

Expert System-Based Post-Stroke Robotic Rehabilitation for Hemiparetic Arm

By

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Abstract

Approximately 50 to 60 percent of the more than five million stroke survivors are moderately or minimally impaired, and may greatly benefit from rehabilitation. It is widely accepted that most of the motor recovery occurs within the first one year from the onset of stroke and tends to plateau soon after. However, in recent years, clinical studies have shown that chronic stroke patients can have motor recovery even after four to ten years. Hence, there is a strong need for cost-effective, long-term rehabilitation solutions. Long-term rehabilitation requires the therapist to provide repetitive movements to the affected limb. In order to provide the repetitive movements, robotic devices have been developed. However, the few commercially available robots lack comprehensive rehabilitation software. Therapists are required to spend a considerable amount of time programming the robot, monitoring the patients, analyzing the data from the robot, and assessing the progress of the patients. This dissertation focuses on designing, developing, and clinically testing an expert system-based post-stroke robotic rehabilitation system for hemiparetic arm. The expert system and the associated software tools help in testing the patient, suggesting treatment options, training the patient, analyzing the data from the robot, and monitoring the patient's progress.

Perhaps the most important step in developing a rehabilitation system is to understand the clinical practices of stroke treatment. In order to accomplish this, interviews and discussions were conducted with physical and occupational therapists. Based on their

input, a survey was conducted among the physical and occupational therapists in Kansas and Missouri. The survey respondents answered many questions regarding stroke rehabilitation in general, as well as robotic rehabilitation of the upper limb. After analyzing the survey responses and perusing the current literature, a robotic rehabilitation treatment protocol was developed with the help of therapists. This treatment protocol was implemented as a rule-based, forward chaining expert system using CLIPS. The associated tools, such as the training and testing programs, were developed using Tcl/Tk, and the data analysis program was developed using C programming language. The expert system-based robotic rehabilitation system underwent a clinical pilot study with two stroke patients.

The clinical study showed that the expert system could produce valuable suggestions to the therapist regarding the treatment options. The developed data analysis tool made it possible for the therapist to administer therapy with minimal supervision by producing a quick summary at the end of each training session. Based on the feedback from the patients it was evident that the robotic training programs were entertaining. The study also showed that robotic rehabilitation is beneficial even for chronic stroke patients. The results of this research clearly suggest that it is not necessary for a therapist to continuously monitor a stroke patient during robotic training. Given the proper software tools for a rehabilitation robot, cost-effective long-term therapy can be delivered with minimal supervision.

Dedicated to my family, friends, and teachers...

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Chapter 1 Introduction

The goal of this work is to investigate a novel methodology that would enable physical and occupational therapy clinicians to provide long-term rehabilitation of the hemiparetic arm for stroke survivors with minimal supervision. Neither the use of robotics, nor the use of artificial intelligence (AI) techniques is new to the field of medicine. However, the idea of applying robotics to the field of rehabilitation medicine is relatively new. It started in the 1990s and has remained popular since then, but mainly within the research community. Robotic rehabilitation has yet to attain popularity among the mainstream clinicians. Although AI techniques have been applied to the field of medicine since the late 1970s, rehabilitation medicine is not one of the areas in which there has been a significant need for computer assisted technologies like AI. With the increased use of robots in rehabilitation medicine, there are numerous opportunities where AI assisted technologies could play a vital role in assisting the clinicians in rehabilitating patients.

This dissertation focuses on designing, developing, and clinically evaluating an expert system-based post-stroke robotic rehabilitation system for hemiparetic arm. The expert system serves as a valuable tool for therapists in analyzing the data collected from the robot when it is used by the patient, helping the therapists to make the right decisions regarding the progress of the stroke patient, and suggesting a future training plan. The expert system is designed, developed, and evaluated by conducting a clinical study. The effectiveness and the usefulness of such a rehabilitation system are

analyzed in this dissertation. The effectiveness of the approach is evaluated based on how acceptable the suggestions of the expert system are to a human expert, i.e., the therapist. The usefulness is evaluated by calculating the amount of time the therapist is required to spend with the patients in the presence of the expert system. This is accomplished by comparing how the therapist makes the decisions about the future exercises and from the therapist's feedback about the system. If it can be shown that the expert system-based robotic rehabilitation is effective and useful for the therapists and the patients, in addition to the development of a valuable tool for the therapists, this work could pave the way for an affordable, easy to use long-term rehabilitation solution for stroke survivors. Moreover, a rehabilitation system that requires minimal intervention from the human therapist will play a significant role in making remote stroke therapy a reality, where a therapist can monitor and administer the therapy from distant locations.

1.1 Motivation

The motivation for this work was derived from the statistics of stroke itself. Stroke is extremely prevalent and its effect is long-lasting; yet the availability of long-term rehabilitation is limited. Prevalence is an estimate of how many people have a disease at any given point or period in time. Every 45 seconds, someone in the United States has a stroke. Stroke killed an estimated 163,538 people in 2001 and is the third leading cause of death in the United States, ranking just behind diseases of the heart and all forms of cancer. Stroke is a leading cause of serious, long-term

disability in the United States. Each year more than 700,000 Americans suffer a stroke; of which about 500,000 are first attacks and 200,000 are recurrent attacks. From the early 1970s to early 1990s, the estimated number of noninstitutionalized stroke survivors increased from 1.5 to 2.4 million, and an estimated 5.6 million stroke survivors were alive in 2004. From 1991 to 2001 the death rate from stroke declined 3.4 percent, but the actual number of stroke deaths rose 7.7 percent. Stroke costs the United States \$30 to \$40 billion per year. In 2004, the estimated direct and indirect cost of stroke for American citizens was \$62.7 billion (American Stroke Association, 2007).

Approximately 50 to 60 percent of stroke survivors are moderately or minimally impaired, and may greatly benefit from rehabilitation (Dombovy, 1993; Broderik *et al.*, 1989; Jorgensen *et al.*, 1995a, b; Wade and Hewer, 1987). Loss of voluntary arm function is common after a stroke, with approximately 85 percent of the stroke patients incurring acute arm impairment, and 40 percent chronic impairment. The loss of arm function is perceived as a major problem by the majority of chronic stroke patients, as it greatly affects their independence (Broeks *et al.*, 1999). In recent years, clinical studies have provided evidence that chronic stroke patients have motor recovery even after 4 to 10 years from the onset of stroke (Taub *et al.*, 1993; Luft *et al.*, 2004). Given this fact, there has been a strong demand from patients and caregivers to develop effective, long-term treatment methods to improve sensorimotor function of hemiparetic arm and hand for stroke survivors. Even partial recovery of

arm and hand sensorimotor function could improve the patients' quality of life, and reduce the socioeconomic impact of this disease-induced disability.

1.2 Problem Statement

The major challenges involved in post-stroke rehabilitation are the repetitiveness of the therapy, and the availability of therapists for long-term treatment. Many rehabilitation techniques involve repetitive mechanical movement of the affected arm by a therapist. In one such common therapeutic technique, called active assist exercise, a desired movement is manually completed for the patient by the therapist, if the patient is unable to complete it on his/her own. The advances in robotics technology, combined with the understanding of rehabilitation that involves mechanical movements, led to the introduction of robotics in rehabilitation in the 1960s and early 1970s (Hillman, 2003). The utilization of robots for rehabilitation has assisted the therapists with the repetitive tasks of the therapy. However, the therapists are still required to spend a considerable amount of their valuable time in programming the robot, monitoring the patients, analyzing the data from the robot and assessing the progress of the patients. Commercial robots are not easy to use for the medical personnel; and hence they remain largely unpopular amongst the medical community. This has led to the high cost involved in robotic rehabilitation. Even the few commercially available rehabilitation robots neither include any tools for analyzing the data from the robot, nor do they have any decision making capabilities. While the commercial rehabilitation robots are controlled by powerful desktop or

laptop computers, they do not take full advantage of the available computing power. Hence, this dissertation focuses on designing an expert system-based robot that contains tools for post-stroke rehabilitation of the upper limb that are easy to use by the therapists. An expert system combined with easy to use tools allows the therapists to provide long-term rehabilitation with minimal supervision. The reason for focusing on upper limb (shoulder, elbow, wrist, and hand) rehabilitation is that the patients' activities of daily living are affected more by impairment to the upper limb (Broeks *et al.*, 1999).

In order to overcome the repetitiveness of the rehabilitation therapy, the interactive robotic therapist (Hogan *et al.*, 1992, 1995) was developed. Since then, many other electro-mechanical devices have been developed for the rehabilitation of upper and lower limbs. Even though a number of rehabilitation robotic systems have been developed, they all have one thing in common – they lack intelligence, and hence are not easy to use by the therapists. They can only provide repetitive exercises to the hemiparetic limb. The training program will have to be changed or a new one selected by the therapist. In many of the systems, even the task of modifying the parameters of the training program requires some programming expertise. Although most of the systems have the capability to collect different kinds of data during patient training, they still require a therapist (or someone assisting the therapist) to analyze the collected data in order to make the decision regarding the changes in the training program. This makes the system difficult to use and it takes the therapist's time away

from the patient. Such systems include a few games in order to make rehabilitation more entertaining for the patients, but due to the lack of system intelligence, there is no active feedback controlling the motion of the robot. This results in the system being nothing more than an expensive game controller without any useful feedback for the therapist on the patient.

The hypothesis of this work is defined as: A group of stroke patients rehabilitated using an expert system-based robotic rehabilitation system will experience the same improvement in the neuro-motor function of the hemiparetic upper limb as the control group in which the stroke patients undergo a rehabilitation program with the same robot but without the expert system. The neuro-motor function of the hemiparetic upper limb will be assessed primarily using Fugl-Meyer and Motor Status Scores (as explained in Chapter 7) for shoulder and elbow (MS1), before and after trainings (Aisen *et al.*, 1997; Volpe *et al.*, 2000).

1.3 Approach

A logical step to further increase the effectiveness of robot-aided motor training is to integrate the robot-aided training with an expert system. This allows a new training program to be selected autonomously by the robot equipped with the expert system, based on the data collected during the patient's training. This essentially serves as a feedback loop. The primary aim of this research work is to design and implement an expert system-based robotic rehabilitation system, evaluate

it in a clinical setting, and compare it with that of robotic rehabilitation without the expert system, for motor recovery of hemiparetic upper limbs in stroke patients. The focus in this dissertation is to develop an expert system-based rehabilitation robot that will be easy to use by the medical personnel (not requiring any type of computer programming expertise) and therefore will reduce the therapist's time while maintaining the same or higher standard of care in the recovery of hemiparetic upper limb in stroke survivors. Moreover, since the expert system is developed using the knowledge acquired from multiple therapists, the decisions made by the expert system are no longer the opinion of one therapist which is the case in conventional therapy.

The primary research question addressed by this work is whether or not an expert system-based robotic rehabilitation system, in which the robot will be able to function autonomously, analyze data, and make suggestions for the appropriate future training exercises depending on the current state and the progress of the patient, can provide the same or better result than the robotic rehabilitation system without an expert system while making the system easier to use for the therapists.

The other aims of this work are to (1) assess the effectiveness of the future training exercise prediction by the expert system (measured from how close the expert system decisions are to that of the therapist); (2) compare the two patient groups in motor performance of hemiparetic upper limb in a specific plan motion using quantitative

measurements, before and after the two robot-aided training programs; and (3) compare the feedback from the therapist regarding the user-friendliness of the rehabilitation system used for the two different groups.

1.4 Dissertation Outline

This dissertation is organized into eight chapters. The next chapter provides an introduction to the medical fields, stroke and stroke rehabilitation of the upper limb. Chapter 3 presents an overview of the current state of robotics in upper limb rehabilitation for stroke. Chapter 4 reviews the relevant literature in the area of expert systems and discusses how expert systems are being applied to robotics as well as health care. This chapter also explains the steps to be followed in order to develop a successful expert system. Chapter 5 provides the details of the research methodology. This chapter describes how the entire system was developed and the rationale behind the design of various system components. In chapter 6, the design and conduct of the clinical study involving human subjects is discussed. The clinical study was carried out to evaluate the rehabilitation system presented in this dissertation. The results obtained from the clinical study are presented in chapter 7. Chapter 8 discusses the results presented in chapter 7, the original contributions of this research work, the limitations of this research, and recommendations for future work.

Chapter 2 Stroke

Stroke (also known as Cerebral Vascular Accident), or brain attack, is a type of cardiovascular disease. Stroke is a medical emergency and can cause permanent neurological damage, or even death, if not promptly diagnosed and treated. A stroke occurs when blood flow to any part of the brain stops. When blood supply to a part of the brain is interrupted, it results in depletion of the necessary oxygen and glucose to that area. The functioning of the brain cells (or neurons) that no longer receive oxygen will be immediately stopped or reduced (National Institute on Aging, 2004) and the oxygen starved neurons will start to die within a few hours (Caplan *et al.*, 1997). The exact point of time at which the brain cells begin to die after the onset of a stroke could not be generalized. However, a recent study has estimated that on average, the brain loses about 1.9 million neurons, 14 billion synapses and 7.5 miles of myelinated fibers per untreated minute during a stroke (Saver, 2006). If the brain cells are partially damaged, they sometimes can be repaired. Brain cells that have died cannot be brought back to life. This means that the body parts that were receiving signals from those brain cells for various functions like walking, talking, and thinking may no longer do so. Figure 2-1(a) shows the angiogram of the normal blood vessels to the brain and Figure 2-1(b) shows the angiogram where many normal blood vessels are not visible due to hampered blood flow to the brain (Higashida, American Stroke Association, 2007).

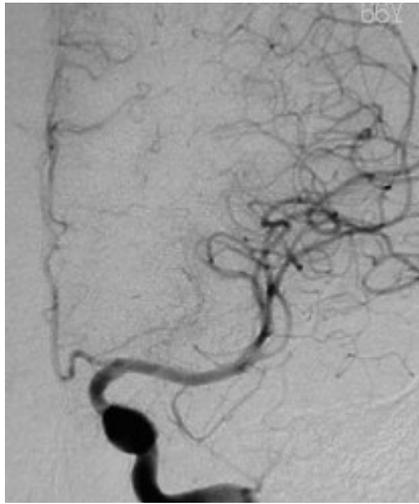


Figure 2-1(a) Angiogram showing normal blood vessels to the brain.
(Higashida, American Stroke Association, 2007)



Figure 2-1(b) Many normal blood vessels to the brain are not visible in this
angiogram due to hampered blood flow to the brain.
(Higashida, American Stroke Association, 2007)

2.1 Types of Stroke

Strokes can be broadly classified into two categories of ischemic and hemorrhagic. This classification is based on how the blood flow to the brain cells can be hampered. Considering a blood vessel carrying blood to the brain, the flow can be blocked if the vessel is clogged from within (ischemic stroke) or the vessel can be ruptured, causing bleeding into or around the brain (hemorrhagic stroke).

Ischemic stroke accounts for nearly 83 percent of all strokes. Ischemic stroke occurs when the blood flow is blocked by a blood clot. One of the main reasons for the formation of blood clot is the development of fatty deposits on the blood vessel walls. This condition is called atherosclerosis. The hardened fatty buildup can lead to the formation of a blood clot around it in the blood vessel. When the blood clot develops in the brain and ultimately blocks the blood vessel, it is referred to as cerebral thrombosis. Sometimes a blood clot develops at another location in the circulatory system, usually the heart or other larger arteries (like the carotid artery or the vertebral and basilar arteries). A portion of the blood clot breaks loose, enters the bloodstream and travels through the blood vessels in the brain until it reaches a vessel that is too narrow to let the clot pass. This type of blood vessel obstruction in the brain is known as cerebral embolism. Another cause of blood clots forming in the heart is irregular heartbeat, known as atrial fibrillation. That can lead to blood clots forming in the heart which in turn enter the blood stream and eventually travel to the brain.

Hemorrhagic stroke accounts for about 17 percent of the stroke cases. This type of stroke occurs when a blood vessel in the brain ruptures and bleeds into the surrounding brain. Cerebral aneurysm and arteriovenous malformation usually result in a ruptured blood vessel. A weakened region of a blood vessel balloons out forming an aneurysm. If left untreated the aneurysm will continue to weaken and eventually rupture. An arteriovenous malformation is a cluster of abnormally formed arteries and veins. This formation is prone to rupturing and bleeding into the brain.

Transient Ischemic Attack (TIA), also known as a mini or brief stroke, occurs when a person briefly experiences stroke symptoms that last from several seconds to even hours, and the symptoms resolve on their own. Even though the symptoms seem to resolve through natural mechanisms, studies show that TIAs are a strong indicator of possible major stroke (American Stroke Association, 2007). TIAs usually result in no permanent brain damage.

2.2 Effects of Stroke

How stroke will affect someone depends primarily on the location of the lesion in the brain and the extent of brain tissue damage. For example, if the lesion occurs toward the back of the brain, most likely some disability involving vision will result (American Stroke Association, 2007). Some of the most important symptoms of a stroke include: unexpected insensibility, weakness or paralysis on one side of the body resulting in a weak arm, leg or eyelid, or a dribbling mouth, difficulty finding

words or understanding speech, sudden blurring, disturbance or loss of vision, especially in one eye, dizziness, confusion, unsteadiness and/or severe headache (Westcott, 2000).

It is important to note that one side of the brain controls the opposite side of the body and hence a stroke affecting one side of the brain will result in neurological complications on the side of the body that it controls. For example, if the stroke causing lesion happens to be in the brain's right side, then the left side of the body (and the right side of the face) will be affected. This could produce any or all of the following complications with varying degrees (American Stroke Association, 2007):

- Paralysis on the left side of the body
- Vision problems
- Quick, inquisitive behavioral style
- Memory loss

If the stroke causing lesion happens to be in the brain's left side, then the right side of the body (and the left side of the face) will be affected. This could produce any or all of the following complications with varying degrees (American Stroke Association, 2007):

- Paralysis on the right side of the body
- Speech/language problems
- Slow, cautious behavioral style

- Memory loss

2.3 Treatment

During the initial critical phase following a stroke, the immediate treatment focuses on stabilizing the condition and preventing further complications. It varies according to the nature of the stroke. The treatment begins with some type of imaging technique that focuses on identifying the nature and the cause of the stroke. Once the cause is identified, the treatment could be as simple as drug therapy or it could involve complex surgeries, depending on the need. In any case, treatment after a stroke can only prevent further damage to the brain. Stroke can cause paralysis, hemiparesis (paralysis of one side of the body), affect speech and vision, and cause other problems (American Stroke Association, 2007).

2.4 Rehabilitation

Stroke survivors have to deal with mental and physical disabilities after the stroke. Stroke rehabilitation is the process by which the survivors undergo treatment in order to return to a normal, independent life as much as possible. Most stroke patients undergo both physical therapy and occupational therapy. Even though these therapies have some overlapping areas of working, physical therapy focuses mainly on major motor functions such as posture, walking, etc., while occupational therapy focuses on relearning activities of daily living such as eating, drinking, reading,

writing, etc. For some stroke survivors, rehabilitation is an ongoing process to maintain and refine skills; and it can involve working with specialists for months or years after the stroke (National Institute of Neurological Disorders and Stroke, 2002). It is known that most of the motor recovery takes place in the first three to six months after stroke. After this period, motor recovery reaches a plateau. However, depending on the therapy, minor but measurable improvement in voluntary hand/arm movement occurs even long after the onset of stroke (Bruno-Petrina, 2004). Some clinical studies have shown that the brain retains the capacity to recover and relearn the motor control even after four years from the stroke onset (Taub *et al.*, 1993; Luft *et al.*, 2004).

Therapy to reestablish the stroke patients' functional movement is a learning process based on the normal adaptive motor programming (Bach-Y-Rita and Balliet, 1987). Current practices in stroke rehabilitation are intended to allow the brain to go through a restructuring process, and thus enable the patient to relearn the movement control with the remaining neurons. The motor relearning of the stroke patients is based on the brain's capacity to reorganize and adapt. It has been reported that rehabilitation and training can influence the pattern of reorganization (Jenkins *et al.*, 1990; Recanzone *et al.*, 1992; Pons *et al.*, 1991; Nudo *et al.*, 1996). Even though many different treatment approaches have been proposed, physical therapy practice heavily relies on each therapist's training and clinical experience. As a result, some researchers have concluded that there is not enough evidence to show that one

treatment method is more effective than any other (Sackley and Lincoln, 1996). In fact, a recent review of post-stroke physiotherapy practices has concluded that the best therapy has not yet been found (Coote and Stokes, 2001). Nevertheless, numerous studies agree with each other on one thing – motor relearning tends to improve with intensive repetitive therapy and it should begin as early as possible after the onset of stroke (Nudo *et al.*, 1996; Loureiro *et al.*, 2003).

