Design and Development of a Weight Support Device for Upper Limb Stroke Rehabilitation

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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:

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Abstract

Upper limb recovery following a stroke is generally quite poor. Upper limb therapy at clinic is usually limited due to lack of time and resources to accommodate the growing stroke population. Consequently, a small percentage of therapy is spent on improving upper limb movement and is generally limited to range of motion and stretching exercises. As a result, upper limb exercises are prescribed to stroke survivors to perform at home. Subsequently, the potential to facilitate self-practice at home has been realized leading to the development of numerous rehabilitative and assistive devices for the upper limb. However, commercially available devices do not tend to be adopted for home use due to practical and economic factors.

This thesis details the design, development, and evaluation of a weight support device for home-based upper limb rehabilitation, driven through a user-designed approach. This was achieved through engaging with stakeholders (i.e. stroke survivors, therapists) throughout the design process via informal interviews, focus groups, and prototype testing, ensuring that their desired requirements were incorporated into the final device.

From this process, a low-cost, portable, weight support device was manufactured with supports for both the upper arm and forearm. Furthermore, an external feedback system was created to provide real-time feedback to the user to help motivate and encourage them to engage in independent practice at home with the weight support device. Testing the device and feedback system with participants in their home environment showed that it was acceptable for home use, suggesting that it could be feasible for aiding with the facilitation of self-practice. Further refinements towards

range of motion and portability of the device will be required as desired by participants in addition to providing a diverse range of feedback applications to engage with.

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List of Abbreviations

ADL	Activities of Daily Living
ARAT	Action Research Arm Test
BASIC	Brain and Spinal Injury Centre
CAD	Computer-Aided Design
CAREN	Computer Assisted Rehabilitation Environment
CCM	Controlled Convergence Method
CIMT	Constraint Induced Movement Therapy
DoF	Degrees of Freedom
EMG	Electromyography
ESD	Early Supported Discharge
EULT	Enhanced Upper Limb Therapy
FIM	Functional Independence Measure
FM	Fugl-Meyer
HDPE	High Density Polyethylene
IMU	Inertial Measurement Unit
MAL	Motor Activity Log
MCID	Minimal Clinically Important Difference
NEADL	Nottingham Extended Activities of Daily Living
NHS	National Health Service
PDS	Product Design Specification
PMI	Plus, Minus, Interesting
PMMA	Poly(methyl methacrylate)
PVC	Polyvinyl Chloride
RCT	Randomised Controlled Trial
RF	Reach Forward
RGS	Rehabilitation Gaming System
RS	Reach Side
RTT	Repetitive Task Training
RU	Reach Up
SIGN	Scottish Intercollegiate Guidelines Network
T-WREX	Therapy Wilmington Robotic Exoskeleton
UEA	University of East Anglia
VR	Virtual Reality
WREX	Wilmington Robotic Exoskeleton
WSD	Weight Support Device

Introduction

Stroke is a serious and life-threatening condition that is caused by a disturbance in the blood supply to the brain either through a blockage (ischaemia) or bleed (haemorrhage) that deprives the cells of oxygen and nutrition leading to cell death (Sacco et al. 2013). This in turn leads to brain injury, disability and potentially death (Warlow et al. 2008). Approximately 85% of all strokes are ischaemic where blood flow to a region of the brain is cut off by a blood clot in an artery caused by either thrombosis or emboli. Haemorrhagic strokes are less common and are caused by bleeding in the brain mainly due to the rupturing of a weakened blood vessel (Intercollegiate Stroke Working Party 2016).

Considered a medical emergency worldwide, individuals having a stroke require immediate treatment via surgery and medication in order to prevent death and limit the neurological damage. While advances in medication and treatment have substantially decreased stroke mortality, it continues to be one of the leading causes of death. On a global scale, there are approximately six million stroke related deaths per year, the second largest cause of death behind ischaemic heart disease with approximately nine million per year (World Health Organisation 2018).

The decrease in mortality has led to a rise in the number of people surviving a stroke with long-term health effects. Consequently, more and more individuals living with stroke experience disability and a decreased quality of life. Within the UK, there are over 1.2 million stroke survivors (Stroke Association 2018); globally, there are estimated to be 80 million stroke survivors (Gorelick 2019). Additionally, it is

expected that the prevalence of those suffering from stroke-related disabilities will only increase over the next two decades (Langhorne et al. 2011). The long-term effects of stroke can differ from person to person and are dependent on the size of the initial stroke lesion, the region of the brain that has been affected, and the degree of subsequent recovery. Since each hemisphere controls the contralateral side of the body, a stroke occurring in the left hemisphere will affect sensation and motor control on the right side of the body (and vice-versa). Furthermore, other functions such as cognition, speech and vision can be affected depending on the location of the injury. The most common and debilitating effects of stroke are the motor impairments, particularly muscle weakness and impaired motor control, affecting approximately 80% of patients. (Canning et al. 2004; Langhorne et al. 2009) This is a direct result of the damage to the neuronal pathways between the motor cortex and the spinal cord, the parts of the central nervous system responsible for generating motor impulses and executing the desired movements when the signal has been received (Raghavan 2015). Difficulty or inability to move the limbs (and trunk) on one side of the body (known as hemiplegia or hemiparesis) lead to problems with walking and balance. Problems also arise in performing daily activities such as eating, toileting and general self-care that require upper limb function. It is estimated that 25-74% of stroke survivors rely on assistance or are full dependent on caregivers to perform activities of daily living (ADL) (Miller et al. 2010).

Upper Limb Impairment and Recovery

Approximately 80% of patients suffer from some form of stroke related motor impairment (Langhorne et al. 2009) with 75% displaying upper limb symptoms following an acute stroke (Lawrence et al. 2001). Until an effective and readily

available medical treatment can help reduce or eliminate impairments post-stroke, rehabilitation interventions remain the best possible solution to recovery (Langhorne et al. 2011). Rehabilitation takes many forms with most taking advantage of the brain's capacity to re-organise its neural pathways, a process known as neuroplasticity (Dobkin 2005). There is evidence that constraint-induced movement therapy and repetitive task training can have beneficial effects towards upper limb recovery (Corbetta et al. 2015; French et al. 2016). However, there is also evidence that a high-level of this intensive rehabilitation is required in order to optimise recovery (Han et al. 2013), which is currently challenging for therapists to provide to patients (Bernhardt et al. 2007).

As mentioned earlier, the increasing number of stroke survivors will continue challenge the ability of health services to provide optimum rehabilitation to each patient due to lack of resources (time, staff, money, etc.). Consequently, self-directed approaches where patients independently perform recovery exercises away from a clinical setting have been adopted though outcomes vary dependant on the approach used and also motivation from the individual to carry out the programmes (Da-Silva et al. 2018).

To help facilitate self-management, various assistive and rehabilitative technologies have been developed for individuals to use (Brackenridge et al. 2016; Mehrholz et al. 2018). These types of devices can help provide a home-based solution to the need for high intensity repetitive rehabilitation while reducing the need for healthcare resources. However, while these devices have been acknowledged as a solution, their adoption for use is minimal due to practical and economic constraints, particularly with regards to self-management at home (Demain et al. 2013).

Research Aim and Objectives

The primary aim of this EngD project was to develop a weight support system that could enable stroke survivors to carry out their own upper limb rehabilitation. The second aim was to develop a feedback system to be used in conjunction with the weight support device to provide real-time feedback and track progress of upper limb exercises. The third aim was to ensure the developed system was acceptable and feasible for home-use.

The main objectives of this thesis are:

1. Review the literature to ascertain the need for a weight support device and evaluate existing technologies.
2. Develop a design specification via a user-centred design process through collaboration with users (stroke survivors, their carers, and therapists), leading to the development of initial concepts with desired attributes from stakeholders.
3. Choose a concept to take forward and build a prototype.
4. Test the functionality of the prototype with a small group of stroke survivors.
5. Modify and build a second version of the prototype based on user feedback in addition to developing an interactive feedback system to be used with it.
6. Conduct a series of case studies using the prototype and feedback system in the home environment to test acceptability.
7. Make recommendations for future development of the system.

Thesis Outline

This thesis is split into six chapters describing and explaining the rationale for the weight support device developed for this project.

Chapter 1 reviews the existing literature in addition to current devices for upper limb rehabilitation. Chapters 2 & 3 explain the design process used starting from product design specification and concept generation (Chapter 2) to finalising and detailing a design towards prototype development (Chapter 3). Chapter 4 details initial feasibility testing of the first prototype. Chapter 5 presents the changes made to the weight support device based on the feedback from participants in the previous chapter. Additionally, it describes the development of a feedback system used in conjunction with the prototype and a usability study with stroke survivors using the device both in the laboratory and home setting. Chapter 6 discusses the project as a whole and future steps for the developed prototype that is outwith the scope of this thesis.

1 Literature Review

Rehabilitation post-stroke is a process that aims to encourage the retraining of neurological pathways that have been impaired or the formation of new ones through means of active and passive exercises (Langhorne et al. 2011). Coupar et al. found that the initial severity of motor impairment or function is the most significant predictor of long term outcome of a patient's recovery (Coupar et al. 2011). Additionally, it is generally accepted that the majority of upper limb function is recovered in the first 3-6 months with patients tending to plateau following this period (Jørgensen et al. 1995; Kwakkel & Kollen 2013). Those showing synergistic movement (i.e. the activation of a group of muscles contributing to a particular movement (Wojtara et al. 2014)) in the arm within 4 weeks of stroke onset do however have a 90% chance of improving their function (Kwakkel et al. 2003). Therefore, providing upper limb rehabilitation to stroke patients who have some natural recovery as soon as possible is necessary to offer the best chance at recovering function.

Understanding the impairments in the upper limb resulting from stroke can be complex. Multiple impairments can be simultaneously present and can alter at different rates over the recovery process. As a result, changes to a patient's therapy programme may be required to adapt to their needs over time (Raghavan 2015). Therapists and researchers have therefore developed and tested different types of interventions to tackle these issues and determine the most appropriate intervention for stroke survivors to maximise their upper limb recovery. As such, stroke survivors may undertake different types of interventions, one that has been tailored to their needs.

1.1 Shoulder Pain, Subluxation, and Preventative Measures

Shoulder pain has often been reported as a common complication after stroke that can delay rehabilitation and have a negative influence on daily life. From a study interviewing stroke survivors (Lindgren et al. 2007), a relationship between the prevalence of shoulder pain and arm motor function was reported. Individuals with limited or no upper limb motor function post-stroke were found to experience more shoulder pain than those with normal upper limb function, highlighting the increased risk in developing shoulder pain for stroke survivors with impaired motor function (Lindgren et al. 2007). Additionally, although no significant correlation has been identified as of yet, it has been hypothesised by several reports that subluxation of the glenohumeral joint may be a contributing factor in the development of shoulder pain in stroke patients (Walsh 2001). Consequently, the development and use of upper limb supportive devices has been explored to prevent and potentially reverse subluxation with the goal of reducing pain and improving shoulder function after stroke.

One Cochrane review (Ada et al. 2005) looked at studies using available supportive devices (slings, wheelchair/chair attachments and other orthoses) with stroke patients to determine their efficacy in preventing subluxation. Four trials were identified (one on slings, and three on strapping) that looked at the effectiveness of using supportive devices against not using supportive devices. From these, there was found to be insufficient evidence that supportive devices prevented subluxation, reduce pain, or increase function. Four observational studies were also examined, providing results for the immediate effects of various slings and wheelchair attachments on shoulder subluxation by observing humeral head position using X-ray. The majority of these produced an immediate effect in reducing subluxation but no other outcome measures

were investigated in these studies nor were the long-term effects of using these orthoses measured. The lack of evidence derives from the limited number of quality randomised controlled trials (RCTs) available for review.

A more recent systematic review looked at three new studies and five from the existing Cochrane review (four observational studies and one RCT) for the prevention and reduction of pain with shoulder orthoses (Nadler & Pauls 2016). Conclusions were similar to that of the original Cochrane review though it did suggest that orthoses might reduce pain and be tolerable by patients following prolonged use. In another trial published after the review, comparisons between the use of hemi-slings and the use of triangular slings and lap-trays over a four week period for rehabilitation was investigated by the same author of the Cochrane review (Ada et al. 2016). Subluxation was measured via X-ray and the difference between intact and affected shoulder were calculated. No statistically significant difference (Mean Difference -3 mm, 95% CI -8 to 3) was found between the two groups providing more evidence that these types of supportive devices are ineffective at reducing shoulder subluxation and in turn, ineffective at reducing pain and improving function.

Despite this, therapists are reported to use slings as techniques for rehabilitation over other methods. One study analysed questionnaires completed by occupational therapists (n=55) enquiring about treatment techniques they employ in managing the impaired upper limb post stroke (Gustafsson & Yates 2009). Their results revealed that techniques with little evidence of improving impairment (pillow supports, positional stretching, and slings) were favoured over treatments with significant supporting evidence. Unfortunately, the study did not explore the clinical reasoning behind these decisions.

Another study looked at the clinical reasoning behind therapists choosing slings for patients with shoulder subluxation in California (Li et al. 2013). In this study, results from a survey sent out to occupational therapists (n=168) appeared to demonstrate that decisions into the chosen rehabilitation technique may have been affected by cost and convenience factors. Furthermore, the results suggested that therapists who had undertaken additional training in rehabilitation after stroke increased their awareness of the slings being prescribed and there adverse effects leading to more "procedural reasoning" (Li et al. 2013). This reasoning related to biomedical and biomechanical approaches to problem solving, as opposed to "pragmatic reasoning", related to organisational and economic considerations in clinical practice (Li et al. 2013).

In the UK, similar results were found where assistive technologies were not being adopted into clinical practice due to lack of awareness, knowledge, and access (Hughes et al. 2014). Using questionnaires it was found that 41% of healthcare professionals and 64% of patients and carers had never used assistive technologies (defined in this study as "electrical or mechanical devices designed to help people recover movement"). Furthermore, healthcare professionals considered research evidence of the effectiveness of assistive technologies to be the most important factor to support their use. However, the technologies they used or prescribed were not supported by research evidence. The next section will discuss various interventions that have been researched to determine if they are effective in promoting upper limb recovery following a stroke.

1.2 Upper Limb Rehabilitation Interventions

Various interventions that aim to provide motor recovery for the upper limb post-stroke have been established and tested (Pollock et al. 2014). These interventions aim to improve specific impairments such as muscle weakness or spasticity, and/or improve functional movements such as reaching and grasping. They can be performed separately or combined to provide a treatment that targets multiple aspects of upper limb recovery. As a result, interventions will vary in difficulty from person to person and while one intervention will benefit upper limb recovery in some, a completely different intervention may have the same effect for a different group that did not benefit from the former. However, this can be difficult to translate into practice due to various factors such as the weight of the evidence behind an intervention, and availability of resources (i.e. therapists) to carry out specific interventions.

Several reviews and documents have been published to provide evidence and guidance on the most effective interventions for improving upper limb impairments and motor recovery (Langhorne et al. 2009). The Scottish Intercollegiate Guidelines Network (SIGN) provide guidelines for clinicians and hospital departments on the management of patients with stroke including rehabilitation (Scottish Intercollegiate Guidelines Network 2010). Based on evidence quantity and quality from systematic reviews, trials (RCTs, case studies, etc.), and professional opinions from clinical experience, the document offers information and suggestions on which interventions should, and should not be used in practice. While the guidelines provide a reasonable basis for recommendations in stroke care, new and updated reviews contradicting some of the recommendations call for updates to the document.

Four Cochrane reviews have been published looking at single interventions for upper limb stroke rehabilitation (Mehrholz et al. 2015; Coupar et al. 2010; French et al. 2016; Corbetta et al. 2015). One Cochrane review (Pollock et al. 2014) looked at single intervention Cochrane reviews in addition to other systematic reviews and articles to collate all information on upper limb interventions. To determine if there is sufficient evidence to support their effectiveness at improving upper limb function, impairment, and activities of daily living (ADL), 18 interventions were identified from 40 systematic reviews of RCTs, containing a total of 503 studies. These interventions were: bilateral and/or unilateral training; supportive devices (e.g. slings); constraint-induced movement therapy (CIMT); electrical stimulation; repetitive task training (RTT); task-specific training; virtual reality; electro-mechanical, and robotic-assisted training; biofeedback; Bobath therapy; brain stimulation; "hand-on" therapy; mental practice; music therapy; mirror therapy; pharmacological interventions; sensory interventions; strength training and stretching and positioning. From the aforementioned Cochrane review, there was moderate-quality evidence that CIMT, mental practice, mirror therapy, sensory interventions, virtual reality, and a relatively high dose of RTT had a beneficial effect on upper limb recovery though there was a lack of evidence that one intervention was more beneficial than others. (Pollock et al. 2014). Furthermore, the optimal dose of a specific intervention could not be determined. As such, it was found that there was no high-quality evidence for any of the interventions used as part of routine practice and further research was still required to determine appropriate interventions in addition to the frequency and intensity they should be administered. For this literature review, the following interventions were reviewed in more detail: bilateral and/or unilateral training; supportive devices (e.g.

slings); CIMT; electrical stimulation;; repetitive task training (RTT); task-specific training; virtual reality and electro-mechanical, and robotic-assisted training.

Constraint-induced movement therapy (CIMT) involves restricting the movement of the non-affected limb by means of a sling or a mitt, thereby forcing the affected upper limb to be used (Corbetta et al. 2015). Large amounts of task specific practice are then performed using an operant conditioning method where a specific task is performed in small increments of difficulty, with praise being given upon completion of the task. Learned non-use of the affected limb can be a common problem for stroke survivors and this intervention could help reduce this issue. CIMT was well documented as potentially having a beneficial effect in improving upper arm function and reducing stroke disability, based on 21 identified RCTs with 508 participants (Langhorne et al. 2009). However, a more recent Cochrane review (Corbetta et al. 2015) of 42 RCTs totalling 1453 participants concluded that while CIMT can improve motor impairments and function, the benefits did not substantially reduce disability as previously hoped, contradicting earlier reviews that CIMT could be superior to conventional rehabilitation. Additionally, there is little information on the long-term effects of CIMT. The intervention is quite intensive, requiring several hours of practice of day with the non-affected arm being restricted for most of the day. In turn, this could lead to some individuals becoming distressed and refusing to participate in this type of intervention. From a questionnaire, healthcare professionals (n=28) said that while CIMT is easy to set up (82%), and safe (93%) it was not fun to use (14%) nor looked good (19%) (Hughes et al. 2014). Additionally, patients and carers (n=4) also said that while it was easy to set-up (100%) and safe (75%), it was not fun to use (25%) nor looked good (0%). Although a small sample size, these opinions suggest that there

could be an issue with compliance with the intervention. Another questionnaire study indicated that patient's (n=208) were not interested (68%) in participating in CIMT, stating concerns with the length of time wearing the device (68.5%), number of days in therapy (60.1%), and number of hours in therapy (63.6%) (Page et al. 2002). Consequently, the SIGN guidelines suggest that healthcare professionals be trained in CIMT and then offer the intervention based on patient acceptability, in addition to the perceived benefits and risks (Scottish Intercollegiate Guidelines Network 2010).

Bilateral training incorporates both arms in performing the same activity. This can be achieved via free movement or through various mechanical or robotic devices to provide assistance in moving the affected limb to match the actions of the non-affected limb. The main goal of bilateral training is to improve upper limb recovery through interlimb coupling through communication between the two hemispheres, via the corpus callosum, to control bimanual arm movements (Coupar et al. 2010). As the unaffected hemisphere is primarily in control following a stroke, performing bilateral exercises is thought to help increase activity in the affected hemisphere and in turn, improve upper limb function. However, from two separate reviews (Coupar et al. 2010; van Delden et al. 2012) it was concluded that there is insufficient evidence to support the effectiveness of bilateral training against other conventional interventions and that these are just as effective at improving upper limb function. Furthermore, based on the literature, there is moderate-quality evidence that unilateral training may be more effective than bilateral training (Pollock et al. 2014).

Electrical stimulation has also been employed to assist with upper limb rehabilitation and to determine if it is suitable to assist with shoulder subluxation (Ada & Foongchomcheay 2002; Nascimento et al. 2014). This refers to the electrical

stimulation of muscles either to help perform functional tasks by stimulating the muscles required or through repetitively stimulating the muscle with the aim of strengthening it. One review reported that the use of cyclical electrical stimulation can increase muscle strength and improve activity following stroke (Nascimento et al. 2014). A combination of controlled trials with or without randomisation from this review showed that electrical stimulation was favoured over the control for trials involving the wrist and finger extensors though each trial used a different combination of frequency and duration of the stimulation applied. Only one trial focussed on stimulation of the shoulder (Kobayashi et al. 1999) finding significant improvement ($p < 0.05$) in subluxation but not in muscle strength ($p = 0.10$).

A similar review (Farmer et al. 2014) suggested that electrical stimulation was beneficial for upper limb stroke care with the exception of the shoulder; exclusive stimulation to this region appeared to have a detrimental effect to upper limb function. However, in contrast, another review (Ada & Foongchomcheay 2002) suggests that there is evidence to support the use of this treatment early after stroke to prevent shoulder subluxation, though not its reduction should it have already occurred. Based on these reviews, there appears to be a lack of clarity on the efficacy of electrical stimulation applied to the shoulder and further research is required to determine its effects on subluxation, and overall upper limb strength and function.

Repetitive task training (RTT) has been suggested to be an effective intervention for improving upper limb function (Pollock et al. 2014). It involves the repeated practice of functional tasks (e.g. picking up a ball or cup) to reduce muscle weakness and spasticity. Additionally, high intensity practice has been hypothesised at improving performance in activities of daily living. Furthermore, it is hypothesised that this type

of intervention could enhance motor learning through active cognitive development and reacquiring functionally relevant skills (Schmidt & Lee 2005). The practice of functional tasks is considered as a separate intervention in the Cochrane review (Pollock et al. 2014) though the ability to combine this with RTT is realised. A Cochrane review that focussed on RTT (French et al. 2016), showed that upper limb function slightly improved relative to conventional therapy ($p=0.045$) though it was reported that the quality of the evidence was low. In contrast, the SIGN guidelines did not recommend the use of RTT for upper limb rehabilitation though this document was published in 2010 suggesting that the guidelines may need to be updated in light of the above review (Scottish Intercollegiate Guidelines Network 2010).

1.3 Technologies to support RTT

One of the benefits of RTT is its relative simplicity and flexibility in that it can be combined with a number of different interventions, providing the potential to enhance rehabilitation. Mechanical and/or robotic devices are one type of technology that can be used in combination with RTT to aid rehabilitation post-stroke. These devices can provide passive or active assistance to the user to aid their training. Thought to provide a distinct advantage over conventional therapies, these devices may help the user perform a larger amount of repetitions during a training session, due to the devices' assistive nature. Additionally, they can increase the user's motivation to train. (Kwakkel et al. 2008).

Several systematic reviews of these types of devices have been published: two focussing solely on robotic devices (Maciejasz et al. 2014; Kwakkel et al. 2008); one on bilateral upper limb devices (van Delden et al. 2012); one on a large variety of devices both mechanical and robotic (Brackenridge et al. 2016), and a Cochrane

Review on RCTs using these devices. (Mehrholz et al. 2015). 34 trials were included in the Cochrane review and it was concluded that using electromechanical and/or robotic devices for upper limb training may be effective at improving activities of daily living in addition to function and muscle strength following stroke (Mehrholz et al. 2015). However, it was noted that although this type of intervention could be used for rehabilitation, the intensity, duration and amount of exercise varied from trial to trial preventing an optimal quantity of each being known. It is likely to be difficult to determine the optimum dosage of treatment as this will vary from person to person in addition to the amount of treatment an individual can receive before fatiguing. Despite this, electro-mechanical and/or robotic devices could provide the opportunity for stroke survivors to perform their rehabilitation exercises independently, outside of therapy sessions (Kwakkel et al. 2008).

1.4 Home-Based Therapy

Following a stroke that causes impairment, individuals will typically spend time in hospital to begin their rehabilitation. Generally, this will incorporate physiotherapy, occupational therapy, and speech and language therapy where required. Furthermore, severity of the stroke will factor into the duration a patient may need to stay in the hospital for; those that suffered from a mild stroke may only be required to stay for a minimum of one night. Those who have suffered from a more severe stroke may be required to stay for a few weeks, as they will require more therapy and are unlikely to be able to travel to and from home for their therapy. From an audit on Scottish Stroke Improvement, 89% of stroke patients discharged during 2018 were admitted to a stroke unit during their hospital stay (Scottish Stroke Care Audit. 2019). The mean stroke unit stay was 22.8 days. Furthermore, as mentioned previously, the current decrease in

mortality rate from stroke has led to an increase in the number of individuals living with stroke (Langhorne et al. 2009).

Consequently, the total hours of therapy required to satisfy this growing population can have a substantial impact on resources in hospitals and clinics. With the growing number of stroke survivors, more therapists and space (i.e. therapy rooms) are required to meet the continuously growing demand leading to an increase in the costs necessary to provide these services to the stroke community. In addition, there is evidence that providing a larger dose of rehabilitation into a stroke survivor's therapy is beneficial for their recovery. Schnieder et al. conducted a systematic review of RCTs that investigated the effects of stroke survivors receiving an extended amount of therapy against those receiving the current standard duration (Schneider et al. 2016). Overall, 14 studies covered 15 comparisons with 11 looking at upper limb rehabilitation and four for the lower limb. However, only seven of the upper limb comparisons were considered useful for the meta-analysis due to two studies with skewed data and another two with missing data. Despite this setback, they found, through pooling the data, that increasing the amount of rehabilitation (an increase of 240% was estimated) would benefit an individual's recovery via an increase in upper limb activity (Schneider et al. 2016).

However, providing an increase in therapy can prove challenging for stroke units and patients. A national survey in England demonstrated that current staffing levels are not meeting the Department of Health guidelines preventing them from providing the recommended amount of therapy to every patient (McHugh & Swain 2014). Clarke et al. reported that the most important factor causing this was the amount of time therapists spent in information exchange (i.e. handover, team meetings, etc.) (Clarke

et al. 2018). Outwith the UK, one study reported that only 20% of patients (n=58) received therapy from more than one therapist and four to 11 minutes of upper limb therapy were provided (Bernhardt et al. 2007). Alternatively, community-based rehabilitation is becoming more common, or being considered, to address the issues associated with the increased stroke survivor population. Various health boards in Scotland are currently at different stages in transitioning to community-based rehabilitation with some currently planning to implement it and others partially or completely implemented (Scottish Stroke Care Audit 2019). These services involve therapists working with patients at their homes to provide them with the necessary rehabilitation to improve performance in activities of daily living and reduce disability. A Cochrane review concluded that therapy programmes targeted towards stroke patients within one year of onset appeared to improve independence in activities through rehabilitation at home although the type and amount of benefit was not detailed. (Outpatient Service Trialists 2003). For stroke survivors' one-year post onset, it is unclear whether rehabilitation at home can improve recovery due to the small amount of evidence available (Aziz et al. 2008). A review focussing on upper limb outcomes following home-based programmes identified four studies totalling 166 participants (Coupar et al. 2012). No significant differences were found in performance of ADL ($p=0.19$) nor functional movement ($p=0.077$) for two of the studies. One study from the review looked at upper limb motor impairment yet no significant difference ($p=0.9$) between the groups were found suggesting a greater amount of evidence is required to determine the effects of home-based therapy over conventional care.

Telerehabilitation is an alternative means of providing rehabilitation via communication and information technologies between a healthcare professional and a patient at home (Laver et al. 2013). The increasing development and advancement of computer and communication technologies has led to an increase in the number of telerehabilitation applications available (Peretti et al. 2017). Communicating with a patient at home can be done through various methods such as phone, video calling, e-mail, texting, or dedicated applications on personal computer, smartphone, and tablets. Doing so can enable reduced hospitalisation times for patients and save costs for both the patient and health care provider. Furthermore, it can allow for treatment of stroke without a direct face-to-face interaction between the patient and therapist solving the potential issue of complexities associated with travelling to and from a rehabilitation clinic or patient's home (Peretti et al. 2017). One Cochrane review looked at telerehabilitation services for stroke to determine whether it improved independence in performing ADL compared to either in-person rehabilitation or no rehabilitation (Laver et al. 2013). No statistically significant ($p=0.99$) results for ADL improvement were found based on 2 of the 10 studies with 611 participants suggesting there is currently insufficient evidence to support the effectiveness of the technique. Furthermore, only two studies with 46 participants looked at upper limb function (no statistically significant difference, $p=0.067$) with participants using computer software to remotely train the upper limb. Again, more evidence is thus required to determine if telerehabilitation can have a beneficial effect on upper limb function. Finally, no trials from the review looked at cost effectiveness of the intervention.

Providing stroke survivors with methods to facilitate self-practice has been investigated as an additional approach to rehabilitation. Rinne et al. looked at using

mobile devices to allow patients to play simple games for improving upper limb function (Rinne et al. 2016). The main aim of the research was to assess the accessibility of these types of devices with stroke survivors to increase the amount of rehabilitation they receive. 87 participants with varying degrees of disability resulting from a stroke (classified as mild, moderate or severe) completed the study that compared using different input methods (finger-swipe, tapping, joystick or tilting) to control a cursor on a tablet or smartphone device. Results were scored based on the level of ability displayed by each participant ranging from zero (no movement) to three (full range of movement plus ability to direct cursor to specific segment). Level of disability was shown to have a significant effect ($p<0.001$) on ability for four of the different control methods with 90% of mildly impaired participants scoring a three compared to 0% of those with a severe impairment. An alternative control scheme using a handgrip incorporating a force sensor was also used. Use of the handgrip showed significantly improved results to participant's scores ($p<0.001$) when compared to the best of the previous four methods with 58% of severely impaired patients achieving a score of three. While this would appear to show that this type of control method is promising for self-practice following stroke, the author acknowledges that a large proportion of stroke survivors may be unable to use this type of intervention due to excluding participants with poor cognition and co-morbidities who were deemed unlikely to be capable of carrying out the exercises. Furthermore, patients exhibiting arm pain were also excluded from the study though the amount of pain an individual was suffering was not quantified. The study showed that making interventions accessible and adaptable for patients with varying degrees of disability can enable engagement with self-practice.

A systematic review focussed on self-directed therapy programmes for upper limb rehabilitation following stroke (Da-Silva et al. 2018) with 40 studies included where over 50% of a patient's therapy was initiated and performed by themselves. Studies were grouped into categories based on specific technologies used for therapy including no technology, CIMT, interactive games, robotic and orthotic devices, and electrical stimulation. Benefits in arm function were found in CIMT ($p=0.05$) and electrical stimulation ($p=0.02$). Results suggest that self-directed approaches to rehabilitations can have a positive effect on upper limb outcomes though more evidence is required for the different types of interventions in order to provide a more robust conclusion. Devices that aid in providing rehabilitation may be able to provide additional opportunities for self-practice to realise this potential fully.

1.5 Upper Limb Rehabilitation Devices

Development of effective upper limb technologies for rehabilitation is an ongoing challenge. A large number of rehabilitation devices have been developed to promote upper limb function though there is a great variety in their design and operation (Brackenridge et al. 2016). These characteristics can include the region of the upper limb targeted (proximal, distal, or both), the number of degrees of freedom (DoF) the device provides, and the method of support to provide assistance ranging from electric motors, pneumatic and hydraulic actuators, to spring and pulley systems. Designing such a system can lead to trade-offs when choosing certain aspects. Providing a system with multiple DoF using robotic actuators can provide a large range of motion and adaptable support to the user but increases the size, complexity and cost of the device making it less likely to be adopted for independent use. In contrast, a simpler mechanical device provides a cheaper alternative potentially more suitable for

independent use at the potential expense of decreased range of motion and support relative to the robotic counterpart. Despite numerous upper limb rehabilitation technologies being developed over the last 15 years, only a small percentage of these have been commercialised and made available for purpose. From Brackenridge et al., it was discovered that from the 141 devices identified, 23 were commercially available as of 2016 (Brackenridge et al. 2016). Furthermore, only 6 of the 141 devices identified were mechanical in nature, with 5 of these being commercialised (83.3%) in contrast to the remaining 17 of 135 robotic devices that were available for purchase (12.5%). This suggests a bias in the research towards the development of robotic-based systems over mechanical alternatives. Furthermore, it implies that mechanical devices are more likely to be approved for sale on the market.

This section of the review will mainly focus on devices approved for commercial use focusing on supporting arm movements at the shoulder and elbow. Table 1.1 displays and highlights the features of the devices.

Table 1.1 - Devices reviewed and their features.

Device	**Device Type**	**Upper Limb Region Targeted**	**Weight Support Mechanism**	**Degrees of Freedom (DoF)**	**Literature Included in this Review**
MIT-MANUS (InMotion ARM, InMotion WRIST and Inmotion HAND)	End-effector system - Rehabilitative	Proximal – Shoulder, Elbow Distal – Wrist, Fingers	Active (DC Motors)	3 (ARM) + 3 (WRIST) + 1 (HAND)	(Krebs et al. 1998); (Lo et al. 2010); (Rodgers et al. 2017); (Rodgers et al. 2019)
ARMin (ArmeoPower)	Exoskeleton - Rehabilitative	Proximal – Shoulder, Elbow Distal – Wrist, Fingers	Active (DC Motors) + Passive (spring)	6	(Nef et al. 2009); (Brokaw et al. 2014); (Klamroth-Marganska et al. 2014)
Wilmington Robotic Exoskeleton (WREX)	Exoskeleton - Assistive	Proximal – Shoulder, Elbow	Passive (bungee cords/spring)	4	(Rahman et al. 2000); (Rahman et al. 1995); (Rahman et al. 2007)
Therapy Wilmington Robotic Exoskeleton (T-WREX) (Armeo®Spring)	Exoskeleton - Rehabilitative	Proximal – Shoulder, Elbow Distal – Wrist, Fingers	Passive (spring)	5	(Sanchez et al. 2006); (Housman et al. 2009); (Bartolo et al. 2014); (Chan et al. 2016); (Cameirão et al. 2012)
Freebal (ArmeoBoom)	Cable suspension system - Rehabilitative	Proximal – Shoulder, Elbow	Passive (spring)	1	(Stienen et al. 2009); (Krabben et al. 2012); (Prange et al. 2015)
Saebo Mobile Arm Support (SaeboMAS)	Exoskeleton - Rehabilitative	Proximal – Shoulder, Elbow	Passive (spring)	4	(Runnalls et al. 2014); (Runnalls et al. 2015); (Runnalls et al. 2016); (Nijenhuis et al. 2015); (Nijenhuis et al. 2017)
ARMON	Exoskeleton - Assistive	Proximal – Shoulder, Elbow	Passive (spring)	4	(Herder 2005); (Mastenbroek et al. 2007)

The MIT-MANUS (commercialised as InMotion ARM) is an end-effector-based system designed to aid in upper limb therapy through helping move and guide the arm during motions and recording them including position, and velocities (Krebs et al. 1998).

A multicentre RCT using the system assigned patients' to three groups: 49 patients receiving intensive therapy with the system; 50 patients receiving intensive comparison therapy, and 28 patients received usual care (Lo et al. 2010). Their aim was to determine if robot-assisted therapy was superior to both intensive comparison therapy and usual care. Following the 12-week intervention, patients receiving robotic therapy scored higher on Fugl-Meyer (FM) scores than those in usual care ($p=0.08$) but worse than the group receiving intensive therapy ($p=0.92$) though neither difference was significant. However, at 36 weeks, FM scores were significantly higher ($p=0.02$) compared to usual care but there was still no significant difference ($p=0.63$) compared to intensive therapy. This suggests that the intensity of therapy is likely to have a greater effect on upper limb outcomes regardless of intervention, provided the intervention is already known to be successful. One of the more important advantages robotic systems offer is the ability to provide similar levels of intensive therapy without constant supervision from therapists. Combining this type of therapy with a gaming environment is also more likely to provide motivation to the users through engaging training sessions with feedback to encourage practice.

A large multicentre RCT recruited 770 participants to determine if using this device can improve upper limb function post-stroke (Rodgers et al. 2017; Rodgers et al. 2019). In the trial, standard of care therapy was compared with an enhanced upper limb therapy programme (EULT) and with robot-assisted training using the MIT-

Manus. Findings from the trial concluded that that robotic-assisted training intervention did not improve upper limb function in comparison to EULT (adjusted odds ratio 0.78 [98.3% CI 0.48–1.27]) or standard care (adjusted odds ratio 1.17 [0.70–1.96]) when comparing Action Research Arm Test (ARAT) scores. Additionally, an economic analysis suggested that standard care was the least costly option at 6 months (average £3785 per participant) whereas robotic-assisted training was the most costly (average £5387 per participant).

The ARMin, commercialised as Armeo®Power, is an exoskeleton robot enabling task-specific training in a three-dimensional environment used for upper limb therapy that has undergone numerous iterations over its lifetime (Nef et al. 2009).

One trial combined the ARMin with another upper limb technology (HandSOME). HandSOME uses adjustable elastic components to enhance coordination of finger and thumb movements during pinching and grasping (Brokaw et al. 2014). Twelve moderate to severely impaired chronic stroke survivors were randomly assigned to either twelve hours of robotic therapy or conventional therapy before switching groups following a one month period after the initial intervention. Fugl-Meyer (FM) scores improved in both groups ($p<0.05$) and robotic therapy provided significantly better improvements in the ARAT than conventional therapy ($p<0.05$) though the authors acknowledge that gains in improvement from the first intervention may have saturated before the second intervention took place, regardless of group. Furthermore, the small sample size (ten of twelve enrolled participants completed the study) required the results to be confirmed in a larger study.

A larger RCT using the device randomly assigned 38 patients to therapy with the exoskeleton and 35 assigned to conventional therapy (Klamroth-Marganska et al. 2014). Significant improvements in FM scores were found in patients assigned to robotic therapy over conventional therapy ($p<0.05$). However, the difference in improvement was small and weak in significance. The mean difference in score was 0.78 points where the minimum threshold for observing a clinically important difference is approximately between 4.25-7.25 points (Page et al. 2012). Consequently, this questions the clinical relevance of the intervention in comparison to conventional methods, particularly an intervention that is large, expensive and requires a trained operator to be present during therapy.

An upper limb orthosis known as the Wilmington Robotic Exoskeleton (WREX) was designed as an assistive device for children with upper limb weakness resulting from muscular dystrophy or partial spinal cord injuries to assist them with activities of daily living (Rahman et al. 2000). The orthosis design is based on the author's previous work using elastic components (e.g. springs) to passively balance moving mechanisms against gravity (Rahman et al. 1995). One study tested the orthosis with seventeen participants, providing the device to them for home use for a duration of two weeks. Results were positive with the majority of participants able to perform tasks easier and quicker with the WREX where previously they performed slower or unable to at all (Rahman et al. 2007). Furthermore, the device appeared to be acceptable for use in the home, receiving positive remarks from most participants with some asking to purchase one to use frequently at home.

A rehabilitative device based on the WREX's design was developed for movement training with stroke patients. The Therapy Wilmington Robotic Exoskeleton (T-

WREX) is an arm orthosis with adjustable weight support that assists the user with arm movements at the shoulder, elbow, and wrist, with locks at each joint to enable therapists to control what areas to focus on during a therapy session (Sanchez et al. 2006). The commercialized version of this product is known as the Armeo®Spring.

Comparisons in therapy using the T-WREX (experimental group) or a table (control group) for gravity support were undertaken in an RCT to investigate upper limb function using these techniques following treatment and after 6 months (Housman et al. 2009). Similar to the ARMin study, the T-WREX improved FM scores significantly following treatment ($p=0.001$) and at 6-month follow up ($p=0.005$) though the difference was small and self-reporting of improvements in function was similar between groups. However, patient satisfaction reports found that T-WREX therapy was preferred. This could be due to the technology being a motivational tool for the patient as it provides both real-time visual feedback, in addition to recording scores and the range of motion attainable by the user, giving them a new target to achieve with every subsequent session.

Bartolo et al. (Bartolo et al. 2014) looked at the effectiveness of incorporating the Armeo®Spring in rehabilitation for acute stroke patients. The RCT recruited 28 first-time stroke patients split into a study group ($n=12$) and a control group ($n=16$). Over 12 sessions in two weeks (six/week), both groups received 60 minutes of conventional physiotherapy with the study group receiving 30 minutes of additional therapy using the Armeo®Spring while the control group received 30 minutes of additional physiotherapy. The study group showed improved range of motion in shoulder abduction-adduction over the control group but both groups had similar improvements in flexion-extension. However, the paper does not mention the type of exercises the

study group performed while using the arm orthosis, whether they were performing similar exercises to the control group or exercises specific to the device. Furthermore, both groups were required to use the Armeo®Spring during the evaluation stage, providing weight support for all participants. It would be expected that the study group would perform better than the control group as they have been used to using the device throughout the trial. While the results suggest that weight support may benefit improving recovery, the kinematic outcome measures could have been more detailed. The arm range of motion was analysed using three reflective markers for motion capture. This analysed the range of motion in the vertical and horizontal axes, but not over specific joints though this may have been difficult as more markers would be required that would most likely be obscured by the device. Furthermore, it was noted that follow-up data was unavailable therefore it was unknown if recovery was sustained when performing daily activities at home. Consequently, the ability to record upper limb movements at home to determine if upper limb function following therapy has been retained or even improved is desirable.

Chan et al. (Chan et al. 2016) investigated the effects of using the Armeo®Spring to promote recovery for varying levels of upper limb impairment. The comparison study recruited 48 subacute stroke patients and organized them into three different groups based on their level of impairment (mild – n=11; moderate – n=20; severe – n=17). Each group received 45-minute sessions of weight support therapy 5 days a week for 3 weeks plus additional conventional therapy. Each group received a different treatment programme using the device based on the severity of their impairment (the severe group focussed on distal movements whereas the mild and moderate groups incorporated proximal movements into their session). Results suggest that the device

is beneficial for stroke patients with moderate to severe impairments and that no adverse effects were caused (i.e. no increase in spasticity) (Chan et al. 2016). However, the study did not use a control group therefore no further evidence as to whether the device provides more benefit than conventional therapy could be attained, which the author acknowledges. Significant improvements in FM scores were found in all groups for both upper extremity and the hand in contrast to the Bartolo study which did not find a significant difference in the scores before and after intervention (Bartolo et al. 2014). This could be attributed to the different methodologies used by each study including type of exercises performed and duration of intervention (participants in the Chan study received 15 minutes longer per session with weight support therapy and more sessions). This again highlights the difficulty in determining the optimal amount of therapy to provide with this device in a clinical setting. In a clinical environment, it is critical to define the optimal dosage, duration, and intensity of this type of therapy to ensure that the individual receives the most benefit from the intervention while also minimising logistical issues regarding staff availability, and room space.

Another study used two Armeo®Spring devices to provide bilateral training and combined this with virtual reality to provide feedback (Cameirão et al. 2012). This setup was compared to two other set ups that did not include the weight support device but still provided feedback, one with VR only and the other using a combination of VR and haptic feedback. However, they found that using the weight support device had the least impact on recovery when compared to the other two systems though all three had significant improvements on recovery. This showed the beneficial effects of using feedback when performing upper limb exercises though the effects of using this type of weight support remained unclear.

To further simplify weight support systems to make them more accessible for rehabilitation training, the Freebal, commercialised as ArmeoBoom by Hocoma, was designed for arm therapy in motor control (Stienen et al. 2009). Through the use of slings to support the arm, the device avoids the complexity found in exoskeleton based designs and devices. Secondly, the use of slings allows a therapist easier access to the user's arm during movements to feel spasticity or muscle tone during a therapy session, something that is less feasible with an exoskeleton. A small pilot study found that stroke survivors (n=8) were instantly able to increase their range of motion by approximately 7% ($p<0.001$) (Stienen et al. 2009).

The Freebal, has undergone a number of trials to determine its effectiveness in upper limb outcomes. One study looked at abnormal upper limb muscle synergies as a result of stroke and how these were effected through training with the gravity compensating device (Krabben et al. 2012). Seven chronic stroke patients undertook 18 half-hour sessions of training using the device over six weeks. Training led to a significantly increased work area (i.e. range of motion) of the affected limb though synergistic movements remained similar following training. An RCT using the device to determine the effects of arm function following weight support training combined with games was conducted recruiting 70 subacute stroke patients (Prange et al. 2015). All participants took part in a six-week training programme consisting of three sessions per week each lasting 30 minutes. Both the control group and experimental group were dose matched where sessions from their regular program were replaced with their respective training for the study. Both groups were given training specifically for the upper limb within their group resulting in the control group receiving a larger dose of conventional upper limb therapy than is normally expected. Training for the

experimental group consisted of playing interactive games while their arm was supported by the device. Results showed significant increases in FM scores in both groups but no significant difference was found between them. Furthermore, whether this type of arm support could increase intensity of the training is not known, as the number of repetitions was not measured in this study. However, the author hypothesized that while improvements may be similar to conventional therapy, the use of a weight support device with feedback could be used as an alternative, providing practice that is more independent for the user, without therapist supervision. Participants in the experimental group reported a greater interest and enjoyment in training, supporting this hypothesis.

The Saebo Mobile Arm Support (SaeboMAS) provides passive support using a spring mechanism for weight compensation, enabling the user to move their arm in a large 3D workspace. The force can be adjusted to provide varying degrees of support to the user for both assistive and rehabilitative purposes. Furthermore, the device has the advantage of increased portability over previous devices discussed with either a stationary stand that can be moved via wheels where necessary, or clamped to a table (e.g. at a patient's home). A number of studies have been conducted on the product's ability and effect at de-weighting the arm. Runnalls et al. looked at the effects of muscle activity at different levels of weight support ranging from full to none (Runnalls et al. 2014). From 13 healthy participants, they observed that weight support reduced activity in the anterior deltoid and biceps brachii for increased levels of support. By reducing the amount of activity required to lift the arm, weight support can help facilitate repetitive movements for stroke rehabilitation exercises. However, this study did not incorporate dynamic tasks, choosing mainly to measure muscle

activity with the arm in a raised, static position. Subsequent studies from the same author added movement tasks for different levels of support to determine the effects on biceps brachii activity (Runnalls et al. 2015), and to observe the effects of a seated or standing posture when using weight support (Runnalls et al. 2016). The two studies also showed reduced effects for the majority of upper limb muscles examined with increased support, further highlighting the potential of the weight support system as a rehabilitation tool. However, the studies included only healthy participants, therefore using the device with stroke survivors is still sought to provide more evidence to the device's effectiveness. While the device is relatively inexpensive (£2-4k) in comparison to the Armeo®Spring (up to £40k) and other robotic alternatives, the SaeboMAS lacks a built-in feedback system to provide users with information on their performance, in real-time nor post-exercise. Studies incorporating their own feedback designs into the SaeboMAS device have been explored. A feasibility study investigated using the device with a separate wrist and hand orthosis combined with motion sensors to track movement allowing the user to control a game for feedback purposes (Nijenhuis et al. 2015). All training using the setup was performed at the user's home with the goal of evaluating the feasibility of self-administered, home-based training. Findings from the 21 participants appeared to show that the system was a feasible tool based on the System Usability Scale (mean score – 69%) for home-based stroke rehabilitation. Following this study, an RCT using the system was undertaken (Nijenhuis et al. 2017). Twenty chronic stroke survivors with upper limb impairment ranging from mild to severe were split evenly into an experimental group performing exercises using the previously described system; the control group used an exercise programme to perform conventional exercises. Both groups were instructed

to practice at least 30 minutes per day, six days per week. Results found a great variation in training duration between participants ranging between 13-423 minutes per week and average time per week was lower for the experimental group (118 minutes) than the control (189 minutes). No difference in improvement between groups for arm and hand function was apparent though increased duration of training appeared to increase the chance of improving function but the changes were non-significant (FM – p=0.079; ARAT – p=0.078). Differences in the quantity of exercises presented to each group (34 for control vs 3 for experimental) were acknowledged as a potential reason for differences in training times. While the experimental setup showed promise as a training system that could be used at home, more varied exercises for motivational and functional gaming were thought to improve engagement with the system and increase the users practice time.

ARMON is another passive orthosis, using a spring-based mechanism designed for people with muscular weakness (Herder 2005). Similar to the SaeboMAS, only one point of support at the forearm is used to lift the arm against gravity using the assumption that the shoulder joint is capable of carrying part of the mass of the upper arm. Therefore, the arm is statically balanced although only 75% of the arm's weight is balanced using this device. While this may prove useful for patients with upper limb weakness, those suffering from shoulder pain and subluxation may be uncomfortable using the device without full support at the shoulder. Early user experience with the ARMON, targeted at those with spinal muscular atrophy was positive although various improvements were suggested to the initial prototype (Mastenbroek et al. 2007). Testing and refining the prototype allowed the designers to arrive at a satisfactory

solution that pleased the majority of users focusing on improvements to size, adjustability, and aesthetics.

In summary, there are a large variety of commercial and non-commercial upper limb devices that have been developed for stroke rehabilitation. However, there is still a limited amount of strong evidence to support their efficacy, particularly for devices with high upfront costs. It can be difficult to recommend using expensive, cumbersome devices for independent home use due to these practical and economic factors. In light of this, developing a cost-effective solution that aims to achieve the same goals as existing devices (i.e. provide weight support to facilitate self-practice) could be more likely to be adopted for home use.

1.6 Feedback

Feedback, when referring to human performance, is defined as information about an individual's performance for a given task, or range of tasks, serving as a basis for future improvement (Winstein 1991). Normally this is achieved intrinsically, where the individual's sensory systems (proprioception, touch, vision, etc.) provide information on the performance e.g. speed, co-ordination, success etc. In contrast, extrinsic feedback is provided outwith an individual's intrinsic feedback system, via other individuals/teams observing their performance and reporting to them. Various technologies and software can also provide extrinsic feedback in the absence of, or in addition to, another person.

Feedback is a key principle in motor learning (Schmidt et al. 2018). For example, for a player practicing a serve in tennis, feedback (intrinsic and extrinsic) on their performance is beneficial to help improve their technique either through positive

feedback when they perform the movements correctly, or corrective feedback to help prevent incorrect movements and allow the player to perform the serve more accurately and quickly.

In a rehabilitation context, feedback (intrinsic and extrinsic) plays an equally important role in re-learning functional movements impaired by conditions such as stroke (van Vliet & Wulf 2006; Cirstea et al. 2006). In stroke, impaired cognition and sensory perception impacts on the intrinsic feedback system meaning extrinsic feedback becomes more important in the re-learning of movement and functional tasks.

Two types of extrinsic feedback can be provided to patients: knowledge of results and knowledge of performance (Schmidt et al. 2018). Knowledge of results refers to feedback of the outcomes of a movement in the context of a specific goal (e.g. number of repetitions of a given task, or maximum range of motion achieved). Knowledge of performance refers to feedback provided about the movement being made (i.e. in a reaching task the shoulder is flexed and elbow extended).

Typically, feedback during rehabilitation activities is provided by a therapist to the patient. Direct, verbal, and tactile feedback may be given concurrently with a patient's movements followed by verbal and written feedback at the end of a session. Therapists will inform patients whether or not they are performing movements successfully and assist verbally and physically with the movement where necessary. However, with the decrease in available therapy time for patients (McHugh & Swain 2014; Bernhardt et al. 2007), alternative methods for measuring and providing feedback have been sought, either to aid or replace existing techniques. Available techniques include virtual reality

(Laver et al. 2017), gaming consoles (Thomson et al. 2014), and wearable sensors to measure activity (Wang et al. 2017).

Incorporating virtual reality (VR) into therapy has been used to support stroke rehabilitation at home. VR based systems allow users to interact with simulated environments and receive real-time feedback on their performance in a given task (Kong et al. 2016). These environments can be created and adapted to provide visual, audio, and haptic feedback that is beneficial to the user (Subramanian et al. 2013). With the development of VR systems for rehabilitation and the integration of VR in gaming consoles, there are numerous platforms in which it can be utilised for stroke rehabilitation (Yates et al. 2016). In addition, the creation of rehabilitation games to be used with VR systems can be a motivational tool and help encourage the user to perform the necessary exercises required for their recovery.

A Cochrane review on VR in stroke rehabilitation identified 72 trials totalling 2470 participants (Laver et al. 2017). The review found that there were no significant differences ($p=0.25$) between VR and conventional therapy for improving upper limb function. However, ten studies that focussed on implementing VR in addition to conventional therapy found significant differences ($p<0.05$) in upper limb function though this could have been the result of an increased dose in therapy rather than the VR itself. However, the minimum amount of extra therapy to provide a difference is currently unknown. Studies that looked at a dosage of less than 15 hours ($p<0.05$) or more than 15 hours ($p<0.05$) were found to have significant differences in function but there was no significant difference between groups ($p=0.83$). The quality of evidence was determined to be low therefore higher quality evidence will be required before recommendations on the effectiveness of VR in rehabilitation can be made. While it

remains unclear whether the effects of VR-based rehabilitation are significantly better than conventional therapies, they do show the potential for creating home-based rehabilitation systems that stroke survivors can use in addition to standard therapy. Bringing VR therapy to the home could be beneficial to users, allowing them to work at their own pace and provide a platform that is readily available to them. Moreover, it can help remove the costs and potential burdens associated with travelling to and from a rehabilitation session at a hospital or gym. Novel VR based technologies and systems have been developed specifically for neurorehabilitation (Cameirão et al. 2010; Crosbie et al. 2012).

The Rehabilitation Gaming System (RGS) was developed to facilitate stroke survivors' upper limb rehabilitation in a virtual environment (Cameirão et al. 2010). Upper limb movements are tracked via a camera that records the position of coloured patches positioned on the wrists and elbows with data gloves used to detect finger movements. These recordings are relayed to an application that displays, on a monitor, a virtual representation of the user's arms that mimics their movements. Games can be developed for the system that can focus on movement speed and accuracy. Furthermore, the system can adjust difficulty for the user automatically based on their performances over time making it more challenging if they are performing well and easier if they are not performing as well. Initial testing showed that the RGS could effectively adapt to the user's performance suggesting the system could be used in an unsupervised manner (Cameirão et al. 2010). Mentioned previously, the Armeo®Spring and other devices have been used with the RGS to aid with upper limb movements to investigate the effects of combining these technologies and their ultimate effect on recovery (Cameirão et al. 2012). An RCT using the RGS was

performed with acute stroke patients (n=8) against an equally sized control group, matched for age and impairment (da Silva Cameiro et al. 2011). Results showed that the intervention group had significantly improved performance in outcome scores between weeks 5 & 12 (FM – $p < 0.05$) but not between week 12 and follow-up. This evidence suggests that the system could be beneficial for stroke rehabilitation and its potential for independent use make it a promising tool provided it is used on a regular basis by the user.

Fully immersive VR systems have also been developed, using a head-mounted display to immerse a participant within a virtual environment. One pilot study used this type of system for upper limb rehabilitation using sensors on the shoulder, elbow and hand to track movements (Crosbie et al. 2012). Tasks such as reaching and grasping, and reach to a target were provided to the participant to perform in the virtual environment. Again, difficulty could be adjusted based on their performance though whether this could be done automatically by the system was unknown. Results showed there were no significant changes to outcome scores (Motoricity Index – $p=0.485$; ARAT – $p=0.139$) although compliance was reportedly high suggesting that such a system is enjoyable and motivating and could readily translate to stroke survivors as part of their rehabilitation. However, due to the complexity of setup and calibration associated with fully immersive VR systems, stroke survivors may have difficulties using them independently.

The CAREN (Computer Assisted Rehabilitation Environment) is a three-dimensional virtual environment developed by Motek Medical (Motek Medical, Amsterdam, the Netherlands), using proprietary software (D-Flow) to control the virtual environment and integrate peripheral hardware such as treadmills and biofeedback systems (i.e.

EMG and optical tracking) (Subramanian et al. 2013; Geijtenbeek & Steenbrink 2011). Through D-Flow, rehabilitation exercises and programmes can be developed and adapted autonomously through various input devices that measure the participant's performance and provide feedback. An RCT using the CAREN for upper limb motor recovery created a virtual supermarket where participants were tasked with reaching and grasping food items on a shelf (Subramanian et al. 2013). These were compared to a control group that were tasked with performing similar tasks but in a physical environment instead. Those in the virtual training programme exhibited an increase in horizontal shoulder adduction and shoulder flexion immediately concluding the sessions (9.5°: $p<0.01$ and 6.3°; $p<0.05$ respectively) and improved shoulder flexion (13°; $P<0.01$) at 3-month follow-up. The author attributed this to motivation and interactivity of the virtual intervention, enhancing the experience for the user and allowing them to track their progress and success.

As it is unfeasible to provide a patient with a home-based motion capture system due to high costs and large space required, alternative home-based options can be explored. Inertial measurements units (IMUs) are small electronic devices that measure linear and angular motion through a combination of three accelerometers and three gyroscopes in their own three dimensional coordinate system (Seel et al. 2014). Through creation of algorithms on a PC or microcontroller, the data generated from an IMU can be used to calculate the device's position and orientation. As these devices are generally small, they can be used as a portable as well as cheaper alternative to the "gold standard" of motion capture systems. In practice, they can be used for measuring upper limb activity (Uswatte et al. 2006; Leuenberger et al. 2017), and upper limb kinematics (Muller et al. 2017),

From a literature review looking at wearable systems for upper limb rehabilitation (not limited to stroke), accelerometers and IMUs were the most frequently used technologies (84%) (Wang et al. 2017). However, it was noted by the authors that clinical evaluations of these wearable devices were lacking and further research will be required to determine their efficacy in helping with upper limb rehabilitation. Regardless, they are an attractive option and the data outputted from IMUs can be implemented as an input to a VR application to provide real-time feedback to the user on their performance (i.e. controlling an object in a game.)

While novel VR games and applications can provide a customisable and adaptable experience for the user, the use of commercial gaming systems for rehabilitation can possibly provide a more widely available approach (lower cost, can be used with family etc.). Such commercial platforms including Nintendo Wii™, Microsoft Xbox, and Sony PlayStation, and their peripherals can provide an effective method for facilitating repetitive arm movements in both a clinical and home setting (Thomson et al. 2014; Yates et al. 2016). Setup and calibration of these systems may be easier for the user than a custom-made system and/or application, possibly increasing the chances of them being adopted for independent use.

The Nintendo Wii™ was evaluated as a potential system for rehabilitation in a feasibility study (Joo et al. 2010) and while improvements were found to be small in comparison to conventional therapy, the participants found using the Wii to be more enjoyable. An RCT using the Wii found that upper limb function improved significantly ($p<0.001$) although there was no significant difference in improvement when compared to dose-matched conventional therapy and a non-dose matched control ($p=0.15$) (Kong et al. 2016). The majority of the participants had severe upper

limb impairment therefore the intervention may have a different impact depending on initial severity. Additionally, participants undertook 12 one-hour sessions over the course of three weeks, in addition to their normal therapy. While an intensive course in a small duration of time, increasing the duration of the programme or encouraging the patient to use it at home, may also benefit upper limb recovery. A larger, multicentre RCT compared using the Wii (n=59) against recreational activities (n=62) for practicing task-specific functions (Saposnik et al. 2016). Both groups improved based on the Wolf Motor Function Test although there were no significant differences (p=0.469) between them with the authors' commenting that non-immersive VR, using the Wii, is no superior addition to conventional therapy. Their results concluded that the type of task used in motor rehabilitation for stroke might not be relevant as long as it can provide high intensity and task-specific practice to the user. Therefore, in addition to improving their rehabilitation, ensuring that the VR technology is safe and engaging for the user could be beneficial for the technology being accepted for clinical and home use.

