen seem good options for use as an input device. However, as older adults lose muscle mass and dexterity, they may experience difficulties pressing buttons on television remote controls. A touchscreen on the other hand requires less strength, and users don't have to divide their attention between a keypad and the screen (Caprani et al. 2012). Also, when compared to a numerical keypad, as often found on a remote control, older adults prefer a touchscreen (Chung et al. 2010). A study comparing the mouse with touch screen and eye gaze found the shortest execution time for touchscreen for all ages, with a more pronounced effect for older adults (Jochems et al. 2013). For some tasks older adults even like using a touchscreen more than other traditional techniques; in an experiment involving elderly subjects, pencil and paper was compared to the use of touch screen computers for conducting surveys. The results showed that using the touch screen led to higher satisfaction (Yarnold et al. 1996). In another study a touch screen was used for older adults learning to send emails, the result showed that this greatly reduced their anxiety about the use of the computers (Umemuro, 2004). This shows that a touchscreen would seem the ideal input device for older adults.

4.4.2 Define

The discover stage shows that current devices used as patient device (e.g. laptops) are not optimal for use in a TR system. Alternatives that were considered here are; the Raspberry Pi, UDOO, and a tablet computer.

The Raspberry Pi is a very cheap (about 30 GBP) compact solid state computer running Linux. It can connect to a TV for output device, and use a keyboard and mouse

as input devices. When coupled to a webcam, it can perform RTVC. But preliminary tests showed that even at the highest overclock setting, there was low image quality and substantial delays, rendering it unsuitable for RTVC. Moreover, it does not have a touchscreen. The UDOO is a similar compact solid state computer running Android as operating system. It has more processing power than the Raspberry Pi, and is able to perform RTVC. However, like the Raspberry Pi, it relies on a keyboard and mouse for input devices, so a touchscreen tablet computer would score better on usability. The latter have seen a drop in prices over the last years and are now very affordable at around 150GBP. They typically have an inbuilt camera and ample processing power thus enabling RTVC. Also, using these devices would provide the advantages of being able to use the existing services (e.g. Google Play) for diffusion of software, and guarantees flexibility due to the mobility that these portable devices offer. Quality is ensured because it is an off-the-shelf product, and tablets generally would accept the CLEG. For these reasons, a tablet computer was chosen as patient device. That leaves the Operating System (OS) to be chosen.

An operating system (OS) provides a more or less user friendly interface between the human on one end, and the machine running 1's and 0's on the other. User friendliness leaped forward with the advent of graphical rather than text based interfaces, a well-known revolution in computing spearheaded by the equally well-known Microsoft Windows. Currently there are many graphical operating systems to choose from, each one having its own set of advantages and disadvantages.

Microsoft Windows nowadays runs on a range of devices from desktop computers and laptops, to tablets and mobile phones. Another well-known computer company is Apple, who makes an operating system called iOS, running on a comparable range of devices as Windows. Although iOS has some claimed advantages over Windows, it's major drawback is that it runs exclusively on Apple devices that are without exception high end, and consequently high cost.

A third OS, released in 1991, is one that is probably less well-known among the general public, but runs on the majority of servers, main frames and super-computers; a version of Unix that was improved by a Finn called Linus Torvalds. Merging the names Linus with Unix gave this OS its name: Linux. The advantage of this OS is that it is both free and open source, meaning anyone can use it for free and is at liberty to make whatever changes to it they see fit. However, it currently does not see widespread use on tablet computers.

For tablet computers, an OS based on Linux sporting a little green robot for a mascot was made; Android. Born as an OS for mobile telephones ("smartphones"), it has since expanded to tablets, embedded devices and televisions ("smartTV's"). This OS was designed to use direct manipulation of objects on a touchscreen rather than a mouse for input, although a mouse can still be used. Like Linux it is free and open source, and has been designed for maximal user friendliness, for instance by doing away with the often incomprehensible error messages a Windows user may encounter. Also, Android makes use of a virtual machine that makes developing applications easier than it would be in Linux (Meier 2012), and has become immensely popular since its first release in 2007. Android was chosen as OS for the patient device because it is available for free, is user friendly and is a popular choice among both tablet manufacturers as well as users.

For 99.99 Pounds an Archos 101 Cobalt Android tablet with a 10.1" screen was purchased to serve as patient device, see figure 4.25.

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Figure 4.25. The tablet that was chosen to serve as patient device.

4.5 Therapist device

For the therapist device, only the first diamond of the design method was used as a suitable device was found.

4.5.1 Discover

As set out in the beginning of this chapter, the therapist device should enable RTVC and data collection. That means this device too would need internet connectivity. Also, it would have to be able to support an electronic patient file (EPF) for data collection. Choosing a suitable input device for this device is less demanding than it was for patients because of the aforementioned good computer skills of therapists (section 4.1.3), and their experience using the most common input devices of keyboard and mouse.

4.5.2 Define

In section 2.3.4 it was found that a TR platform should fit into an organisation's work practice if it is to stand a chance of reaching implementation. That means that a therapist device should be chosen based on its potential of being adopted by AHP

services. There are two known interactive tele-communications devices that are already used; (mobile) telephones and PCs, typically running the Microsoft Windows OS. Modern smartphones would be a viable choice for use in this TR platform, and they would have a benefit over PCs in that they are mobile. However, this advantage is not of big consequence to therapists who would normally do their work from a central location. Moreover, using smartphones would open up a variety of data security issues that would not arise when using the PCs that have been used by AHP services for some time. Also, PCs are already owned by the AHP services and hence would not have to be purchased, keeping cost of the platform down and consequently improving cost effectiveness. Therefore, the Windows PC is chosen as the therapist device.

4.6 Software

Without suitable software, the above developed and chosen devices cannot perform any of their functions. It is therefore important to select or develop this software.

4.6.1 Discover

The functions of 1) communication, 2) outcome measurement, 3) electronic patient file, 4) providing information and social support, 5) exercise games and 6) biofeedback will have to be provided by the software. For the patient device this software should run on an android tablet, for which there is a large supply of applications easily available through the google “play store”. Most of these “apps” are free, a considerable advantage for a low cost TR platform.

A RTVC app will be needed that works on both patient- as well as therapist-devices. For use in practice the communication should be safe and private. Therefore such an app should use the xmpp protocol as this offers these properties. The second function, outcome measurement, was found to require both quantitative as well as patient reported measures in chapter 3. Because of this, applications that allow for

quantitative data collection using the CLEG will be needed, as well as apps for the OKS and EQ5D. These apps should run on the patient device, and their data needs to be communicated to the therapist device from where it would be stored in an EPF. This EPF should be safe, sensitive to privacy and comply with laws (phase 4 barriers), and needs to run on the therapist device. The therapist could then send updates to the patient, although it would be preferable if the EPF was accessible from the patient device too. Providing information was shown beneficial in long term conditions. This could be provided in the form of a function where information can be provided to the patient by the physiotherapists. Social support is also beneficial and a forum of sorts where patients can discuss amongst themselves or with their family by leaving messages on a message board would also be valuable. This rehabilitation social network needs to be accessible to patient devices. The function of exercise games, games that use an exercise as input, would need a game that runs on the patient device and can use knee extension and flexion as measured by the CLEG as input. Biofeedback would have to be provided by an app, also running on the patient device, and giving feedback on performance. This feedback is known to work well when a stick-figure and colour changing joints to indicate performance are used to give patients insight into their movement patterns (MacDonald et al. 2010).

4.6.2 Define

The CLEG software is very specific to this project and hence will have to be made. Concerning the software to be used on patient or therapist device, existing software may be used. The play store was searched for apps that are suitable for use; communication (RTVC) should be done using the xmpp protocol. Currently, there is an app in development (Jitsi) enabling xmpp RTVC between the patient device running the Android OS, and therapist device running Windows. Unfortunately, at the time of writing there was no stable version released yet. So Skype will be used instead for the usability studies, as it can provide the cross-platform functionality (it works between an Android and a Windows device) that is needed. It is known that Skype does not meet the

requirements of data security, however these apply to barriers in the final development phase and will be tolerated during this first phase of development.

Outcome measurement will involve the CLEG, for this, a data collection and communication app will be needed. This communication is here done by using e-mail as it would allow the TR platform to benefit from the inbuilt security of e-mail providers, and it is a mode of communication that will be easy to implement into AHP services' organisation. Also this would ensure that the therapist is in control of what happens to that data, helping to overcome professional possessiveness. An app that was able to do this was found in "ColorNote", this app that accepts keyboard entries and has a built in e-mailing function, see figure 4.26 for a screenshot. The inbuilt function allows users to select their preferred e-mailing app, here Google's Gmail is used.

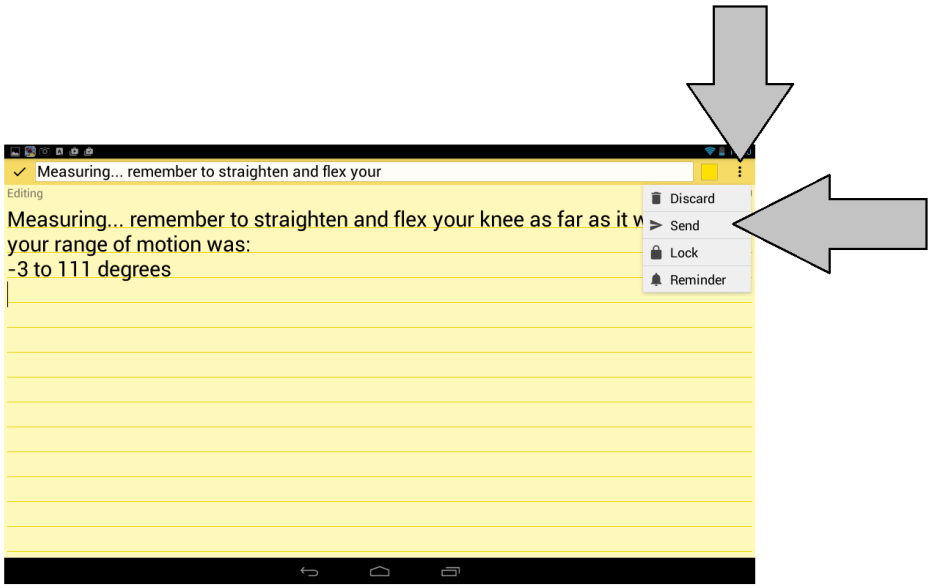


Figure 4.26. The ColorNote app with inbuilt e-mailing functionality.

Another form of outcome measure are patient reported ones, giving an insight into quality of life and perceived function. The OKS complemented by EQ5-D was found best suited for the task, however, no apps could be found. Instead these questionnaires could be administered by e-mail or an app could be made for them. This is straightforward but because of time restraints this will not be a part of this work.

The electronic patient file needs to be accessible from the therapist device and should be safe, sensitive to privacy and comply with the law (phase 4 barriers). For these barriers, the literature review of chapter 2 revealed cooperation as a possible solution. Therefore cooperation was sought with a manufacturer of electronic patient files that would run on a Windows PC (the therapist device). Data could be communicated via e-mail and then entered into the patient file. Using the EPF would enable keeping track of progress, as therapists could e-mail progress reports based on the EPF to their patients.

Information too, could be sent to patients via e-mail. The social support that is needed might be provided using a rehabilitation social network. For now, a well-known cross platform social networking site, Facebook, will be used although this will likely need to be changed in the future in order to comply with data security.

A potential candidate for an exercise game was found in a helicopter game called "C.H.O.P.S.". This game uses only one input signal to control the height of a helicopter on the screen. Whilst flying forward, the helicopter has to be lowered or heightened to avoid hitting obstacles and collect coins. The CLEG can serve as input device for this game, translating a high knee flexion to a descending helicopter and a low knee flexion to an ascending one. Please see figure 4.27 for an impression of this game.

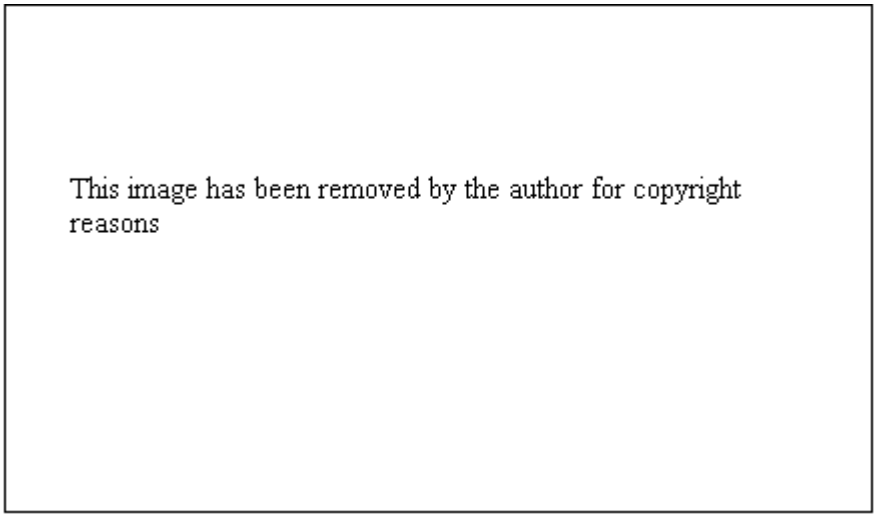


Figure 4.27. The helicopter must be steered clear of obstacles.

Concerning Biofeedback no app could be found. This means that one will have to be made in the second diamond of the design process.

In the second diamond of the software design process, a central TR portal should be made as well. This front page would direct users to the various apps in a way that optimises usability among older adults. In this way all the apps could be made into a whole rather than a loose collection of apps. This approach is also believed to aid flexibility when compared to one TR application with the sub-functionalities "hard wired" in, as with this modular approach every app can be exchanged separately. If the aforementioned cross platform xmpp RTVC app for instance becomes available, it could be swapped in favour of Skype with very little effort.

4.6.3 Develop

CLEG

The CLEG's software needs to translate the values read in from the potentiometers to knee angles using the calibration formulae, and communicate them to various apps. The frequency with which the potentiometer values are sampled is set using one of the microcontroller's pulse width modulated digital outputs and a digital input. Set at 50% duty cycle and 490Hz, the rising edge of the output pin signal was detected using the digital input pin and the following code.

Code section 1

```
1 Clockvalueold = Clockvalue;
2 Clockvalue = digitalRead(clockPin);
3 if (Clockvalue>Clockvalueold) { Clockcounter++;}    //rising edge
4 if (Clockcounter > 4){Clockcounter=0; code here}    //98Hz, 5 clicks
```

For validation purposes, the main part of the CLEG software is then executed in the "if" loop of line 4; when the "Clockcounter" reaches 5, the counter is reset and the

code is executed; all parameters the CLEG has determined are output serially. Because 490Hz/5=98Hz, this happens at a frequency of 98Hz.

After sampling the potentiometer values, the values from the two potentiometer calibration curves are used to determine which of the calibration polynomials is used to translate the digital readings of the potentiometers into an angle. Summating the angle for both potentiometers produces the knee angle, see code section 2.

Code section 2

```
1 if (Lowerpot == 505){Lowerangle=0;}
2 if (Lowerpot>505){
      Lowerangle=-0.00004*Lowerpot*Lowerpot-.214*Lowerpot+118.36;   }
3 else if (Lowerpot<505){
      Lowerangle = 0.00005*Lowerpot*Lowerpot-0.3036*Lowerpot+140.31; }
4 if (Upperpot == 520){Upperangle=0;}
5 if (Upperpot>520){
      Upperangle = -0.00006*Upperpot*Upperpot-0.184*Upperpot+111.5 ; }
6 else if (Upperpot<520) {
      Upperangle = 0.00005*Upperpot*Upperpot-0.3*Upperpot+142.3 ; }
7 Kneeangle = -1*Lowerangle + Upperangle;
```

The CLEG software then needs to communicate these knee angles to the helicopter game, to the biofeedback app, and to the data collection and e-mailing app. The game that was chosen uses one input signal. In the original game, tapping of the screen is used to control helicopter height. The higher the proportion of time that the screen is being tapped, the higher the rate of climb of the helicopter. To serve as this input for the game, the CLEG knee angle will be used. The biofeedback app on the other hand needs two input signals; knee angle and thigh orientation in order to represent both. To enable communication with both apps, a function was written that makes the microcontroller in the CLEG behave like a mouse, see code section 3.

Code section 3

```
1 Mouse.press();
2 Mouse.move(KneeAngle,ULAngle,0);
3 delay((90-KneeAngle));
4 Mouse.release();
5 Mouse.move(-KneeAangle,-ULangle,0);
6 delay(KneeAngle);
```

By simulating a mouse who's button is pressed for an amount of time measuring 90ms -KneeAngle (lines 1 and 3) the games input function can be accessed at a frequency of 10 Hz, set using the "Clockcounter" from code section 1. As clicking of the mouse is analogous to tapping the screen in Android, the amount of time that the game believes the screen is being tapped decreases if knee flexion increases. Then the mouse button is released, and there is a delay of an amount of milliseconds proportional to the knee angle (lines 4 and 6), increasing the amount of time the screen is not being tapped as a result of increasing flexion. Thus the ratio of tap/ no tap decreases with increasing knee flexion, and the helicopter goes down. When the knee is extended, flexion decreases, the opposite will happen and the helicopter goes up. In order to provide the two input signals for the biofeedback app, the mouse also has a simulated movement between pressing and releasing the button, like a mouse drag. After pressing the button, the mouse is moved horizontally (left) by an amount of KneeAngle, and vertically (up) by an amount of ULAngle (line 2). After the button has been released, the mouse is moved back to its starting position (line 4).

For the data collection and e-mailing app, the CLEG was fitted with a selection switch that enables its data to be sent not by emulating a mouse, but a keyboard. During the health professional interviews (Chapter 6) it became clear that therapists do not want to spend their time analysing data, and that an activity recognition function may be useful. Therefore the CLEG software calculates the relevant parameters such as range of motion and number of repetitions in real time at a frequency of 98Hz, and when the measurement is ended outputs the data by emulating a keyboard. Apart from range of

motion, the CLEG also determines what sort of activity was performed, using a simple algorithm that uses the maximal thigh orientation and maximal knee flexion as input to calculate an activity recognition index (ARI), see code section 4.

Code section 4

```
1 if (Kneeangle > MaxKnee)
      {MaxKnee=Kneeangle;}
2 if (Hiporientation > MaxHip)
      {MaxHip=Hiporientation;}
3 if (Kneeangle>50)
      {Flag=1;}
4 if (Kneeangle<20)
      if (Flag==1)
      {Rep=Rep+1; Flag=0;HM=MaxHip; KM=MaxKnee;  MaxHip=0; MaxKnee=0;}

5 ActRec=HM/KM;
6 Keyboard.println("your range of motion was:");
7 Keyboard.print(Minknee);
8 Keyboard.print(" to ");
9 Keyboard.print(Maxknee);
10 Keyboard.println(" degrees");
12 Keyboard.println("repetitions:");
13 Keyboard.print(Rep);
14 Keyboard.println("ARI:");
15 Keyboard.print(ActRec);
```

Typical activity recognition methods employ one wearable accelerometer and, depending on the body segment this is attached to, can provide insight into rehabilitation progress, postural sway, detection of falls, energy expenditure, postural position and aid management of for instance obesity and cardiovascular disease, but lack information about joint kinematics (Mannini et al. 2013)(Yang & Hsu 2010). The activity recognition method described above does provide information about the joint kinematics, and would allow activities such as sit-to-stand and squatting to be recognised, and enable remote monitoring of functional strength found desirable in the

interviews with physiotherapists described in chapter 6. The ARI is calculated every time there is a maximum in the knee flexion value, determined by the knee flexion value exceeding 30° and the value subsequently falling below 20° again. This means activity can be recognised per repetition, provided a repetition involves at least 30° knee flexion and returns to below 20°. Although this method may well require refining in the future, it enabled the feasibility of the ARI to be investigated as a single step, squat, or sit to stand can be recognised instead of assigning an activity to a time period. For movement intensity to be determined the time it takes for a repetition to be completed may be used. In this way for instance a 5 times sit to stand test could be performed, or energy expenditure assessed, but this was not a part of this feasibility study.

Patient device

The previous design stage showed that for most functions a suitable app could be found, not so however for biofeedback. Therefore a prototypal biofeedback app was made using the Eclipse Integrated Development Environment (IDE) 4.3 for Java. The CLEG mouse-drags are used as input to draw the lines representing upper and lower leg. Depending on the value of the knee angle, the knee joint is drawn as a red, yellow, or green circle, see figure 4.28.

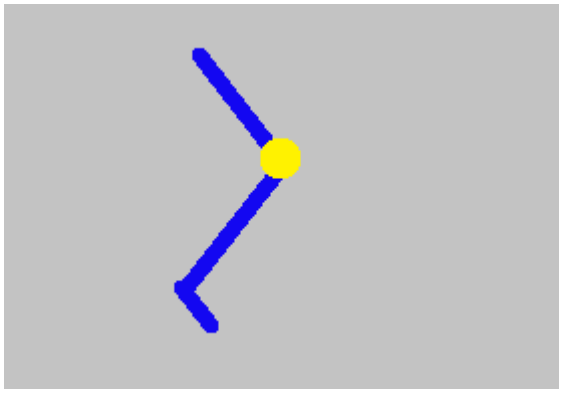


Figure 4.28. Biofeedback.

Like the biofeedback app, the portal app cannot be found on the play store and so will be made, again using the Eclipse IDE. As older adults are more likely to be suffering from deteriorations in motor skills, visual acuity and hearing, ensuring usability poses challenges for the software design. Also reductions in memory and attention, as well as an increase in computer anxiety are known to occur. Therefore, special considerations were given to human factors in the design of the portal.