These evidences have evoked new treatment approaches including muscle strength training, task-specific practice, forced use of hemiparetic limb by restraining the contralateral limb, and robot-aided motor training. Studies of robot-aided motor training for stroke patients have demonstrated its effectiveness in upper limb motor recovery. This type of therapy is not only more productive for patient treatment, but it is also more effective in terms of functional improvement of the hemiparetic upper limb after the training than the conventional physical therapy (Burgar *et al.*, 1999; Krebs *et al.*, 1998). The robot-aided motor training could have great potential to evolve into a very effective clinical treatment in the future.

Chapter 3 Robotics in Upper Limb Rehabilitation

In order to overcome the repetitiveness and increase the accuracy involved in rehabilitation therapy, robots have been introduced to the field of physical and occupational therapy. One of the earliest robots developed for manipulation of the human arm was the interactive robotic therapist (Hogan *et al.*, 1992; Hogan *et al.*, 1995). The concept of an interactive robotic therapist was first developed in the late 1980s and early 90s. This interactive robotic therapist allows for simultaneous diagnosis and training by therapists through interactions with patients. This system is also used for the quantification of the patients' recovery and progress. Additionally, a therapist can provide a patient with therapy by controlling the robotic therapist with another remotely located robotic device. Following the successful results of this robotic therapist, several rehabilitation robots were designed, including the Hybrid Arm Orthosis (HAO) (Benjuya and Kenney, 1990), Mirror-Image Motion Enabler (MIME) (Burgar *et al.*, 2000), Assisted Rehabilitation and Measurement Guide (ARM Guide) (Reinkensmeyer *et al.*, 2000; Reinkensmeyer *et al.*, 2002), Motorized Upper-Limb Orthotic System (MULOS) (Johnson *et al.*, 2001), and GENTLE/s haptic system (Loureiro *et al.*, 2003).

3.1 MIME Rehabilitation System

MIME is a rehabilitation system in which a robot manipulator with six degrees of freedom (DOF) applies forces to the affected limb through a customized

forearm and hand splint (Burgar *et al.*, 2000). The robot's six DOF allows the forearm to be positioned within a wide range of positions and orientations in three-dimensional space. A unique feature of the MIME system is that it has a bimanual mode. In this mode (as shown in Figure 3-1) the two forearms are kept in mirror symmetry. A position digitizer measures the movement of the unaffected arm and provides the desired coordinates for the robot controller so that the affected arm can be assisted or passively moved by the robot. The movement is based on the master-slave principle where the patient themselves can guide the affected arm by moving the unaffected arm in a mirror-like fashion.



Figure 3-1 A subject with right hemiparesis undergoing bimanual therapeutic exercise (Burgar *et al.*, 2000).

3.2 ARM Guide

In ARM Guide, shown in Figure 3-2, the subject's forearm is strapped to a splint that slides along a linear constraint, while a motor assists or resists the arm movement along the linear bearing (Reinkensmeyer *et al.*, 2000). The orientation of the linear bearing can be manually changed in the horizontal or vertical planes. ARM Guide was designed to be used as a diagnostic tool for assessing movement impairment as well as being a therapeutic tool to treat hemiparetic arm. As a diagnostic tool, ARM Guide can potentially be used to assess some common motor impairments such as abnormal tone, spasticity, and incoordination. As a therapeutic tool ARM Guide provides active assisted therapy. If the patient is unable to complete a movement, then the robot can help complete the motion by providing the necessary assistive force.

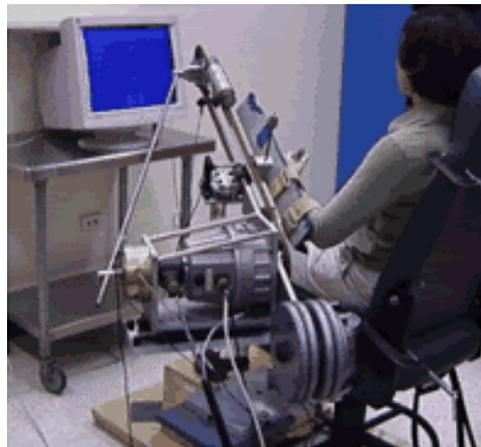


Figure 3-2 ARM Guide rehabilitation system (Reinkensmeyer *et al.*, 2000).

3.3 MULOS

Motorized Upper Limb Orthotic System (MULOS) is a five degree of freedom upper limb assistive orthotic device, designed for the elderly and disabled (Johnson *et al.*, 2001), as shown in Figure 3-3. The orthosis allows the movement of the shoulder, the elbow and the forearm. The system has the capability to allow for full ranges of motion at the shoulder. The available modes of operation are assistive, continuous passive motion (CPM), and exercise mode. In assistive mode, the patient can make the orthotic arm provide movement for his or her affected arm using a suitable interface such as a joystick. The CPM mode can be used for rehabilitation, where the orthosis can be programmed to provide repetitive passive movement; and the exercise mode can be used to provide resistance against the user's active movement. Although reports on the device were positive and the approach appeared to have potential, its development was stopped in 1997.

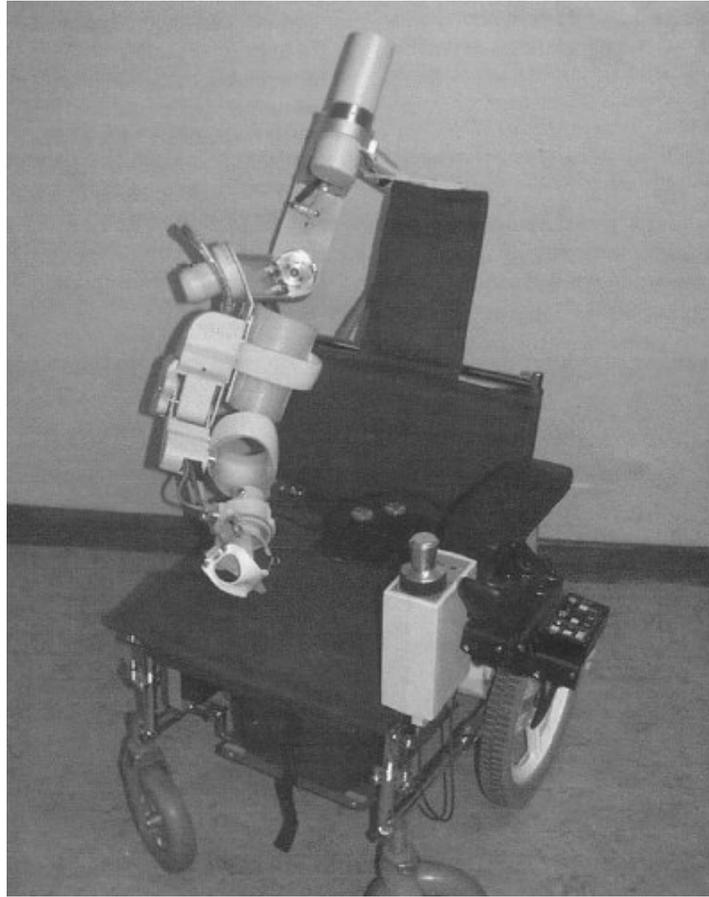


Figure 3-3 MULOS, five degree of freedom orthotic device fitted to a wheelchair

(Johnson *et al.*, 2001).

3.4 GENTLE/s

The GENTLE/s project has been sponsored by the European Commission to evaluate robot mediated therapy in stroke rehabilitation (Loureiro *et al.*, 2003). This project utilizes haptic and virtual reality (VR) technologies. A haptic interface uses constrained motion devices to replicate some of the tactile sensory effects. In the prototype described in Loureiro *et al.* (2003), a commercially available three DOF

force-controlled haptic interface called HapticMASTER (manufactured by Moog FCS Inc., 2007) is used to implement the three commonly utilized modes of robotic therapy – active mode where the patient does most of the movement except for correcting forces from the robot, active assisted mode where the patient initiates the movement and then the robot assists the patient in completing the task, and passive mode where the patient remains passive and the robot takes the patient’s arm along a pre-defined movement path. The most notable feature of this system is the integration with a virtual environment. For example, one of the virtual environments is a detailed three-dimensional room in which patients can interact with the objects by moving them from one location to another. This work is relying on the fact that the use of haptics and VR technologies will enhance patient attention and motivation during repetitive task-oriented movements and thereby will facilitate a more effective rehabilitation process for the affected arm.

Most of the rehabilitation devices described in this section have undergone clinical trials to some extent. Although the conditions of the subjects vary between the clinical trials (some trials enrolled chronic stroke patients with a wide range of time elapsed from the first onset of stroke, and some enrolled acute stroke patients), researchers agree that in general, compared with conventional treatment, robot-assisted treatment definitely has therapeutic benefits (Krebs *et al.*, 1998; Burgar *et al.*, 1999, 2000; Lum *et al.*, 2002). Robot-assisted treatment has been demonstrated to improve strength and motor function in stroke patients. In one clinical trial even

follow up evaluations for up to three years revealed sustained improvements in elbow and shoulder movements for those who were administered robotic therapy (Aisen *et al.*, 1997; Volpe *et al.*, 1999; Volpe *et al.*, 2000).

3.5 InMotion² Robot

The InMotion² robot is the commercial version based on the patented MIT-MANUS technology (Interactive Motion Technologies, Inc., 2005). This robot has proven to be a novel tool for teaching and therapy in manual and manipulative skills. It is capable of safely “shaping” motor skills – a machine implementation of “hand-over-hand” instruction (Hogan *et al.*, 1992). The InMotion² robot can be programmed to interact with a patient to shape his/her motor skills by guiding the patient’s limb through a series of desired exercises with a robotic arm. The patient’s limb is brought through a full range of motion along a single horizontal plane to rehabilitate multiple muscle groups (Hogan *et al.*, 1995). This robot has been effectively tested at Burke Rehabilitation Hospital, White Plains, NY (Krebs *et al.*, 1998), and other hospitals for almost 10 years. The InMotion² robot is available in the Neuromuscular Research Laboratory (NRL) at the University of Kansas Medical Center (KUMC) and was used for the work presented in this dissertation. Figure 3-4 shows the InMotion² robot mounted on a desk along with the monitor that displays visual feedback to the patient using the robot. Figure 3-5 shows the robot being used by a patient at the Neuromuscular Research Laboratory.

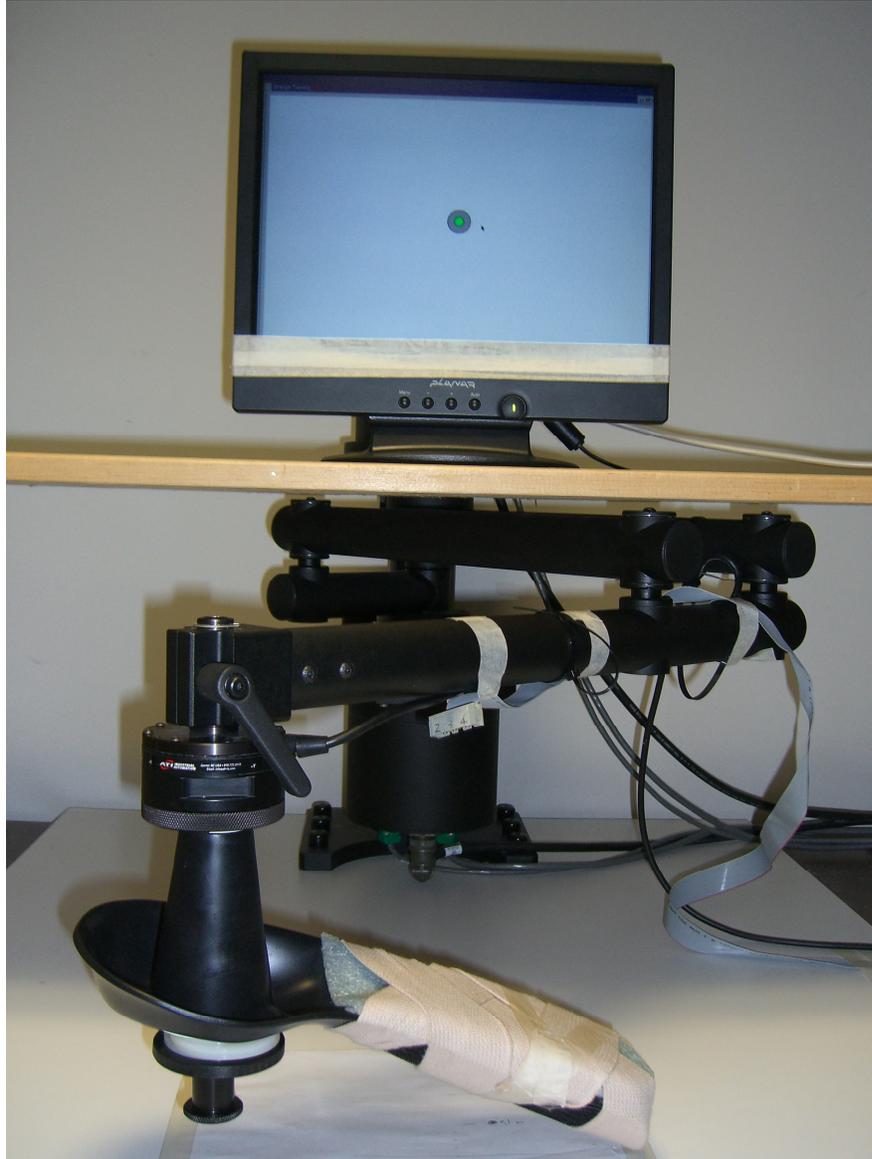


Figure 3-4 InMotion² robot at the Neuromuscular Research Lab.



Figure 3-5 InMotion² robot being used by a patient.

InMotion² Hardware

The InMotion² robot, which was first introduced as the MIT-MANUS, is designed for safe, stable, and compliant operation in close physical contact with humans. The robot has a key feature known as low mechanical impedance which makes it back-drivable, i.e., it can smoothly and quickly yield under the action of external forces giving it a “soft” feel (Krebs *et al.*, 2003). The robot consists of a planar module that gives two degrees of freedom for elbow and forearm motion. The planar module consists of a direct-drive five bar-linkage SCARA (selective compliance assembly robot arm) mechanism driven by two motors. The motors also

include precision position, velocity, and torque sensors (Krebs *et al.*, 1998). The commercially available InMotion² robot also has a multi-axis force transducer mounted at the end of the arm, to detect forces in the x , y , and z directions.

The InMotion² robot is equipped with a control panel, a junction box, standard personal computer, and an LCD monitor. These hardware components are controlled through a data acquisition (DAQ) board in the computer by reading data from and writing data to analog to digital (A/D) and digital to analog (D/A) channels on the DAQ board.

InMotion² Software

The software system for InMotion² runs on Linux kernel augmented with RTLinux (Real Time Linux). RTLinux provides Linux with low-latency for interrupts and other real-time requirements, by running the Linux kernel as a subordinate task under a tiny RTLinux microkernel. The main robot control loop runs as a Linux Kernel Module (LKM). The robot control loop performs tasks such as reading data from the robot sensors, writing control data to the robot motors, calculating controls based on input data, and so on. The control loop LKM is written in C, the language of the Linux kernel.

Programs that provide reference source data, save log data, and interact with a graphic display are separate from the control loop LKM. These are user-mode Linux programs, and they communicate with the control loop. The user-mode programs

such as graphical user interfaces (GUIs) and data sources and sinks are written in Tcl/Tk because of its GUI capabilities. The InMotion² software includes many Tcl programs and C functions that can be used as application program interfaces (APIs) to control the robot.

Chapter 4 Expert Systems

The concept of expert system was developed as a branch of artificial intelligence (AI) in the mid-1960s (Liao, 2005). The basic idea behind expert systems is that domain-specific knowledge is gathered from one or more human experts and stored in the computer. Although the exact definition of an expert is arguable, in general a domain expert is one who is highly skilled in the technical aspects of his or her domain/field and well enough informed so that the judgments made by that person are deemed appropriate by his or her peers (Delitto *et al.*, 1989). An expert system is an interactive computer-based decision tool that uses both facts and heuristics to solve difficult decision problems based on the knowledge acquired from human experts (Badiru and Cheung, 2002). The expert system can make inferences to arrive at a specific conclusion and explain, if necessary, the logic behind the inferences and the conclusion. Ever since the introduction of the concept of expert system, it has been applied in a variety of application domains. Expert systems provide powerful and flexible means to solve complex problems that are difficult to tackle using traditional methods (Liao, 2005). Any application that needs heuristic reasoning based on facts is a good candidate for expert systems. Some of the earliest expert systems were developed to assist in areas such as chemical identification (DENDRAL), speech recognition (HEARSAY I and II), diagnosis and treatment of blood infections (MYCIN), computer configuration (XCON), airline gate assignment

and tracking (GATES), identification of minerals and selection of drilling sites (PROSPECTOR), and foreign exchange auditing (FXAA) (Ignizio, 1991).

4.1 Expert System Development Process

Figure 4-1 illustrates the basic components of a standard expert system during the developmental stage (Ignizio, 1991). The interactions between the various components of the expert system are shown in the figure. The human components are represented using ovals, the volatile memory (working memory) is represented using a dashed rectangular box, and the permanent software components are represented using solid rectangular boxes.

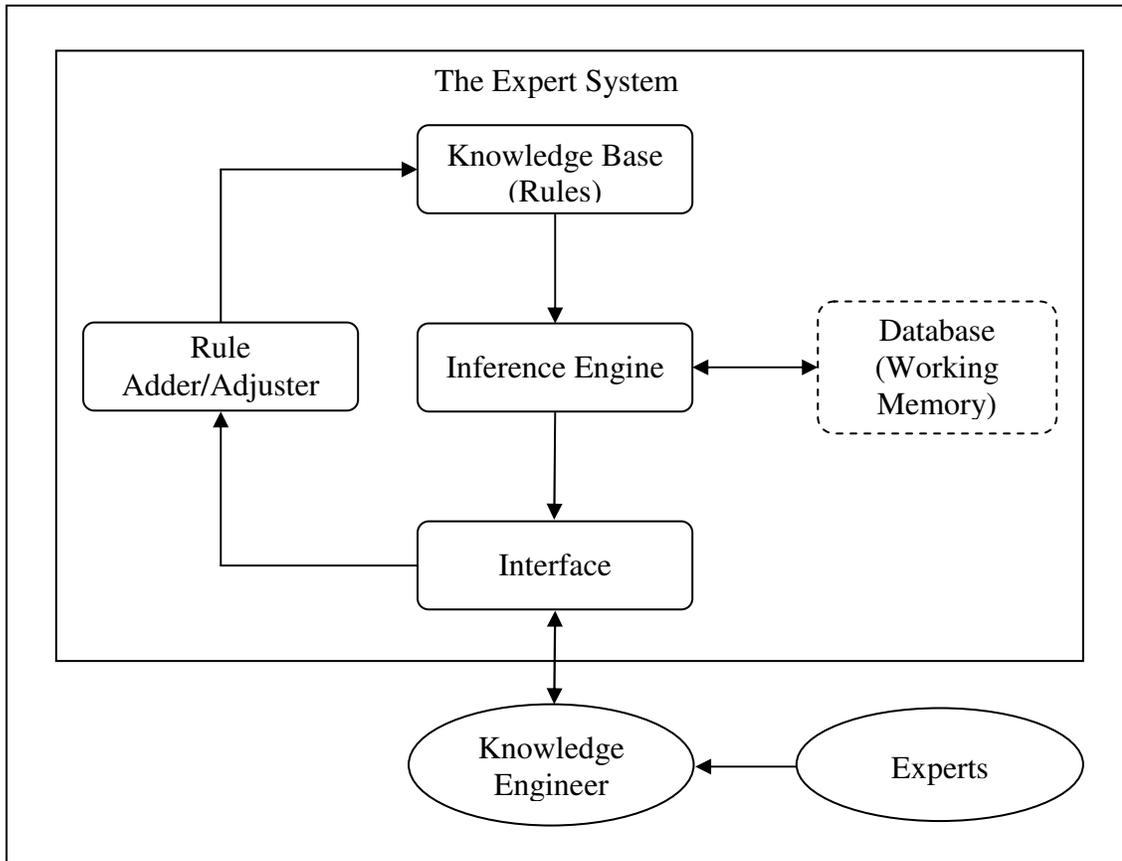


Figure 4-1 The expert System during development.