Sony's EyeToy is a small video camera that records the user and projects their image onto a monitor within a virtual environment, a potential device for stroke rehabilitation (Rand et al. 2008). The device detects gestures from the user allowing them to interact with various games. A small scale RCT looked at participants receiving 30 minutes of therapy playing games with the device whereas the control group watched the sessions but did not have any physical improvement; both groups received conventional therapy as well (Yavuzer et al. 2008). Significant improvements in Functional Independence Measure (FIM) score were found (p=0.018). Another study comparing the EyeToy

with the Wii for usability found that those using the EyeToy elicited a higher level of activity compared to the Wii (Neil et al. 2013).

Microsoft's Kinect platform is an infrared camera that can be used to track a user's movements in real-time without the need for optical markers. As the user's input does not rely on using a controller to interact with the system, the device is not reliant on a baseline of motor skill in the upper limb to use it (Yates et al. 2016). An RCT using the Kinect for stroke rehabilitation of the upper limb reported improved upper limb outcomes than the control group although the groups were not dose-matched making it unclear whether improvements were a result of the intervention or the increased therapy time they received (Sin & Lee 2013). A similar RCT also showed improvements in upper limb function in the intervention group but the control group also received less overall therapy time (Aşkın et al. 2018). A larger scale study with dose-matched groups may be required to provide a clearer indication of the effects of the Kinect system.

Givon et al. used a variety of video game consoles as an intervention within a group setting with chronic stroke survivors for a three-month programme entailing two one-hour sessions per week, finding that their use within a group setting was feasible and safe (Givon et al. 2016). Similar to the Wii study (Kong et al. 2016), there were no significant differences in upper limb improvements (ARAT – p-value not reported) between groups but the participant reported satisfaction of using video game systems was significantly higher than that of the control group ($p=0.026$). As such, the potential for using commercial gaming systems as an alternative or addition to conventional therapy is realised. However, as these products serve their own purpose (i.e. as

entertainment systems), some are no longer manufactured and may no longer be available for purchase (unless acquired second hand).

In summary, feedback can be incredibly beneficial to a stroke patient during their therapy therefore establishing the appropriate method of feedback is crucial. There is a large variety of options in providing feedback to the user on their rehabilitation exercises via wearable sensors, commercial gaming systems, and bespoke virtual applications. A combination may also be beneficial to the end user but ultimately, user compliance and preference will differ on an individual basis and one method of feedback that works for one patient may have the opposite effect on another. Choosing the most appropriate method for the individual will provide the greatest benefit in terms of motivation when undertaking their rehabilitation exercises.

1.7 Conclusion

In conclusion, there are currently a large and varied range of interventions that have been developed to assist in upper limb rehabilitation. Interventions that can encourage self-practice can be important for users willing to perform more exercises at home outwith or following their therapy programme, especially with increasing evidence that RTT can have significant effects on upper limb recovery. Upper limb weight support devices can help facilitate this aim, of which there are currently a large and varied amount available on the market. Variations include the level of support provided, how this is controlled, the areas of the upper limb supported, and the DoF the device provides.

While there is research suggesting these devices can aid in upper limb rehabilitation and encourage RTT, the complexity, size and/or cost of currently available devices

creates a barrier for entry for patients and therapists. Thus, there is an argument for a simple low cost and weight support device for upper limb rehabilitation. To achieve this, the device would need to meet user-defined criteria such as being easy to operate independently and relatively small and lightweight to make it suitable for home use. The role of feedback during rehabilitation is well established as being critical to the recovery of good quality functional movements. Providing a simple method to provide feedback to the patient while using the device is likely to be beneficial for motivation, encouraging continued practice and correcting movement errors.

The following chapters of this thesis will consider these points during the design and development phases. Furthermore, a user-centred design approach will be employed in order to obtain a unique perspective on the requirements of a design, based on the experiences of stakeholders with existing devices and upper limb rehabilitation as a whole.

2 Design & Evaluation of an Upper Limb Weight Support Device

2.1 Introduction

Design processes are employed by engineers to create solutions to a particular problem. This can often involve developing a product to meet specific needs in a market area and/or to perform a particular task. The process involves:

- Defining the problem
- Background research
- Development of a product design specification
- Brainstorming and generating solutions
- Evaluating and choosing the best solution
- Developing a prototype of the chosen solution
- Testing and redesign of the prototype if necessary

The design process is iterative and the various stages mentioned above do not necessarily have to be completed in order. Developing a prototype can provide insight into areas of improvement if the design does not meet the criteria required for the solution. Going back and redesigning the solution would therefore be necessary to ensure the desired solution can be achieved.

Several models have been generated to facilitate the design and development process. Although every product generated through the design process is unique, the stages undertaken to achieve this goal can be seen as generally similar each time. Process models help communicate these routine sequences to designers and engineers and serve as a guide from defining the problem to the final product (Wynn & Clarkson 2018).

The design process model used for this project is the Double Diamond model developed by the British Design Council (Design Council UK 2019). Divided into four distinct stages: discover, define, develop, and deliver, a visual representation of this model is shown in figure 2.1. These stages illustrate the type of work and research typically used by engineers in the design process.

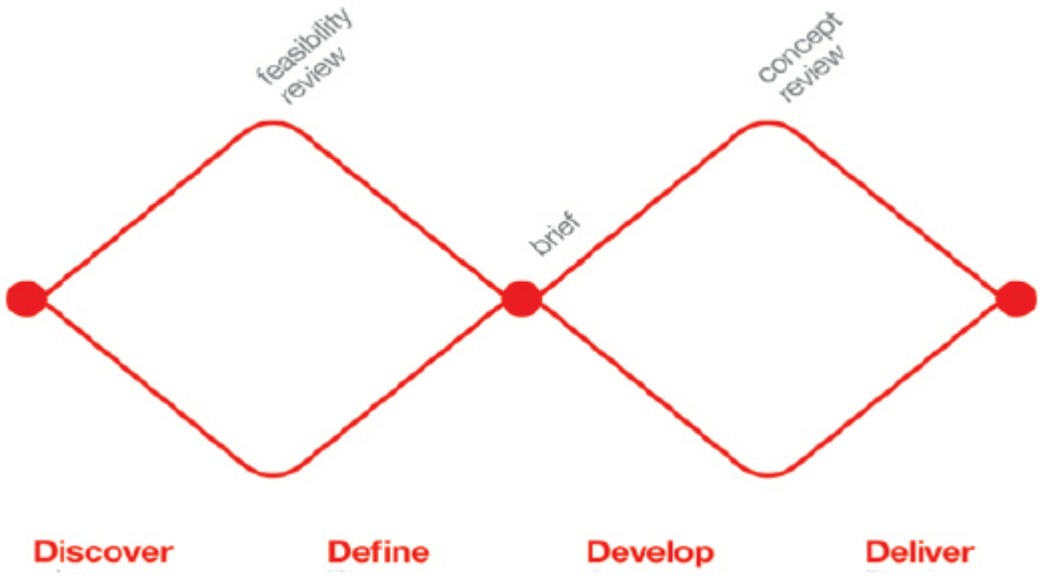


Figure 2.1 - Double Diamond Design Model (Design Council UK 2019)

The discovery phase consists of research into the problem, incorporating market research into existing products to identify gaps, and user research to determine user requirements. For this project, a user-centred design was a key focus to ensure that the needs of the various users (e.g. stroke survivors and therapists) were met, thereby giving it a better chance of being adopted into routine rehabilitation practice.

Furthermore, including the intended users into the design process can reduce any potential bias that may occur during the generation and evaluation of concepts. The defining phase involves collating all of the information collected in the discovery phase and creating/generating criteria for the intended solution. This is realised

through a product design specification (PDS). Following this, the development phase involves brainstorming, generation and assessment of solutions/concepts to solve the design problem. Various techniques can be used to facilitate this process, which will be discussed in future sections in this chapter. This phase can also include the development of various working models, and redesign based on feedback from these visualisations from designers and stakeholders. Finally, the deliver stage incorporates building and testing the prototype, continuously iterating the design and product towards its final release in the relevant market. The release of a final product into the appropriate market is out of the scope of this thesis.

This chapter will focus on the design process used to generate and evaluate concepts for an upper limb weight support device. Creation of the PDS will be discussed first, followed by the generation of concepts. Next, the evaluation of these concepts will be described which leads into the generation of three-dimensional computer-aided design (CAD) models. Finally, the user evaluation process of the shortlisted concepts via focus groups will be discussed before explaining the reasons for choosing the final concept. A block diagram of the concept generation and evaluation process used can be found in figure 2.2.

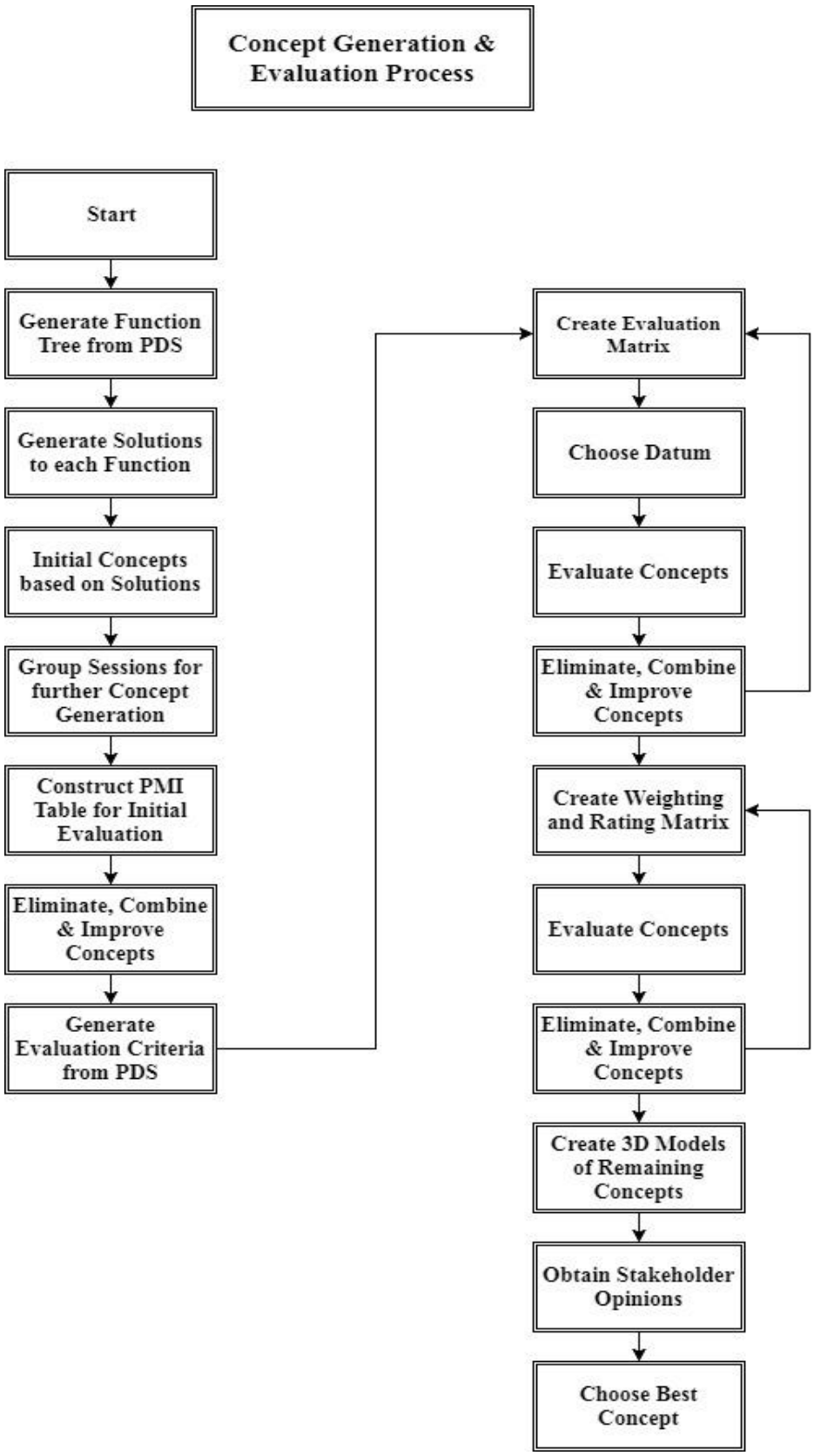


Figure 2.2 - Block Diagram illustrating the concept generation and evaluation process for this project.

2.2 Product Design Specification

A product design specification (PDS) is a document detailing how a design should be created specifying requirements that the intended product must comply with. It aims to ensure that the design process and subsequent development of a product meets the needs of the end user. While the document serves as a basis for generating concepts towards the desired solution, it is an iterative document and criteria can be added, removed, and/or altered throughout the duration of product design, development and testing.

A PDS was generated following Pugh's method for product design (Pugh, 1991). The PDS has numerous sections related to the product's design such as performance, weight, size, and aesthetics. Additionally, this type of PDS has sections related to competitors (i.e. existing devices), shipping and packaging, and other sections not specifically related to the device itself. This section will describe creation of the PDS document made and the criteria chosen to fill it. At this stage, particular focus was given to the performance criteria over the other sections of the PDS. This was decided because it would allow for the concept generation process to be more flexible and provide the potential for creating unique and interesting features not limited by size, weight, and/or aesthetic restrictions.

2.2.1 Product Brief

The primary goal was to design and develop an upper limb weight support device to aid stroke survivors with their rehabilitation at home and/or in a clinic. Furthermore, by providing a means of assistance, this could help improve outcomes of upper limb function through facilitation, and in turn, increase of self-practice. To achieve this, a mechanism was required to support the weight of the upper limb while allowing the

device to facilitate movements of the arm to perform exercises as part of rehabilitation. An additional requirement was the inclusion of a monitoring system to track progress, provide feedback on performance and motivate the user while they carried out their rehabilitation exercises.

To enable self-rehabilitation the device should be practically simple to set up and operate by the end user (stroke survivor), and provide support for the user's arm without being uncomfortable or hazardous.

2.2.2 Main Performance Criteria

Below is the list of desirable performance criteria from the PDS deemed necessary for the device to provide the best performance for the end user. These criteria were created based upon review of the literature and existing devices, and informal discussions with stroke survivors and therapists.

- The device should be able to support (with the ability to vary the amount of support provided) the weight of the user's arm. As the severity of the stroke will determine the impact it has on a stroke survivor's capabilities, providing different levels of support can ensure that the device can be used by a large population of users and allow the degree of support to change should there be an improvement in ability.

- The device should detect and provide adaptable support based on the user's own ability. Stroke survivors with more severe impairment and little to no arm movement may benefit more from having the whole arm supported whereas those with milder to moderate impairments and relatively higher arm function will benefit from partial weight support of the arm (e.g. 50% support).

Additionally, if function improves during rehabilitation, gradually increasing the difficulty of the task through decreasing the support will maintain the training stimulus until activities can be performed without support.

- The device should allow as full a range of movement as possible for the whole arm. Ensuring that the device can move while supporting the arm will aid in performing different movements while exercising the arm.
- The device should be simple to set up and operated by a single user (i.e. with one functional arm). As the majority of stroke survivors are limited in the activities and actions they can perform with an impaired upper limb, enabling them to set up and use the device without difficulty could help facilitate self-practice without the need of help from therapists or family members, increasing the amount of potential therapy time.
- The device should provide feedback to the user (visual, audio and/or haptic):
    - With real-time movement feedback that would allow interactive rehabilitation games, for example virtual reality activities. Providing feedback to the user while they are performing specific tasks can be beneficial in letting them know whether they are successfully performing a repetition which can help with motivation. Feedback should also be provided post activity to allow the user to appraise their performance before the next session.
    - After completion of an exercise and displaying the user's results, letting them know if they have improved or not from previous efforts. Allowing

the tracking and recording of progress can show the user the improvement of their recovery over time.

- The device should be comfortable and not painful for the user to operate. Shoulder pain can be a common issue with upper limb impairments because of stroke (Lindgren et al. 2007). Providing a solution to reduce or eliminate pain to this region while using the device will make it more welcoming to the end user, and allow them to engage with it without fear of pain or discomfort. As subluxation of the shoulder is the main cause of shoulder pain following stroke (Walsh 2001), supporting the shoulder is crucial to prevent this from worsening.

- The device should be safe to use for the end user therefore no adverse events should occur during use. Ensuring that when in use the device avoids exceeding the range of movement capable in the user's upper limb will help prevent pain and/or injury.

2.3 Concept Generation

Once the list of performance criteria had been created, concept generation could proceed. The first step was to create a function tree and morphological chart. The function tree (figure 2.3) utilised the performance criteria and condensed them into smaller phrases that described the desired functions of the device. Within the tree, the lowest branches are considered sub-functions. These are required to perform the necessary function above that it branches off. As such, finding solutions for all the sub-

functions is essential to solve the overall problem (i.e. providing weight support to facilitate upper limb rehabilitation).

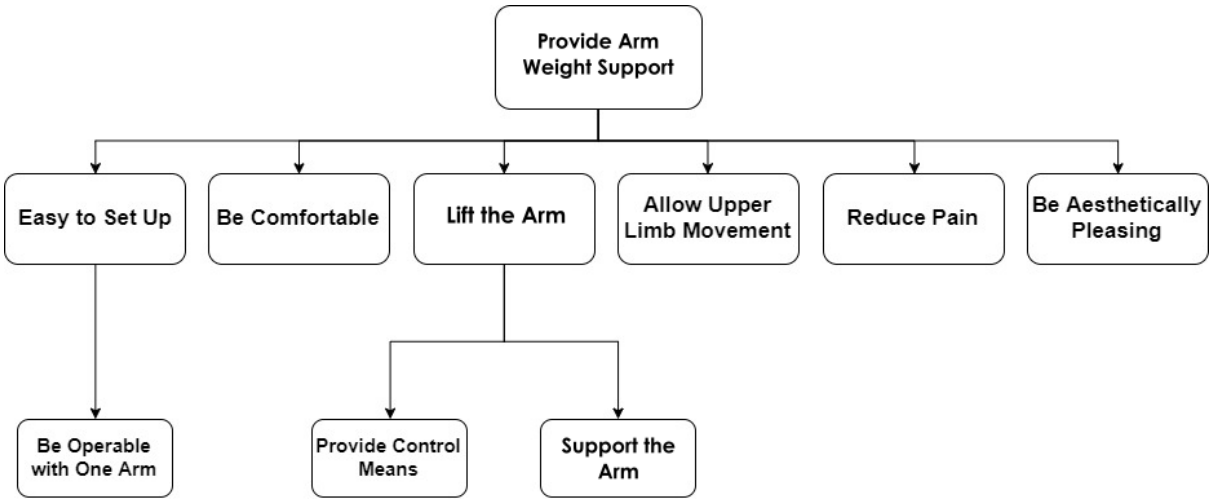


Figure 2.3 - Function Tree

Using this diagram, a morphological chart was created by taking the bottommost sub-function from each branch and generating as many solutions as possible for it. From this, a solution can be taken from each function to generate a concept combining each chosen solution. Six initial concepts were sketched using the morphological chart and function tree as guidance.

To further increase the number of concepts to generate a wide variety for evaluation, group-brainstorming sessions were organised. The 6-3-5 method is a useful tool for generating a large number of concepts in a group format (Rohrbach 1969; Schröer et al. 2010). Supervised by a moderator, the method consists of six contributors that are required to come up with a maximum three ideas based upon a short design brief and criteria presented to the group at the beginning of the session. These ideas are drawn or written down on a worksheet during a five-minute period. Contributors are then required to pass their worksheet to the next person and repeat the process. This

continues until the contributors receive their original worksheet. Aiming to accelerate the innovation process, the technique allows participants to be inspired by ideas generated by their neighbours from previous rotations. They can then choose to contribute further to existing ideas by completing them or integrating certain aspects into a new idea. Alternatively, they can ignore these and create a new concept from scratch. Completion of a 6-3-5 session should produce 108 ideas in a small space of time (minimum of 30 minutes excluding time taken to pass sheets and read the new worksheet before repeating the generation activity). One of the main advantages of this method is that it is quick and straightforward to teach and learn. Furthermore, it enables and encourages participation from all members of the group, where some individuals may be more hesitant to do so in other types of brainstorming activities. While the wealth of ideas that can be produced in a small space of time is advantageous, the quality of the suggestions may suffer as a result. Stress due to the time constraints can have a substantial impact on the participant's output, leading to three ideas with minimal detail or, only one fully detailed idea generated in the period. The exercise is also mostly done in silence, which can lead to similar ideas being produced without realizing though this could be perceived positively as an idea to consider more if it was generated independently by separate participants.

Two 6-3-5 sessions were organised, the first group consisting of post-graduate research students (n=6) in various fields of biomedical engineering (e.g. prosthetics, rehabilitation engineering). The second group included post-graduate research students (n=3) independent from the first group and research associates (n=3) based in biomedical engineering with clinical experience in medical devices, orthopaedics and rehabilitation engineering involving stroke. The purpose of the design project was

explained to the individuals in each session and the PDS was shown and explained. The performance criteria from the PDS were displayed to the participants on a projector screen throughout the session. Each individual was then given a sheet of A3 paper and asked to generate up to a maximum of three concepts based on the displayed criteria within a five-minute period. Once this period was over, the sheet of paper was then passed to the individual's left and everyone was asked to repeat the same task as before. This process was repeated until individuals received their original sheet of paper.

From the group sessions, 32 concepts were generated in total, substantially less than the 216 that would be expected from two sessions, highlighting the difficulty of meeting the quantity expected in a short period. However, this was expected and the number of concepts created using this technique was considered sufficient to begin evaluation. Sketches from the morphological chart generated an additional six concepts giving 38 concepts from individual and group input. Concepts created from the 6-3-5 sessions were re-sketched by the main investigator for evaluation.

2.4 Concept Evaluation

Evaluating conceptual designs is a necessary procedure to confirm that the most appropriate design is taken forward for detailed design and prototype production (Ullman 2010). It is an iterative process as each stage of evaluation presents the opportunity to improve, combine, and remove concepts until all ideas have become exhausted. Evaluation of the all the generated concepts (n=38) was achieved by following four evaluation processes in the following order shown in figure 2.2. These were:

- Plus, Minus, Interesting (PMI) Table
- Evaluation Matrix following the Controlled Convergence Method (CCM)
- Weighting and Rating Matrix
- Focus Groups for Feedback (section 2.5)

2.4.1 PMI Table

For the first stage of the evaluation process, a PMI table was created. Each concept was reviewed by the main investigator and every positive (plus), negative (minus), and interesting or unique aspect was noted in the table. The table provided a reasonable, though not in depth, insight into which concepts were stronger based on the number and value of the positive aspects, in addition to highlighting unique features that may not have been considered as a part of the device's design up to this point. Noting the negative features identified opportunities for improvement, either through a new solution, or by incorporating solutions from other concepts.

All 32 concepts from the 6-3-5 sessions were included in the PMI table. The six concepts generated via the morphological chart were not included because more time was spent on these relative to the group sessions. Therefore, it was concluded that there was already sufficient detail in these sketches to include them in the next stage of the evaluation immediately. From the list of 32, 13 concepts were sketched in more detail, and seven were considered for potential improvement or combination; twelve concepts were eliminated and not considered for future stages. Due to the iterative nature of the design process, the PMI table can be revisited for inspiration when adding to and improving designs.

2.4.2 Controlled Convergence Method

Developed by Pugh, the Controlled Convergence Method (CCM) is a non-numeric and iterative process for evaluating designs for concept selection (Pugh 1991). The method uses a matrix for evaluation that compares concepts against pre-defined criteria. Using this method requires several steps. First, all the concepts being compared within the matrix must be sketched to the same level of detail and communicate their main idea (text can be used as an additional descriptor that could be beneficial, but it is not necessary). Following this, the matrix is prepared. Each concept is placed in its own column along the horizontal axis of the matrix and the pre-defined criteria are placed down the vertical axis. The criteria should be easy to understand and identifiable with the concepts. Following this, a datum must be selected to compare all of the concepts against; ideally, the datum should be an existing design or product that can be regarded as a "gold standard" in which the concepts try to exceed. With a datum selected, the evaluation process can proceed. Each concept is compared to the datum for each criterion. If the concept is regarded as better than the datum, then a "+" is marked in the corresponding space. If it is deemed worse than the datum, it is marked with a "-". If the concept and the datum are considered the same for that criterion (i.e. no defining positive or negative comparison can be made), then an "S" is marked. The total number of "+", "-", and "S" are then calculated for each concept. Subtracting the quantity of "-" from the "+" provides a final score for that concept, allowing them to be ordered from highest scoring to lowest scoring. Upon completing the matrix, areas for improvement on low scoring concepts can be identified by identifying enhancements in areas where a "-" or "S" was scored. If this is not possible or feasible, the concept can be eliminated from the matrix. Any positive aspects from an eliminated concept

are then noted for consideration of inclusion in the remaining concepts. In addition, identifying positive criteria in a concept can inspire improvements in other designs where the same criteria scored negatively.

Following improvement, combination, and deletion of concepts from the first run of the matrix, another iteration can be performed until the desired number of concepts is achieved. With each successive matrix, the highest scoring concept from the previous run should be chosen as the new datum for comparison in the following matrix. If there are several concepts with the highest score, then one is chosen as the datum.

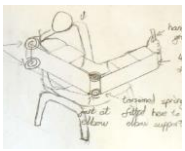
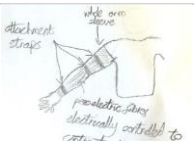
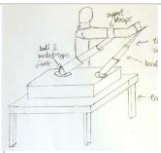
Nineteen concepts (six from the sketched individual designs and thirteen refined concepts taken from the PMI table) were evaluated using the CCM. The datum chosen was an existing device, the SaeboMAS (SaeboMas, Saebo, Inc., Charlotte, North Carolina, USA). This is a commercial weight support device that provides support for the upper limb at the forearm. Criteria chosen for the evaluation matrix were taken from the PDS giving a list of thirteen. These were:

- Degree of weight support – How much weight support could the device provide and how much of the arm is supported.
- Range of Movement – The amount of range of motion that can be achieved when using this device.
- Ease of use – How easy the device is to set up and use.
- Safety – How safe the device will be during use to avoid personal injury.
- Comfort – How comfortable the device will be to use.
- Set up time – How quick can the device be set up for use.

- No. of parts – How many parts are required to build the device? (Fewer being better)
- Deterioration – How much is it expected that the device will deteriorate during use.
- Feedback – The feasibility of implementing feedback in this system.
- Portability – How portable is this device.
- Size – How small/large is this device.
- Cost – The expected manufacturing cost of this device.
- Aesthetics – How aesthetically acceptable is the device.

An example of the CCM with a few concepts from the first iteration is shown in table 2.1.

Table 2.1 - Evaluation matrix using the controlled convergence method (CCM) comparing three different concepts against the datum.

				
Concepts		Concept 1	Concept 2	Concept 3
Criteria				
Degree of weight support	Datum	+	-	+
Range of movement		+	-	+
Ease of use		S	+	-
Safety		-	S	S
Comfort		+	+	S
Set up time		-	+	S
No. of parts		-	+	+
Deterioration		S	-	S
Feedback		S	S	S
Size		S	+	+
Portability		S	+	S
Cost (Expected manufacturing cost)		+	+	+
Aesthetics		-	+	S
Σ+		4	8	5
Σ-		4	3	1
ΣS		5	2	7

('+' = Better than datum; '-' = Worse than datum; 'S' = Similar to datum).

From the first run of the evaluation matrix, 19 concepts were reduced to 12, where removal of concepts was based on those that scored the most '-', and areas for improvement could not be identified. The remaining concepts were refined and improved based on positive and negative aspects identified relative to the datum. The highest scoring concept from the first run was chosen as the next datum (figure 2.4). This concept was designed to be placed on a table or elevated surface with the intention of it being operated by the user while seated. Two cylindrical beams protrude from the base with supports, one for the upper arm and one for the forearm. Both beams can rotate along their respective longitudinal axes, and can be raised and lowered, giving two degrees of freedom per beam in order to provide the user a reasonable working range of motion. Velcro straps are attached to the end of each support in order to secure the upper limb in place.

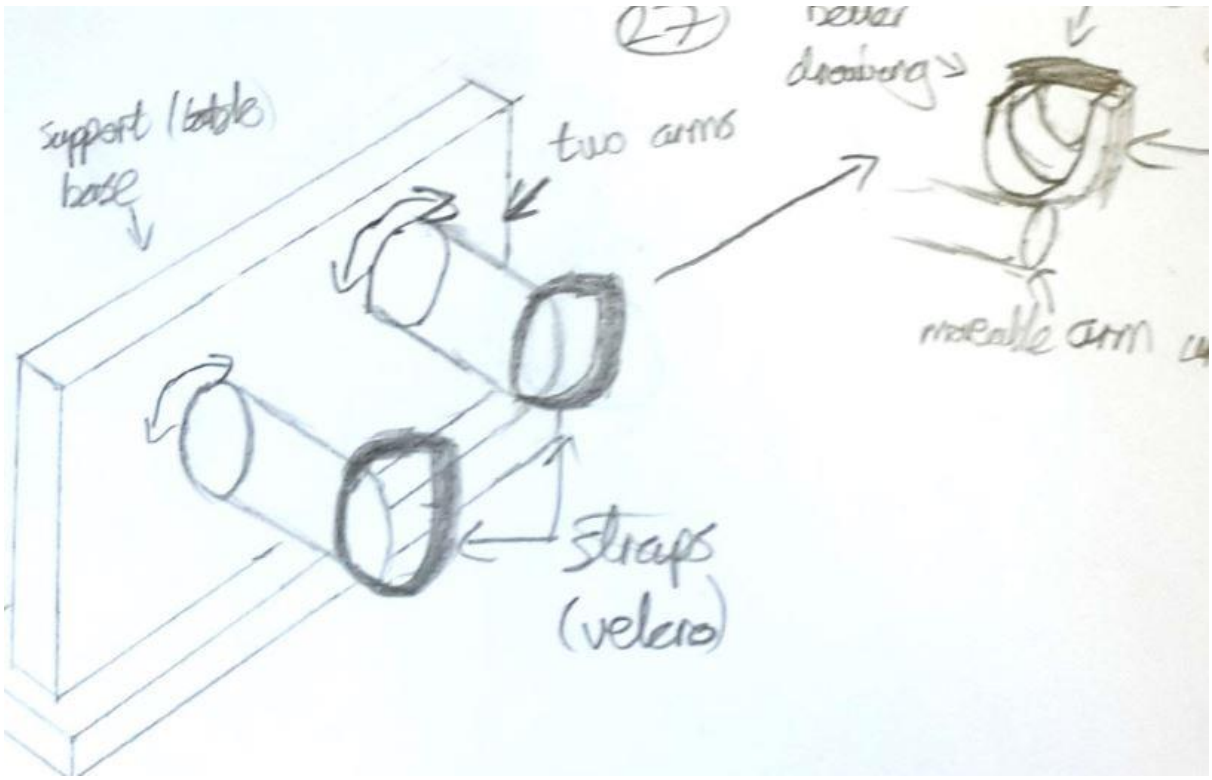


Figure 2.4 - Highest scoring concept from the first run of the evaluation matrix.

The next section will explain and display ten of the highest scoring concepts from the next evaluation stage.

2.4.3 Second Iteration of CCM: concept descriptions

Concept 1 utilizes torsion springs for its weight support mechanism where tightening and/or loosening the tension in the spring will alter the degree of support the device provides. The device has two degrees of freedom at the shoulder joint and one at the elbow joint. There are two sets of straps, one for the upper arm and one for the forearm to provide two points of support to the user in addition to a handle to be used for gripping. A clamp is used to mount the device to a table.

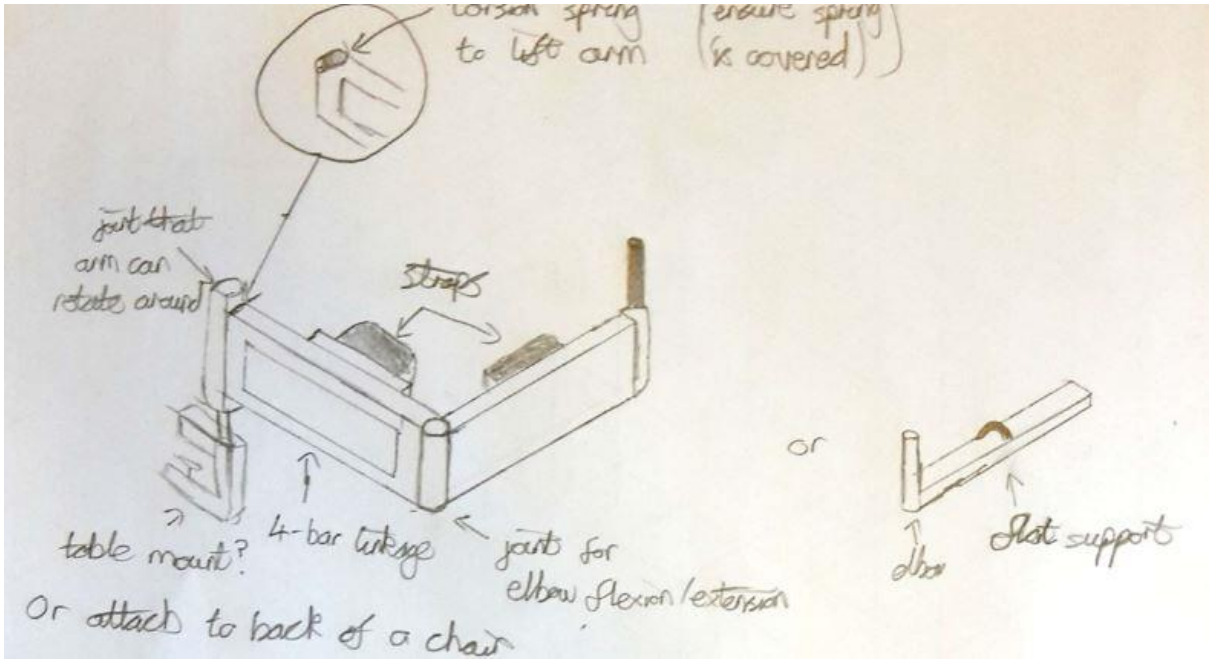


Figure 2.5 - Concept 1

Concept 1 has the advantage of being compact and portable while still providing support for the upper limb. Providing support more proximal to the shoulder was deemed as critical to reduce shoulder pain, a feature not present in the original datum (SaeboMAS). The device could benefit from additional degrees of freedom to enable a greater range of movement during use (i.e. enable reaching movements).

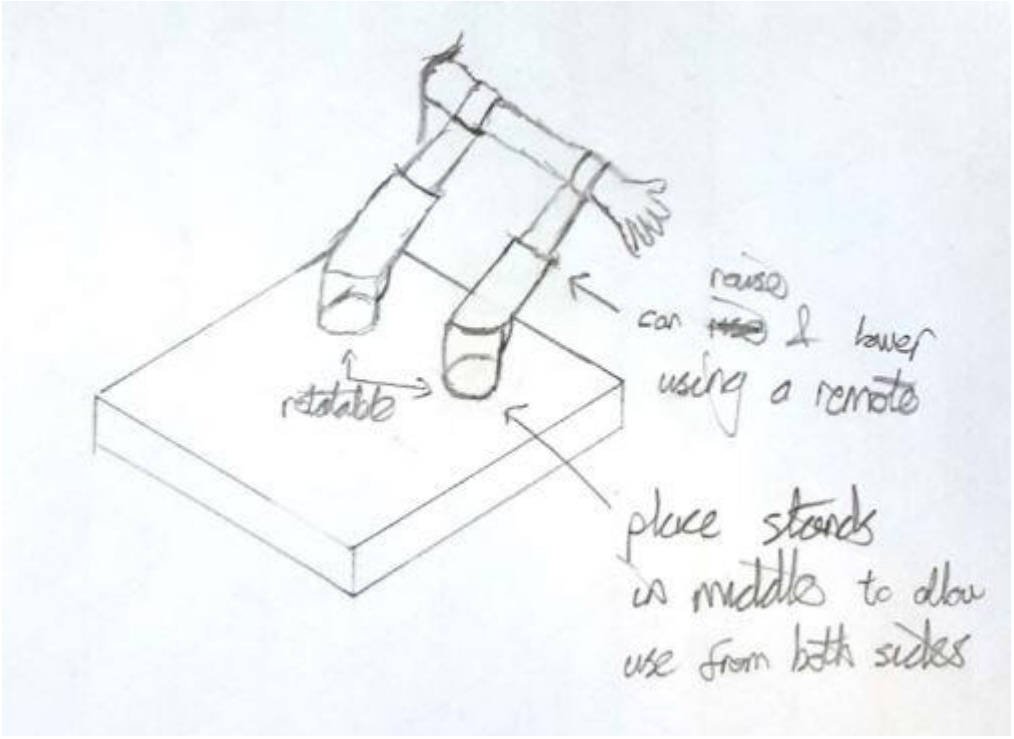


Figure 2.6 - Concept 2

Concept 2 is designed to be placed on a table space. Extruding from the base are two telescopic arms that extend and retract determined by the upper limb's position in the working area. The two arms also provide points of support for both the proximal and distal regions of the upper limb. Each arm functions like a ball and socket joint from the base to provide a distinct range of movement for the arm. An advantage of this system is that it is hoped that it can be easily adjusted for either the left or right upper limb, depending on the user's impaired side.

Problems arose with this concept in deciding an appropriate weight support mechanism for this system. It was decided that it would be difficult to implement such a mechanism with this concept relative to the datum and therefore this concept was eliminated.

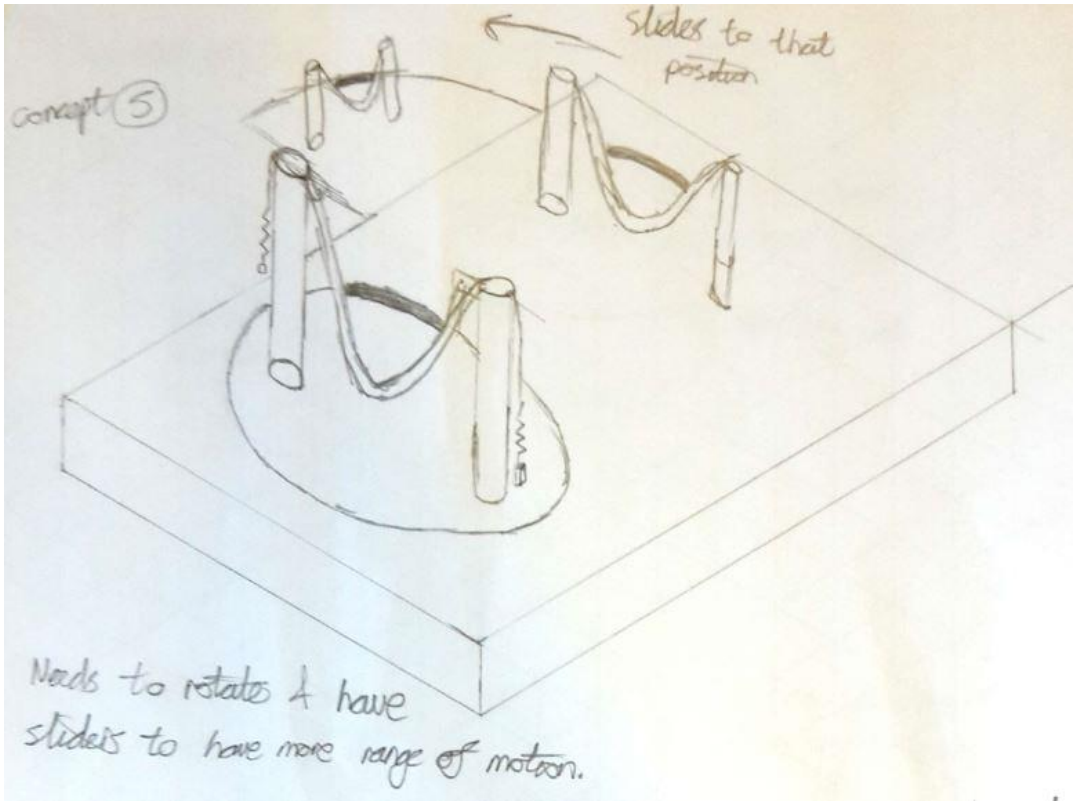


Figure 2.7 - Concept 3

Concept 3 is placed on a table consisting of two points of support for the upper limb. Each support consists of a sling suspended from two vertical supports. A counterweight or spring is attached to the ends of the sling over the vertical supports to lift the sling and provide adjustable weight support for the arm. Each support sling is placed on a turntable like platform to provide extra degrees of freedom. Despite these added degrees of freedom from the turntable, the concept appeared to leave the upper limb quite restricted in movement (i.e. would only facilitate movement in one plane such as elbow flexion/extension). Adding wheels or roller to the bottom of the supports could provide an increased range of motion but at the expense of safety and security as it would no longer be a fixed device and could lead to the risk of falling off the table.

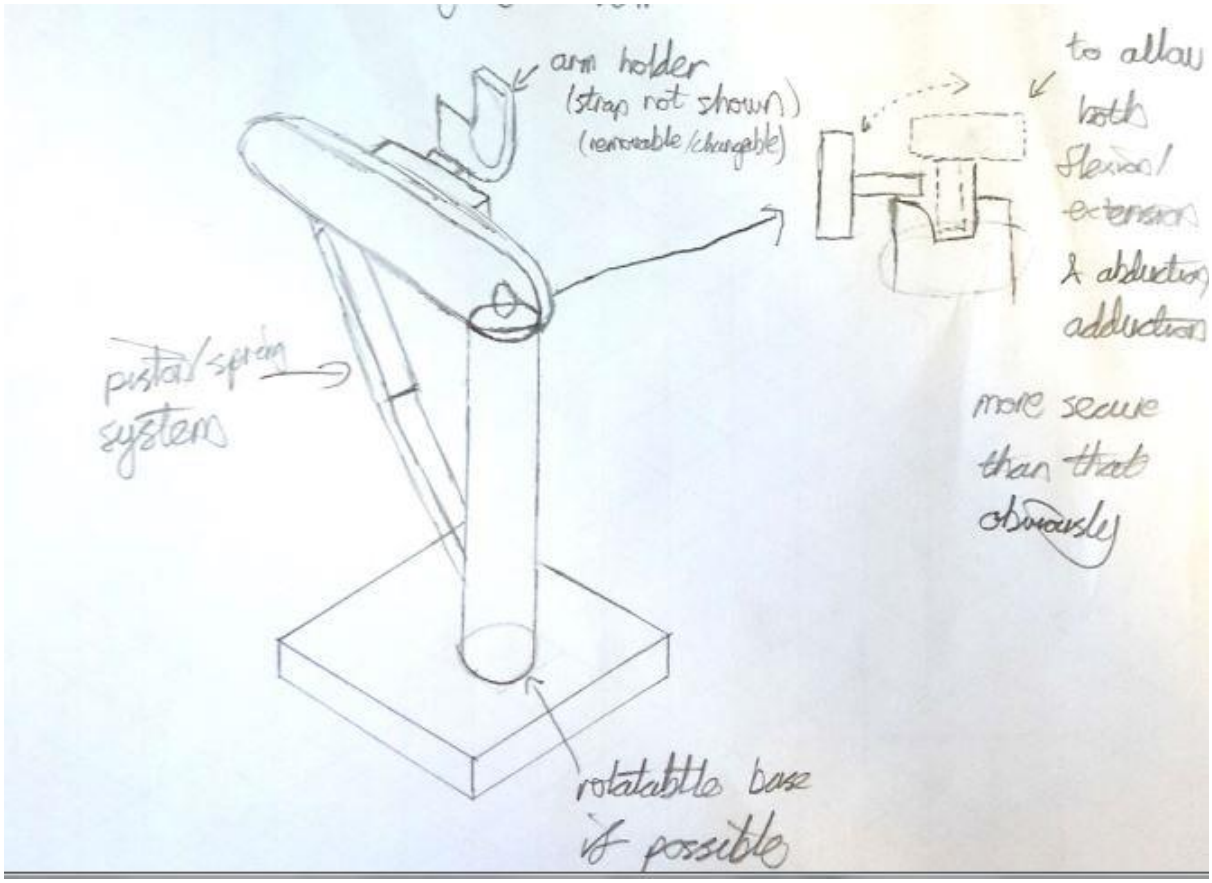


Figure 2.8 - Concept 4

Concept 4 consisted of a platform to be placed on the floor. A pillar extends from a base that can rotate along its longitudinal axis. Attached to the top of the pillar via a hinge joint is a beam with a support to hold the upper limb in place. The beam can be raised or lowered via a piston attached between the beam and pillar allowing the mechanism to rotate with the upper limb while the device is in use. This concept showed strengths in providing suitable weight support and range of movement. However, the size of the device makes it unlikely to be portable or lightweight.

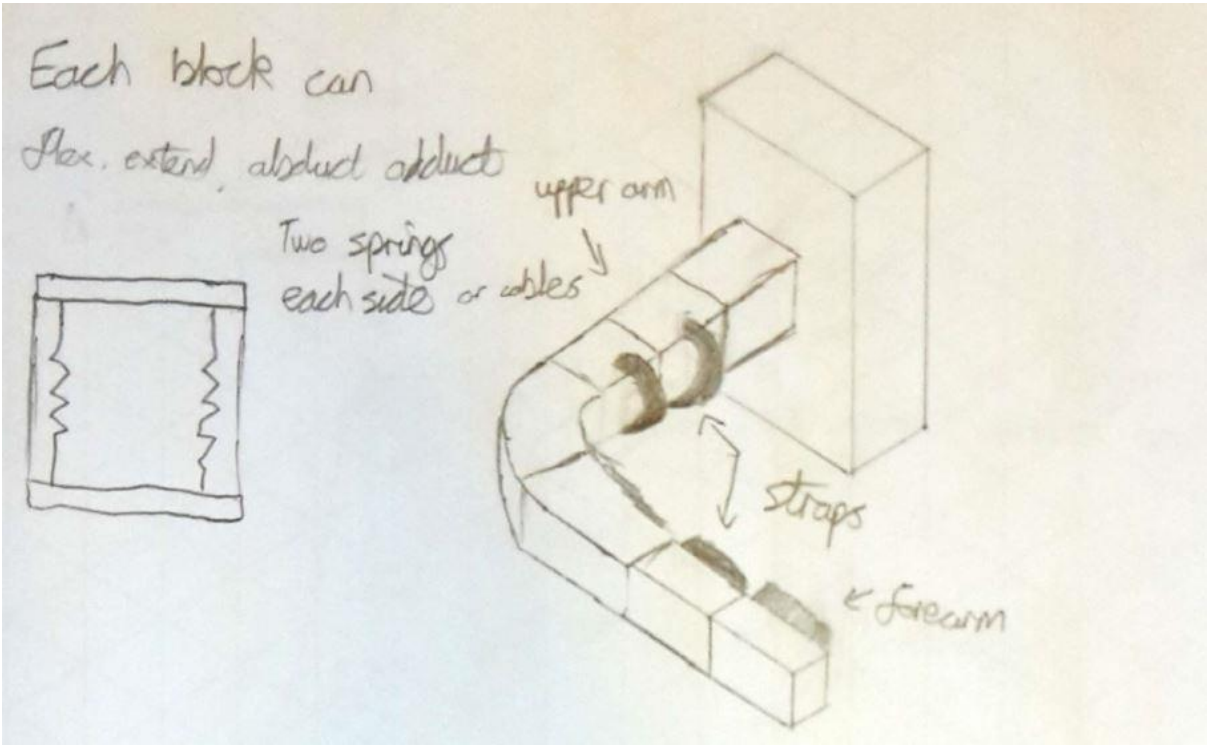


Figure 2.9 - Concept 5

Concept 5 consists of modular blocks that can be added or removed from a base to make a flexible support in which the upper limb can be strapped. Each block consists of four cables with one at each corner that can be manipulated to support the weight of the upper limb and potentially guide its movements in three-dimensional space. The main intention with this concept was that each cable can be controlled independently enabling a large range of motion to be achieved in addition to being able to provide adjustable support for the arm. Being a modular device, there are no limits to the number of blocks that can be added to the device, providing the user the opportunity to customize the system to their own preference. Although the concept showed promise in providing support in providing a beneficial range of motion while also providing support for the upper limb, its complexity (i.e. customising the modular system) may make it difficult for independent use with stroke survivors. Additionally,

this may also make the system complex to manufacture relative other concepts, likely increasing manufacturing costs and in turn, overall cost of the device.

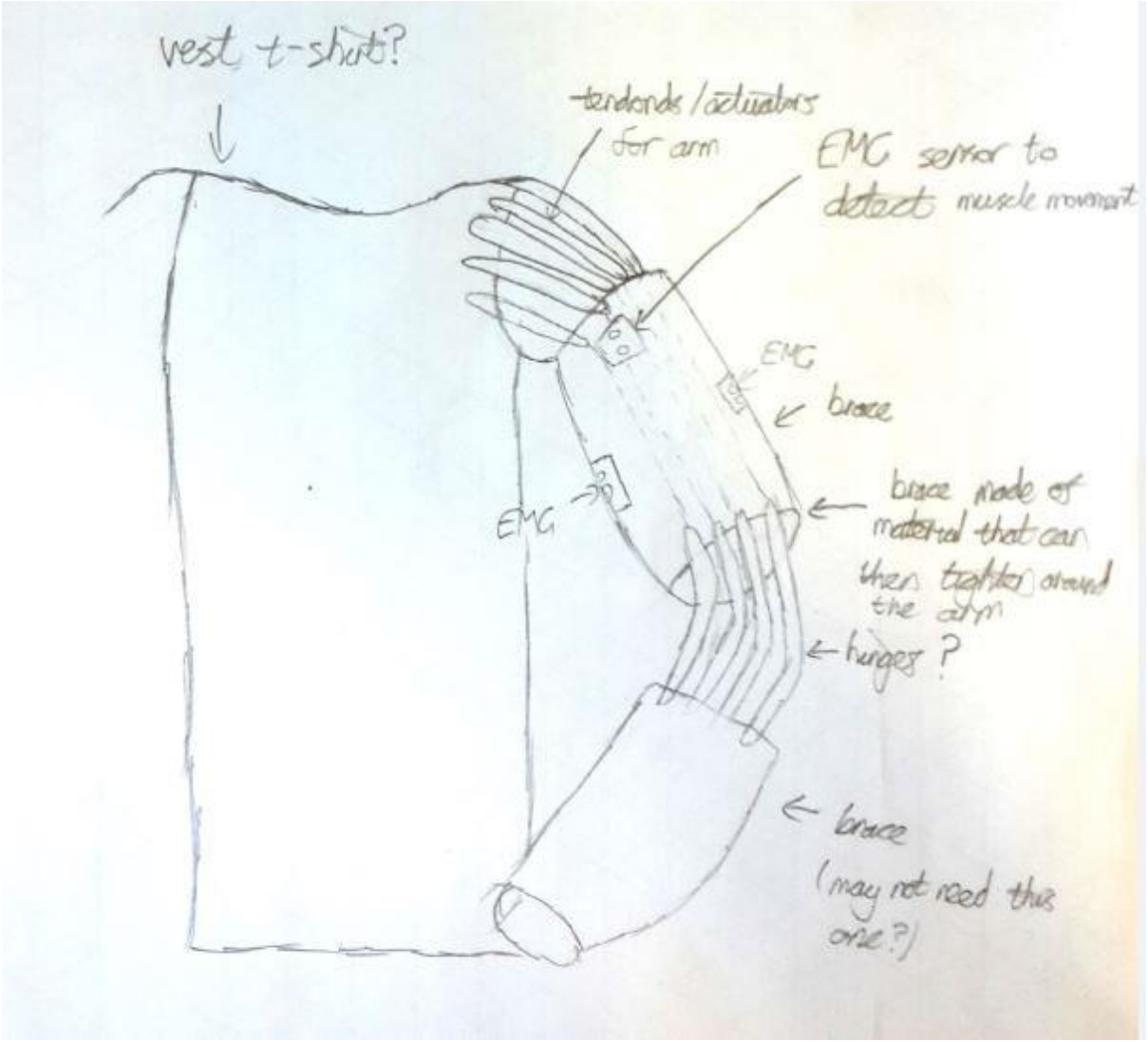


Figure 2.10 - Concept 6

Concept 6 is a wearable system consisting of an outer garment with two braces for the upper arm and forearm. These components are attached together using flexible tendon-like actuators controlled by small motors. Furthermore, electromyography (EMG) sensors are attached to the interiors of the upper arm brace to detect muscle activity. Upon detection of muscle activity past a specified threshold (calibrated beforehand based upon the user's capabilities), the motors are activated to lift the upper limb at

the shoulder and to assist in its motion. Being a wearable system, the device is advantageous in that it provides portability for the user, allowing it to be used in various environments. However, donning and doffing the device was considered to be potentially difficult for a user living with stroke to perform independently and therefore may present a barrier to regular use.

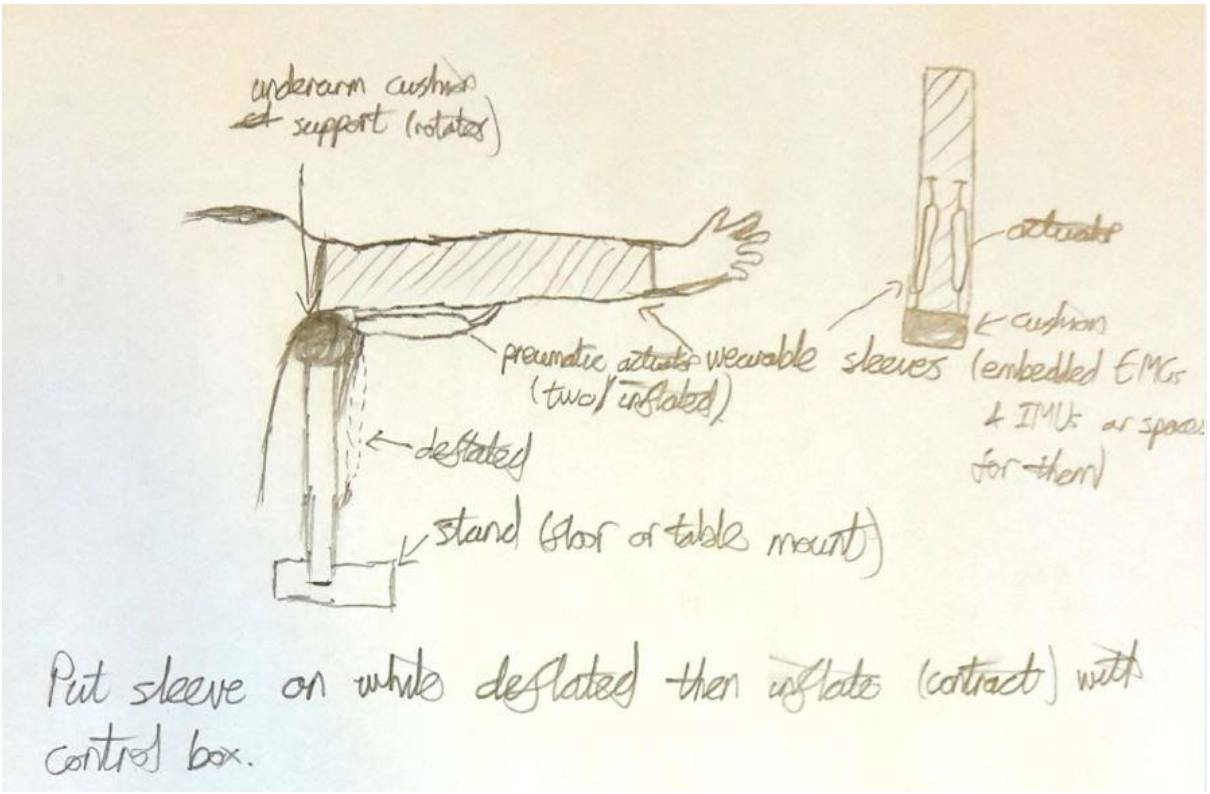


Figure 2.11 - Concept 7

Concept 7 consists of a wearable sleeve attached to a support using pneumatic artificial muscles. A stand for either the floor or table can rotate around its longitudinal axis and provides a cushioned support for the underarm at the top. The user can detach the sleeve from the device to don separately. Following this, there are landmarks on the sleeve to show the correct positioning for attachment to the support mechanism. Using this method, the user can safely attach their upper limb to the device before activating the weight support system via a simple control system (i.e. a switch or button).

Furthermore, to incorporate feedback to the concept, it was considered that inertial measurement units (IMUs) and EMG sensors could be embedded into the wearable sleeve to record muscle activity and joint angles. This could be employed while using the device, or to monitor daily activities where the sleeve is worn without the device.