A simple menu structure was created using large buttons. Highly contrasting colours were chosen to create the monochrome menu structure; blue and white. Any writing in the menu uses capitalised words, and the number of options in the menu was limited to 6. The number of layers in a menu was limited to 2, to accommodate reduced attention and memory skills. Recommendations in terms of button sizing for older adults were adhered to, ensuring they are at least 20mm square and there is 3.17 to 12.7 mm space between them (Caprani et al. 2012). Providing some form of feedback upon pressing, either haptic, visual, or auditory, can assist interaction with computers and compensate for age related impairments (Jacko et al. 2004) (Lee and Zhai 2009). For this reason a visual feedback on touch option was activated in Android. See figure 4.28 for an impression of what the visual aspect of the portal app looks like. By navigating the menu structure presented by the portal app, the substituent apps such as the game, or biofeedback app are launched. As can be seen from figure 4.28, this version of the Portal has a navigation bar, to let users know where they are in the program and aid their memory. The programming languages used for this are XML for the layouts and JAVA for the actual programming, please see code sections 5 and 6 for an impression of XML and JAVA respectively.

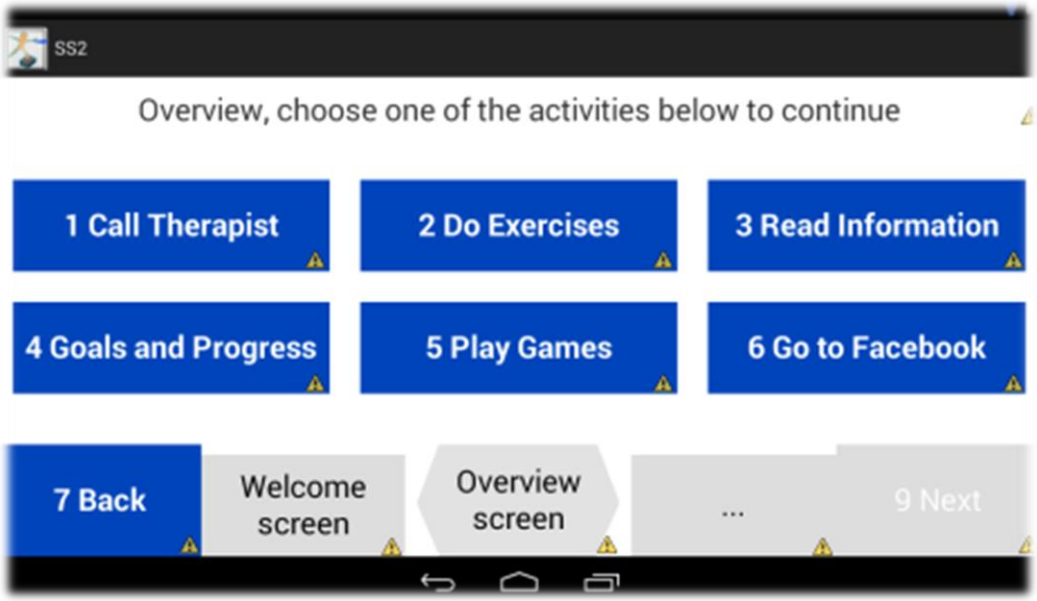


Figure 4.29. The portal.

Code section 5

```
<TableLayout xmlns:android="http://schemas.android.com/apk/res/android"
    xmlns:tools="http://schemas.android.com/tools"
    android:layout_width="match_parent"
    android:layout_height="match_parent"
    tools:context=".WelcomeScreen"

    android:gravity="bottom"
    >

    <TextView
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:text="Overview, choose one of the activities below to
continue"
        android:gravity="center"
        android:textSize="30sp"
        android:layout_marginTop="15dp"

        />

    <TableRow
        android:id="@+id/tableRow1"
        android:layout_width="match_parent"
        android:layout_height="match_parent"
        android:layout_weight="2"
        android:gravity="bottom"
        android:paddingTop="50dp"
```

```
        >

        <Button
            android:id="@+id/button1"
            android:layout_width="0dp"
            android:layout_height="match_parent"
            android:text="1 Call Therapist"
            android:textSize="30sp"
            android:textStyle="bold"
            android:textColor="@color/white"
            android:layout_weight="1"
            android:background="@color/buttonVisible"
            android:layout_marginLeft="15dp"
            android:layout_marginRight="15dp"
            android:gravity="center"
            />
```

Code section 6

```
package com.example.ss2;

import android.app.Activity;
import android.content.Intent;
import android.os.Bundle;
import android.view.Gravity;
import android.view.KeyEvent;
import android.view.Menu;
import android.view.View;
import android.widget.Button;
import android.widget.Toast;

public class WelcomeScreen extends Activity {

      @Override
      protected void onCreate(Bundle savedInstanceState) {
            super.onCreate(savedInstanceState);
            setContentView(R.layout.activity_welcome_screen);

            //create Button called button1 R. indicates a resource
                        final Button button1 =
(Button)findViewById(R.id.button1);
                        final Button button2 =
(Button)findViewById(R.id.button2);
                        final Button button3 =
(Button)findViewById(R.id.button3);
                        final Button button4 =
(Button)findViewById(R.id.button4);
                        final Button button5 =
(Button)findViewById(R.id.button5);
```

```
                        final Button button6 =
(Button)findViewById(R.id.button6);
                        final Button button7 =
(Button)findViewById(R.id.button7);
                        final Button button8 =
(Button)findViewById(R.id.button8);
                        final Button button9 =
(Button)findViewById(R.id.button9);
                        final Button button10 =
(Button)findViewById(R.id.button10);
                        final Button button11 =
(Button)findViewById(R.id.button11);


            button1.setOnClickListener (new View.OnClickListener() {

                                @Override
                                public void onClick(View v) {
                                      Intent intent1 = new
Intent(WelcomeScreen.this, Messages.class);
                                      startActivity(intent1);

                                }
            });          //end onclick listener
```

4.6.4 Deliver

In this stage, the software will be finalised. The CLEG software performed as expected, and no changes to it were made. For the biofeedback app a more detailed stick figure application was made showing orientation of both upper and lower leg whilst simultaneously presenting the knee angle numerically. The stick figure is drawn on the screen according to the thigh orientation and knee angle. Depending on whether the user chose to have biofeedback for exercises where the foot is kept on the ground, or for exercises where the foot is lifted off the ground, the figure is drawn starting from the hip or starting from the foot. If "foot on ground" is selected, the foot does not move and the rest of the stick figure is arranged to represent the thigh orientation and knee angle. When "foot off ground" is selected the figure's hip does not move and the foot can move across the screen freely. See figure 4.30 for an impression of this biofeedback application.

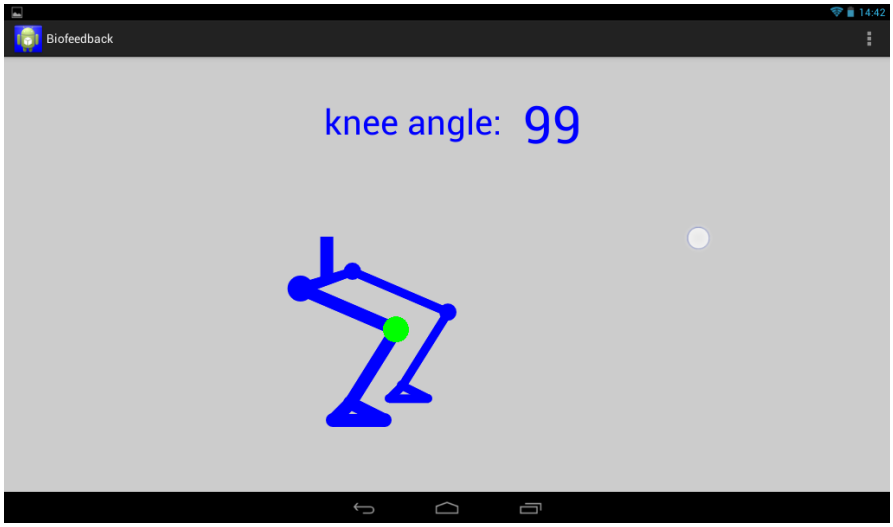


Figure 4.30. The biofeedback application.

For the portal app, the deliver stage focussed on making the app simpler. The welcome screen was removed, as it was an extra step that was not necessary. The navigation bar was removed as well as there is a navigation bar built in in Android which can be seen in the bottom of figure 4.31. This leaves just one screen with six buttons, leading to the substituent apps.

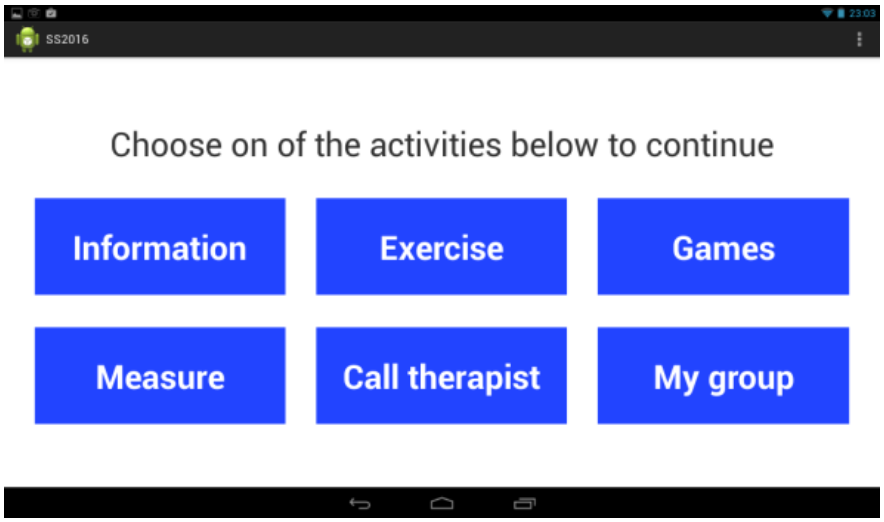


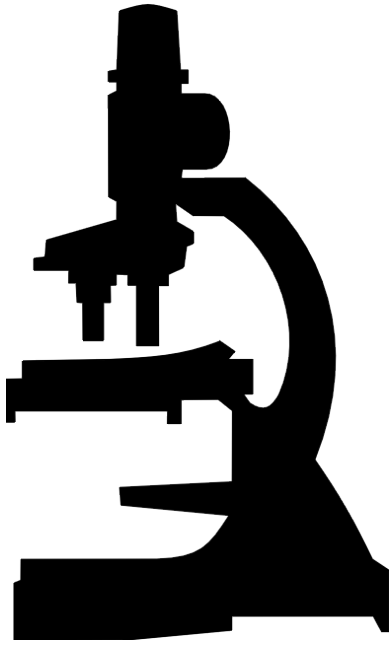
Figure 4.31. The portal application.

Conclusion

The design delivers the functions of communication, outcome measurement, electronic patient file, information and social support, exercise games and biofeedback. It also ensures the properties of low cost with roughly £97 for the CLEG and £100 for the tablet, flexibility because of the modular approaches in software and hardware, and quality because of the use of off the shelf products where possible. Whether or not the additional properties of usability, and requiring minimal training and technical support are met by the design will be investigated in Chapter 6. But first, Chapter 5 will investigate performance of the CLEG.

Chapter 5

Chain linked electro goniometer tests



5.1 Introduction

The first chapters have provided the rationale for a TR platform and outlined the design specifications. The following chapter focussed on design with the final version providing all desired functions. A prototype of the TR platform was then presented to AHPs who indicated that activity recognition was a desired function for the CLEG, see chapter 6 for details. This and other functions required further testing in healthy participants to confirm the desired performance in terms of long term use, robustness, validity, reliability, sensitivity and that, above all it is safe to use. This chapter describes these tests.

5.2 Bench tests

5.2.1. Drift

In order to assess the general performance, first a drift-test was performed on one CLEG that was positioned in 0° and powered on. Ten seconds after power on, data were collected for 1 hour with the CLEG outputting its reading to a computer at a rate of 10Hz, see figure 5.1.

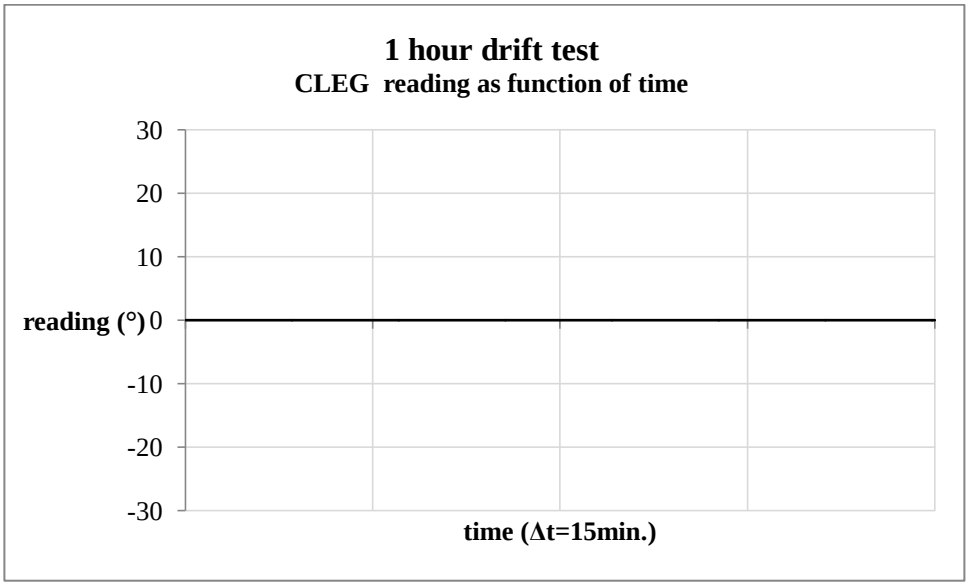


Figure 5.1. 1 hour drift test.

No sign of drift could be found within the one hour period. Although no standard test could be discovered, there are various ways of quantifying drift, for instance by testing departures from the null hypothesis of no drift with a t-test (Busetti and Harvey 2002). However the CLEG results did not deviate from the initial one at all, so whatever method is used to quantify drift, the result would be 0.

5.2.2. Electromagnetic interference

As the TR platform progresses through the development phases and reaches the fourth phase of implementation, cooperation with various parties would become necessary to ensure that it meets all relevant norms, rules, laws and regulations. When it comes to electromagnetic interference, the norm that the CLEG would have to adhere to would be EN 55 011, depending on whether it would be classed as a medical device. As mentioned before, this work is limited to phase 1; developing a prototype of the technology with all the required properties and functions. Nonetheless a rudimentary test into whether or not the CLEG is sensitive to electromagnetic interference was tested by placing it beside an electric power drill (Bosch PSB 650 RE). Data were collected for 1 minute whilst the drill was powered on and off in a pattern of on for 6 seconds, then off for 6 seconds. The drill was held beside the potentiometers, as well as beside the box housing the microcontroller and accelerometer and no artefacts could be discovered in the potentiometer or accelerometer signals being output to a computer at 98Hz.

5.2.3. Agreement with set angles

A comparison against set angles was performed using an angle setting jig that could be set to within 1°. The three CLEGs were consecutively attached to the jig and moved over the range of -150° to 150° and then back from 150° to -150°, in increments of 10 degrees. Figure 5.2 shows a CLEG attached to the jig in both 90° and -150°. There were a total of 61 values generated by each CLEG in this way, making for a total of 183

values generated as each of the three CLEGS was tested. These values are presented as a function of the set angles in figure 5.3.

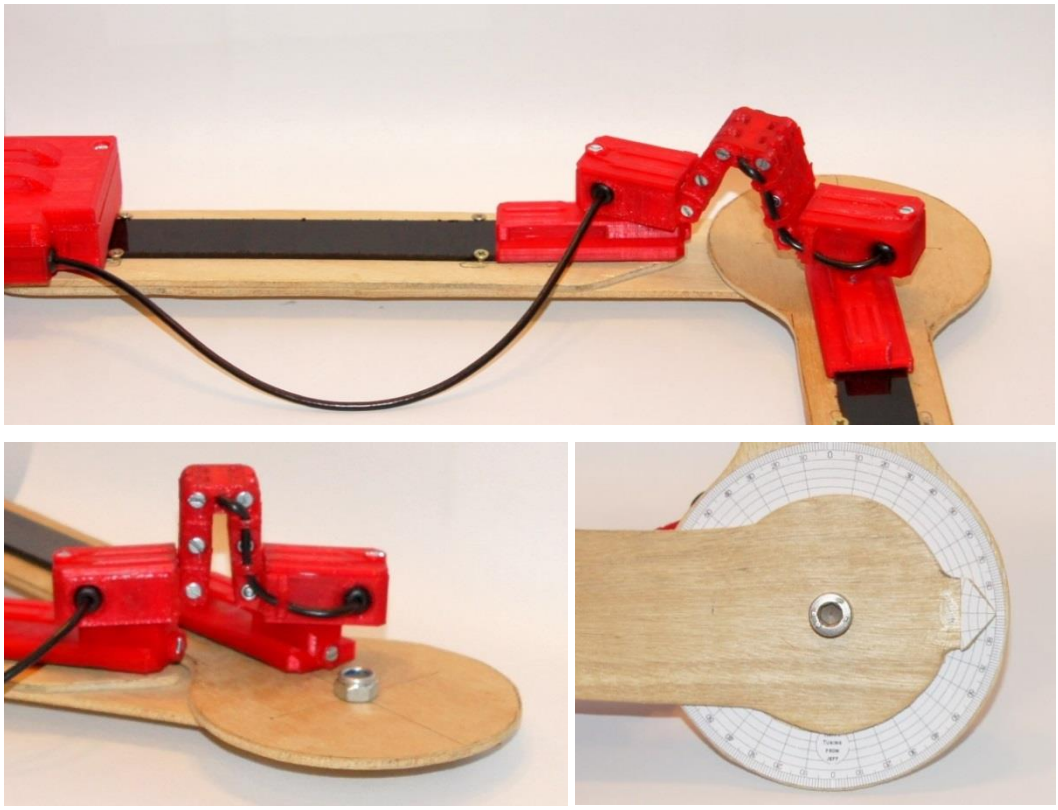


Figure 5.2. CLEG attached to the angle setting jig.

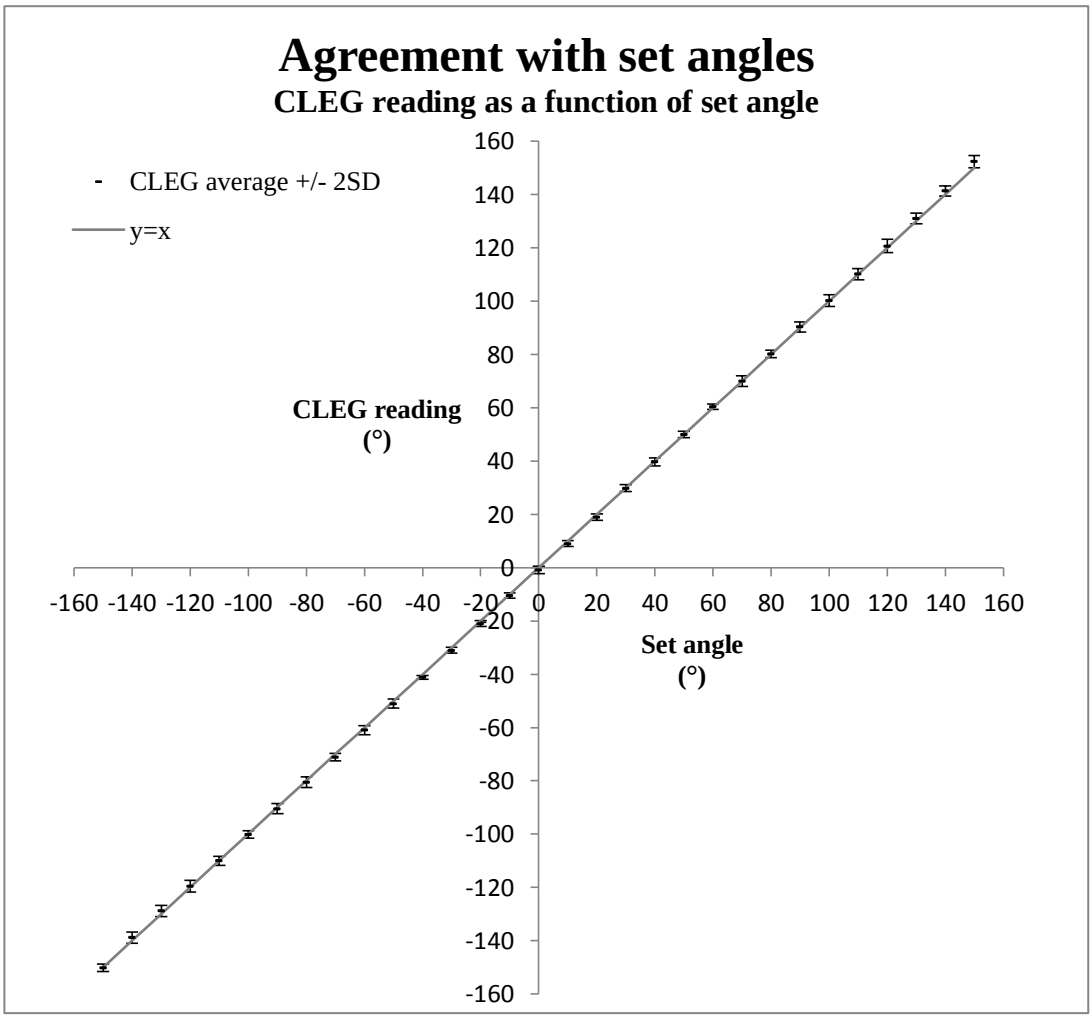


Figure 5.3 CLEG values relative to set angles, +/- 2SD.