The development of an expert system is a multi-phase process. Although the naming convention and sometimes the order may vary from one source to another, researchers refer to the same steps. The expert system development process consists of the following phases (Ignizio, 1991; Liebowitz, 1998):

- Knowledge acquisition
- Knowledge representation
- Tool selection and development
- Verification and validation

Each phase of the expert system development process is discussed in detail in this chapter.

4.1.1 Knowledge Acquisition

The term knowledge acquisition refers to any technique by which computer systems can gain the knowledge they need to perform some tasks (Stefik, 1995). Knowledge acquisition implies that knowledge begins with a domain expert and that the objective is to get the knowledge into a computer. Knowledge often goes through stages of refinement in which it becomes increasingly formal and precise. Part of this process involves identifying the conditions under which the knowledge is applicable, and any exceptional conditions. It also involves organizing the representations so they can be used by a problem solver or other interpreter.

In order to design the knowledge base, the participatory design approach was used (Stefik, 1995). Initial informal discussions with physical and occupational therapists were conducted. In these meetings, the capabilities of the rehabilitation robot were demonstrated to the therapists. In subsequent discussions, the therapists agreed that an expert system is definitely feasible and that it would be beneficial. Based on the initial discussions, it was clearly understood that the expert knowledge in the field of physical therapy was very complex, based on practical experience, very subjective to the patient and the type of motor impairment. In order to address this issue to some extent, a combination of the methodologies adopted in Magnusson *et al.* (1997) and Boyette *et al.* (2001) was followed. Several discussions with experts from the fields

of physical and occupational therapy were carried out initially. Later, a pilot survey to better understand the current clinical practices in stroke rehabilitation was conducted among physical and occupational therapists in Kansas and Missouri. The entire knowledge acquisition process and the results are described in detail in the next chapter.

4.1.2 Knowledge Representation

The knowledge-based expert system should encapsulate the expertise of the professional therapists (occupational and physical therapists), in order to be an effective tool during rehabilitation therapy. The captured information takes into account many factors that are relevant to stroke rehabilitation such as:

- The general principles of therapy
- The initial conditions of the stroke patient
- The most effective training exercises that could be prescribed for a patient, along with the determinants for each exercise
- The typical performance of a healthy subject during the selected exercises or the typical performance of an unaffected arm during the exercises
- The methodology by which therapists assess the patient's progress

The knowledge gathered from the experts is first refined in a manner such that it is applicable to the robot InMotion² which is used for stroke rehabilitation of the arm. Next, the refined knowledge is represented using a standard format such as a production system. A production system is a system based on rules. A rule is a unit of

knowledge represented in the following form (Grzymala-Busse, 1991; Giarratano and Riley, 1994):

IF conditions THEN actions

or alternatively,

conditions → actions.

The origin of the idea of production system dates back to the 1940s (Post, 1943) and has remained popular with expert systems since the 1970s (Buchanan and Feigenbaum, 1978). Representing knowledge in the form of rules is common because of the following reasons (Giarratano and Riley, 1994):

- It provides an easy way to expand an expert system simply by adding more rules
- It makes it easy to include explanation within the rules
- Rules are intuitive to the human cognitive process and hence makes it easier for human understanding, as well as to structure the acquired knowledge

The expert knowledge represented as a production system is used to make the decisions regarding the selection and/or modification of any training exercise. The expert system is used to monitor the progress of patient's motor learning and select the new training exercises. From the accumulated records of the movement patterns and the patient motor skill scores, the progress of the patient can be evaluated. The detailed protocol of the clinical study, the functioning of the expert system, including

the different movement parameters that are considered to make decisions, and the assessment methods are presented in later chapters.

4.1.3 Tool Selection and Development

Before developing an expert system it is very important to carefully consider the domain in which the system is being developed, the complexity of the acquired knowledge, the users of the expert system, the software/programs that interact with the expert system, and the budget limitations. The expert system was developed to indirectly control the InMotion² rehabilitation robot. The reason that it is called “indirect control” is because the expert system is allowed to make any modifications to the training, by selecting new exercise or by modifying the parameters of the exercise, only at the end of every two training sessions. It is the intention of this research to keep the cost of the rehabilitation system low. Hence the logical choice for the tools to develop the expert system would be open-source software. One of the most popular and commonly used open-source tools for developing expert systems is C Language Integrated Production System (CLIPS). Moreover, CLIPS, being an open-source tool, is available for multiple operating systems and has extensive documentation (Giarratano and Riley, 1994; O’Brien, 2000). These factors make CLIPS a good choice for developing the expert system. For analyzing the raw data collected during the patient training sessions, some programs are developed in C programming language. Since CLIPS was developed using C it has the capability to easily interact with other programs created in C. Furthermore, Tcl interpreter which is

used for the user interface of the robot has the ability to easily incorporate any external functions created in C language.

A training exercise is defined as a sequence of tasks or training goals. The rule-based expert system analyzes the symbolic information provided by the system, such as the initial subject conditions, the various movement parameters, the current movement pattern, and evaluates the subject's progress. As a result of the assessment, the expert system can modify the training exercise, as required. The modification could include selecting a new exercise from the given set of exercises, and/or determining how the determinants of the exercise should be adjusted. In some cases the same exercise could be selected with different determinants (such as the range of motion, velocity of motion, and assistive or resistive forces). The expert system can be viewed as high-level intelligence for the robot controller programs. This high-level intelligence monitors the progress of the patient and issues appropriate guidance to the rehabilitation robot for its low-level motion control. Furthermore, based on the movement pattern of the patient, it identifies the nature of defects and sets up intermediate goals according to the therapeutic expertise. The interaction and cooperation between the various components of the expert system is continuous and autonomous, working toward the goal of the rehabilitation of the stroke patient.

Figure 4-2 shows the architecture of the expert system while it is in use. The expert system remains transparent to the subject in the study. The "subject interface" shown

refers to the training program interface which the therapist and the subject will be able to see; while the therapist interface is exclusively for the therapist. The entire system is designed in such a way that the rule base for the expert system can be updated at any point without having to modify the robotic training programs. However, the knowledge base is not modified during clinical trials in order to maintain the integrity of the trial results.

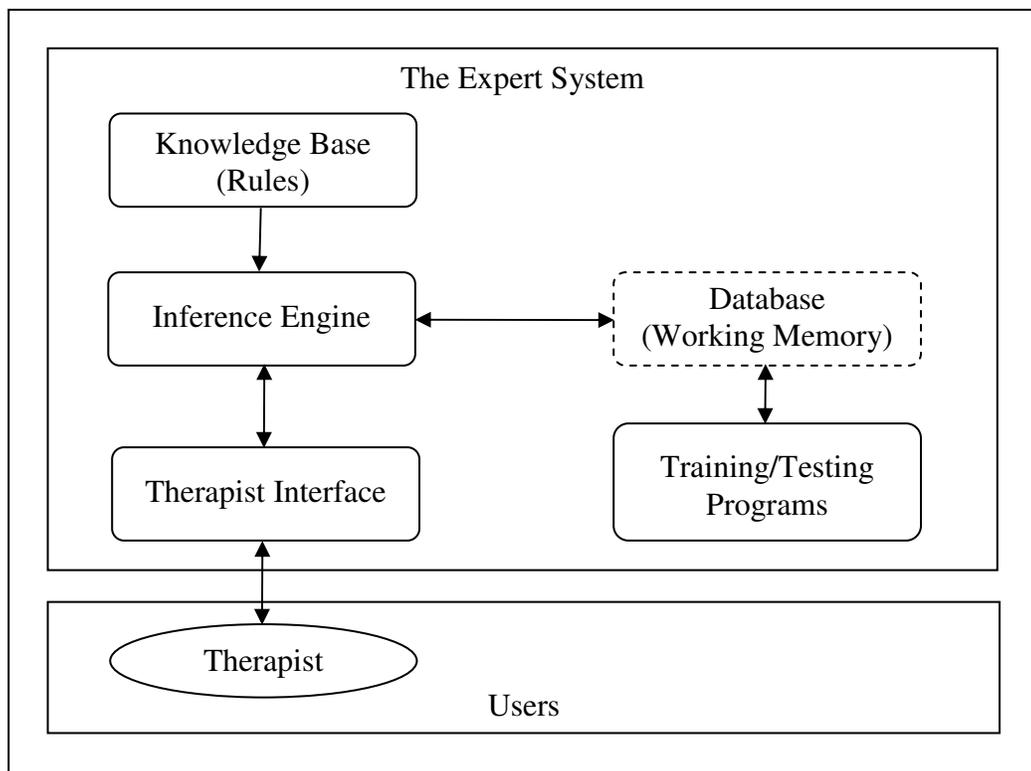


Figure 4-2 Expert System while in use.

4.1.4 Verification and Validation

It is imperative for any system development process to include a testing stage, i.e., the combination of verification and validation. Verification ensures that the

specifications of the system meet the requirements, and validation ensures that the developed system actually works according to the requirements and solves the given problem within the acceptable error margin.

The expert system is tested at the Neuromuscular Research Laboratory of the Department of Physical Therapy and Rehabilitation Sciences at the University of Kansas Medical Center (KUMC). All the test cases and the results are documented and analyzed in the following chapters. During the testing process some potential limitations in the system were identified for future improvements. Next, the expert system was demonstrated to some therapists at KUMC in order to be validated. The experts presented different cases and made sure the expert system satisfies the requirements. Once the expert system had been satisfactorily tested, the implementation was carried out. The implementation of the expert system made sure that the various components of the robotic rehabilitation system were able to interact and any connectivity issues were resolved.

4.2 Expert Systems in Robotics

The field of robotics involves a wide range of control systems, ranging from simple to complex. The control system emphasizes the formality and generality of mathematical modeling of the robotic system. With the advancement of the field of robotics, a significant amount of research has been done in the area of intelligent machines. The functions of an intelligent control system combine the high-level

decision making of the digital computer with the advanced mathematical modeling and synthesis techniques of systems theory (Jordanides and Torby, 1991). There are several areas within robotics that have benefited from the use of expert systems, such as robot vision and image analysis, robotic sensory systems, robot control, etc. Specific examples of the use of expert system in the field of robotics are listed. Pang (1990) examines the potential and usefulness of an expert system application in the domain of real-time control of an autonomous mobile robot in a hazardous material spill emergency situation. An expert system was used to determine a good grasp configuration on 3-D objects for a three-fingered robotic hand (Bison *et al.*, 1995). The work presented by De la Sen *et al.* (2004), describes the development of an expert system to optimize and improve the adaptive control of planar robots.

4.3 Expert Systems in Healthcare

Expert systems have been implemented and used successfully in one of the major areas of health care, namely, diagnosis. Since complex medical decisions are often made when many uncertainties are present and when the stakes are extremely high, expert systems are ideally suited for decision analysis. Motivations for the development of expert systems in medicine have been numerous. Assisting the physician in making diagnoses and treatment recommendations is the most commonly found application of expert systems in medicine. A physician may have knowledge of most diseases, but, due to the vast number of diseases and symptoms, physician could benefit from the support provided by an expert system to quickly isolate the disease

(Liebowitz, 1998). Conventional clinical diagnosis is dependent on the examining physician's knowledge and experience. As a physician gains experience, the amount of medical knowledge grows and it may become difficult for physicians to keep up with all of the information gained. Furthermore, an inexperienced physician may not have the same expertise in making complex diagnosis due to the lack of clinical experience. Hence an expert system can certainly be helpful for inexperienced physicians in making medical diagnosis as well as for experienced physicians in supporting or verifying complex decisions (Meesad and Yen, 2003). Apart from medical diagnosis, some of the other tasks for which medical expert systems have been applied include selection of therapy or treatment plan, patient management, and treatment monitoring (Goethe and Bronzino, 1995; Hodges *et al.*, 1991; Sandell and Bourne, 1985; Shortliffe and Perrault, 1990).

Developing an expert system for the field of medicine is not a trivial task. Development of a medical expert system should be undertaken only if it would meet certain goals. Specifically, the goals of developing expert systems for medicine are as follows (Shortliffe *et al.*, 1979):

1. "To improve the accuracy of clinical diagnosis through approaches that are systematic, complete, and able to integrate data from diverse sources."
2. "To improve the reliability of clinical decisions by avoiding unwarranted influences of similar but not identical diseases."

3. “To improve the cost efficiency of tests and therapies by balancing the expenses of time, inconvenience against benefits, and risks of definitive actions.”
4. “To improve our understanding of the structure of medical knowledge, with the associated development of techniques for identifying inconsistencies and inadequacies in that knowledge.”
5. “To improve our understanding of clinical decision-making, in order to improve medical teaching and to make the system more effective and easier to understand.”

An expert system should be used in medical practice only if it improves the quality of care at an acceptable cost in terms of time or money, or if it maintains the existing standard of care at a reduced rate in time or money. Miller *et al.* (1985) defined improved quality of care by one or more of the following criteria: improved diagnostic accuracy; improved therapeutic results; an improved sense of patient's well-being; easier and more rapid access to patient information via better record-keeping systems; and a better representation of facts in medical records and better documentation of the reasons for the physicians' actions. Thus there exists a set of criteria in order to evaluate an expert system applied in a clinical setting.

Chapter 5 Research Methodology

The methodology for this research work addresses the design, development, implementation, and clinical evaluation of an expert system-based post-stroke robotic rehabilitation system using the InMotion² robot. The expert system is designed to assist the therapist by selecting a training program, given the condition of the patient, and then the data gathered during the robotic training exercise is analyzed. Based on the result of the analysis, the expert system makes decisions regarding the patient's progress and accordingly modifies the training exercise for the patient. The entire system consists of several components developed using different tools and computer languages. This chapter explains in detail the design and development of all the components and how the rehabilitation system is used in a clinical setting.

Rehabilitation treatment decisions are a prime area for applying expert systems (Liebowitz, 1998). This is because the decisions must be made by the therapist at a point in the diagnostic process that has produced relatively stable determination of the patient's problem and where specific treatment or more testing options are being considered. The proposed rehabilitation system is designed to improve the quality of care by using the expertise of a group of therapists instead of just one therapist, to reduce the time the therapist needs to spend with each patient for monitoring during therapy, and to analyze the results of the training session to determine the future course of action. Since the new rehabilitation system requires minimal supervision, it

allows the therapist to treat more patients efficiently in a shorter period of time and therefore lower the cost of long-term rehabilitation after a stroke.

The first step in developing this rehabilitation system is to understand the current stroke rehabilitation practices. When a stroke patient goes to a therapist, the therapist examines the patient and makes an initial assessment. In order to understand how this initial assessment is carried out, experts in physical and occupational therapy were interviewed as well as the current literature was reviewed. Based on the interviews and the literature review, a list of patient conditions that are particularly important for robotic therapy was generated. This was presented to the experts for further discussion and a revised version of the initial patient conditions list was prepared.

The next step is to create a survey questionnaire in order to acquire the knowledge from a large group of therapists. The questionnaire is developed with the help of a few therapists in the same manner as the initial conditions list was prepared. The entire process of how knowledge acquisition was carried out is explained in detail in a later section. Following the survey conducted among the therapists, the survey results were discussed with experts. With the help of the therapists and current literature, the survey results were refined and organized in a manner suitable for robotic rehabilitation. A list of different training exercises and the determinants (variable parameters) of each training exercise, along with a list of patient's progress

assessment methods were generated. This became the knowledge base (also known as rule base) for the expert system.

The panel of experts who were involved in developing the questionnaire and the knowledge base was chosen based on several criteria similar to the ones adopted in Boyette *et al.* (2001):

- They have conducted research studies in stroke rehabilitation.
- They have published extensively in stroke rehabilitation.
- They have clinical experience with stroke patients.

All experts chosen for consultation had postgraduate degrees.

After the knowledge base for the expert system was finalized, the protocol for the clinical study was developed. Based on the requirements of the clinical study, the software components of the system were developed and implemented. Various software components are described in detail in later sections. Following the implementation of all the software components, the entire system was tested and the clinical study was conducted upon approval from the Institutional Review Board. The details of the clinical study are presented in the ensuing chapters.

5.1 Design Requirements

In the conventional rehabilitation procedure, the therapist performs an initial examination of the stroke patient and assesses the patient's sensorimotor skills. Many standard tests, for example Fugl-Meyer, and Motor Status Assessment are widely accepted by the medical community as quantitative, though subjective, tests. Based on the initial assessment of the patient, the therapist chooses one or more exercises for the patient and starts the rehabilitation process. This cycle of assessing the patient and administering therapeutic exercises is repeated as long as it is feasible.

5.1.1 Current Robotic Therapy

In post-stroke robotic rehabilitation, even though a variety of studies have shown that robotic therapy can be effective, there is no published literature that outlines a comprehensive and generic treatment procedure that could be applied to patients. In most of the reported research studies, a therapist makes an initial assessment of the patient and then chooses one or more exercises with suitable determinants (the variable parameters for each exercise) for the patient and begins the robotic rehabilitation process. The exercises can be classified as active-assisted, passive, and resistive movements. In the active-assisted mode, the patient completes partial movement and the robot assists in the remainder of the movement by providing the necessary assistive force. In the passive mode, the patient provides no movement and the robot moves the patient's arm by providing all of the forces required to complete the motion. In the resistive mode, the robot resists the motion of

the patient's arm when the patient tries to complete the movement. When the patient undergoes therapy with the rehabilitation robot, the therapist visually observes the various motor skills of the patient and assesses the progress of the patient. In some cases the therapist manually analyzes the data collected from the training programs and makes a decision regarding the patient's progress. Depending on the therapist's assessment, once again one or more training exercises with suitable parameters are chosen for the patient. Each time a training exercise is selected, any or all of the parameters for that exercise can be modified by the therapist manually. This process is repeated as many times as the therapist deems it necessary.

5.1.2 Expert System-based Rehabilitation System

In the proposed expert system-based rehabilitation system, instead of the therapist continuously monitoring the patient and providing the robot with the training exercise and the parameters, the expert system makes the necessary decisions. The data collected during the training phase is analyzed and the future training exercise and the associated parameters are chosen by the robot autonomously with the help of the expert system. The expert system along with the associated software components undertakes the usually time-consuming task of analyzing the voluminous training data in order to periodically evaluate the patient's progress without the intervention of the therapist. The expert system then presents the future training exercise and the parameters along with the explanation for the decisions. All the decisions made by the expert system along with the explanations need to be reviewed by the therapist. Once the therapist approves the training exercise and the

parameters, the robotic training is repeated. This allows the therapist to supervise the entire process for multiple patients within a short amount of time. For the therapist, it is not necessary to monitor each patient continuously. In this system, the analysis of the patient scores is also done by the expert system and therefore relieves the therapist from the burden of manually analyzing the collected data.

The determinants or the variable parameters of each robotic training exercise should include but are not limited to the single plane movement patterns, the number of repetitions or desired time duration, velocity of the training motion, assistive forces, resistive forces, and range of motion. These parameters need to be selected and modified by the expert system after taking into consideration the various patient conditions. The following are examples of some specific scenarios of how the variable parameters need to be chosen and modified:

- During passive training the robot arm has to provide assistive force and take the patient's arm in a specified motion pattern.
- If the patient is exhibiting spasticity, which needs to be determined with the training program by calculating the resistive force applied by the patient on the robot arm, then the velocity of the motion will be decreased.
- The resistive force has to be modified based on the strength training requirements for the patient.

The entire decision tree for the expert system is presented as the treatment protocol, in later sections of this chapter. The treatment protocol was developed based on the past research and the knowledge acquired from the therapists.

5.2 System Overview

While it is not the aim of this research to replace the therapist, a rehabilitation system such as the proposed one would be an invaluable tool in assisting the therapists. The first prototype of the rehabilitation system is developed such that it satisfies the requirements presented previously. In addition to satisfying the general requirements of robotic therapy protocols, the prototype system is designed such that it satisfies the protocol of the clinical study conducted with stroke patients. An overview of the entire system architecture is shown in Figure 5-1. The double-sided arrows denote that there is interaction in both directions between the components. Ovals are used to represent the human components, a solid rectangular box denotes the hardware of the InMotion² robot, and software components are denoted by the dashed rectangular boxes.

