DESIGN AND DEVELOPMENT OF A ROBOTIC GLOVE FOR HAND 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:

Previously Published Work

This thesis contains work that the author has been submitted for publishing during their period of research that this submission covers. Any replicated diagrams from these papers have been marked to highlight this. One of these has been published by IEEE in Transactions on Neural Systems & Rehabilitation Engineering and the other has been submitted to the Journal of Healthcare Engineering.

Signed:

Date:

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Abstract

In the western world there is an issue in healthcare being created by an increasing number of people who experience disability. Whilst the reasons for these occurring are multiple, the common treatment to aid recovery from this condition is therapy that requires manual stimulation of the musculature form a therapist. Due to the physical demands that this process places on the therapist it is thought that a possible solution to meeting the increasing future demand for therapy is with developments in robotic technology. This thesis proposes and develops the design of a cable-driven glove to assist patients to grasp, this direction of design was chosen after a consultation with former patients found that this was the activity of upper limb motion that they felt was the most difficult to control after therapy. Their design requirements resulted in the creation of a lightweight glove that maximised the performance of the cable driven system through the use of a vacuum to secure the cable and use the joints of their body to control the flexion. This design resulted in the development of a first generation prototype that was assessed firstly by operating a 3D printed hand to grasp a collection of balls and cubes. After this the prototype was tested by unimpaired volunteers to provide feedback on the comfort and control they have when using the device, which was then compared to the findings from the initial consultation. This showed that the glove was successful in performing the intended motion and was considered comfortable (3.5/5) as well as providing them control (3.83/5). The device was used in a consultation with medical workers as

well, who were impressed with the strength of the device, but highlighted improvements that could be made to refine it further.

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Introduction

As society has developed in the field of medical technology there have been improvements in both general life expectancy and survivability from serious traumatic incidents. Whilst this is a laudable aim, there is an unintended consequence that occurs as physical disability becomes more common (The World Health Organization believes that approximately 15% of the world's whole population have some form of disability [1]). This disability can result from a combination of muscular weakening due to an ageing population, poor lifestyle choices from the patient along with the damage, both mechanical and neurological, that can result from traumatic injuries. The severity and locality of the damage will vary across conditions and patients, and whilst there are remedial interventions that can be made, such as surgery, the recovery process will always require therapy that can for example range from physical exercise, manual therapy, splinting, transcutaneous electrical nerve stimulation or the use of corticosteroids to encourage recovery [2 & 3].

An increase in the number of disabled patients creates a conundrum for the medical field in terms of treatment, as to directly support an increase in the number of patients this growth must be matched proportionally with increases in the number of medical workers that are available to treat them. Increasing spending on skilled labour of medical workers is a challenge that becomes further compounded in countries which are scaling back government spending on health and social care services, in England for example the number of occupational therapist roles available dropped by 14.29% in the period between 2011 and 2015 [4]. This appearing deficit creates the

requirement for additional solutions to be developed that are lower cost than the current process of recruitment and training for therapists [5 & 6].

The best way to support this therapy is to develop a wearable device that can guide the wearer through the activities that they need to perform in rehabilitation as conceptually this will enable the same recovery to be made whilst reducing the workload of the therapist. A final stage device could theoretically enable the therapist to take on a completely observational role, where they assess output data to review performance and propose alterations that could then be made to the patient's training regime, which would be directly controlled by the worn device.

Meanwhile in the interim it will be beneficial to patients to develop devices that could assist them to perform the activities required in therapy independently. The purpose of this thesis is to develop a low cost support that could, in theory, be distributed to patients to keep and use in their own time as both a supporting tool to their recovery as well as an assistive device for daily living. This thesis outlines the discussions conducted with patients to form the background research that was undergone to find firstly the design principles that went into the development of a novel robotic glove that could be used in rehabilitation. Firstly it was developed as a concept and then afterwards a first stage prototype of a novel cable driven vacuum glove was built from this theory. Having developed a functional system this research then conducted an initial test to prove the validity of the concept with an artificial hand. This was then taken on to a second stage of testing with healthy volunteers and a consultation with medical workers so that they could

provide constructive feedback on how the device performed when being used that could then be contrasted with the initial data collected from the patient consultation. This feedback had both positives and negatives, with the main positive being the strength of its grasp and the main negative being comfort issues created by the components being one size that was not transferrable for wearers of different shapes and sizes, with improvements for future versions of the prototype suggested. The design was considered to be applicable for use with some disabled patients, which could be increased further by taking on board the suggested adaptations.

This thesis includes:

- An investigation into the needs of former patients with regards to improvements in future rehabilitative care.
- A unique design for a cable-driven exoskeleton glove intended for home use.
- The development of a low cost first stage prototype.
- The feasibility testing of this prototype with a 3Dimensional printed hand.
- Practical testing with unimpaired volunteers to provide feedback on the functionality of the design.
- A review conducted with hospital staff into the prototypes performance and a consultation on the changes that should be made before it is used with patients.

Chapter 1 Literature Review

Chapter 1 Literature Review

In this chapter the author will introduce why this thesis has resulted in the development of an innovative robotic to assist human motion. To achieve this there will be a review of previous designs for robotic interventions in upper limb rehabilitation highlighting their strengths and weaknesses. Additionally this will be done with examples of the most commonly used control systems that are placed on these devices.

1. Robotics in Treatment of Disability

In medically advanced societies there has been a reduction in the frequency of fatalities that occur from traumatic injury and medical conditions. These improvements in medical care have resulted in increased life expectancy across the developed world; however this has an unintended consequence where the survivor may now experience a disability instead. These disabilities can be both physical and mental and are not limited in their impact, where some can broadly impair mobility others may be acutely restrictive, such as the loss of hand control from a spinal cord injury [7] in comparison to the hemispherical impairment that may result from a stroke [8].

The varied causes of disability results in a wide range of remedies with differing goals, such as slowing down future degeneration, initiating recovery or managing the condition. This treatment is conducted by a team of skilled workers with a wide field of expertise such as physical therapists, occupational therapists and rehabilitation doctors whose skills are used to

achieve the best result possible for the patient. There are some patients who may be in such an advanced stage of their condition that they cannot regain control of their mobility, for these individuals there is still an option to try to enable them to interact with the world around them, as a result robotic aides have been developed to help power their motion.

The therapy process has many activities that can be performed to improve the patient's mobility with exercise and manual therapy being the most prominent active interventions that they use [9]. If this is not started quickly in the aftermath of the event that caused the disability then the problem can become compounded as issues such as contractures occur amongst bedridden and inactive patients. One possible solution to this issue can be in the use of serial casting [10], where their joint is cast in a flexed position to stimulate blood flow in between therapy sessions.

Manual therapy is conventionally applied directly by the therapist onto the patient's body tissue in a 'hands-on' manner however there has been a recent desire to see their expertise utilised in an analysis role and creating a demand for mechanical systems, such as the BrightArm [11] which was found to produce clinical benefits on a motor, emotive and cognitive level. All participants in the initial testing of this device displayed improvements in their range of shoulder movement, shoulder strength and grasp strength. This system was not mounted to the user, but was instead a table that they would rest their arm on and it would tilt as required, causing the arm to slide on the surface and gravity to exercise the limb.

The use of robotic technology in therapy is a recent trend; these devices are proposed to assist the manual component of the therapist's role, allowing them to take an observational position that would be centred on assessing their progress and planning ahead. The positives and negatives of such a move are the same arguments as made when any industry begins to mechanise its processes; that the machines can operate for longer and with a greater consistency than a human could in this role, allowing for more patients to be seen each day and for longer periods of time. Giving the patients more time dedicated to their therapy should then improve the level of their recovery. Counter to this the 'loss of the human factor' can be considered as a criticism, whilst this is considered no great loss in mass production, it may create issues in a service orientated industry such as healthcare. The patient, in this case after having possibly just experienced a traumatic injury, possibly feeling vulnerable from their impaired ability to interact with the world around them, may appreciate the direct interaction and motivation that another person could provide as opposed to an artificial training device.

A systematic review [12] has suggested that patients treated with a robotic system can gain independence and improve motivation towards their treatment, however many of the studies lack a control group to validate that this improvement is a consequence of the device. Two of the studies in the review used a control group for comparison, both noting improvements from using the mechanical system over conventional therapy; however one of those studies [13] allowed the robot therapy group an additional four to five

hours per week of training, which could have significantly impacted the noted improvements. It does however support the previously listed supporting argument that using a mechanical system will allow the therapy sessions to be longer, which will in turn give the patients more exercise time and increase their recovery.

Despite the over-arching signs in published papers that the use of robotic technology can improve the level of physical recovery in neurorehabilitation the rate of uptake at the clinician level remains low [14]. This is in part due to the lack of access and cost of the devices that are on the market, particularly for locations where the number of patients is lower; as this increases the cost of treatment on a per patient level. Additionally, there is a lack of quantitative data on the market, as robotic devices are usually tested in small numbers and often lack comparative tests not against physical therapy, but also in comparison to one another [12]. As a consequence it is important that developed systems are comprehensively tested to show the benefits to therapists and their patients as well as making economic sense so that health services will invest in them.

Integrating technology into the recovery process also opens the opportunity for more home based improvements, trialling of a computer controlled reaching training program was shown to increase shoulder flexion by 13° and elbow extension by 9°, where the patient conducted their treatment in their own home under periodic webcam observation [15]. Advancements in observational systems used for home entertainment have the potential for patients to get automated feedback and suggestions on advancements in

their exercise [16]. To achieve this aim the device would need to be capable of assessing both the direction and orientation of the participant. Potentially this device could be also be connected to the internet and allow for their therapist to observe their performance live, by recording or as a returned data feedback, so that they could tailor their advice to the patient's needs, a setup of this nature that is installed in the patient's home could also enable patient's to increase their training volume, assuming that they have their therapist's support.

Despite the robotics field still being in its infancy, there are already a great number of designs that exist to assist patients. This is a result of the diverse range of conditions that can result in a physical impairment requiring a diverse range of solutions. Conditions such as Multiple Sclerosis (MS) can affect the brain or spinal cord by causing the erosion of the insulating covers of the nerve cells. This damage can then impact the nervous system and may result in difficulties controlling muscles within their body, with the variety and severity varying from person to person, where some may struggle to walk or grasp, others may suffer vision problems or lose control of their bladder [17]. It is a condition that will generally progress and spread across the body to affect multiple areas. Hand dysfunction in particular is believed to predominantly occur when the upper brainstem is affected [18]. As no cure has been developed for MS it is currently an issue that requires management to assist the patient as much as possible. This treatment will predominantly feature medications that are dependent on the patient's

condition; this is supported by a neurologist, speech and language therapist as well as a physiotherapist [19].

When trialling physical assistants, there are often interactive challenges that are used in association with the device to generate engagement from the user, however there are questions that can be raised over if they actually improve the patients performance or only train them to complete the tasks [20]. In this example robot supported training using the HapticMaster robot with a virtual learning environment resulted in increased efficiency of movement when using the device that was not repeated in clinical testing. In contrast improvements in hand speed have been noted when using a musical keyboard in rehabilitation that resulting in improvements from testing [21]. This may be due to nature of the feedback increasing focus from the patient to ensure that they are pressing the correct key as opposed to the limited scope of activity from the HapticMaster.

There are also physical injuries that can occur that require extensive treatment such as at the Brachial Plexus, the name given to the network of nerves that connect the spinal cord to the hand. They connect from the lower four cervical nerves as well as the first thoracic nerve (C5-C8 and T1) through the axilla and down to the hand [7]. As the main signalling pathway to the hand this means that any damage that occurs to this area will impact a patient's control of their hand. It is an injury that is stereotypically associated with accidents in higher risk activities such as motorcycle riding or contact sports, as analysis finds that approximately 40-70% of Brachial Plexus Injuries (BPI) are of a traumatic nature [22]. Childbirth injuries are the result

of problems in a traumatic birth, where the shoulder and neck are stretched apart damaging the nerves [23], which will predominantly show as a weakness or inability to externally rotate the shoulder, however if treatment is unsuccessful as the child gets older this can invert and pronation becomes the main source of muscle weakness with the issues also spreading to the forearm [24]. These injuries result in an impairment of motion of the shoulder, elbow and hand joints, the classification system for these injuries was formed in 1943 and is still in use today [25]. There are three forms of injury, neurapraxia, axonotmesis and neurotmesis in increasing severity. Severe cases of BPI require an immediate intervention to maximise the probability of recovery, however milder injuries have a strong response rate where patients can expect to recover 90-100% of the function in their arm in time [26].

Treatment for the injuries obviously depends upon its severity; solutions can range from surgery to splinting or physical therapy, there are also some, predominantly infants, who will recover without treatment [27]. Physical therapy is central to preventing muscle atrophy from setting in in the aftermath of the injury, and will take the form of flexion/extension, elevation/depression and abduction/adduction exercises to rehabilitate the joints in the affected arm and ensure that the muscles remain in use [28]. With an injury such as brachial plexus that has a high association with impact injuries there is a probability of patients experiencing physical pain. The first attempts to remedy this will come through the prescription of nonsteroidal anti-inflammatories for pain or through surgical procedures such as a nerve

transfer [29], where the damaged nerves are dissected and grafted to a new location where the signal electrical signal can transfer through, for example to in effect rewire the triceps brachii to give their subject control again over elbow extension. If these are unsuccessful then an innovative intervention may be the installation of a peripheral nerve stimulator to the nerve branch [30], this suggestion eliminated pain for over 70% of its targeted patients 12 months post implantation. During the attempted recovery of the neurological system there will be an element of physical therapy at a low intensity and not include actions which will place additional strain on the joints, such as by lifting the arm over the head. As the patient's sensitivity increases the therapy will adapt to their improved flexibility and action can then be taken to compensate for the imbalances that will have been created in the earlier therapy.

Whilst an injury to the brachial plexus is classed as a traumatic body injury and has a specific impact, a stroke is a traumatic brain injury with a wide range of impairments and severities. It is a result of a blockage or haemorrhage restricting the blood flow from an area of the brain, the grey matter comprising this area becomes physically damaged, impairing the transmission of signals within the brain. This will obviously have a distinct functional impact on the patient; with issues ranging from vocal problems to paralysis of a limb. It is common for stroke patients to have two main functional differences in their movement from the unimpaired, that there is little smoothness to the motion that they perform as well as there being little co-ordination between the joints [31].

Functional electrical stimulation (FES) was devised to replace the command role of the central nervous system and integrate with the peripheral nervous system to try and recreate muscle activation. The application of electrical impulses direct to the muscle to generate movement has been shown to be successful in helping patients to recover their ability to grasp [32]. Functional electrical therapy (FET) is the title often given to the process of using a neuroprosthesis to stimulate muscular recovery. It has had success previously [33] where the system is used to help the patient perform basic motion tasks such as grasping on top of their conventional therapy. The process was found to create a faster recovery amongst the patients as the process re-established familiarity in their actions and as with FES, FET should be applied as early as possible after the incident, as the paretic arm can recover 'near normal' functionality within six weeks and retain it [34]. The study found that the subjects who were given FET during the acute phase of their recovery displayed a greater range of motion 18 months post stroke.

As a stroke can often affect a whole hemisphere of a body it is interesting that there is a historical discrepancy between the level of recovery of the upper and lower limbs [35]. There have been developments in recent years in the upper limb, with devices such as the MIT-Manus [36], the MULOS [37] the MEDARM [38] and the KINARM [39] have been developed as possible solutions. Further hand orientated designs include the J-Glove [40] and X-Glove [41], that are cable driven systems that assist patients to repeatedly perform flexion and extension exercises.

There is also diversity in the impact of Muscular Dystrophy (MD), the title given to a collection of degenerative genetic muscular diseases that result in the impairment of the patient's movement [42]. Estimates have placed the rate of loss of function as 3-4% per annum [43] which increases their risk of falling and further injury. Some forms of the condition also spread to the muscles that are responsible for working with the heart and lungs making it potentially life-threatening. As there is no developed cure at present the disease must be managed to enable the patient to retain their standard of living for as long as possible.

Doing this requires a combination of aerobic exercise, physiotherapy and low intensity steroids to reduce the rate at which their musculature degrades. It has also been shown that electrically stimulating the musculature can have a positive effect on muscular weakness and excitability in the arm and shoulder [44 & 45], although there are question marks over this methods efficiency and if there are any consistent gains beyond traditional techniques [46]. There is also evidence to suggest that passive stretch exercises coupled with inhibitors can be of benefit to patients by improving the signalling pathways to improve fibre regeneration [47]. The stretching was found to increase the fibre density and diameter of the triangularis sterni muscle in mice after two months.

Robotic aides for patients with MD have been in development for a while, with both active and passive systems being trialled [48]. The EMAS II is an example of a robotic device that has been tested with MD patients [49], it was a four degree of freedom device that was set up to support the user when

eating and was controlled by pre-set switches and enabled subjects to eat a meal in less than 20 minutes that they would otherwise be expected to take 30 minutes for. Due to the degenerative nature of MD consideration must be given to the interface such a device would have with the patient, as many would struggle with the grasping controls used in many upper limb devices, experimentation with a computer screen GUI was shown to be a possible alternative that the patient groups were satisfied with [50].

Many of these conditions will be diagnosed when the patient is an adult, whereas Cerebral Palsy (CP) is a condition that is diagnosed at a young age. It is a result of damage in the motor control regions of the brain [51] and can set in at any point between pregnancy and early childhood, although it is believed that almost half of the children with CP have been born prematurely and this has been a contributing factor to its onset. It is estimated that one in 400 people in the UK are affected by CP [52] and are classified into three forms that are dependent on the impairment they have suffered and how this impacts the activities that they can perform: spastic, ataxic and athetoid. Spastic is the most common form of CP, occurring between 63 and 76.9% of all cases [53], and is the result of a lesion on the muscle which in turn impairs the nerve receptors in the spine creating muscle spasms that they struggle to overcome. Ataxic is the rarest form of CP and is a result of damage to the cerebellum and consequently appears as an issue with balance and visual processing. Athetoid CP is a mixed muscle tone, creating involuntary motions that make it difficult to stand upright and walk around; the result of

this is that it takes considerable concentration to perform tasks that can be completed intuitively by a healthy individual [54].

Traditionally when treating spastic CP the hand is constrained with a splint to prevent adaptation of the soft tissue, this can then be built upon with physical therapy to further improve the level of recovery achieved [55]. It is likely that the best results will arise when the recovery is structured to the individual needs of the patient, with improvements in step and stride length ($p = 0.022$ and 0.017 respectively) being seen [56]. Additionally some patient groups may experience greater recovery when also supported by constraint induced therapy (CIT) [57, 58 & 59], with improvements noted in speed and control of their fingers to perform a grasping motion. Other research has suggested that virtual environments can be constructed to engage child users in a non-formal manner with improvements being noted in movement of the shoulders and elbows [60 - 64].

There is also evidence to suggest that training with a robotic aid can improve the smoothness of movement as well as manual dexterity of their grasp, although these findings do not always transfer over from observable measures of performance into improvements in functional activities [65 & 66]. As CP is a condition for which there are many children who suffer from it, the treatment method must encourage engagement. The BiADLER system [67] was a pair of robotic arms that suspends the patient's arms and enables them to move around and interact with objects in a set working area. This should help child patients to perform many tasks, such as eating or their school work that is often a struggle for CP patients. The working area was

originally developed as a table top and the mechanical arms were operated by a combined positional and force control of which one was passive and offered six degrees of freedom and the other was had seven degrees of freedom of which five were active.

Another degenerative condition that affects the whole body is Parkinson's disease (PD) which impacts the nervous system. Traditionally it will cause a degeneration of the basal ganglia of the brain which results in the motions stereotypically associated with the condition, shaking, rigidity and difficulty walking [68]. With no developed cure for the disease it is currently an issue of managing the condition to offset its development. This is predominantly done with a combination of medications initially to offset development and laterally to reduce the symptoms and control fluctuations that can occur from the primary stage of medication [69]. Previously attempts to treat the disease had been conducted with surgery; whilst this was mainly phased out after the development of levodopa it is increasing in its commonality again due to improvements in surgical techniques [70].

Whilst shaking hands may be the diseases distinctive feature it is not consistently assessed, as a study of occupational and physical therapists found that only 54% of this group would consistently assess the upper limb capability of their patients [71]. It is believed that intensive exercise can be beneficial to Parkinson's patients by their improving their cardio-respiratory fitness and has a knock on benefit to their balance and walking performance [72]. As there is evidence to suggest that patients who have Parkinson's may change their hand usage to compensate for the main affected hand it

outlines the importance in attempting to limit the loss of motion they will experience in their hand to help to interact with the world around them [73], with benefits being found in manual dexterity and grip strength from a single exercise session [74]. This therapist led training session with therapeutic putty and a visual demonstration was thought to encourage self-correction from the patients that improved their performance. Other research has suggested that a two week physiotherapy program can reduce the severity of the freezing effect that impairs stepping in the gait of patients [75]. This training program lasted for a combined three hours and was orientated towards the larger muscles of the legs and some testing has suggested that either strength or aerobic training will see improvements in outcomes in the lower body whilst physical therapy may not [76]. This raises a question over how successful the process can be with the smaller precise movements of the hands, as occupational therapy has had mixed results, although the suggestion is that the best results are likely to occur when the treatment is individualised to the patient as it helps to promote self-management [77]. Some research suggests that there can be benefits to motor performance from task specific physical activity training [78]. Unfortunately there is little evidence to suggest that these training gains are transferrable to other factors of their impairment, so there are limitations to these short-term, task specific gains.

As Parkinson's disease affects the whole body there is a primary focus on improving the patient's walking to give them the mobility to achieve a basic level of independence. Robotics have been shown to assist patients with a

mild level of PD to improve the length of their step and stride when walking after a month long training program [70]. Robotic training aids have also been experimented with in upper limb recovery, with an early trial using a mixture of both active and passive training to create improvements in the performance of the nine-hole peg test [79].

Due to the wide variety of conditions that can afflict patients, coupled with the variety that can occur between patients with the same conditions there have been a range of devices that have been developed. Some specialise in one joint at either the wrist or elbow, others target the hand and some look to assist with the full arm. This range of ideas is beneficial for therapists it as creates opportunities to tailor the supporting tools to a patient's needs; however the cost of this approach may become excessive. A further issue that arises from the variety of approaches is that there is not a consistent standard of measurement that has been defined to fully compare and contrast each devices relative strengths and weaknesses. There is the possibility that these can be integrated to form a clearer picture, however relies on the assumption that the testing protocols are measuring the same underlying principle [80].

2. Engineering Solutions

Scientists and engineers have been attempting to bolster the human existence with the power of machines for decades, with studies going as far back as 1967 [81]. Although the Hardiman Program was not directed

towards rehabilitation but human enhancement, it still established the ground rules for the development of machinery designed to be intuitively used by a human operator. The Cybernetic Anthropomorphous Machine showed that instinctive control for basic motion will be best achieved through the development of a symbiotic relationship between the machine and the user. This would be achieved by ensuring that the machine responds proportionally to the user's commands, is responsive to the user's body position, creates a balance point for the user that would apply if they were performing the action without the machine and provide sensory feedback that will permit adaptation as the situation changes (visual, auditory and tactile). Without the provision of accurate feedback the system will be limited in its scope as the operator would be unable to tell if they are applying insufficient or too much force to an object. The system should be straightforward and comfortable to control, therefore the control set-up should be reflective of the natural motions and reflex responses that the user would display if they were outwith the system.

Extenders were a similarly intended system for improvement in human performance; they were designed to increase the user's strength in the moving of heavy objects whilst still giving the user complete control [82]. The system was designed for heavy loading tasks, where it would replicate the motions of the operator, such as grasping and lifting, but they would only feel 5% of the object's weight. A closed-loop positioning system was used as this would negate the impact of friction on the system to allow the device to display a linear dynamic response to the user's inputs. The closed-loop system also ensures that the device would be more stable when it is not

being worn, which consequently makes it far safer than possibly dropping objects when the user is not in constant control of the system. The force required to operate this system is a result of the activity of the muscles in the arm and the position that the device is being moved into, a factor that is adjusted by the impedance of the arm. For the closed-loop system to remain stable, it is important that the strength of the compensators are monitored, as a lack of strength will make the device difficult for the operator to move whilst making it overly responsive creates the issue of the system jarring back and forth to slight corrections from the user, which presents a threat to their well-being.

Developing robotic systems to treat patients with disabilities is both time consuming and costly, so there will always be those who question why this investment should be made when it is possible to make an artificial work-around. Such an example is Dusty [83]; a machine developed to pick up items dropped on the floor and raise them to such a height that the patient can then retrieve them from the fitted platform. Whilst such a system can help those with mobility issues to retrieve dropped items from the floor, it ultimately creates a reliance on the machine that is detrimental to the patient's long term recovery and social reintegration. Consequently the designs in this field are aiming to help give the patient the ability to take action independently firstly to engage them in their therapy so that can feel they are taking control of their recovery, as well as encouraging them to become self-sufficient for when their treatment period has finished.

To justify the uptake of physical therapy supported by robotics it must be proven that there is a tangible benefit from using the robotics alongside the conventional therapy. A comparison between these two methods of treatment [80] showed that the use of robotics provides a significant improvement ($p < 0.01$) for stroke patients in the scores recorded for motion with the Fugl-Meyer test, one of the most prominent assessments of motor impairment.

The end-effector system was also intended to encourage patient recovery through relearning of motion. These systems, such as MIT-MANUS [36] were external devices that would take hold of the patient's limb and guide their motion to encourage the recovery of muscular activity. They were found to be mostly successful in assisting user performance, but do have issues, firstly the machines are often rather large, making it difficult to move them. Consequently the patient is not able to use the system to support themselves outside of their therapy sessions.

There is also the challenge that even within the therapy session the patient is restricted to a chair so that the machine can function around them. Assessment of the device shows that it is successful in their primary aim; that of increasing the patient's accuracy and range of motion [85]. Improving the accuracy of motion is an important step in particular as it allows patients to become more self-assured and attempt to help themselves in small daily tasks that non-impaired people may take for granted. As a result of its importance in performance outcomes accuracy is a factor that is noted in observable assessments of activity such as the Fugl-Meyer test.

First generation models had issues with the range of motion covered by the device, which was not conducive to physical therapy. Initially the end-effector systems such as MIME [86] were capable of recreating the flexion and extension of the elbow as well as the rotation of the forearm. This was found to limit the repeatability of the arm, eventually being upgraded to include motion of the shoulder to allow for a greater variety of motions. End-effector systems raise the problem of how to create an external system that can replicate the full range of motion displayed by the human hand without consequently impeding it. Traditionally, the system is placed alongside the patient, however this presents a problem as the patient will always be unable to reposition their arm to where the mechanisms are located, as their arm cannot pass through that space. This means that a full replication of human movement will not quite be possible, which should be sufficient for assisting daily living but an expansive range of movement with limited restrictions in retraining would benefit patients who were more active before their impairment and aim to be regularly active again. An alternative solution would be to place the core machinery outside the range of the patient's movement; however this would then create a challenge to ensure that the system can retain both the accuracy as well as generate the necessary force to manoeuvre each limb independently.

When testing MIME's capabilities [87] there were four training settings incorporated to the design, firstly passive mode, where the patient would relax and the robot would manipulate the motion of their limb for them. For the active-assisted mode the subject would instigate the force and direction

motion and was supported by the robot to complete motion, this compares to the active-constrained mode, where again the subject would be responsible for directing the motion, but in this instance the robot would push back and resist their motion. During each of these trials the patient's healthy arm was restrained for Constraint-Induced Therapy (CIT), as it had been found to be more successful than neurodevelopmental treatment. The final training setting, bimanual mode, could not be conducted with one arm restrained as both hands would move in tandem as the subject would direct their unaffected limb towards the targets whilst the robot would mirror the motion with their affected arm. During each training exercise the objective would be for the subject to attempt to fully reach towards a target, which had four possible directions and three possible heights, making 12 locations in the patient's range of motion. The protocol was sampled in two slightly different training procedures for patients, dependent on the severity of their condition. The patients who were classed as 'high-level' did not participate in the active-assisted stage, instead performing 20 minutes of complete active-constrained motion, whilst the 'low-level' subjects had a 20 minute session comprising of seven to eight minutes of active-assisted movement, with active-constrained exercise making up the remainder of the 20 minute timeframe.

The use of Fugl-Meyer Assessment (FMA) testing suggested that the robot was beneficial for the initial time period after their treatment; however the control group had caught up with the improvements displayed by the robot treatment group by the six month point post treatment. This trend is also repeated in the subject's strength and reach assessments. It suggests that

whilst the individual therapy is important to patient recovery, the follow-up work that enables the patient to learn activities they can perform at home to keep developing themselves is just as important, and shows that there is still plenty of scope for the skills offered by physical therapists. It should also be noted that the subjects for this study were six months post CVA before the study began, so were at least a year post stroke when the final assessments were made in this study. That the subjects were still able to show a significant improvement at this stage should be seen as a positive indicator of continual recovery in stroke therapy.

Further work with MIME [88] has shown there to be an increase in work output in the arm over eight weeks of training with the device, but this was not carried over to reflect on the patients FMA, suggesting that although the limb is doing more work, it did not improve its range of motion. This may be a result of a decrease in the antagonist forces within the bicep as well as agonist muscle activity within the middle deltoid and triceps, as was displayed by a sub-group within the study. This trend was common to all motions that were completed at shoulder height, but the pattern was not fully observed during the motions that were completed at table top level. At this level two of the four attempted motions showed an increase in EMG amplitude for antagonist muscles, with no increases in EMG amplitude for the agonist muscles. They hypothesized that this may be a result of compensatory action being completed by the shoulder girdle at this height, reducing the workload that the muscles would undertake. There were also

further recorded improvements in the speed and smoothness of motion displayed by the subjects.

The effects of treatment using the various activity modes built into the design of MIME were also assessed [89]. Subjects were separated into groups testing unilateral motions, bilateral motions and a combination of both. By the midpoint of the study the unilateral and combined motion groups had significantly passed the study's control group. As with the researchers previous work [87] by the stage of the six month follow up period the robot training group reported similar improvements to the control groups, with the robot group benefiting by achieving this recovery in a faster timeframe. Of the three conditions tested, bilateral movement was found to display the lowest improvements in FMA post-stroke, with no significant differences being reported between the combined and unilateral groups. This was surprising as the unilateral patients would spend more dedicated time focusing solely on their paretic limb, however it may have been balanced by those subjects using the robot for significantly less training time than the other subjects. This was most likely a result of fatigue due to the active-constrained mode being a maximal exercise. This also meant that these subjects had additional resting time during their one hour time slot for the training. The effect of a greater specialist training time appears to have been counterbalanced by providing the combined group with more total training time, suggesting that there is a control benefit to the user from performing combined co-ordinated motion.

The natural progression from these ideas of supporting the motion would be the development of a system that could directly guide the motions and provide the relevant support to the actions that the patient completes during their therapy. The most efficient way to achieve this would be to place the arm within a mechanism that will manoeuvre it in response to the patient's commands and facilitate the arm's recovery. This would provide the patient with an experience that is both directly engaging and more interactive. Exoskeletons are designed and developed to provide both aid and rehabilitation for those who unfortunately lose the capacity to fully actuate their body, or to further enhance the performance of those who are unimpeded physically. Traditionally they are designed to encase the limb and allow a predefined range of motions at each joint. Depending on the motions selected, the systems will then be set up to encourage motion along these axes. Unfortunately due to the complex nature of its design no single exoskeleton has, as yet, been capable of replicating the full range of motion available in the human arm.

Irrespective of the motions set out in its individual design, the main functional process is to provide physical actuation of the limbs to complete the intended task. Designing limbs that encourage the body to fully replicate its natural motion appears to be the greatest challenge in this respect. It was suggested that this may be the result of the exoskeletons being too restrictive of the degrees of freedom that are present in the natural arm [90]. It was felt that the designs were limited to ensure greater control, however they consequently were not giving the user complete freedom to fully replicate

human motion. The conservative designs were considered to be an outcome of the lack of consistency across the field of biomechanical modelling; resulting in uncertainties that creates approximations in the design and control was subsequently restricted to enable the user to feel a greater sense of control. They developed a combination of formulas and design rules that would remove the redundancy of some components, whilst not subjecting it to the creation of a singularity.

As the range of exoskeleton designs grows, there remains no established practice for assessing its performance. Whilst the outcome measures can be assessed by numeric factors, such as range of movement, the speed of these motions and the torques that are applied to the limb by the system, there is not one for how the system and the user interact with each other. There is a lack of acknowledgement in previous studies that performance assessments for the devices are comparing a natural and assisted movement [91]. This is an issue as the arm has additional degrees of freedom that are not required to conduct the motion, and comparing the performance at the endpoint of motion does not give a complete reflection of everything that goes before it. The arm also contains more locations that produce forces and torques then a robotic arm, which will also produce a difference in the performance of the system.

They proposed a three-level model for assessment, looking at endpoint trajectory generations, joint rotations and dynamic interactions. It was used to review the performance of the ABLE four degree of freedom model, which showed that despite allowing the subject to reach the same endpoint with the

aid of the robots, the trajectory displayed a curved deviation in each direction, that may also contribute to the variation in velocity of the movement as well as the time increase to completion. Testing of the joint angles showed that the reviewed system was found to decrease the elbow extension and raise the shoulder function. Assessment of the dynamic interactions also highlighted forces from factors that were outwith the design of the system, as it had been designed as a zero torque model.

The lack of design consistency has given birth to a wide variety of motion systems with a variety of testing and results. So far patient testing has predominantly been small scale in terms of participant numbers and few studies have operated a control group alongside. Meta-analysis of the randomised clinical trials [92] suggests that there were no significant improvements in either the recovery or the functional ability of the arm in these studies ($p<0.05$). However, when the shoulder and elbow joints are isolated from the remainder of the arm they were found to have a significant improvement in range of motion. These improvements were found to be between 7% and 8% better for robot assisted motion over forms of therapy when measured by either FMA or the Chedoke McMaster Stroke Assessment Scale (CMSA).

There is also variability in the possible treatment methods, for example for treatment of the upper limb with multiple sclerosis some may want choose to treat the patient with reaching tasks, whilst others may integrate the reaching with a manipulation task [93]. After eight training sessions with a robotic handle it was found that the reaching task improved the patient's grasp

testing performance by 29.5%, whilst the integrated task increased performance by 77.4%. There were no significant differences in the improvement for performing precision grip activities as neither training protocol provided direct stimulation for these activities. This additional difficulty in fine control could also be compounded by the reduction in tactile sensitivity, which in turn gives the patient less feedback of what they are doing and makes fine tuning the interaction difficult.

2.1. Individual hands

It has been proposed that there are two approaches to take in the development of the robotic hand, that of placing emphasis on the output performance by mimicking motion and function, or by emphasising the aesthetics, that is similarity in size and weight [94]. Many studies look at the issue from the position of the former as whilst the devices are used exclusively in a lab environment then the components being excessively large or complicated to don and doff and its impact that can be worked around by the continual presence of the researcher. It is also hoped that by the time sufficient funding would be given to the field to consider mass production, that the components will have been sufficiently improved by developments in their own fields. The later model also presents a greater technical challenge, as the greatest possible motion is to be achieved with the fewest resources. Previous attempts to minimise the weight of the hand unit whilst maintaining the functionality have replicated nature by moving the

actuator components out of the hand to the forearm, as whilst the weight remains it is now more evenly dispersed.

A significant drawback of the exoskeleton design, which is most noticeable at the hand, is the lack of a sufficient control system to generate the commands for the device. This is necessary as the exoskeleton is deemed to best operate in a master/ slave relationship, however if the command cannot be clearly made and interpreted then the relationship breaks down. Theoretically, the best solution would be to directly connect the component to its operator however this would not be possible as the human and machine components are unable to directly interface with one another. Also the use of revolute joints limits the range of motion in some areas, such as the fingers, Kawabuchi [90] proposed getting around this issue by implementing circuitous joints that would move the finger mechanism forward to keep the joint axis and virtual axis of the device in line. This system was operated by a motor that was set outwith the finger, and reeled in a wire to create the straightening motion, with a spring set up to apply the force for flexing the fingers. This permitted several fingers to be set up in tandem and moving the whole finger in a steady and consistent manner with only one motor operating the system.

Early study of the finger kinematics was made to isolate the motion of the individual digits and to match the rotational forces that are applied during this motion [95]. In what was one of the first studies to embrace dynamics as a factor in finger movement they developed an experiment that was contrary to the previous norm, using cyclic movements to gather their data, by opting to

allow variation in the user's speed of motion into three groups, slow, "natural" and fast.

They found that the interactive moments were proportionally larger than the muscle moments that are used during finger motion. This implies that there will be an increased torque produced at these points during motion as well, that must be factored in to any measurements taken during multi-joint activity. Muscular activity was shown to be higher than previously anticipated as the muscle was not only producing the required movement for the body, but also countering the interaction torques being created by the segmental linkage. When attempts are made to flex the distal phalange of the finger, traditionally the whole finger complex will flex bringing the tip around and into contact with the hand; however this segment of the finger can be moved independently provided the remaining segments are secured in their positions. This motion when unrestrained has been attributed to excess interaction torques causing the proximal phalanges to move although they were not the intention. These torques were found to be even greater when the finger was moved at a higher speed.

Unfortunately the excess muscular activity may not necessarily be completely applied as the interaction torque, with suggestions of muscles being activated to counter the torques of opposing muscles as well as the interaction torques, as there is often an increase in activity of the antagonist muscles as well. There is also the factor of the metacarpophalangeal joint having multiple axes of motion; flexion/extension as well as abduction/adduction; the possibility of motion activity in an additional plane cannot be ruled out as

contributing to the increased muscular activity. They hypothesised that three-dimensional modelling would be the best solution to try and gather a complete picture of just what happens during finger motion.

Developing a system that allows each component to progress equally is a challenge as it has been shown that the individual recovery is not uniform for that individual, indeed the recovery of activation has been found previously to be directionally dependent [96]. This means that muscle groups acting in one direction may recover faster than the muscles pulling in the opposing direction, it is believed that this is caused by the alterations made to muscle activation patterns after stroke. The index fingertip was found to display a greater capacity for flexion activities and an increased muscle activity, but the findings were inconsistent across the other muscles of the finger.

The findings of this study are underpinned by the level of impairment that the subject had when they started. The more impaired subjects also began the study with a greater disparity between their flexion and extension capabilities, whilst this disparity was not noticeable for the patients who were least severely affected. The patients with the greatest impairment contrasted from the control subjects by displaying greater palmar-directed than dorsal-directed forces in the activity of the flexor digitorum superficialis and extensor digitorum communis muscles. They deemed finger strength to be an accurate measure of control as it was found to correlate with the greatest range of motion amongst the stroke patients, unlike in their control subjects who were only using submaximal contractions

Further attempts at recovery of the rotation of the phalanges of the finger were attempted with the FingerBot exoskeleton [97]. This was a specialist device designed to exercise the muscles of the index finger to attempt to recover their function. The FingerBot design attaches to each phalange of the finger independently, with three independent servomotors being aligned with its anatomical joints and a double bearing used at each joint to limit the effect of resistance between the segments. This allows the finger to be manipulated independently but it is also restrictive in terms of the movements it can permit; only allowing movement to occur in the sagittal plane. The other fingers of the hand remain free to be moved at the subject's discretion but their wrist is secured in a fibreglass cast that is fixed to the table to ensure that the index finger remains in a stable position. The design allowed the system to avoid the problems of joint singularities and errors being created along the kinematic chain, such as joint torques, problems that are common in devices that move the finger with a combined component. The design of the FingerBot also required that the system was adjustable to accommodate for patients whose fingers would come in various shapes and sizes. Finger segments of differing sizes were fitted where the C-piece and the FingerBot connect; this allowed the device to be able to fit a variety of differently sized fingers.

During the study the system was tested using three separate performance conditions, spring-like, constant extension and passive. The spring-like motion provided an extension torque that was proportional to the phalanges angular displacement from its neutral position, with the constant extension

force being equal to that required to keep the finger in its neutral position, whilst the passive setting placed no demand on the user. The device complemented the motion of stroke survivors most in its constant extension condition, as opposed to the passive motion condition, allowing the participants to be 5.9±6.2mm closer to their intended target. The study's spring-like condition was found to impair subject performance, as the spring-like bias was found to increase as the finger went further into extension, making it harder for them to extend their finger to complete the motion, consequently the workspace area for this setting was 57% smaller than for the constant extension condition. Workspace area was the term used to describe the area of movement available to the distal phalange of the index finger. The testing criteria used through this study would suggest that the constant extension condition provided the user of the greatest range of motion as well as accuracy; however no follow-up study was conducted to see if this performance was retained.

In contrast to the FingerBot exercising one finger independently, the Amadeo robotic device [98] exercises all of the fingers with a cable driven system that allows the fingers to operate independently. The device was used in a six week training programme for stroke patients, with improvements being reported in the battery of testing protocols that the patient was asked to perform. In the Fugl-Meyer test for example there was an average increase of five points after use and it was felt that this was a result of using both the device's position-controlled active assisted exercise mode as well as its

isometric mode in conjunction with a computerised game for visual feedback during for 20 minutes sessions.

Improvements in movement accuracy were also found with the iHandRehab device [99], a cable driven exoskeleton offering four degrees of freedom to each finger. The device was also capable of measuring joint angle data from each joint to ensure that an equal displacement was achieved during finger flexion. To allow for the device to be used by multiple volunteers of varying hand sizes there were also adjustable elements in the fingers to enable alterations to be made to fit the differing phalange lengths of the subjects. The unimpaired volunteers when using the device were able to retain over 70% of the joint angle rotation that they would have without the device, as this loss was mitigated by the setup of the device but is still higher than the mobility that a patient could expect to have this is an encouraging sign of the design's potential. The system is not without its downsides, as a large computer based device this limits the field of motion that can be reached when it is being worn, this physical appearance may additionally be intimidating for patients if they were to attempt to set it up in their own home. Consequently, whilst the iHandRehab device may produce impressive performances patients will unfortunately have limited access to use the device in their rehabilitation.

There were also improvements spotted with the use of the EMG powered BRAVO hand [100] an exoskeletal hand with linkages between each phalange and an on board actuator to power the motion. Whilst this system addressed many of the issues raised with the iHandRehab it raised several of

its own if it were to be used at home, most notably how the patients would successfully complete positioning the EMG electrodes on both of their arms as the vast majority will not possess the expertise to position the sensors accurately. A production model would presumably aim to integrate the sensors into worn components to avoid this. The device was successful though in replicating the intended pressure level for grasping a collection of bottles without damaging them, which should help in rehabilitating their motor control.

Instead of treating the fingers separately the HEXORR hand system, developed by Schabowsky [101], attempted to stimulate action in the fingers by moving them as a group. It was an attempt to optimise the components required for accurate hand control by utilising only two actuators for motion as opposed to Kawasaki's [102] eighteen. The number of actuators was cut as the system was operated by a series of low-friction gear trains and motors, which allowed for control of the hand position and the torque that was being applied at each joint. HEXORR was a mounted hand component that fixed the wrist in place and allowed the user to both flex and extend their fingers and thumb, whilst also offering thumb abduction/adduction (Fig. 1). Unfortunately the model design restricted the movement of the fingers to act in unison rather than independently, this should be sufficient for early treatment but an alternative would be required if the patient aims for independent articulation of their fingers. The fingers were capable of rotating 90° at the metacarpophalangeal (MCP) joint and complementing the motion at the proximal interphalangeal (PIP) joint to allow the fingers to fully replicate

Figure 1: Image of the HEXORR Device with the Wearer's Hand in Extension and the Thumb in Full Abduction [101].

their range of motion that they display before a stroke. The motion of the finger components was guided by a four bar linkage, that was aligned with the MCP and PIP joints. The fingers were coupled together as they would move as one unit in the device, with the rotation of the two joints being near synchronised to try and replicate the finger tips trajectory when the finger is flexed.

In the testing of the device, the subjects were secured to the system and were given a practice time of between 30 and 60 minutes. Their healthy volunteers were charged with testing if HEXORR was capable of replicating the motion performance of their hand, with significant differences only noted in the fourth and fifth digits. The fourth digit reported a reduced rotation inside the device at the MCP joint whilst the fifth digit displayed a reduced rotation at both MCP and PIP joints. These fingers were unable to complete

their full angular rotation due to the design of the device which had a rigid flat surface positioned with respect to the third finger, as this finger's MCP joint is the most distal from the wrist. The device may have provided a more accurate replication of human hand motion if the surface had replicated the sloped positions of the MCP and PIP joints, although this would have been complicated by the differing lengths of the phalanges. The HEXORR is felt to be able to replicate accurate extension trajectories, but improvements could yet be made in the performance of the fourth and fifth fingers.

The stroke patients were found to unintentionally produce flexion signals during the extension exercises; however the integration of a "flexion catch" with the system restricted this and caused an increase of 35% for extension movements. The hand's range of movement was increased for the patients in the force assistance mode, although two patients displayed a negative thumb torque, suggesting that the system had been over assisting them and caused a reduction in effort on their part at this joint. The authors felt that this could be counteracted by upgrading the controller to review past subject performances and then adjusting the assistance accordingly for the user.