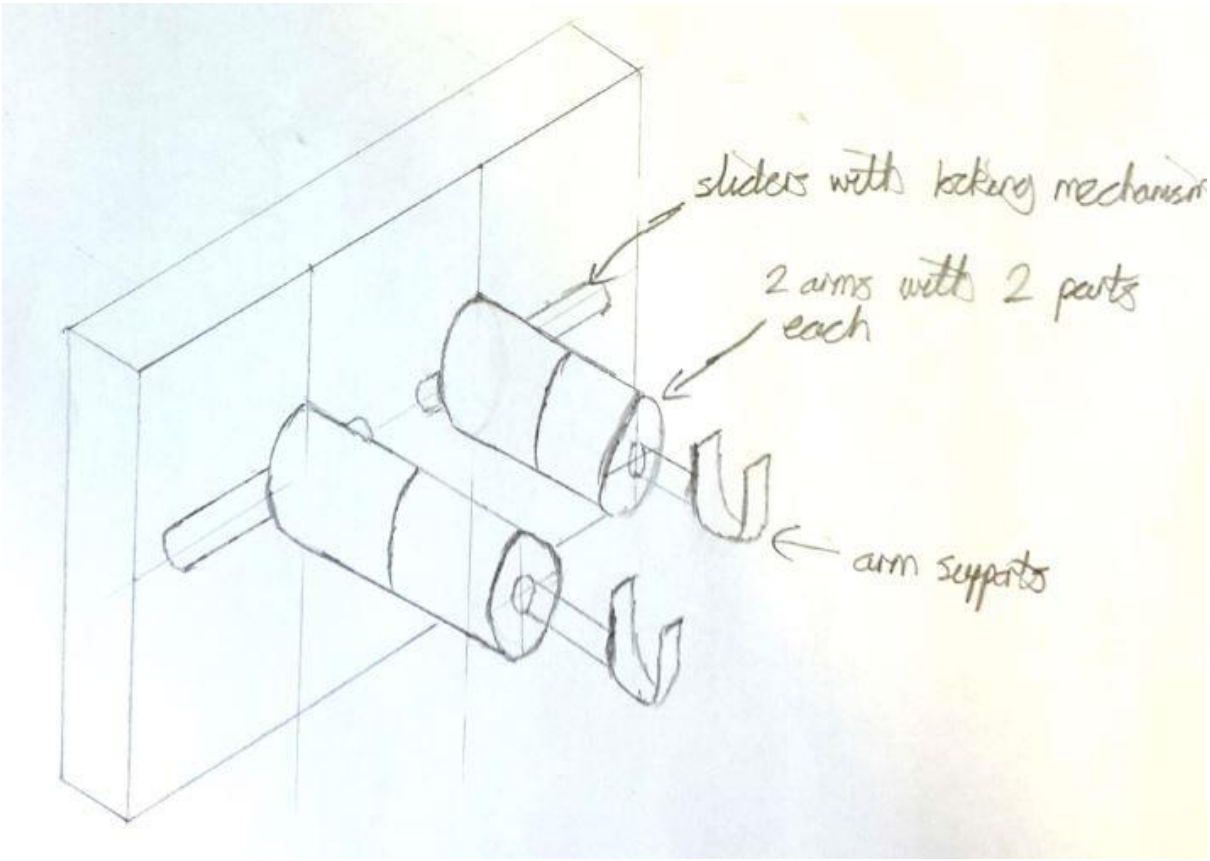


Figure 2.12 - Concept 8

Concept 8 is an improvement on the datum chosen for this run of the evaluation stage. It utilizes two points of support for the upper limb via two cylindrical beams connected to a rectangular base that sits upright on the user's workspace. Providing two points of support was considered advantageous as it provides the user support at the shoulder to assist with issues associated with subluxation. Additionally, having the second support for the forearm could help the user feel more in control of the device by enabling them to facilitate movement through elbow flexion/extension where required. For the weight

support mechanism, a cable and pulley system was suggested for each individual support. A cable would be anchored to the support at a fixed point and travel over a pulley on top of the rectangular base. On the opposite end of the device, the cable would be attached to a counterweight system; adding or removing the appropriate amount of weight could achieve the effect of balancing the arm against gravity. Furthermore, each support can slide forward and backward along a track with the arm to provide the user with a greater range of motion while the device is in use relative to the datum. It is also desired that this articulation be lockable to enable the user to put their arm in and out of the device more easily. One of the advantages of this concept is that it is relatively straightforward to use following initial set up, potentially reducing the overall setup time should the user decide to keep the device on their workspace permanently.

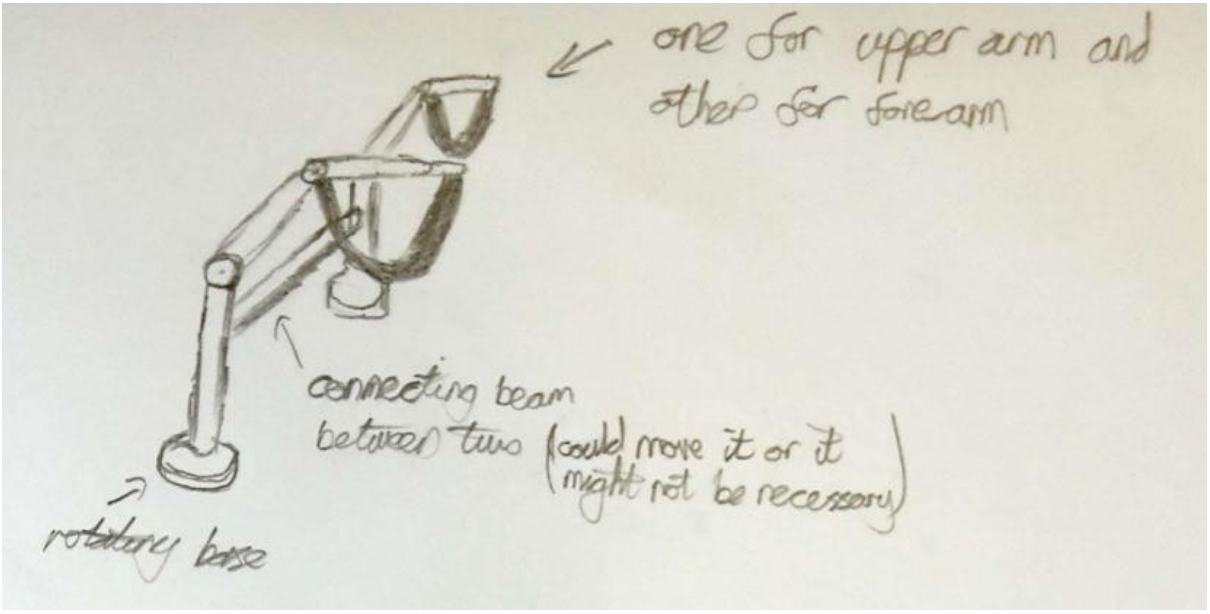


Figure 2.13 - Concept 9

Concept 9 consists of two hoists connected to each other that act as two points of support for the upper limb: one for the upper arm and the other for the forearm. The

base of each hoist rotates around its axis and each one contains two hinge joints further up from the bases to allow the hoists to move up and down. To provide weight support, a spring system for each hoist would be utilised to balance the arm against gravity. However, it was deemed likely that the device could fall over when in use. Increasing the size and weight of the bases can help prevent this issue but would decrease the portability of the device.

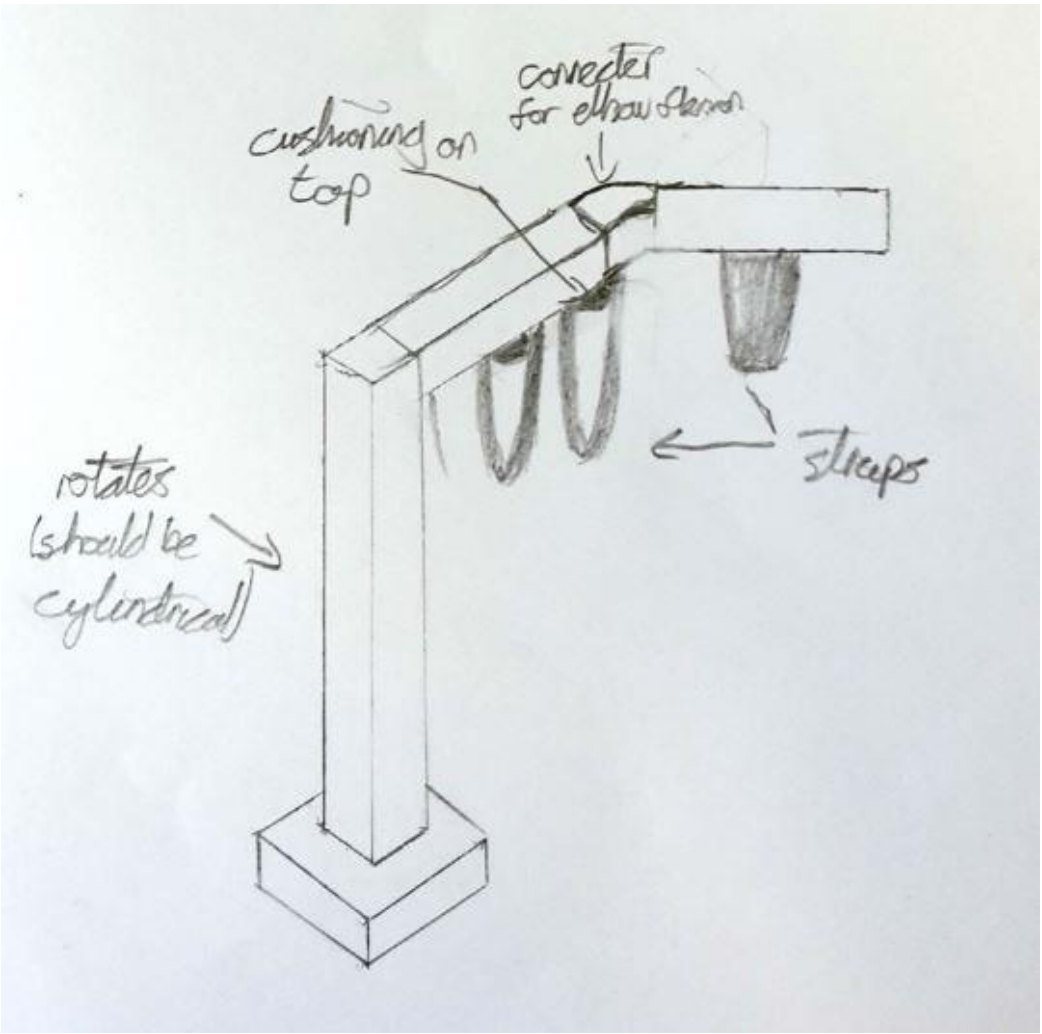


Figure 2.14 - Concept 10

Concept 10 is intended to provide support for both the upper arm and forearm and provide three rotational degrees of freedom. The device is placed on the floor next to a seated user and can be height adjustable to accommodate the user's requirements.

There are two straps to secure the upper arm in place and one for the forearm though these can be added and/or removed if desired. Provision of weight support would likely incorporate a motorised or pneumatic system built within vertical base of the device in order to lift the arm. While the device is quite large and unlikely to be portable, the concept was designed to be easy to use as the user would only be required to secure their arm in the straps and operate the lifting mechanism with a switch or button which should be straightforward with their unimpaired arm. However, there is the possibility of adding wheels that are lockable to the bottom of the device to add some degree of portability.

Following two runs of the evaluation matrix, six concepts were selected for further refinement with the remaining concepts eliminated from the process. The refined concepts were given new numbers (11-16). The next stage of the evaluation procedure adopted a different approach, a weighting and rating matrix.

2.4.4 Weighting and Rating Matrix

An alternative technique for design evaluation is a weighting and rating matrix, or weighted decision matrix (Pugh 1991). It involves creating a list of pre-defined criteria for a product or design and then assigning each one a numerical weighting with respect to their perceived importance. The criteria are then evaluated for each concept and given a score based on how well they succeed in meeting the desired performance for each criterion. The score is then multiplied by the weighting to provide an overall score for that criterion. All the scores are then added together to provide a final score for each concept. Finally, the scores for the concepts are compared to determine the highest and lowest scoring concepts in addition to defining which features may require improvements based on their weighting and rating.

The weighting and rating matrix was utilised for the remaining six concepts in order to create a final shortlist of 3-4 concepts to show at user focus groups. The criteria chosen for evaluation was the same as that for the controlled convergence method. Each criterion was assigned a weighting ranging from one (lowest) to five (highest) in terms of importance (table 2.2). Degree of weight support and range of movement were considered the most important aspects of the design based on informal discussions with stroke survivors and therapists. Aesthetics and number of parts estimated in the design were considered the least important, at this stage. This section will evaluate the remaining six concepts using this method and the reasons for their scores.

Table 2.2 - List of criteria and their associated weighting.

Criteria	**Weighting**
Degree of weight support	5
Range of movement	5
Ease of use	4
Safety	4
Comfort	4
Set up time	4
Deterioration	3
Size	2
Portability	2
Cost	1
Aesthetics	1
No. of parts	1

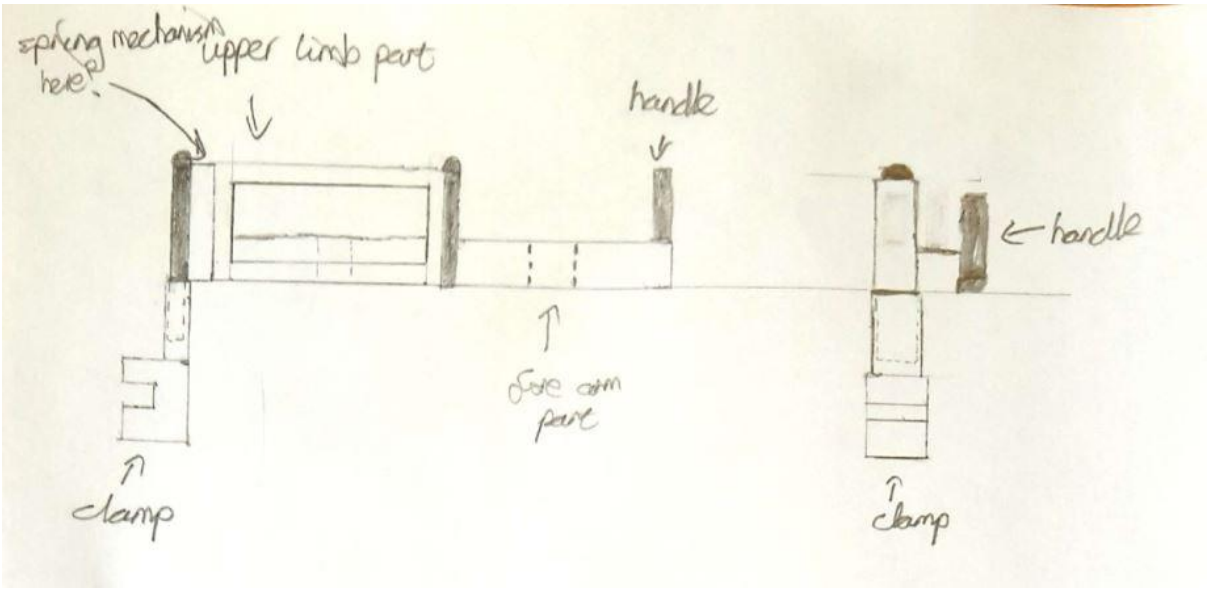


Figure 2.15 - Concept 11

Concept 11 is an improved version of concept 1 from the CCM while keeping several attributes (i.e. table clamp, range of movement and two points of support). While the device can provide support for the upper arm and forearm, it was decided to make the forearm part a modular part of the device. This would be advantageous for the user depending on their upper limb function and exercises they wished to carry out. In contrast to the previous iteration of this concept, torsion springs have been replaced in favour of an extension spring to support the weight of the device and the user's arm. To increase compactness, the spring will be an internal component of the device; this will also help prevent injury to the user in the event of mechanical failure.

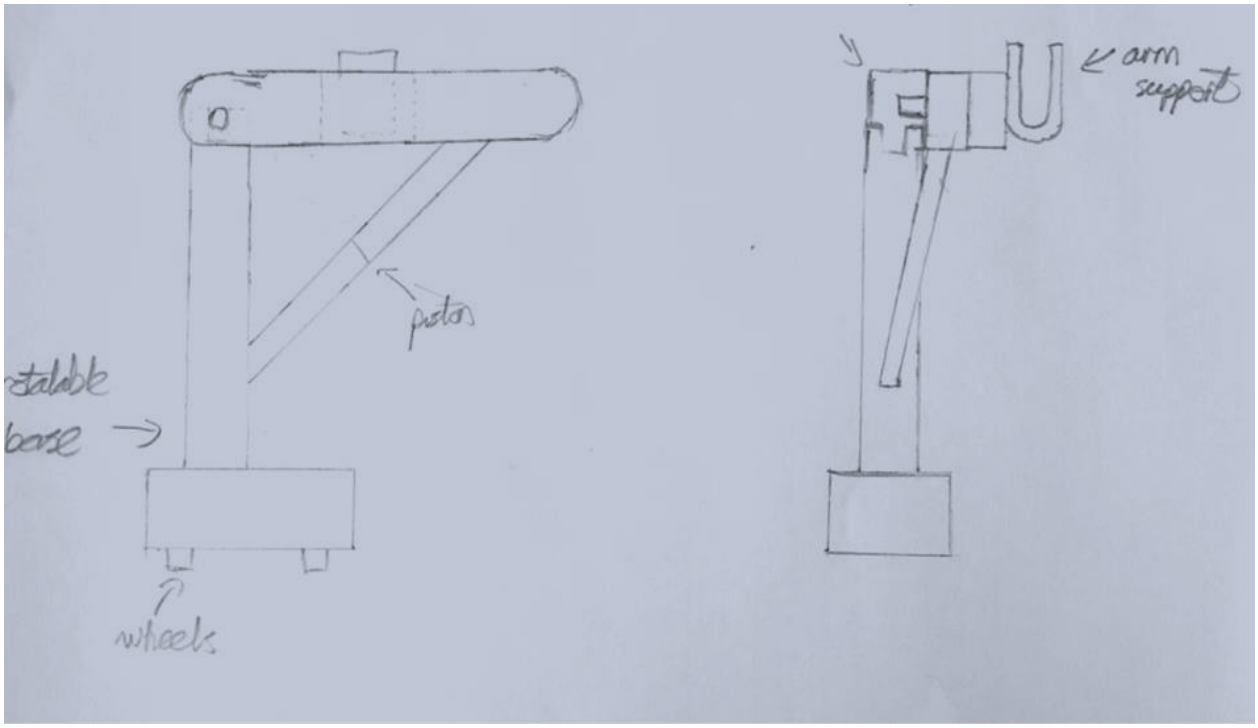


Figure 2.16 - Concept 12

Concept 12 remains unchanged from concept 4, as it had scored well against the datum previously. Areas that were determined for improvement were safety, size and portability. However, it was difficult to identify improvements in size (i.e. making it smaller) without sacrificing other important aspects of the design (i.e. the weight support). Therefore, it was decided not to implement improvements to this area. For portability, adding wheels to the bottom of the device would help assist in transporting it easily within a home or clinical environment. To prevent the risk of movement during device use however, the wheels would need to be lockable or be able to retract into the base of the device. To increase safety further, it would be necessary to ensure that the piston system desired was stable and could support the various loads. When the arm is placed to be lifted by the system, the mechanism should perform the lift in a slow and controlled manner to ensure the user feels at ease and for their safety while the device is in use.

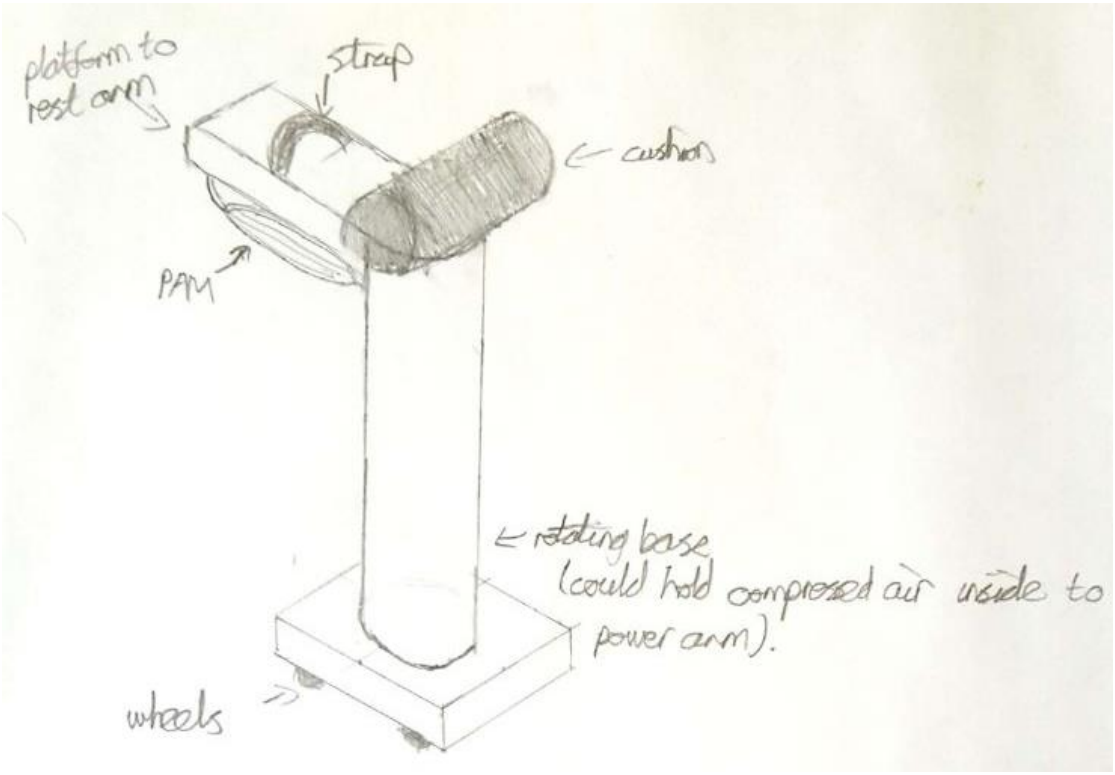


Figure 2.17 - Concept 13

Concept 13 is a follow-up to concept 7. The wearable sleeve that attaches to the weight support system has been replaced with a platform attached to the device for the upper limb to rest on. This was chosen to make it simpler for the user to setup and to reduce the number of components in the design. Size is still an issue though it could be possible to make the rotating base collapsible in order to make it more compact for storage.

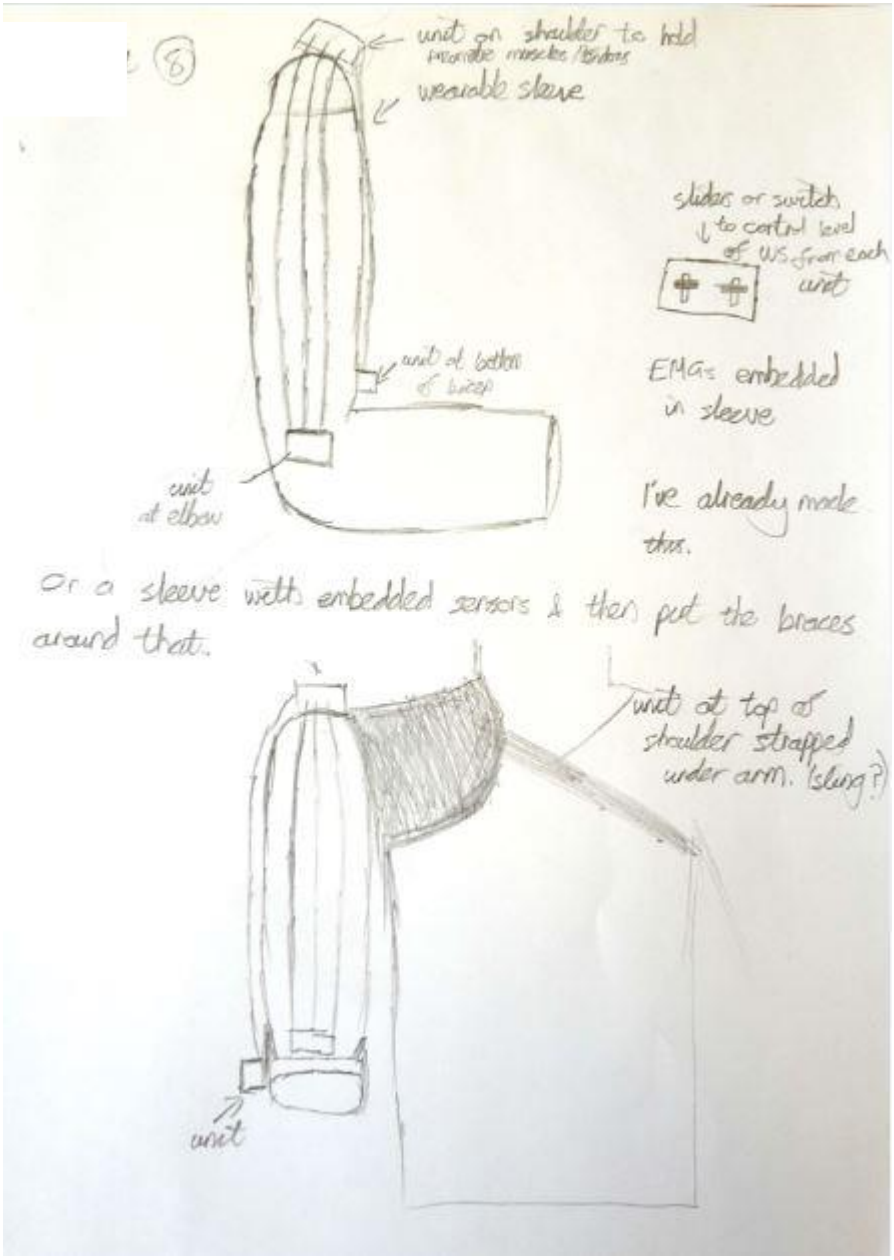


Figure 2.18 - Concept 14

Concept 14 is a wearable system similar to concept 6. The use of two braces was exchanged for a wearable sleeve with attachment points for a pneumatic artificial muscle system. Increasing the number of cables on the sleeve and ensuring they are strong but flexible is desirable. To hold the system that will contract the cables to lift the arm, a small backpack or sling that the user can wear will be incorporated. A few methods for activating the system were suggested. Firstly, a simple switch (either

wireless or attached to the system) could be used to contract and relax the cable that would be manually operated with the user's healthy limb. Alternatively, creating an autonomous system using EMG sensors embedded within the sleeve could be incorporated. A threshold for each individual's muscle activity for lifting their arm could be set and once the sensors detect that this threshold has been surpassed, the sensors could detect this and activate the system, raising the upper limb at the user's will. However, adding the EMG system would likely increase the cost and complexity (in terms of setup) of the system for the user. As a whole, the system benefits in size and portability having the potential to be used outwith the home and clinical environments and in a public space should the user desire. As a wearable system, however, users may struggle to don and doff the device on their own and may require assistance.

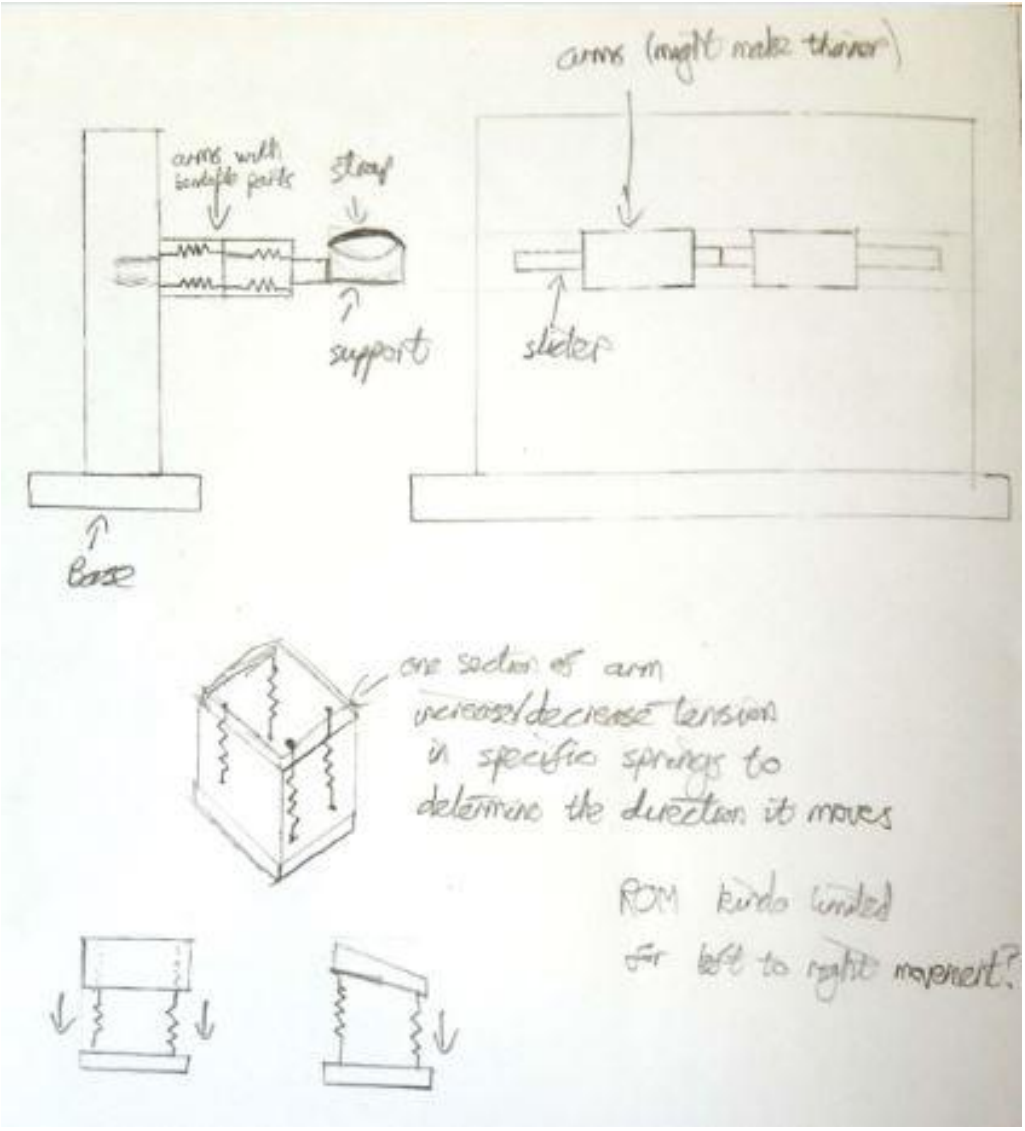


Figure 2.19 - Concept 15

Concept 15 builds upon concept 8. Using a modular based spring system for both supports was proposed for the weight support mechanism. Each arm of the device would contain a minimum of two blocks, each with their own built-in springs before a support is attached at the end for the upper limb. Each block contains up to four springs, one at each corner, and a cable is attached to the proximal end of each one. This cable travels along the support arm and into the base. Though not shown in the diagram, it is intended that each cable would travel along a pulley within the base and up to the top of the base where it is anchored. At this point, an adjustment knob or

lever would be used to increase or decrease tension in the cable and in turn, the spring it is connected to, increasing or decreasing the lift provided to the user's upper limb. Additionally, to enable the user to move their arm when strapped into the device. Each arm support was intended to slide forward and backwards with the user's upper limb. This would ensure that the point of contact between the upper limb and support remained the same. However, it is likely that the whole weight support mechanism (cable, pulleys, adjustment system) would need to slide in line with the supports to maintain consistent weight support throughout the device's use. This will greatly increase the complexity of manufacture and may not be feasible to explore in comparison to simpler alternatives. The portability of the concept appears relatively acceptable, and manufacturing it out of lightweight materials would further enhance this if the device had to be moved regularly.

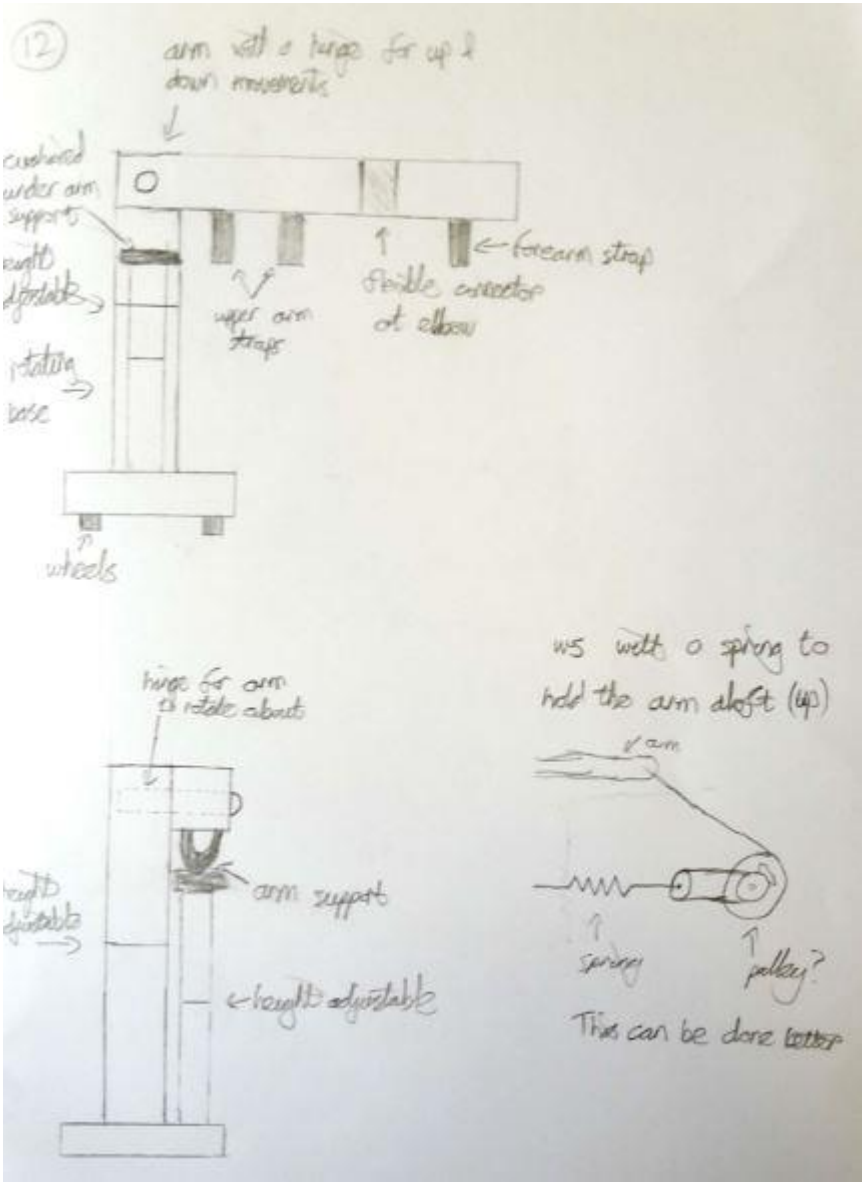


Figure 2.20 - Concept 16

Concept 16 enhances concept 10, adding a cushioned underarm support. Similar to the previous design, the device is height adjustable to accommodate different users' dimensions. The cushioned underarm support is also height adjustable. Additionally, the device retained three degrees of rotation to enable shoulder flexion/extension, shoulder internal/external rotation and elbow flexion/extension but not shoulder abduction/adduction. The weight support mechanism also remained within the vertical base of the device though replacing the pneumatic based system with springs, cables

and pulleys was considered. Wheels at the bottom were added to improve portability though these, similar to concept 12, will need to be lockable or retractable to remain safe for the user during operation of the device. The size of the device remains unchanged.

2.4.5 Results

Table 2.3 displays the results of the weighting and rating matrix for the remaining six concepts. Concepts 11, 12 and 16 scored similarly (250, 254 and 248 respectively). Concepts 14 and 15 scored lower (209 and 213 respectively) with concept 13 scoring in between (237).

Weight support was highly scored among all concepts except concept 14. This was based on the opinion that it could be difficult to develop an effective and efficient weight support system while also ensuring that the device was wearable and portable for the user. Movement (i.e. degrees of freedom) scored highly among all concepts except concept 15 where the degrees of rotation and movement available to the user were quite limited. As these two criterion had the highest possible weighting, they contributed most to each concept's overall score.

The weighting scale was changed from 1-5 to 1-10 since it was desired that there be a greater range in the weighting scale in order to better differentiate the importance of the criteria. For example, ease of use and safety were regarded as more important than comfort and setup time though all received a weighting of four relative to the other criteria. As such, an updated matrix with the new weighting scale was created to optimise the evaluation (table 2.4) and assess if there would be any differences compared to the original scale (table 2.3).

Table 2.3 - First weighting and rating matrix

		Concept 11		Concept 12		Concept 13		Concept 14		Concept 15		Concept 16	
Criteria	**Weighting**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**
Weight Support	**5**	9	45	9	45	9	45	5	25	8	40	9	45
Movement	**5**	8	40	8	40	8	40	8	40	5	25	8	40
Ease of use	**4**	6	24	8	32	7	28	5	20	6	24	8	32
Safety	**4**	7	28	6	24	6	24	4	16	7	28	7	28
Comfort	**4**	5	20	6	24	8	32	5	20	5	20	8	32
Set up time	**4**	6	24	8	32	6	24	4	16	7	28	6	24
Deterioration	**3**	7	21	8	24	3	9	5	15	5	15	6	18
Size	**2**	7	14	4	8	4	8	8	16	6	12	4	8
Portability	**2**	8	16	6	12	6	12	10	20	3	6	5	10
Cost	**1**	6	6	3	3	3	3	5	5	5	5	4	4
Aesthetics	**1**	7	7	5	5	7	7	8	8	5	5	6	6
No. of parts	**1**	5	5	5	5	5	5	8	8	5	5	5	5
Final Score			**250**		**254**		**237**		**209**		**213**		**252**

Table 2.4 - Second weighting and rating matrix.

		Concept 11		Concept 12		Concept 13		Concept 14		Concept 15		Concept 16	
Criteria	**Weighting**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**
Weight support	**10**	9	90	9	90	9	90	5	50	8	80	9	90
Movement	**10**	8	80	8	80	8	80	8	80	5	50	8	80
Ease of use	**8**	6	48	8	64	7	56	5	40	6	48	8	64
Safety	**8**	7	56	6	48	6	48	4	32	7	56	7	56
Comfort	**7**	5	35	6	42	8	56	5	35	5	35	8	56
Set up time	**7**	6	42	8	56	6	42	4	28	7	49	6	42
Deterioration	**5**	7	35	8	40	3	15	5	25	5	25	6	30
Size	**3**	7	21	4	12	4	12	9	27	6	18	4	12
Portability	**4**	8	32	5	20	6	24	10	40	3	12	5	20
Cost	**2**	6	12	3	6	3	6	5	10	5	10	4	8
Aesthetics	**1**	7	7	5	5	7	7	8	8	5	5	6	6
No. of parts	**1**	5	5	5	5	5	5	8	8	5	5	5	5
Score			**463**		**468**		**441**		**383**		**393**		**469**

From the second run of the weighting matrix, the results are similar. At this stage, concept 14 was removed from consideration as the lowest scoring concept. It was deemed unfeasible to improve the weight support mechanism without increasing the size and weight of the device. Furthermore, it was expected that this design would be difficult for a user living with stroke to operate on their own, potentially increasing the risk of injury. While having another individual help set the device up, ensuring that the design can be simple to set up and operate by the user themselves is one solution, this is undesirable for a device that is intended for independent use.

The next lowest scoring design was concept 15. While scoring higher on degree of weight support the device was predicted to provide, it was weaker regarding the range of motion available. However, potential was seen in greatly improving this aspect by including a method to incorporate extra degrees of rotation for the user. Additionally, while perceived as less portable than the other concepts, the design is relatively more compact than the larger designs making it more likely to be acceptable in a home environment. For these reasons, this concept was chosen to be on the shortlist once improvements to enable a greater range of motion have been implemented.

Concept 11 was chosen for the shortlist as it scored high in most areas. Although size and portability were given a low weighting for the matrix, these aspects looked promising for the device if used in a home environment.

From the remaining concepts (12, 13 and 16), since they all followed a similar theme (a floor-based device with a rotatable base), it was decided to choose one of these to put into the shortlist. The remaining two concepts would then be removed and standout aspects of them may be implemented into the chosen design. Concept 16 was kept as

it scored the highest out of the three concepts at 469 relative to 468 and 441 for concepts 12 and 13 respectively. The addition of a cushioned underarm support and a strap for the forearm was deemed as a beneficial trait that the other two concepts lacked.

2.5 Three-Dimensional Modelling

After evaluating and narrowing down the list of concepts, 3D computer-aided design (CAD) models were developed using CAD software (Solidworks® Student Edition 2016-2017, Dassault Systèmes, Vélizy-Villacoublay, France). Creating 3D models of the designs aided in highlighting any issues in each concept making it possible to improve flaws that may not have been apparent from the sketches. In addition, generating these models was necessary in order to show to focus groups and obtain external feedback on the designs. This section will describe the models generated for the remaining concepts selected from the evaluation procedures and explain any issues and changes made during this process. To avoid confusion each of the remaining concepts have been re-identified as follows:

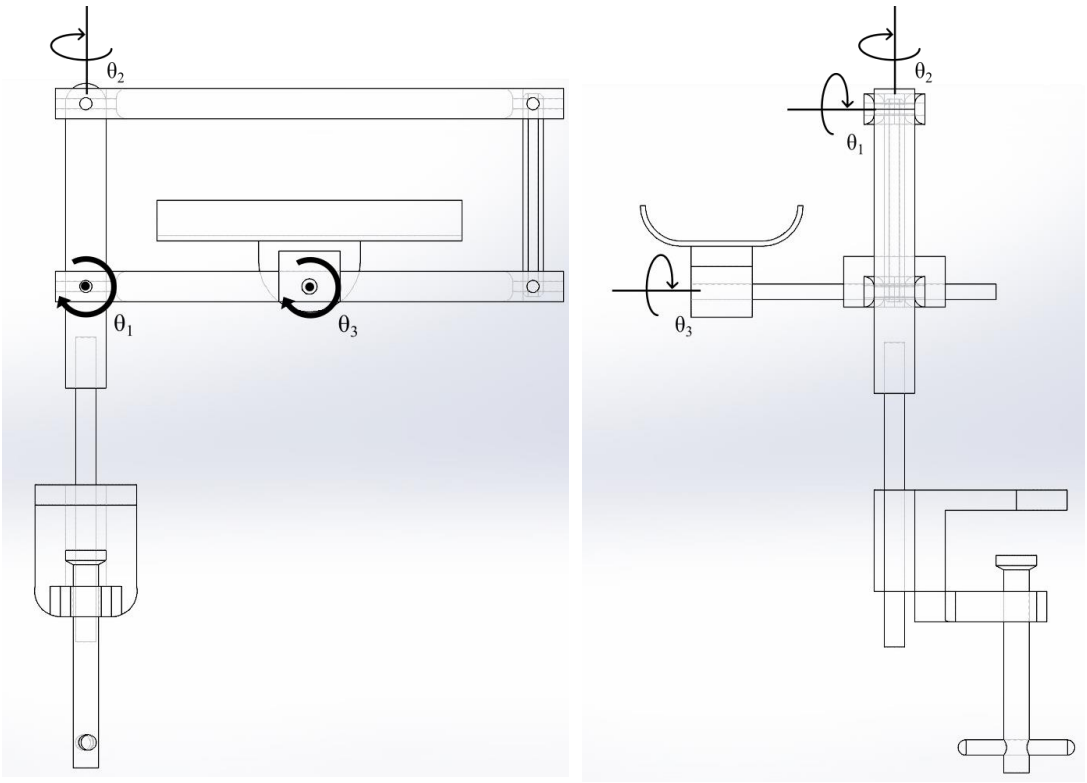
- Concept 11 = Concept A
- Concept 15 = Concept B
- Concept 16 = Concept C

2.5.1 Concept A - Description

Concept A (Figure 2.21) consists of a four-bar linkage that can be raised and lowered to support the weight of the upper limb (θ_1). A support for the upper arm is attached to the bottom bar of the linkage in which the limb can be secured. The fixed bar can pivot around the vertical axis providing a second degree of rotation (θ_2). For the weight

support, a spring-based mechanism was considered for placement within the vertical base with a strong and flexible cable tied to one end of the spring. The opposite end of the cable will then be anchored to either the bottom or distal bar of the four-bar linkage; the tension of the spring will enable the weight of the device and the upper limb to be supported against gravity. To secure the upper limb to the device, a hook and loop fastener around the upper arm support will be implemented. In addition, to lessen the restriction on the upper limb when in use, the support will be made to rotate freely (θ_3). Additionally, a clamp allows the device to be fixed to a table or other fixed surface. Finally, the height of the device relative to the clamp can be adjusted to the user's needs. Depending on the desired application, there is potential to allow the range in height to be great enough to enable the user to operate the device either sitting or standing. In total, the device provides three degrees of rotation.

(a)



(b) *(c)*

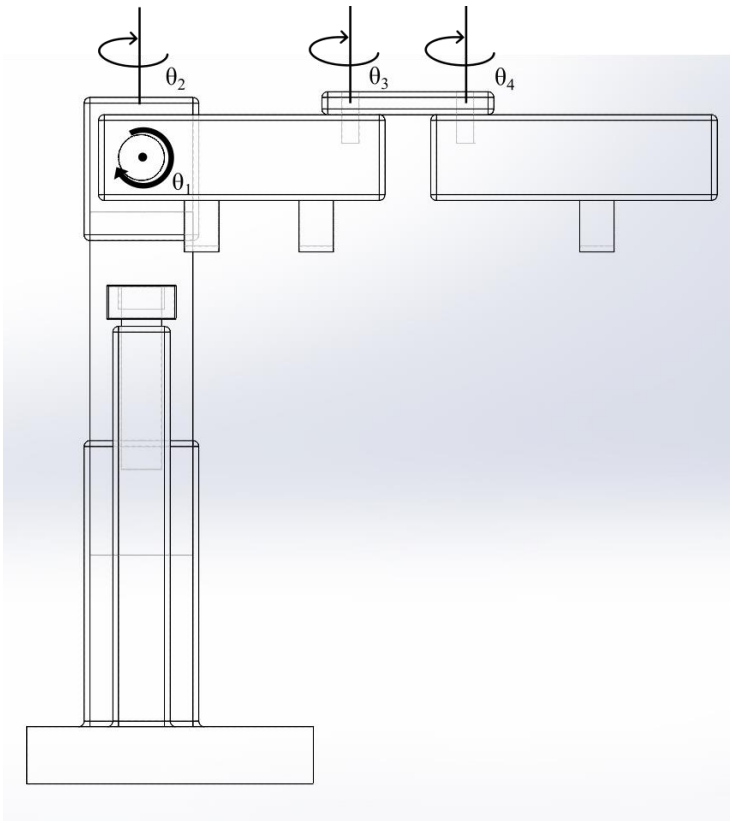
Figure 2.21 - Concept A: (a) Rendered Isometric View; (b) Elevation view; (c) End Elevation view

2.5.2 Concept B - Description

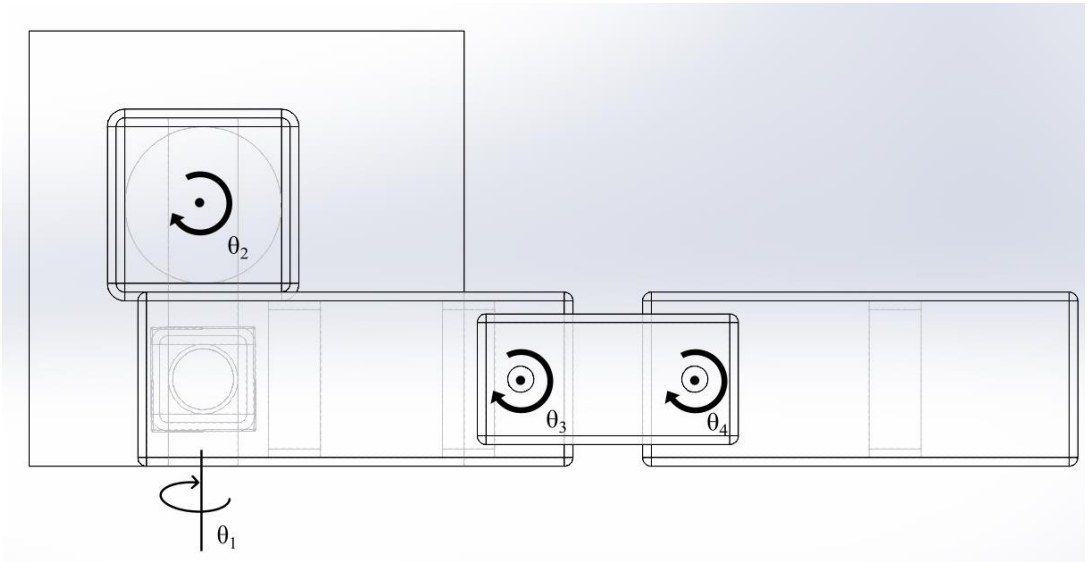
Concept B (Figure 2.22) is the largest of the three concepts consisting of a base that sits on the floor and has two tower-like structures extruded from it. The larger structure supports the weight of the upper limb (θ_1) from above with two separate bars, one for the upper arm and one for the forearm, both containing straps to support and secure the upper limb in place. Both arms can be moved together pivoting about the larger structure (θ_2). The forearm support can also be moved independently to accommodate for elbow flexion and extension (θ_3, θ_4). The force mechanism to lift the combined weight of the upper limb and the supports will be achieved using springs and/or motors placed within the larger tower, that will contract cables within the bars to raise them

against gravity. The smaller tower is designed for comfort, with a cushioned support for the user's underarm while they operate the device. In total, the device has four degrees of rotation.

(a)



(b)

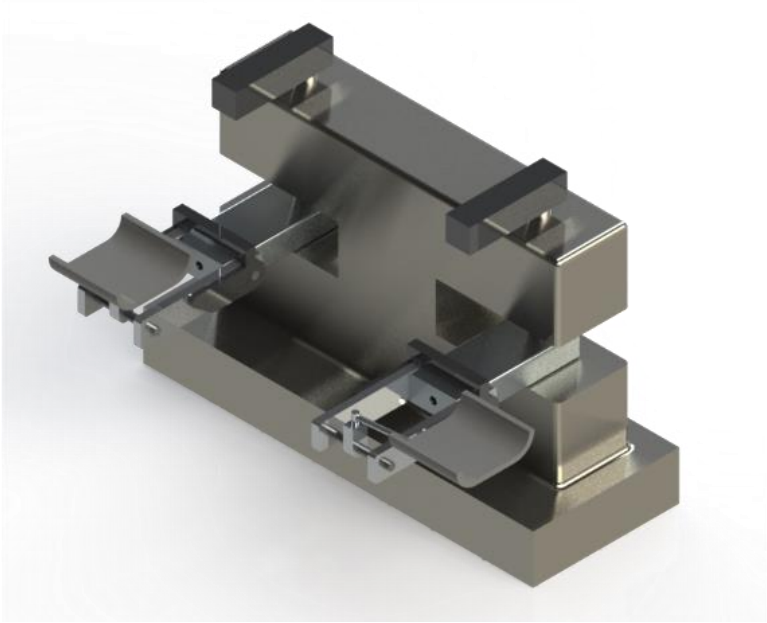


(c)

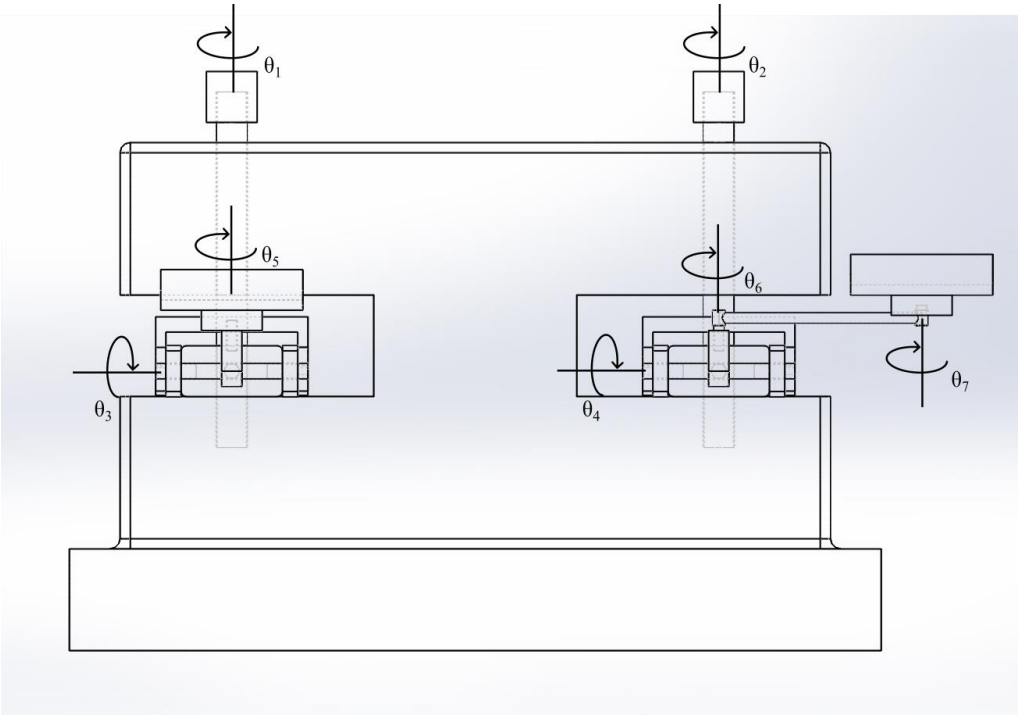
Figure 2.22 - Concept B: (a) Rendered Isometric View; (b) Elevation View; (c) Plan View

2.5.3 Concept C - Description

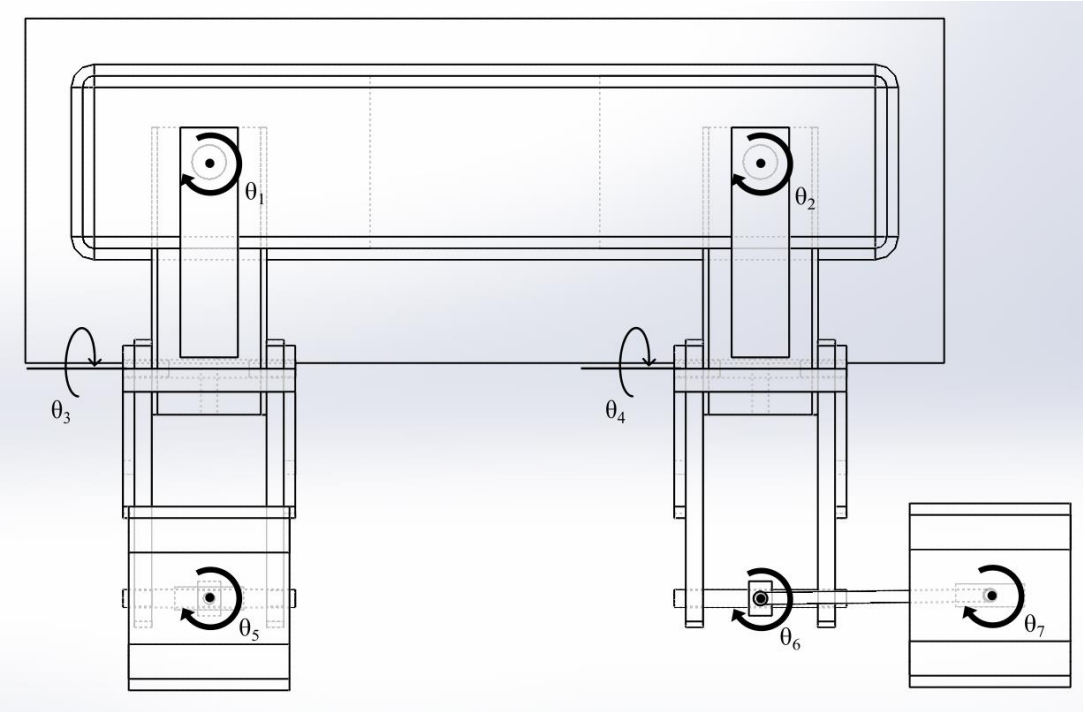
Concept C (Figure 2.23) is designed to be placed on top of a desk or table. It has two separate horizontal bars each with their own support for the upper arm and forearm respectively. Each bar has its own independent weight support aided by smaller bars protruded from the top of the device (θ_3, θ_4). Each bar can also independently rotate around its respective vertical axis (θ_1, θ_2). For the forearm support, an extra bar has been added that can pivot, allowing elbow flexion and extension to be possible (θ_6). Additionally, each support can rotate around its vertical axis (θ_5, θ_7). Both supports utilise independent but similar weight support mechanisms that will incorporate a cable wrapped around a handle at the proximal end of the support bar travelling up towards the respective bar at the top of the device. Pulleys will then be used to allow the cable to travel down the back of the device where either a spring or counterweight will be used to balance the weight of each support bar and the upper limb. The upper arm support has three degrees of rotation and the forearm support has four giving a total of seven for the whole device.



(a)



(b)



(c)

Figure 2.23 - Concept C: (a) Rendered Isometric View; (b) Elevation View; (c) Plan View

These drawings and models served as a basis for displaying to focus groups the shortlist of concepts generated from the design and evaluation process. Additionally, animations of the 3D models were created for these groups to highlight the degrees of freedom of each concept to provide a better understanding to the groups.

2.6 User Feedback

These three concepts (A, B & C) were presented to focus groups of users to gather feedback.

2.6.1 Introduction

A focus group is defined as a small sample of people who are brought together to give their opinions and perceptions on a new product or design. Their responses are examined to determine what the expected response would be from the greater

population. Questions are asked by the interviewer in an interactive group setting where participants can freely converse with their fellow group members, creating a more natural conversation pattern compared to a one-to-one interview.

Focus groups have been used as a qualitative research tool for stroke research in the past. Topics ranging from robotic exoskeletons and other assistive technologies for stroke therapy have been discussed in group settings (Demain et al. 2013; Elnady et al. 2018).

Splitting focus groups into distinct stakeholders can be beneficial to design and research as it can provide a range of different perspectives and opinions that might not have been addressed if only one specific sample group was used. In the case of stroke research, these stakeholders can include people living with stroke, healthcare professionals (doctors, therapists, nurses, etc.), family and caregivers, and other designers and researchers.

For this investigation, it was determined that two different focus groups would be suitable to obtain relevant feedback on the designs; people living with stroke and healthcare professionals.

2.6.2 Participants

Three participants living with stroke and six occupational therapists were recruited for their respective focus group. For participants living with stroke, the inclusion criteria were: (1) have suffered a stroke at least 12 months ago affecting their upper limb function; (2) have experienced (currently or in the past) difficulty performing activities of daily living involving their upper limb; (3) have experienced a period of rehabilitation, including exercise, for their stroke, either within the NHS or another

provider; (4) are able to communicate in English, both written and spoken; (5) are able to attend an interview (approximately one hour) at the BASIC rehabilitation centre (Salford).

For healthcare professionals, inclusion criteria were: (1) have experience in the rehabilitation of stroke survivors and the upper limb in particular; (2) are able to attend an interview (approximately 30 minutes) at their respective workplace within the Glasgow and Lanarkshire area.

Exclusion criteria for both groups were: (1) individuals who are unwell during the investigation period or are taking medication that may compromise their ability to participate; (2) individuals with significant speech problems which could limit communication with the investigator and/or staff (e.g. informing that they are unwell) and which would present a barrier to the interview process; (3) individuals who have significant learning difficulties, serious mental health issues and/or cognitive impairment that would affect their ability to provide informed consent.

2.6.3 Protocol

Background information from both groups was collected from each participant before the focus group interviews were conducted. For individuals living with stroke, they were invited to fill out a form to obtain demographic information (i.e. age, gender), information regarding their stroke such as time since stroke and side of body affected (if any). Additionally, information on their current residence (e.g. whether living alone or not and how far they have to travel to attend rehabilitation sessions) was obtained.