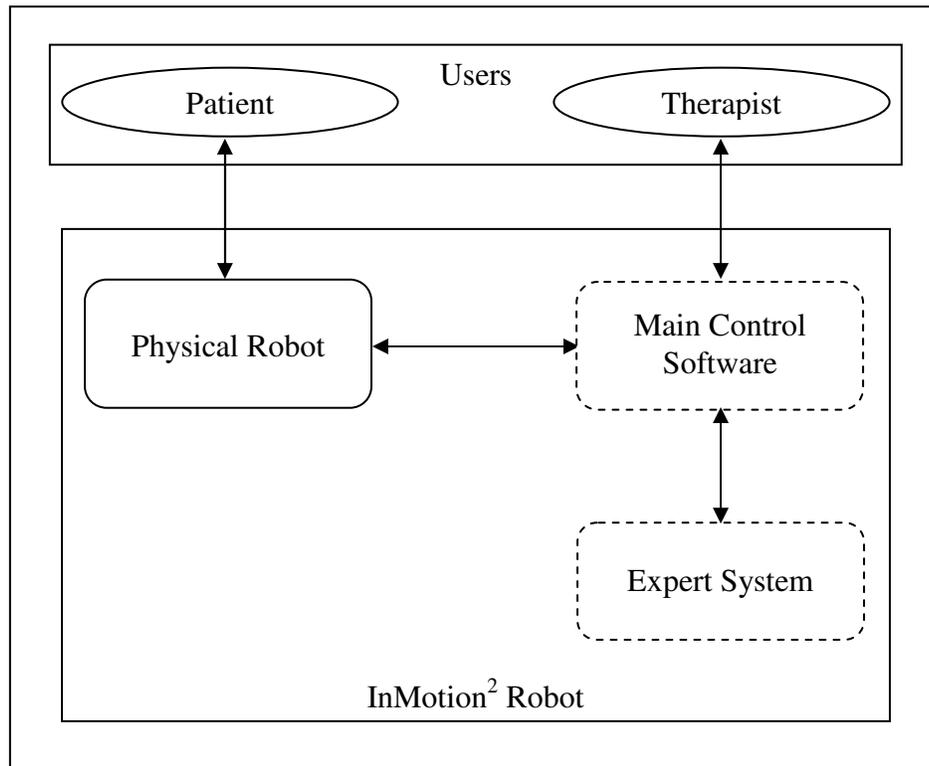


Figure 5-1 System Architecture.

5.3 Knowledge Base Development

Understanding the current practices is imperative for the development of an expert system-based robotic stroke rehabilitation system. The knowledge collected from clinical experts enabled the development of the rehabilitation system's knowledge base which guides the motion of a robotic arm in terms of its position, velocity, and forces when used in motor training of stroke survivors. In addition to developing an expert system, the information on current practice and their supporting evidence may greatly impact the decisions of policy makers and the desire of

professionals in delivering the best continuing education to make the current clinical practices more effective.

Historically, several treatment approaches have been introduced and adopted by physical and occupational therapists. The stroke rehabilitation methods adopted by therapists vary widely, depending on the therapists' background knowledge, clinical experience, clinical skills, and personal preferences (Nilsson and Nordholm, 1992; Carr *et al.*, 1994; Sackley and Lincoln, 1996; DeGangi and Royeen, 1994). The availability of a plethora of treatment methods shows that stroke rehabilitation practices are continually evolving. Previous studies used a survey to determine common treatment practices in stroke rehabilitation of physical therapists (Lennon 2003; Lennon *et al.*, 2001). These studies aimed to identify key theoretical beliefs underlying physical therapy treatment of stroke. While considering theoretical beliefs that drive treatment, another important aspect to contemplate is the delivery of treatment. Given the broad range of therapy approaches, it is important for educators and researchers to obtain data on what stroke rehabilitation methods are actually being used by clinicians. Furthermore, the previous studies (Lennon 2003; Lennon *et al.*, 2001) surveyed only therapists in the United Kingdom (UK). There is no consolidated information on the stroke rehabilitation methods that are currently used by therapists in the United States. It is equally important to discuss whether those approaches are supported by sufficient evidence given the fact that all rehabilitation professionals are moving towards evidence-based practice.

Surveys have been conducted in countries including Sweden, Australia and the UK to determine the clinical practices and the underlying theoretical beliefs in stroke rehabilitation (Nilsson and Nordholm, 1992; Carr *et al.*, 1994; Sackley and Lincoln, 1996). A survey has been conducted in the US to understand in particular the current practice of clinicians who use the Neurodevelopmental Treatment (NDT) method (Lennon 2003). While these surveys give some idea about the practices in stroke rehabilitation, many of them are either outdated or narrow in their scope, and therefore not representative of the current practice in the US. A pilot survey as part of this work was aimed at understanding the current stroke rehabilitation practices of physical and occupational therapists who at the time of the survey were providing care in two Midwest states: Kansas and Missouri. Due to the lack of resources, the survey was limited to these two states and hence it is considered as a pilot for possible extensive future work in this area.

5.3.1 Methods

Questionnaire

Initially, interviews were conducted with a few clinical researchers and clinicians who are working in the field of stroke rehabilitation. A sample of the semi-formal interview/discussion with the therapists is presented in Appendix C. During the discussions the experts provided valuable insight on post-stroke rehabilitation, such as how the robot could be used in therapy, what kind of information could be gathered from other experts, and other information that were beneficial for

conducting this research. A questionnaire was developed based on their suggestions and from previous studies conducted in stroke treatment methods (Nilsson and Nordholm, 1992; DeGangi and Royeen, 1994; Lennon, 2003). The questionnaire consisted of 39 items (included in Appendix A) and was divided into six sections. There were questions pertaining to the background information of the clinicians, the aim of their treatment, how the clinicians treat tone, their approach to facilitate movement and function, specific questions in motor rehabilitation, and a few questions that pertained to robotic rehabilitation. After preparing a draft version of the questionnaire, interviews were conducted with the researchers for a second time to discuss the questionnaire. Modifications were made according to their suggestions. The final version of the questionnaire consisted of close-ended questions (a write-in option of 'other' was included where appropriate) to make the questionnaire easier to complete and more objective. The final version of the questionnaire and the accompanying cover letter were approved by the Institutional Review Board (IRB) at the University of Kansas Medical Center (KUMC).

Survey Protocol

Contact information of physical therapy and occupational therapy clinicians/clinical sites in the states of Kansas and Missouri was provided by the Department of Physical Therapy & Rehabilitation Science and the Department of Occupational Therapy Education at KUMC. In May 2006, the questionnaire along with a cover letter and a postage-paid return envelope was sent to 320

clinicians/clinical sites. The cover letter explained to the participants the aim of this study and the fact that responding to the survey was entirely voluntary. Since the questionnaire itself did not contain any individually identifying questions, it posed no risk to the participants' privacy in any way. When the surveys were received back from the participants, they were assigned an identification number (for future data verification purposes) and stored in a secure place. The number of responses received for the survey was considered sufficient for the "pilot survey" and hence no reminder of any kind was sent to those who did not respond.

Survey Analysis

The survey responses were manually entered in an Excel spreadsheet and analyzed using Excel, Matlab, and Weka data mining tools (Witten and Frank, 2005). Out of the 320 questionnaires sent out, nine were returned as undeliverable due to various reasons and seven were returned unused because the respondents stated that they do not have experience in stroke rehabilitation. A total of 110 respondents returned a completed questionnaire, giving a response rate of 36.2%. Of these 110, however, three respondents who completed the questionnaire also indicated that they do not have any experience in stroke rehabilitation. Their responses were excluded and the remaining 107 responses were analyzed. Out of the 107 respondents, at least 106 answered each question pertaining to aim of treatment, tone, facilitation of movement, and function. This gives an incompleteness rate of less than 1% for each question in those sections. For sections that posed specific questions in motor

rehabilitation, 102 or more respondents answered each question, giving an incompleteness rate of less than 4.6% per question.

5.3.2 Survey Results

Profile of Respondents

Of the 107 clinicians who met the inclusion criteria, 55 were physical therapists, 51 were occupational therapists, and one clinician was certified in both physical therapy and occupational therapy. Out of the 103 clinicians who specified their educational background, 47 have a Master's degree or higher and 56 have a Bachelor's degree, and 93 respondents had specified the year of graduation from school. The respondents' median year of graduation with their terminal degree was 1996 ranging from 1970 to 2006. For those with only a Bachelor's degree their graduation year was considered, for those with a Master's degree only their Master's graduation year was considered and for those with a Doctorate their Doctoral graduation year was taken into account. The average clinical experience of the respondents working with stroke patients was 12.6 years with a standard deviation of 8.2 years. About 72% of the clinicians reported at least eight years of experience working with stroke patients.

Background and Treatment Approach

The clinicians were asked which treatment approach for stroke they had been taught in their professional education and which approach they use in their current practice. Their responses are summarized and shown in Figure 5-2.

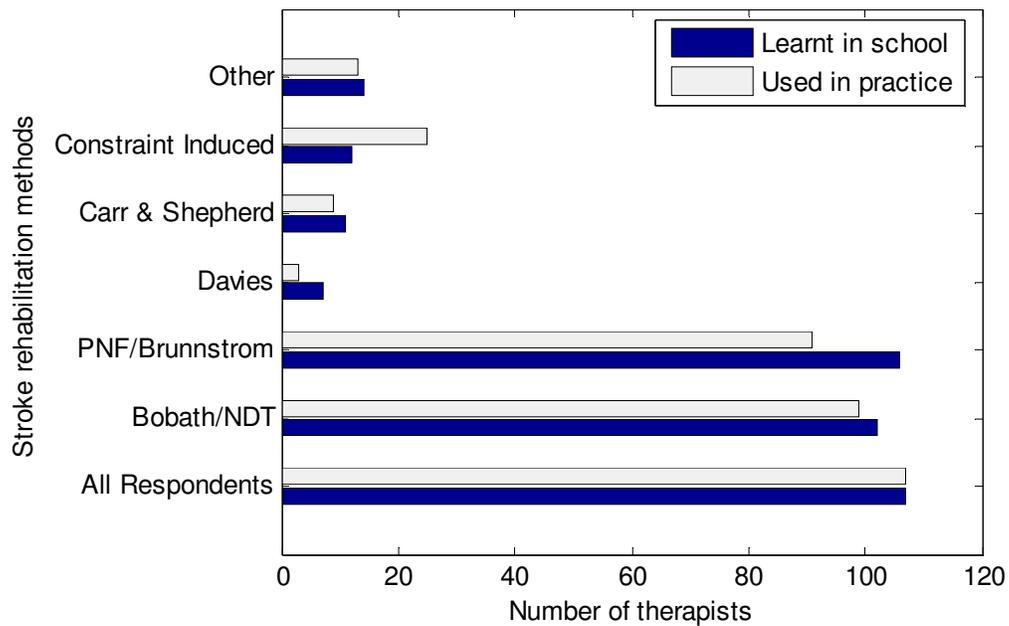


Figure 5-2 Bar graph showing the number of therapists that have learnt each treatment method in their school education and the number of therapists that are using each treatment method in their practice.

It should be noted that the respondents were allowed to choose multiple treatment approaches for both questions (Appendix A). It can be seen that the Bobath/Neurodevelopmental treatment (NDT) approach and the proprioceptive neuromuscular facilitation (PNF)/Brunnstrom are the most popular treatment approaches. Figure 5-3 shows the relationship between the year of graduation and the treatment methods taught in school.

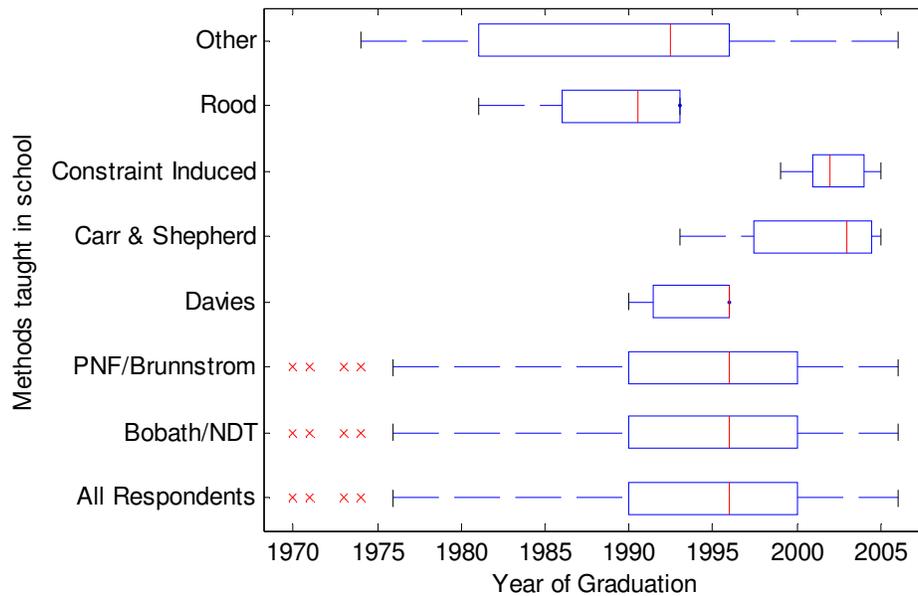


Figure 5-3 Box plot showing the relationship between the year of graduation of the therapists and the methods taught in their school education.

The box plot in Figure 5-4 shows the relationship between the years of experience treating patients with stroke and the treatment methods currently practiced. It can be seen from Figure 5-3 that Carr and Shepherd and constraint induced approaches are recent additions to education. Figure 5-4 reveals that even those who did receive formal education in these newer approaches obtained knowledge of them and adapted them into their current practice.

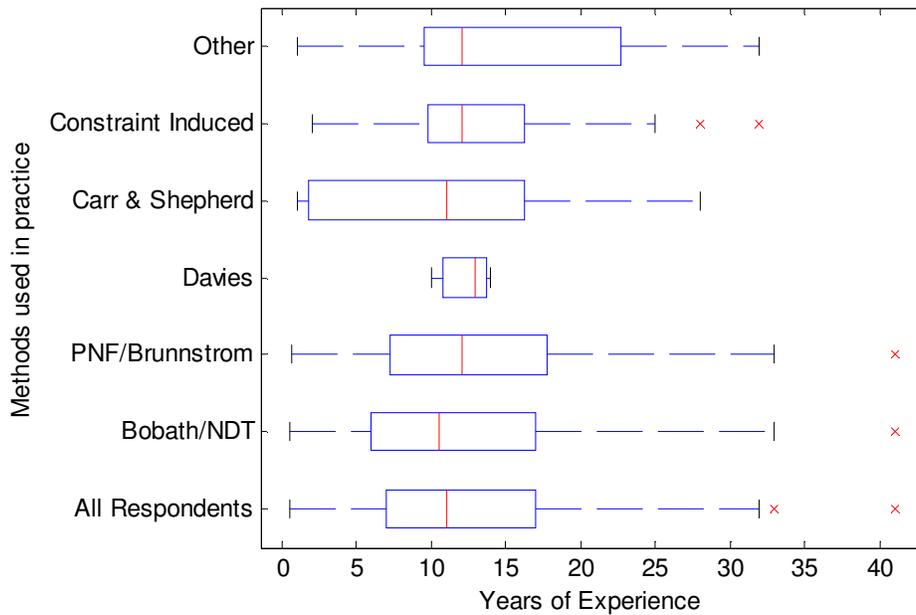


Figure 5-4 Box plot showing the relationship between the years of experience of the therapists and the methods used by them in their practice

Out of the 106 clinicians who specified whether they treat adults or children, 75.5% worked exclusively with adults, 3.8% worked with children and the remaining 20.7% worked with both adults and children. Approximately two-thirds (71 out of 105) of clinicians specified that they have received additional training specific to stroke rehabilitation after graduating from school. All but one of the clinicians (106 out of 107) reported participating in some form of continuing education. Only 47 out of the 107 respondents (44%) read stroke-related professional literature on a regular basis (4 weekly and 43 monthly) while 62 respondents rarely read and two never read the literature. However 74 out of 105 (70.5%) clinicians agreed that they incorporated

concepts of motor learning from current literature in their practice while nine respondents disagreed and 22 were unsure.

Aim of Treatment

A vast majority (93% or higher) of the clinicians agreed on the main aims of physical and occupational therapy. Table 5-1 shows the statements presented in the questionnaire regarding the aim of treatment and the clinicians’ level of agreement with the statements. Even though re-educating normal movement and facilitating adaptation to function represent different treatment approaches, 92% of the clinicians agreed with both aims.

Table 5-1 Survey responses regarding the aim of treatment.

<i>Statements</i>	<i>Agree</i>	<i>Unsure</i>	<i>Disagree</i>
1) Re-educate normal movement	99%	1%	0%
2) Facilitate postural adjustments	99%	1%	0%
3) Facilitate adaptation to function	93%	5%	2%
4) Prevent secondary complications in neuromuscular function	94%	5%	1%
Strongly agree and agree categories were combined; strongly disagree and disagree categories were combined. All percentages have been rounded.			

Pertaining to Tone

The three statements pertaining to tone and the level agreement of the therapists are presented in Table 5-2. There was a consensus of 79% or greater in agreement with all the statements. Even though the majority (89%) of the therapists agree that normalizing tone is important they (81%) also point out that it does not automatically result in movement.

Table 5-2 Survey response to statements pertaining to tone.

<i>Statements</i>	<i>Agree</i>	<i>Unsure</i>	<i>Disagree</i>
1) In patients where tone is present, normalizing tone is important when facilitating movement.	89%	6%	5%
2) The practice of functional tasks may normalize the patient's tone and access more normal movement patterns.	79%	12%	9%
3) Inhibition of spasticity does not necessarily result in movement; movement needs to be facilitated.	81%	13%	6%
Strongly agree and agree categories were combined; strongly disagree and disagree categories were combined. All percentages have been rounded.			

Facilitation of Movement

The statements on facilitation of movement and the level of agreement of the therapists are listed in Table 5-3.

Table 5-3 Survey response to statements about facilitation of movement.

<i>Statements</i>	<i>Agree</i>	<i>Unsure</i>	<i>Disagree</i>
1) Proximal stability is a pre-requisite of distal selective movement.	87%	6%	7%
2) Treating proximal stability will not necessarily result in recovery of distal movement in the limbs; distal movement needs to be facilitated.	86%	9%	5%
3) The therapist's role is to facilitate normal movement components.	90%	5%	5%
4) Stroke patients need hands-on training.	95%	4%	1%
5) Stroke patients need task oriented functional practice.	96%	3%	1%
6) Stroke patients need hands-on and task oriented functional practice.	96%	3%	1%
7) Activating movements bilaterally makes use of ipsilateral movements to promote recovery of the affected side.	86%	13%	1%
Strongly agree and agree categories were combined; strongly disagree and disagree categories were combined. All percentages have been rounded.			

More than 85% of the clinicians agreed with all the statements. Therapists (86%) believed that while proximal stability is required it will not necessarily result in recovery of distal movement and hence distal movement needs to be facilitated.

Function

Table 5-4 shows the statements pertaining to function and the corresponding level of agreement of the therapists. Therapists were evenly split on whether single plane movement patterns would translate into improved function (question #3 in Table 5-4). Over one quarter of respondents are unsure of what the outcome of this practice might be. Even though the majority (63%) of clinicians believed that therapy should be delayed when abnormal movement patterns are observed, a number (20%) of them disagreed as well. As far as robotic rehabilitation is concerned, almost half the respondents are unsure about its clinical practice.

Table 5-4 Survey response to statements pertaining to function.

<i>Statements</i>	<i>Agree</i>	<i>Unsure</i>	<i>Disagree</i>
1) In patients where the potential for recovery of normal movement exists, therapists should delay performing certain activities if they are reinforcing abnormal movement patterns.	63%	17%	20%
2) Changing the patient's ability to move does not necessarily improve the patient's ability to perform functional tasks.	73%	8%	19%
3) Intensive training of single plane movement patterns can carry over into activities of daily living.	37%	26%	37%
4) If proper software tools are available and easy to use, you would incorporate robotic therapy in addition to standard therapy treatments.	27%	49%	24%
Strongly agree and agree categories were combined; strongly disagree and disagree categories were combined. All percentages have been rounded.			

Specific Questions in Motor Rehabilitation

A number of specific statements in motor rehabilitation were presented to the clinicians and the results are presented in Table 5-5. There was some disagreement regarding the amplitudes of movement that should be practiced in subjects who have limited range of motion.

Table 5-5 Survey response to some specific statements in motor rehabilitation.