For the values collected, the largest error between the CLEG reading and the set angle was 3°. Deviations of this magnitude were not frequent, hence the RMS error was just over 1° for each CLEG. The Red CLEG scored 1.09°, the Green one1.11° and the Blue one 1.06°. Relative non linearity in the CLEG readings was quantified using the methodology proposed by Emancipator and Kroll 1993; the RMS error is divided by the difference between maximum and minimum assayed values. This results in a relative non linearity of 0.37% or better for the tested CLEGs. As evidenced by the small RMS errors, any hysteresis effects are small and are not investigated further.

5.2.4 Robustness

Robustness testing is a field of testing involving various different tests to ensure that an instrument or device performs its intended function regardless of exceptional inputs or exposure to stressful environmental factors that may be encountered during use. To test robustness of the CLEG comprehensively would be development phase 4 work, where the platform as a whole needs to be made to meet all norms and standards and cooperation with various parties, including robustness testing professionals, would be required. Nonetheless, in this phase 1 work the CLEG's robustness was investigated by dropping one cleg onto concrete from a height of 1m as this was believed to be the most common stressful environmental factor. After the fall, The CLEG did not show any signs of damage and functioned as before.

5.3. Participant tests

5.3.1. Objectives

The objectives of this investigation are to:

A) Indicate whether or not the CLEG influences knee kinematics during gait in order to ensure that it is safe to use.

B) Quantify how closely the CLEG results agree with those of stereo-photogrammetry in order to assess validity of the goniometer.

C) Determine if the CLEG produces the same results after re-attaching, test-re-test reliability. Also, determine if the CLEG is sensitive enough to detect clinically relevant differences.

D) Determine if the CLEG produces the same results when attached by the participant over trousers.

E) Investigate the feasibility of the activity recognition algorithm.

5.3.2. Methods

Ethical permission to conduct the study was sought from the departmental ethics committee and awarded under reference DEC/BioMed/2016/76. Twelve healthy participants without any known issues leading to altered gait or squatting knee kinematics or any possibility that the participant may be pregnant were then recruited.

The average age for these participants was 26.5 +/- 5.3 years, 8 participants were female and 4 were male. After receiving the information sheet they were given at least 24h before consent was requested. Participants were asked to change into tight fitting cycling shorts and their own top, and using skin friendly hypoallergenic double sided tape, were fitted with reflective markers to key anatomical landmarks in accordance with Vicon's plug in gait model, see figure 5.4. Subjects were allowed to wear their own socks and shoes.

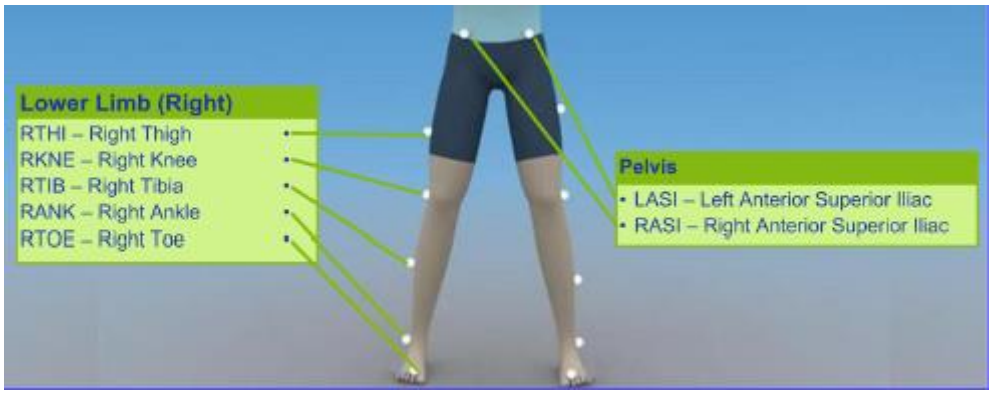


Figure 5.4 Lower limb marker placement. Not pictured are two more markers placed on the right and left posterior superior iliac spine.

The Vicon system used consisted of six T40 cameras and six T160 cameras, coupled to the Nexus 2.3 software. Sampling rate was set at 100Hz and trajectories were filtered using a Butterworth filtering routine.

The participants were first asked to walk for a short distance of about 6 metres, the condition called "walking normal" (**WLN**). The researcher then attached the CLEG to the participant's leg using Velcro straps. Because proper placement of the CLEG would interfere with the Vicon markers, it was attached at a slight offset. Again, the participant walks around 6 metres. This condition is called "walking with goniometer"

(**WLG**), see figure 5.5 for a picture of the CLEG and reflective markers attached to the researcher wearing cycling pants, socks and shoes.

Figure 5.5 Goniometer and reflective markers as they are attached to participants.

The participant was then asked to perform a deep squat twice, pausing for 3s. at what he or she estimates to be 30°, 60°, 90°, 120° and maximum flexion. The researcher demonstrated one such squat, and instructed the participant to "squat to 30° and pause", "squat to 60°and pause" etc. without feedback on their performance. This was called squatting (**SQ1**). The participant is then given a 45cm high stool to sit down on, and asked to stand up, and sit down again for three times, called sit to stand 1 (**SS1**). The CLEG is now removed, and re-attached by the researcher after 1 minute. Following this, the participant is asked to repeat the squatting movement twice, called squatting 2 (**SQ2**). The CLEG as well as the reflective markers were then removed and the participant got dressed, after which the participant is asked to attach the CLEG themselves over his/her trousers, and again perform the sit to stand exercise twice, (**SS2**).

Data analysis

A) Vicon **WLN** vs **WLG** data was analysed and maximum flexion and minimum flexion from one randomly selected stride in WLN is compared to the matching one in WLG. Data were tested for normality using scores of skewness and kurtosis calculated using IBM SPSS23 which was used for all statistical testing hereafter. If normality was found, data were tested for statistically significant differences (α=0.05) using paired t-tests, in the absence of normality a non-parametric test was used.

B) Vicon **SQ1** and **SQ2** were compared to CLEG **SQ1** and **SQ2**. Data was extracted from the kinematics in the middle of a stable period in every instructed flexion range. Because of the offset with which the CLEG was attached, CLEG data were corrected for the offset to agree with Vicon when the participant was standing (0° knee flexion). The method of comparison proposed by Bland and Altman in 1999 was used and does not require normality. Heteroscedasticity of the data was checked visually. The data were then analysed and 95% limits of agreement (LOA) were calculated. Data from **SS1** were also assessed to inform whether a lack of agreement can be explained by soft tissue artefacts (STA) known to be an issue for the Vicon. One randomly selected Vicon ROM between standing and sitting, and the matching CLEG one will be analysed for each participant.

C) CLEG **SQ1** vs CLEG **SQ2** maximum flexion angles were compared and the differences between them tested for normality. The SEM was then calculated as the RMS average of the SD between measurements in order to assess repeatability after re-attaching. The minimal difference needed to be considered real was then calculated to inform on the CLEG's sensitivity.

D) CLEG **SS1** ROM between standing and sitting from one randomly selected sit to stand was compared with a matching CLEG **SS2** value and, after normality has been confirmed, paired t-tests were used to see whether there was a significant difference if the CLEG is attached by the participant over trousers, rather than by the researcher over cycling shorts.

E) Maximal thigh orientation and knee flexion was determined from the CLEG data during walking (**WLG**), sit to stand (**SS1**), squatting to an instructed 30° (**SQ1** 30) and

maximal squatting (**SQ1** max). Using this data, the activity recognition index (ARI) was calculated using the maximal thigh deviation from vertical divided by maximal knee flexion for every repetition of a certain movement. The second repetition's values were then tested for normality and sphericity and analysed using a one way repeated measures ANOVA to determine if the ARI was significantly different between the activities. A Bonferroni post hoc test was employed to indicate which activities could be considered significantly different as this method guarantees control over the production of type 1 errors. Knee flexion was defined in section 3.2.2 as being zero when the shafts of femur and tibia are parallel to one another, see figure 5.6 for an illustration.

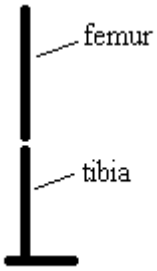


Figure 5.6. The definition of zero knee flexion is when the shafts of femur and tibia are parallel.

5.3.3. Results

A) Data from two participants could not be analysed due to marker occlusion in one case and knee axis alignment issues for the Vicon system in the other. The 10 datasets were analysed for minimal flexion angle around heel strike and maximum flexion angle around mid swing using Miscrosoft Excel 2010. See figure 5.7 for a typical graph.

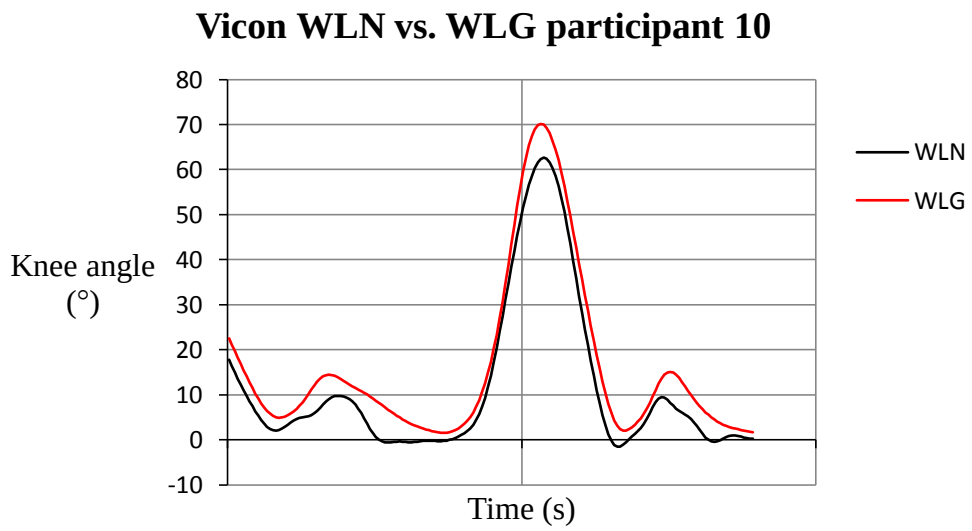


Figure5.7. Participant no.10 Vicon data.

The resulting minimal and maximal flexion angles are presented in table 5.1.

Table 5.1. Vicon knee flexion angles for WLN and WLG.

	min knee angle (°)		max knee angle (°)	
participant	WLN	WLG	WLN	WLG
1	2.7	4.8	70	69.7
3	5.7	4.8	67.6	64.9
5	1.9	6.8	60.5	63
6	16	16.1	73.7	70.5
7	1.2	-9.2	77	69.5
8	-2.2	-5.2	56.9	55.3
9	-2.9	-2	70.9	76.2
10	-0.6	1.5	62.6	70.2
11	-0.2	10.2	54.1	60
12	0.2	0	65.2	65.1
mean	2.18	2.78	65.85	66.44
SD	5.17	7.04	7.00	5.72

The data were found to be normally distributed. WLNmin versus WLGmin was paired t tested for a difference of means, as was WLNmax versus WLGmax. Both tests did not achieve significance at p=0.73 for WLNmin versus WLGmin and p=0.701 for WLNmax versus WLGmax (n=10).

B) The squatting data from two participant's proved unanalysable due to Vicon marker occlusion. The remaining 10 participant's data was plotted, see figure 5.8 for a typical graph, and data extracted from the middle of the stable period in every instructed knee flexion range. This data is presented in table 5.2. Note that for two of these ten participants (numbers 3 and 6) not all instructed knee flexion angles could be analysed due to Vicon marker occlusion at higher knee flexion angles. As can be seen from figure 5.8 the knee flexion angle determined by Vicon is less than that determined by the CLEG. As the drift test indicated zero drift, any effect of time can be excluded, moreover it is known that stereo photogrammetry underestimates knee flexion angles during activities such as sit to stand due to soft tissue errors. For this reason CLEG will be compared to Vicon during sit to stand.

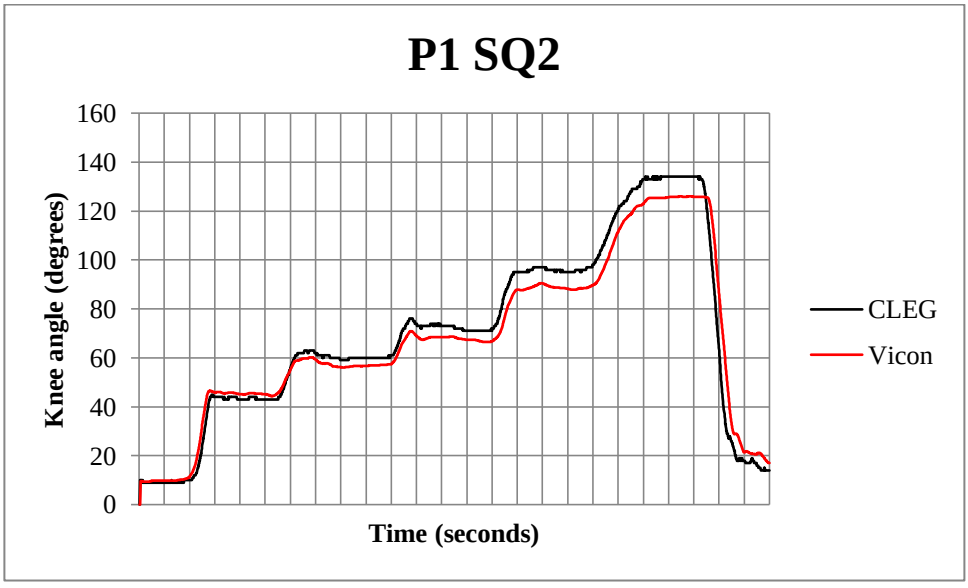


Figure 5.8. a typical graph of CLEG vs Vicon knee kinematics during squatting.

Table 5.2. Squatting data for CLEG and Vicon.

participant no.	instructed knee flexion (°)	CLEG SQ1 (°)	Vicon SQ1 (°)	CLEG SQ2 (°)	Vicon SQ2 (°)
1	0	12	9.9	9	9.8
	30	41	42.1	44	45.6
	60	53	52.2	61	57.9
	90	76	72.8	71	67.4
	120	95	88.6	95	88.6
	max	130	122	133	125.2
3	0	-12	-5.5	-13	-7.1
	30	54	61.9	61	67.7
	60	89	95.9	92	98.9
	90	117	124.5	117	123.6
	120	135	141.3	134	139.4
	max	151		151	
5	0	19	12.7	16	6.8
	30	68	62.7	67	59.8
	60	87	83.3	83	76.1
	90	108	103.8	101	97.6
	120	122	119.3	118	116.5
	max	145	139.2	132	131
6	0	25	9.6	19	11.1
	30	82	62.2	80	66.7
	60	101	82.1	100	86.4
	90	125		124	113.6
	120	139		138	
	max	169		163	
7	0	5	2.7	7	2.3
	30	47	36.8	50	37.1
	60	71	51.3	73	51

	90	97	74.8	94	70.6
	120	134	117.2	124	102.5
	max	150	137.6	149	131.3
8	0	-2	-6.3	-2	-6.3
	30	48	35.1	49	40.6
	60	74	57.7	78	66.4
	90	91	78.7	100	89.7
	120	113	106.6	116	110
	max	135	132.6	142	138.3
9	0	3	-6.6	-2	-4
	30	64	52.6	41	41.6
	60	85	76.3	66	70.3
	90	106	101.2	84	90.8
	120	142	141.9	111	121
	max	147	153.6	136	155.1
10	0	-7	8.4	-9	3.6
	30	52	68.1	59	76.8
	60	64	81.7	72	90.2
	90	79	95.5	90	108.4
	120	93	109.9	105	124.3
	max	136	148.4	132	150.8
11	0	-3	-2.2	7	-0.7
	30	46	43.6	62	38.8
	60	71	64.3	90	76.1
	90	105	109.8	113	117.8
	120	130	142	132	146.1
	max	144	157.8	155	162.5
12	0	19	8.7	16	5.4
	30	59	44.2	55	38.7
	60	80	63.3	85	67
	90	95	77.5	97	76.8
	120	114	93	112	89.5

max	150	129.6	151	130.8

The CLEG data from table 5.2 was then corrected for offset so that it agrees with Vicon when standing (0° knee flexion) and used to plot the difference between the two readings as a function of the average of the two, known as a Bland-Altman plot, depicted in figure 5.9. The mean of these differences was found to be -1.4°, indicating that over the 10 participants and all instructed knee flexion angles the CLEG results were larger than those of Vicon by an average of 1.4°. The SD of the differences was 8.4°, leading to 95%LOA of -17.9° and 15.1°, calculated as mean +/- 1.96 SD.

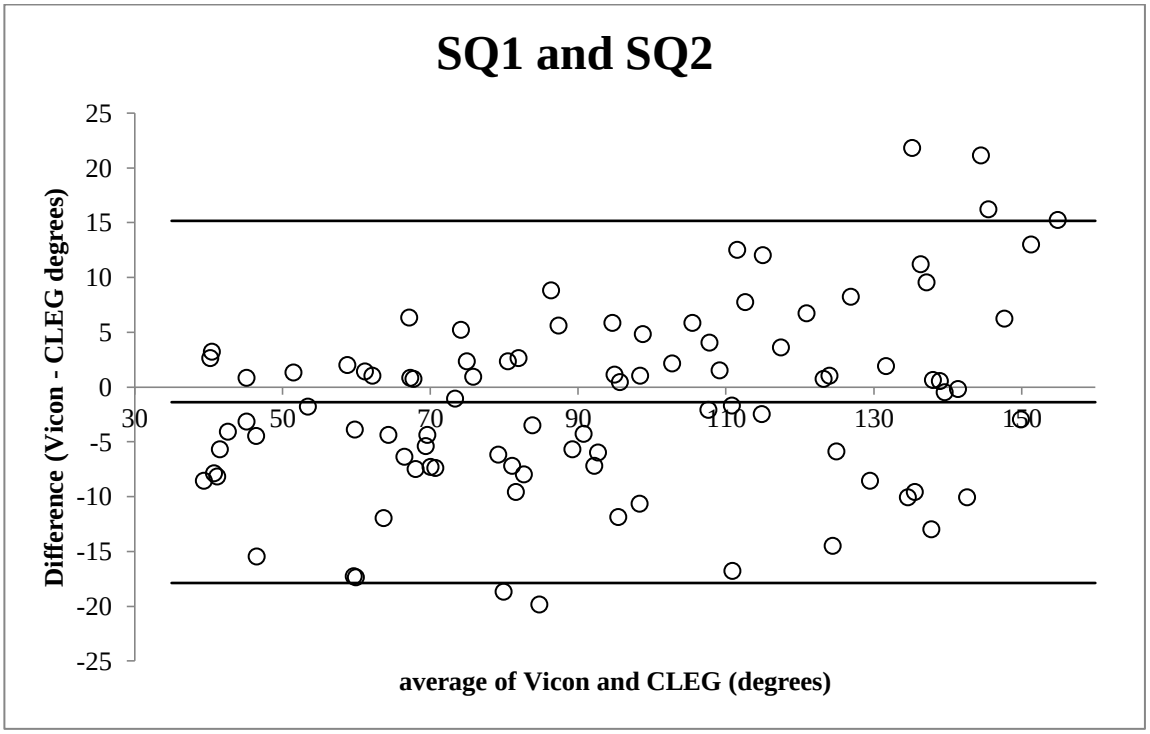


Figure 5.9. Bland Altman plot of the squatting data.

To indicate whether the lack of agreement can be explained by soft tissue artefacts, CLEG and Vicon data from **SS1** was plotted, see figure 5.10 for an example.

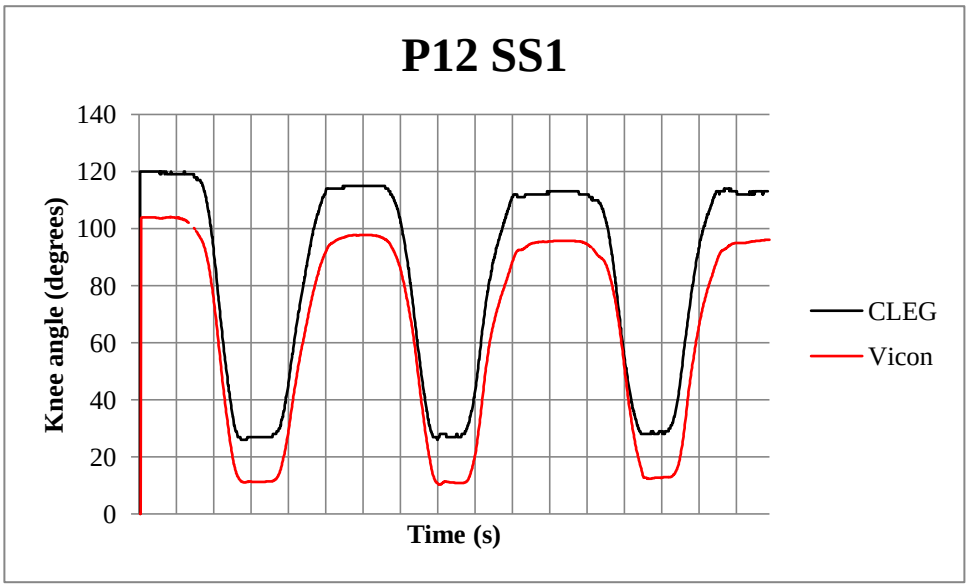


Figure 5.10. typical graph of a sit to stand movement concurrently measured by CLEG and Vicon.