During the focus groups interviews, each group were asked questions specific to their group before the various concepts were displayed and described to them. For stroke

survivors, they were asked about their experience with rehabilitation, how frequently it was, how long it lasted and what it consisted of. Questions regarding their experience using equipment/technology during these sessions were also asked. Finally, they were asked specific questions regarding upper limb practice (did they do it, how often, did they use equipment etc.). For health care professionals, their experience in rehabilitation was also asked but from the perspective of delivering rehabilitation sessions to patients including their opinions on treatment efficacy. Questions included: do they provide upper limb training as part of therapy; what do they like the most about current methods for upper limb training; what are the current difficulties of these methods. Furthermore, questions related to providing feedback to patients and the types of functional assessments used regarding the upper limb were asked.

Following the questions about rehabilitation experiences, the concepts for the proposed weight support system were then presented to the groups. A rendered, isometric view of each concept was shown on a laptop/projector in addition to a short animation (one-minute each) demonstrating each concept. Their features and functionality were explained. Participants were asked to provide their feedback on each concept, and discuss any positive or negative aspects of them. Feedback received during the interviews were recorded with a digital voice recorder for transcription purposes and written notes were taken by the investigator.

The focus group with individuals living with stroke was conducted at the Brain and Spinal Injury Centre (BASIC), Salford and the group with healthcare professionals (occupational therapists) was conducted at Wishaw General Hospital, Wishaw. Each session lasted approximately one hour.

2.6.4 Results

2.6.4.1 Stroke Survivors

Question 1: Have you ever found performing day-to-day tasks with your upper limb difficult since you have had a stroke?

All participants noted that they struggled to perform activities of daily living (i.e. changing, washing or making a cup of tea). For some tasks, they said that they required assistance from a family member or use other parts of their body to help ("I have to use my right arm to move my left arm"; "I have to use my teeth and everything just to put a t-shirt on").

Question 2: How often would you say you exercise your arm just now? Would you like to practice more upper limb exercises more often?

One participant mentioned that they try to do it daily but worry that they might be pushing themselves too much and that could lead to injury; another participant performs passive exercises 2-3 times per week (they use their functional upper limb to move and stretch the impaired one). Participants would like to do a bit more exercise that is focused on reaching and gripping.

Question 3: If there was a rehabilitation device that allowed you to perform upper limb exercises and could be used at home for self-training, do you think you would use it?

All participants agreed that they would like and use a device to help them with their upper limb exercises.

Question 4: Would you be interested in your movements being measured to provide you with feedback and track your progress as you perform the exercises?

All participants agreed that they would be interested in receiving feedback on their performance. One participant referenced the Fitbit as an example of a device that the feedback could be similar too. Another participant exclaimed that since they are unsure of how well they are performing on their own, they would like external feedback to check if they are meeting their targets with regards to range of motion. Audio feedback to signify that they had reached their target was preferred.

Question 5: Have you ever used any sort of equipment that focusses on upper limb, either here or elsewhere?

The participants said that they typically use the machines that are available to them at their gym (BASIC). These consisted of mainly assisted machines that move the upper limb for them ("So you just sort of hang on and it does it for you"). One participant commented that they would rather know that they are performing the movements themselves and noted that some users push against the machine despite not needing too as they want to try perform the movements independently. Another participant explained that they were unable to use any of the gym equipment, as they do not have sufficient range of motion or the ability to grip with their impaired upper limb.

Concept Feedback and Comments

Concept A

One participant liked the size of the device feeling that it contributed towards its portability ("that one's small that I can pack…"). They appreciated the idea that it could be clamped onto a table allowing them to take it with them when they travel.

Another participant commented that the support provided for the upper arm could help them with moving their forearm (i.e. elbow flexion/extension) when practicing

reaching tasks. They also liked that it could potentially help with movements at the shoulder as well ("You just need that support there because your arm is dense and you've just not got the power you know.").

The final participant preferred concept A because of its small size and portability ("Because you want something you can use in your house.") while also providing the support and range of motion available, enabling them to practice the movements recommended by their physiotherapist.

Recommendations for improvement included potentially adding a second support for the forearm and/or a handle for gripping while using the device. Participants also requested the device be manufactured with lightweight materials to compliment the portability but not at the expense of strength and stability of the device.

Concept B

One participant preferred this concept over concept A as it provided multiple points of support for the upper limb ("Because it's got your upper arm, it's got your arm up as well so like your shoulder's moving.").

Comments from another participant were not as positive, stating that the device was large ("bulky") and could be uncomfortable to use. Even with the cushioned underarm support, the participant argued that this would still be painful during use ("Even if it's got a cushion on it, it's gonna be rubbing your arm all the time"). The participant also commented that they would prefer to put their arm on top of a support (e.g. Concept A and C) as opposed to underneath with this device ("…the best thing is putting your arm on top. I won't put my arm underneath that.").

Recommendations included a handle for gripping at the end of the device so that the participant may feel more in control while using the device in addition to performing hand exercises. Additionally, two participants agreed on the possibility of developing a separate sleeve or brace that could attach to the device instead of directly placing their arm in the device ("...you could put it on if it was attached to some kind of brace you could wear."; "That would probably be a better bet instead of having that [cushion] rubbing under your arm where it's causing blisters and stuff.").

Concept C

One participant liked the range of motion the concept would be able to provide and another participant for the multiple points of support available for the upper limb.

Two participants acknowledged that the concept would need to be fixed to the table or have a heavier base as they believed there was a risk of the device tipping over when their arm is placed ("Because that's where I think mine would fail because you're pushing hard, you'd probably end up using your bodyweight as well so it might tip over"). A method to fix it to the table was suggested to prevent an increase in the device's potential mass ("If you could put two lockdowns on that, either side. Because that seems heavier.").

Other Comments

One of the participants noted that the devices would likely need to be as lightweight as possible otherwise they would be unlikely to be used, particularly for the elder population who may be unable to lift their arm and/or the device in order to set it up properly.

One participant noted that they had never seen or heard of existing devices before and was surprised any information was not readily available ("I just think it's a really good idea. It is strange how someone has not thought of bringing something like this out previously.").

2.6.4.2 **Occupational Therapists**

Following the stroke survivor group and before the occupational therapist group, concept B was removed from the shortlist. This was decided because concept B was deemed too large and potentially daunting for users, its large size being a detrimental factor if it were to be used in the home environment. One participant's mention of the cushioned underarm support having the potential to cause soreness was also taken into consideration when removing the concept.

Question 1: What current methods for upper limb training do you find most useful with regards to stroke?

It was agreed that activities that incorporate some form of functional tasks are likely what patients gain the most from in terms of recovery. Constraint-induced movement therapy (CIMT) was mentioned by one participant but only for patients who have already demonstrated return of function in their arm. This type of therapy was noted as a beneficial program that can be completed at home while incorporating repetitive practice ("And constraint can incorporate repetitive task practice as well. So that is a lot of what we do and very much it is on a functional level, lots of repetition.").

The participants also said that it was difficult to determine whether to continue therapy with patients who are not demonstrating a return of upper limb function. For patients who need a lot of hands-on therapy, there is a greater challenge in their ability to

perform any exercises/activities independently at home. Furthermore, therapists are currently limited with the amount of time they can see a patient to assist with their therapy ("…you're very limited in community with how many times you can visit a patient. I'm lucky if I can see someone twice a week."). This in conjunction with whether or not the patient is motivated and willing to engage with their therapy can make it less likely for them to get the maximum benefit of recovery.

However, one participant stated that it was good to have a range of different interventions, as various patients will respond to treatments differently. For example, they have used a weight support device for patient's that exhibit tone in their upper limb to provide some assistance with their therapy ("…that's the only thing I've only really used that's got the de-weighting aspect that takes gravity away so they've got that wee bit more movement that really helps with tone and things as well…").

Question 2: How do you personally provide feedback to patients regarding performance?

One participant said that they go over a patient's results regularly, stating whether they have improved their range of movement, dexterity and/or fine motor skills. They also ask the patient what they are able to do functionally at home in order to identify if positive changes in upper limb movement have a positive impact on activities of daily living ("It's okay saying yeah I've got an extra ten degrees movement but what does that actually do functionally, what does that help you do?").

Another participant mentioned that they used visual feedback by recording their patient's performance before and after an intervention to show them the improvements in their function ("Because some people can't remember how they performed. It's very

difficult so I think that [video] works really well…"). Encouraging patients to film themselves or have a family member assist them was also discussed as a suggestion for practicing independently at home ("And most people have a smartphone now").

The Motor Activity Log (MAL), an outcome measure, was the most commonly used feedback and assessment method used by the group, comparing the scores with the patient before and after intervention. Another method for providing feedback to the patient was timing their ability to perform functional tasks before and after a period of rehabilitation, particularly if the patient struggles to comprehend that their function is gradually improving ("So lots of subjective things to try and show them because it is difficult sometimes if they're perspective can be skewed.").

Question 3: Do you think stroke survivors are provided with enough opportunity to perform upper limb exercises?

The consensus within the group was that stroke survivors were not currently being given enough opportunities in terms of upper limb practice. This was attributed to lack of staffing and the amount of varied work associated with assessments and paperwork for each individual. Furthermore, when time is allocated to upper limb movements, it can still be minimal ("You don't have anyone who's just there specifically to do just upper limb all day. So you have to mix it up a bit so they might get two sessions of upper limb per week and it might be for 30 minutes so that's one hour of an entire week."). Therefore, the group said that it is important to enable the patients to engage with self-directed therapy more. However, the group noted that benefits of self-directed therapy might be dependent on whether the patient has relatives living at home to assist them. Additionally, they noted that it could be difficult to manage for stroke

survivors with cognitive impairments and/or upper limb pain discouraging them from carrying out their exercises ("Self-management is great but there's a lot of things that need to slot into place before that is going to be a positive thing.").

Question 4: If there was an upper limb rehabilitation system that could be used at home and/or a clinical environment for self-use by stroke survivors as well as assisting therapists, do you think it would be useful?

All participants agreed that it would be a useful tool to have and that they would be willing to purchase one if it was available. One participant noted the benefits of having a weight support device at home to facilitate independent practice when they are not at a clinic ("Think of the benefits though that you get when you do de-weight somebody's arm as a hands-on therapy session. You know they are not going to get that stimulation when you leave.").

Concept Feedback and Comments

Concept A

One participant asked which part of the arm the cuff would support. They also suggested that if a forearm support was made for it, something for the participant to grip onto would be beneficial ("…if you're supporting the forearm and they've got very poor wrist and hand movement you might need something to hold onto."). It was also asked if it would be possible to clamp the device onto chairs and wheelchairs as well as tables.

Participants also suggested that the device be as light as possible and come with an easy to carry container for storage and transport ("As a community worker, could you make it as light as possible?"; "To make it easy to carry."). Furthermore, concerning

infection and prevention control, they requested that the device easy to clean (i.e. with an alcohol wipe) and "no furry bits" for extra comfort as this would be difficult to clean and likely need to be discarded.

Concept C

The group noted that the device would need to be clamped to a desk before using with a patient for safety purposes. One participant was worried that although the design had two points of support, they were quite short so suggested lengthening them ("I would feel more comfortable with a full [support] rather than a little bit there and a little bit here").

One participant stated that the concept in its current form would limit the user to the amount of upper limb movements they could achieve. For example, they stated that external rotation of the shoulder is important when doing exercises with patients and they said that the device would likely get in the way and hinder that movement from being performed. They suggested that maybe flipping the device upside down but moving the supports up higher to allow more range of motion as patients would be less likely to collide with the device. Another participant suggested implementing a ball and socket design for both points of support as this could potentially allow for movements in all directions.

Other Comments

In terms of range of movement, one participant said that having a device that does not restrict movement at the wrist would be beneficial ("we were looking for a good bit of movement from the wrist and we don't want something where we're going to restrict that."). Another participant acknowledged the difficulty in designing a device that

provides both the support but also provides sufficient range of motion too. Additionally, not restricting the ability to pronate/supinate the arm was desired as this forms part of the natural movements when reaching for an object. When this is restricted to a certain position (i.e. palm facing down during the movement), the therapists said that this carries a risk of shoulder impingement when performing a reaching task ("So you can get a lot of nerve impingement in your shoulder when you're reaching from that position. So that kind of neutral position, that's the kind of movement we would want to be doing.").

One participant had concerns about the height at which the shoulder would be when the upper limb is supported ("Because normally, your shoulder would be in that position in a neutral position so you don't really want to put something on it that bring the shoulder up and out there. So, I don't really know where you would position it? You'd have to drop the table down or something."). The participants agreed that having a height adjustable device to solve this concern was a good idea.

Of the two concepts, the group believed that concept A was the better option. Concept C was seen as "cumbersome" and unattractive in comparison to concept A ("I think that would scare patients. Do you know looking at it, it's a bit… oh what, are you gonna do with my hand in that?"). They also agreed that concept A was easier for portability, which is important for home-use when rehabilitation at a clinic is unavailable ("we don't have access to a day hospital/outpatient setting in South Lanarkshire so all patient rehab is done at their home.").

One therapist mentioned that seating is an issue as well and that an appropriate chair is essential for stroke patients to get the most out of their therapy. In some cases,

patients may not have the necessary furniture to use these devices ("Certainly my physio colleagues are outspoken on how stroke patients should be treated and they can't do a lot of their treatments in a home environment is what their opinions are."; "People don't often have tables, they don't have chairs, they have sofas."). As a result, some therapists from the group who perform home-based therapy sessions have problems getting patients into suitable and comfortable positions for them to perform their rehabilitation ("I tried to do upper limb therapy with a lady today who was on the couch in her living room and I said we need to get lots of pillows. That's not a good position for your arm."; "It kind of defeats the purpose for me in a therapy session.").

While the group acknowledged that there is a need for therapy to be done at home, they noted that there is also a need for some patients to be seen in an outpatient setting. However, they said that there is currently pressure to focus more on home-based rehabilitation. Therefore, technologies and equipment to assist with rehabilitation need to be designed to accommodate for this.

2.6.4.3 **User Requirements and Final Concept Choice**

Figure 2.23 displays the eight main user requirements for an upper limb weight support device based upon feedback from both stakeholder groups. These attributes mostly confirmed the existing criteria in which the concepts were evaluated (i.e. range of motion, portability) in addition to expanding on others (e.g. handle for gripping and adjustability falling under the ease of use criterion). Portability was expressed as a key attribute for both groups as this would make the device more suitable for home use while also giving the option to transport the device to other locations (e.g. day hospital/clinic).

Three different concepts (A, B, & C) were presented to a focus group of stroke survivors. Following this, two concepts (A & C) were presented to a group of occupational therapists. Based on feedback from both groups, concept A met most of the user requirements desired by the two groups with a total of six (easy to clean, facilitation of functional tasks, portability, range of movement, lightweight, and adjustable). Therefore, concept A was chosen as the final concept to take forward for detailed design and prototype production with the aim to achieve the requirements it met in its conceptual form.

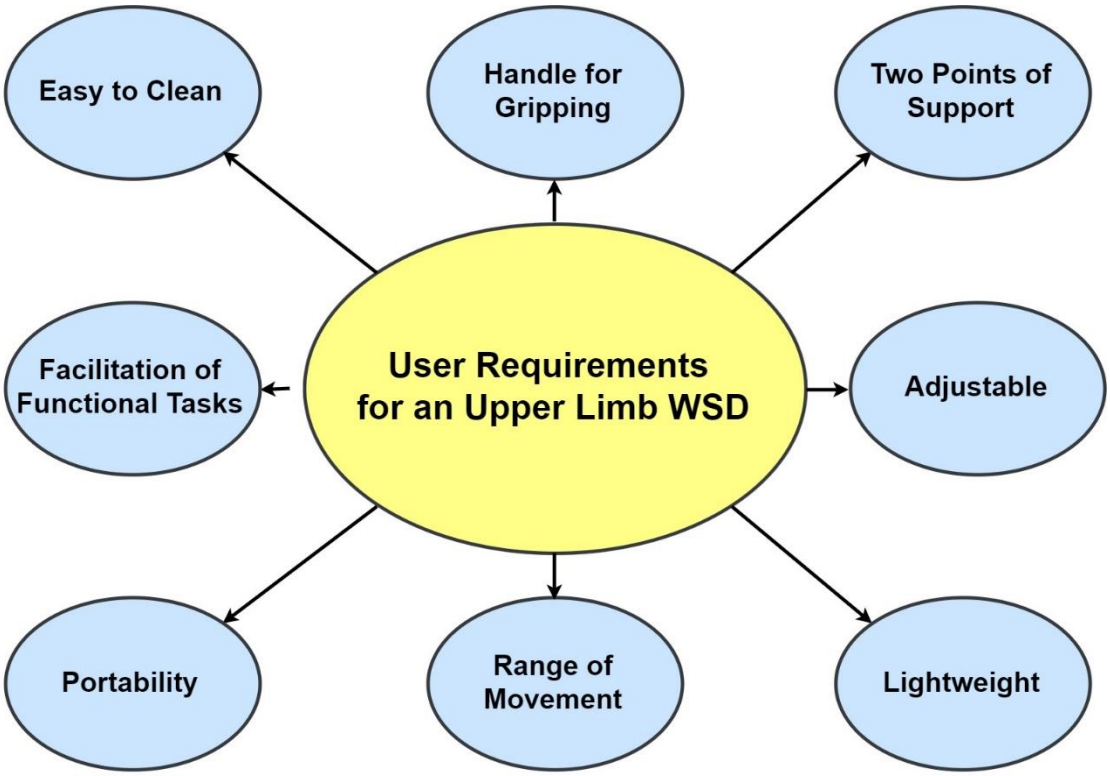


Figure 2.24 - User Requirements from the focus groups.

2.7 Discussion/Conclusion

This chapter described the concept design and evaluation process for an upper limb weight support device for stroke rehabilitation (figure 2.2). Thirty-eight concepts were generated from individual and group brainstorming before going through a rigorous

evaluation procedure, reducing the list to three concepts for user feedback. Following feedback from two focus groups (stroke survivors and occupational therapists respectively), one final concept was chosen based upon user preference and desired requirements for this type of device.

Generation of the initial list of concepts was based predominantly on the performance criteria from the PDS as this was deemed the most important section in order to create applicable ideas. Additionally, for the 6-3-5 sessions, it is generally easier to present a shortlist of criteria that the group's ideas should attempt to meet rather than present the whole design specification, which would increase the time taken for the whole process. This also broadens the scope of concepts that can be created as opposed to providing additional criteria, imposing restrictions to the group. Ultimately, it was decided that factors such as size, weight, and expected cost would be brought into consideration for the evaluation process in order to allow more freedom during the concept generation process.

As mentioned previously, from utilising two separate 6-3-5 sessions, there is the potential to generate 216 ideas. In practice however, only 32 unique concepts were created. Despite explanations of the process to group members beforehand, it can still be incredibly difficult to create three individual ideas in a short period. As was stated as one of the potential drawbacks of this method, the majority of members focused on detailing one concept during the first run before quickly generating one or two more if they had time remaining. Subsequent runs had more success with participants actively engaging in improving or commenting on other participant's ideas as the worksheets were shared. The focus on quality over quantity (i.e. more detail than number

generated) was deemed satisfactory as the concepts would be easier to manage during the evaluation procedure compared to the projected amount.

The use of the PMI table before other evaluation techniques was applied as a quick and simple method to eliminate less detailed concepts and ideas that did not have any striking positive features. Additionally, only concepts created from the group sessions were implemented in this table, suggesting bias towards the individually generated sketches. However, as all remaining concepts would be put through a more laborious evaluation procedure, this decision was thought to be acceptable.

The CCM, or Pugh's decision matrix (Pugh 1991) was employed as it is a relatively simple and proven effective method for comparing concepts (Frey et al. 2009). One of its major advantages is its flexibility, allowing the designer (or design team) to combine, improve, and eliminate designs should the opportunity present itself. In light of this, this method aims to enhance the alternative concepts relative to the datum through iteration while also converging towards a final concept design. Moreover, the evaluator is also free to add or remove criteria to the matrix where applicable (e.g. if an existing criterion cannot realistically be improved upon in any design by the designer relative to the datum). When employing the weighting and rating procedure, the decision was made to remove feedback from the criteria list as it was still undecided whether methods for feedback would be extrinsic and/or intrinsic to the device. Therefore, methods for applying feedback to the system were chosen to be researched following initial prototype design. This allowed more time to be spent on evaluating the remaining criteria. Following the evaluation procedure, it was realised in hindsight that the removal of other less defined and less important criteria may have been beneficial. Removing aspects such as expected cost and deterioration that were

difficult to define at this stage of the process may have allowed for a greater analysis of the remaining criteria.

With the flexibility of using decision matrices, other alternatives could have been employed during the evaluation process. For analysis of concepts in this chapter, two iterations of a decision matrix using pairwise comparisons of each criterion were made between the datum and each concept. This was then followed by two runs of a magnitude-based scoring system with the weighting and rating matrices. For the pairwise method, this equated to 247 and 156 comparisons for the first and second iterations respectively. While this could arguably be a time-consuming process, using pairwise evaluations can be beneficial to the assessor by providing them with a "gold standard" on the market in which their designs can be effectively critiqued. Choosing the appropriate datum is vital to ensure concepts are being reviewed fairly and effectively. In this chapter, the SaeboMAS was chosen as the datum to initiate the analysis. It was chosen due to its simplicity in providing upper limb weight support relative to other devices on the market (Armeo®Spring, Armeo®Power, MIT-Manus, etc.), a key aspect in the new design that was aimed for this project. As such, choosing the SaeboMAS proved successful, as it allowed for more effective decision-making against a datum similar in scope to the intended product.

Weighting and rating matrices were employed to provide a different perspective in the evaluation process by providing each criterion its own quantitative value for each concept. Doing so can enable the designer a better insight into the concept's ability to meet each requirement and the final scores for each design can then be calculated, compared, and checked for potential developments. However, following the first run of the weighting and rating method, no concepts were altered for the next run because

it was difficult to find areas of improvement. Instead, the weighting scale was altered as some criteria were weighted similarly despite not being considered as similar in value. Furthermore, although this technique was used as an alternative, it may have been beneficial to continue with the pairwise comparisons but add the weighting scale as it can be effective to determine what criteria needs to be improved relative to the datum based on its perceived value to the design.

To fully reap the benefits of the decision matrices, it is recommended to work as part of a design team as discussion and arguments for and against criteria can provide a better indication of what scores to provide. Unfortunately, employing a team-based approach for the evaluation was not feasible due to time and resources therefore the majority of evaluation was carried out by a single researcher, leading to the potential of self-doubt and bias in the decision-making. To help mitigate this bias, focus groups were used to determine their preferred concept from the remaining list in addition to adding any user requirements to the design that may have been absent previously.

Regarding the focus groups, although opinions from the occupational therapist group on concept B may have been helpful, it was removed from the list beforehand. There was a substantial gap between conducting the two focus groups and following analysis of the stroke survivor's opinions, concept B was unlikely to meet the portability, and potentially safety requirements. While it can be difficult to predict the overall requirements based on a small group's opinions (n=3), the detrimental aspects were noted as major factors against the design. General feedback from the occupational therapy group also suggested this consensus with some appreciating the idea of carrying/travelling with a device. Concept B would not have been able to realise this without significant changes to the design. Another point to take into account is that

some therapists noted that the relatively smaller concept C also looked bulky and cumbersome.

Based on both groups, it is apparent that portability and, while not explicitly stated, aesthetics are important considerations for the consumer. This could be due to the groups anticipating that the devices will perform as intended (i.e. lift the upper limb and allow movement) based on the videos shown. If the device looks awkward, bulky, and/or potentially dangerous, the intended user is very unlikely to engage with the product. However, this has the benefit of providing the designer more insight into the criteria they had previously not considered as important. Consequently, less time was spent on highlighting and/or improving those aspects.

Finally, although a final design has been selected, there is always the potential, and sometimes necessity, to come back to the product design specification and conceptual designs for inspiration and guidance in implementing the detailed design.

3 Prototype Design and Development

3.1 Introduction

Following selection of the final concept choice (chapter 2, section 2.6.4.3), the next stage of the design process involved completing the details of this design so that a working prototype could be built. Developing a prototype was necessary in order to identify any issues that may not have been clear from a 3-D CAD model (i.e. size, functionality, etc.). This chapter will focus on this prototype building stage. It will detail the final concept refinement and production of a full-scale 'mock-up' model for further critique. Changes to the design based on feedback from the 'mock-up' were implemented in the production of the first working prototype. This was then presented to researchers and therapists for feedback.

3.2 Final Concept and Initial Modelling

3.2.1 Design Changes

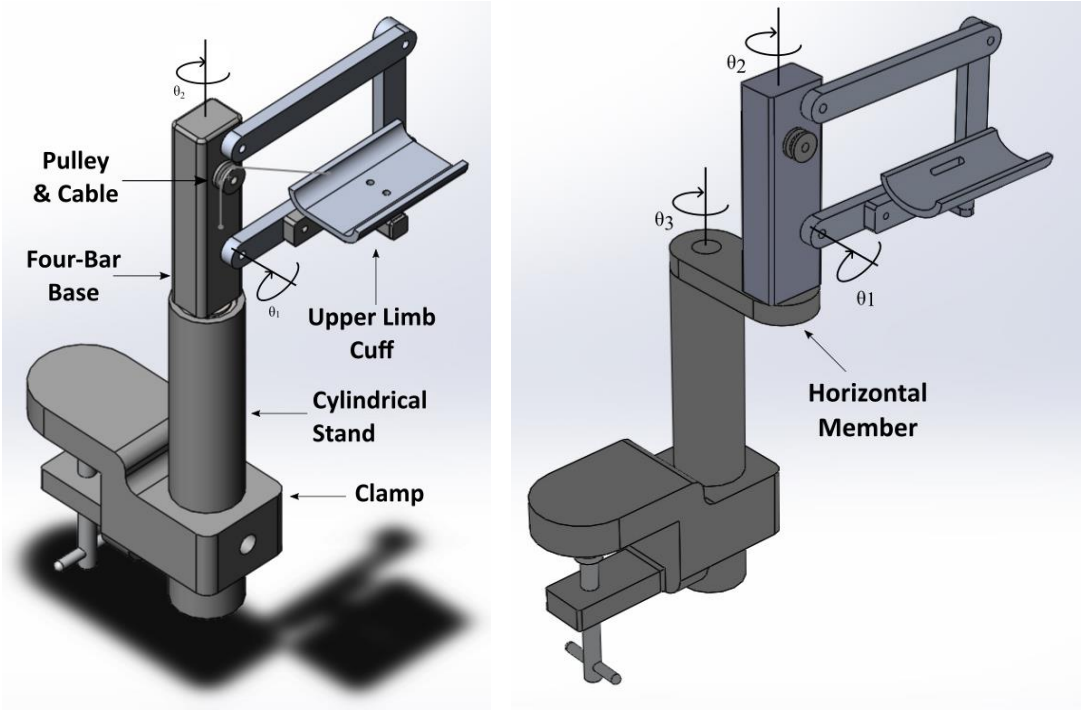
Upon choosing a final concept, a more detailed CAD model was developed using Solidworks (Solidworks® Student Edition 2016-2017, Dassault Systèmes, Vélizy-Villacoublay, France). As mentioned previously (section 2.5.1), this concept was a four-bar frame that could be raised and lowered to support the weight of the arm. A cuff for the upper arm was attached to the bottom bar of the frame in which the arm can be secured. The frame was able to pivot around the vertical axis providing a second degree of movement. Additionally, the whole device was attached to a clamp that could be fixed to a standard table.

Some changes to the model were made compared to the concept design in figure 2.21. Firstly, the four-bar linkage design was simplified by having the top and bottom bars

of the frame be flat bars that attach to one side of the base (figure 3.1(a)). The initial design composed of bars that are enclosed around the base at the respective joints at the top and bottom. It was realised that during movement of the device, these bars would eventually collide with the base and not be able to provide the full range of motion required.

Secondly, with the exception of the upper limb cuff, the majority of the components were made thicker. This was altered to increase the strength of the prototype, particularly for the cylindrical stand that supports and allows the four-bar frame to rotate along the vertical axis (θ_2).

To experiment with ideas for the weight support mechanism, a pulley was added to the side of the four-base in line with the upper and lower bars. A cable would be used in conjunction with the pulley to lift the four-bar linkage against gravity, facilitated by a counterweight or spring.



(a) *(b)*

Figure 3.1 - Initial concept design. (a) - Showing two axes of rotation. (b) - A third axis of rotation was added via a horizontal member to provide forward and backward movement of the device.

Finally, a third degree of movement was included by adding a horizontal member between the bottom of the base of the four-bar frame and the top of the clamp assembly shown in figure 3.1(b). This was chosen to allow forward and backward movement of the linkage through rotation around the top of the clamp assembly while still allowing the frame to rotate around the vertical axis. In turn, this would increase the range of motion of the device. Furthermore, a knob was added to the side of the clamp that can be tightened and loosened to adjust the height of the device in order to adjust to the user's height and/or capability.

3.2.2 Concept Drawings and Dimensions

Table 3.1 shows the rough dimensions of the four-bar assembly, the support assembly that attaches to it, the horizontal member (Four-Bar Connector) that permits the third degree of freedom, and the cylindrical stand that connects the aforementioned

components to the clamp assembly. Figure 3.2 shows an isometric exploded view of the design displaying the intended components required to create the mock-up model.

Table 3.1 - Rough Dimensions and Volumes for the four-bar and support assemblies of the first iteration of the design.

Four-Bar Assembly	**Component**	**Length (mm)**	**Width (mm)**	**Thickness (mm)**	**Diameter (mm)**	**Volume (mm^3)**
	Four-Bar (Top)	340	40	20	N/A	2.72E+05
	Four-Bar (Distal)	220	40	20	N/A	1.76E+05
	Four-Bar (Bottom)	340	40	20	N/A	2.72E+05
	Four-Bar (Base)	300	80	60	N/A	1.44E+06
Support Assembly	**Component**	**Length (mm)**	**Width (mm)**	**Thickness (mm)**	**Diameter (mm)**	**Volume (mm^3)**
	Support Base	150	40	20	N/A	1.20E+05
	Support Arm	120	20	10	N/A	2.40E+04
Other	**Component**	**Length (mm)**	**Width (mm)**	**Thickness (mm)**	**Diameter (mm)**	**Volume (mm^3)**
	Four-Bar Connector	250	100	30	N/A	7.50E+05
	Cylindrical Stand	500	N/A	N/A	100	3.93E+06

At this stage, it was decided not to include the dimensions of the clamp assembly as an off the shelf clamp would be used to fix the model to a work surface/table. The cuff for the upper limb and the pulley to assist with the weight support mechanism were also not given specific dimensions as off the shelf components would also be sourced to implement this function.

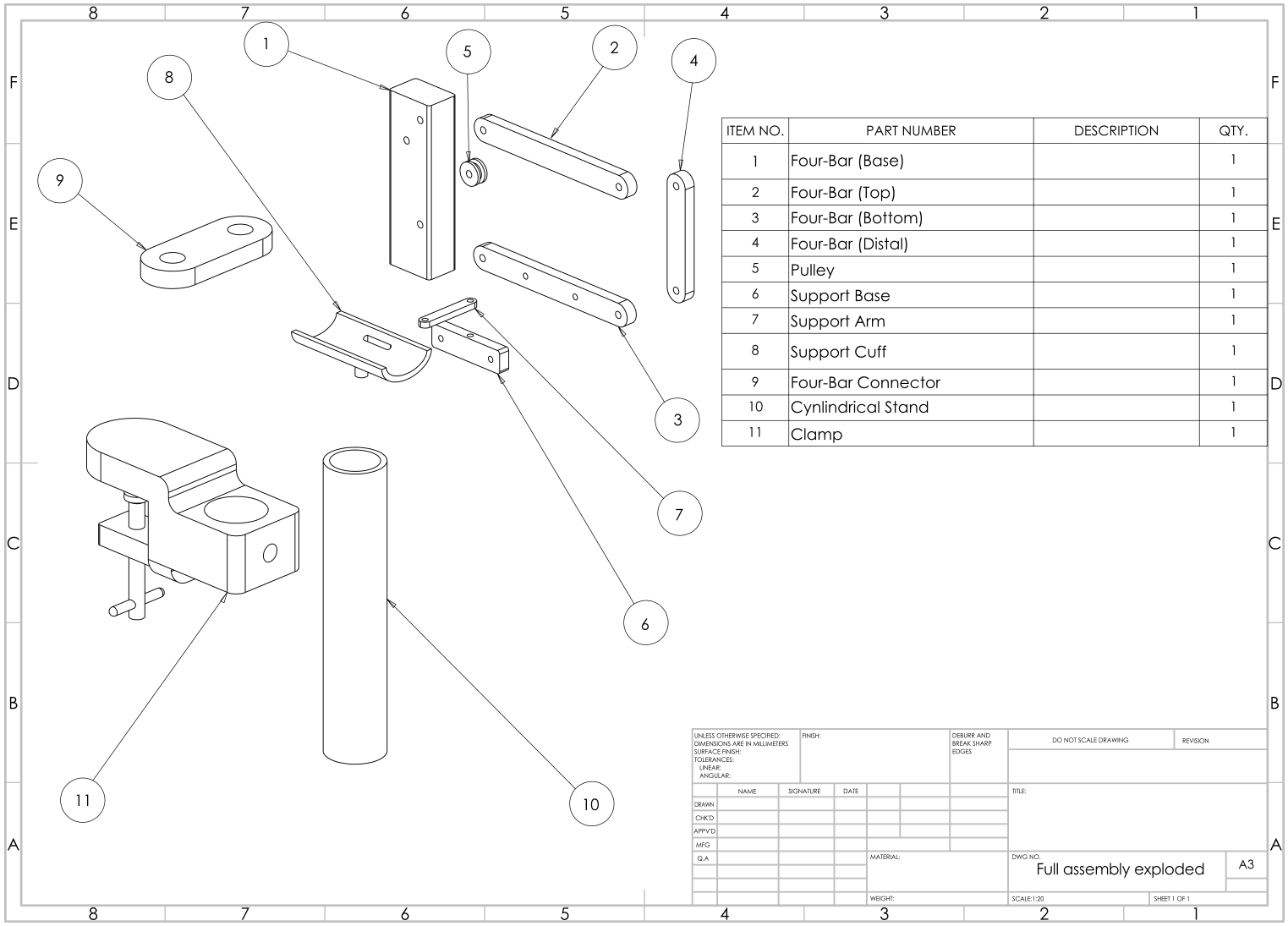


Figure 3.2 - Isometric Exploded view of the design used to create a mock-up model.

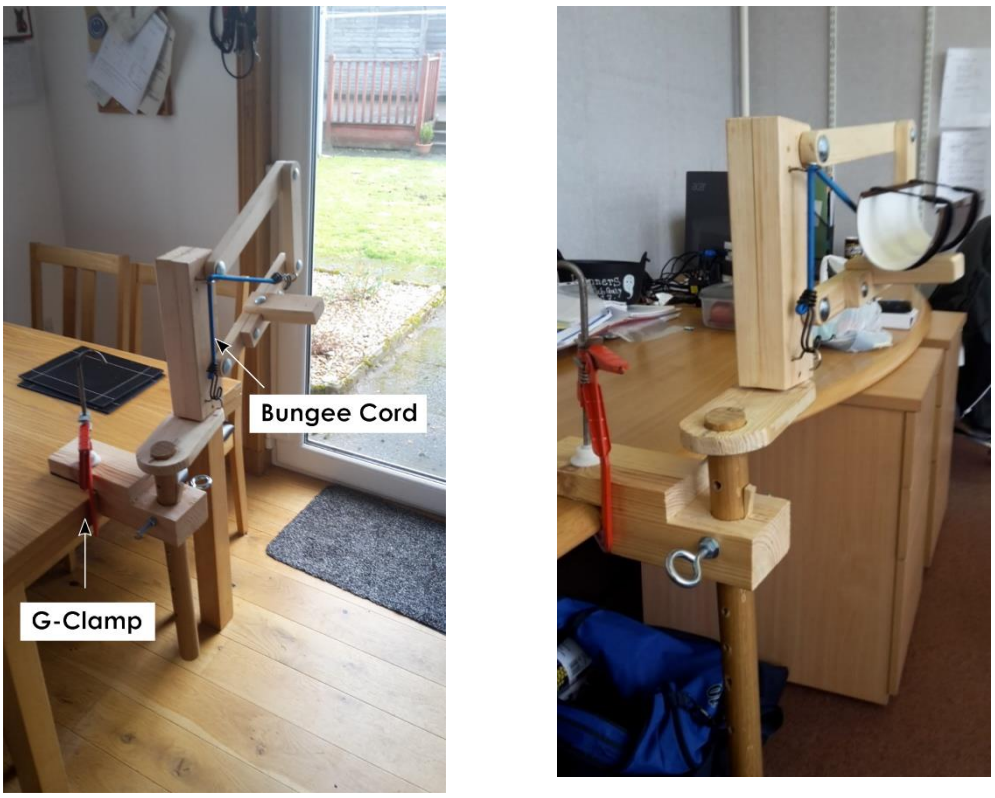
3.2.3 Mock-Up Model and Further Design Considerations

A full-scale mock-up of the updated concept design (figure 3.3) was created with the majority of parts made from spare cuts of wood. A G-clamp was used to fix the device to a table surface. For the upper limb cuff, a section of polyvinyl chloride (PVC) pipe was cut to roughly 200mm to provide reasonable coverage for placing the upper limb. The pipe was screwed on top of the support arm. To implement the spring mechanism for the weight support, a bungee cord with both ends attached to hooks screwed into one side of the device was used. A third hook was implemented further up the four-bar base to produce the pulley system.

While not intended to be a working prototype, the mock-up provided good insight into further changes the design required. Firstly, it was decided that the overall size of the device was too large if it were to be used at home. This was because it was felt that it took up a substantial amount of workspace (e.g. on a desk). To remedy this, the dimensions, particularly the thickness and width, of the four-bar frame should be decreased in order to reduce the size, and in turn weight of a working prototype.

Secondly, it was decided that the spring mechanism would be placed inside the base of the four-bar linkage and covered. A cable attached to the spring will then come over the top of the base around a pulley and then anchored to the bottom bar of the linkage. Furthermore, it was decided that the cable should travel on the opposite side of the frame from the upper limb cuff. Both this and covering the spring within the base were chosen for safety purposes so that in the event of mechanical failure, the spring would remain within the base and the cable is less likely to cause injury to the user.

As mentioned in the conceptual stage of its design (see section 2.5.1), a fourth degree of rotation was implemented to the device at the upper limb cuff demonstrated in figure 3.3(c). This was chosen in order to maximise upper limb freedom of movements and therefore make them feel more natural.



(a)

(b)

(c)

Figure 3.3 - Mock-up of the weight support device using a bungee cord. (a) – Device clamped to a table in a home environment. (b) – Device with upper limb cuff attached. (c) – Additional degree of rotation for the upper limb cuff.

3.3 Working Prototype Design

Following considerations of improvements based on the mock-up model, design refinements were then made to improve a working prototype. This stage involved specifying the materials for the components, altering the dimensions with the goal to decrease the device's overall size, and finalising the weight support mechanism to lift the upper limb and the device.

3.3.1 Materials

Material selection for components is a crucial part of the design process (Ashby & Jones 2012). Choosing the appropriate material for the application incorporates several different factors. For this device, the materials were required to be lightweight for portability (one of the desirable attributes, see section 2.7) and easy to operate for the end user. They also needed to be strong to prevent mechanical failure while transporting, setting up, and using the device. The cuff, in which the upper limb will rest, also needs to be made of a sufficiently strong material but also needs to be comfortable, therefore something with less rigidity would be desirable.

The cost and availability of materials was also an important factor for the selection process. As the intention with this device was to provide something that is cost-effective for the consumer, the materials used to manufacture must comply with this low-cost intention.

This section will briefly describe several different materials considered for the components before comparing their material properties (figure 3.4 & 3.5) in order to choose the appropriate ones for the prototype.

Stainless steels have high tensile strength (515-860 MPa) and stiffness (elastic modulus – 193-200 GPa) and are highly resistant to corrosion making them beneficial for device longevity. Stainless steels, however, have a relatively high density (approx. 8 g/cm^3). Consequently, using it as the main material for the components (e.g. four-bar assembly, clamp assembly, etc.) will make the device heavy and potentially difficult to transport and set up, particularly for stroke survivors.

Aluminium alloys have a relatively lower density (approx. 2.71 g/cm^3) than steel while also exhibiting corrosion resistance. While they generally have lower tensile strengths (124-310 MPa) compared to stainless steel, for the intended application of the weight support prototype, they are strong enough and unlikely to fail when in use.

Several different plastic materials were also considered for the components including high density polyethylene (HDPE), polyvinyl chloride (PVC), and poly(methyl methacrylate) (PMMA). These have lower densities (0.959. 1.44, and 1.19 g/cm^3 respectively) relative to steel and aluminium but have a lower elastic modulus (1.08, 3.28 and 2.74 GPa respectively) and tensile strength (22.1, 40.7 and 48.3 MPa respectively). As such, these materials may be more suited for the upper limb cuff as they are less rigid and may feel more comfortable for the upper limb to rest in.

Carbon fibres are miniature fibres comprised of carbon atoms that are used to combine with other materials to form a composite. The most common of these is carbon fibre-reinforced polymer, commonly known as carbon fibre, where these fibres can be used to reinforce various polymers, depending on the application. They exhibit high tensile strength (2500-6350 MPa) and stiffness (elastic modulus – 230-400 GPa) while having a lower density (approx.1.78 g/cm^3) relative to other high-strength materials. While

this makes it beneficial for developing strong components that are lightweight, carbon fibre is quite expensive when compared to the other materials described here.

The following six materials were compared: Stainless steel alloy (304), Aluminium alloy (6061), Carbon Fibre (Intermediate Modulus), HDPE, PVC, and PMMA. Their tensile strength and elastic modulus were plotted against their density (figure 3.4 and 3.5 respectively).

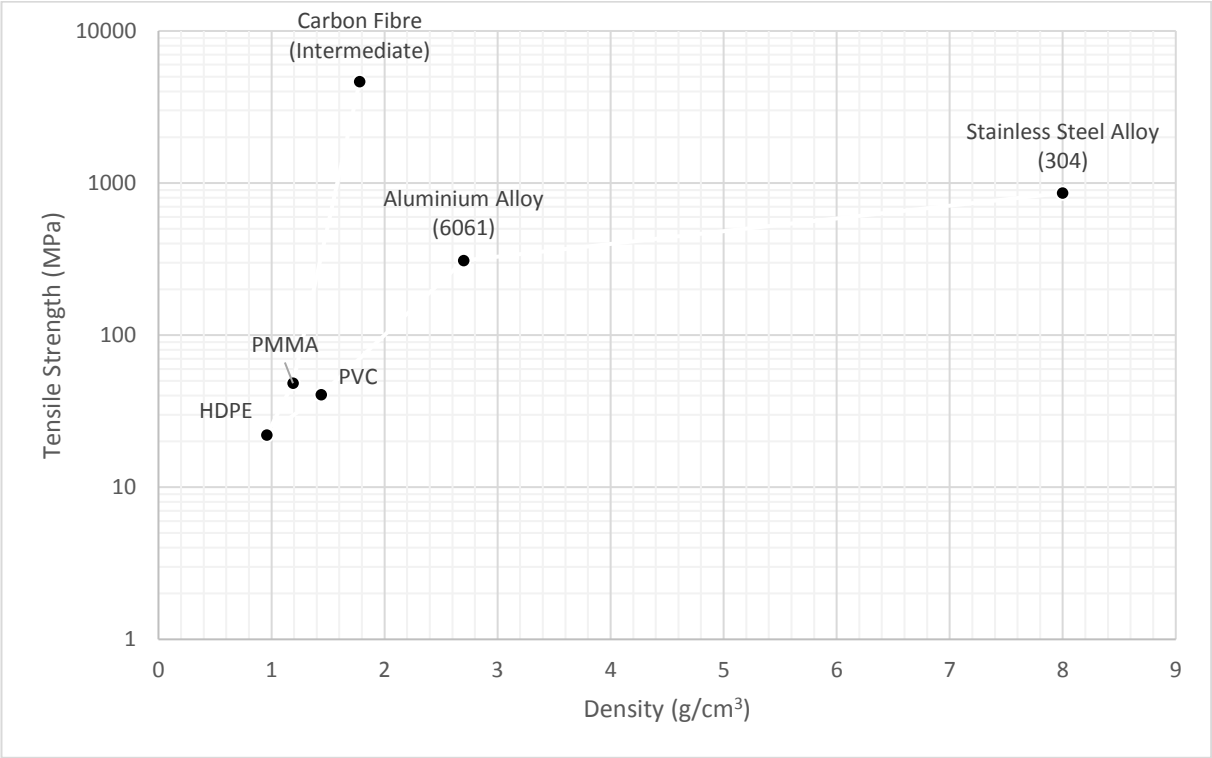


Figure 3.4 - Tensile Strength against Density for select materials.

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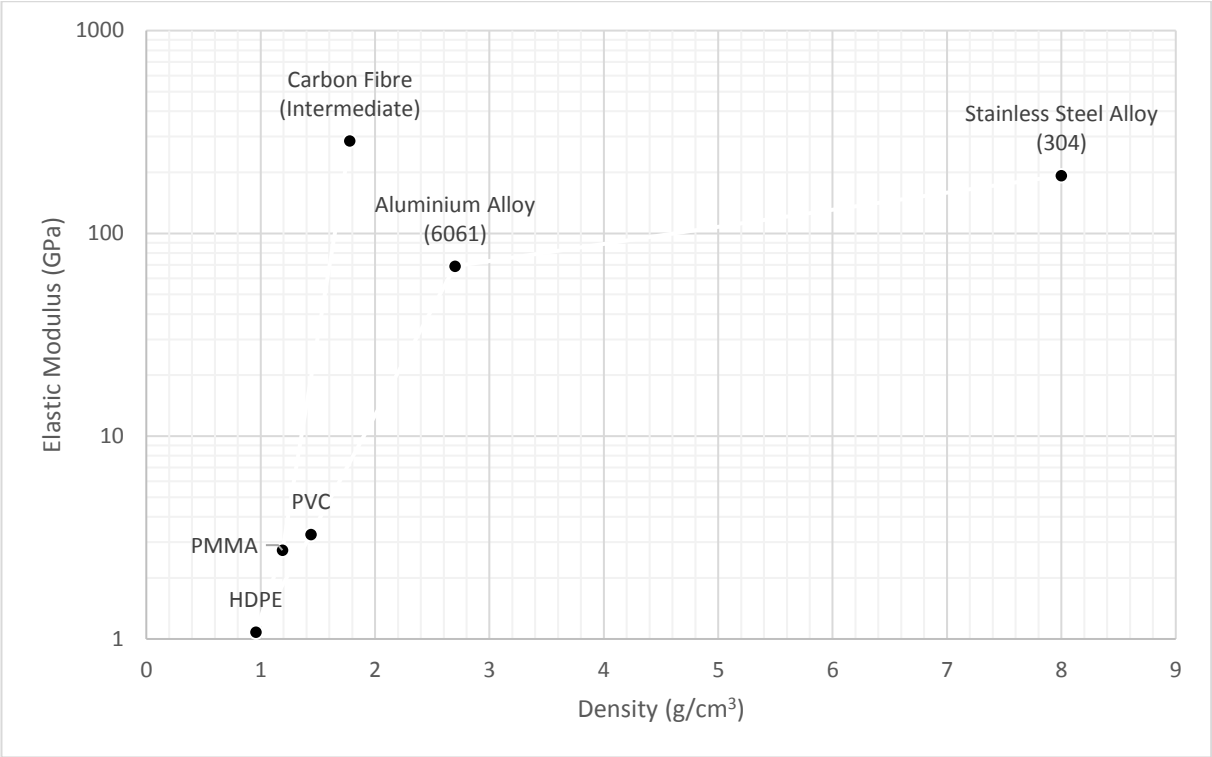


Figure 3.5 - Elastic Modulus against Density for select materials.

From these figures, it was decided not to choose stainless steel as the main material for the components. While it has a large tensile strength and elastic modulus, it has a substantially larger density than the other materials selected, which as predicted, will make the device heavier (using mock-up dimensions: approx. 15kg) for the end user, reducing portability and increasing setup time. Furthermore, the weight support mechanism will also need to balance the weight of the four-bar linkage. Therefore, lighter weight materials are desired.

From carbon fibre and aluminium, carbon fibre excels in having higher tensile strength and elastic modulus while also having a lower density making it a stronger material at a lighter weight. However, when looking at costs, carbon fibre is more expensive than aluminium leading to a device that will be more expensive for the end user. For a two-

metre square tube (20x20mm), aluminium was priced at £12.77 (https://www.aluminiumwarehouse.co.uk/20-mm-x-20-mm-x-2-mm-aluminium-square-tube - 17/12/2019) whereas carbon fibre was priced at £68.10, five times the cost, (https://www.easycomposites.co.uk/#!/cured-carbon-fibre-products/carbon-fibre-box-section/carbon-fibre-box-section-20mm-17mm.html - 17/12/2019). For these reasons (cost, strength and weight), aluminium was chosen as the material for the majority of components of the device despite being third in terms of tensile strength and stiffness, as it had a substantially lower density (2.7 g/cm^3) than stainless steel (8 g/cm^3) and a cheaper cost than carbon fibre.

Regarding the upper limb cuff, PVC was used for this component. This was chosen for its lightweight, toughness and ability to be easily cut and shaped into a variety of different shapes, which is beneficial to shape into a support that is comfortable for the upper limb.

3.3.2 Components and Dimensions

As mentioned in section 3.2, the sizes of the components, particularly for the four-bar assembly, were deemed too large by the designer following initial use. Therefore, reductions in the dimensions were necessary to decrease the volume of each component. This in turn, would decrease the device's total weight, increasing the likelihood of achieving portability for the end user.

Appendix A shows the dimensions for the components of the proposed prototype. Unlike Table 3.1, the clamp component is included at this stage as it was decided to design a custom-made clamp for the device. In order to create a device that could affix to most table surfaces, a sufficient gap between the bottom and top of the clamp was

desired to accommodate for thicker tables, and/or tables that have supports underneath that require extra clearance to bypass. Furthermore, the clamp should have sufficient reach across the table. Similarly, this was to ensure that any extra support underneath the table would be bypassed. Additionally, this would help the assist the user fix the clamp to the table without risk of it falling off.

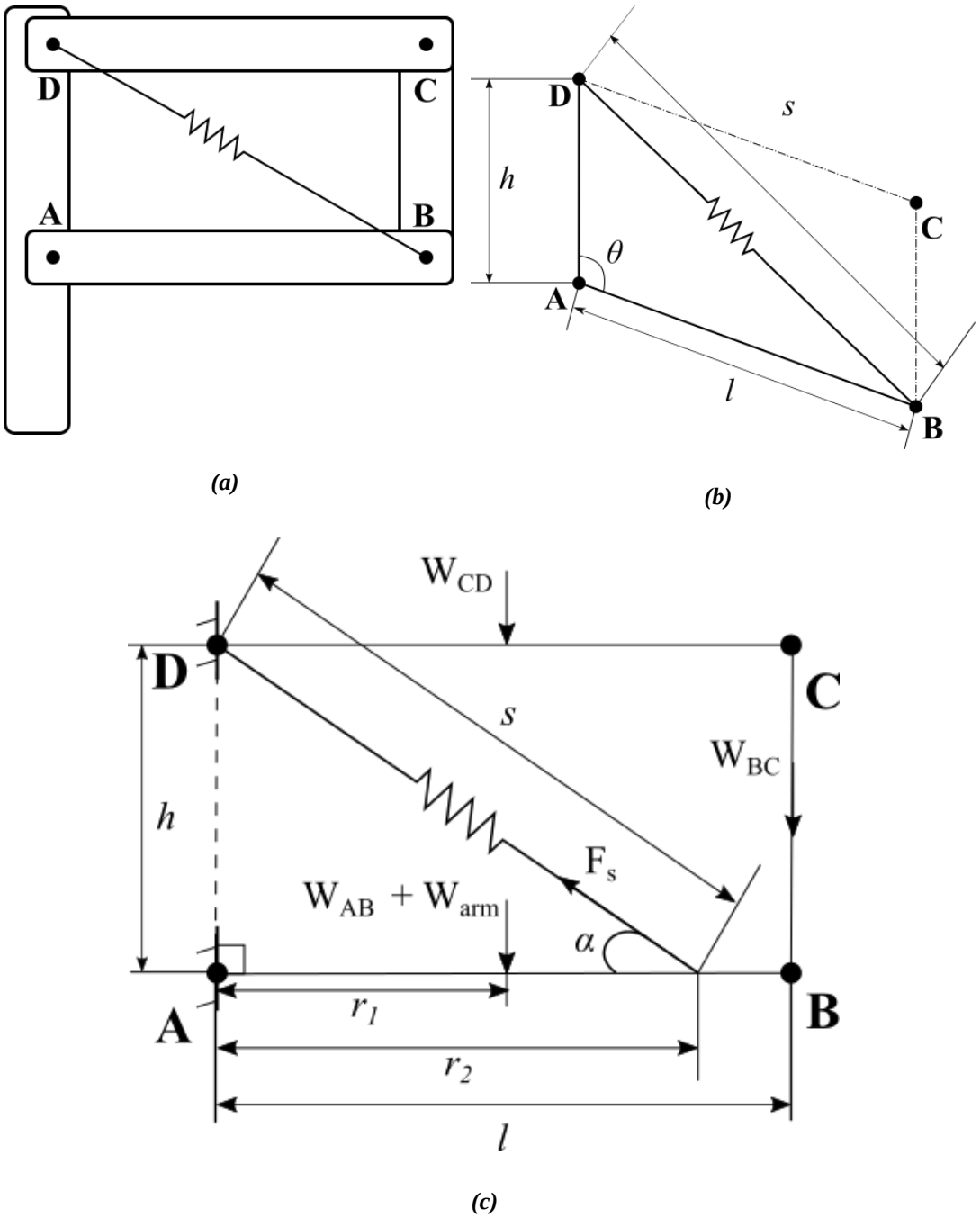
In Appendix A, Volume without cuts refers to the calculated volume of the component determined by the length, width and thickness dimensions. Volume with cuts refers to the true volume of the component following removal of material in CAD to create fixation points and joints in order to assemble the components, in addition to removing as much unnecessary material as possible to reduce final component weight.

3.3.3 Justification of Weight Support Mechanism

As previously mentioned, the mock-up used a bungee cord to provide an initial support mechanism. This can be considered as a simple spring with equation:

$$F_s = kd, \tag{1}$$

where F_s is the spring force, k is the spring constant and d is the displacement of the spring from its original length (s_o) either in compression or extension ($d = s - s_o$) (Hibbeler 2016). Consequently, the force the spring exerts can be adjusted through changing the spring constant or the deformation that the spring undertakes. The elastic properties of the cord enabled it to support the weight of the mock-up against gravity. For analysis, the spring can be modelled with the proximal end fixed to the joint of the proximal and top bar of the four-bar frame **D**, and the distal end of the spring attached to the joint of the bottom and distal bar of the frame **B** (figure 3.6(a)).



(a) *(b)* *(c)*

Figure 3.6 - (a) – Diagram of a four-bar mechanism with spring attached to joints B and D. (b) – Geometry of the mechanism at angle θ. (c) – Free body diagram of the mechanism for the working prototype.

Additional weight can be supported (i.e. the upper limb) through increasing the spring force. This was not possible with the mock-up as it did not incorporate an adjusting

mechanism to change the force. To achieve this effect in a working prototype, a method for altering the spring constant *k* and/or the spring displacement *d* is required.

For a typical off the shelf helical spring, the spring constant is fixed, determined by the properties and machining of the spring. Therefore, it was decided that the spring force would be altered through changing the displacement. Looking at the geometry of the four-bar design (Figure 3.6(b)), *h* is defined as the distance between joints **A** and **D,** *l* the distance between **A** and **B,** and *s* is the length of the spring. Through changes to angle θ the spring length *s* can be determined using the following equation:

$$s = \sqrt{l^2 + h^2 - 2lh\cos\theta} \qquad (2)$$

When in use, it is intended that the upper arm be secured to the cuff between the elbow and the shoulder, with the forearm unrestrained. To balance the weight of the upper limb against gravity, the loads associated with both the upper limb and the device need to be considered. When in static equilibrium, the forces and moments acting on the device are balanced giving a resultant of zero. To simplify the analysis, it is desired to orientate the four-bar linkage so that, $\theta = 90°$.

A free body diagram for the working prototype showing the external forces acting on the four-bar linkage is shown in figure 3.6(c). In this design, the distal end of the spring has been affixed at a point between joint **B** and the centre of mass of the arm and bar **AB** defined as, r_2. The decision to move the spring position was necessary in order to avoid potential interference with the distal bar **BC,** which could have led to damage to either the spring or the four-bar structure. As a result, decreasing the moment arm requires a larger spring force in order to balance the weights of the upper limb and the four-bar structure.

To balance the weight of the arm, the moments generated by the weight of the arm and linkage, and the force exerted by the spring must be balanced. By analysing the forces and moments at each link separately, the reaction forces at each joint can be determined. Subsequently, since the moments at joint **A** must be zero for the system to be in equilibrium, the required spring force can be determined:

$$F_s = \frac{(W_{arm} + W_{AB} - W_{CD})r_1 - W_{BC}l}{r_2 \sin\alpha} \tag{3}$$

where,

$$\alpha = \tan\left(\frac{h}{r_2}\right) \tag{4}$$

Table 3.2 shows the corresponding weights and dimensions for four-bar mechanism of the working prototype based on the materials chose. For this analysis, the weight of the upper limb cuff was deemed negligible.

Table 3.2 - Anticipated dimensions and external forces of the four-bar mechanism.

Parameter	**Value**
$\boldsymbol{F_s}$ [N]	?
$\boldsymbol{W_{arm}}$ [N]	?
$\boldsymbol{W_{AB}}$ [N]	2.77
$\boldsymbol{W_{BC}}$ [N]	0.56
$\boldsymbol{W_{CD}}$ [N]	0.96
$\boldsymbol{l}$ [mm]	300
$\boldsymbol{h}$ [mm]	180
$\boldsymbol{r_1}$ [mm]	150
$\boldsymbol{r_2}$ [mm]	240
$\boldsymbol{\alpha}$ [°]	36.87

W_{arm} is the weight of the upper limb, which will vary between users. For one example, if we let the mass of the upper limb be 3kg, W_{arm} will be 29.43N. Substituting this value and the given values in table 3.2 into equation 3 provides a spring force, $F_s = 31.37$N.

While the above equations show the required spring force to balance the system, in practice the user will be moving their upper limb while using the device. As such, it is expected that the user will have to provide some amount of support themselves at the shoulder in addition to the support provided by the spring in order to balance the system at different heights. Figure 3.7 shows a free body diagram of the system taking into account the support moment at the shoulder for different heights of the device.