<i>Statements</i>	<i>Agree</i>	<i>Unsure</i>	<i>Disagree</i>
1) Active assistive movement is useful in patients with muscle weakness.	96%	2%	2%
2) Patients presenting with limited active range of motion would begin with small amplitude movements.	68%	17%	15%
3) Patients presenting with limited passive range of motion would begin with small amplitude movements.	64%	20%	16%
4) Passive range of motion is important for treatment.	83%	10%	7%
Strongly agree and agree categories were combined; strongly disagree and disagree categories were combined. All percentages have been rounded.			

Two more questions pertaining to motor rehabilitation (Appendix A) were included in the questionnaire and the results are presented in Table 5-6. In addition to these questions, two subjective questions that directly relate to robotic rehabilitation were posed to the clinicians. Clinicians were asked to rank different single plane movement patterns in the order that they think would be most beneficial to the patients during therapy. The patterns were circular, square, diagonal, and there was a write in “other” option as well. The diagonal pattern was ranked as the most beneficial by the clinicians. Next the clinicians were asked to rank different aspects of movement they

prioritized during therapy (speed, accuracy, strength, number of repetitions, and other). A majority of the therapists ranked accuracy as the most important aspect followed by strength, number of repetitions, speed, and others. The statistics of the survey results are presented in Appendix B.

Table 5-6 Survey response to specific questions in motor rehabilitation.

<i>Questions</i>	<i>Increase</i>	<i>Remain Constant</i>	<i>Decrease</i>	<i>Unsure</i>
1) In your opinion, what should be done to the speed of movement for individuals with <i>high</i> tone? Velocity should _____.	3%	21%	74%	2%
2) In your opinion, what should be done to the speed of movement for individuals with <i>low</i> tone? Velocity should _____.	51%	42%	4%	3%
All percentages have been rounded.				

5.3.3 Discussion of Results

The stroke rehabilitation methods adopted by therapists vary widely depending on several factors. The survey responses were separated into two groups, physical therapists (PTs) and occupational therapists (OTs), to analyze any differences in their opinions. The results for each individual group are presented in Appendix B.

The respondents to the survey averaged over 12 years of experience treating people with stroke. Nearly all respondents received both proprioceptive neuromuscular facilitation (PNF)/Brunnstrom and Bobath/neurodevelopment treatment (NDT)

training in school and an equal number report practicing these techniques clinically, despite the lack of evidence to support these approaches (Paci, 2003). Therapists seem to adopt an eclectic approach and combine principles from different approaches in their current practice. This may be an indication of a need for an optimal approach to be developed through more research. It is interesting to note that even though re-educating normal movement and facilitating adaptation to function represent different treatment approaches, 92% of the clinicians agreed to both aims. The therapists may be applying both forms of treatment to patients but with different emphases depending on individual conditions. Even though the majority agreed with both aims, all (100%) of the occupational therapists (OTs) agreed with the aim of adaptation to function, whereas 5% of the physical therapists (PTs) disagreed and nearly 9% of the PTs were unsure about this practice.

The clinicians self-reported inconsistently reading current literature. In a continuously evolving field like stroke rehabilitation, reading current literature should be an integral part of the clinicians' profession. Reading current literature will enable the clinicians to keep abreast with the latest and effective rehabilitation practices. This could also be perceived as another reason for clinicians practicing some older techniques despite the lack of evidence to support those approaches.

Clinicians suggest that tone should be normalized when facilitating movement. This response is closely tied to NDT/Bobath approach, which encourages facilitating

normal movement patterns while inhibiting tone. Current literature (Paltz *et al.*, 2005; van Vliet *et al.*, 2005; Wang, 1994; Wang *et al.*, 2005; Hafsteinsdottir *et al.*, 2005; Luke *et al.*, 2004; Lennon *et al.*, 2006) show that the benefits of NDT/Bobath and PNF methods over other treatment options are still debatable. Despite the evidence supporting constraint induced movement therapy (CIMT or CI therapy) (Taub *et al.*, 1993; Wolf *et al.*, 2006), only 12 clinicians (11% of respondents) report being trained in CIMT and 25 clinicians (23% of respondents) report using this efficacious method for treatment.

A majority (63%) of the therapists believe that activities should be delayed if they are reinforcing abnormal movement patterns. However, there is currently little to no evidence available that suggests preventing or delaying a patient from moving will worsen abnormal tone and movement (Lennon, 2003; Pomeroy and Tallis, 2000). Therapists responded with uncertainty on whether the single plane movement patterns would ultimately improve function. This is in direct contrast to the evidence obtained from clinical studies (Aisen *et al.*, 1997; Volpe *et al.*, 1999). The reason for this high uncertainty became evident upon examining the comments given by some of the respondents. The wording of the statement does not clearly explain the context and meaning of “single plane”. This question is directly related to robotic rehabilitation. The InMotion² used in this research work is limited to movements along a single horizontal plane (parallel to the ground surface). Since the survey was conducted to

understand clinical practices in general and not just robotic therapy, information regarding the InMotion² robot was not included in the survey.

No significant difference was found between the opinions of PTs and OTs. In general, the difference in the level of agreement was within 10% between the PTs and OTs, except when a large number of clinicians were unsure about the practice in question. The statements that produced larger differences of opinion between the PTs and OTs included:

- Statement #3 in Table 5-1 where the 2% of disagreement comes from PTs, all of the 5% of unsure respondents were PTs, whereas all of the OTs were in agreement.
- Statement #1 in Table 5-2 where all of the 5% of disagreement comes from PTs.
- Statement #3 in Table 5-4 where 42% of PTs disagreed but only about 30% of OTs disagreed.
- Statement #4 in Table 5-5 where all of the 7% of disagreement comes from the PTs and no disagreement from the OTs.

Though the difference of opinion between PTs and OTs is minimal, it can be observed that the OTs are focused more on functional rehabilitation as compared to the PTs who are more concerned about the musculoskeletal mechanisms of rehabilitation.

5.3.4 Survey Limitations

There were some limitations to this survey and hence the results should be subjected to future verification by other methods. This was a pilot survey which was conducted among therapists (n = 107) within the states of Kansas and Missouri. The results from such a narrow sample space may not be a true indicator of practice across the nation. However the results from many sections of the survey showed similarities to the surveys conducted in Sweden, UK and Australia.

The wording of the statements and the corresponding closed responses might have limited the therapists' understanding and hence their responses. Some of the respondents in fact added some comments explaining why they were (or were not) choosing a particular answer. Even though the survey was anonymous, it should be acknowledged that the respondents' verbal reports about their clinical practice may be different from their actual practice or could have changed after the survey was conducted.

Future questionnaires should attempt to delineate which specific techniques from each of the predominant approaches (Bobath/NDT and PNF/Brunnstrom) are used clinically. Questions directed primarily at upper extremity rehabilitation of stroke might provide clinical context for answering explicit questions. For the statements given in Table

5-1, the responses show that the comprehensive treatment goal is to improve movement and function. Since the statements presented were in no particular order, additional investigation of clinical practices should focus on prioritizing the statements regarding the aim of treatment in stroke rehabilitation.

Regarding statement #3 in Table 5-4, future query should aim to determine if functional practice is performed in a single plane clinically. Additional clarification in relation to “plane” is necessary when discussing movement patterns, as well. The movement plane should be defined in respect to the plane of movement through space, not to be confused with the multi-planar perspective of arthrokinematics of joint movement to resolve any confusion with interpretation.

5.3.5 Survey Conclusions

This survey on clinical practices in stroke rehabilitation provided data from over 100 clinicians (PTs and OTs combined) in the Midwest. The majority of responses from the clinicians were directly used to construct the knowledge base of the expert system for robotic rehabilitation. Due to the limitations of this survey some questions pertaining to robotic rehabilitation still remain without definite answers. The self-reported background information of the clinicians correlates with the dated treatment choices reported in sections of the questionnaire. This data emphasizes the need for continuing education of clinicians in efficacious treatments and implementation. Therapists must also continuously scrutinize their beliefs and update their practice as new evidences become available. In order to make use of the updated

evidence base in their practice, clinicians should be encouraged to actively read professional literature. The uncertainty among clinicians revealed in some sections of the survey shows that more evidence of clinical approaches is needed to ensure efficacious treatments. Development of a comprehensive treatment protocol based on basic and clinical scientific evidence should be investigated. Further inquiry of prioritizing treatment approaches and specific components of treatment methods should be investigated. Due to some of the limitations mentioned in the previous section, further investigation should be carried out among a broader group of clinicians spread out across the entire nation in order to substantiate the results of this pilot study.

5.4 Knowledge Representation

The knowledge-based expert system is designed such that it encapsulates the expertise of the occupational and physical therapists who have completed the questionnaire. For many questions, after conferring with the current literature, only the majority answers were considered. The knowledge is implemented as rules for the expert system. These rules are used by the expert system to determine the appropriate robotic training for the patients during the clinical study.

A step by step treatment protocol has been developed in conjunction with the knowledge gathered from the experts and the current evidence-base literature. The developed treatment protocol was again presented to the experts who were involved

in developing the questionnaire for the survey and the protocol was deemed acceptable. This protocol is given in a diagrammatic format in this section.

This protocol is then represented using a standard format such as a production system. The expert knowledge represented as a production system is utilized to make all the decisions regarding the selection of training exercise parameters. During the training of the patient, data are collected regarding all possible aspects of the patient's movement. At the end of each training session, the inference engine within the expert system is able to compare the summary of the collected data with that of the initial conditions or the previous training, and with the help of the rule base make decisions about the future training exercises. Different patient scores and assessment methods to be employed are listed in later sections.

5.4.1 Treatment Protocol 1

The treatment protocol 1 for robotic rehabilitation was developed based on the results of the survey, as well as stroke rehabilitation literature. When a stroke patient begins the robotic therapy, the therapist makes an initial assessment which includes all the base-line evaluations. During the initial assessment three main conditions of the patient are determined, namely, tone, strength, and Passive Range of Motion (PROM). For each patient, tone can be normal or high, strength can be diminished, and PROM can be limited or normal. Figure 5-5 shows the treatment plan that has to be followed if the patient's tone is normal and the PROM is limited.

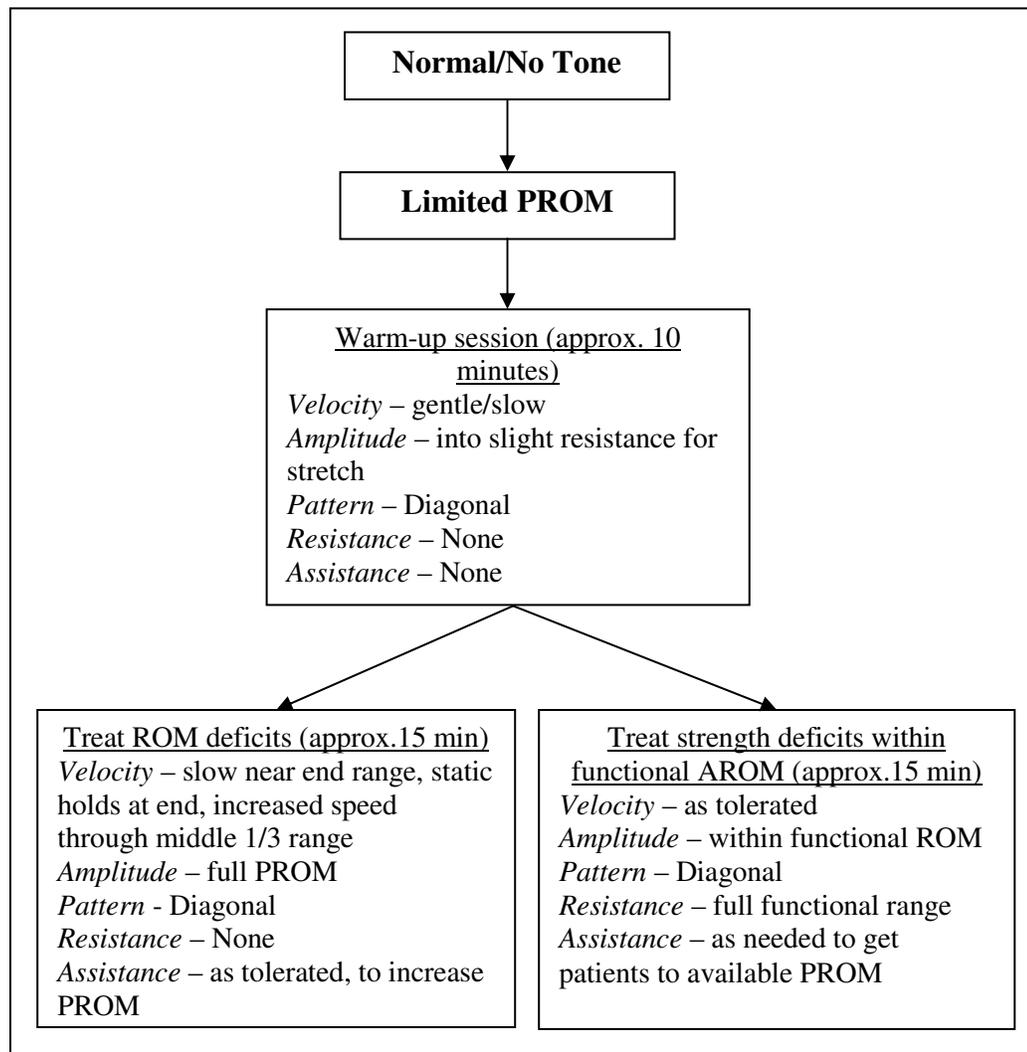


Figure 5-5 Treatment Plan 1 – normal tone and limited PROM.

Figure 5-6 illustrates the treatment plan that has to be followed if the patient's tone is normal, strength is diminished, and the PROM is normal.

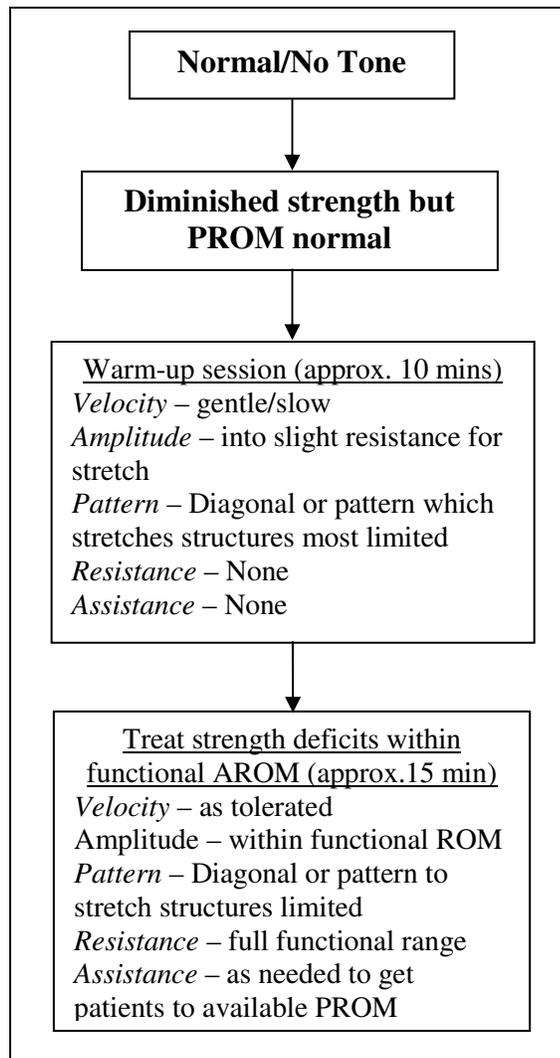


Figure 5-6 Treatment Plan 1 – normal tone, diminished strength and normal PROM.

Definitions of acronyms used in the treatment plan include:

- ROM – Range of Motion of the patient
- PROM – Passive Range of Motion, the range in which the patient is unable to actively contract the muscles to perform the movement on his/her own.

- AROM – Active ROM, the range in which the patient is able to actively contract the muscles to perform the movement on his/her own.

Patient's progress during the stretching treatment is monitored primarily using the range of motion. Subsequent training exercise parameters are modified as:

- Increase amplitude as tolerated to increase ROM.

Considerations for the therapist with stretching exercises:

- Heterotrophic ossification from aggressive stretching.

Patient's progress during the stretching treatment is monitored primarily using the accuracy. Subsequent training exercise parameters are modified according to the following:

- Accuracy of 90% or better over a given number of repetitions, number of trials, or time.
- Progress resistance for patients functioning with AROM.
- If applicable, wean patients off assistance as tolerated.
- Adjust time demand.
- Modify target constraints to make task more difficult.

Considerations for the therapist with strengthening exercises:

- Heterotrophic ossification from aggressive strengthening.

- Fracture secondary to osteoporosis from aggressive strengthening.
- Incorporation of bilateral training to elicit greater force production of affected limb.
- Manual guidance early in task training to correct movement pattern if patient compensates.

5.4.2 Treatment Protocol 2

Figure 5-7 shows the treatment plan that has to be followed if the patient's tone is high and PROM is limited. If PROM is normal, then treatment plan 1 should be followed.

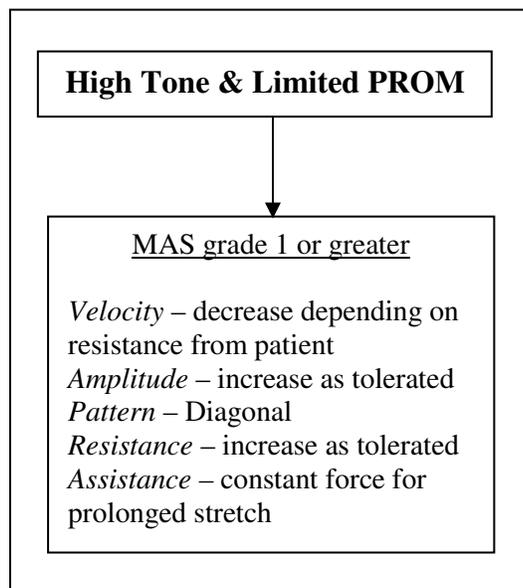


Figure 5-7 Treatment Plan 2 – high tone.

Definitions of acronyms used in this treatment plan include:

- AAROM – Assisted Active Range of Motion, the range in which the patient is able to complete partial movement while the robotic arm assists by providing external force required for completing the movement.
- MAS – Modified Ashworth Scale used to measure muscle tone.

Patient's progress during the stretching treatment is monitored primarily using the accuracy:

- Progress resistance for patients functioning with AROM.
- Decrease assistance given for patients functioning with AAROM.

Considerations for the therapist with tone treatment exercises:

- Spasticity is velocity dependent and would need to be closely monitored to allow for full ROM.
- If tone normalizes, velocity should be increased.
- If non-neural (soft tissue) component is causing tone, velocity may be increased within a practice session as viscoelastic changes occur with warming and stretching of the tissue.
- Qualify tone by describing specific muscle groups or part of range where resistance is encountered.

5.5 Software Implementation

The prototype software components in this research were developed according to the needs of the clinical study. As the clinical study involves a robot and human subjects with stroke, it is considered to be sensitive in nature. As a result, ensuring the safety of the human subjects was a priority in designing the study protocol. To assure maximum safety, the software components were designed such that they can all work independently as well as be monitored and controlled by a human user at all times. This also made it easier to find and fix any software defects during the development and testing stages. The design provides the human user full control and maximum flexibility for manual override at any point during the clinical study. The entire software is implemented on the same computer platform that is used to control the InMotion² robot.

Figure 5-8 gives an overview of the software architecture. The system consists of various components developed using different tools or languages. The components can be grouped into three categories:

1. The expert system developed using CLIPS
2. The robot testing and training programs developed using Tcl/TK
3. The analysis program developed using C

Figure 5-8 illustrates the sequence in which the different components are active, as well as the flow of data through the system. All the data files are represented using parallelograms and the software components are represented using round-edged

dotted rectangles. Different dotted styles are used to show the different languages and tools used to create the components.

