University of Alberta

Upper Extremity Neurorehabilitation

by

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Abstract

The work presented in this dissertation was focused on developing an affordable, automated, upper extremity exercise system suitable for individuals with stroke and spinal cord injury (SCI). The three studies presented in this thesis demonstrated the efficacy of functional electrical stimulation-assisted exercise therapy (FES-ET). Furthermore a protocol was developed to implement FES-ET in participants' homes via tele-rehabilitation. The protocol included the use of an improved version of the "bionic glove", an FES device that enhanced hand grasp and release in SCI individuals in combination with a custom-built workstation that enabled task-oriented rehabilitation in the home setting, supervised over the Internet.

In the course of these studies, an objective hand function assessment tool was developed to complement tele-supervised FES-ET and provide the therapist with an unbiased evaluation of the participant's impairment. A major section of this dissertation is concerned with the development and testing of a novel exercise workstation named the "ReJoyce" (Rehabilitation Joystick for Computer Exercise), that can assess hand function electronically. The ReJoyce is an instrumented workstation that provides standardized upper extremity rehabilitation based on

ADLs, in the guise of computer games played by manipulating attachments on the device. The three studies presented in this thesis focus on the scientific merits and the logistics of providing tele-supervised FES-ET with this workstation. The first study demonstrated the feasibility of treating and assessing individuals who had recently suffered a stroke on the workstation. The second study explored the relationship between the quantitative assessment of hand function with the workstation and two widely-used clinical tests. The last study involved daily, tele-supervised FES-ET or conventional exercises and therapeutic electrical stimulation (TES), maintained for 6 weeks, with SCI participants spread out over a large geographical area. FES-ET performed with the workstation resulted in statistically significant and clinically important improvements in hand function that were greater than those produced by the more conventional protocol. The results demonstrated the importance of including a range of exercises aimed at improving both strength and dexterity. It is concluded that tele-supervised FES-ET on a standardized workstation is feasible, effective and affordable in the current healthcare setting.

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I wish to extend my outmost gratitude to my PhD supervisor, mentor, and friend, Dr. Arthur Prochazka. Our first meeting on the 5th floor of the Heritage Medical Research Centre has fundamentally changed my life for the better. Your passion and dedication to help those that suffer from permanent disability is extremely admirable and noble. The unwavering support I have received throughout my stay as your graduate student has been remarkable even during times of extreme hardship. Working with you, I have learned much more then is described in this dissertation and for every interaction I am extremely grateful. I look forward to a very long and prosperous friendship.

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List of Abbreviations

Abbreviation	Definition
ADL	Activities of Daily Life
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
AOU	Amount of Use
ARAT	Action Research Arm Test
ASIA	American Spinal Injury Association
AutoCITE	Automated Constraint-Induced Therapy Extension
BDNF	Brain Derived Neurotrophic Factor
CIMT	Constraint Induced Movement Therapy
CKS	Combined Kinematic Score
CMC	Carpometacarpal
CNS	Central Nervous System
CPM	Continuous Passive Motion
CSF	Cerebrospinal fluid
df	degrees of freedom
DIP	Distal Interphalangeal
EBRSR	Evidence-Based Review of Stroke Rehabilitation
EMG	Electromyography
ES	Electrical stimulation
FES	Functional Electrical Stimulation
FES-ET	FES-assisted Exercise Therapy
FIM	Functional Independence Measure
FMA	Fugl-Meyer Assessment
FMRI	Functional Magnetic Resonance Imaging
fROM	functional Range of Motion
H-reflex	Hoffmann reflex

Abbreviation	Definition
HSD	Tukey Honestly Significant Difference
ICH	Intracerebral Hemorrhage
MAL	Motor Activity Log
MCID	Minimal Clinically Important Difference
MCP	Metacarpophalangeal
NDT	Neurodevelopmental Treatment
PC	Principal Component
PIP	Proximal interphalageal
PNF	Proprioceptive Neuromuscular Facilitation
PNS	Peripheral Nervous System
QOM	Quality of Movement
RAHFT	ReJoyce Automated Hand Function Test
ReJoyce	Rehabilitation Joystick for Computer Exercise
ROM	Range of Motion
SCI	Spinal Cord Injury
SCIM	Spinal Cord Independence Measure
SCIRE	Spinal Cord Injury Rehabilitation Evidence
SSD	Sums of Squared Differences
TES	Therapeutic Electrical Stimulation
TMS	Transcranial Magnetic Stimulation
VNC	Virtual Network Computing
VR	Virtual Reality
WMFT	Wolf Motor Function Test

Chapter 1

Introduction

The incredibly complex system of the arm and hand has a remarkable 31 degrees of freedom of movement and has allowed the human species to excel far beyond other organisms. Our hands have been used for manipulating objects, communication, expression, balance and a variety of other functions. This system is made up of bones, joints, ligaments, tendons and muscles controlled by the nervous system. The system's complexity and our dependence on the upper extremity for daily activities, is reflected in the relatively large proportion of the sensorimotor cortex dedicated to the control of our hands. Nevertheless we tend to take this system for granted, and our overwhelming reliance on normal hand function only becomes apparent once we incur deficits.

Normal hand function is of utmost importance for an individual's independence. Loss of hand function can severely affect the activities of daily life (ADL) one can perform [1] [2]. For example, severe motor impairment can result in the inability to care for oneself, and an increased dependence on others for help in performing simple tasks. It also tends to compromise an individual's ability to participate in work, social and family life. There are numerous injuries that can cause loss of hand function including but not limited to arthritis, stroke, cervical spinal cord injury, peripheral nerve injury, complications following hand surgery and edema. Of all of these, stroke, and spinal cord injury are the leading causes of disability worldwide, with strokes making up the largest group [3] [4].

Poor hand function directly influences the quality of life of stroke survivors [5]. It incurs a lifetime cost of over $100,000 per person living with stroke [6], and between $500,000 and $2 million for an individual with a spinal cord injury [7]. Improving hand function should be made more of a priority as it can increase personal independence and quality of life and in doing so, reduce the financial burden to society of these devastating neurological injuries.

1.1 Anatomy of the hand

The hand has a complex anatomy, containing 27 bones including the 8 located in the wrist. The wrist and hand should be considered one functional unit as the majority of the muscles used to power the hand and wrist are located in the forearm. The incredible range of movements, forces and manipulative capabilities exhibited by the human hand is the product of its anatomy, muscle properties and neural control.

1.1.1 Joints

Due to differences in anatomy, the fingers and thumb will be described separately. At the base of each finger, beween the metacarpal bones and the phalanges is the metacarpophalangeal (MCP) joint. The proximal interphalageal (PIP) joint is located between the first two phalanges of the fingers. The distal interphalangeal joint (DIP) makes up the last knuckle between the second and third phalanges.

At the base of the thumb near the wrist is the carpometacarpal (CMC) joint, also considered a joint of the wrist. The other two joints of the thumb are the metacarpophalangeal (MCP), and the interpahlageal (IP) joint. The thumb MCP joint is located at the base of the first thumb phalange whereas the IP joint is the more distal joint

The wrist is composed of 8 small bones each contributing to the movement of the wrist. To simplify we can refer to proximal carpal row joints and midcarpal joints. The proximal carpal row joints interface with the ulna and radius forearm bones. The midcarpal joints are involved in metacarpal movement.

Figure 1 illustrates the various bones and joints of the hand.

The forearm contains 2 joints, the distal radioulnar joint that completes the wrist, and a proximal radioulnar joint that with the ulnohumeral, and radiohumeral joint comprises the elbow. These forearm joints are important for rotational movements of the hand known as pronation and supination.

The most proximal joint in the upper extremity is the shoulder which in fact consists of the scapulothoracic joint, the acromioclavicular joint, the coracoclavicular joint and the glenohumeral joint.

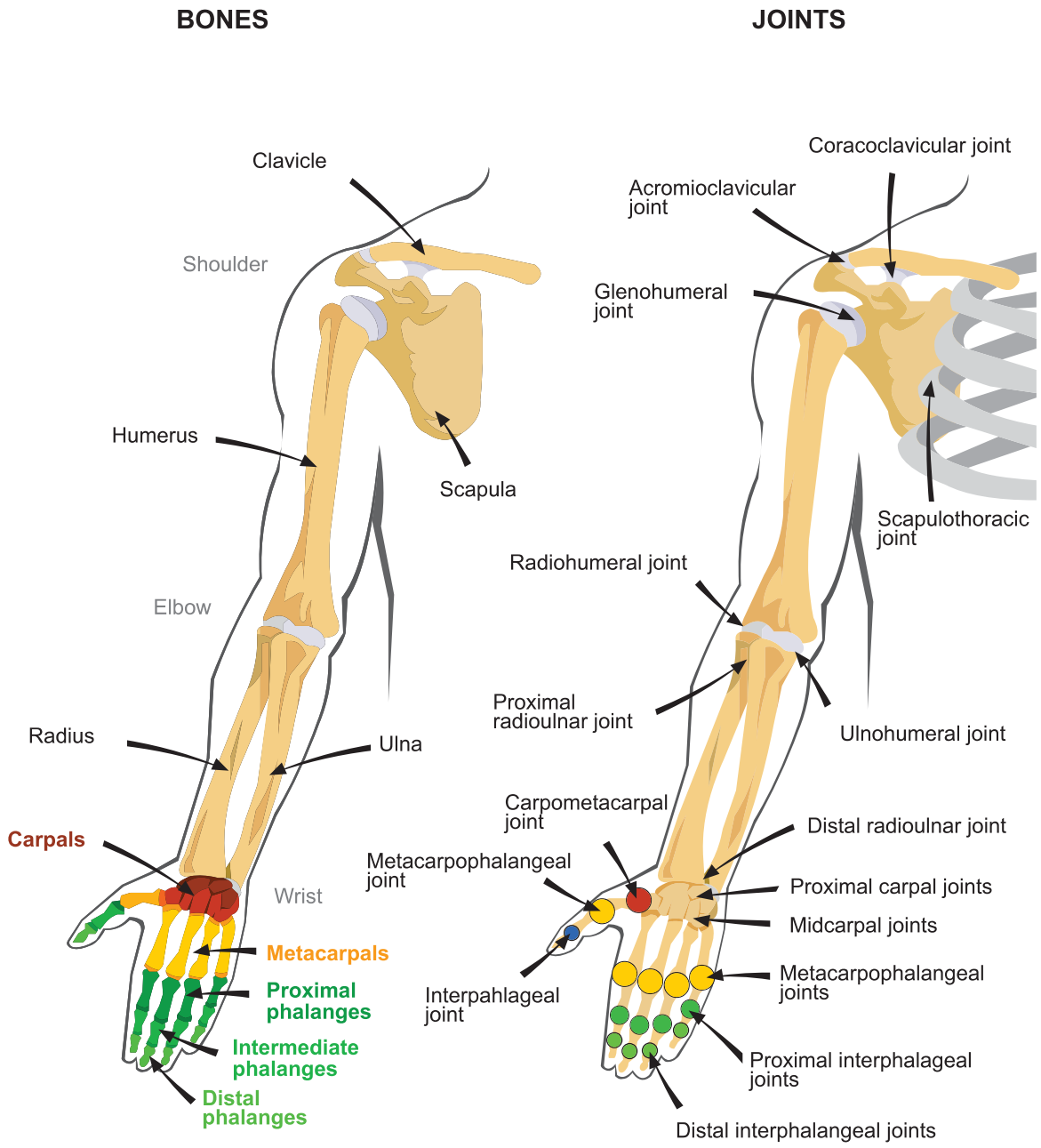


Figure 1:

Illustration of the bones and joints of the upper extremity.

1.1.2 Muscles

Hand muscles can be generally subdivided into intrinsic muscles, those that are located in the hand, and extrinsic muscles with the main muscle body located within the forearm. Gross motor movements such as the movements required for grasping large objects are typically performed by the extrinsic hand muscles, as these muscles can generally generate much larger forces then intrinsic hand muscles. Furthermore these muscles can be sub-classified as flexors, used for grasping, and extensors, used to release objects and expand hand aperture. Extensors are located on the dorsal side of the hand and forearm, and their role is primarily to straighten the fingers. The digital extensor mechanism is a term used to describe the unification of tendons that are involved in finger extension, the muscle that powers this mechanism is the extensor digitorum communis. The bulk of the extensors in the forearm are involved in extending the wrist, these include the extensor carpi radialis, and the extensor carpi ulnaris. As a general rule, extensors in the arm tend to be weaker then their flexor counterparts [8].

Fingers have two long extrinsic flexors that attach by tendons to the phalanges on the palmar side of the hand. The deep flexor, flexor digitorum profundus attaches to the distal phalanx whereas the superficial flexor, flexor digitorum superficialis, attaches to the middle phalanx. The index has an extra extensor called extensor indicis, facilitating independent extension. Similarly the small finger also has an extra extensor, the extensor digiti minimi.

The thumb also has one long flexor in the forearm and a short flexor in the thenar muscle group. In addition the adductor pollicis brevis, the abductor pollicis brevis and abductor pollicis are involved to varying degrees in different types of grasp. The thumb has two extrinsic extensors namely the extensor policis brevis and the extensor policis longus.

Very fine motor control is typically accomplished with the intrinsic hand muscles which include the abductor pollicis brevis, abductor pollicis, opponens pollicis, flexor pollicis brevis and the first dorsal interosseous. These muscles compose the thernar muscle group and participate in varying degrees in complex movements of the thumb. Other intrinsic hand muscles such as the lumbrical and the interosseous muscles are responsible for MCP joint flexion. Please see figure 2 for illustrations of muscles of interest adapted from Netter's Atlas of Human Anatomy [9].

1.2 Plasticity and neural control of the hand

Although bones and joints form the scaffolding of the hand, and muscles power that structure to allow for the performance of an incredible range of tasks, without proper neural control the hand is effectively useless. The nervous system can be described as having two separate parts; the central nervous system (CNS), consisting of the brain and spinal cord, and the peripheral nervous system (PNS), composed of all nerves leading away from and to the spinal cord. Figure 3 illustrates a

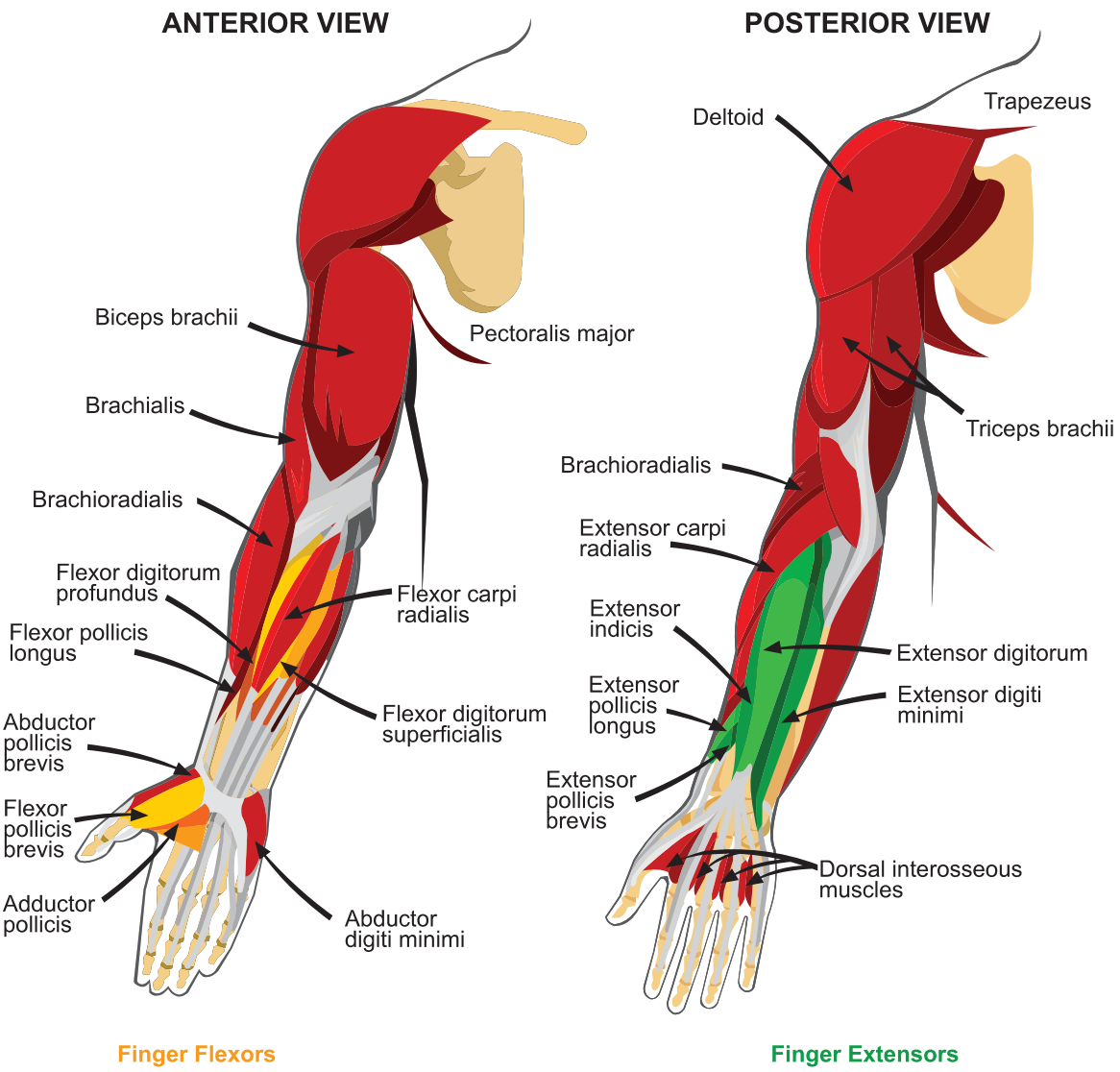


Figure 2:

Illustration of the muscles and tendons involved in upper extremity functional movements. Finger flexors are seen in the anterior view of the arm and illustrated in yellow. Finger extensors are seen in the posterior view and illustrated in green. Certain muscles have been excluded for visual simplification.

simplification of some of the nervous system components involved in activating the hand muscles.

In a normal individual the force he/she can generate does not solely depend on muscle mass. Although the greater the muscle mass the greater the potential for force generation, motor unit recruitment plays a pivotal role in force generation. A motor unit is defined as a single alpha motor neuron and all the muscle fibers it innervates. To generate adequate muscle force we coordinate the activation of numerous groups of alpha motoneurons together, and in precise sequence. These groups are referred to as motoneuron pools. As a general rule the more precise a movement needs to be, the more motor units a muscle may have and the fewer muscle fibers each motoneuron innervates. This allows the nervous system to have very fine control over the muscles that are used for fine manipulations. For example the abductor pollicis brevis is involved in fine manipulation and has fewer muscle fibers per motor unit than the biceps brachii muscle, which tends to be used in tasks requiring large forces and displacements.

Volitional movements tend to be complex and multi-variate, requiring the constant input of somatosensory and visual information to the brain. In contrast, reflexive movements are relatively automatic, stereotyped movements in response to simple stimuli. Both volitional and reflexive movements use some of the same neural machinery and it is therefore the interpretation of the stimuli by the nervous system that determines the extent to which a movement can be considered to be reflexive or volitional [10]. Please see figure 3 for simplified schematics of the motor and sensory systems involved in upper-extremity movements.

In individuals that suffer an injury to the nervous system affecting areas involved in volitional movement generation, the fine balance of control between volitional and reflexive movements is greatly compromised. In response to this, the nervous system has the ability to dynamically alter its function through various mechanisms; this is known as neural plasticity. It has been shown that areas in the motor cortex corresponding to certain limbs will reassign themselves to other areas of the body if that limb receives more training. Nudo et al first showed that cortical motor maps (electrically evoked movement representations in the cortex) in squirrel monkeys enlarged and retracted depending of the amount of skilled tasks performed [11].

1.2.1 Neural changes in response to type of training

Motor training in normal individuals will result in different neural changes, depending on the tasks being performed. The more complicated a task is, such as an acrobatic task, the greater the increase in synaptic number and synaptic generation in the motor cortical regions responsible for the movement of the body parts involved in the task [12]. In the same way, skilled reach training increases the complexity and density of forelimb motor cortical dendritic processes and synapses [13 14]. Transcranial Magnetic Stimulation (TMS) and Functional Magnetic Resonance Imaging (FMRI) in humans [15, 16] has indicated that cortical reorganization is not due just to the increased use of the limb, as studies show that simple movements performed with large numbers of repetitions do not achieve the same effect as task-

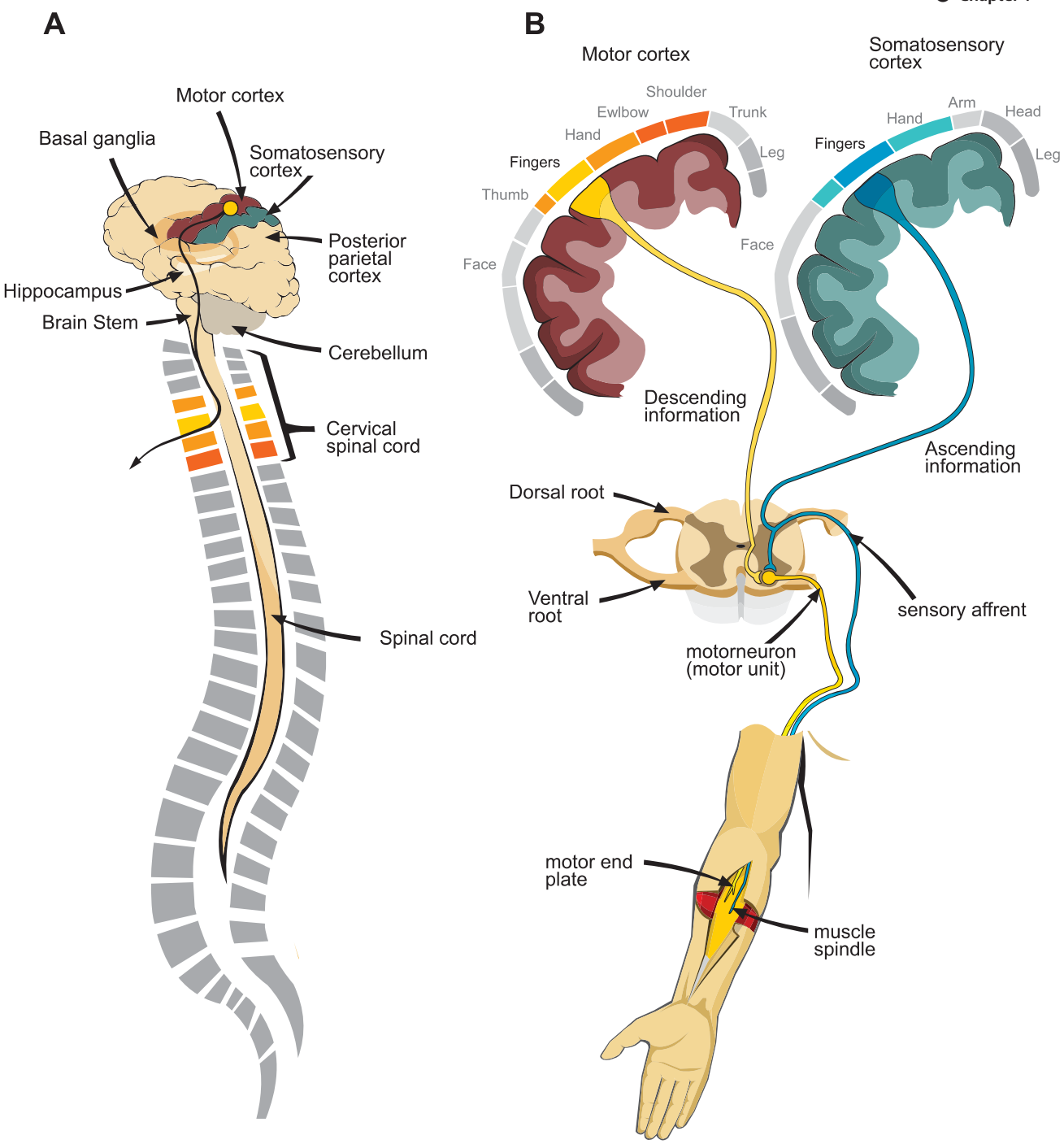


Figure 3:

A illustrates some of the important anatomical regions in the CNS involved in movement of the hand and arm. **B** illustrates the simplified descending information from cortical areas to the desired muscles via the spinal cord. Ascending information from muscle receptors and other sensory receptors traveling to the somatosensory cortex is shown in blue. Cortical areas shown in **B** demonstrate the approximate amount of cortical area dedicated to the upper extremity both in sensory and motor areas.

related movements requiring some level of skill [17] [14]. Studies by Kleim et al. indicate that protein synthesis is required for the reorganization of the motor map in response to skilled reach training [12, 14, 18]. Figure 4 adapted from Adkins et al. [19] illustrates the hypothesized time course of molecular, anatomic and physiological plasticity in the motor cortex during skill training.

Interestingly, apart from known muscle changes during strength training, neural changes occur as well. Strength training programs are designed to increase the force generated by the trained muscles over the course of several weeks. It has been noted that significant strength gains occur before any muscle hypertrophy can be observed [20] [21] and strength increase in one task does not transfer over to other tasks in which the same muscles are involved [22] [23]. Further evidence for neural involvement in strength training comes from studies looking at unilateral training, and how it increases the strength of the muscle on the untrained side [24]. This effect is referred to as cross-education [25].

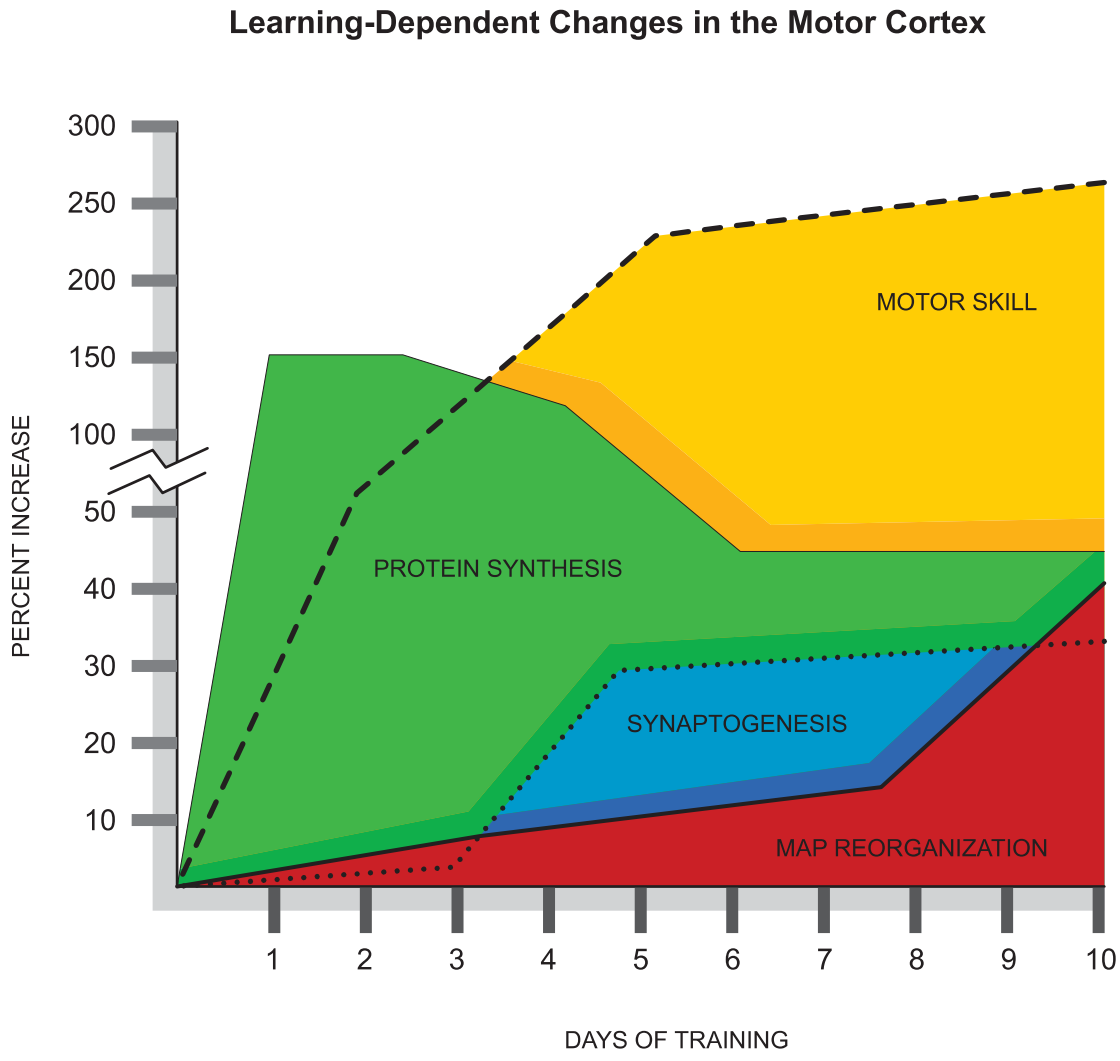
Endurance training results in a different kind of cortical plasticity, it is mostly centered around vascular changes in the motor cortex: angiogenesis occurs, augmenting blood flow to the cortical region responsible for the training effect [26] without necessarily changing the motor cortical maps or altering the synaptic number [27]. This adaptation to increased vascular demands by the selected group of neurons demonstrates that even the neural support mechanisms are plastic and respond to training.

As in the cortex, neural changes can also occur in the spinal cord in response to different types of training. The bulk of our knowledge in this respect is based on studies of changes in spinal reflexes as measured by the Hoffmann reflex (H-reflex). The H-reflex is the response of muscles measured with electromyography (EMG) to single pulse electrical stimulation of sensory fibers (mainly Ia afferents originating from muscle spindles). Studies have demonstrated that in primates, the H-reflex can increase or decrease over time with skill-oriented training [28] [29]. Furthermore Strength training may lead to increased motoneuron excitability [30] and increased synaptogenesis in the spinal cord [31].

Understanding normal neural responses to different types of training and neural mechanisms involved in controlling the upper extremity is useful in tackling the pathophysiology of neural disorders, in that it suggests possible rehabilitation protocols that may augment function following injury.

1.3 Activities of Daily Living (ADLs)

ADLs are groups of activities that individuals perform in order to take care of themselves and to participate in everyday life. These are basic human needs and determinants of well-being[32]. ADLs are not limited to self care, but also include work and leisure activities that enable a person to enjoy life and contribute to the social and economic framework of society [33]. Generally ADLs have been subdivided into two groups, instrumental and personal. Instrumental ADLs may include tasks such



modified from Adkins et al. (2006)

Figure 4:

Time course of protein synthesis, map reorganization and synaptogenesis within the motor cortex in response to skill reach training. All are expressed as a percent increase from baseline or control. Motor skill acquisition is shown in yellow, Protein synthesis in green, Map reorganization in red and synaptogenesis in blue.

as communication, transportation, cooking, shopping and housekeeping. Personal ADLs tend to focus more on tasks directly related to self care, such as eating, toileting, dressing, grooming and bathing [34]. Proper functioning of the hand is integral in performing a wide range of ADLs, which require many different types of manipulative and dexterous movement [1 2].

1.3.1Types of grasp

Humans are capable of manipulating objects of various sizes and shapes. Our hands have evolved to generate numerous types of grasps while performing various ADLs. There are eight main types of grasp that can be performed by normal hands.

1) The hook grasp requires flexion of all fingers but not to their full range of motion and is normally used to hold handles or bags. It has also been referred to as the diagonal volar grip or power grip as it is involved in holding objects and tools such as hammers with a substantial amount of force.

2) Palmar prehension or the pincer grasp is used to hold an object such as a coin between the first finger and the thumb.

3) The cylindrical grasp, also known as a transverse volar grip is used to pick up and hold cylindrical objects such as a pop can or small water bottle.

4) The spherical grasp is used to hold spherical objects such as a ball, in the palm of the hand.

5) Key pinch or lateral prehension, is used to hold and twist a key by pressing the thumb toward the side of the index finger when the index finger is in flexion.

6) The chuck grip or tripod pinch is used to hold objects between the thumb , index and middle finger.

7) The extension grip is used when lifting larger flat objects such as dinner plates.

8) A five finger pinch grip is used when picking up small objects such as peanuts.

Please see illustrations of all grips used in ADLs adapted from Smith & Buterbaugh and Sollerman et al. in figure 5 [35 36].

1.4 Stroke and traumatic brain injury

The term “stroke”, generally refers to a cerebrovascular disorder caused by an acute disturbance in the blood flow to the brain. There are numerous types of stroke but usually they are subdivided into either ischemic or hemorrhagic. Ischemic strokes are the more prevalent [37] and are due to a blocked supply of blood resulting from thrombosis or an embolism that causes a cerebral infarction. Hemorrhagic strokes on the other hand are a result of bleeding into the skull, compressing brain tissue. In that respect hemorrhagic strokes are very similar to traumatic brain injuries and may result in a similar prognosis and pathophysiology.

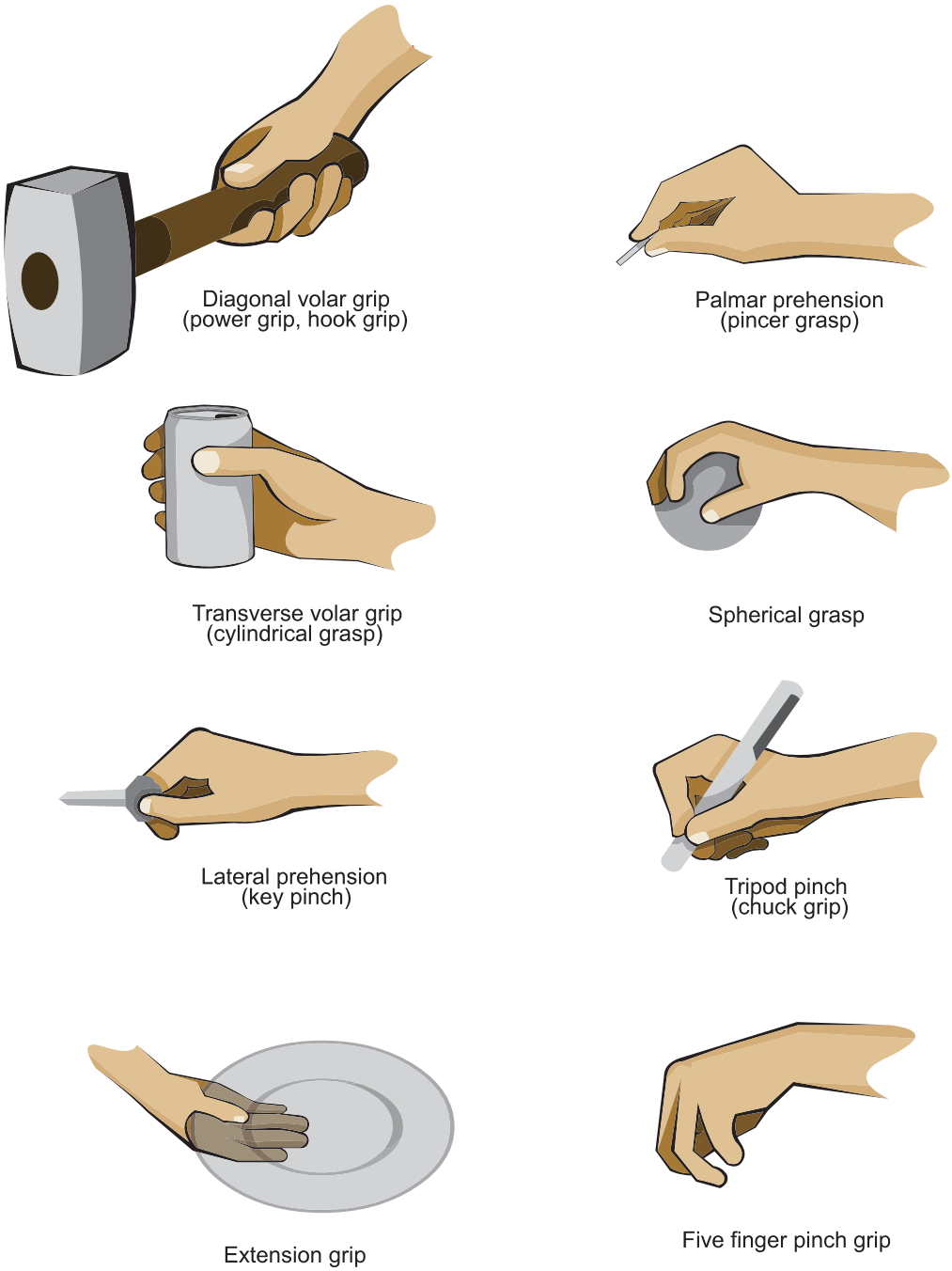


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Figure 5:

Illustration of the eight different grips used to perform activities of daily living

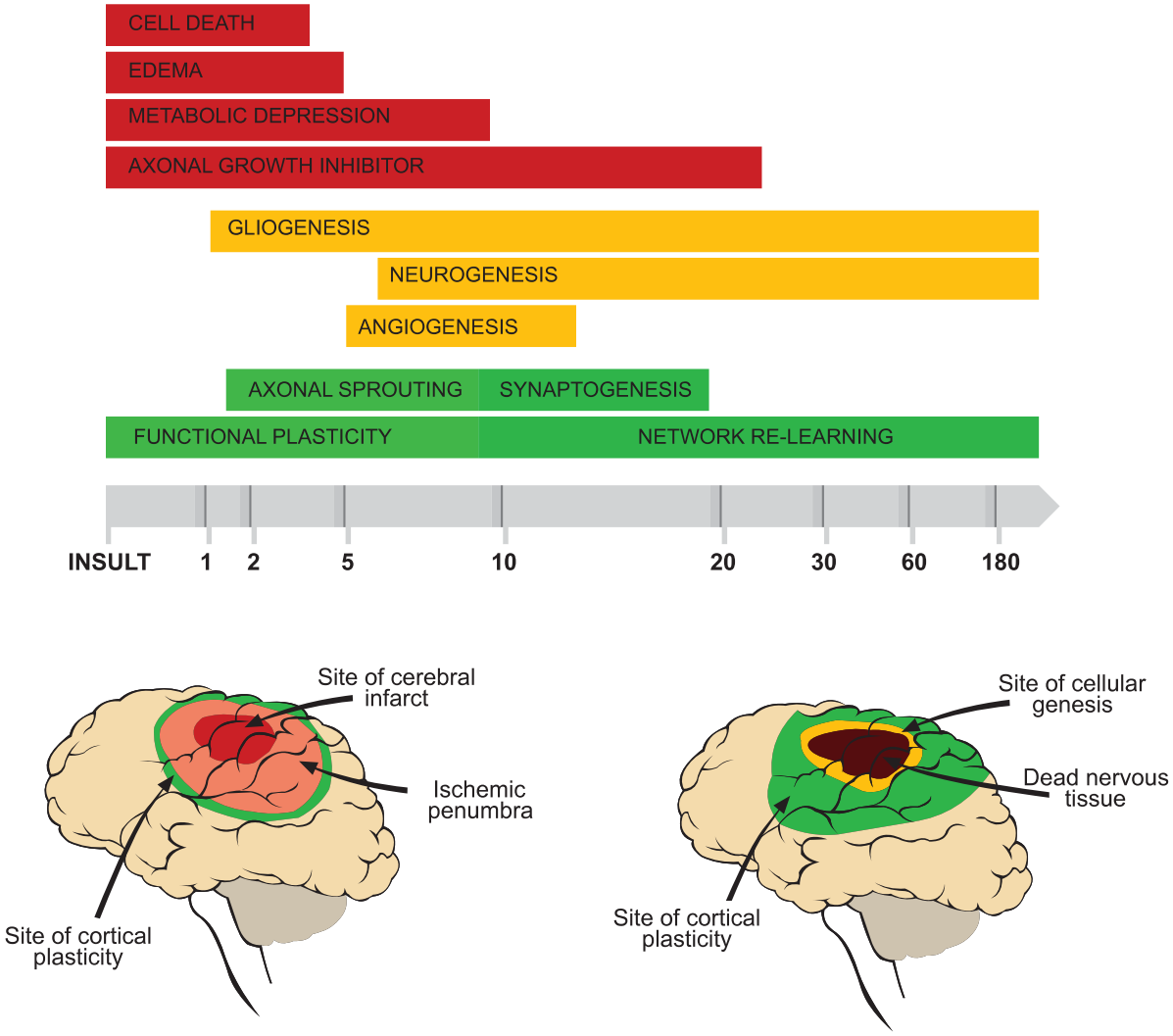
In the acute phase, during and immediately after a stroke, neurological function is lost in the infarcted area. Typically most stroke survivors will have one-sided weakness in the body, known as hemiparesis or one sided paralysis (hemiplegia). Hemiplegia or hemiparesis occur on the side of the body opposite to the site of infarction. Some neurological function recovers in the following months but one third of all stroke survivors are left with severe, permanent disability [38]. The loss of function in stroke is due in part, to neuronal cell death and cellular dysfunction in the ischemic penumbra. The penumbra encompasses all surrounding tissues that survived the initial insult but are underperfused and fail to perform their normal functions. The penumbra is very unstable and may result in permanent loss of neurons if the tissue does not recover properly [39]. The ischemic penumbra has been the focus of numerous neuro-protective therapies [40].