Follow-up testing on the HEXORR system, Godfrey [103], showed that it would be best applied to those patients who had moderate tone and were already partially capable of extension. The study's only subject with high tone in their hand, which was increased during the period of testing, was found to show the least improvements in their finger range of motion as well as no improvement in their thumb. HEXXOR has been shown to be beneficial to subjects with impairment in the use of their hand, provided this is

slight as there were limited benefits for using the system to those who are more severely affected. It may be possible that this added impairment could be compensated for by an increased exposure to the device; however for this study all of the patients were given the same timetable. The HEXXOR system has two main functional modes, known as spring and tone [104]. The spring mode sees an increase in the assistive force provided as the distance to the target increases, whilst the tone mode counterbalances the muscle tone in extension by measuring the hand's passive resistance.

The recovery of the hand also extends beyond the fingers, with devices such as the IIT-wrist robot [105]; it was developed to assist the wrist in its full range of motion (flexion/extension, abduction/adduction and pronation/supination). It was designed as an independent wrist component that would enable the patient to exercise their wrist in each degree of freedom, but only one would be exercised at a time. The testing of range of motion was conducted before testing and after it, consequently whilst there were improvements in the range of flexibility of most of the motions, wrist flexion was considerably reduced, this may have been due to fatigue that was not accommodated for in the experiment as pre testing it had the most flexibility for all of the subjects. The design of the device was also restrictive, with the subject having to grab a hold of a large handle at all times and their forearm being secured down, and the bulk of the machinery being placed below the wrist. This combination is likely to have had a fatiguing effect on their arm, so the device was fitted to a supporting unit to bear the weight. They attempted to accommodate the natural minor joint misalignments that

occur in the wrist by fitting a sliding component between the wrist and the robot.

A similar concept to IIT- wrist robot was attempted with the Supinator Extender (SUE, [106]) living up to its name by attempting to aid the flexion and extension of the wrist as well as supination and pronation of the forearm. They developed a robot that placed practical features at the core of the design, such as keeping the mechanism away from the user's hands and face to give the user a safe workspace to operate in. The device was operated by electric motors that were highly geared, creating the necessary force to ensure movement of the wrist but risking an increase in back-drivability as a result. Testing of eight stroke patients provided unexpected results, with several of the subjects being able to take the system to its limits without assistance from the device (seven for wrist flexion, with two and three for supination and pronation respectively), suggesting that a larger range of motion, which was restricted as a safety feature, is required for the system to fully test improvements that the device made to performance. The remaining subjects display an improvement on average in their performance with total flexion and extension of the wrist increasing by 15°, whilst total pronation and supination of the forearm improved by 10° in the wrist compensation stage. The greater number of patients that could use SUE optimally compared to IIT is most likely to be a result of the limited range of motion available in the design. A comparative study would better display any differences in user recovery between the systems.

The SUE's linkage was operated by pneumatic cylinders that were designed with the intention of reducing the impact of the seal friction element that restricts the output torque. This was achieved by increasing the diameter of the cylinder and shortening the length of its stroke as the friction force experiences a proportional increase; however the torque has a proportional relationship with the squared value of this diameter, causing the torque to increase at a faster rate than the friction. Solenoid valves were used to control airflow into each valve, these are practical in terms of weight, but have a limited functionality of either 'on' or 'off' that limits how progressive the control that the users experiences is. The fine control required for patients was integrated into the system by increasing the speed at which the system opens and closes; this switch could be made in the final model in one millisecond.

The principle of on or off control can also be applied in cable driven systems, where examples such as the J-Glove [40], or X-Glove [41] have utilised the principle with success. These were hand designs that are intended to extend the fingers as opposed to helping the fingers to flex to replicate a grasping motion (Fig. 2). This can help stroke survivors for example, as many have reported difficulties in releasing an object that they have grasped [40]. These systems are motorised and cable driven to pull against the contraction force created by the spasticity, resulting in an extension of the fingers and straining the muscles to encourage stimulation of control. This design solves a specific problem but is not without issues, namely in how to effectively get the

device on and off as patient experiencing spasticity will have their hand set in a clenched shape making fitting the fingers into the glove challenging.

The same results can also be used by pushing the fingers into extension rather than pulling, for example using a pneumatic system to fill an air bag that would extend the fingers [107 & 108]. This currently functions as a training tool but would likely struggle to be used as an assistive device, as when the participant wishes to release an object that has been grasped then air is pumped into the air bladder on the palmer side of their hand, the changes in shape here may destabilise the object, resulting in it being dropped rather than a controlled release. The system was tested in a constrained virtual reality environment and was found to improve upper extremity movement when tested with the Fugl-Meyer protocol [108].

The theory of these designs [40, 41, 107 & 108] is born out of the principle that the stretch reflex responses can be used to quantify the severity of spasticity in the MCP [109]. It is believed that both the stiffness and length of the fibres in the MCP flexors is a strong indicator of the stiffness in muscular spasticity. Subsequently the intention is to exercise the joint to increase the length of the muscle fibres, which will in turn reduce stiffness of the finger joints and lessen the severity of spasticity. Computer simulation has suggested that reducing the length of the tendons will result in an increase of activity from all three of the finger joints [110].

Further studies with cable driven gloves have also seen improvements in performance, such as BiomHED [111], which was able to produce joint angle

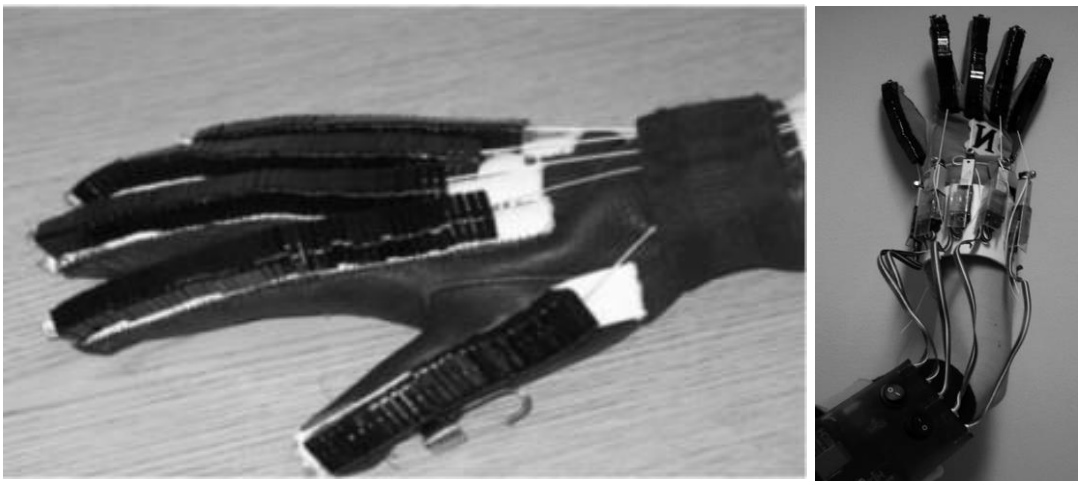

Figure 2: Images of the tested J-Glove (left) and X-Glove (right) prototypes [40 & 41].

displacements that were not significantly smaller than those produced by unimpaired volunteers as well as increasing the stroke patient's kinematic workspace by 63-1014%. Unfortunately this discrepancy in improvement will in part be due to the fingers not being able to operate independently and not receiving the specialised treatment that the fingers require. This cable driven glove also had the benefit of being bidirectional, as the forearm unit that was worn was able to be fitted with a cable driven mechanism on both the dorsal and ventral sides, giving the wearer an increased level of control. When this is coupled with its lightweight this system is a strong candidate for a device that a patient could utilise at home, however there is the key issue that central cable driven mechanics are exposed, which in a home setting would likely result in the device being frequently damaged and requiring repair.

Many of these devices are developed with the intention of minimising the presence of a required therapist so that the subject can perform rehabilitation exercises on their own [102]. The hand motion assist robot was built for this purpose, providing the subject the capacity to exercise their hand through

activities led by their healthy hand. This device was designed to allow 18 degrees of freedom to the hand, providing flexion/ extension as well as abduction/ adduction motion of each finger as well as thumb opposability. It also allows for both palmer flexion/ dorsiflexion of the wrist and pronation/ supination of the forearm. Unfortunately the considerable scope of this project resulted in the device being very large and cumbersome; as it is also surface mounted it would be too impractical for someone to use in everyday activity, although the results gathered from testing the device are very encouraging, as there were no significant differences found in the joint angles for the fingers compared to a healthy subject.

Each finger in this device has an independent mechanism for operation. The mechanism supported the flexion and extension of the finger joint, as well as assisting with the abduction and adduction of the fingers at the MCP joint. Three motors were installed for each finger, with two at the hand to manoeuvre the MCP, with one further along to move the first phalangeal joint. The second phalangeal joint was directed by two passive joints between the two fixtures that connect the finger to the mechanism. As the most independently flexible component of the hand, the thumb's mechanism has a redistribution of the motors, with only one at the base, and two in the supporting body of the robotic finger. There is also an additional motor built into the design, positioned above the thumb at the peak of a semi-circular form that is used to guide the thumb in abduction and adduction. This was chosen as the guide for this mechanism as the authors felt the thumb's movement was representative of a conical motion, with the tip being located

in the wrist and the thumb tracing the shape of its base. The mechanisms of the fingers and thumb are not directly attached to the finger to guide their motion, but are instead secured at the finger fixtures by Velcro to the back of a glove that the user wears during its operation. When the motors are active the fingers of the robot will then gently push or pull on the glove to guide finger flexion and extension from the patient.

The logical extension of these devices is rehabilitation without the therapist, which has already been proposed [112]; the study developed a basic assistor for finger flexion that had its microchip connected to a laptop. They proposed the possibility that this could then forward the data through the internet to a central computer, allowing the therapist to potentially monitor the performance of several subjects at once, which would then reduce the expense of the therapy process. Unfortunately an experienced user was still required to ensure that the device had been correctly fitted to the subject. A possible evolution of this design would be to convert the assistor into a made-to-fit glove that the patient would then be able to don and doff on their own, although this can be a challenge as the patient's lack of fine motor control can make positioning the fingers difficult.

Hand performance improvements have also been highlighted without the need for a constantly worn hand exoskeleton [113 & 114]. They used an intensive period of virtual reality training to evaluate if performance occurred in finger range of movement, speed of movement, fractionation and strength. Fractionation is an exercise where the patient flexes one of their fingers maximally whilst keeping the other fingers extended, an exercise which is

believed to improve individual finger movement. Training was conducted for five hours per day for nine days, with 1-1.5 of these hours being dedicated to the virtual reality training, with the remainder dedicated to rehabilitative exercise. The data were collected through use of the Cyber glove measuring the joint angles of the fingers and thumb, as well as the Rutgers Master II-ND gathering the force feedback data. Each criteria of review was tested individually, with separate testing for the fingers and thumb, whilst the fractionation test was the only one where the fingers were to be individually co-ordinated. Each subject's testing difficulty was adjusted based on their performance the previous day, if they successfully completed the task, the difficulty would then be raised by one standard deviation, whilst it is lowered by the same amount if it cannot be completed. Whilst this allowed for each subject to have a specifically tailored training experience that may have accelerated their improvement, it would also impede a combined review of the testing performance, as not all of the subjects would undergo the same testing criteria. All of the subjects displayed an increase in all of the assessed criteria except for one subject showing no increase in their finger range of movement; however they began the testing with a full range of movement in their fingers already. The subject who began the testing with the greatest impairment struggled for improvement in fractionation and mechanical work in comparison to the other subjects.

An artificial hand has even been attempted to aid motion for those who have Parkinson's disease [115]. The theory was that by compensating the movement by providing an assistant force then the motion would have

greater consistency to help the patient to perform interactions with the world around them. The principles of this study were later taken on to be tested with pilot group of patients [116], the study found that robot arm training could indeed improve the functional performance of the hand after receiving just 10 45 minute training sessions a week for two weeks. This suggested that 900 minutes of physical therapy was able to elicit significant improvements in the nine-hole-peg and Fugl-Meyer tests.

One area of hand therapy that is frequently overlooked is the adjustments made by the body of the hand, as this is often treated as a rigid body, where for prosthetic systems it is a cuboid which the fingers wrap around and orthotic systems will push and pull the fingers into recognisable patterns of flexion and extension whilst not adjusting the position of the hand. The result of this is that the hand functions more like a claw that pincers around its target in a manner more akin to a carnival game than an integral component of the human hand. Metamorphic mechanisms have been used previously to develop a hand based on a five bar linkage to allow the fingers to be brought together to grasp a target [117, 118 & 119]. This Metahand creates a triangular palm workspace whilst creating a contact point for the fingers that is a hypothetical spherical joint. Unfortunately the five bar linkage cannot be translated directly into an orthotic device for disability as it would compress on the hand harming the patient.

2.2. Elbows & Forearms

Traditionally patients undergo intensive physiotherapy to recover the use of their limbs in the aftermath of their incident. Whilst this is the accepted practice the improvements in the performance of devices has resulted in a shift of how best to treat the condition, as creating technology that can perform the repetitive task training can free the therapist to increase the number of patients they can treat and provide a more patient centric experience. It was therefore inevitable that the therapist and machine would have their performance compared to see which method provides the greatest benefit [120]. The device they used for comparison was formed from pieces of thermoplastic moulded to the subject's arm, with the motion of the elbow being guided by a motorised pulley.

The elbow is the joint of the arm that is easiest to replicate the motion of as it can be viewed as a uniaxial hinge joint, although this ignores the contribution of the synovial superior radioulnar joint. As the system is limited to one axis this also limits the control criteria, needing only the activity data of the main muscle group in each motion, the biceps and triceps to confirm when to activate the motion, although wrist force can also be integrated into a fuzzy-neuro control system in an attempt to ascertain user intention and provide a greater level of control [121]. This system was found to considerably reduce the size and time period of the EMG signal in the biceps for a basic lifting task. It was designed with a ball screw drive shaft built into the upper arm, linked to two components that would move in tandem to create the desired range of motion in the elbow. It was an early design that was large and

bulky, but was directed by flexion of the biceps and triceps brachii muscles for their respective motions. These signals were then transferred to a fuzzy-neuro network to determine the level of response. The system was set up with 17 combinations of input data from the four EMG sensors in the arm and the further one in the wrist, with four possible actions in its outcome layer.

Whilst it has been shown to be successful, it is perhaps an over simplification to claim that the elbow joint contains only one axis of rotation and that its impact can be fully replicated by a single hinge joint. As a case in point, it has been found that it would not be possible to create an artificial elbow support that will perfectly trace the axis of rotation for the elbow complex [122]. When experiencing flexion and extension, the biceps and triceps muscle will flex differently, causing the support to slide as the humerus moves from the muscle acting on it. This discrepancy is approximately a two centimetre shift in the centre of rotation, however these alterations were not found to obstruct the devices functionality or create discomfort for the user [122]. As there is no functional impact created by this discrepancy, it is always discounted in the final design.

The elbow has a restricted range of motion that is limited by its anatomical design. Actions such as extension are severely restricted by the elbow units design in terms of both muscle and bones. The proximal ulna dorsal angulation, a bony prominence on the ulna has been shown to affect the arms capacity for elbow motion [123], where it was found that if the angle of this prominence was below 4.9°, the range of motion for the elbow was greater by, on average, over 5° in total. There was no difference in elbow

flexion between the groups, with a significant change in elbow extension creating this disparity.

There is also the issue of forearm rotation in this region, which is often overlooked as it significantly complicates the elbow component. Many designs move this component to the wrist as this is where the motion's output is most noticeable, however the elbow complex directs and guides the motion, with the radial head spinning around the capitulum with the radial notch of the ulna acting as a brake pedal for the motion. Consequently there are two approaches taken with supination and rotation of the forearm, some designs include it as part of the wrist component whilst others include it at the elbow. It has been suggested in previous work that the torque generated by the pronation/ supination axis has no detrimental effect on the time for the arm flexor muscles to fatigue [124]. This outcome should be considered in conjunction with the finding from the same study that the subjects with a high correlation between the EMG amplitude readings for the arm flexors also displayed a high correlation with changes in the pronation/ supination torque. Whilst the diversity of subjects would suggest no errors in the study, the suggestion that the torque may impact the fatigue pattern of those with a more co-ordinated approach to motor control but not others is noteworthy.

Combining these two degrees of freedom has been tried previously [125], again utilising EMG to gather the data and integrating a neuro-fuzzy control system to process the signals and interpret the action. The device was operated by two dc motors, one for each axis, attached to a large metal frame that the subject would stand next to operate. The elbow motion was

controlled by a ball screw system whilst the forearm was manoeuvred by a wire system (Fig. 3). The number of EMG channels to operate the system was increased from four for just the elbow motion to eight for the two axis system, along with a specialist wrist component to measure force. Of these eight channels, three are used for pronation, three are used for supination, three are used for flexion and two are used for extension, with the pronator teres and biceps brachii having input for two motions. The control system gets past the potential problems here by learning the muscle activation patterns of each patient by making small adaptations to the neuro-fuzzy system. They found when performing dual motion of the forearm and elbow there was an average reduction of 66.5% in the EMG signal of the biceps brachii across their subject pool. When the experimental load was removed, the reduction became 35.9%. Large reductions in the size of the EMG signal were also noted in other muscles, as well as when the combination of motions were changed in either axis.

The most practical data input system for a powered exoskeleton is the use of surface electromyogram signals (sEMG), as this does not carry the surgical risk or unknown long term dangers of implanting EEGs in the brain. sEMG is however complicated by the inconsistencies of human muscle, which changes shape as the limbs and joints alter their composition. The use of mechanomyography (MMG) can negate this issue, as it responds to the vibrations and oscillations in the musculature and is consequently better at interpreting signals in the deeper muscle, however it is still an in development field and does not have the accuracy of EMG at present [126]. Previous

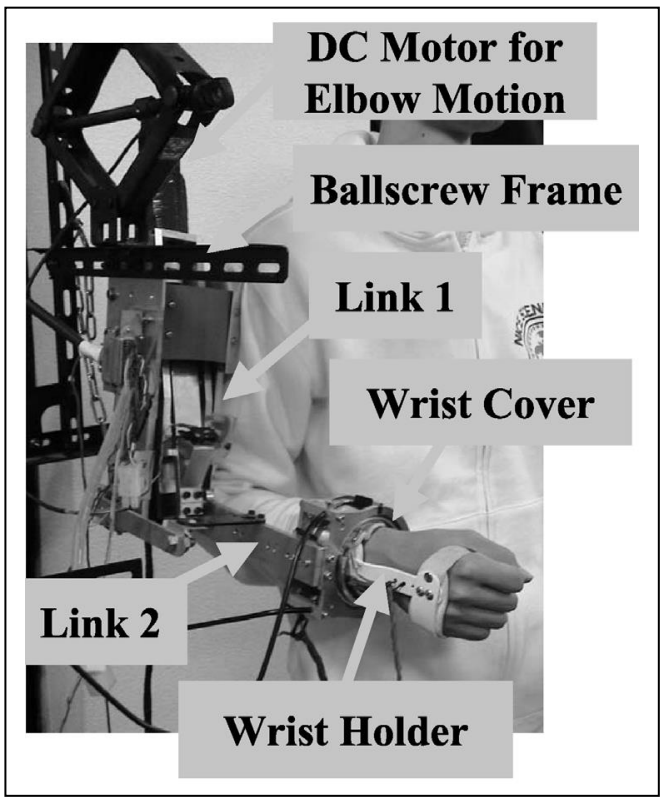

Figure 3: Annotated Image of a previously developed two degree of freedom forearm [125].

investigation [127] sought to clarify if the changing angle of the elbow joint had a noticeable impact on the EMG signals of the main muscles for flexion and extension. They found a significant change in the force generated in a maximum voluntary contraction, optimised at approximately 80°, for both flexion and extension. There was however no change in the size of the EMG signals for Maximum Voluntary Contraction (MVC), and only low angle triceps extension displayed any alteration in the force-EMG relationship. The median frequency of the EMG signal was affected by the force level for the biceps and brachioradialis with the joint angle affecting the relationship between frequency and force level for the biceps and triceps. The experiment positioned the arm in a neutral orientation and measured the

relative force as opposed to the absolute and the study's results suggest that the mechanical properties of the muscle dictates how much the muscle force is affected by muscle length. This was believed to be the result of the muscle fibres narrowing in width, allowing less room for the signal to transfer. This suggests that the EMG signal should be able to remain consistent on a per subject basis, but may require alteration to its functioning for individual patients. When developing a control mechanism for a system, it would be important to consider the effect that the starting angle of the arm may have on the output power level, as not every motion made in daily living begins from a resting position.

The muscles control the motion of the arm, yet they are challenging to use to control a mechanical device that would replicate this motion as they are multi-function components that, when operating, emit similar signals irrespective of the task performed. In addition some of the muscular groups are positioned on top of one another; this cross talk can create discrepancies as to which muscle is actually the source of the signal. Pattern recognition is a technique that can partly work around this problem by drawing the data from multiple sites, and allowing compound analysis of these signals to determine the correct response. This theory presumes that the electrical impulses follow specific routes to ensure that all of the relevant muscles are activated, however in reality these patterns are subject to criteria such as fatigue or even how fast the limb will move as different muscles can be recruited to control motion at differing speeds. This is further complicated by changing recruitment patterns as the patient recovers as well as the patient

varying their muscle recruitment, so some redundancy must be factored in. These factors must also be weighed on top of the dual functionality that is common to many muscles.

The medial collateral ligament has three components, the anterior and posterior bundles, along with the transverse ligament. The anterior bundle can be separated into nine further ligaments that do not behave uniformly during elbow flexion and extension [128]. It was found that four of these ligaments are isometric in motion whilst five are not, with the three proximal to the axis becoming taut in extension, and the other two distal to the axis becoming taut in flexion. These components function as “checkreins” to contain elbow motion. Inconsistency in the muscles displayed in testing may make it challenging to set up a definitive control system, as if the system is given too wide a range of signals for operation, it may struggle to differentiate the signals to generate specific commands, whilst if it is too narrow it may not be responsive for some users. The best solution to this issue would be to increase the number of channels that the data are being retrieved from, with multiple channels on the larger muscles, so that data can be assessed on the main factors for these alterations, muscular fatigue and speed of motion. If the data are drawn from a large pool of subjects with a large and consistent set of measurement criteria then the data collected should provide an accurate range for the motions.

Forearm systems are predominantly orientated to aid the recovery of the elbow; however some forearm systems have also had success with helping the motion of the wrists, such as Bi-Manu-Track [129]. This system was

used in conjunction with neuromuscular electrical stimulation to aid chronic stroke patients and found that aside from improving the recovery from the elbow, there were also significant improvements in the performance of the wrist and hand from assessments such as the Modified Ashworth Scale (0.049) and Wolf Motor Function Test (WMFT, p=0.019). Interestingly a difference was not spotted in the Fugl-Meyer Assessment which is a commonly used assessment tool and has shown improvements with other devices, such as MEMOS and InMotion 2.0 [130, 131].

2.3. Whole arm systems

The largest conundrum to be overcome for the development of a mechanical arm is tracking the motion of the shoulder. This is because the joint is considered a ball and socket device that changes its position during the motion of the arm. For example in the act of abduction, the tendon of the supraspinatus muscle is initially withdrawn under the fornix humeri to make space for the limb to move, and in later motion the tendon is then raised by the apophysis, consequently partly obstructing motion of the acromion and the coracoacromial ligament. However further abduction can yet be achieved by outward rotation of the humerus, pushing the tendon and apophysis back underneath the acromion, making more space [132]. The subdeltoid bursa sits between these sections to lessen any friction that constant motion of this section will create. This act displays the issue for accurate replication of the motion, if the both the joint centre and the humerus will move and rotate

during abduction and perform the reverse of these motions for adduction, creation of a system that can replicate the motion whilst retaining both its shape and support for the body are a challenge. There is also a mechanical challenge in terms of replicating this action as the muscle is unlikely to do this from external stimulation.

Part of this challenge stems from that, as was done above, the shoulder joint is often referred to as a “ball and socket joint” when the socket is in actuality rather flat, but the rounded humeral head rotates on the glenoid fossa [133]. This is not the only mistitled component of the shoulder joint as the “shoulder girdle” is considered a misnomer due to the scapulae not being directly attached to each other, and do not even have a bony attachment to the costal cage, except for the sternoclavicular joint that of course has a range of motion of its own. The various muscular groups hold the system together and are needed to act synergistically to allow for motion in the shoulder complex. In the past it was felt that forcing this exercise of the joint had no beneficial effect, instead only increasing the risk of possible harm. Jones suspected that this proposed treatment method had resulted from a misinterpretation of the previous claims of Codman [134], who had proposed two alternative treatment models, firstly the fixing of the arm in an abducted position, as this would relax the tendon and also allow an increase in blood flow to the joint, whilst the second method consisted of gentle “stooping exercises” that would lessen the damaged surfaces of the lesion. However as illustrated in many of the other articles referenced here, it is apparent that the debate over treatment methods has conclusively moved towards

repetitive motion of the joint as the most effective treatment for paralysis of the shoulder joint.

The singularity is a term used to describe an instance when two axes of rotation align in a manner that would cause the loss of another degree of freedom, limiting the motion available [135]. Systems replicating human arm motion may find this occurring in the shoulder joint, as there are five active degrees of freedom between the sternoclavicular and glenohumeral joints. Attempting to avoid creating this scenario, and subsequently impairing the patient's ability to replicate motions, is the reason why most shoulder joints are limited in their degrees of freedom, it is also possible to cause this scenario in the wrist, where it is considered four axes all meet in the same area. When this occurs the device will require to be repositioned to 'reset', however this a temporary fix to a scenario that will reoccur. In the standard Gimbal lock scenario, the traditional method to avoid this problem is the addition of a fourth axis that retains a large axis between roll and yaw to avoid the axes becoming parallel and creating the 'lock'. The fourth axis requires to be continually driven by motor to ensure that it does not come into alignment with the other axes. This is not directly applicable as the axes involved in these joints do not have a full 360° of motion, but is a feature to consider in shoulder range of movement.

The clavicle is considered to be a key component in guiding the motion of the arm. It combines to produce two axis of rotation, acromioclavicular and sternoclavicular that, along with glenohumeral motion, combines to control the motion of the arm. Alterations to the size of the clavicle have an impact

on the position of the scapula [136], a conclusion that was reinforced by cadaveric study of shoulder positions. The orientations of both of the clavicular joints were altered as the clavicle was shortened. This was also combined with changes being made to the moment arm of the pectoralis major, as it has a point of insertion on the clavicle, which reduces its final power level, which may be associated with a reduction in the peak elevation value. Further physiological changes are made by alterations of the surrounding muscle to the new position of the scapula; it is no longer tilted as much along with having an increased lateral rotation and protraction. The alterations to the position of the scapula have a knock on effect to the acromion, with its anterolateral component moving further in that direction, creating an alteration to the shape of the subacromial space, this has an association with causing impingement, but the study found no evidence of it. Also the position of the glenoid is altered, moving the location of the contact force; this is believed to create an increased burden on the rotator cuff to maintain stability as well as increasing the size of the joint contact force.

Often the shoulder joint in these rehabilitative exoskeletons is set up as three degree of freedom components. It has been proposed that due to the current models not replicating the motion of the shoulder girdle [38] that this can limit their rehabilitative impact, as once independent of the device the patient will have to use the shoulder girdle in motion. The MEDARM was the proposed solution to this issue by giving the user access to five degrees of freedom in the shoulder (two at the sternoclavicular joint and three at the acromioclavicular) along with flexion and extension of the elbow. Their

device achieved this by making the shoulder girdle to be a separate component mechanism exerting control of two degrees of freedom that control the relative positions of the glenohumeral joint and the torso (elevation/ depression and protraction/ retraction). It is a large component with the mechanism placed behind the user, with the motion axes meeting posterior to the sternoclavicular joint and being driven by electric motors and timing belts.

Less than a year later the control mechanism was being tested as a component of the KINARM [39]. The cable drive was installed to allow for the mechanisms for the original device to be moved behind the user, taking them away from the head for user comfort, whilst the curved track system remained to guide the motion of the arm in the horizontal plane. Otherwise, the MEDARM and KINARM both function as a three degree of freedom device with one axis at each of the arms main joint centres. These axes control the systems motion in the horizontal plane and both are structured as a 4-bar linkage with linkage-driven carriages applying the motion to the limbs. This allows the placing of the device below the user's arm and provides a better balance to the system as the weight will be directly supported by the carriage at the elbow. Single thumbscrew and quick release clamps were fitted to the device to make it easy to adjust to users of different dimensions and to secure them to the device when using it. When testing the model, they have found stiffness to be a large contributor to performance, as a lack of stiffness increases the difficulty of getting the joint angles correct, as the system does not retain them as well. The KINARM had a considerably

greater stiffness than then MEDARM; however this could be remedied by doubling the diameter of both the cable and the pulley, as stiffness is dependent on the squared value of both.

A system that envelopes and supports motion of the arm is deemed to be a considerable challenge of design, one of the main reasons for this belief is the concept that the natural arm has seven degrees of freedom whilst only six are required to position the wrist and orientate the palm [137]. This process makes it possible for multiple combinations of movement that achieve the same result. The study resulted in the production of an algorithm that could be factored into arm control; and consequently in an estimate of position that was on average less than 5° out. This would enable accurate estimates of the patient's range of motion to be drawn, and when it was applied to an actual device (EXO-UL7) was found to reduce the power usage by 20%. The development of this model required the calculation of a theoretical point outwith the axis of movement for the arm to allow for the swivel from the redundant degree of freedom. This system is intended to produce greater improvements if it is used bilaterally for therapy [138], as the programs that are operated with the device are predominantly designed for bilateral function as well as providing additional challenges such as moving targets.

Range of motion would serve as the best measure to illustrate the greatest recovery of the larger muscles in the arm such as the bicep, which form the basis for the application of the Wilmington Robotic Exoskeleton (WREX [139]). Having previously been developed for children with muscular

dystrophy, the system was adjusted and redeployed to be used amongst a stroke patient population. They provided additional degrees of freedom so that the user could rotate their arm at both the upper and forearm locations, whilst also adding locks to all of the joints so that the therapist could arrange to focus the therapy onto specific regions. The subjects were asked to attempt to reach 12 individual markers that were distributed about the arm workspace, once without assistance and the other whilst wearing WREX. The use of the WREX device was found to help the patient's motion be 22% closer to its intended target, irrespective of the height and angle that the target had been placed at. The peak speed of motion was reduced by 13%, and this peak also occurred at an earlier stage of the total motion. These improvements were found despite the device preventing the user from placing their arm into full extension or abduction. By increasing the range of motion that can be achieved by the user it was proposed that this system could be used to amplify the effects of physical therapy. It also has the benefit of being the only gravity-compensation system that allows the user to raise their arm over 90° in flexion or abduction.

When a subject experiences loss of motion due to a stroke the first phase of physical rehabilitation is for a physical therapist to assist the patient in moving their limbs again. This process requires the therapist to support the limb and aid it in rotating in the desired direction. The system is employed as it is the most practical way of guiding the body's recovery whilst also highlighting and allowing remedies for potential synergies. Unfortunately the process is also very time intensive and tiring for the therapist, as it limits the

number of patients that can be treated each day as well as the length of their individual sessions being shorter, possibly impairing the patient's progress. As the therapist is also a skilled worker, this makes the process very expensive for health services worldwide and is a cost that will only increase as the population gets progressively older. In an effort to reduce costs, the process may be able to be mechanised, so that the therapist does not need to take on as much of the manual work, which will allow them to be able to assist more patients each day. A proposed system [140] recorded the motions made by the therapist so that they could be consistently repeated without the therapist having to physically move the patients arm. The patient would be strapped into the arm which would then begin to perform the planned movements for their therapy, getting the device to replicate these patterns would ensure that the patient performed consistent and decisive motions, as opposed to being reactive to a user input that may have a weak or inconsistent transmission. It also meant that the system does not need to gather and interpret input data, nor does it need to assemble an upper limb configuration. They found that the mechanical system produced a different final configuration from the therapist as the robot did not move the upper arm as high as the therapist.

When the device is intended to work as one to move the entire arm as a unit, it is important to consider the manoeuvrability of the whole unit. Initial attempts at user operated devices had resulted in devising three degree of freedom arms, whilst these designs provided users a basic aid to some motion they lacked sufficient flexibility to be considered suitable as an aid to

the elderly through continuous passive motion or as a rehabilitative device for those suffering from degenerative conditions. The MULOS was amongst the first to attempts to develop a powered orthotic exoskeleton to specifically aid this population [37], designed to act as an assistive orthosis with an intention for reapplication to neurorehabilitation at a later date. The MULOS provides users with five degrees of freedom: shoulder flexion/ extension, abduction/adduction, medial and lateral rotation of the upper arm, elbow flexion/ extension and forearm pronation/ supination. The MULOS systems control mechanism was operated by a "four-plus-one degree-of-freedom" command set controlling the speed of motion of each joint, this system could be integrated with numerous control components such as switches or joysticks depending on the level of disability present in the user. For the final design they selected the joystick and it was set up such that side to side motion would control the axial movement, although they concede that this will not be an effective set-up for those with bilateral disorders. No hand motion was reviewed for this study, and the device was designed to be mounted onto a wheelchair. Wheelchair mounting has traditionally been done with the mechanisms to enable the patient to have some mobility of the device, as their weakened leg may struggle to support its weight.

Gopura proposed a six DOF model exoskeleton (SUEFUL-6 [141]), which was the result of combining two three DOF components that had been developed separately, the upper arm developed by Kiguchi and Gopura's W-EXOS for the forearm ([142] & [143] respectively). The most prominent changes to the design were the removal of the old forearm unit developed

previously by Kiguchi, which consisted of a forearm holder and a force sensor to support the device, and the attachment of W-EXOS in its place, as well as disconnecting the upper arm from its original wheelchair base, although it retains the capacity to be attached to it. The upper arm enabled the user to move their upper arm through vertical flexion/ extension and adduction/ abduction, as well as combining these for horizontal flexion/ extension. It also assisted with flexion and extension of the elbow joint. The addition of the W-EXOS then included forearm supination/ pronation, as well as flexion/ extension of the wrist combined with ulnar and radial deviation of the wrist. Both systems use an EMG based design for receiving control signals, with the upper arm using RMS signals from the EMG supported by Force based signals from the wrist sensor when the muscular signal dropped in strength, whilst the W-EXOS uses a fuzzy-neuro design to collect control data. They found these systems to provide effective support, however there were only five subjects used in total between the three studies, each of whom were healthy, therefore it was not definitively tested amongst the subject pool that would use it regularly.

By contrast, the six degree of freedom ARMin II [144] was used in a comprehensive eight week training regime, with each patient receiving between 24 and 32 hours of therapy during this time. All of the subjects in this study displayed an improvement in the upper limb FMA and WMFT post therapy with one making further gains in WMFT at the six month follow-up. This patient was also the one who had the most impaired functionality before testing; suggesting that this continued development was likely to be a by-

product of their continued therapy. This study can show that irrespective of how the device is set-up, it is important to test the subjects for a further follow up to see if there have been additional developments from the end of a period of structured training.

An alternative approach would be to design the system to provide passive support as opposed to being active. This would of course limit the support offered by the system, as passive components are unlikely to aid heavily impaired patients, but would ensure that more mobile patients take an active role in their recovery. Devices such as the Freebal and Dampace [145 & 146] provide passive support to the patient in an attempt to place more emphasis on them during their recovery.

The Freebal system was designed to support the arm by suspending it anterior to the body and using the sling system to counter the effect of gravity applied to the subject. As a simple suspended sling the system also did not require a power source or active control system making it lighter, however it was built as a large frame, making it impractical to be mobile. Experimentation with the system also concluded that the patients preferred to receive support at the wrist and elbow, instead of the mass centres of the limbs resulting in the device providing more stable support to the user. The dual support on the arm was also found to limit the discomfort that had been shown in previous designs by reducing the strain placed on the shoulder joint. Dampace was developed to support the shoulder joint using a similar set up to the Freebal that of an overhanging sling with an exoskeleton arm added that was operated by a hydraulic disk brake. Both of these devices

fulfilled their design criteria by developing systems that could be used frequently for prolonged periods without requiring a large amount of maintenance whilst not placing excessive weight on the user. These devices may be more appropriate for those who are not as heavily impaired as others due to the limited range of motion and assisted support that they offer.

The main issue that restricts the development of individualised exoskeleton components is the considerable cost of such a project. The design of these exoskeletons utilise many small and expensive components, such as EMG sensors and motors. Attempts have been made to limit the expense by using alternate components [147 & 148], the design of RUPERT I and II embraced the concept of using pneumatic muscles to power and guide their motion. The component has several key positive attributes: low stiffness, low cost, low profile, low noise during action as well as being lightweight. Unfortunately they were neither as fast nor as precise in their response as the motor would be. If consistency could be achieved with components that could be adjusted for patients of all shapes and sizes, it would be a significant step in giving all patients an equal level of treatment and recovery. An adapted version of RUPERT was also developed to assist hand grasping that was operated by FES and was coupled with pneumatic muscle actuation to help provide control [149]. The system was successful in helping the testing volunteers to grasp, however the humerus was fixed in place to aid them, if this was not secure then there may have been cross stimulation from FES, resulting in poorly controlled motion.

Not all robotic designs have been found to definitively improve physical recovery [20], as it has been shown that the use of a robotic sling device with multiple sclerosis patients can cause an improvement in efficiency of movement when wearing the device which does not translate into the unsupported clinical testing conditions. None of the Motricity Index, Hand grip strength, Fugl Meyer, Action Research Arm Test or Motor Activity Log showed a significant increase in performance despite 30 minutes of rehabilitation three days a week for eight weeks. It is possible that this training time period must be increased before results can be seen as well as advancing the difficulty of the tasks a greater rate to increase the training workload that the patient performs, as other papers cited here have used at least double the total training time [144], whilst others have used the device for five hours per week or more [13 & 84] obtaining positive results. Additionally treatment methods such as task based rehabilitation therapy provide better results when the patient has an increased period of treatment [150], and it is possible for robotics to be used as a supporting tool during this treatment [151].

Obviously the arms are a dual system that can operate in tandem as well as independently, whilst many systems will work exclusively with the impaired arm, it can also be beneficial to develop a bimanual system that allows both arms to be exercised in tandem. This enables the patient to practice using both hands together, such as for co-ordinated flexion/extension or pronation/supination [152]. This bimanual system has less functional assistance than other devices but has an integrated feedback system that

communicated the torque from the impaired hand and applied it to the unimpaired hand to ensure that the hands operated in tandem.

2.4. Full body systems

After achieving success with a lower limb system (HAL-3, [153 & 154]) Kawamoto and Sankai then integrated this component with an upper body to create a full body exoskeleton (HAL-5). This device has an attached battery pack and control unit to control the device and should be capable of functioning independently for 2hours and 40 minutes [155]. It has a dual control system, termed as the Cybernic Voluntary Control (CVC) and Robotic Autonomous Control System (RACS). The CVC is EMG based, where bio-electrical signals are read from the skin and converted into complementary movements from the joints, whilst the RACS uses a pattern recognition process to identify a series of smaller commands and correlate them into a full motion, the process is likened to the way a sentence is recognised by the collection of words forming it. The HAL-5 (Cyberdyne Inc., Tokyo, Japan) system has not been assessed in a peer-reviewed study, but is believed by its manufacturers to increase lifting capacity of the human operator by 40kg. this would suggest that the system can be used for reinforcing the healthy body, providing it is found to be successful it would be interesting to see the possibility of a full body rehabilitative device, as a stroke will traditionally impact on an entire hemisphere of the brain, affected the arm, leg and face on one side.

2.5. Non-exoskeleton systems

As there are a wide range of physical impairments that can occur, injuries can occasionally result in unconventional solutions to restore arm movement. Due to the nature of the subject's unconventional injuries reported, the proposed resolution was an innovative orthosis [156]. The subject of this case study had, after a skiing accident, lost the control of his shoulders and elbow flexion whilst retaining power of extension and control of their hands and wrists. After varied success with several pre-existing models, the researchers developed the Dynamic Triceps-Driven Orthosis (DTDO). This device connected the wrists by a cable that was balanced around the subject's neck, essentially the subject would use forearm extension in the opposing arm to raise the hand they wished to use into a flexed position for activity. After one year of use the subject had regained antigravity strength in the right biceps and deltoid and near antigravity strength in the left biceps and deltoid. .

The original robotic aids such as Hardiman or the Extenders were designed as manipulators that could be directed by the user, however for physical therapy this principle is applied in reverse. For exoskeletons the structure fits the patient's skeleton to replicate movement patterns, but external end-point manipulators are also able to provide this effect [157 & 158]. This device helped to increase the reaching distance that the participant was able to achieve, as the device is not bound to the user, and is consequently not providing potential boundaries to maximal rotation or extension (Fig. 4). The device was designed as an independent free-standing unit that was bound to

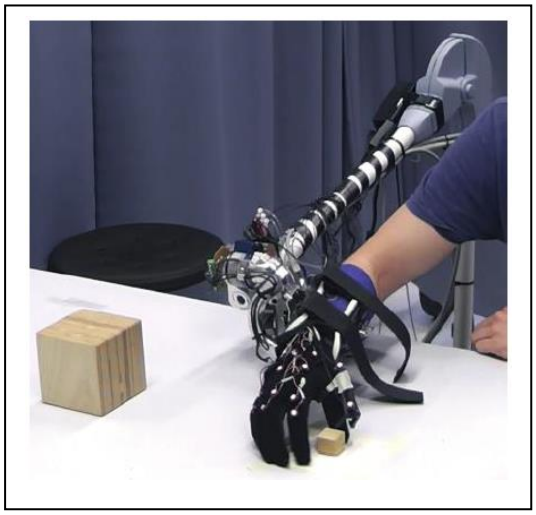

Figure 4: Photograph of prototype end-point manipulator [158].

arm at the wrist joint, and is consequently adaptable to either the left or right arm without alteration. The movement was orchestrated by a nine electrode system with a predictive model which achieved 33-87% success with unimpaired volunteers, whilst the success rate was below 25% for stroke subjects. These returns are comparatively poor and may be a result of the preprograming in the control system not being suitably adjusted for a stroke patient's muscular activity.

3. Control systems

To make a device that is compatible with daily wear there is a balance that must be struck over the number of commands it is able to perform as whilst the greatest control would enable complete replication of movement from the wearer this may result in difficulties with specifying the exact command that is intended. The greatest clarity of intention is observable at the brain and

becomes more complex once the signal moves beyond the anterior horn of the spinal cord due to the overlapping musculature structure of the arm. Whilst a device fitted within the brain or muscle would provide the clearest control signal, this would require additional risks to firstly install with further issues arising for maintenance or corrections to be made. Whilst this best fits with the ideas of neuroplastic recovery it is possibly excessive and not necessarily cost effective for a system that will mostly be deployed in a rehabilitative setting, being operated with multiple users each day for the duration of their rehab program, which will most likely be a small time period for the total lifespan of the device.

However the principles behind the concept of implanting have been shown to be successful in application, where used with a monkey it was possible for arm implants of 1mm in length to be able to ascertain 95% accuracy in a finger flexion exercise [159]. They were used in conjunction with a UEA implant in the motor cortex of the brain that unfortunately protruded from the skull and would certainly not be considered aesthetic for human standards, but this process did allow for the interpretation of the finger intention.

The electroencephalogram (EEG) is a lower risk concept than implanting within the brain, but uses the same principle for signal gathering. Whilst still an electronic system that may interfere with a patient as the implant might, this system has the option of being removed when the patient wishes to sleep. Questions have been raised about this system's reliability [160] as unfortunately a system is yet to be developed that can keep up with the rate of change in the signals that are emitted by the brain. Consequently the

system is unable to keep up with the small and precise movements that are required to participate in daily activity. It can however be used to receive and interpret commands, as long as the subject provides a concentrated single thought, such as ‘up’ or ‘down’. Current levels of performance using EEG are limited to applying basic actions to tasks [161], where the subject, through the use of EEG, became capable of gripping, lifting, lowering and releasing a glass, performing the process required to drink from it after processing a command signal in the brain for five seconds. Consequently the total process took 50 seconds and the photographic evidence provided suggests that the subject was not capable of achieving adequate finger flexion to correctly grasp the stem of the glass, they were however capable of supporting it. As technology develops to match the rate of change within the brain, EEG will become able to direct standard activities in the same manner that a healthy individual would. Indeed if the EEG is developed properly it can then be used to augment previously developed exoskeletons to provide the patient with a means of direct control [162].

When developing such a system it would also be important to consider which hand was the patient’s dominant one as there is an observable increase in neural activity in the non-controlling motor hemisphere when the non-dominant hand is being used [115]. Additionally it should be considered that each person’s brain has slight differences, and this translates into differing signal strengths [163], that may be misinterpreted in terms of intended motion speed. There are also issues of guaranteeing the correct intention from someone who has experienced a brain injury to cause their disability, such as

stroke, that may damage the accuracy of the measurements. Additionally it is also possible that a traumatic non-brain injury may still impact how the patient's brain processes command signals for the affected limb.