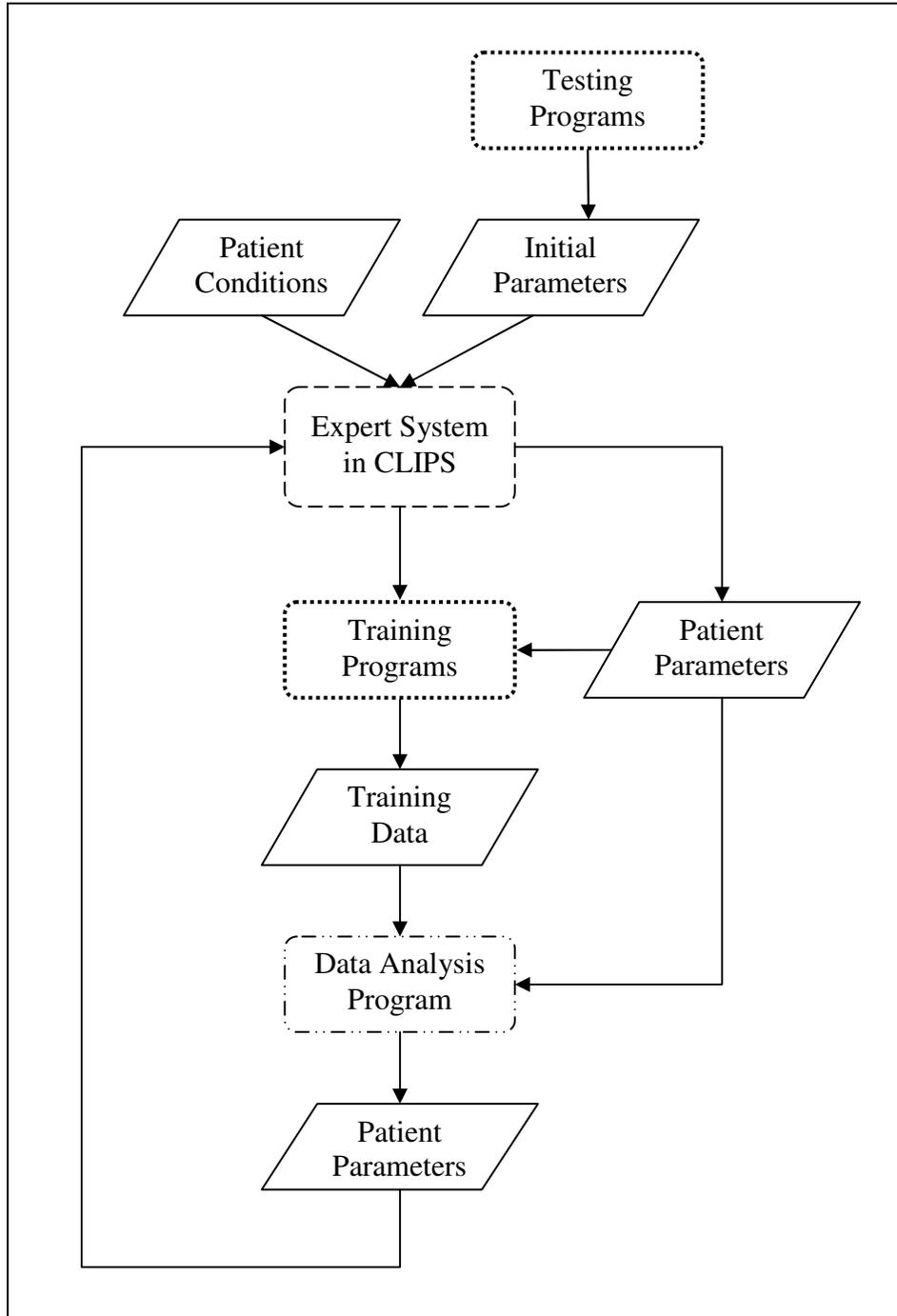


Figure 5-8 Overview of the software components.

The functioning of the overall system can be explained in a step by step manner as follows:

- When the patient is brought in for the first time, certain initial testing with the robot is done. During this test various initial parameters are recorded and saved in the parameters data file. The list of parameters is given in Table 5-7. During the initial visit the patient's conditions regarding tone, strength, and PROM are also noted and saved in the conditions data file.
- After finishing all the testing, the expert system runs. The expert system takes the two data files (conditions and parameters) as input and selects an appropriate treatment regimen for the patient. This selection is made according to the knowledge base as shown in Figures 5-5, 5-6, and 5-7. In addition to selecting the training exercises, the expert system also makes the necessary modifications to the parameters data file.
- Next the subject goes through the treatment plan. The robot training program developed in Tcl/TK takes the parameters data file as input and provides the appropriate exercises to the patient.
- During the training phase, the program records all the important data regarding the patient's movement, approximately every 30 to 40 milliseconds. The data recorded includes the x and y position of the arm, x and y forces on the robot arm, the x and y velocities of the robot arm, and the time accurate to a millisecond for every data point. Since the patient's arm is connected to the

robot's arm using a sling like handle, the recorded data directly corresponds to the patient's arm as well.

- At the end of every two training sessions, the data saved in a data file are analyzed by the analysis program. This program calculates the average deviation from a straight line path, the percentage accuracy with respect to the length of the straight line, the average velocity based on the time taken to complete each motion segment, and the average of the peak resultant velocity. The analysis program stores the calculated values back in the parameters data file. This analysis is done once every two training sessions instead of every session in order to minimize the error from the patients' daily physical changes.
- The new parameters data file is used as input by the expert system. The expert system checks if the new parameters are different from the old parameters in terms of accuracy, range or motion, velocity, etc., as shown in the treatment plan. If they are different, the conditions for progress are checked and subsequently any applicable changes are made to the parameters data file.
- This new parameters data file is used as input by the training program and the cycle repeats for the length of the clinical study.

The structure of the parameters file is given in Table 5-7. The explanation of how many of the parameters are represented in the InMotion² robotic training is provided.

Table 5-7 Patient parameters in the data file.

Parameter	Description
AROM	Active Range of Motion (meters)
PROM	Passive Range of Motion (meters)
resist_force	Maximum tolerable resistance (Newtons/meter)
assist_force	Minimum required assistance (Newtons/meter)
center_y	Center position, origin of y-axis (\pm meters)
deviation	Average deviation from straight line path (meters)
accuracy	Average % accuracy with respect to length of motion segment
velocity	Average velocity calculated from time taken (meters/sec)
max_res_vel	Average of the peak resultant velocity (meters/sec)

Center of y-axis – The center position (origin) of y-axis can vary from patient to patient due to reasons such as the position of the chair in front of the robot, the length of the patient’s arm, etc. That is why this is measured during the patient’s first visit as a part of the testing procedure.

ROM – The range of motion is represented as the radius of a circle. This implies that the range is not direction specific. For example, if a patient has AROM of 0.14m then it can be understood that the patient can actively move the arm under his/her own power to any point within the circle of radius 0.14m from the center (the origin) position.

Resistance – In the InMotion² robot, any force is a function of a parameter called stiffness. This stiffness is similar to that of the stiffness of a spring called the spring constant. The robot itself is not a spring loaded device but instead uses electric servo motors. However the robot is designed to be back-drivable giving it a soft, spring-like feel. This stiffness is measured in Newtons per meter. For a spring, it is amount of force required to stretch the spring by one meter, and it can be represented as:

$$F = -k x$$

where k is the spring constant, x is the displacement of the spring, and the negative sign denotes that the force exerted by the spring is opposite to the direction of motion. It can be seen that this force exerted increases linearly with the displacement. Thus when the robot arm is set to be stationary at a point and if one tries to move the arm, one will be moving against the resistance of the arm. This resistance will be felt like the stiffness of a spring and the force experienced will increase as the arm is moved farther away from the set position. This method is used in the strength training exercises.

Assistance – The assistive forces applied to a patient's arm by the robot arm is manipulated in the same way as the resistive force, as a function of the stiffness. When the patient can move his/her arm actively, meaning the patient does not need any assistance from the robot, the stiffness can be set to 0. This equates to no force whatsoever from the robot. As the stiffness is increased and if the robot arm is programmed to move along a specified path, then it will exert assistive force on the

patient's arm. Higher stiffness means that the robot arm follows the programmed path more closely and provides increased assistance to the patient's arm.

Deviation – During training the robot is programmed to record the position data about every 30 to 40 milliseconds. The data file also stores the information about the desired straight line path in the form of starting point and ending point. If the starting point is given as (x_1, y_1) and the ending point is (x_2, y_2) then the equation of the straight line can be given as:

$$Ax + By + C = 0 \text{ where}$$

$$A = y_2 - y_1, \quad B = x_1 - x_2, \text{ and} \quad C = (x_2 \cdot y_1) - (x_1 \cdot y_2)$$

Using this equation of the line, the perpendicular distance to the line from any given point, (x_p, y_p) , can be calculated as follows:

$$d = \left| \frac{x_p \cdot A + y_p \cdot B + C}{\sqrt{A^2 + B^2}} \right|$$

The calculated distance is given as the deviation from the desired straight line path.

Accuracy – The calculated accuracy is an extension of the deviation. The average deviation is represented as a fraction of the average length of the motion segments. For example, more than 96% accuracy means that the average deviation is less than 4% of the length of the motion segment.

Velocity - The velocity is calculated from the time taken to complete a motion segment. Although the instantaneous velocity is recorded every 30 to 40 ms, this velocity is not constant. The velocity profile for the movement of the robot arm along a straight line is a bell curve that normally looks like the one shown in Figure 5-9. Therefore, in order to calculate the average velocity of the patient's arm, the time taken to complete each motion segment is noted. Based on the time and the distance of the motion segment the average velocity is determined.

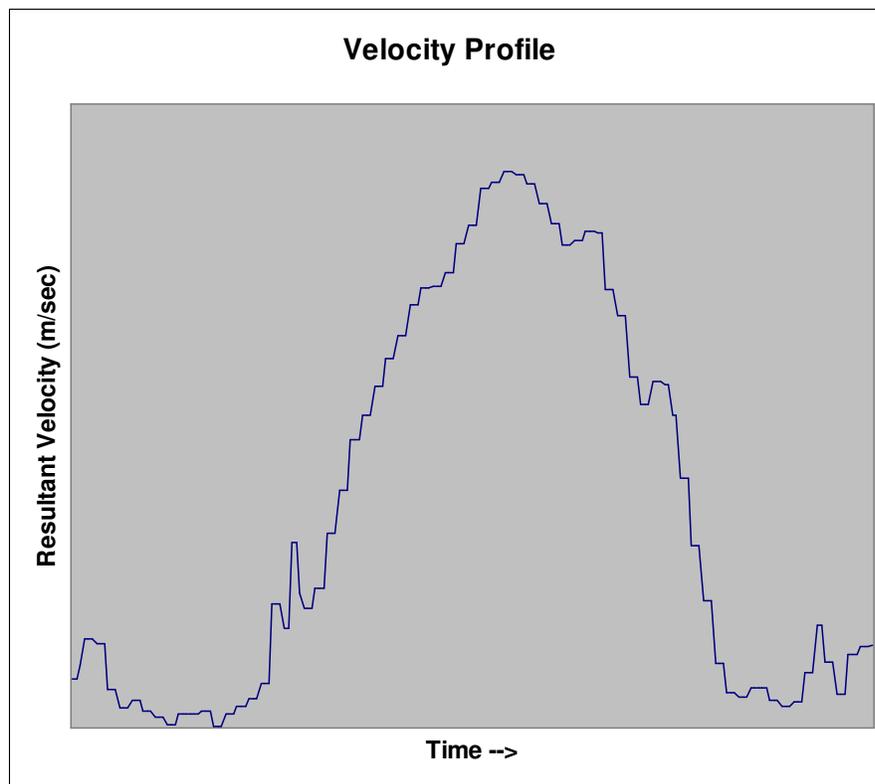


Figure 5-9 Velocity profile for the InMotion² robotic arm.

Resultant Velocity – The velocity recorded in the data file from the robot controller is the instantaneous x and y velocity vectors. In order to get a true sense of the actual

instantaneous velocity, the magnitude of the resultant vector is calculated for every recorded data point. The resultant is calculated using the formula,

$$R_{vel} = \sqrt{(x_{vel})^2 + (y_{vel})^2}$$

After all the software components were developed and tested, the entire system was implemented. The whole system was then tested for its readiness for the clinical study. The next chapter presents the details of the clinical study that was conducted.

Chapter 6 Clinical Study

According to the National Institute of Health (NIH), “clinical research” is defined as patient-oriented research. Any research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with the human subjects is considered as patient-oriented research (National Institutes of Health, 2006). The research work presented in this dissertation satisfies this definition. Consequently, during the course of this research, all the federal guidelines were followed.

The aim of this clinical study is to test various aspects of the newly developed expert system-based stroke rehabilitation system in a clinical setting. At first, the protocol for this clinical study was developed to test the system on a large group of about 10 to 20 stroke patients. However, in order to test the feasibility and effectiveness of the approach, the protocol was modified into a pilot study. The pilot results of the clinical study will serve as “proof of concept” for a possible full-length study in the future.

6.1 Institutional Review

The Human Subjects Committee (HSC) is designated as the Institutional Review Board (IRB) for the University of Kansas Medical Center (KUMC). The purpose of the HSC is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of the people participating

as research subjects, regardless of the source of funding for research. The HSC also ensures that all personnel involved in research activities understand and comply with the ethical standards of research. In order to approve human subjects research the HSC must determine that the research meets all federal criteria. For this study all the personnel involved in the research underwent the Human Subjects Protection training.

For any new clinical research at KUMC the HSC accepts applications under one of the three categories – exempt research, expedited review, and full committee review. For one part of this research an exempt research review was granted and for another part a full committee review was required. During the knowledge acquisition phase of this research, the survey that was conducted among the therapists in Kansas and Missouri was approved by the HSC in the exempt category. For the clinical study of the new rehabilitation system it was determined that a full committee review was required. The following steps were taken in order to complete the institutional review:

- The appropriate application for a full committee review was completed. As a part of the application process, the protocol for the clinical study was developed.
- The study protocol was sent for a peer review in the Department of Physical Therapy and Rehabilitation Science. The feedback included suggested changes and some clarifications. After the changes were made the departmental approval was obtained.

- The application for the full committee review, along with the supporting documents such as the consent form, protocol summary, and the departmental approval, were submitted to the HSC.
- The HSC started the review process after first verifying that the application material was complete and that all the personnel involved had completed the Human Subject Protection training and the Health Insurance Portability and Accountability Act (HIPAA) compliance training. The full committee of the HSC consists of members from different backgrounds that will promote complete and adequate review of the research activities. The committee meets twice a month for review of proposals.
- After the review, the committee requested for further clarifications regarding the InMotion² robot, the study protocol, and the consent form.
- In the reply to the review the additional information requested by the committee was provided, and the questions and concerns of the committee were addressed.
- After the committee deemed the documents and the research procedures to be satisfactory, final approval was granted for this clinical research to proceed.

The consent form used for this study is given in Appendix D.

6.2 Protection of Human Subjects

Data Protection – All data for this study was collected for research purposes only. Data resulted from qualitative and quantitative measurements conducted in the Neuromuscular Research Laboratory at the University of Kansas Medical Center. All research related records and information obtained from this study will be kept confidential by storing the related documents in a locked file cabinet in one office inside the laboratory and all electronic files in the computer are password protected. Access to data files will be restricted to associated personnel only. The subjects' identity was separated from the data collected and will not be revealed in any publications. The data collection procedure was also examined periodically to ensure that it is appropriate.

Protection Against Risks – There were only minimal risks to human subjects in the clinical study. Participants may experience muscle fatigue during functional tests and/or robotic training. This was resolved by the resting period between each training and testing trial. Subjects were free to stop any training or testing at any time.

Potential Benefits – There were no payments made for participation in the clinical study. The direct benefit for participating in the study is the possible improvement of sensorimotor function of the hemiparetic arm of human subjects. Only minimal risks are anticipated, such as mild muscle fatigue. However, participation in the study may lead to significant improvement in the treatment of stroke rehabilitation. Therefore,

the minimal risks are reasonable in relation to the anticipated benefits to the human subjects specifically, and stroke patients in general. The study is meant to examine the effectiveness of a new approach to post-stroke robotic rehabilitation for hemiparetic arm. The information obtained in the proposed study can potentially provide a novel direction for future development of approaches in stroke rehabilitation.

6.3 Study Population

Two chronic stroke patients were recruited for this study from the Kansas City metropolitan area with the help of the Kansas Stroke Registry, established at the University of Kansas Medical Center. The World Health Organization's (WHO) definition of stroke was used in this study (Aho *et al.*, 1980). Subjects in this study were adults, greater than 21 years of age, who are diagnosed patients with symptoms of rapid onset and of vascular origin reflecting a focal disturbance of cerebral function, excluding isolated impairment of higher function.

6.4 Inclusion Exclusion Criteria

This section presents the inclusion and exclusion criteria that were used to recruit and enroll potential subjects for the study.

The inclusion criteria include:

1. First time “diagnosed” carotid distribution ischemic, hemorrhagic, or brainstem stroke, at least one month after the incidence, age greater than 21, living in the community prior to stroke, independent in basic activities of daily living prior to stroke, and admitted to KUMC hospital rehabilitation unit after acute stroke.
2. Mild to moderate stroke based on two assessments: Orpington Prognostic score greater than 2.8 and less than 5 (Kalra and Crome, 1993) and Fugl-Meyer Motor score between 40-95 with sub-score for upper extremity greater than 20 (Fugl-Meyer *et al.*, 1975).
3. Folstein Mini-Mental score greater than 25 (Folstein *et al.*, 1975).
4. The patient is ambulatory for 25 feet without assistance of another person.
5. The patient is free of major post-stroke complication (e.g., recurrent stroke, hip fracture, myocardial infarction).

Exclusion criteria include:

1. Stroke due to subarachnoid hemorrhage.
2. Lesions in either temporal or parietal lobe leading to asomatognosia/unilateral neglect, with progressing dementia.
3. Posterior circulation stroke.
4. Not expected to live one year, obtunded or comatose.
5. Unable to follow three step commands.
6. Poorly controlled diabetes, amputation, blindness, progressive neurological diseases (e.g. Parkinson’s disease), and peripheral nerve pathology.

7. Patients living more than 60 miles away from University of Kansas Medical Center.

6.5 Human Subject Recruitment

Stroke patients who were recruited into this study were chronic stroke patients who were familiar with stroke rehabilitation research carried out at the Neuromuscular Research Lab. Even though it was not a requirement, all the patients who took part in this study had at some point participated in other stroke related clinical research conducted at KUMC. Subject recruitment also used the information from the Stroke Registry at the KUMC, in which stroke patients indicated their desire to participate in research activities. Any individual who met the eligibility criteria received a phone call from a research physical therapist. A brief phone interview was conducted during which the purpose of the proposed study was reviewed, the procedures involved were described, and the potential risks and benefits of the study were discussed with the stroke patient. If the candidate expressed willingness to participate in this research, the patient's primary or rehabilitation physician was contacted with the study details seeking permission to enroll the patient in the study. A sample of the letter, the consent form, and the study protocol that was sent to the physicians are provided in Appendix E.

With the physician's consent, a screen examination was conducted by the research physical therapist on all candidates in their first visit to the Neuromuscular Research

Laboratory. Once the candidate was selected based on the inclusion/exclusion criteria and the screening tests, using the consent form that was approved by the HSC, a written informed consent from the patient or a family member was obtained prior to enrollment.

A post-doctoral fellow and a research physical therapist at the Neuromuscular Research Laboratory helped in recruiting the study subjects and conducted all the physical evaluations of the subjects.

6.6 Study Protocol

The goal of this research project is to design and develop an expert system-based robot-aided motor training system and to verify its potential as a reliable and effective method for rehabilitation of hemiparetic upper limb in stroke patients. For this study, two stroke patients with motor deficits were recruited and randomly assigned to an experimental or a control group, resulting in one subject in each group. The assignment method in this pilot clinical study does not have much importance due to the small number of subjects. However, if this study is to be considered as a precursor to a larger study, then it is important to randomize the subjects in order to avoid any unintentional bias. As the human subjects are enrolled in the study sequentially, they should be randomly assigned to the appropriate group. It is also important to make sure that in a larger study, the two groups contain subjects representing similar conditions (such as the age of the subject, time elapsed after

stroke, site of injury, gender and left-handed or right-handed) as much as possible. Subjects in this study were unaware of the group to which they were randomly assigned. The subjects in the experimental group underwent training with the expert system-based rehabilitation system. Subjects in the control group underwent training with the rehabilitation robot but without the expert system.

The subjects were not asked to change any of their regular physical therapy treatment routines. The subjects were informed at the time of enrollment that the robot training is not a substitute for any of their regular physical therapy sessions. The subjects received robot-aided motor training in addition to their routine exercises and/or physical therapy. Subjects in both groups were evaluated for their sensorimotor function in baseline and end-treatment tests. The effectiveness of the expert system-based robot-aided training program was assessed through the comparison of outcomes of the two training groups. The accuracy of the treatment protocol and the expert system was evaluated based on how often the therapists agree with the decisions made by the expert system. The usefulness of the whole system is determined from the feedback of the therapist.