ROMs were determined for all participants except two who proved unanalysable due to marker occlusion, and listed in table 3. The average ratio of Vicon ROM / CLEG ROM was 97.7% with an SD of 7.2% (n=10).

Table 5.3. CLEG vs Vicon STS data

Participant no.	CLEG standing knee angle (°)	CLEG sitting knee angle (°)	ROM (°)	Vicon standing knee angle (°)	Vicon sitting knee angle (°)	ROM (°)
1	12	97	85	12.07	88.92	76.85
2	9	91	82	9.3	90.8	81.5
3	-8	117	125	-1.32	122.72	124.04
5	17	106	89	6.02	99.59	93.57
6	23	103	80	7.02	88.62	81.6
7	9	92	83	5.93	76.2	70.27
8	0	95	95	-5.25	79.55	84.8

9	10	97	87	-1.98	92.93	94.91
10	-9	65	74	7.07	81.74	74.67
12	26	115	89	11.1	97.76	86.66
mean	8.90	97.80	88.90	5.00	91.88	86.89
SD	11.19	13.87	13.20	5.56	12.52	14.41

C). Normality was found for the differences (n=10) between the two offset corrected CLEG measurements of maximal squatting in table 5.2, the SEM was calculated for the maximal knee flexion and found to be 3.23°. The minimal difference needed to be considered real can be calculated from the SEM (Weir 2005) by multiplying it by 1.96*sqrt(2), which leads to an MD of 8.96 °, roughly 6% of the total range. For the Vicon one participant failed to register a maximal squat due to marker occlusion. The SEM for the remaining n=9 matching measurements of maximal squatting was found to be 2.25°, leading to an MD of 6.24°.

D) Two participant's CLEG data were not saved successfully. For the remaining 10 participants minimal knee angle, maximal knee angle and ROM between standing and sitting from one arbitrarily selected sit to stand from SS1 and one from SS2 are listed in table 5.4. The clothing the 10 participants changed between the two test conditions ranged from jeans to a knee high skirt.

The differences between ROMs for SS1 and SS2 averaged at -3.1° +/- 6.1° and were found to be normally distributed by examining Z scores of skewness and kurtosis, both of which were <1.96. Subsequently data was tested with a paired t-test. No significant difference was found (p=0.14).

Table 5.4. CLEG ROM for SS1 and SS2.

participant no.	SS1 minimal knee angle (°)	maximal knee angle (°)	ROM (°)	SS2 minimal knee angle (°)	maximal knee angle (°)	ROM (°)
1	12	97	85	5	93	88
3	-8	117	125	-11	109	120
4	16	109	93	7	115	108
5	17	106	89	22	110	88
6	23	103	80	9	99	90
7	9	92	83	7	95	88
8	0	95	95	7	103	96
9	10	97	87	-2	91	93
10	-9	65	74	4	78	74
12	26	115	89	28	114	86
mean	9.6	99.6	90.0	7.6	100.7	93.1
SD	11.39	14.04	13.04	10.41	11.16	12.07

E) One participant's CLEG data were not saved successfully, for the other 11 the ARI was calculated by the CLEG in real time, see figures 5.11 and 5.12 for an impression. The values for SS1 and SQ1 max for participant 6 and the value for SS1 for participant 12 were not determined in real time because the knee angle did not fall below 20°, which is used as a trigger to calculate the ARI on board the CLEG. These values were calculated post hoc, as were all values for the condition SQ1 30° because the measurement protocol did not allow for the knee angle to fall below 20° here. The ARI was selected from the second step during WLG, second sit to stand during SS1, and second squat during SQ1, and presented in table 5.5.

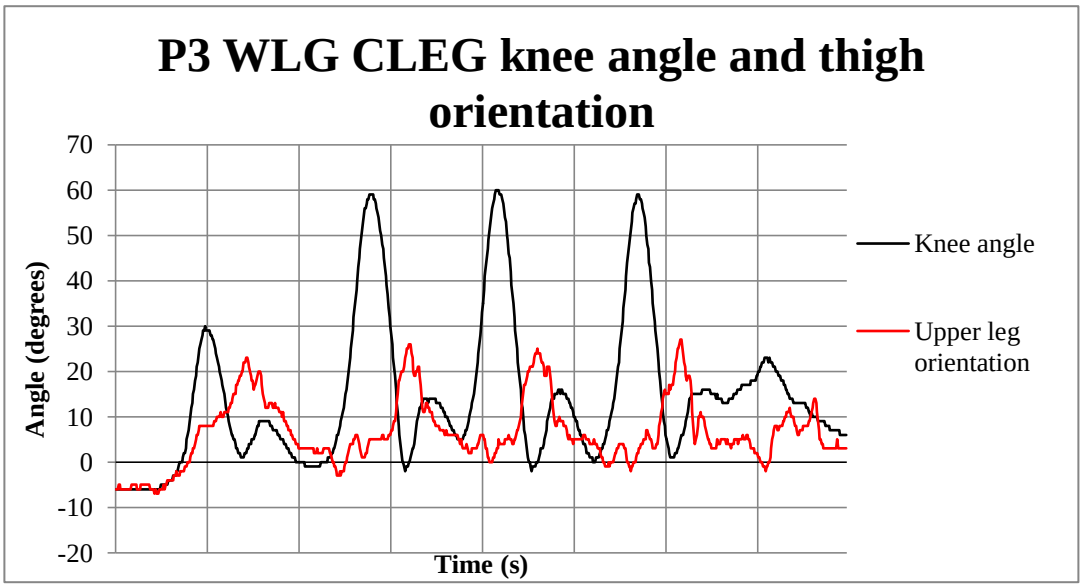


Figure5.11. Example of CLEG knee flexion and thigh orientation data during WLG.

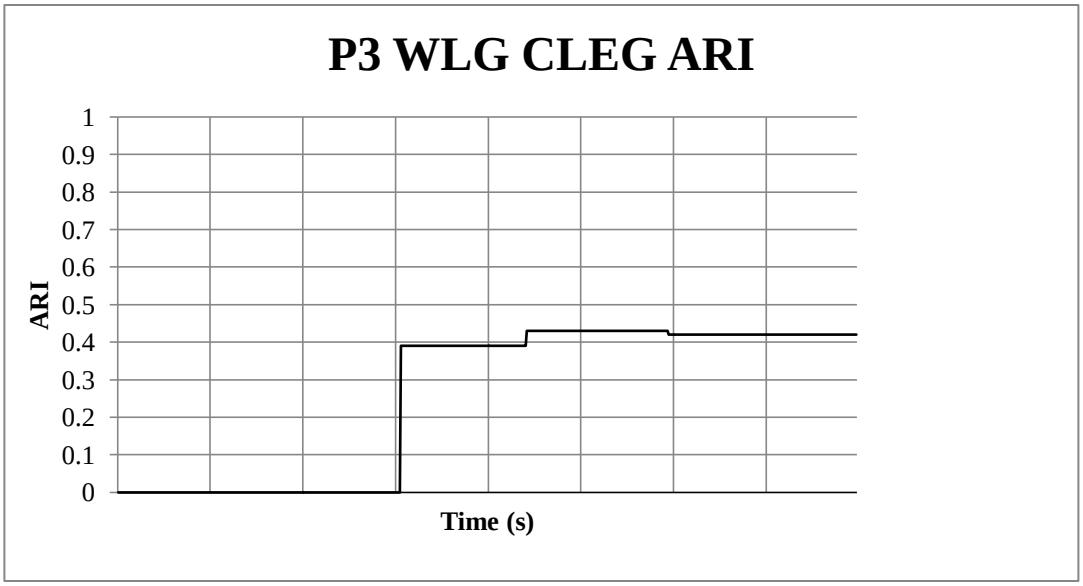


Figure 5.12. Example of ARI during WLG.

Table 5.5. ARIs calculated using the CLEG.

Participant no.	WLG ARI	SQ1 30 ARI	SQ1 max ARI	SS1 ARI
1	0.37	0.51	0.83	0.94
2	0.47	0.72	0.63	0.82
3	0.43	0.64	0.8	0.84
4	0.29	0.5	0.8	0.76
5	0.33	0.59	0.74	0.93
6	0.4	0.53	0.77	0.91
7	0.39	0.49	0.62	0.83
8	0.3	0.5	0.74	0.96
9	0.36	0.44	0.82	0.98
10	0.48	0.64	0.87	1
12	0.38	0.41	0.74	0.81
mean	0.38	0.54	0.76	0.89
SD	0.06	0.09	0.07	0.08
min	0.29	0.41	0.62	0.76
max	0.48	0.72	0.87	1.00

Normality for the ARIs within groups was tested by examining Z scores for skewness and kurtosis, which were all found to be below 1.96. Mauchly's test for sphericity did not show the data to deviate from being spherical ($p=0.26$), hence a repeated measures ANOVA was used to test for a significant difference between the activities, which was consequently found ($p<0.001$). The bonferroni post hoc test was performed to see which activities differed significantly from each other, and it was found all did. SQ1 30 vs. SQ1 max scored a p value of 0.001, and SQ1 max vs. SS1 scored $p=0.002$. The remaining comparisons scored $p<0.001$.

5.4 Discussion

5.4.1 Bench tests

The first test that was performed on one CLEG was a drift test that showed no sign of drift within the one hour period. An electromagnetic interference test too did not uncover any sign of interference. This illustrates the CLEG's long term stability and ability to use it in an environment where it may be exposed to electromagnetic interference such as a home. Subsequently agreement with set angles was investigated for all three CLEGs over a large range of motion; -150° to 150°. All three CLEGs performed very well, with RMS errors just over 1° for each CLEG (Red CLEG 1.09°, Green CLEG 1.11° and the Blue CLEG 1.06°). To put this in perspective, an IMU instrument successfully used in a previous TR initiative exhibited an average error of around 5° over a range of 90° when attached to a jig (Ayoade et al. 2011). Finally the CLEG's robustness was shown by dropping one from a height of 1m onto concrete without damaging it. This confirms that the CLEG has the properties of robustness and an adequate measuring range as set out in section 4.3.1. The low RMS errors are encouraging, but whether the CLEG has sufficient validity will be confirmed in the participant tests.

5.4.2 Participant tests

A) The first participant tests set out to indicate whether or not the CLEG influences knee kinematics during gait and if it would be safe to use. Both the minimal as well as the maximal knee flexion angle during gait were found not to be influenced by wearing the CLEG, $p=0.73$ and $p=0.701$ respectively. Hence the CLEG is deemed safe and provides a true record of knee motion during gait.

B) This part investigated the validity of the CLEG by examining agreement of knee flexion angles determined by the CLEG with those concurrently determined by Vicon during squatting. The mean difference between Vicon and CLEG data was found to be -1.4°, indicating that over all participants and all instructed knee flexion angles the CLEG

results are larger than those of Vicon by an average of 1.4°, well within the set validity goal of 5° of section 4.3.1. However, the SD of the differences was 8.4°, leading to 95%LOA of -17.9° and 15.1° This indicates that although on average the two instruments agree closely, this is not always the case and a disagreement of up to roughly 18° can be expected, a dramatic increase from maximal 3° error the CLEG showcased when compared to set angles.

This lack of agreement may be caused by soft tissue artefacts (STA) influencing either the CLEG, or Vicon, or both. It is known that Vicon is sensitive to STA. When compared to fluoroscopy, Vicon errors of up to 24.3° RMS were found in 4 young healthy male participants during open chain knee flexion (Akbarshahi et al. 2010). In this study the magnitude of the error was participant dependent, and in general in motion capture these errors are known not to be reproducible among participants (Leardini et al. 2005). This may explain the large variance in agreement between CLEG and Vicon. For two female TKA patients it was found that Vicon underestimates knee flexion during STS by 10-20% when compared to fluoroscopy, with the magnitude again participant dependent (Stagni et al. 2005). A study involving ten TKA patients comparing Vicon to fluoroscopy during STS found Vicon to underestimate true flexion angles by an estimated 10% again. (Kuo et al. 2011). When Vicon STS data were compared to concurrently collected CLEG data, Vicon was found to underestimate ROMs by 2.3% compared to the CLEG. This implies that the CLEG results may be closer to the true value than those of Vicon, but the difference is not as big as would be expected (10%).

It is not clear at this point if this is because the CLEG suffers from some of the same STA induced underestimation that Vicon does, just less so, or that the Vicon markers were less prone to STA because of the CLEG that was strapped to the participant's leg which may have stabilised the soft tissues to some extent. In order to provide conclusive data on the CLEG's validity a comparison with fluoroscopy would therefore be needed. Beside its application in TR, this further research would be warranted given the performance of the CLEG when compared to set angles, its low cost and its potential to acquire data in a home setting,

C) Here it was determined how much the maximum knee angle for a deep squat as measured by the CLEG differs after re-attaching it. Data for 10 participants were analysed and the SEM was found to be 3.23°, comparable to the average error found when using a universal goniometer (UG) (Edwards et al. 2004, Lavernia et al 2008). From this the minimal difference needed to be considered was calculated to be 8.96°. The Vicon system scored a SEM of 2.25° on concurrent measurements. The CLEG had been re-attached between the measurements of maximal squatting however, while the Vicon markers had not. The SEM indicates that the CLEG is reliable to within an average 3.23 degrees after re-attaching, and the MD indicates that if the CLEG is used over a longer period of time, e.g. to monitor progress in the context of TR, a difference of 8.96° is needed in order to consider that difference real. This is below the MCRD of 15° indicating that the CLEG is sensitive enough to detect clinically relevant changes after it has been re-attached.

D) Ten participants changed from cycling shorts into their own clothing, ranging from jeans to a skirt, and attached the CLEG themselves. The differences between ROMs for SS1 (wearing cycling shorts) and SS2 (own clothing) averaged at -3.1° (+/- 6.1°). These differences were not found to be statistically significant (P=0.14). This indicates that the CLEG produces comparable results when attached over trousers, and that it is feasible to have TKA patients attach the CLEG themselves. However it should be noted that all but two of the participants were either biomedical engineering or prosthetics and orthotics students who are expected to have a better understanding of how to attach the CLEG in order to measure knee flexion. Also all participants had had the CLEG attached to their leg by the researcher twice before in the course of the study. Whether the CLEG can be attached successfully without prior training will therefore have to be determined during the usability testing.

E) The feasibility of a simple activity recognition index (ARI), calculated as the maximal thigh deviation from vertical divided by the maximal knee flexion seen in a

particular activity, was investigated by comparing the results of the activities walking, squatting to an instructed 30°, maximal squatting and sit to stand. Statistical testing showed significant differences between all these activities, implying that the ARI is capable of differentiating between them. This would enable the CLEG to function as an activity monitor, however much more research is needed to refine the ARI and explore it's performance during different activities. Also, although the activities differ significantly, it is not guaranteed that fixed boundaries will always classify a movement correctly. As can be seen from table 5.5, ARI values show some overlap between activities and choosing fixed boundary values may be too crude to differentiate between activities whose ARIs are close to each other. In these cases the boundary values may have to be calibrated for each individual user. Nonetheless these findings indicate the potential for the ARI as simple yet accurate activity recognition algorithm.

5.5 Conclusion

Unlike IMU's the CLEG doesn't require calibration for each participant because its potentiometer based measuring principle is absolute; if the arms are aligned to the underlying bones correctly, the measurement will reflect what it is aiming to measure. In addition to this, it had previously met the properties of low cost, flexibility and portability because of its design. Whether it also met the properties of long term usability, robustness, adequate measurement range, validity and reliability, was investigated in this chapter.

Bench tests confirmed long term usability by a one hour drift test during which no signs of drift could be detected, and an electromagnetic interference test showed the CLEG not to be influenced. One CLEG survived a 1m drop test undamaged, showing it is not fragile. Three CLEGs were tested over a range from -150° to 150°, exceeding the desired measurement range and showing very good agreement (just over 1° RMS error) with set angles for all three CLEGs.

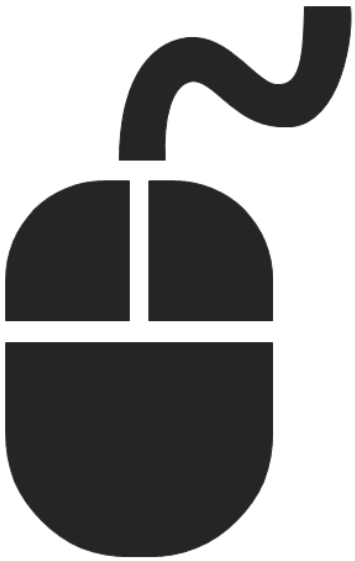
During participant testing, the CLEG was found not to influence walking kinematics and hence was found safe to use. In terms of the average agreement with

Vicon during maximal squatting, the validity requirement has been met. However, the 95%LOA ranged up to roughly 18°. This is believed to be caused to some extent by STA but more research is needed to conclusively confirm this. After re-attaching when determining STS ROM the CLEG exhibited reliability, with a SEM of 3.23° leading to a MD of 8.96°. Well below the MCRD of 15°, which means the CLEG satisfies the sensitivity requirement. When used for Tele-Rehabilitation (TR) it would be advantageous if the CLEG could be attached over patient's normal clothes. It was found that the ROM determined during STS is comparable whether participants wore cycling shorts or their own clothing, so the CLEG is deemed usable over normal clothing. The feasibility of a simple activity recognition algorithm (activity recognition index or ARI) was investigated, with encouraging results. More research will be needed however in order to refine the algorithm and enable its use in practice.

The CLEG thereby has shown to have all the properties set out in section 4.3.1, except for the suitability as perceived by the clinician and usability of the platform by the patient which will be investigated in the next chapter

Chapter 6

Service acceptability and platform usability



6.1 Introduction

In this chapter the opinions of health professionals were collected using structured interviews. As mentioned in chapter 4, their input was used to help guide the design of the platform. Next to the health professional perspective, the usability of the platform as well as the need for training and technical support from the patient's perspective are assessed by means of a usability study.

6.2 Health professional interviews

The opinions of Health Professionals (HPs) were gathered using structured interviews. The goals of these interviews was to determine whether in the opinion of HPs the TR platform can be used to help achieve the goals of post TKA rehabilitation, and whether the HPs were comfortable with the choice of a windows PC as therapist device. Additional goals were to inform on the choice of e-mail for data communication, whether or not HPs believed the platform would be easy to use, and if they would want to use it in a future study.

6.2.1. Methods

Four health professionals involved in post TKA rehabilitation were interviewed; one senior physiotherapist (Female, 60 years old), one senior nurse (Female, 50 years old) one specialist physiotherapist (male, 40 years old) and an extended scope physio therapy practitioner (Female, 45 years old). A brief presentation explained the need for and the workings of the TR platform prototype, including the EPF made by partner SILCK clinical solutions ltd., followed by a demonstration of the platform. After this the HPs were asked a series of open questions.

6.2.2 Results

Q1: What are your goals for post TKA rehabilitation? Could you achieve them using the TR platform prototype?

All HPs mentioned the achieving of an adequate ROM of the knee as a goal, and all HPs believed the TR platform prototype could help achieve this goal, or at the least let them know if the goal was not being achieved.

Additional goals of recovering strength and function were mentioned by two of the four HPs, but they agreed that if functional limitations were due to issues with ROM, the platform has the potential to help achieve the function rehabilitation goal. To gather more information about functional recovery, one HP suggested adding activity monitoring capabilities to the platform, which could also give some insight into a patient's strength.

HP: If they had an activity monitor that might be a better idea. So if someone says to me I can get up... Or if I look at them and I'll ask them to get up, maybe in and out of a chair ten times, and if they can do that then I'm kind of looking at their strength as being pretty good. Or if I know that they walked up and down stairs in their flat, or walked a mile to the shop and back, I'm starting to assume that their strength is not a big issue".

Alternatively, the real-time video conferencing (RTVC) function of the platform was recognised as a way to assess strength remotely, by observing the patient perform exercises such as chair rises. Having patients perform strengthening exercises such as squats as input for the gaming or biofeedback function was seen as enabling the TR platform to aid in recovery of strength as well, although it was noted that there would have to be measures to make sure the patient performs the exercises at the correct speed. One HP also mentioned the goal of pain management, but believed the TR platform prototype not currently to be of added value in reducing pain.

Q2: How do you feel about using a windows PC for the TR platform prototype

As expected due to the widespread use of PC's in the professional environment none of the HPs had any objections, although two of the four HPs remarked that a few hours of training for the software to be used would be appreciated.

HP: "...good teaching support to show us what we're doing with it, probably practice ourselves with it to get some feedback. Nothing that's new is easy."

Q3: How do you feel about getting the patient measurements in your e-mail?

Again none of the HPs had any objections, provided that they would get a ROM in their e-mail. The raw data was not desired despite the added richness of information it would provide, as the data analysis would result in an unwanted increase in workload that would ultimately reduce time available for patient care.

HP: "My bug bear a bit; technology coming into our job is meant to save us time, but often it doesn't. All you're doing is not seeing the patient, instead just working on the IT. That's detrimental because you're actually reducing patient care by asking us to sit in front of a computer."

One HP also stressed the importance of training patients in the use of the CLEG to ensure that the data that gets collected is valid.

Q4: How do you feel about using an electronic patient file?

All HPs were fine with the idea of using an electronic patient file.

HP: "we've been paperless for quite a while now so that would be fine."

Q5: Did you find the TR platform prototype easy to use (for patients)?

All HPs agreed the platform was very easy to use, but all HPs also recognised the difficulties that could arise for the elderly, or any other patients that have no ICT skills. Therefore, two HPs believed that in addition to a manual, a short training would be necessary for patients.