3.1. Muscular Control through EMG

Whilst issuing commands to the system directly from the brain is the inevitable conclusion of work in this field, whilst it is not yet ready for production then acquiring an accurate and responsive feed of data to interpret commands must come from another source. The balance of signal quality and practicality is often considered to be best struck by the sEMG. The complication for applying this control mechanism is that it is not capable of predicting the users intended motion. This is mainly due to the arm muscles being used for multiple motions and there being no consistent signal pathways within the muscle for each command [164]. When these muscles are then placed on top of one another, it can then create a large amount of confusion for the system to interpret which action the user wishes to perform. The other main factor affecting the outcome is the angle of the local joints, for example the work required for the biceps brachii to flex the elbow is affected by the angle of the shoulder. Consequently the sEMG can detect that the muscle should be acting, but is unable to determine which action the device should be taking, in terms of direction or force. Kiguchi proposed resolving this problem with the use of a hierarchical neuro-fuzzy control system. This was a three stage system, firstly looking at control from the basis of muscle

activity levels, then the angle of the shoulder and elbow were reviewed to select an appropriate control system and finally the torque level is calculated before motion could begin. In stage one the muscles at the shoulder and upper arm were used to gather command data, however if they were producing low level signals then the wrist force sensor acted as the reference to motion. The elbow and shoulder joint angles were divided into three stages each with an individual control system for those stages. As the joint angle changed, there would be a transition between the control systems, with dual control in the crossover periods. The final stage utilised a conventional fuzzy control system, which integrated the elbow commands with the shoulder position. Each system was broken down into two parts to deal with the main effect of each muscle as well as the knock on effect of the muscles. Their system was found to reduce the required size of the EMG signals in the shoulder and upper arm for motion, making these motions easier to instigate.

Kiguchi evolved the theory by developing a five stage neuro-fuzzy control system to operate a seven degree of freedom robotic arm [165]. This system had adjustable impedance that was found to reduce the RMS value of a lifting motion in comparison to when the impedance was of a fixed value. The RMS value of the muscles EMG signals were used to estimate the torque that the arm was experiencing in motion. The impedance was applied to the users hand force vector in an attempt to make the motion more natural. The device's neuro-fuzzy control system contained a matrix modifier that aimed to make the device adaptable with every upper limb motion that can be devised. The system was structured in five layers for commands; input,

fuzzyfier, rule, defuzzifier and output motion. They performed three basic lifting motions at four differing power levels that impacted the assistance. The discrepancies between the results suggested that providing too much assistance to the muscle may cause a detrimental effect on motion performance. Kiguchi has utilised EMG as a control mechanism in several studies since the turn of the millennium [121, 125, 142 & 164-168] and has found it to be a successful system when paired with a neuro-fuzzy control system to attempt to interpret commands (Fig. 5). This set-up provides reliable results, where a power assistance factor of 1.5 reduces the root mean square value for grasping a cup to 67%, allowing for a robot to provide a scaled assistance to the user. The experimental set up however is not practical for a patient to utilise at home as specialist knowledge is required to ensure that the 16 sources of input data are positioned correctly.

Unfortunately a neuro-fuzzy control system is only able to interpret the signals it has been designed to measure and respond in the manner it has been programmed to. A proposed alternative was the use of a neuromuscular interface [169], previous work in this field has been mostly directed at locating abnormalities in motion, meaning this model must function differently as the emphasis was placed on having instantaneous responses to signals. As with the neuro-fuzzy systems the EMG data were drawn from the biceps and triceps muscles but no further factors provided an input to the control system. As a result the system was developed as a single axis device, but they believe their mechanism can be reapplied to other axial movement. The system measures the muscular dynamics, joint

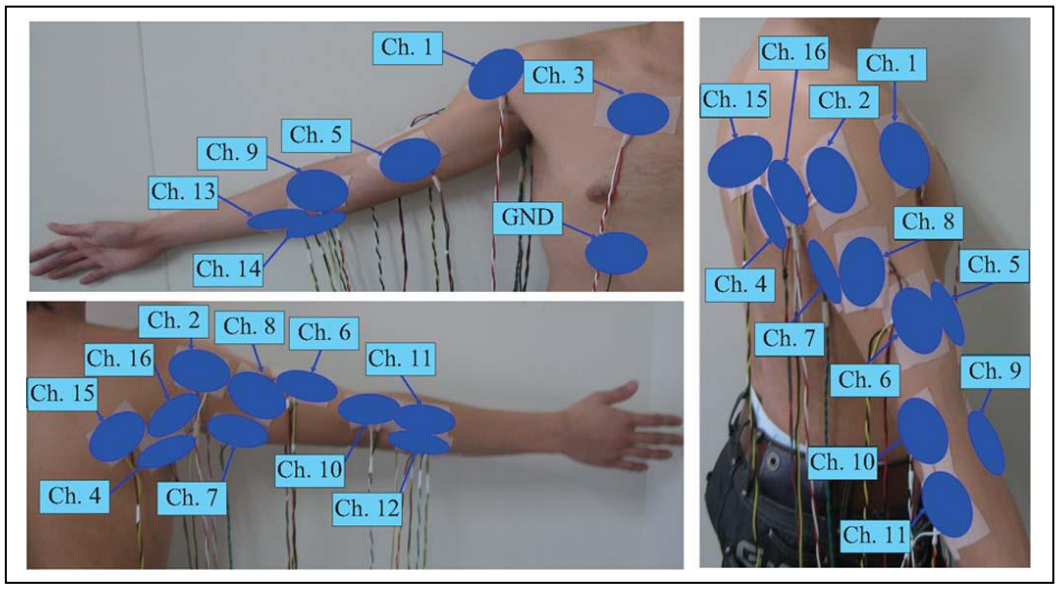

Figure 5: Developed EMG system for control of a seven degree of freedom exoskeleton [165].

geometry and rotational kinematics to calculate joint torque, angle and velocity to estimate motion. Their model was able to identify both different and new trajectories that were not full cyclical motions with some accuracy. This was a result of the variation in the muscular activation within the arm for repetitive movements. The only issue raised over the performance of the model was for multiple cyclical movements, as it struggled to follow the variability of the muscle signals for a repeated motion. They felt the discrepancy was due to the tuning process, where fixed parameters were used in a genetic algorithm that impaired its ability to detect local minimums and consequently struggled with variability.

It is also feasible to develop the system with individuated networks managing each joint instead of an integrated system [170]. This allows for quantification and review on a joint by joint basis instead of reviewing the output in isolation. When this principle was tested it was found to produce at

least similar results to integrated systems if not better [171]. A large part of this will be the result of being able to treat the wrist independently, allowing the user to replicate more natural shapes with their hand.

Interpreting this data is made additionally more complicated as patients will have a differing muscular response to healthy volunteers, and there will be even further complicated when comparing across conditions as a neurological condition such as stroke affects each patient separately and will result in differing ranges of motion which will have an impact on activity patterns for each set of arm muscles [172, 173 & 174]. It must also be considered that the level of recorded activity produced within the muscle will change with the velocity [175] and the angle of the joints [176] which requires the programming to be adaptive to the needs of the user and interpret them appropriately. The use of high density EMGs can help here [177 & 178] as they use an array of sensors to collect the data, however they can be quite large and intrusive as well as requiring a high level of expertise to put on. It has though been shown that when combined with a wavelet packet transform to be capable of determining 20 different upper limb motions from stroke patients [179]. The activity that is undertaken to collect the data should also be considered as many systems will be based from the use of maximum voluntary contraction to collect EMG measures of the patient's maximum capability, but it has been shown that a more accurate measure to the patient's capacity will be gathered by a maximal voluntary dynamic concentric contraction [180]. This change in assessment method resulted in an increase in the mean EMG recording by 45%.

Shoulder joint studies have suggested that there is a specific recruitment pattern for muscles that the body follows irrespective of the intensity of motion [181 - 185], and is purely dependent on the directionality of this intended motion, a pattern that can also be observed in the hand [186 & 187]. That said there are extra factors to consider that can affect the quality of signal received from an EMG, primarily that whilst the muscles behave in a consistent and predictable manner, as they change shape, this moves the relative position of the EMG sensor and body of the muscle which has an impact on the quality of the recorded signal, additionally the overlapping structures of the muscles can create issues with cross-talk, particularly for the long muscles connecting the forearm to the fingers [188]. It has also been shown that the temperature of the skin in contact with the EMG affects the quality of the received signal [189]. Indeed it suggested that a 2°C increase in skin temperature can reduce the responsiveness of the EMG from 99.7% to 86.2%. If the EMG were a component of a device that was intended to be worn for a prolonged period then there would be a reduction in its efficiency the longer that the device is worn for. Most EMG systems also require a gel base to assist with the signal collection; increasing temperatures would cause the quality of this connection to erode.

If the system is to be directed by sEMG, then consideration must also be given to the role of fatigue, and its possible effect on the control signal. Previous research has provided mixed results, with studies of the lower limbs suggesting that leg exoskeletons have a negative impact on their metabolic performance, whilst ankle exoskeletons were found to increase it. The

control mechanism was found to make an impact on the assistance a system may offer [190] with gravity compensation and the oscillator based approach showing the most marked improvement. The gravity compensation method is impractical for this study as it continually attempted to extend the knee, forcing the user to use their weight to flex the knee and lower their torso. This specific method tested best but its reapplication to the upper limb is questionable, as the experiment had the exoskeleton mounted to the ground and asked the subject to repeatedly squat in this position. It would be debatable if a disabled patient could overrule the mechanism attempting to extend the limb and maintain the system in a stable position, without a mounted point for assistance. The also beneficial oscillator process uses a formula based approach to estimate the required frequency, making it ideal for repetitive motion and could be applied if the system is utilised in a therapeutic role, but is not as practical if it were to be used in a regular activity.

Multiple muscles have also been found to act in synergy to guide the motion of forearm pronation [191]. It was found that there was an electrical impulse in the short and long heads of the biceps brachii, radial nerve, brachioradialis, pronator teres and lateral head of the triceps brachii muscles,. Each of these impulses, whilst varying in size for each muscles role in the action of pronation, started and finished at approximately the same time in the motion. They also made comparisons with a group of subjects who have radial nerve palsy, and found that they did not display this unity of muscular action when performing the required task. This would suggest that

there will be some differences between the arm activity readings for people experiencing different physiological conditions. The system will require a control device such as pattern recognition to differentiate and interpret the signals.

If the input data for the system is coming from EMG, then the motions will traditionally be performed by motors, as it is a strong and stable device that is successful in transferring power to the joint. However this combination is not able to interpret the commands it receives meaning it may potentially harm the user if they were to experience a spasm in the limb. A proposed alteration is from the HYPER Project, where the elbow joint is controlled by a magnetorheological clutch that sits between the motor and the limb to control and transmit the torque [192]. This material is able to change its viscosity instantly so it can provide greater resistance and a smoother motion to limit the chance of an injury occurring as the result of a spasm. The system should also be able to be customised through the assistance torque, so that it can be tailored to each patients therapy needs.

Traditionally EMG has been used with the larger muscles in the arm, such as the biceps brachii, as these provide a wide base to position the sensor and are not as influenced by the background noise created by other nearby muscles. As we move distally along the arm this becomes harder, firstly as the muscle narrows providing a smaller target body towards the wrist, as well as the separate muscles and tendon heads breaking off to connect to the individual fingers of the hand. However it has been shown to be possible to use EMG to interpret the motor unit action potential of the tissue to

differentiate flexion commands from the muscle [193]. This was a simple set up with only one EMG lead that subsequently was not able to differentiate between the fingers. With the principle of hand control through EMG being successfully demonstrated in a virtual environment [194], enabling the user to control the finger motion with 2.24° of error. Conventionally data of this nature will be collected from able-bodied participants before being trialled with disabled populations [195 & 196], where a 32 electrode design was able to provide 90% accuracy to a transradial amputee volunteer. This has previously been achieved with a smaller number of electrodes for an accuracy of 77% [197], with further improvements for accuracy in partial hand amputees (85% [198]) due to the musculature being intact at the wrist than transradial amputees. It has also been suggested previously that the main impediment to misclassification of hand movements is due to differences in the orientation of the wrist [199], therefore it is possible that inclusion of rotation of the forearm may help to improve the accuracy of EMG software, alternatively error can be reduced by integrating the static and dynamic wrist motion, with error reductions being found to be 35% [200].

The greatest challenge in developing an EMG controlled system is to ensure that there is a consistent and accurate response to the activity patterns produced by the patient. It has been shown that fractal dimensions are a possible tool that can be used to differentiate activity for both the rate of motion as well as the changing of the load that is being manipulated [201]. This should enable the signal to be characterized and allow some room for an interpretation of intention to be applied. The principle of fractal dimension

lowers the effect of background noise and signal crosstalk to provide a clearer output picture and has been used to identify the differences in forearm flexion/extension as well as supination/pronation [202]. It has also been suggested that it is possible to use these principles to interpret finger flexion and extension [203 & 204], which in turn would enable the direct control of a possible hand grasper or rehabilitative device.

3.2. Mirror movements to guide motion

The concept of mirror movements (MM) has been proposed as a possible control strategy for rehabilitative tools. The theory is that when motion commands are made for one limb that a duplicate signal is also issued to the opposing limb, being able to detect this signal may then allow a stroke patient, suffering a paresis of one limb to control the motion of a robotic aid that can exercise the paretic limb. There has even been a suggested correlation between the level of MM for their unaffected arm and the level of paralysis within the opposite arm [205]. For those with a higher level of MM, they would also experience a lower level of motion. In a test of squeezing patterns, they found that repetitive squeezing most highlighted the differences in MM levels between the stroke patients and the control group over sustained squeezing. MM levels were also found to not develop in tandem as the levels within the paretic hand that is those mirroring the signals from their unimpeded arm were found to resemble the results of the control subjects.

This suggests that the process of MM is engaged by the body to attempt a repair of arm control, other work has suggested that MM originates for one of two reasons [206]; either one which is acquired as a response to an initial motor deficit with a strong possibility for recovery, or one that is acquired as a secondary compensation method that actually impedes recovery. Uttner's study found no distinct differences in the level of MM between controls and a group of people who have suffered from a unilateral adult onset brain lesion.

It has been found that there are control signals for MM that originate within the brain [207], noting increases in the M1 motor cortex, Supplementary Motor Area and Cerebellum. These signals became more pronounced as the isometric force of the active limb was increased, and the changes were equal in size between the brain and muscle. The findings of Bologna [208] suggest that MM can be reduced through focused training, and that short-latency interhemispheric inhibition could be used as a predictor of reduction in EMG signal size. These changes are believed to occur as a result of better targeting of commands through training resulting in less spill-over to the mirroring side, whilst those with a higher s-IHI will have a greater capacity for controlling the mirroring in training. The implication from this is that mirror signals weaken as the muscle in use becomes stronger, which makes it a strong measure of the progress being made by rehabilitation, however to be employed as a control system would require the system to adjust the responsiveness depending on the user's stage of recovery, suggesting that the device will be required to interpret their progress on its own. There is also the factor that the devices physical limits would be harder to test, as it

would be safer to test them with someone who had the physical strength and responsiveness to resist any unanticipated motion, however the stronger their arm is, the weaker the MM or control signal the system will receive.

3.3. Pattern Recognition

EMG models and the neural networks that are often integrated within them require base software to analyse the signals being produced by the muscle and to interpret the appropriate response. This is completed by the process of pattern recognition, where the locality of the electrical activity and the size of the signal would then be reviewed by a program to assess what the user wanted to move as well as how quickly it should be moved. Although there are several different methods for the program to gather and assess the data it has been suggested that a single proportional system, where a EMG sensor is positioned on the agonist and antagonist muscles for the desired motion with the amplitude envelope of the signals being used to distinguish the commands, is thought to be the most effective [209].

For the method to work it is important that there is a distinct pattern of activity within the muscles that consistently occurs with motion so that the program is able to review and compare the input signal with the output commands. There are many established studies for muscular activity in the arms [210 - 212], but they are less established in the signals for control of the hand. As a result of this there has difficulty in developing a device that can perform motions of the hand as successfully as the motions of the arm [213], an issue

that is caused by the wide range of precision actions that the hand can achieve.

3.4. Predictive Models

As opposed to a system that is reactive to specific muscular activity to trigger motion a manner similar to an on/off switch, the theory of predictive models has greater potential for hand disability. Instead of merely receiving a signal to be active or inactive this program assesses the signal and then estimates the motion for the intended output. A design of this nature is more complicated to develop as there are additional data that are required to help construct the network beyond the EMG reading of the pattern recognition system, a predictive model would also be required to know where the hand is positioned as well as the joint angles. Collecting this data requires additional sensors as well as circuitry to manage the system, making any wearable design bulkier and heavier, which may discourage use due to it being less comfortable. Wireless communication could be integrated to reduce these issues by allowing the signal processing and instructions to be controlled by an external computer.

This process has successfully demonstrated how the forearm can be controlled from combining the activity of the shoulder muscles with the orientation of the shoulder joint with approximately 5° of error in both pronation/supination and flexion/extension [214 & 215]. The application of the theory to predicting the motion of the fingers has also been successful

with testing of an individual finger was achievable with just two EMG leads and an accelerometer [216] with a root means square variation of 0.085-0.163 depending on the speed of the assessed motion. The integration of the electromechanical delay for the EMG signal [217] enabled an improved accuracy, which was most accurate at the proximal joints. They also found that cyclical motion produced the most consistent results, as the correlation dropped from 0.92 to 0.85 when the motion became nonperiodic to replicate real dynamic motion. Increasing the number of sensors fitted to the muscle allowed the system to predict which finger would be moved with 100% accuracy and was correct in the positioning 97.75% of the time [218].

3.5. Adaptive Models

Both the pattern recognition and predictive models share a fundamental flaw; that the program can only replicate motion from commands that it has been shown how to interpret. This is not an issue with healthy testing subjects the data are traditionally drawn from as their muscular activity will follow predictable patterns. This also applies to the amputation patients that the systems were designed for; as the nerve clusters will remain in the same locations so that direction application can be replicated. When the patient group is changed to a disabled group such as stroke patients, the inter-patient variability makes the success of such a program harder as it will need to be tailored to each individual patient's condition to maximise the possible improvements. Subsequently the most effective control system would be one

that is capable of adapting to learn from the wearer and then adjust its responsiveness to compensate.

Such a system can achieve this by firstly learning a patient impairment model which is then coupled with assist-as-needed finger decay to allow the FINGER mechanism to help guide the user through a repetitive grasping motion [219]. This model was found to decrease the required control effort for a single finger where each phalange was considered to be an independent segment, as opposed to the higher force required for moving a unified single mass for the finger, however the theory was tested on an unimpaired population, so their performance improvements are not guaranteed.

3.6. Direct control methods

These advanced methods certainly have benefits to the wearer, but they also have issues. The first and most obvious being that these can be expensive systems to develop and produce, increasing the cost to health services to provide them. Systems that are responsive to the wearer's internal muscular signalling also have questions of consistency, as factors such as muscle density and signal pathway functionality will fluctuate from patient to patient, this may result in systems that are not useable for some patients or require extensive practice to prepare them to operate the system.

This then makes the prospect of systems that are directly user controlled more probable in the early stages of recovery, as they are accessible to all

users and will not have discrepancies in the responsiveness for the wearer. Systems controlled by switches or buttons can give the user direct control of their activity in treatment, however this lacks the intuitive responsiveness of the alternatives, making it primarily a tool rather than an active assistant. Systems of this nature will only function with an on or off condition, and consequently not be capable of replicating the minor adjustments that the human hand goes through when grasping, as well as lacking the immediacy of this adaptation. Using it as a control mechanism will also result in a passive component that does not fit with the principles of motor learning, limiting its use. Additionally this control method requires the user to interact with it to manage movement, meaning that they cannot perform bimanual motion as their other hand is required to operate the impaired hand's mechanism.

Motion would be controlled directly by the user giving them an interactive experience that may help them to remain engaged with their therapy. Increasing participant engagement should improve the level of their recovery in therapy. It is a design that would benefit most from a game scenario, to immerse the participant and disguise the lack of responsive feedback, whilst encouraging them to engage and providing positive feedback, in much the same manner as a computer games console controller is operated.

Conclusion

In conclusion there are currently a wide and varied range of devices that have been developed to assist patients when they have experienced an upper limb disability. This variation exists in terms of which joints are supported, how the system is controlled and whether its primary function is treatment or assisting in completing tasks. This variety results in devices that have a range of sizes and costs and can then be acquired based on the needs of the treatment provider and their patients.

With some research suggesting that patients can benefit from longer treatment time in methods such as task based rehabilitation therapy there is a case to be made for robotic devices to fill this gap, with some tested devices also improving patient outcomes from longer exposure times. In terms of practical application this creates the opportunity of improving patient outcomes by providing them with the tools to conduct some of their treatment at home provided there are systems in place for monitoring the patient. To do this a device would need to be easy for the patient to operate as well as low cost if they were to be provided to multiple patients. Additional novelty from allowing the wearer to be mobile with the device and additionally use it for practical tasks would be beneficial to its application.

For the next stage of the process these points should be considered alongside the opinions of former patients, as representatives of the final users of any device who have been in their position they will have a unique perspective on the requirements of any design.

Chapter 2 Design Rationale

Chapter 2 Design Rationale

Whilst the overall intent of the design has already been set out it is important to consider the opinions of those who would be using such a system on a daily basis. As such this section lays out the framework for an investigative discussion with former patients to gather information on their experiences so that this can be factored in to improve the design process. These factors can then be integrated with the process of Quality Function Deployment (QFD) to produce outcomes that make the basis of design. Traditionally QFD is a four stage model, but here only the first two stages of modelling are used to review the results of a combined questionnaire and interview with former patients. The first stage of the process is the product planning stage that outlines the designs requirements, whilst the second is concerned with the characteristics of the parts and how they are deployed. The third stage is used to outline the key process operations that go into planning with the fourth outlining the production requirements. These final stages are orientated around the development process for a final product, as the thesis is only developing a prototype stages one and two are the key factors, where what the customer perceives as benefits are broken down and converted into features that can be used in the design [220]. This process has been used previously in the design of cochlear implants [221] and power wheelchairs [222].

QFD Study

There is an increase in the frequency of disability in the general population of western countries which is partly a result of poor lifestyle choices in terms of diet and exercise as well as greater high-risk activity participation. There is also a large contribution from improvements in medical care, as many patients will now survive from traumatic conditions such as strokes or heart attacks which would previously have been fatal. This means that there will be an increase in patients experiencing the repercussions of these conditions, such as physical disability. The consequence of this is that this increased commonality of disability will require treatment, and whilst there are various surgical methods that have been proposed as alternatives to helping remedy the numerous ways that the disability has been created, the model for aftercare always is always built on the backbone of rehabilitation.

An upper limb device that could be used in rehabilitation can have two potential roles, firstly to exercise the joints as a therapy tool or to support them in motion as they perform activities of daily living (ADLs). Ideally any solution would be capable of fulfilling both roles, however when considering resource allocation it is important to firstly address the main needs of the patient population. As the thesis is intending to develop a low cost device that patients could use at home, key information can be best collected through direct discussion with former patients, as their experiences can provide the clearest indication of where supporting approaches should be considered to improve the recovery process. Depending on the success of

their therapy they may also require assistance with movement tasks, making them potential stakeholders in the final outcome of the research.

To gather this information a consultation was devised, where the researcher would contact exercise groups in the central Scotland for former stroke patients and firstly ask them to complete a questionnaire about their recovery and then to participate in an interview of their results to allow the researchers to build a detailed picture of how they felt their experience could have been improved. The questionnaire would ask them to rank the importance of various design features that would be considered when developing the device. This will provide quantitative data to work from in the design, along with the qualitative data from the interview, which should help to organise the relevance of the design features to ensure that it is as beneficial to patients as possible.

These factors and how they would influence the intended design were then reviewed through the use of QFD. This is a model of design that originates in Japan and provides a reasoned process for how decisions can be reached. It places the needs of the user at the centre and is considered to be the most reliable means of collecting market data. Whilst QFD is traditionally applied to developments in business production [223], it has also been used with success in improving healthcare services [224 & 225]. Healthcare is not often represented by QFD as there can be an issue of defining what is the product and who is the customer [224] as healthcare is such a wide and varied field, however there are precedents in using the process to help in the design of diagnostic devices [226], cochlear implants [221] as well as a

power wheelchair [222], suggesting that considering patients as the customer and the design as the product should produce a valid outcome.

Method

After receiving ethical approval from the University Ethics Committee, permission was sought from local physical activity groups to ask them if they were interested in distributing a questionnaire to those members with the possibility of conducting future interviews with them. Three groups responded and the questionnaire was distributed with stamped addressed envelopes to return the document. There were 37 participants across the three groups, 13 of whom responded (35.14% response rate). Of these four were incomplete and unable to be used, and eight of the remaining nine responses also chose to opt-in to the follow up interview which was arranged at a time that was convenient to them. The respondents ranged from being one to eighteen years post stroke. The design and process for this study was cleared by the university's ethics committee in consultation with a Scientific Officer representing the National Health Service.

The questionnaire was divided into five categories for the main features of the design (joint motion, function, control, wearability and other remaining factors, a collection of aesthetic and practical functions). These five categories were then subdivided into a further five criteria each, these five criteria would then be ranked in terms of their importance to the participant. For further clarification of the results, they were also asked to rank the

categories as a whole against each other (as without this clarification there would be five groups of five design features that are all considered to be of equal importance). Whilst the intention was to integrate as many of the 25 design criteria into the design as possible, there are occasions where these features will clash; as such the emphasis should be placed on the higher ranking criteria.

The interview questions were framed around the responses that the participant had provided in the questionnaire, as the study sought to find out what made the highest ranked features the most important for them along with why they felt that the lower ranked features were not as important, using these positions as a starting point for discussions over the merits of the features within each category. Discussion of the connections between the criteria, even those that cross categories, was encouraged to form a deeper dialogue and gain a clearer picture of how they felt the criteria integrate and how the key features of the design could then be adapted to meet their functional needs. Due to the number of respondents, results that yield definitive solutions that could be extrapolated over the whole population were not possible; however the discussions still generated some points that could be used to influence the design priorities.

Results

The findings are displayed in Table 1 & 2, the QFD stage 1 table shows the factors that the participants were consulted on and compares them to

possible engineering characteristics of the design, whilst the QFD stage 2 table takes these design characteristics and compares them to specific components to be considered in the design. The relationship between the factors of the table is noted numerically with the numbers one, three and nine indicating the strength of this relationship, where one indicates a weak relationship whilst nine illustrates a strong relationship. For example the wearability factors of comfort, weight and stability have a strong association with the design feature of being easy to fit, which in turn are associated with securing it in place, this role could be performed by the use of Velcro strapping, which also has the benefit of being low cost. The first column shows the average importance, which was scored by the participants in the questionnaire.

The statistical difference between the scoring of these factors was reviewed by a two tailed T-test with the results shown in Table 3; although from a sample of this size it is conceded that definitive results cannot be drawn for the whole population. Additionally the traditional analysis methods for small sample pools, Spearman's rho and Pearson's correlation, both require the compared data to be derived from independent sources, which the ranking system for the questionnaire negates. The factors of each category are aligned both horizontally and vertically to allow for comparison between them. For example the act of grasping was found in the study to have had a significant difference in opinion of its importance in comparison to lifting (0.035), tilting/rotation (0.00039) and reaching (0.000015) at the 95%

confidence interval in comparison to the act of releasing (0.1211) which did not have a significant difference.

Table 1: QFD Stage 1 Table [230].

Category	Design Criteria	Importance (Ranking of 1-5)	Range of Motion	Ease of Control	Consistency of Response	Independence	Long life	Ease of fitting	User Protection	Low Cost	How Much?
Joint Motion Category Importance: 4	Shoulder	2.56	9	3	9	9	9	3	3	3	5 dof
	Elbow	2.89	9	3	9	9	3	3	3	9	2 dof
	Wrist	2.67	9	3	9	9	3	3	3	3	3 dof
	Fingers	3.78	9	3	9	9	9	3	3	9	4 dof
	Thumb Opposability	3.11	9	3	9	9	9	3	3	9	3 dof
Function Category Importance: 4.78	Grasping	4.63	3	9	9	9	9	3	3	9	Clinical Evaluation
	Lifting	3	9	9	9	9	9	3	9	3	Clinical Evaluation
	Releasing	3.63	3	9	9	9	9	3	1	9	Clinical Evaluation
	Tilting/ Rotation	2.25	9	9	9	9	3	3	3	3	Clinical Evaluation
	Reaching	1.5	9	9	9	9	3	3	1	3	Clinical Evaluation
Interaction /Control Category Importance: 2.67	Ease of selection	4.22	9	9	9	9	9	9	3	3	Testing
	Starting motion	2.56	3	9	9	9	3	1	3	9	Testing
	Stopping motion	1.44	3	9	9	9	3	1	9	9	Testing
	Effort	4.44	3	9	9	9	9	1	3	3	Clinical Evaluation
	Feedback	2.33	1	1	9	3	9	1	9	3	Haptic Devices
Wearability Category Importance: 2.22	Comfort	3.67	3	1	3	3	9	9	3	3	User Feedback
	Weight	4	3	3	1	9	9	9	9	3	<2.5kg
	Stability	2.33	9	1	3	3	9	9	9	3	Clinical Evaluation
	Tightness at joints (Fit 1)	2.33	3	1	3	3	9	9	3	9	Clinical Evaluation
	Tightness at muscles (Fit 2)	2.67	3	1	3	3	9	9	3	9	Clinical Evaluation
Other Category Importance: 1.33	Set up	2.89	3	3	1	9	9	9	9	9	Market Analysis
	Appearance	1.78	9	1	1	3	9	1	1	3	User Feedback
	Noise	1.56	1	1	1	3	9	1	1	3	User Feedback
	Freedom	4.44	9	9	9	9	9	9	9	3	Clinical Evaluation
	User safety	4.33	9	9	9	9	9	9	9	9	Clinical Evaluation

Analysis

When asked to overview the importance of the categories the participants clearly prioritised the range of movement that they could achieve and how it performs in helping them with tasks (scores of 4 and 4.78/5 respectively). This is understandable for two reasons, firstly that a system that enables them to interact with the world will always be a more engaging prospect for patients [15] (there are also questions that can be posed about how realistic their expectations are in this matter, for example one participant reflected that they would like to be able to play the piano again), and also secondly there may be an element of bias as the study spoke to post therapy patients who have already experienced gains from their rehabilitation, so they may view a process that they have already completed as being of less importance. These remaining criteria sets (interaction/control, wearability and other additional features) were considered to be of low importance if the device was incapable of completing its primary purpose.

For the data collected from the questionnaire (see the importance column of Table 1 for the average score) it was clear that there was no significant difference between the mobility of the joints before therapy began (each p-value was higher than 1.49). The difficulty in moving the finger and thumb scored the highest (3.78 and 3.11/5 respectively) but they were not significantly different from the difficulty in moving the shoulder, elbow or wrist joints (2.56, 2.89 & 2.67/5). This is supported by the discussion with the participants where they all reported that post stroke they had difficulty experiencing sensation through their entire arm, rather than in specific areas.

Post therapy this changes, with the activity of grasping being significantly harder to control than shoulder orientated activities such as reaching, which was considered the easiest (4.625 compared to 1.5/5, p = 0.000015). This was also supported in the discussion, where the participants were more than willing to demonstrate the level of flexibility they had recovered in their shoulder along with the difficulties they had in controlling their fingers.

The distinction is most likely due to a combination of the easier recovery of the larger muscle groups due to the shorter signalling pathway for the

Table 2: QFD Stage 2 Table.

	Joint selection	Driver/Actuator	Motion activation	Adjustable Components/ Mechanisms	Wearer comfort	Lightweight materials	Aesthetics	Haptic Devices	Secured in place
Range of Motion	3	3	3	3	3	3	1	1	3
Ease of Control	9	9	9	1	1	3	1	9	1
Consistency of Response	9	9	9	9	3	1	1	9	9
Independence	3	3	3	3	9	9	3	9	3
Long life	9	9	9	3	9	9	3	3	9
Ease of Fitting	1	3	9	9	3	9	3	3	9
User Protection	3	3	9	9	9	3	3	3	9
Low Cost	3	3	9	1	3	3	9	1	9
	Hand motion only	Micro motors	On/off/on switch	Joints to be loosened/ tightened as applicable	Padded contact areas	< 2.5kg	Aesthetics relaxed	Strain reapplication to user	Velcro Strapping

muscles that are easier to repair coupled with therapy focused on macro motions to improve posture [227]. Whilst these factors are inherently beneficial to the patient the end result is that the recovery of the hand is left behind, therefore any device that would be developed for the patient should follow one of two approaches, firstly where the device is a replacement and must therefore replicate the improvement of the shoulder and elbow as well as hopefully being able to improve the recovery of the hand, alternatively it can be developed as an addition, where the device would be used in conjunction with their therapy and could therefore focus on the hand in an attempt to bring the level of recovery into line with the rest of the arm.

When planning mobility for the fingers the same question is raised as for the shoulder: how much freedom should they be allowed? As whilst flexion and extension are the most prominent action that they perform their ability to abduct and adduct is what allows for intuitive grasping of objects [228]. The small spaces involved with the hand makes it challenging for a device to be developed that could help with this motion, as there is often considered to be only enough space for individual finger components that deal with flexion and extension. The components that would be required to enable these additional degrees of freedom are possible, but would in turn make the device bulky, so it would most likely be unable to be worn independently and would need to be mounted to a stationary surface such as a table to act as a base. Consequently this would go against the role of supporting function that the participants were hoping for as their most important criteria, along with not meeting the preferred criteria of being lightweight (4/5) and providing the

wearer with some level of independence (4.44/5), as both criteria were ranked as the most important feature in their respective categories.

Often in mechanical treatment the fingers are viewed as a set, this can create

Table 3: Comparative Data Results from the Questionnaire [230].

	Importance	Joint Motion	Function	Interaction	Wearability	Other
Joint Motion	4	N/A	0.06528478	0.02850921	0.00058196	0.00001529
Function	4.78	0.06528478	N/A	0.00032041	0.00006532	0.00000005
Interaction	2.67	0.02850921	0.00032041	N/A	0.44681333	0.01142455
Wearability	2.22	0.00058196	0.00006532	0.44681333	N/A	0.05160895
Other	1.33	0.00001529	0.00000005	0.01142455	0.05160895	N/A
Joint Motion		Shoulder	Elbow	Wrist	Fingers	Thumb
Shoulder	2.56	N/A	0.63053608	0.89606922	0.23611504	0.50770165
Elbow	2.89	0.63053608	N/A	0.75992297	0.29290489	0.75314164
Wrist	2.67	0.89606922	0.75992297	N/A	0.14911670	0.57763523
Fingers	3.78	0.23611504	0.29290489	0.14911670	N/A	0.28153692
Opposable thumb	3.11	0.50770165	0.75314164	0.57763523	0.28153692	N/A
Function		Grasping	Lifting	Releasing	Tilting/Rot	Reaching
Grasping	4.625	N/A	0.03542516	0.12112229	0.00039143	0.00001463
Lifting	3	0.03542516	N/A	0.40509395	0.22160142	0.02628739
Releasing	3.625	0.12112229	0.40509395	N/A	0.05434357	0.00612321
Tilting/Rotation	2.25	0.00039143	0.22160142	0.05434357	N/A	0.19702207
Reaching	1.5	0.00001463	0.02628739	0.00612321	0.19702207	N/A
Interaction		EoS	Start	Stop	Effort	Feedback
Ease of selection	4.22	N/A	0.00352202	0.00002641	0.59426402	0.00454422
Starting motion	2.56	0.00352202	N/A	0.04035065	0.00066491	0.71883630
Stopping motion	1.44	0.00002641	0.04035065	N/A	0.00000636	0.15355473
Effort	4.44	0.59426402	0.00066491	0.00000636	N/A	0.00707767
Feedback	2.33	0.00454422	0.71883630	0.15355473	0.00707767	N/A
Wearability		Comfort	Weight	Stability	Fit 1	Fit 2
Comfort	3.67	N/A	0.56319426	0.14111328	0.10378649	0.30520137
Weight	4	0.56319426	N/A	0.02416573	0.00539088	0.09607159
Stability	2.33	0.14111328	0.02416573	N/A	1.00000000	0.61954375
Fit 1 - Joints	2.33	0.10378649	0.00539088	1.00000000	N/A	0.63053608
Fit 2 - Muscles	2.67	0.30520137	0.09607159	0.61954375	0.63053608	N/A
Other		Set-Up	App	Noise	Freedom	Safety
Set-Up	2.89	N/A	0.06188556	0.02220390	0.00542273	0.02602469
Appearance	1.78	0.06188556	N/A	0.59426402	0.00004367	0.00000049
Noise	1.56	0.02220390	0.59426402	N/A	0.00000391	0.00012037
Freedom	4.44	0.00542273	0.00004367	0.00000391	N/A	0.75992297
User safety	4.33	0.02602469	0.00000049	0.00012037	0.75992297	N/A

issues as they are of varied length and also connect to the metacarpals at different positions, this results in the joint centres all being at different locations, where a unified treatment would benefit more from the fingers being homogenised. The differences can then impact how the patient's angular rotation recovers [101]. There is also the issue that over-constriction of the fingers can limit how comfortable the user finds the device (3.67/5).

When considering how to make the design as wearable for as prolonged a period as possible the participants felt that the weight was the key feature here, as a result a target weight of 800grams was set to try and minimise how much the hand is weighed down. Whilst this is of course lighter than the actual limb, external weights always feel heavier as they do not have the interconnected support of the muscles that the actual arm has. Additionally this weight does not need to be exclusive borne by the arm, depending on the set up it would be possible for some of the components to be distributed around the wearer's waist, this would apply in particular to patients who have an additional impairment of the shoulder and would struggle to support the target weight on their arm. With factors such as weight it is also important to consider how the weight is distributed; the participants were split with no significant difference in opinion between securing the weight of the device around the muscles or the joints, although there is a slight favouritism towards the muscles (2.67 compared to 2.33/5). As there is no preference then it is best to look at it from the perspective of performance, this would suggest that it is best to place the weight of the device on the muscles, as this would lessen any possible obstruction of the joints although there is an

increased risk of the device moving around as the size and density of the muscles will vary from user to user [229]. It should also be considered that the contraction of the muscles will also result in shape changes for the underlying surface. The best way to accommodate this is to secure it in place with restraints that offer variation in their size, such as Velcro strapping or a wearable sleeve to allow the tightness of the restraint to be adaptable to a level that is secure but also comfortable for the user to wear for a prolonged period by enabling the muscles to contract when necessary.

The comfort issue is also an important area to address when considering if users would be happy to wear the device, this could be addressed in part with the use of softer materials such as padding for the larger contact areas. Attempts should be made to limit hard metal surfaces or areas with sharp edges from making contact with the wearer. To achieve the most comprehensive recovery possible it is important that the patient utilises the system for as long as possible, subsequently it is important that the device is then comfortable to wear, as whilst the most dedicated to recovery may persevere with an uncomfortable aid if it shows a marked improvement, many patients are likely to be put off. This point was a non-dominant factor in the QFD (3.67/5) that recurred in the patient discussion, suggesting that a preferable solution is to have a softer material contacting with the skin, provided it can retain a firm shape without compromising the flexibility of the joints and does not create excessive movement as the musculature moves underneath it. The easiest fit would be to use adjustable components, allowing the device to have a stable fitting for patients of differing sizes, and a

mounting for the actuators to ensure that they are applied at the same location rather than leaving it to the discretion of the user, as this will create an inconsistency of performance. The increased stability should lessen the chances of components becoming bent or bashed by wear and tear, whilst a consistently applied and more durable system will have a higher chance of being used in the long term. The sampling of potential components for the prototype will be discussed further in Chapter 3.

It is possible that such performance could then be supported through the use of a haptic system to provide feedback to the user to stimulate an association with the desired motion and improve their learning. There are issues with this concept, firstly that these additional components require extra weight, contrary to the primary concern of the comfort category (weight), as well as increasing the cost to produce. This is also compounded by being a factor with low scoring importance to the users in the QFD (2.33/5), although this may be a result of a lack of technical understanding amongst the patients and their being unable to fully understand how such principles would assist their recovery. It is a feature with interesting potential but is outwith the target aims of the study; that of developing a low cost therapy aid for treatment of the hand.

In order to give the user the greatest feeling of control the most important factors were that any future system should be responsive to the wishes of the user and that the motion should not require a large concentrated effort to power it (4.22 and 4.44/5 respectively). Obviously these features partly oppose each other, as more options are provided for possible responses the

harder it can become to differentiate between the commands for these various activities. Consequently the design should look to support the higher scoring factor, that of making it easier to control. If the range of motions can be restricted to a core set of activity then a direct controller could be created to manage these actions. As such it was decided to focus on controlling the fingers and thumb, the core physical action that the hand completes, as these are opposing actions it should be straightforward to develop a control mechanism to operate such a device.

To give the user control of this system it is important once they have identified what they intend to do that it is easy for them to trigger the starting (2.56/5) and stopping (1.44/5) of motion. The simplest way to achieve this would be with a binary on/off system so that there is no room for ambiguity that for example a rotational switch controlling the speed of motion may create. Linear controls such as this would then also assist in making the system easier to set up (2.89/5), as there is no personalisation that would need to be accommodated for example in an EMG controlled system the user would have some responsibility to ensure that the connections were making a clean contact with right areas of their muscle to function properly [125]. A switch operated system only requires positioning and securing in place before being ready to operate. The main strength of this system is its simplicity; however this is also its main drawback, as the options are limited by the set-up. Whilst more advanced options, such as using a touch screen enable more options to be provided in return for more complexity. Any control of this nature still requires direct application from the wearer, where

alternatives such as EMG control allow the wearer to signal their intention through the underlying musculature instead of activating an external trigger that may require additional exertion for the patients.

The dominant desire made clear in the interviews with former patients was that any developed system needs to provide them with a practical use for it as opposed to being something that would merely exercise their joints. They felt that they would get a better sense of progress in their recovery if they were able to able to perform tasks that had a tangible purpose, such as moving items from a cupboard, rather than an arbitrary exercising of their joints. It should of course be noted that the population for this study was drawn from subjects who had already completed these standard practices and would be looking towards a later stage of recovery. An interesting note that arose from the interviews was that there was some variation in the former patient's attitude towards their own safety, where many of them did not rank their safety as importantly as may have been expected from people who have suffered a severe traumatic injury. Just over half of the subjects interviewed (55.5%) were found to prefer a device that would enable them to move around when they used it rather than that the device would ensure their safety, with some even considering it of less importance than the length of time it would take to set up and get off. It is also unclear if the patient volunteers, who were likely more motivated to recovery than other subgroups of stroke patients, could be taken as fully representative of all patients on the issue of personal safety. Protecting the well-being of the user is a core feature of any design that cannot be ignored and needs to underpin every

decision in design, as failure to do so could be considered to be neglecting the duty of care towards patients, for which the developer and distributor of any device would be considered liable.

The aesthetic factors were shown to be the least relevant to the user group (1.78 for appearance and 1.56/5 for noise), suggesting that as previously mentioned with regards to safety that functionality is king for this post stroke therapy population. This is beneficial as tending to aesthetics is an additional cost, which is contrary to the intended direction of design, where the device is a low cost development. Subsequently they should only be considered as additional features to the initial design. This also bears into consideration the size of the system as if it were large and complex in appearance this may be awkward for the therapist to get on or off of the patient or intimidate the patient, both of which are likely to curtail user engagement.

As the first component of this study was a postal questionnaire the response rate was high, with the return rate for the groups ranging from 33.33% to 58.33%. It is unclear if this response rate was due to the group's enthusiasm to participating or by the experimenter attending a session with each group before the questionnaire was distributed, this level of personal contact may have contributed to the group member's being more willing to participate. The volunteers did come across as eager to find out if developments could be made to help their recovery, but as they are members of groups that are already working to assist that recovery it is unlikely that their enthusiasm could be extrapolated over the wider stroke patient group, or even all upper limb disability groups. It is also unclear if their enthusiasm was what made

them become part of the group or if being in the group created the enthusiasm, this could not be verified as it would not be possible to locate the patients that are out in the community without access to records from local health services. The caveat to these criticisms is that patients of this nature would be the ones who are most likely to use such a system and as a result their opinions have a greater weight in the direction of the design than those who are unlikely to use it.

On reflection, the process for the questionnaire may require to be reviewed as some of the participants struggled to understand the scoring method for the questions; as such the answers had to be discounted. They were answering the questionnaire from the perspective of 'how important is this factor?' and scored it from 1-5, when the question was really 'which factor is most important?' and the results should be ranked from 5-1. Possible ambiguity in how to complete the questionnaire may also have had the effect of putting off others who were approached but chose not to participate. Concerns about whether they had completed the questionnaire correctly were also raised by the participants at the interview discussions, as one phrased it "it is a different way of thinking" to gear their mind to a more complex question of comparing the factors, as many questionnaires that they are given will ask them to score how they feel about their recovery without quantifying it against other factors. The ambiguity issue may be contributed to by testing a stroke population as it is a traumatic brain injury and as such their capacity to interpret is impaired, it is possible that there would be no misinterpretation from disability groups who are solely physically impaired.

The final outcome of this analysis has proposed some key design factors for the design from an intended possible user group along with some conceivable options to be taken on and developed further in the design stage. Making a device that is effective in both training and function is a complex task, especially when those same users would like it to be lightweight as well as easy to use and provide them with some sense of freedom to move around. When considering the thesis' intended feature of a low cost of production, a system that uses the wearer's body as the core of the exoskeleton, but provides automation of the joints is the best solution. If the device is small and made of lightweight materials it should then be able to be held in place by methods as basic as Velcro strapping. The intention is for the device to provide the user with direct control over both grasping and releasing of their fingers to enable them to primarily exercise these joints in the event of disability, with the potential for future development as a home based independent physical activity aid that can work alongside their therapy.