Baseline evaluation of motor function was conducted for each subject in the Neuromuscular Research Laboratory (NRL). The subjects then came to the NRL for a training program for about one and a half hours per day, two days per week, for a

total of four weeks. The outcome of the training programs was assessed using an end-treatment evaluation, at the end of the four week period.

6.6.1 Experimental Apparatus

Computer generated 2D images and moving visual objects were used in this study to provide the target and visual feedback of arm movement by displaying those images on an LCD monitor. An interactive robot, InMotion² robot (Interactive Motion Technologies, Inc.), was used to interact with study subjects by providing different training exercises by varying the target movement pattern, the force fields, and the range of motion. The subjects are instructed to perform arm movement tasks depending on the training exercise. While the patient was performing the training exercises, data are collected regarding the patients' arm movements, including position, velocity, and forces.

6.6.2 Experimental Procedures

Three experiments were conducted in this study. Experiment 1 familiarizes the subjects under various visual feedback conditions using the LCD monitor and the robot. In addition, experiment 1 is used to collect the initial treatment parameters for the patient, such as the range of motion, velocity, etc. Experiment 2 was used to test motor learning in subjects under different arm movement patterns using visual feedback and the interactive robot. In this experiment the aspects of movement were determined by a therapist. Experiment 3 was used to test motor learning in subjects

while moving the robot handle to specified targets in the presence of varying assistive and resistive forces, as determined by an expert system. Not all subjects were tested in all three experiments. Half of the subjects were assigned to the control group and tested in experiments 1 and 2. The other half were assigned to the test group and tested in experiments 1 and 3. Each subject was tested in one experiment during each visit to the research laboratory. Both the control group and the experimental group underwent training with the InMotion² robot.

Experiment 1

The subject is seated in front of an LCD monitor. The subject's arm is strapped to a sling connected to the arm of the rehabilitation robot. During the experiment, the subject is instructed to move the robot handle to various positions. The subject's arm movement is translated into movement of a virtual object providing 2D visual feedback for the subject. The subject is instructed to perform a reaching movement to the visual targets, multiple times.

In this familiarization experiment, the subject is presented with different visual patterns and asked to move the robot handle to various targets on the pattern. This is repeated for about 10 trials with resting periods between trials. During these trials the movement data are recorded by the robot software. The recorded data are then processed to determine each patient's initial parameters for robotic rehabilitation. The following are the variables of interest: patient's range of movement, average velocity

of movement, accuracy of movement, the assistive forces required by the patient, and the resistive forces (if applicable) tolerable by the patient. These data are used to create subject specific training exercises.

Experiment 2

The subject is seated in front of an LCD monitor. The subject's arm is strapped to a sling connected to the arm of the rehabilitation robot. During the experiment, the subject is instructed to move the robot handle to various positions. The subject's arm movement is translated into movement of the virtual object providing 2D visual feedback for the subject. The subject is instructed to perform a reaching movement to the visual targets multiple times.

In this experiment, each subject is presented with a training exercise pattern and asked to move the robot handle to various targets on the pattern. The subject's arm movement is influenced by the presence of assistive and/or resistive forces as determined by a therapist. This is repeated for about 10 trials with resting periods between trials. Each trial has two repetitions. During these trials the data are recorded by the robot software for each of the primary variables (range of motion, average velocity of movement, and accuracy of movement). The subjects are required to repeat this experiment for a period of four weeks with two sessions of about one and a half hours each per week.

Experiment 3

The subject is seated in front of an LCD monitor. The subject's arm is strapped to a sling connected to the arm of the rehabilitation robot. During the experiment, the subject is instructed to move the robot handle to various positions. The subject's arm movement is translated into movement of the virtual object providing 2D visual feedback for the subject. The subject is instructed to perform a reaching movement to the visual targets, multiple times.

In this experiment, each subject is presented with a training exercise pattern and asked to move the robot handle to various targets on the pattern. The subject's arm movement is influenced by the presence of assistive and resistive forces as determined by the expert system along with the robot software. This is repeated for about 10 trials with resting periods between trials. Each trial has two repetitions. The subjects are required to repeat this experiment for a period of four weeks with two sessions of about one and a half hours each per week. During these trials the data are recorded by the robot software for each of the primary variables (range of motion, average velocity of movement, accuracy of movement, and assistive and resistive forces).

6.6.3 Step-by-Step Overview of the Study Protocol

Experimental group – robotic training with the expert system

Control group – robotic training without the expert system

STEP 1. Base-line (initial) testing should be done for all subjects.

- Therapist should conduct the tests and measure the Fugl-Meyer score, Motor Status Score for shoulder and elbow (MS1), and Motor Activity Log (MAL). This will be used for post-training comparisons.
- Therapist should conduct tests and find out the patient conditions regarding Passive Range of Motion (PROM – limited / normal), and tone in the passive range (normal / MAS1 / MAS1+ / MAS2). Store the results in *patient_conditions.dat* file.

STEP 2. Initial testing using the robot – should be done for all subjects.

- Center_y: Measure the subject's center of y position and record it.
- AROM: Measure the Active Range of Motion (AROM) using the *testing_AROM* program. This program allows the subjects to reach each of the eight targets on their own and measure the shortest range. Subjects will be asked to perform this at a comfortable speed. Run the *testing_AROM* program again and verify the measured AROM. Save the recorded data file.
- Velocity: Use the measured AROM in the *testing_vel* program. Now measure the slowest speed. Subjects will be asked to perform this at a comfortable speed and as accurately as possible. Save the recorded data file.
- PROM: Measure the Passive Range of Motion (PROM) using the *testing_PROM* program. This program is similar to the *testing_AROM* program.

For this program increase the range to be beyond the AROM value and the therapist will manually stretch the arm to reach the targets. Note the maximum range at which the subject is able to reach all targets. Save the recorded data file.

- *Assist_force*: Measure the minimum required assistive force using the *testing_assist* program. Set the range to the measured PROM value and slowly increase/decrease the assistive force. Record the minimum required force to reach all targets. Save the recorded data file.
- Determine the strength of the unaffected arm. Measure the maximum tolerable resistive force of the unaffected arm using the *testing_resist* program. Use the measured AROM value. The handle will be at the center. Ask the subject to reach each of the eight targets. Now slowly increase/decrease the resistance value. Record the resistance value at which the subject is not able to reach at least one target. This gives a quantitative measure of strength in the unaffected arm.
- *Resist_force*: Measure the maximum tolerable resistive force using the *testing_resist* program for the affected arm within the active range. If this value is the same as the unaffected arm then strength is not diminished. In the *patient_conditions.dat* file record if the strength is diminished. Save the recorded data file.

Initial testing is done. Send the subject home.

(Steps 3, 4, 6 and 7 are for the experimental group. For the control group only step 5 is given; however the parameters for step 5 are manually calculated and verified by the therapist.)

STEP 3. Use the recorded data file from *testing_vel* program and run the *dyn_analyze* program on it. This program calculates the average deviation, accuracy, average velocity and peak resultant velocity, and stores the results in *curr_params.dat*. Copy *curr_params.dat* as *prev_params.dat*.

STEP 4. Run the expert system on the *patient_conditions.dat* to determine the steps in training.

STEP 5. Subject training – run the training programs as suggested by the expert system after the parameters are verified by the therapist.

- *begin_A* and *begin_B* are warm-up programs to slowly stretch the ROM and slowly increase the velocity. There are five trials each with two repetitions on the diagonal pattern. The subject is given rest between each trial. Resistance and assistance is minimal. No analysis is done at the end of these programs but data are saved for future verification purposes.
- *train_ROM* and *train_strength* programs: They are used for stretching the range and for strengthening the affected arm. They use *curr_params.dat*. There will be

10 trials each with two repetitions. The subject is given rest between each trial.

Data during the training should be saved for analysis.

STEP 6. After every two sessions (i.e., one week of training with the same parameters) use the recorded data file from the training sessions and run the *dyn_analyze* program on it. This program calculates the average deviation, accuracy, average velocity, and peak resultant velocity, and stores the results in *curr_params.dat*.

STEP 7. Run the expert system to determine the progress and the future training steps.

Repeat steps 5, 6 and 7 for four weeks (two sessions per week).

STEP 8. End-treatment testing. Repeat step 1a and 1b to collect all the end-treatment data.

Chapter 7 Experimental Results

As explained in the study protocol two human subjects were recruited for this study. One of the subjects was assigned to the experimental group and one to the control group.

7.1 Baseline Evaluations

In the screening examination conducted at the first visit of each patient to the NRL, eligible patients had their medical history carefully reviewed, including all past and current medication use, and they went through a neuromuscular examination. The examination included standard clinical tests of muscle strength, deep tendon reflexes, two-point discrimination, and joint proprioception. The screening examination also included a Mini-Mental Status Examination (Folstein *et al.*, 1975). The scoring sheet used for Mini-Mental Status Examination and the various other base-line evaluations are included in Appendix F.

A baseline evaluation was conducted for each qualified subject immediately after the screening examination to assess the patient's sensorimotor function. Primary measure for the motor function of the hemiparetic upper limb are the Motor Status Score for shoulder and elbow (MS1) and Fugl-Meyer Assessment (FMA) score for upper extremity. The MS1 has been found to be one of the most sensitive clinical scores in detecting changes in motor function after robot-aided training (Aisen *et al.*, 1997;

Volpe *et al.*, 2000). A quantitative assessment of motor function of hemiparetic upper limb was also conducted using the robot. All sensorimotor evaluations were conducted by a physical therapist that was unaware of the subject's group assignment (experimental versus control group). Other neuromotor functional assessment techniques which were used include: Motor Status Score for wrist and fingers (MS2), Motor Activity Log (MAL), and Modified Ashworth Scale (MAS).

Motor Status Score – The Motor Status score (MSS) is an expanded Fugl-Meyer assessment to increase the number of isolated muscle groups assessed in the hemiparetic limb (Ferraro *et al.*, 2002). The MSS for shoulder and elbow (MS1) consists of a sum of scores given to 12 shoulder movements and five elbow/forearm movements (maximum score = 40). MS1 uses a six-point ordinal (unequal intervals) grading scale (0, 1-, 1, 1+, 2-, and 2), ranging from no volitional movement to faultless movement. The MSS for wrist and fingers (MS2) consists of a sum of scores for three wrist movements and 12 hand movements. The MS1 is capable of detecting a significant advantage of robot therapy for shoulder and elbow (Aisen *et al.*, 1997; Volpe *et al.*, 2000).

Fugl-Meyer Assessment – The upper extremity motor section of the Fugl-Meyer Assessment (FMA) scale is applied to measure the ability to move the hemiparetic arm outside the synergistic pattern (impairment level) on a three-point scale (maximum score of 66 points). The FMA scale has been found to be valid (Fugl-

Meyer *et al.*, 1975), reliable (Duncan *et al.*, 1983), and responsive in the first six months after stroke (De Weerd and Harrison, 1985). The FMA scale is widely used in evaluating the effectiveness of robot-aided therapy (Burgar *et al.*, 2000; Lum *et al.*, 2002).

Motor Activity Log – Amount of use (AOU) and quality of movement (QOM) of the hemiparetic upper limb are assessed by means of the Motor Activity Log (MAL), a questionnaire evaluating 14 specific activities on a six-point scale (Taub *et al.*, 1993). The AOU scale ranges from 0 (never use the affected arm for this activity) to 5 (always use the affected arm for this activity). The QOM scale also ranges from 0 (inability to use the affected arm for this activity) to 5 (ability to use the affected arm for this activity just as well as before the stroke). The sum of the ratings on the MAL is divided by the number of specified daily activities that the patient actually performed, resulting in a mean score per item.

Modified Ashworth Scale – The Modified Ashworth Scale (MAS) is a six-point rating scale that is used to measure muscle tone. This test is also performed by moving the part through the joint range of motion (ROM), with no specification as to the speed of the movement.

Quantitative assessment of motor function for upper extremities – The motor function of the hemiparetic arm/hand is also evaluated using the InMotion² robot. At

the time of initial testing, in addition to the motor evaluation by a therapist, the subjects were tested using the robot. Quantitative assessment done utilizing the robot uses some Tcl/Tk programs that provide the user interface as well as control the robot through the Linux kernel module. The testing program display a circular pattern with eight different targets along the circumference and the subjects are asked to move the robot arm from the center of the circle to each of the targets sequentially. Figure 7-1 shows a screenshot of the testing program. During this movement the velocity of the motion, the active and passive range of motion, the accuracy of movement, and the required assistive/resistive forces are measured and recorded. These values provide a quantitative assessment of the subject's upper limb motor function. This data can be used to compare with the values obtained from the end-treatment testing which uses the same programs as the initial testing.

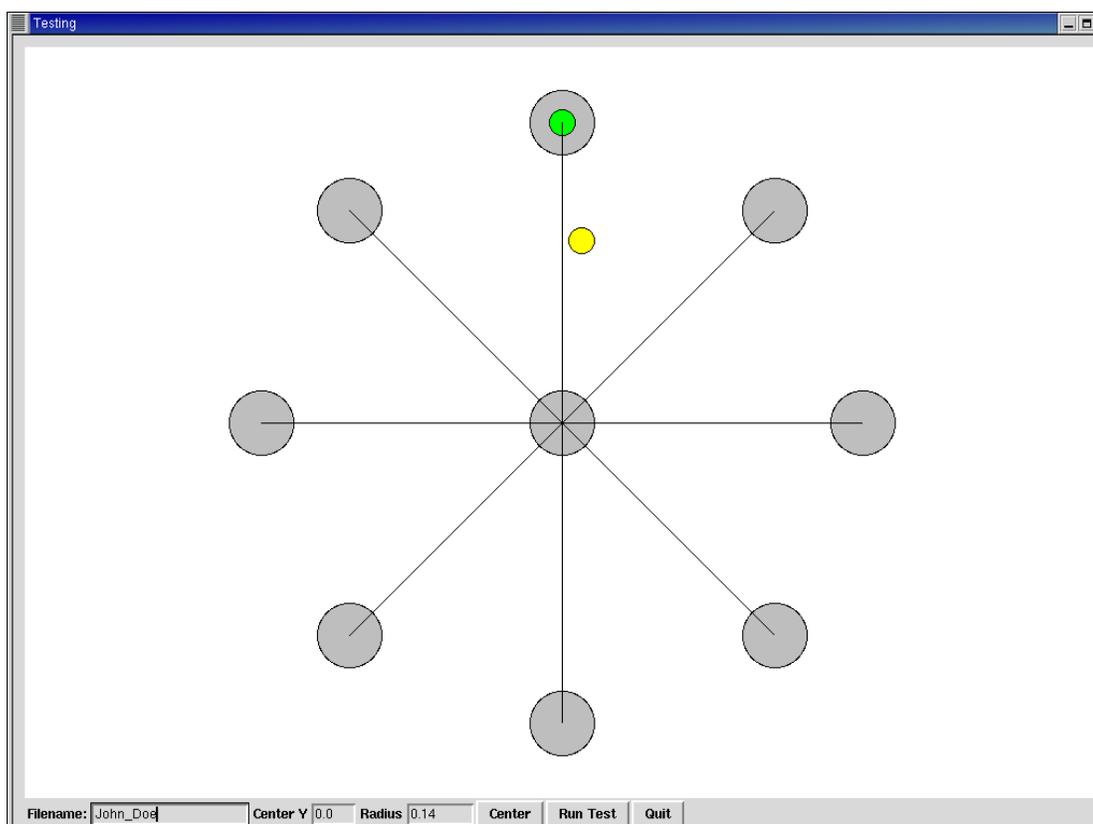


Figure 7-1 Screenshot of the testing program.

Baseline Evaluation Results

The evaluation of the two chronic subjects who participated in the study presented with similar neuromotor function in the affected arm. Apart from the number of years since the stroke, the two cases are very similar. This can be seen from Table 7-1, which provides a comparison of the baseline values for the two subjects. Having similar cases in the control and experimental groups provides a good scenario for post treatment comparison.

Table 7-1 Baseline comparison of experimental and control subject.

Characteristics	Experimental Subject	Control Subject
Years post stroke	7	34
Affected side	Left	Right
FMA Score - Sensory	3	6
FMA Score - Motor	32	30
MSS shoulder/elbow (MS1)	28.8	23.8
MSS wrist/hand (MS2)	9	7
Modified Ashworth Scale	2	2
AROM	0.17 m	0.17 m
Velocity	0.05961 m/sec	0.02371 m/sec
Assistance	N/A	N/A
Resistance	43 N/m	22 N/m
Accuracy	86.1%	93.3%

The baseline value for the minimum assistive force required is not available for either subject because of the high active range of motion (AROM) value. The safe workspace of the robot is limited to about 0.17m (17cm) radius and in most clinical studies involving the InMotion² robot, therapy is administered within a ROM value of 0.14m (14cm) (Dipietro *et al.*, 2006). Assistive force is required only for passive movement of the arm in the subject's passive range of motion (PROM). The passive range is usually beyond the subject's active range. In this study, both subjects have an AROM of 0.17m, thereby eliminating the need for passive movement training and the assistive forces associated with such a movement.

7.2 Subject Training

The therapist who evaluated the subjects and the subjects themselves were unaware of the subjects' group assignment. Hence the therapist's opinion was sought regarding the best robot-aided treatment option for both subjects. The therapist opined that since the subjects do not have PROM limitation (i.e., within the applicable range of robot therapy), they should be trained for improving strength and accuracy. Even though both subjects exhibited moderate tone on the Modified Ashworth Scale, according to the therapist, the tone was pronounced only in the passive range. Thus, if the robot training is limited to the active range, tone is not a concern.

7.2.1 Experimental Subject Training

For the experimental subject, the expert system is used to determine the treatment plan. Since the subject does not have PROM limitation, the expert system chose strength training treatment. For the robot training, the parameter values are chosen from the initial testing data. However for the AROM, if the subject's AROM is greater than 14cm, then it is automatically capped at 14cm. As in this case, the subject's AROM was 17cm and so the training program uses an AROM value of 14cm.

As shown in Figure 5-5, where protocol 1 indicates that before strength training there is a warm-up session. The warm-up program consists of five trials. For the first trial the ROM is set to be the subject's AROM (which is capped at 14cm) minus 4cm,

resulting in 10cm. Then for each of the subsequent trials the ROM is increased by 1cm. For this subject, the ROM values for each trial during the warm-up session are 10cm, 11cm, 12cm, 13cm, and 14cm. Thus the subject slowly goes from a smaller range to full AROM which provides a gradual stretching effect in their arm.

In the strength training exercise, the robot is positioned at the center of a square and the targets are placed at the four corners of the square. A screenshot of this program is shown in Figure 7-2, and a subject using the training program is shown in Figure 7-3. The subject is asked to reach the targets moving along the diagonal of the square. The robot arm resists any movement away from the center position. The maximum tolerable resistance measured during the testing session is used by the training program. The training session consists of 10 trials with ample resting period between each trial. In each trial the subject is required to reach the targets twice, i.e., two repetitions in each trial. The training program also keeps track of the number of targets missed by the subject. Each target has a maximum time-out period of about two minutes after which the target expires and moves to the next position.

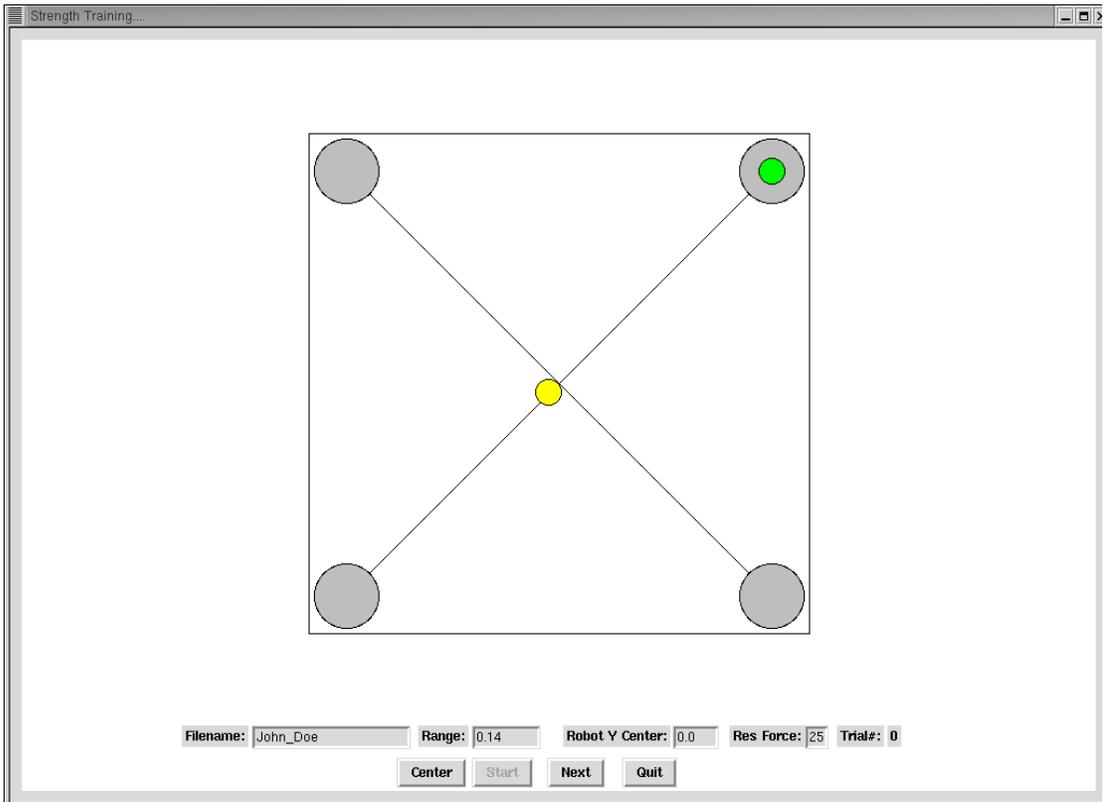


Figure 7-2 Screenshot of the strength training program.