In the case of hemorrhagic stroke the bleeding can be within brain tissue as in intracerebral hemorrhage (ICH) or within the subarachnoid space or the space between the brain and tissues that surround it. This bleeding is referred to as subarachnoid hemorrhage. Hemorrhagic strokes account for approximately 15% of all strokes, and are associated with high mortality rates [41]. Hemorrhagic, unlike ischemic strokes result in an acute rise in intra-cerebral pressure caused by a hematoma (blood pooling). The size and expansion of the hematoma is a good predictor of mortality [42]. In addition to the initial site of injury the remaining brain tissue can be damaged due to pressure produced by the hematoma and hydrocephalus that results from impaired cerebrospinal fluid (CSF) circulation [43]. Additional injury can be incurred by cerebral edema as a result of the weakening of the blood brain barrier by the immune response [44]. Finally molecular factors such as iron in hemoglobin, released from the blood into the brain can aggravate the situation resulting in rapid onset oxidative stress and ischemia of the surrounding tissues [44, 45].

1.4.1 Stroke recovery

Over 3 million stroke survivors live with hemiparesis resulting in chronic disability in North America alone. Upper extremity motor deficits are a major contributor to stroke related disability. The recovery of upper extremity motor function involves 3 phases; first, activation of cell repair, second, functional cell plasticity and finally, neuroanatomical plasticity. Figure 6 is an illustration of these phases adapted from Wieloch and Nikolich [46]. It also includes a timeline demonstrating the progression of stroke recovery. Phases 2 and 3 involve two different types of neuroplasticity, both of which are involved in normal learning and training. Functional cell plasticity involves changing existing neural pathways, whereas neuroanatomical plasticity is associated with the formation of new connections. The repaired penumbra and peri-infarct areas are responsible for all compensatory processes that lead to motor recovery.

Generally motor recovery occurs from proximal to distal movements, volitional finger movements being the last to recover. Recovery also tends to follow from mass undifferentiated movements, to fine and isolated movements. When



modified from Wieloch et al. (2006)

Figure 6:

An overview of various time dependent processes activated following brain injury is shown in. Detrimental processes are indicated in red, processes involved in cell generation are in yellow, adaptive plasticity is shown in green.

discussing the recovery of functional grasping, the hand typically starts flaccid. It then progresses to mass flexion of the fingers in synergy, followed by flexion and extension of fingers in synergy. Finer control recovers later with lateral prehension first, palmar prehension, and finally individual finger movements [47] [48].

1.4.2 Impairments affecting functional recovery

Impairments following a stroke that can affect functional motor recovery include abnormal synergies, shoulder subluxation, contractures and spasticity. Edema or accumulation of fluid in tissues occurs due to the reduced circulation and loss of muscle activity in the affected limb of stroke patients [49]. Edema prevents many patients from regaining full range of motion especially around the fingers as the swelling impedes movement. Massage of the affected limb has been used to reduce the swelling and allow for greater movement.

Abnormal synergies are patterned movements that are a result of the patient's inability to control individual muscle movements. Common synergies are flexion and extension synergies that occur in response to the person trying to perform a relatively isolated flexion or extension movement respectively. A common flexion synergy involves the flexion of the fingers, wrist and elbow, while the forearm is supinated and the shoulder extended and externally rotated.

Shoulder subluxation is well-recognized as a complication associated with stroke and refers to the significant displacement or dislocation of the shoulder joint. It affects the shoulder joint because this joint is very mobile and lacking in stability compared to other joints. When the limb is flaccid and there is very little muscle tone, it is easy for the limb to drag the shoulder into subluxation. Slings have been used to prevent shoulder subluxation but these tend to cause soft tissue contractures and improper balance [50]. Recently the use of electrical stimulation has been proposed to alleviate this complication [51].

Spasticity has been classically referred to as an increased resistance to a passive stretch as a result of a velocity-dependent increase in tonic stretch reflexes [52]. Recently it has been suggested that this definition may need to be revised as changes in intrinsic muscle properties have been shown to contribute to the increased tone [53] [54]. About a quarter of stroke patients develop spasticity [55], which tends to interfere to varying degrees with motor performance, causes pain and leads to other complications [56]. Nevertheless it has been suggested that too much emphasis may have been placed on treating spasticity in relation to its clinical importance [53] [55], as the majority of patients are non-spastic.

The degradation of internal limb dynamic representations may further impair the hemiparetic arm [57] in addition to all of the above-mentioned impairments. Recovery from stroke is not a straightforward process; therefore the approaches used for upper extremity stroke rehabilitation should not be one dimensional. They should address as many of the impairments as possible.

1.5 Spinal cord injury (SCI)

The spinal cord is part of the central nervous system (CNS) and is a tubular bundle of nervous tissue that is subdivided into four major regions; cervical, thoracic, lumbar, and sacral. The spinal cord functions primarily to transmit nervous signals between the brain and the rest of the body. Each region contains several segments with ventral and dorsal roots that exit or enter the spinal cord. Dorsal roots are responsible for transmitting sensory information from the body to the brain and other regions of the spinal cord, whereas the ventral roots convey motor information from the brain and spinal cord to the muscles via motoneurons. Anatomically, the spinal cord is composed of regions of white matter (myelinated axons) and grey mater (unmyelinated cell bodies, axons and supporting cells). Apart from transmitting information, the spinal cord also contains neural circuits that process sensory information, generate simple rhythmical movements, and mediate reflexes. Consistent with higher order brain areas in the CNS, the spinal cord is also a site for neural plasticity.

A SCI, as the name suggests, is an injury to the spinal cord resulting in permanent neurological damage. A SCI can range from a small contusion, resulting in minimal motor and sensory deficits, to a full transection, with devastating motor and sensory outcomes. SCI is of a neurological nature, an individual may sustain a back injury, damaging the vertebrae, without damaging the spinal cord itself.

If a SCI occurs in the cervical area of the spinal cord it can result in tetraplegia, affecting the arms, legs and trunk. Paraplegia or paralysis of the lower extremities can result if the injury occurs below the cervical level. Approximately 2.5 million people live with a SCI worldwide, Wyndaele et al suggest that the incidence of SCI is between 10.4 to 83 per million [58]. Lifetime costs can exceed 2 million dollars to care for individuals with a SCI [7]. Recent data indicates that proportionately a larger number of SCI survivors are afflicted with tetraplegia than before [58]. The motor and sensory deficits resulting from an SCI are very dependent on the exact location and magnitude of the injury; see figure 7 for more details on how location affects motor and sensory impairments.

Initially a SCI leads to formation of cysts and cavities at the site of injury. Cell death follows very rapidly, including neurons and supporting cells such as precursor cells, oligodendrocytes and astrocytes [59]. Although typically white mater is spared in the initial phases of a SCI, secondary damage causes further loss of function. Secondary damage is believed to be due in part to the immune response to the initial insult. It includes apoptosis and loss of myelin [60]. Secondary damage is initiated by resident and infiltrating inflammatory cells such as microglia, macrophages and T cells [61]. Secondary damage leads to the formation of a glial scar that exhibits axon growth inhibitors [62]. The scar is composed of astrocytes, fibroblasts, Schwann cells, microglia and macrophages and is considered relatively impenetrable and non-conducive to axonal sprouting or growth [63] [61]. Apart from glial scar formation, secondary injury processes can affect areas of the spinal cord initially not damaged, and the damage can progress over the months and years after injury. Though some limited spontaneous neural repair can also occur [64], the majority of the observed

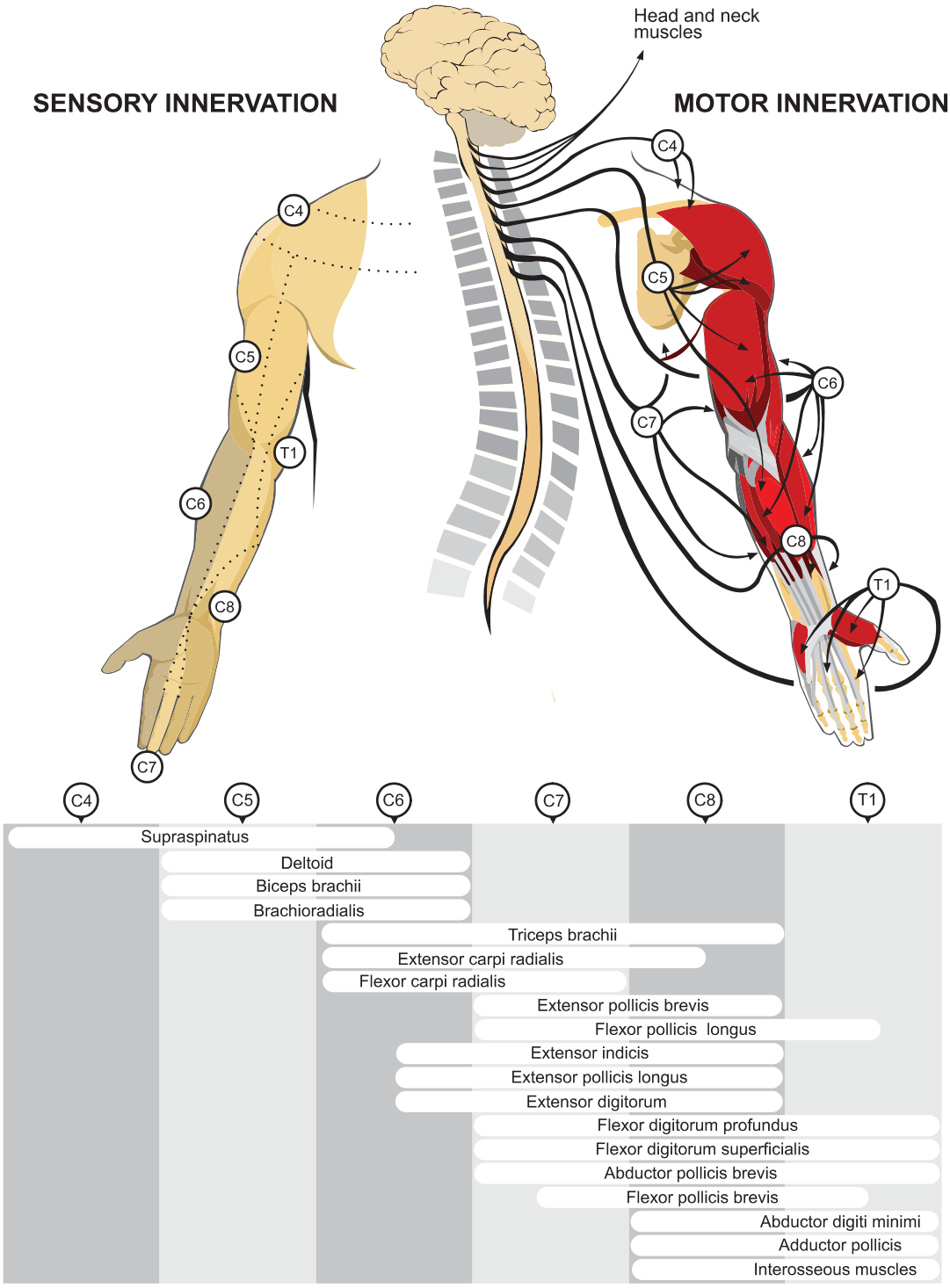


Figure 7:

Muscle and sensory innervations related to the upper extremity. Injury or damage to the cervical spinal levels shown can result in impairments of the muscles and sensory areas innervated by those segments.

compensatory recovery has been attributed to spinal, brainstem and cortical plasticity [65].

Numerous studies have been performed with the aim of minimizing or reversing the secondary damage seen after a SCI. These therapies either focussed on implanting different types of cells into the damaged spinal cord or injecting different molecular factors to promote cellular recovery, axonal sprouting or novel neural circuit formation. Cells that have been proposed as potential treatments and currently being tested in clinical trials include peripheral nerve grafts[66], olfactory stem cells[67], Schwann cells[68] , macrophages[69], embryonic stem cells[70], and adult stem cells[71]. Some attempted molecular therapies include the delivery of growth factors such as brain derived neurotrophic factor (BDNF) [72], neurototphins [73], axonal sprouting agents such as cyclic AMP[74], antibodies to block a growth inhibitors like Nogo-A [75], and various other agents. These molecular therapies are in their infancy, with most still not in human trials. It has become apparent that no single one of these therapies will result in a "cure". Currently the consensus favours a treatment involving a cocktail of cellular and molecular approaches in combination with intensive task-oriented rehabilitation [76].

A recent influential survey found that individuals suffering from tetraplegia ranked the recovery of arm and hand function as their first priority, far exceeding the restoration of locomotion for example. The participants felt that regaining hand function would most improve their quality of life [77]. Similar results have been reported by others, with the suggestion that even partial improvements in arm and hand function can have a significant impact on independence [78] [79].

Secondary complications from SCI include pain, contractures and musculoskeletal injuries [80]. As the upper extremity in SCI patients is particularly susceptible to musculoskeletal injuries, it follows that much effort should be made not only to augment hand function but also to prevent upper extremity injury in this population. This is particularly important in relation to the design of safe rehabilitation protocols.

A common compensatory strategy which is taught to individuals with tetraplegia while undergoing rehabilitation is the tenodesis grip. The tenodesis grip allows individuals to close their hands by passively stretching the finger and thumb flexor muscles and tendons during wrist extension. The forces generated by a tenodesis grip tend to be very small but in combination with compensatory movements of the more proximal limb segments, they allow paralyzed hands to achieve some simple tasks such as picking up and transferring light objects [81].

1.6 Hand function assessment

Valid and reproducible hand function assessment is important for diagnostic purposes, evaluating the level of impairment, selecting appropriate care and treatment and evaluating the effectiveness of these procedures. Standardized testing also allows for inter-subject comparisons to be made. There have been more

than 27 tests developed for assessing impairments of the upper extremity in stroke alone [82]. Traditionally grip strength[83] or pinch strength[84] measured with a dynamometer, have been the only objective measurements of hand function, yet these have been shown to bear little relation to actual hand function [85]. Subjective evaluations of strength, range of motion and quality of movement form the basis of clinical assessments, but these evaluations tend to be performed in non-standardized ways, and therefore depend on the training and attitudes of the clinicians involved. Researchers have proposed numerous more quantitative tests that could be used for diagnostic purposes, but clinical acceptance of these tests has been poor.

Currently for a hand function test to be accepted clinically, it needs to be relatively simple, achievable with minimal equipment within 5 to 10 minutes, well defined, reliable, validated, and standardized. It is unlikely that any single test can be used to fully assess all impairments in the clinic [86] as measuring hand function and impairment rigorously can be very time-consuming for the therapist and the patient. Rating hand function based on the performance of ADLs has been gaining popularity in the research community as well as in the clinical world. It allows clinicians to foresee difficulties that the individual may encounter on a daily basis. Therapeutic efforts can then be directed to overcome specific deficits in ADLs, which affect the person's independence and quality of life. With the promise of new therapies in the near future, it is crucial now to develop tests that quantify improvements, rather than relying on the current qualitative testing procedures.

1.6.1 Minimal Clinically Important Difference (MCID)

For an upper extremity function test to be successful it needs to be responsive to change and capable of detecting the minimal clinically important difference (MCID). The MCID is different for each test and it helps to determine a threshold within a given test that is considered to be an important improvement [87]. The MCID helps in the interpretation of test scores and makes a distinction between statistically significant differences that may have little or no impact on the quality of life of an individual, and differences that are significant to the tested individual in this respect. Some clinical assessments are not designed to detect the MCID such as elbow kinematic measurements, yet these measurements can be very useful in predicting the recovery of hand function following an injury [88].

1.6.2 The Action Research Arm Test (ARAT)

The Action Research Arm Test (ARAT) is an independently validated hand function test designed for assessing impairments in individuals with cortical injuries. The test was initially proposed by Carroll [89], and then reorganized by Lyle using a Guttman scale [90] decreasing the time to administer the test to under 15 minutes [91]. The test is based on the assumption that if individuals can perform a certain task, they will be able to perform a similar task that is easier. This assumption has been recently criticized as it prevents blinded rating of the test via video and is not based on any

experimental evidence [92]. The ARAT is sub-divided into 4 subtest sections of grasp, grip, pinch, and gross movement with a maximum overall score of 57. Each task in the test is scored using an ordinal 4 point criterion scale. Recently it has been suggested to incorporate performance time to help differentiate between scores [82] [93]. The ARAT has a well established inter-rater reliability (0.98), test retest reliability (0.99) [94], and correlates well with other hand function tests [95] [96]. The ARAT has also been suggested as a measure for detecting the MCID in stroke patients [97] [98] even though it has known ceiling and floor effects [92].

1.6.3 The Fugl-Meyer Assessment (FMA) and Chedoke-McMaster Stroke Assessment

The FMA is composed of upper and lower extremity portions. Here I will discuss only the upper extremity portion [99]. The original assessment was based on Brunnstrom's concept of sequential stages of regaining motor function [100]. The sensorimotor assessment comprises an ordinal 3 point scale used to score different volitional movements of the arm and hand as well as some grasping tasks. A total of 33 tasks are included in the upper extremity portion of the FMA, the maximum overall score being 66. The test isolates the active range of motion about the shoulder, elbow, wrist and hand. The FMA has been validated [101] [102] and has been extensively used in stroke research. The test's main limitations are the time required to perform all the tasks and a ceiling effect [103].

The Chedoke-McMaster Stroke Assessment [104] is a similar test to the FMA that also incorporates stages of stroke recovery as described by Brunnstrom [100]. The test is composed of a physical impairment component and a disability component that is designed to measure clinically important changes in physical disability. It has been more readily accepted in the clinical word as it is designed to be used in conjunction with the Functional Independence Measure (FIM) [105]. The Chedoke-McMaster Stroke Assessment , much like the FMA, has a hand component but is not limited to the upper extremity as it is designed as a more global evaluation of the patient.

1.6.4 Wolf Motor Function Test (WMFT)

The WMFT was developed to study the effects of Forced Use Therapy, now known as Constraint Induced Movement Therapy (CIMT) in the stroke population [106]. The WMFT consists of 15 tasks arranged in order of difficulty and progresses from proximal to distal joint use. Two simple measures of grip are also included. The tasks are performed in two different positions, from the side or from the front. Tasks performed from the side include moving the forearm to a tabletop, moving the forearm from the table onto a box placed on the table, extending the elbow on the tabletop with and without a weight and moving the hand onto a tabletop. Front-facing tasks involve moving the hand onto the tabletop in a front-facing position, moving it onto the box, retrieving a weight by elbow flexion, lifting a can, pencil and paperclip from the tabletop, stacking checkers, flipping cards, turning a key, folding a towel, and finally lifting a weighted basket. Each task is timed and rated on the

quality of movement being performed. This test has been validated and used in the field of CIMT [107].

1.6.5 Other ADL functional assessments

The Jebsen-Taylor Test is a time-scored functional assessment of 7 common tasks [108]. The tasks scored are writing, simulated page-turning, picking up small objects, simulated feeding, stacking checkers, picking up large light objects and picking up large heavy objects. The test has been used to assess hand function impairments due to a variety of disorders, including stroke[109 110], multiple sclerosis[111], arthritis [112], burns [113] and even to study the effect of age on hand function [114].

This test is very comprehensive and in some respects it is considered a gold standard of testing hand function. The main drawback is the time needed to administer it and therefore some attempts have been made to use just a few sub-tests from the original [110].

Many other hand function tests have been developed; these are largely based on assessing specific impairments. The Sollerman hand function test assesses ADLs with a variety of standardized tasks [36]. The Box and Block test [115] is a quick way of assessing gross motor movements by timing a patient moving blocks from one box into another. The Box and Block test, although quantitative, leaves much to be desired in terms of assessing ADLs in general, as it only involves a particular combination of movements. The Sollerman and Jebsen-Taylor tests, although validated for assessing ADLs, rely heavily on the judgment of the person administering and scoring the tests. An interesting approach was proposed in order to assess hand function quantitatively by the use of robotic devices [116]. Although fully automated and quantitative, robotic assessments have not yet been satisfactorily correlated with the performance of ADLs.

1.6.6 Pegboard tests

Pegboard tests such as the Nine Hole Peg Test [117] and the Purdue Pegboard Test [118] are typically used to assess dexterity and fine motor tasks. The Nine Hole Peg Test has been used extensively by occupational therapists as it is a very simple and a quick means of assessing finger dexterity. It consists of picking up and placing 9 short lengths of dowel into 9 holes while being timed. The Purdue Pegboard test on the other hand was initially developed in the 1940's to select individuals for certain industries, and was later adapted to be used as a clinical assessment tool [119]. The test is much more demanding then the Nine Hole Peg Test as the pegboard used has two rows of 25 holes and requires the use of pegs, collars and washers.

1.6.7 Self-assessment questionnaires.

A common means of assessing deficits has been the use of self-assessment questionnaires. These tend to be very subjective, as they are based on patient

interpretation of hand function in relation to ADLs. An example of such a questionnaire is the Motor Activity Log (MAL) developed specifically to assess ADLs for CIMT [120]. Two versions of the MAL have been validated, a 30-item MAL and a 14-item MAL for stroke patients. The MAL is a structured interview assessing the quality and ability of an individual to perform ADLs [121 122]. Each item of the MAL is assessed in terms of quality of movement (QOM) and amount of use (AOU), both the QOM and AOU are assessed on a 5 point ordinal scale.

Another self-assessment questionnaire commonly used is the stroke impact scale. This assessment is a psychometric outcome measure, developed to address impairment following a stroke. The scale is much broader than the MAL as it includes cognitive function, bowel function, balance and a variety of ADLs, each of which are scored on a 5 point scale [123].

1.7 Current therapeutic approaches

Various approaches to upper extremity rehabilitation are currently practised, depending on local facilities, funding, treatment strategies and ideologies. Most of the treatments focus on hemiplegia, as it is the leading cause of upper extremity disability worldwide, but the principles have been carried over to other disorders. Conventional therapy is not well defined and usually varies tremendously from location to location. The general focus is on patient independence with financial and time constraints being the most important limiting factors. Therapists tend to train individuals to be more self sufficient with various non-standardized items of equipment and off-the-shelf devices. As neurophysiological knowledge has advanced, various protocols have emerged over the last 50 years. One very influential metod is the Bobath Neurodevelopmental Treatment (NDT) [124 125]. The aim of NDT is the normalization or reduction of enhanced muscle tone and synergies prior to the facilitation of voluntary and automatic movements. The abnormal muscle tone is usually treated with the application of appropriate reflex-inhibiting patterns of movement. Great emphasis is placed on the generation of qualitatively normal movements, and on maximizing bilateral function. Proprioceptive Neuromuscular Facilitation (PNF) [126] is another popular method, which uses the stretch reflex as a tool to elicit movements. This physiotherapeutic method focuses on generating isometric contractions combined with passive stretching, as well as the use of mass-movement patterns. The Brunnstrom protocol [100] emphasizes the development and use of flexor and extensor synergistic patterns with the intent of generating relatively involuntary movements that become more voluntary over time. Interestingly, these various techniques apparently do not differ significantly in producing improvements in motor function [127 128 129]. Furthermore it seems that they may not be as effective as task-specific rehabilitation [130].

1.8 Emerging rehabilitation technologies

The greater understanding of how people adapt to neurological damage and the boom in electronic technology has lead to the development of new methods of upper-extremity neurorehabilitation. The general aim of these new techniques is to be more effective in delivering rehabilitation, reducing the associated costs and most importantly, in producing greater functional gains in patients than traditional approaches.

1.8.1 Constraint Induced Movement Therapy (CIMT)

The concept of "Learned Non-use" of the upper extremity after CNS damage derived from studies on deafferented monkeys [131] with purely sensory deficits. Learned non-use refers to a behavioral change that occurs following a neurological injury, namely the avoidance of use of the affected arm and preferential use of the non-affected arm. In the monkey trials, restricting the non-affected hand and arm reversed learned non-use and resulted in permanent improvement in motor function of the de-afferented limb. This lead to the development of CIMT in stroke patients as a means to improve hand function through the rigorous training of the affected paretic limb [120]. Typically the therapy is performed by restricting the less-affected limb with a mitt, thereby discouraging the use of that limb for around two weeks. The mitt is worn for an extended period of time; up to 90 percent of the waking hours over the course of treatment.

All the randomized clinical trials examining the effectiveness of CIMT have reported positive functional results, but meta studies have not been as enthusiastic [132 133]. In studies that considered the MCID the results did not meet the threshold [134]. Clinically relevant improvements were only noticed in small patient subgroups [133]. It has been suggested that the theory of learned non-use many not necessarily apply to all patients and that in some countries that provide more comprehensive rehabilitation treatments in the acute and subacute phase of stroke recovery the severity of learned non use may be much less than in North America [135]. There is little evidence for the existence of learned non-use in stroke patients, the support for this theory is primarily based on clinical observations and lacks empirical verification. Learned-non use may in fact be associated with hemi-neglect [133]. The evidence supporting CIMT requires further exploration as it is not yet convincing.

1.8.2 Continuous Passive Motion (CPM)

Splinting and immobilization results in profound joint alterations including scar formation that lead to joint stiffness [136]. The concept of Continuous Passive Motion (CPM) has emerged as a means of preventing inappropriate scar formation, preventing stiffness and maintaining a good range of motion. The therapy involves moving the joint for extended periods of time by either a therapist or a robotic device. It is much easier to administer this therapy to large joints that can be

isolated such as the elbow, shoulder, knee, and hip [137]. There are various devices available that have been tested for use in the hand [138] [139]. This type of therapy requires at least 8 hours a day to be effective [139] and the effects may only last 24 hours [140]. Continuous Passive Motion focuses on maintaining joint integrity and is questionable as a means of neurorehabilitation [141].

1.8.3 Robotics

Numerous robotic devices have been proposed for upper extremity rehabilitation. Traditional upper extremity rehabilitation is labor-intensive and so robotics was seen as an alternative way to deliver repetitive, high-intensity and task-specific treatment in an interactive manner. The use of robotics also allows for the objective monitoring of patient progress. Trials of robot-aided therapy have involved either custom-built robots designed specifically for the task at hand such as the MIT-Manus [142], adapting existing robots to rehabilitation as in "MIME therapy" which uses the Puma robot [143] or adapting arm-support devices to become robotic such as the T-Wrex [144].

In recent systematic reviews, robot-aided therapy has not been found to improve functional abilities or result in improvements relevant to ADLs although some short term improvements in muscle activation patterns and speed of movements has been noted[145, 146] [147]. These devices tend to be more suited to improve proximal upper extremity strength but they are typically very costly [148]. In fact it seems that the more conscious effort produced by patients the greater the result will be yet many robotic treatments reduce the required effort and produce movements without the contribution of the patient [145]. This type of therapy, initially conceived to automate rehabilitation, has recently been judged to be an unlikely replacement of the therapist in the near future [149].

1.8.4 Functional electrical stimulation (FES)

Electrical stimulation (ES) has been used for numerous clinical applications, including pain relief [150], improving tissue health [151], muscle function [152] and therapeutic effects after stroke. Functional electrical stimulation (FES) refers to stimulation that replaces lost function or augments an individual's residual voluntary ability. FES has been incorporated in hand neuroprostheses aiding individuals in performing ADLs [153] [154] [155] [156] [157]as well as a therapeutic tool for rehabilitation of the upper extremity [158] [159].

FES systems can be divided into three categories: surface devices, percutaneous devices, or implantable devices.

Surface FES stimulators are well suited for upper extremity neuro-rehabilitation, at least initially, as they do not require a lengthy surgery, and are significantly less expensive than their implantable counterparts. The drawbacks to these devices are typically less selective and sometimes painful stimulation, the need for daily

adjustment of electrode positions, lengthy donning and doffing in some cases, and the lack of grading of muscle activation.

Percutaneous devices are typically used as a temporary solution. In this arrangement an electrode lead is implanted in or on a muscle or nerve and protrudes through the skin. These devices are not suitable for long-term use as the location where the electrode emerges from the skin is prone to infection. The advantage is that percutaneouos electrodes can activate deeper muscles selectively.

Implantable devices are intended for long-term use as permanent neuroprostheses [160]. They require surgical implantation. Recently a hybrid system, which draws on the advantages of both implantable and surface stimulators, has been proposed [161]. All the above types of FES devices are illustrated in figure 8, adapted from Peckham and Knutson [160].

FES results in the generation of action potentials in nerves that in turn activate muscles to produce functional movement. The stimulus threshold to produce action potentials in nerves is an order of magnitude lower than that to produce action potentials in muscle fibers. Thus for FES to be useful, it is crucial to have undamaged motor neurons leading to the targeted muscles. As a general rule, large diameter axons (of the larger motor units) are recruited first, with lower currents than small axons [162]. This is the inverse of the normal recruitment order of motoneurons in the CNS during voluntary movement.

Surface stimulators require a minimum of 2 electrodes located over the motor point of the targeted muscle. The motor point, as defined by Duchenne in the mid 1800s, refers to the location where the muscle will produce the largest isolated contraction with the least amount of current; usually it corresponds to the entry point of the nerve into the muscle. Due to their simplicity, relatively low cost and non-invasive nature, surface stimulators tend to dominate in the clinic. There are examples of wearable devices with built-in electrodes such as the Handmaster (H200 BioNESS) [155] [163] and the Bionic Glove [156]. The H200 is currently the only commercially available stimulator specifically designed for the upper extremity. Unlike the H200, which requires the pushing of a button on a tethered control box, the Bionic Glove used wrist position to stimulate either finger flexors or extensors, with all the electronics built into the garment. Another control mechanism that has been used for many years is EMG-triggering [164]. Using residual function, some subjects can trigger the stimulator to augment the desired movement. Surface FES has been validated as a plausible treatment in combination with task-specific training for SCI [165] and in stroke to improve motor control [166] [167].

Percutaneous systems seem to be providing very similar effects to surface FES systems [168] [169].

Fully implantable FES devices such as the Freehand system [170] were developed for chronic applications in individuals with SCI. These systems were expensive and required extensive surgery for the placement of multiple electrodes in the forearm leading to a hermetically-sealed package similar to a cardiac pacemaker located

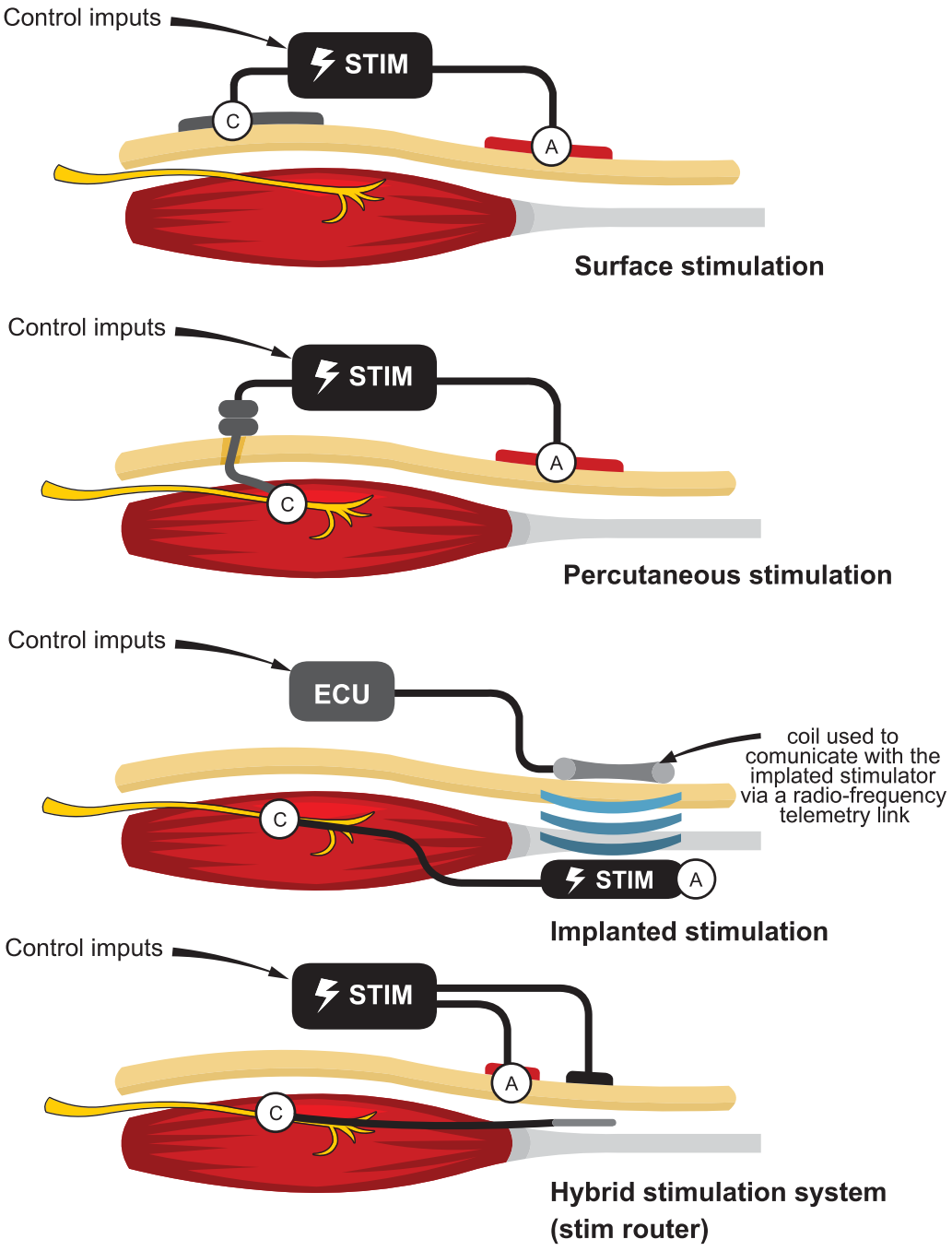


Figure 8:

Different functional electrical stimulation configurations are illustrated; these include surface stimulation, percutaneous stimulation, implanted and a hybrid system (all single-channel monopolar stimulation). Stim refers to the stimulator, A to the anode (reference electrode), C to the cathode (stimulating electrode), ECU to an external control unit.

subcutaneously on the chest wall. They were effective in generating or augmenting pinch and grasp forces, and helping in the manipulation and moving of objects, thereby increasing patient independence [154]. Over 200 SCI patients were implanted with this device worldwide, but Neurocontrol, the company that developed and manufactured the device, ceased operations in 2001.

Electrical stimulation, when used for rehabilitation purposes is classified as therapeutic electrical stimulation (TES) [167]. The therapeutic mechanism underlying TES is not well understood. It was believed that TES improved motor function, permitting functional tasks to be performed better. Recently it has been proposed that a large component of the functional improvements after TES could be due to sensory stimulation [171] [172]. This could have implications for implantable and percutaneous devices that are more specific, targeting motor function and by-passing sensory stimulation. More research is needed to understand the mechanisms involved in this type of rehabilitation as it could lead to even greater functional gains.

1.8.5 Computer games and virtual reality

Since the introduction of the computer game in 1962 the computer industry has propelled the technology at an incredible rate. Computer games have now been proposed as a means of providing upper-extremity therapy in a purposeful and motivating manner with the possibility of in-home rehabilitation. Early attempts at utilizing this technology have proven to be partially successful [173]. Advances in telecommunication have also allowed the introduction of tele-rehabilitation. Tele-rehabilitation allows for the remote access and delivery of computer-oriented rehabilitation protocols. Many people suffering from upper extremity motor deficits have difficulty with transportation, so tele-rehabilitation may significantly improve the type and duration of upper extremity rehabilitation that can be administered to these individuals.

There has recently been an initiative to incorporate the advances in Virtual Reality (VR) in upper extremity motor rehabilitation [174] [175]. VR is the implementation of computer software that enables the simulation of real-world situations and movements through haptic interfaces, real-time motion tracking and unique displays. The technology has been developed by the entertainment industry and because it is targeted at a mass market, it is likely to be affordable. There are some drawbacks to VR including "cybersickness" (motion-sickness-like symptoms) [176], but it has proven to be beneficial in training individuals for complex tasks such as piloting commercial airplanes. It has been found that tasks learnt in a VR environment can then be practiced in the real world [177]. VR has been shown to be potentially superior to real-world training as it can provide unique environments that optimize learning [178]. This approach, with the addition of tele-rehabilitation, has been applied to stroke patients with some success [179].

1.9 Dissertation summary and outline

Over the past two decades there has been tremendous interest in finding a "silver bullet" to cure SCI and stroke via neuro-regeneration and adaptation. The approaches used have been pharmacological, cellular, genetic and immunological in nature. Some have reached the human trial stage, but their efficacy, costs and associated risks remain to be determined. On the other hand the field of neurorehabilitation has demonstrated that extensive task-oriented upper extremity training can result in clinically significant improvements that lead to increased quality of life and more independence. The aim of this thesis is to evaluate several upper extremity rehabilitation protocols that incorporate methods derived from different fields and to suggest ways of delivering this rehabilitation in a cost-effective way that is attractive to therapists and subjects alike.