HP: "It's much easier for someone to demonstrate to you how to use rather than read an instruction. I think the instruction manual is a backup with lots of photographs to help."

Q6: Would you participate in a follow up study where you would use the TR platform prototype on some of your patients?

All HPs would be happy to participate.

HP: "Yes, absolutely. I think we need to look at advancing things a bit."

6.2.3 Discussion

The general impression after the interviews is that the HPs involved in post TKA rehabilitation interviewed here were all in agreement with regards to the answers they gave. They all believe the platform could help them achieve their rehabilitation goals, and were comfortable with a windows PC as the therapist device. E-mailing data was accepted, and HPs believed the platform would be easy to use. They also all seem to have a positive attitude toward the technology, in contrast to the professional possessiveness often listed as a barrier to adoption. This might be due to the design that emphasizes the platform is merely a tool for the therapist and is not aiming to replace them. However, the HPs interviewed here were a self-selected sample which means results may be biased as it is expected that those HPs with a more positive attitude to the technology would be more likely to volunteer to be interviewed.

A possible improvement to the prototype uncovered by the HPs is automated data analysis. Instead of e-mailing raw data, the prototype therefore sends reports of analysed data; ROM of the knee, the ARI and number of repetitions. This could be expanded on by adding movement time. In this way the platform could for instance communicate the results of a 5X STS test, providing insight into functional strength. Due to time constraints this was not part of this work however.

A concern voiced by the HPs was that of training, both for the HPs themselves as well as for patients, thereby confirming the training barrier to implementation.

All HPs interviewed would like to use the platform in a follow up study, showing that on first sight, the platform is accepted.

In the next development phase, training will have to be developed and tested before moving on to acceptance trials. For this phase 1 work, the focus is on developing functional technology as well as exploring the need for this training. For HPs, a few hours was believed to be sufficient. For patients, the usability study will provide more detailed information on the training needs.

6.3 TKA patient usability study

The aim of this study is to uncover any factors that limit usability when used by total knee replacement patients, so that these may be addressed in development phase 2. The study also aims to provide insight into the amount of training and technical support that would need to be developed in additional development phases.

6.3.1 Methods

Ethical permission to conduct the study was sought from the NHS ethics committee and awarded under reference 16/LO/1295. NHS R&D approval was granted (reference number GN16PY622).

Participants

The participants that were recruited had undergone a TKA and meet the inclusion criteria of aged 18 years or over, having received a total knee arthroplasty on one leg only, between 3 months and one year ago at the time of the study. Exclusion criteria include any neurological impairment leading to lack of comprehension regarding the study or ability to give informed consent, and any other lower limb impairments (apart from the affected knee) which inhibited normal functional movement, any visual impairment which may prevent the use of the platform, contra lateral TKA surgery within 18 months leading up to participation in the study, and any possibility that the participant may be pregnant.

In usability testing it has been proposed that four to five subjects is enough to highlight the main issues (Nielsen, J. 1994). Virzi et al. 1992 claim that within four or five subjects 80% of usability problems are expected to be found, with the most severe problems likely to be detected within the first few subjects. Additional subjects after five are less and less likely to reveal new information, as the relation between the proportion of uncovered problems (U) and the number of participants (n) is governed by the chance of finding this problem in one participant (p) as follows; $U=1-(1-p)^n$ (Virzi et al. 1992). According to the formula by Virzi et al., when considering problems that have a chance of being found in one participant of 50%, the proportion of those problems found after just three participants would be 88%, increasing to 94% for four participants, and 97% after five participants. After 6 participants the proportion would only rise by one more percent to 98%. Therefore 5 participants were recruited.

Following their 3-12 month check-up, patients were asked if they would be interested in taking part in the study by their Arthroplasty practitioner. If so, they were provided with the researcher's contact details and the participant information sheet. After a patient contacted the researcher a date was arranged on working days between 9am and 5pm for them to visit the clinical research facility at the Glasgow Royal Infirmary, on the condition that the information sheet had been contemplated for at least 24 hours.

After making sure the prospective participants met inclusion and exclusion criteria, the platform and documentation were placed on a table and briefly shown to them, and the procedure of the study was explained. After making sure there were no further questions, the participant signed their consent form and commenced the study. The researcher ensured that patients who consented had a thorough understanding of what was asked of them. The usability study asked participants to work through a task scenario that mimics the use of the platform for their rehabilitation and fill out pre- and post-test questionnaires. This took approximately one and a half hours of their time. The amount of time it took to complete a task was measured, as was perceived ease of use

for the platform as a whole. The study had no effect on the service delivery for the patients. All underwent routine postoperative rehabilitation as is current practice in Greater Glasgow and Clyde. Using the platform was unfamiliar for the patients and could therefore potentially cause stress. However, it was pointed out to the participants that the platform is being tested, not them, as is good practice in usability testing.

Schedule of tests

After having been given opportunity to ask questions and signing their consent form, participants were asked to fill out a brief pre-test questionnaire. Following this, the researcher read to them an orientation script, explaining exactly what would happen next. If the participant had no further questions he or she was asked to perform various tasks using the platform, according to the task scenario. Participants were provided with a quick start guide that has the instructions needed to perform the task. The time it took to complete a task was monitored, and if a certain task could not be completed in the maximum time to completion (MTC), the researcher aided the participant. After completion of the task scenario, the participant was asked to fill out a brief post-test questionnaire. See figure 6.1 for a schematic representation of the time course of the study. Please refer to table 6.1 for an overview of the various different tasks to be performed during the task scenario. The questionnaires, quick start guide, orientation script and task scenario can be found in the appendix.

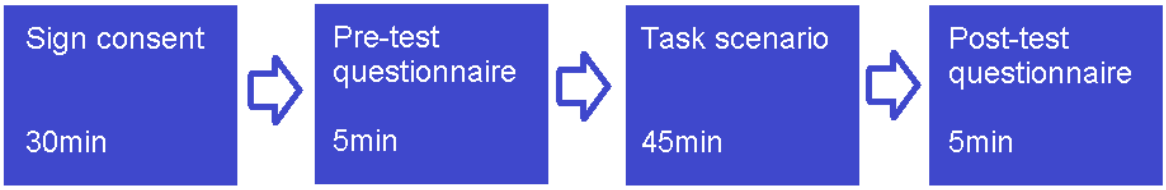


Figure 6.1. Schematic representation of the course of the study.

Table 6.1. The tasks to be performed.

Task no.	Task description	Task detail
1	Unpack the tablet and CLEG	Req: unopened box, quick start guide Success criteria: tablet and CLEG removed from box and ready for further preparation. MTC: 3 min
2	Power-on and unlock the tablet	Req: charged tablet, quick start guide Success criteria: tablet turned on, unlocked and ready for further preparation. MTC: 3 min
3	Launch the portal application	Req: unlocked tablet with portal installed, quick start guide Success criteria: portal app launched. MTC: 2 min
4	Navigate to "information/read"	Req: portal launched, quick start guide Success criteria: e-mail inbox opened. MTC: 2 min
5	Strap on, and plug in CLEG	Req: one CLEG, quick start guide Success criteria: CLEG attached right side up, and on outside of leg. CLEG connected to USB. MTC: 5 min
6	Navigate to "exercise" and do some squats	Req: CLEG attached successfully, quick start guide Success criteria: biofeedback app launched and CLEG switched to mode 1. MTC: 4 min
7	Navigate to "measure" and measure one squat	Req: CLEG attached successfully, quick start guide Success criteria: notepad app launched, CLEG switched to mode 2, one or more squats measured, data e-mail ready. MTC: 5 min
8	Navigate to "Games"	Req: CLEG attached successfully, quick start guide Success criteria: Game launched, and menus navigated. Once in game, CLEG switched to mode 1. MTC: 4 min
9	Navigate to "Information/progress"	Req: quick start guide, Gmail account Success criteria: launched e-mail inbox MTC: 4 min
10	Navigate to "Call Therapist"	Req: quick start guide, skype account Succes criteria: logged in to skype. MTC: 3 min
11	Navigate to "My group"	Req: quick start guide, facebook account Success criteria: facebook launched. MTC: 4 min

As can be seen from table 6.1 (step 5) the participants will have to strap on and plug in the CLEG. See figure 6.2 for an illustration of how this looks. All activities are performed whilst sitting at a desk. As mentioned in the above, using the platform for participants who are unfamiliar with it and have had no prior training whatsoever can potentially cause stress, especially if a participant repeatedly fails and can't work out how to perform a task. To let participants struggle on with a task they can't perform would be a waste of time and unethical as their sacrifice would not lead to any greater good. This is why the MTC time limits are used, as is good practice in usability testing.

Figure 6.2. The CLEG as it would be worn during the study. Note the cable plugged in to the tablet computer.

Outcome measures

In the pre-test questionnaire, the participant's sex and age were recorded as well as their previous experience using computers and the internet and their perception of the TR platform using multiple choice questions and statements that can be scored on a 5 point scale ranging from strongly agree to strongly disagree. During the task scenario, the time it took a participant to complete a task was monitored, this was the primary outcome measure. The post-test questionnaire provided the secondary outcome measure;

participants perceived ease of use of the platform which is measured using statements that were scored on a 5 point scale from strongly agree to strongly disagree.

Data Analysis

No inferential statistics will be used. Instead results will be reported using descriptive statistics of average +/- standard deviation time to complete a task.

6.3.2 Results

Two participants were unable to attend their scheduled appointments and were thus unable to participate. The remaining three participants and their experiences using the TR platform are described below after which their data is presented.

Participant 1 was a 71 year old male who owned an Android tablet or telephone and had used the internet before, including G-mail. Before using the platform he disagreed that the platform looked easy to use, but did agree that the documentation looked easy and intuitive. While using the platform he was confident, working everything out very quickly. He has a brief look at the manual, knows what to do and does it. He doesn't seem to be experiencing any difficulties, happily chatting away and completing all tasks within the MTC. However, when launching the portal application (task 3) he had difficulty finding the green pictogram on a green background. The participant also experienced some difficulty navigating the notepad app that was used to measure a squat (task 7). During this, he also switched the CLEG into the wrong position, but recovered quickly. Attaching of the CLEG was quick and easy, and the CLEG fitted well. The participant seemed to enjoy playing the game and happily accepted two more chances to play after crashing the helicopter. The biofeedback application did not seem as interesting to him as the game, although it did remind him that his nurse had told him he would not be allowed to leave the ward unless he could get a knee flexion of at least 90°. After using it, he agreed that the platform is easy to use but also agreed that the quick start guide is necessary. He was neutral on whether training prior to use or more detailed documentation would make the system easier to

use, and disagreed that training would be necessary. The portal application was found particularly easy to use, particularly difficult was the glare on the screen of the tablet.

Participant 2 was a 61 year old female who owned a tablet or smartphone, but not an Android. She had used the internet before, including G-mail and Skype. Before using the platform she was neutral on whether the platform and documentation looked easy to use. Whilst performing the tasks she worked methodically, going between manual and tablet. She was focused on the task at hand and completed all but one tasks within the MTC. She too had some difficulties finding the green pictogram on a green background (task 3) and when trying to navigate the notepad app in order to e-mail her squatting results (task 7), but was able to complete these tasks within the time given. Task 5, strapping on the CLEG, she could not finish within the MTC, it took her a lot of time to understand how the straps worked and which part of the CLEG should be attached to the thigh and which to the lower leg. She then ran over time with the CLEG attached to the inside of her leg. The researcher at this point helped her attach the CLEG, when it became clear that the CLEG's strips were too long for her causing the lower ankle strap to run under the malleolus instead of above. This participant too seemed to enjoy playing the game and happily accepted two more chances to play after crashing the helicopter. She seemed interested in the biofeedback application and liked how the knee joint indicated bad medium or good flexion depending on the knee joint colour. After completing all tasks she did not agree that the platform was easy to use, and agreed that the quickstart guide was both necessary and adequate. She disagreed that more detailed documentation would make the platform easier to use, but agreed that training prior to use would make it easier to use. Moreover she agreed training was necessary. Navigating the tablet was believed particularly easy to use, strapping on the CLEG particularly difficult.

Participant 3 was a 60 year old female who did not own a tablet or smartphone and had never used the internet before. Despite this she strongly agreed that the TR platform looked easy to use, and agreed that the quickstart guide looked easy and

intuitive. While using the platform her lack of ICT experience quickly became clear as she failed to turn on the tablet (task 2). It took her some time to find the on/off button, and once she did she didn't know she had to press it for about 10 seconds. This is communicated clearly in the quickstart guide, but she didn't consult it. She seemed to prefer working things out for herself and didn't consult the guide for all but one task. She found the pictogram for the portal application without any trouble, but failed to strap on the CLEG (task 5) despite consulting the guide for this task. She struggled to understand the pullback straps and ended up with the CLEG attached to her leg inside out before running over time. Again the CLEG was too large and after the researcher helped attach it, the participant complained about it poking into her ankle. This was remedied by loosening the lower strap a little. Navigating from the information section (Gmail) back to the portal in order to do exercise with the biofeedback app (task 6) proved too difficult and she exceeded the MTC for this task. The researcher helped by explaining that she has to tap the "back" arrow, part of the standard Android navigation bar at the bottom of the screen. After this she tried the biofeedback and seemed to be enjoying it. She tried to flex her knee as far as she could and tried to better her previous score several times. When moving on to task 7 she forgot to turn the CLEG off. The researcher intervened and turned the CLEG off to enable her to try the rest of task 7. She proceeded, navigating the notepad app with some difficulty. She then switched the CLEG into the wrong position despite the "toast" message explaining what position the CLEG should be switched into. She didn't recover from this before going over the MTC for this task. The researcher now helped and after a measurement was taken asked her to try and finish the task, but navigating the notepad app in order to e-mail the results proved too difficult, the small button marked with three dots in the top right of the screen was not considered a button. After this the participant was asked to navigate to "games". She remembered how to navigate the tablet and this was now no problem. Whilst navigating the menu's in the game she seemed unsure but managed to start the game and she switched the CLEG into the right position. After her first game ended she forgot to turn the CLEG off again. Like the other participants she seemed to enjoy the game and accepted two more chances to play, and this time remembered to turn the

CLEG off. All other tasks were completed within the MTC and after using it the participant has an optimistic view of how things went, she strongly agreed that the platform was easy to use, and strongly agreed that the documentation was both necessary and adequate. She strongly disagreed that more detailed documentation would make the platform easier to use, but agreed that training prior to use would. Despite considering training as something that would make the platform easier to use, she was neutral on whether training was necessary. Despite failing to complete several of the tasks within the MTC, the participant listed games, the tablet, the biofeedback app, the CLEG and the information function under things that were particularly easy to use. Particularly difficult to use she found the CLEG straps.

Participants 4 and 5 were unable to attend their appointments and a suitable alternative date could not be found within the timescale of the ethics permission for this study. The results of the pre-test questionnaire can be found in tables 6.2, task timings for the three participants that did successfully take part are presented in table 6.3. Where not all three participants completed the task within the MTC, no average was calculated. Regarding the perceived ease of use, participant 1 agreed to the statement "overall, I found the system easy to use". Participant 2 disagreed, Participant 3 strongly agreed. See table 6.4 for these and other post-test questionnaire results.

Table 6.2. The pre-test questionnaire results

pre -test questionnaire		P1	P2	P3
General information	Age	71	61	60
	Sex	male	female	female
Are you experienced using a tablet or smartphone?	Yes, I own one or more	**X**	**X**	
	Yes, but I don't own one			
	No			**X**
what operating system does it use?	Android	**X**		na
	Apple OS		**X**	na
	Don't know			na
Have you used the internet before?	Yes	**X**	**X**	
	No			**X**
Have you used an e-mailing program before?	Yes, Gmail	**X**	**X**	
	Yes, but not Gmail			
	No			**X**
Have you used a video conferencing program before?	Yes, Skype		**X**	
	Yes, bu not Skype			
	No	**X**		**X**
The Tele-Rehab system looks easy to use	Strongly disagree			
	Disagree	**X**		
	Neither agree nor disagree		**X**	
	Agree			
	Strongly agree			**X**
The accompanying documentation looks obvious and intuitive	Strongly disagree			
	Disagree			
	Neither agree nor disagree		**X**	
	Agree	**X**		**X**
	Strongly agree			

Table 6.3. Time to completion for the various tasks

Task	Time to completion (s.)			
	P1	P2	P3	Average (s.)
1. unpack tablet	30	6	19	18.3 +/- 9.8
2 power on tablet	99	61	-	-
3 launch portal	120	47	13	60 +/- 44.6
4 info	5	2	11	6 +/- 3.7
5 strap on CLEG	190	-	-	-
6 exercise	50	100	-	-
7 measure	80	90	-	-
8 games	73	100	100	91 +/- 12.7
9 info	10	10	6	8.7 +/- 1.9
10 call therapist	20	30	14	21.3 +/- 6.6
11 my group	25	5	4	11.3 +/- 9.7

Table 6.4. The post-test questionnaire results

post-test questionnaire		P1	P2	P3
Overall, I found the system easy to use	Strongly disagree			
	Disagree		**X**	
	Neither agree nor disagree			
	Agree	**X**		
	Strongly agree			**X**
I found that the documentation was necessary to complete the tasks	Strongly disagree			
	Disagree			
	Neither agree nor disagree			
	Agree	**X**	**X**	
	Strongly agree			**X**
I found that the documentation was adequate	Strongly disagree			
	Disagree			
	Neither agree nor disagree			
	Agree	**X**	**X**	
	Strongly agree			**X**
I think that more detailed information will make the system easier to use	Strongly disagree			**X**
	Disagree		**X**	
	Neither agree nor disagree	**X**		
	Agree			
	Strongly agree			
I think that receiving training prior to use will make the system easier to use	Strongly disagree			
	Disagree			
	Neither agree nor disagree	**X**		
	Agree		**X**	**X**
	Strongly agree			
I think that receiving training prior to use is necessary to be able to use the system	Strongly disagree			
	Disagree	**X**		
	Neither agree nor disagree			**X**
	Agree		**X**	
	Strongly agree			

6.3.3 Discussion

The aim of this study was to uncover any factors that limit usability when the platform was used by total knee replacement patients, and provide insight into the amount of training and technical support that would need to be developed in additional development phases. To this end 5 participants were recruited, of which 2 were lost to follow up. This leaves 3 participants, which according to the formula by Virzi et al. 1992, is expected to uncover 88% of the problems with a chance of being found of 0.5. However, this does not mean that three participants are enough to provide conclusive evidence of usability, as such a small sample size cannot be generalised to a population in general (Caulton 2001). Also, not every usability problem is equally easy to detect. Intractable problems can lead to a slower progress than predicted by the formula (Schmettow 2008). However, it would be a better of use of resources to correct the problems that have been found so far before recruiting more participants. When interpreting the results it should also be considered that this is a self selected sample and that the patient population in general may be more averse to using technology.

In general the three participants performed well, and were able to perform most tasks without any prior training. Participant 1 completed all tasks within the MTC. However, he did experience factors that limited usability; the green pictogram on a green background, the notepad application, the CLEG switch, and glare on the screen of the tablet. Participant 2 experienced some of the same factors to limit usability for her; the green pictogram and navigating the notepad application. Moreover she was unable to successfully strap on the CLEG within the MTC, and it turned out the CLEG's strips were too long for her leg. Participant 3 did not own a tablet or smartphone and experienced more difficulties; she did not manage to turn on the tablet within the MTC. Like Participant 2 she was unable to strap on the CLEG, which was too large for her as well. She also experienced the general tablet navigation as a factor that limited usability, but learned how to do this within the duration of the study. Like Participant 1 she also experienced the position to switch the CLEG into as a factor that limited usability and like both other participants had difficulties navigating the notepad app. Whilst playing

the games she forgot to switch the CLEG off, although again she learned to do this within the duration of the study. Some of these factors that limit usability were recognised by the participants themselves as they listed glare on the screen and strapping on the CLEG as particularly difficult in the post test questionnaire. Whether they thought training would be necessary varied among the participants, participant 1 successfully completed all tasks within the MTC and did not think training would be necessary. Participant 2 experienced more difficulties as she failed to strap on the CLEG and she believed that training would be necessary. Participant 3 experienced the most difficulties but she explained that she had a good support network in the form of her children and husband who could help her if she were to be given the platform and was neutral on the need for training.

The green pictogram is an obvious mistake in the design that hinders usability but one that is easily rectified by choosing a pictogram colour that has a higher contrast with the background. Despite being explained clearly in the quickstart guide, switching the tablet on and navigating it using the bottom bar was a problem for one participant, as it was not her style to consult the guide. However she learned how to navigate the tablet within the duration of the study. Therefore it is believed a minimal amount of training would be sufficient to overcome this usability limitation. The notepad application that was used to collect data was found to be a limitation for all participants. This was a general notepad application that because of time constraints was sourced from the Google Play Store. It was not developed with usability as a priority, as for instance the portal and biofeedback applications were, and it is believed that if such an application was developed along the lines of the portal and biofeedback applications, training for it would not be needed. The CLEG can be used successfully without training as P1 demonstrated, but this is not the case for all users. Strapping it to the leg, and the three position switch is complicated. For this training will be needed, which would be a good time to also fit the CLEG to a user's leg. Before rushing into developing training however, the CLEG and indeed the platform as a whole should go through another design round to take away as many of these factors as possible. This would minimise the

need for training which would be more cost effective in the long term and would increase chances of adoption among a more technology averse user group. Technical support as needed to remedy e.g. broke cables or defective tablets was not needed throughout the course of the study although it should be noted that these may constitute the more intractable problems and more research will be needed before the need for this service can be determined conclusively.