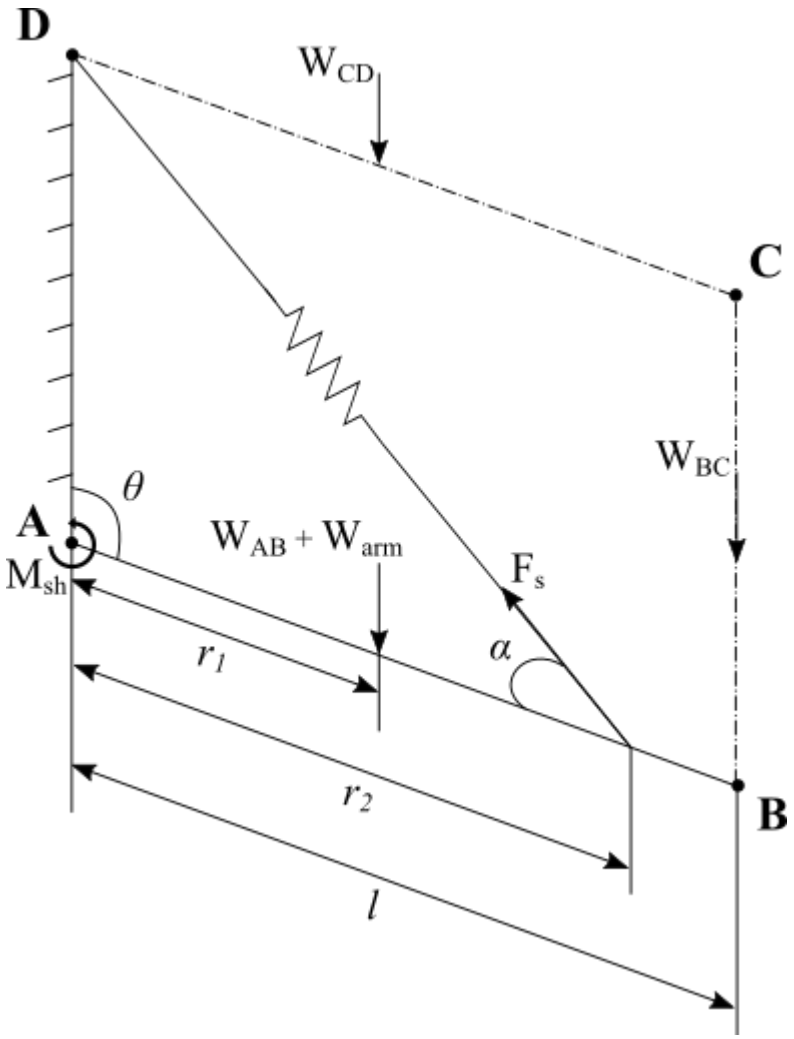


Figure 3.7 - Free body diagram of the weight support system. While in use, the user's shoulder will provide some support in addition to support provided by the spring in order to balance the system.

Assuming that the shoulder joint is in line with joint A with the four-bar linkage, the moment about the shoulder can be determined in order to keep the system in equilibrium:

$$M_{sh} = F_{s_x} r_2 \cos(\theta) + F_{s_y} r_2 \sin(\theta) - (W_{AB} + W_{arm} - W_{CD}) r_1 \sin(\theta) - W_{BC} l \sin(\theta) \quad (5)$$

where,

$$F_{s_x} = F_s \sin(180 - \theta - \alpha) \quad (6)$$

$$F_{s_y} = F_s \cos(180 - \theta - \alpha) \quad (7)$$

3.3.4 Spring Selection

As mentioned in section 3.2.3, it was desirable to have the weight support mechanism (i.e. the spring) enclosed within the base of the four-bar linkage. Having the spring as an internal component of the system was deemed necessary in order to improve safety for the user in the event of mechanical failure. Additionally, having the spring out of sight may make it more aesthetically pleasing for the user.

In light of this, there are several factors to be considered when choosing a spring. These are its spring diameter, its maximum extended length, and its stiffness (i.e. the spring constant). In order to keep the device as compact and lightweight as possible, the dimensions of the four-bar base were finalised first. As shown in figure 3.8, a 15x20x204mm section was removed from the component in order to place a spring and other components necessary for the adjustment mechanism. Subsequently, the desired spring requires an outer diameter of less than 15mm and a maximum extended length of less than 204mm while demonstrating enough tension (or force) that enables it to support the weight of the upper limb and the device.

Rather than design a spring to meet these requirements, it was chosen to select an off-the-shelf extension spring that already met these parameters. Table 3.3 shows a shortlist of springs and their parameters for comparison.

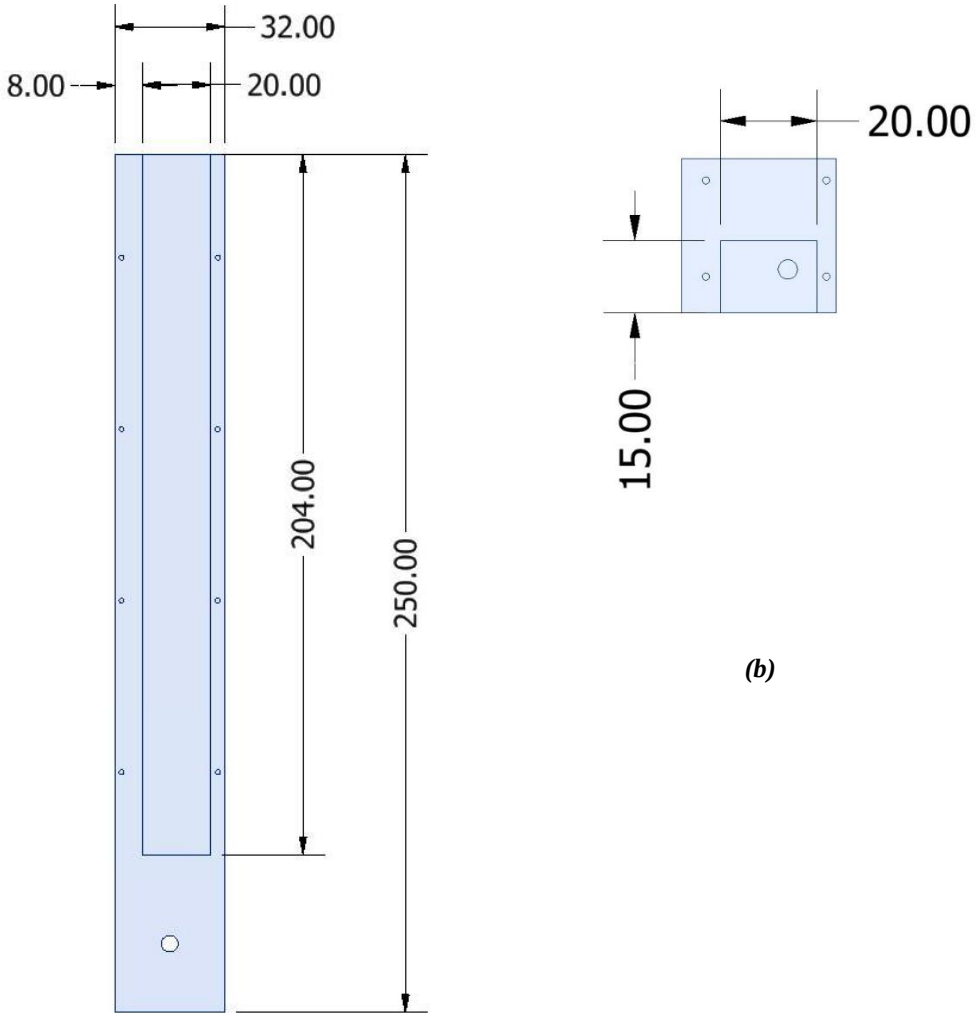


Figure 3.8 - Dimensions (mm) for the section cut from the four-bar base to incorporate a spring. (a) Elevation view (b) Plan view

Table 3.3 - Comparison table of four off the shelf extension springs.

Spring Number	**Outside Diameter (mm)**	**Free Length (mm)**	**Wire Diameter (mm)**	**Max Extended Length (mm)**	**Initial Tension (N)**	**Spring Rate (N/mm)**	**Tension when fully extended (N)**
A	12	80	1.5	142.13	9.78	1.1	78.12
B	14	80	1.7	141.38	11.97	1.37	96.06
C	12.7	76.2	1.63	129.25	11.62	1.53	92.79
D	11	69	1.35	142.34	11.18	0.97	82.32

Spring **A** exhibits the lowest initial tension (the tension that holds the spring coils together) but also the lowest tension when the spring is fully extended. Springs **B** and **C** have higher ultimate tensions of 96.06N and 92.79N respectively but have larger outer diameters (14mm and 12.7mm respectively). Due to the 15mm depth that was cut from the four-bar section, it was decided to remove spring **B** from the shortlist as it had the largest outer diameter leading to it more likely coming into contact with the other components inside the four-bar base. Spring **D** has a lower max tension relative to **B** and **C** but higher than **A**. It also has the smallest outer diameter and free length but the largest maximum extended length of all the springs.

Despite having the largest extended length of the four springs, it was decided to use spring **D** for the weight support mechanism. This was chosen primarily for its small outer diameter while still exerting a reasonable range in tension from fully coiled to full extension, enough to support the weight of the upper limb and the four-bar linkage.

Although it will use up the most amount of space lengthwise when fully extended, there is still enough space within the cut section for the spring to stretch to this length.

3.4 Working Prototype

Figure 3.9 shows the working prototype of the weight support device. As mentioned previously (section 3.3.1), the four-bar linkage was manufactured using aluminium. The bottom bar had several holes machine drilled for connecting the upper arm support. The upper arm support is attached to the bottom bar and can be adjusted through sliding up and down the bar before securing in place. A cylindrical shaft is extruded from the support base through a bearing, and an upper limb cuff is attached to the end of the shaft. The bearing allows the shaft to rotate freely, and in turn create the extra degree of freedom desired in figure 3.2(c). While not shown in figure 3.9, a Velcro strap is attached around the cuff to secure the user's arm in place.

Figure 3.9 - Working prototype of the weight support device.

The bottom of the proximal bar was affixed to the horizontal member also made of aluminium. Washers were placed on either side of the horizontal member to reduce friction therefore allowing the proximal bar to rotate freely around its axis. The opposite end of the horizontal member is affixed to the top of the clamp assembly. This consists of a modified pole removed from a standard elbow crutch. This was then secured to the horizontal member. This fixation is similar to the proximal bar, allowing the horizontal member to rotate around the vertical axis at this joint. For everyday use, the height of an elbow crutch can be adjusted to the user's needs by depressing the spring buttons and adjusting to the appropriate height. Once this is achieved, the spring buttons are released to engage in the adjustment holes and secure in place.

Subsequently, this feature was employed to adjust the height of the prototype where required.

The bottom half of the elbow crutch is slotted and secured into place into a support on a custom-made G-clamp. Using the clamp allows for the whole device to be secured to a table/work surface. Choosing an appropriate length and gap between the top and bottom edges of the clamp when the clamp is fully loosened (i.e. the threaded screw is at its lowest point) was important to ensure the clamp can be secured to tables with a support underneath the table edge that would interfere when securing in place. Increasing the length and gap of the clamp should allow the device to be fixed in place without any issues.

For the support mechanism (figure 3.10), the selected spring was placed within the base and covered to prevent injury to the user in case of mechanical failure. One end of the spring is anchored to a roller at the top of the base. A cable is attached to the opposite end of the spring that travels around a roller at the bottom of the base and out travelling along the bottom bar to its pulley. The cable then goes around another pulley at the top bar and back into the base over the same roller that anchors the spring. The end of the cable is then secured to a nut that can travel freely along a threaded shaft within the base. The threaded shaft can be turned using a knob on top that will adjust the height of the nut and in turn, exert a greater or lesser force on the spring. As such, increasing the tension on the spring will result in more effort on the user's part to push the device downwards. A 1mm nylon cord was used as the cable for the mechanism for its small diameter and flexibility.

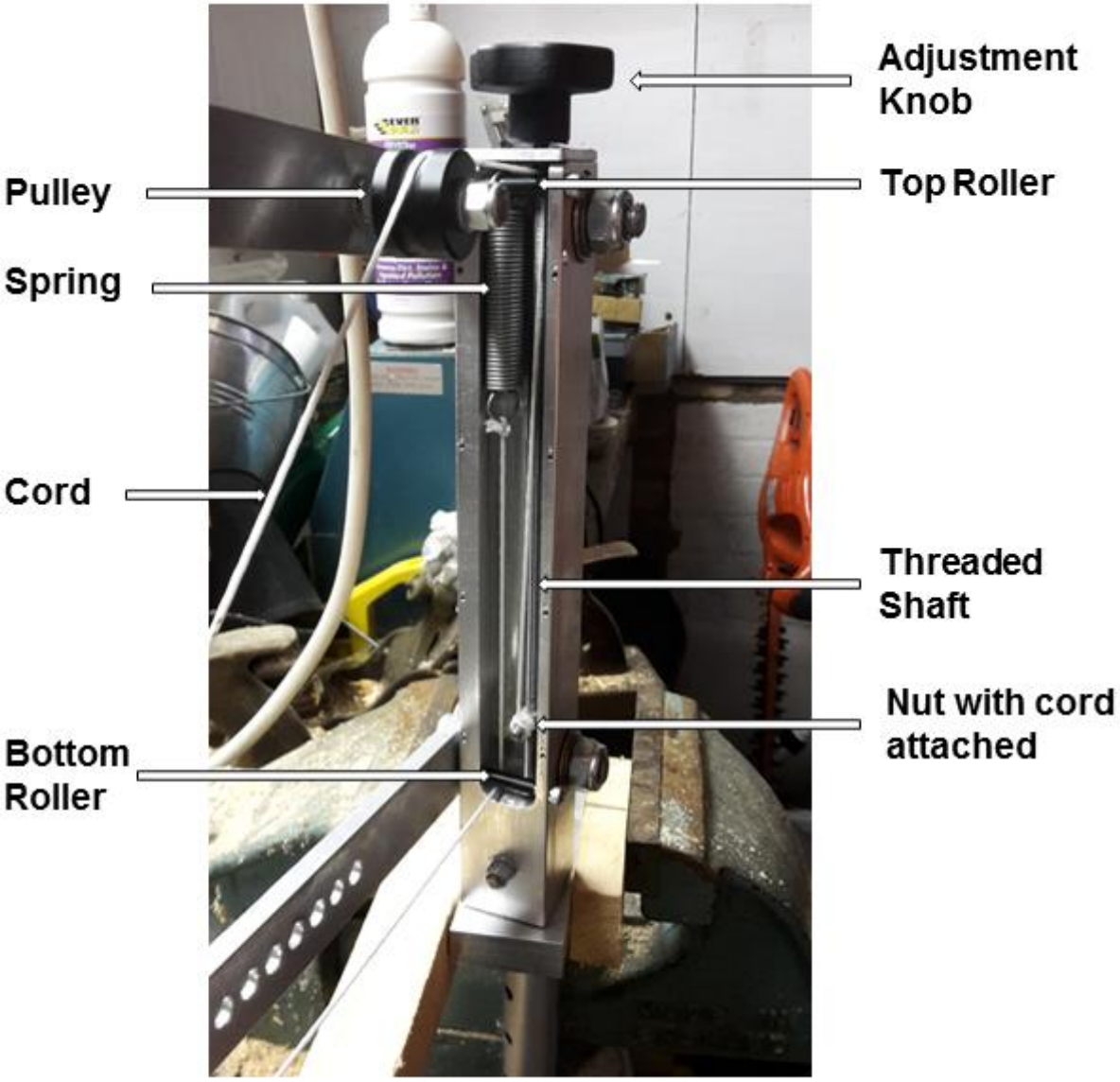


Figure 3.10 - Spring mechanism within the proximal bar of the four-bar linkage (uncovered).

3.5 Initial Prototype Feedback

3.5.1 Introduction

During the prototype manufacturing process, a visit to the University of East Anglia (UEA) rehabilitation research group was arranged to observe the rehabilitation work they do with stroke patients and present the device for feedback. Additionally, through the UEA rehabilitation group's links with the NHS, visits were also arranged to the Colman Hospital, Norwich, a specialist neurological rehabilitation centre, and Norfolk Community Hospital, Norwich, which provides an in-patient ward for stroke rehabilitation and an early supported discharge (ESD) team for patients living at home. Hospital visits were organised to shadow therapists and observe the therapy they deliver to stroke patients and patients with other traumatic brain injuries. Furthermore, it provided the opportunity to acquire more feedback from stakeholders (researchers, physiotherapists, stroke survivors). The prototype (excluding the clamp assembly – incomplete at the time of the visit) was presented to stakeholders allowing them to visualise a full-scale model and interact with the device, opening up more opportunities for constructive feedback.

3.5.2 Methodology

Visits were arranged with four separate groups to present and discuss the prototype to stakeholders: (i) UEA with researchers focussed on the development, evaluation and implantation of rehabilitation interventions (including stroke); (ii) Colman Hospital with therapists; (iii) Stroke rehabilitation unit at Norfolk Community Hospital with physiotherapists and stroke survivors; (iv) The ESD team at Norfolk Community Hospital.

For UEA, a 10-minute presentation on the research project was given to the group, highlighting the current issues associated with upper limb therapy, existing devices on the market, and the design process leading into the development of the prototype and its functionality. Following this, feedback on the design and prototype was sought from the research group.

Hospital visits were limited to informal discussions on-site due to staff availability. As such, volume of feedback was varied between groups. Each discussion involved showing pictures of the CAD models and a wooden mock-up followed by showing the physical prototype, providing a brief explanation of its capabilities and intended benefit for rehabilitation. Staff were also encouraged to interact with the device before feedback was requested.

Since all parts of the prototype had not yet been manufactured, the assemblies that were complete were taken for display. This included the four-bar assembly (excluding spring mechanism) and part of the support assembly (excluding the cuff); the clamp assembly had not yet been manufactured at this stage. This was explained to each of the groups and that the completed prototype would utilise the clamp for placing on a desk or work surface and the cuff to secure the user's arm in place.

3.5.3 Results: Expert Feedback

3.5.3.1 UEA

The researchers agreed that the upper arm support would be useful for helping with rehabilitation. However, they noted that the user would require their shoulder to be properly aligned with the device to ensure pain was not an issue. It was suggested that having a physiotherapist initially assess and correctly align the patient with the device

before allowing them to use it. Additionally, the group proposed letting the user operate the device at a lower height and become familiar with how it operates before engaging the weight support and lifting their upper limb. It was noted that this might be difficult with this current prototype as it would be likely it would collide with the table/work surface the device would be clamped on.

One researcher made it aware that the weight support provided would need to be changeable to accommodate arms of varying weights. As the spring mechanism was not incorporated into the prototype at this stage, the proposed adjustability was explained.

The group also agreed that the joint to facilitate reaching and grasping could be better, suggesting a frictionless joint to enable the user to move the device forward and back in conjunction with their upper limb. Furthermore, the group suggested that the range of motion available for reaching could be increased.

Finally, the group suggested that a plethora of rehabilitation equipment (e.g. gloves to facilitate hand and finger movement) and exercises could be incorporated with the device to give the user options for their rehabilitation while using the device.

3.5.3.2 Colman Hospital

One physiotherapist stated that facilitation of forearm extension would be required for a patient's rehabilitation therefore the device should be able to provide this. All physiotherapists agreed that the intended final prototype would likely benefit some stroke participants a little bit with their recovery though trying it out on patients would be necessary to confirm this.

3.5.3.3 Norfolk Community Hospital Stroke Rehabilitation Unit

One senior physiotherapist said that they would like support to be provided at the table to enable a greater range of motion to the patient. Furthermore, they asked if it could be possible to mount the device onto a work surface (i.e. in a kitchen), chair, and/or a bed. They also noted that by having the upper arm secured in the cuff, the patient's movement is more likely to be restricted when attempting to perform a reach to grasp movement. Other therapists liked the idea of having a second cuff for the forearm. To assist with placing the arm in the device, a locking mechanism was suggested to allow the patient to strap themselves in more easily.

Biofeedback was also proposed, particularly audio feedback being incorporated as part of the system. One idea mentioned was using a light-gate system that played different pitches and notes depending on where the patient moved their arm in the working area.

3.5.3.4 Norfolk Community Hospital ESD Unit

One member of the ESD team said that support at the forearm/elbow could be better than support at the shoulder in terms of mobility. Facilitation of lateral/medial rotation at the shoulder by the device was considered by some of the therapists as a selling point of the device since it is a movement they practice with their patients. With further regards to movement capabilities, a ball and socket joint to connect the weight support assembly to the clamp was suggested to increase reach by allowing the device to move with the patient's trunk.

Providing different attachments and/or grips for the device was mentioned, as it would provide the user with options to customise their self-practice at their leisure. Moreover,

one therapist suggested using a platform or flat surface for the arm to rest on instead of using a cuff.

For feedback, attaching a laser or light to the end of the device was recommended to act as a pointer that would be used as a gauge of the user's range of motion; targets could be assigned on a board for the user to hit with the laser/light. By tracking their scores, this could add a motivational factor to the patient's rehabilitation by providing them with their score and encouraging them to improve next time.

Finally, infection control was asked to be considered, particularly for a device that would be used by multiple patients, should the device be used within the NHS. Therefore, the therapists advised making the device easy to wipe and clean thoroughly.

3.6 Conclusions

This chapter described the detailed design process of an upper limb weight support device for stroke rehabilitation taking forward the final concept chosen in chapter 2. Component dimensions and materials were selected based on the desired design criteria with focus on functionality, size, weight and cost. Furthermore, incorporating a simpler design compared to existing products could be beneficial in relation to costs but also to public perception. This was realised using a standard extension spring for the weight support mechanism and a clamp for mounting to a table.

Initial feedback from stakeholders on the partially complete prototype was constructive, with each group providing useful suggestions for improvements such as movability (e.g. increased range of motion) and functionality (e.g. locking cuff position to secure the upper limb in place easily). Providing feedback to the user was also highlighted as crucial in terms of motivation to the patient and tracking progress

over time. However, it was decided to perform feasibility testing with the complete prototype first before moving on to potential design improvements and implementation of an interactive feedback system.

4 Feasibility Study

4.1 Introduction

Prototype testing is a necessary stage of design and development. It provides practical insight into the limitations of a design that may not have been initially apparent to the designer in sketches and CAD models. Furthermore, it can provide an opportunity for stakeholders to engage with the researcher/designer and their product, offering invaluable advice through identification of key features and flaws from a consumer perspective as seen in other studies using upper limb devices. (Herder et al. 2006; Sanchez et al. 2006).

This chapter will focus on a feasibility study undertaken with healthy participants and participants living with stroke. Each participant was tasked with performing specific tasks with their upper limb both with and without the prototype. Data on their performance was recorded via motion capture and their experience with the device was sought via semi-structured interviews.

4.2 Methodology

4.2.1 Participants

Eight healthy participants and five participants living with stroke were recruited for this study. For healthy participants, the inclusion criteria were: (1) have normal upper limb function and (2) able to attend a two-hour appointment at the University of Strathclyde during working hours (9-5) Monday to Friday. The single exclusion criterion was: Individuals who were unwell during the investigation period or were taking medication that may have compromised their ability to participate.

For participants living with stroke, the inclusion criteria were: (1) have suffered a stroke at least 12 months ago, which has resulted in reduced upper limb movement and function; (2) able to communicate in English, both written and spoken and (3) able to attend a two-hour appointment at the University of Strathclyde during working hours (9-5) Monday to Friday. The exclusion criteria were: (1) Individuals who were unwell during the investigation period or were taking medication that may have compromised their ability to participate; (2) Individuals with significant speech problems that could have limited communication with staff (e.g. informing staff they were feeling unwell) as well as presenting a barrier to the interview process; (3) Individuals with learning difficulties or/and cognitive impairment of a level that could have affected their ability to provide informed consent, cognition being assessed with the Mini-Cog test and (4) Individuals with musculoskeletal injuries or conditions affecting the shoulder or elbow that were unrelated to their stroke.

4.2.2 Study design

The investigation was a pilot feasibility study using a mixed cohort of stroke and healthy participants.

4.2.3 Setup

Participants interested in the study were provided with an information sheet containing details of the study and were invited to sign an informed consent form should they wish to take part. Each participant was invited to the University of Strathclyde to carry out the study. They were shown a demonstration of the weight support device and how it operated before being asked if they would like to continue to take part in the investigation. Participants living with stroke were asked to fill in a questionnaire to

provide additional information about themselves (age and gender) and details about their stroke (i.e. time since diagnosis, time spent performing rehabilitation exercises, and if they perform upper limb exercises independently.).

A workspace using four, square tables was set up in the motion capture lab of the university (figure 4.1). Each participant was asked to perform three different tasks on this workspace with their upper limb (healthy using their non-dominant side and stroke using their impaired hemiplegic side): (1) reaching forward (RF) for an object; (2) reaching to the side (RS) for an object and (3) reaching up (RU) for an object on an elevated platform (figure 4.2). The platform was a small foldable table with a height of 37cm; the object used was a small cylindrical wooden block. For the RF and RS tasks, each participant was asked to reach as far as they could on the workspace before the task began; the object was then placed just short of their maximum reach.

Figure 4.1 - Four table workspace used for the study. The participant was asked to sit at one of the four tables and the study equipment was setup around them. The WSD (not pictured) was placed on the table to the left or right of the participant.

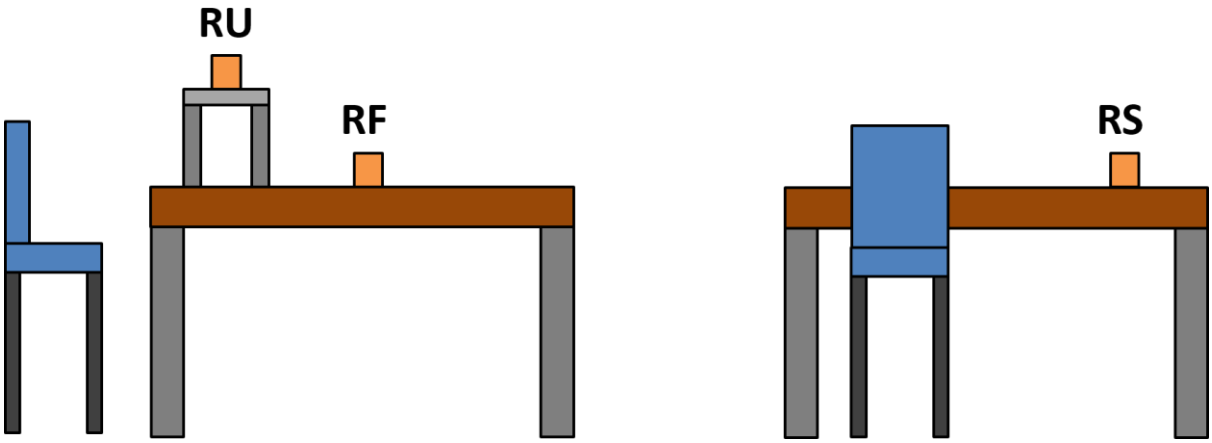
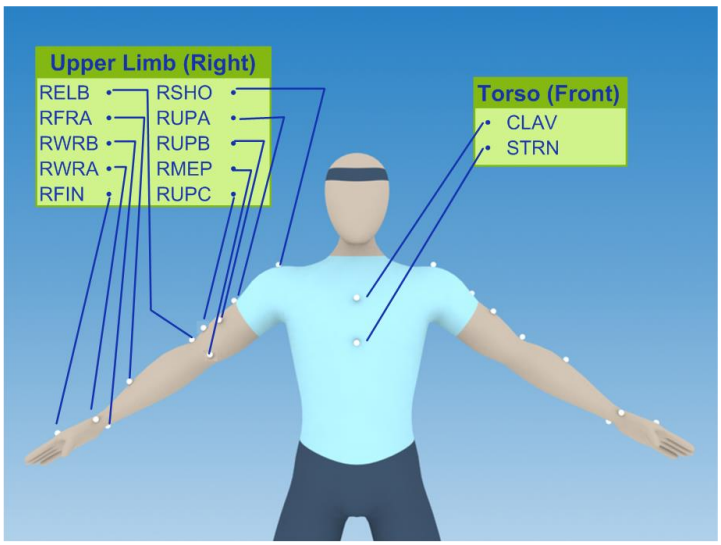


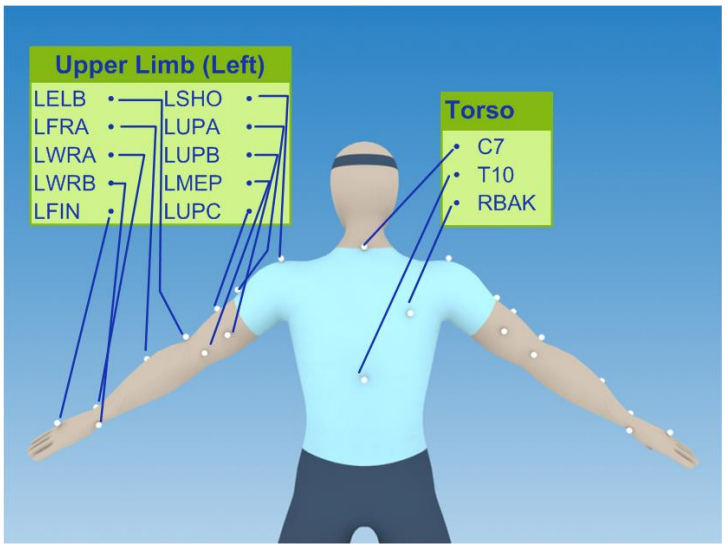
Figure 4.2 - Diagram of the setup for the study. The participant was seated and asked to reach for an object (orange) in three different positions (shown simultaneously here). RU = Reaching Up, RF = Reaching Forward, RS = Reaching to the side.

4.2.4 Motion capture

The movement of each participant's arm was tracked by a three-dimensional (3-D) motion analysis system (Vicon Motion Systems, Oxford, UK). This involved the attachment of 14 small (14mm) spherical retro-reflective markers to the skin and clothes of each participant following the Upper Limb Model which is a biomechanical model adapted from the full body model (Plug-In Gait) used for upper limb motion capture (Vicon Motion Systems 2007; Yang et al. 2002). Markers were placed on the participant's torso and upper limb that was used to perform the tasks; no markers were attached to the opposite limb. Markers were attached with double-sided sticky tape. A model showing the position of these markers is shown in figure 4.3. Table 1 describes the position of each marker. Once the markers were satisfactorily placed, they were tracked in three dimensions using eight Vicon T-Series motion capture cameras that track the reflected infrared light from the markers.



(a)



(b)

Figure 4.3 - Upper Limb Model marker placements from Vicon Upper Limb Model Guide. RBAK was not required for this study therefore was not placed on the participant.

Table 4.1 - Marker definitions and placements for the upper limb model.

Marker Label	**Definition**	**Marker Placement**
C7	7th Cervical Vertebra	On the spinous process of the 7th cervical vertebra
T10	10th Thoracic Vertebra	On the spinous process of the 10th thoracic vertebra
CLAV	Clavicle	On the jugular notch where the clavicles meet the sternum
STRN	Sternum	On the xiphoid process of the sternum
LSHO/RSHO	Left/Right Shoulder	On the acromioclavicular joint
LUPA/RUPA	Left/Right Upper Arm Marker A	On the lateral upper left/right arm
LUPB/RUPB	Left/Right Upper Arm Marker B	On the lateral upper left/right arm
LUPC/RUPC	Left/Right Upper Arm Marker C	On the lateral upper left/right arm
LELB/RELB	Left/Right Elbow	On the lateral epicondyle approximating the elbow joint axis
LMEP/RMEP	Left/Right Medial Epicondyle	Left/Right humerus medial epicondyle
LFRA/RFRA	Left/Right Forearm	On the lateral left/right forearm
LWRA/RWRA	Left/Right Wrist Marker A	at the thumb side of left/right radial styloid attached symmetrically with a wristband on the posterior of the left/right wrist, as close to the wrist joint centre as possible
LWRB/RWRB	Left/Right Wrist Marker B	at the little finger side of left/right ulnar styloid attached symmetrically with a wristband on the posterior of the left/right wrist, as close to the wrist joint centre as possible
LFIN/RFIN	Left/Right Finger	Just below the left/right third metacarpus

Following placement of the markers, the participant was asked to sit in a standard chair or, if required, their wheelchair, in front of the workspace. Figure 4.4 shows one of the

participant's from the stroke group with the upper limb marker set attached and their arm strapped into the WSD.

4.2.5 The Movements

Participants were then asked to perform each task test three times with and without their arm supported in the device, 18 movements were therefore performed. In the case of a participant being unable to perform all 18 movements, data were recorded from the executed movements only.

4.2.6 Data extracted for analysis

Shoulder flexion/extension, shoulder abduction/adduction, and finger marker trajectory within the respective planes of movement were compared to determine any differences in range of movement with or without the device. These movements were selected to assess reach (via finger marker) and if movability of the shoulder was enhanced or restricted when using the device.

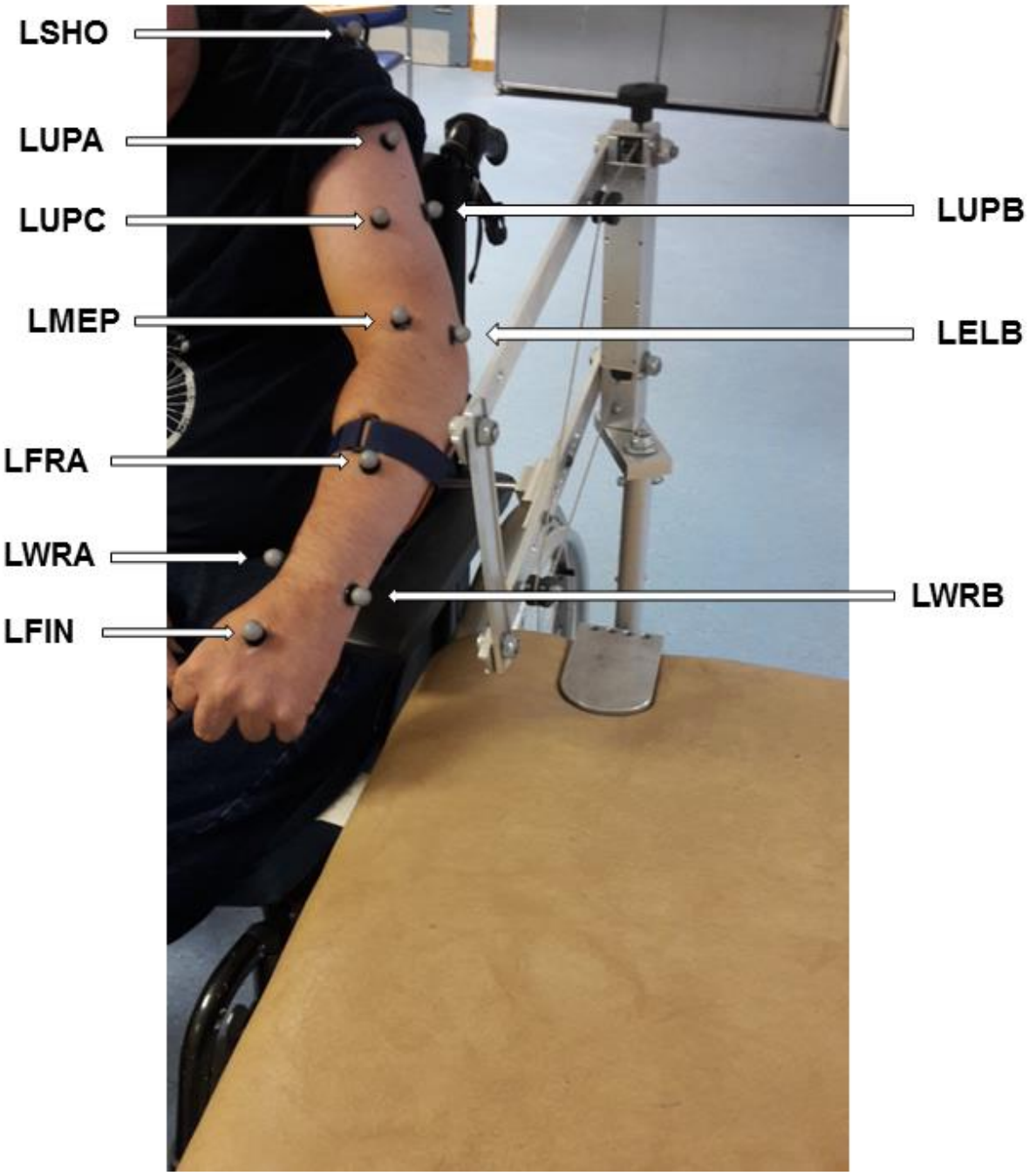


Figure 4.4 - Participant with upper limb attached to the WSD. The upper limb model marker set was attached to their impaired arm to record measurements with the Vicon motion capture system.

4.2.7 Interview

Participants from both groups undertook a short (15 minutes) interview following the motion capture. Participants were asked about their experience with the device and their opinions on its feasibility and acceptability for frequent use as a rehabilitation

technology, in addition to comfort and ease of use. Suggestions for improvements to the device were encouraged with particular reference to self-practice with the device at home.

Both groups were asked the following questions:

1. Did you find it easy to use?
2. Did you find the device comfortable?
3. Would you find it easy to set up?
4. Do you think you could set it up on your own at home?
5. What would you improve about the device?

For participants living with stroke, the following additional questions were asked:

1. Were you happy using the device?
2. Do you think the device could improve your arm function?
3. Can you see yourself using this on a regular basis? Daily? Weekly?
4. Have you used other arm movement training techniques/equipment before?
5. If it were possible, would you like to have one of these in your home?

Following these questions, participants were asked if they had any other comments related to the device and/or the whole study.

4.2.8 Data Management and Analysis

For the stroke survivor group, motion capture data were recorded, filtered and processed using Vicon Nexus (Vicon, Oxford, UK) software before being analysed in MATLAB (MATLAB®, Version 2016a, MathWorks Inc, Natick, Massachusetts). A MATLAB plug-in (Biomechanics Toolkit, http://biomechanical-

toolkit.github.io/about/) was used to read and analyse the exported c3d files from Vicon Nexus. Plots of each desired measurement were plotted, mapping both movement with the device and movement without the device onto the figure for each respective task. Mean and standard deviations of the desired measurements were also calculated and tabulated to compare the movements with and without the device. Interview responses were noted and common themes identified and described.

4.3 Results

Considering the purpose of the device, only the motion capture data from the participants living with stroke were used in the analysis with the healthy group being used primarily to test safety and basic functioning of the device. Interview responses from both groups were included with emphasis given to the responses from participants living with stroke.

4.3.1 Interview Responses

4.3.1.1 Healthy Participants

Question 1: Did you find it easy to use?

Most participants found the device easy to use with one finding the arm being quite restrictive relative to normal function. Contrasting opinions occurred where one participant liked the forwards and backwards movements where another felt that this could be improved upon. Side-to-side movements worked well for most participants. Two participants also worried that since the device was a prototype that they might break and were therefore hesitant to have the device support the full weight of their arm.

Question 2: Did you find the device comfortable?

All participants found the device comfortable and commented on areas of improvement. Two participants felt that the device was too high up for them to use properly even with the device at its lowest height. Furthermore, one participant's arm began to tire following prolonged use throughout the session.

Question 3: Would you find it easy to set-up?

All participants agreed that they would be able to easily set it up although one noted that this could be potentially difficult for a person with one fully functioning arm.

Question 4: Do you think you could set it up on your own at home?

Similar to the previous question, all participants agreed that they would be able to easily set this up in their own home.

Question 5: What would you improve on the device?

Participant feedback was varied. Three participants said that they would like there to be more adjustability in the height than was currently available. They noted that the lowest height the device could be set at was still too high for their shoulder. One participant wanted their arms to be able to rest on the table when relaxed but this was not feasible as a result of the orientation and support of the device.

Range of motion of the device was also highlighted as requiring improvements. The forward and backward movement in particular was difficult for some participants to achieve while performing the tasks.

4.3.2 Stroke Survivor Participants

While setting up the prototype and demonstrating it to the first participant, the cable used for the weight support mechanism snapped, resulting in device failure. The fault was unable to be resolved within the participant's allotted time in the laboratory therefore their participation in the study was withdrawn. A temporary replacement cable was ordered and fitted to the device for the next participant (Participant 02). The new cable was a 7x7 2mm white PVC coated galvanised steel wire rope replacing the 1mm nylon cord previously used. A more permanent solution, a 0.7mm steel wire, was ordered and fitted for the remaining three participants.

4.3.2.1 Motion Capture Data

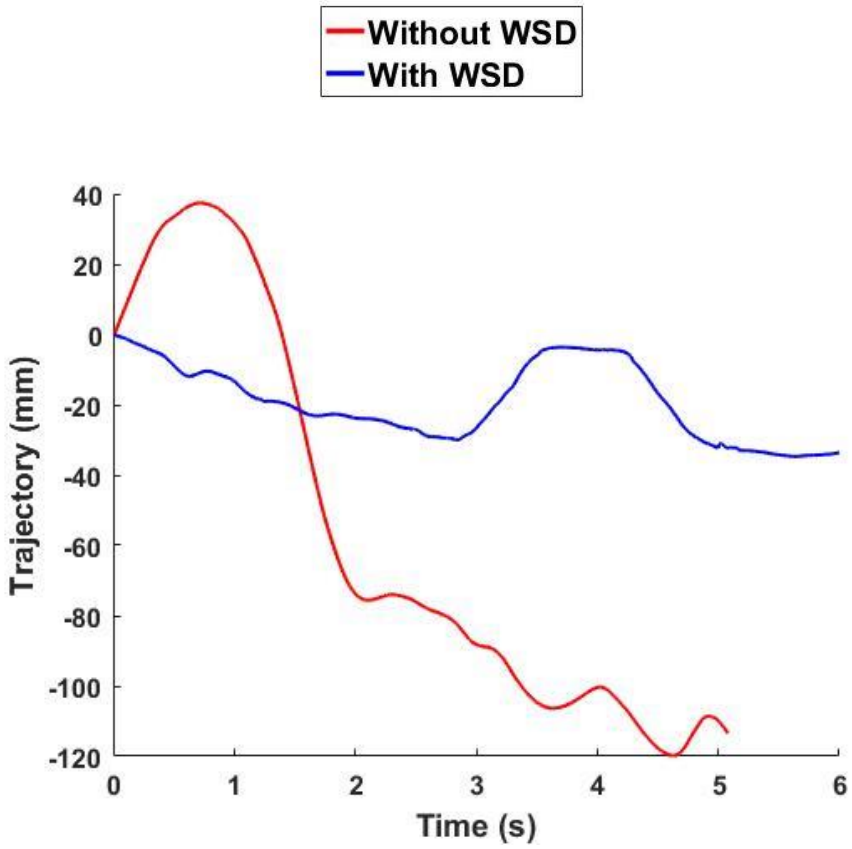
4.3.2.1.1 Participant 02

Participant 02 successfully performed all three repetitions for the RF task. For the RS task, the participant had difficulty completing the task both with and without the WSD therefore no valid recordings were obtained. The participant could only perform one repetition of the RU task due to fatigue at this point in the session. The participant was also seated in a wheelchair as this was the most comfortable for them creating some difficulty in setting the device up for their upper limb. A solution was found using a plinth (figure 4.4) of adjustable height to clamp the WSD to, enabling an appropriate height for the user's upper limb to be achieved. Table 4.2 shows the average range of motion for participant 02. Figure 4.5 and 4.6 show the range of motion for each selected measurement from one repetition for the RF and RU tasks respectively.

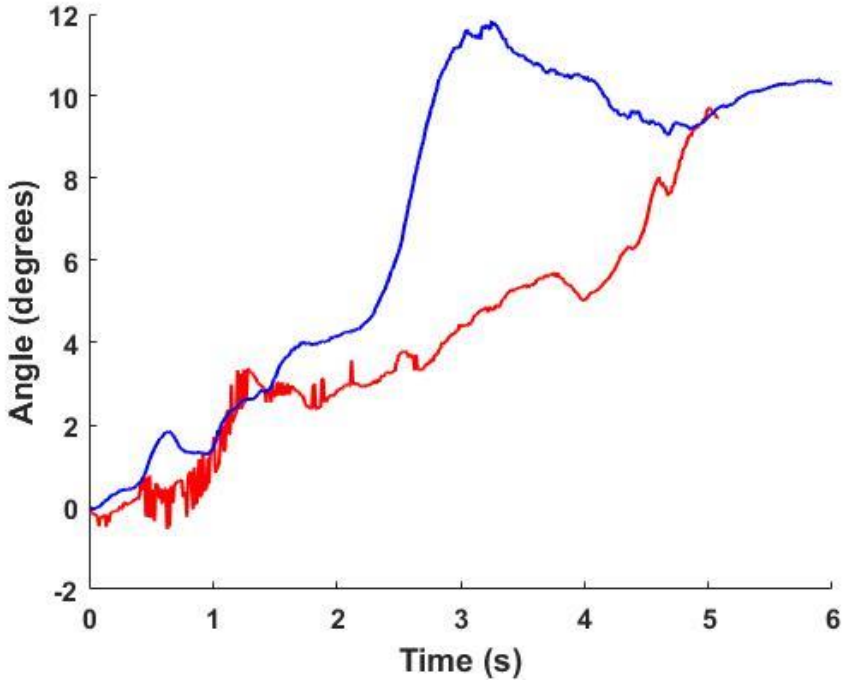
Table 4.2 - Average ± SD upper limb measurements for Participant 02. N/A denotes where the participant was unable to perform the task successfully.

Participant 02	**Reach Forward (RF)**		**Reach to Side (RS)**		**Reach Up (RU)**	
	Without WSD	With WSD	*Without WSD*	With WSD	*Without WSD*	With WSD
Shoulder Flexion/Extension (°)	5.7±2.1	8.2±3.6	N/A	N/A	10.4	9.3
Shoulder Abduction/Adduction (°)	4.9±4.6	12.4±0.6	N/A	N/A	8.9	10.1
Finger Marker Trajectory (mm)	116.1±38.7	52.0±17.4	N/A	N/A	221.6	68.5

For the RF task, the participant experienced slight increases in range of motion for shoulder flexion/extension and shoulder abduction/adduction but decreased movement in finger trajectory with WSD. For the RU task, the participant also had decreased movement in finger trajectory and minimal change in shoulder flexion/extension and shoulder abduction/adduction.


Without WSD
With WSD
Trajectory (mm)
Time (s)
40
20
0
-20
-40
-60
-80
-100
-120
0
1
2
3
4
5
6

(a)



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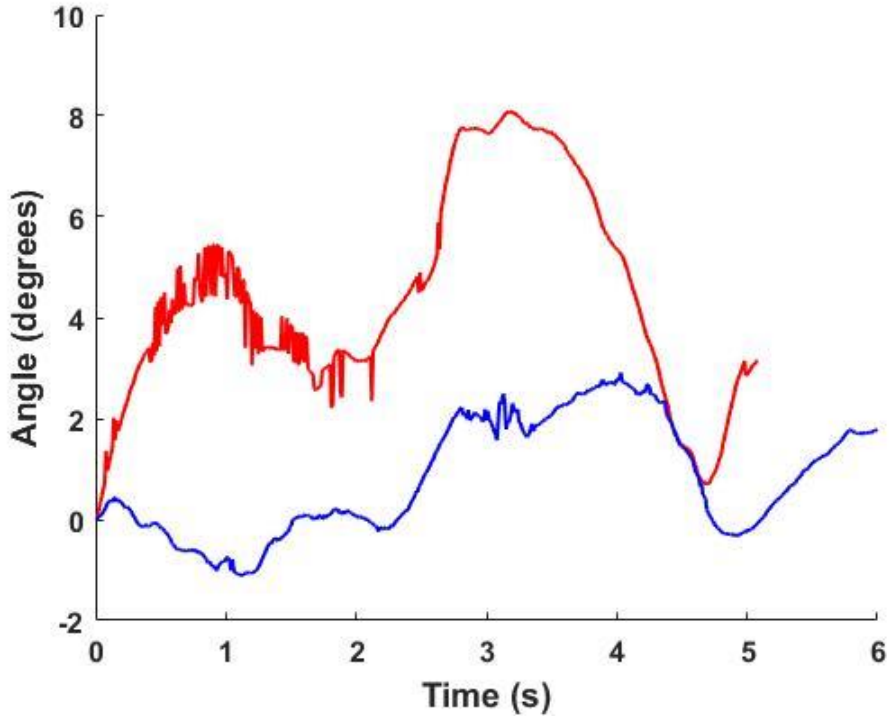
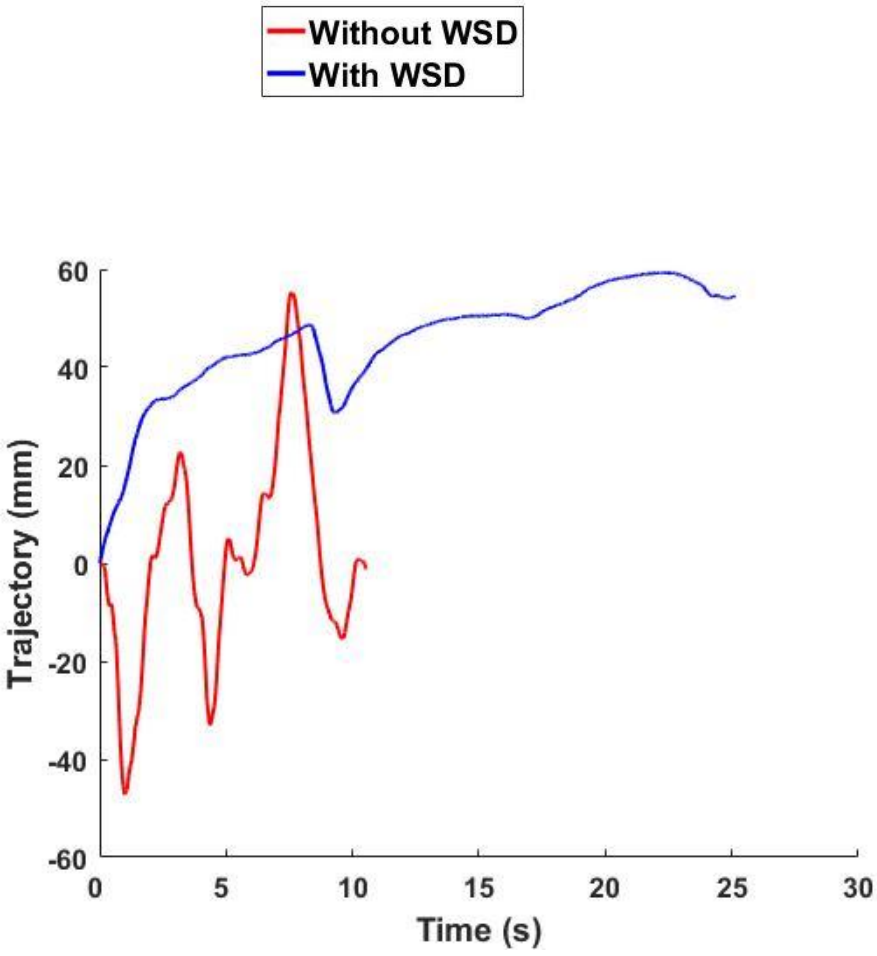
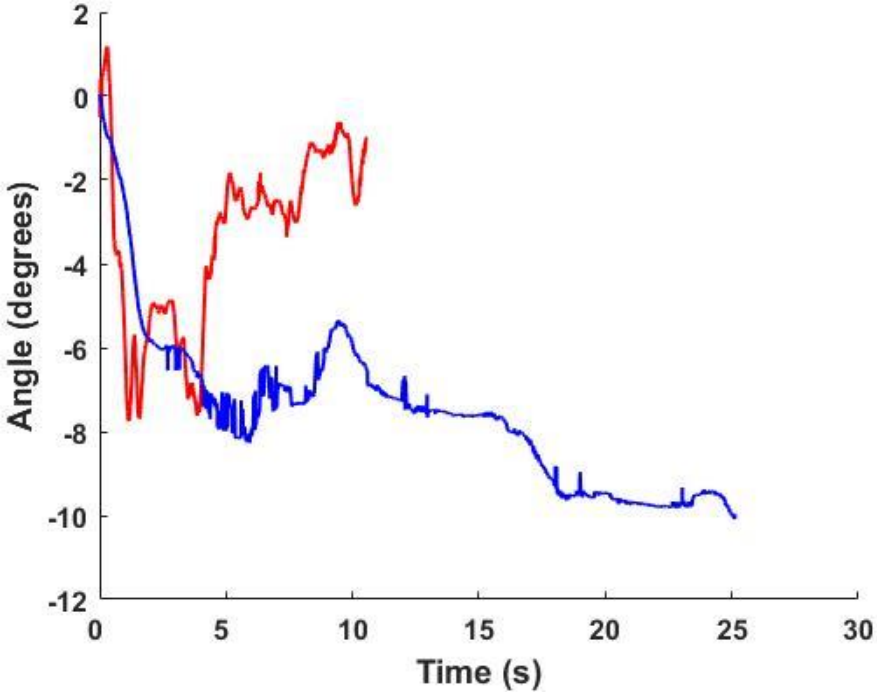


(c)

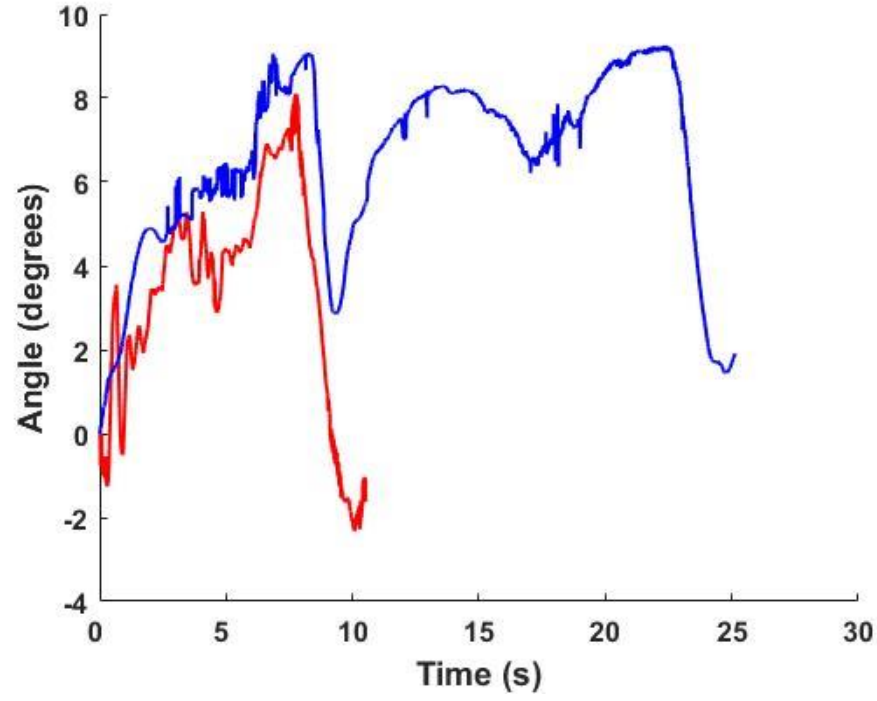
Figure 4.5 - Participant 2 range in upper limb measurements for one repetition of the RF task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).


Without WSD
With WSD
Trajectory (mm)
Time (s)
60
40
20
0
-20
-40
-60
0
5
10
15
20
25
30

(a)



(b)



(c)

Figure 4.6 - Participant 2 range in upper limb measurements for one repetition of the RU task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).

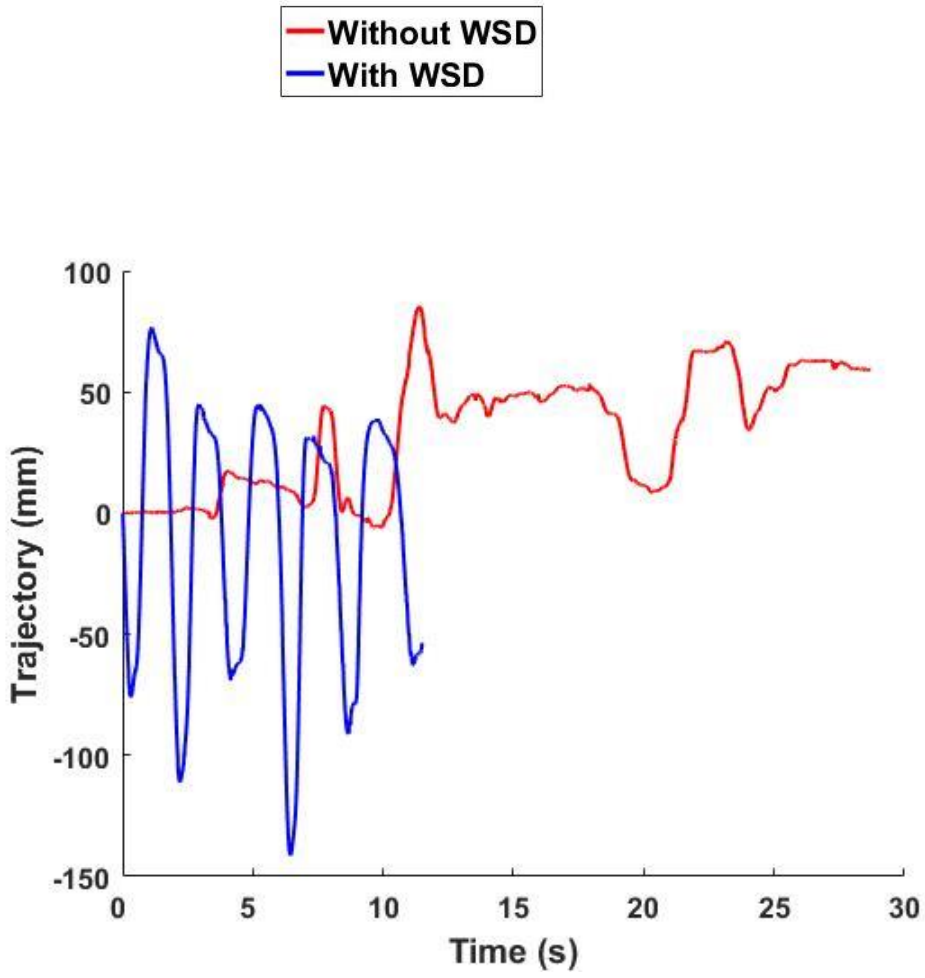
4.3.2.1.2 Participant 03

Participant 03 presented with substantial loss of upper limb movement and had difficulty executing both the RF and RU tasks, being unable to perform either of them successfully. RS was, however, achievable with the participant able to perform multiple repetitions as seen in figure 4.7. Table 4.3 displays the average measurements of the RS task with and without the device.