1.9.1 Chapter 2

This thesis begins by introducing a combined treatment for upper extremity rehabilitation in the sub-acute stroke population. The primary goal was to assess task-oriented repetitive training using FES in combination with an instrumented workstation. The instrumented workstation was developed as a potential platform for increasing interactivity while performing ADLs and as a novel means of quantifying hand function. Using a workstation as an alternative to traditional hand function tests, could allow objective, quantitative assessments of ADLs to be performed.

1.9.2 Chapter 3

Following the sub-acute trial, a new workstation named the ReJoyce (Rehabilitation Joystick for Computer Exercise) was developed with the intent of using it in the home setting. The ReJoyce was much more compact then the previous version of the workstation, and had all of its items attached to the unit, preventing anything from falling off. The idea was to provide all the ADLs used in the previous workstation without the drawbacks encountered in the original system. Numerous workstation designs were developed, culminating in the ReJoyce, which met all of the the criteria we had set and allowed for the objective measurement of functional Range of Motion (fROM) that has been incorporated into a new hand function test, named the ReJoyce Automated Hand Function Test (RAHFT). The RAHFT was tested in SCI subjects and compared to two widely-used hand function tests, namely the ARAT and the FMA.

1.9.3 Chapter 4

As a result of the knowledge gained using FES in combination with the original workstation, we tested the ReJoyce in a randomized controlled trial with home-based tele-rehabilitation in tetraplegic people. This trial was unique in two respects. First, the FES device incorporated a novel triggering mechanism whereby small tooth-clicks were used to trigger hand opening and closing. Second, this was the first in-home tele-rehabilitation trial that employed FES and a workstation to train subjects in ADLs while playing computer games.

1.9.4 Chapter 5

This chapter provides the design steps taken to develop the ReJoyce system and the experiences of setting up a tele-rehabilitation trial involving all of the features listed above.

1.9.5 Chapter 6

Chapter 6 summarizes the results of the in-home telerehabilitation trial. Future directions for this emerging field are discussed.

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Chapter 2

Upper-Extremity Functional Electric Stimulation–Assisted Exercises on a Workstation in the Subacute Phase of Stroke Recovery*

In developed countries, about 1.5% of the population live with the after effects of stroke (≈5.5 million in North America).[1] Functional recovery of the upper extremity on average is quite poor, with 55% to 75% of patients having significant permanent deficits in performing activities of daily living (ADLs).[2,3] In many hemiparetic subjects, functional electric stimulation (FES) of the hand muscles can increase arm function by generating hand opening and a functional grasp.[4,5] Voluntarily triggered FES has been the focus of recent studies of recovery in the upper extremity following a stroke.[6-12] A recent review concluded that "positive results were more common when electrical stimulation was triggered by voluntary movement rather than when non-triggered electrical stimulation was used."[12(p65)]

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Kowalczewski J, Gritsenko V, Ashworth N, Ellaway P and Prochazka A.
Arch Phys Med Rehabil Vol 88: 833-839, July 2007

FES-assisted exercise therapy (FES-ET) has been found to improve hand function both during the subacute stage of recovery from a stroke[13-16] and the chronic stages[17-19]. Despite numerous studies, the relative efficacy of different durations and intensities of exercise remains unclear. Furthermore, the exercises performed in most studies to date have been poorly defined and rarely quantified. Accordingly, our study had 2 main aims were: (1) to compare functional outcomes in subjects randomly assigned to higher and lower intensity FES-ET groups and (2) to quantify these outcomes with an exercise workstation incorporating instrumented manipulanda representing ADLs. Our hypothesis was that the higher-intensity FES-ET group would develop better upper-extremity function whether they were tested with or without FES. Preliminary reports have been published.[20,21]

2.1 Methods

2.1.1 System

The therapeutic system consisted of a second-generation workstation that evolved from a previous design[18] and a custom 2-channel FES stimulator. The workstation comprised a circular desk with a Lazy-Susan rotatable upper surface that supported a number of exercise objects (fig 1). These objects and the exercises associated with them represented items commonly manipulated in ADL. Each task required subjects to reach with their affected hand forward from an armrest, open their hand, grasp the object, manipulate it, release it, and bring their hand back to the armrest. Electronic sensors monitored displacement or transit time of each object. Appendix table details the objects, sensors, and exercises. The purpose of instrumenting the workstation was to provide the experimenters with quantitative data.

The sensor signals were digitized at 20 samples per second with a custom-built control circuit incorporating a microcontroller[a] and stored on a desktop computer.

A custom FES stimulator was used in this study.[18] It provided trains of stimuli (50 per second; 200μs biphasic, current-controlled pulses). A pair of electrodes, comprising 5cm diameter wetted cloth pads backed with stainless steel mesh and plastic covers, were fixed to the subject's forearm with elastic straps. The cathodic electrode (negative-going voltage in the first phase of each biphasic pulse) was positioned approximately over the extensor digitorum communis muscle. The reference electrode was fixed to the dorsal surface just proximal to the wrist joint. Optimal placement and stimulation strength for maximal hand opening aperture were determined by trial and error.

2.1.2 Participants

Nineteen volunteers from Edmonton's Glenrose Rehabilitation Hospital with stroke-induced hemiparesis participated in this study. The diagnosis of stroke was

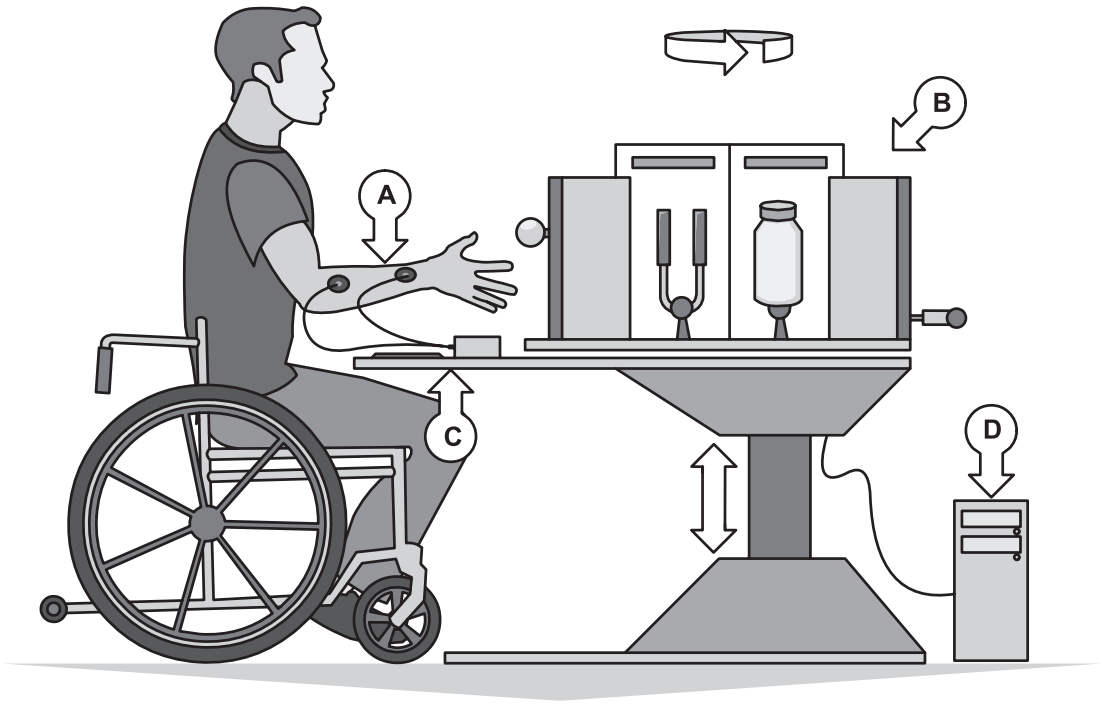

Figure 1:

The FES exercise therapy workstation. (**A**) FES electrodes attached to hemiparetic arm. (**B**) Custom-built workstation with instrumented objects representing tasks of daily life. Objects included a jar with a screw-top lid, a handle attached via a cord and pulley to an adjustable set of weights, a spring-loaded caliper, a spring-loaded doorknob, and a box and a jar on position-sensing pads at different heights and locations. (**C**) Rest-position sensing pad and trigger button (on nonparetic side) to control FES. (**D**) Laboratory interface and computer to collect sensor data. The workstation layout was kept constant throughout the trial, and subjects were positioned in front of it in a standard way.

confirmed in the acute care facility on the basis of clinical evaluation and computed tomography scans. In all cases, subjects had only suffered 1 stroke.

Subjects were randomized into low-intensity (9 subjects) and high-intensity (10 subjects) treatment groups. Inclusion criteria were: (1) stroke less than 3 months prior to the onset of participation; (2) inability voluntarily to grasp and release any 3 objects on the workstation; (3) Brunnstrom stage for the arm and hand less than 4[22]; (4) Mini-Mental State Examination score of greater than 16[23]; and (5) tolerance of the level of FES needed for hand opening. Exclusion criteria were: (1) inability of FES to open the impaired hand sufficiently; (2) no voluntary movements of the shoulder and elbow; (3) visual hemineglect (on the letter cancellation test, more than 2-letter difference)[24]; (4) severe depression (Center for Epidemiologic Studies–Depression Scale score >16)[25]; (5) other serious medical conditions; and (6) injuries to arms or hands. The procedure was approved by the University of Alberta Health Research Ethics Board and all subjects signed a letter of informed consent after receiving an information document describing the project.

2.1.3 Intervention

Subjects took part in the trial every workday for 3 to 4 weeks, in addition to their regular physiotherapy (described below). The high-intensity FES-ET group practiced 1 hour of FES-assisted exercise on the workstation every workday for 3 to 4 weeks (15–20 sessions). Each session consisted of the subject manipulating 3 objects on the workstation using his/her affected hand for about 20 minutes per object. The task was repeated as often as possible in the 20 minute span allocated. The 3 most challenging tasks the subject was able to manipulate were chosen on the first day of therapy and maintained throughout the treatment period for that subject. If an object was mishandled or the task not performed properly, the trial was disregarded and the data were not saved.

The exercises focused on reaching, grasping, manipulating (pulling, rotating, etc), and releasing objects. If the subject was unable to reach for the tasks a conventional partial weight-support sling and frame was used to assist in the movements. FES-mediated hand opening was controlled by the subject with a pushbutton on a side arm of the workstation. If the subject had trouble coordinating button pushing with performance of the task the therapist pressed the button instead. At the end of the treatment period, subjects were returned to their normal physiotherapy (PT) regime. No special instructions were given to them about exercise or rehabilitation after their release from hospital, and between the 2 follow-up evaluations at 3 and 6 months post-treatment.

We had originally intended to have a control group that did not receive any treatment beyond standard PT. However, this experimental design is open to the criticism that beneficial effects of the treatment could be partly due to a placebo effect of participation in a trial featuring a nonstandard component, namely, electric stimulation. To eliminate this effect, 4 days a week we provided the control group with 15 minutes of sensory electric stimulation of the dorsal surface of forearm causing sensation but no motor activation. On the fifth day each week, this group

performed 1 hour of FES-ET on the workstation to allow comparisons of kinematic scores obtained from the workstation sensors with those of the treatment group. Rather than continuing to call this a control group, we have called it the low-intensity FES-ET group. Subjects were informed at the outset that they would be assigned to 1 of 2 treatment protocols, but that there was no way of knowing ahead of time whether 1 protocol would produce a better outcome than the other. The 2 therapists who assisted subjects were instructed not to divulge any aspects of the alternative treatment. The third therapist who performed the assessments (see below) did not know to which group subjects belonged, nor did she take part in any of the treatment sessions. We therefore believe that the conditions required of a single-blind study comparing 2 levels of treatment were successfully achieved.

In addition to the above exercise treatments, subjects received regular hand function therapy in 1-hour sessions, 3 to 4 times a week. This was customized both in time and type of exercise for each patient by the staff of the rehabilitation hospital and occurred independently of our study. Treatment focused primarily on learning compensatory strategies to cope with disability and increase independence. It included stretching, range of motion (ROM) exercises, guiding objects on a shaped track, whole arm resistance exercises with Thera-Band[b]; placement tasks, use of a hand cycle and in the few subjects who had sufficient upper-limb function, shaping Thera-Putty.[b]

2.1.4 Assessment

Two types of outcome measure, clinical and quantitative, were used to gauge improvement in upper-extremity function.

First, clinical tests were performed and scored by a second therapist blinded to a given subject's treatment. The Wolf Motor Function Test (WMFT)[26] was chosen as the primary outcome measure, as it focuses on motor impairments assessed during tasks representative of ADLs. This test has been independently validated[27] and was performed the same number of times on subjects in the high- and low-intensity FES-ET groups in our study. For comparison, we also included the upper-extremity portion of the Fugl-Meyer Assessment (FMA),[28] which assesses elements of motor behavior including movement about single joints, synergies, ROM, and grasp. The FMA does not specifically evaluate ADLs. The Motor Activity Log (MAL)[29] provided self-reporting of the involvement of the affected extremity in ADLs. The WMFT, FMA, and MAL were performed and analyzed pretreatment, post-treatment, and at 3- and 6-month follow-ups.

Second, kinematic scores were derived from sensor readings on the workstation acquired every fifth day during the treatment session. Except for the shelf placement task, kinematic scores were obtained for each of the 3 tasks allocated to a given subject by dividing the maximal displacement by the time taken. For each task, this score was normalized to that of a group of 4 healthy subjects. The mean of the 3 normalized task scores was calculated. We call this the combined kinematic score (CKS). The CKS provided quantitative information on improvement in motor performance of the specific tasks on the workstation. Because workstation tasks

were performed many more times by the high-intensity group, the CKS presumably reflected specific task learning as well as general motor improvement.

2.1.5 Statistical Methods

The Shapiro-Wilks W test for normally distributed data[30] was implemented for each set of scores in Excel 2003.[c] To test the null hypothesis that the scores obtained by the high- and low-intensity treatment groups were from the same population, we performed F tests equivalent to an analysis of covariance with the regression package in SigmaPlot.[d] For each outcome measure, linear regressions were performed on the data obtained from the high- and low-intensity groups and then on the combined data.[31] Sums of squared differences (SSD) between the 3 regression lines and the three sets of data (2 separate, 1 combined) were computed. If the separate sets of data were significantly different, $SSD_{combined}$ was larger than the sum of the separate SSDs. F values were computed from the SSDs and corresponding degrees of freedom (*df*) according to the equation below, and the null hypothesis was tested ($P<.05$).

$$F = [(SSD_{combined} - SSD_{separate}) / SSD_{separate}] / [(df_{combined} - df_{separate}) / df_{separate})]$$

The Tukey honestly significant difference (HSD) was used post hoc to test for the significance ($P<.05$) of differences between the mean scores obtained by the high- and low-intensity treatment groups at given time points (eg, 3-mo, 6-mo follow-ups).[32] All data sets (WMFT, MAL, FMA, CKS) were normally distributed according to the Shapiro-Wilks W test.

2.2 Results

Table 1 shows the characteristics of subjects randomized into the high- and low-intensity treatment groups. Age, functional level, time poststroke, and treatment duration were well matched.

Figure 2 provides the CONSORT chart showing details of subject participation.

2.2.1 Clinical scores

Table 2 shows group mean WMFT scores of motor impairment and median time taken to perform tasks during and after the treatment period. Each subject performed 15 tasks, each of which was timed and scored on the range 0 to 5 for function. The means of these 15 scores were calculated, and these were used to calculate the group means and standard deviations (SDs) of the means (standard errors) shown in the table. An F test showed a significant difference between the high- and low-intensity groups in both parts (ability and median time) of the WMFT (F test, $P<.05$). Post hoc paired comparisons of the mean WMFT ability scores showed no significant difference between the groups at the onset of treatment. The

Details of Subjects Participating in the Study

Variables	High-Intensity Treatment Group	Low-Intensity Treatment Group
Patient Demographic		
Age (y)	59.4±19.7	61.7±11.0
Total no. of subjects	10	9
Male subjects, % (n)	40 (4)	67 (6)
Mean Brunnstrom stage: hand	1.8±0.4	1.9±0.6
Mean Brunnstrom stage: arm	2.1±0.3	2.2±0.6
Mean treatment duration (wk)	3.8±0.4	3.7±0.5
Months poststroke at onset	1.6±0.5	1.6±0.7
Percentage of right hemisphere strokes, % (n)	60 (6)	78 (7)
Percentage dominant hemisphere strokes, % (n)	50 (5)	33 (3)
Percentage of ischemic infarcts, % (n)	80 (8)	67 (6)
Percentage of hemorrhagic infarcts, % (n)	20 (2)	33 (3)
Patient workstation performance		
Hours exercising on the workstation	19.0±2.1	4.8±0.4
Percentage of subjects using the placement task, % (n)	100 (10)	100 (9)
Percentage of subjects using the doorknob task, % (n)	70 (7)	78 (7)
Percentage of subjects using the jar opening task, % (n)	20 (2)	22 (2)
Percentage of subjects using the handle pulley task, % (n)	50 (5)	67 (6)
Percentage of subjects using the spring loaded caliper task, % (n)	40 (4)	22 (2)

Table 1:

NOTE. Values are mean ± standard deviation or as indicated.

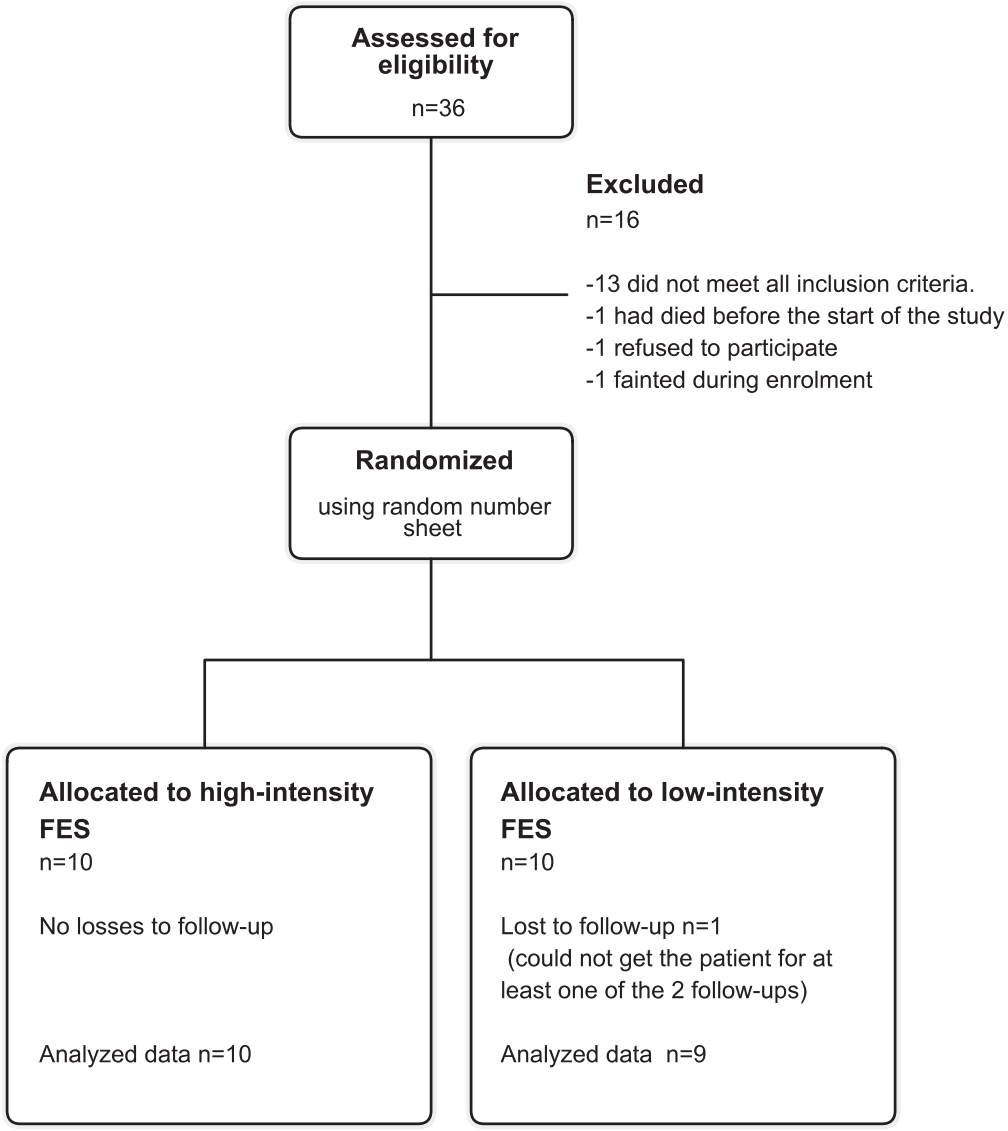

Figure 2:

CONSORT flowchart showing details of subject participation.

Mean Clinical Test Scores

Test	Pre	Post	3 Months	6 Months
WMFT ability score				
High-intensity group	1.31±0.10	1.87±0.14	1.96±0.17*	2.36±0.33
Low-intensity group	1.24±0.15	1.39±0.18	1.35±0.17	1.96±0.32
Effect size (Cohen *d*)		0.95	1.40	0.48
WMFT median time taken				
High-intensity group	115.5±4.5	45.5±16.4*	36.5±15.2*	23.7±13.5
Low-intensity group	99.3±13.8	90.7±13.5	91.0±14.7	69.7±17.4
Effect size (Cohen *d*)		0.95	1.15	0.93
MAL AOU				
High-intensity group	.006±.004	.040±.017	.073±.027	.152±.044
Low-intensity group	.020±.011	.035±.012	.006±.004	.086±.036
Effect size (Cohen *d*)		0.09	1.09	0.56
MAL QOM				
High-intensity group	.006±.004	.047±.019	.083±.027*	.161±.043
Low-intensity group	.017±.010	.032±.013	.008±.004	.089±.039
Effect size (Cohen *d*)		0.29	1.2	0.56
FMA				
High-intensity group	7.8±1.5	14.2±2.6	17.0±3.8	23.1±4.7
Low-intensity group	6.0±2.0	9.6±2.8	12.3±3.5	19.0±5.4
Effect size (Cohen *d*)		0.53	0.47	0.30

Table 2:

NOTE. Values are mean ± standard error.
Abbreviation: AOU, amount of use scale.
* Statistically significant differences between high- and low-intensity groups (post hoc Tukey HSD)

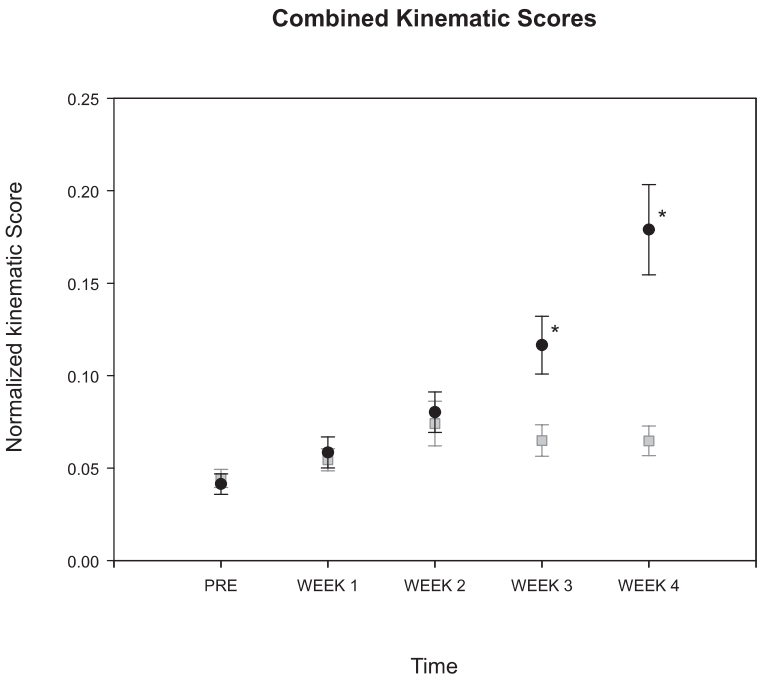

Figure 3:

Combined kinematic scores (CKS) measured by the workstation

difference immediately following treatment just failed to reach significance (*P*=.054) after correction for repeated measures (Tukey HSD). A significant difference had developed by the 3-month follow-up but significance was lost at 6 months.

Though individual paired post hoc comparisons of the mean MAL scores in table 2 did not reach significance, apart from 1 case (MAL quality of movement [QOM] at 3 months), F values of 3.32 (MAL amount of use) and 3.36 (MAL QOM) were significant..

FMA scores did not differ significantly between the high- and low-intensity FES-ET groups.

2.2.2 Combined Kinematic Scores (CKS)

Figure 3 shows mean CKS values pretreatment and then at weekly intervals during the 4-week treatment. In all cases, these values were obtained during a single workstation session. In the treatment period, this session occurred at the end of each week. Unfortunately, no kinematic data could be collected at the 3- and 6-month follow-ups due to the logistical difficulties of bringing subjects back to the hospital-based workstation from their home environments.

The mean CKS in the high-intensity group began to diverge significantly from that of the low-intensity group after 3 weeks of therapy (F test with post hoc Tukey HSD, *P*<.05; effect size, .80). By the fourth week, the CKS in the high-intensity group had more than tripled whereas in the low-intensity group, it had only increased by about 20%. The difference was significant (F test with post hoc Tukey HSD).

2.3 Discussion

In this study, we compared the rehabilitative effect in subacute hemiplegic subjects of 2 levels of FES-ET performed on an instrumented workstation. Both groups showed improvements in the primary outcome measure, as might be expected from previous studies.[12,33] The high-intensity group had significantly better WMFT scores overall than the low-intensity group.

Regarding the clinical importance of the differences between the high- and low-intensity groups, 1 measure in the literature is the Cohen *d* for effect size (difference between mean scores divided by the pooled SD[34]). For the WFMT functional ability scores, the Cohen *d* value was .95 immediately post-treatment, 1.4 at 3 months, and 0.48 at 6 months. Cohen defined an effect size of 0.2 as small, 0.5 as medium, and 0.8 as large. Thus the WMFT's ability score showed a large effect size post-treatment and at 3 months, and a medium effect size at 6 months. Unfortunately, there are no data in the literature on the minimal clinically important difference (MCID) for the WMFT,

The F test indicated that the mean MAL scores were significantly larger in the high-intensity FES-ET group than the low-intensity FES-ET group, though post hoc

analysis of specific time points, with the Tukey correction for multiple comparisons indicated that the difference only reached statistical significance in 1 case (MAL QOM at 3mo). The effect sizes were medium to large, but this may have been because the absolute MAL scores in both groups were very low. Regarding clinical significance, the MCID for MAL scores has been quoted as 0.5.[35] The largest increase in MAL score in our study was only .16, indicating that the gains in upper-extremity function in the absence of FES were not clinically significant. It is important to note that, in the absence of FES, the majority of patients in both groups could still not voluntarily open their more affected hand at the end of treatment.

The mean FMA evaluates whole-arm ROM. The upper-extremity exercises in our study may have been too specific to produce large enough improvements in this outcome measure to reach significance in our sample.

On the other hand, by the end of the 4-week treatment period, the high-intensity FES-ET group had more than tripled their CKS, whereas the low-intensity FES-ET group had not shown a significant change. The effect size of the difference between the high- and low-intensity groups at 4 weeks was 1.3 (large). It is worth stressing that, in both groups, the CKS data refer to workstation sessions in which FES was used, and furthermore the final CKS attained by the high-intensity group was still less than 20% of that of able-bodied subjects. The CKS data therefore show that FES-assisted motor function improves by a significant amount with higher-intensity FES-ET. This has not been shown before and is of importance in relation to the long-term neuroprosthetic use of FES in daily life.

A recent study[15] showed that 0.5 hours a day of FES-assisted therapy continues to improve motor function for up to 12 weeks. This is also supported by previous studies with more intense and prolonged therapy sessions.[19,36,37] Our study of subjects in the subacute stage of stroke recovery adds further support to the general conclusion that FES-assisted exercise therapy introduced in the early stages of rehabilitation leads to clinically important improvements in upper-extremity function.

We cannot exclude the possibility of a learning effect in the CKS data, as the high-intensity FES-ET group performed the workstation tasks for 5 hours a week compared with 1 hour a week in the low-intensity FES-ET group. However, the high-intensity group also had significantly larger improvements in the WMFT, which tests performance in a different and more widely ranging set of motor tasks than those on the workstation. The learning of the specific tasks on the workstation thus apparently generalized to a broader range of motor activities.

Regarding the design of our trial, previous studies of FES-ET have either used patients as their own controls in a repeated-measures design,[18,19] or they have compared treatment groups with control groups either receiving no treatment other than conventional PT, or some additional amount of conventional PT not involving electric stimulation.[13,14,38] At face value, these designs provide a cleaner dichotomy between treatment and control groups. However, in our opinion, they do not take into account the motivational aspect of taking part in a clinical trial of a new form of treatment. The sensory electric stimulation and the 1-hour-a-week

workstation sessions in our trial provided a plausible alternative treatment that we believe matched the motivational effect in the 2 groups.

Quantitative evaluation of motor improvement will, in our opinion, become increasingly important in the future, not only for evaluating and comparing treatments, but also for providing those participating in exercise treatments with unbiased feedback and incentive. This was our rationale for introducing the workstation concept[39] and developing it further in this study. Regarding the design of the workstation used, some features were more successful than others. Overall the device was judged to be too bulky, especially if it is to be deployed in subjects' homes, as would be crucial if FES-ET is to be extended after release from the rehabilitation hospital. The rotating support surface, while good in principle because it allowed task modules to be positioned in front of subjects, turned out to be too heavy for subjects to rotate without assistance. Sometimes, nonattached objects on the workstation fell or moved out of reach, requiring the assistance of the supervising therapist. Accordingly, we have developed a new workstation in the form of a spring-loaded arm with attached manipulanda for future work.[40]

2.4 Conclusions

The results of this study suggest that conventional therapy supplemented with FES-ET at a workstation for 1 hour a day over 4 weeks can provide improvements in upper-limb motor impairment in the subacute phase of stroke recovery, although further work needs to be done to qualify clinically significant improvements in this group of patients. The study therefore offers further evidence in support of FES-assisted rehabilitation as a complement to traditional rehabilitation.

2.5 Acknowledgments

We thank Michel Gauthier and Allen Denington for their help with design of the workstation. We also thank Carmen Tuchak, MD, Mark Ewanyshyn, OTR, Rhondda Jones, OTR, and Nicola Feilden, OTR, for their clinical advice and assistance.

Details of Objects on Workstation

Object	Sensor	Task
A spring-loaded doorknob	Potentiometer signaling rotational displacement	Rotation of the doorknob
A handle attached via a cord and pulley to an adjustable set of weights	Potentiometer signaling displacement	Pulling the handle toward the body
Rectangular blocks and cylinders of different sizes; shelves at 2 heights above surface	Photoelectric sensors signaling presence of object on pads or in docking bays	Transferring a block or cylinder from 1 location to another
A jar with a screw-top lid	Photoelectric sensor signaling 1 complete turn	Unscrewing the lid
A spring-loaded caliper	Potentiometer signaling displacement, from which force was derived	Squeezing the 2 arms of the caliper together between thumb and fingers

Appendix table:

Details of objects on workstation, sensors attached to them and the associated exercises

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2.6.1 Suppliers

a. Model MC68HC811; Motorola

b. The Hygenic Corp, 1245 Home Ave, Akron, OH 44310.

c. Microsoft Corp, One Microsoft Wy, Redmond, WA 98052.

d. Version 9.0; Systat Software Inc, 1735, Technology Dr, Ste 430, San Jose, CA 95110.

Chapter 3

A Fully-Automated, Quantitative Test of Upper Extremity Function*

Upper extremity motor deficits are major contributors to chronic physical disability following stroke and spinal cord injury. In North America 3 million people live with hemiparesis (one-sided weakness) resulting from stroke or trauma [4]. An additional 300,000 people with spinal cord injury (SCI) are tetraplegic, with upper extremity weakness or paralysis bilaterally. Up to 60% of all these people find it hard or impossible to perform activities of daily life (ADL) [5]. A growing body of evidence suggests that intense, task-oriented rehabilitation improves functional outcomes [6]. In recent years several groups have explored ways of automating rehabilitation [7 8 9], primarily to reduce costs, and more recently, to allow a continuation of tele-supervised rehabilitation exercises in patients' homes after they leave the clinical environment [10 11].

Robot-assisted therapy has been developed and studied for over a decade, but there is uncertainty as to whether the mechanical assistance provided by robotic devices is an advantageous or even necessary component of the therapy [12 13].

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*Adapted from an original publication:
Kowalczewski J, Davies C and Prochazka A.
In review

Furthermore, the extremely high cost associated with robotic devices for upper extremity rehabilitation has prevented them from being accessible to the large majority of stroke and SCI patients in treatment centres, let alone for home-based treatment.

The exercise tasks performed by patients in the conventional rehabilitation setting tend to be repetitive and boring. Compliance in self-administered rehabilitation of this type is marginal [14]. In order to maintain patient interest there is an increasing trend to incorporate computer games into treatment protocols [10]. Another way of improving compliance outside the clinic is to use tele-rehabilitation [11 15]. The introduction of computer games into rehabilitation [16] has been accelerated with the advent of the Nintendo Wii console[17 18]. The Wii has achieved rapid and widespread acceptance into many rehabilitation centers even in the absence of clinical studies showing efficacy, because it is affordable and it provides entertaining ways of performing conventional exercises. The Wii allows users to play computer games by moving a hand-held motion sensor. While it is useful for large, unloaded, range-of-motion exercises it does not address the need to practise the dextrous manipulation of objects. Furthermore because the motion signals from the sensor are not available for display or analysis, quantitative functional assessment is unavailable.

Hand function tests are useful in tracking clients' progress and in directing their rehabilitation. Traditional methods of assessment are mainly qualitative and therefore prone to rater bias. Ideally, hand function tests should be performed on standardized equipment that allows various parameters of performance to be quantified. However, in order for this to be feasible either in the clinic or in clients' homes, the cost of the equipment and the time taken to perform the assessments must be affordable. Several motion and force analysis systems have been developed over the last few years, but few have been deployed in clinics as alternatives to traditional qualitative assessments. For an automated hand function test to become clinically accepted, first and foremost, it must be shown to be substantially equivalent to existing clinical tests The equipment involved should be affordable and simple to use, with software that provides the assessments in standard formats such as printed reports or computer files. Ideally the equipment should also be useable for upper extremity exercises. The Rehabilitation Joystick for Computer Exercise (ReJoyce) was developed by our group with these criteria in mind.

The ReJoyce is a passive workstation comprising a segmented arm that presents the user with a variety of spring-loaded manipulanda (Figure 1). Each manipulandum is instrumented with one or more sensors, whose signals are fed to a computer. The signals are analyzed with custom software to control computer games, and to run the "ReJoyce Automated Hand Function Test" (RAHFT). The purpose of this study was to examine the RAHFT and see how well it correlated with two conventional, clinically accepted hand function tests.

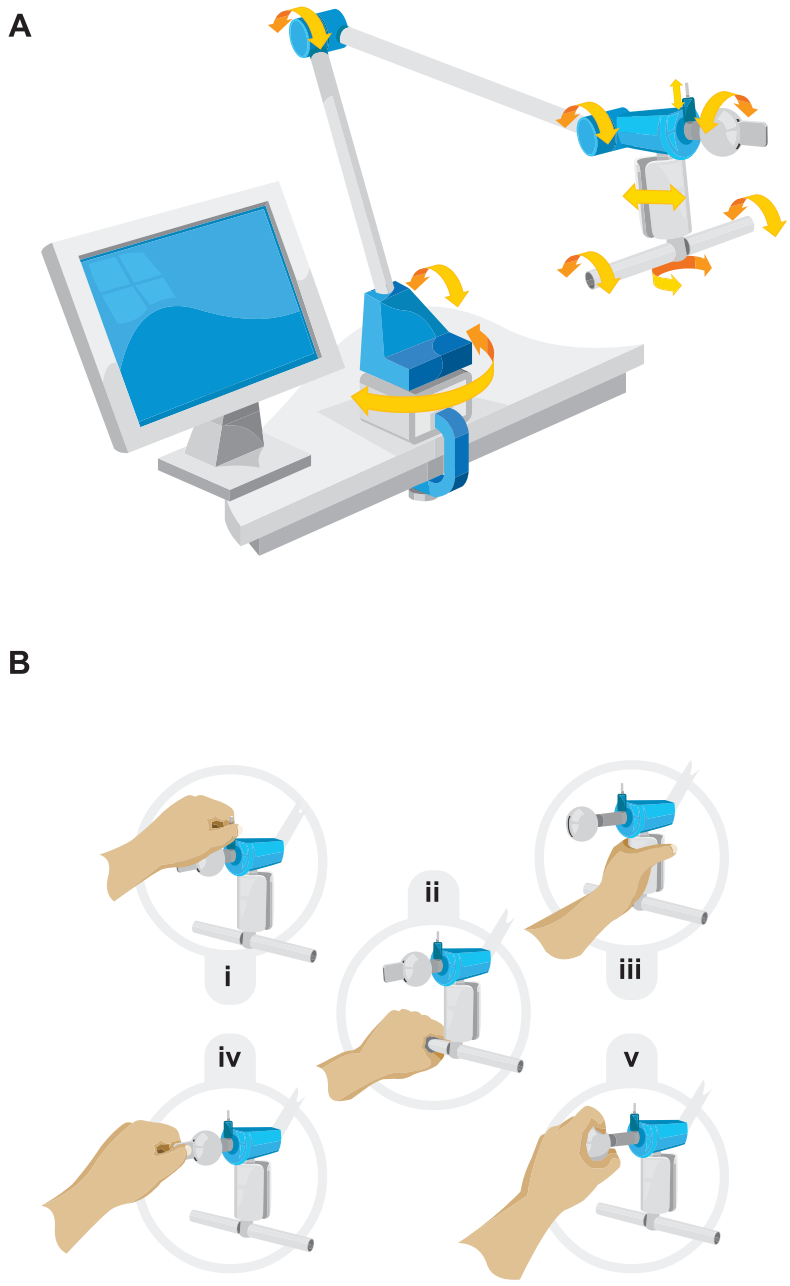

Figure 1:

A) Schematic of the ReJoyce (Rehabilitation Joystick for Computer Exercise). Subjects performed a variety of tasks while playing computer games, or performing the ReJoyce Automated Hand Function Test (RAHFT). The device is instrumented with sensors that provide quantitative information on displacement of the manipulanda, and the force of a grasp. **B**) types of grasp required to perform the RAHFT.