6.4 Conclusion

The HPs believed the TR platform could help achieve the goals of post TKA rehabilitation and accepted the platform. They also indicated that they believed a few hours of training to be necessary for patients as well as themselves. After three participants for the patient study, the following factors that limit usability were found; a pictogram for the portal application that had too little contrast with the tablet background, unfamiliarity with a tablet computer (powering on and navigating), the notepad application, the CLEG straps and its switch. Some of these factors may be overcome by improving the design of the platform, and where possible this should be done as it would help minimise the need for training. However it is clear that the service of training will have to be provided, but training needed appears to be in the order of minutes rather than hours. Although one participant was able to perform all tasks within the MTC without any prior training, this did not apply to the other participants. If the pictogram and notepad application are improved, it is believed a half hour or so of training would suffice for the patients to become familiar with the tablet and CLEG. The healthy participants in the previous CLEG study all managed to strap the CLEG on after having watched the researcher do this just twice, and the usability study participant who struggled with navigating the tablet learned to do so within the duration of the study. However, although these results suggest the need for training to be minimal, the question of whether a one-time training will suffice, can only be answered conclusively once a training program has been developed and tested. Technical support was not needed in this study, but for this too more research is needed to provide a conclusive answer as to whether or not this service will be required.

Chapter 7

Discussion

7.1 Introduction

In the introductory chapter it was shown that long term conditions (LTC) such as diabetes and arthritis are the biggest challenges facing health systems worldwide. In the UK they currently account for 60% of all hospital bed days and 80% of all GP visits. Due to the predicted ageing of the population, it is expected that a growing number of people will suffer from a LTC which will increase the cost of care. By 2031 the cost of care in Scotland is expected to increase to nearly 8 billion pounds, from 4.5 billion pounds in 2007/2008.

Improving the efficiency of care delivery and preventing disease in old age, especially LTC, will therefore become increasingly important. This is recognised by the Scottish government and the NHS and they promote "a care delivery paradigm shift" in which AHPs will play a central role. The AHPs are to drive the shift toward assisted self-management in order to meet the vision of older people living full and positive lives in their own home.

However, AHP services are already overburdened which is counterproductive in the long term. If current practice is continued, driving the paradigm shift would exacerbate this. It is therefore imperative AHPs service delivery becomes more efficient. For this they will need the right tools; better measurement, data collection and the use of ICT to reduce the need for travel. TR, defined as the use of ICT to deliver the clinical service of rehabilitation over distance, was found to be this tool. Unfortunately evidence regarding the clinical- and cost-effectiveness of TR is lacking which is preventing its use in practice. Furthermore, providing this evidence is currently not feasible as it requires large scale studies, but there is no TR technology available that can be used at large scale. The aim of this work therefore was to develop a scalable TR platform and test its feasibility.

It was found in chapter 2 that TR holds many possible advantages over CR; it improves access to the service, and seems a viable method for teaching self management. It would enable the acquisition of more data more objectively, and is believed to reduce the cost of treatment. Patient adherence to an exercise program could

be improved and social support enabled. Arguably most importantly, TR could enable a drastic increase in the amount of rehabilitation a patient undertakes. In order to maximise the effectiveness of a TR platform, and thereby cost effectiveness, a platform should ideally provide all of these advantages. Therefore it would have to enable the functions of communication, data acquisition and storage, providing information, enabling social support, exercise games, and biofeedback.

TR has a limitation however as it cannot be used in all areas of rehabilitation due to the physically manipulative nature of some areas. For a TR initiative to be successful, an area of rehabilitation needs to be found in which there is little or no need for physical manipulation or contact, and where there is cultural readiness and a compelling need. This was found in the area of post TKA rehabilitation. In addition to choosing a suitable area of rehabilitation, a phased development model should be adhered to in order to improve chances of scaling up the technology and overcoming multidisciplinary problems. In the first out of four phases the focus is on developing functional technology which was the aim of this work. The additional phases of small scale pilots, large scale (cost) effectiveness research, and finally operational products that can be implemented should not be ignored however, as each one has a unique set of barriers that need to be overcome. In phase 1 there are the *hands on approach* and *psychological* barriers that can be overcome by choosing a suitable area of rehabilitation, and *usability*, *quality* and *flexibility* that will have to be ensured by having an adequate platform design. In phase 2 the services of *training* and *tech support* will have to be developed before small scale pilot studies can be conducted. Following this, large scale studies are to be performed in phase 3, meaning large numbers of willing participants and of the platform will be required. The barriers of *diffusion* and *financing* will have to be overcome for this, which is why the platform should use open source software and hardware wherever possible. In fact the platform should itself be open source as this has the potential to maximise return on the public investment needed to develop it, and would facilitate duplication of studies. In phase 4 there are then the barriers of *legislation and organisation* to overcome; the technology needs to comply with laws and fit into work

practice which is why cooperation with care professionals and an electronic patient file manufacturer was sought.

To overcome all of these barriers, a TR platform would need the properties of usability, quality, flexibility, minimal need for services, low cost, and being open source, as well as the previously mentioned functions combined into one design. Also, the functions of the platform need to be tailored to the area of rehabilitation it is to be used in. Which emphasizes that the platform should be flexible, in order to have generic value. To the best of the author's knowledge there has not been a TR initiative that has offered all of the aforementioned functions. Neither has there been one that offered all of the properties, let alone one that combines all these functions and properties. Doing so is ambitious, but necessary in order to develop a platform that is scalable, which was the aim of this work.

The area of rehabilitation that was chosen for this phase 1 work was post TKA rehabilitation. A TKA costs on average £8404,- and over 7500 TKAs are performed in Scotland annually. In the future this number is expected to increase due to population ageing. 99% of these joint replacements are performed to remedy arthritis, aiming to alleviate pain, improve function and improve QOL. Before the TKA surgery, the joint generally has seen reduced use in an effort to reduce pain, and the bones, ligaments and muscles surrounding the joint have degraded. Shortly after the surgery these degradations typically worsen due to surgery and hospitalisation. In order for patients to regain function after their TKA they need extensive rehabilitation. Currently however the routine is for patients to undergo a few days of inpatient rehabilitation and are then sent home with a booklet and the advice to do their exercises for at least three months. Improvements in knee function have been shown to occur for years after the operation, indicating the need for long term rehabilitation which could be provided using TR. This leads to the main research question:

Can a TR platform with all functions believed beneficial be developed, with all properties required to maximise scalability?

To answer this question the following research objectives were implemented;

1- *Develop the platform to have sufficient usability*

2- *Develop the platform to have sufficient quality*

3- *Develop the platform to have sufficient flexibility*

4- *Develop the platform to require minimal training*

5- *Develop the platform to require minimal technical support*

6- *Develop the platform to have a low cost*

7- *Develop the platform to provide e-health*

8- *Develop the platform to provide better measurement*

9- *Develop the platform to provide data collection*

10- *Develop the platform to provide exercise games*

11- *Develop the platform to provide information*

12- *Develop the platform to provide biofeedback*

The platform design had to ensure that all functions were provided whilst meeting all properties. A user centred design in combination with the double diamond design method was used which resulted in a novel electro goniometer, existing patient and therapist devices being chosen and a mixture of existing and custom made software. It was shown that as people age changes in cognition, motor skils, visual and auditive senses are known to occur and this was taken into account when designing the technology.

The goniometer, or CLEG, was designed to meet the requirements of 1: low cost, 2: usability, 3: robustness, 4: flexibility, 5: require minimal training and tech support, 6: have an adequate measurement range, 7: be valid, 8: be reliable, 9: portability, 10: have long term usability, 11: be sensitive enough to detect the MCRD. At a cost of £93.29 the CLEG costs less than £100,- and meets the low cost requirement. Because of it's modular construction it offers flexibility and because of its compact size and low weight

it is portable. How the remaining requirements are met was the subject of the CLEG tests and will be addressed in section 7.2.

A suitable patient device was found in touchscreen tablet computers. The touchscreen was found to be the best input device for a patient population, and tablet computers meet the low cost requirements, are portable, enable the use of existing networks to aid diffusion, and being off the shelf products guarantee sufficient quality. The operating system that was chosen is Android as it is free and open source and was specifically developed to maximise usability. A 10.1" screen tablet costing £99.99 was chosen, keeping the total cost of the platform below £200,-. This is well below the upper limit of £320,- and increases the platform's cost effectiveness.

For therapist device, a windows PC was chosen, as this would fit into AHPs work practice, and they are already owned by the various AHP services.

The software to run on the CLEG was custom made, as were the portal and biofeedback applications for the tablet. All other software was sourced from the Google Play Store, and although this software leaves to be desired in terms of usability and data security, it enables answering of the main research question within the time constraints of this project.

In this way a TR platform was made that provides the functions of communication (RTVC), data acquisition and storage, providing information, enabling social support, purposeful games, and biofeedback, with the properties of flexibility, quality and low cost. At £200,- the platform costs less than 2.5% of the cost of arthroplasty and is equivalent to 4 hours of direct physiotherapy time. The remaining properties of usability, minimal training and minimal technical support were answered in the platform usability and need for services study.

7.2 CLEG tests

The CLEG was found to be safe to use as it does not influence walking kinematics, and it was found feasible for users to attach the CLEG themselves over their own clothes. Its use as an activity monitor was found to be feasible when using the simple ARI algorithm developed for it. Typical wearable accelerometer activity monitors (e.g. ActivPal) can only differentiate between sedentary, upright and ambulatory activities, but lack information about the precise kind of ambulatory activity that is performed. Because of the small size of accelerometer based activity monitors they are preferable if comfort and unobtrusiveness are preferred over detail of information. The ARI however has shown potential for providing more detailed information by differentiating between activities such as sit to stand, squatting and walking. This makes the CLEG and ARI suitable for use in TR, where this more detailed information can provide insight into progress, activity levels and strength if for instance a 5 times sit to stand test is administered using it. This makes the ARI a valuable addition to existing knowledge as it would enable accurate activity monitoring, but more research will be needed to substantiate this claim. Additional tests were conducted in order to answer whether the CLEG meets it's requirements. It was found to have long term usability as no signs of drift or electromagnetic interference could be detected. This is in contrast to the IMU/MARG approach to acquiring joint kinematics that can be unstable when used for more than a few minutes due to the filtering algorithms used, but more importantly can be sensitive to electromagnetic interference and the presence of ferromagnetic materials which renders them useless in a home environment. The CLEG was also found to be robust and therefore suited for use in a home setting unlike flexible electro goniometers (FEGs). When CLEG results were compared to set angles over a range of -150° to 150°, an RMS error of just over 1° was found, indicating that the CLEG satisfies the measurement range requirement. Moreover the CLEG was found to be valid when measuring flexion angles in healthy participants during maximal squatting, with an average deviation from concurrently measured Vicon values of 1.4°. This indicates that the DOF afforded to the CLEG by it's unique chain linked construction allow it to

follow the movements of the underlying bones, and it is not hindered by a lack of validity when measuring flexion angles greater than 90° to 100° as potentiometric electro goniometers (PEGs) are, making it in the authors opinion the first instrument capable of validly acquiring long term knee kinematics in a home setting. Reliability for the CLEG was given by a SEM of 3.23° during maximal squatting after re-attaching, from this the MD was calculated which at 8.96° is below the MCRD of 15° indicating adequate sensitivity. The CLEG's novel measurement principle thereby is a valuable addition to existing knowledge as it enables various forms of research that were previously not possible, for instance monitoring the knee kinematics that are exhibited in daily life, and keeping track of outcomes after various surgical procedures or therapeutic interventions. Whether the CLEG is also of added value in the context of TR depends on whether it meets the requirements of usability, and minimal training and tech support which were tested in the service acceptability and platform usability chapter.

7.3 Service acceptability and platform usability

Whether the platform has sufficient usability, and required minimal training and tech support was investigated by interviewing four health care professionals and in a usability study involving three TKA patients who volunteered to participate. The patients were asked to perform all the platform functions without having received any prior training and were provided only with a simple manual, the quick start guide.

Involving the health care professionals in the design process of the platform turned out to be crucial as they indicated that they did not want raw data, instead the technology should aim to help minimise their workload and free up as much time as possible for them to spend with patients. They also indicated that adding activity monitoring functionality would be valuable and thereby their opinions had a substantial positive influence on the technology that was eventually developed. They indicated that they accepted the platform by a unanimous willingness to participate in a future study

involving the platform, but indicated that they believed a few hours of training would be necessary for both themselves as well as patients.

When used by total knee replacement patients, several factors that limited usability of the platform were found; the pictogram for the portal application that didn't contrast with the tablet computer's background, general tablet use (switching on and navigating), the notepad application, strapping on the CLEG, and switching the CLEG in the right position. One participant also noted glare on the screen as being difficult, a known problem for some ageing eyes. The tablet computer used for the study was modestly priced however, and more expensive ones have better screens that are expected to reduce this problem. Seeing as it would be well within the budget of maximal £320,- future studies should aim to use the devices with better screens. The pictogram colour is easily changed, which should be done for a next version of the platform. General tablet use was found to be a problem for the participant who had no previous experience using tablets. It is expected that there are a number of patients who, like this participant, lack that experience, indicating that training will be needed for this. The participant learned how to navigate the tablet within the duration of the study however, suggesting a minimal training would suffice to ensure users of the platform can switch the tablet on and navigate it.

The notepad application sourced from the Google Play Store caused issues for all participants. Rather than provide training for this, this application should be developed along the lines of the portal and biofeedback applications; large highly contrasting buttons, no distractions, and simple menu structures. In this way it is believed that this part of the platform could be used without any prior training, like the biofeedback and portal application which were listed as particularly easy to use by participants. Strapping on the CLEG was found to be a serious limitation of usability as two of the three participants failed in doing so within the MTC. Training will have to be provided for this, however it is believed that minimal training would suffice as one of the three participants did manage to strap the CLEG on successfully without any prior training or knowledge, and because the healthy participants of the CLEG tests in chapter 5 all

managed to strap the CLEG on successfully after having the researcher strap it on to their leg twice. During this training the CLEG strips could then also be cut to size to ensure a good fit, and the therapists could convince themselves that the data the patient will collect using the CLEG is valid, a concern expressed during the health professional interviews.

Switching the CLEG into the right position, and turning it off again, was found to limit usability. This could be addressed during training, and given the fact that the participants who experienced difficulties with it either recovered quickly or learned how to use the switch within the duration of the study it is expected the training need for this is also minimal. Nonetheless, it would be preferable to have a CLEG that does not require multi position switching as this would reduce the need for training. This could be accomplished by developing the data collection app to accept the same input signal that the games and biofeedback application do.

Despite these factors, two of three participants found the platform easy to use, and two of the three patients did not agree that training would have been necessary to successfully use the platform. From the above it is clear however that the service of training will have to be provided, but that a one-time short session is expected to suffice, as participants learned to overcome most of the factors within the duration of the study. The service of technical support was not needed during the study. The limited number of participants is a limitation of the study however, and there may be additional factors that limit usability, as well as needs for technical support that have not been uncovered yet. However, it would be a better use of resources to correct the problems that have been found before recruiting more participants. This could be done during phase 2, where it could also be confirmed whether the one time short training session suffices. At the end of this first development phase it is clear that the platform meets its research objectives of sufficient usability, quality, and flexibility, it requires minimal training and tech support and is low cost. At the same time the platform offers better measurement, data collection and e-health through its various functions, as desired by the reablement policy. And although it was developed for post TKA rehabilitation, the platform has

generic value and could eventually be scaled up and so aid the progression of TR toward implementation.

7.4 Conclusion

It was shown in the introductory chapters that there is a need for TR in practice, and that the main obstacle to implementation of TR is the lack of scalable technology, preventing the large scale (cost) effectiveness research that policy makers need. Therefore the aim of this work was to develop a prototype TR platform, that is scalable, and confirm its feasibility.

It was found that cost effectiveness is expected to be one of the main motives for implementing TR, and so the technology that is developed should aim to maximise cost effectiveness. This is why the platform was developed to provide the functions of communication, data acquisition and storage, providing information, enabling social support, exercise games, and biofeedback as these functions combined are expected to maximise effectiveness. At the same time the platform was developed to be low cost. Being the denominator of the cost effectiveness equation, low cost would contribute substantially to maximising cost effectiveness. Additional properties of flexibility, quality, usability, and requiring minimal training and technical support were found to be necessary for the platform to be scalable.

A phased development model was adhered to which resulted in a suitable area of rehabilitation being chosen and a design for the platform to be decided on. A new type of electro goniometer (CLEG) was developed which was found to enable valid acquisition of knee kinematics in a home setting, which had previously not been possible due to the limitations of instruments available. This goniometer was also made to be modular and it is potentially suited for a range of other joints, although more research would be needed to confirm this. An activity recognition algorithm was developed for the CLEG which would enable accurate activity monitoring, again previously not possible due to the limitations of technology available. But here too, more research will be needed to confirm this.

The platform as a whole was found to meet the research objectives of *usability* as the majority of participants found it easy to use, *quality* as no problems occurred for any participant, *flexibility* as it is mobile, offers synchronous and asynchronous services, and allows for interoperability, requiring *minimal training* as the majority of participants did not indicate that training would have been necessary, requiring *minimal tech support* as none of the participants required it, and *low cost* at just £200,-. The platform also meets the research objective of providing e-health as it enables RTVC for communication, offers better measurements enabled by the CLEG, provides data collection as the data can be e-mailed and stored in an EPF, provides exercise games, information via e-mail, and biofeedback. This means that all research objectives have been met, the platform provides all functions and has all properties.

Therefore the research question; *Can a TR platform with all functions believed beneficial be developed, with all properties required to maximise scalability?* can be answered. Yes, this sort of platform can, and has been, developed. Also it was shown that training is needed, even if a platform is developed with usability in mind. The platform's feasibility was confirmed by gaining acceptance from therapists, and patients being able to use it. Although this was only shown for post TKA rehabilitation, the platform has generic value and could be scaled up to provide evidence based practice and eventually be implemented into clinical practice where it is urgently needed. The study aim has therefore been successfully completed.

This generic value is enabled by the platforms modular nature. As mentioned in section 4.3.4, the CLEG's communication module can be attached to a variety of body parts, and the chain can span a variety of joints. For instance hip flexion and extension and ankle kinematics could be measured, and the CLEG may also have some potential for acquiring kinematics of arm joints. When used for alternative joints and thereby alternative areas of musculoskeletal TR, the games and biofeedback applications could easily be swapped as the software was also made in a modular fashion. When this software is changed, the scope of the platform could also be expanded to additional areas of TR, not just musculoskeletal ones. If different low cost and robust measuring devices such as for instance respirometers that connect to the same communications module

developed for the CLEG were developed, the platform could be used for pulmonary rehabilitation as well.

To the best of the author's knowledge such a platform has not been produced in the 58 years since the first documented use of TR. The advantages of TR have been extensively researched before, but the success of TR in reaching implementation into clinical practice, where it's advantages could come to fruition, depends on scalable technology. Until now it has not been known that developing this technology is possible, and that from a technological point of view TR can currently be implemented into clinical practice. Therefore it would be possible to implement TR and deliver rehabilitation more efficiently, enabling AHPs to become the agents of change that drive the rehabilitation paradigm shift.

7.5 Limitations

In section 4.3.1 the robustness aspects of the CLEG were defined as being able to survive daily use and a 1m fall onto concrete. After the 1m drop test as well as the participant testing that included letting untrained participants attach the CLEG themselves no damage whatsoever was sustained, which indicates that the CLEG meets the robustness aspects as they were here defined. However, as mentioned in section 5.2.4, robustness testing is a field of testing involving various tests, and more tests would be required to show that the CLEG performs its function regardless of other stressful environmental factors such as for instance temperature. This is a limitation of this study as any claims of robustness pertain only to robustness as here defined.

The CLEG measures only ROM. Although it was pointed out in section 3.6.3 that quadriceps strength is considered a critical factor in knee health and that it is generally assessed by measuring knee extension torque, with isokinetic measurements being the golden standard. Consecutive knee torque assessments can be used to quantify treatment efficacy and it would be a valuable outcome measure. It was also explained that predicting function from torque measurements however, or even assessing whether it is in a poor, fair or good range for a certain patient, is not as straightforward as it is for

knee angles. Relating knee extension torque to age and sex matched normative values is still very subjective It was therefore decided more straightforward to use a performance based measure such as the five times sit to stand (5xSTS), shown to have an adequate correlation with quadriceps strength in TKA patients. Despite only measuring ROM the CLEG would be able to be used to perform a 5xSTS test, in addition to this, the Health professionals interviewed recognised the activity monitoring function as a possible indicator of strength, as well as the possibility of remotely administering a 5xSTS using the video conferencing function. Nonetheless the CLEG cannot measure knee extension toque and the 5xSTS functionality has not been implemented for this phase 1 work hence muscle strength cannot currently be recorded by the CLEG, this is a limitation.

As set out in section 4.3.1, the current gold standard for dynamic measurements of joint angles is stereo fluoroscopy, a technique that uses a series of X-rays. Because of the invasiveness of these X-rays it would not be ethical to compare the CLEG to this gold standard without first having explored its performance using the non-invasive, widely used, stereo-photogrammetry. However, because the comparison with stereo fluoroscopy was not performed, the validity of the CLEG could not be conclusively determined as mentioned in section 5.4.2. This is a limitation.

The CLEG tests for healthy participants were intended to explore the CLEG's performance, before for instance a comparison with stereo fluoroscopy is performed. These tests were performed mostly on young participants with a mean age of 26.5 years, whereas the target user group is on average much older. However, older people did not volunteer to take part. It is possible that due to differences in body composition, e.g. muscles mass and fat mass, the results from these tests cannot be generalised to an older population. Because of the small sample size, results should not be generalised to any population, before this can be done much more research will be needed as mentioned in section 5.5. The non-generalisability is a limitation.