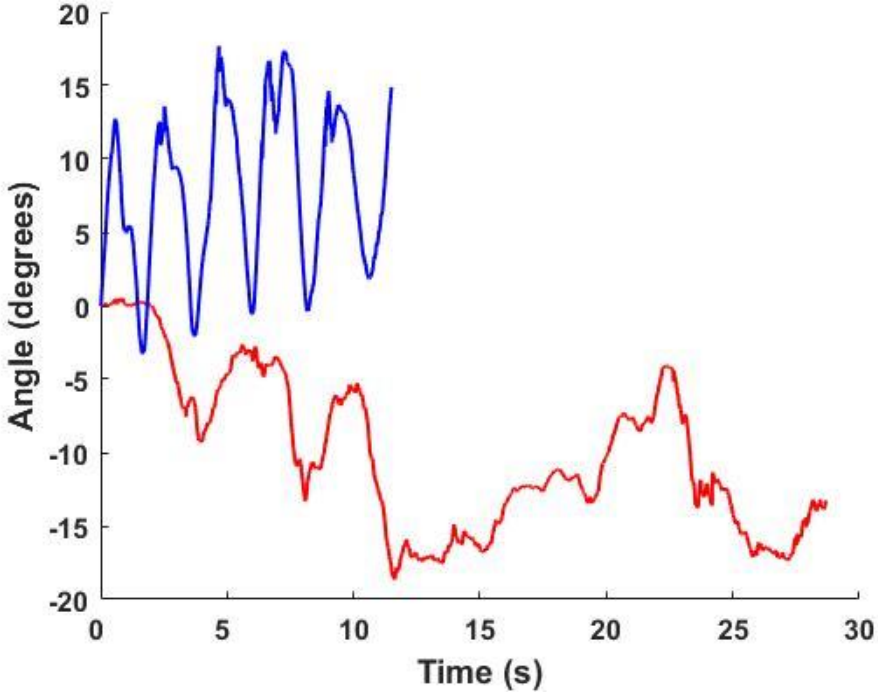
Table 4.3 - Average ± SD upper limb measurements for Participant 03. N/A denotes where the participant was unable to perform the task successfully.

Participant 03	**Reach Forward (RF)**		**Reach to Side (RS)**		**Reach Up (RU)**	
	Without WSD	With WSD	*Without WSD*	With WSD	*Without WSD*	With WSD
Shoulder Flexion/Extension (°)	N/A	N/A	30.4±4.8	11.2±2.2	N/A	N/A
Shoulder Abduction/Adduction (°)	N/A	N/A	22.0±3.1	18.4±5.5	N/A	N/A
Finger Marker Trajectory (mm)	N/A	N/A	148.7±49.8	192.6±35.2	N/A	N/A

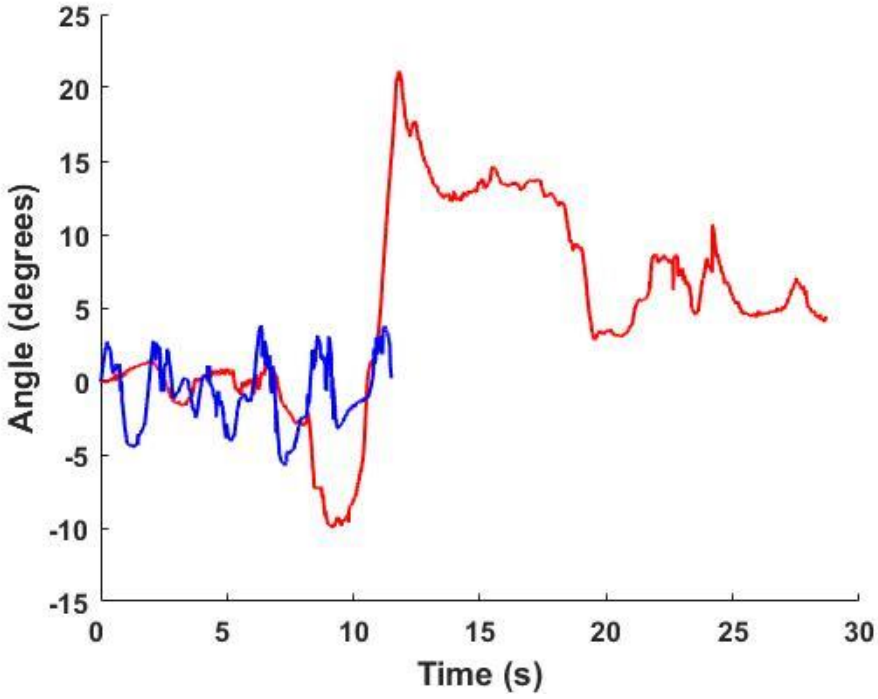
For the completed task, the participant exhibited decreased range of motion in shoulder flexion/extension and shoulder abduction/adduction but increased reach as shown by the finger trajectory. Furthermore, figure 4.7 shows that the participant was able to perform more repetitions of the task in a shorter amount of time (approximately 5 repetitions in 12 seconds with WSD compared to approximately 4 repetitions in 30 seconds for this recording).


Without WSD
With WSD
Trajectory (mm)
Time (s)
100
50
0
-50
-100
-150
0
5
10
15
20
25
30

(a)



(b)



(c)

Figure 4.7 - Participant 3 range in upper limb measurements for one repetition of the RS task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).

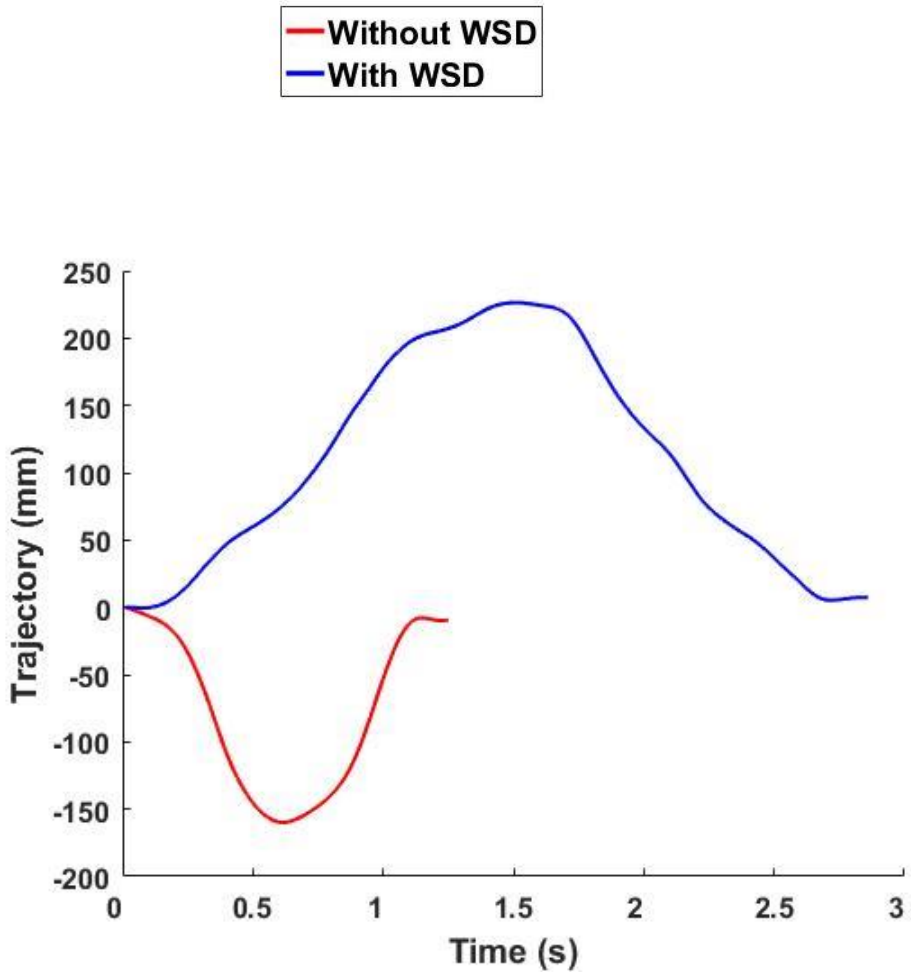
4.3.2.1.3 Participant 04

Participant 04 also presented with substantial loss of upper limb movement and was unable to perform the RF task successfully with the WSD therefore a comparison without WSD could not be made. Table 4.4 displays the range of motion in upper limb measurements for the RS and RU tasks. Figures 4.8 and 4.9 displays one repetition for the RS and RU task respectively. In the RS task, the participant performed 5 repetitions with and without WSD instead of the intended 3 and these were all included in the calculation of the average range of motion.

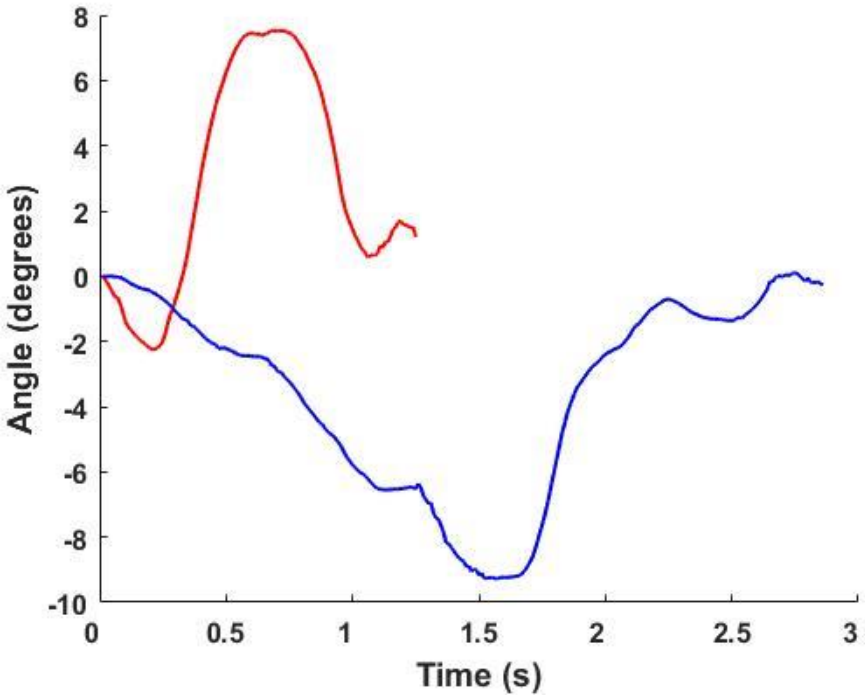
Table 4.4 - Average ± SD upper limb measurements for Participant 04. N/A denotes where the participant was unable to perform the task successfully.

Participant 04	**Reach Forward (RF)**		**Reach to Side (RS)**		**Reach Up (RU)**	
	Without WSD	With WSD	*Without WSD*	With WSD	*Without WSD*	With WSD
Shoulder Flexion/Extension (°)	N/A	N/A	7.7±1.8	8.5±2.5	22.1±3.2	15.4±2.5
Shoulder Abduction/Adduction (°)	N/A	N/A	9.2±2.4	9.7±2.2	14.4±4.4	8.4±0.7
Finger Marker Trajectory (mm)	N/A	N/A	147.2±23.0	226.8±11.9	116±16.7	176.2±26.5

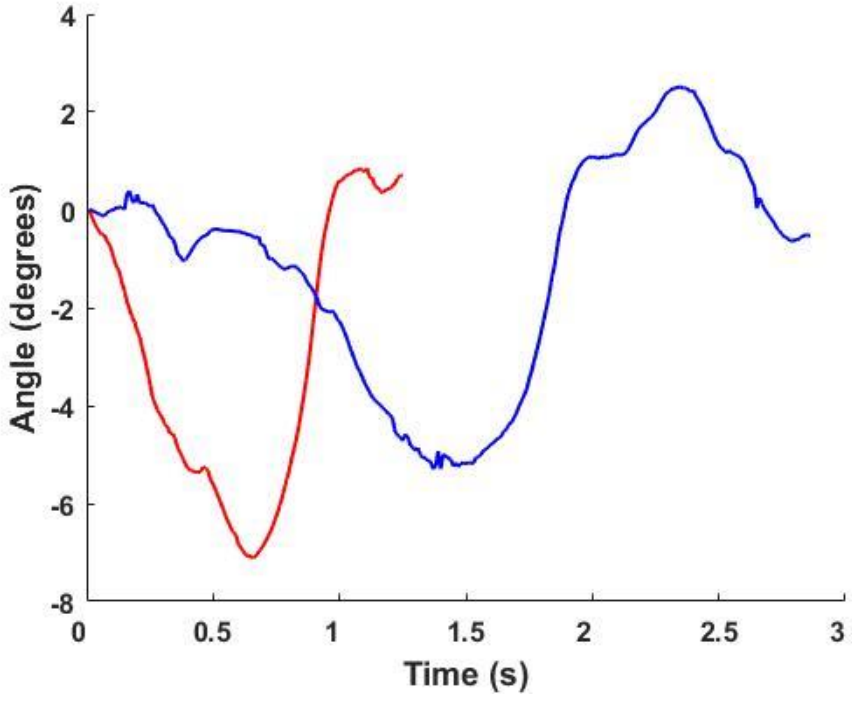
In the RS task, there was minimal change in shoulder flexion/extension and shoulder abduction/adduction but an increase of approximately 80mm in finger trajectory. In the RU task, there was a decrease in shoulder flexion/extension and shoulder abduction/adduction but an increase in finger trajectory of approximately 60mm.


Without WSD
With WSD
Trajectory (mm)
Time (s)
250
200
150
100
50
0
-50
-100
-150
-200
0
0.5
1
1.5
2
2.5
3

(a)

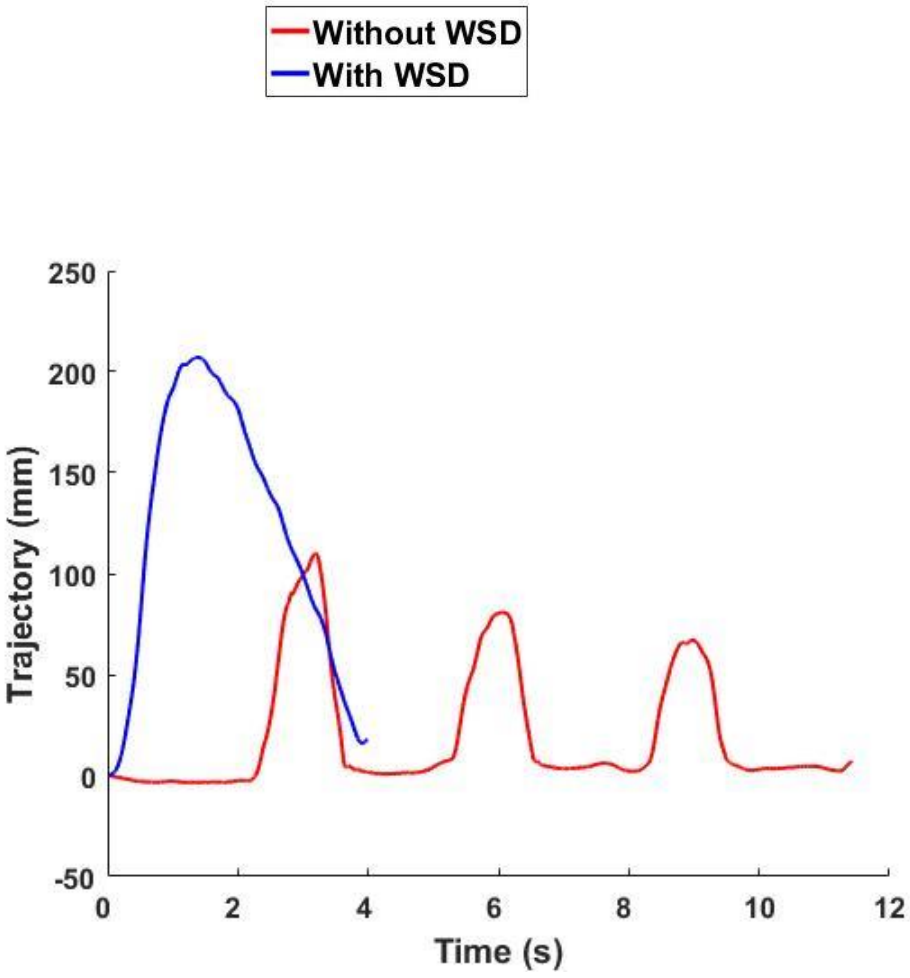


(b)

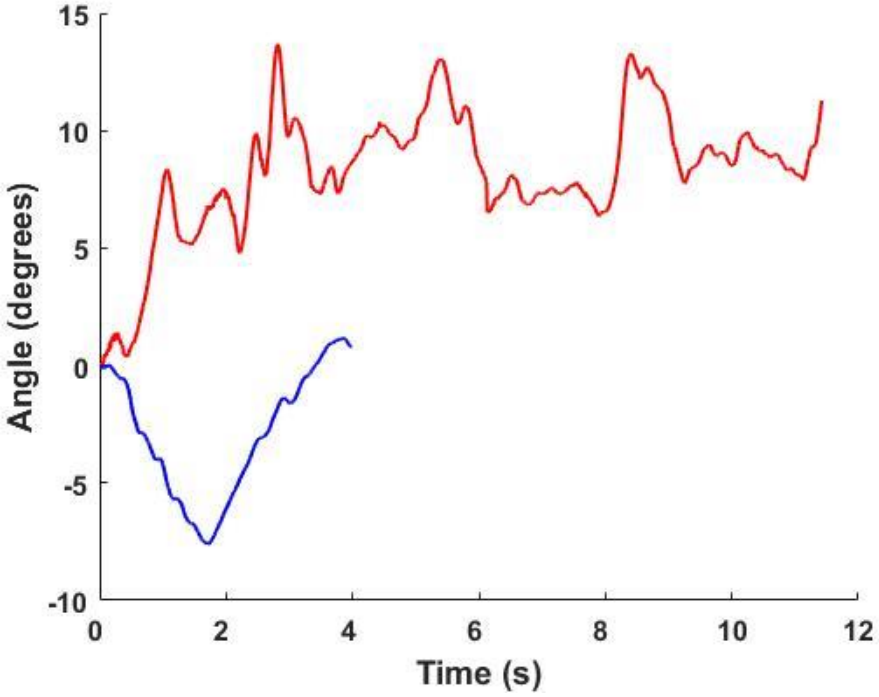


(c)

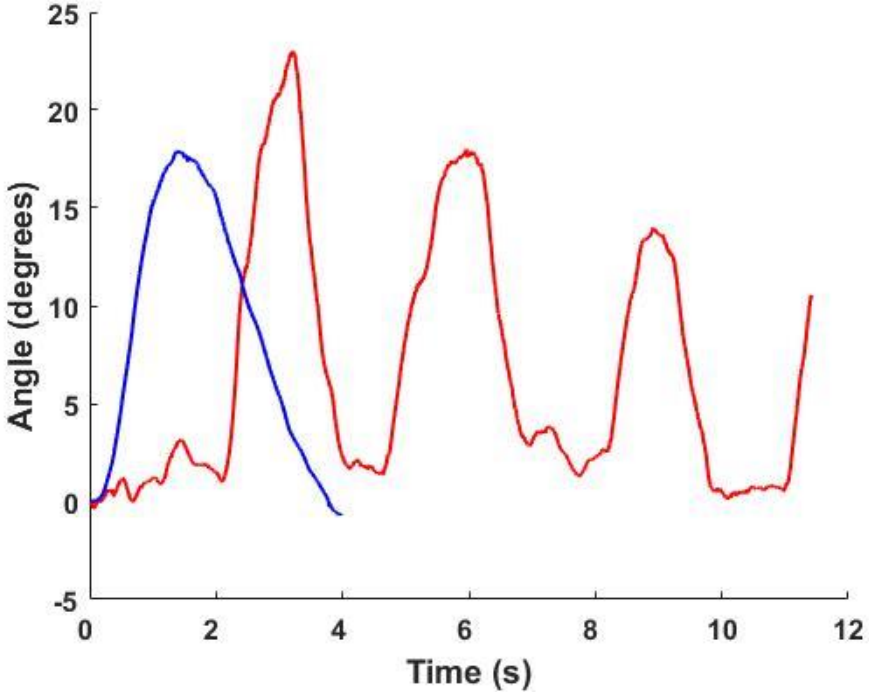
Figure 4.8 - Participant 4 range in upper limb measurements for one repetition of the RS task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).


Without WSD
With WSD
Trajectory (mm)
250
200
150
100
50
0
-50
0
2
4
6
8
10
12
Time (s)

(a)



(b)



(c)

Figure 4.9 - Participant 4 range in upper limb measurements for one repetition of the RU task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).

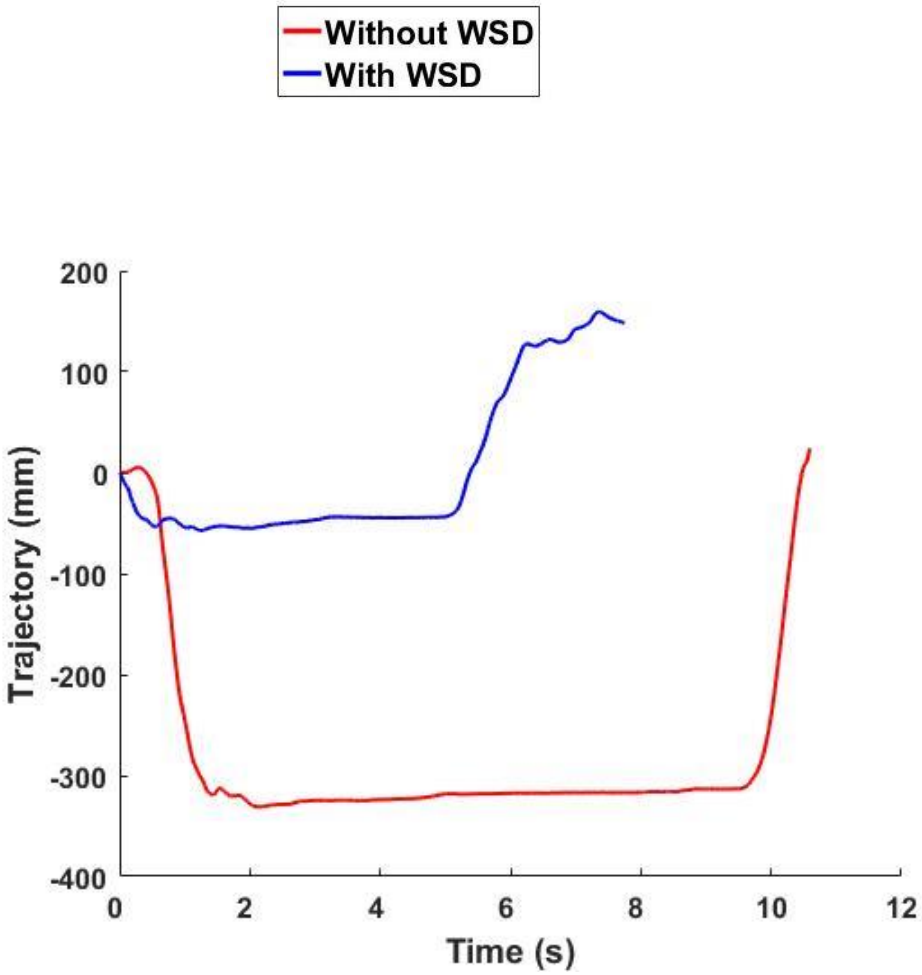
4.3.2.1.4 Participant 05

Participant 05 exhibited moderate upper limb impairment relative to the other participants. Consequently, they were able to successfully complete all of the required tasks with the exception that they could only perform one repetition of the RF task with the WSD due to difficulty moving with the device.

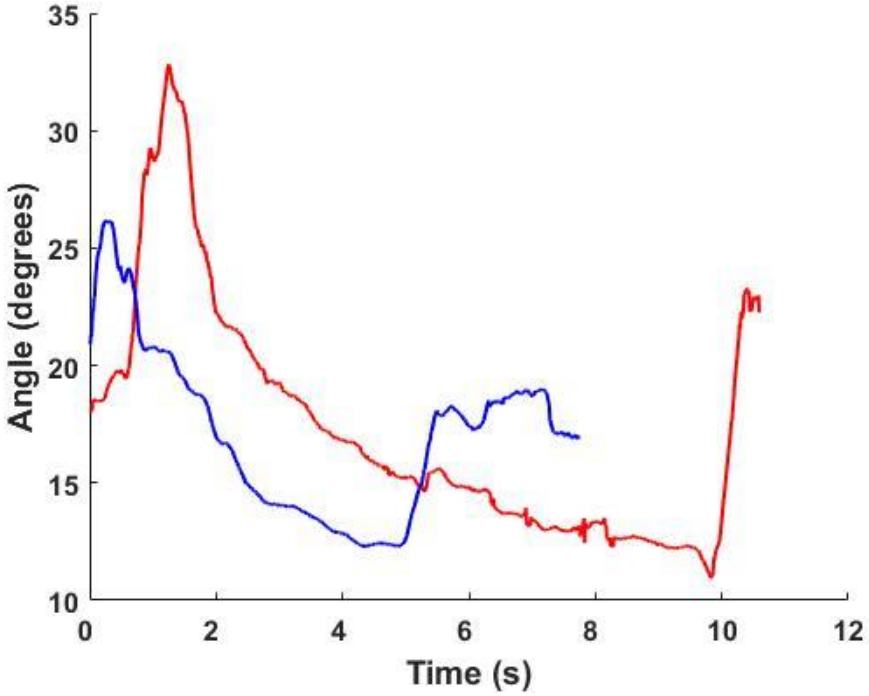
Table 4.5 - Average ± SD upper limb measurements for Participant 05.

Participant 05	**Reach Forward (RF)**		**Reach to Side (RS)**		**Reach Up (RU)**	
	Without WSD	With WSD	*Without WSD*	With WSD	*Without WSD*	With WSD
Shoulder Flexion/Extension (°)	41.8±5.9	10.1	12.4±3.0	17.3±1.1	38.0±5.1	21.9±3.9
Shoulder Abduction/Adduction (°)	21.6±3.8	13.9	33.7±3.0	50.1±1.4	15.9±2.0	29.1±9.3
Finger Marker Trajectory (mm)	101.6±18.2	189	391.8±28.8	604.6±21.4	296.7±35.3	267.4±20.3

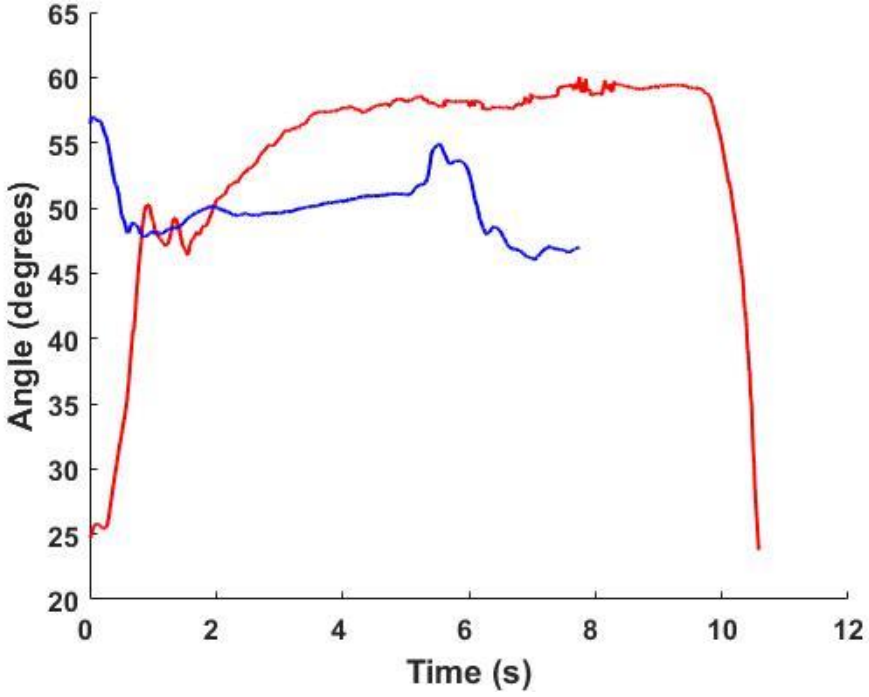
In the RF task (figure 4.10), the participant had decreased range of motion in shoulder flexion/extension and shoulder abduction/adduction but increased finger trajectory of approximately 90mm. In the RS task (figure 4.11), range of motion increased for all three measurements with average finger trajectory increasing by 212.8mm. For the RU task (figure 4.12), increase in shoulder abduction/adduction were exhibited but shoulder flexion/extension and finger trajectory decreased.


Without WSD
With WSD
Trajectory (mm)
200
100
0
-100
-200
-300
-400
0
2
4
6
8
10
12
Time (s)

(a)

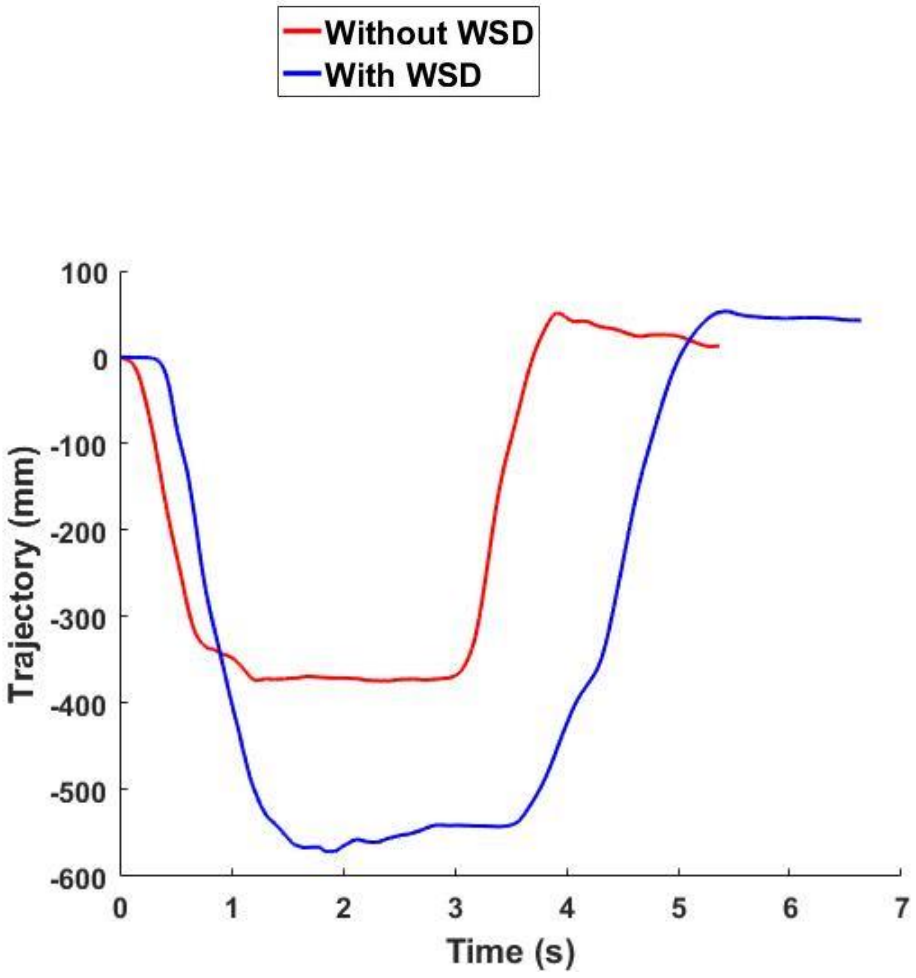


(b)

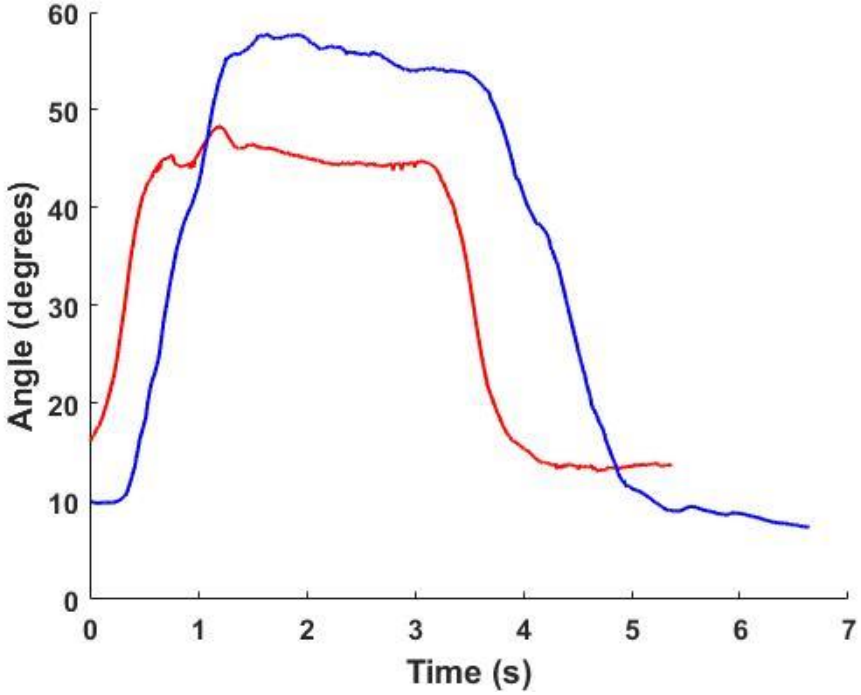


(c)

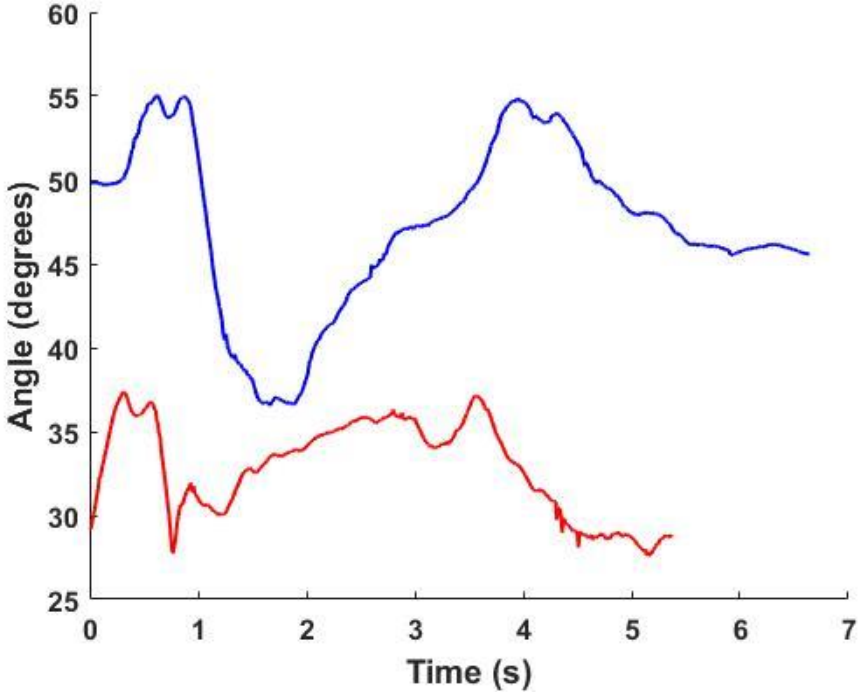
Figure 4.10 - Participant 5 range in upper limb measurements for one repetition of the RF task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).


Without WSD
With WSD
100
0
-100
-200
-300
-400
-500
-600
Trajectory (mm)
0
1
2
3
4
5
6
7
Time (s)

(a)

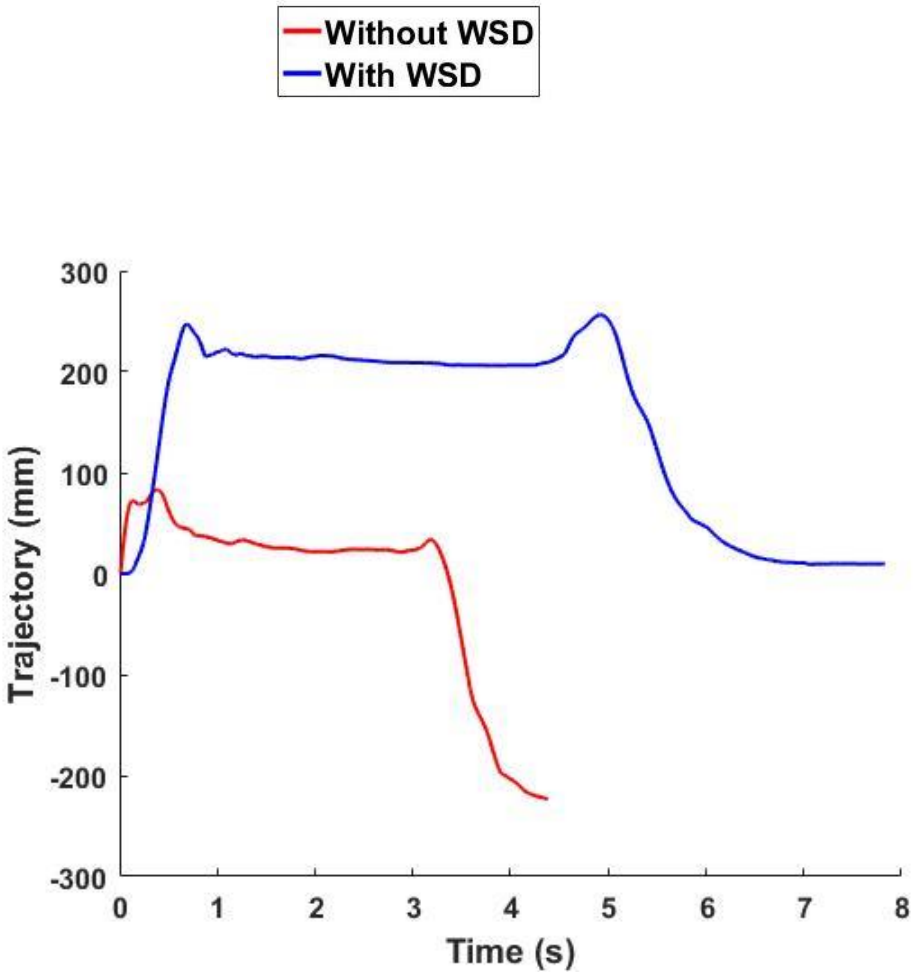


(b)

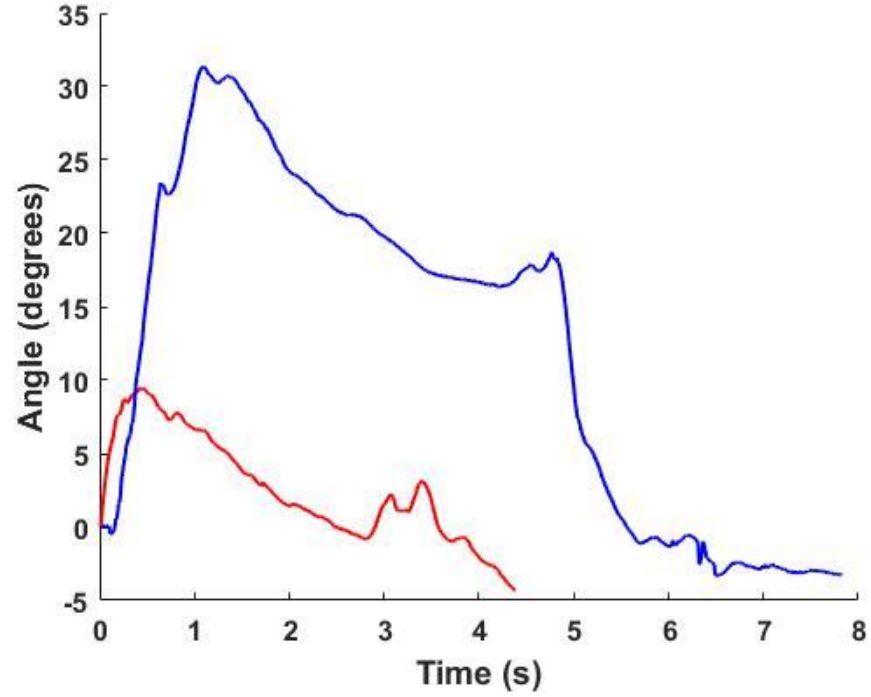


(c)

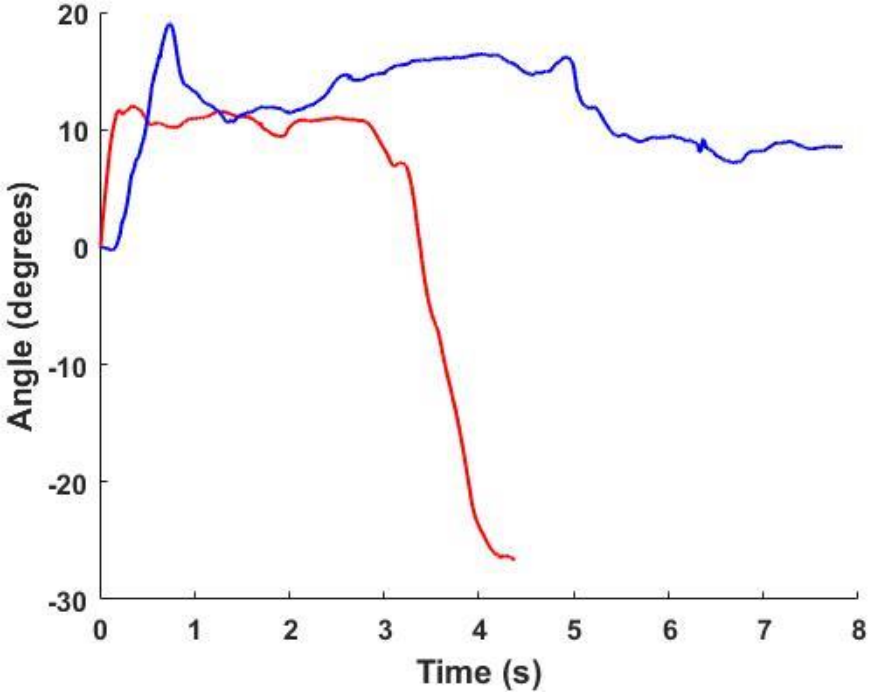
Figure 4.11 - Participant 5 range in upper limb measurements for one repetition of the RS task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).


Without WSD
With WSD
Trajectory (mm)
Time (s)
300
200
100
0
-100
-200
-300
0
1
2
3
4
5
6
7
8

(a)



(b)



(c)

Figure 4.12 - Participant 5 range in upper limb measurements for one repetition of the RF task without (red) and with (blue) the WSD. Measurements were finger marker trajectory in the respective plane of motion (a), shoulder abduction/adduction (b), and shoulder flexion/extension (c).

4.3.2.2 Interviews Responses (Stroke Participants)

Question 1: Were you happy using the device?

All participants were happy using the device though some noted that they were not able to do much in terms of movement currently in order to properly assess it. One participant said that they could see themselves improving if they could use it for a longer period of time.

Question 2: Did you find it easy to use?

Three participants found the device straightforward to use although one of the three noted it would be quite challenging for them to get their arm into the device on their own. One participant said it was quite difficult for them to use as a result of their upper limb function.

Question 3: Do you think the device could improve your arm function?

Two participants believed that the device would be beneficial to their upper limb function over time due to the support provided. The other two participants were unsure after one use if the device could help improve their arm function, one saying it was a result of their current arm function and the other feeling they would need to use it repeatedly in order to see a difference.

Question 4: Did you find the device comfortable?

All participants found the device comfortable for the majority of usage. One participant noted slight discomfort in their upper arm but that they were happy to get some movement and sensation in that area.

Question 5: Would you find it easy to set-up?

Two participants noted that they would need help initially to set up the device and to put their arm into the support. In contrast one participant noted that if they were shown a demonstration or provided instructions, it should be relatively simple to set up. Another participant noted that it would be straightforward to set up as "it's just a clamp."

Question 6: Do you think you could set it up on your own at home?

Opinions for setting up at home were similar to question 5. One participant commented that they have a table in their kitchen they could use for set up and use of the device.

Question 7: Can you see yourself using this on a regular basis (e.g. daily, weekly)?

Participants commented that they would like to use the device repeatedly, some wanting to use it every day to a few days a week on a regular basis.

Question 8: Have you used other arm movement training techniques/equipment before?

Participants had used a variety of arm movement training techniques/equipment before. One participant had used an exercise wheel and a tea towel on a surface to enable them to move their arm along and across a surface. The participant noted that using the tea towel was not engaging and quite boring to perform.

Another participant typically performed arm exercises as guided by their physiotherapist and had also used an arm exercise bike at a local gym to help with range of motion. For stretching, one participant used a pain roller to assist with stretching and opening their hand.

Question 9: What would you improve on the device?

Suggestions for improvements included incorporating a motor into the device to provide some amount of movement to users with severe impairment resulting in limited upper limb movement. One participant who felt slight discomfort during the study requested making a comfier support. Another participant requested a method for supporting the upper limb better as it kept slipping out of the support strap during the study. Two participants recommended that the forward and backward movement be fixed as it was difficult to perform these movements for the aforementioned RF task. One participant commented that a slider similar to a device they had used before could help facilitate this and hopefully allow the device to slide with the upper limb effortlessly.

Question 10: If it were possible, would you like to have one of these in your home?

Each participant would like to try it in their home to see if it would be feasible to use regularly but most were happy with prototype. However, some participants noted that it would need to be relatively cheap and within their budget if they had to purchase one.

4.4 Discussion

This study compared the performance of specific upper limb tasks with and without the use of the upper limb WSD prototype. Results associated with upper limb measurements in the stroke survivor group were mixed across the participants with some showing slight improvements in tasks with WSD whereas some comparisons

were unable to be made due to difficulty in performing the task both with and without WSD.

Feedback regarding the device was mostly positive with various aspects identified for improvements. Participants in the stroke survivor group generally felt the device would be able to help improve their upper limb function, acknowledging that they would need to use it multiple times to determine if there would be any benefit. Most participants also found the device comfortable while noting that there would be some difficulty setting themselves up with the device on their own (i.e. placing their arm in the cuff and strapping it in place). Furthermore, two participants expressed that they would likely require assistance to set up the device onto a table or work surface in its current state. It could be possible to initially set up the device in the user's home and left indefinitely for them to use at their convenience though this may not be feasible or desirable for all participants.

As mentioned earlier, healthy participants' measurements were not analysed from the motion capture system as they had a fully functioning upper limb. The majority of healthy participants' found that the device was too high making the device slightly uncomfortable for them to use. This was mirrored in the stroke survivor group leading to the use of a plinth with an adjustable height to bring the device down to a suitable and more comfortable position for these users (figure 4.4). Consequently, this identified issues related to the ease of use and portability that would not necessarily translate well into intended home use in the future.

A critical issue that required improvement was the cable for the weight support system. Initially a nylon cord, this was subject to considerable wear and tear and fraying from

the previous sessions. Ultimately, this led to the cord snapping during demonstration to one of the participants in the stroke survivor group. Subsequently, this session was suspended and unfortunately the participant could not be rescheduled for another visit. Replacing the nylon cord with the 2mm steel cable was employed as a temporary solution for the subsequent participant (Participant 02). This cable presented its own issues as it tended to get stuck between the rollers and the top interior wall of the device due to its larger diameter. As a result, the weight support mechanism was not as smooth as desired presenting some usability issues with the user. A more permanent solution was achieved using a 0.7mm steel wire, which had minimal interference with the device interior providing a smoother action for the remaining users. This wire was used for the remainder of the study.

One of the main points identified from this feasibility study was the difficulty participants experienced performing all of the tasks. This was, in part at least, due to the severity of their impairment but appeared to be confounded by movement restrictions of the WSD. In particular, moving the device forward and back due to weight of the arm pushing down on that revolute joint between the horizontal member and the crutch assembly preventing it from rotating freely. Using a revolute joint to provide this type of movement was determined in order to reduce the overall size of the device while still being able to provide suitable range of motion to the user. However, in practice this was not feasible. In addition to the weight of the four-bar mechanism, placing a load (i.e. the participant's arm) in the cuff, in turn, generated a moment perpendicular to the vertical axis of the revolute joint, preventing it from rotating efficiently in this axis as intended.

As mentioned previously, each participant only used the device for one session with time engaged with the device ranging from 10-30 minutes per participant. This was due to lack of resources in time and lab space, in addition to fatigue reported by some participants in the stroke survivor group. Consequently, another study is advisable, following improvements to the prototype, to gauge user engagement and enjoyment with the prototype over multiple sessions. One study provided people with muscular weakness a mobile arm support for a period of 2-6 months with the expectation that they use it daily (Herder et al. 2006). While only providing the device to three different users, the extended length of time in which the device was used can provide greater indication of compliance and understanding of how the device works in addition to providing a better understanding of the user's needs and clear evidence for areas of improvement.

The upper limb measurements chosen for recording were the range of motion in shoulder flexion/extension, shoulder abduction/adduction, and finger marker trajectory in the respective plane of motion (i.e. RF task – x-axis; RS task – y-axis; RU task – z-axis). These specific measurements were chosen over others (i.e. elbow flexion/extension) because the device was intended to support the upper arm near the shoulder. Therefore, movement in this area was decided to be focused on whereas measurements from the elbow to the hand were not included as it was not anticipated that there would be any differences in these areas. Bartolo et al. measured range of motion for shoulder flexion/extension and shoulder abduction/adduction for participant's undergoing weight support training for the upper limb (Bartolo et al. 2014). However, they achieved this using only three markers, one on each shoulder and one on the handle of the weight support device and not using a full upper limb

marker set. Furthermore, the author calculated normalised jerk of the participants' upper limb movements to provide a measurement of the smoothness of the movements. While jerk was not measured in this study, it could be interesting to explore this in future studies as an indication of device performance (i.e. can it hold the arm in place and allow the user to perform movements with minimal shuddering). Movement smoothness has been use as a therapy target regarding motor learning as it implies movement that is more efficient (Balasubramanian et al. 2015). Figure 4.5 provides an example of the device allowing the user to perform the movements with less jerk than without in the RF task. However, this difference was not exhibited as prominently with the other tasks and/or participants though this could have been a result of lack of familiarity with the device.

Participants in the stroke survivor group exhibited moderate to severe upper limb impairments with three exhibiting severe complications. An increased number of participants would have been beneficial to obtain more feedback on the system but also to obtain more results from various levels of impairments, particularly at the mild to moderate level. As stroke is a heterogeneous disease, having a larger cross section of patients exhibiting different types and levels of impairments can help improve external validity of the device. Nijenhuis et al. also reported that mild to moderately impaired patients were more likely to benefit from their intervention noting that all participants in the study were chronic stroke patients (Nijenhuis et al. 2015). In contrast, a study looking at subacute patients with levels of impairment ranging from mild to severe reported that moderate to severely impaired patients benefitted more with greater gains in range of motion for shoulder flexion (Chan et al. 2016). Other studies have only recruited participants exhibiting moderate to severe impairments

(Rodgers et al. 2017; Klamroth-Marganska et al. 2014), suggesting that those with mild impairments may not benefit from this type of training though these implemented robotic-assisted training as opposed to gravity-assisted only such as with the proposed prototype for this project.

One goal of this project (see Introduction – Research Aims and Objectives) was to incorporate feedback with the prototype in the form of interactive games/exercises. Doing so could potentially engage the user more and encourage them to use the device on a more frequent basis. Nijenhuis et al. reported that in a study combining a motivational game environment with an upper limb and hand device, participants found the training interesting and were more likely to be actively engaged in this type of training for a prolonged period (Nijenhuis et al. 2015). Another study employing the T-WREX system for upper limb therapy reported that 90% of users preferred this over conventional therapy with the majority finding the system "less boring, less confusing and easier to track their progress" relative to their conventional therapy via table-top exercises (Housman et al. 2009). Furthermore, they also measured reaching range of motion deficit, calculated as the mean distance between a marker on the participant's wrist and the a target that the participant had 5 attempts to reach (Housman et al. 2009). Adding measurements related to task completion could be beneficial to determining whether the user is improving their performance, which in turn can be relayed back to them for motivation/encouragement. In light of this, a feedback system incorporating interactive games and score tracking will be designed and included in conjunction with the next iteration of the WSD prototype.

4.5 Conclusion

This small (healthy participants – n = 8; participants living with stroke – n = 5) feasibility study showed that the proposed prototype was acceptable for use with stroke survivors although improvements will be necessary to further enhance its capabilities. These included refining the forward and backward movement of the device, increasing the range of height adjustability, and methods to prevent the upper limb from slipping out the cuff during use.

Upper limb measurements for the stroke survivor group were inconclusive as to whether the device could help improve upper limb function. Multiple sessions per participant will be required to provide a better indication of the device's performance in providing assistance with upper limb exercises. Furthermore, implementing interactive exercises with the system could help engage the user in their exercises through real-time feedback and score tracking and progression.

The next chapter will focus on improving the prototype based on the feedback provided in the last two chapters followed by a study testing the next iteration with stroke survivors both in a laboratory and home setting.

5 Prototype Revision and Final Study

5.1 Introduction

Upon completion of the feasibility study, a wealth of qualitative data had been obtained on the initial prototype. Continuing to follow the Double Diamond model from the British Design Council, the next stage involved using these data from stakeholders and translating it through new features and/or improving characteristics that were identified as needing improvement during the initial trial (Design Council 2019). Testing this next iteration is crucial to ensure the changes made are suitable for the intended market.

A major addition to the work, in conjunction with the prototype alterations, was the inclusion of performance feedback to the user in the form of interactive games. This was included to enhance the user's overall experience by providing pre-set targets for the reaching tasks and generating audio-visual feedback on performance. The primary reasons for this addition were: (1) to improve motivation for carrying out the exercises and (2) to promote motor re-learning by providing feedback on movement performance (see section 1.6 for more detail).

This chapter will detail the changes made during the design and development of the next iteration of the weight support device in addition to the creation of the feedback system. Additionally, it will present the methods and findings of the final study which incorporated both the device improvements and feedback to participants living with stroke. This was to determine the usability and feasibility of the overall system over multiple sessions, including home use, as would be normal practice in rehabilitation.

5.2 Prototype Updates

Several features were identified for improvement. Firstly, the mechanism to enable the device to move forwards and backwards was identified as needing improvement as this movement was found to be the most difficult to execute in the feasibility study (see section 4.3.3.2). Subsequently, the need for smooth movement was identified as a key issue for development. Secondly, the first cable used for the weight support mechanism was not suitable for multiple uses as it degraded through repetitive use. Therefore, a new component was required to accommodate this function while also increasing longevity to enable use for a sustainable amount of time. Thirdly, the upper limb would occasionally slip off the cuff while being used by participants living with stroke. Thus, a method to prevent this from occurring was required through modification to the assembly. Finally, an extra support for the forearm that could potentially facilitate elbow flexion/extension was included in the design to improve comfort as well as range of motion.

5.2.1 Forwards and Backwards Movement

To enable the device to easily move forwards and backwards during reaching movements, a component to facilitate this was required. A slider in the form of a linear guide and carriage (figure 5.1), was considered the best solution. To accommodate this new component, the horizontal bar that connected the four-bar assembly to the clamp and enable it to rotate around the vertical axis at that joint was removed. The balls bearings within the carriage allowed it to run smoothly back and forth along the rail even with a substantial load applied. In the case of the upper limb, the average load (assuming a range of 30-50N) was deemed suitable enough to allow the carriage to

move efficiently up and down the slider with minimal friction. As the linear guide and carriage used was an existing one from the university's workshop, the exact make and model was unknown. Furthermore, the component was modified slightly to incorporate it into the prototype successfully. Based on the dimensions of the component, similar models were found online (Automotion Components, Chichester, United Kingdom). The closest matching model used a rail width of 15mm. The static load capacity of the carriage (the maximum static load that can be applied before plastic deformation of the ball bearings and rail occurs) was 19.9kN. The dynamic load capacity (the maximum moving load that the system can withstand) was 11.67kN. Assuming the upper limb mass can range from 3-5kg, the applied load corresponds to approximately 30-50N. Including the weight of the four-bar assembly and forearm assembly (see section 5.2.3) at approximately 20N gives a total range from 50-70N, substantially lower than the capacity values therefore deformation to the bearings from using the prototype with the upper limb as intended would be unlikely. Therefore, as previously described, the device could run smoothly along the rail. Custom made mounts were also made in order to attach the linear guide to both the four bar assembly and the clamp (see figure 5.2).

5.2.2 Cable Replacement

As reported in chapter 4, the nylon cord initially used in the feasibility study snapped after multiple uses (approximately 100s of repetitive loads) as a result of fraying from wear and tear, specifically friction over the bottom roller in the four-bar base (see figure 3.8). Subsequently, two replacements were used. Firstly, a 7x7 2mm white PVC coated steel wire rope was used (GSPRODUCTS, Dudley, United Kingdom). However, the diameter of the steel wire was too large to comfortably fit in the gaps

between the rollers and the interior of the four-bar base leading to increased friction between the surfaces and causing the weight support mechanism to improperly function. This rope was only used for one participant as a temporary solution. For the remaining participants, a 7x7 0.7mm steel wire rope with a capacity of 23kg (corresponding to approximately 226N) was purchased, allowing it to be comfortably incorporated within the support mechanism and be more resilient to the wear and tear that damaged the nylon cord, causing it to fail. This cable was included in the next iteration of the prototype for its small diameter and strong mechanical properties.

5.2.3 Forearm Support

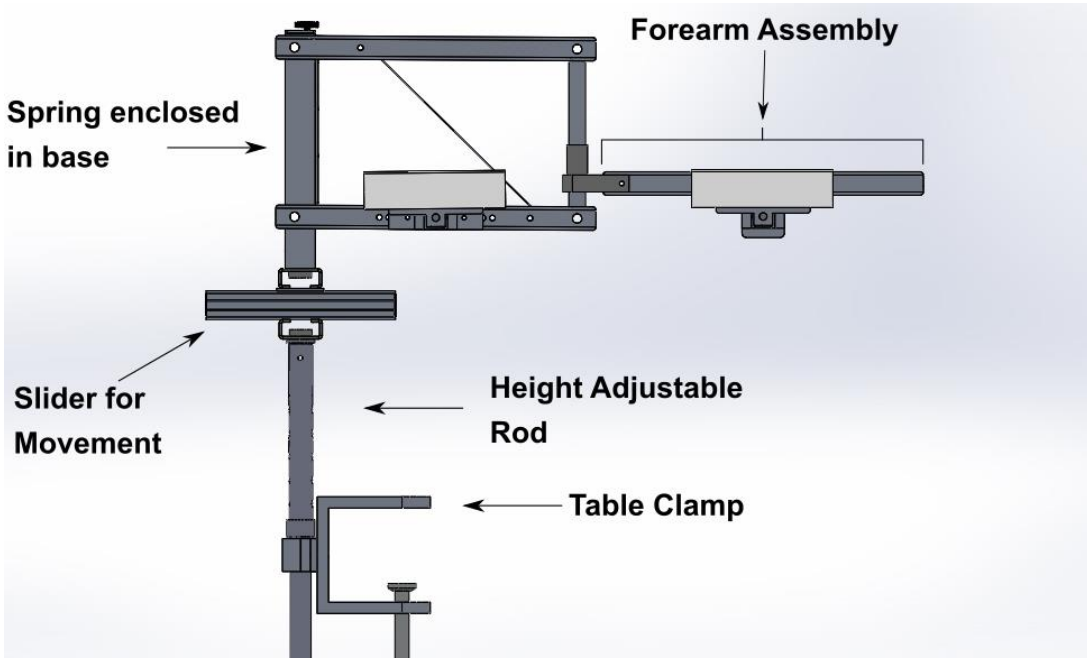
While the original prototype was designed to support the upper arm, feedback from stakeholders (see section 2.6.4) included support for the forearm. This was to improve comfort and allow more severely affected stroke survivors to use the device, primarily as it was believed that an extra point of contact would make the user feel more secure and/or in control when using the device (see section 3.5.3). An extra assembly was created for attachment to the four-bar assembly to provide this support (see figure 5.1, 5.2 & 5.3). To achieve this, another four-bar linkage was added to the opposite side of the four-bar assembly in order to slot the extra support assembly in place. This design enabled the upper limb cuff to be placed on either side of the prototype allowing the device to be easily configured for the left or right side, a feature missing from the first iteration of the device. The extra three bars to create the second four-bar linkage were of the same dimensions of those in the first linkage to make the device symmetrical. Holes to secure the support cuff on the bottom bar were also aligned similarly.