3.1 Methods

3.1.1 Participants and Ethics Statement

Thirteen people aged between 24 and 56 with tetraplegia resulting from a C5-C6 SCI participated in this study, as part of a broader project comparing two treatments, either 6 weeks of FES-assisted, tele-supervised exercise sessions on the ReJoyce workstation or six weeks of tele-supervised conventional exercises (Ms in preparation). Approval of the project was granted by the Health Research Ethics Board of the University of Alberta. All subjects provided written, informed consent. The study was registered with the NIH (clinicaltrials.gov identifier NCT00656149).

3.1.2 Procedures

Three hand function tests were performed in randomized order in single sessions that took place at 2-weekly intervals during the 6-week treatment periods. The three tests were the Fugl-Myer Assessment (FMA), which mainly tests upper extremity range of motion and strength, the Action Research Arm Test (ARAT), which is a comprehensive test of hand dexterity and arm function and the ReJoyce Arm-hand Function Test (RAHFT), described in detail below. The FMA and ARAT tests were videotaped and scored by a blinded, independent rater.

3.1.3 Apparatus

Each of the six manipulanda in the ReJoyce workstation was designed to represent a task commonly encountered in daily life. A clamp at the base of the spring-loaded arm was used to attach the device to a table or desk. The arm had 4 degrees of freedom of movement and was instrumented with rotational potentiometers about each joint. In addition, there were switches, rotational potentiometers and linear potentiometers in the manipulanda. The spring loading of the arm provided some elastic resistance to movement and ensured that the manipulanda returned to a neutral position when they were released. It also supplied some weight support to the user's hand and arm. The manipulanda included a pair of horizontal handles that could be rotated about their long axis, a vertical peg that could be lifted, a gripper the size of a pop can that could be squeezed and a spring-loaded door knob with an exposable key-like element, both of which could be independently rotated. The handles were situated at the bottom of the manipulandum assembly and in the neutral position of the arm they were at the level of the base of the device. The easiest task to perform was to grasp one or both of the horizontal handles and to pull the manipulandum assembly in and out, up and down or left and right (Figures 1 and 2). The gripper, the door knob, key and

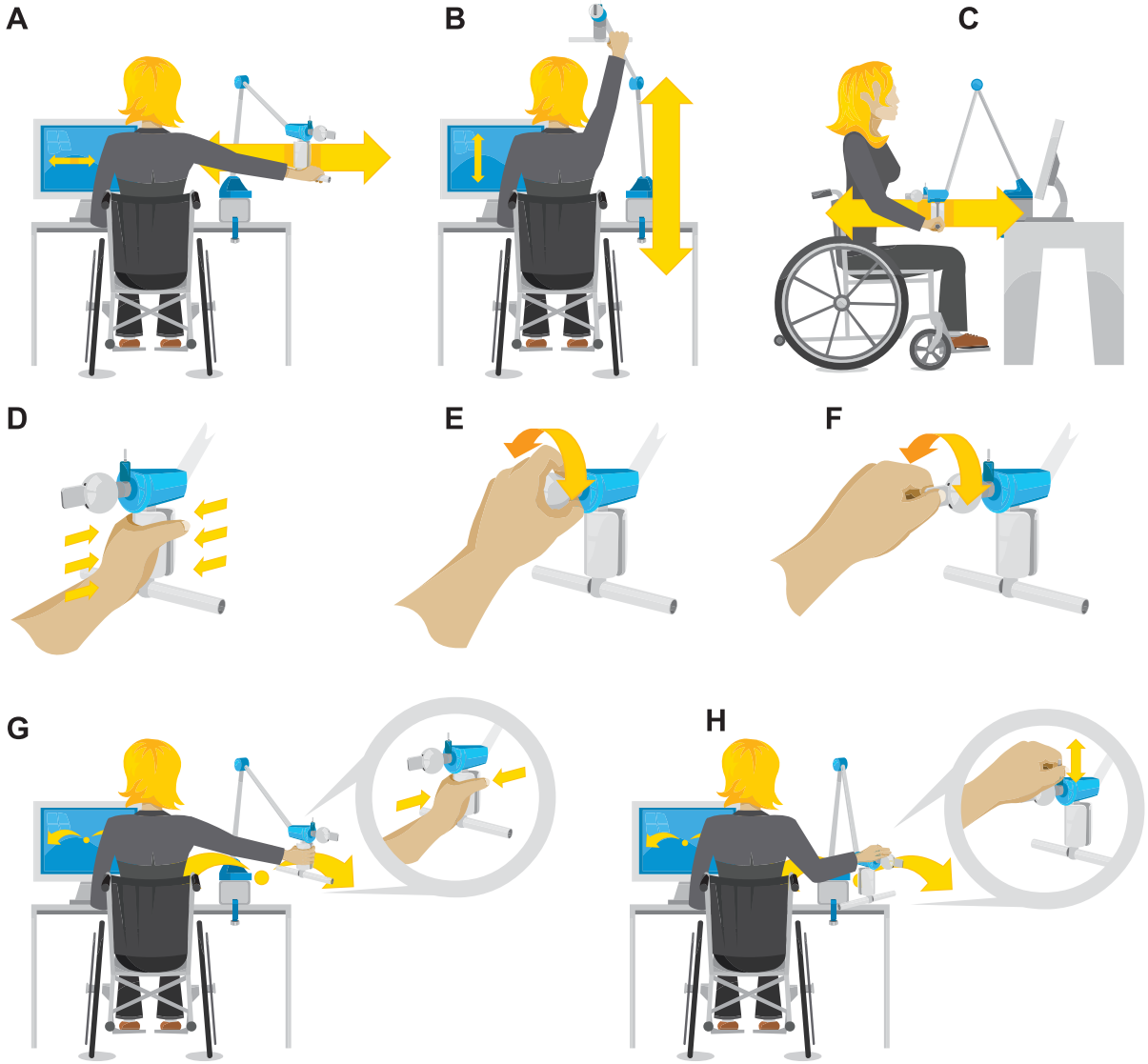

Figure 2:

The ReJoyce system, showing all components of the RAHFT. **A**) move to left and right; **B**) move up and down; **C**) move in and out; **D**) grasp and squeeze rubber cylinder; **E**) rotate springloadeddoor-knob; **F**) rotate spring-loaded key; **G**) grasp, move and release, using the cylinder; **H**) pinch peg, lift, move and release.

peg, were located above the handles in an approximately ascending order of difficulty of use.

We will refer to an individual's workspace as the functional range of motion (fROM). This is the volume of space in which the person is able to perform functional tasks. The ReJoyce system focuses not on the kinematics or kinetics of arm movement, but rather on a person's ability to move and manipulate objects within their fROM. It allows for a number of different grips to be used as well as combinations of grips and displacement that mimic tasks of daily life such as grasping and twisting a doorknob and opening the door. Figure 1B illustrates the manipulanda and some of the grasps and movements used during the RAHFT or during routine exercise training.

A MAKE Controller Kit (MakingThings LLC Ca. USA) in the base of the ReJoyce arm digitized the analog signals from sensors in each component of the manipulandum assembly. The microprocessor sent the information in digital form via a Universal Serial Bus (USB) to a local computer. The information was processed by the computer with custom software that computed the coordinates of the arm segments and manipulanda in 3-dimensional space, the displacement of the "gripper" manipulandum, the rotation of the key or doorknob, and the elevation of the peg. These various signals were used by the software to control the RAHFT and interactive games.

3.1.4 The RAHFT

The RAHFT consisted of three parts: functional range of motion (fROM), grasp, key-grip, pronation-supination tasks and placement tasks (Figure 2). The users (subjects or therapists) initiated the RAHFT software program by clicking on a desktop icon, after which it ran automatically, taking its cues from signals from the ReJoyce device or inputs from the subject's computer keyboard. As the test progressed, the RAHFT software introduced each component of the test with a 3-dimensional animation accompanied by an audio recording, which ended with a 3 second countdown. The user was then allowed up to 60 seconds to perform the task. If the task was completed within this time, the user or therapist could advance to the next task by depressing the keyboard spacebar. On some occasions the RAHFT was also performed remotely during tele-supervision sessions, but these data are not included in this report, as they were not obtained with concurrent FMA and ARAT tests.

1) fROM. The subject was first asked to hold the horizontal handle on the manipulandum assembly and move it as far to the left and then as far to the right as possible (Figure 2). Sixty seconds were allocated for this task. The second and third tasks were similar, comprising up and down and in and out ranges of motion. The spring-loading of the manipulanda provided a spring stiffness of 16 N/m, in the left and right direction (x-axis), 26 N/m in the up and down direction (y-axis) and 20 N/m in the in and out direction (z-axis).

2) Grasp. The subject was asked to grasp and squeeze the gripper on the manipulandum assembly three times as hard as possible. The gripper was a spring-loaded, split cylinder the size of a pop can. It required 10 N of force to be applied to bring the two halves of the cylinder together through a distance of 1.5 cm. The spring stiffness in this range of movement was 667 N/m

3) Doorknob. The subject rotated a spherical, spring-loaded doorknob clockwise and counterclockwise, the mechanism being based on that of commercially available doorknobs with a rotational stiffness of 0.34 Nm/rad.

4) Key. The subject rotated a spring-loaded key-shaped object normally hidden within the doorknob manipulandum (same rotational stiffness as doorknob). Pushing the doorknob inward along its shaft exposed the key and closed a switch, which informed the system of activation of the key task. Rotation of the key was then monitored by the software.

5) Placement tasks. The first of these involved picking up a virtual pop can displayed on the computer screen, by holding the gripper loosely, moving it so as to position crosshairs onto the screen image of the pop can, squeezing the gripper to "hold" the virtual can and move it to a position over one of two virtual "garbage bins" located on each side of the screen. The virtual pop can was then dropped into the bin by releasing the gripper. A new virtual pop can then appeared in the middle of the screen, requiring the subject to grasp, move and drop it into the other bin. The second placement task was similar, in that it required a peg located at the top of the assembly to be grasped, lifted, moved and released. A corresponding virtual peg was displayed on the subject's screen. The task was to move it over one of two virtual "holes" and release it. As in the case of the pop can task, a second virtual peg then appeared and this had to be dropped into the second virtual "hole." In both placement tasks, if the object was not dropped into the inappropriate receptacle, the task had to be repeated until it was completed successfully or 60 seconds had elapsed.

3.1.5 Scoring the RAHFT

All fROM tasks were scored as a percentage of the maximal displacement of the handle in the required direction (e.g. left, right, up, down). The grasp, doorknob and key tasks were similarly scored as percentages of the maximal displacement possible (Table 1). Each placement task comprised two components: a movement to the left and a movement to the right. In this case each component was scored in terms of the time to completion according to the equation:

% score = 50 – (time*5/6)

Thus if a left placement (e.g. dropping a can into the left bin) was performed in say 6 seconds the score for that portion was 45%. If the subsequent right placement was also completed in 6 seconds, it also scored 45% and so the summed score for that

task was 90%. On the other hand, if the left placement took 6 seconds and the right placement took 30 seconds, the summed score was 70%.

At the end of the RAHFT the software automatically computed the overall RAHFT score as the mean of all the individual task scores.

3.1.6 Statistical Methods

Principal Components Analysis was performed with Matlab v. 7.0.1 (The MathWorks, Natick, Ma) software. Principal components (PCs) were computed from the test scores of all three hand function tests and the same software was used to perform a linear regression of the scores of each individual test with respect to the corresponding values along the axis of the first principal component. Each of the hand function tests had different ranges of possible scores: ARAT 57, FMA 54, RAHFT 100, we converted the raw scores to percentages of the full range for each individual test. This allowed the scores from the three tests to be more easily compared.

3.2 Results

The three hand function tests (ARAT, FMA and RAHFT) were performed in randomized order in a total of 36 different single sessions during the 6-week treatment periods with 13 subjects. Figure 3 shows the normalized scores from each session as a data point in a 3-dimensional plot. The first three PCs are shown as orthogonal lines running through the data points in Figure 3. The first PC (PC1), is shown as the long bold line. PC1 accounted for 91% of the variance in the data. The second and third PCs are short, reflecting the much smaller variances of the data in these directions.

The relationships of each of the three tests to their corresponding values of PC1 are shown in Figure 4. Linear regressions were performed, resulting in the following correlation coefficients: ARAT on PC1: $r^2 = 0.98$, FMA on PC1: $r^2 = 0.64$, RAHFT on PC1: $r^2 = 0.93$.

It is customary to validate a new motor test by comparing it to existing, validated tests. In this case we were interested in validating the RAHFT against the ARAT and FMA. Figure 5 and 6 show plots and linear regressions of the RAHFT against these two validated tests. For the sake of comparison, we also included plots and regressions of the FMA and ARAT against each other. The RAHFT was well correlated with the ARAT ($r^2 = 0.88$), and in fact much better correlated than was the FMA with the ARAT ($r^2 = 0.53$). Not surprisingly in view of these results, the RAHFT and ARAT were only moderately correlated with the FMA ($r^2 = 0.49$ and $r^2 = 0.53$ respectively).

The ARAT took the longest time to administer with a mean time of completion of 7.8 $\pm$ SD 1.6 minutes), followed by the FMA which took a mean time

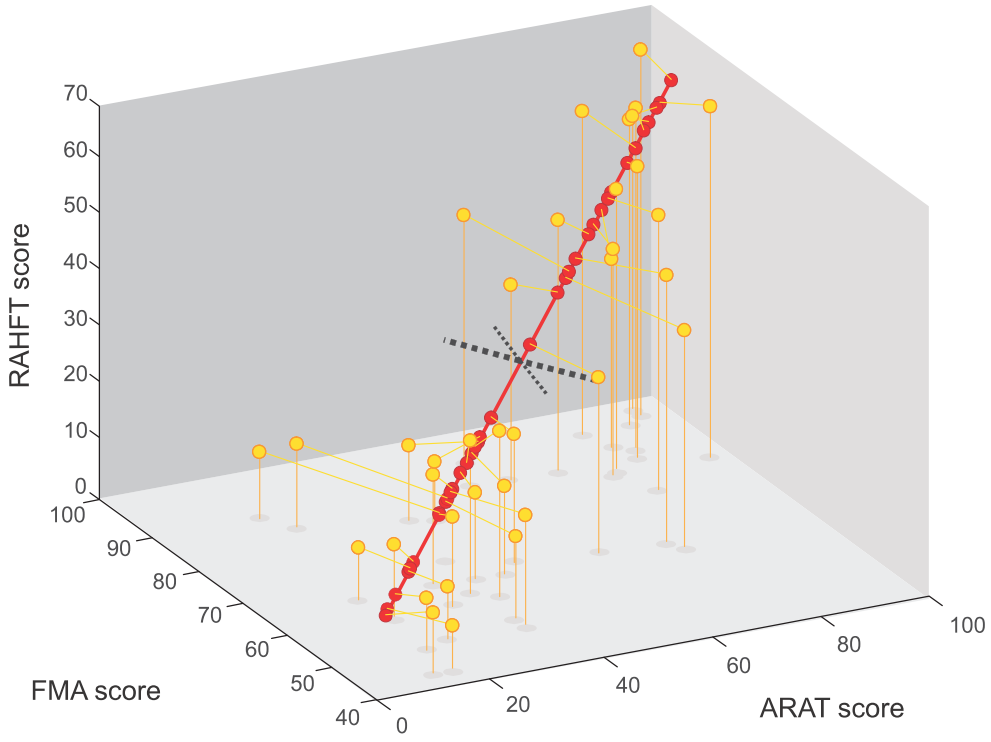

Figure 3:

Principal components analysis of three hand-arm function tests (ARAT, Fugl-Meyer (FMA) and RAHFT) performed on 34 occasions. Each yellow point shows the normalized scores of thethree tests in a given tetraplegic subject in a single session. The red line is the first principal component (PC1) of the yellow data points, the red dots are the nearest points on PC1 to each data point, with yellow joining lines

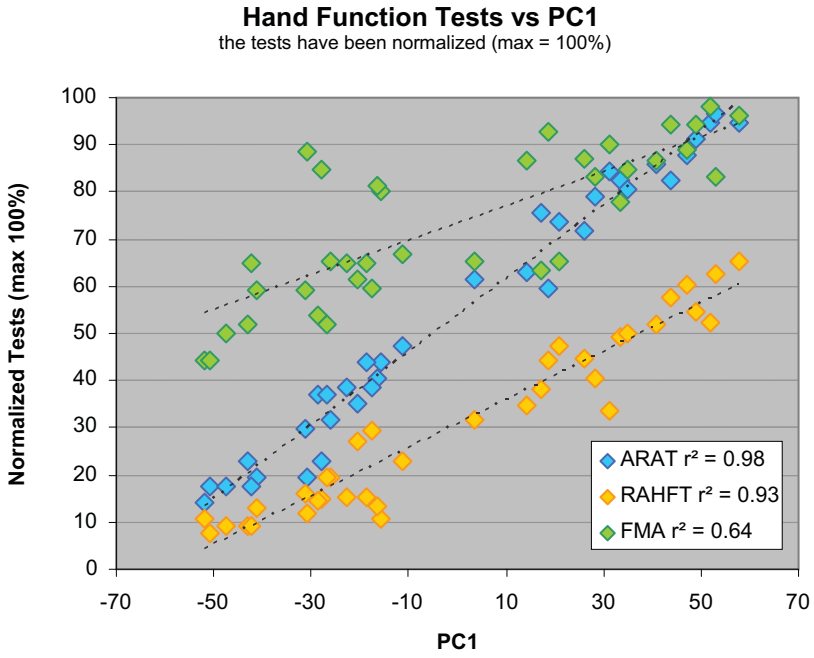

Figure 4:

Individual plots of each hand function test versus PC1, with regression lines and coefficients. All three tests are well correlated with PC1. The ARAT and RAHFT are better correlated with PC1 than is the FMA. The ARAT shows potential floor and ceiling effects (covering 97% of its possible range), while the FMA shows a possible ceiling effect and the RAHFT a possible floor effect.

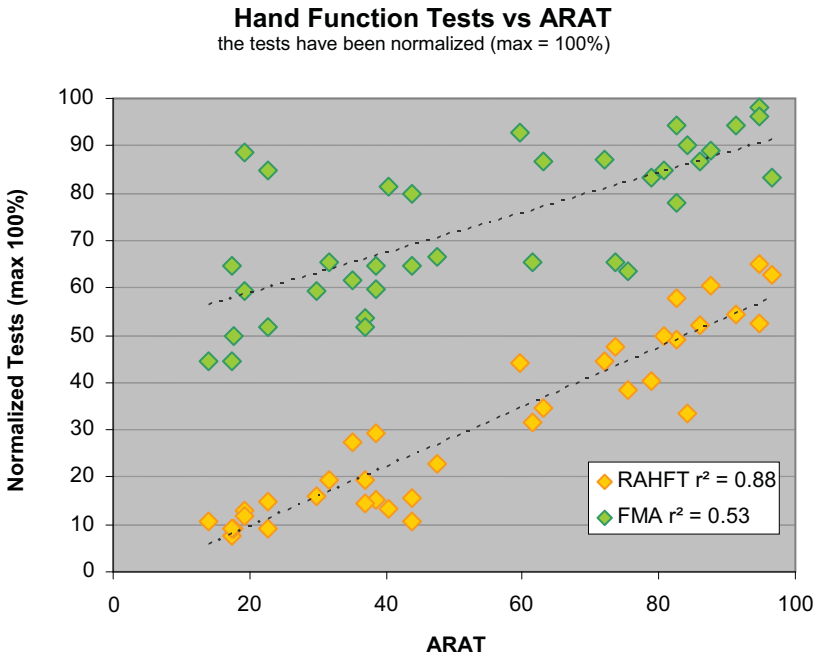

Figure 5:

Individual plots of the RAHFT and FMA versus ARAT, with regression lines and coefficients. The RAHFT correlated significantly better than the FMA.

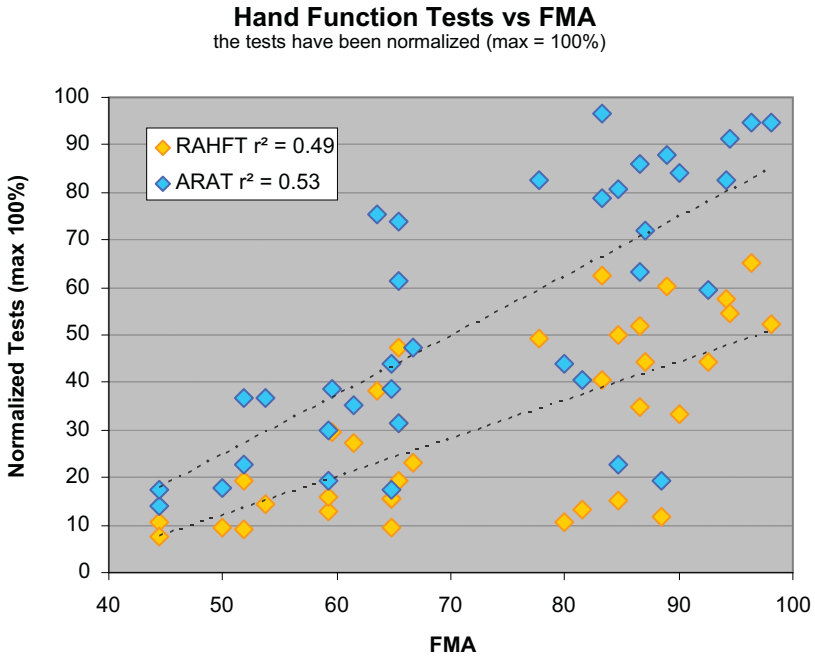

Figure 6:

Individual plots of the RAHFT and ARAT versus the FMA, with regression lines and coefficients.

of 5.2 $\pm$1.0 minutes. The RAHFT was performed in the least amount of time, taking a mean of 3.8 $\pm$0.90 minutes).

3.3 Discussion

The purpose of this study was to see how well the RAHFT correlated with two widely accepted hand function tests, the ARAT and the FMA. In addition to simple regression analysis, principal components analysis was used to quantify the relationships between the three tests. This is a relatively new way of assessing and comparing motor function tests [19] and has the advantage of showing how well the scores from an individual test match the scores of all the tests available in the comparison. The RAHFT was highly correlated with PC1 of our data set, as was the ARAT. The FMA was less well correlated. Furthermore, the correlation between the RAHFT and ARAT was stronger than that between the FMA and either of the other tests. In retrospect, the greater correlation between the RAHFT and ARAT was to be expected, as these tests are designed to assess upper extremity function in ADLs, whereas the FMA primarily focuses on range of motion at individual joints.

Although the ARAT correlated the best of the three tests with PC1, Figs 4 and 5 show that at the top end of the range, subjects scored nearly 100% of full scale. Because the corresponding RAHFT scores were less than 70% of full scale, this indicates that the ARAT has a "ceiling effect". This was supported by the observation that some of the SCI subjects we tested who received near perfect ARAT scores, exhibited visible deficiencies in upper extremity function compared to normal individuals. The FMA also showed a ceiling effect. Thus the ARAT and FMA may be less sensitive than the RAHFT to improvements in high-functioning subjects. At the other end of the scale, there was a potential floor effect in the ARAT and RAHFT, in that low-functioning subjects who had little active grasp or release, but who nonetheless had a reasonably good range of motion, received near-zero scores. The corresponding FMA scores were above 40% of full scale, indicating that the FMA may have an advantage in this respect. It is sensitive to small movements that are not necessarily very functional. The FMA might therefore be more responsive than the ARAT and RAHFT to small changes in the range of motion following an intervention in low-functioning subjects.

Regarding the applicability of our findings to other motor disorders, the majority of the SCI participants in our study had a good to very good range of motion about the shoulder and elbow, resulting in relatively high FMA scores. In people with hemiparesis caused by stroke or head trauma, poor hand function is generally coupled with poor mobility about the proximal joints. Further testing would be needed to determine the relationship between the RAHFT, ARAT and FMA in hemiparesis and other motor disorders.

When assessing new tests of motor function it is common to evaluate inter-rater reliability, validity and responsiveness. Regarding reliability, the advantage of quantification and standardization through automation is that qualitative

judgement and rater bias are removed. This eliminates inter-rater variance. However other sources of variance that are common to most if not all existing motor function tests are likely to remain. For example although our protocol includes guidelines for positioning the subject in relation to the device, as do some of the existing tests, there is a limit to how well this can be defined and adhered to. Inevitably there will be deviations between subjects and between test centres in this regard. Another factor that can lead to variance is the degree to which subjects comply with the automated audio-visual instructions. In the present study, a therapist was always present to ensure compliance with each portion of the RAHFT (as well as the ARAT and FMA). It remains to be seen whether compliance can be guaranteed when subjects perform the test either under tele-supervision or in the complete absence of supervision. One safeguard we have since built into the ReJoyce software is the automatic detection of an absent response to an instruction, which triggers up to two repeats of the instruction before the system passes on to the next component of the test.

Regarding validity, the regression and principal components analysis showed that the RAHFT compared well with two widely-accepted clinical tests, the ARAT and FMA. It would be desirable to expand this comparison to include other types of tests such as SCIM [20] and FIM [21]. The RAHFT correlated better with the ARAT ($r^2 = 0.88$) than with the FMA ($r^2 = 0.49$). This was not too surprising, because each component of both the RAHFT and the ARAT was chosen to represent a specific class of ADLs.

The primary function of the ReJoyce system is to serve as a workstation for rehabilitation of upper extremity function. The RAHFT was developed when it was realized that the signals from the sensors allowed us not only to control computer games, but also to quantify performance. The scenario whereby the device is used both as a rehabilitation tool and as a means of assessment has the advantage that each user's progress can be accurately monitored on a regular basis, especially as the test can be performed in less than 5 minutes. However, the disadvantage of frequent testing is that there would most likely be a training effect, so that the results obtained on the RAHFT would not necessarily generalize to a larger variety of tasks encountered in daily life. It will be important to clarify this issue in the future, since the RAHFT can be performed in the subject's home on a daily basis with or without tele-supervision, if so desired.

In conclusion, many task-oriented hand function tests have failed to transfer from laboratories to everyday clinical practice because of the need to train those who administer the tests, those who rate the tests and difficulties in obtaining the standardized test items, as well as long set-up and performance times. The system described in this report offers a novel solution to this unmet need.

3.4 Acknowledgements

We thank Su Ling Chong, PT, for help in recruiting subjects for this trial, Kelly Brunton, PT, for the blinded rating of the ARAT and FMA clinical hand function tests, Andrew Prochazka for help developing the ReJoyce hardware and Antoni Kowalczewski, Jeremy Burns and Al Adsit for their contribution to the ReJoyce software. The following agencies provided funding for the study: International Spinal Research Trust (ISRT), Canadian Foundation for Innovation (CFI), Alberta Heritage Foundation for Medical Research (AHFMR) and the Canadian Institutes of Health Research (CIHR). Jan Kowalczewski and Dr. Arthur Prochazka have filed for a patent encompassing the ReJoyce system and the RAHFT. Dr. Arthur Prochazka is a stakeholder in Rehabtronics Inc. a spinoff company that has been assigned the rights to the ReJoyce system.

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Chapter 4

ReJoyce: Novel At-Home Upper Extremity Tele-Rehabilitation.

An estimated 2.5 million people live with a Spinal Cord Injury (SCI) worldwide according to the International Campaign for Cures of Spinal Cord Injury Paralysis (http://www.campaignforcure.org/iccp/) with an incidence between 10.4 to 83 per million [1]. These injuries can range from a contusion or partial transection that spares most of the axons passing through the injured region and therefore only results in mild motor or sensory deficits, to a complete transection with devastating motor and sensory outcomes, particularly if both the upper and lower extremities are paralyzed (tetraplegia). People with severe tetraplegia become dependent on care-givers or relatives to perform even the simplest manual tasks. With a lifetime cost between $500000 and $2 million [2] to care for people with SCI, [3], finding new ways to improve their functional independence is a very worthwhile financial goal, not to mention the moral imperative.

In the last two decades, much research effort and funding has gone into the search for a "cure" for SCI, focusing primarily on neural regeneration and adaptation induced by cellular, immunological, genetic and pharmacological approaches. Because there is the potential for doing more harm than good with some of the suggested treatments, the transition from animal studies to human clinical trials has been slow, though several promising clinical trials are now underway. By the same token, it is well known that a rigorous program of upper extremity rehabilitation can, in some cases, greatly improve the quality of life of individuals with tetraplegia

by increasing their ability to perform manual tasks [4] as well as provide other benefits such as preserving bone mass [5]. Small improvements can sometimes make a large difference to the independence of these people [6 7]. For this reason optimizing and further developing new rehabilitation regimes to provide the best possible outcomes are as crucial as attempts to promote regeneration and adaptation of neural pathways. It is worth noting that in a recent study, people with tetraplegia ranked the recovery of hand and arm function as their top priority, over sexual function, trunk stability, bladder, bowel, elimination of autonomic dysreflexia, restoration of walking movement, normal sensation and the elimination of chronic pain [8]. Recent data suggest that a higher percentage of people with SCI have tetraplegia than in previous decades [1].

The ultimate goal of any upper extremity rehabilitation protocol is to improve arm and hand function when performing activities of daily life (ADLs). Rehabilitation is a process that focuses on improving function by the repetitive training of certain movements. There are numerous obstacles in upper extremity rehabilitation for individuals afflicted with tetraplegia; they include 1) large costs associated with transportation, therapist time and specialized equipment, 2) lack of motivation to perform repetitive exercises and 3) the physical limitations imposed by a SCI, restricting the type and quantity of hand-oriented repetitive tasks these people can perform. Faced with similar obstacles in the stroke population several groups have been attempting to automate upper extremity rehabilitation [9 10 11].

Currently one of the means of reducing costs is to provide patients with home-based, self-administered treatments. However the repetitive and boring nature of the protocols used so far has resulted in poor compliance [12]. A plausible means to keep participants interested in performing repetitive tasks is the use of tele-rehabilitation [13 14] and computer games [15].

In this cross-over, randomized, controlled clinical trial, we explored the use of these new approaches in two different treatments focusing on improving hand function in C5-C7 SCI patients. This is, to our knowledge, the first attempt to provide daily in-home tele-supervised rehabilitation for the upper extremity in SCI. One treatment involved combination occupational therapy and the other involved the use of a novel workstation (the ReJoyce: Rehabilitation Joystick for Computer Exercise). Both treatments incorporated electrical stimulation of muscles and tele-supervision of in-home exercises (1 hour/day, 5 days/week for 6 weeks). The treatments were chosen to be feasible alternatives to self-administered therapy in today's healthcare environment. As such, both needed to be cost-effective and relatively simple to administer. In the combination treatment a therapist designed training sessions for each participant involving 1) 20 minutes of strength training, 2) 20 minutes of cyclical therapeutic electrical stimulation (TES) of hand muscles, 3) 20 minutes of accuracy training using a computer trackball. The test treatment involved manual tasks performed on a custom workstation (the Rehabilitation Exercise Joystick for Computerized Exercise: "ReJoyce"). In this case grasp and release were assisted with an electrical stimulator garment that delivered functional electrical stimulation (FES). FES refers to stimulation that is controlled by the user to assist in performing functional tasks. It has been shown not only to assist hand grasp and release, but

also to strengthen muscles and improve coordination so that ADLs are improved even when the device is not used [16]. Participants in our trial manipulated spring-loaded attachments on ReJoyce workstations. These included a doorknob, key, peg and gripper, all chosen to represent ADLs. The attachments were instrumented with sensors whose signals were used as inputs to the computer, to control a variety of computer games. The games were custom-designed to elicit a range of hand and arm movements. One aim of the study was to explore the feasibility of regular, in-home exercise therapy tele-supervised over the Internet. Another aim was to compare combination training with FES-assisted exercises performed on ReJoyce workstations.

4.1 Methods

4.1.1 Study design

The study was a randomized, controlled trial comparing two treatments in a cross-over design. In both treatments, participants performed upper extremity exercises for 1 hour/day for 6 weeks, tele-supervised over the Internet. In the combination treatment the exercises were performed with the use of conventional rehabilitation equipment detailed below. In the ReJoyce treatment the exercises were performed on an instrumented workstation (the ReJoyce system), with the use of an FES device that improved grasp and release. Participants were block-randomized into two protocols, 1 and 2, those in protocol 1 receiving the combination treatment first, followed by a 1 month washout period and then the ReJoyce treatment. Those in protocol 2 received the two treatments in reverse order, also with an intervening 1 month washout period. All treatment sessions were performed at home with remote tele-supervision, except for 3 sessions performed in the laboratory at the University of Alberta at the end of weeks 2, 4 and 6 in each treatment. In these sessions participants took part in a battery of functional, electrophysiological and sensory testing.

In this paper we report the outcomes of the functional testing. The primary outcome measure was the Action Research Arm Test (ARAT) [17 18]. Secondary measures included grip and pinch force measurements with a dynamometer and the ReJoyce Automated Hand Function Test (RAHFT) [Kowalczewski In revision].

Written, informed consent was obtained from all participants. The study was approved by the Health Research Ethics Board of the University of Alberta and registered with the National Institutes of Health (identifier NCT00656149 at www.clinicaltrials.gov).

4.1.2 Participants

The flow of participants through the trial is illustrated in the modified CONSORT chart (Fig. 1). Twenty two individuals with tetraplegia resulting from a primary injury

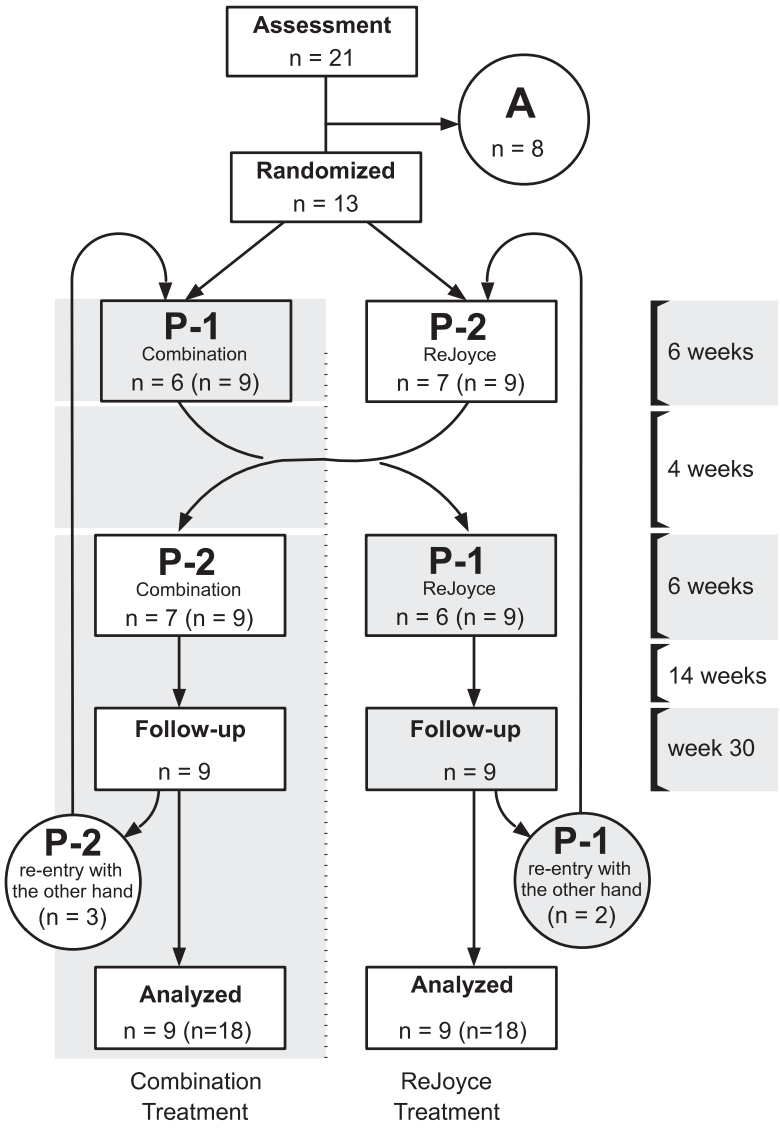

Figure 1: Modified CONSORT Flow Chart Diagram

A represents eight individuals that have been assessed but were excluded, this includes those that did not meet the inclusion criteria (unable to stimulate muscles electrically n=3, high risk of seizures n=1, too high functioning n=1), as well as those that could not come in for the regular lab visits (n=3). **P-1 Combination** depicts the first treatment (Combination) in protocol 1, with 6 initial assignees combined with 3 that re-entered the trial with their other hand (n=9). **P -1 ReJoyce** represents the 6 weeks that individuals in protocol 1 received the ReJoyce treatment, following the completion of the protocol some re-entered the trial with their other hand shown in P-1 re-entry with the other hand (n=2). Individuals that reentered the trial following the successful completion of a protocol re-started in the other protocol. **P-2 ReJoyce** depicts the start of protocol 2 and 6 weeks of the ReJoyce intervention, **P-2 Combination** designates the combination intervention for protocol 2 following the crossover. There were no follow-up dropouts and all data was analyzed.

at C5 to C7 segmental level were assessed. Of these, 13 (7 men, 6 women) were recruited into the study. The inclusion criteria were C5-C7 complete or incomplete tetraplegia of at least 9 months standing, voluntary control allowing the hand to be positioned on a table surface in front of the person and responsiveness of hand muscles to electrical stimulation so that weak to moderate grasp and release movements could be elicited. Subjects were excluded if they had inadequate proximal muscle control, if their hand muscles were denervated and therefore unresponsive to electrical stimulation, if they had contractures, if they had had tendon transfers, if they were unable to commit to 5 hours/week of tele-supervised training at home, or to attend test sessions at the University of Alberta.

All participants resided in Western Canada within a radius of 780 km of the University of Alberta. Table 1 shows the clinical and demographic features of the participants. In 5 cases, after completing the two-part protocol with either the left or right hand, participants re-entered the trial to treat their other hand. These cases were treated as independent samples, thus the trial involved a comparison of the two treatments in a total of 18 cases.

4.1.3 Treatments

Both interventions involved Internet-based tele-supervision. Participants were provided with a laptop computer running Microsoft® Windows software, a webcam, and an Internet connection if they did not possess one. Each laptop computer had the following software installed: 1) Virtual Network Computing (VNC) allowing the participant's computer to be remotely controlled by the supervisor, Skype, allowing verbal communication and a two-way video stream whereby the supervisor could observe the exercise session and provide advice and encouragement, 3) custom software operating the ReJoyce workstation. In most cases the laptop was connected to the Internet through a local wireless network in the participant's home (see table 1).

The tele-supervisors, who were equipped with a similar laptop and webcam connected to the Internet, initiated sessions from the laboratory, their own home, or even hotels and cafes, according to their schedule and location. Each tele-supervisor was trained by the physical therapist in charge, to maintain the same standard of care throughout the trial and over both protocols. Session schedules were flexible and dependent on patient and supervisor availability; emphasis was placed on convenience rather then adhering to strict daily timelines.