Conclusion

The QFD process traditionally allows the customer to have their wishes placed at the centre of design; in this case it is the wishes of the end user that are being used to determine the direction of the design. From the discussion with former patients it has been established that the focus of the design should be placed on the hand, in particular the act of grasping, as this is the area that that the discussions have suggested to be the most in need

of assistance in therapy. There is also an expressed desire to make the device's control system straightforward and low effort to perform. Consequently the QFD process has suggested that this would be best completed with a switch based control system when balanced against cost. The study also highlighted the importance of making it as lightweight as possible to enable them to them to have additional freedom to move around when they are using the system at home, designing a device that allows this would to happen could be considered a significant development in support and rehabilitation. It is also important to ensure that such a device is produced as cost-effectively as possible. The combination of these results refines the scope of the design to follow.

Chapter 3 Design & Prototype Development

Chapter 3 Design & Prototype Development

The previous chapters have established the framework of the design. This chapter will outline how these outcomes were applied to firstly develop the principle of a glove design that assists with grasping motion. It will also detail the components that were selected to make a functional low cost prototype of the design that could be taken forward for initial testing.

Design of the Glove

Having gathered opinion from former therapy patients there were several common themes in what was desired. The most important of these was that the majority of the respondents felt that recovery of their hand was not given the same focus as other parts of their body. The result of this was that the former patients could move independently but struggled to use their impaired limb to interact with the world around them, becoming over dependent on their unimpaired hand for activity. Placing this outcome centrally in planning meant the focus of the design was orientated towards a hand device that was a therapy aid as its primary function, with use as an assistant for motion being considered as a secondary function.

To accomplish this dual purpose the device would need to encapsulate the fingers and be able to manually guide them through the motion. Traditionally this would be performed by a frame assembled from either metal or plastic that would be secured to the finger by strapping. For the design in this thesis a novel approach was sought from nature, looking at how an octopus is

capable of tightly gripping an object and then moving synchronously with it. This principle could be used to allow an external force to be applied to the internal object (in this case the hand) to manoeuvre the fingers through the process of hand grasping and releasing required. The design needed to encapsulate the fingers and the body of the hand, securely wrapping around them before a motor could power a cable driven mechanism to contract the finger, with the motor acting in reverse and the subsequent slackening of the cable being used to control releasing.

The fingers, as with every part of the body, vary in size and shape for each person. The result of this is that if a mechanical frame were built to fit the hand then it would require many adjustable components to ensure that the device could accommodate the range of sizes for the hands and fingers. When using the principle of an octopus it was thought that the use of the wearer's own hand as a frame would negate this issue.

The device was based on the use of a glove, with inspiration being drawn from an octopus' ability to tightly grasp an object and move with it through suction. It was thought that the use of a vacuum being created would allow a glove made with suction cups built into it to tightly fit onto the skin and would also be adaptable to hands with some variation in sizes. The variation would be limited to hands that are physically too big to fit inside the glove at one extreme as well as those which are so small that the vacuum creates several folds and air pockets in the design that impair the angles that the fingers can achieve in flexion.

This glove could then be powered in motion through the use of a cable-driven mechanism that overlaid the fingers. Using the patient's own hand as a frame for the device negates the need for adjustable components to develop an exoskeleton that can accommodate multiple users. Removing the necessity of these components in turn helps the design to meet further criteria by keeping the final component lightweight, as well as making it easier to get on and off. It will also enable patients with hands of a range of sizes to be able to wear the same device; this would save therapists from having to rigorously measure the dimensions of the hand to ensure a tight fit and efficient performance. It should also be considered that if the same device were to be used amongst a group of patients then there are hygiene issues to be considered from sharing the glove, hence why the low cost model is intended in the design, so they could be issued as one for each patient.

Cable driven gloves have been used before [40 & 41]; however their design presents a fundamental vulnerability, that to give the cables maximum mechanical efficiency for finger flexion they must be placed on the palmar face of the hand and fingers. This means that they will be making contact with any object that the user interacts with, placing potential limitations on its performance; firstly by potentially obstructing the cables contraction reducing the range of movement and secondly exposed cables are vulnerable to impact forces that may result in them being broken, damaged or displaced which will reduce or impair the system's functionality. The design provides a novel solution to this issue by cocooning the cable in a vacuum to protect it,

whilst motion is aided by encasing the cables in sections of plastic tubing to protect the cable from impact forces whilst also allowing for rotation to occur. This has two outstanding issues, firstly that the plastic tubing has no set direction, so if it is impacted then cable may be redirected and not operate as efficiently, secondly when the cable shortens it will push against the outer layer, and this friction force may damage it. To resolve the first issue the suction cups where then also used as a guiding path for this cable to ensure that there was no cross over and the most direct route was taken between the motors and the fingertip. This cabling would still be subject to loading forces during use so it was best to position it between the two layers so that the outer layer would protect the cable, limiting any damage that may occur from impact.

With the cabling being threaded through the cups and acting in a manner similar to those of the tendons in the hand they would require an anchor point in a similar manner to the insertion point of a muscle tendon to allow rotation through contraction to occur. This anchor role would be fulfilled by the use of

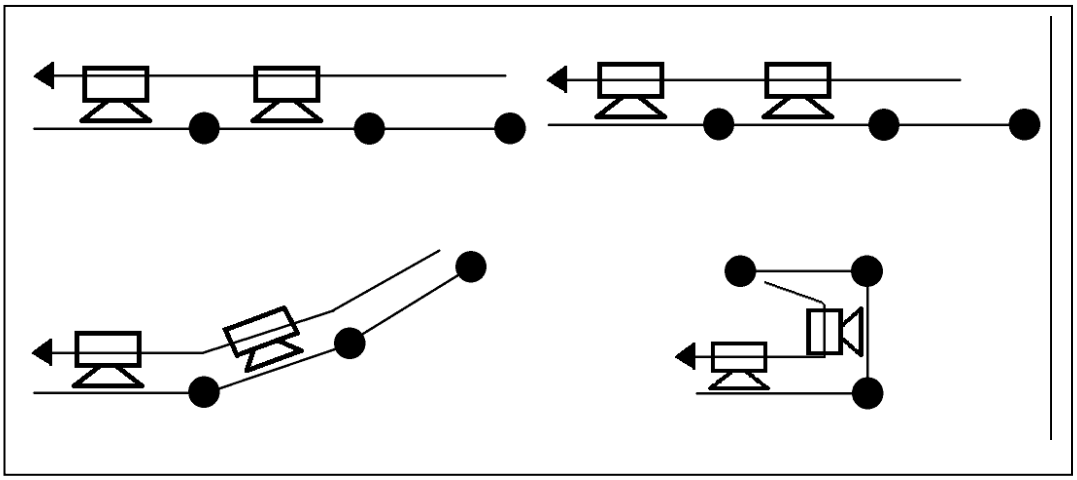

Figure 6: Illustrated demonstration of the principle for movement in the cable driven finger.

a plastic cap that would sit over the fingertip between the layers, with one end of the cable tied to this and secured to the motor pulley at the other. It means that as the motor turns the cable would shorten and with the position of each end not being distorted by the strain in the cable it creates an upward force on the cups to try and straighten the cable to shorten the route between the two anchor points, this force is cancelled out by a combination of the vacuum force pulling the cup towards the finger along with the force that the material applies where it is connected to the cup. The use of the suction cup as a mooring point stops the cable from pushing outwards, if this did not happen then the cable would push away from the surface of the hand and into the outer layer, potentially damaging or deforming it. As a result of the mooring, the finger joints must rotate to accommodate the strain on the shortening cable (Fig. 6) creating a motion that can be used to replicate finger flexion. This imitation however can only be performed in one axis, that of flexion and extension, so the replication of movement that can be achieved is not fully reflective of the complexities of finger motion.

Although this project is creating a first phase prototype it is important to ensure that the cups are positioned to best accommodate the wearer. Ideally the cup should be positioned in the centre of the phalange so that it will attach to allow the best balance of rotational angle and uplift from the cable. If the cups are positioned too proximally to one another they will impede each other during movement and limit the maximal angle that the joint can achieve. In contrast if they are positioned too distally the angle will be increased, but when the angle increases the cable will push out further from

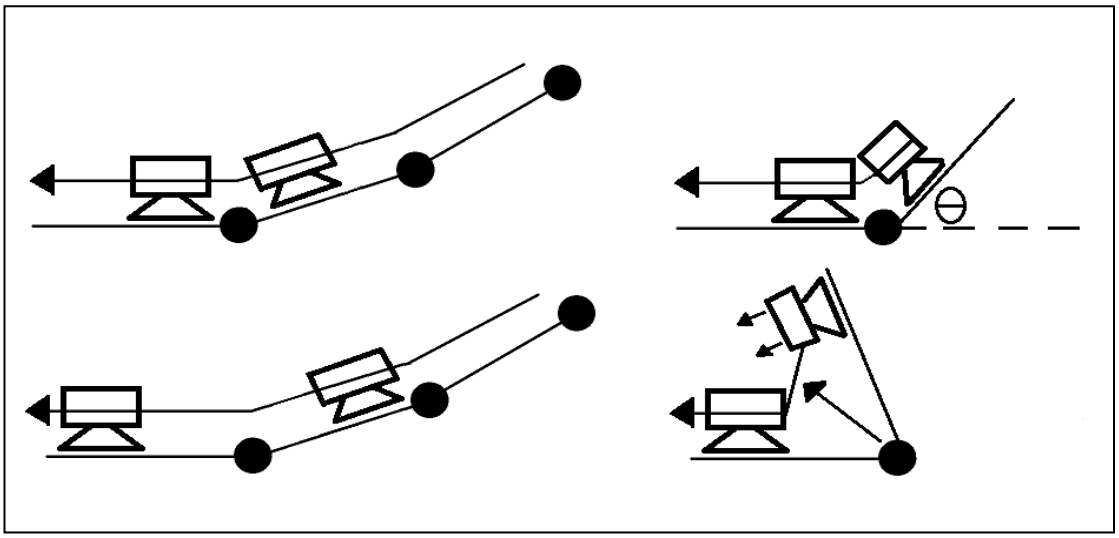

Figure 7: Illustration of the issues that occur in the finger flexion when the suction cups are positioned too close together (top) and too far apart (bottom).

the joint centre, this increases the force pulling the suction cups away from the skin as well as increasing the friction force occurring between the cable and outer layer (Fig. 7).

For the prototype it was crucial to confirm the material that the layers of the gloves would be assembled from. The gloves had to be made from air tight materials for the vacuum principle to be effective, ruling out many styles of fabric glove. Obviously any glove made from thick layers of material for insulation were discounted as their size would firstly interfere with the patients ability to grasp objects as well as requiring an increase in the force used by the motors to drive the cable system. Subsequently the tested gloves were a range of latex and rubber gloves that are intended for domestic use. The latex gloves were found to be a poor option as once the incisions had been made in them to accommodate the suction cups the structure would then easily tear when being put on and off. This meant that the glove would be made from a combination of rubber gloves; a standard

glove was coupled with a dual-layered one. Experiments using the standard rubber glove for both layers resulted in the fingers being narrow, the result of this is that when the user was putting the glove on and off it would result in the suction cups rubbing against both layers and being dislodged, additionally this outer layer is not as durable and is consequently vulnerable to being torn if coming into contact with a sharp edge, which would compromise the vacuum. By contrast using the dual-layered glove for both layers resulted in the fingers being stiff to move, as the dual-layered glove had a layer of rubber on top of a fabric interior, this double layer in both gloves also meant that the device was considerably warmer to wear for prolonged periods. Subsequently the final design used a standard rubber glove for the internal layer for its flexibility immediately against the skin whilst the thicker dual-layered glove was used for the outer layer to provide the protection to the system; the proposed design can be viewed in Fig. 8.

When the vacuum is activated the suction cups will press tightly to the hand due to the extracted air and will compress down to fit the shape of the wearer's hand, with the cable capable of moving unimpaired through the internal structure created by the plastic tubing. This creates a dual layered glove tightly fitting the hand (Fig. 9). Initially the cups were considered to be pressed against the skin using a tighter glove to speed up the formation of the vacuum however this poses potential harm to the patient as it would not give the skin of the hand an opportunity to return to its original shape when the vacuum is switched off, which may result in circulation issues for the

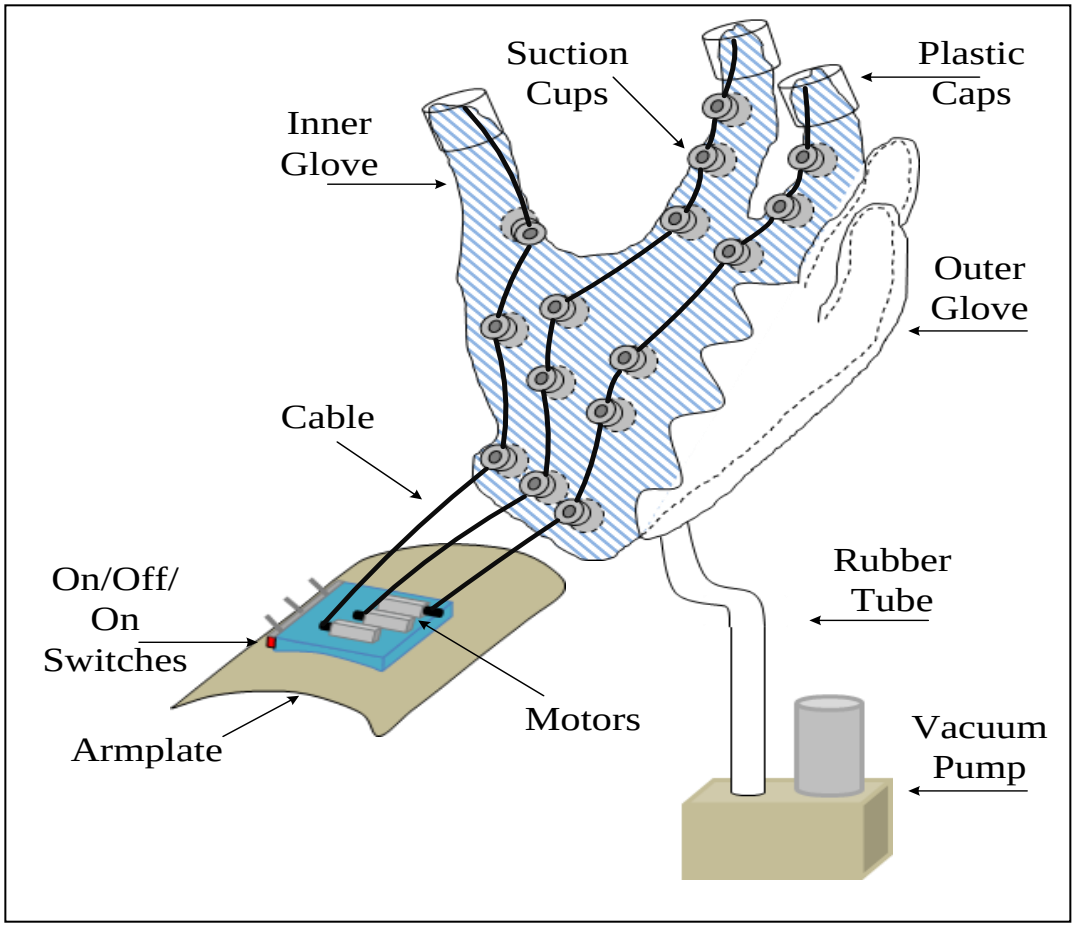

Figure 8: Diagram of planned design for vacuum glove structure and required components [231].

user. It also has the practical limitation by being smaller in that it limits the range of wearers that the glove would be appropriate for.

This raises questions about the forces being applied whilst the glove is in motion. Beyond the obvious motor driven motion of the cable there is movement of both glove layers in response to the vacuum, resistance forces coming from the elastic band along with movement of the plastic finger tips, suction cups and tubing creating further pull factors on the inner glove. These forces interact in a manner that enables the parts to remain stable in relation to one another whilst the finger subsequently rotates in flexion.

To best estimate how the forces within the glove interact to control the movement it is best to consider the body of the hand as a cantilever beam with further beams representing each phalange of the finger that are adjoined to the free end by hinge joints, as illustrated in Fig. 10. When the beam undergoes a loading force along its vertical length this force is consistently transferred through the base of the cantilever and retracts the cable resulting in the total length shortening. As each end of the cable is anchored the finger must rotate at the hinges and creates the impression that the beam is bending. This would create a horizontal loading force on the final beam that changes as the angular components of the beams before it change.

Each finger and the hand are being considered as four section beams; the first of these (the hand) is fixed in place and does not rotate. This means that the force on the cable is always expressed as a vertical component equal to the force generated by the motor. As the joints rotate and the finger goes through flexion this should not change along the length of the cable, however the direction of application for the horizontal and vertical forces will change, altering how these forces are directly applied to suction cup. The forces of the suction cup must also remain in balance to ensure that it primarily does not become detached from the skin as breaking the vacuum will reduce the strength of the finger's rotation and secondly to ensure that the cup does not change position as this will place additional strain on the material of the inner layer, and likely result in the cups becoming dislodged from their mooring, reducing the performance of the finger rotation.

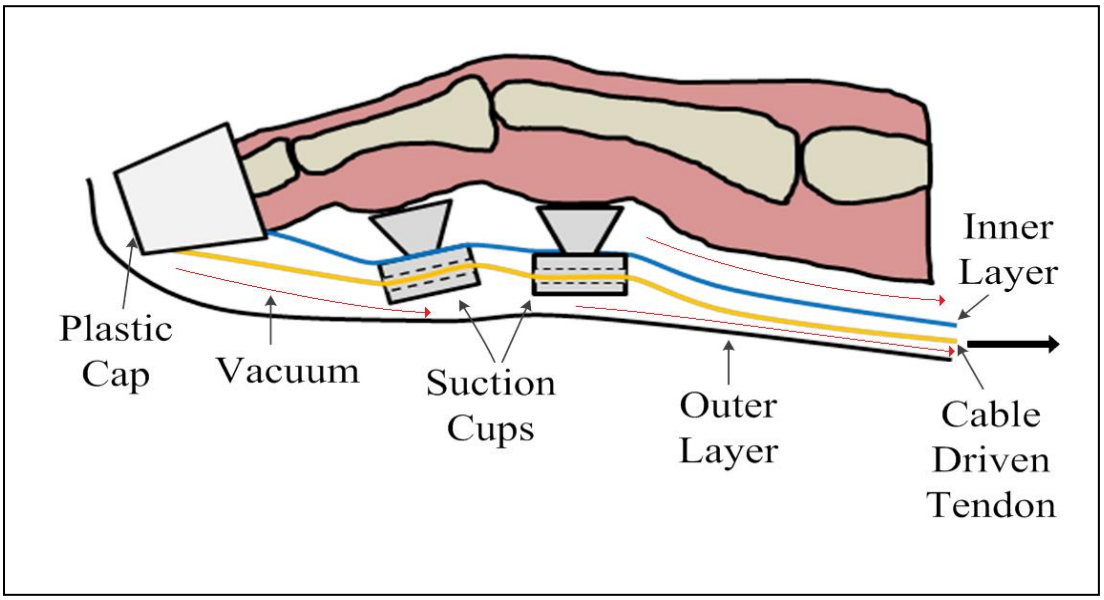

Figure 9: Demonstration of the vacuum principle that will be used to move the finger. The red arrows illustrate the direction of air flow when the vacuum pump is active [231].

When estimating the forces within the device several assumptions should be made, firstly that each beam that makes up the model is of the same thickness and has no uneven or angled edges, secondly that the cable driving force is applied parallel to the beams instead of taking the shortest route between fixed sections. It should also be assumed that the system operates with no friction along the cable nor is there an effect from the outer layer pushing down on the internal cable when the vacuum is created, as this factor is too irregular to assess due to the differences in sizes of the two layers resulting in inconsistencies in how the two layers are relatively positioned and how any forces between the layers are applied. Additionally it can be assumed that the suction cup has no direct impact on the cable as when the cable passes through the suction cup it is within the plastic tubing, which is made from a stiffer material than the silicone cups, consequently when the downward pressure of the suction is applied to the tubing it resists

and the suction cup compresses vertically and expands horizontally around the tubing. Whilst the vertical force is insufficient to distort the shape of the tubing it does aid in holding it in a stable position.

Once the design of the glove component has been refined to accommodate the hand the next issue raised is where to position the actuator. As the device has been devised as a glove an internal mechanism is not an ideal location for an actuator for a cable driven mechanism, firstly as the mechanism would make the glove harder to for the user to don and doff, for those with an impairment of one hand this may be too difficult. Additionally, as the act of flexing the fingers means that there is a reduction in the amount of space available on the hand for placement of the components, approximately 25% of the hand's surface area that does not adjust or contract (the area of the hypothenar, Fig. 11). The red sections in the top right and bottom left images illustrate which areas of the hand do not move during finger and thumb flexion and are stable for the cups to be positioned on, whilst the blue section shows that the base of the thumb does not distort its surface during flexion so a cup could grasp onto it, but it does move when the thumb is flexed so may impact the consistency of performance. The changing shape of the hand during finger flexion leaves one stable region on the Hypothenar (Fig. 11, bottom right image); however this would be too small an area to position actuators for multiple fingers.

Also attaching the actuator to the material of the glove would, due to the creation of the vacuum and the contraction of the material around it, create the potential for the actuator to have a variation in where it is positioned.

Consequently the cable would experience variations in its component forces which may in turn apply additional friction forces damaging the cable as well as changing the output motion, which may have a negative impact on the possible recovery achieved by the wearer. Either positioning them on the hand or attaching to the material are not appropriate sites to house the actuation of the fingers as they are not suitably large for the actuators to be positioned without the actuator itself getting in the way; therefore an external location was required.

Because of these issues the forearm was selected for this purpose as it was ideally placed to permit the cable driven action to occur linearly whilst not being subject to an adjusting shape in response to the actions of the fingers via the cable driven mechanism, it also allows for the weight of the mechanism to be more evenly distributed making it less likely to weigh down the hand, lessening the strain on the wearer and making it easier to don and

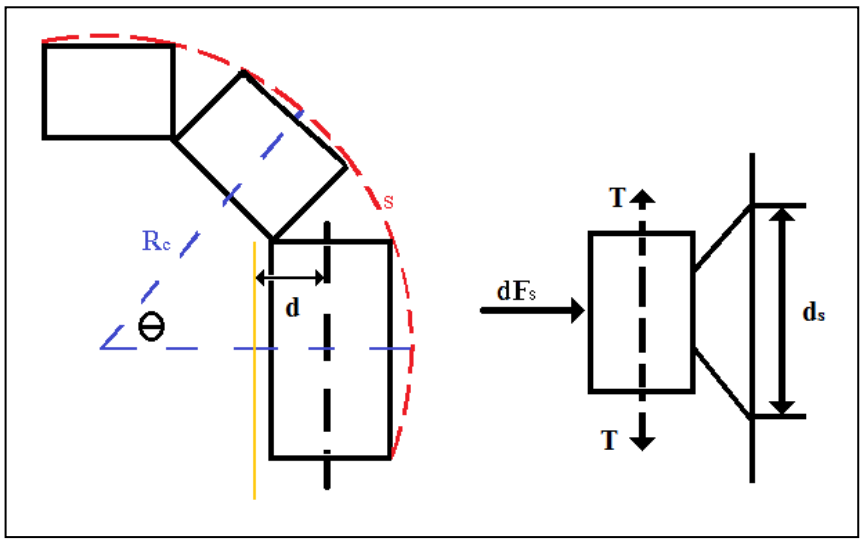

Figure 10: Diagram of finger mechanics for rotation (left) and close up of forces acting on the suction cup (right).

doff. This could be very important for users who have experienced a physical impairment, as their physical strength will have been compromised. The cables would then be distributed in a similar manner to that of the muscle tendons in the hand, such as flexor digitorum profundus, which runs the length of the forearm, crosses over the hand and connects to the distal phalange of the fingers (as visible in Fig. 12). To reduce the weight of the design and simplify the layout of the control unit three motors were selected to control the motion of three fingers (the thumb and the first two fingers) as they are the primary fingers in human grasping, with the theory for flexion explained above. Giving the fingers independent control in this set up would allow the wearer to perform both 2-finger and 3-finger pinch grip movements.

Prototype Development

Firstly the rubber gloves were cut to an appropriate length before vertical incisions were made on the palmar face of the inner layer for the suction cups to be threaded through; these were then sealed into position with rubber cement. The suction cups were positioned on locations where the skin did not move during flexion to ensure that they did not interfere with the rotation of the joints nor possibly been deformed by twisting. The reasoning for which areas of the hand are appropriate is illustrated in Fig. 11. Consideration was given to the possibility of stitching the cups onto the inner layer, if this was were done externally it would make the cup more secure in its position on the inner layer as well as making the glove easier to don and doff. This however

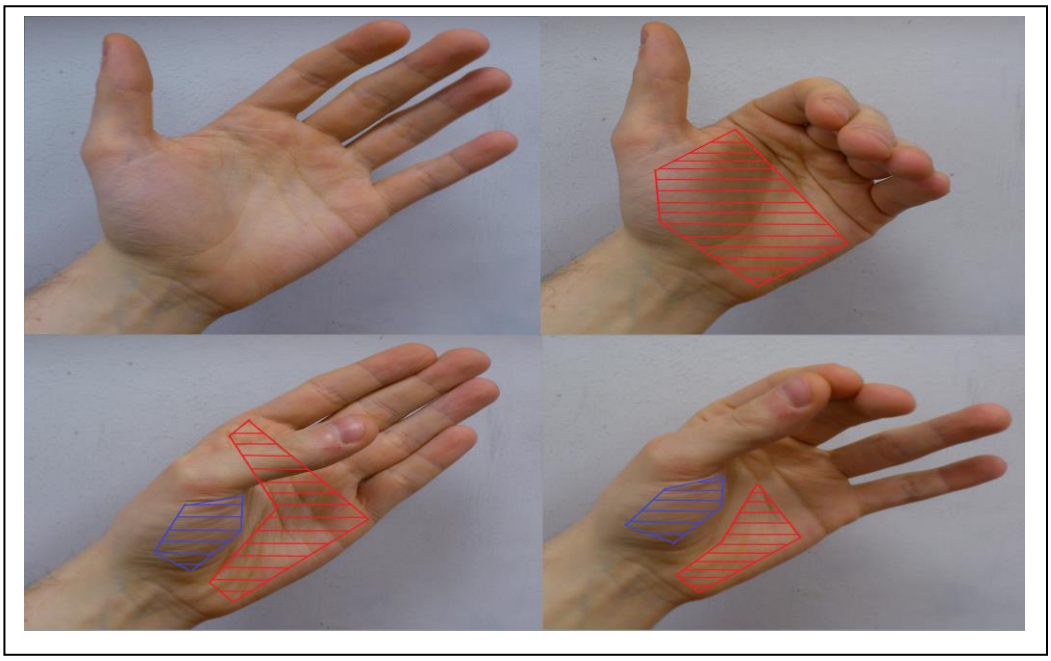

Figure 11: Illustration of the stable areas of the hand surface during flexion (red), as well as those that remain flat but change position (blue). Clockwise from top left: resting hand position; finger flexion; power grasp; pinch grasp.

would result in an inconsistency in the positioning of the cups, which would then be subject to movement of the inner layer before it contacted the skin, which would result in different horizontal forces acting on the cable and change the level of the device's performance. Additionally it was considered if it were possible to thread the cup through the inner layer and then stitch it, however as the base of the cup will expand when compressed against the wearer's skin this may cause stretching of the inner layer that could result in it tearing.

The cups were constructed from elastosil, a silicone-rubber compound (Hennig UK Ltd, Coventry, UK). Incisions were also made into the sides of the cups through which the plastic tubing was threaded to support the cable (Fig. 13); these were not secured in place with the adhesive as the material of the cups provided enough resistance to constrict movement of the tubing,

also the use of rubber cement may have impaired the performance of the suction cup in the vacuum. Additional sections of tubing (approximately one centimetre in length) were fitted between the cups to protect the cable from getting caught or twisting during contraction. These sections were secured in place by stitching them to the surface of the inner layer and then gluing over the top of both the tubing and the stitching.

With the cups and plastic tubing set in position the cable was then strung through each component to connect the fingertip to the wrist. The cable was tied to the plastic cap that would contain the fingertip at one end to provide the anchor at one end before being similarly tied to the motor pulley at the other end later. Originally it had been intended to use monofilament fishing line for the cable, however when testing it was found that this line was not stiff enough and lacked the elasticity to revert to its original form once the

Figure 12: Photograph of an early model inner layer for the prototype displaying the cable pathways. The final model inner layer had the tape removed as it restricted movement [231].

stress had subsided. A braided line was used in its place as it did not deform when under loading.

The selected actuators to drive the finger flexion were micro motors (212-403 Precision Microdrives, Precision Microdrives Ltd, London, UK) which were fixed in place on a custom designed 3D printed motor housing. This base unit had slots built into it to accommodate each motor which then had an aluminium plate fitted over the top to secure it in place, whilst the base was secured to the arm plate by glue with additional screw holes drilled through

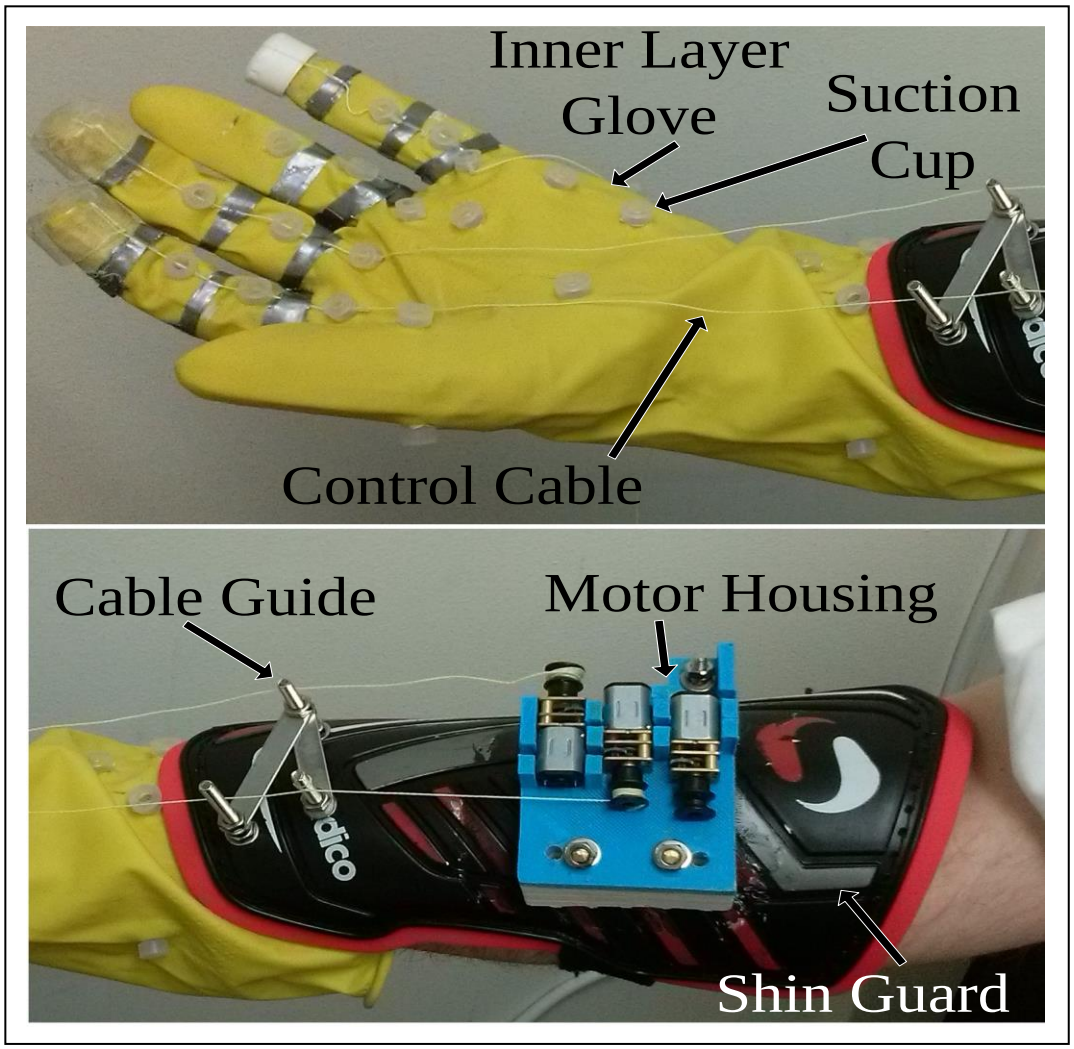

Figure 13: Annotated images of an early stage inner layer prototype model (top) and the arm plate (bottom). Some of the suction cups have been threaded with the cable at this stage, whilst others have not [231].

both to ensure the unit would not move. An additional plate was later fitted for the switches to be threaded through to keep the controls conveniently placed and was screwed into the original base unit.

For the prototype the arm plate used was a sports shin guard (youth size) as it was a suitable length and width to fit the forearm and had an outer surface that the base plate could be fitted to with the use of adhesive paste and when then secured in place with two bolts. The model of shin guard used could also be secured in place by a singular fixed Velcro strap around its midpoint that would then grip to the preferred contact area from the QFD of the arm muscle. Due to the results of the QFD the aim had been to provide a comfortable soft contact surface to interact with the user. The shin guard has a foam contact area that would achieve this, additionally a fabric sleeve was sampled that could fit around the forearm and a base component could then be secured on top. The fabric layer was beneficial as it would adjust to the wearer's arm unlike the fixed shape of the shin guard, however the base component would be a fixed shape which provides some restriction to the final structure. Potentially in future models this component could be moulded to fit the wearer's arm. Additionally if the wearer had a smaller arm the extra weight of the secured unit would result in the sleeve not moving with the arm, which would then result in needing secured with an adjustable strap in the same manner as the shin guard. At this stage of development the shin guard was the better option as it was preassembled at a lower cost along with allowing adjustable tightness to accommodate the wearer's forearm.

The final unit also had an additional component fitted for the switches to be threaded through to give the circuit stability, and the wiring between the motor and switches was then secured around the base of the unit. A set of three on-off-on switches were fitted for direct control of each motor for grasping and releasing.

These switches were wired for so that the direction of the stick matched the direction of movement, aiming the switch towards the user would allow finger flexion, whilst release was controlled by pushing the switch distally towards the hand. It was considered that this set up was the best way to accommodate the previously outlined control features of starting and stopping motion, where the user would have two directional controls coupled with a neutral stop condition between them, this also provides an ease of selection between the available actions. The motor system would respond instantaneously to the user's command and with practice they would be able to improve the level of co-ordination between their intention and making the

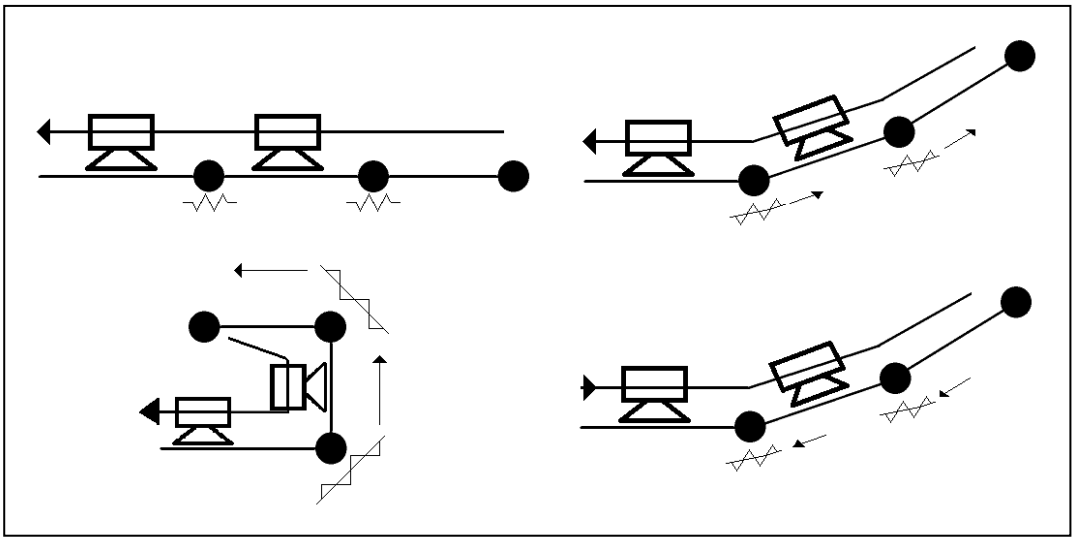

Figure 14 Illustration of spring action used by elastic band for finger release

command so that it would become second nature.

Grasp release was controlled by the motor rotating in the opposite direction and thus increasing the length of the cable in the finger whilst returning the finger to its starting position was powered by an elastic band that was stitched into the dorsal side of the hand and finger's in the inner layer. During flexion the elastic band would be stretched and store up potential energy which would be released when the cable tension is slackened by the reverse action of the motor, returning the finger to its initial point of limited tension (Fig. 14). The mechanics of the skeletal joints in the fingers would prevent the elastic band from fully reverting to its original length to allow the extended fingers to be set as a retained shape. This will allow the device to perform a basic manipulation of the fingers for grasping and releasing, but will not achieve the necessary extension force to assist a spastic hand.

A proposal for how the mechanics of the fingers in the design can be conducted by considering the finger as a cantilever beam that is broken into three components, which when deflected follows the outline of a circular arc. This assumption is made as the joints of the finger do not move independently; there is always an arched unified motion. A beam of this nature is illustrated in Fig. 10 (page 133), where the finger is illustrated as a three bar chain with each connecting joint being positioned on the curve. The circular curve can be defined as

$$\emptyset(s) = \frac{s}{R_C - d} \qquad (1)$$

Where the arc length, *s*, contacts the dorsal surface of the fingers and *Ø(s)* represents the angle between the points of the arc. R_C is the radius of the arc that passes through the centroid at the proximal and distal end of the phalanges that make up the finger and *d* is the distance between the centroid and the cable. The definition of curvature can be used to differentiate the dorsal curve.

$$k := \frac{d\emptyset}{ds} \tag{2}$$

$$k(d) = \frac{1}{R_C - d} \tag{3}$$

Assessment of this curvature will allow for projections to be made of the devices performance. There are several assumptions that have been made about the cable, the first of which is that the cable is always parallel to the surface of the finger. Consequently it is also assumed that there is no friction force applied by the cable contacting any of the surfaces along its route and that no force is applied directly to the cable by the activity of the vacuum. As the model is structured as a free body diagram it must also be assumed that forces applying to circular surfaces, such as the base of the suction cups, will only take action as a line the length of its diameter. This free body diagram is illustrated in Figures 15 and 16.

The cable is acted upon by three forces, one at each end contributing to the tension, *T*, and the orthogonal contact force applied by the suction cup, dF_S. As the axial components cancel each other out, the differential orthogonal contact force that only applies in the orthogonal direction can be assessed.

$$dF_S = Td\emptyset \tag{4}$$

Division by the diameter of the suction cup, d_S will allow for calculation of the magnitude of the distributed load, w, whilst k_t represents the constant curvature of the presumed arc.

$$\begin{aligned} w(s) &:= \frac{dF_S}{d_S} \\ &= Tk_t \end{aligned} \tag{5}$$

The design poses an interesting dilemma for the internal mechanics, as firstly to ensure stability of the device the forces acting around the base of the fingers must be greater pushing the glove towards the finger than in the intended direction of movement:

$$\begin{aligned} L_1F_1 + L_2F_2 + L_3F_3 + F_{U1}L_{U1} + F_{U2}L_{U2} + F_{U3}L_{U3} \\ \leq F_{S1}L_4 + F_{S2}L_5 + F_CL_3 \end{aligned} \tag{6}$$

Where F_S describes the combined force applied by the suction cup as well as

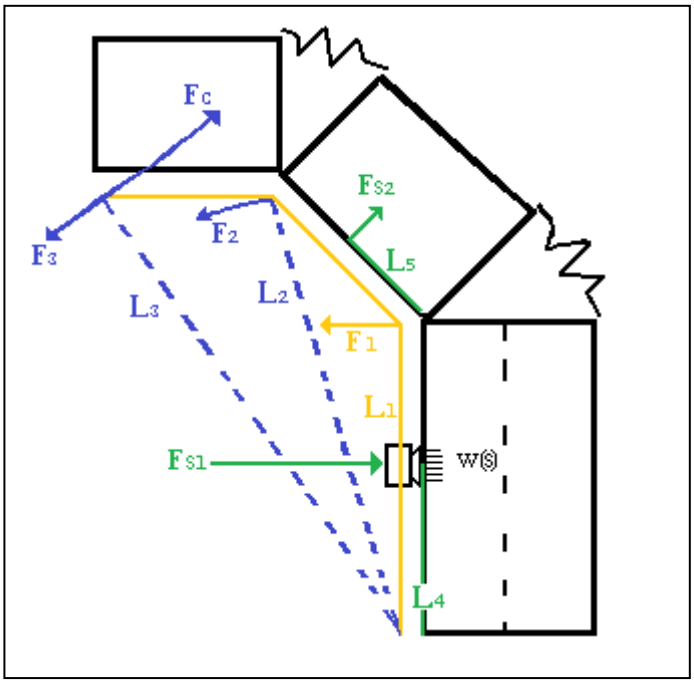

Figure 15: Free body diagram of the finger during rotation and the kinematic forces acting during this motion.

the adhesive applied to the cup acting through the centre point of the suction cup a distance L_4 and L_5 from their respective joint centres. The size of these forces F_{s1} and F_{s2} must be greater than the respective uplift forces pulling outwards on the cup. As the cable is assumed to be operating parallel to the surface of the finger these forces would be expressed as components of the rotational force of the distal phalanges, therefore the proximal suction cup would be acted on by the uplift forces F_{U1} and F_{U2}, and the distal cup would be acted on by a force F_{U3}, where the moment arms L_{U1}, L_{U2} and L_{U3} are the distance between the centre of the suction cup and the joint centre of the bend in the cable. If this balance is not achieved then the tension forces in the cable will pull the suction cups out of their moorings in the inner layer and cause the device to fail. At the same time, to achieve flexion of the finger then the rotational force of the phalanges, F_1, F_2 and F_3, acting at distances L_1, L_2 and L_3 from the fixed point connecting the proximal phalange to the hand require an increase an additional component, the tension of the cable, F_T, must be greater than the tension of the elastic band, T_E, which acts at a distance equal to the radius of the finger plus the material of the inner layer, d_r, from the centroid. This total moment activity must be:

$$L_1F_1 + L_2F_2 + L_3F_3 + F_Td + F_{U1}L_{U1} + F_{U2}L_{U2} + F_{U3}L_{U3} > F_{S1}L_4 + F_{S2}L_5 + T_Ed_r \quad (7)$$

In finger flexion the resistance force applied by the plastic cap, F_C, is applied equally to both sides of the mechanism as it is secured to both the cable and the elastic band. This has the effect of cancelling out the force applied.

When looking at each joint in isolation, their joint rotation moment (assuming a fixed base) can be defined from Fig. 10 with the following formula:

$$\Sigma M_J = T_v d_H + T_H d_V \tag{8}$$

$$Where\ T_V = \frac{\cos(180-\theta)}{T}\ and\ T_H = \frac{\sin(180-\theta)}{T} \tag{9}$$

This also assumes that the tension of the cable remains constant under loading. In the illustrated Figures 15 and 16 there are assumed to be two forces present on the finger segment the cable tension and the distributed load *w(s)*. As the assumed tension is linearly connected to the base of the finger it must be considered as an equivalent contact force that represents with *w(s)* called F_{eq}. To achieve this *w(s)* must be integrated, considering Euler rotation will allow for the distributed load to be redefined.

$$R_a^e = \begin{bmatrix} cos\emptyset & -sin\emptyset \\ sin\emptyset & cos\emptyset \end{bmatrix} \tag{10}$$

$$w(s) = R_a^e[-Tk_T, 0]^T \tag{11}$$

After defining the external forces and moments in the finger it is possible to form the static equilibrium equations for the position of the fingers, considering the reaction force of the finger.

$$\begin{gathered} \Sigma F = 0 \\ \Sigma F = F_{eq} + F_T + F_r \\ F_r = -T[-sin\emptyset_b, cos\emptyset_b - 1]^T - R_a^e[0, -T]^T \\ F_r = [0, T]^T \end{gathered} \tag{12}$$

This then allows for the reaction moment, M_r, to be calculated:

$$\Sigma M = 0$$

$$\Sigma M = r_t x F_T + r_{eq} x F_{eq} + M_r \quad (13)$$

$$M_r = -Td$$

Where r_t and r_{eq} are the position vectors of the cable tension and the equivalent contact force. The internal mechanics shows that the key component in enabling the device to function is the pump creating the vacuum forces F_{S1} and F_{S2}, as it enables the suction cups to remain fixed to the fingers and secures the internal components whilst the cable driven system works through it. The vacuum for the prototype would be created by a small air pump connecting it to the glove by rubber tubing. This pump was a 65 Kpa mini negative pressure pump powered by a 12 DC voltage. An

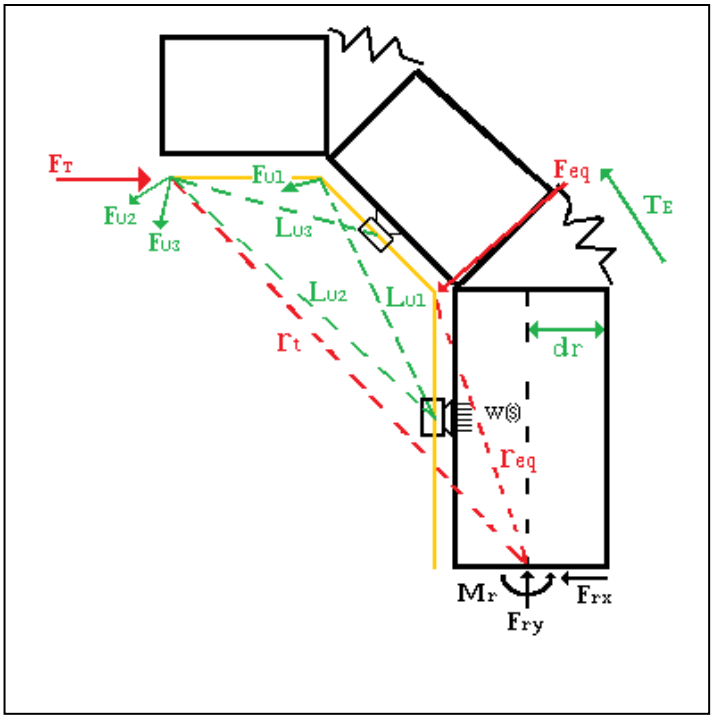

Figure 16: Free body diagram of the finger during rotation and the uplift and reaction forces acting during this motion.

incision was made in the back of the outer glove which the tube was filtered through before being secured in place with rubber cement. The vacuum pump was separated from the rest of the device to reduce the total weight that the wearer would have to bear; the tubing was cut to a length of one metre to accommodate this. Once the parts were assembled the inner and outer layers were sealed together at the base by the rubber cement, creating a pocket that the air could be extracted from so that the vacuum could be formed.