To generate the forearm assembly, a cylindrical tube was inserted between the two distal bars of the now amended four-bar assembly. A cylindrical outer sheath was placed around this tube and a small custom-made clamp placed around the sheath. The bar to be used for the forearm assembly was then attached to this clamp. The outer sheath can then rotate around the cylindrical tube and in turn allow the forearm bar to rotate around the vertical axis, allowing flexion/extension to occur at the elbow. Small holes were drilled out of the forearm bar to allow the second support assembly to be fitted and to allow the user to customise the position of the support.

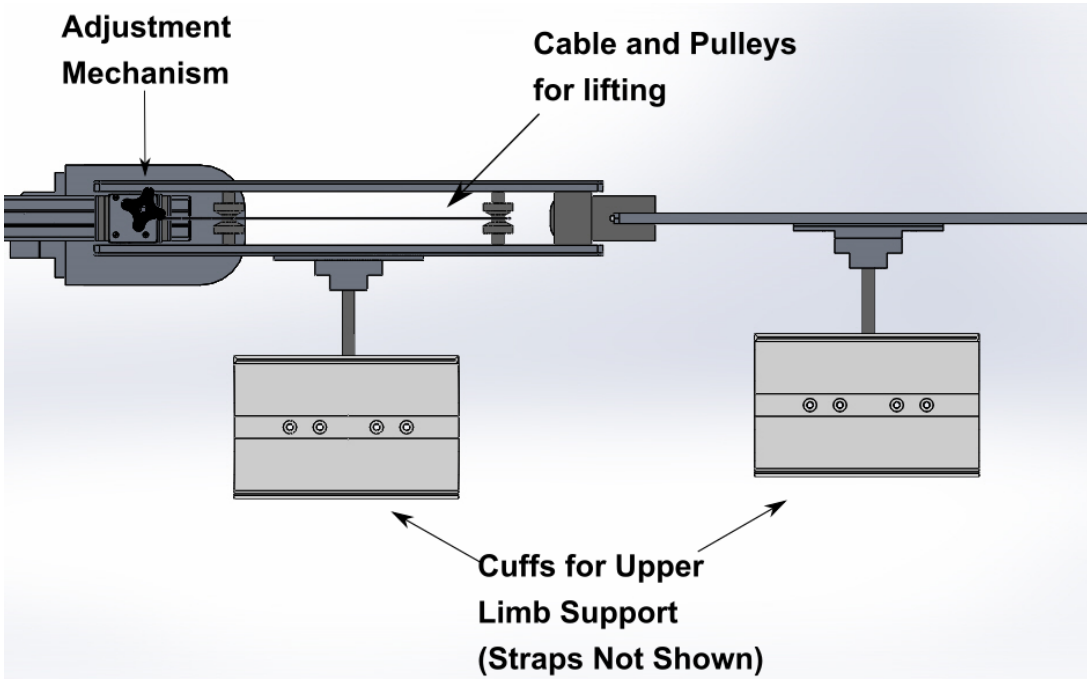
Finally, to help prevent the user's upper limb from slipping out of the cuff, a second Velcro strap was attached to each support to secure the arm in place.

5.2.4 Final Prototype

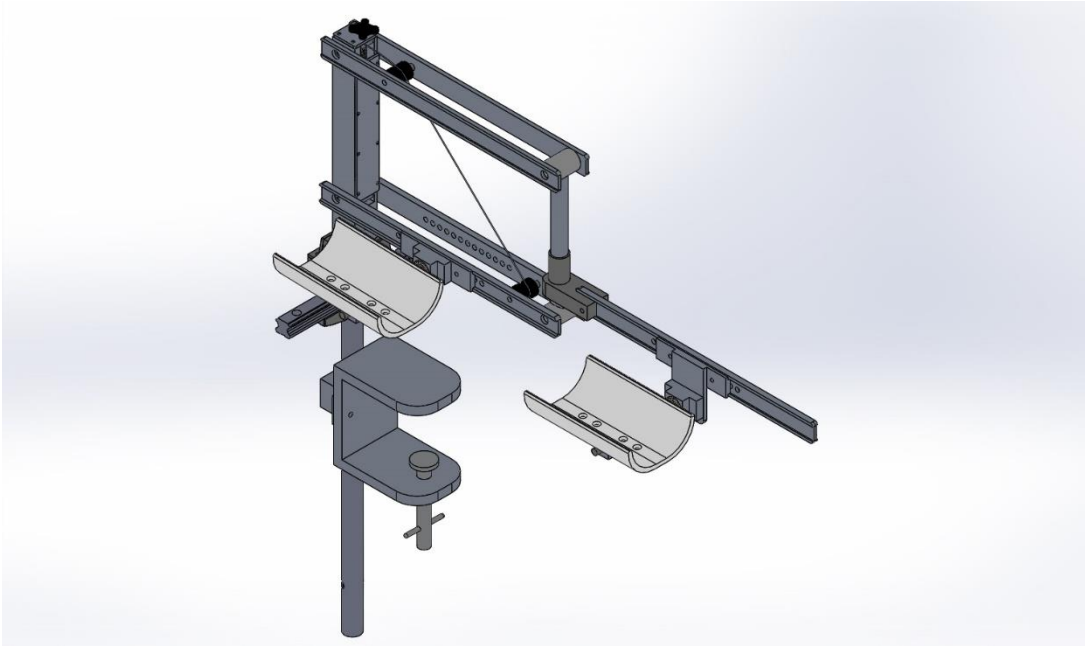
Figure 5.1 shows a Solidworks (Solidworks® Student Edition 2016-2017, Dassault Systèmes, Vélizy-Villacoublay, France) model of the second iteration of the prototype. Figure 5.2 and 5.3 show the physical prototype following modifications to the first iteration based on the Solidworks model.


Forearm Assembly
Spring enclosed
in base
Slider for
Movement
Height Adjustable
Rod
Table Clamp

(a)


Adjustment
Mechanism
Cable and Pulleys
for lifting
Cuffs for Upper
Limb Support
(Straps Not Shown)

(b)



(c)

Figure 5.1 - Solidworks model of the second iteration of the prototype. (a) – Elevation view; (b) – Plan View; (c) Isometric view. The final slider and mount assembly is shown in (c) as the slider shown in (a) was modelled as a rough concept of the slider mechanism.

Due to the addition of another four-bar linkage, the forearm assembly and the slider assembly, the overall size and in turn, weight of the prototype has increased (from approximately 2.3 to 3.2kg). However, the anticipated benefits of these extra features were deemed essential in improving the usability and accessibility of the device for the user, though further feedback will be required to confirm.

Though not initially intended during the design of the second iteration, the slider can be rotated via the crutch before being clamped in place allowing for the user to perform movements with their arm in other directions. However, rotating the slider requires the use of hex keys with this iteration of the prototype which may be challenging for some users without assistance. Additionally, it was decided to make the forearm support an optional component of the device dependant on user preference and/or the severity of

their upper limb impairment. The assembly can be attached and detached from the four-bar assembly without the requirement of tools allowing for the user to decide if they wish to include the second support when using the device.

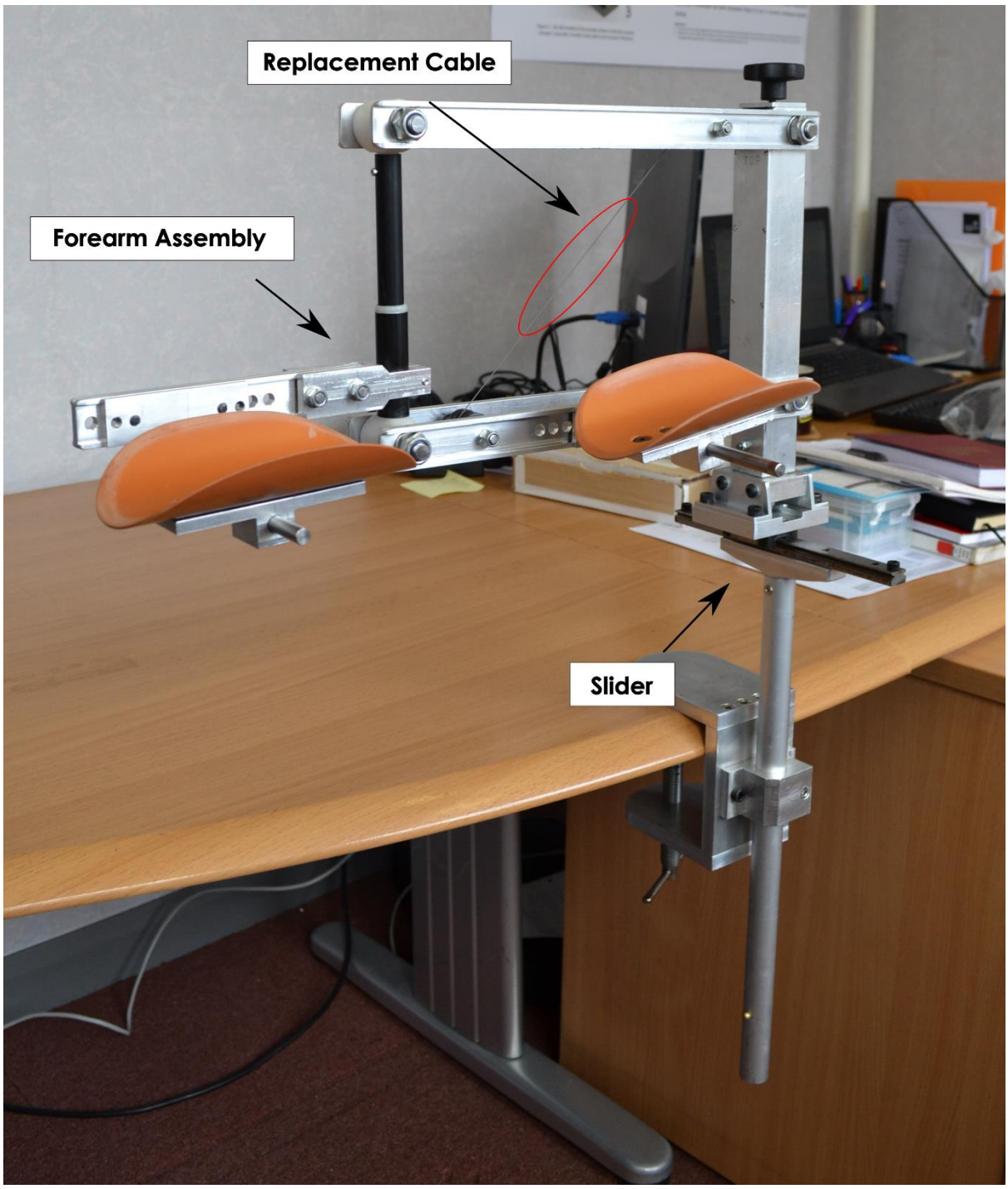


Figure 5.2 - Second Iteration of the weight support prototype clamped to a desk with updated features labelled (replacement cable highlighted in red). The slider mechanism allows the assembly mounted onto it to move in either direction along its rail.

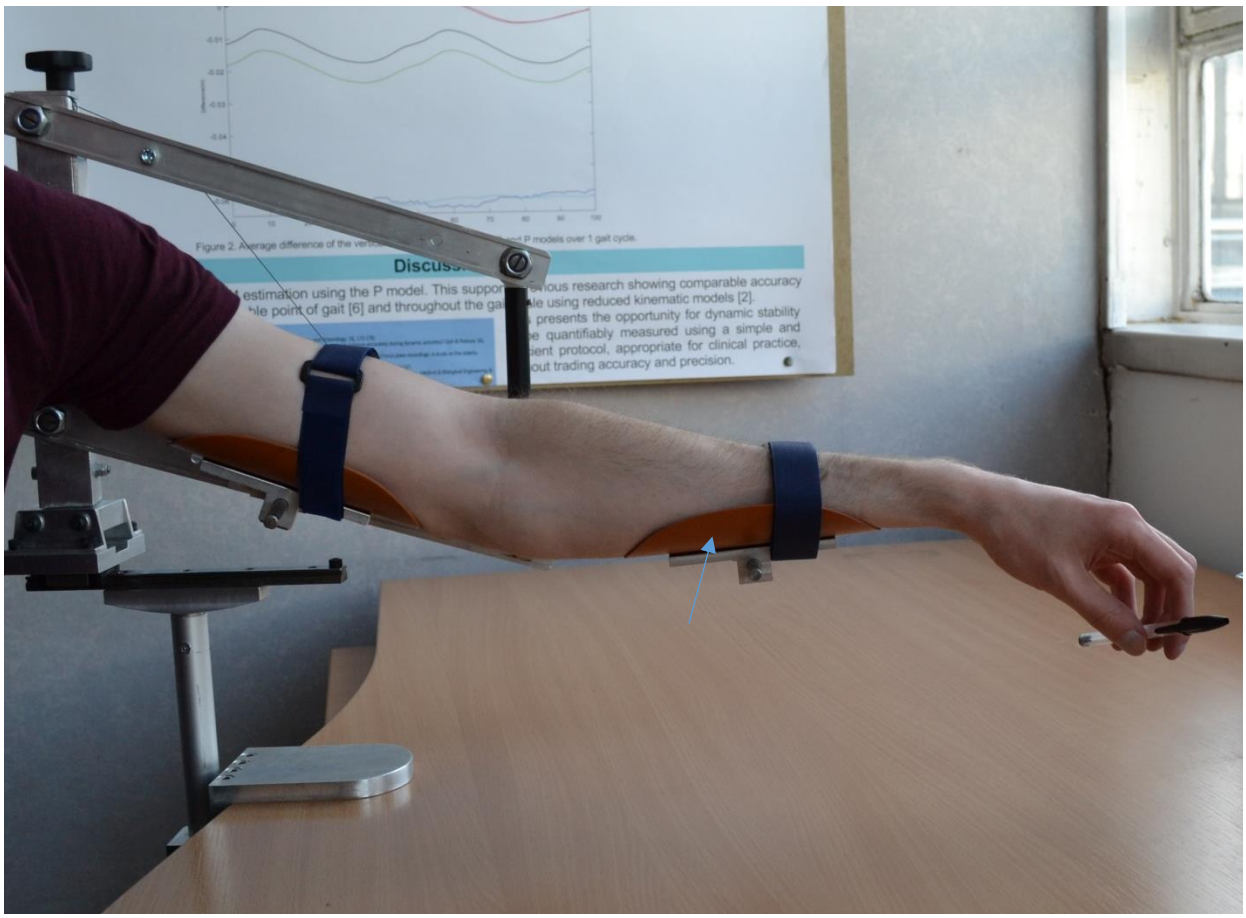


Figure 5.3 - User with an unimpaired upper limb with their upper limb secured to the prototype.

5.3 Game Feedback System

In order to develop a feedback system to be used in conjunction with the prototype, the appropriate hardware and software to develop the feedback system was explored. The overall aim was to develop a system that was simple to set up and understand while providing feedback on arm movements. D-Flow (D-Flow, Version 3.28.0, Motek Medical BV, Amsterdam The Netherlands) is a visual programming software designed to develop interactive virtual reality applications for clinical research and rehabilitation (Geijtenbeek & Steenbrink 2011). The software provides the user with a workspace in which they can drag and drop various modules that range in function

from controlling specific types of hardware, to generating text and data and outputting this to a virtual environment. A key feature of the software is that the subject interacting with the applications developed is considered an integral part of the real-time feedback loop. A range of input signals (e.g. 3D trajectories from a motion capture system and motion sensors such as an inertial measurement unit, IMU, and proximity sensors) can be included as part of an application to monitor subject performance and output this to the user via tactile, auditory, or visual feedback. Moreover, this feedback loop can be used to alter the virtual environment and increase/decrease the difficulty in real-time depending on the participant's progression.

Communication between modules can be achieved in two different ways; data-based and event-based. Each module contains a number of input and output channels. For data-based communication, each output channel from a module can be connected to the input channel of another module creating a link between the modules where data can be transferred. Select data can then be displayed to the user via this communication. For example (see figure 5.4), a participant's score outputted from a "Stopwatch" module can be fed to a "3DText" module and provide a visual display of the score to the user.

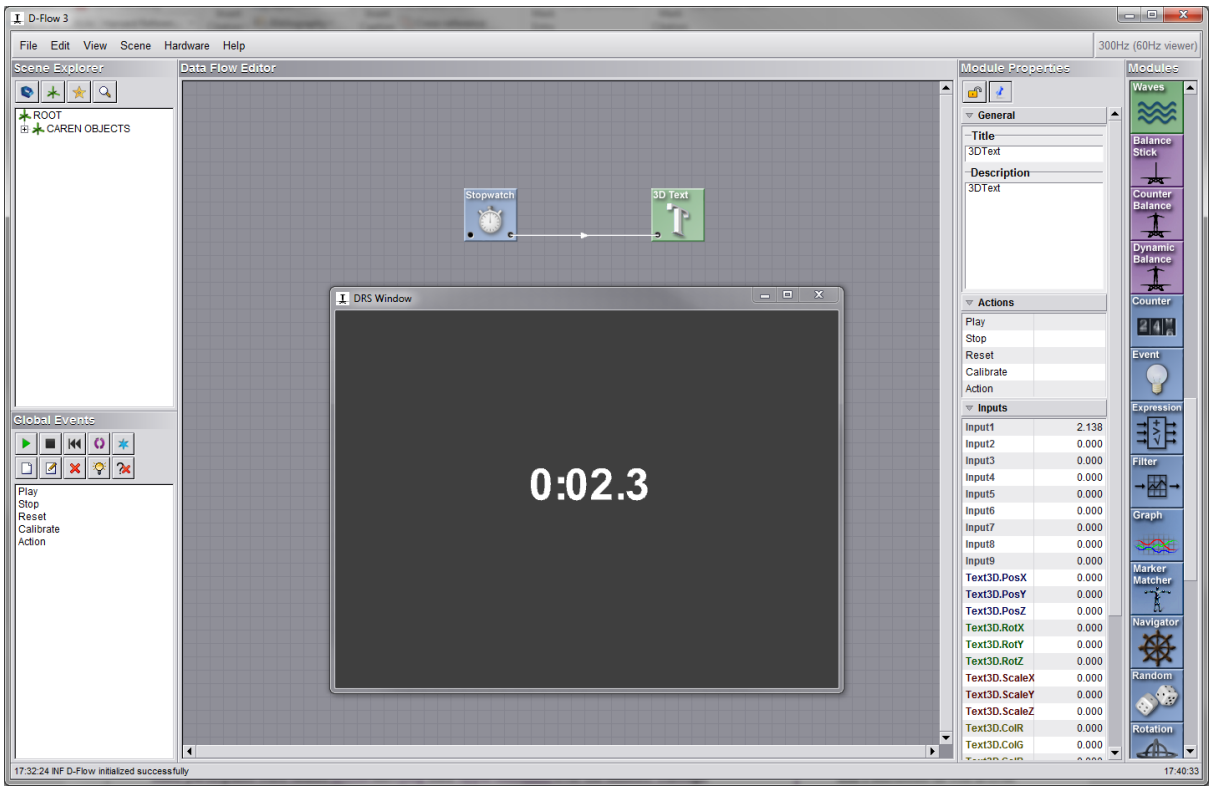


Figure 5.4 - Example of the D-Flow visual workspace and display window. The workspace shows a stopwatch module connected to a 3D text module. The time outputted from the stopwatch is displayed on the display window via communication between the modules.

Event-based communication relies upon the operator defining a set of global events for an application. Should these events be broadcast during the application (e.g. an event is triggered if a value reaches a certain threshold), each module in the visual interface can be set to respond to this event if required. This can range from showing or hiding objects in the user display window, incrementing a counter, or stopping the application if the goal of the application has been achieved. Additionally, D-Flow offers an internal recording module that can be used to save pre-selected input and output data in an application. For the following applications to be described, the user's repetition count was recorded in each one to monitor progress.

Using the D-Flow software, applications involving the subject reaching for several different targets were created. From a hardware perspective, these targets were

implemented as 10cm infrared reflective sensors (Phidgets Inc., Calgary, Alberta, Canada), which are also called proximity sensors. These sensors can detect the presence of an object within a 10cm range. When there is no presence of an object within this range, the device outputs a value of 1; when it detects an object (i.e. the user's upper limb) in range, it outputs a value of 0. These values can then be inputted into script modules in order to increment score counters, or control objects within an application. As such, participants were asked to move their hand over the sensors. Through D-Flow, several applications were created using these sensors as input devices.

5.3.1 Game Task 1 - Reaching Task

For this task, each sensor was visualised on a computer screen as a small red cube before the game began. When the game starts, one of the cubes is randomly selected and increases in size, changes colour (green) and begins to rotate to signify to the subject which sensor to reach for (figure 5.5).

Each object is numbered and a text instruction on the display is provided to the user on which target they are required to reach. The position of the sensors on the user's physical work surface reflect the virtual position on the screen (see figure 5.9). The data provided by the sensors were then inputted into the script module that checks if the subject has reached the intended target and triggers an event if they have. The event trigger increases the counter (no. of targets reached) by one and the script module then resets the target object and updates the next target the subject must reach. The target selection was randomised however each new target was different from the previous

one, to minimise repetition. The subject was asked to reach as many targets as possible within a specified time limit (e.g. 30 seconds).

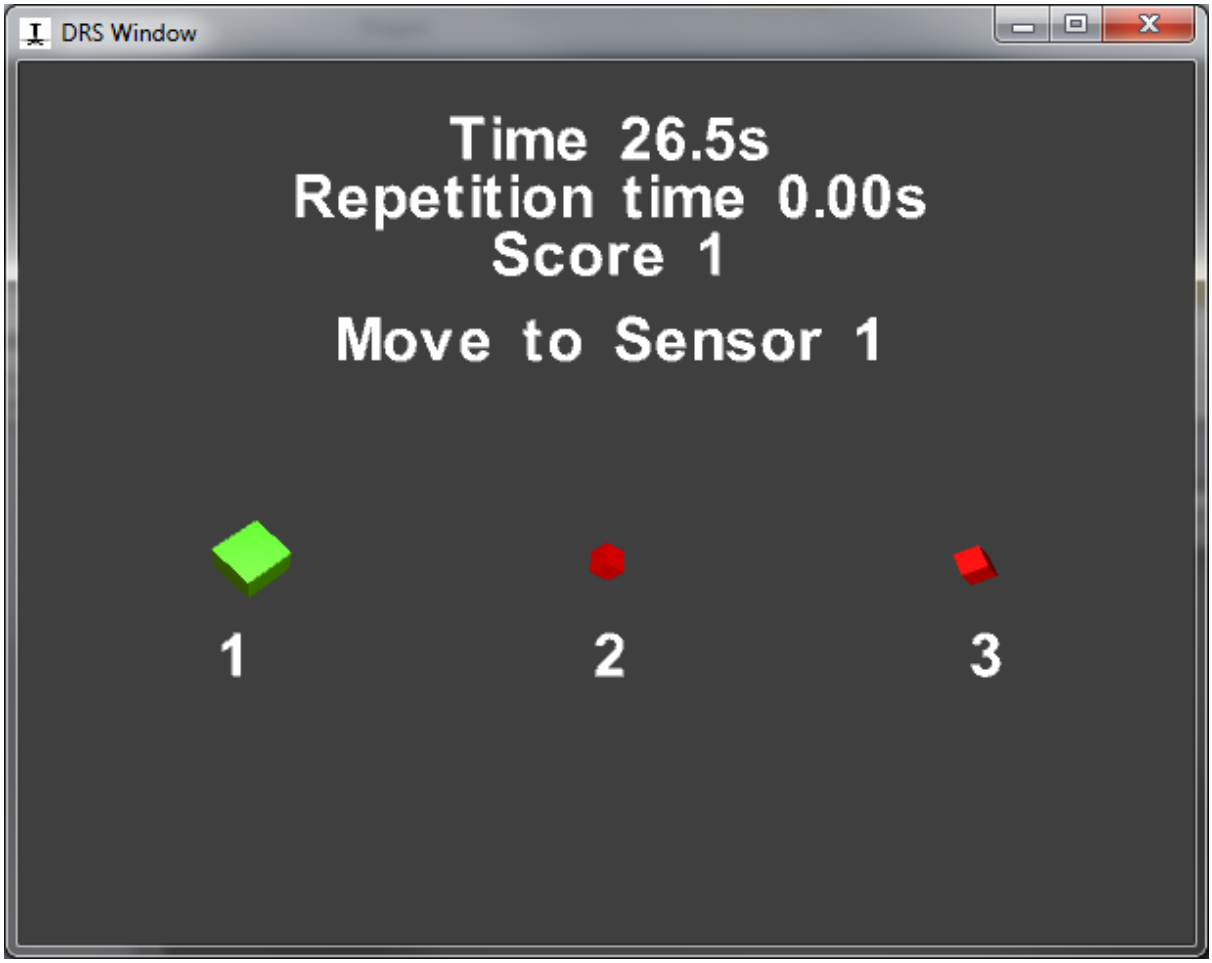


Figure 5.5 - Visual display of the reaching task in D-Flow. Each cube represents one proximity sensor placed in front of the participant in the same layout as on screen. The display communicates to the participant which sensor they are tasked with reaching and adds to their score when it is reached while also randomly selecting a new target.

An advantage of this game design was the ability to vary parameters such as reach distance, sensor numbers and game duration to increase or decrease the difficulty of the exercise for the subject in addition to providing them with different scenarios to try while using the device to reduce chance of boredom. Consequently, the setup could

be decided collaboratively between the user and therapist/carer and altered according to any change or desire for new challenge.

5.3.2 Game Task 2 - Moving Arm Side-to-Side

For this task, participants were asked to steer a red ball down a track using the sideways motion of their arm and use it to collect yellow cubes (figure 5.6). Should the ball collide with a cube in the game, an event is triggered similar to Task 1 and the counter (score) increments by one. The cubes are set equidistant from each other along the length of the track and have set positions on either the left, right, or middle of the track. These placements were set in a random configuration with each repetition of the exercise. To control the ball, two proximity sensors were placed at opposite ends of the participant's physical work surface on the left and right. Placing their upper limb over the left sensor causes the ball to move left and over the right sensor to move right. The ball continues to move down the track moving to the left or right dependent on the proximity sensor triggered. The participant was required to navigate the ball down the track collecting as many cubes as possible before the end. To change the difficulty of the game, both the speed of the ball and the distance between the sensors can be altered.

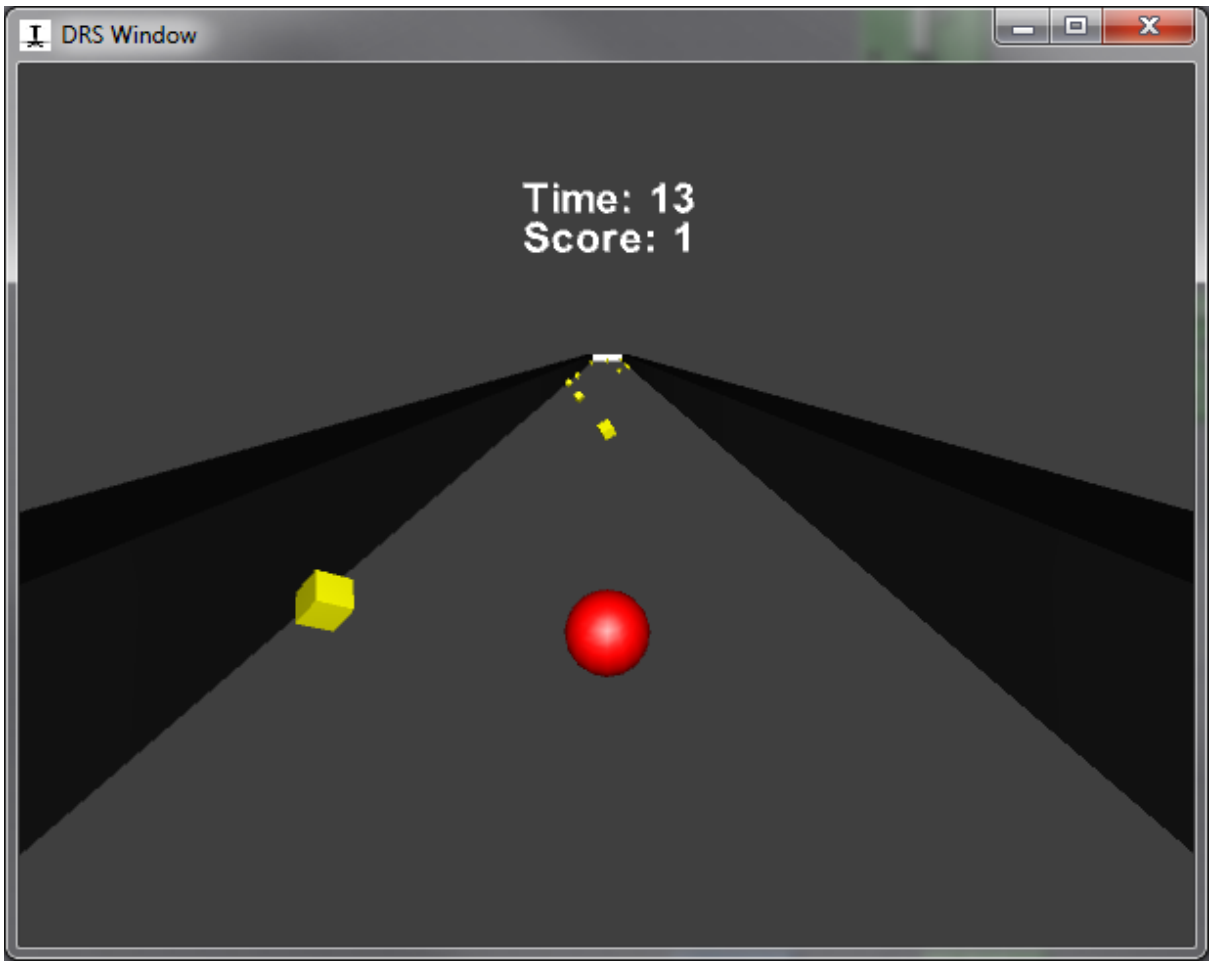


Figure 5.6 - Visual display of the application for moving the upper limb side to side in D-Flow. The participant is tasked with steering the red ball left and right to collect the yellow cubes as it continuously moves forward down a track.

5.3.3 Game Task 3 - Moving Arm Up and Down

This task has a similar design to Game Task 2. In this case, the participant's perspective of the game is altered. In this version the participant is shown a bird's eye view of the track with a 90 degree rotation of the track, meaning the ball continuously moves towards the right along the track (figure 5.7) and the ball can be moved vertically by the participant interacting with the proximity sensors. For this exercise, the sensors are placed at different points of elevation. In this exercise, the sensor to move the ball down will be placed on the users work surface with the sensor to move the ball upwards

placed at a suitable height above the work surface (placed on a box on the table). The difficulty can be increased or decreased similarly to the previous task (altering sensor distance and speed of the ball).

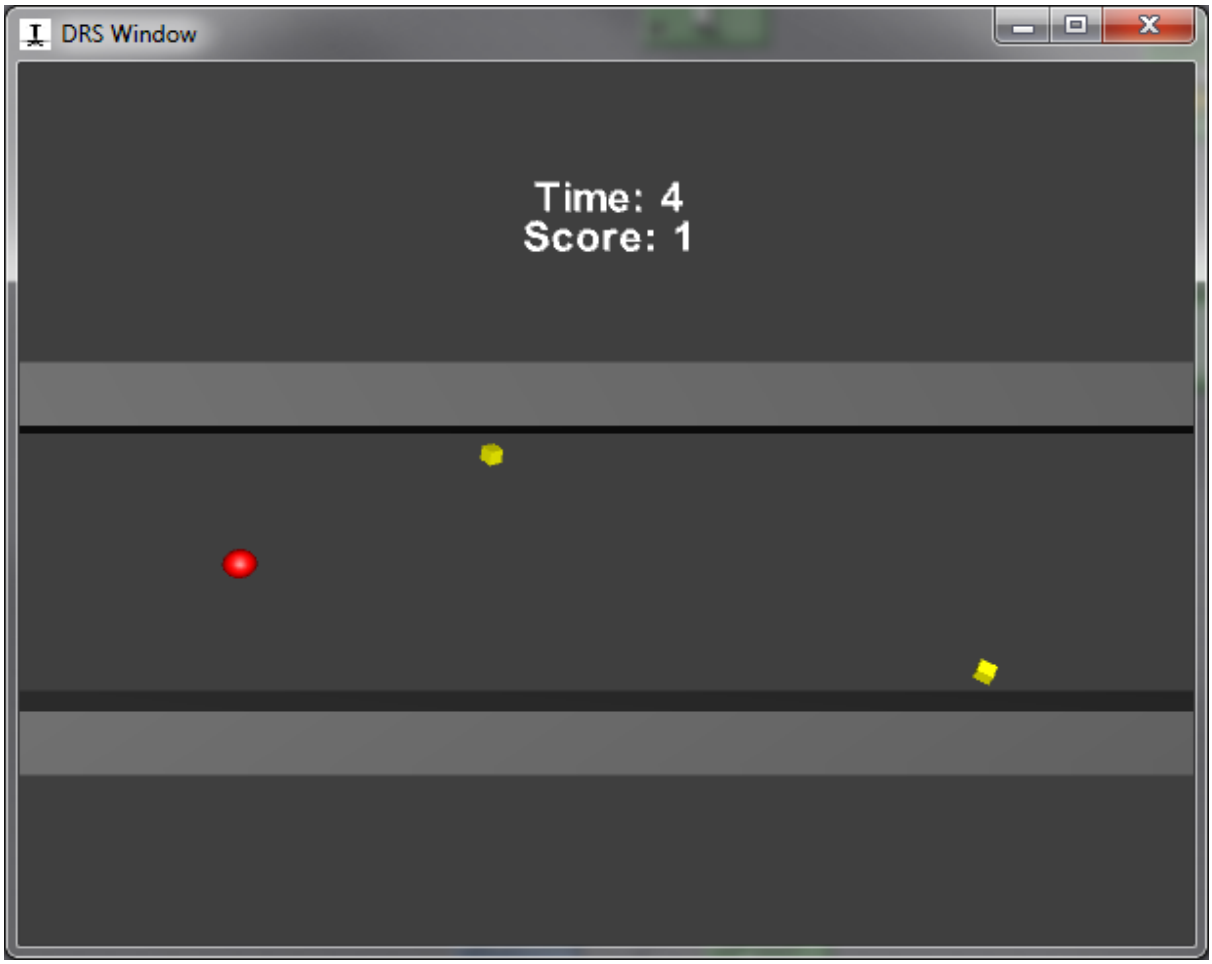


Figure 5.7 - Visual display of the application for moving the upper limb up and down in D-Flow. The participant is tasked with steering the red ball up and down to collect the yellow cubes as it continuously moves to the right along a track.

5.3.4 Game Task 4 - City Ride Application

The final task used an existing D-Flow game that was altered to enable the proximity sensors to be used as input devices. In this application, a car continuously drives forward down a road while avoiding oncoming traffic (figure 5.8). Similar to Task 2,

the user controls the car by steering it left and right via the proximity sensors. In this task, the participant must make the car travel as far as possible down the road while avoiding oncoming traffic and not steer the car to the edges of the road. The further the participant's car travels down the road in the allotted time (60 seconds), the more points they score. The car continually accelerates up to a pre-determined maximum speed and continues to travel at this speed until it collides with the sides of the road or another vehicle. If a collision occurs, the car slows significantly and must accelerate again to its top speed. The difficulty for this can be increased through increasing the maximum speed the car can accelerate to, allowing the participant to increase their score but require them to react quicker to oncoming traffic. In contrast, decreasing the speed of the car will allow the participant to more easily navigate the car down the road but also decrease the maximum possible score they can achieve. Similarly to the other tasks, the distance between the sensors can also be altered to increase/decrease the difficulty of the task based on the user's capabilities and preferences.

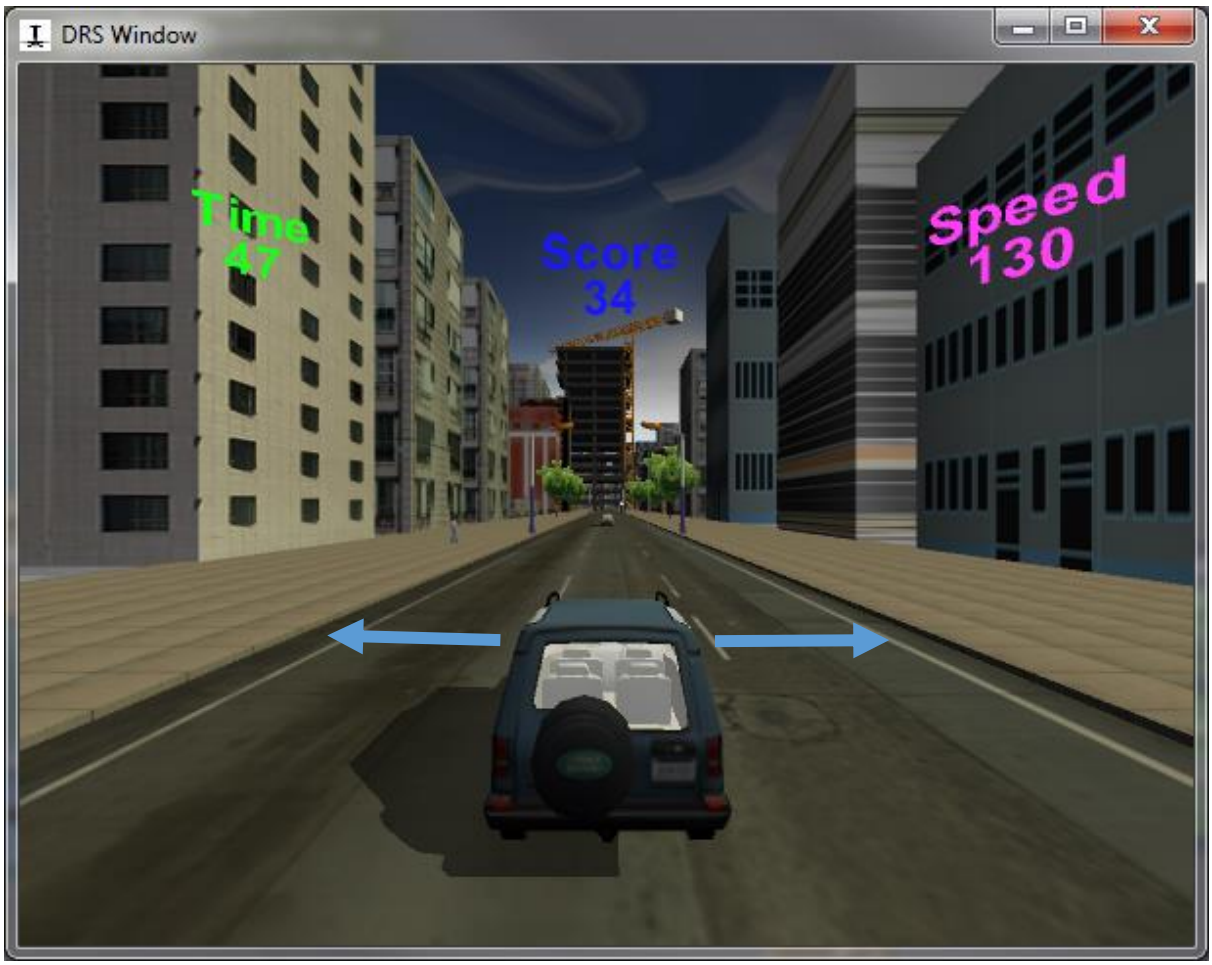


Figure 5.8 - Visual display of the application where the participant is tasked with steering a car travelling down a road. The goal is to make the car travel as far as possible while avoiding oncoming traffic and colliding with the pavement which slows the car down. The remaining time (top left – green), score (blue-middle) and car's speed (right-pink) are displayed at the top of the screen.

5.4 Final Study

With the completion of the second prototype and inclusion of the feedback games, another acceptability feasibility study was conducted. In order for user's to acquire a better understanding of the prototype, participants were able to use the device over multiple sessions to become familiar with it compared to the single session used in the previous study. Furthermore, where possible, conducting sessions with the device at

participants' homes was also desired in order to assess the device's feasibility and potential in the home environment.

5.4.1 Protocol

5.4.1.1 Design

This study adopted a single-case research design with a small number of participants acting as their own controls. Literature has described these types of studies as beneficial for determining the effectiveness of rehabilitation on a case-by-case basis by repeatedly measuring the outcome variables, and sequentially applying, varying, or withdrawing the intervention over time based on the individual's performance, tailoring it to their needs (Graham et al. 2012; Barnett et al. 2012). This design was chosen for the final empirical study in this thesis to fully explore the user experience (including home use) with the device as well as change in movement performance and function. Collecting large amounts of data from a small number of potential users was considered a more productive method for informing future iterations of the device, preparing proof of concept registrations and patent applications.

5.4.1.2 Participants

A small ($n<10$) convenient sample of individuals likely to use the device was targeted for recruitment using the criteria listed below.

The inclusion criteria were: (1) have suffered a stroke, which has resulted in reduced upper limb movement and function; (2) over the age of 18 years old; (3) able to communicate in English, both written and spoken though participants were invited to bring someone to assist them with this if required; (4) are able to attend 1-2 90-minute appointments per week for four weeks at the University of Strathclyde during working

hours (9-5) Monday to Friday; (5) are willing to use the device in their home for a 2-week period if the device is deemed suitable for their home environment; (6) are able to provide informed consent. The exclusion criteria were: (1) individuals who are unwell during the investigation period or are taking medication that may compromise their ability to participate; (2) individuals with significant speech problems that could limit communication with staff (e.g. informing staff they are unwell) presenting a barrier to the interview process; (3) individuals who have significant learning difficulties or/and cognitive impairment that would affect their ability to provide informed consent as assessed using the Mini-Cog test; (4) individuals with musculoskeletal injuries or conditions (e.g. arthritis) at the shoulder, elbow, wrist or hand unrelated to stroke; (5) individuals who are unable to participate more than once per week; (6) individuals who have any problems with their sight that have not been corrected with glasses; (7) individuals who have any problems with their hearing that have not been corrected with hearing aids. This study was approved by the university ethics committee.

Potential participants were sought from adverts distributed to local stroke clubs and charities and asked to get in contact via email. Participants from the previous feasibility study (Chapter 4) were also contacted if they would like to participate via email, this was desirable given their knowledge of the first iteration. Four participants were recruited to this study following informed consent. Two participants had participated in the previous feasibility study (see Chapter 4).

5.4.1.3 Methods

Potential participants were given over 24 hours to read the study information sheet and if they wanted to participate, they were invited to the university for an initial meeting to provide informed consent. Participants were able to claim travel expenses if making their own arrangements to travel to the university. If unable to arrange their own travel, transport to and from the university was arranged by the department via car. Following consent, participants were asked to complete a questionnaire providing details about their stroke and any existing rehabilitation and/or exercise equipment they had used for their upper limb.

Immediately following completion of this questionnaire, participants undertook the baseline assessments consisting of the Action Research Arm Test (ARAT) (Yozbatiran et al. 2008) and Nottingham Extended Activities of Daily Living Scale (NEADL) (Wu et al. 2011). Each participant was then invited to try the prototype with and without the game feedback system. Participants were then asked a few questions about their experience with the device, if they would like to continue to take part in the investigation and if so, if they would be interested in the investigator visiting their home to allow them to use the prototype there. Participants that wished to continue the investigation were invited to the university 1-2 times per week for 90-minute appointments. At the participant's next appointment, baseline measurements of the ARAT and NEADL were taken again before beginning the intervention.

Each participant was asked to perform between 15 and 30 minutes of upper limb exercises (as comfortable) using the weight support prototype and feedback system. Rest periods between each set of exercises (at least 1 minute) was designed to minimise

fatigue. At the end of each session, participants were asked a few questions about the session. With each successive session, participants were asked if they would like to increase the amount of time spent performing the upper limb exercises, allowing the inclusion of more tasks into the session (the first session would involve the first two tasks (see section 5.3.1 and 5.3.2) and subsequent sessions would add the others if the participant was willing). Participants were also asked if they would like to increase or decrease the difficulty based on their current performance.

Following two weeks of appointments at the university, if the participant agreed to use the prototype at their home and their home was deemed suitable to do so, the investigator conducted the remaining two weeks of the intervention at the participant's home. If this was not requested or not feasible, the participant was invited to continue the study at the university for the remaining two weeks. Following the four-week intervention period, each participant was assessed a final time with the ARAT and NEADL. Most importantly, at this point, a detailed interview was conducted with each participant to obtain their opinions and experience using the device.

For the university sessions an adjustable height folding table (length 1.22m, width 0.61m) was set up as the participant's working surface (figure 5.9). The height from the floor was set to 0.74m. The prototype was affixed to one corner of the table determined by the impaired side of the participant. An armless chair with a backrest was provided for the participant to do the exercises while seated. A laptop running the game with D-Flow software was placed on the table with the screen facing the user. The proximity sensors (see section 5.3) were connected to the laptop and software. The sensors were laid out on the table in accordance with the specific task for the

participant to interact with and receive feedback during their exercises. Figure 5.9 shows an example of the layout for sessions conducted at the university.

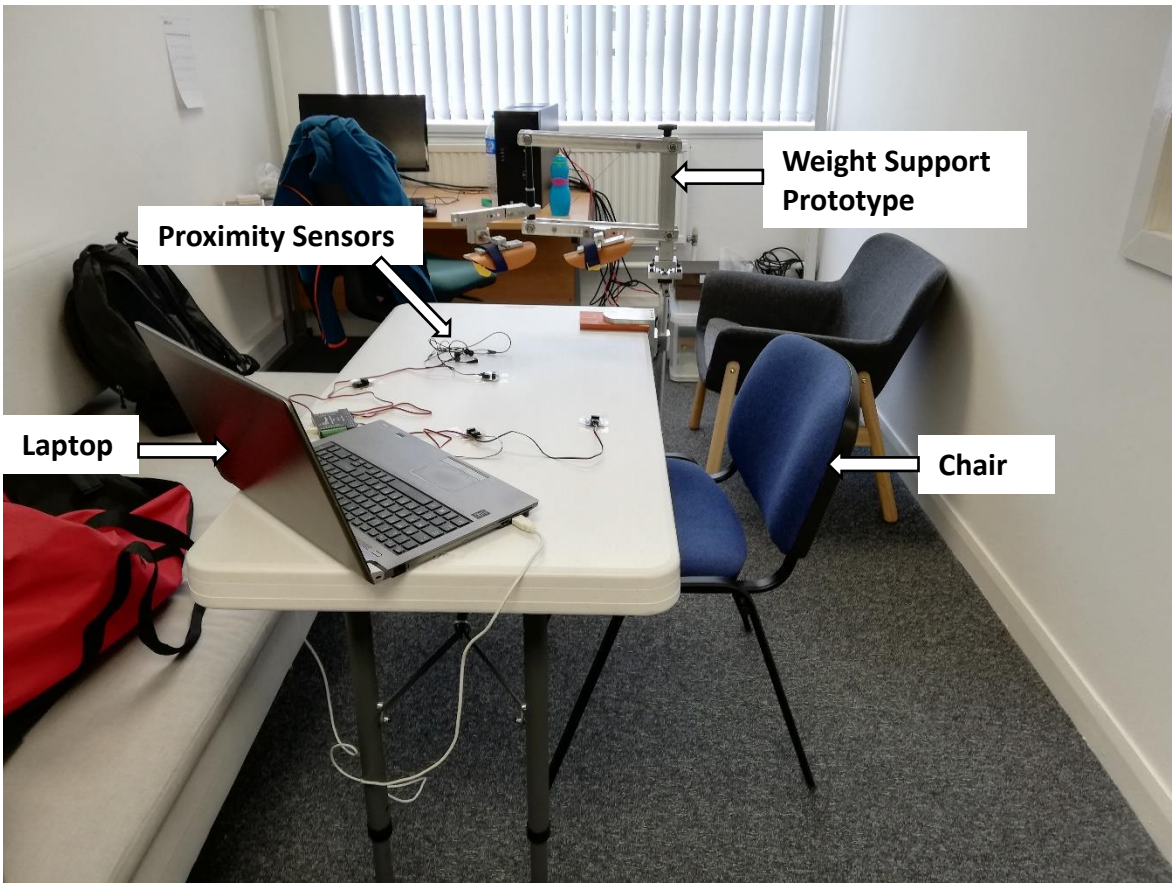


Figure 5.9 - Layout for the sessions conducted at the university. A folding table was used as the participant's workspace where the weight support prototype, sensors and laptop (labelled) were all placed.

Home sessions consisted of the same equipment and procedures as the university session and were set up and conducted by the investigator. As each participant's home would be unique, alterations to the layout were made where necessary to suit the participant's environment and needs.

5.4.1.4 Interview

Following completion of the final training session (week 4), each participant was interviewed by the researcher. These interviews were conducted in a semi-structured

fashion with questions intended to encourage discussion with the participant. The participants were also encouraged to offer opinions freely and frequently both in the interview and throughout the study. Questions were separated into three sections covering: (1) practicalities of the device, (2) potential for home use and (3) experience with the feedback system.

Similar to the previous study (Chapter 4), questions related to the device included feasibility and acceptability for use in frequent rehabilitation, comfort, ease of use, and if any improvements were required. Feedback related questions included engagement and enjoyment, and if there were any improvements that participants would have liked. Questions relating to home use asked if participants saw themselves using the device at home, how often they would use it and if they would have any difficulty setting it up at home.

Questions related to the device, section 1, were as follows:

1. What were your general thoughts about using the device?
2. What did you think about the device in terms of accessibility and usability (i.e. was it straightforward to use)?
3. Do you think the device could improve your arm function?
4. How did the device feel to wear and use?
5. Do you think you could set it up on your own at home or require assistance?
6. Can you see yourself using this on a regular basis? Daily? Weekly?
7. Have you used other arm movement training techniques/equipment before?
8. Are there any improvements/changes you would make to the device?

9. If this device was not available through the NHS, would you be willing to pay for it?
    a. If so, how much would you be willing to pay for it?

Questions related to using the device at home, section 2, were as follows:

1. Do you think the device is suitable for use in your home?
2. Could you see yourself using the device at home?
    a. If so, how often do you think you would use it?
    b. If not, what are your reasons?
3. Is there anything you would improve with the device to make it more suitable for you?

Questions related to the feedback system, section 3, were as follows:

1. What are your thoughts on feedback on your performance?
2. What did you think of the feedback system you used?
3. Did you find the information presented understandable?
4. What did you think of the feedback system in terms of engagement and enjoyment?
5. Is there anything you would add to improve:
    a. The information provided?
    b. To make it more enjoyable?

5.4.1.5 Data Management and Analysis

Participant metadata (age, gender, month since stroke) were recorded at the beginning of the intervention. This data was used to describe the sample for the purposes of external validity. Data collected to analyse change in arm movement and function consisted of assessment scales (ARAT and NEADL), participant performance scores from the games (i.e. number of repetitions and time taken). A range of movement and participation parameters were also recorded in the D-Flow exercises using D-Flow's internal data recording module as described in section 5.3, such as speed and duration.

Interviews were recorded, transcribed and analysed using NVivo qualitative analysis software (NVivo, QSR International, Melbourne, Australia). Using this software the transcript data were analysed for common themes among the participants to find similar or contrasting opinions on a particular aspect (Chun Tie et al. 2019).

5.4.2 Results

As these were individual case studies, each participant's assessment scores and experiences during the sessions will be described first with the analysis of interview answers discussed in the next section.

5.4.2.1 Participant 1

Participant 1 was a 66-year old male with a right sided upper limb weakness resulting from a stroke 99 months previously. They had participated in the feasibility study (chapter 4) with the first prototype. The participant had five sessions with the upper limb support including use of the game, the first three at university and the final two at home.

Outcome Measures

ARAT score, left-hand 57/57, right-hand 0/57. NEADL score was recorded as 14/22. For the second appointment, the ARAT score was similar with 57/57 for the participant's left side and 0/57 for the right.

Table 5.1 displays the participant's average scores for each respective session and tasks undertaken at that session. Comments from the participant at each session are detailed in the subsequent sections.

Table 5.1 - Average Scores across each session and game tasks without and with the device for participant 1. Due to recording issues, task 2 and 3 scores were not available for session 4.

Game Task No.	Session No.	Average Score	
		Without Device	*With Device*
1	**1**	4	9
	2	4	13
	3	6	15
	4	8	13
	5	14	20
2	**1**	9	9
	2	9	9
	3	8	12
	5	12	11
3	**2**	6	8
	3	10	12
	5	9	9

University Sessions

The participant's first session consisted of six repetitions of Task 1 and Task 2 (three without the device and three with the device). In task 1 the participant scored an average of 4 without the device, and 9 with the device (i.e. number of times the participant successfully reached for each sensor in the task). For task 2, the participant

scored an average of 9 both with and without the device (i.e. number of cubes collected by the ball the participant controlled using the sensors). During the session, the participant reported some return of tactile sensation in their arm near their shoulder and that the device was helping him move his shoulder back. He also mentioned that the device could help him straighten his arm out.

For the second session, the participant said that they were able to open their hand while using the device which they had struggled to do on their own. As a result, the participant spent some time picking up and placing objects on the workspace in addition to the D-Flow tasks which he was delighted at.

For the third session, the participant again took part in tasks 1-3 with the same number of repetitions.

Home Sessions

The remaining two sessions took place at the participant's home. They had a table that the device could clamp to and allow them to perform the same exercises. The height of the table was a bit higher than the previous sections so to compensate, the participant used a stool with adjustable height.

For the first home session, the participant took part in tasks 1-3 with the same number of repetitions as the university sessions. Figure 5.10 shows the participant performing task 2 in their home with the prototype. Unfortunately, due to recording issues with D-Flow, the scores for tasks 2 and 3 were not saved. The participant noted that they had been struggling to stretch their arm out in general. When using both supports, he said that it felt a bit tight on his upper arm.

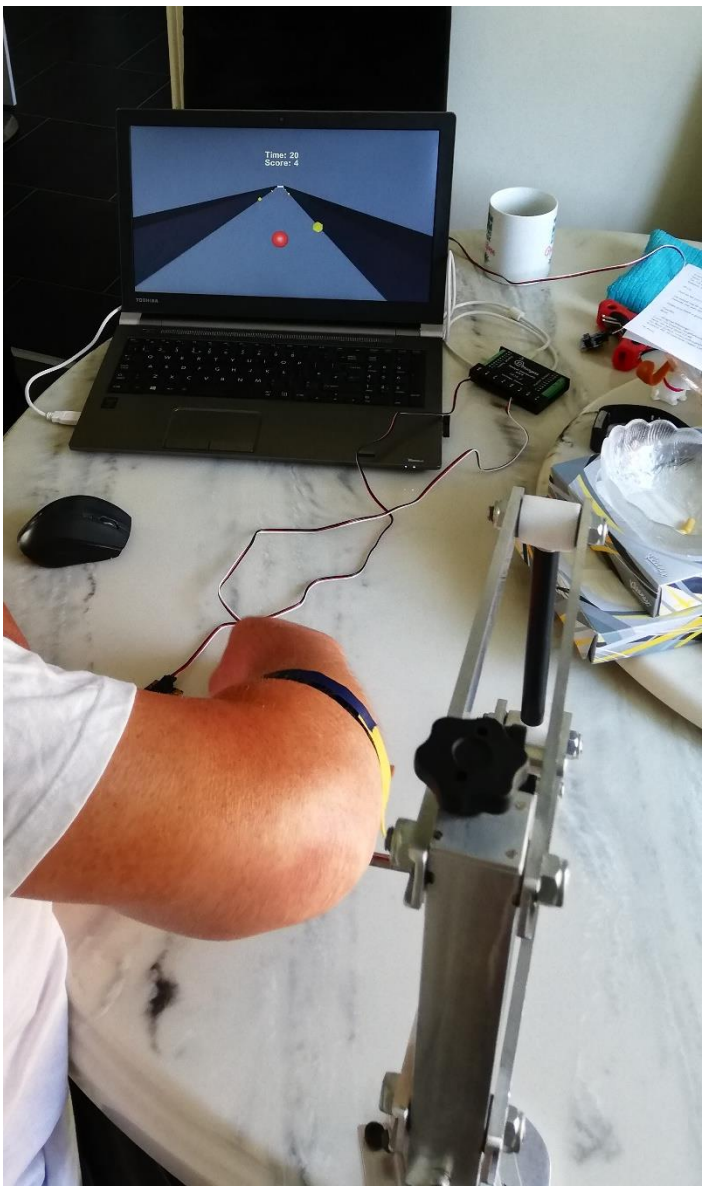


Figure 5.10 - Participant 1 performing task 2 with the prototype in their home. Only one support was used for this session.

For the final session, the participant performed the same tasks and repetitions as before. During the session, it was observed that the participant would hold on to the stool with their unimpaired arm to keep himself stable while using the device. He mentioned that taking part in the tasks helps move his shoulder (even without the device). When placing his arm into the device without assistance, the participant

required the use of other items in his house to hold the support in place before strapping his arm in. When it felt too tight on his upper limb, he would adjust the straps accordingly. The participant said that he enjoyed the consistency of using it on a weekly basis and lots of practice seemed to be helping him out.

Final Assessments

In the final appointment, the ARAT score was recorded as 57 on the left-hand side and 1 on the right-hand side via an increase in grasp score. NEADL score was recorded as 15, an increase of one. Table 5.2 displays their assessment scores from their baseline visits and final visit.

Table 5.2 - Outcome measures (ARAT and NEADL) for participant 1 at baseline visits and their final visit.