4.1.4 The combination treatment

In this intervention the physical therapist in charge prescribed individualized exercise sessions based on the abilities of each participant. The equipment used was commercially available and commonly used by occupational and physical therapists. Each session was divided into three 20 minute sections, one for strength training, another for accuracy training and the third for TES (Figure 2). Strength

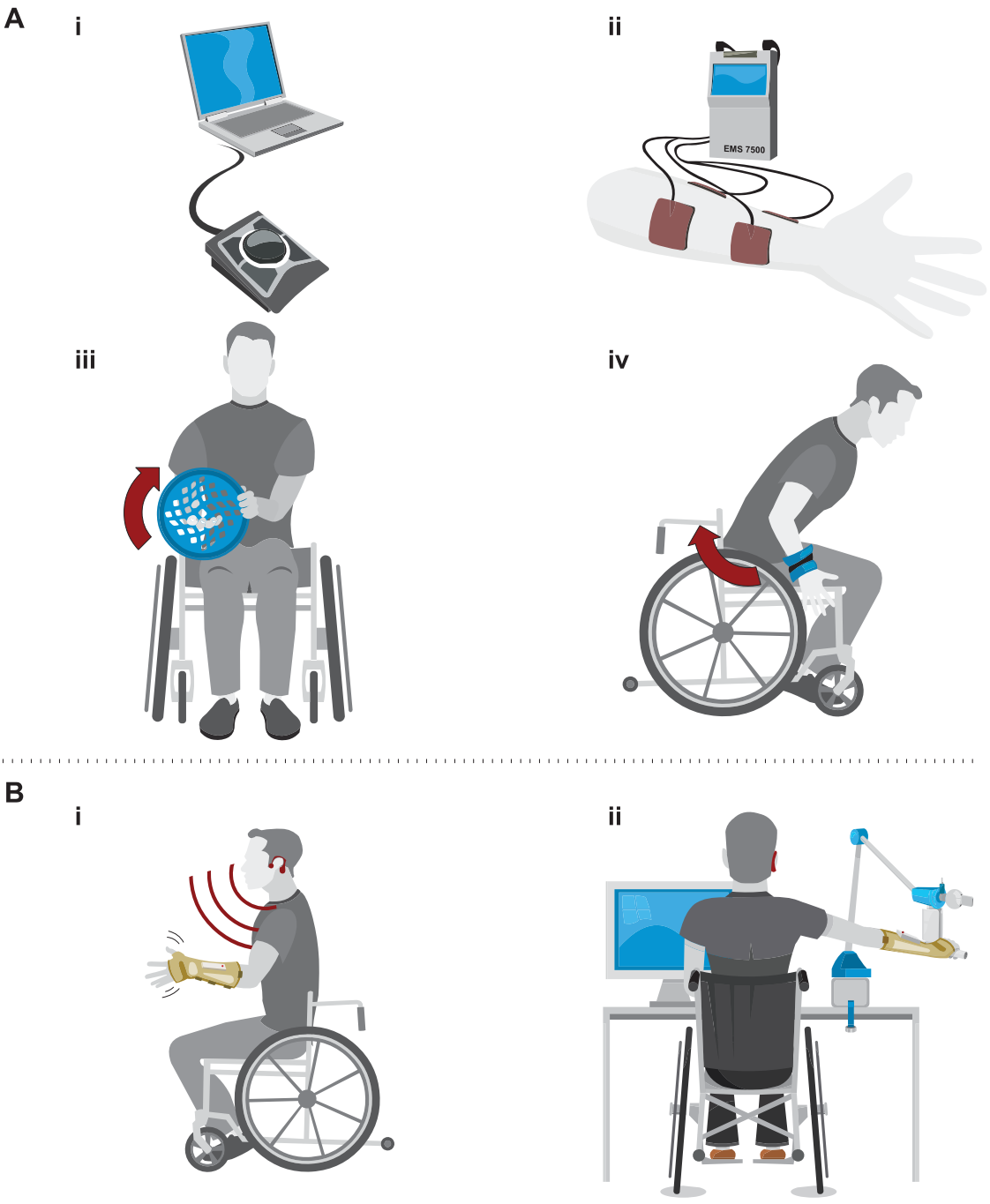

Figure 2:

Exercises performed by participants while tele-supervised at home. **A**) Combination treatment, A-i, 20 minutes daily of accuracy training using a trackball, A-ii 20 minutes of cyclical FES A-iii and iv resistance training using a Powerweb ® and ankle weights respectively. **B)** illustrates the ReJoyce treatment, specifically B-i, the tooth click activated stimulating garment, and B-ii the entire system used to play games at home.

training was performed using wristlets with insertable weights and/or a circular ring holding a rubberized mesh (the Powerweb ®). Participants worked to strengthen muscles involved in hand grasp as well as more proximal muscles such as the deltoids, biceps and triceps. Accuracy training consisted of playing computer games with a Kensington ® Trackball. This required small, accurate arm movements and mouse-clicks performed with the hand. The games played were chosen according to the participants' and supervisors' preferences. TES (5 sec on, 5 sec off) was delivered by a 2-channel EMS 7500 physiotherapy stimulator connected via surface electrodes to motor points on the forearm. The electrode positions were determined by the therapist at onset of the intervention and re-evaluated at weeks 2 and 4 when the participant visited the laboratory for assessments.

4.1.5 The ReJoyce apparatus

Each of the six manipulanda in the ReJoyce workstation was designed to represent a task commonly encountered in daily life. A clamp at the base of the spring-loaded arm was used to attach the device to a table or desk. The arm had 4 degrees of freedom of movement and was instrumented with rotational potentiometers about each joint. In addition, there were switches, rotational potentiometers and linear potentiometers in the manipulanda. The spring loading of the arm provided some elastic resistance to movement and ensured that the assembly of manipulanda returned to a neutral position when these were released. The manipulanda included a pair of horizontal handles that could be rotated about their long axis, a vertical peg that could be lifted, a gripper the size of a pop can that could be squeezed and a spring-loaded door knob with an exposable key-like element, both of which could be independently rotated. The handles were situated at the bottom of the manipulandum assembly and in the neutral position of the arm they were at the level of the base of the device. The easiest task to perform was to grasp one or both of the horizontal handles and to pull the manipulandum assembly in and out, up and down or left and right. The gripper, the door knob, key and peg, were located above the handles in an approximately ascending order of difficulty of use.

4.1.6 The ReJoyce treatment

The ReJoyce intervention consisted of 1 hour of exercises on a ReJoyce workstation with FES of hand muscles delivered with a 3-channel stimulator enclosed in a fingerless glove-like garment. The garment was custom-made for each participant. The stimulator was a miniaturized version of that used in the "Bionic Glove" previously developed by our group [19]. Similarly to the Bionic Glove, the new device allowed for the stimulation of finger extensors, finger flexors and thumb abductors or flexors. The main new feature was the triggering of stimulation by toothclicks. These were detected by an earpiece that transmitted radio frequency pulses to a receiver in the FES device. The earpiece contained a sensitive 3-axis accelerometer tuned to detect transient vibrations in the tragus, the cartilage anterior to the ear, when the participant made gentle toothclicks [20]. This allowed individuals to control

hand grasp and release without requiring button-pressing as in conventional stimulators or wrist movements as in the Bionic Glove. Controlling the device with toothclicks resulted in a more natural grasping pattern, and allowed the use of both hands to perform tasks bimanually if so desired. To grasp a manipulandum on the workstation the participant clicked his/her teeth once to trigger hand opening, a second time to trigger grasp and a third time to cease stimulation. A given state such as hand opening could be skipped by doing two tooth clicks in a rapid succession.

The home-based 1 hour/day tele-supervised exercise sessions involved participants playing computer games specifically designed for the ReJoyce workstation. The tele-supervisor could control the participant's computer to set or adjust the difficulty, speed and range of motion required to play each game, as well as selecting the manipulanda involved. The manipulanda used were the handles, gripper, door knob, key and peg. To successfully play any of the games a participant had to grasp at least one of the manipulanda and with this, move the whole manipulandum assembly within their functional range of motion (fROM) [Kowalczewski et al. submitted] (see figure 2). Six games were provided, each game configurable for a variety of different movements. The software automatically increased the difficulty and speed of the games gradually over the course of play, requiring the participant to try harder as the game progressed.

4.1.7 Outcome measures

Primary outcome measure: the Action Research Arm Test (ARAT: Carroll 1965; Lyle 1981). This test, though not specifically designed for tetraplegia, has been validated in several studies, and shown to be highly correlated to most of the other hand function tests used in clinical studies of the upper extremity (Lang et al. 2006; Rabadi and Rabadi 2006).

Secondary outcome measures:

1) ReJoyce Arm Hand Function Test (RAHFT) [Kowalczewski et al. submitted]. The RAHFT is an automated test that is performed on the ReJoyce workstation. The main advantages of this test include sensor-based quantitative scoring and automated administration that is standardized across testing sessions.

2) Grasp and pinch force measured with standard physiotherapy dynamometers. The pinch force measurements were performed on a B&L pinch gauge (B&L Engineering, Santa Ana, CA). An analog JAMAR dynamometer (Sammons Preston Rolyan, Bolingbrook, IL) was used to assess grasp force, the grasp force was also assessed with data from the gripper in the ReJoyce device.

4.1.8 Statistical methods

This was a randomized, controlled crossover trial comparing two possible home-based, tele-rehabilitation protocols. Hand function test scores and force data were obtained on two occasions prior to treatment, at weeks 2, 4 and 6 during treatment

and at follow-up sessions after treatment. The ARAT data were transformed to display a percent improvement of the maximum possible score (57) using the following formula:

Percentage improvement = 100*(raw score - mean baseline score for that individual)/57

RAHFT scores were computed as a percentage of the mean score of a cohort of able-bodied subjects. Improvements in RAHFT scores were obtained by subtracting the subject's mean RAHFT baseline score from his/her test RAHFT scores. Force measurements were similarly normalized by subtracting the appropriate baseline values from the values obtained during the assessments. The data were subjected to a series of statistical analyses, Descriptive statistics including means and standard deviations (SD), were calculated for all dependent variables. A repeated measures analysis of variance (ANOVA) was first used to determine if a difference existed between the two protocols for each outcome measure. Another repeated measures ANOVA was performed to determine whether a significant difference in improvements occurred between the two treatments. The data from each treatment, pre and post-crossover were grouped together for analysis. The clinical importance of the results was assessed in two ways, first using the minimally clinically important difference (MCID) commonly regarded as an improvement of 10% of the maximal possible outcome measure [21], and second, the effect size (Cohen's d). Cohen proposed that coefficients of 0.2 represented small effects, 0.5 medium, and 0.8 large. The "General Linear Models for Repeated Measures" utility in PASW Statistics 17.0 for Windows (SPSS of Chicago Il, U.S.A.) was used to analyze the outcome measures.

4.2 Results

Table 1 lists the characteristics and demographics of the 13 participants. Because the inclusion criteria were broad, participants displayed a large range of upper extremity impairments at the onset of the trial. All data is presented as Mean ± Standard deviation unless otherwise noted.

Functionally the participants starting in the two different protocols were closely matched in their baseline ARAT scores, RAHFT scores, pinch forces, RAHFT grasp forces but not JAMAR grasp forces. The mean baseline ARAT scores were: 25.5 ± 12.8 for participants in protocol 1, 26.0 ± 12.5 for those in protocol 2 and 25.8 ± 12.4 across all participants. The mean baseline RAHFT scores were 22.8% ± 14.7% for protocol 1, 20.7% ± 12.1% for protocol 2 and 21.8% ± 13.1% across all participants. The mean baseline pinch grip forces were 1.61N ± 1.80N for protocol 1, 1.9N ± 1.1N for protocol 2 and 1.7N ± 1.5N across all participants. Corresponding mean baseline grasp forces measured with the JAMAR dynamometer were 0.3N ± 1.1N for protocol 1 and 6.2N ± 18.1N for protocol 2 and 3.2N ± 13.0N across all participants. Only 4 hands out of 18 registered any force on the JAMAR device throughout the trial. We

Clinical and Demographic Features of Participants

Age (years)	35.92308	±	11.96148	(n=13)
Sex	7M/6F		(54% Male)	(n=13)
Time post SCI (years)	3.615385	±	2.116934	(n=13)
Affected level of the cervical spinal cord				(n=13)
C5	7		(54% Affected)	
C6	11		(85% Affected)	
C7	6		(46% Affected)	
Completeness of injury	4		(31% Complete)	(n=13)
Hand dominance	12 R/ 1 L		(92% Right Hand Dominant)	(n=13)
Hand most functional post injury	8 R / 4 L		(62% Right Hand)	(n=13)
Treated hands (18 hands treated)	10 R / 8 L		(56 % Right Hand Treated)	(n=18)
Distance from testing site in km	212	±	262	(n=13)
Wireless Network Used	9		(69 % of connections were wireless)	(n=13)
ARAT score at onset of trial (out of 57)	25.75	±	12.36	(n=18)
RAHFT score at onset of trial (%)	21.75	±	13.11	(n=18)
Pinch Force score at onset of trial (N)	1.73	±	1.49	(n=18)
JMAR Grasp Force measurement at onset of trial (N)	3.21	±	13.01	(n=18)
RAHFT Grasp Force measurement at onset of trial (N)	3.72	±	3.59	(n=18)

Table 1:

Clinical and demographic features of participants. All data presented as MEAN ± SD. Since 13 subjects participated in the trial and 5 reentered the trial with their other hand all the functional scores are with an n of 18, whereas patient demographics are with an n of 13. Participants could also be affected in more then one spinal cord level (e.g. subject 1 had an injury at the C5 and C6 level)

therefore relied more on the RAHFT measurements The grasp forces registered on the RAHFT were 3.9N ± 3.3N for protocol 1, 3.6N ± 3.7N for protocol 2 and 3.7N ± 3.6N across all participants.

4.2.1 Comparing the two protocols (Figure 3)

The mean improvements in hand function measured with the primary outcome measure (ARAT) after the 16 week treatment period expressed as percentages were 14.3 % ± 9.9% for protocol 1 and 13.6% ± 10.7% for protocol 2 At the time of follow-up, the mean improvement in protocol 1 had dropped to 11.2% ± 6.8% while in protocol 2 it had risen to 17.3% ± 6.8%. Similarly in the RAHFT, there were mean improvements of 16.1% ± 10.3% at the end of treatment in protocol 1 and 19.4% ± 8.7% in protocol 2. At follow-up the improvements had changed slightly to 15.0% ± 12.0% and 21.4% ± 8.5% for protocols 1 and 2 respectively.

Repeated measures ANOVAs were performed for each of the outcome measures (ARAT, RAHFT pinch force and grasp force). In each ANOVA the protocol was entered as the between-subjects factor and the time of testing was entered as the within-subjects factor. The between subjects test showed a significant difference between the two protocols in both the ARAT and RAHFT scores (F_{ARAT}=10.48; p<0.001), (F_{RAHFT}=16.55; p <0.001). The within subjects test showed a significant time of testing effect in both ARAT and RAHFT scores (F_{ARAT}=5.44; p= 0.033) (F_{RAHFT}=8.21; p=0.011). The interaction of time of testing and protocol was significant in the RAHFT (F_{RAHFT}= 4.04; p<0.001) but not the ARAT (F_{ARAT}= 1.70; p=0.106). These tests indicate that both protocols resulted in improvements over time, but that there was a difference between the protocols and in the case of the RAHFT the time courses of improvement differed.

Pinch, JAMAR grasp forces and RAHFT grasp forces did not show a difference between protocols (F_{PINCH}=0.093; p=0.764), ($F_{J\text{-}GRASP}$= 0.64; p=.435),($F_{R\text{-}GRASP}$= 2.25; p=.153), or a significant time of testing effect (F_{PINCH} = 1.86; p=.071), ($F_{J\text{-}GRASP}$= 0.95; p=0.480). Grasp force measured with the RAHFT gripper did however show a significant time of testing effect ($F_{R\text{-}GRASP}$= 5.26; p<0.001). The interaction of time of testing and the protocol was significant in the pinch force improvements (F_{PINCH}= 2.19; p= 0.032) but not the both grasp force measurements ($F_{J\text{-}GRASP}$= 0.83; p= 0.577),($F_{R\text{-}GRASP}$= 1.45; p=.182).

4.2.2 Comparing the two treatments (Combination and ReJoyce) (Figure 4)

The treatments were compared by grouping corresponding scores from the two protocols (referring to the CONSORT chart, the P-1 and P-2 Combination Treatment scores were grouped and the P-1 and P-2 ReJoyce scores were grouped, allowing a comparison of data from 18 hands per treatment). The mean improvements assessed with the ARAT after the 6 week treatment period was 4.2% ± 9.7% for the combination treatment and 13.0% ± 9.8% for the ReJoyce treatment. Likewise, an

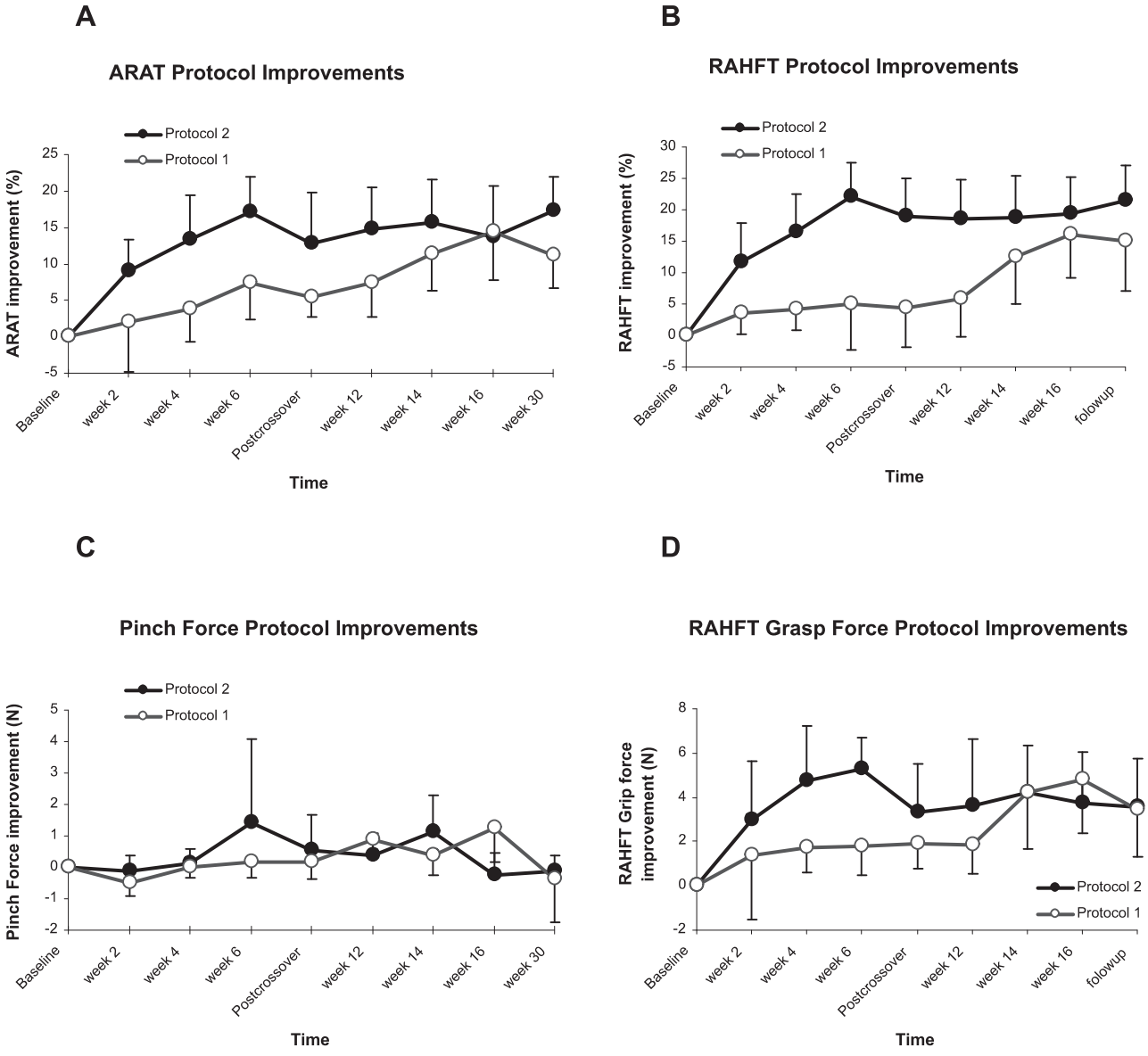

Figure 3:

Improvements observed over the duration of the trial for the two treatment protocols (Protocol 1 and Protocol 2). The graph in **A**) shows the mean changes in ARAT scores with error bars indicating 2 Standard Errors (2SE). Improvements in RAHFT scores observed over the duration of the trial for the two treatment protocols shown in **B)**. Improvements in pinch force and RAHFT grip strenght are shown in **C**)and **D**) respectively. Each protocol represents the data of 9 participants.

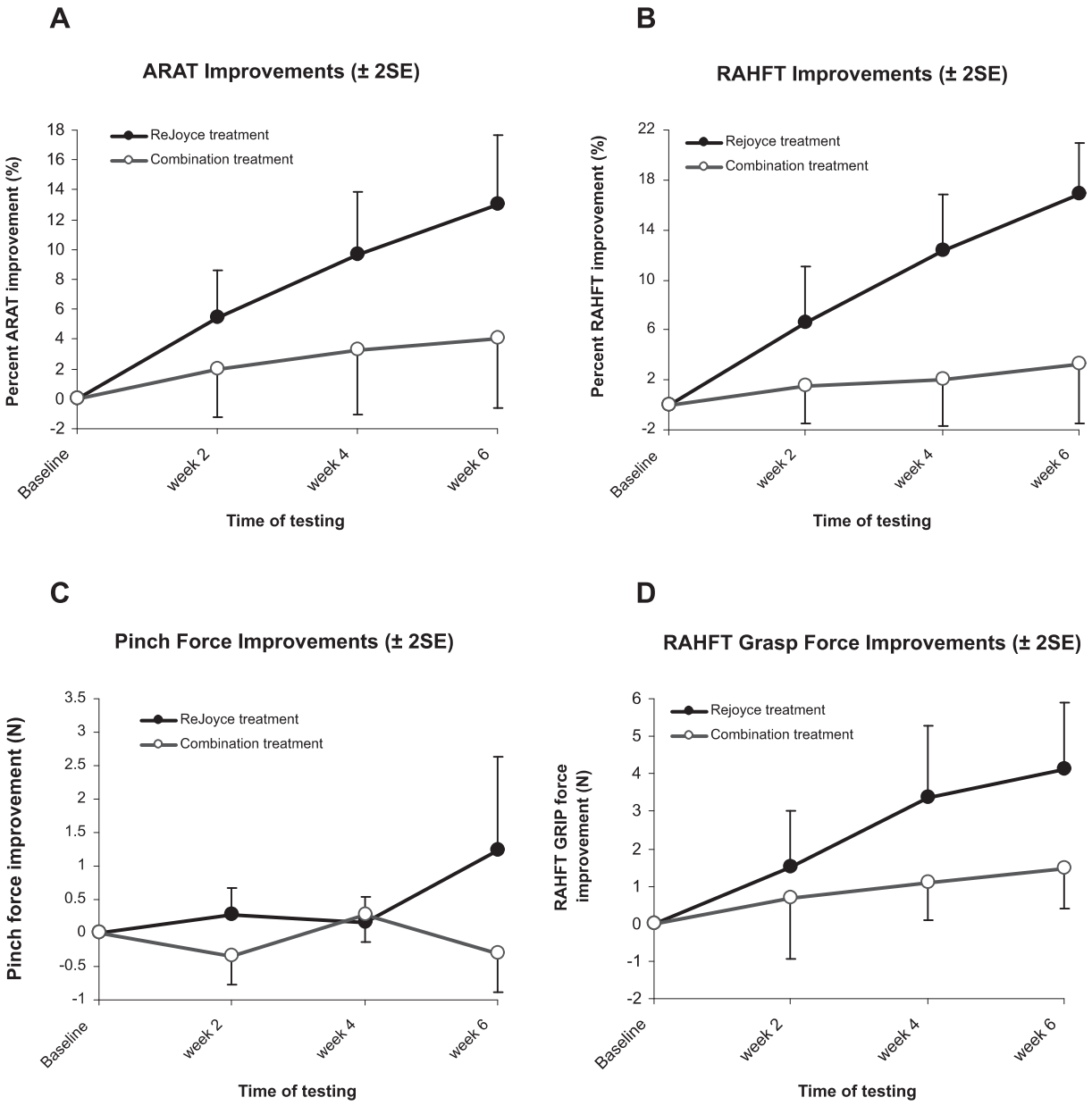

Figure 4:

A) Improvements in ARAT scores in the Combination and ReJoyce treatments (n=18 per treatment) over the course of 6 weeks. **B)** Improvements in RAHFT scores in the Combination and ReJoyce treatments (n=18 per treatment) over the course of 6 weeks. **C**) Improvements in pinch force in the Combination and ReJoyce treatments (n=18 per treatment) over the course of 6 weeks. **D**) Improvements in RAHFT grasp force in the Combination and ReJoyce treatments (n=18 per treatment) over the course of 6 weeks.

improvement in the RAHFT of 3.3% ± 10.2% was observed for the combination treatment and 16.9% ± 8.6% for the ReJoyce treatment. The mean improvements assessed with the B&L pinch dynamometer after the 6 week treatment period was -0.3N ± 1.2N for the combination treatment and 1.2N ± 3.0N for the ReJoyce treatment. In the combination treatment the mean improvements in grasp forces were 0.1N ± 1.2N measured with the JAMAR dynamometer and 1.5N ± 2.3N measured with the RAHFT gripper. In the ReJoyce treatment the mean improvements in grasp forces were 2.1N ± 9.0N measured with the JAMAR dynamometer and 4.1N ± 3.8N measured with the RAHFT gripper.

Repeated measures ANOVAs were performed for each of the outcome measures (ARAT, RAHFT, pinch force and grasp force). In each ANOVA the treatment was entered as the between subjects factor and time of testing was entered as the within-subjects factor. The between subjects test indicated that there was a significant difference between the two treatments in both the ARAT and RAHFT (F_{ARAT}= 13.88; p<0.001), (F_{RAHFT}=19.34; p<0.001) with a significant time effect (F_{ARAT}=7.71; p=0.009),(F_{RAHFT}= 14.64; p=0.001). The interaction of treatments and time of testing was also significant (F_{ARAT}=3.57; p=0.017)(F_{RAHFT}= 10.31; p<0.001). These tests indicate that both treatments resulted in improvements over time, but that there was a difference between the treatments and that the time courses of improvements differed between treatments.

Pinch and JAMAR grasp forces did not show a difference between treatments (F_{PINCH}=1.43; p=0.240),($F_{J\text{-}GRASP}$= 0.10; p=0.398), or a significant time of testing effect (F_{PINCH}=3.42; p=0.073),($F_{J\text{-}GRASP}$= 0.26; p=0.614). The interaction of time of testing and the treatment was significant in the pinch force improvements (F_{PINCH}=4.05; p=0.009) but not the grasp force ($F_{J\text{-}GRASP}$= 1.78; p=0.155). The between subjects test indicated that there was a significant difference between the two treatments in grasp forces measured by the RAHFT ($F_{R\text{-}GRASP}$= 4.58; p=0.040) with a significant time effect ($F_{R\text{-}GRASP}$= 11.00; p<0.001). The interaction of treatments and time of testing was also significant ($F_{R\text{-}GRASP}$= 2.74; p=0.047).

4.2.3 Effect size and minimally clinically important difference (MCID)

The improvement effect sizes (Cohen's d) for the Combination treatment comparing baseline measurements to those of week 6 were 0.43 for the ARAT, 0.32 for the RAHFT, 0.26 for pinch,force,,0.10 for JAMAR grasp force and 0.64 for RAHFT grasp force. The corresponding improvement effect sizes for the ReJoyce treatment were 1.32 for the ARAT, 1.95 for the RAHFT, 0.41 for the pinch force, 0.23 for the JAMAR grasp force and 1.09 for the RAHFT grasp force. In terms of the MCID described by van der Lee et al [21], improvements observed with the ARAT in both protocols were significant even at the 30 week follow-up. Improvements seen in the ReJoyce treatment were of clinical significance, with a mean ARAT improvement of 13.0% ± 9.5%. Similarly, the mean RAHFT improvements clinically significant with changes of 16.9% ± 8.6%. Clinical significance was not observed in the Combination treatment

following the 6 week intervention (mean ARAT improvement 4.2% ± 9.7% and mean RAHFT improvement 3.3% ± 10.2%).

4.3 Discussion

This study represents, to our knowledge, the first randomized, controlled trial designed to assess the effectiveness of home-based, upper extremity tele-rehabilitation. Our results support the notion that supervised at-home tele-rehabilitation is not only feasible but also beneficial for individuals experiencing upper extremity motor deficits due to a C5 to C7 SCI. These benefits were of clinical relevance and were maintained for up to 3 months. Our findings also suggest that the type of treatment being performed in the home setting was important.

The primary outcome measure (ARAT), the secondary outcome measure (RAHFT) and RAHFT grip force measurements showed statistically significant improvements resulting from FES training on the ReJoyce device. These improvements are sub-divided into individual components of the test in the case of the RAHFT (Figure 5). Interestingly the largest contributors to the improvements in the RAHFT in the ReJoyce treatment were the grasp and placement test scores. The placement test involved picking up a virtual pop can displayed on the computer screen, squeezing the gripper to "hold" the virtual can and move it to a position over one of two virtual "garbage bins" located on each side of the screen. The virtual pop can was then dropped into the bin by releasing the gripper. A new virtual pop can then appeared in the middle of the screen, requiring the subject to grasp, move and drop it into the other bin. The peg placement task similar to the pop can placement tasks but performed with the peg manipulandum instead of the gripper also contributed to the observed improvements, suggesting an increase in finger dexterity. This is not surprising as the focus of the ReJoyce treatment was to improve ADLs. The doorknob and key tasks remained rather unchanged throughout the trail, these tasks required significantly greater forces to be successfully manipulated, and may have been too difficult for many of our participants. The doorknob and key manipulanda may therefore be more appropriate for the training of higher functioning individuals.

The pinch and JAMAR grasp force measurements did not show statistically significant changes. The majority of our participants had very low hand function at the onset of the trial. In retrospect, some of the test equipment used may have been too insensitive to assess the expected changes. The analog JAMAR grasp dynamometer had a dead space of about 20 Newtons and did not record anything below that mark. Only 4 hands out of 18 managed to register a reading over the course of the entire trial on this device. In retrospect, we realized that the gripper component of the RAHFT was sensitive within the 0-10N range, which allowed us to analyze grasp force data from the RAHFT from all 18 hands throughout the trial. The improvements observed on the RAHFT grasp measurements closely matched those of the ARAT and RAHFT. The B&L Pinch dynamometer was more sensitive than the JAMAR dynamometer and so a trend similar to that seen in the ARAT, RAHFT and

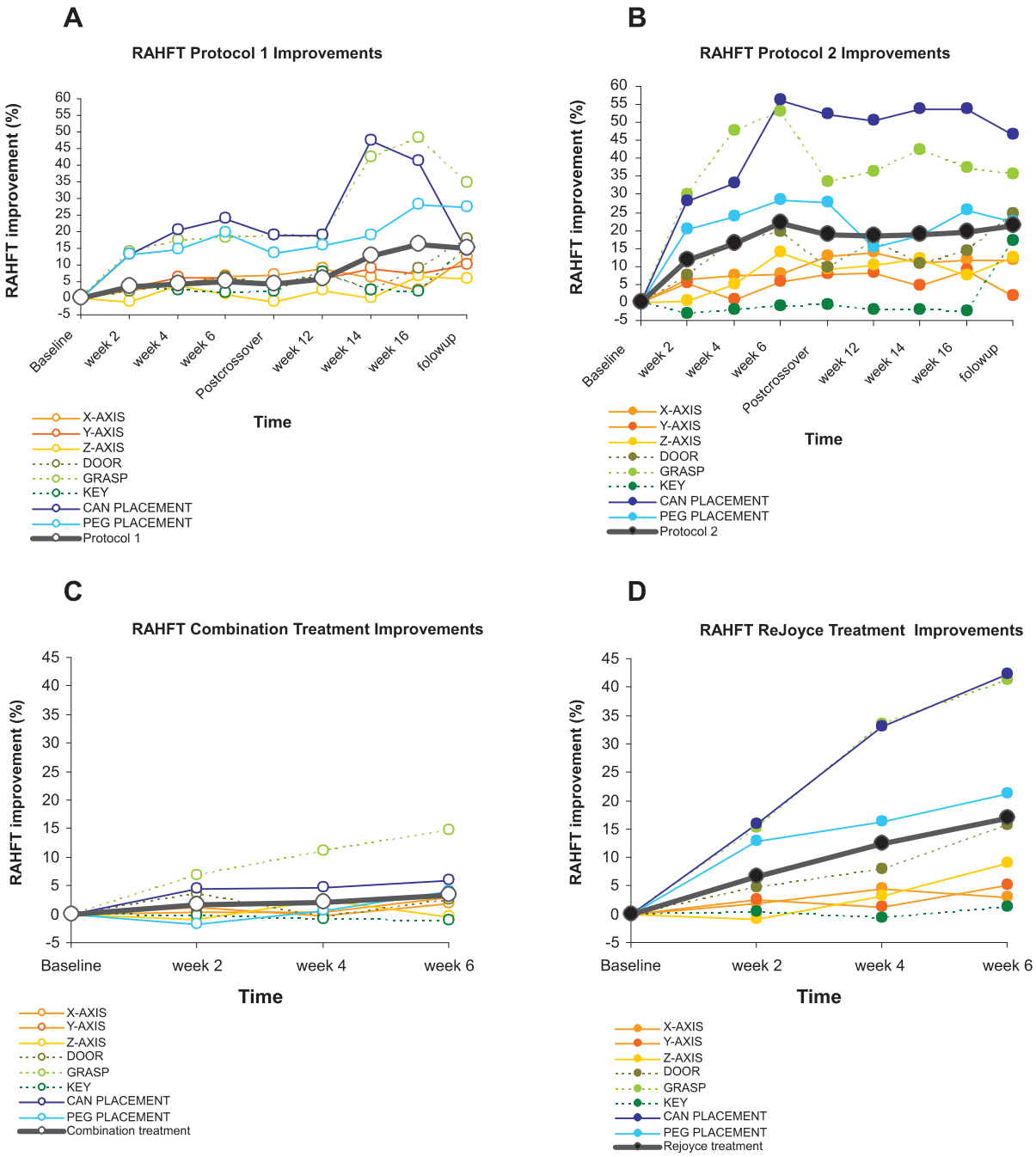

Figure 5:

Improvements observed in the RAHFT subdivided into individual RAHFT tasks. **A**) Protocol 1 improvements, **B**) Protocol 2 improvements. Each protocol, represents the data of 9 participants. **C**) illustrates the Combination treatment improvements and **D**) illustrates the ReJoyce treatment improvements over a 6 week period. Each treatment, represents the data of 18 hands.

RAHFT gripper force was observed but failed to reach statistical significance. The interesting possibility arises that grasp improved more than pinch grip because grasp depends more on C6 than C7 spinal motoneurons. Neuronal networks in the C6 segment may have more scope for plasticity and adaptation because they are just below the level of the original injury. Although they are a reasonable measure of disability, force measurements may not be good predictors of function, as proficiency in performing certain ADLs can be greatly improved without significant increases in strength [22]. Some ADLs, such as writing, are more dependent on the speed and accuracy with which they can be performed.

Comparing the two treatments, our data support prior suggestions that task-oriented training is more effective than indiscriminate exercise [23 9], and that electrical stimulation should be combined with volitional movements [6 9]. The neuronal mechanisms that result in this difference are still largely unknown, though recent studies suggest that sensory stimulation may play an important role in this respect [6 7]. The type of the stimulation provided is but one of many possible factors contributing to the observed functional gains.

A novel component of the ReJoyce treatment involved the hour-long intense ADL repetitive training under the guise of entertaining computer games. This may have been another contributing factor to the observed differences in treatments. When participating in ReJoyce treatments, subjects tended to be more involved in their exercises than when they took part in the Combination treatments. In the Combination treatment, subjects were prescribed a minimum number of repetitions of tasks by the therapist and there was little incentive to surpass this number. In the ReJoyce treatments on the other hand, continuous effort and coordinated whole arm movements were required and there was no set number of repetitions. Participants were constantly challenged to perform faster and more complex movements in order to excel in computer games that gradually increased in difficulty.

In stroke it has been suggested that bilateral movements enhance the activation of the primary motor cortex [24]. This enhanced activation results in greater functional recovery. In some cases participants in the ReJoyce treatment assisted the hand being trained with the other hand. It is unclear whether this augmented or diminished the amount of recovery achieved. Some of the tasks practiced on the ReJoyce workstation were performed better when the other hand was used for stabilization, much like in some ADLs. This was especially noticed in lower functioning individuals.

Regarding the design of our trial, crossover was used in order to maximize the number of subjects involved in the two treatments, while still allowing for a blind comparison of data obtained within the same home settings. The 1 month rest period, chosen as the washout period was clearly too short to allow function to return to its baseline state (see Fig. 3). It is plausible that some of the improvements generated were permanent, as they were maintained even at the 30 week follow-up. Individuals that started with the ReJoyce treatment did not improve further on their second treatment, yet those that started with the Combination treatment improved further once they undertook the ReJoyce training sessions. This raises the

question of whether the improvements had reached their maximum following 6 weeks of treatment. It would be desirable for future studies to extend both the treatment and washout periods to address these questions.

Although there is no minimally important clinical difference (MICD) in the literature for the RAHFT, this test correlates well with the ARAT (Kowalczewski et al submitted) and so using a benchmark of 10 % seems reasonable. Participants experienced statistically and clinically significant improvements with strong effect sizes following the ReJoyce treatment, but not the Combination treatment. It would now be interesting to study variants of the ReJoyce treatment in a larger population of subjects. A multicentre trial is currently underway to compare 5 days/week training with 1 day/week. Studies in stroke subjects are planned.

4.4 Acknowledgments

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Chapter 5

Considerations for an Upper Extremity FES Tele-Rehabilitation Trial

One of the objectives of the study described in Chapter 4 was to evaluate the feasibility and effectiveness of a novel delivery method for upper-extremity treatments. Combining functional electrical stimulation (FES) of the upper extremity with repetitive task oriented training in a home setting presented numerous novel challenges. Little information is available describing some of the obstacles that can be expected with such a trial and how they can be overcome. The goal of this chapter is to present technical information and experience acquired in conducting the tele-rehabilitation trial. First, because a therapist was not physically in the same location as the participants exercise sessions, the equipment had to be easy to use and reliable in every respect. Tetraplegic people have numerous physical disabilities which limit the type of equipment that can be used. Third a reliable means of communication needed to be established, allowing for two-way conversations and video streams between the remote therapists and the participants. The software and hardware had to allow the therapist to observe, instruct and guide the participant through each session. Monitored rehabilitation in the participant's home provides unique safety and legal challenges by itself which may need to be resolved before such treatments are available to the larger population [1].