Lastly, to stop any crossover of the cables between the motors and the hand the cables were directed by the use of three bolts, which were vertically secured through the shin guard. These bolts were also fitted with metal strips cut to an appropriate length and threaded through the bolts to ensure that the bolts retained their shape and position when experiencing the loading forces. The loading forces would be applied by the cable being placed within the thread, which would then allow for the angular change in the direction of the cable whilst having a smooth surface to reduce the size of any frictional forces on the cable during motion. The bolts performed the role of acting as a guide for the cable which would then coil around the miniature pulleys attached to each of the motors (Fig. 13).

The miniature pulleys were of 10mm outer diameter with an inner diameter of 5.5mm. At a 10.7mm width it would fit on top of the motor spindle once the central hole had been drilled to the appropriate size and a further hole was drilled into the outer component of the pulley for the cable to be threaded

Figure 17: Demonstration of how the device fits the user when worn [231].

through. Once the cable was threaded it could be secured in place by knotting the cable.

Once the glove had been donned by the user a final Velcro strap was wrapped around the base of the glove to seal the air gap between the inner layer and the skin and allow for vacuum formation to occur. The prototype model was powered by a power supply unit that would sit independently, in future models the intention is to create a purpose built power supply that can be worn by the user externally, such as on a belt. This belt will also accommodate the vacuum pump to keep the pump's weight off of the hand and arm. The final prototype can be viewed in Fig. 17 and 18. The current design is quick to set up as the wearer is only required to put on the glove

and forearm components which are then secured in place with Velcro straps. The time and complexity of setting up the device were design issues that were raised in the patient discussion, however were felt to be more of a useful addition than a key feature. The strapping for the forearm support was positioned around the body of the muscle and the glove's strapping was wrapped below the wrist, as this was the preferred set up from the previous discussion, in terms of not being secured to the joints, as well as offering the advantage of allowing the wearer freedom to move their wrist.

The prototype was assembled at a low cost, with the components being sourced in local shops or from online retailers. The hardware used to make the components displayed in Fig. 17 & 18 cost £105.35, with the only outstanding expense being the power supply used to operate the pump, which was borrowed internally as a viable alternative had not yet been sourced. From a materials standpoint this is low cost for a single unit, which could then be reduced further in the future due to economies of scale if it were intended for mass production.

Conclusion

This chapter has shown how the previously gathered findings from the QFD process have been formulated into a functional design for rehabilitation. They were used as the core principles behind the development of a vacuum glove, with a motorised cable driven system for finger flexion. This is a novel approach to cable driven devices as no frame is required to be worn allowing

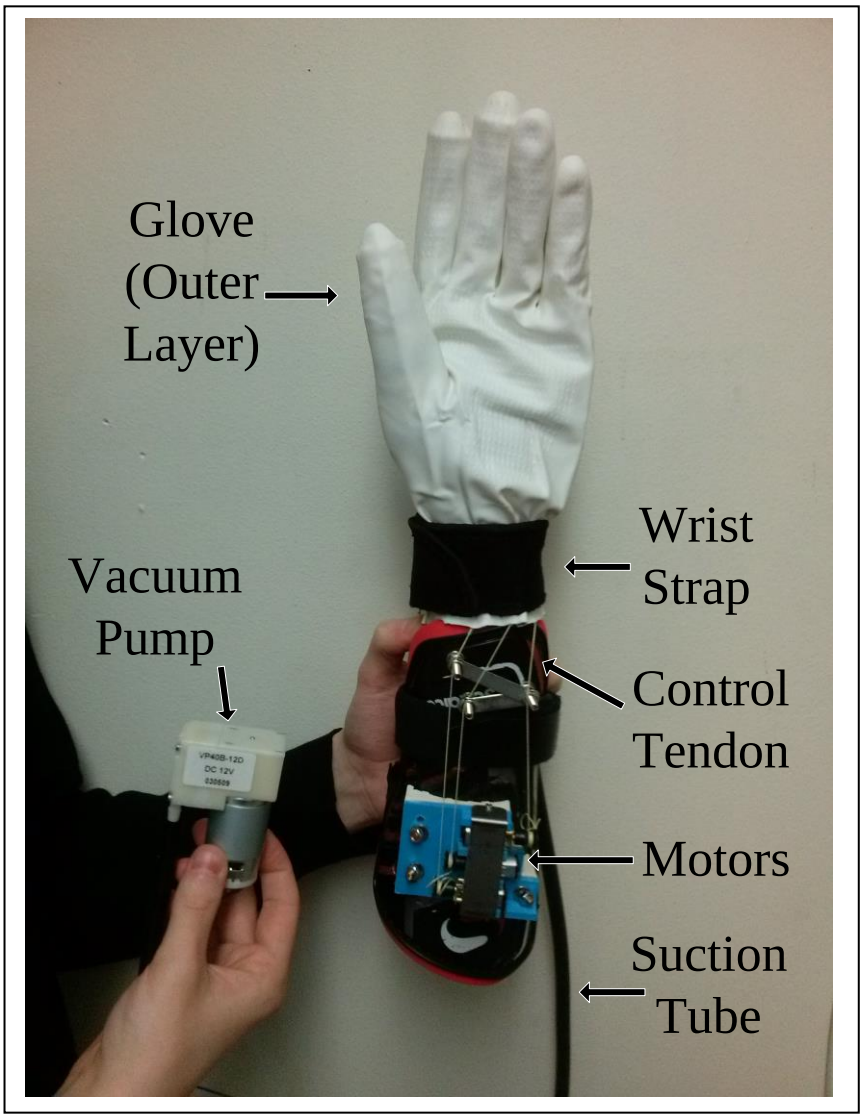

Figure 18: Annotated Image of the completed prototype [231].

the device to be adaptable to the shape of the wearer's hand whilst protecting the mechanism from impact damage. The device distributes the weight across the forearm to make it more comfortable for the wearer.

These design ideas were then considered when acquiring the materials to develop a prototype. This prototype is lightweight and assembled at a low cost, which would be ideal for a system that could be distributed to patients to use in their own home. Due to the limitations of the current design the device

would be most suited to orthopaedic patient populations, although it is possible that by inverting the mechanism to the dorsal side of the hand it could be used to act as an extender for other patient populations. This developed device was then taken on to its first stage of assessment to ensure that the design principles were successful.

Chapter 4 Prototype Evaluation

Chapter 4 Prototype Evaluation

Having developed a principle design that has resulted in the development of a working prototype, to test the validity of the design it is important to assess the prototype. For this study a motion analysis assessment was conducted to review how the device moved the wearer's hand as well as a 3D printed hand and compared these to how the hand moves for the same tasks without wearing the device. This chapter will also explain the design of the virtual hand model used in the motion analysis as well explaining the construction of the testing rig that was used. The findings of this testing trial have been agreed to be published [231].

Feasibility Study

With a functional prototype assembled the next phase of development is to test the prototype. The author aimed to get the prototype to replicate the motion that the fingers go through when a volunteer without disability would grasp at a selection of shapes as this would suggest that the device could be capable of providing an additional assistive role to patients alongside their therapy. To measure the angular changes in the fingers and assess their consistency motion analysis of the hand and fingers was used when a participant was asked to grasp a selection of spheres and cubes and lift them in the air before returning them to the surface and releasing them. The testing conditions to be compared were:

1. Normal use of the hand – the participant does not wear the device (control condition)
2. Normal use of the hand – the participant does wear the device but does not activate the motors (baseline for change of output due to the glove changing the shape of the hand)
3. Device powered movement – the participant wears the device and keeps their hand limp
4. Device powered movement – a 3D printed hand is powered by the device to grasp (simulating user with no control at all over their hand and no tactile feedback)

The results validity would be improved further if this were possible for objects of differing shapes and sizes, reflecting some of the basic sizes and shapes that a patient may attempt to interact with at home, subsequently a selection of items were made for the participant to grasp. These items were drawn

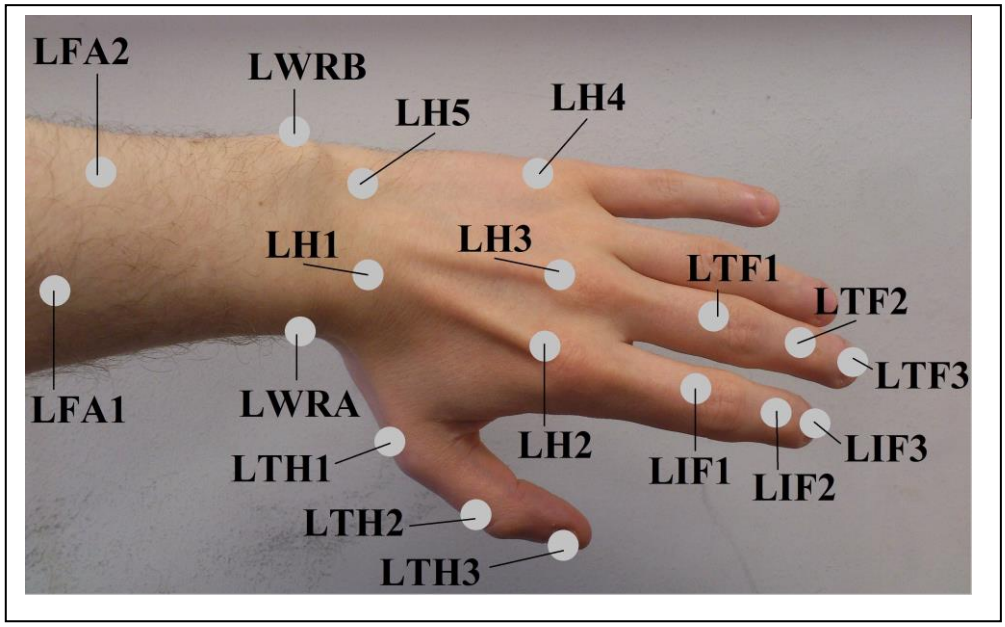

Figure 19: Annotated illustration of the custom hand marker set used for the recorded data in the trials

from the assessment protocol of the Action Research Arm Test (ARAT [232]). The items selected were; one large block (10x10x10cm), one small block (5x5x5cm), one cricket ball (rubber practice version) and one marble.

During the testing the participant would take a seated position in the centre of the motion analysis laboratory, if they were performing condition 1 then the tracking markers would be distributed over their hand, if they were performing the other conditions the markers would be secured to the outer glove of the device. Once the recording was started they would be asked to grasp and then lift the selected item (the selected order of activities was random) over their head, holding it in place for a count of two before returning it to the table and releasing the item (this was repeated three times for each item). The movements would be recorded by the Vicon motion analysis system (Vicon Motion Systems, Oxford, UK) with an adjusted version of their default Hand BodyLanguage Model RHAND marker set used on the hands to monitor the angular changes in the finger joints. The Vicon system is considered to be the market leader in three dimensional motion analysis software due to its highly reported performance in accuracy and consistency when tracking moving objects [233 - 235].

It works with the use of infra-red cameras emitting light towards a focal point. Between the cameras and this point reflective markers are positioned which the camera sees as returned light to its sensor. The time taken for the signal to return to the sensor enables the camera to make a projected calculation of the markers position which becomes more accurate as more cameras, and more data, are introduced to the system. The recordings of these will appear

as a set of dots moving around a three dimensional space, however they can be combined with the coding from the BodyLanguage program to convert the raw data into an active model. This model will record the changing relationship between the points and allows for calculations to be performed of the markers speed, acceleration and the angular change between points, the last of which will be reviewed in this feasibility study.

Experimental Set-up

A single participant (male, 27 years old) was used in each testing condition as well as operating the device and providing the elevation for the plastic

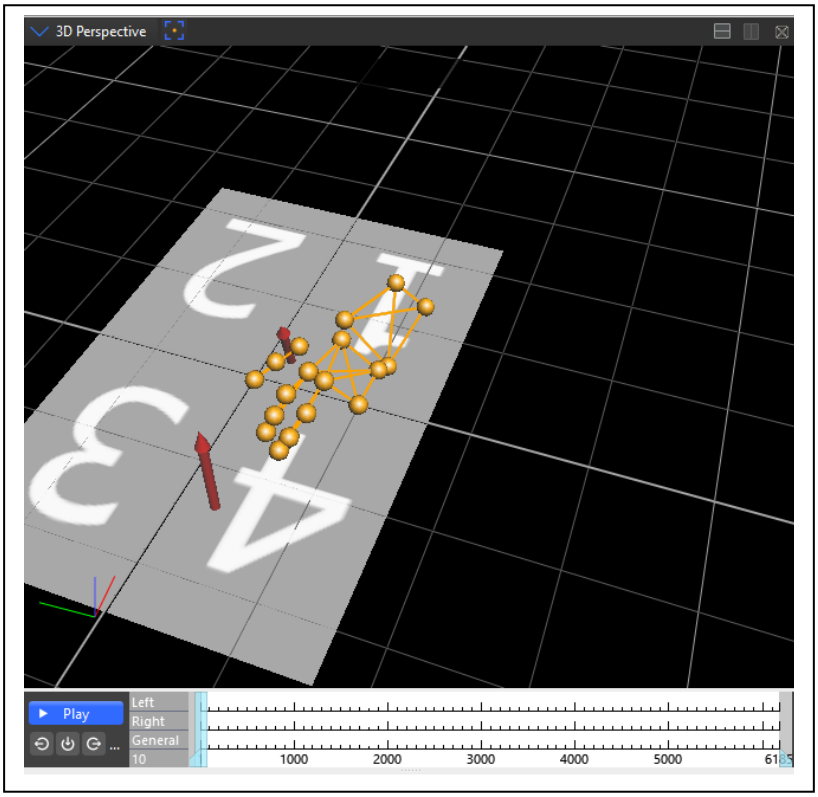

Figure 20: Image of Vicon display produced by hand model.

hand in the final testing condition. For the purpose of this study a custom marker set was devised for the Vicon system, as the university has a dedicated laboratory for motion analysis with a 12 camera set-up at 100Hz. Originally the intention was to use an established marker set that is available through the Vicon user website, however due to the fixed position of the tracking cameras they struggled to differentiate between the micro-markers (25 in total). As a result the model was restructured to an 18 marker set (four on the forearm, five on the hand and three on each of the thumb, index and middle fingers, Fig. 19), stopping the image overlap issue from occurring and allowing a consistent recording quality. The marker set recorded the positional data of the joints of the finger relative to the body of the hand and adjustments to the BodyLanguage (see Appendix) coding enabled the calculation of the angle at each joint of the three recorded digits during the recording and can be viewed in Fig. 20 with a synopsis of the specific locations available in Table 4. Three joints were recorded for each finger, the MCP, PIP and DIP for the index and middle fingers, as well as the carpometacarpal, metacarpophalangeal and interphalangeal joints for the thumb. In a previous review [236] this model was found to have a lower standard deviation in the results for markers in each phalange than the Motion Analysis Research and Rehabilitation Centre (MARRC) Joint Centre Model but more than the MARRC 2Phalanx Marker Model, however due to the differentiation errors previously outlined from the experimental set up this model was not an available option. The selected model was also found to have a lower mean peak flexion angle for the MCP and PIP joints, but with an

increase at the DIP in comparison to both MARRC models. This output data were then filtered with a moving average of 50 data points for the first two conditions and 100 for the third and fourth to limit the background noise in the recording. This filter was selected to smooth out fluctuations in the data collected over a time period, with the number of data points used for filtering being decided due to the length of the recording timeframe. Visual observation of the recording was performed to assess what time period marked the beginning and ending of the grasp period so that comparisons could be made between the recordings.

As stated previously, there are four testing conditions to this trial, the participant not wearing the device, wearing the device but not automating motion, wearing the device and using the control system as well as fitting it to an artificial hand. Testing in this controlled situation should allow for any flaws in the prototype to become apparent before being used for testing with a larger human population. These allow for the observation of any differences that may occur between stages, for example differences between the first two conditions would illustrate that wearing the glove creates changes to the shape of the hand that the cameras will see, as the motion being recorded should be exactly the same, which should then be considered as a factor with any changes that are observed between the first and third conditions.

For the final testing condition an artificial hand was required to test the strength of the device when being completely unsupported by the wearer. The artificial hand that was selected for use was a 3D printed hand (Fig. 21).

Table 4: List of Marker Positions for Custom Model

Marker	Location
LFA1	Body of radius
LFA2	Body of ulna
LWRA	Styloid process of radius
LWRB	Styloid process of ulna
LH1	Base of second metacarpal
LH2	Head of second metacarpal
LH3	Head of third metacarpal
LH4	Head of fifth metacarpal
LH5	Base of fifth metacarpal
LTH1	Head of first metacarpal
LTH2	Head of first phalange of the thumb
LTH3	Head of second phalange of the thumb
LIF1	Head of first phalange of the index finger
LIF2	Head of second phalange of the index finger
LIF3	Head of third phalange of the index finger
LTF1	Head of first phalange of the middle finger
LTF2	Head of second phalange of the middle finger
LTF3	Head of third phalange of the middle finger

Using the 3D printed hand, whilst lacking the complex anatomy of a real hand, allows for an estimation of the gloves supporting capacity to mobilise a large hand with stiff joints for a user who would experience no tactile feedback and would represent a test of the secondary function, supporting daily living. As this hand stopped at the wrist there was no location for the forearm unit to attach to; consequently the hand was screwed into a wooden beam of a similar diameter to act as a replacement forearm. After this was

completed it then became possible for the 3D printed hand to wear the glove in the same manner as a user would, with finger flexion being powered by the motorised cable driven system (Fig. 22). The experimental process was approved by the Biomedical Engineering Department's Ethics Committee in accordance with the Declaration of Helsinki.

Results

The changing relationship in the proportional motion of the finger joints for each experimental condition can be observed in Fig. 23. The most notable outcome of this data is the change in the contribution of the MCP for the index finger, when not wearing the device it does proportionally less work in the lifting of large items (between approximately 10-14% of the fingers total angular rotation) than is done at the DIP. The exception to this is in grasping the marble, where an even distribution of work is performed, and the MCP makes the largest contribution to the total motion (37%). The difference in the action of the MCP can be observed in Fig. 24; this illustrates the increased rotation of the MCP to compensate for the small size of the marble and complete the grasp, whilst at the same time the DIP has negligible change from its resting position. The tracking data of the angular changes can be observed for each testing condition in Figures 24-31, with the graphs contents sub-divided into the individual recordings for each activity. From the data displayed in these graphs there are observable differences in the behaviour of the fingers for interacting with the items.

Figure 21: Image of the test rig 3D printed hand [231].

The differences in performance are repeated in the middle finger action across the activities; however there is a change in the motion when gripping the marble, where the index finger has a minor inversion of its activity, with the main contribution coming from the MCP with the smallest contribution occurring at the DIP. The middle finger by contrast has a very even distribution, as each joint performs between 32.3 and 34.9% of the total motion. This is a result of when attempting to grasp the marble equally between the fingers there is an alteration due to their differing lengths. As the middle finger is longer the index finger must rotate more at the MCP and less at the DIP compared to the even distribution shown by the longer middle finger, although the position of the thumb will play a large role in this.

Subsequently the finger tips cover the same distance between their connection to the hand and their end target, but the longer finger takes the required longer route.

When wearing the device the prominence of the joints inverts, as DIP activity drops and MCP increases, for example when lifting the ball the DIP drops from 31.74±2.38° in condition 1 to 15.08±1.2° in the second, 14.64±2.24° in the third and 21.48±2.92 in the fourth, whilst the MCP increases from 7.22±1.61° in the first condition to 22.24±3.17°, 31.99±3.12° and 29.21±1.6 respectively (Figures 24-31). There is also an additional increase in the

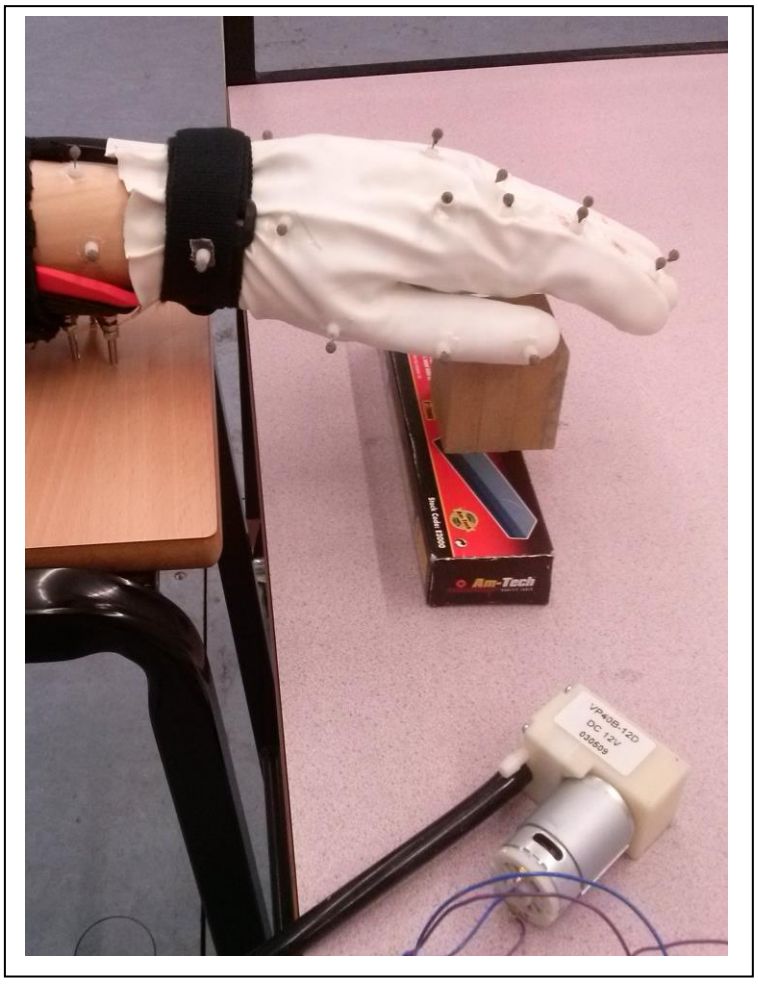

Figure 22: Image of the hand wearing the prototype device and with the marker set attached [231].

activity of the PIP, giving the process a profile more reflective of grasping the marble in condition 1 than any other object. The 3D printed hand was incapable of grasping the marble as the base of the thumb was positioned too distally on the 3D hand and consequently the thumb and fingers were unable to form the required ‘pincer’ shape to grasp the marble, as this shape could be achieved when a user wore the device it would suggest that the issue was a result of the shape of the hand. This posture issue can be seen in Fig. 21, but was partially corrected by the glove, however insufficiently to enable grasping the small marble, unfortunately the timescales were not practical for a replacement to be made. This also suggests that there may be a benefit in the future to include the action of thumb abduction and adduction to enable interaction with a greater range of objects and to give a greater sense of control.

The findings show that the activity contribution of the DIP was reduced when the glove was worn by a user, with the range of movement decreasing from 23.44-40.84° for the index finger without the device to 7.61-14.64° when it is worn. As the activity increases again when the 3D printed hand is used in the device (25.61-41.51°), this would imply that the decrease is due to the design of the glove, where the finger may still be making the required movement but would be doing so at the level of the inner layer and not seeing the same amount of rotation from the stiffer outer layer of the glove, however once the larger 3D printed hand was within the glove there was no additional space within the gloves material for rotation to occur and consequently movement at the DIP was detected. The subsequent increase

with the 3D printed hand is also possibly a result of a lack of cross joint coupling in the 3D hand as each joint is independent. This biomechanical coupling principle, where the flexor digitorum profundus and flexor digitorum superficialis cross the MCP joint and contribute to its rotation without a connection to an adjoining phalange improves the performance of each joint by making the hand an integrated system, this lack of interconnectivity in the 3D hand results in an increased rotation of the DIP to ensure that pressure from the finger is exerted directly onto the target via the fingertip instead of being an combined effort from the whole finger. This can be factored into computer modelling [109 & 110] as well as being a consideration in glove design [40]. The cable driven mechanism would be anticipated to have a greater rotation at the distal end, due to the DIP being closest to the anchor end that is being pulled, it would subsequently be made to contract first as cable tension increases under loading, assuming that the friction of each joint is equal. Biomechanical coupling contradicts this idea and results in the loosest joint taking the increased motion. The 3D printed hand's lack of biomechanical coupling then sees an increase in the DIP again, but the overall motion is still influenced by which joints in the hand design are the most flexible.

Changes between the index and middle fingers can be influenced by technique as outlined previously; they may also be impacted by where on the item the user initiates contact, as if when grasping the cricket ball one finger presses against the central seam with the thumb at the other end, the remaining finger will only take on a supporting role for lifting and have little

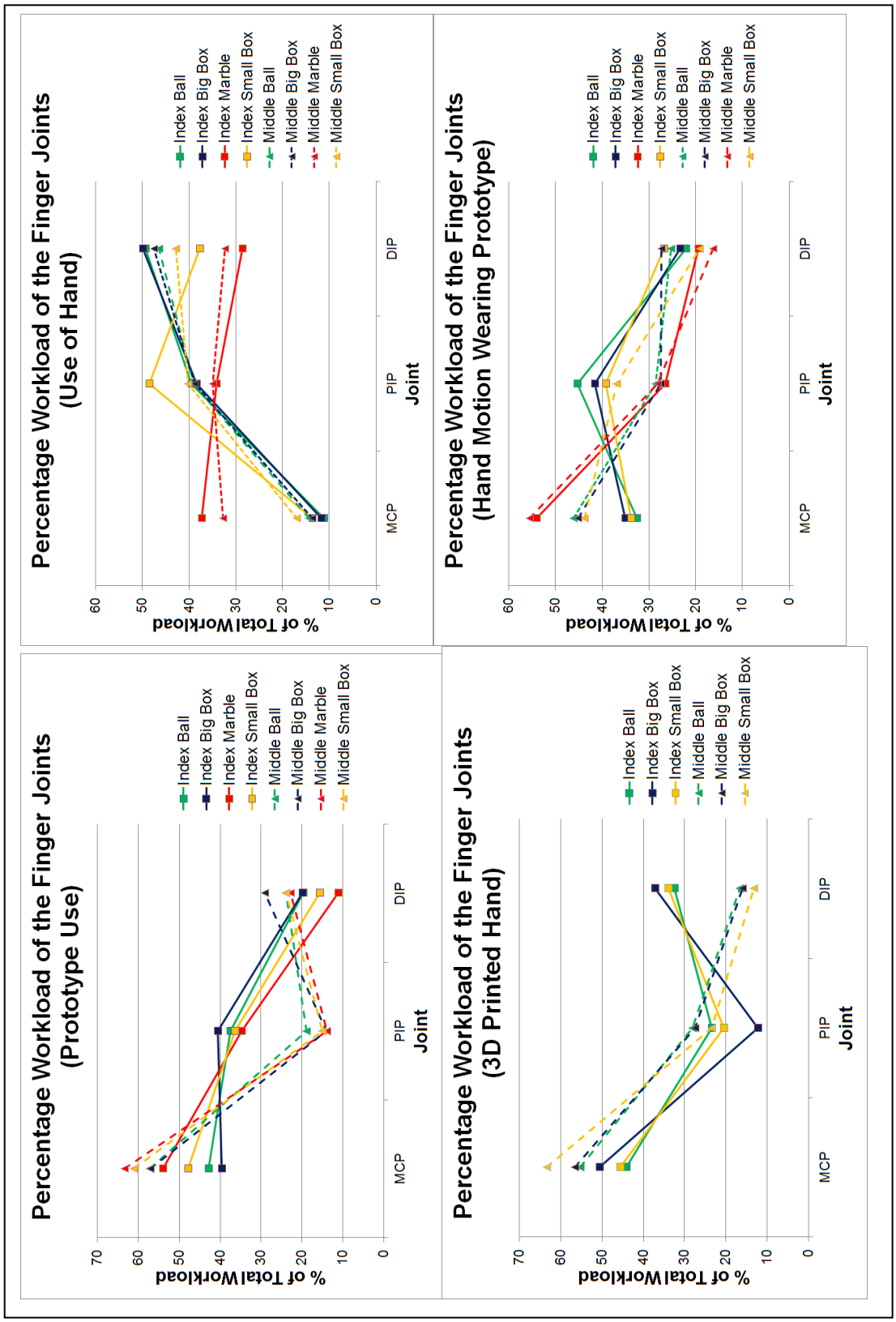

Figure 23: Overview of the changes in percentage based motion distribution across the finger joints. Condition 1 (top left) shows the control condition of the user's hand when not wearing the device, condition 2 (top right) shows the performance when the user is wearing the device but not using the motors. Condition 3 (bottom left) is when the user is operating the device as intended and condition 4 (bottom right) is the device being worn by the 3D printed hand. Square markers indicate the index finger and triangular markers indicate the middle finger [231].

contribution to the grasp, subsequently the joint activity for this finger will be

larger as it rotates further to find a contact point with the item. Also the contact point of the finger could be a factor as if, for example, the initial point of contact is with the first phalange of the finger, the object may resist some rotation a the PIP joint, which must then be compensated for by the DIP.

Analysis

The results give the impression of an inversion of the finger joint activity when the device is used, where the action of the MCP and DIP increase and reduce respectively around the action of the PIP, although in some cases the equal motion distribution between some of the joints is more reflective of the grasp pattern for lifting the marble in condition 1. This was a finger orientated pinch grip, where the palm plays no role in supporting the weight of the item, so the finger joints take on an equal share of the load to support the object. For the MDF blocks this grasp pattern is firstly difficult to complete, and if successful will not be as efficient as using a power orientated grasp.

The pinch grip applies three balanced forces that are distributed around the circular surface of the marble, which allows the user to support as well as wield the grasped object. Meanwhile for the power grasps the metacarpals and proximal phalange form a base for the target object whilst the distal phalanges wrap around the object and push it into this base. This allows the fingers to grasp with larger forces as it is a ‘clamping’ action securing the object to the palm of their hand and is not focused on movement rather than manipulation of any grasped object. These trends are illustrated in Figures

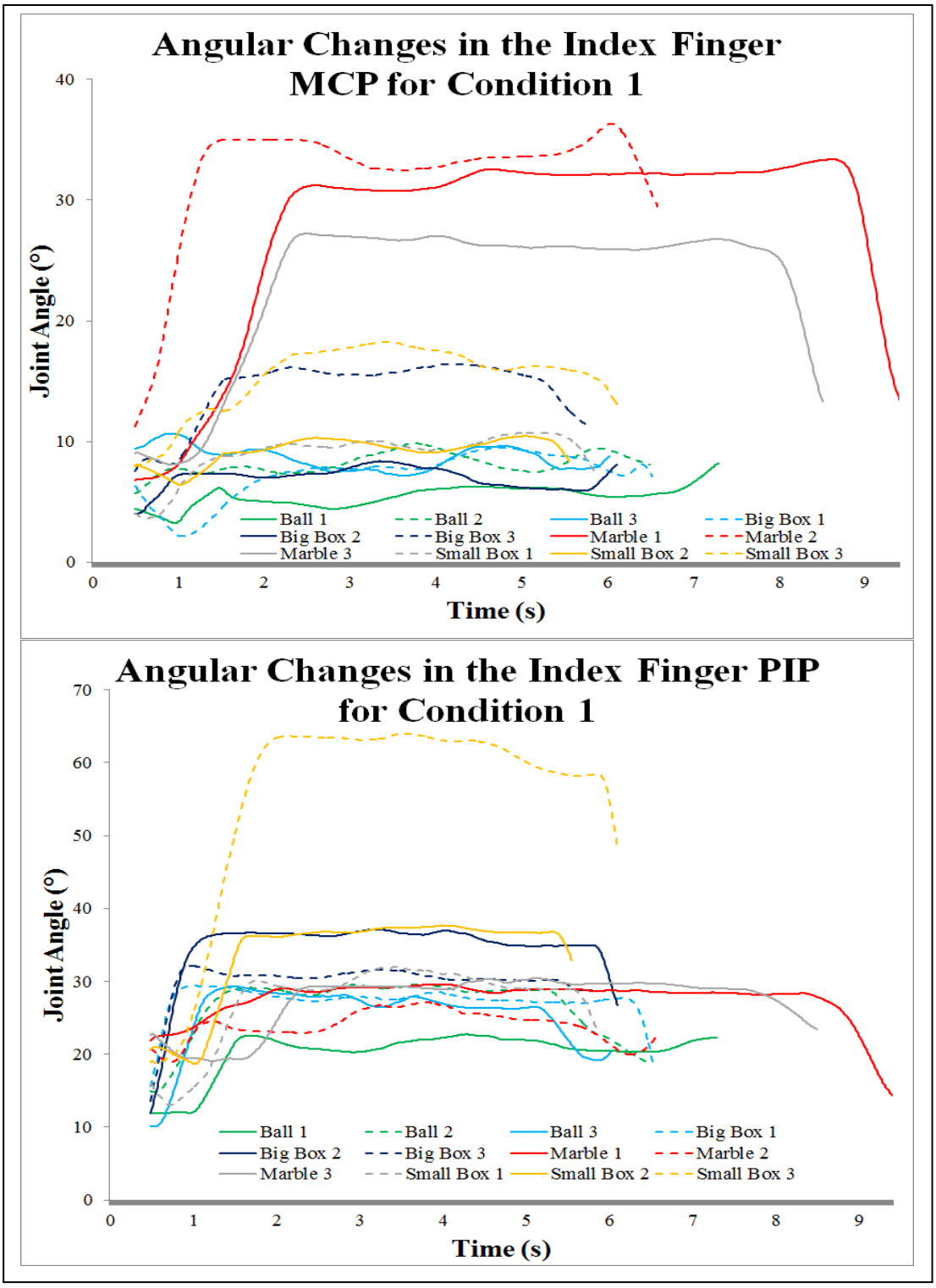

Figure 24: Joint angle variations in the index finger for grasping the four testing items without the device. The data are filtered for a moving average of 50 data points. MCP joint (top), PIP joint (bottom), DIP joint (overleaf) [231].

26 - 29, showing the patterns of movement for the first testing condition. A

higher degree of rotation from the MCP can be seen when grasping the marble, coupled with a reduction in the rotation of the DIP. These patterns displayed by the index finger are replicated by the middle finger, with a similar spread distribution of work being done when grasping the marble. The index finger has an increase in activity at the proximal MCP with a decrease in contribution from the distal DIP compared to the even motion distribution of the middle finger, this is a result of the differing lengths of these fingers and how they are positioned to grip onto a target.

When the user dons the device this movement for the index finger activity inverts, with the DIP dropping from 31.74±2.38° in condition 1 to 15.08±1.2° in the second, 14.64±2.24° in the third and 21.48±2.92 in the fourth, with the MCP increasing from 7.22±1.61° in the first condition to 22.24±3.17°,

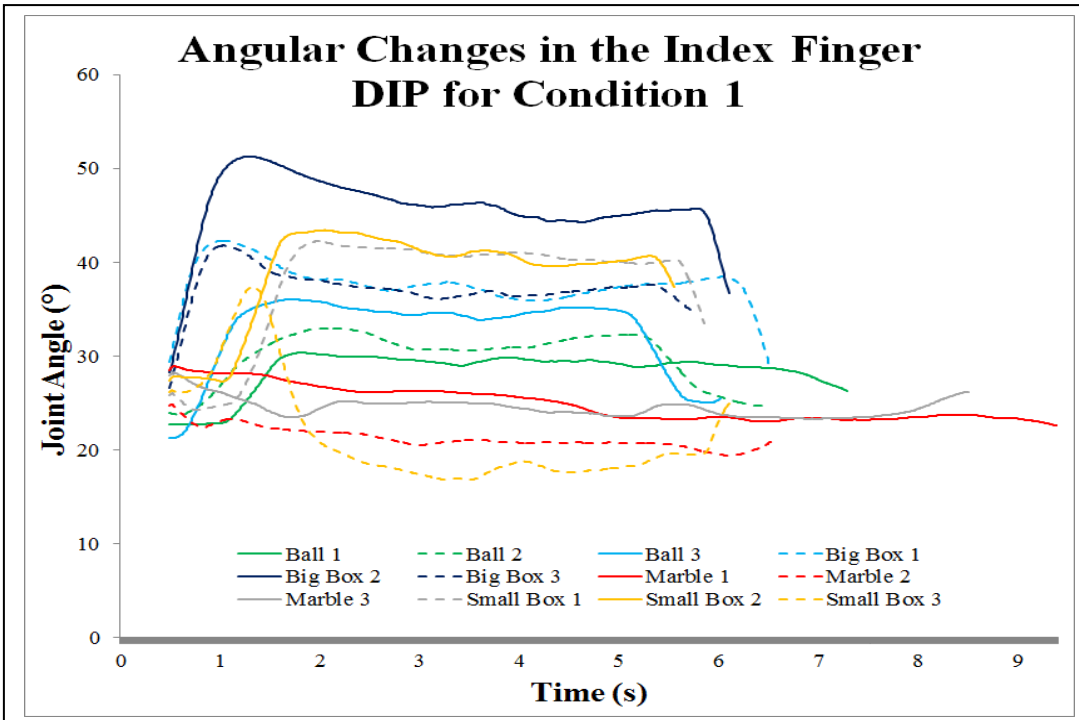

Figure 25: Joint angle variations in the DIP joint for grasping the four testing items without the device. The data are filtered for a moving average of 50 data points [231].

31.99±3.12° and 29.21±1.6 for conditions 2, 3 and 4 respectively (Figures 24-31). Intuitively it would be considered that the greatest rotation would occur primarily at the distal joint, as this will receive the initial tension of the cable and will be pulled on first. This does not occur in the worn testing, suggesting that other factors should be considered in how the movement occurs. The first of these is cross joint coupling within the musculature of the hand, where the muscle tendons in the hand cross over several joints, this means that to move the distal components there must be some proximal activity to stimulate its motion. Secondly there is also the factor of joint stiffness; this prospect is suggested by the increase in activity that occurs at the DIP contribution when using the 3D printed hand, as there is no interconnection between the joints so the internal friction is the deciding factor in how much motion occurs at each joint.

Changes in joint contribution may also be a result of the wearing the device changing how the user would normally approach grasping the object, for example they may position the fingers differently to ensure that the weight would be supported such as when grasping the large box, the participant was capable of grasping the box on two sides, however when wearing the device the object required to be rotated by 45° so that the user could apply force to three sides of the cube to support the weight. Adjustments to the user's contact areas with the target would impact the angular rotation of the finger joints. A further example is when grasping the ball with the 3D printed hand it was important to secure the central axis in place to avoid the ball from moving along the table, this meant that the index and middle fingers would

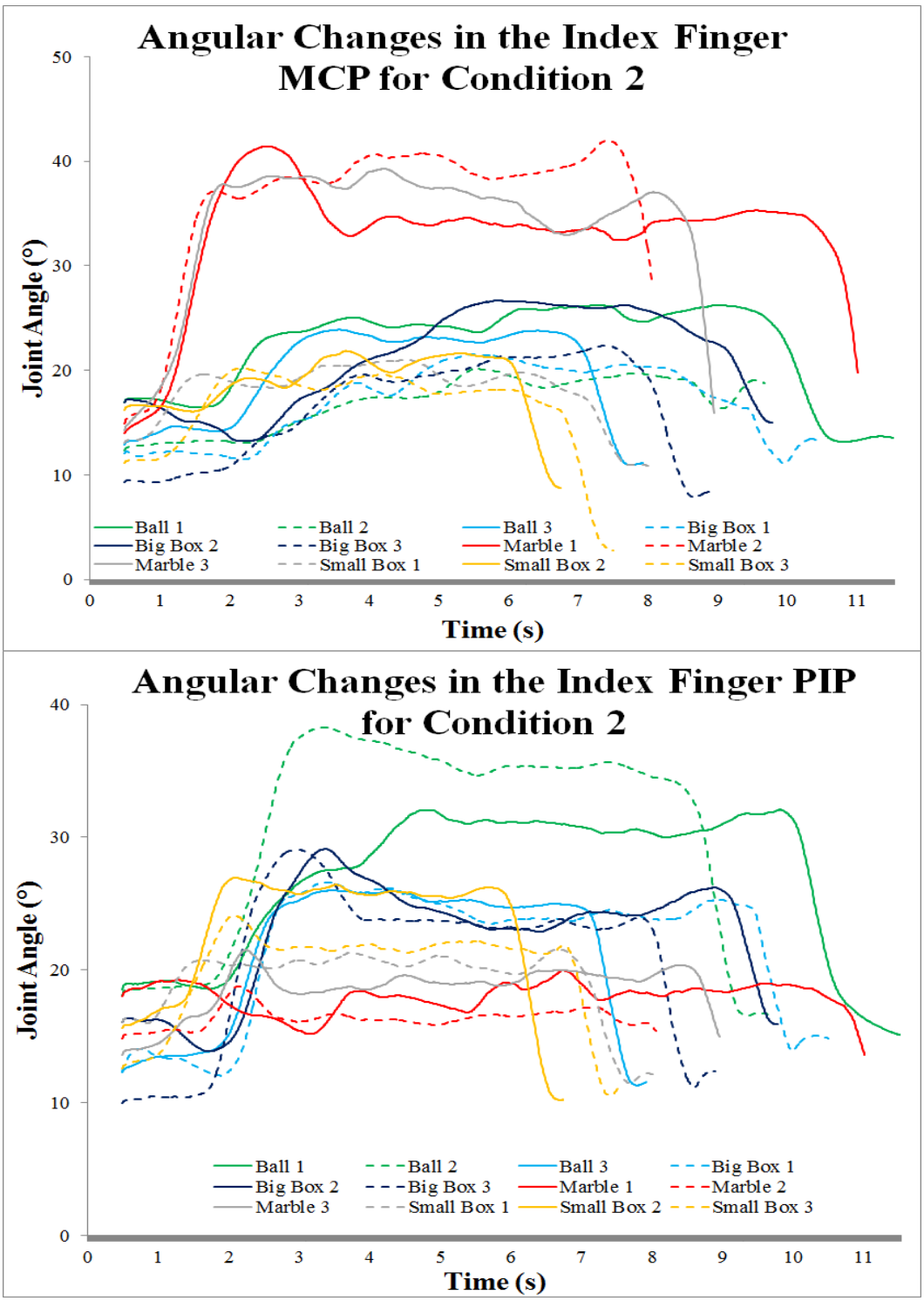

Figure 26: Joint angle variations in the index finger for grasping the four testing items whilst wearing the device with no vacuum or motors used. The data are filtered for a moving average of 50 data points. MCP joint (top), PIP joint (bottom), DIP joint (overleaf) [231].

not be as evenly distributed as they were for the testing in condition 1. It also

meant that the distal phalanges would be pressed against the ball and not be able to rotate as much as they would otherwise, meaning that the MCP is made to compensate with increased activity to secure the ball in place.