This work aimed to successfully complete phase 1 of the four development phases described in section 2.4. In this first phase the aim was to develop a prototype of the required technology to set up a TR service. That developing this technology was possible was itself not evident because of the multitude of functions and properties required from such technology. In the consequent development phases services such as technical support and training will have to be developed and provided before small scale pilots can be performed. Although in this work the need for those services was researched and preliminary evidence found it to be minimal, the services themselves have not been developed as this as well as the evaluation of the developed services would be phase 2 work.

A prototype was developed and tested, but further testing and user evaluation is desirable. This should be done first in a small pilot, later in larger studies until such point where all lessons learned have been incorporated into the technology and service that is being set up for as far as possible. In phase 2 for instance changes may be made to the CLEG that make it easier for health professionals to fit it to a patient's leg, in phase 3 the training developed for phase 2 may be refined to increase scalability, and in phase 4 software may be refined to comply with certain legislation. However this work was limited to phase 1, and this additional refinement has not yet been performed which is a limitation.

Sufficient usability was here defined as the majority of participants indicating that they found the platform easy to use, which they did. Considering that these participants had not received any prior training at all, although it was expected that training would be necessary, this suggests that the design emphasizing usability paid off. However only 3 participants were tested so conclusive evidence of usability could not be provided, this is a limitation.

The ARI could be used as a major outcome measure, although as mentioned in section 5.4.2 much more research is needed to refine the ARI and explore it's

performance during different activities. Also, although the activities differ significantly, it is not guaranteed that fixed boundaries will always classify a movement correctly. This is a limitation.

7.6 Original contributions

The original contributions arising from this work are;

-A TR platform prototype that meets all desired properties and provides all desired functions and is therefore scalable.

-A novel electro goniometer that offers full freedom of movement in the sagittal plane.

-A novel activity recognition method.

Chapter 8

Future work

8.1 Introduction

The aim of this work was to develop a prototype of a scalable TR platform that can provide better measurement, data collection and e-health, and test it to confirm its feasibility. This aim was successfully met, and with it the first phase of a development cycle completed. But as set out in section 2.1, developing a prototype is not sufficient for the TR platform to reach implementation.

There currently is emerging evidence that TR can provide patients with the same clinical outcomes as traditional rehabilitation services and that it can do this cost effectively, as described in section 2.3. However there is a dearth of long term large scale studies that would provide authorative evidence on acceptance, but arguably more importantly on clinical effectiveness and cost effectiveness of TR. Especially the cost effectiveness evidence is expected to be instrumental in the further expansion of TR. Providing this evidence would complete another phase in the development cycle of an implementable TR platform, but would not be sufficient to reach implementation.

Reaching implementation is very challenging; there are so many barriers that a layered implementation model becomes necessary to improve the chances of coping with inherent multidisciplinary problems and scaling up the technology. In this layered model, there are four phases. The first one focusses on the technological barriers and has been the subject of this work. Additional barriers in the realms of user acceptance, financing, laws and regulations are the subject of the consecutive three phases that will have to be completed before the TR platform can be implemented into practice. This chapter outlines the future work to be performed in those additional development phases.

8.2 Phase 2

The second phase, like the first one, will have to start with development. Instead of just technology however, services will also have to be developed in this phase. In section 2.4.2 it became clear that without training, users will be unfamiliar with any new system. This may lead to frustration and consequently abandonment of use, regardless of how usable the system was made to be. Similarly, the service of Tech-support was found to be needed because without it, problems during use of the system lead to de-motivation and a high probability of abandonment of the system.

The need for these services was confirmed in chapter 6. The Health professionals that were interviewed indicated that they accepted the platform by a unanimous willingness to participate in a future study involving the platform, and also indicated that they believed training to be necessary for themselves, as well as for patients. Although two out of three TKA patients indicated that they didn't agree training would have been necessary after they were asked to use the platform without any prior training, the results of section 6.3 indicate that training will in fact be necessary. Two participants failed to strap the CLEG to their leg successfully, and one of these two participants also failed to turn the tablet computer on, as well as failing to navigate it. However, one participant managed to perform all the functions the TR platform has to offer without any prior training, and the other participants learned to overcome most of the hurdles they encountered during the duration of the study. This confirms the Health professional's belief that a single training session would suffice. During phase 2, this training would have to be developed, as well as a Tech-support service. Following this, the phase 2 milestone of acceptance research would be enabled. But before the services are developed and the acceptance research performed, phase 2 should start by refining the technology developed in phase 1 so that the issues that were found to limit usability in section 6.3.3 are resolved.

When it comes to refining the phase 1 technology, first the green pictogram for the portal application should be changed as it is an easily rectified mistake in the design that was found to hinder usability. The pictogram should be changed into one that guarantees contrast regardless of the background colour being used. This pictogram could also emphasize the fact that the system, preliminarily named "SteppingStone", and the AHP are there to help but that the patient has personal responsibility over their rehabilitation process. In line with the 'Realistic medicine' care delivery paradigm that emphasizes personal responsibility. Please see figure 8.1 for an illustration of such a pictogram made as a first step for the phase 2 work for this TR platform.

Figure 8.1 The "SteppingStone" pictogram that emphasizes personal responsibility and offers good contrast.

Following the changing of the pictogram, a notepad application should be made to replace the one that was used for phase 1 as this one was found to be a limitation for all three participants in chapter 6. The portal and biofeedback applications were developed with the factors known to hinder usability among older adults described in section 4.6.3 in mind, e.g. limited number of layers in a menu, sufficient button spacing, and they proved not to be a limitation. It is therefore believed that if a notepad app were developed along the same lines as the portal and biofeedback application training for it would not be needed. This would allow the training session that is given to patients to be shorter and therefore more cost effective. When this notepad application is made it should also aim to use the same input signal that the CLEG provides to the biofeedback

and game applications, as this would allow the CLEG's to use an two position (on/off) switch instead of the current three position switch that was found to be a limitation in terms of usability in chapter 6. Finally the OKS and EQ-5D questionnaires need to be made into an application that also follows the usability principles, and the 5X STS functionality needs to be programmed into the CLEG. Following these refinements, the services need to be developed.

Training for both AHPs as well as patients will have to be provided if a TR platform is to be used, regardless of whether this use would be for research purposes or clinical practice. It would be ideal if AHPs could train patients in the use of the platform during the in-hospital stay following their operation because this would allow the AHP and patient to develop a working relation, it would allow the AHP to size the CLEG correctly during a face to face session, and because the patient has already travelled to the hospital enabling this contact without any further travel. The training program that would have to be developed should therefore consist of three parts. It should enable the AHPs to use the platform in clinical practice e.g. how to access the data that a patient has sent them, teach them how to adjust a CLEG's size by cutting its flexible strips, and it has to teach them how to train patients. Once such a training program is developed, a Tech- support service must be established as well.

By choosing off the shelf products, the Tech-support service of the product manufacturers, for instance for the tablet computer and internet connection, may be used. For the custom made software and CLEG however, this will have to be provided. How elaborate such a service needs to be is at this point unclear, but it would be good to have one centralised point for patients to turn to if they experience any difficulties. For this second phase, this service could be provided by the researcher who can answer phone calls and e-mails, and liaise with tablet manufacturers and internet providers as well as troubleshoot issues with CLEG or software.

Once the technology has been refined in the above way, training has been developed and a rudimentary tech-support is in place the phase 2 milestone of acceptance research can be reached. During this research the focus is on gathering data that informs to what extent patients and AHPs accept the TR platform, and it is important to gather feedback from both AHPs and patients regarding usability and need for Tech-support. Using this usability data would enable the training methods to be refined, and any newly discovered limitations of the developed technology to be addressed at the start of phase 3.

8.3 Phase 3

The third development phase focusses on scaling up and when done successfully would enable the milestone of large scale research. The services developed in phase 2 would have to be refined according to the data gathered in the acceptance research and additional possible improvements in the technology should be executed. Following this the training, as well as study designs, and blueprints and software of the platform should be made Open Source. This would enable researchers from around the world to join the collective effort of gathering data regarding the platforms clinical and cost effectiveness, spearheaded by a clinical trial performed by the researchers charged with this phase 3 work. The services of phase 2 need to be adapted according to the data gathered, and the technology refined according to the usability data. In preparation of the effectiveness trial to be performed as the milestone of this third phase, the generic helicopter game used thus far needs to be replaced by a custom made one. This is because the generic game offers no control over the range of motion that the knee is moved through, nor over the speed at which movements are executed which means that any therapeutic effect of the generic game cannot be guaranteed. A custom game could offer control over the range of motion, speed of movement, and number of repetitions by creating a sort of tunnel that the helicopter would have to be flown through. As the "SteppingStone" platform is a Scottish initiative, it might be appropriate to have this tunnel consist of Bens and rainclouds, and replace the helicopter with a golden eagle. See figure 8.2 for an illustration of what such a game could look like. The range of

motion would then depend on the highest Ben that would have to be cleared in combination with the lowest rain cloud. For instance a patient would have to first extend their knee to 10 degrees flexion or less to get the eagle over a Ben, and then flex their knee to 90 degrees or more to successfully fly under an overhead cloud. The gradient of the tunnel created using these Bens and clouds would determine the speed at which a patient would have to bend and extend their knee, and the number of Bens would dictate the number of repetitions required. Thus, different maps would represent different exercises with number of repetitions, speed, and range of movement predetermined.

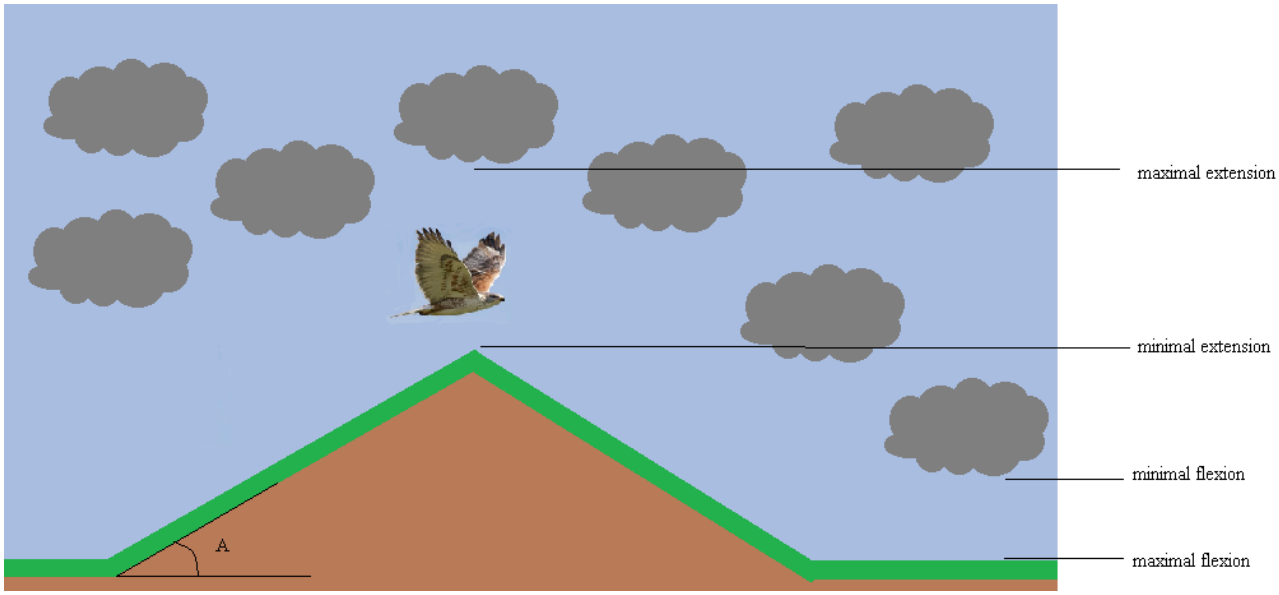


Figure 8.2. An illustration of what the exercise game could look like. Maximal and minimal extension of the knee are determined by the height of the raincloud and the Ben respectively, as minimal and maximal flexion are by the height of the cloud and Glen. Speed of movement is determined by the gradient A.

Once such a game has been made, a trial to be performed at the end of this third phase would aim to demonstrate both clinical as well as cost effectiveness in a pilot group. To this end the study design employed would be that of a randomised clinical trial as this is considered the most robust method for minimising selection bias and maximising generalisability (Eccles et al. 2003). Post TKA patients would be recruited to participate and randomly assigned to a Tele-Rehabilitation group or a Conventional Rehabilitation

group. This randomisation would ideally be stratified according to age (below or equal to the average TKA patient age of 68, or over) because age is a factor in computer experience and might bias results if not stratified. Outcomes regarding clinical effectiveness would be assessed using the short battery of outcomes described in section 3.6.4 (OKS complemented with the EQ-5D, maximum knee extension- and flexion-angle and the activity during which they were achieved, and 5xSTS performance), as well as the cost for the rehabilitation delivered to both groups to calculate cost-effectiveness. A time period of 6 weeks is chosen for duration of the pilot study as it is the recommended minimum length of time that exercises should be done. The researchers, health professionals and patients would be aware of the group they were assigned to due to the presence or absence of the technology. Therefore blinding in the strict sense would be impossible. However, outcome assessors could be assigned that are blind to the group that the data they are assessing belonged to, in an effort to minimise bias in the outcome measurement. For such a pilot RCT a minimum sample size of n=12 per group is recommended (Julious 2005) therefore 24 participants would be recruited.

This pilot RCT would provide data on cost and effectiveness, but only on a small scale. Following this pilot however, the entirety of software, blueprints, services and study design can be made open source because it can use existing structures for dissemination, and the 3D drawings could be downloaded and printed anywhere in the world. Thus, researchers anywhere in the world can use the SteppingStone platform and gather data with it, so overcoming the barriers of diffusion and financing, and facilitating the duplication of studies. This would enable the milestone of large scale research, providing decision makers with the data they need. Also, researchers around the world could now start to adapt the platform for other conditions thanks to its modular nature and generic value. For instance the CLEG's communication module can be attached to various body parts, and the chain can span various joints. For instance, the communication module could be worn on a waistband on the back, and one end of the chain could be attached laterally to the same waistband. The other end of the chain could be attached to a strip strapped to the thigh, in this way the CLEG could measure hip

flexion and extension. But also ankle and elbow kinematics could be acquired by adapting the CLEG, and heart rate monitors and respirometers that connect to the same communications module as the CLEG may be developed thusly expanding the TR platform's scope.

8.4 Phase 4

After making the platform Open Source and large scale evidence regarding clinical and cost effectiveness has been provided in phase 3, the gap in the evidence base for TR would have been filled. Policy makers would now be in a position to approve TR for implementation into clinical practice, but before TR can be implemented the technology needs to meet all laws and regulations, and fit into work practice. During the development of the prototypal technology in phase 1, cooperation with healthcare professionals and electronic patient file manufacturers was sought in order to align the prototype with the demands it would face during this fourth and final development phase. Before a new medical device can be brought to market it needs regulatory approval to ensure its safety and effectiveness. Most commonly used is the 510(k) pathway of the Food and Drug Administration (FDA) (Marcus et al. 2016). This pathway is used if a new device is substantially equivalent to a predicate device, whereas premarket approval is the regulatory pathway if the device is not substantially equivalent and requires reasonable evidence of safety and effectiveness (Marcus et al. 2016). When a device has the same intended use and technological characteristics it is considered substantially equivalent. Since the CLEG has the same intended use and employs potentiometers, it is substantially equivalent to other potentiometric electro goniometers and it would qualify for the 510(k). It would therefore not require additional testing. However, although it is the most commonly used pathway, the 510(k) is an American one and different ones would apply for different parts of the world.

As the TR platform scales up, it may have to gain American regulatory approval, but it is in first instance developed with the needs of the Scottish NHS in mind, and would therefore require a European Union (EU) regulatory approval. Every medical

device in the EU must have a CE mark. Manufacturers have to check which EU legislation is applicable to their products and may only bring it to market if it complies with all applicable regulations. Medical devices are roughly divided into four classes in the EU, Class 1, 2a, 2b or Class 3, described in article 9 of council directive 93/42/EEC. For all but the lowest risk Class, the manufacturer needs to issue a declaration of conformity that is verified by a certificate of conformity, issued by a notified body. This notified body is an organisation that has been accredited to validate the compliance with the European directive. To ensure that the TR platform developments in phase 4 reflect these demands, manufacturers are one of the parties with whom cooperation should be sought.

To ensure that every EU member state transposes these requirements into national law, the government of each member state must appoint a competent authority. In the UK, this is the Medicines and Healthcare products Regulatory Agency (MHRA). This agency is a part of the department of health and social care and is responsible for ensuring that medical devices work and are acceptably safe, and would be one of the parties with whom cooperation should be sought in phase 4 to ensure that the TR platform conforms to all relevant regulations and laws. The exact demands a medical device needs to meet are described extensively in the ISO norms 13485 and 14971, with further standards pertaining to battery powered electrical devices such as the tablet computer and CLEG described in IEC60601-1. To acquire copies of these standards is a costly affair, and it would be of little use to invest resources into this phase 4 work at this point in time. These resources would be of better use applied to phase 2, and after that phase 3 as they have to be completed before phase 4 can be started. However, some of the things that would likely need to be taken into account before implementation can occur would be; packaging standards, biocompatibility, cleanliness of the delivered product, software privacy, software robustness, mechanical robustness, electrical safety and reliability.

8.5 Conclusion

As has become clear throughout this thesis, if TR is to be implemented a TR service needs to be established. There is a vast amount of future work to be done for this to happen. Training needs to be developed, some form of technical support service provided, and a small scale RCT conducted. Before the RCT is started however, the technology needs to be further developed; some of the factors that were found to limit usability should be addressed at the least. In additional development phases also the scope of the platform could be expanded by validating the CLEG for different joints and developing additional validated devices that could connect to the CLEG communications module and enable its use in different LTC. Before implementation the robustness of the CLEG and the platform as a whole should then also be further investigated, including long term drift testing and investigation of any required safety measures in accordance with all the relevant norms. The automated data analysis that the Health professionals desired for this prototype meant that ROM would be e-mailed in favour of raw data. In the future this could be expanded on by e-mailing ROM, ARI, number of repetitions and time taken, in this way for instance the results of a five times sit to stand test could be communicated effectively and efficiently.

Whilst following the development model here described, the technology would eventually be developed to the point where it can be made Open Source and shared with interested parties anywhere in the world. Many devices would be required and the platforms scaling potential would be a great benefit, thereby enabling large scale studies to be done, provided the services of training and tech support are ready to be deployed at scale as well. These studies should be done as part of a multi-centre RCT which would focus on cost effectiveness, as this is expected to be the most important driver toward implementation, and it is the evidence that is currently lacking, thereby preventing policy makers from investing in TR.

After the required large scale evidence has been provided, the platform would be ready to move from the prototype form into a mass produced version that conforms to all laws, norms and regulations and is ready for implementation. By this time a lot of cooperation between health care organisations, policy makers, legal professionals and

EPF manufacturers is likely to be required and its general use in the patient population could be studied.

It is clear that getting TR into clinical practice will require a lot of concerted effort by various stakeholders in times to come. The technology will have to go through at least three more development cycles, and at least one pilot and one large scale study before the platform could be implemented for just one form of rehabilitation.

In the current typical academic project for a PhD, one development phase can be completed, meaning the technology goes through one development cycle and evaluation studies are performed. To successfully undertake one development cycle, literature needs to be researched, prototypes made and tested, research methodology planned, a lengthy ethics approval process completed, a study performed, and results published. Finishing this process within three years imparts serious time constraints and the chances of projects failing increase as a result. To enable the successful completion of the successive development phases it is believed that at the very least the duration of these projects where TR technology, or any other new technology that will require patient testing, is involved should be increased to 4 or 5 years. In this way the three remaining TR development phases could be completed within 12 to 15 years.

There are financial pressures on the NHS now however, and the sooner technology can relieve some of these pressures the better. Also, the development of this prototype platform has showed that knowledge and insights from wide ranging fields are required to develop TR technology; the health professionals to ensure the technology delivers what they desire, biomedical engineering to enable data acquisition, computer sciences for the ICT, Human factors and Usability experts, NHS ethics guidance, and looking toward the future, business and legal professionals. It is therefore believed necessary to start a TR working group composed of individuals or even teams from these various backgrounds to accelerate the development of TR.

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Appendices

Usability pre-test questionnaire

Please write the following on the line:

What is your age? _____ years old.