5.1 Muscle stimulators.

Two different types of muscle stimulators were employed in these studies. The EMS 7500 surface stimulator was an affordable, commercially available consumer device designed to deliver stimuli via self-adhesive gel electrodes placed over appropriate motor points. It was found necessary to mark the locations of the electrodes on the participants' forearms in order to ensure accurate and repeatable stimulation patterns. A permanent marker was used every two weeks to refresh the locations of the electrodes. The placement of the electrodes was most often performed by an aid or family member. Following a few sessions the electrode adhesive lost its stickiness and so participants were provided with neoprene straps that helped keep the electrodes in place when this happened.

The other stimulator employed in the trial is described in Chapter 4. It was the latest version of the "Bionic Glove" [2]. The original Bionic Glove was a garment containing a built-in stimulator and wettable electrodes. It was controlled by wrist movements. The version of the device used in our study was controlled in a different way. The participant generated small tooth-clicks to advance the stimulator through a cyclical sequence of three states corresponding to hand opening, grasp and relaxation [3]. The tooth-clicks were detected by a small wireless earpiece similar to a hearing aid that contained a 3-axis accelerometer that rested on the tragus, the small cartilage in front of the ear. When a tooth-click occurred, the earpiece sent a coded transmission to the stimulator in the participant's glove. This caused the device to advance to the next state in the stimulation sequence. The electrodes were secured on the inner surface of the garment, so when this was donned, they tended to be on or close to the desired motor points. The electrode positions within the garment were re-evaluated at every laboratory visit. The donning of the device required some learning as inappropriate positioning could lead to inadequate or ineffective stimulation. Unlike the adhesive electrodes used in the EMS 7500, the electrodes in the garment needed to be moistened with tap-water before each use. Wetting and reconnecting the electrodes to the glove was most often performed by an aid or family member.

As in previous studies, there were features of the design of the stimulator garment that were not ideal and which limited the types of manipulation the participants could perform (Fig. 1). In particular, the original design of the Bionic Glove, which was initially supplied to the participants, tended to resist movements about the wrist and also to impede thumb adduction and flexion. The garment was re-designed during the course of the trial so as to expose the palm of the hand. It is well known that skin friction on the palm is important for activities of daily life (ADLs) performed with a tenodesis grip. Covering the palm area even with high-friction materials does not generally work as well as the person's own skin. Furthermore covering the palm, the thumb-index webspace and the back of the hand with a single piece of material tends to increase the resistance to thumb flexion and abduction. The garment was therefore re-designed so that the obligatory electrode on the thenar eminence was held on by an elastic loop (Fig. 1),

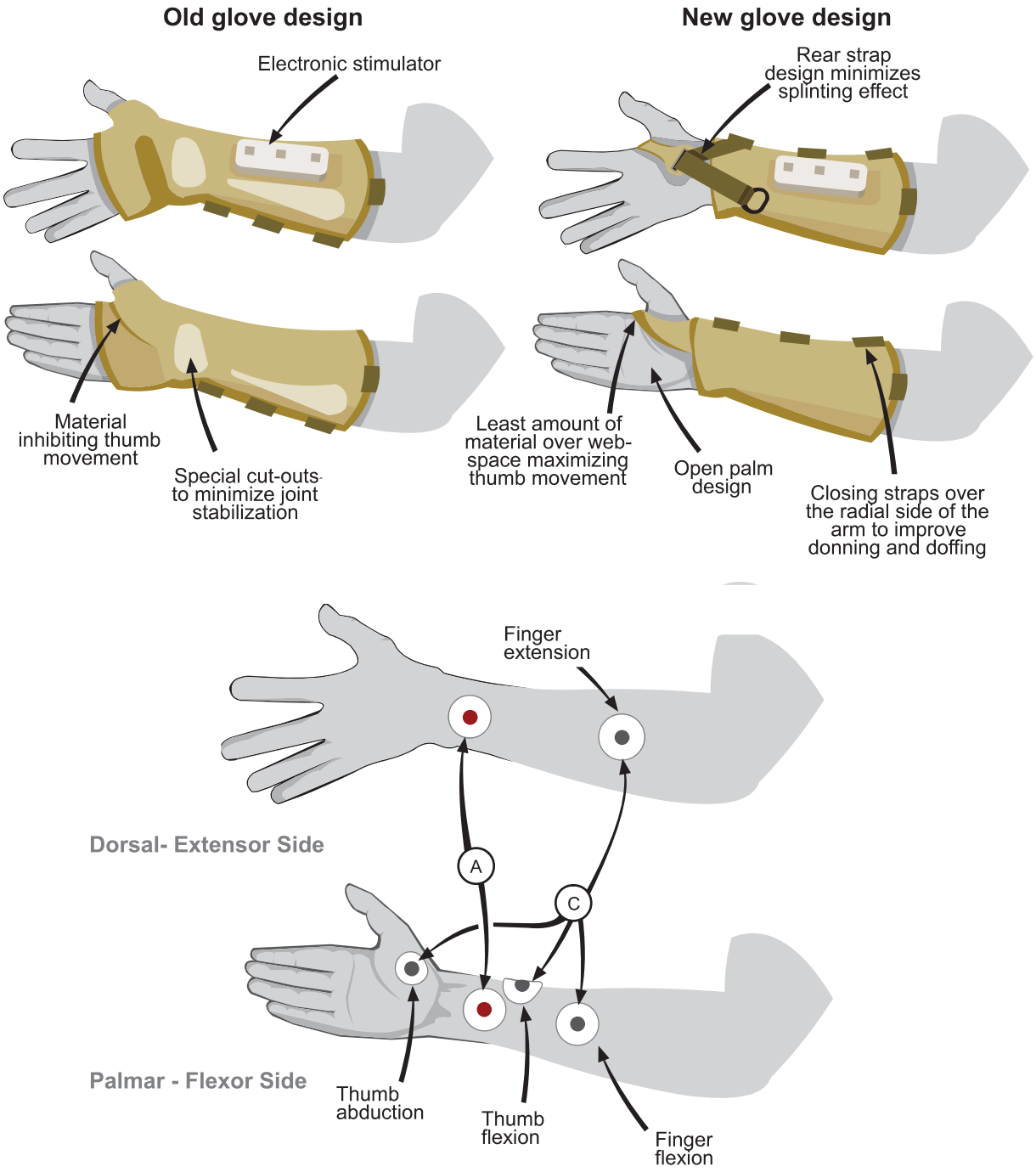

Figure 1:

New glove design in comparison to old design , as well as typical position of electrodes under the garment. A refers to anode or reference electrode positions used, C refers to cathode or stimulation electrode.

which provided a smaller resistance to thumb movements. The ease of donning and doffing the device was also improved by this modification.

5.2 Evolution of the workstation

The workstation described in Chapter 2 contained a variety of instrumented objects representing ADLs, but it had some important inadequacies. Primarily there was no direct means of calculating the participants' range of motion. Furthermore a computer could not be easily used to provide tele-supervision as the sheer size of the workstation would require substantial head movements back and forth in order to observe the computer screen while performing the tasks on the workstation. Several of the objects, such as the blocks used in the shelf placement tasks, were not attached to the workstation. These objects were frequently dropped, which required an aid or therapist to retrieve them. Participants were also unable to switch tasks without assistance. Finally the workstation did not have a means of measuring fine motor tasks.

The goal was therefore to redesign the workstation to be more versatile and to address these shortcomings. Three different workstation designs (Fig. 2) were built, tested and evaluated following before the final version, the ReJoyce, was developed.

5.2.1 Semi-robotic workstation

Robotics have been used by numerous groups to automate exercises performed for upper extremity rehabilitation [4 5 6]. We conceived of a semi-robotic device that would present the user with objects to be manipulated. This approach was also adopted by one of the originators of Constraint-Induced Movement Therapy, Edwin Taub, in his "Automated Constraint-Induced Therapy Extension (AutoCITE)" [7 8]. We built a prototype that moved objects horizontally by means of a long rack and pinion (Fig. 2). Initial testing indicated that the presentation of objects was too slow. Some tasks took over a minute to reposition. When the mechanism was redesigned to be faster, it was unacceptably noisy and possibly even unsafe. The motor-drive system, the required heavy construction materials and custom metal work all contributed to a cost that was prohibitive for all but financially well-endowed clinics. More importantly, movements of the objects once they were correctly positioned was still fairly restricted and the workstation failed to quantify the user's range of motion (ROM).

5.2.2 Suitcase workstation

A "suitcase" model was developed in response to the cost of the semi-robotic workstation. It provided the same task-objects as the previous workstation but in small modular units that could be pulled out of their docking ports, positioned and stabilized with the less affected hand. This version was significantly cheaper and it was successfully tested on a number of stroke patients. Again the main drawback was the inability to quantify the user's ROM. Another problem with this design was that the majority of the movements and tasks became planar. The suitcase model was not well suited for individuals with bimanual deficits as it depended on tasks being stabilized with one relatively normally functioning upper limb, while training the other.

5.2.3 Joystick workstation

It had become clear by this point that what was needed was a device that would present users with a number of objects or appendages that would provide exercise tasks, that these should all be tethered to the workstation in some way, that they should contain sensors to quantify task performance and that the device should allow the objects to move within as much of the normal physiological workspace of the normal hand as possible. To fulfill these requirements, we decided to adopt and extend the approach of Reinkensmeyer [9] by utilizing a similar design to a joystick commonly used in the computer entertainment industry. The joystick illustrated in Fig. 2 had a gimble joint at its base and a telescopic shaft. This allowed the manipulanda at the top of the telescopic shaft to be moved in 3-dimensional space. The joystick also contained a sliding card manipulandum designed to train the type of lateral and palmar prehension and push-pull movements involved in inserting credit cards into automatic bank machines. A prototype was manufactured in the laboratory and tested at the G.F. Strong Rehabilitation Hospital in Vancouver by our colleague Maura Whittaker on 4 SCI participants, as well as some stroke subjects. Although the attachments at the top of the joystick could be moved in three dimensions, the workspace was restricted to a relatively small volume determined by the plane of the base and constrained by the lengths of the lower and upper shafts. It was difficult to maintain the same grasp on the attachments at different shaft angles, and friction within the shaft at oblique angles resisted movement. The only fine motor task on this workstation was the card sliding mechanism. Some users with restricted ROM could not even reach the manipulanda at the top of the joystick, which at its shortest, was still 35 cm above the table surface. The main lesson learnt from this prototype was the importance of positioning the easiest tasks closest to the user so that they were accessible even to low-functioning people.

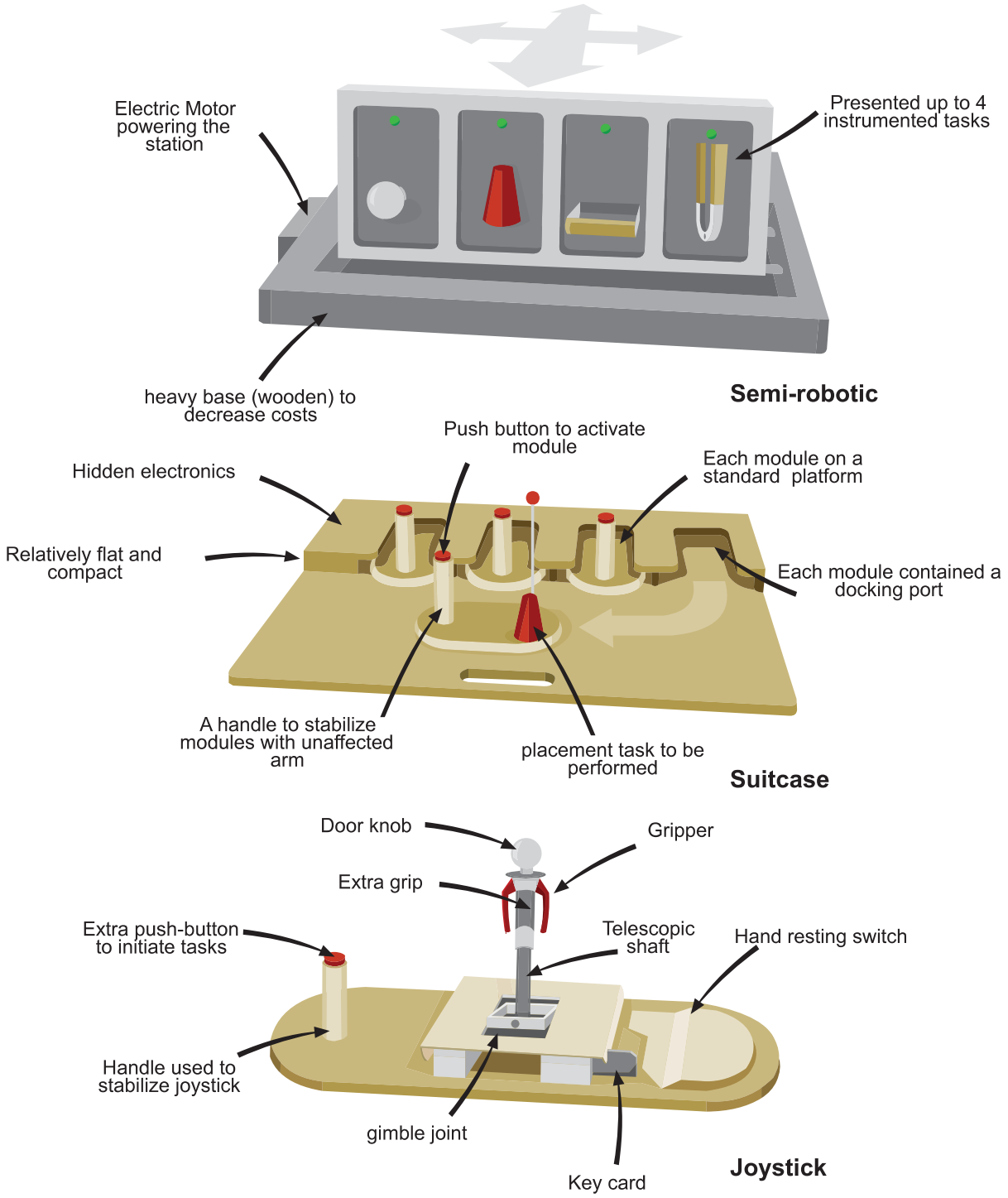

Figure 2:

The various workstations tested before the ReJoyce system, including a semi robotic , a suitcase and a joystick workstation

5.2.4 The ReJoyce System

The ReJoyce system is extensively described in Chapters 3 and 4 as well as in Appendix 1 (patent application encompassing the system). The spring-loaded, swiveling arm allows movements of the manipulanda within the full physiological workspace of a normal user. Sensors in each joint enable on-line calculation of the end-point position and therefore of the user's functional ROM (fROM). The device allows a variety of tasks representing ADLs to be performed.

The device was built with the intention not only of providing standardized exercises but also of testing hand function quantitatively. Accordingly, most tasks were chosen based on the types of hand movements included in existing hand function tests. For example, the gripping device was the size of a pop can, which is used for assessment in the Wolf Motor Function Test, the ARAT, the Jebsen Hand Function Test. Furthermore the peg was based on the 9-hole peg test, and was of a similar circumference to a standard pencil or pen. A manipulandum not commonly found in hand function tests but one that was chosen to be included in the device was the doorknob. This object and the tasks associated with it were chosen as they were representative of spherical grasps used in standard hand function tests and they allowed for the training of pronation and supination. The doorknob tasks were among the most successful in the training of participants in the stroke trial, and they were endorsed by the therapists involved. All manipulanda underwent extensive testing on participants prior to incorporating them on the ReJoyce workstation.

Currently there are two versions of the ReJoyce; the first laboratory prototype used in the study described in Chapter 4 and a commercial version that was developed from this prototype. These, although similar in basic design, differ is some important respects. In the new device, the caliper-style gripper of the prototype has been replaced with a rubberized hollow cylinder the size of a pop can. The cylinder is air-filled and contains a pressure sensor that allows grip force to be measured. The laboratory prototype used a calibrated spring and a potentiometer to measure force indirectly through deflection. This was not an ideal solution as grip force depended to some extent on how the user grasped the calipers. The new gripper is much less sensitive to the positioning of the user's thumb and fingers during grasp. The new version of the ReJoyce also includes two new task modules: spring-loaded discs to mimic the picking up of coins, and a spring-loaded cover that mimics a jar lid. The manipulandum assembly was re-designed to eliminate sharp corners, elevated screwheads, indentations and angled connections between parts that had occasionally caused fingers to be squeezed or scraped in the laboratory prototype. This had required protective tape to be placed over sections of the device. Apart from the numerous hardware changes, the software was completely redesigned to include new games, automatic data storage, Internet connectivity allowing one therapist to tele-supervise up to six users simultaneously with two-way audiovisual communication, and to take control of their computers remotely.

5.3 Software requirements

We found that to successfully conduct one-on-one tele-supervision using the Internet, the software requirements on the supervisor's and participant's computers were modest and the recurring costs were negligible. Internet-based tele-rehabilitation requires a minimum of 2 computers connected reliably to the Internet, webcams, speakers and microphones or headsets consisting of headphones and a microphone (recommended for echo-cancelation). Standard desktop or laptop computers were used and had sufficient processing power to handle the large video and audio streams and the processor-intensive games.

We found that it was very important to have a robust internet connection. In our case the majority of the participants successfully used a wireless router system in their homes. Having remote access to the wireless routers was very useful as electrical storms, router resets and modem resets corrupted the wireless links in several cases. Remote access to the router allowed most internet-related problems to be overcome, though on a few occasions the problem could only be solved with a home visit. The majority of internet-related difficulties emerged in the first few days of treatment.

The use of remote access software to take control of the participant's computers enabled the remote supervisor to adjust the difficulty of games and download performance data. In our trial we used Virtual Network Computing software (realVNC®: www.realvnc.com). There are two types of VNC. The first, used by realVNC®, is a direct computer-to-computer link. The second uses a third party server to access the participant's computer (e.g. www.logmein.com). VNC software that uses a third party server is more convenient as it does not require the use and configuration of an internet protocol (IP) address to log in. The drawback to using a third party server is the greater potential for a breach of security. Even the use of direct computer–to-computer VNC software does not guarantee security; in fact poor set-up of such software can be much more risky.

No software existed prior to this trial that was specifically designed for the management of multiple patients by a single therapist simultaneously. Tele-conferencing software is not suited for tele-rehabilitation unless it involves open group sessions. The main problem with the current tele-conferencing software systems if used for rehabilitation is that no privacy feature is available that allows the confidential interaction between the therapist and one of his/her clients, while he/she can still access and monitor all of the other participants. The first attempt at providing this type of software specifically for rehabilitation was by Angeltear (www.angeltear.com) in a system called Angeltear Vision. Internet based tele-rehabilitation software is now commercially available and specifically designed for the ReJoyce system by Hometelemed (www.hometelemed.com). The latest software allows a therapist to manage, and interact via audio and video with numerous participants simultaneously, or privately, including setting the type and difficulty of the games to be played.

5.4 Games

Not all computer games were of equal value to our rehabilitation protocol. The types of computer games used in upper extremity rehabilitation vary from very simple games [9] to virtual reality simulation of the real world with force feedback [10 11]. An example of a successful device that provides virtual reality games is the Nintendo Wii, which has become popular in rehabilitation clinics for providing ROM exercises of the whole upper body[12 13]. The controller provided with the Wii does not have attachments requiring manual dexterity, nor are the movement signals available for analysis. The primary role of a computer game used in upper extremity rehabilitation is to increase compliance with the treatment. Therefore the games need to be entertaining, but more importantly they need to provide feedback on performance. This can be something arbitrary such as an overall score or something more specific, such as the time to perform a given task. Games that provided this type of feedback to the users were among the most utilized by the tele-supervisors and requested by patients undergoing our trial. Feedback on performance evidently provides a "hook" that plays on the competitive nature of the participant. Participants are more inclined to improve on their previous performance when they are provided with a measure of this performance and rewarded for a better outcome. Games that incorporated a reward mechanism had the highest rate of acceptance and usage.

Our tele-rehabilitation trial also suggested that improvements in upper extremity function did not require fully submersive 3-dimensional games. All the games developed for the ReJoyce were built with 2D game technology, and did not require 3D graphic acceleration, VR displays or haptics. It was clear however, that variety in games was desirable. The more games the participant and supervisor could choose from, the higher was the chance of a game appealing to the participant. Although computer game preference has been related to gender in young adults [14], and children [15], gender may not be such an important factor in people involved in upper extremity exercises rehabilitation. The games most played in this trial where those that involved the gripper and handle manipulanda. These were associated with the easiest games, which most participants started on and reverted back to if and when fatigue had set in during the course of exercise sessions.

Unlike many games designed only for entertainment, the games used in this trial were specifically built for rehabilitating and retraining upper extremity movements. The advantages of using custom games included the ability to 1) train unique movements that could not be trained on pre-existing consumer-oriented games; 2) modify difficulty settings during the training process in order to optimize the therapy. 3) automatically compute difficulty settings on the basis of RAHFT scores; 4) embed the games in the tele-rehabilitation software suite, minimizing the need to learn how to use non-customized games; 4) design the games to be used played with the various manipulanda on the workstation. Six games were developed and used in the tele-rehabilitaiton trial, including a car racing game, a gardening game, a boxing game, a timing game, a target shooting game, and a catching game.

It became clear during the course of the project that different treatment regimes are needed for different motor disorders. Thus stroke survivors benefit from the training of range of motion and hand extension movements, whereas spinal cord injured participants benefit from training hand grasp and tenodesis grip. If a game allows for the independent adjustment of range of motion and required grasps then both populations may use the same game and benefit in different ways from it.

5.5 Fatigue

We found that therapists involved in tele-supervision needed to be careful not to over-exert their subjects undergoing upper extremity exercise. Overexertion in SCI participants can lead to consequences such as muscle strain and soft tissue injury. Furthermore in SCI, fatigue can aggravate pre-existing pain, depression and spasticity as it also has cognitive and emotional components [16]. On the other hand *moderate* physical activity in SCI has been shown to *lower* pain, fatigue and depression [17]. Therefore it is important to judge the appropriate amount of exercise on an individual basis.

Muscle fatigability associated with electrical stimulation was observed throughout this trial in all participants. It is known that muscles lose fatigue resistance following SCI [18]. The loss occurs rapidly, primarily within the first 2 years following injury and it is not age dependent [19]. Loss of fatigue resistance can be reversed to some extent with repeated electrical stimulation delivered early after SCI [20]. Traditionally muscle fatigability in response to electrical stimulation is quantified by measuring the torque generated by a given muscle or group of muscles [21]. In our tele-rehabilitation trial no such quantitative measure was available, but it was commonly observed that most participants were unable to complete a full hour of FES-assisted exercise in the first week of ReJoyce training sessions. Initially muscles would only respond to stimulation for a few minutes. This improved as the treatment progressed and by the second week all participants were able to generate functional movements with FES during the entire 1 hour of exercise sessions.

Interestingly Fig. 3 shows this effect in the ARAT and RAHFT scores measured before and after exercise sessions on the day of the first evaluation at the 2 week point in the ReJoyce treatment (Protocol 2) but not for Combination treatment (Protocol 1). Statistical analysis indicated that the ARAT and RAHFT scores differed significantly pre-and post-exercise in the ReJoyce treatment at the 2-week point (two-tailed t-test, ARAT; $p=0.038$, RAHFT: $p=.043$).

Experiencing rapid muscle fatigue following electrical stimulation was very discouraging for the participants. During the first two weeks it is therefore important that participants be made aware that electrical stimulation can rapidly fatigue muscles but that with training the muscles build fatigue resistance.

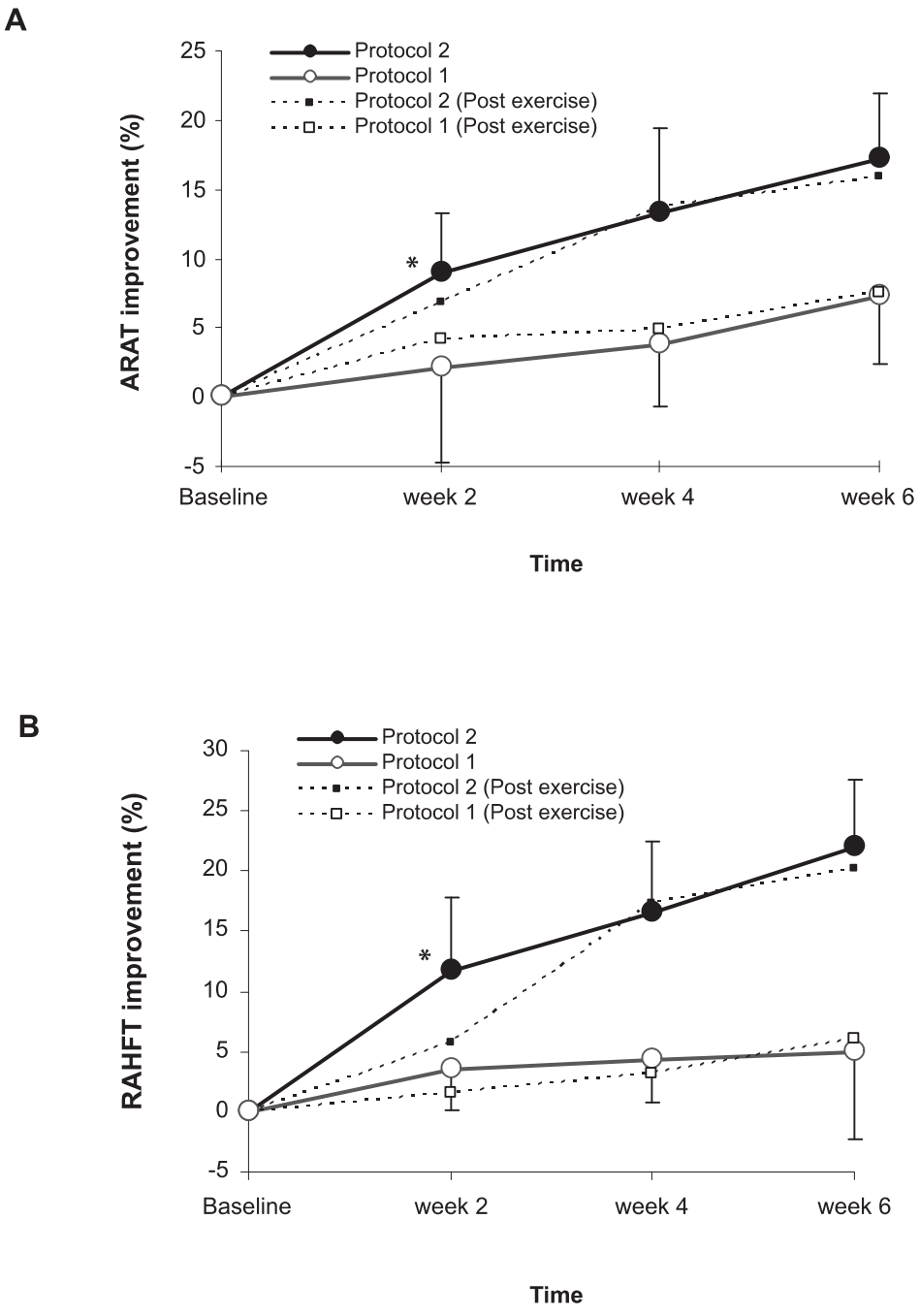

Figure 3:

Functional outcome measures pre and post 1 hour of exercise measures during regularly scheduled laboratory visits. **A**) ARAT improvement scores pre and post 1 hour of exercise. **B**) RAHFT improvement scores.

5.6 Limitations

The main limitation of the ReJoyce workstation is that it is both a treatment and an assessment tool. Although this does not pose a problem if the device is used just in treatment or just in assessment, but if it is used in both capacities, the training effect becomes an issue. The use of an independently validated test can show if the improvements suggested by the RAHFT translate to non-practised tasks, alleviating this problem to a large extent. This issue is not limited to the ReJoyce workstation, nor the studies presented in this thesis. Rather it is a very general problem associated with the field of rehabilitation. Numerous tasks practised with a therapist are inevitably the same or similar to those used to assess the individual's abilities in standard hand function tests.

Some patients responded better to the treatment than others. Out of 13 participants, five reported that they had gained useful new movements. Figure 4 illustrates improvements in ARAT scores observed in the ReJoyce and Combination treatments plotted against the corresponding pre-treatment scores. The data indicate that participants in the mid-range of starting impairment experienced the largest improvements.

The ReJoyce system is unable to measure the ROM of individual joints, nor the mechanical impedance to movement (tone). But as mentioned previously the ability to quantify fROM may be the more useful attribute.

Technically the ReJoyce system is limited to the games developed specifically for it. The unit cannot be used in conjunction with existing games or game consoles. If this feature were made available, a vast number of games from the consumer industry could be employed in upper extremity rehabilitation. However it could also be argued that this is a positive feature of the device as will result in standardized care with purpose-designed games.

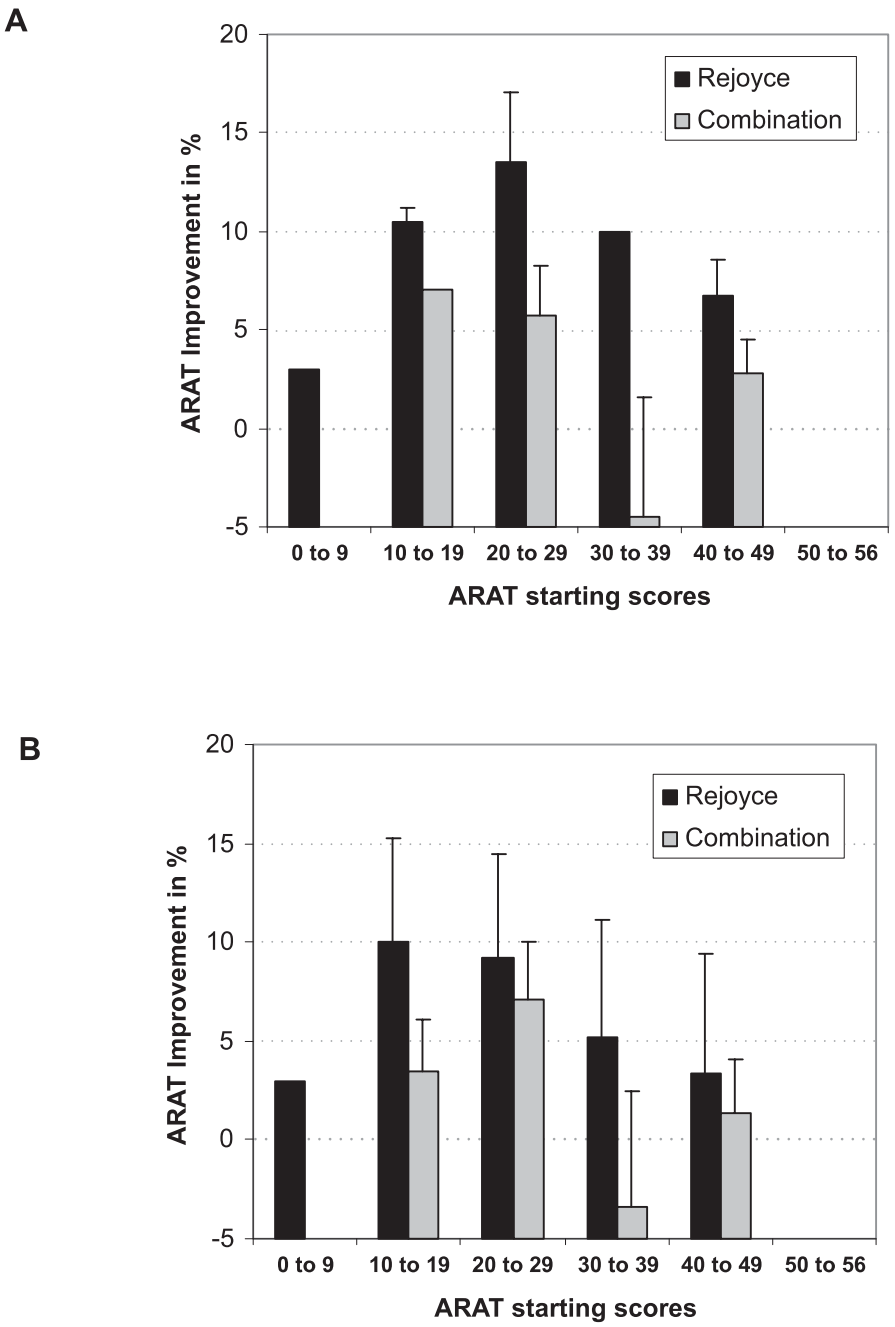

Figure 4:

ARAT scores after 6 weeks of training in relation to initial ARAT scores. **A**) illustrates the first 6 weeks of protocol 1 and 2. **B**) represents the improvement scores of all ReJoyce and Combination treatment blocks combined in relation to their appropriate baselines.

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Chapter 6

General discussion and future considerations

The restoration of movement following CNS injury is a complex problem. The studies described in this thesis are an attempt at utilizing our current knowledge of how the neuromuscular system can be retrained following injury in the most effective and affordable manner. The information acquired from the study described in Chapter 2 constituted the building blocks for the trial presented in Chapters 3 and 4 as well as the hardware and software redesign described in Chapter 5. In this thesis I have addressed the pros and cons of the following approaches to upper extremity rehabilitation:

- The use of task directed massed practiced rehabilitation.
- The use of Functional Electrical Stimulation (FES) in combination with exercise therapy (FES-ET).
- The quantification of hand function with a passive workstation.
- The employment of computer games for motivational purposes.
- The use of remote tele-supervision in the home setting.

The study in Chapter 2 introduced the possibility of using an instrumented workstation in combination with FES in the sub-acute stroke population. It further compared high-intensity FES-ET to low-intensity FES-ET, showing that the former was more effective than the latter. An important component of this study was the objective rating of hand function with the use of the workstation and automated software. This was tested in more detail in the study presented in Chapter 3. A structured, automated test for upper extremity function was found to correlate well with existing clinical tests. I believe this to be the first fully automated hand function test to have been validated against existing clinical outcome evaluations. Chapter 4 presented the complete system developed over the course of my thesis work for upper extremity tele-rehabilitation. The study described in that chapter suggested that the type of exercises performed, and the use of FES to assist these exercises (as opposed to TES to strengthen muscles) were important factors. The study also demonstrated that daily in-home tele-supervision sessions are feasible and affordable with current technology and should be pursued further. Chapter 5 provided insights that could be valuable if and when this or a similar technical approach to in-home tele-rehabilitation is implemented in the future. It also emphasizes the importance of FES-induced fatigue, the value of computer games and the importance of suitable equipment design.

There are many indications in the scientific and clinical communities, in patient support groups, and in particular at government levels that this field is poised for rapid growth. This growth will be heavily influenced by the advancement of electronics, computers, information technology and electrophysiological techniques. For example, projects are underway to use cortical neuro-prostheses interfacing with robotics for CIMT [1]. Although this prospect is scientifically very exciting, attention must be paid to cost and feasibility. This thesis work concentrated on approaches that used currently available technology in a novel manner that is affordable in the current healthcare climate. It became very clear from the process of commercializing the devices described here that cost and feasibility are top priorities in the translation of experimental treatments into the real world of clinical practice. Evidence-based outcomes and cost considerations have become crucial in developing standards of care in all medical fields, not least rehabilitation.

6.1 Evidence-based upper extremity rehabilitation

Only recently has the field of rehabilitation considered evidence-based treatment approaches through the establishment of clinical meta-studies such as Spinal Cord Injury Rehabilitation Evidence (SCIRE) (www.icord.org/scire) and the Evidence-Based Review of Stroke Rehabilitation (EBRSR) (www.ebrsr.com). The field of rehabilitation has been relatively slow in providing evidence-based care to patients compared to

other medical fields for a couple of reasons. Rehabilitation as a field relies heavily on customization; therapists frequently are faced with unique injuries and obstacles that require patient-specific adaptation of protocols and equipment. This customization is difficult to validate scientifically, unlike other medical fields that are founded on scientifically validated protocols. Another possible cause of this divergence from other medical fields is the relatively close association of rehabilitation with the field of physical training. Physical training to this day is plagued by gurus, fashion-based exercises, and myths that have little or no scientific grounding. Furthermore, rehabilitation has been slow at reaching a consensus on the best course of treatment, as it is very difficult to run properly blinded rehabilitation trials. Unlike using a placebo sugar pill in pharmacological trials, designing proper placebo treatments is complicated in non-pharmacological trials [2]. Patients can quickly determine if they are receiving the placebo, therefore it is wiser to pair different intensities of treatment as in Chapter 2 or assess two plausible, rival treatments as in Chapter 4. Rehabilitation also takes a substantial amount of time, so getting enough participants to have a large effect size in a given population can be extremely time consuming and costly. Finally most assessments in rehabilitation have been subjective and their use has not been standardized. Only recently has it been possible to look at improvements from various trials and compare them to each other.

6.2 ADL workstation based rehabilitation

This type of rehabilitation has been proposed for CIMT [3] and successfully demonstrated in Chapter 2 and Chapter 4. Training individuals on an instrumented workstation designed for improving ADLs has numerous advantages, including the ability to standardize the care being delivered as well as training individuals on tasks that could result in increased independence and improved quality of life. More importantly the workstation also allows for the quantitative rating of hand function hand function that is not influenced by rater bias.

The introduction of the RAHFT, the first fully-automated quantitative hand function test from Chapter 3, has the potential to significantly impact the field of upper extremity rehabilitation. For the first time hand function can be measured in a way comparable to measuring blood pressure. Although this does not guarantee any change in the care provided by therapists worldwide, it will hopefully alter the perception that this field cannot be based on quantitative research or assessments, paving the way for future quantitative approaches.

6.3 Home-based Upper extremity rehabilitation

A well established reason for the decreased amount of upper extremity rehabilitation provided to individuals afflicted with a stroke or SCI is the cost and the

inconvenience of providing such treatment. Furthermore the focus of many therapists in motor rehabilitation is to get patients mobile following CNS injury and all other aspects of care tend to be treated as secondary. This mind-set is driven by the increased pressure on healthcare systems to get patients mobile to allow for a larger throughput and therefore it is seen as a priority. But as demonstrated by Anderson [4] in some cases this is inappropriate.

Allowing for upper extremity rehabilitation to be performed at home opens up the possibility of increasing care at an affordable cost to current healthcare organizations and third party payors. Numerous groups have attempted to deliver motor rehabilitation [5 6], TES [7 8], and even robotic [9 10] protocols in a home setting. The study described in Chapter 4 supports these attempts. Chapter 5 presents some of the technical difficulties and solutions associated with this type of delivery method. It seems that pairing the chosen rehabilitation approach with tele-supervision will effectively maximize compliance, and be superior to self administered protocols.

6.4 Importance of proper equipment design.

Equipment in rehabilitation can have a large impact on outcomes. As described in Chapter 5, changes in FES glove design can result in improved functional abilities. As movements and muscle strength in SCI and stroke survivors is often minimal, significant effort is required to minimize the restriction of movement by the very devices intended to augment hand function.