The 3D printed hand for condition 4 was incapable of lifting the marble as due to the size of the hand the thumb was positioned too laterally to effectively wrap around and support the marble in a pincer with either of the two motorised fingers resulting in the marble rolling off the hand when it was attempted to be lifted, although there may also be a contribution to this from the rubber surface of the glove lacking a sufficient friction force to keep the marble still, this factor was amplified further when grasping the rubber ball due to the rubber-rubber contact allowing the ball to move within the grasp. With spherical objects it is also important to practice the timing of the finger

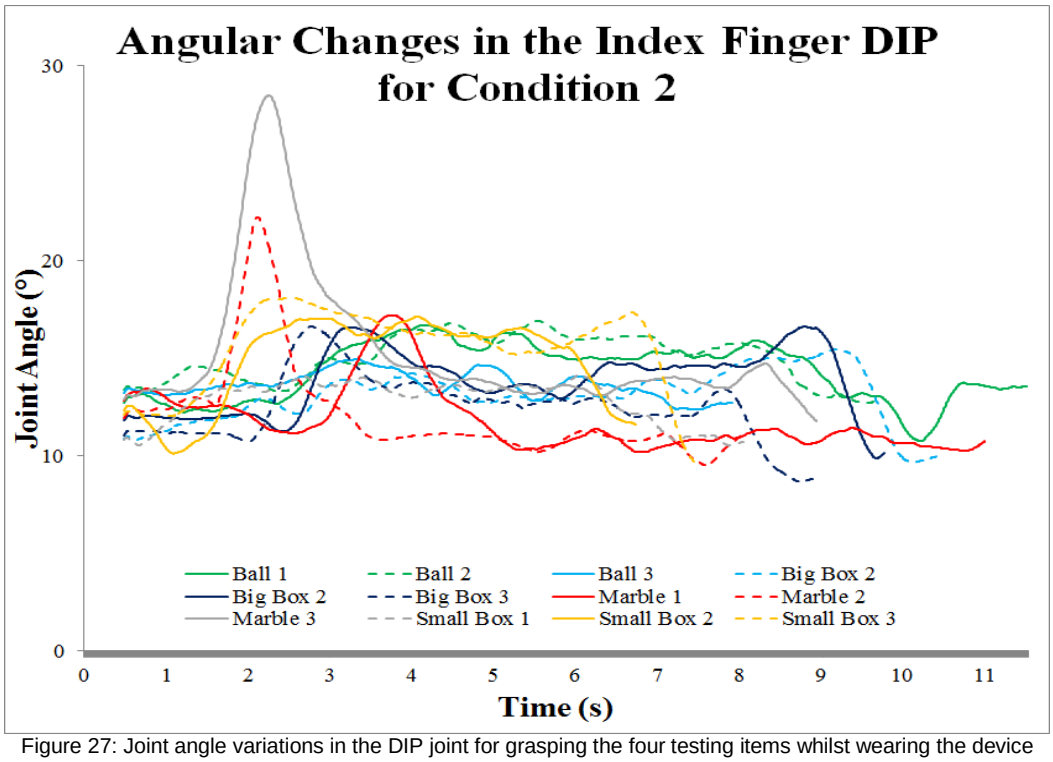

Figure 27: Joint angle variations in the DIP joint for grasping the four testing items whilst wearing the device with no vacuum or motors used. The data are filtered for a moving average of 50 data points [231].

motions, as if the wearer does not flex all of the fingers to grasp in unison it will only result in the spherical object being pushed along the surface. When using the 3D printed hand the spread of the fingers made it possible to grasp and lift the large block with 10 centimetre dimensions, however once it was approximately 20 centimetres above the surface of the desk the weight (0.73 kilograms) it became too much to support on its own. Successful further experimentation with a sanding stone showed that this was due to the spread fingers being unable to support the weight as they were unable to form a secure supporting cradle for the block.

When the angular rotation is viewed as a percentage of the total motion the behaviour of the finger joints is consistent within each condition but experience some variation across the conditions (Fig. 23). The most obvious difference across the conditions is the reduced contribution of the MCP when not wearing the device (approximately 10-14% of the fingers total rotation). The increase in angular motion for the MCP was not as prevalent when interacting with the marble (37%), as due to objects size a different grasp pattern was required from the non-impaired participant which had a much flatter motion distribution (for example the middle finger has a motion distribution of 32.79, 34.93 and 32.28% across the respective joints). The pinch grip used to grasp the marble had a more similar pattern of work to the motion created by the device, where the fingertips will grasp around the target with no assistance from the palm. The similar angles of rotation allows for a more controlled distribution of power, hence why it is used more often for precision tasks.

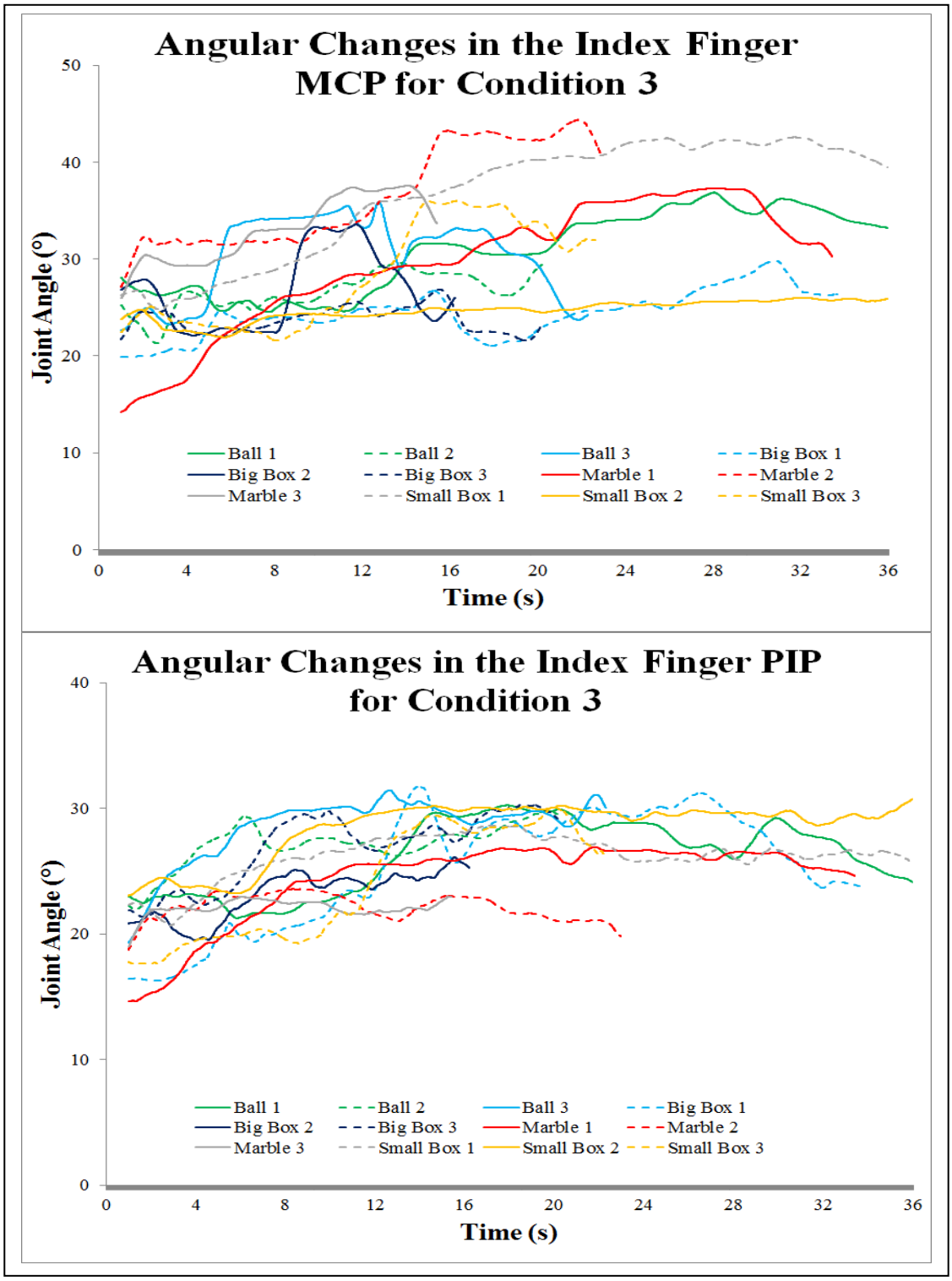

Figure 28: Joint angle variations in the index finger for grasping the four testing items whilst wearing the device, keeping their hand limp. The data are filtered for a moving average of 100 data points. MCP joint (top), PIP joint (bottom), DIP joint (overleaf) [231].

By comparison the PIP of the index finger retains the same level of

contribution through the first three conditions (~40% of the total motion), with the middle finger's contribution decreasing over conditions 2 and 3. This is most likely to be the result of a change in technique by the wearer, observation of the recordings showed the participant to approach the object with their wrist and forearm raised partially as this was needed to access the control system, which appears to have impacted the grip that was used to secure the object. There is also a further reduction in the joint's contribution for condition 4, however there is little difference in the angular outputs recorded, this change is due to the increase in the angular activity in the DIP for the plastic hand.

In conditions 1 and 2 there is no motorisation of the joints and both actions are performed by the same participant, it would be fair to consider that they

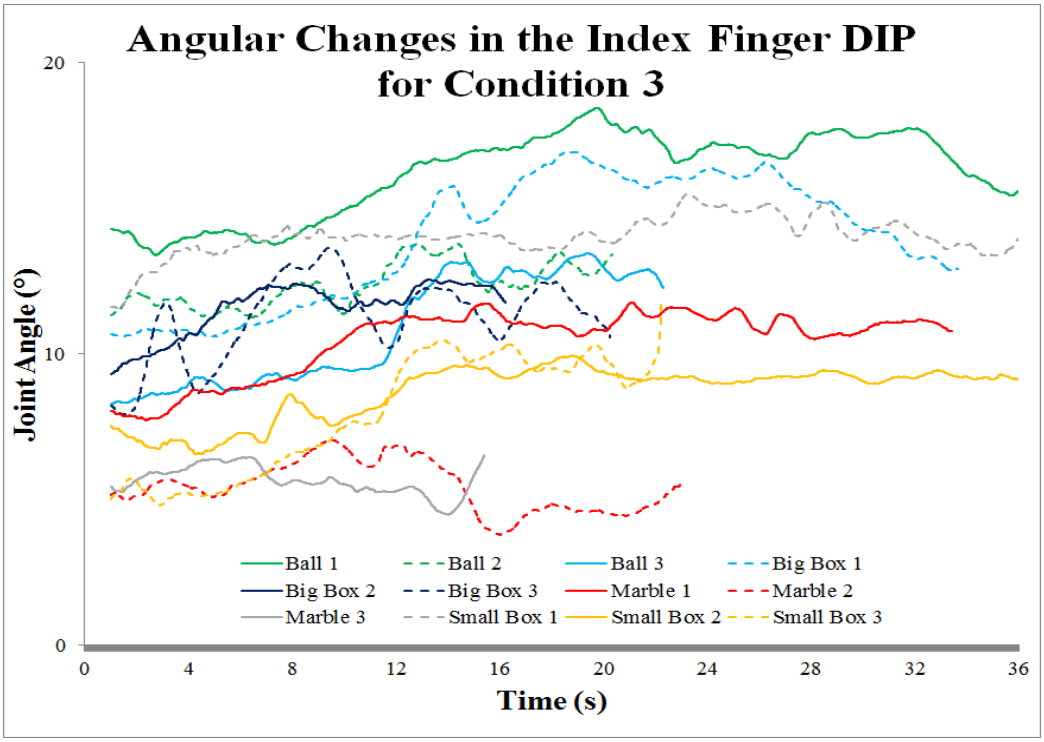

Figure 29: Joint angle variations in the DIP joint for grasping the four testing items whilst wearing the device, keeping their hand limp. The data are filtered for a moving average of 100 data points [231].

would approach the object in the same manner and perform the same motion, however a comparison of Figures 24 – 27 shows some discrepancy in the performance, primarily a reduction in both PIP and DIP for both the index and middle fingers. This could be contributed to by the motion of the internal glove within the outer glove that is unseen by the cameras, meaning that more motion is actually being undertaken by the joint but is not detected by the cameras. This would be the result of air pockets forming due to the size differences in the gloves. This anomaly in the performance is repeated in the third condition (Figures 28 & 29) and then does not appear in the fourth (Figures 30 & 31) which would suggest that the issue may be a result of the glove being a poor fit for the user's hand, whereas the 3D printed hand had a wide body and fingers, stretching the inner layer and limiting the movement that can occur internally. Therefore an emphasis should be placed on ensuring the quality of the fit to the wearer's hand, this can be achieved by the use of tighter fitting gloves, which will in turn have less excess material impeding the performance as well as reducing the time for the vacuum to form, or the use of a more flexible outer layer may also achieve this. The same participant was used in each testing condition, and whilst there were discrepancies in performance in each condition the participant was already familiarised with how to operate the device, it is possible that for a novice operator these differences would be even more pronounced due to their unfamiliarity with control the system and a reduced awareness of how to position the objects which would result in lower success rate when lifting the items.

Tip velocity also decreases when the device is used, with an average speed

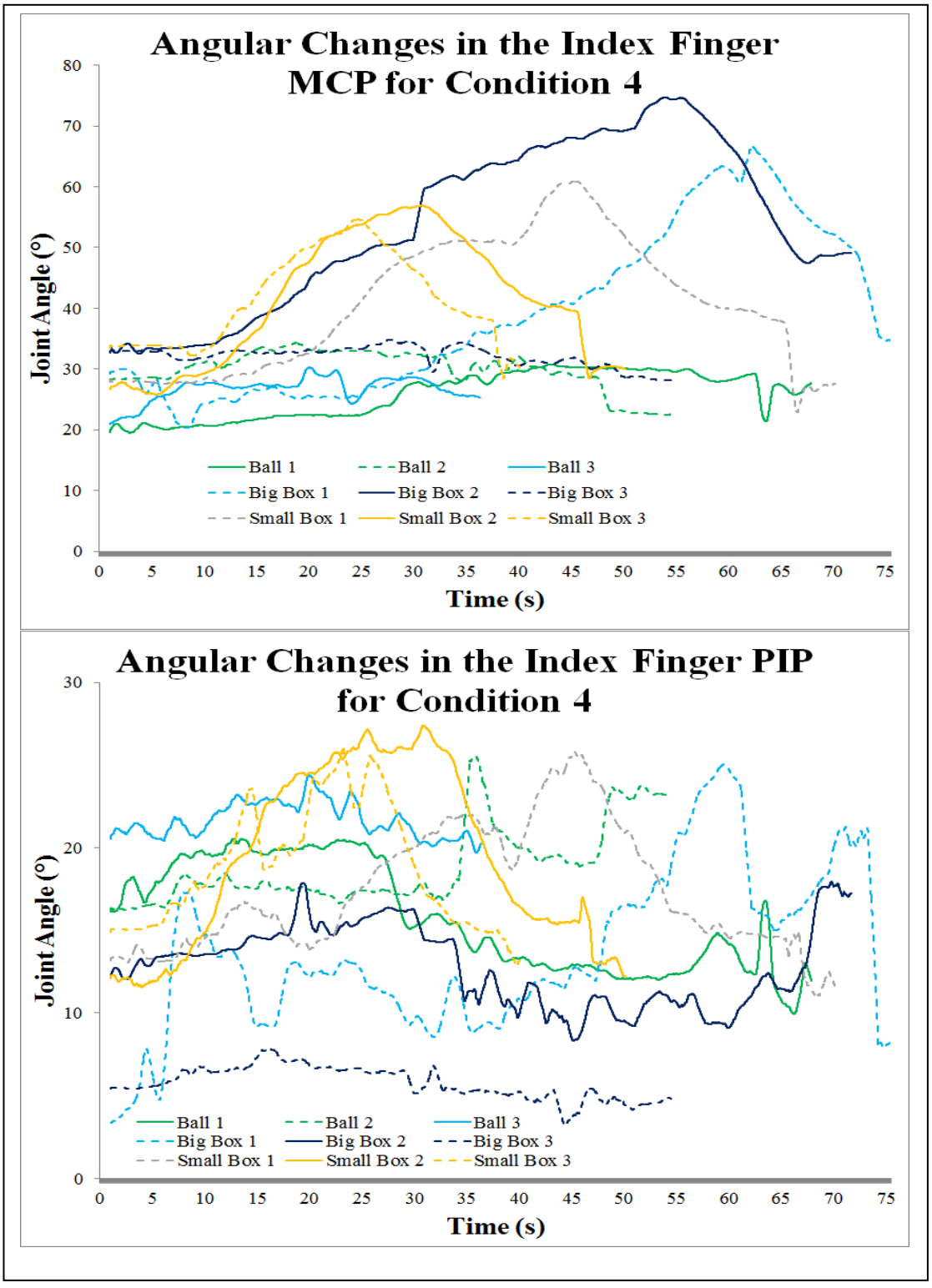

Figure 30: Joint angle variations in the index finger for grasping the four testing with the 3D printed hand wearing the device. The data are filtered for a moving average of 100 data points. MCP joint (top), PIP joint (bottom), DIP joint (overleaf) [231].

of 74.13°/s rotation for condition 1 in comparison to 1.09°/s for condition 4. When the user was wearing the device for condition 3 the average rotational speed was 3.66°/s, suggesting that the joints of the larger 3D printed hand provided a greater resistance to the cable driven system than the user's limp hand, which may have been a result of the rigidity of the hand, in particular at the joints, whether this would remain the case if the user were for example arthritic is currently unknown. The motors currently being used for the prototype were operating at 19 rpm rather than their rated 51 rpm in the testing stages to protect the wearer, increasing the power supply to the motor in future versions of the device will improve the performance in this area. Alternatively the use of a higher torque motor may be beneficial to overcome the lower rotational speed of the 3D printed hand.

The total angular rotation of the fingers shows differences between the

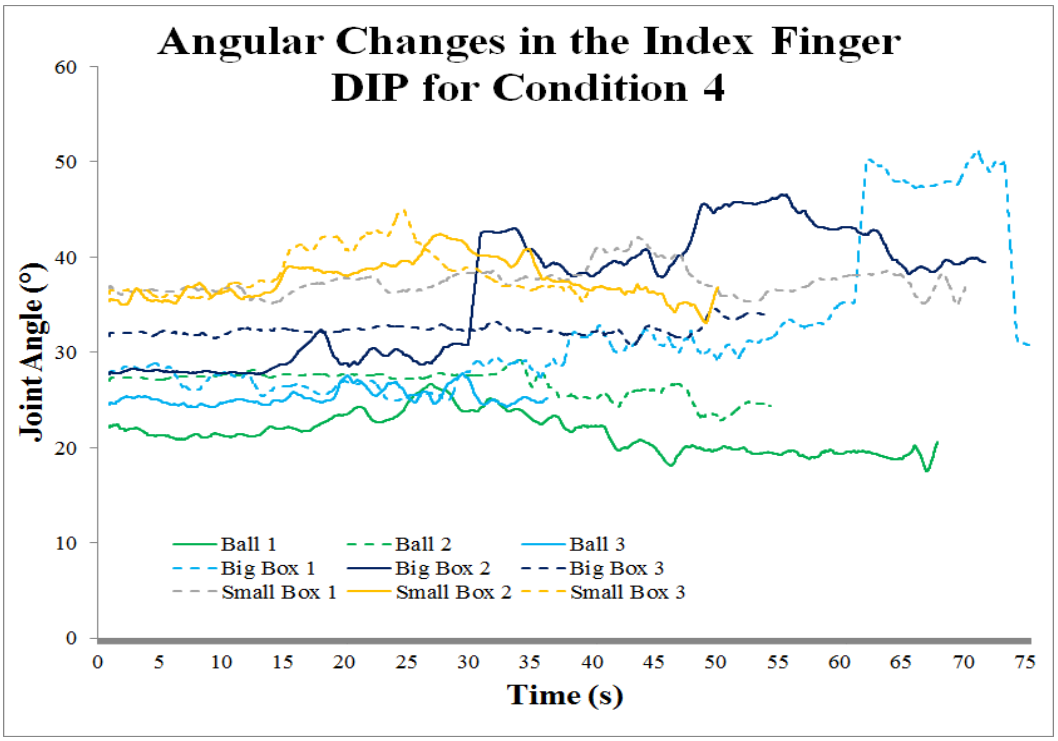

Figure 31: Joint angle variations in the DIP joint for grasping the four testing with the 3D printed hand wearing the device. The data are filtered for a moving average of 100 data points. [231].

conditions. When the participant was not wearing the glove the index finger joints completed 82.28±11.21° of total rotation in comparison to 68.6±9.62° when the glove is being worn. As the same user was performing the same motion in these trials this would suggest that the stiffer outer layer of the glove was concealing some of the rotation, if this repeated in the third testing condition it would suggest that the total degree of finger rotation when using the device is closer to the motion of not wearing the device than is suggested by the recording. When the user is operating the glove as designed the total finger rotation is recorded as 74.23±5.89° and increases to 108.49±25.42° for the 3D printed hand. It is unlikely that the fourth condition would also benefit from movement within the outer layer as seen in condition 2 as the larger fingers were tight within the glove so there would be no joint rotation occurring within the device. The variation in the final condition suggests that the 3D printed hand goes through increased rotation to grasp, whilst this is different from how the hand grasps without the device the additional rotation should assist in providing extra stability in grasping for a user who is without tactile feedback. As there is variation amongst each testing condition it does support the theory that the glove alters how the wearer will complete grasping.

The angular changes seen in Figures 24-31 show the consistency within each condition; however it also shows that there is a distinct variation across the conditions, these changes support the suggestion that the main source of the variation would be in how the user interacts with the objects in the grasping activities.

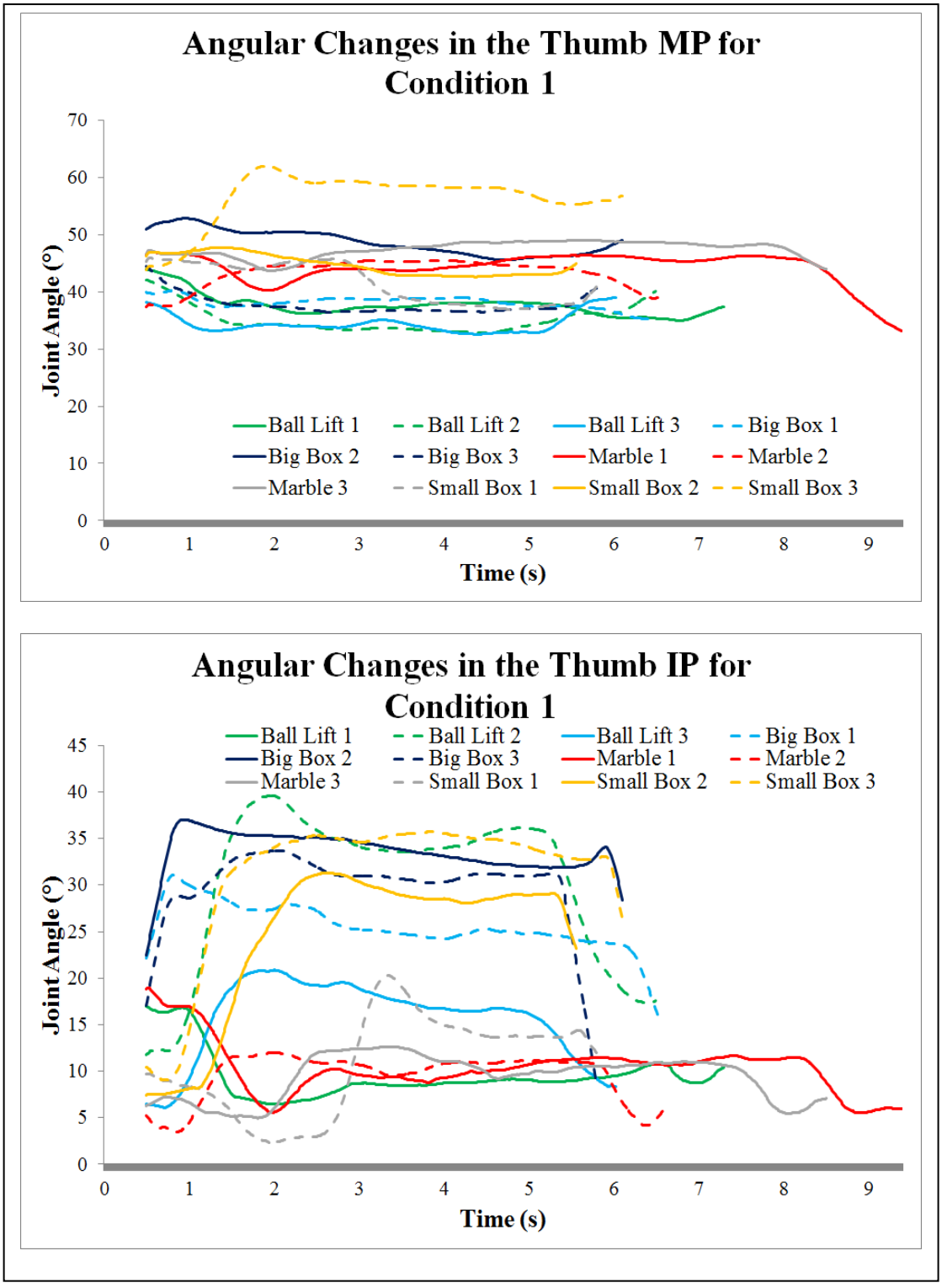

Figure 32: Joint angle variations in the thumb for grasping the four testing items without the device. The data are filtered for a moving average of 50 data points.

On first inspection it would seem that the increase in MCP motion is purely

compensation for the reduction in PIP and DIP, however analysis of the recording shows that this is an oversimplification, as there is a change in technique employed by the wearer to complete the grasp. The changes allow for an increased role for the palm of the hand and wrist to be used in supporting the weight, as the increased height of approach that can be observed in the recording shows the fingers and thumb to grasp two sides of the object, and downward movement of the forearm allows the palm to grip onto a third face of the boxes to secure them for lifting. This change in approach may be an attempt from the wearer to protect the suction cups in the fingers from taking the weight of the items and receiving damage.

The activity of the thumb was also recorded in three joints, firstly the large Carpometacarpal joint (CMC) at the base of the thumb as well as its metacarpophalangeal (MP) and interphalangeal (IP) joints. The CMC at the base of the thumb experienced negligible movement during all of the recording periods, irrespective of the recording conditions that the operator was tested in. This would suggest that the joint has too much natural resistance for the motors to successfully pull against it; it would also suggest that the surface of the hand on top of the Flexor Pollicis tendon is more stable than initially expected (Fig. 11). As the joint is connected to the wrist it often only takes action when grasping large objects, however was not required when the lifting the large block, whose sides are 100cm^2.

When the subject was attempting to grasp the larger objects there was also limited change in the performance of the MP joint, however movement at this joint became more pronounced when used with the 3D printed hand, in

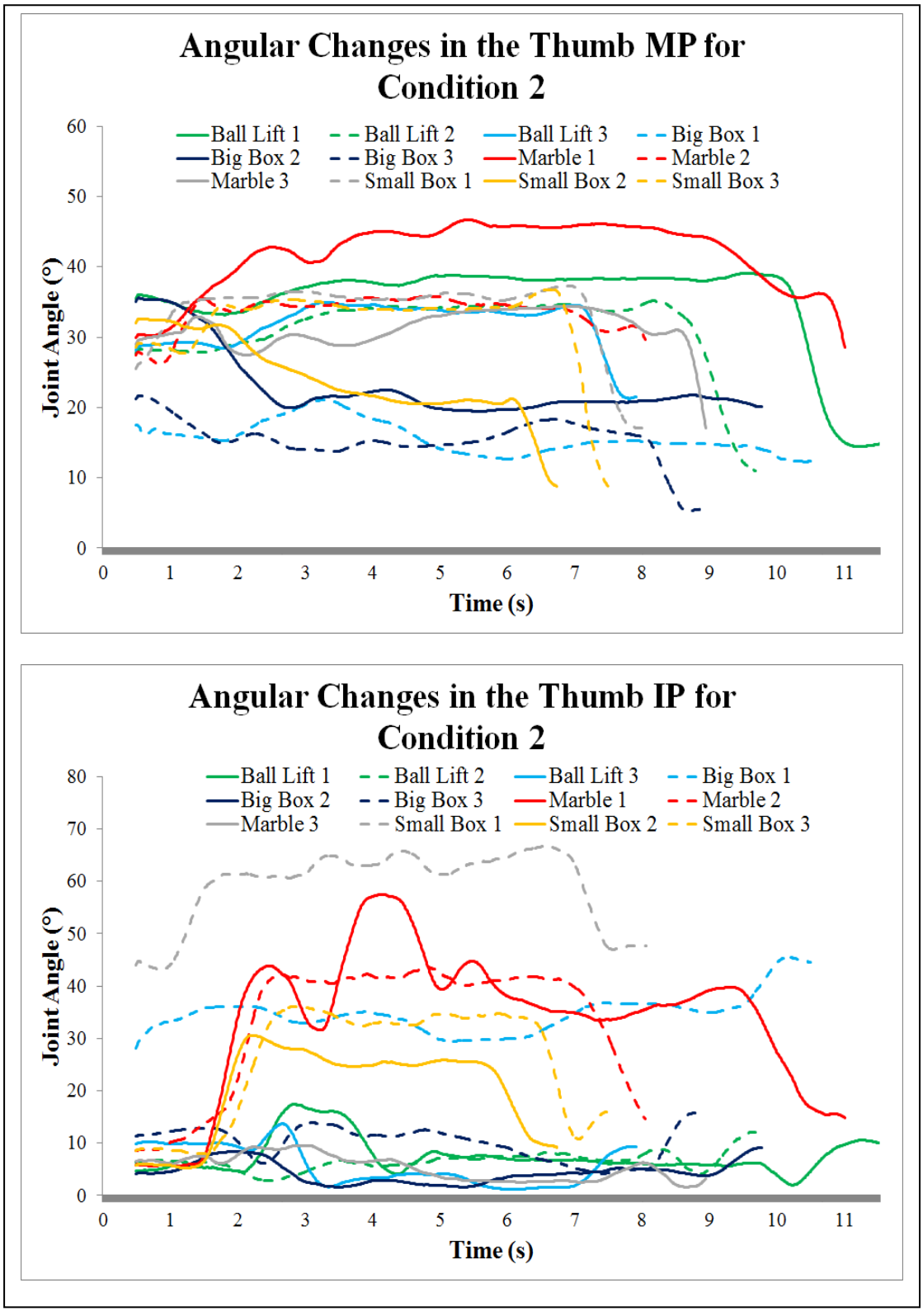

Figure 33: Joint angle variations in the thumb for grasping the four testing items whilst wearing the device with no vacuum or motors used. The data are filtered for a moving average of 50 data points.

particular for grasping the small box. In each instance at this stage the MP

joint goes through at least an additional 20° of rotation to grasp this object (Figures 32 - 35). There is a less pronounced increase in the activity of the IP joint; however this increase occurs across all of the testing conditions.

The issue with powering the thumb's rotation is that if the thumb starts in a wide position then the much of the force used for motion will be occurring laterally and consequently not be an efficient transfer of the rotational force from the motor to the cable within the finger, reducing the range of motion that could be achieved. This creates an inefficiency in the performance of the motors that increases the strain placed on the suction cups in the thumb by the cable and subsequently means that the contraction force in the cable is reduced. As this is unavoidable due to the posture of the thumb the reduction in contraction results in the thumb not flexing as quickly as the other fingers will and reduces the total angular movement that can be achieved.

The most obvious difference across the testing criteria is the change in the recording time, as the motors are incapable of acting as quickly as the musculature of the natural hand, as there will always be some inefficiency as at the interface between the user and the control system. The time for the grasping motion was measured in each recording through the use of visual inspection frame by frame to identify the beginning and ending of the grasping motions. The frame numbers were then correlated with respective times to enable the total time period for the grasp to be calculated. For testing condition 1, all of the trials were completed within 10 seconds (with 75% of those being completed within seven), in comparison to condition 3

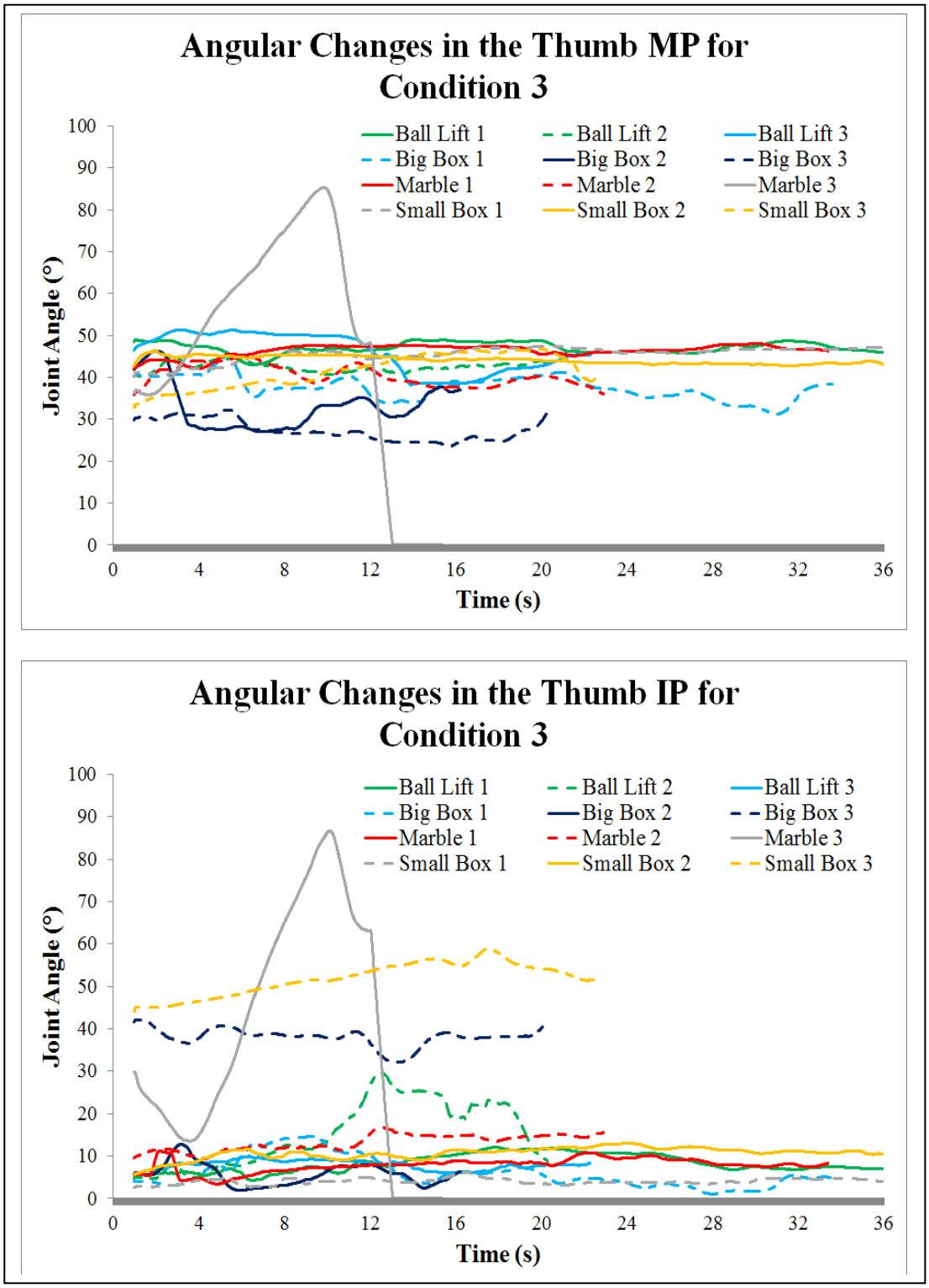

Figure 34: Joint angle variations in the thumb for grasping the four testing items whilst wearing the device, keeping their hand limp. The data are filtered for a moving average of 100 data points.

where 83% took over 20 seconds to complete with one taking over 50

seconds (this was a result of poor grasping technique with the small block, after a couple of attempts their fingers were not positioned correctly and the item was unstable for lifting as well as moving around, subsequently they moved the item more slowly to ensure that it was not dropped. In condition 1 the initial grasp took 0.68±0.4 seconds to complete, which increased to 8.47±4.5 seconds in condition 3 or could otherwise be described as being twelve times as long. The change in the speed is a discouraging outcome for the possible uptake of such a system to be used for support in daily activity, for example if a patient were wanting to open a door they are unlikely to approach the door and then take over eight seconds to grasp the handle before turning it and then taking a further eight seconds to release it. In that scenario they would most likely use their unimpaired hand or may ask for assistance, negating the purpose of the device however it can still be used to grasp objects and would be utilised when they are looking to lift with both hands. There will of course be some patients who are extremely dedicated to the possibility of recovery who will be happy to persevere with any inconvenience, as were met for the earlier patient discussions.

Improvements will be needed to be made to the initial prototype before it would be ready to be taken on as a possible assistant for daily activity or as a therapy tool. Currently the design is most likely to be helpful for patients with orthopaedic conditions. To improve the device beyond this it would need improvements to be made to the performance of the motor, for example by increasing the torque. Whilst an externally controlled mechanical system will never be able to bridge the time difference created by reaction time, the

difference in rotational time would require a very high torque motor, however a compromise must be struck to ensure that the motors are not too large and bulky so that the user retains the capacity to move around whilst wearing the device. As the prototype has been shown to have the strength and technique to be capable of lifting small and medium sized objects it should be possible to make small revisions to the design that will enable patients with hand disability to perform many basic activities of daily living, but improvements must be made in the speed of the devices operation before it would be considered suitable for use in this role.

An externally controlled mechanical system will always have a delay in its performance as it will never be able to operate at the speed of the human nervous system due to the transferring of internal signals within the muscle; however developments in EMG and EEG may change this in the future. The difference in rotational time would require a very high torque motor, however a balance must be struck to ensure that the motors would not be too large or bulky and would subsequently weigh down the user too much when wearing the device, allowing them to retain an element of independent movement when using the system. The prototype has been shown in the testing to be capable of lifting small and medium sized objects and it is believed that with some revisions to the design could be used to help patient who have experienced a hand disability to complete their physical rehabilitative exercises and in the future regain a level of independence.

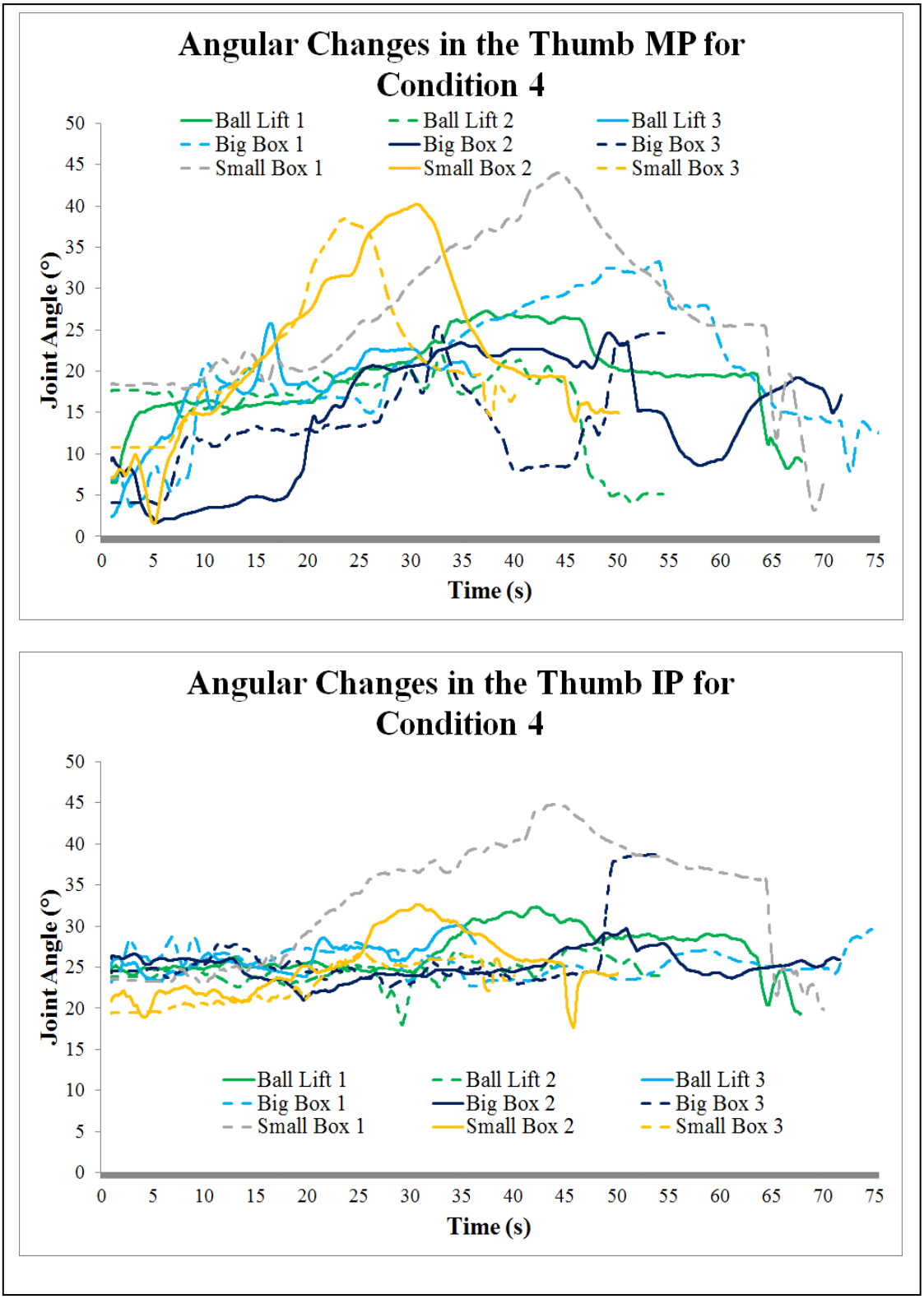

Figure 35: Joint angle variations in the thumb for grasping the four testing with the 3D printed hand wearing the device. The data are filtered for a moving average of 100 data points.

Conclusion

This chapter outlines the successful preliminary testing of the prototype, where the system was trialled for grasping and lifting a selection of items. To do this a testing rig was assembled and a programme model was developed to operate with the motion analysis system. The testing protocol was successful in showing that the cable driven glove was able to guide an artificial hand with no further assistance to replicate a pincer grip to securely lift the items, suggesting that it could be used to assist daily motion for patients who have no mobility in their hand as a result of a neuromuscular condition for example. The device was also tested with a participant; however participant testing needed to be expanded further to get a more definitive picture of the consistency of performance, which was performed in the next chapter.

Chapter 5 Feasibility Study with Subjects

Chapter 5 Feasibility Study with Subjects

Having shown in the previous chapter the success of the design in its initial testing, it was felt that a more comprehensive test of the prototype's feasibility could be established through subject testing. This chapter will outline the formation of the testing protocol that was selected, along with how successful the testing protocol was with the participants.

As the testing was recruiting a group of participants who were unfamiliar with the construction of the prototype it was also thought that this would be an ideal opportunity to get direct feedback on the performance of the device as it is worn. This chapter also includes details of how this feedback was collected as well as how this relates to the initial QFD assessment in Chapter 2 that forms the basis of the design.

An additional consultation was also carried out with medical workers at the National Rehabilitation Aids Research Center in Beijing, where the workers were given an opportunity to practice using the device to pick up objects before being asked for their feedback as to whether they felt the device could be beneficial to the patients that they treat. A review of this feedback and the possible improvements that can be made to device as a result of it are included in this chapter.

Feasibility Study

With the theory of the device established and the prototype tested, the next stage was to test the device with a group of users to gather their feedback on the design. The study chose to speak with unimpaired participants for two reasons, firstly that they will be better prepared to handle the device in the event of an error with the control system occurring whilst at the same time being able to rigorously assess the experimental protocol before the process would be applied to impaired patients. The second reason is that they will have a full sensitivity in their hand, and will therefore be best placed to comment on just how comfortable the device is to wear for a prolonged period of time. For example, if the device were fractionally too tight and impaired blood circulation to the wrist this would be noticed by a healthy volunteer but may not be noticed by an impaired wearer until afterwards, by which point further damage may have occurred. Preliminary testing with unimpaired volunteers has been performed before with the SUEFUL-6 [141], W-EXOS [143] and ABLE [91] systems. Beyond this study the aim is to apply the prototype to a range of patient groups in the future to assess how well the device assists them to perform basic grasping actions.

To gather their opinions the author arranged a practice session based on the previous protocol. Once again the participants would be asked to perform actions based on the activities set out in the ARAT assessment that would test the functionality of the glove, for example the reaching tasks and grasping marbles with their third finger were removed as they are movements' outwith the scope of the glove's design. Once they have utilised

the device to complete a range of grasping actions a consultation was staged with them to get their views on how the device performed during the testing.

Method

6 participants in good health (3 male and 3 female, average age 28.3±9.9) who had no history of physical impairments in their upper body were randomly recruited from the University's body of students and staff. They were asked to wear the device for the performance of the tasks, with the movement of their fingers again being tracked by the Vicon motion analysis system (Vicon Motion Systems, Oxford, UK) due its strong track record for recording fine movements from the body [233 - 235]. The system used in this assessment had motion capture cameras and recorded the data at 100Hz. The calculation of the joint angle measurements was completed by the user model developed in Chapter 4, which was developed to monitor the three fingers of the prototype that flex from the cable-driven system. It was logical to retain the model from the previous assessment as it would allow the results of the common trials to be directly compared. The experimental protocol was cleared by the department's ethics committee in accordance with the Declaration of Helsinki.

The specific tasks to be completed as well as their order were as set out by the ARAT assessment [232]. Whilst many other therapy devices will test with protocols such as the Fugl-Meyer test, this testing measure is orientated towards impairment of the upper limb. As the device being tested exclusively

Table 5: Table of Physical Activities Used in Study with Weight of Items Lifted

Activity	Weight (grams)
Grasp Tasks	
Lift Block (10cm)	730
Lift Stone	470
Lift Ball	125
Lift Block (7.5cm)	325
Lift Block (5cm)	100
Lift Block (2.5cm)	25
Grip Tasks	
Lift Tube (2.25cm)	70
Lift Tube (1cm)	25
Place washer over bolt	5
Pour water from cup to cup	225
Pinch Tasks	
Lift large marble – first finger and thumb	25
Lift large marble – second finger and thumb	25
Lift small marble – first finger and thumb	10
Lift small marble – second finger and thumb	10

assists with movement of the hand in the act of flexion, a larger amount of relevant data would be collected from using a function orientated testing protocol, such as ARAT. All of the tasks in Table 5 were to be performed in this study, unlike in the traditional assessment, where successful completion of the more challenging initial tests mean the simpler tasks in each set are not required. The activity list and the weight of each item are included in Table 5. The tasks that did not assess the functionality of the glove, such as

the participant touching the top of their head, were removed from the testing protocol as they would not provide an assessment of the glove.