	First Visit	**Second Visit**	**Final Visit**
ARAT:			
• Left	57	57	57
• Right	0	0	1
NEADL	14	n/a	15

5.4.2.2 Participant 2

Participant 2 was a 54-year old male with right-sided upper limb weakness resulting from a stroke 51 months previously. The participant took part in four sessions using the upper limb device and feedback for their upper limb. Due to scheduling issues and with the participant's permission, only one session was conducted at the university and three were conducted at the participant's home. All tasks were performed using one support unless otherwise stated.

Outcome Measures

ARAT score, left hand 57/57, right-hand 8/57. NEADL score was recorded as 21/22. For the second appointment, the ARAT score was 57/57 for the participant's left side and 12/57 for the right.

Table 5.3 displays the participant's average scores for each respective session and tasks undertaken at that session. Comments from the participant at each session are detailed in the subsequent sections.

Table 5.3 - Average Scores across each session and game tasks without and with the device for participant 2.

Game Task No.	Session No.	Average Score	
		Without Device	*With Device*
1	**1**	23	14
	2	25	18
	3	24	21
	4	22	18
2	**1**	9	12
	2	10	12
	3	11	14
	4	10	13
3	**2**	11	14
	4	11	15

University Sessions

The participant's first and only university session consisted of three repetitions of Task 1 and Task 2 for each variation (i.e. without and with the device). The participant said that the support was quite sore when initially placed at his upper arm/elbow, but when moved to his forearm it felt more comfortable. He noted that his shoulder felt quite tight initially but started to feel better after using the device for a bit.

Home Sessions

The remaining three sessions occurred at the participant's home. The device was attached to the participant's dining table which had sufficient space for them to perform the exercises. The participant's own dining chair was of a suitable height for them to comfortably perform the exercises both with and without the weight support device.

At the first home session, the participant took part in tasks 1-2 with the same number of repetitions as before. They also performed 4 repetitions each without and with the device for task 3. It was observed that the participant was more inclined to move their trunk to reach the proximity sensors with their upper limb when not using the device.

For the second home session, the participant took part in tasks 1-2 with four repetitions without and with the device for each task. The participant utilised both supports in this session and noted that his shoulder gets quite painful when extending and externally rotating his upper limb. It was also observed that he had some difficulty with elbow flexion while using both supports. After using the device for approximately 30 minutes, the participant described that his upper limb and fingers were more relaxed compared to the start of the session.

For the final home session, the participant completed three repetitions without and with the device for task 1 and four of each for tasks 2-3. The participant had no issues strapping his upper limb into the device himself. The participant mentioned that he found task 3 quite difficult but that using the device made it slightly easier. He explained that after using the device his arm begins to feel more relaxed as opposed to

tight and that at least 30 minutes seems to help him though wished he could use it for longer.

Final Assessments

In the final appointment, the ARAT score was recorded as 57/57 on the left-hand side and 15/57 on the right-hand side via improvements in grasp, grip, and gross movements. NEADL score was recorded as 21/22. Table 5.4 displays their assessment scores from their baseline visits and final visit.

Table 5.4 - Outcome measures (ARAT and NEADL) for participant 2 at baseline visits and their final visit.

	First Visit	**Second Visit**	**Final Visit**
ARAT:			
• Left	57	57	57
• Right	8	12	15
NEADL	21	n/a	21

5.4.2.3 Participant 3

Participant 3 was a 57-year old male with a left sided upper limb weakness resulting from a stroke 41 months previously. They had previously taken part in the feasibility study (chapter 4) with the first iteration of the previous prototype. The participant took part in four sessions with device and feedback system. One session was conducted at the university and due to scheduling issues, three were conducted at the participant's home. All tasks were performed with one support unless otherwise stated.

Outcome Measure

ARAT score, left hand 0/57, right hand 57/57. NEADL score was recorded as 7/22. For the second appointment, the ARAT score was similar with 0/57 for the participant's left side and 57/57 for the right.

Table 5.5 displays the participant's average scores for each respective session and tasks undertaken at that session. Comments from the participant at each session are detailed in the subsequent sections.

Table 5.5 - Average Scores across each session and game tasks without and with the device for participant 3. The participant did not perform task 2 in session 3 without the device.

Game Task No.	Session No.	Average Score	
		Without Device	*With Device*
1	**1**	4	6
	2	12	8
	3	10	11
	4	9	4
2	**1**	7	8
	2	9	8
	3	-	10
	4	7	11
3	**2**	10	10
	4	7	10
4	**3**	153	307
	4	239	260

University Sessions

The participant took part in tasks 1-2 in their first and only session at the university. They explained that they were able to lift their hand a bit after a couple of repetitions and getting used to the setup. They enjoyed the idea of the tasks even if they were a

bit difficult. He mentioned that he likes the device and if he had more movement in his arm, he would likely use it more.

Home Sessions

The participant had a dining table in their home in which the device could be clamped too and provided sufficient space to carry out the tasks. The participant used a dining chair to perform their exercises while seated.

For the first home session, tasks 1-3 were performed with three repetitions of both with the device and without the device. Task 4 was also performed with the device only therefore no comparison could be made. Although a direct comparison could not be made, the participant achieved an average score of 255 in task 4 while using the device. The participant commented that he enjoyed tasks 3 and 4 and mentioned that his wrist began to feel a bit more flexible towards the end of the session as it felt stiffer before the session. He mentioned again that he liked the device but that his upper limb mobility isn't good enough to feel like he would get any benefit from it.

In the second home session, task 1 was performed with three repetitions with and without the device. Task 2 was performed 3 times with the device only while using two supports instead of one. This was followed with task 4, where two repetitions were performed without the device and three with the device. It was observed that the participant would move their trunk a lot more without the device when performing the tasks. Additionally, he would use his unimpaired hand to lean on the table to provide stability when using the device. While using both supports, he mentioned that it "dug" into his arm quite a bit and while he could move slightly, his upper arm felt restricted. Despite this, he mentioned that the extra support does help is upper limb feel

supported. The participant was also unable to strap his upper limb into the device and required assistance each time.

For the final home session, the participant performed all four tasks with three repetitions both with and without the device. Task 1 was completed while using both supports and the remaining tasks with one support. The participant had mentioned that they were quite tired during this session before beginning and that they had some back pain but wished to continue with the tasks. He mentioned that it was quite difficult to move his upper limb with both supports and that it felt tight on his upper arm again. When moving back to one support, he said it felt a bit better for the remaining tasks. During the session, he mentioned that his shoulder was starting to feel sore but explained that he liked that because to him it meant he was using it more. Overall, he enjoyed this session as he felt he could get more movement compared to previous sessions although he acknowledged that he was not completely feeling up to it due to his tiredness that day.

Final Assessments

In the final appointment, the ARAT score was recorded as 0/57 on the left-hand side and 57/57 on the right-hand side, and. NEADL score was recorded as 3/22. Table 5.6 displays their assessment scores from their baseline visits and final visit.

Table 5.6 - Outcome measures (ARAT and NEADL) for participant 3 at baseline visits and their final visit.

	First Visit	Second Visit	Final Visit
ARAT:			
• Left	0	0	0
• Right	57	57	57
NEADL	7	n/a	3

5.4.2.4 Participant 4

Participant 4 was a 47-year old male with a left sided upper limb weakness resulting from a stroke 10 months previously. They took part in four sessions with the device and feedback system: two at the university and two at their home. All tasks were performed with one support unless otherwise stated.

Outcome Measures

ARAT, left hand 7/57, right hand 57/57. NEADL score was recorded as 15/22. For the second appointment, the ARAT score was 6/57 for the participants left side and 57/57 for the right.

Table 5.7 displays the participant's average scores for each respective session and tasks undertaken at that session. Comments from the participant at each session are detailed in the subsequent sections.

Table 5.7 - Average Scores across each session and game tasks without and with the device for participant 4.

Game Task No.	Session No.	Average Score	
		Without Device	*With Device*
1	**1**	17	13
	2	17	11
	3	18	12
	4	17	9
2	**1**	8	8
	2	8	7
	3	9	9
	4	11	8
3	**2**	8	8
	4	9	9
4	**2**	259	231
	3	274	208
	4	258	254

University Sessions

For the first session, the participant performed tasks 1-2 for three repetitions with, and without the device. It was observed that the participant held onto his chair when not using the device while performing the tasks. They noted that the device inhibits his routes of motion and forces it to move in a mechanical way. He explained that he wanted to focus more on his distal function rather than at the shoulder.

In the second session, they performed tasks 1-4 with the same number of repetitions as previous with the exception of task 4 where two repetitions without and with the device were performed. During task 1, the participant mentioned it would be a good idea to display the fastest repetition time achieved at the end of the exercise to the user to offer them more performance feedback. While performing task 2, the participant

said it was a bit easy and not very engaging. To amend this, the layout of the cubes were arranged to five pre-defined positions as opposed to three to provide more of a challenge to the participant. As a result, they found this more engaging. The participant found task 3 more difficult as he struggled to raise his arm to reach the relevant sensor. Task 4 was more enjoyable and engaging from the participant's perspective though he felt the sensitivity of the controls could be altered to make it more manageable.

Home Sessions

For the home sessions, the participant had a large dining room table to affix the device with sufficient space to perform the exercises.

In the first home session, the participant undertook tasks 1 and 4 with three repetitions for both variations. They also performed task 2 with 4 repetitions of each variation. However, taking the participant's feedback into account, they performed two repetitions of the original configuration of the exercise before performing the other two with the altered configuration mentioned in the previous section (increase from three to five pre-defined positions of the target cubes). Throughout the exercises, the participant's arm had a tendency to slip out of the cuff requiring it to be strapped back in multiple times. They were able to put the cuff on themselves though the support would spin a lot making it more difficult to manage. He mentioned having to find the right balance point for the cuff before placing his upper limb into it to hold in place. While he felt he had more control of his upper limb without the device, he felt it could be beneficial for his hand function as the support relieved the pressure at his shoulder. From observations, the participant seemed to be more engaged with the more challenging exercises. They mentioned that the device prevented him from reaching as far as he wanted to at times. Furthermore, they said that task 3 was the most difficult

for them as it required them to raise their arm more which the device was able to make easier. When using two supports, the participant exhibited more restricted movement but they noted that supported his arm better.

In the second home session, the participant performed tasks 1, 3 and 4 with three repetitions for both variations like the previous sessions. Similarly, they also undertook task 2 with two repetitions of each configuration of the exercise without and with the device.

Final Assessments

In the final appointment, the ARAT score was recorded as 8/57 on the left-hand side through an increase in the grip score, an increase of two from the baseline appointments. ARAT score was 57/57 for the right-hand side, and. NEADL score was recorded as 15/22. Table 5.8 displays their assessment scores from their baseline visits and final visit.

Table 5.8 - Outcome measures (ARAT and NEADL) for participant 4 at baseline visits and their final visit.

	First Visit	**Second Visit**	**Final Visit**
ARAT:			
• Left	7	6	8
• Right	57	57	57
NEADL	15	n/a	15

5.4.2.5 Summary

In summary, the majority of participants showed minimal to no increase in ARAT (with the exception of participant 2) and NEADL scores. With regards to game tasks, all participants completed the tasks given with variability in score differences with and

without the device; some participants had an increase in average score with the device whereas others resulted in a decrease in score.

5.4.3 Interviews

Tables 5.9, 5.10, and 5.11 summarise the key points made by each participant for each question.

Table 5.9 - Summary of answers from participants related to the practicalities of the device.

Practicalities of the Device			
Participant 1	**Participant 2**	**Participant 3**	**Participant 4**
Q1 - What were your general thoughts about using the device?			
Excellent ("for me, out of 100, about 90"). Helped keep his "brain engaged" Observed that it as a bit difficult initially but after some use he became familiar with it.	"Absolutely Fantastic" By using every day, he hopes it will help his arm relax and allow him to use it more.	"Pretty good" Problem is that his arm is "pretty stiff". He liked it and thinks the support helps his arm.	"It is a good idea but it is very difficult to mimic the motions of the shoulder joint." "a bit clunky" Found that he found it difficult when his forearm would slide out of the strap.
Q2 - What did you think about the device in terms of accessibility and usability (i.e. was it straightforward to use)?			
"No problem"	Found it "quite easy"	"nothing too hard" in terms of using the device to support his upper limb	It was usable and set it up himself if needed. Mentioned that he has used more complicated devices that were more difficult to setup.

Q3 - Do you think the device could improve your arm function?			
Believes it would. He sees himself using the device a lot in addition to attending the gym.	"100%" Believes it will help with his upper limb function particularly as he is determined to keep trying.	Said he would need to spend a bit more time with it in order to practice.	"Main benefit is it relieves the strain on the shoulder allowing for more distal function." Could potentially help with distal function Using in combination with another device for hand functionality could be beneficial.
Q4 - How did the device feel to wear and use?			
"It was okay." With two supports, he felt like it was "strangling" or nipping the upper part of his arm. No issues with one support though would like to try and use both more in the future.	At certain positions it was "quite sore" Had to adjust himself to find a more comfortable position. With both supports it was "fine"	"Felt alright" The strap was sometimes too tight leading to it "pinching" his upper limb. With two supports, "I felt more support basically. It felt more solid."	"A bit clunky but in general was okay." Comfortable although worried his arm might slip out. Having one support was preferable as it felt more "comfortable and natural."

Q5 - Do you think you could set it up on your own at home or require assistance?			
"No problem" While he was able to place his arm in the cuff on his own, it was quite difficult as it would keep rotating and not stay in a neutral position.	Unable to do it himself currently.	Definitely would require assistance.	Yes, they were able to set up similar devices themselves.
Q6 - Can you see yourself using this on a regular basis? Daily? Weekly?			
Daily basis, as much as possible. "If I get up in the morning, get ready and sit, and [the device] would be there. I'd do about half an hour to an hour. I'd start playing the piano, make myself a cup of tea, and then I'd go back into it again."	Multiple times a day. "Probably like one hour, then leave it. Then maybe another hour. And just try and try."	"Would like to have a go at it" A couple of days a week for approximately 10-15 minutes per session.	Unlikely as it is "quite a big piece of machinery." It might be something he would use if he had worse shoulder function.

Q7 - Have you used other arm movement training techniques/equipment before?			
Uses a paint roller at home for upper limb exercises. Also uses gym equipment consisting of cable machines and weights to exercise his upper limb (60 minute sessions).	Goes to a local gym Works on shoulder press with weights in addition to cycling and running	Uses equipment at the gym including a hand-bike to exercise his upper limb.	Has used another device for his upper limb at home for a few months (used most days).
Q8 - Are there any improvements/changes you would make to the device?			
Cannot think of anything though acknowledges it is a prototype.	There are no improvements or changes he would make.	Would like the device to provide a greater range of motion for him to explore while using it. Would like it to enable more extension in his upper limb. A method to allow movement at the wrist was also desired.	"Though it might make the device more complicated, it would be good to incorporate other shoulder movements such as abduction and adduction." Would be more open to using the device if it was smaller. Could potentially make a glove/sleeve that could go over the forearm and slot that into the device before use.

Q9 - If this device was not available through the NHS, would you be willing to pay for it? **a. If so, how much would you be willing to pay for it?**			
Yes, £80-100	Yes, no figure provided.	Yes, £30-40	No

Table 5.10 - Summary of answers related to potential for home use of the device.

Potential for Home Use			
Participant 1	**Participant 2**	**Participant 3**	**Participant 4**
Q1 - Do you think the device is suitable for use in your home?			
Suitable for use in his home. Would need to adapt and find things to hold the support in place in order for him to place and strap his arm into it.	Suitable for use ("Absolutely, 100%").	Suitable for use but would need someone to set it up for him.	Suitable for use.
Q2 - Could you see yourself using the device at home? **a. If so, how often do you think you would use it?** **b. If not, what are your reasons?**			
Yes, 5-6 times a day.	Yes, multiple times a day, several days a week with the occasional day off.	Yes, a couple of days a week, 10-15 minutes per session.	Yes, a few times a week (30 minute sessions)
Q3 - Is there anything you would improve with the device to make it more suitable for you?			
Did not think there was anything required to make it more suitable ("brilliant")	There was nothing he would improve.	Would like some method to extend his arm out and passively stretch it while strapped in as part of his exercises.	Would like the device to be smaller and more portable for use at home.

Table 5.11 - Summary of answers related to the participant's experience with the feedback system.

Experience with Feedback System			
Participant 1	**Participant 2**	**Participant 3**	**Participant 4**
Q1 - What are your thoughts on feedback on your performance?			
He thought he got on well ("8/10"). Thought it was brilliant, referring to task 2 as like "ten-pin bowling"	Would want someone to write down and say to him "again and again." Explained that he would like feedback over several days about how he is doing and if he is improving.	He like having a target to aim for. "I've always liked that. A wee target to aim for."	Good to have feedback and having a goal in mind is good for motivation.
Q2 - What did you think of the feedback system you used?			
"Great"	Enjoyed Task 3 the most saying that it was "good" and "understandable".	He enjoyed having an incentive to beat his last score with every successive attempt which helped motivate him.	The scores were okay. Task 4 was more engaging though was more difficult to control. His favourite was task 1 which he also thought was the "simplest".
Q3 - Did you find the information presented understandable?			
Had no problem understanding the information and found it easy to follow.	The information presented was understandable.	The information was understandable and easy to follow.	The information was understandable.

Q4 - What did you think of the feedback system in terms of engagement and enjoyment?			
Enjoyed using it a lot. Task 3 was the most difficult as it involved lifting his arm up but found in the last session he was able to move it "all the way up and down" While he found it difficult, he enjoyed it as well because it challenged him.	"Fantastic" Found it both enjoyable and engaging.	He liked the games stating that he would keep playing them to try and beat his scores. Would more likely play the games rather than use the device. "It's the target thing I like. To just try and improve the score each time. I know it is progression."	It was not something he would choose to do that was enjoyable but it was "better than nothing".
Q5 - Is there anything you would add to improve: **a. The information provided?** **b. To make it more enjoyable?**			
The information provided was good and he did not think anything else needed to be added. For enjoyment, he felt that more games would be beneficial to add variety when interacting with the system.	Thought that there could be more info presented but could not think of anything specifically.	He would like a method of recording the scores to keep track of his progress.	Suggested that scores be uploaded to online leader-boards to allow other users to compete with each other.

In summary, the device was feasible and acceptable for home use with further areas for improvement identified (e.g. improve accessibility via locking/unlocking the upper

limb cuffs, increase range of motion and decrease size to improve portability). Three out of four participants exclaimed that they would use the device on a regular basis as part of their rehabilitation exercises. All participants enjoyed the feedback system used in conjunction with the device though all felt that it could be improved upon to increase engagement and enjoyment (e.g. increased variety in games, provide more detail in the information, and score-tracking).

5.5 Discussion

This chapter described the alterations to the prototype suggested in the previous chapters to develop the next iteration of the design based on stakeholder feedback (Design Council 2019). It also described the development of the feedback system to be used in conjunction with the prototype. Finally, the chapter presented the final study which was designed to evaluate the feasibility of the second prototype and assess its acceptability for deployment in the home environment.

Based on feedback from the first feasibility study (chapter 4), several changes were made to the original prototype as opposed to making a new prototype with the updated design. This was decided as the central concept and core design had been well received by participants. Based on observations, during participant's practice sessions and the general feedback, these amendments to the first iteration of the prototype greatly improved the user experience and performance of the movements.

5.5.1 Review of Changes to First Prototype

5.5.1.1 The Slider

The addition of the slider (section 5.2.1) greatly improved the user's ability to perform forward reaching movements, a movement that was limited in the first prototype (see section 4.4). The length of the slider (20 cm), however, still restricted two participants who were unable to move through their full available range of motion. Increasing the length of the slider up to twice or three times as long would likely improve this with due consideration to the problem of contact between the four-bar assembly and the track when pushing the upper limb down, a problem which was observed occasionally in the current prototype. Increasing the slider track length could make this contact more

likely, particularly if the user has moved the four-bar assembly all the way to the back of the track.

5.5.1.2 The Forearm Support

Making the forearm assembly a modular component of the device was thought to be beneficial to the user, as it provided them with options on how they wished to proceed with their upper limb exercises, providing an individualised experience. With this in mind, all participants preferred performing the upper limb tasks with one support without the forearm assembly. While the majority agreed that two points of contact provided more support, the increased restriction in their mobility from using both supports was undesirable. Therefore, options for improving the second support and facilitating flexion at the elbow with minimal restriction will need to be explored. Additionally, providing a handle for gripping as another modular component will also need to be explored as this could provide more control for the user while having something to grasp onto as they are moving with the prototype.

5.5.1.3 The Weight Support Mechanism

The same spring from the previous iteration of the prototype remained unchanged therefore replacing this with a stronger spring may have been beneficial to prevent this collision. Furthermore, with the addition of the second four-bar linkage and forearm support, a stronger spring would help lift the increased weight of the device. However, as mentioned in section 3.4, the user would be required to push down against the force of the spring to move their arm down which would now be more difficult. Therefore, an alternative option may be required for the weight support to solve these issues.

5.5.2 Usability

All participants were asked to strap their own upper limbs into the device to assess the feasibility of setting up the device independently. Three of the four participants managed, when asked, to strap their upper limb into the device though not without difficulty, though ability to do routinely was not requested. The main issue observed was the upper limb cuff continuously spinning along its axis while the participants tried to steady it in place in order to place their impaired upper limb. Consequently, participants had to adapt to this unintended challenge in order to secure their arm to the device without assistance. In light of this, alterations to this assembly will be required in order to lock the upper limb cuff in place (i.e. with a pin) in order for the user to safely and easily place and secure their arm before unlocking the cuff when using the device.

5.5.3 Interactive Games

Interactive feedback systems in stroke rehabilitation are not a novel concept. Many studies have used various forms of these systems to provide feedback and motivation to participants from virtual reality to using commercial gaming products with the goal of motivating the user and encouraging high repetitions of movements (Thomson et al. 2014; Laver et al. 2018; Givon et al. 2016; Saposnik et al. 2016; Kong et al. 2016). For this project, D-Flow was used to create custom-made applications that the user could interact with via simple input devices (in this case, infrared proximity sensors). Through the software, different types of applications could be created through programming the inputs to control different parameters such as being used as targets in task 1 or to control an object on the screen in tasks 2-4. Other input devices could

have been included into the system such as inertial measurement units, force sensors, distance sensors or radio-frequency identification, all of which were compatible inputs with D-Flow software. It was decided to use only the proximity sensors as the input device, as they are simple to set up and easy for the user to understand quickly compared to using multiple different input devices. Despite this, having one type of input device may affect the user's engagement with the system with one participant in the study describing the exercises as "a bit boring" after multiple sessions. Furthermore, this could be related to the visual information provided on the screen. The same participant was more engaged in game 4 (City Ride) as there was more visual information/stimulus on the screen to maintain their interest compared to the other games. From the interviews, one of the common themes that was mentioned across the board was motivation during the exercises. All participants agreed that motivation was important when performing their tasks and having a set target to achieve or exceed for each exercise was important to keep them engaged. As mentioned in literature, there seems to be good rehabilitation outcomes associated with patient motivation and engagement (Langhorne et al. 2011). Moreover, there seems to be indication that use of games may help with motivation and engagement for stroke rehabilitation, particularly with self-directed approaches (Yates et al. 2016; Barrett et al. 2016) For this study, this gave the participants a goal for the subsequent session to break their previous scores. Therefore, recording and incorporating the participant's previous scores into their next session will be beneficial to continually track their progress.

5.5.4 Study Design

Single case study designs have been used previously in rehabilitation research (Graham et al. 2012). While randomised controlled trials (RCTs) are the gold standard

of research design and have been critical in guiding service planning of stroke care and rehabilitation (Langhorne et al. 2011), they can be a costly and time-consuming process. Furthermore, in terms of rehabilitative technologies it can be difficult to provide the same intervention process for each participant recruited to the study (Barnett et al. 2012). Each individual's rehabilitation and recovery is unique and as such, modification to the technologies may be required during the trial. Additionally, subjects in the control group's rehabilitation are also likely to be individualised based on the subject's abilities and needs. In light of this, comparing a rehabilitative device against a control group can be difficult. In terms of design and development of this prototype, individualised case studies provided an opportunity to gather a rich amount of data from individuals, allowing for a greater exploration of individual experiences with the device. In contrast, this would be difficult to obtain from large RCT designs that are aimed at testing statistically significant effects in a larger group. Since each participant's home is unique, a case-study approach allowed for this to be evaluated as part of the process as opposed to the standardised approach found in RCTs, where typically the participant's upper limb function would only be measured.

The outcome measures employed in this study (the ARAT and NEADL) showed minimal improvements for all participants though this was to be expected for a study involving a minimum of 4 sessions with 15-30 minutes of upper limb activity per session. Additionally, this could also be attributed to the small number of participants recruited who were in the chronic stages of their stroke where recovery has either plateaued or slowed. In literature, the minimal clinically important difference (MCID) for the ARAT in chronic stroke patients has been reported as 5.7, 10% of the scale's 57 points (Van Der Lee et al. 1999). Only participant 2 had an MCID in ARAT score

for their impaired side, but only when comparing their first and last visit (8 & 15 respectively). The participant had an ARAT score of 12 on their second visit before they participated in the intervention; comparing this with the last visit suggests that there was not an MCID as a result of using the device. However, the main goals of the study were to assess acceptability and feasibility of the device for use in the participants' homes via participant feedback. In light of the study's design, participants' scores were therefore not compared against each other.

5.5.5 Researcher Bias

While the case study design was a good fit for the intended purpose of assessing acceptability and feasibility, unintended researcher bias is likely to have influenced some of the outcomes and interview feedback as the researcher/device designer was present during all aspects of the study and conducted the ARAT, NEADL and interviews for each participant. This close involvement with the testing and feedback is likely to have had some effect on the overall scores achieved by the participant. Researcher bias in qualitative research can lead to questioning the validity of the results, and as such, the credibility of the research undertaken (Creswell & Miller 2000). In contrast to statistical analyses in quantitative research, investigators conducting qualitative research aim to design and conduct appropriate strategies to ensure validity and trustworthiness of the findings they obtain (Noble & Smith 2015). For this study, all interviews were recorded, transcribed and analysed to help reduce bias as much as possible but an independent interviewer would have benefitted the overall results by preventing any leading questions from being asked by the investigator. However, as the researcher also conducted all of the sessions with the participants, the personal relationship between the participant and the researcher made

it highly likely that there would be social desirability bias in the interview results (Nederhof 1985). Participants could potentially have been more likely to provide positive responses to the researcher/designer as they were aware that it was designed by them. While difficult to mitigate, the researcher made it clear to the participant to be honest with their experience with the device and feedback system, be it positive, neutral and/or negative.

An experienced independent assessor for the ARAT would also have helped to reduce potential biases in the scores. Moreover, this also could have provided different and potentially more accurate data as the researcher conducting the assessments was inexperienced in conducting the ARAT with participants. However, a lack of resources resulted in difficulty acquiring an independent reviewer/assessor to conduct these data gathering sessions.

5.6 Conclusion

This chapter outlined the changes made to improve the user experience and performance of the prototype based on feedback in chapter 4. Specifically, this was a low friction slider to increase forward/backward movement, a more durable cable, and a forearm support. The subsequent single case study showed that this second iteration of the prototype was acceptable and feasible for use in the home environment though improvements will be required to further minimise restrictions on mobility while maintaining support for the upper limb. Other prototype improvements relating to accessibility were identified by the users such as locking the upper limb cuffs for independent setup. Motivation was found to be an important factor in self-rehabilitation therefore providing automated performance feedback to the user through

interactive games was a step in the right direction with opportunities to develop this further.

6 Discussion and Future Considerations

6.1 Introduction

This concluding chapter of the thesis will bring together the key discussion points from the thesis, compare the outcomes with published literature and make suggestions for the future development of the weight support device (WSD).

6.2 Summary of Thesis Contribution

6.2.1 Key attributes

The thesis presented the design and evaluation process for a new WSD designed specifically for home-based stroke rehabilitation. This was realised through a rigorous design process, prototype development and refinement through ongoing communication and testing with stakeholders. The initial outcomes from this process were key attributes of the WSD, namely:

1) It should have a low assembly cost in order to make it financially accessible to the intended market (NHS and individual stroke survivors).
2) The magnitude of support provided by the WSD should be adjustable to accommodate different levels of impairment and enable progress,
3) The design should be lightweight and portable to enable the end user to set up and use (easily) in their own home.

To further motivate and maintain this practice, interactive games to provide real-time feedback and progress reports were considered desirable. These requirements were designed, developed, and tested with the local stroke community as part of the

currently ongoing design process working towards a final model that could be sold as a commercial product.

6.2.2 The Design Process

Throughout this project, the proposed WSD went through several iterations, both in conceptual design and prototype development. These processes followed the Double Diamond design framework (Design Council 2019). This consisted of four key steps (see Chapter 2): Discover, Define, Develop, and Deliver.

6.2.2.1 Discover phase

The discover phase consisted of the review of scientific literature and existing devices for upper limb stroke rehabilitation (Chapter 1) to identify gaps in the research/market. This was supplemented through informal interviews with stakeholders (in this case, stroke survivors and therapists working in stroke rehabilitation). From this review, there was indication that a new, simpler design could be implemented that emphasised self-practice. This was based on the ever increasing population of stroke survivors who require upper limb rehabilitation, and the limited resources available to carry out these rehabilitation sessions efficiently in clinics due to the increased demand (Langhorne et al. 2011; Bernhardt et al. 2007). Within the UK, therapists are more inclined to prescribe upper limb exercises to patients outside of therapy at their homes (Connell et al. 2014). These exercises tend to be low intensity such as range of motion or stretching exercises despite evidence that high intensity, repetitive-task training can have a greater impact on upper limb recovery (French et al. 2016). In the context of the growing need to support more intensive upper limb rehabilitation, developing a device that could physically support these activities was clear. Several upper limb

devices, mechanical, robotic, or a hybrid of the two, have been developed with the goal of assisting individuals with upper limb training (Mehrholz et al. 2018; Brackenridge et al. 2016) although the evidence of their effectiveness remains low primarily due to poor quality study design and low sample sizes (Bartolo et al. 2014; Nijenhuis et al. 2017). Irrespective of this current conclusion, there are currently a large number of devices on the commercial market and various designs published in scientific literature suggesting that there could be potential for these devices to provide benefit to upper limb recovery in the future. (Brackenridge et al. 2016). It is crucial that any device not only helps facilitate these rehabilitation exercises, but that that they are accessible to the user, both physically and economically. For example, a multicentre RCT compared standard of care therapy with an enhanced upper limb therapy programme (EULT) and with robot-assisted training using the MIT-Manus (Rodgers et al. 2019). Findings from the trial concluded that there was no evidence that this robotic-assisted training intervention improved upper limb function in comparison to EULT or standard care. It was also reported that the MIT-Manus was not a cost-effective solution. Even if it had the potential to positively affect upper limb recovery, cost is arguably a key factor in the adoption of a device with individuals living with stroke. Additionally, the user would most likely require assistance from an operator trained with the device in setting it up for them. Taking this into consideration, developing a device that was accessible, both in terms of cost effectiveness, and ease of set up and operation become key design aspects.

6.2.2.2 Define phase

Leading into the define phase of the design framework, a product design specification (PDS) was generated as described at the start of chapter 2. A template design

specification taken from Pugh's method of design was completed based on the findings from the discovery phase of the project (Pugh 1991). While this specification contains over 30 categories to guide the design of the product, in general, the performance criteria were the foremost for consideration (see section 2.2.2). While these performance criteria were arguably the most important to address in the design, ideally all aspects of the PDS should be met. However, this can be difficult to implement on the first design iteration as the development of concepts and prototypes can highlight new areas for inclusion or aspects that may not be feasible without substantial trade-offs. To account for this the design process is a continually evolving mechanism and the PDS can be updated to reflect any new knowledge gained in later stages of the project. For example, the inclusion of real-time feedback in the design was initially identified as a key aspect, however during the shortlisting of concepts during the development stage, it became apparent that it would be more straightforward to focus on ensuring the upper limb WSD was functional and accessible for the user. It was decided to implement a feedback system at a later stage in the project once the initial prototype had been tested and deemed feasible and acceptable for use. In doing so, more time was spent on developing the WSD as that was seen as the most fundamental part of the project. This also prevented any delays by initially excluding methods of integrating a feedback system into the design.

6.2.2.3 Develop phase

Similar to the PDS, Pugh's method for total design was implemented for the develop stage of the design framework initially using the controlled convergence method (Pugh 1991). This option was chosen as it provided a simple comparison-based evaluation for each design criterion and provided the opportunity for innovation through

reflection against a "gold standard" product. The risk of designer bias using this approach was, however, high as a large proportion of the evaluation was performed by one individual (the researcher). While aiming to perform a user-centred design approach throughout the project, this was not possible at this stage as evaluation of the large number of concepts would be unfeasible due to the large amount of time required in addition to being potentially overwhelming to a stakeholder group who may have little to no experience in design. Taking this into account, the initial run of evaluations could have potentially been of poor quality. To counteract this, a weighting and rating evaluation method was also employed to provide a different perspective (Pugh 1991). Ultimately, however, there was not much difference in the results. However, as described by Fricke (1996), employing a heuristic method was found to be beneficial as an individualised approach as it provided the flexibility to engage in different methods throughout the evaluation process (Fricke 1996). Doing so was necessary to keep the designer engaged in the process and prevent fatigue, switching to a different method once all possibilities in the former had been exhausted.

Due to the high risk of bias from an individual approach to engineering design, the desired user-centred approach was finally employed with a shortlist of concepts. This was realised with two focus groups: stroke survivors and occupational therapists (section 2.6), a method used in existing studies to obtain information on upper limb devices/technologies in stroke rehabilitation (Demain et al. 2013; Elnady et al. 2018). Incorporating the opinions on the designs from key stakeholders was crucial to reduce as much bias as possible though this could not be completely avoided as only a fraction of the initial list of concepts were shown, those deemed the most appropriate with respect to the design criteria. Furthermore, the focus groups were limited in scope. The

stroke survivor focus group only recruited three participants, half the amount from the therapist focus group. Furthermore, the investigator had limited experience in leading focus group sessions potentially resulting in a reduced amount of information extracted from the participants as well as unconscious bias. Responses to some questions lacked depth, merely consisting of an agreement or disagreement with minimal discussion on why the choice was made. It may have been beneficial to ensure that for questions with one-word answers, the investigator requested further information and clarification on the participants' choices. Additionally, creating physical scale models of the shortlisted concepts may have benefitted the group sessions by providing the concepts that can be touched as well as shown. Subsequently, this approach may have opened up more opportunities for feedback as opposed to only displaying pictures and videos to the participants.

6.2.2.4 Deliver phase

The final stage of the double diamond model was the deliver stage taking up most of the project. This began by taking the final concept chosen in chapter 2 and specifying the dimensions, materials and mechanisms in more detail in order to generate a working prototype (Chapter 3). Based on the feedback obtained from the focus groups, a key focus was to develop something accessible and portable for the end user. As such, using strong, lightweight but also cost-effective materials was the logical approach when designing the components of the device. In contrast to larger, more complex and, consequently, more expensive devices such as the ARMin, ArmeoSpring, and MIT-Manus, the aim was to develop a smaller, simpler, and cost-effective device that provides the minimum requirements to the user (i.e. facilitate upper limb movement via lifting the arm against gravity) (Klamroth-Marganska et al.

2014; Housman et al. 2009; Rodgers et al. 2019). While providing multiple degrees of freedom to the user would provide them with a large range of motion while using the device, this was limited to four with the initial prototype. As a result, the device assisted mainly with shoulder flexion/extension and external/internal rotation while abduction/adduction was more difficult to facilitate. Furthermore, the device could not provide assistance in performing elbow or wrist flexion/extension nor pronation/supination of the upper limb. However, crucially, weight support was provided at the shoulder to help reduce the effects of shoulder subluxation and in turn, pain for those that may exhibit it, as is common in stroke patients (Gamble et al. 2000).

6.3 Limitations

6.3.1 Detailed Design

Limitations during the detailed design stage of the project mainly consisted of the limited design experience of the researcher and time pressure to develop an initial prototype for testing and feedback sessions. Regarding feedback, the prototype was not completed in time for the visit to NHS institutions and the University of East Anglia in Norwich, potentially leading to key feedback being missed (section 3.5). In light of this, the first prototype was not optimal though this was to be expected as part of the ongoing design process. Testing, redesigning and repeating forms the basis of this iterative design stage (Design Council 2019).

6.3.2 Feasibility Study

The initial feasibility study highlighted the main issues with the first prototype. Testing initially with healthy participants was beneficial to determine that the WSD would be safe for use and allowed for potential issues to be identified early (in this case, comfort

and mobility issues). These problems were fully realised with the stroke survivor group, particularly as the cable used to support the mechanism snapped between participant sessions. This issue was resolved quickly for the next participant but the prototype should have been properly fatigue tested to assess how long this component would last. Additionally, the difficulty of facilitating forward and backward movement of the device was highlighted as a key issue for modification. While initially seen as awkward to manoeuver with healthy participants, when used with stroke survivors it was incredibly difficult to manoeuver, particularly with those with a more severe impairment. Consequently, the device appeared to hinder movement more than without using the device (section 4.3.2.1). Furthermore, one participant who used the device while in their wheelchair found it quite difficult to operate, as the device had been initially designed for use with participants sitting in standard chairs.

Regarding feedback, each participant only participated in a single session that lasted approximately 60 minutes, including set up. As a result, they were potentially unable to familiarise themselves with the device in that time possibly limiting the full range of feedback that could be provided for the first iteration of the device. Despite the above limitations and short time spent with the device, participants expressed that they had a positive experience with it. They believed that it could help them perform upper limb exercises and potentially benefit their upper limb recovery provided the issues mentioned were resolved.

Regarding the outcome measures, upper limb measurements provided via Vicon motion analysis served as an initial indicator of the changes in movement availability with and without the device. Statistically significant results using this outcome measure could not, however, be generated unless performed in a full clinical trial,

using the device over several weeks/months and comparing the difference in range of motion before and after device intervention. An alternative method for upper limb measurement, not used in this study, is smoothness of movement. This has been used as a measure of motor control for both healthy participants and subjects living with stroke, particularly as it has been reported that movement becomes smoother during recovery following stroke. (Rohrer et al. 2002; Bartolo et al. 2014; Kerr et al. 2017). While not implemented in the study it could be potentially useful as a measure to determine if training with the device has an impact on movement quality, which is an important feature of normal movement (Rohrer et al. 2002), either immediately or through prolonged training.

Following from the initial study and continuing the deliver phase, the feedback and results obtained guided the development of the second iteration of the WSD. Additionally, a feedback system to be used together with the WSD was designed.

6.3.3 Feedback System

In light of the time constraints for the project, it was decided not to incorporate an internal feedback system with the device. As such, this was not developed for the initial prototype nor tested in the initial feasibility study. Instead, it was chosen to use an external feedback system to be used in conjunction with the device. For this project, custom-made applications (or games) were created that implemented simple input devices (i.e. proximity sensors) to allow the user to manipulate objects on a computer screen. The games created for this project do not necessarily need to be used in conjunction with the WSD. There are a wealth of interactive systems (both commercial

and non-commercial) available for rehabilitation practice defined in the literature as "virtual reality" (Laver et al. 2017).

There is potential that some of these pre-existing systems could be used instead of custom-built applications with the WSD to provide weight support of the arm for the user and interactive games for the user to receive feedback on their performance. While the literature states that use of virtual reality to augment rehabilitation does not necessarily improve outcomes in upper limb rehabilitation relative to conventional therapy, the individuals undertaking it tend to find it more enjoyable (Kong et al. 2016). As a result, it was thought that this type of intervention could be employed as an alternative for individuals to use at home, particularly where resources to provide conventional therapy are limited (Saposnik et al. 2016; Bernhardt et al. 2007). Furthermore, where part of the role of the therapist is to provide motivation and encouragement to the patient during their rehabilitation, this intervention may help fill this gap that would be absent in self–practice. In doing so, it can allow the user to continually engage in independent repetitive task training while hopefully not becoming mundane where the user becomes bored of performing the tasks and in turn, hindering potential recovery. Repetitive task training has been reported to have a beneficial effect on upper limb recovery (French et al. 2016). Therefore, motivating the individual with feedback on their scores and progression could help encourage them to self-train and, with facilitation from the WSD, perform repetitive upper limb exercises. Furthermore, it allows the individual to determine the best solution for them though this may raise issues with the required costs as well as time. Regardless, this approach could provide a unique rehabilitative experience in terms of interactivity and the feedback the user receives as it would preferably be tailored to their requirements.

6.3.4 Final Study

The next iteration of the WSD was developed in parallel with the feedback system. The alterations described in Chapter 5 were seen as essential to ensure future participants could use the device with fewer issues than the first prototype. Rather than build a completely new prototype, additions and modifications were made to the existing model to save on costs and materials during the design phase.

To overcome the issues associated with having participants only participate in one session in the initial feasibility study (chapter 4), the next study undertook a case study approach (chapter 5). In light of this, despite there being fewer participants overall, each participant would be able to take part in more sessions (approximately 4-5 per participant depending on availability). Consequently, the more time each participant engaged with the WSD, the more likely their understanding of it would increase, enabling them to communicate their feedback effectively. Furthermore, the second study provided the opportunity to assess the ability of one of the WSD's key goals: accessibility for home use. Developing a device that can be successfully used in the participant's home was one of the main aspects desired for the project. In doing so, it potentially opens up another avenue for home and/or community-based self-directed rehabilitation, providing stroke survivors with an accessible alternative (Da-Silva et al. 2018; Rinne et al. 2016).

Results from the study showed that the WSD could be employed as a suitable alternative though again with more changes required to the device. However, this was on the basis that all participants had their own workspace in order to set up and perform the task (i.e. a table, chair, and sufficient dedicated space). Though not implemented

in time for this project, it may be beneficial to develop bespoke clamps for various furniture and equipment such as wheelchairs or beds where the WSD can be fitted for use based on the patient's needs/desires. While the WSD was considered acceptable for use in the home by the participants (n=4), keeping the user engaged is crucial to ensure they use it frequently. Response to the feedback system was mostly positive with criticisms consisting mainly of comments about the game's simplicity with the possibility of it becoming boring after a while. Furthermore, some participants expressed a desire that the scores they achieve be recorded and displayed (i.e. their high score) as a benchmark. In turn, this would potentially motivate them and attempt to improve each time by providing them with an evolving target.

Providing other means of feedback could also be beneficial to the user regarding activity. For example, activity monitors strapped to the user's upper limb could provide an indication of the amount of activity they engage in both with and without the WSD (Uswatte et al. 2006; Leuenberger et al. 2016). In doing so, it can provide individuals living with stroke both a short-term and long-term method for recording their daily activities of their impaired upper limb and allow them to continually track progress. Looking back at the initial conceptual designs from Chapter 2, one concept looked at using a Lycra sleeve that the participant could wear and then attach to a WSD in order to take part in their exercises. A similar method could be employed but the potential of adding sensors to the sleeve as well to monitor activity could be effective for the user when performing their exercises or for tracking their normal daily activities. As such, this could also be a potential solution to allow them to self-assess their progress while using the WSD for their rehabilitation exercises.

6.3.5 Summary

In summary, the main limitations of the thesis were:

- Limited design experience of the researcher and high risk of bias in design choice.
- Inexperience of the researcher in conducting focus groups and interviews leading to undetailed feedback and potentially unconscious bias in the results.
- Small samples sizes in both studies (see chapters 4 & 5) resulting in limited qualitative data on feasibility and acceptability of both the WSD and feedback system.

6.4 Recommendations for Future Work

As stated previously, this project showed that the upper limb WSD created was accessible and feasible for use by participants to use as part of their stroke rehabilitation in the home environment. The next stage for developing the device should continue the double diamond approach focussing on iterating and delivering the final product for the consumer (i.e. stroke patients with upper limb impairment).

Similar to the changes from the first to second iterations of the prototype, the suggested feedback and recommendations for improvement need to be considered and how they could be taken forward. Based on the feedback provided from the final study (see section 5.4), several recommendations were suggested by participants to further improve the WSD design. These were:

- Range of Motion – some participants found the device quite restrictive therefore improving the design to facilitate a greater range of motion was

desired. This could be achieved through either increasing the degrees of freedom in the device itself, or via enhancing the adjustability of the device to enable the user to modify aspects of the device (e.g. height, cuff placement) to their preferred specification.

- Safety and Comfort – All participants noted that although in general using the device was okay, all at some point during the study felt some discomfort or worry while strapped into the supports. Facilitating a method to allow the user easily adjust position of the supports for their upper limb could help alleviate this issue. Furthermore, one participant was worried that their arm would slip out of the supports, particularly their forearm as their elbow was not supported. Extending the support to the elbow while still allowing for flexion/extension of the joint would be desirable to increase participant safety.
- Accessibility and Portability – One participant stated that although the device could be used relatively easily in their home, they would have liked it to be smaller and more portable, acknowledging that they would be more likely to engage with and use a more compact version. Furthermore, a smaller and more portable version of the design could increase the user base and potentially ease independent set-up. Further to this, developing a locking mechanism for the upper limb cuffs would also improve set-up, potentially making it easier for the user to place their upper limb in the device independently, a task that was challenging for the participants in the final study.
- Feedback – Most participants enjoyed using the feedback system though all had recommendations for improvement. A greater number and variety of games was suggested, particularly if the user would be using the device long-

term, in order to maintain engagement with the system. Furthermore, developing a system to consistently record a participant's progress in the games and allow them to track their progress was suggested, in order to provide feedback both in the short and long-term and also to aid with motivation.

Currently, the most up to date prototype for this project has been taken forward with the University of Strathclyde's innovation programme receiving over £10,000 in funding towards development into a commercial product. This has been used to conduct a patent review of competing products and for the development of a new prototype through collaboration with Shapemaster Global Ltd (Shapemaster Global Ltd, Honley, Holmfirth, United Kingdom), an exercise equipment company, and Design 4 Plastics Ltd (West Yorkshire, Wetherby, United Kingdom), a product design consultancy. Through this collaboration, it is hoped that the majority of issues highlighted by participants have been resolved. In particular, the next prototype is proposed to contain a constant force spring, to provide constant weight support for the arm in all configurations. In turn, this should remove the difficulty in pushing the support down by the user when the spring tension is increased. To confirm that the issues have been resolved, several devices will be made and tested at the University of Strathclyde (Glasgow), the Brain and Spinal Injury Centre (Salford), and at participants' homes.

Moreover, the proposed feedback system will require enhancements in functionality, customisation, and enjoyment to keep the individual engaged during their exercises and provide them with accurate and consistent tracking of their progress. Alternatively, as mentioned earlier, there may be potential in combining existing interactive games and systems with the WSD.

Finally, once the main issues are deemed resolved, conducting a pilot randomised controlled trial with the WSD is recommended. This should be conducted to test: (a) recruitment feasibility; (b) outcome measure viability/acceptability; (c) device safety when used in the home environment and (d) generation of sufficient numbers to calculate a sample size for a trial statistically powered to test the efficacy of the device.

6.5 Conclusion

To conclude; a low cost, portable WSD was conceived, developed and evaluated for stroke survivor's with hemiplegia to assist with their upper limb rehabilitation in a home environment. Through continuous testing, feedback with stakeholders and iterations, a working prototype was developed that could feasibly be used in the user's home to facilitate self-practice. Furthermore, while not integrated into the WSD, the prototype can be used successfully in conjunction with external feedback systems to provide real-time feedback, track progress, and motivate the user, encouraging them to engage in independent practice.

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Appendix A – Final Prototype Dimensions

Group Name	Component Name	Length (mm)	Width (mm)	Thickness (mm)	Diameter (mm)	Volume without Cuts (mm^3)	Volume with Cuts (mm^3)
Four-Bar Assembly							
	Four-Bar Top (x2)	340	25	5	N/A	4.25E+04	3.26E+04
	Four-Bar Bottom (x2)	340	25	6	N/A	5.10E+04	3.61E+04
	Four-Bar Base	250	32	32	N/A	2.56E+05	1.71E+05
	Four-Bar Base Top Cover	170	32	3	N/A	1.63E+04	1.62E+04
	Four-Bar Base Front Cover	32	32	3	N/A	3.07E+03	2.98E+03
Support Assembly							
	Support Base – Upper Arm	100	25	6.5	N/A	1.63E+04	1.33E+04
	Support Base – Forearm	100	70	11.5	N/A		
	Support Bearing Housing (x2)	45	25	20	N/A	2.25E+04	1.31E+04
	Support Shaft (x2)	125	N/A	N/A	4	6.28E+03	6.16E+03
	Support Cuff Holder (x2)	100	25	21	N/A	5.25E+04	2.03E+04
	Support Arm Rest (x2)						3.25E+04

Clamp Assembly							
	Clamp	124	120	80	N/A	1.19E+06	3.14E+05
	Crutch Clamp	70	37	35	N/A	9.07E+04	4.68E+04
	Crutch Top	210	N/A	N/A	30	1.48E+05	1.27E+04
	Crutch Bottom	400	N/A	N/A	22	1.52E+05	3.85E+04
Forearm Assembly							
	Forearm Bar	340	25	7	N/A	5.95E+04	3.67E+04
	Forearm Connector	70	30	18	N/A	3.78E+04	2.78E+04
	Distal Tube	170	N/A	N/A	18	4.33E+04	9.03E+03
	Distal Outer Sleeve	50	N/A	N/A	22	1.90E+04	6.28E+03
Slider Assembly							
	Rail	200	N/A	N/A	N/A		5.60E+04
	Truck				N/A		5.85E+04
Rail to Four-Bar Mount Assembly							
	Mount Brackets (x2)	60	28	17.5	N/A	2.94E+04	7.12E+03
	Four-Bar Mount	50	40	15	N/A	3.00E+04	2.30E+04
	Truck Mount	75	60	12	N/A	5.40E+04	4.87E+04

Appendix B – Ethical Approvals

From: Linda Gilmour
Sent: 03 July 2017 12:03
To: Andrew Kerr
Cc: Ross Collins
Subject: Approval Paper DEC.BioMed.2017.115

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

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Ross Collins

From: Ethics
Sent: 15 August 2018 10:11
To: Ross Collins
Cc: Andrew Kerr; Avril Thomson; Ethics
Subject: Approval: UEC18/50 Kerr/Thomson/Collins: Feasibility study on a weight support device (WSD) for upper limb rehabilitation.

Dear Applicants

ETHICAL AND SPONSORSHIP APPROVAL
UEC18/50 Kerr/Thomson/Collins: Feasibility study on a weight support device (WSD) for upper limb rehabilitation.

I can confirm that the University Ethics Committee (UEC) has approved this protocol and appropriate insurance cover and sponsorship have now also been confirmed.

I would remind you that the UEC must be informed of any changes you plan to make to the research project, so that it has the opportunity to consider them. Any change of staffing within the research team should be reported to UEC.

The UEC would also expect you to report back on the progress and outcome of your project, with an account of anything which may prompt ethical questions for any similar future project and with anything else that you feel the Committee should know.

Any adverse event that occurs during an investigation must be reported as quickly as possible to UEC and, within the required time frame, to any appropriate external agency.

The University agrees to act as sponsor of the above mentioned project subject to the following conditions:

1. That the project obtains/has and continues to have University/Departmental Ethics Committee approval.

2. That the project is carried out according to the project protocol.

3. That the project continues to be covered by the University's insurance cover.

4. That the Director of Research and Knowledge Exchange Services is immediately notified of any change to the project protocol or circumstances which may affect the University's risk assessment of the project.

5. That the project starts within 12 months of the date of this letter.

As sponsor of the project the University has responsibilities under the Scottish Executive's Research Governance Framework for Health and Community Care. You should ensure you are aware of those responsibilities and that the project is carried out according to the Research Governance Framework.

On behalf of the Committee, I wish you success with this project.

Kind regards
Angelique

Angelique Laverty
Research & Knowledge Exchange Services (RKES)

Ross Collins

From: Ethics
Sent: 06 March 2019 14:44
To: Ross Collins
Cc: Andrew Kerr; Avril Thomson; Ethics
Subject: Approval: UEC19/08 Kerr/Thomson/Collins: Evaluating user acceptability of an upper limb weight support device incorporating performance feedback for stroke rehabilitation.

Dear Applicants

ETHICAL AND SPONSORSHIP APPROVAL
UEC19/08 Kerr/Thomson/Collins: Evaluating user acceptability of an upper limb weight support device incorporating performance feedback for stroke rehabilitation.

I can confirm that the University Ethics Committee (UEC) has approved this protocol and appropriate insurance cover and sponsorship have now also been confirmed.

I would remind you that the UEC must be informed of any changes you plan to make to the research project, so that it has the opportunity to consider them. Any change of staffing within the research team should be reported to UEC.

The UEC would also expect you to report back on the progress and outcome of your project, with an account of anything which may prompt ethical questions for any similar future project and with anything else that you feel the Committee should know.

Any adverse event that occurs during an investigation must be reported as quickly as possible to UEC and, within the required time frame, to any appropriate external agency.

The University agrees to act as sponsor of the above mentioned project subject to the following conditions:

1. That the project obtains/has and continues to have University/Departmental Ethics Committee approval.

2. That the project is carried out according to the project protocol.

3. That the project continues to be covered by the University's insurance cover.

4. That the Director of Research and Knowledge Exchange Services is immediately notified of any change to the project protocol or circumstances which may affect the University's risk assessment of the project.

5. That the project starts within 12 months of the date of this letter.

As sponsor of the project the University has responsibilities under the Scottish Executive's Research Governance Framework for Health and Community Care. You should ensure you are aware of those responsibilities and that the project is carried out according to the Research Governance Framework.

On behalf of the Committee, I wish you success with this project.

Kind regards
Angelique

Angelique Laverty
Research & Knowledge Exchange Services (RKES)

Appendix C – Game Code Example – Three Sensor Game

Game Setup

```
--Global variables
--Game components
ball = ball or 0
capsules = capsules or {}
capsules_drs = capsules_drs or {}
score = score or 0

--no of capsules wanted
capsule_no = capsule_no or 3

--Variable indicating the active sensor from the script
k = k or 0
init = init or 0

--Function Definitions
--Create Game World

function createWorld()
      w1 = world.createworld()
      local floor = world.createfloor(w1, 0, 1, 0, 0.082)
      world.creatematerial (w1, "Wallmat", 0)
      world.setgravity(w1, 9.81)
      world.setworldproperties(w1, "linear_damping_threshold = 10")
end

--Create Capsules

function createPickups()
      world.creatematerial(w1, "Pillmat", 0)
      --number of capsules to be created
      local j = capsule_no
      for i =1, j do
            capsules[i] = world.createcapsule(w1, 0.5, 0.5,
            "Pillmat")
            local posX = 0
            local posY = 0
            local posZ = 0
            --Positioning capsules in a horizontal line for this
            application
            if i == 1 then
                  posX = 0
                  posY = 10
            elseif i == 2 then
                  posX = 15
                  posY = 10
            elseif i == 3 then
                  posX = 30
                  posY = 10
            end

            body.setposition(capsules[i], posX, posY, posZ)
            body.setorientation(capsules[i], 45, 300 * (i-1) % 2,
            45)
```

```
            capsules_drs[i] = object.create("Cube", "Red")
            body.connectdrsobject(capsules[i], capsules_drs[i])
            capsules_drs[i]:setcastshadows(false)
      end

return capsules

end


function resetObjects()

      --Change color of the last known active sensor to red.
      o = capsules_drs[k]
      o:setscaling(1.0, 1.0, 1.0)
      m = object.getmaterial(capsules_drs[k])
      m:setdiffusecolor(2, 0, 0)
end

function updateObjects()
      --rotate pickups
      rotationPill = rotationPill or 0
      rotationPill = rotationPill + 0.5

      k = inputs.get(2) --Active Sensor
      body.setorientation(capsules[k], 45, rotationPill + (k*100),
      45)

      --Capsule_drs is the object. Capsules is the body?
      --Change the color of the current active sensor to green.
      o = capsules_drs[k]
      o:setscaling(2.0, 2.0, 2.0)
      m = object.getmaterial(capsules_drs[k])
      m:setdiffusecolor(0, 2, 0)
end

--Initialization
if init == 0 then
      createWorld()
      capsules = createPickups()
      k = inputs.get(2)
      init = 1
end

--Update code--
time = inputs.get(1)
world.update(w1, framedelta())
if time > 0 then
      resetObjects()
      updateObjects()
end
```

Interface Kit with Proximity Sensors

```
--Global Variables

--Sensors
Sensor = Sensor or {}

--Time from stopwatch (Might not be necessary - can just link
stopwatch to output.)
time = time or 0

--Variables for determining time between repetitions
start_time = start_time or 0
rep_time = rep_time or 0
rep_time_f = rep_time_f or 0

--Incremental counter for each repetition
counter = counter or 0

--Initialization variables
init = init or 0
first = first or 0
SensorTest = SensorTest or 0
repInit = repInit or 0
active = active or 0
activeTest = activeTest or 0

--Functions
--Initialization
if (init == 0) then
      for i = 1,3 do
            Sensor[i] = 0
      end

      active = 0
      activeTest = 0
      time = 0
      start_time = 0
      rep_time = 0
      counter = 0

      first = 0
      SensorTest = 0

      init = 1
end

--Update
time = inputs.get(7)

--Choose the first sensor
if first == 0 then
      active = math.random(table.getn(Sensor)) --Choose a random
      sensor (table.getn returns
      the array size)
      SensorTest = active
      outputs.set(5, active) --Check which sensor is active
      first = 1
end
```

```
--Obtain values of each Sensor
for i = 1,table.getn(Sensor) do
      Sensor[i] = inputs.get(i)
end

--Check if Sensor has been activated
--Phidget 10cm IR Proximity Sensors read approx. 1 when nothing is
activated and 0 when
they are.

if Sensor[active] <= 0.5 and activeTest == 0 then
      counter = counter + 1    --Add to counter
      rep_time = time - start_time  --Calculate time taken to reach
the target

      --outputs.set(8, table.getn(Sensor))
      activeTest = 1
      broadcast("Increment") --Play audio feedback.

      --check if rep_time is faster than previous
      if rep_time > 0.1 and repInit == 0 then
            rep_time_f = rep_time
            repInit = 1
      elseif rep_time > 0.1 and rep_time < rep_time_f then
            rep_time_f = rep_time
      end
end

--Ensure a different sensor is chosen for next time after the target
has been reached.
while activeTest == 1 and Sensor[active] >= 0.5 do
      active = math.random(table.getn(Sensor))
      if active ~= SensorTest then
            start_time = time --Reset timer to calculate time taken
            for the next target.
            SensorTest = active
            activeTest = 0
      end
end


--Output Sensor values
for i =1,table.getn(Sensor) do
      outputs.set(i, Sensor[i])
end

outputs.set(5, active)
outputs.set(6, counter)
outputs.set(7, rep_time)
outputs.set(8, rep_time_f)

--Finish point
if counter == 30 or time > 30 then
      broadcast("Stop")
end
```