Proper exercise equipment design is also critical, and has been explored with various workstation prototypes in this thesis. Inappropriate design can prevent a participant from performing certain tasks, it can result in increased costs, inadequate measurement capabilities, injury and increased reliance on an aid or a therapist. Properly designed equipment on the other hand, will decrease the time spent by the therapist modifying and customizing equipment for his or her patient, resulting in more productive therapy sessions.

6.5 Future directions.

Upper extremity rehabilitation is evolving as a field and is poised to benefit tremendously from all the improvements in electronic technology. Electronic technology that is most likely to impact the field includes communication devices and software, neuro-prosthetics and electronic entertainment software. Communication devices will provide new delivery vehicles for various rehabilitation protocols, and decrease some of the costs associated with rehabilitation, primarily by reducing the need for transportation and allowing for a therapist to manage

numerous patients at once. Neuro-prosthetics will migrate from laboratory prototypes to commercial devices such as the Bioness H200, making them more affordable and accessible to patients. As more of these devices will be made available they will most likely become cost- effective therapies to be used in TES. The entertainment industry has potentially the most to offer the field of upper extremity neuro-rehabilitation. Computer games and entertainment hardware are gaining a very large acceptance in rehabilitation clinics as they are extremely effective in motivating individuals. But the systems currently in use are specifically designed for entertainment, not rehabilitation and as a result are limited in their efficacy. Computer games specifically designed for rehabilitation may in the near future employ the latest advances in computer game technology such as advanced 3D engines, multi-player online capabilities and virtual reality. Yet games that will likely prove most effective will be the ones that optimize therapy time by combining many aspects of rehabilitation into a single package, for example games that will merge upper extremity training with cognitive rehabilitation for stroke patients.

In conclusion, this thesis presents a novel means of upper extremity neuro-rehabilitation and upper extremity functional assessment. The hope is that the work in this dissertation will help direct future efforts in this field and result in greater outcomes as well as an improved quality of life for those afflicted with upper extremity deficits.

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Kowalczewski et al. (43) **Pub. Date: Nov. 15, 2007**

(54) **METHOD AND APPARATUS FOR AUTOMATED DELIVERY OF THERAPEUTIC EXERCISES OF THE UPPER EXTREMITY**

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(22) Filed: **May 11, 2007**

Related U.S. Application Data

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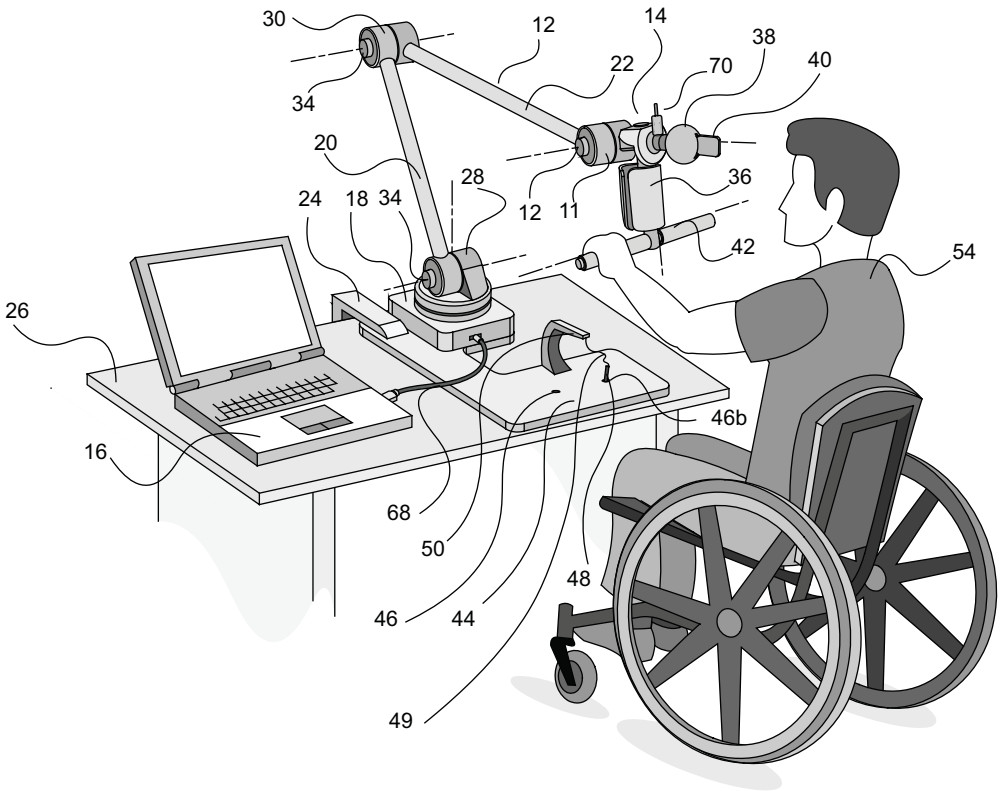
A63B 21/00 (2006.01)
A63B 26/00 (2006.01)

(52) **U.S. Cl.** **482/92**; 482/142

(57) **ABSTRACT**

The invention provides a method and apparatus to enable a user to perform upper extremity exercises. The apparatus includes an arm with one end connected to a base to securely support the arm while locating the other end adjacent to the user, proximate the user's upper extremities. The arm is formed with a plurality of joints at or between its ends, each joint having one or more rotational degrees of freedom while providing resistance to rotational movement in the one or more degrees of freedom, such that the free end of the arm can be moved in three dimensional space, and such that the arm is self-supporting. A manipulandum assembly including a plurality of manipulanda is attached to the free end of the arm, each manipulandum being positioned within hand grasping range of the user, and each manipulandum being or representing an object encountered in an upper extremity activity of the user's daily life. Sensors on the arm, joints or manipulanda sense movement or force, and relay signals to a processing device in order to sample, display, store and process the signals into kinematic or kinetic variables. These variables may be processed to control software programs such as computer games and to allow quantification of performance for outcome evaluation of therapy regimes.



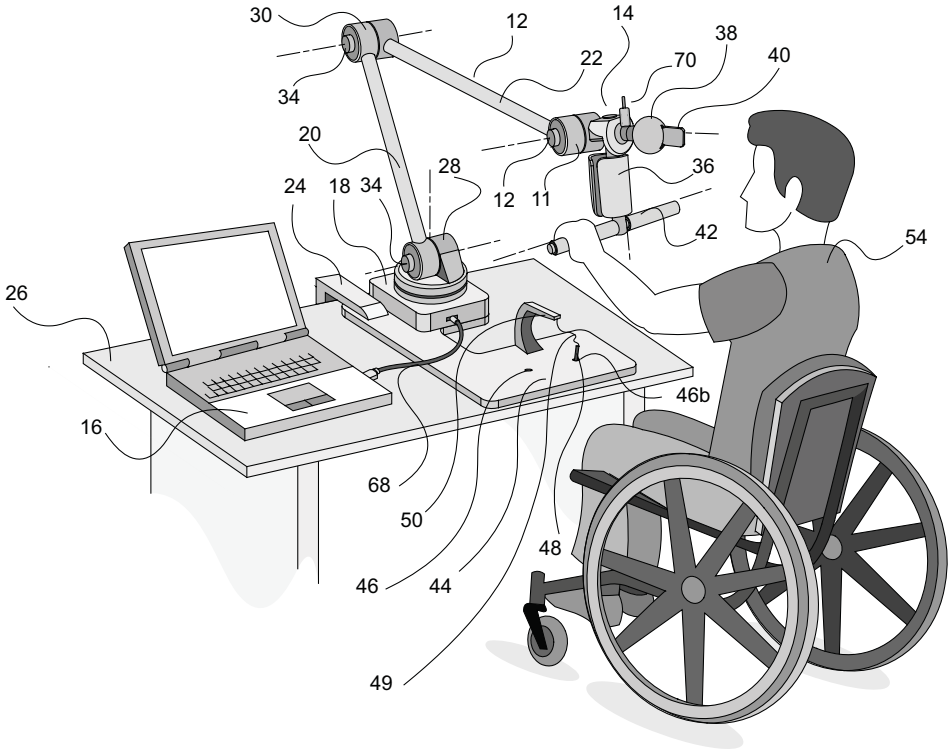

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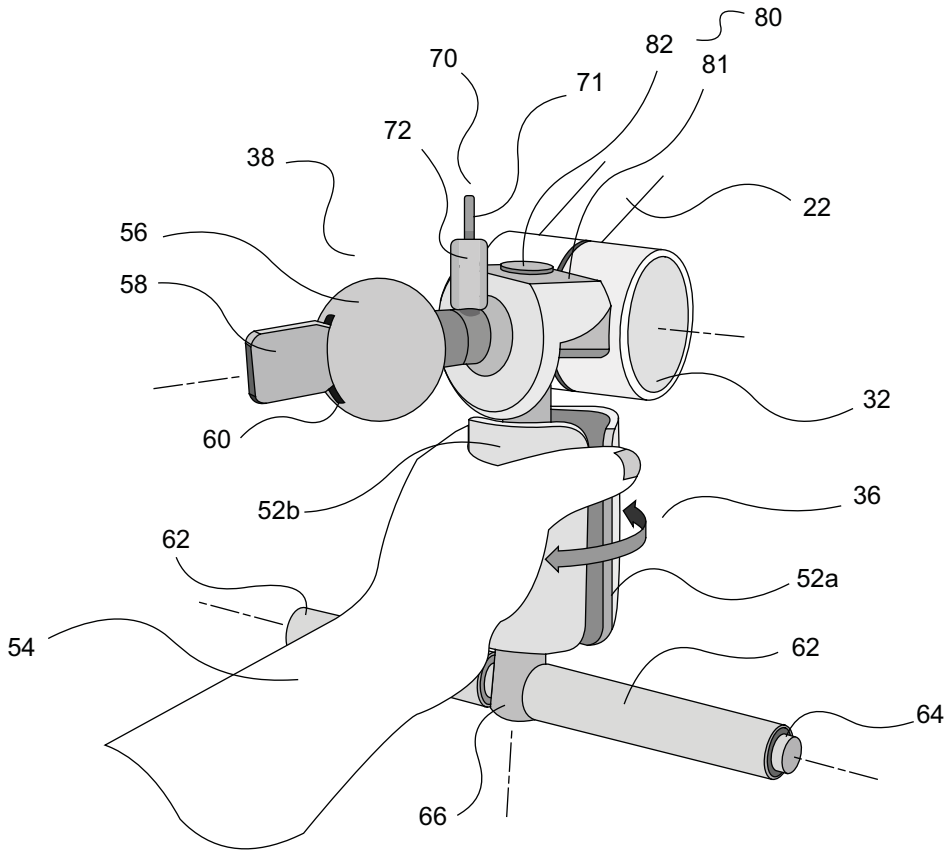
FIGURE 1



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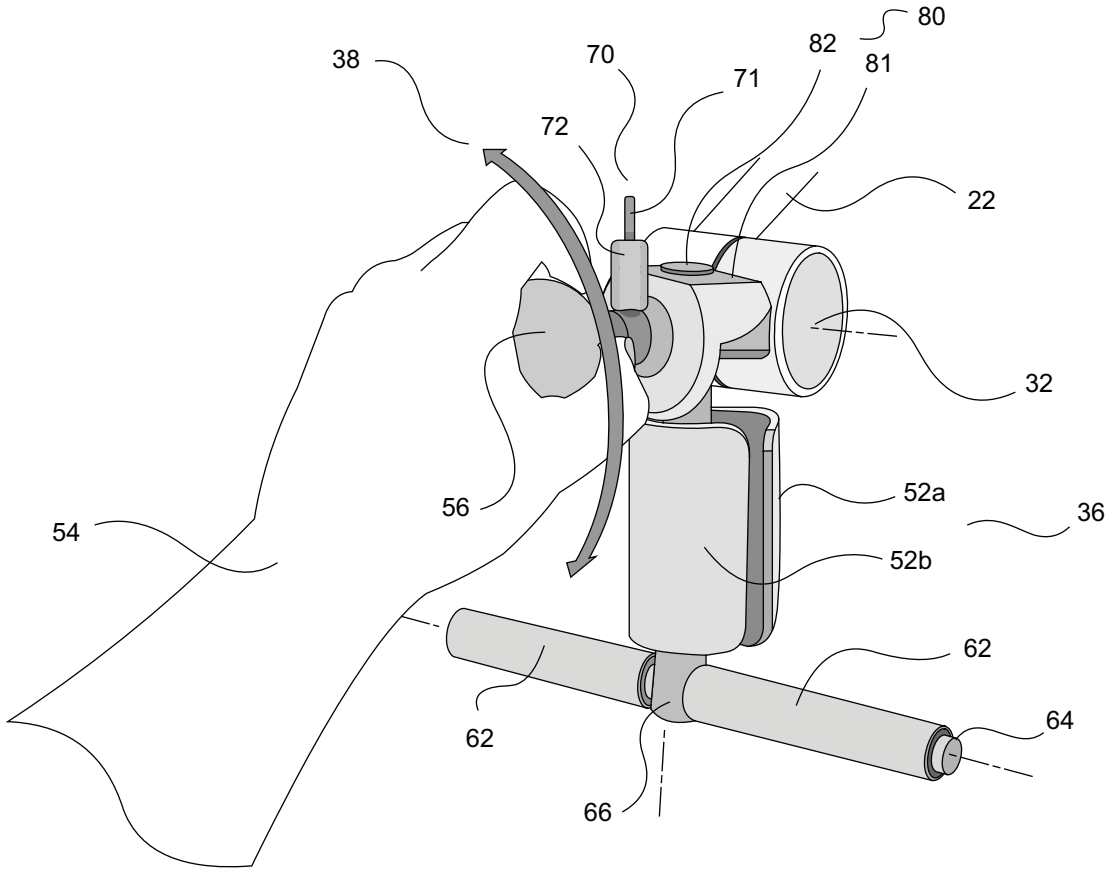


FIGURE 3A

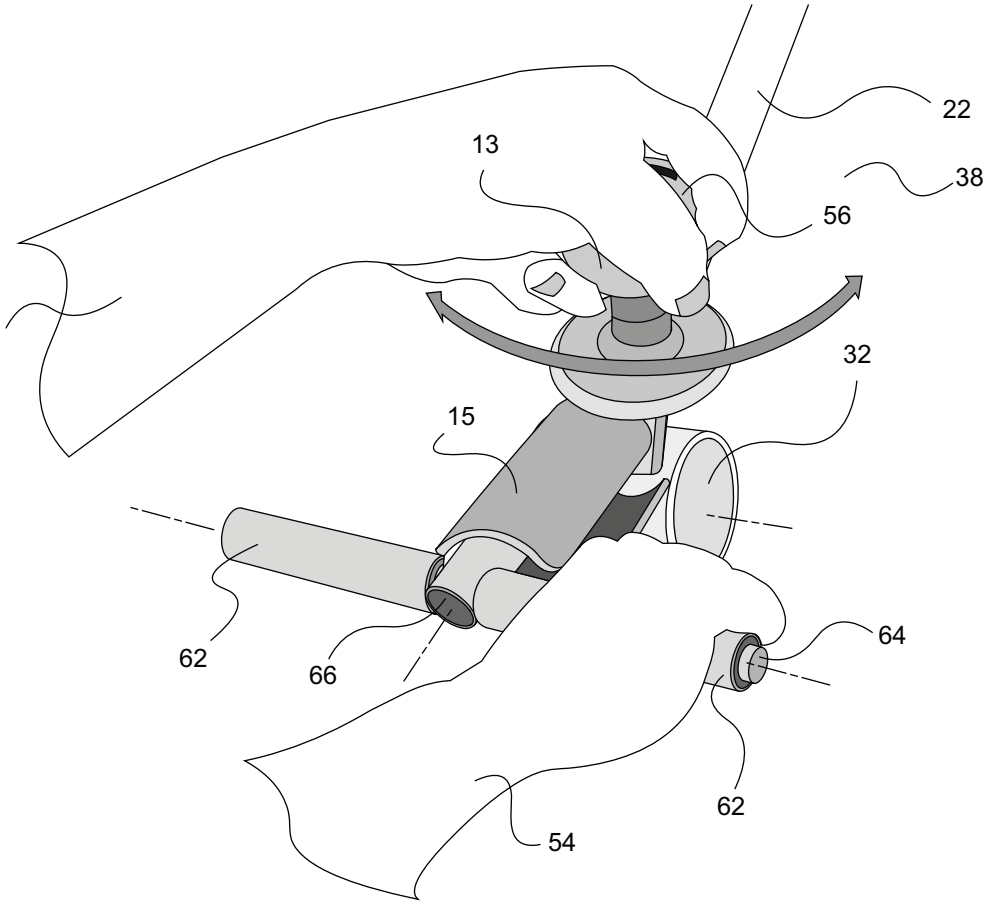


FIGURE 3B

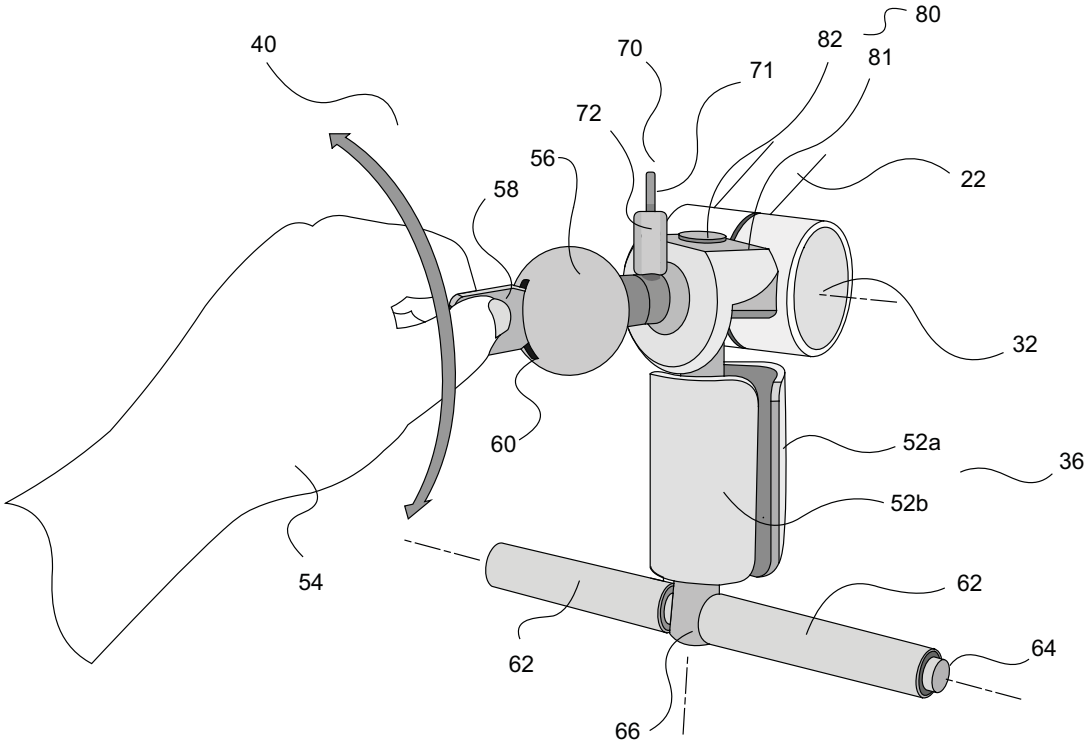
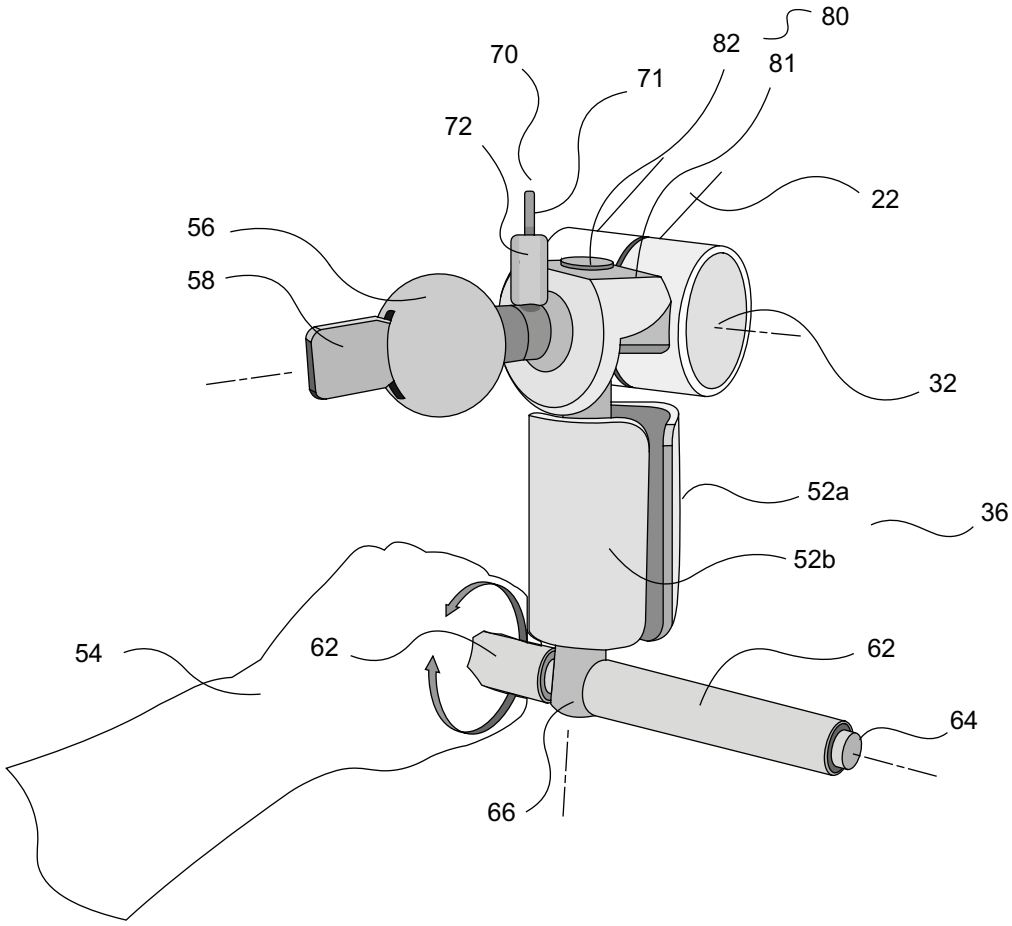


FIGURE 4



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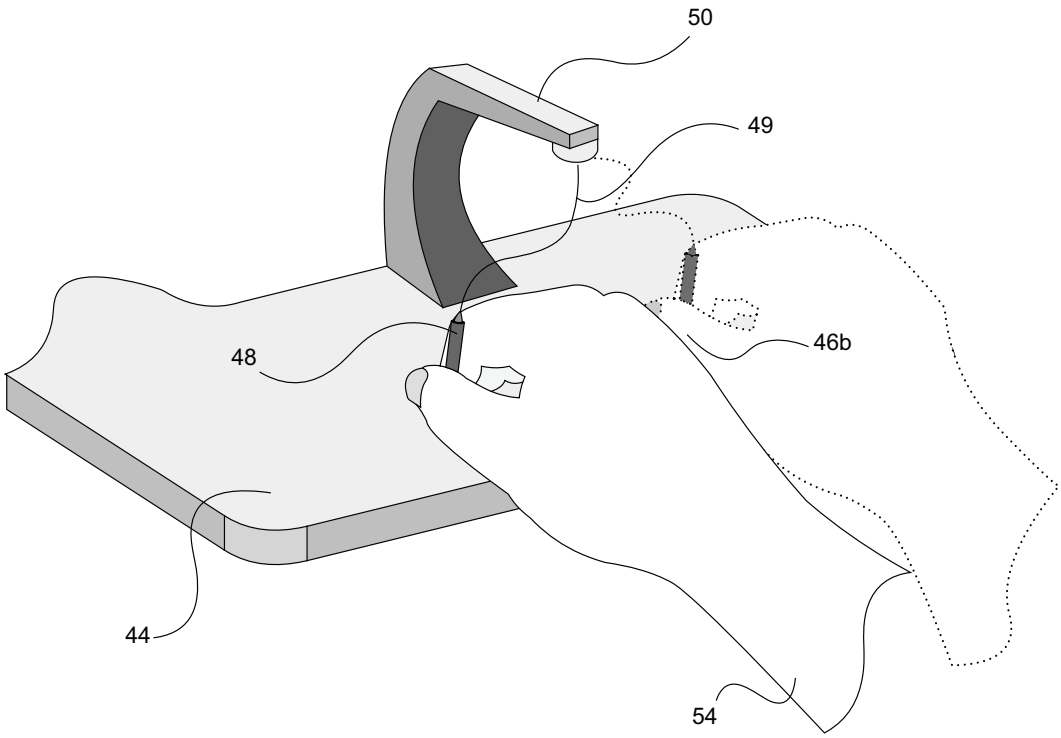

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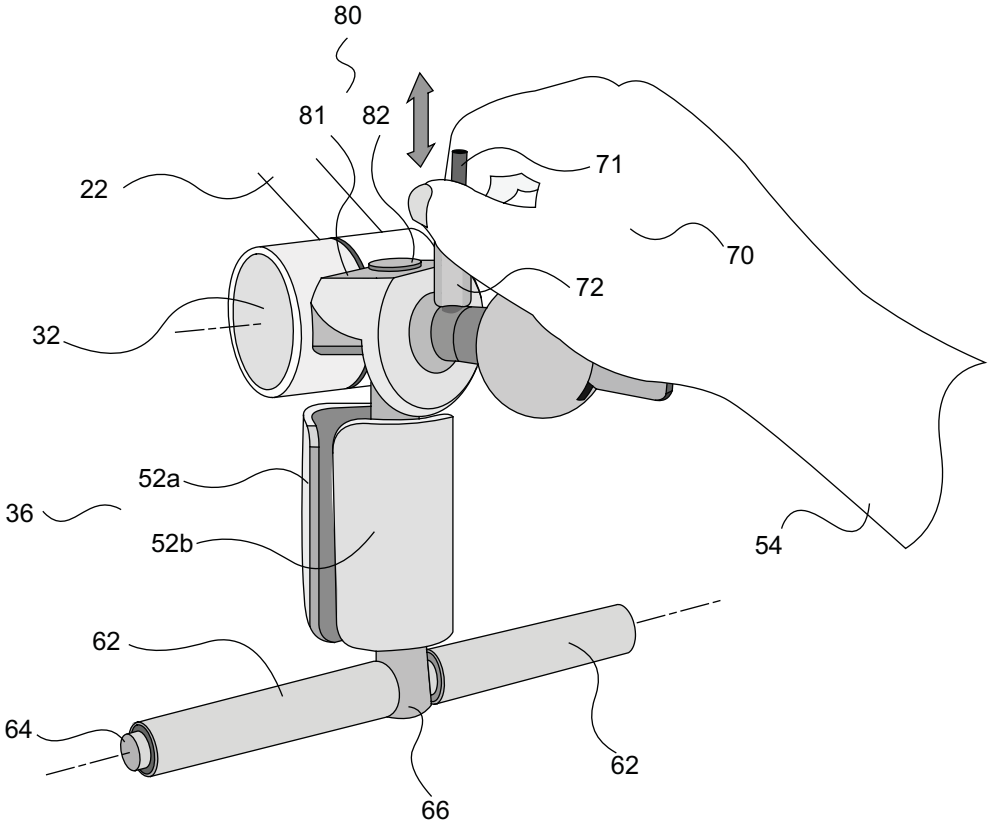


FIGURE 7A

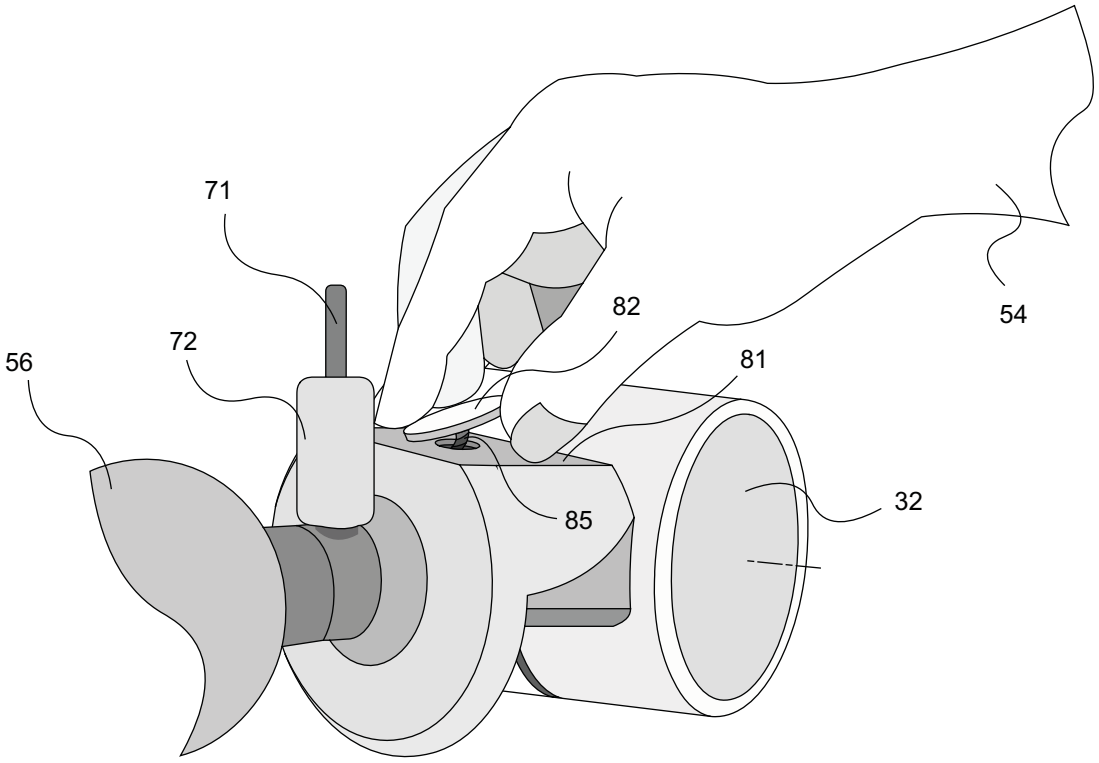


FIGURE 7B

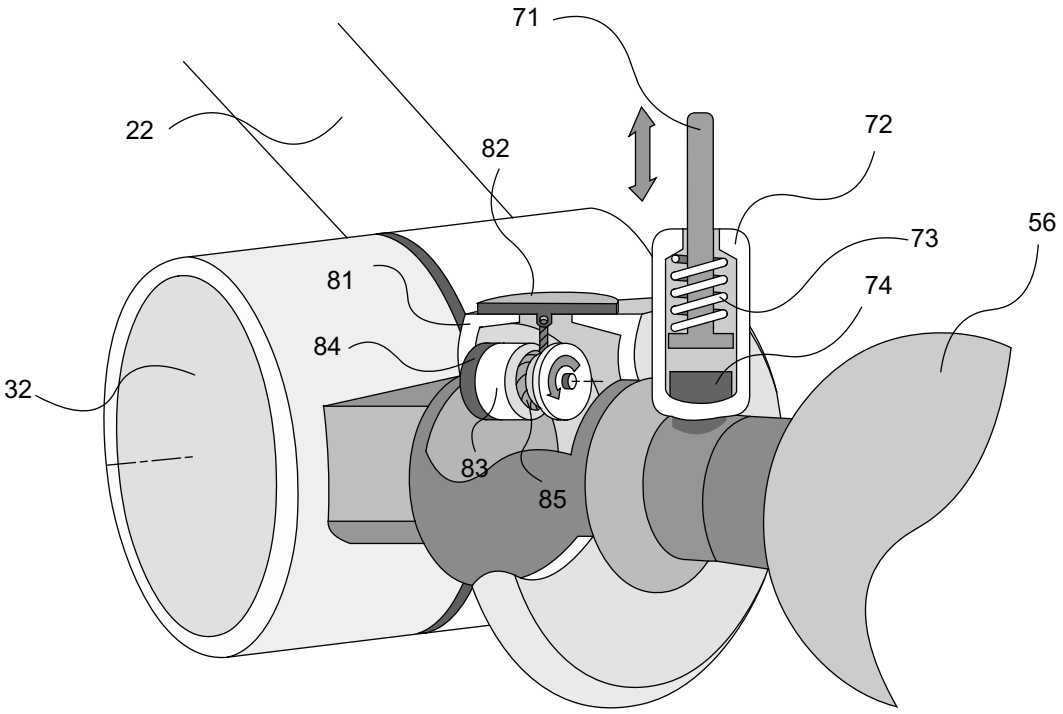
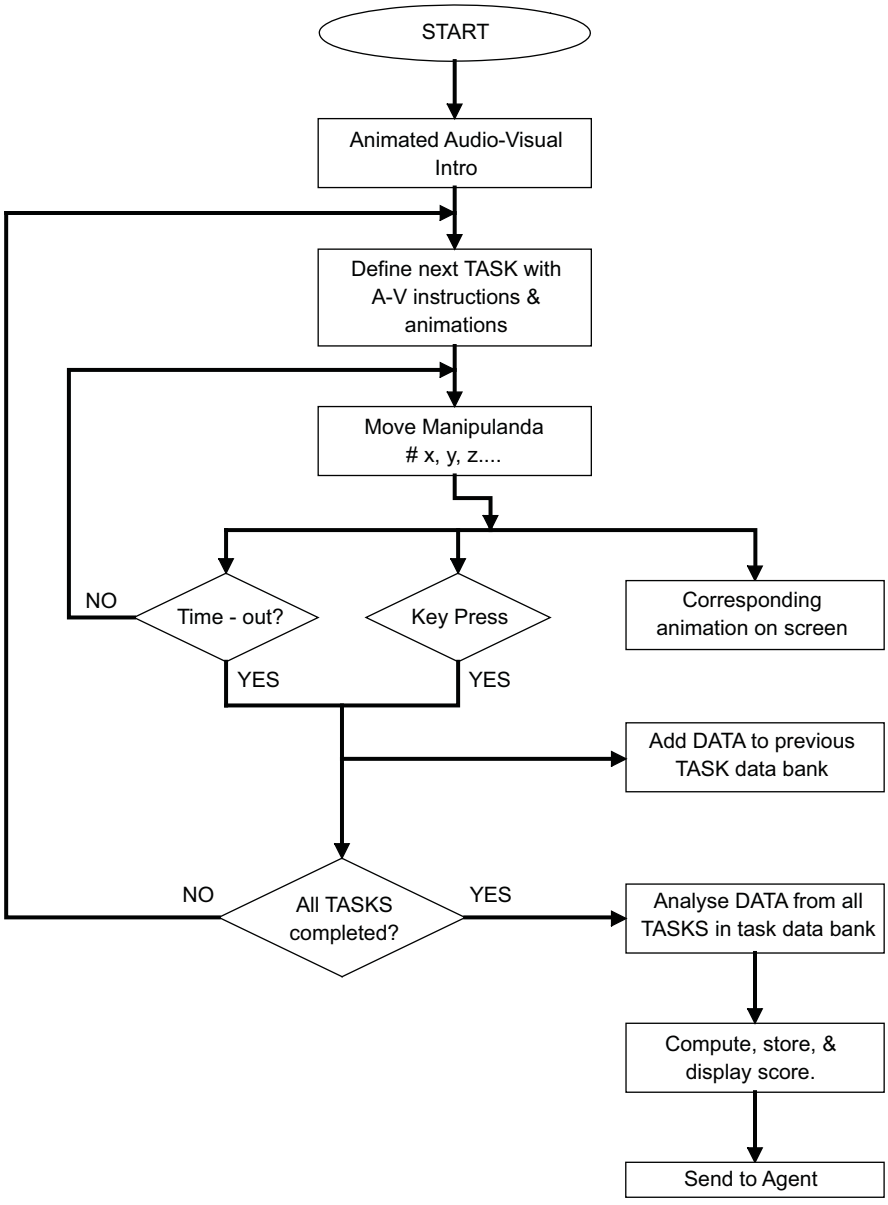


FIGURE 7C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Corresponding animation on screen
YES
YES
Add DATA to previous TASK data bank
NO
All TASKS completed?
YES
Analyse DATA from all TASKS in task data bank
Compute, store, & display score.
Send to Agent

FIGURE 8

METHOD AND APPARATUS FOR AUTOMATED DELIVERY OF THERAPEUTIC EXERCISES OF THE UPPER EXTREMITY

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit under 35 USC §119 of U.S. Patent Application No. 60/747,084, filed May 11, 2006, the disclosure of which is incorporated herein by reference in its entirety to the extent not inconsistent herewith.

FIELD OF THE INVENTION

[0002] The present invention relates to a method and apparatus for rehabilitation, specifically in relation to physical therapy applied to the upper extremity.

BACKGROUND OF THE INVENTION

[0003] Impaired movement of the upper extremities often accompanies neuromuscular disorders such as stroke, spinal cord injury, multiple sclerosis, peripheral nerve damage and arthritis. The motor deficits result in a loss of independence, reduced quality of life and high costs of care. Stroke is the leading cause of upper extremity dysfunction. In developed countries, about 1.5% of the population live with the after-effects of stroke or about 5.5 million people in North America (American Heart Association, 2006). Functional recovery of the upper extremity after stroke is quite poor, with 55% to 75% of patients having significant permanent deficits in performing activities of daily life (Lai et al., 2002).

[0004] The most widely used rehabilitative techniques are Neuro-Developmental Treatment and Proprioceptive Neuromuscular Facilitation. Both are forms of exercise therapy which have been shown to be effective if performed on a regular basis over weeks or months (Dickstein et al., 1986). Another technique, Constraint Induced Therapy, was recently developed specifically for the rehabilitation of upper extremity function and involves intensive exercise therapy of the affected arm and hand, typically six hours per day for two weeks (Taub et al., 1999). Constraint Induced Therapy has been widely adopted around the world since large gains in function of the hemiplegic extremity in activities of daily life are achieved after two weeks.

[0005] However, the above techniques are time-consuming for therapists in that such techniques require one-on-one supervision, ideally on a daily basis. Furthermore, the types of exercises involved tend to vary from one treatment facility to another. Reimbursement is usually limited to the time patients are in a rehabilitation hospital. Following a hospital stay, patients are required not only to travel to physical therapy clinics, but also to absorb the costs of such services themselves. Such disadvantages prevent the large majority of potential beneficiaries of exercise therapy from receiving it.

[0006] Those skilled in the art have attempted to provide methods and devices suitable for machine delivery of exercise. For example, U.S. Pat. No. 6,007,459 to Burgess describes the use of an interactive video communications link which allows a therapist to supervise exercises performed by subjects located elsewhere, for example in their homes.

[0007] Another approach is to provide a subject with an interactive robotic system attached to the subject's limb. For example, U.S. Pat. No. 5,466,213 to Hogan et al. describes a robot which guides the limb along desired movement paths comprising a series of upper extremity exercises. The subject's robot can also be controlled remotely by a physical therapist using a second identical robot. The system can include a teleconferencing system allowing subject and therapist to communicate with each other. However, this technology is highly expensive, precluding it from widespread usage.