Once the subject had read through the instructions and was seated in an upright position the device would be fitted to their arm, they were then given the opportunity to practice operating the device after the experimenter had demonstrated for them how the controls directed the finger motion. For the practice session the volunteer was entrusted to control the operation independently, as such they required a brief practice period to adjust to operating the motors. Once they were comfortable with the process the testing would begin, with each task performed individually to ensure that they were differentiated on the recordings. The experimental set-up can be viewed in Fig. 36.

After the trial session had been completed the consultation would be

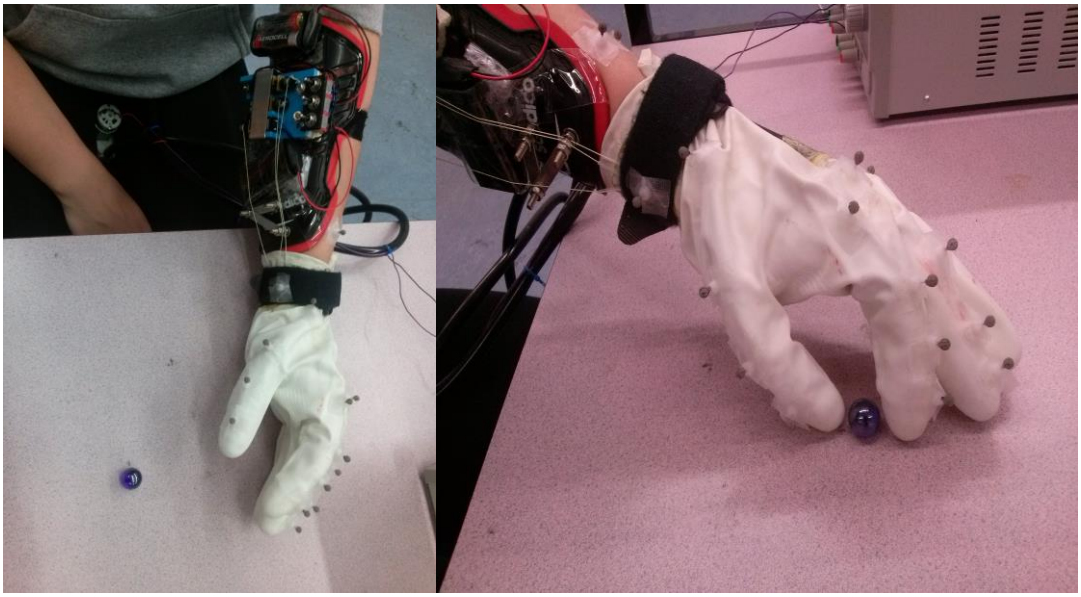

Figure 36: Images of the experimental set up for the study (left), as well as the prototype performing the penultimate action (right).

performed, where the participants would be interviewed for their opinion on the device's performance to complete the tasks they had just been asked to complete. These questions were related to the factors that had been raised previously in the QFD consultation, asking their opinions on its functionality and comfort for example and they were asked to score it between one and five, where one was very poor and five was very good.

Results

As with Condition 3 of the previous trial the percentage of the individual joints to the total finger motion showed that the two proximal joints, MCP and PIP, are the main contributors to total index finger motion (Fig. 41). The motion of these joints will normally fluctuate between 35 and 50% with the remaining 10-30% of total movement being provided by rotation of the DIP. Over each task the range of contribution from the PIP is more consistent, with the main fluctuations occurring in the MCP and DIP, and the balance between these factors is determined by the size of the object, where the four largest of these, the ball (26.74/27.3%), cup (19.67/28.83%) as well as the 10cm (21.54/34.85%) and 7.5cm boxes (25.03/29.76%) have a greater contribution from the DIP joint due to the spread of the fingers around the object.

Combining the results for each joint to assess the total angle of rotation achieved by the fingers was also done (Fig. 38). This shows clearly pronounced periods for the flexion and extension of the fingers from Subject 6 when they were grasping the washer and placing it on a bolt. It also shows

an increased activity from the middle finger in comparison to the index, with approximately 30° additional rotation being undergone during the recording period. This will predominantly be due to additional length of the finger, so extra rotation is required to keep the fingertips level.

It was shown through the data that the smallest increase occurs at the most distal joint, as well as the thumb CMC and is predominantly due to these joints having the lowest range of rotation naturally, this is also coupled with the short distance between the final cup and the plastic cap, as a result it is difficult for the device to lever the joint without the PIP being fixed in place, as happens when grasping a large object such as the 10cm box. These trends are displayed in Fig. 39.

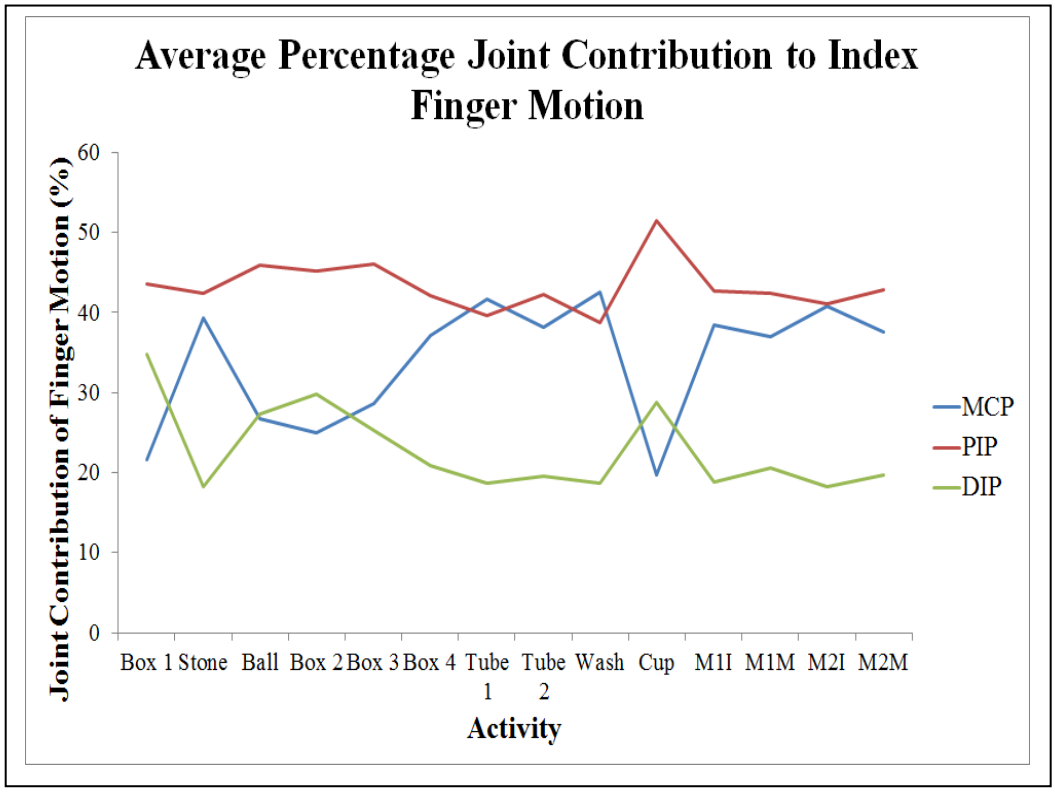

Figure 37: Collated percentage contribution from each finger joint in grasping separated by activity for the recording of all subjects.

After the previous prototype trial the inner layer of the device was replaced. This new inner layer had the route of the cable streamlined as the 3D printed hand was no longer being used; previously the suction cups would get caught between the base of the thumb and the body of the hand when this joint rotates, resulting in a different inner layer having to be fitted for use with the 3D hand model. This new route was more direct as a result and would most likely see a reduction in the amount of force being exerted horizontally, improving the efficiency of the device and saw the average time grasping time reduce from 8.47±4.5 to 5.54±2.15 seconds.

With regards to the feedback discussions, it was important to keep the reviewed criteria relevant to the initial concepts that were used as the basis for the design. As such the scoring to assess the device was based around the criteria used in the previous QFD discussions, the average scoring of this can be viewed in Fig. 40.

Analysis

One feature of the design that quickly became apparent as an issue was that for female participants particularly along with males with smaller bodies the shin guard being used as a base for the mechanism was too large. Whilst they were still able to operate the device and use it, it placed a considerable restriction on how far they were able to flex their elbow joint, many of them struggled to get any flexion in their elbow as a result, although only two reported it back as in issue in the discussion, so whilst it appears to have

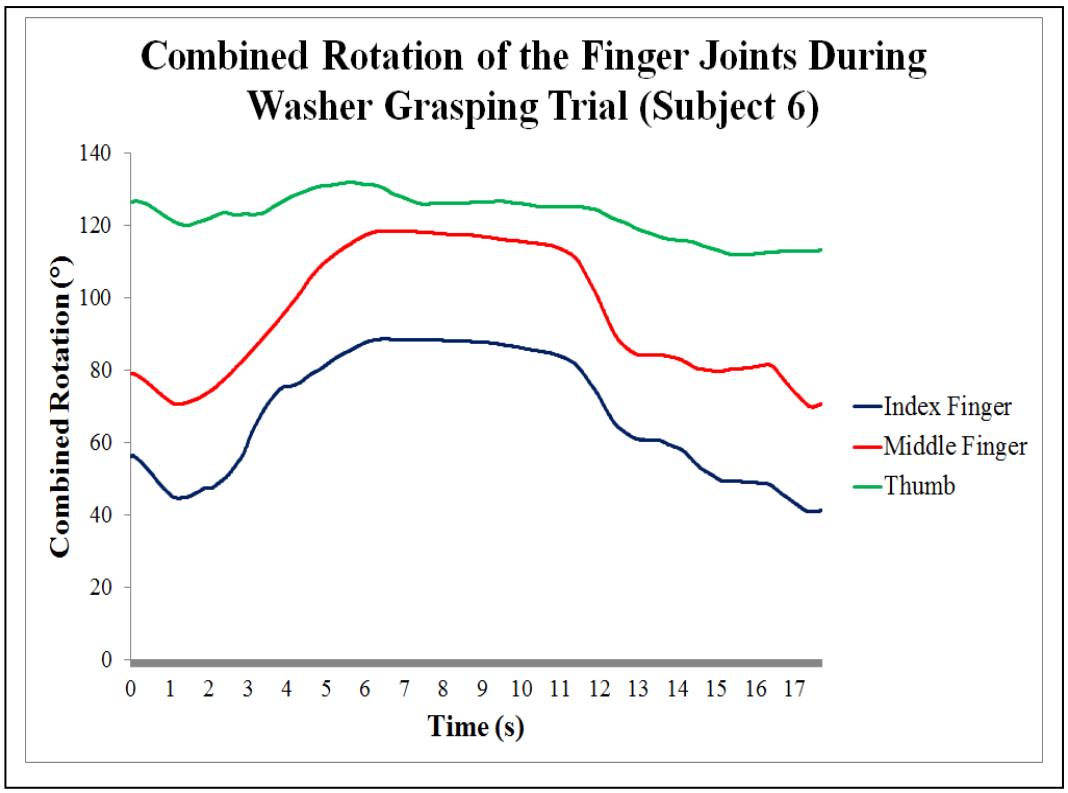

Figure 38: Combined joint angle data for each finger in the act of grasping. The data are filtered for a moving average of 50 data points.

impaired performance it has not been a source of discomfort. By contrast the participants with a larger frame had no issue with the fitting of the shin guard but found the glove challenging to get on due to tightness at the wrist as well as the suction cups protruding within the fingers making them narrower. This would suggest that the design requires scaling to fit the variation in wearer's body shapes before it can be fully assessed as a treatment tool and assistive device. As the shin guard has unused areas on its surface this should not be an issue in future designs and will not compromise performance. Additionally gloves of set sizes could be developed to ensure that there is a comprehensive range available to enable the widest variety of hand shapes to be accommodated.

It is also important to look into the materials used for the dual layer glove as the majority of the participants commented on the temperature of the glove after they were wearing the device for between 90 and 120 minutes. Obviously it is crucial to ensure that any future materials allow the vacuum principle to be replicated whilst allowing the hand to be cooled. The majority of worn materials for the hand do not overheat the wearer as they are usually loosely fitted at the wrist, allowing air to pass in and out of the glove and reducing the temperature. To maintain the vacuum the glove must be tightly wrapped at the wrist so that air cannot seep inside, whilst if the material is thin enough for air to pass through then the vacuum will never form, this principle applies to the outer layer, as the inner layer can still be changed for

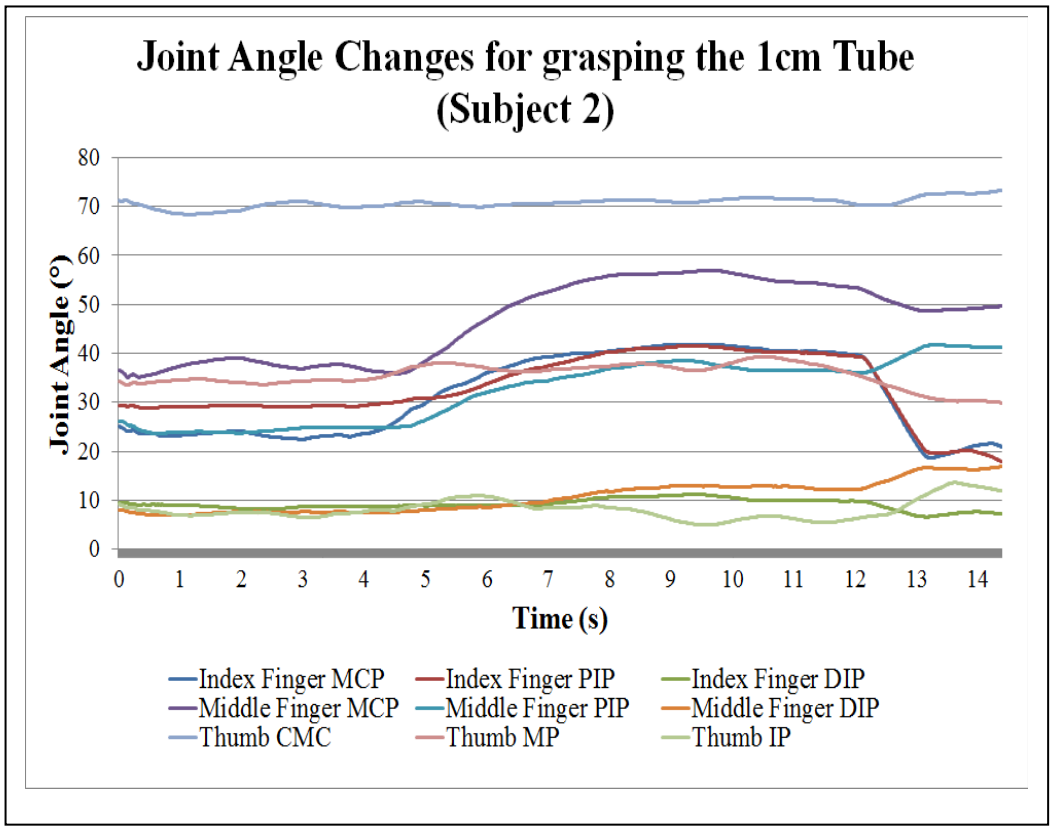

Figure 39: Recorded angular changes of each joint of the hand for subject 2 when grasping the narrow tube. The data has been filtered for a moving average of 50 data points.

an alternative that is made from a lighter material which should reduce the amount of sweating that occurs. This leaves the design needing a feature that can be switched on and off, such as an adjustable wrist strap or some form of valve on the glove that can be plugged when the device is to be used.

Some participants struggled with the initial trials, the heavy block items that needed to be lifted. As the running order of the tasks is set in the protocol it is unclear if this is due to the weight of the items (the heaviest is 730g) or if it is due to being the first items tested and could then be resolved by increasing the practice time for the volunteers. It is possible that this could be remedied in future assessments by randomizing the order the activities are performed in, as the original order of the ARAT has an intention of factoring fatigue, which was not an issue with this subject group, however if the assessment were expanded to test disabled populations then this becomes an important consideration. The glove also struggled to assist the volunteers in the highest precision task, that of placing a washer on a bolt. The first problem for the participants is with grasping the washer as due to its profile the device was unable to grasp it from a surface of the table; subsequently it needed to be placed in the grasp of the device by their free hand. Secondly there were difficulties found in releasing the washer in a controlled manner as all six failed to successfully place it on the bolt. This will most likely be a result of inexperience from the user, as it is the only task that requires them to accurately release the item onto a target, which is an important component of therapy due to its increased difficulty for patients. Whilst all of the participants had no problems releasing the washer, the issue was created by

the initial grasping method, as the volunteers all chose to grasp both circular faces of the washer and then drop it onto the bolt, where it would be easier to grasp by its ‘poles’ and position it on the bolt before releasing. The result of their selected method was that as the washer was released it would slide along the fingers and drop off the end. When the washer cleared the precipice it would catch on the end of their finger, creating a minor rotation that resulted in the washer not falling directly onto the bolt, whereas if it were grasped at its ‘poles’ it could be lifted into position in a manner similar to a crane and then released. Given time and practice it can be expected that most participants could refine their technique to get the maximum performance from the device for precision tasks such as this.

All of the participants were required to grasp the cup around its body for the water transfer task as the dual glove, when fitted with the marker set, was unable to fit through the handle without causing the markers to fall off. This meant that the participants approached the cup in a similar manner to the tubes, but treating it as a larger version of them. For some this was their usual technique for grasping a mug and made no difference to how they approached it, however a change of technique was required from those who would normally grasp a mug by the handle.

In terms of the recorded motion data, there was consistency in the rotation of the angular motion of the finger joints. For example, when lifting and transferring the water between the cups the middle finger would reach an average angle of 34.51, 30.44 & 19.20° at the MCP, PIP and DIP respectively, giving a combined joint angle of 84.15° to grasp the cup. This

distribution is encouraging, as the device is intended to be used as an assistive tool that can aid patient activity, so it is beneficial for each finger joint to contribute to motion.

When compared to the previously assessed control condition there is a similarity to the recorded motion of the joints proportional motion relative to total movement, however some variation will always occur in the actual degrees of rotation depending on the size of the object and where on the palm of the hand the user grasps the item.

When looking at the average rotation for the joints there is a discrepancy between the male and female subjects, where the female participants have a greater contribution of the PIP joint in grasping (8.76±4.65°), whilst the males have a greater contribution from the DIP joint (10.82±1.92°). This discrepancy occurred in each activity and would suggest that the male participants were grasping the items more distally than the female participants resulted in a reduced rotation of the PIP as the grasped object would be obstructing rotation of this joint.

The revised inner layer that was used in this testing protocol produced a reduction in the time to grasp the target objects, this is due to making the path for the index finger cable linear, reducing the horizontal load across the hand and meaning that more could be used to power finger flexion. The improved motion of the index finger resulted in a drop from 8.47±4.5 to 5.54±2.15 seconds (in comparison to 0.68±0.4s with no device worn in the previous trial). Further to this point the final tasks require the participant to lift

two differently sized marbles with the index finger and thumb as well as with the middle finger and thumb, when discounting the results of Subject 3 who took multiple attempts to lift the marble in one of their trials there was a significant reduction in the time taken to lift the marbles with the middle finger than when using the index finger. This difference is most likely the result of the improved linearity of the pathway for the cable tendon improving the efficiency of the motorisation and increasing the force applied to improve the efficiency of the finger joints.

Within the study there was limited variation in the timescales for completing the grasps, this is an encouraging sign of the device's consistency of performance. If the device has an established baseline for how quickly the joints will rotate this will be beneficial, as firstly it makes it easier to monitor the performance of the device as well as providing an indication for the therapist as to the severity of the patient's disability, as those patients with considerably stiffer joints will experience an additional resistance at the joints reducing the rate of rotation. Compensating for this issue will require the device to be fitted with pulleys made from a material with a higher strain threshold than the plastic model pulleys used for the prototype to ensure that there is no degradation or wear from the motor not performing with maximum efficiency.

User Feedback

Overall the subjects claimed to be impressed with the design and did not find it to be as uncomfortable as they were expecting from its visual appearance. A further two participants had been lined up to contribute to the study, however the device had suffered an internal failure and the index finger was unable to function correctly, subsequently no data were able to be recorded in their trials. Interestingly these were the only participants who found the glove uncomfortable to wear, particularly around the index finger, which would suggest the importance of maintaining the condition of the components as a material failure may result in an uncomfortable and ineffective performance from the device, and should obviously be sought to be avoided in future versions of the device. Despite the positive feedback, the main issue of comfort raised was the temperature, as after wearing the device for over 90 minutes the users found it would get quite warm and some subsequently had issues with sweating, which made it harder to remove the device. The size of the device was also noticeable for the smaller participants, with some considering the forearm unit to be impairing the movement of their elbow joint; however aside from two participants raising concerns over the weight on the forearm after prolonged wearing the remainder did not consider it to be uncomfortable. The participants who struggled with the weight of the device were less than half of the total participants, and were those who had shorter forearms, where the shin guard in those cases was the full length of their forearm and restricted the flexion of their elbow. For these participants the additional weight of the device made

their elbow feel stiff and created the discomfort. In future models this issue can be remedied firstly by taking the main source of the weight, the batteries, away from the forearm, which will in turn allow the forearm plate to be condensed to provide a better quality of fit for patients with shorter limbs. When asked to score the comfort out of five, where one is very poor, five is very good and three is average, the device averaged a score of 3.5 (Fig. 40). In the QFD analysis (Chapter 2) it was found that both the weight and the comfort were the main factors in whether the patients felt that the device was wearable, the prototype has been successful in these areas in its early stages but can still be refined to improve it further.

One of the participants suggested for possible improvements the use of

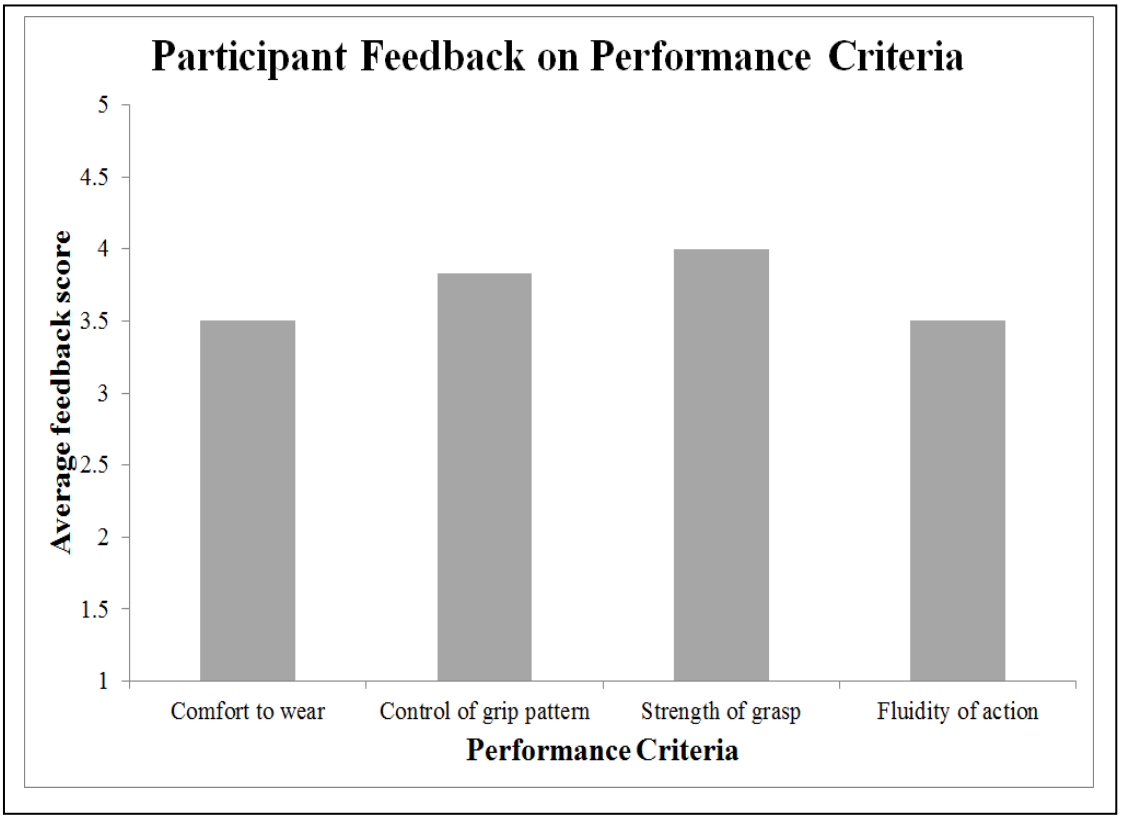

Figure 40: Bar chart illustrating the average scored responses for the feedback discussion points from the unimpaired volunteers [230].

talcum powder which would assist in taking the device on and off, and will also help to absorb some of the sweat the wearer may experience. This could potentially ease some of the difficulty that was found when putting the glove on for individuals who have particularly large hands, produce excess sweat or wear the device for a prolonged time period, however increases the time that would be taken to put it on as well as the cost of use. The other suggestion to ease the recurring issue of hand temperature was a change in the material of the gloves, whilst the stated preference was for a fabric based material to be used, with the added thought that it could also improve the flexion of the fingers. This is a possible consideration for the inner layer that will be against the wearer's skin and should increase the comfort, however for the material of the outer layer to be considered 'breathable' to reduce the temperature would mean that it is not completely air tight so the vacuum would not seal and the central design component would not function correctly, subsequently this is a concession that would require further research into the performance properties of a range of materials. The addition of a valve in contrast should allow for the air to be let into the device when not in use but also ensure the integrity of the vacuum when required.

When discussing with the participants how the device changed their approach to grasping tasks, it was felt that no change was needed for the device when grasping generic shapes, however there were changes for the items being grasped for a specific task, in particular the cup, as the fingers were too large to fit through the handle, and the washer, as they could not pick it up from the surface without the assistance of their spare hand due to

its narrow profile. Several volunteers did note that it was challenging, particularly for the washer, to remain completely passive when performing a specific precision task, as they were fighting their natural impulse to actively participate when aiming to place the washer onto the target of the bolt. Placing the washer on the bolt was perhaps too precise a task for the device's capabilities, as all six of the participants were unable to successfully drop the washer onto the bolt when using the device. It scored an average of 3.83 across the participants for how much control was available to them, although this score is subject to heavy influence from the items selected for interaction. The QFD discussions showed the importance to patients of helping them to work on their grasping of objects in therapy, whilst the participants also felt that the device offered them a straightforward control system, which was the dominant factor in terms of improving control according to the patients.

The device was tested on a physically varied group, with a range of hand sizes, subsequently the quality of the fit also dictated how much the glove interfered with their grasping, as the volunteer with the smallest hands had large sections of unused material in the fingers, which upon the creation of the vacuum would create folds in the outer layer that made it harder for them to pick up smaller items due to the excess material in effect making the fingers larger. Consequently this excess material was not supported by the wearer's skeleton underneath and was contorted when it came into contact with a solid object, the outcome of which is that it obstructed the completion

of the intended activity. This emphasises the importance of making sure that the glove is a good fit for the size of the wearer's hand.

The volunteers did struggle in the initial stages of the testing, this may be due to the ARAT task order, where the larger items go first, and could be negated by a randomised trial. This should show if the issue is purely due to a lack of practice time of behalf of the participants. Alternatively it may be purely due to the item's weight, as the participants were asked to leave their hand completely passive so the device would do all of the work, which will have placed additional strain on their wrist joint when lifting. When used with patients this would be the case in the initial stages if they experienced a disability of the hand, however as their sense of control returns it would take on an increased supporting role, which should make it safer for patients to use for lifting heavier items. Consequently in the discussion afterwards the majority of the participants (4) found the large block to be challenging to securely grasp as it was prone to slipping. In contrast, two of the participants stated that they felt the washer was not securely grasped in the device due to its small, narrow profile.

If the weight is shown to be an issue this may be considered a limitation on the practical role the device could offer, as it may only be considered safe to be used when grasping objects of a certain weight. A randomised trial could clarify if the weight is indeed the issue or if it was merely a case of inexperience of operating affecting their performance. Aside from issues with the largest of the blocks, which weighed 730 grams, the participants felt comfortable with the strength of the device, scoring it with 4/5 on average,

although as with the grip pattern this is subject to the objects included in the testing parameters.

As the participant group was drawn from physically unimpaired volunteers, three of them admitted to struggling to adapt to the pace of motion and found they had to consciously resist the temptation to grasp the target object manually. This change of tempo and being asked to remain completely passive was a challenge that unimpaired wearers have to adapt to, but would not recur with a patient population as they would lack the capacity to manually override the performance of the device. The motors used in the device were running on 3V from a pair of AA batteries, which is lower than their rated operating voltage of 12V and resulted in the motors rotating at a lower speed of 19rpm, compared to the motors rated speed of 51 rpm and was done to ensure the wearer's safety in the early testing. This means that to improve the speed in future designs the motors should be connected to a more powerful battery, one possibility is to operate each component from a singular rechargeable power supply. Additionally replacement motors could be used to gain a greater number of revolutions per minute without lowering the torque.

In terms of practical application, the participants felt that the glove did not change how they interacted with the items, however their process was changed, as their conscious effort in terms of how to position their hand was increased, an action that normally would be completed instinctively. They also had to consider where the thumb in particular was positioned as it was only capable of moving along its solitary degree of freedom where normally it

would have 360° of rotation. As some participants felt they made noticeable adjustments to how they would have interacted with the items without the device on the natural action was scored at 3.5/5 in the discussion. The reduction in the number of fingers that could be used in flexion to contact the item was a change, but was not considered to be an impediment to their ability to lift the items, with exception of the large wooden block as it would be easier to secure with five fingers rather than three. The only technical change in approach for an item was the grasping of the cup to transfer the water as the fingers of the device were too wide to fit through the handle with the tracking markers attached. One participant suggested that they would have attempted some of the activities with two hands; in particular the placing of the washer, using the device means that more preplanning is required for this as the wearer must always have some capacity to keep their non-glove hand free so that they are able to reach the other forearm to activate the control switches. As bimanual activities are a standard component of therapy adjustments could be made to enable this, such as the use of computer command that could be set to grasp for a time period before releasing, or a voice command system so that the user could issue commands and perform the activity without having to stop their action with their unimpaired hand. As the long term intention is to make the device capable of supporting patients in daily living it is important to consider how best to revise the control system to enable wearers to intuitively and quickly control the device whilst not having to stretch across their chest to operate their other hand. If the aim were to develop a device that could support bimanual activities then it would need to

be controlled by a system that is responsive to the intention of the operator, this would most likely require an EEG or EMG interface to interpret the signalling within either the musculature or the brain, this would follow in the footsteps of the majority of current devices for rehabilitation, the development and maintenance costs of a system of this nature is outwith the remit of this design. Another alternative would be a parallel system, where the device would mimic the activity of the unimpaired hand, such a system may encounter issues when the hands are needed to perform differing tasks in tandem. The current control set up is adequate for the supporting single handed motion, as it provides a stable base from which to control hand grasping and releasing. That the user can perform the majority of actions in a manner that replicates their natural actions, as well as the device being lightweight and simple to control should suggest that it will be able to help patients regain some element of freedom of movement, as long as use of the device is supported by therapy for the other limbs.

Rehabilitation Worker Consultation

Whilst the device is designed to be orientated around the needs of the patient it is important to get feedback from professionals in the rehabilitative field as well, firstly to confirm that there is a potential benefit to patients and secondly because they are the ones who would recommend or prescribe a device to the patient. To accumulate this feedback it is important to provide the staff with an opportunity to test out the device so that they can feel for themselves

how it performs, and should be able to make an informed estimate from their experience of how successful it could be with patients.

The prototype was trialled by the staff at the National Rehabilitation Aids Research Centre in Beijing, where they were given an opportunity to put on and try out the prototype's function to grasp and release large and small everyday items of their choosing around the department before discussing what they felt were the positives and negatives of the prototype. There was also an opportunity for the discussion of where they felt that changes needed to be made to better suit the requirements of the patients.

15 staff members (five Rehabilitation Doctors, four Physical Therapists, one Occupational Therapist, one Orthopaedic Surgeon, three Orthotists and one Prosthetist) with an average experience of 6.4 years in their role volunteered to sample the device and provide feedback on its function. As with the feedback from the volunteers, it was rated on a five point scale where five was considered to be very good and one was considered to be very poor with three as average. The average scores can be viewed in Fig. 41. The staff were also asked if they had any patients in their workload who they felt would benefit from the use of this device as well as improvements that they felt could be made to the device to make it better for patients.

Results

When they were asked if they thought the device may be able to assist with some of the patients that they are currently treating ten of thirteen answered

positively, the remaining two were discounted due to not currently having patients in their caseload that the device is designed to accommodate; they were a physical therapist that was completing their internship and did not presently have patients of their own, as well as the prosthetist who would require a considerably different tool to accommodate their patients who have had amputations. Of the three who answered negatively, two predominantly worked with spasticity patients that would require an extension function for the device to be useful to them, whilst the other felt that in their experience the device was not useable for patients with dual hand impairment, and those with hemiplegia would normally adapt to use their other hand for the majority of tasks instead.

For the ten who answered positively they were thinking of similar groups of patients who would benefit, predominantly those who were impaired only in the hand, but retained movement in the shoulder and elbow to support the device in its current form. Examples ranged from musculoskeletal diseases to spinal cord injuries that result in the patient having low tension in the finger muscles but the arms proximal joints are not impacted, additionally one speculated that some tetraplegia patients may be able to use the device if they have someone to assist them in taking it on and off. The group of patients who could benefit from this device is smaller than had been hoped for initially, however the staff were not averse to considering the device for use with a larger group of patients in the future if improvements were made, particularly in the forearm unit where the most concerns were raised.

As can be seen in Fig. 41, the area of the prototype that the staff were most happy with was the strength of the grasp (4.333±0.617) as when allowing them to test the prototype it was capable of grasping and lifting any object that the staff attempted to use it with except for plastic water bottles, which deformed as the device exerted pressure and would cause them to move within the hand. This grasping issue is a result of the limitations in the devices tactility in the fingers as well as not supporting finger abduction/ adduction to allow the fingers to change position as the outer texture of the target changes. Subsequently the staff felt that the prototype had sufficient grip strength to be capable of supporting daily living, but would prefer that the device makes the wearer aware of just how much strength they are exerting to avoid a situation where they leave the device on too long and subsequently strain their fingers by over flexing.

The weight of the prototype (3±1.134) is a key factor in how well it would be received by patients and would be highly subjective based on the personal circumstances of the patient. The range of responses that it returned from the staff is reflected in the standard deviation, as every option was selected at least once. The two contrasting components have contributed to this conflict, with the respondents stating that they were happy with the weight of the glove, but were concerned about the weight of the forearm unit. To take this device forward to a stage where it would be tested with patients it should have the forearm unit redesigned as whilst it is logical in terms of providing each motor with their own control, it is not very practical as this increases the number of batteries that it will carry the weight of. The concerns over the

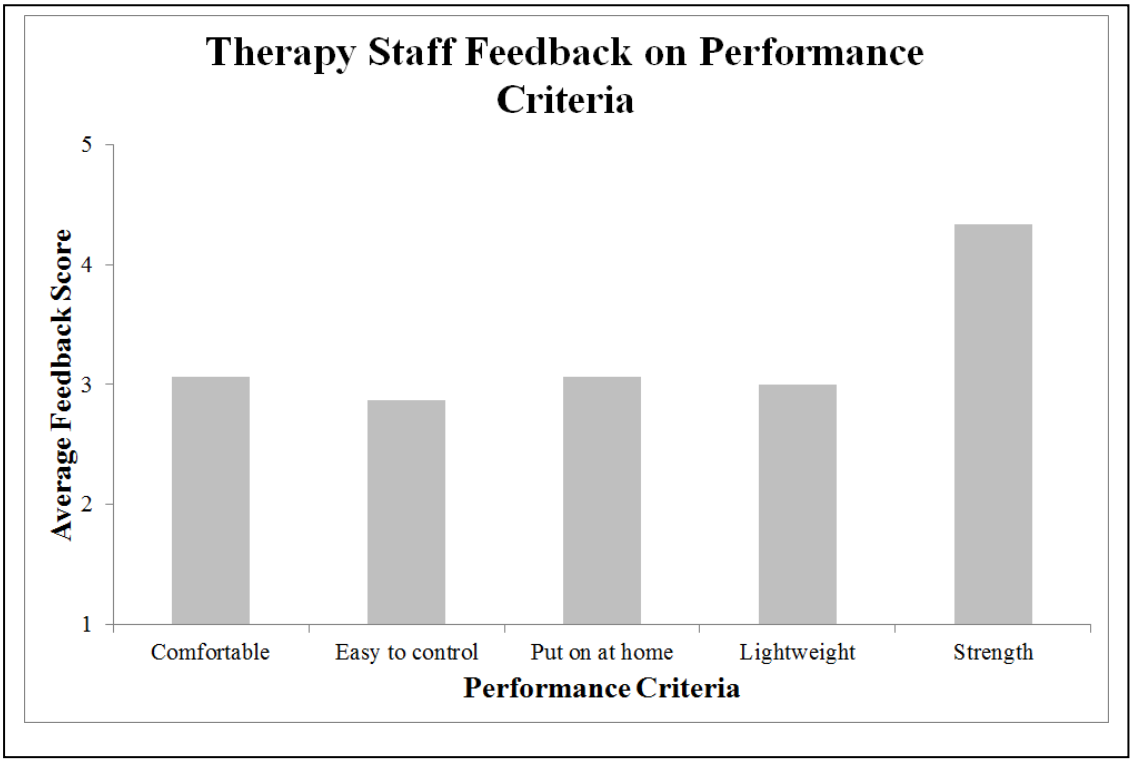

Figure 41: Bar chart illustrating the average scored responses for the feedback discussion points from the Medical Staff [230].

weight of the device are also likely to be a contributing negative factor to the scores for the comfort (3.067±0.799) and the ease of putting it on (3.067±1.032), as when discussing the comfort the weight of the forearm was often mentioned to be the main source of discomfort, in part due to the size of the unit obstructing motion at the elbow for the wearer as well as the weight. From this feedback it is clear that the forearm unit should be redesigned to improve both of these factors by reducing the number of components that are required.

The other factor contributing to the comfort of the device was the tightness at the wrist, although the lower scores the volunteers here who had issues with tightness at the wrist, as with the previous participant testing, appear to be associated with having smaller wrists and forearms, this results in the

strapping needing to be tightened further to ensure that there are no air gaps due to the excess material, it is likely that this issue can be resolved by making gloves of varied sizes to best fit the wearer as well as tailoring the length of the Velcro strapping to their body, however this can still possibly be tightened too much, so alternative methods of sealing the glove and creating the vacuum will be considered.

With respect to donning and doffing the device (3.067±1.032) the patients living situation has to be considered, as a patient who has a dual impairment of the hands will not be able to get the device on without assistance, and would also present a challenge for a hemiplegic patient unsupported. It was widely considered from the discussion that with assistance, the device becomes very easy to put on. They felt that the main sources of this difficulty in hemiplegic patients was tied into the weight of the forearm making it difficult to keep their impaired arm stable when putting it on as well as having to secure the strapping with no sensitivity in their wrist will make it difficult to determine if it is tight enough, or if it is too tight and they then risk impairing their circulation to the hand. Both of these factors are to be reviewed in light of their impact on the wearer's comfort so these concerns are additional factors for change. Getting the device on and off has a further challenge, that they are putting on a dual layered glove, this makes the wearer unsighted to the position of their fingers in the glove and as the sensory feedback they receive will be reduced this could result in them pushing their hand into spaces within the glove that it cannot fit, this risks twisting and harming the fingers as well as possible damage to the internal mechanics of

the glove. A solution to this would be to form the gloves from a transparent layer so that they can see where each finger is to make sure that they are positioning them correctly.

The only criteria to score below the average line was the control system (2.867±0.64), whilst their concerns were multifactorial, the main one was that the pulley system required a considerable amount of management due to the cables leaving their groove and wrapping around the spindle. After the previous trials, it was found that the device was wearing down the inner hole in the plastic pulleys that resulted in a decline in performance that would eventually lead to minimal rotation. Consequently these components were replaced by metal alternatives, however the groove on these pulleys was not as deep, consequently at full flexion the cables would overspill the pulleys and begin to wrap around the spindle. This was a distraction that the user has to manage that may result in them watching the cables when operating the device rather than paying attention to what they are doing and becomes increasingly challenging for the patient if they are unable to ascertain the strength of the force that the cable is exerting on their hand. This potentially runs the risk of harming the user if not properly managed and is obviously not an acceptable performance. The cables were kept intentionally long so that the forearm could be positioned at a comfortable location for users with longer arms, so this would need to be scaled to fit the user and the excess cable removed for the next stage of development. This will partly reduce the probability of this error occurring and reduce the risk, that could be further lessened by the fitting of a mechanical brake to stop the rotation of the

motors passing a specified point, that could also be adjusted to suit each patient's needs along with possible training for the patient and any carer that they have, this was seen as a possible negative by the staff as it means that the device is not completely intuitive and may require more regular support and maintenance to ensure its performance. Additionally the nature of the control system means that it is limited to patients with a healthy hand or carer to operate the control system. The choice of switches received mixed feedback, with some thinking it was good that they were to be pointed in the direction of movement whilst others thought that they may be too stiff for patients to activate coupled with the risk of them catching when moving around. Replacing the switches with buttons would resolve these issues, but still carries the concern that multiple switches meant each finger required individual management that may be too much for some patients to use and would benefit from a unified control system that operated all of the fingers at once. To get multiple control options unified onto one singular control would require a computerised component such as a touchscreen, where the control options could be displayed on a menu that would allow the user to pick out the desired command and perform it. This also runs the risk of the patient observing the screen rather than observing what they would be doing as mentioned previously, but the electronic display would allow for feedback to be illustrated on the screen that should keep them aware of the their hand position.

Discussion

From the discussion, the forearm unit was the greater source of concern for the staff, in particular with respect to its weight and size. It was an expressed concern that patients with shoulder and elbow impairments would not be strong enough to lift their arm when wearing the device, however for patients with acute impairments that are limited to the hand, such as some spinal cord injuries; there is a scope to use the device for support. For the current prototype model the forearm's size is due to necessity, so an optimisation of the components should create an opportunity to reduce its size to one that would be more appropriate for those with smaller limbs. The primary way this will be achieved is by unifying the power supply from multiple sets of batteries into a single rechargeable lithium battery.

With the amount of required surface space being reduced this also allows for the possibility for the forearm unit to be crafted to fit the patient's arm specifically, although consideration must be given to whether a mould or 3D printed forearm would increase the cost of production too significantly to contradict the low cost aim of the design. Additionally two of the respondents expressed concerns over the comfort of the forearm unit due to the vibrations of the motors, this issue could be resolved through making the forearm a complete unit that the motors are integrated with should reduce the possible vibrations that are transferred between the components.

Concerns were also raised over the cable and pulley system, as the cables of the prototype were scaled to ensure that they could be used by comfortably

by a wearer with long forearms, this meant that for those with shorter limbs there was excess cable that could result in an overspill from the pulley when in use that would often result in the cable wrapping around the body of the pulley instead of the groove, which reduces the performance and can also result in the user watching the cables instead of what they are attempting to grasp. This should be resolved in two parts, firstly by scaling the length of the cables to the user to reduce the amount of excess cable in the device as well as increasing the depth of the groove of the pulley. Making these changes should result in the device not requiring micro management to operate and should result in giving the wearer an improved sense of control.

There were two factors for how control of the device is managed that, firstly in term of the interface that patient has with the device and secondly with the individual control of each finger. For the first it was considered that the switches may be too stiff to operate for weakened or aged users, and they also carry the risk of impacting other objects when moving around and unintentionally switching the device on. It was considered that a button or touch screen control system would be more suitable for the patient as there are no strength requirements, as well as not having to remember the directionality of the switches. Whilst touch screen technology is a young field, due to its prominence in modern personal electronics the technology is advancing rapidly in terms of capability and cost so should be less of issue for low cost production in the near future. For the current model of prototype each finger is independently controlled by the user, which offers flexibility of control to a skilled user but may be challenging to operate for a novice. It

was thought that the device would benefit from an integration of the fingers that would provide a more linear control system, and if integrated with the previously mentioned touch screen, this would allow numerous combinations of possible movement.