Tick the box that best represents your opinion

1. What is your sex?

☐Male ☐Female

2. Are you experienced using a tablet or smartphone?

☐Yes, I own one or more ☐Yes, but I don't own one ☐No

3. What operating system does it use?

☐Android ☐Apple OS ☐Don't know

4. Have you used the internet before?

☐Yes ☐No

5. Have you used an e-mailing program before?

☐Yes,Gmail ☐Yes, but not Gmail ☐No

6. Have you used a video conferencing program before?

☐Yes, Skype ☐Yes, but not Skype ☐No

7. The Tele-Rehab system looks easy to use.

_____ Strongly disagree

_____ Disagree

_____ Neither agree nor disagree

_____ Agree

_____ Strongly agree

8. The accompanying documentation looks obvious and intuitive

_____ Strongly disagree

_____ Disagree

_____ Neither agree nor disagree

_____ Agree

_____ Strongly agree

Usability Post test questionnaire

1. Overall, I found the SteppingStone system easy to use

_____ Strongly disagree
_____ Disagree
_____ Neither agree nor disagree
_____ Agree
_____ Strongly agree

2. I found that the documentation was necessary to complete the tasks

_____ Strongly disagree
_____ Disagree
_____ Neither agree nor disagree
_____ Agree
_____ Strongly agree

3. I found that the documentation was adequate

_____ Strongly disagree
_____ Disagree
_____ Neither agree nor disagree
_____ Agree
_____ Strongly agree

4. I think that more detailed documentation will make the SteppingStone system easier to use

_____ Strongly disagree

_____ Disagree

_____ Neither agree nor disagree

_____ Agree

_____ Strongly agree

5. I think that receiving training prior to use will make the SteppingStone system easier to use

_____ Strongly disagree

_____ Disagree

_____ Neither agree nor disagree

_____ Agree

_____ Strongly agree

6. I think that receiving training prior to use is necessary in order to be able to use the SteppingStone system.

_____ Strongly disagree

_____ Disagree

_____ Neither agree nor disagree

_____ Agree

_____ Strongly agree

7. I found the following aspects of the SteppingStone system particularly easy to use (please list from 0-5 aspects)

A

_____

B

_____

C

_____

D

_____

E

_____

8. I found the following aspects of the SteppingStone system particularly difficult to use (please list from 0-5 aspects)

A

_____

B

_____

C

_____

D

_____

E

_____

Usability orientation script

Explains what will happen during the test and should be read out verbatim. Intended to put participants at ease and remind them that the product is being tested, not them.

Tele-rehabilitation is the provision of rehabilitation over distance using information and communication technologies (ICT). We are here to test how easy it is to use a tele-rehabilitation system, and we'd like your help.

You will be performing some typical tasks with this system today, that I will read out to you one by one shortly. I'd like to ask you to perform as you normally would. For example, try to work at the same speed and with the same attention to detail that you normally do. Do your best, but don't be all that concerned with the results. This is a test of the system which is still in a prototype form, and it may not work as you expect. While you are performing the tasks, I would appreciate it if you would think out loud, speak your mind. If you are having trouble with a task, please consult the manual. If you are having trouble understanding the manual, again please think out loud and mention the bits that are not clear.

During the test, you can ask questions at any time, but I may not answer them since this is a study of the system and its written support materials, and we need to see how they work with a person such as yourself working independently.

After the test I'll also be asking you to fill out a form and answer some questions. It is important that you answer truthfully. My only role here today is to discover flaws in the system from your perspective. So don't answer questions based on what you think I may want to hear. I need to know exactly what you think.

While you are working I'll be sitting nearby taking some notes and timings. Do you have any questions?

If not, then let's begin.

Usability task scenario *Read out step by step to the participant*

You had a successful knee replacement and have been sent home with a box. After settling in at home, you open the box. Following this, we will begin our session.

-Please unpack the box and setup the tablet etcetera as you normally would at home. If you normally would consult the quick start guide first, please do so today. If you normally don't use it until you get stuck, then work that way today.

-Now turn on the tablet, and start the "SteppingStone" application.

-Once it has loaded, please navigate to "information" and read the information guide on knee replacements "some info" until you feel you've read enough.

-You now remember that the physiotherapists at the hospital told you that it is important to do your exercises, and you feel like doing them. Therefore, strap on the knee device, and connect it to the tablet.

5 minute break in which the researcher checks the attachment of the knee device

-Then navigate to "Exercise". Note this takes you to a new menu where you can choose between "foot on ground" or "foot off ground". Choose the exercise you would like to do and bend your knee a few times while you watch the stick figure, try to get the knee to change colour until it's green.

-You are now in a playful mood, and having read that exercise is so important for your recovery in the information section, you feel like playing a game while exercising your knee. Navigate to "Games" and play a game.

-Doing the exercises made you curious as to how well your new knee is performing. Navigate to "Measure" and move your knee through its entire range of motion.

-Now remove the knee device and e-mail the results to your physiotherapist at **tom.gerards@strath.ac.uk**.

-By now the physiotherapist has had a look at the measurement you sent him/her. Navigate to "Information" to have a look at the progress report they sent you. You will need to enter *steppingstonep1@gmail.com* for username, and *hakunamatata1* for password.

-There were some things in the report you would like to talk to your physiotherapist about, navigate to "Call therapist" and give him/her a call. You will need to enter *pone steppingstone* for username, and *hakunamatata1* for password.

-After this, you feel like you want to share your experiences of using SteppingStone with other patients you met at the hospital, your friends, and family. Navigate to "my group" and leave a message on your experience using the "SteppingStone" Tele-Rehabilitation platform. You will need to enter *steppingstonep0@gmail.com* for username, and *hakunamatata0* for password.

Stepping Stone

Tele-Rehabilitation Platform

Quick start guide

1. Power on and unlock tablet

2. General tablet navigation

3. Portal application: launching and navigating

4. Information: selecting message and opening attachments

5. Knee Device: attaching and connecting

6. Exercise: choosing exercise form and starting

7. Measure: New measurement, start measurement

8. Games: starting a new game and playing it

9. Call Therapist: making and ending a call

10. My Group: leaving a message

1. Power on and unlock tablet

A] Power on: press and hold power button for 5-10 seconds.

Note: it may take a little while for the tablet to start up.

B] Unlock: place finger on lock symbol and drag right

Note: this takes you to the home screen, pictured on the right.

2. General tablet navigation

A] Previous screen: tap the arrow icon in the bottom bar

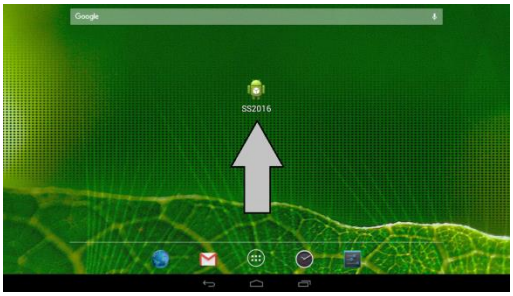
Note: if you press the button often enough you will end at the home screen

B] Home screen: tap the house icon in the bottom bar

3. Launching and navigating the portal application

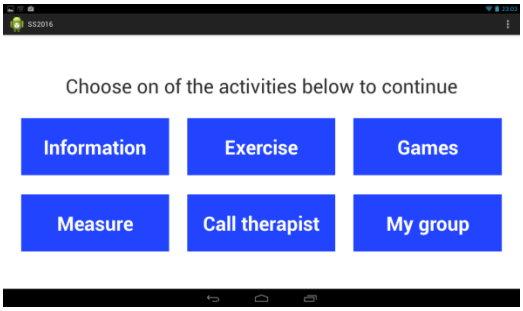
A] Launching the portal application: tap the SS2016 icon

Note: the SS2016 icon is in the centre of the home screen



B] Navigating the portal application: tap one of the six blue buttons

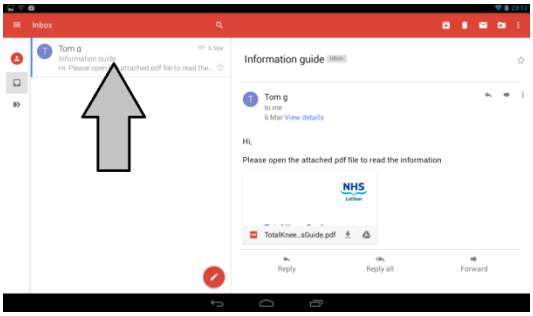
Note: you can exit the portal by tapping either the home or arrow icon in the bottom bar



4. Information function

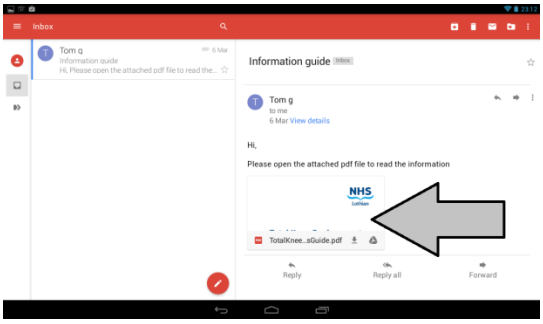
A] Selecting a message: tap the message in the left column

Note: the message will show up in the right column



B] Opening an attachment: tap the box in the message

Note: tap the arrow or house icon to close an attachment once opened



5. Knee Device

A] Attaching: firmly tighten the Velcro straps whilst standing or sitting

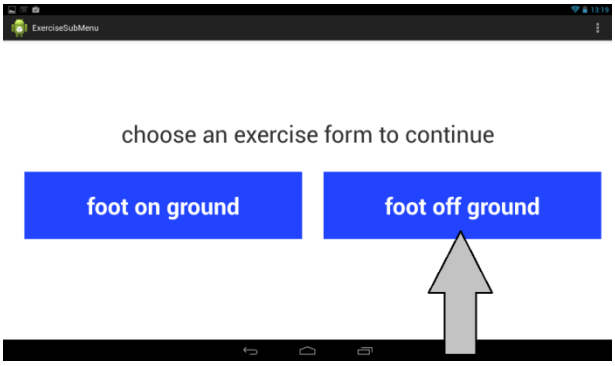
Note: align the black arms of the device with your leg; if unsure align with trousers seam.

B] Connecting to tablet: insert the usb plug into the usb port

Note: make sure the device is switched to mode “0” and insert the plug the right way up.

6. Exercise function

A] Choose exercise form: tap “foot off ground” for your sitting exercises

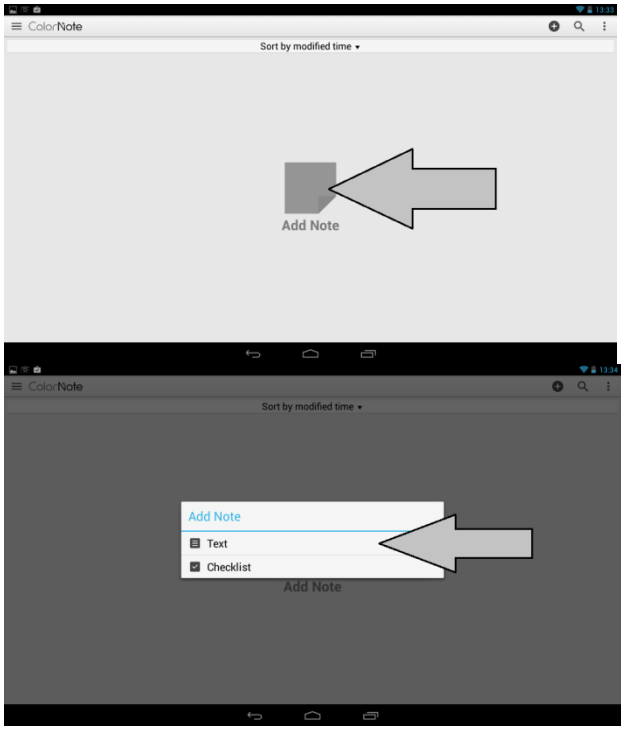


B] Start exercise: Switch the knee device into position “II” and do your exercise

Switch the knee device back to “0” before exiting the exercise function

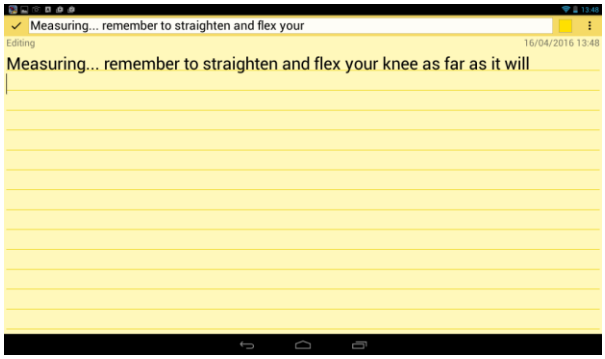
7. Measure function

A] New measurement: tap add note, then text



B] Start measurement: switch the knee device into position “I”

Note: the following message will appear on the screen:



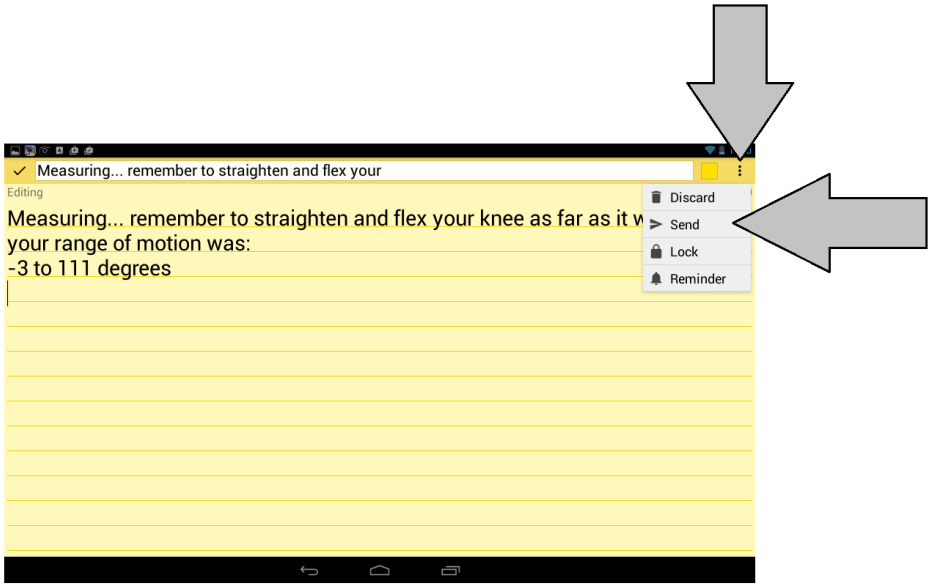
C] Stop measurement: switch the knee device into position “0”

Note: the results will now appear on the screen as well

D] Disconnect the Knee device: unplug the device from the tablet

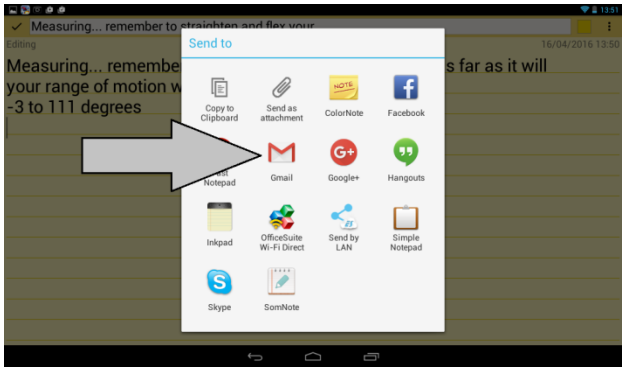
Note: If you leave the knee device plugged in, your on screen keyboard will not appear

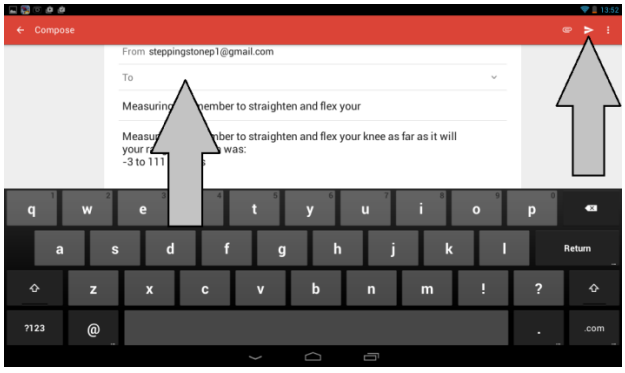
E] Mail measurement: tap the three dots in the top right, then “send”



F] Mail measurement: tap “Gmail”, enter address at “To:”, then tap the kite

Note: enter your therapist’s e-mail address at “To:”





8. Games function

A] Starting a new game: tap the welcome screen then tap the play icon

B] Playing the game: switch the knee device into position “II”

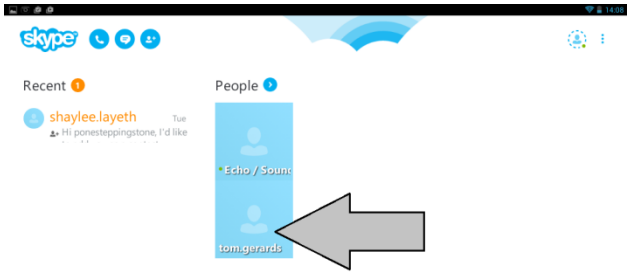
Note: straightening the leg will make the helicopter rise, flexing the leg will make it descend

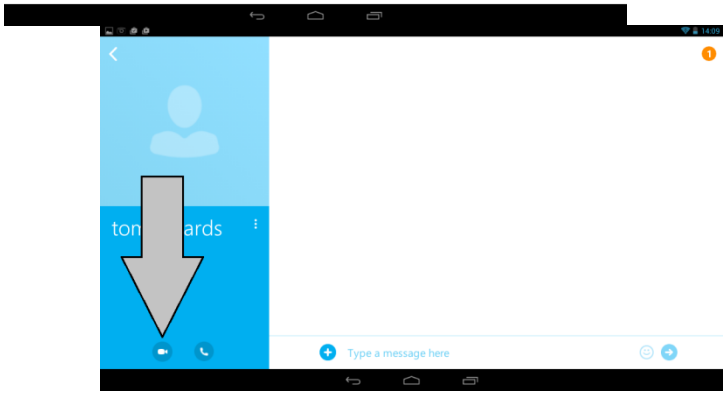
Switch the knee device back to “0” as soon as you stop flying the helicopter

e.g. after you crash

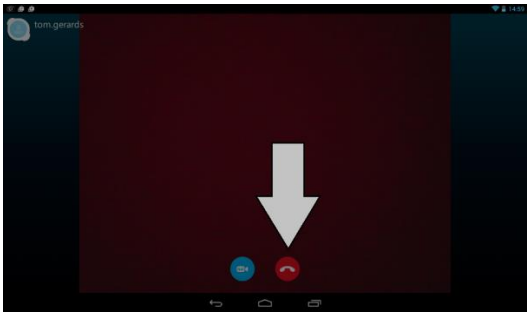
9. Call Therapist function

A] Making a call: in the column “people” tap “tom.gerards” then tap the video camera icon.



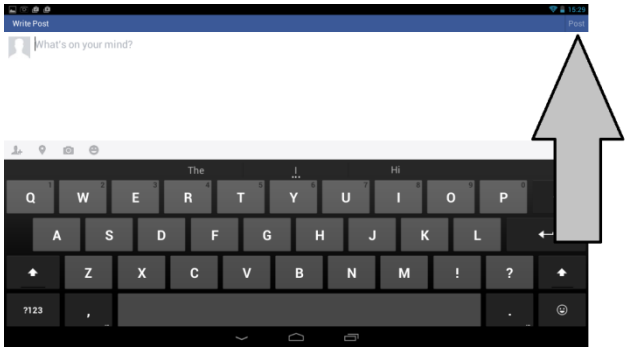


B] ending call: tap the red phone symbol



10. My Group function

A] Leave a message: tap “status”, then type your message and tap “post”



DEC/BioMed/2016/76 ethics permission

Thank you for the above revised ethics application.

The Departmental Ethics Committee is satisfied with all changes in the revised application and gave their approval for this project with immediate effect.

Good luck with your project and remember you must inform us in writing of any changes to the project and any unforeseen circumstances which arise during the project.

Regards

Linda Gilmour *(Secretary to)*

Departmental Ethics Committee

Department of Biomedical Engineering

University of Strathclyde

Wolfson Centre

106 Rottenrow East

Glasgow G4 0NW

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South East Coast - Surrey Research Ethics Committee
Bristol Research Ethics Committee Centre
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Lewins Mead
Bristol
BS1 2NT

Telephone: (020) 71048053

06 July 2016

Prof Philip Rowe
University of Strathclyde
Wolfson centre
106 Rottenrow
G4 0NW

Dear Prof Rowe

Study title:	**Usability study of a scalable post total knee arthroplasty Tele-Rehabilitation platform prototype**
REC reference:	**16/LO/1295**
Protocol number:	**1.1**
IRAS project ID:	**198594**

The Proportionate Review Sub-committee of the South East Coast - Surrey Research Ethics Committee reviewed the above application on 05 July 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mr Raj Khullar, nrescommittee.secoast-surrey@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee 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.

Management permission must be obtained from each host organisation prior to the start of the

study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

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").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials TWIMC 1516]		20 July 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Combined Liability TWIMC 1516]		20 July 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [PI TWIMC 1516]		20 July 2015
Interview schedules or topic guides for participants [task scenario]		20 April 2016
IRAS Checklist XML [Checklist_24062016]		24 June 2016
Non-validated questionnaire [pre test questionnaire]	1	10 April 2016
Other [post test questionnaire]	1	10 April 2016
Other [orientation script]	1	10 April 2016
Participant consent form [consent form]	1	10 April 2016
Participant information sheet (PIS) [PIS]	1	10 April 2016
REC Application Form [REC_Form_24062016]		24 June 2016
Research protocol or project proposal [study protocol]	1	10 April 2016
Summary CV for Chief Investigator (CI) [CI CV]	1	11 April 2016
Summary CV for student [student CV]	1	11 April 2016
Summary CV for supervisor (student research) [supervisor CV]		

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

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 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 HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

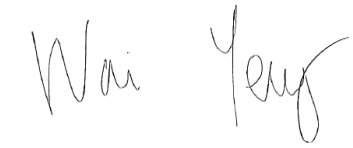
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

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

16/LO/1295	**Please quote this number on all correspondence**

Yours sincerely



PP - Dr Mark Atkins
Chair

Email: nrescommittee.secoast-surrey@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Mrs Helen Baigrie*
Mr Mark Blyth, NHS Glasgow Royal Infirmary

South East Coast - Surrey Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Mark Atkins	Consultant Virologist	Yes	
Mrs Chrissie Lawson	Nurse Specialist	Yes	
Mr Robin Walsh	Retired Professor of Physical Chemistry	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Wai Yeung	REC Assistant