[0008] Other devices that impose movements on the hand have been suggested. For example, U.S. Pat. No. 5,746,704 to Schenck et al. teaches a motorized exercise device for imposing movements along a specified path on a digit of the hand. Such passive motion devices are problematic, either in being limited to particular anatomical parts such as a single digit, or not enabling active exercise of a representative range of upper extremity movements required for activities of daily life.

[0009] U.S. Pat. No. 5,755,645 to Miller et al. teaches a multiple degree of freedom passive exercise device in the form of a joystick with a telescopic arm, whereby the user grasps a handle and moves it in a three-dimensional workspace. Computerized control of two or more brakes creates programmable mechanical resistances within the workspace. This device allows the performance of many types of movement such as throwing a ball or swinging a baseball bat. Handle attachments including tennis rackets, golf clubs and hockey sticks are described. However, the complexities of the mechanism, controllers and software place this device into a price category unaffordable for widespread distribution into peoples' homes. U.S. Pat. No. 6,988,977 to Webber et al. describes a passive exercise device with a multi-jointed arm. This device is intended as part of a weight-lifting machine for upper body training. Both Miller et al. and Webber et al. describe manipulanda in the form of handles which are easily grasped; yet, such manipulanda are not even representative of the differently sized and shaped objects encountered in activities of daily life and which are most problematic for people with impaired hand function.

[0010] Exercise workstations have been designed with instrumented objects of different sizes and shapes and sensors attached to the objects to provide kinematic data to a computer. Gritsenko et al. (2001) describes a workstation in the form of a desk surface, with fixed objects such as a spring-loaded doorknob, a spring-loaded caliper, a weighted handle and loose objects such as blocks and cylinders. Gritsenko and Prochazka (2004) describes a workstation in the form of a circular table with a rotatable upper surface, bearing a similar range of fixed and loose objects. Taub et al. (2005) describes a cabinet with eight sets of fixed and loose objects arrayed on four work surfaces, each of which may be selected and manually pulled toward the subject from the cabinet. All of the described workstations are difficult to adjust, mechanically complex, bulky and expensive, rendering them undesirable for widespread usage in peoples' homes.

[0011] U.S. Pat. No. 6,613,000 to Reinkensmeyer et al. describes a more affordable passive exercise device. A mass-produced computer input device such as a joystick intended for computer games is used by the subject to perform hand movements. Signals from the joystick sensors are used to provide input to a computer that communicates

to a server computer through a computer network. The server computer downloads individualized information to the subject's computer, specifying desired therapy and assessment exercises. The therapy and assessment exercises can be performed autonomously without real-time supervision from a therapist. The drawback of the device is that the range of movements performed by the subject is limited to the motion of the top of the joystick, namely a curved surface. The joystick knob is relatively easy to grasp, unlike many objects encountered in activities of daily life.

[0012] There is clearly a need for an inexpensive, straightforward device which addresses significant daily tasks such as grasping, lifting, lowering, moving side-to-side, twisting and otherwise manipulating objects of different sizes and shapes.

SUMMARY OF THE INVENTION

[0013] The present invention provides a method and apparatus for a range of movement exercises representative of activities of daily life. Significantly, the invention can incorporate various exercise tasks considered important by physical therapists. The invention can provide quantified measures of performance suitable for computerized patient records. Advantageously, the invention is simple and affordable, such that the health care system may be able to acquire and distribute it to the large numbers of people requiring sustained exercise therapy to improve upper extremity function.

[0014] In a broad aspect, the invention provides a method for performing upper extremity exercises by providing one or more manipulanda connected to a multi-jointed, self-supporting arm, the one or more manipulanda capable of being manipulated by a user to simulate movements representative of activities of the user's daily life.

[0015] In another broad aspect, the invention provides an apparatus to enable a user to perform upper extremity exercises, the apparatus comprising:

[0016] an arm having a fixed end and a free end, the fixed end being connected to a base for securely supporting the arm and to locate the free end adjacent to the user, proximate to the user's upper extremities;

[0017] a plurality of joints formed in the arm at or between its fixed and free ends, each joint having one or more rotational degrees of freedom while providing resistance to rotational movement in the one or more degrees of freedom, such that the free end of the arm can be moved in three dimensional space, and such that the arm is self-supporting; and

[0018] a manipulandum assembly comprising a plurality of manipulanda attached to the free end of the arm in a manner such that each manipulandum can be moved by the user through the one or more rotational degrees of freedom provided by the plurality of joints, each manipulandum being positioned within hand grasping range of the user, and each manipulandum being or representing an object encountered in an upper extremity activity of the user's daily life.

[0019] In a preferred embodiment, the plurality of manipulanda are fixed or tethered to the free end of the arm such that the manipulanda so connected remain accessible to the user without dropping or becoming lost.

[0020] In another preferred embodiment, one or more of the manipulanda are attached to the free end of the arm such that an additional rotational degree of freedom is provided to the manipulanda so attached.

[0021] In another preferred embodiment, one or more of the manipulanda are mounted on a rotatable shaft connected at the free end of the arm such that the additional rotational degree of freedom is provided along the long axis of the shaft.

[0022] In another preferred embodiment, the plurality of joints provides passive resistance against rotational movement, and thereby returns the arm and the manipulandum assembly to an equilibrium rest position when the user releases the manipulandum assembly.

[0023] In yet another preferred embodiment the arm is positioned above a floor, and wherein the arm is formed in two interconnected segments with a first segment extending generally upwardly from the base and a second segment extending generally forwardly toward the user to position the free end proximate the user's upper extremities, the first segment having the fixed end connected to the base through a first joint providing a rotational degree of freedom in a horizontal axis generally parallel to the floor, and a rotational degree of freedom in a vertical axis, the first and second segments being interconnected through a second joint providing a rotational degree of freedom in a horizontal axis, and the free end of the second segment being attached to the plurality of manipulanda through a third joint providing a rotational degree of freedom in a horizontal axis.

[0024] Preferred and exemplary manipulanda of the present invention are selected from a vertically split cylinder, a doorknob manipulandum, a key-grip manipulandum, horizontal handles manipulandum, a peg manipulandum and a coin manipulandum.

[0025] In a further preferred embodiment the apparatus includes one or more sensors located in one or more positions selected from the first, second and third joints, the first and second segments, and the plurality of manipulanda, the sensors being operative to detect movement or force and to generate an electrical signal representative of movement or force generated.

[0026] In another broad aspect, the invention extends to a method for providing an exercising therapy for the user's upper extremity comprising providing an apparatus as described above, and causing the user to manipulate the plurality of manipulanda with the user's hand to simulate movements representative of activities of the user's daily life. Preferred forms of manipulating include grasping, squeezing, releasing, pinching, lifting, lowering, moving from side to side, twisting and rotating.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The present invention will be further described by way of example only and with reference to the following figures in which similar references are used in different figures to denote similar components, and wherein:

[0028] FIG. **1** is a perspective view of one embodiment of the present invention, showing the multi-jointed arm providing multiple rotational degrees of freedom to the plurality of manipulanda attached to the free end of the arm.

[0029] FIG. **2** is a perspective view of the split cylinder manipulandum of one embodiment of the present invention, showing the user grasping and squeezing manipulations on the split cylinder.

[0030] FIGS. **3**A and **3**B are perspective views of the doorknob manipulandum of one embodiment of the invention. FIG. **3**A is a perspective view of the doorknob manipu-

landum positioned towards the user. FIG. **3**B is a perspective view of the doorknob manipulandum in a rotated, upright position.

[0031] FIG. **4** is a perspective view of the key-grip manipulandum of one embodiment of the invention.

[0032] FIG. **5** is a perspective view of the horizontal handles manipulandum of one embodiment of the invention.

[0033] FIG. **6** is a perspective view of the pegboard and tethered peg manipulandum of one embodiment of the invention.

[0034] FIG. **7**A is a perspective view of the peg manipulandum and the coin manipulandum of one embodiment of the invention.

[0035] FIG. **7**B is a perspective view of the peg and coin manipulandum of FIG. **7**A, showing the peg and coin housing parts in cross section to show the spring loaded peg, tethered coin and sensor details.

[0036] FIG. **7**C is a perspective view of the coin manipulandum of FIG. **7**A, showing the user manipulating the coin manipulandum in a manner to simulate picking up the coin element.

[0037] FIG. **8** is a flowchart illustrating one embodiment of computer software which might be used for interactive user prompting, scoring and transmitting to a remote location.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0038] The invention broadly provides a method and apparatus for physical therapy for various disorders in which movement of the upper extremity is impaired. The apparatus has a multi-jointed, self-supporting arm, the joints of which provide resistance (preferably passive resistance) to rotational movement in one or more degrees of freedom. One end of the arm, a connected end, is connected to a support for securely supporting the arm and for positioning the arm at an appropriate user height. The other end of the arm, the free end bears one or more manipulanda simulating movements representative of activities of the user's daily life. The design of the arm allows movement to any point within the biomechanical workspace of the user's hand. Each manipulandum in the assembly is designed to provide a specific hand and/or arm exercise involving certain movements representative of those occurring in an activity of daily life. The specific exercise provided by each manipulandum is similar to those used in conventional physical therapy for subjects with impaired movement of the upper extremities resulting from neuromuscular disorders. Such disorders can include, for example, stroke, spinal cord injury, multiple sclerosis, peripheral nerve damage and arthritis.

[0039] The following description is a preferred embodiment of the invention by way of example only and without limitation to the combination of features necessary for carrying out the invention into effect.

[0040] The invention is described with reference to the drawings in which like parts are labeled with the same numbers in FIGS. **1** to **8**. The apparatus is shown generally at **10** in FIG. **1** to include a multi-jointed arm **12** with a connected manipulandum assembly **14** and computer **16**.

[0041] The arm **12** is composed of a base assembly **18**, a first segment **20** and a second segment **22**. The base assembly **18** is securely anchored by appropriate securing means, for example a clamp **24**, to a horizontal support **26**, for example, a desk, table or other suitable support. The base assembly **18** is connected to the fixed end of the first segment **20** by a first spring-loaded joint **28**, preferably having two rotational degrees of freedom (as indicated by dashed lines in FIG. **1**—showing rotational movement about a horizontal and a vertical axis). The first segment **20** is linked to the second segment **22** by a second spring-loaded joint **30**, preferably having a single rotational degree of freedom (as indicated by the dashed line in FIG. **1**—showing rotation about a horizontal axis). The manipulandum assembly **14** is connected to the free end of the second segment **22** by a third spring-loaded joint **32**, preferably having a single rotational degree of freedom (as indicated by the dashed line in FIG. **1**—showing rotation about a horizontal axis). In FIG. **1**, the free end of the arm **12** (or segment **22**) terminates at the third joint **32**.

[0042] The first and second segments **20**, **22** can be formed of a rigid material. Alternatively, telescopic, elastic, or rotational segments can be used to provide additional degrees of freedom beyond those of the rigid segments **20**, **22** illustrated in FIG. **1**. Such segments may be instrumented to measure deflection, extension, compression and rotation.

[0043] Each of the spring-loaded joints **28**, **30**, **32** can be locked in a certain position using any known locking means (not shown) within its respective range of motion if so desired. One example of suitable locking means is a bolt and wing nut. Each spring-loaded joint **28**, **30**, **32** provides passive resistance to angular deflection away from a static equilibrium position (equilibrium rest position) determined by the mass and spring properties of the components of the apparatus **10**. In this manner, the multi-jointed arm **12** is self-supporting, and will return to its equilibrium rest position when the user completes a particular manipulation, releasing a manipulandum. Springs are incorporated in the joints **28**, **30**, **32** to achieve a desired amount of passive resistance in movement. Alternatively, a desired amount of resistance is achieved using friction bearings, dampers or weights, although springs are preferable. It is understood that these means of resistance may be varied, thus allowing for alterations in manipulanda, user and user capabilites. Each spring-loaded joint **28**, **30**, **32** in the arm **12** is preferably equipped with a sensor **34** for electrically measuring its angle of deflection around its respective rotational axis or axes.

[0044] The exemplary embodiment incorporates spring-loaded joints **28**, **30**, **32**. It is possible to modify the invention to incorporate other suitable types of joints, for example, joints having additional rotational degrees of freedom, differing or absent spring-loading, differing or absent locking means, and different instrumentation. For instance, a ball and socket joint can be used to connect the first and second segments **20**, **22**. The ball and socket joint may be spring-loaded, or may rely on friction to maintain a position. Advantageously, the ball and socket joint has rotational degrees of freedom around two axes, and can be instrumented with sensors **34** that measure deflection of the joint around its two degrees of freedom.

[0045] In general, any joints or linkages which provide one or more rotational degrees of freedom with some resistance to rotational movement are suitable. Most preferably, the joints provide only passive resistive force against rotational movement, such as by frictional, spring, gravitational, or inertial force. It should be understood that the

provision of passive resistance to rotational movement in the joints is meant to exclude the use of force generators or robotic devices.

[0046] One or more moving components of the apparatus **10** (for example, arm, segments, joints, manipulanda, and pegboard holes) are instrumented with electronic sensors **34** (see also sensors **74**, **84** described below with particular manipulanda). The sensors **34** detect the movement of one or more moving components and generate electrical signals representative of the movement. The electrical signals are then transmitted to a suitable processing device, such as the computer **16**, which then samples, displays, stores and processes the signals into kinematic or kinetic variables. Secondary variables such as, for example, net displacement, velocity, acceleration, force and torque, are computed from the kinematic or kinetic variables to generate performance ratings or scores. It has been found advantageous to compute a single performance rating by first normalizing each individual rating corresponding to a given exercise and combining all such ratings into a single score (see for example, Gritsenko & Prochazka, 2004).

[0047] Various types of sensors **34** are appropriate with the apparatus **10**. The exemplary embodiment uses potentiometers to determine the angle of a joint or the position of the first and second segments **20**, **22**. Other non-limiting examples include potentiometers, gyroscopes, accelerometers, linear variable displacement transducers, optical encoders, strain gauges, electrical contacts, photo-electric sensors or other sensors known to those skilled in the art. Optical, electro-optical, magnetic, capacitive, inductive or other types of sensors can be used to quantify movement, position, orientation, or force applied to all or any combination of joints, segments, and manipulanda. In this manner, movement sensors located on one or more of the arm **12**, segments **20**, **22**, joints **28**, **30**, **32** and manipulandum assembly **14** can be used to detect and transmit information from which one may calculate angles, starting and end point positions of components so as to generate information relating to the x, y and z co-ordinates of one or more of the manipulanda being moved by the user **54**.

[0048] The manipulandum assembly **14** is connected to the free end of the second segment **22** through the joint **32**. The manipulandum assembly preferably includes a platform **81** which extends forwardly from (i.e., toward the user), and is connected to, the joint **32**. In this manner, the manipulandum assembly **14** can suspend a plurality of hand function manipulanda in front of the user, allowing the user to grasp each manipulandum with one or both hands, and move the manipulandum through the multiple degrees of freedom allowed by the joints **28**, **30**, **32**. The platform **81** can be positioned generally horizontally, as shown in FIG. **3**A, or it can be moved to be generally vertical as shown in FIG. **3**B, by rotating the joint **32** along its horizontal axis. The manipulandum assembly **14** preferably also includes a shaft **66** mounted perpendicularly to the platform **81** (preferably below, as shown in FIG. **3**A). The shaft **66** is preferably connected to the platform **81** for rotation about its long axis (shown in FIG. **3**A as a vertical dotted line representing a vertical axis when the manipulandum apparatus **14** is in its upright position). This allows for connection of manipulanda as described below to this rotatable shaft **66**, adding an additional rotational degree of freedom to a manipulandum of the manipulandum assembly **14**. As shown in FIG. **1**, the user **54** can move the manipulandum assembly **14**, relative to the user, forwardly or rearwardly, up and down, and in a twisting or side to side movement, with the twisting or side to side movement being achieved through the vertical axis through joint **28** and/or the long axis of the rotatable shaft **66**. Locking of one or more of these joints **28**, **30**, **32** or the rotatable shaft **66** to limit any of these rotational degrees of freedom may be achieved with the locking means (not shown), as mentioned below. Thus, the multi-jointed arm **12** allows for 3-dimensional movement of the manipulandum assembly **14**, which can be sensed to generate x, y, and z components of the movements of the individual manipulandum by the user.

[0049] Another preferred feature of the manipulandum assembly **14** is that it allows for the one or more manipulanda to be fixed or tethered at the free end of the arm **12**. In this manner, the manipulanda remain accessible to the user, without individual components being dropped or lost by the user.

[0050] The manipulandum assembly **14** is comprised of an electrically instrumented set of manipulanda which are self-supporting and provide resistance. Movement of such manipulanda requires upper extremity movements similar to those occurring in activities of daily life. Varied manipulanda are attached or detached from the arm **12**, depending on the user's disorder, requirements or maintenance needs. It will be appreciated by those skilled in the art that different manipulanda can be connected to the arm **12** at different locations and with differing and/or additional degrees of freedom (i.e., additional to the rotational degrees of freedom provided by the joints **28**, **30** and **32**). As described in more detail below, additional sensors (i.e., in addition to sensors **34** located on the arm **12**, segments **20**, **22** and/or joints **28**, **30** and **32**) are preferably included to measure displacements of different manipulanda within the manipulandum assembly **14**, from which secondary variables (for example, kinematic variables) are computed.

[0051] Without being limiting in any manner, the manipulandum assembly **14** may include, for example, one or more of a vertically split cylinder manipulandum **36**; a doorknob manipulandum **38**; a key-grip manipulandum **40**; a horizontal handles manipulandum **42**; a peg manipulandum **70**; a coin manipulandum **80**, or other suitable hand function manipulanda as used in conventional physical therapy for users with impaired movement of the upper extremity. As described more fully below, these manipulanda are preferably attached to the platform **81**, to rotate with the joint **32**, and/or to the rotatable shaft **66**.

[0052] As shown in FIGS. **1** and **6**, stationary manipulanda may be provided on a horizontal support **26** in front of the user. FIG. **6** shows one such exemplary additional manipulandum in the form of a pegboard **44** defining one or more holes **46** and having at least one peg **48** tethered by a tether **49** from a gantry **50** can be used alone or in combination with the apparatus **10**.

[0053] FIG. **2** shows the vertically split cylinder **36** defining two halves **52***a*, **52***b* mounted on the rotatable shaft **66**, and which are biased slightly away from each other by one or more stiff springs (not shown). The split cylinder **36** doubles as a caliper for squeezing or a familiar object such as a pop can. Force may be sensed indirectly by displacement of the spring separating the two halves **52***a*, **52***b* of the split cylinder **36**, or by a force transducer such as a strain gauge attached to part of the cylinder (sensor not shown). FIG. **2** illustrates the user **54** applying force to squeeze the

two halves **52***a*, **52***b* of the split cylinder **36** together. The user **54** can also practice moving the split cylinder **36** from one position to another position within the workspace, mimicking the transfer of a familiar object such as a pop can from one location to another location.

[0054] FIGS. **3**A and **3**B show the doorknob manipulandum **38** comprising a rotatable spring-loaded doorknob **56** fixed for rotation to the platform **81**. The doorknob **56** provides twisting (pronation-supination) exercises for the user **54**, as shown in FIG. **3**A. Conveniently, the doorknob **56** is rotatable into a vertical position, whereby the exercise requires a movement similar to that of twisting the lid of a screw-top jar, as shown in FIG. **3**B. In other embodiments of the invention, the doorknob **56** can be replaced by different manipulanda. Non-limiting examples include a sphere, oval, lever or other shapes which simulate other activities of daily life.

[0055] FIG. **4** shows a key-grip manipulandum **40** comprising a key-like tab **58** extending outwardly from a key way **60** defined in the doorknob **56**. The key-like tab **58** is configured to be pulled outwardly from the key way **60** by the user **54** to a pre-configured locked position, so that the key-like tab **58** cannot be completely removed from or drop out of the key way **60**. The key-like tab **58** can be twisted in a movement which mimics the turning of a key in a lock.

[0056] FIG. **5** shows the horizontal handles manipulandum **42** comprising horizontal handles **62** freely rotatable on an axle **64** which is secured to the base of the rotatable shaft **66**, below the split cylinder **36**. The handles **62** are positioned perpendicular to the split cylinder **36** (when in the equilibrium rest position) and extend horizontally beyond the periphery of the split cylinder **36** so as to be accessible to both the left and right hands of the user **54**. The handles **62** rotate freely on the axle **64** which is connected to the manipulandum assembly **14**, which, when combined with the degrees of freedom of the arm **12**, allow any orientation of the user's hand **54** in the three-dimensional workspace. Advantageously, the handles **62** provide range-of-motion exercises encompassing virtually the entire biomechanical range of possible positions of the user's hand **54**.

[0057] The exemplary embodiment can also be provided with a pegboard **44** attached to the horizontal support **26** as shown in FIG. **6**. The pegboard **44** defines one or more holes **46**, and has at least one peg **48** tethered by a tether **49** from a gantry **50**. The pegboard **44** can be used alone or in combination with the apparatus **10**. In use, the user **54** moves the peg **48** from a first hole **46***a* to a second or other hole **46***b* in order to practice side-to-side movement of the hand **54** (the movement of the hand **54** is shown in phantom in FIG. **6**). Sensors **34** can be positioned within the one or more holes **46** to monitor or assess the user's progress.

[0058] FIGS. **7**A, **7**B and **7**C show exemplary embodiments of a peg manipulandum **70** and a coin manipulandum **80** also provided at the free end of the arm **12**, preferably forward of the platform **81**. A peg **71** with an enlarged base is held captive in a hollow housing **72**. A spring **73** within the housing normally pushes the enlarged base of the peg **71** against a sensor **74** such as a microswitch located at the bottom of the housing **72**. In use, the user **54** grasps the peg **71** in a pinch grip and pulls it part of the way out of the housing **72** against the resistance of the spring **73**. This changes the state of the sensor **74**. In addition to peg **71** being pulled partly out of the housing **72**, it may also be moved in any direction in 3-dimensional space by virtue of its attachment to the moveable manipulandum assembly **14**. The movement of the peg **71** and attached manipulandum assembly **14** may be computed from signals from the sensors **34**.

[0059] The coin manipulandum **80** is shown to be mounted on the platform **81**, although it might be mounted at an alternate convenient location on the manipulandum assembly **14** (it might still alternatively be mounted on the horizontal support **26**, if desired). A coin element **82** is held flat on the platform **81**. The coin element **82** may be tethered beneath the platform **81** in any suitable manner such that its removal from the platform **81** as the user picks up the coin element **82** may be sensed. FIG. **7**B shows one exemplary embodiment in which the cross sectional details show a tether **85** connected to the underside of the coin element **82**. The tether **85** is secured below the platform **81** to a self retracting spring biased reel **83**. A motion sensor **84** may be mounted to the reel **83** in order to sense rotation of the reel **83** as the user **54** picks up the coin element **82**.

[0060] While not specifically shown in the Figures, it will be understood by one skilled in the art that the apparatus and method of this invention may include one or more supporting devices for the user's hands or arms. Such supports might include, for example, elbow supports or overhead slings. As well, the invention might be adapted to use hand straps with one or more of the manipulanda in order to assist a user.

[0061] When the apparatus **10** is in use, the user **54** is generally seated and facing the manipulandum assembly **14**, as shown in FIG. **1**. The user **54** engages one of the manipulanda by grasping and lifting, lowering, pulling, pushing, twisting or otherwise moving it according to the activities of daily life being simulated, and according to a series of instructions provided by software in the computer **16**, for example on the display or by a remote therapist communicating via a telecommunications link such as that mediated by the computer **16** through a network. The movements of the first, second and third spring-loaded joints **28**, **30**, **32** and first and second segments **20**, **22** of the apparatus **10** are detected by the sensors **34**. The sensors **34** in turn generate electrical signals representative of the movement, and transmit the electrical signals by suitable transmission means **68** (for example, a wire or wireless means) to a processing device such as the computer **16**, which then samples, displays, stores and processes the signals into kinematic or kinetic variables. The kinematic or kinetic variables can be further processed to obtain secondary variables.

[0062] The computer **16** runs a software program that provides feedback and instruction to the user **54** based on the user's movements. The computer **16** also stores data captured by the sensors **34**. The data may be processed subsequently to quantify changes in the user's ability to perform simulated activities of daily life over a period of time. A report of the user's progress may be periodically sent over a computer network to a computer located remotely for a therapist or trainer for analysis, for example through the Internet. The therapist or trainer can issue commands to the computer **16**, locally or over a computer network, to modify or change the feedback and instruction the user **54** receives from the computer **16**.

[0063] The computer interface can comprise different assemblies including, for example, both wired and wireless interfaces, for example USB and 802.11b, respectively.

Computer programs of different types and levels of network and device connectivity can be used. Without being limiting in any manner, such types can include stand-alone applications, applications run from remote locations over a computer network, game applications, exercise applications and training applications. The computer program may offer many kinds of feedback to the user including audio and/or video. For instance, the computer program can allow an administrator either locally or by means of a computer network to communicate with the user in real time, or with a delay, by way of text, audio visual, or other type of communication.

[0064] One example of computer software that can be used to guide the user **54** through a series of motor tasks that collectively comprise a standardized test of upper extremity function is shown in the flowchart of FIG. **8**. Communication with the user **54** may be in the form of automatically generated voice commands, displayed text, pictures, videos and animations on the user's computer display **16**. Alternatively or additionally, an administrator or therapist may provide verbal and visual guidance. As described above, the administrator may be in the same location or elsewhere, communicating verbally and visually by telecommunications means, for example with the use of the Internet. The software may record signals captured by the sensors **34** etc. during the performance of the standardized test and use these signals automatically to detect whether a specific task has or has not been attempted and prompt the user accordingly. The software may automatically compute performance scores from the captured data and thereby provide outcome measures from the standardized test.

[0065] The computer **16** can be a standalone workstation, or connected to a computer network. When connected to a network, the computer program can use a wide range of connectivity protocols over a link with the network. The computer **16** can be connected to multiple forms of networks simultaneously, for example a computer network and a cellular network.

[0066] The exemplary embodiment can be provided with an electrical stimulator (not shown) to activate the nerves and muscles of the user **54** to assist in the performance of the exercise (see for example, International Patent Application Publication No. WO 2004/034937 and U.S. Pat. No. 6,961,623 issued Nov. 1, 2005, both to Prochazka).

[0067] All references mentioned in this specification are indicative of the level of skill in the art of this invention. All references are herein incorporated by reference in their entirety to the same extent as if each reference was specifically and individually indicated to be incorporated by reference. However, if any inconsistency arises between a cited reference and the present disclosure, the present disclosure takes precedence. Some references provided herein are incorporated by reference herein to provide details concerning the state of the art prior to the filing of this application, other references may be cited to provide additional or alternative device elements, additional or alternative materials, additional or alternative methods of analysis or application of the invention.

[0068] The terms and expressions used are, unless otherwise defined herein, used as terms of description and not limitation. There is no intention, in using such terms and expressions, of excluding equivalents of the features illustrated and described, it being recognized that the scope of the invention is defined and limited only by the claims which follow. Although the description herein contains many specifics, these should not be construed as limiting the scope of the invention, but as merely providing illustrations of some of the embodiments of the invention. One of ordinary skill in the art will appreciate that elements and materials other than those specifically exemplified can be employed in the practice of the invention without resort to undue experimentation. All art-known functional equivalents, of any such elements and materials are intended to be included in this invention. The invention illustratively described herein suitably may be practiced in the absence of any element or elements, limitation or limitations which is not specifically disclosed herein.

[0069] As used herein, "comprising" is synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements. The use of the indefinite article "a" in the claims before an element means that one or more of the elements is specified, but does not specifically exclude others of the elements being present, unless the contrary clearly requires that there be one and only one of the elements.

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What is claimed is:

1. An apparatus to enable a user to perform upper extremity exercises, the apparatus comprising:

an arm having a fixed end and a free end, the fixed end being connected to a base for securely supporting the arm and to locate the free end adjacent to the user, proximate to the user's upper extremities;

a plurality of joints formed in the arm at or between its fixed and free ends, each joint having one or more rotational degrees of freedom while providing resistance to rotational movement in the one or more degrees of freedom, such that the free end of the arm can be moved in three dimensional space, and such that the arm is self-supporting; and

a manipulandum assembly comprising a plurality of manipulanda attached to the free end of the arm in a manner such that each manipulandum can be moved by the user through the one or more rotational degrees of freedom provided by the plurality of joints, each manipulandum being positioned within hand grasping range of the user, and each manipulandum being or representing an object encountered in an upper extremity activity of the user's daily life.

2. The apparatus as set forth in claim **1**, wherein the plurality of manipulanda are fixed or tethered to the free end of the arm such that the manipulanda so connected remain accessible to the user without dropping or becoming lost.

3. The apparatus as set forth in claim **2**, wherein one or more of the manipulanda are attached to the free end of the arm such that an additional rotational degree of freedom is provided to the manipulanda so attached.

4. The apparatus as set forth in claim **3**, wherein one or more of the manipulanda are mounted on a rotatable shaft connected at the free end of the arm such that the additional rotational degree of freedom is provided along the long axis of the shaft.

5. The apparatus as set forth in claim **4**, wherein the plurality of joints provides passive resistance against rotational movement, and thereby returns the arm and the manipulandum assembly to an equilibrium rest position when the user releases a manipulandum of the manipulandum assembly.

6. The apparatus of claim **5**, wherein the arm is positioned above a floor, and wherein the arm is formed in two interconnected segments with a first segment extending generally upwardly from the base and a second segment extending generally forwardly toward the user to position the free end proximate the user's upper extremities, the first segment having the fixed end connected to the base through a first joint providing a rotational degree of freedom in a horizontal axis generally parallel to the floor, and a rotational degree of freedom in a vertical axis, the first and second segments being interconnected through a second joint providing a rotational degree of freedom in a horizontal axis, and the free end of the second segment being attached to the plurality of manipulanda through a third joint providing a rotational degree of freedom in a horizontal axis.

7. The apparatus of claim **6**, wherein the first, second and third joints are spring-loaded joints or ball and socket joints.

8. The apparatus of claim **7**, wherein the plurality of manipulanda are selected from a vertically split cylinder manipulandum, a doorknob manipulandum, a key-grip manipulandum, a horizontal handles manipulandum, a peg manipulandum and a coin manipulandum.

9. The apparatus of claim **8**, wherein, the apparatus further comprises a platform connected for movement to the third joint such that the platform is generally horizontal in the equilibrium rest position, and the rotatable shaft is connected to be generally perpendicular to the platform in the equilibrium rest position, and wherein, if present:

the vertically split cylinder manipulandum comprises two cylinder halves which are spring biased apart and which are mounted on the rotatable shaft such that the user may squeeze, rotate on the rotatable shaft, or move the cylinder in the rotational degrees of freedom of the arm;

the doorknob manipulandum comprises a rotatable doorknob attached to the platform such that the user may rotate the doorknob relative to the platform, and may move the doorknob in the rotational degrees of freedom of the arm;

the key-grip manipulandum comprises a key way formed in the doorknob and a key tab fixed or tethered in the slot such that the user may rotate the key tab in the doorknob, pull the key tab in the key way, or move the doorknob in the rotational degrees of freedom of the arm;

the horizontal handles manipulandum comprises one or more handle mounted for rotation on an axle connected to the rotatable shaft in a manner such that the handles are generally horizontal in the equilibrium rest position, such that the user may rotate the handles on the axle, move the handles in a twisting motion along the long axis of the rotatable shaft, and move the handles in the rotational degrees of freedom of the arm;

the peg manipulandum comprises a peg which is spring biased in a housing connected to the platform such that the user may pull the peg against the spring and move the peg in the rotational degrees of freedom of the arm; and

the coin manipulandum comprises a coin tethered to the platform such that the user may pick up the coin from the platform.

10. The apparatus of claim **6**, further comprising one or more sensors located in one or more positions selected from the first, second and third joints, the first and second segments, and one or more of the manipulanda, the sensors being operative to detect movement or force and to generate an electrical signal representative of movement or force.

11. The apparatus of claim **9**, further comprising one or more sensors located in one or more positions selected from the first, second and third joints, the first and second segments, and one or more of the manipulanda, the sensors being operative to detect movement or force and to generate an electrical signal representative of movement or force.

12. The apparatus of claim **10**, further comprising a processing device for processing the electrical signal representative of movement or force, and means for transmitting the electrical signal to the processing device.

13. The apparatus of claim **12**, wherein the one or more sensors are selected from potentiometers, gyroscopes, accelerometers, linear variable displacement transducers, optical encoders, strain gauges, electrical contacts, and photo-electric sensors.

14. The apparatus of claim **13**, further comprising an electrical stimulator for activating nerves and muscles of the user to assist in manipulating the plurality of manipulanda.

15. The apparatus of claim **13**, wherein the first and second segments are formed of a rigid material.

16. The apparatus of claim **13**, wherein the first and second segments are telescopic, elastic or rotational segments.

17. The apparatus of claim **11**, further comprising locking means for locking one or more of the first joint, the second joint, the third joint, the rotatable shaft and the handle axle.

18. A method for providing an exercising therapy for a user's upper extremity, the method comprising the steps of:

a) providing the apparatus of claim **1**; and

b) causing the user to manipulate the plurality of manipulanda with the user's hand to simulate movements representative of activities of the user's daily life.

19. The method of claim **18**, wherein manipulating includes one or more of grasping, squeezing, releasing, pinching, lifting, lowering, moving from side to side, twisting and rotating.

20. The method of claim **18**, further comprising:

c) providing one or more movement or force detecting sensors positioned in one or more locations selected from the arm, the plurality of joints or one or more of the manipulanda;

d) detecting with the one or more sensors, movement or force of any of the arm, the joints or the manipulanda;

e) generating an electrical signal from the detected movement or force; and

f) transmitting the electrical signal to a processing device to monitor the user's progress.

21. The method as set forth in claim **20**, wherein the plurality of manipulanda are fixed or tethered to the free end of the arm such that the manipulanda so connected remain accessible to the user without dropping or becoming lost.

22. The method as set forth in claim **21**, wherein one or more of the manipulanda are attached to the free end of the arm such that an additional rotational degree of freedom is provided to the manipulanda so attached.

23. The method as set forth in claim **22**, wherein one or more of the manipulanda are mounted on a rotatable shaft connected at the free end of the arm such that the additional rotational degree of freedom is provided along the long axis of the shaft.

24. The method as set forth in claim **23**, wherein the plurality of joints provides passive resistance against rotational movement, and thereby returns the arm and the manipulandum assembly to an equilibrium rest position when the user releases the manipulandum assembly.

25. The method of claim **24**, wherein the arm is positioned above a floor, and wherein the arm is formed in two interconnected segments with a first segment extending generally upwardly from the base and a second segment extending generally forwardly toward the user to position the free end proximate the user's upper extremities, the first segment having the fixed end connected to the base through a first joint providing a rotational degree of freedom in a horizontal axis generally parallel to the floor, and a rotational degree of freedom in a vertical axis, the first and second segments being interconnected through a second joint providing a rotational degree of freedom in a horizontal axis, and the free end of the second segment being attached to the plurality of manipulanda through a third joint providing a rotational degree of freedom in a horizontal axis.

26. The method of claim **25**, wherein the first, second and third joints are spring-loaded joints or ball and socket joints.

27. The method of claim **26**, wherein the plurality of manipulanda are selected from a vertically split cylinder manipulandum, a doorknob manipulandum, a key-grip manipulandum, a horizontal handles manipulandum, a peg manipulandum and a coin manipulandum.

28. The method of claim **27**, wherein, the apparatus further comprises a platform connected for movement to the third joint such that the platform is generally horizontal in the equilibrium rest position, and the rotatable shaft is connected to be generally perpendicular to the platform in the equilibrium rest position, and wherein, if present:

the vertically split cylinder manipulandum comprises two cylinder halves which are spring biased apart and which are mounted on the rotatable shaft such that the user may squeeze, rotate on the rotatable shaft, or move the cylinder in the rotational degrees of freedom of the arm;

the doorknob manipulandum comprises a rotatable doorknob attached to the platform such that the user may rotate the doorknob relative to the platform, and may move the doorknob in the rotational degrees of freedom of the arm;

the key-grip manipulandum comprises a key way formed in the doorknob and a key tab fixed or tethered in the slot such that the user may rotate the key tab in the doorknob, pull the key tab in the key way, or move the doorknob in the rotational degrees of freedom of the arm;

the horizontal handles manipulandum comprises one or more handle mounted for rotation on an axle connected to the rotatable shaft in a manner such that the handles are generally horizontal in the equilibrium rest position, such that the user may rotate the handles on the axle, move the handles in a twisting motion along the long axis of the rotatable shaft, and move the handles in the rotational degrees of freedom of the arm;

the peg manipulandum comprises a peg which is spring biased in a housing connected to the platform such that the user may pull the peg against the spring and move the peg in the rotational degrees of freedom of the arm; and

the coin manipulandum comprises a coin tethered to the platform such that the user may pick up the coin from the platform.

29. The method of claim **25**, further comprising one or more sensors located in one or more positions selected from the first, second and third joints, the first and second segments, and one or more of the manipulanda, the sensors being operative to detect movement or force and to generate an electrical signal representative of movement or force.

30. The method of claim **28**, further comprising one or more sensors located in one or more positions selected from

the first, second and third joints, the first and second segments, and one or more of the manipulanda, the sensors being operative to detect movement or force and to generate an electrical signal representative of movement or force.

31. The method of claim **29**, further comprising a processing device for processing the electrical signal representative of movement or force, and means for transmitting the electrical signal to the processing device.

32. The method of claim **31**, wherein the one or more sensors are selected from potentiometers, gyroscopes, accelerometers, linear variable displacement transducers, optical encoders, strain gauges, electrical contacts, and photo-electric sensors.

33. The method of claim **32**, further comprising an electrical stimulator for activating nerves and muscles of the user to assist in manipulating the plurality of manipulanda.

34. The method of claim **32**, wherein the first and second segments are formed of a rigid material.

35. The method of claim **32**, wherein the first and second segments are telescopic, elastic or rotational segments.

36. The method of claim **30**, further comprising locking means for locking one or more of the first joint, the second joint, the third joint, the rotatable shaft and the handle axle.

37. The method of claim **34**, wherein the electrical signal is processed to generate feedback.

38. The method of claim **34**, wherein the electrical signal is processed to generate feedback in the form of an interactive computer game.

39. The method of claim **34**, wherein the electrical signal is processed to generate performance ratings to evaluate a treatment or an exercise schedule.

40. The method of claim **34**, further providing a telecommunications link between a computer located at the user's site and a remote computer under the control of a therapist.

41. The method of claim **34**, further comprising prompting the user to manipulate the plurality of manipulanda through a series of movements from a standardized performance test.

42. The method of claim **34**, further comprising:

providing a horizontal support adjacent to the user; and

providing one or more stationary manipulanda on the horizontal support within the reach of the user.

43. The method of claim **42**, wherein the stationary manipulanda includes a pegboard defining one or more holes and at least one peg tethered from a gantry positioned on the pegboard, and wherein the user is caused to move the peg into the one or more holes.

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