With respect to the glove the two main concerns were over the tightness of the strapping at the wrist as well as the warmth of the gloves, where if the inner layer is exposed to sweating from the wearer it can increase the difficulty to remove the glove depending on the size of their hand. Both of these issues are resultant of the creation of the vacuum and are therefore not as easy to remove. The simplest solution to reduce the temperature would be to remove the fixed connection between the tubing and he outer glove and replace it with a valve that would allow the tubing to be detached when the vacuum is not in use and allow air to flow into the glove at a higher rate, the downside of this is that it creates another vulnerability where the vacuum can fail as well as asking the patient to remember to manage it when they are using the device. As for the tightness at the wrist, the Velcro strapping must be tightly secured to ensure that no air is entering the glove at the wrist and compromising the vacuum, however as the patient's wrist gets smaller then the number of times the strap is wrapped around their wrist increases, increasing the pressure. This can be uncomfortable due to the prominent blood flow at the joint, and if the strap is secured too tightly, then there is a risk of obstructing this flow. The strap is a component that would benefit from being scaled to fit the wearer as this will mean that it is not excessively wrapped around wrist, however this is no guarantee of comfort. One

possible solution is to change the method with which the wrist is secured, such as by utilising a zip or tying it in place. Tying the glove to secure the vacuum could increase the complexity of getting the love on if the patient were fitting it to their own body, as tying laces is traditionally a two hand job, whilst the zip would be dependent on the glove's wrist diameter always being an exact match to the patient's wrist and forearm as there is no adjustable element. It is possible that an elastic strip, such as those used in stretchable clothing may provide a solution here. Alternatively, if the previously discussed reduction of the forearm unit is completed then it becomes possible for the gloves to be extended further down the forearm and away from the wrist which should improve the comfort by moving the strapping from the joint.

The tightness of the rubber material, particularly when coupled with sweating can increase the difficulty of getting the device on and off the hand, this is particularly noticeable when a participant with a larger hand wore the device as some of the components near the wrist within the glove could become dislodged from their mooring. The obvious first stage to correcting this is to tailor the size of the gloves to the size of the user's hand; however this will not stop the material from becoming sticky when the user wears the glove for a prolonged period and sweats inside it. For this a less tacky material is required for the inner layer to stop an accumulation of sweat around the wrist that makes the rubber become sticky. Additionally two of the respondents considered the fingertips of the outer layer to have insufficient friction to retain a grasp on a plastic bottle, whilst it was sufficiently high to grasp raise

and tilt the bottle, once the arm was fully pronated the bottle would slide out of the grasp of the hand. This may in part be due to the friction of the plastic used in construction of the plastic bottle, additionally it may be the result of the hand only gripping the bottle with three fingers or due to thumb only being able to move in flexion and consequently not taking an ideal supporting position. The rubber gloves are designed to be non-slip when wet, but would seldom be used with objects that can crumple under pressure, placing a high friction fibre on the fingers may increase the friction force at the fingertips and improve the grip strength of the device. Beyond the material of the fingertips it may be beneficial to investigate the possibility using all five fingers for flexion as well as the possibility of an additional axis for the thumb to allow abduction and adduction to be completed.

Regarding other areas of the device's functionality that the medical workers would like to see improved was a request by seven of the staff to provide the device with the capacity to operate in extension as well. Several others also commented that the device could be improved further by extending the design to support a wider range of arm motion, such as supination to improve its validity, as whilst many expressed an interest in the design and thought that they had patients who may benefit from the use of a future version of the prototype they hoped that support for the full arm would be possible to work with those who have a greater impairment than just the hand. Making an extension version of the prototype should be straightforward as the principle of the device is easily transferrable, but operating both flexion and extension from a single motor is increasingly more complicated due to the rotation of

the pulley, as if both cables for flexion and extension are connected to the pulley as it rotates they will both rotate around the axis and shorten, only pulling the end point of the finger towards the motor with no allowance for rotation to occur.

Many of the staff also stated that they would like the device to be able to accommodate fine motor control in addition to the current grasping; these ideas were also suggested alongside creating an additional axis for the thumb to improve control as well as increasing the variety of movements that can be achieved by the device. Additional thumb movement would be to integrate abduction and adduction which would give the thumb a greater range of motion and make it more reflective of how the thumb is used by healthy patients as the flexion/ extension currently provided is strong but is not reflective of the complexities of the motion that the thumb has. Fine motor control will require the removal of the plastic caps in the fingertips as they are too large for precision tasks and deny the wearer the opportunity to receive tactile data from what they are in contact with. Changing the posture of the fingers that are achieved by the device will however require a revision of the gloves internal mechanics as the cable system only enables one way of moving the finger due to its simplicity of design, but this may be able to be revised in the future. If the device can be developed to enable fine motor control then it would make sense to integrate as many motions as possible into the design, although care must be taken in how they are presented to ensure that the patient is able to fully utilise its functionality, if multiple patterns of movement are to become a feature of the device it would make

sense to move to a touch screen control to ensure that the user can have a clear choice in movement pattern.

There were also requests from the staff to consider integrating a force feedback system to the device so that the patient could get an indication of how they were using the device, as currently the only indication of how much flexion the fingers are undergoing is through observation, which is not intuitive and provides no perspective on when contact occurs with the object they are attempting to grasp nor how tightly it is being grasped, which may result in rushed attempts to lift heavy objects or squashing objects that are not rigid in structure. When providing feedback there are alternative directions, applying a reduced force back onto the user's forearm may give a direct correlation to help the wearer understand how much force is being exerted, but this relies on the patient having full sensitivity in their arm to interpret it. Other alternatives include light emitting diodes or an audible warning, whilst if a touch screen is being integrated for the control mechanism the it is entirely possible to provide direct information for the user whilst it is in use, however it is important to ensure that the screen does not becoming the sole point of focus for the user to ensure that they are aware of where the hand is to ensure that it does have a good grasp on the object.

One of the orthotists also suggested that it would be beneficial to move the control unit away from the forearm, whilst there is a benefit to moving some of the components away from the forearm to reduce the weight, the issue that moving the control system raises is where to position it, as it could result in the wearer not looking at the position of their hand whilst they are

interacting with the control and may result minor accidents occurring, such as knocking over cups or glasses which they are planning on picking up, whilst this may also happen with the control on the forearm, the hand should still be in the field of vision of most patients to reduce this possibility.

Lastly the aesthetic factors were also mentioned as an area to improve, namely the outer appearance of the device and the noise that is generated by the pump. This is understandable if the intention is to provide a device for home use, as the patient should be comfortable with its appearance and would not want to be put off f using it by the amount of noise generated, particularly in their home. For the pump a smaller version may be beneficial that generates fewer vibrations when in use, alternatively there are 'silent' options available for pumps, but the level of performance must be balanced against amount of noise that it generates to suit the requirements of the device. From an appearance perspective, the concept of making the device as a single integrated unit is beneficial, and may also benefit the process of getting it on and off as well in the performance of the device as mentioned previously

Conclusion

Successful testing of the prototype with subjects is an important stage of development, as it proves that the principles of the design and the mechanisms are capable of performing finger flexion. The testing protocol was also found to be successful for the device to complete the desired

activities. These measured performances were supported by the feedback that has been gathered from discussions after testing with the participants. The discussions showed that the participants were impressed with the level of control that was available to them given that the prototype only provides control of three fingers and it is a motorised cable driven system. There were concerns about the comfort of the device; part of this was the weight, although this can be negated in future designs by relocating some of this weight. The other issue of comfort was related to the temperature of the device when worn, however gloves with alternative materials could be developed to reduce this. Further sampling with medical workers showed that the device's main asset is in its grasp strength and that whilst the staff did have some patients whom they felt could benefit from using the device in its current format, there were further improvements and refinements that they wished to see to before they would consider using it with other patient groups, most notably for the weight of the forearm unit and the tightness at the wrist. The feedback that they provided will form the basis for future design improvements to be made to the device.

Chapter 6 Discussion and Conclusions

Chapter 6 Discussion & Conclusions

Discussion

This thesis has outlined the process that has been undertaken to develop a cable –driven motorised glove that secures to the wearer using a vacuum. The design developed in this thesis is intended to be assembled at a low cost whilst being adaptable to a range of patients as well as being an option for home use on their own as both a tool for exercise as well as for assisting them in daily living. This system has also been trialled with unimpaired volunteers and medical workers who have reviewed its performance and provided feedback on their experience. It is hoped that with the highlighted refinements to be made in the future this concept could be used as a tool in therapy of the hand for impairment.

The development of this prototype glove has gone through several stages; initially there was a review of previously conducted research to assess the strengths and weaknesses of previous robotic designs, as there are a wide range of theories on how to get the best results in therapy. Because there was not an established base to develop from it was thought that the best way to develop a system that patients would want to use was to discuss with former patients how they felt about their therapy and what areas needed to be targeted for improvement. The findings of the interviews and questionnaires from this investigation were combined into the QFD process to assess what the key features of design were for patients. It is a design route that has been used in the development of designs for impaired

populations previously [225 & 226]. The finding with respect to its function was that patients were most disappointed with the level of recovery that had occurred in their hand, in particular with the act of grasping. When coupled with the design prerequisites this meant that the device was intended to be a low cost hand grasper that patients could practice with at home. Further key design considerations that were featured from the QFD were that they wanted the device to be lightweight with a straightforward and responsive control system that allows them the freedom to move around whilst using it. It is an understandable criticism of this design that it was based from the feedback of a small sample of former patients who were post treatment. Although they were asked to reflect on their treatment when answering the questions it is possible that current patients would have provided different feedback that may have influenced the design differently.

The outcomes of this component of the study led to the creation of a design for a cable-driven vacuum glove that powered the flexion of the thumb and first two digits. Whilst cable driven devices have been used before [40 & 41] this one used a novel solution to the problem of sizing the device and securing it to the hand by making a dual glove that a vacuum was used to extract the air from to position suction cups that composed the frame of the device. This low cost design could then utilised by a wider range of patients, as the size of the device could be assessed in general terms, such as small, medium or large. The position of the external actuator was intended to reduce the total weight of the design whilst a prototype was assembled using home brand rubber gloves with the other components sourced at a low cost.

When assembled the device was a wearable mechanism that did not fix the wearer in position.

This developed prototype was then tested, firstly to assess its feasibility for powering grasping by controlling a 3D printed plastic hand. The motion tracking test showed that the artificial hand was capable of lifting some items, but due to the shape of the hand struggled to lift the largest and smallest of these. Some differences were also noticed in the angles of the joints when the device was put on, this suggest that the structure of the glove contributed to the differences in the recorded performance. As there was consistency in the results for when the wearer was grasping items both with and without the mechanism in action it would suggest that the remaining difference in the findings between the natural hand and the movement and the 3D printed hand was a result of the differences in the shape of the hand. From the later volunteer and rehabilitation worker discussions the strength of the prototype was considered to be impressive (4/5 and 4.333/5 for the groups respectively), whilst the testing suggested that there was a reduced joint rotation distally, that appeared to be compensated for at the MCP and PIP joints. This may be a result of the cable pulling on the fingertip in a manner similar to a tendon, but with the forces acting externally to the finger rather than internally as the cable shortening principle rotates the proximal joints first. It is possible that the discrepancy in performance for the 3D printed hand was a result of the lack of biomechanical coupling [109 & 110] that assists with integrated action of the finger joints, suggesting that the 3D printed hand activity was based on the stiffness of the joints instead.

Having proven that the prototype could perform its intended action with an artificial hand it was tested again with unimpaired volunteers. These volunteers performed a larger range of activities over a period of 90-120 minutes. All of the volunteers were able to perform all of the tasks whilst keeping their hand passive, although some struggled with the largest item due to a combination of the weight and their hand not being large enough to fully support it. After these trials had been performed, the volunteers were interviewed to get their feedback on their opinion of using the device. Overall the device was considered positive, but they also provided constructive feedback for adjustments to improve the device before it is used with a patient population.

Further to this trial a consultation was arranged with medical workers at a hospital to gather their perspective on the devices strengths and weaknesses based on their experiences with patients. After using the device to grasp objects that a person may encounter on an everyday basis they were asked for their opinions, with most feeling that the strength was sufficient for its intended purpose and may assist some patients that they are currently treating whilst specifying developments that they would like to see in the design to make it more useful to them.

The developed prototype glove achieves its stated aim of assisting the hand to grasp and release the fingers. This device is intended to be able to be used as a domestic aid to therapists as well as a tool for assisting living. The discussions from with the medical staff resulted in 10 of the 13 respondents saying that they believed the device could benefit some of their existing

patients. Whilst this feedback is positive, the discussions highlighted areas in which the device would need to be improved upon to increase the number of patients. The main groups that the prototype was considered to be beneficial to were spinal cord injuries and those with musculoskeletal diseases, if the device is intended to be compatible with a larger range of patients in the future then some adjustments and modifications would be required.

From the previous discussion with former stroke patients it was felt that recovery of hand motion could be improved if it were possible to provide them with a system that they would be able to use at home. To achieve this it was important to develop a system that was lightweight, easy to put on and also low cost to assemble. The discussions with the volunteers suggested that this was mostly achieved; however there were concerns with the weight if wearing the device for prolonged periods, in future designs the batteries will be removed from the arm unit to ease this strain and make it more comfortable. These observations were furthered by the opinions of the medical staff that were concerned about the weight of the forearm unit for disabled patients as well as the tightness in the wrist from the strapping (3/5 and 3.067/5 respectively); both of these factors increased the difficulty of using the prototype and getting it off after use and will need to be improved in future designs. The weight in particular is a primary concern as it limits the range of possible patients, as those with shoulder issues would be unlikely to be able to support the prototype in its current form.

The initial design has had to compromise on the aesthetic factors, however discussions with patient had shown these factors should take a secondary

place to the functionality of the device. The testing protocols showed that the device was able to grasp a range of objects provided consideration was given to the positioning and timing of the finger motions. Testing the device with a 3D printed hand found limitations with grasping large wooden blocks and marbles as the extreme ends of its capabilities, whilst the marbles were no issue for the volunteers and success with the $10cm^3$ wooden box was harder for those with smaller hands.

The motorised mechanism provides a straightforward control system to operate the device; however this can be advanced further through the use of a circuit which could unify the actions of the motor and make grasping responsive to a singular switch. Alternatively the circuit could have a second switch that would enable the wearer to differentiate between a pinch grip between the index finger and thumb and a full hand grasp so that the hand commands can be set depending on their requirements. This would allow us to progress further in terms of meeting the requirements of the patients outlined in the QFD. The discussion with the volunteers showed that they were happy with the level of control offered (3.833/5) by the device and were surprised at its strength as they were holding their hand in a passive manner. The staff had a lower opinion of the control system (2.867/5) which may have been influenced by the replaced pulleys which were made of metal so were more durable than the previously used plastic components but were shallower, resulting in more observation of the cable being required to manage the operation of the device. They also emphasised the importance of being able to provide the patients with a control system that allows for

multiple fingers to be controlled at once as well as offering a variety of grip patterns. These amendments would improve the amount of support that the device could offer to patients by enabling them to perform a greater range of activities.

The main change that the staff expressed was that they would like to have seen the addition of an extension component. The device has been developed with the intention of primarily being a rehabilitative device that also provides assistance to patients with grasping objects, as this was the most common concern of the patients that the author spoke to when gathering the initial information. The design's cable driven operating principle can be easily adjusted to accommodate those whose primary need is with help for extending the fingers, where the tendons and motors could be moved to the dorsal side of the hand to act as a controller for releasing objects. With further development and miniaturisation of the component pieces it could even be applied to motorise both the flexion and extension of the finger movement and give the patients remote control of their hand positioning.

It is intended for the final model of this design to have an built-in power supply that, along with the pump can be stored on the user without adding further weight to the hand or forearm, for example as a belt component. This would help to reduce one of the main concerns from both feedback groups that the device received (weight) as well as helping the design to better meet the stated requirements of the patients. As the device is intended for home use it could potentially be developed to operate with a mains power supply; however this will restrict the mobility that a patient could then achieve with

the device, as they would need to remain within range of the mains to operate it. Helping them to have some freedom of movement is one of the main areas that the patients were interested in from the QFD discussions so giving the patient an extended power cord could partly resolve this to allow them some mobility but would then add an element of risk, as there is an increased probability of someone who is less mobile tripping over the cord.

The volunteer and staff testing highlighted the importance of ensuring that each component fitted the wearer, as there was difficulty putting the device on for those with larger hands whilst those with small hands also had excess glove material that folded upon itself when the vacuum was active and lessened the effectiveness of the device. The forearm plate was also too large for small participants and constricted the range of motion they had at their elbow. The forearm can be readily adapted as there is excess material that could be removed to make the device smaller for all users, which will be increased if the batteries are removed from this surface, whilst the gloves will need to be developed as a range of sets if the device is to be taken to patient testing so that the efficiency of performance can be maximised across the patient groups, with the best fit being used. It is also important to consider appropriately sized gloves to accommodate children with CP for example. This is to ensure that the device is comfortable for the wearer to use, as this was a key objective from the discussion with patients. These issues contributed to the staff feeling that the device may be tricky for a patient to put on their own depending on the extent of their impairment (3.067/5),

however if they have a carer living with them who could assist it was believed there would be no issue.

Referring to the QFD stage 2 table set out previously, it was decided that an appropriate target weight for any device was to be 800 grams as it is a technology that is intended to be worn on the hand and arm. The final prototype, when looked at in its two parts had its weight measured at 525 grams, with the shin guard weighing 350g and the glove component weighing 175g. This is under the target weight for the device, although this aim may have been set initially high as during the sampling some of the participants voiced their frustration with the weight of the device. This may have in part been due to the decision to secure the power supply for the motors to the arm plate, with the additional weight of the batteries increasing the downward strain on the wearer. Future designs may remedy this issue by placing the power supply away from the device on a support placed on the torso. This should help to balance out the weight distribution across the wearer's body to make the experience more comfortable for them. This may increase the complexity of setting up and maintaining the device, so an alternative option is to condense the power supply into a lighter, singular battery that remains part of the arm unit. Both of these directions have their advantages over the initial prototype, but share the benefit of reducing the weight that is borne by the wearer. Achieving this is the largest obstacle in making the current design a system that can be worn by a patient whilst not impacting their mobility.

The majority of rehabilitative devices are designed to assist with finger extension, as the intention is to counteract finger spasticity that is common with conditions such as multiple sclerosis or stroke. In contrast the device detailed in this thesis operates to assist finger flexion as this was the main request from the discussion with former patients raised in chapter 2. This differs from the direction of many rehabilitative devices in the field, and the research direction may have deviated from the norm due to the small sample size for the discussion or may have been the stage of recovery that the volunteers were from. Ultimately as the device is intended to compete with the current range of artificial assistants there are plans to develop the device further in the future to enable it to perform both flexion and extension of the fingers as was requested by the medical workers. A comparison of the prototype's features against those for the available to purchase products that are listed here can be viewed in Table 6.

The most established device in the field is the MIT-Manus (MIT, Boston, MA), which is a robotic arm with a handle attachment that can be moved by the operator and these commands translate into instructions for an on-screen display to complete interactive tasks. MIT-Manus utilises an impedance control within the device to ensure that it remains compliant in users of varying muscle tone. It is used in physical therapy by patients, however to operate the system their affected arm is strapped into the unit and the patient is secured to the chair in front of the computer screen. This provides a solid and consistent platform for the movement, however prohibits them from moving when coupled with its weight of 271kg, so it cannot be additionally be

used as an assistive tool as the prototype is intended. Additionally its estimated cost of $9977 per patient for treatment makes it a considerably greater investment than is intended for the prototype.

The MIT-Manus does have an established record of improving patient outcomes in the long term when they are using the device regularly [246 & 247] and has worked with a range of conditions such as stroke and cerebral palsy [248]. The successor to the developments of the MIT-Manus was the InMotion (Bionik, Cambridge, MA), where the computer and working area were integrated into one movable unit, whilst the patient was still required to grasp a control stick to operate the program as well as being strapped into the chair in front of the monitor [249].

Both the SaeboFlex and SaeboGlove allow finger flexion but both of these devices use a splint to keep the hand in a start position with finger extension. This splint also supports wrist posture which is a feature that has not been addressed with this developed prototype. Whilst the Velcro strap may be used to provide some assistance to wrist position, this would not be to a suitable level of consistency or accuracy to replicate the benefits of wrist splints to hand position [250]. However as the forearm unit will be getting redesigned as per the request of the rehabilitation workers, there is the possibility to consider a wrist support as an additional feature in the future.

Table 6: Table of Market Rehabilitation Devices

	Prototype	MIT-Manus	SaeboFlex	SaeboGlove	SaeboStretch	Maestra Portable	Gloreha	MusicGLove
Cost	£105.35*	$9977 [237]	£924 [239]	£309 [239]	£177 [239]	$5594.59 [241]	€89.60 (per patient per 30 days) [243]	$489 [245]
Weight	0.525kg	271kg [238]**	0.4kg [240]	0.14kg [240]	0.22kg [240]	3.5kg [242]**	5kg [244]**	0.34kg [245]
Portable	Yes	No	Yes	Yes	Yes	Yes***	Yes***	Yes
User Interaction	Passive	Active/ Assistive	Active	Active	Active	Passive	Passive	Active
Control System	Switch					Hand Control Pad	Computer	

*Cost of componets.
**Total weight of device not worn weight
*** Additional unit for function must be carried with it

Both the SaeboFlex and SaeboGlove (Saebo Inc., Charlotte, NC) have adjustable components at the MCP allowing them to accommodate changes in finger length. That there is no means to adjust for the length of the distal phalanges is a limitation in the fit that these systems can achieve, as it is possible that the joint centres of the fingers will not match with the device in the SaeboGlove, whilst the SaeboFlex removes this issue by not assisting with motion of the DIP, as the two distal phalanges of the finger are contained within a moulded plastic cap which is anchored to the hand. These caps are available in a range of sizes and each component is custom fitted to the patient, which has an impact on the cost of the system. The vacuum principle used in the prototype in contrast allows the device to envelope fingers of any size provided that they are within the limits of the material, but as highlighted in Fig. 7 there can be variations in the level of performance if the cups are not well positioned on the phalanges. Developing gloves in a range of sizes would negate this issue in future iterations of the design, making it an advantage. Both the SeaboFlex and SaeboGlove are lighter than the currently developed prototype, as this is a feature that was targeted in Chapter 2 it is disappointing, but the intended adjustments to the forearm unit should allow the device to become lighter than the SaeboFlex for the wearer. Making the device lighter than the SaeboGlove may not be possible as it is 10g lighter than the current glove component on its own, and the SaeboGlove has no additional components, however changes to the materials in the glove layers may allow the glove to become lighter. The cost of the components for the prototype, £105.35, is

lower than the retail cost of both SaeboFlex (£924) and SaeboGlove (£309) respectively so the prototype has achieved this design goal.

For the SaeboFlex the four fingers of the hand are all moored to the same spring for motion, this reduces the independence that each finger can achieve in motion as the spring tension is set to keep all of the fingers in extension at once. Whilst the SaeboGlove keeps the fingers independent, increasing control, the device is intended for patients who display mild tone compared to the increased tone that is assisted with the SaeboFlex. The device proposed in this thesis is set out to give independent motion to each finger through the individual motors and switches on the control unit, which is different to the active motion for use of the SaeboFlex and SaeboGlove, meaning that they accommodate different patient populations. In terms of grasp support, the device uses the grip support provided by the rubber glove used in the outer layer, as well as the plastic caps between the layers, which provides a solid and consistent contact surface for grasping, however it lacks a tactile responsiveness to the surface of the grasped object, which is similar to the rubber coated fingertips that are used by the SaeboFlex but are in contrast to the non-stick grip surface the fingers of the SaeboGlove. Both of these design directions are considered to improve their respective devices grip strength, and the SaeboFlex has been shown in assessment to improve the performance of the shoulder and elbow joints, but has inconsistent returns on the performance of the wrist and fingers [251 & 252].

Saebo's other main device is the SaeboStretch, which is a dynamic splint that allows the fingers to be stretched and lessens the chances of

contractures becoming an issue which may happen with static splints. The system is capable of being adapted by replacing one component to accommodate differing levels of spasticity. The SaeboStretch also allows for positioning of the thumb and wrist to help with posture, and whilst the fingers can be repositioned they are set up to move as one unit. This means that the consistency of motion is reliable but the fingers do not get an opportunity to move independently, limiting the use the device can take on as an assistive tool. It is however the cheapest of these Saebo products (£177) and is slightly heavier than the SaeboGlove (0.22kg).

The Kinetec Maestra Portable (Thera Tech Equipment, Bloomingdale, IL) is a small hand and forearm unit that can be used to guide the fingers through both flexion and extension. The motorisation unit is positioned on the dorsal side of the hand and runs parallel to the fingers, each fingertip has an attachment covering the distal phalange that are connected together by a curved bar. As the parallel finger moves through finger rotation the connected bar will then move the fingertips in unison to complete both flexion and extension. It uses a bilateral forearm to support the wrist in motion and has a 15 minute pause capacity that can be used for a controlled stretch and rest period [253]. Both of these features are beneficial in comparison to the prototype, but come at the expense of weight, which in total is 3.5kg [242] although the control unit is not worn by the user so the weight directly applied to a patient will be lower than this. That said the control unit must still be carried around by the wearer for operation, which will allow them increased mobility but means that their unimpaired hand carries the control unit, limiting

the bimanual activities that can be performed as they move. The retail value of this device ($5594.59) is also considerably higher than the cost of materials that went into the prototype which is a positive for the design.

Cable driven gloves have been developed previously to help with finger extension, such as the J-Glove [40]. The unique feature of this actuated glove is in its multiple control methods, as like the prototype it can be operated by manual control switches, but can also be controlled by EMG signalling in the arm or by voice recognition, the three methods can even be integrated together to adapt it to the needs of the user. The integrated control method was advised from this study as using the EMG alone was not always definitive for interpreting commands when trialled with volunteers who have had a stroke. It is also impressive that the voice activated system requires only two minutes to set up for the user, given that it must be set up to respond to the wearer.

Further testing of the EMG system suggested that improvements in the control system had been made as the device helped the subjects to perform some grasping tasks faster, whilst there was no improvement in the lifting of a pencil [254]. Additionally some of the subjects showed increased muscular activity when performing the activities after 18 hours of practice over six weeks.

The J-Glove benefits over the developed prototype by having a greater number of control options as well as having a developed motor unit that is worn on the back instead of the arm, which would lessen the weight applied

to the upper limb. However the motion assistance for each finger is run from the same actuator, meaning that the device cannot differentiate between the fingers to give the patient more nuanced control of their hand.

The X-Glove uses similar principles to the J-Glove to assist with finger extension but is closer in design to the prototype from this thesis, where the control system for movement is stored in a unit on the upper arm instead of the forearm, although there is also a forearm unit that contains the actuators to avoid the performance being impacted by the elbow position, whilst also acting as a splint to support the position of the wrist. This results in a series of cables connecting the units that are more vulnerable to damage than with the prototype. Both the prototype and the X-Glove have designs that allow for motion of the fingers to be operated independently in contrast to the J-Glove's single actuator system which makes the devices more compatible with the requirements for an assistive role for patients. When trialled the X-Glove was used for repetitive passive stretching that led to a significant improvement in performance time, with 12% increase in grip strength and a 66% improvement in grip termination time, however these improvements had great variation across the subject groups [41].

A criticism of the device developed in this thesis is that the supported offered is passive rather than encouraging the patient to take on an active role in using the device. There is some research supporting the use of a passive device in rehabilitation, such as the Gloreha device (Gloreha, Lumezzane, Italy). Studies with a patient population [244] have shown the device to have beneficial impacts by reducing spasticity as well as increasing the Motricity

Index score in the upper limb (23 compared to 5.2 for a physical therapy group), although the patients used with the device did require a base level of mobility (Modified Ashworth Scale score below 3) to be considered suitable for the testing. There were also improvements noted in the subject's manual dexterity and grip strength after a six week intervention program (Nine hole peg test scores 0.16 compared to 0.02, Grip and Pinch tests 0.27 and 0.07 compared to 0.03 and 0.02 for the physical therapy group). These improvements were not observed in a previous study conducted over a two week training period, where the changes in outcomes were inconsistent across the subject group [255]. Another study found no improvement in the Motricity Index score but significant improvements in subject's Modified Ashworth Scale score ($p=0.03$, 0.005, 0.01 and 0.047 for the elbow, wrist, fingers and supination respectively) after a three week training period [256]. As the greatest performance improvements have been observed when the patient group were exposed to a longer intervention period this would suggest that extending the length of the intervention period would be beneficial to patients and is an argument for the merits a system that patients could use at home to allow them to have more exposure to a training schedule.

Like the device in this thesis the Gloreha uses a motor controlled cable driven system to control the activity of the finger joints but with the Gloreha the motors are positioned on the hand as the only forearm component is strapping to secure the components in position. The glove also leaves the palm and first two phalanges of the fingers uncovered, which should provide

a better tactile sensation for the wearer when using the device over the prototype, however the glove sheath comes in a set of sizes and cannot adjust to fit the wearer's hand in the same way that the prototype does so consequently for wearers with smaller hands the glove material may contort to fit their hand, as the cable is fully attached to the material in the fingers this can cause the cable to not be perfectly straight. Some adjustment is possible with the cables so as not to impact the wearer; however the loose material that accumulates may result in the cable twisting and not operating as efficiently as it would under ideal conditions.

The Gloreha system has an additional forearm brace that can also be used to exercise the elbow, which furthers the possible gains for patients, however both of these components utilise a computer program for practice that provides both audio and visual feedback to their performance, as well as having a large supporting power component which means that the device cannot be used in an assistive manner as the patient's range of movement is limited by the device. This is a limitation that is shared with the current iteration of the prototype; however future models of the design will remove this factor, making it an advantage as whilst the Gloreha glove weighs 35g and the brace 45g, the total of the system is 5kg, over 9 times the weight of the current prototype. In turn the separately stored computer component reduces the proportion of the device's weight that the user must bear which is an advantage of the Gloreha. The estimated price to use the system is €89.60, this is per patient and for a period of 30 days [244], so whilst the

value is less than the material cost of the prototype, as the period of usage gets longer this becomes beneficial in the prototype's favour.

The Isolated Orthosis for Thumb Actuation (IOTA, [257]) has a similar, but smaller mechanical set up to Gloreha as it was developed with the intention of home use. As the title suggests the device was intended to support motion of the thumb and was developed for use with a paediatric patient population. As the main mechanical drivers for the device were stored in an additional unit that could be placed on a table top alongside the child this meant that the user would bear a weight of 0.23kg, this is less than half the weight of the currently developed prototype however the prototype is able to accommodate two additional fingers and further efficiencies are intended in future models to reduce the weight. The initial developed model was monitored with on board angle sensors for the thumb joints and was able to be controlled both actively and passively with a cut out for the motors if the user began actively moving their joints.

The MusicGlove (FlintRehab, CA) is a developed system that uses a computer program to encourage the patient to actively move their hand to complete a task from a computer game that is used in tandem with it. Using a format similar to the Guitar Hero computer game the patient is encouraged to move their thumb and a selected finger into contact in time to the music. Volunteer reporting suggests that the users were more engaged when completing the activities in co-ordination with the music [258] and that improvement in the patient for successful 'notes hit' correlates with Box and Blocks testing scores. Further testing showed an increase in the hand

function (a 3.21 increase in Box Block Test scoring as well as an increase of 2.14 for the 9 hole peg test score) a month after a two week trial period with the device [259].

Whilst the MusicGlove is a device that requires active motion from the user to produce results, there is also anecdotal evidence to suggest that it can be used passively, where it is used in an adapted form of mirror therapy with a volunteer replicating the movement of their unimpaired hand when completing the program, including replicating mistakes. This resulted in a post stroke patient who had been diagnosed as completely flaccid to be able to twitch their fingers again [260]. With a worn weight of 0.34kg this is lighter than the prototype, but it is hoped that the next generation of the prototype will be lighter than this weight. The glove component costs $489, which is an advantage of the current prototype. There is also the option of purchasing the training suite for $1775 [261], with the computer system increasing the total weight to 1kg, which are both greater than the prototype.

The prototype developed in this thesis is intended to have two functions, as both a tool to support therapy and as an assistive device for daily living. The discussion with the rehabilitation workers would suggest that the device is closer to the later, as the grasp strength was considered to be good enough for that purpose scoring 4.333±0.617, however the discussion highlighted that improvements should be made in the weight (3±1.134), comfort (3.067±0.799) and control system (2.867±0.64) before looking to trial at home with patients, as they may encounter issues trying to get it on and off on their own (3.067±1.032). The key areas to improve on here are the

weight of the forearm unit, the tightness at the wrist and to change the currently used pulleys to reduce any need to micromanage the device, with the use of a touchscreen control being considered a secondary need, the details of which have been discussed in Chapter 5.

As a passive system, the prototype developed in this thesis has limitations placed on how effective it can be as a treatment tool in therapy. This was supported by the discussion with the rehabilitation workers, where they suggested it would be of most use to those with spinal cord injuries or muscular diseases. However the Gloreha system has suggested that there may be further scope for passive devices in rehabilitation provided the patient population is targeted correctly [244, 255 & 256]. Before the prototype could be used for testing of this nature it is important to address the outcomes that were raised from the feedback discussions, primarily the weight of the forearm and tightness of the wrist from a comfort perspective as well as integrating an extension feature that can work. If these adjustments are made to the design then the next stage of development is to trial the device with the previously outlined patient groups and if successful look for ways to develop the device to take it to a wider range of patients.

This future research could integrate an improved version of the device with a control system that allows for direct interaction, such as the use of a data glove [262 & 263] for bimanual action in a manner similar to the anecdotal story of using the MusicGlove for rehabilitation [260]. Alternatively the use of EMG system could be considered to control motion, as have been used with other hand control systems [100]. Further advancements in MMG technology

may see it surpass the capabilities of EMG, making them more suited for use with rehabilitative devices [126]. In the long term the ideal control system to integrate with the device would be an EEG as this would allow the patient to take direct and immediate control over their motion and could see this device be capable of assisting with the motor learning principles for neuroplasticity recovery.

Conclusion

This thesis attempted to design and develop a novel device that can be used as a tool to assist upper limb therapy as well as providing assistance in performing activities of daily living. To establish the requirements of what patients needed for home use a consultation was devised with former patients, where the key principles were highlighted through the use of QFD and were placed as the central concepts of design. The results suggested that the former patients were most eager for a device that could support hand movement and would provide them with the capacity to move. Unfortunately this sample was not as large as would be desired for such a project so it is not appropriate to draw definitive conclusions about the wider cohort of former therapy patients.

As it is intended to be used as a tool that the patient could take home to use for both practice and assisting living it was important to develop the design at a low cost, so the components of the prototype were sourced locally where possible. The design utilised the wearer's own body to provide the basis for

the exoskeleton, and was secured in place by the use of a vacuum, this resulted in the novel concept of a device that was loose-fitting when not in use but could quickly and consistently be secured into position when it needs to be used. This meant that the glove was adaptable to hands of a range of sizes, so there was no need for components that would require adjustments, helping to make it cheaper to produce. A cable driven mechanism was then utilised to power the flexion of the fingers, allowing the device to grasp and lift items of a variety of shapes and sizes.

The performance of the device was assessed through comparing motion analysis of a 3D printed plastic hand and a user performing grasping and lifting activities. In this the testing it was found that the prototype increases the contribution to joint rotation of the MCP and sees a reduction of the DIP. Consequently the device was strong enough to assist the 3D printed hand to grasp a selection of items, although its stiff joints contributed to the 3D hand not being able to fully replicate the motion of the real hand.

This was followed up by trialling the device with healthy volunteers and rehabilitation workers to gain their feedback on the device. These discussions were helpful in clarifying future directions for the design to ensure that it achieves its intended aims, as the first prototype of this design has been successful in performing the act of grasping, but had some concerns over the comfort. The healthy volunteers provided feedback on the features of the prototype, whilst their positive feedback on the strength of the device is encouraging it is not as definitive as this feedback would be from a patient population. Their feedback on how comfortable the prototype was,

where some concerns were raised over the sizing of the components as well as the temperature of the glove have been constructive and beneficial for further developments of the design.

For the rehabilitation workers there were similar concerns, with additional interest in improving the control system of the device as well as the weight to improve the mobility that could be achieved by a patient. Once these issues have been resolved in future designs a wearer will be free to walk around and operate the device which is a significant factor in the design of assistive devices. Once again the grasping strength was considered to be a positive for assisting daily activity, however too much weight was centralised on the forearm. The discussions suggested that whilst the device required some refinements in future research so that it would be able to be fully classed as comfortable for patients the prototype would be useable with orthopaedic patients but revisions should be made to the components before testing. This thesis has achieved:

- Conducted a consultation with former therapy patients to ascertain where their recovery had not been as successful as desired to identify what could be complemented by a robotic device, as well as which design features such a device should have.
- Designed a unique and novel exoskeleton that could be developed for use at home as an assistive and rehabilitative tool.
- Developed a first generation prototype at low cost.
- Tested the function of the prototype on an artificial hand that has no driving force.

- Practical testing with unimpaired volunteers to get their opinion on the comfort and function of the design.
- Conducted a discussion with rehabilitation workers over the strengths and weaknesses of the design as well as how they would like to see the device altered in future versions.

Submissions from the Research

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Appendices

Questionnaire 2: Patient Needs from Physical Therapy

** Please read the Participant Information Sheet as well as signing and dating the Consent From before you begin. Responses will only be acknowledged if they are received with a completed Consent Form. If you are unable to complete this form yourself an appointed person may assist you. **

Role: _____

Would you be willing to participate in a follow up interview? If Yes please complete the final page Contact Details to enable us to contact you to arrange the interview. This is not required if you have already provided these details in Questionnaire 1.

Yes: ☐ No: ☐

** A scoring system is used in this questionnaire. It is broken up into **topics with titles in bold.** They each have 5 factors to be assigned a ranking of between 1 and 5 this number should only be assigned once for each topic. **

Please mark the relevant box with a cross to indicate your score (X) if you wish to change your score please put a horizontal line through the previous response (X̶) and circle your final answer (⊗).

Joint Motion: which joint was the hardest to move before physical therapy began? (please rank each factor from 1 to 5 with 5 being the joint that was the hardest to move)

Shoulder:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Elbow:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Wrist:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Fingers:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Opposable thumb:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Function: which of the following actions were the hardest to do after physical therapy? (please rank each factor from 1 to 5 with 5 being the action which was hardest to perform)

Grasping: being able to grip objects

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Lifting: having the ability to pick up objects you are holding

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Releasing: allowing you to place objects down gently

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Tilting/ Rotation: turning the gripped object to use it such as keys in a lock or drinking from a cup

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Reaching: touching distant objects

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Interaction: which factor will give you the greatest feeling of control? (please rank each factor from 1 to 5 with 5 being the area that is most important)

Ease of selection: ability of the system to understand what you would like to do

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Starting motion: the ease of making the parts begin to move

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Stopping motion: the ease of making the parts finish moving

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Effort: the amount of focus needed to control the arm

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Feedback: the system interacts with you to tell you what position it is in

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Wearability: the factors that would most influence the time period the device is worn for (please rank each factor from 1 to 5 with 5 being the area that is the most important)

Comfort: should the device provide additional padding to support you?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Weight: how well balanced is the weight of the system?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Stability: does the device remain fixed in position during its use?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

(Fit 1) Tightness at joints: will the device be tight around the joints?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

(Fit 2) Tightness at muscles: will the device be tight around the muscles?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Other: additional factors to be considered (please rank each factor from 1 to 5 with 5 being the most important factor)

Set up: How long the system takes to set up?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Appearance: is the device large and bulky?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Noise: how much noise the device makes in motion?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Freedom: would the device allow you to walk around whilst using it?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

User safety: how important is ensuring the user comes to no harm?

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Topics (please rank each factor from 1 to 5 with 5 being the topic with the most important set of factors)

Joint Motion:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Function:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Interaction:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Wearability:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Other:

1:☐ 2:☐ 3:☐ 4:☐ 5:☐

Contact Details

** This form will be destroyed in line with the University's Data Protection Policy to ensure your personal details are not obtainable, no copies will be made of this form. **

Name: _____

Contact telephone number: _____

Contact e-mail address: _____

Appendix 2: BodyLanguage coding

!MKR#2

[AUTOLABEL]

LFA1 Left lower forearm thumb side

LWRA Left wrist bar thumb side

LH1 Base of second metacarpal(Left Hand)

LTH1 Head of first metacarpal (base of thumb)(Left Hand)

LTH2 Head of proximal thumb bone(Left Hand)

LTH3 Tip of thumb(Left Hand)

LH2 Head of second metacarpal (base of index finger)(Left Hand)

LIF1 Head of proximal index finger bone(Left Hand)

LIF2 Head of middle index finger bone(Left Hand)

LIF3 Tip of index finger(Left Hand)

LH3 Head of third metacarpal (base of third finger)(Left Hand)

LTF1 Head of proximal third finger bone(Left Hand)

LTF2 Head of middle third finger bone(Left Hand)

LTF3 Tip of third finger(Left Hand)

LH4 Head of fifth metacarpal (base of pinkie)(Left Hand)

LH5 Base of fifth metacarpal(Left Hand)

LWRB Left wrist bar pinkie side

LFA2 Left lower forearm pinkie side

Root = LH1,LH2,LH3,LH4,LH5

LeftLowerArm = LFA1,LWRA,LWRB,LFA2

LeftThumb = LTH1,LTH2,LTH3,

LeftIndexFinger = LIF1,LIF2,LIF3

LeftThirdFinger = LTF1,LTF2,LTF3

Root,LeftLowerArm

Root,LeftThumb

Root,LeftIndexFinger

Root,LeftThirdFinger

[Output Markers]

LFA1 Left lower forearm thumb side

LWRA Left wrist bar thumb side

LH1 Base of second metacarpal(Left Hand)

LTH1 Head of first metacarpal (base of thumb)(Left Hand)

LTH2 Head of proximal thumb bone(Left Hand)

LTH3 Tip of thumb(Left Hand)

LH2 Head of second metacarpal (base of index finger)(Left Hand)

LIF1 Head of proximal index finger bone(Left Hand)

LIF2 Head of middle index finger bone(Left Hand)

LIF3 Tip of index finger(Left Hand)

LH3 Head of third metacarpal (base of third finger)(Left Hand)

LTF1 Head of proximal third finger bone(Left Hand)

LTF2 Head of middle third finger bone(Left Hand)

LTF3 Tip of third finger(Left Hand)

LH4 Head of fifth metacarpal (base of pinkie)(Left Hand)

LH5 Base of fifth metacarpal(Left Hand)

LWRB Left wrist bar pinkie side

LFA2 Left lower forearm pinkie side

LH1,LH2

LH2,LH3

LH3,LH4

LH4,LH5

LH5,LH1

LFA1,LWRA

LWRA,LWRB

LWRB,LFA2

LFA2,LFA1

LH1,LTH1

LTH1,LTH2

LTH2,LTH3

LH2,LIF1

LIF1,LIF2

LIF2,LIF3

LH3,LTF1

LTF1,LTF2

LTF2,LTF3

LHNDV1

LHNDV2

LHNDV1,LH3

LHNDV2,LH4

%line

[Output Angles]

LeftThumbJ1ProjAngles

LeftIndexFingerJ1ProjAngles

LeftThirdFingerJ1ProjAngle

LeftThumbJ1AbsAngles

LeftThumbJ2AbsAngles

LeftThumbJ3AbsAngles

LeftIndexFingerJ1AbsAngles

LeftIndexFingerJ2AbsAngles

LeftIndexFingerJ3AbsAngles

LeftThirdFingerJ1AbsAngle

LeftThirdFingerJ2AbsAngles

LeftThirdFingerJ3AbsAngles

LeftThumbJ1ProjAngles2

LeftIndexFingerJ1ProjAngles2

LeftThirdFingerJ1ProjAngle2

LeftThumbJ1ProjAngles3

LeftIndexFingerJ1ProjAngles3

LeftThirdFingerJ1ProjAngle3

[SEGVIS]

ORIGINLHand1

XAXISLHand1

YAXISLHand1

ZAXISLHand1

ORIGINLHand1,XAXISLHand1

ORIGINLHand1,YAXISLHand1

ORIGINLHand1,ZAXISLHand1

Appendix 3: Discussion with non-patient volunteers

1. Did you find the device comfortable to wear? (please score from 1-5 and expand for detail)

2. Do you feel that changes to the material or structure could improve your comfort? (please expand for detail)

3. Did you consider the glove to be a hindrance when grasping any of the items? (please score from 1-5 and expand for detail)

4. Did you feel that the items were secure when you lifted them? (please score from 1-5 and expand for detail)

5. Do you feel that using the device changed how you would have attempted to grasp the device? (please score from 1-5 and expand for detail)

Appendix 4: Rehabilitation workers Questionnaire (English version)

Job Title/Role

Experience

1. Do you believe that the device is comfortable to wear?

1	2	3	4	5

2. Do you believe that the device is easy to control?

1	2	3	4	5

3. Do you believe that patients would be able to put this on at home?

1	2	3	4	5

4. Do you believe that it is sufficiently lightweight to be used at home?

1	2	3	4	5

5. Do you believe that the device has a strong enough grip to assist patients at home?

1	2	3	4	5

6. Do you have patients that you believe could benefit from using this device?

6.1. If yes, which groups of patients?

6.2. If no, why not?

7. What areas of device do you feel could be improved to make the device useful to patients that you treat?

Appendix 5: Rehabilitation workers questionnaire (Chinese version)

Job Title/Role

Experience

1. 您认为这款设备穿戴起来是否舒适？

1	2	3	4	5

2. 您认为这款设备的控制和操作是否简单容易？

1	2	3	4	5

3. 您认为病人在家里是否有能力戴上这款设备？

1	2	3	4	5

4. 您认为这款设备的重量是否足够轻，从而使这款设备能够让病人在家使用？

1	2	3	4	5

5. 您认为这款设备是否有足够强大的抓握力，使其能够在家里辅助病人？

1	2	3	4	5

6. 您是否有病人能够从使用这款设备的过程中受益？

6.1. 如果有，哪种类型的病人可从中受益？

6.2. 如果没有，为什么？

7. 为了使这款设备能够对您的病人起到帮助，您认为这款设备还可以从哪些方面进行改进和提高？