Figure 7-3 A subject during strength training treatment.

After every two strength training sessions, the analysis program is used on the experimental subject's training data to measure the average deviation, percentage accuracy, and velocity of movement. The reason for consolidating two training sessions instead of analyzing every session is to allow for the day to day variations in the motor functions of the hemiparetic arm. Following the analysis of the training data, the expert system is used again to determine any progress made by the subject. According to the expert system, perceivable progress is made only if a number of conditions are all satisfied:

- At least 95% of the targets are reached
- Measured accuracy is better than 90%
- Velocity has improved (i.e., greater than the last velocity measured)

For the experimental subject, only once during the four week training did the expert system detect progress and subsequently increased the resistance value for future training. This change in resistance was approved by the therapist.

7.2.2 Control Subject Training

As mentioned earlier, the therapist determined that strength training would be appropriate for the control subject as well. The control subject used the same strength training program under the supervision of the therapist. The therapist also felt that the warm-up program is appropriate, and used it for the control subject as well. The main difference in the treatment for the control subject is that the performance of the subject during training was visually monitored and manually noted if any targets were missed by the subject. Then at the end of every training session, based on this observation it was determined whether the subject has made enough progress to warrant any increase in resistance. Both the control and the experimental subjects received verbal encouragement during the training sessions.

7.3 End-Treatment Evaluations

The end-treatment evaluation was conducted within five days after the completion of the training. The same tests that were used during the baseline

evaluation were used again to assess the neuromotor functions of the subjects. The results of the end-treatment evaluations of the two subjects are given in Table 7-2. In addition, the table also shows the change in scores compared to the baseline values.

Table 7-2 End-treatment comparison of experimental and control subject.

Characteristics	Experimental Subject		Control Subject	
	End-treatment	Improvement	End-treatment	Improvement
Years post stroke	7	N/A	34	N/A
Affected side	Left	N/A	Right	N/A
FMA Score - Sensory	5	+2	6	0
FMA Score - Motor	34	+2	33	+3
MSS shoulder/elbow (MS1)	26.8	-2	19.8	-2
MSS wrist/hand (MS2)	4	-5	6	-1
Modified Ashworth Scale	2	0	2	0
AROM	0.17 m	0	0.17 m	0
Velocity	0.0787 m/sec	+0.0191	0.02672 m/sec	+0.003
Assistance	N/A	N/A	N/A	N/A
Resistance	46 N/m	+3	28 N/m	+6
Accuracy	86.6%	+0.5%	95.3%	+2%

7.4 Effectiveness of the Rehabilitation System

After the initial testing, the expert system was used to determine a treatment plan for the experimental subject. The expert system arrived at the conclusion that strength training should be carried out because the subject had no PROM limitation

within the range of the robot. The therapist agreed with this decision of the expert system and the subject went through strength training for four weeks. During the four weeks, after every two training sessions the expert system was used to monitor the progress. Only once during this period did the expert system detected progress and increased the resistance. After reviewing the data, the therapist agreed with that decision as well.

For the control subject, after the initial assessment, the therapist determined that strength training would be most suitable. After the therapist made the decision, the control subject's initial conditions were input to the expert system and it arrived at the same conclusion as the therapist. After the first two sessions of strength training, according to the therapist's observation the subject had made progress and so decided to increase the resistance. Similar to what was done at the beginning, the therapist's decision was checked against the expert system. The training data from the first two sessions were fed to the analysis program and the expert system. The expert system did not detect enough progress with the subject because the velocity had not improved.

Apart from the expert system, the therapist was very pleased with the analysis program. The data collected during a training session typically contains close to 115,000 data points (one data entry for every 30ms). The analysis program makes it possible to quickly analyze and summarize the data from an entire training session.

For an average person, in order to analyze the training data using a standard spreadsheet program, it will take at least about one to two hours. The analysis program eliminates the need for this kind of manual analysis.

Chapter 8 Conclusions

The objective of this work is to design, develop, and evaluate an expert system based post-stroke robotic rehabilitation system. The new rehabilitation system can be a valuable tool for therapists in analyzing the data from the robot, helping them make the right decisions regarding the progress of the stroke patient, suggesting future training exercises, and delivering robotic therapy.

In order to develop an expert system to aid in stroke rehabilitation, solid understanding of the current stroke rehabilitation practices is imperative. Hence, a survey was conducted among the clinicians in Kansas and Missouri. The majority responses from the clinicians were directly used to construct a treatment plan for robotic rehabilitation. The treatment plan was implemented as the rule base of the expert system. The delivery of robotic rehabilitation required the development of certain testing programs and training programs, and a data analysis program that can analyze the voluminous training data and summarize it to the expert system. These associated components were developed as part of a new robotic rehabilitation system.

Once the rehabilitation system was developed, it was evaluated in a clinical setting. A protocol was developed to conduct a pilot clinical study to test the rehabilitation system. Following the approval from the Institutional Review Board, the clinical study was conducted with two human subjects.

This clinical study is not intended to verify the effectiveness of robot-aided treatment but to verify the effectiveness of the newly developed expert system-based rehabilitation system. The effectiveness of the expert system, the testing and training programs, and the analysis program was evident from the fact that the therapist agreed with the analysis and the decisions made by the system.

8.1 Discussion

The expert system-based rehabilitation was studied both for its correctness and usefulness. The correctness of the expert system was evaluated based on how close its decisions are to that of the therapist. Twice the expert system made decisions regarding the treatment plan and regarding the progress of the subject in the experimental group. Both these times the therapist agreed with the decisions and was satisfied by the reasons provided. The reasons are explanatory statements provided by the expert system on how it reached its decision. For the control subject the therapist made the decisions about the treatment plan and the progress. When the expert system was used to test the therapist's decision, it produced the same treatment plan but not the same decision about the subject's progress. Although the numbers are not statistically significant (due to the small number of subjects involved), the decisions of the expert system still coincided with the therapist's decisions three out of four times. The one time in which the expert system produced a different result can be attributed to the fact that the therapist made the decision about the subject's progress

based mainly on visual observation. The therapist did not use any tools to analyze the quantitative data. The therapist followed the procedure that clinicians follow in everyday practice.

The training programs record data at an interval of about 30 to 40 milliseconds. The data file produced by the training programs on average consists of about 115,000 data points. Manual analysis of one of the data files using a standard spreadsheet program such as Microsoft Excel could take an average computer user anywhere from one to two hours minimum. A therapist using the robot does not have that kind of time to quantitatively analyze all of the patient's data. The data analysis program developed as part of this rehabilitation system can analyze the data file and produce summaries within a few seconds. It produces information such as the average deviation of the subject's arm from the targeted straight line path, calculates the percentage accuracy as a fraction of the length of the path, calculates the average time taken to reach the targets and thereby the velocity, the average x and y directional forces, and the mean peak resultant velocity. Having this information immediately after a training session would enable the therapist to make sound decisions based on quantitative data. The ability to summarize a training session also means that the therapist does not have to observe the patient continuously. The therapist can simply look at the summarized results at the end of a training session and make decisions.

Although this clinical study was not intended to show the effectiveness of robot therapy, the results show that a subject trained with the robot tends to show improvement in his/her motor functions. This result is consistent with many other studies that have shown that robot therapy improves motor function in hemiparetic arm of stroke patients (Aisen *et al.*, 1997; Burgar *et al.*, 1999; Lum *et al.*, 2002). Figure 8-1 shows the movement of the affected arm of the experimental subject before and after robot-aided strength training. Figure 8-2 shows the movement of the affected arm for the control subject. From Figure 8-1, it can be seen that the accuracy has improved marginally. The mean deviation before the therapy was 0.0139m and after the therapy it was 0.0134m.

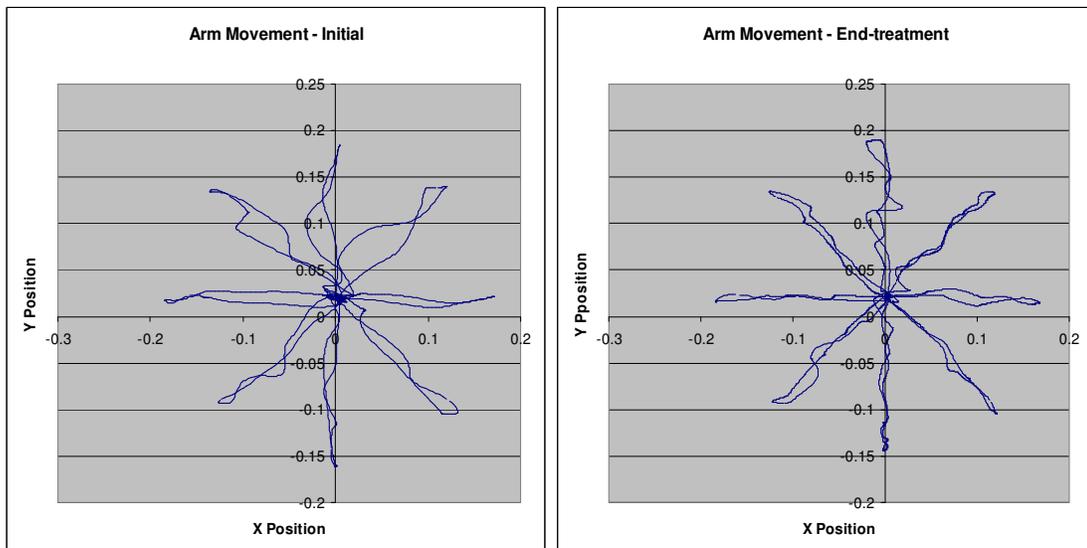


Figure 8-1 Graph depicting the movement of the experimental subject's arm along the x - y plane, before and after treatment. The graph on the left shows the data from the initial testing and the graph on the right shows the data from the end-treatment testing.

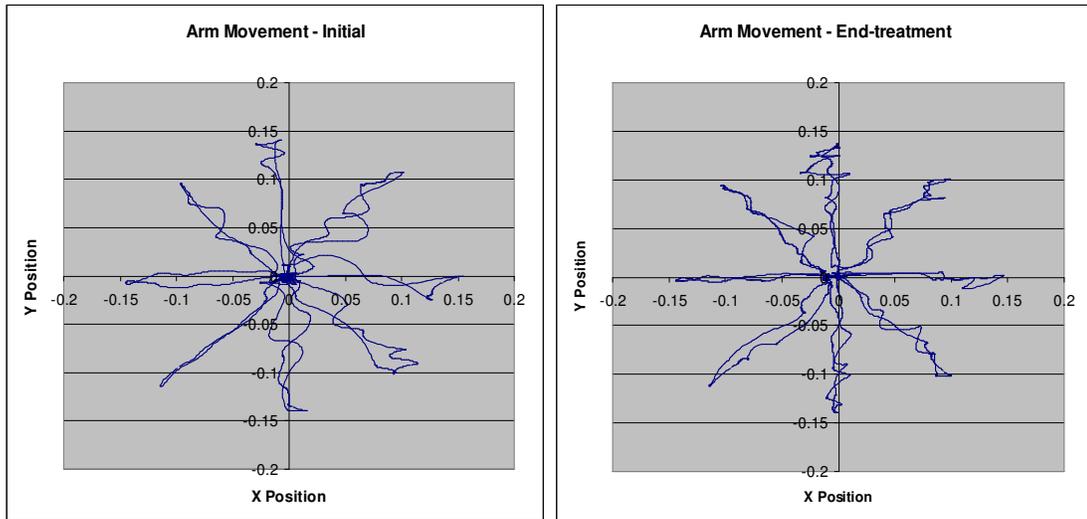


Figure 8-2 Graph depicting the movement of the control subject's arm along the x - y plane, before and after treatment.

Figure 8-2 shows that the control subject's accuracy has improved as well. The mean deviation before the therapy was 0.00675m and after the therapy it was 0.00468m and the percentage accuracy has improved from 93.25% to 95.21%

The results of this clinical study presented in Table 7-2 also show that the experimental subject's Fugl-Meyer Assessment (FMA) for both sensory and motor scores improved by two. Similarly for the control subject, the FMA motor score has improved by three. The FMA score is a criteria widely used by clinicians to assess improvement in stroke patients. The end-treatment testing with the robot also revealed that the experimental subject had a marked improvement (32%) in the velocity of the affected arm. There is also a slight increase in arm strength of both

subjects as measured using the robot. It is observed that the robot therapy had no effect on the active range of motion of the affected arm. This is expected because the subject was given strength training only. There was no training provided to stretch the range of motion of the subject. Moreover, in chronic stroke subjects improvement could take much longer than four weeks.

At the end of the clinical study, both subjects were asked to fill out an exit survey. The questionnaire used for this survey is shown in Appendix H. Because this is a pilot study the survey does not provide any statistically significant results. However, it does show that the subjects who participated in the study were comfortable and enjoyed using the robot. This illustrates that robotic therapy in addition to being effective, can be entertaining and enjoyable for stroke patients as well.

The results presented in Table 7-2 show that both the control subject and the experimental subject benefited from robotic therapy. The improvement in motor performance was similar for both subjects. This proves that the quality of care provided by the expert system-based rehabilitation system is comparable to the care provided by a therapist using existing robotic treatment methods.

8.2 Contributions

A main objective of this research is that the development of a comprehensive treatment plan and the necessary tools to minimize the therapists' time could make

robotic rehabilitation ubiquitous in clinics and hospitals. Consequently, it would make long-term post-stroke rehabilitation affordable for the majority of stroke survivors.

The following are the original contributions of this research:

- Gathered the collective knowledge about current stroke rehabilitation practices from several physical and occupational therapists in Kansas and Missouri.
- Based on the gathered knowledge through the survey and the current literature, a comprehensive treatment protocol for robotic stroke rehabilitation was developed.
- Designed and developed an expert system that can make decisions about treatment options, provide valuable suggestions to the therapist regarding the progress of the patient, and select future training exercises. The expert system uses the knowledge gathered from the clinicians.
- Developed robotic testing and training programs that can safely deliver therapy to stroke patients and record all the data for future analysis.
- Designed and developed software that can analyze and summarize the data from the stroke rehabilitation robot.
- Designed a clinical study protocol and conducted a pilot study to evaluate the effectiveness of the expert system-based robotic rehabilitation procedure.

The results of this research clearly suggest that it is not necessary for a therapist to continuously monitor a stroke patient during robotic training. Given the proper software tools for a rehabilitation robot, therapy can be delivered with minimal supervision. Hence such a rehabilitation system makes it feasible to implement

remote stroke therapy, in which the therapist need not be present physically with the patient, but can monitor and administer therapy from remote locations.

8.3 Limitations

The main limitation of this rehabilitation system is that stroke therapy is very subjective, varying from therapist to therapist and also from patient to patient. Although care was taken to capture the knowledge from several experts, there is no consensus among the therapists regarding the best treatment options. It is still possible that a therapist might reach a conclusion different from that of the one suggested by the expert system based on his/her beliefs and clinical experience.

The survey that was conducted to gather the knowledge regarding stroke rehabilitation had its own limitations. The survey was limited to clinicians in Kansas and Missouri. In addition, the survey was not specific to robotic rehabilitation and hence certain questions pertaining to robotic rehabilitation were out of context. Moreover, robotic rehabilitation is still in its infancy and therefore it is important to familiarize clinicians in the field before gathering their knowledge.

What is more, stroke therapy changes as stroke related research progresses and as medical experts learn more about stroke and the human brain in general. Hence it is imperative that the knowledge base of the expert system be periodically reviewed and updated to include the latest stroke rehabilitation practices.

The clinical study conducted to evaluate the rehabilitation system is a pilot study limited to only two stroke patients. The results of the pilot study should be construed as a “proof of concept” because the results are not statistically significant.

8.4 Future Work

One area of immediate focus following this research could be modifying the expert system to control the InMotion² robot directly. In other words, the expert system will behave as a low-level intelligent controller for the robot producing a real-time adaptive system. In this research, the expert system is allowed to modify the training exercise parameters only after the training session has been completed. Instead the expert system could be allowed to monitor the data and modify the exercise parameters in real-time during the training session. For example, instead of making a patient go through strength training for 10 trials with a constant resistive force, the expert system could be allowed to make changes at the end of each trial or even in the middle of a trial. If the patient reached all targets in this trial then the system increases the resistance. The forces and other parameters of the exercise can also be made direction specific. If the patient is not able to reach all the targets then the system decreases the resistance. Of course, before implementing such a system, stroke rehabilitation literature and experts should be consulted to verify that such a system would be beneficial to stroke patients.

It is also important to conduct a larger clinical study to generate statistically significant results proving the effectiveness of an intelligent rehabilitation system. It is also important to conduct a survey among the patients in the study. Many stroke patients may not be comfortable with the idea of training with a robot on their own (minimal supervision). Understanding the needs of the patients will enable researchers to develop better, more patient friendly robot-aided rehabilitation systems.

Upon conducting initial discussions with some researchers in the field of physical therapy and rehabilitation, it is evident that there is a need for a comprehensive knowledge base. There are numerous evidence based studies conducted regarding the efficacy of various rehabilitation techniques that it would not be possible for clinicians to keep track of all the practices. Hence a comprehensive treatment plan such as the one developed for this expert system could be expanded into an open source resource where any expert, anywhere in the world can input their valuable knowledge and at the same time have it as a reference guide.

Another area directly related to this research is tele-rehabilitation. There are researchers who are currently investigating the possibility of delivering stroke therapy from remote locations. An intelligent rehabilitation system such as the one presented in this dissertation proves that minimally supervised therapy is possible. A rehabilitation robot can be made available at a community clinic and a therapist from

a remote location can periodically review the suggestions made by the expert system in order to approve or modify it.

Another area of focus could be the incorporation of virtual reality (VR). Some rehabilitation systems such as the GENTLE/s have already started implementing VR based therapy. The future post-stroke robotic rehabilitation therapy could include haptic feedback devices and virtual reality based training. In this type of training, the patient will be wearing head-mounted virtual reality goggles which will display a virtual training environment. The robotic device will contain a haptic feedback device which will provide sensory feedback to the patient depending on the level of interaction with the virtual environment.

The success of using the InMotion² robotic rehabilitation system could be followed by the development of a stable exoskeleton arm. The exoskeleton will be designed in such a way that the patient's arm will be covered by the exoskeleton while it will guide the patient's arm as required by the training exercise. The exoskeleton can be combined with any of the aforementioned research concepts.

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Appendix A - Survey

This appendix contains the questionnaire that was used to collect the experts' knowledge regarding current stroke rehabilitation practices, and the accompanying cover letter that was included in the survey.

A.1 Survey Cover Letter

April 29, 2006

Dear Therapist,

I am a graduate student at the University of Kansas currently working on my Ph.D. Dissertation. We are inviting you and your colleagues to participate in a research project to better understand the current practices in **upper extremity rehabilitation of CVA/stroke patients**.

Along with this letter is a short questionnaire that asks a variety of questions about CVA/stroke rehabilitation therapy. We are inviting you, your PT and OT peers to look over the questionnaire and, if you choose to do so, please complete it and send it back to us. The survey should take you about 10 minutes to complete. We hope that you will take the time off your busy schedule to complete this questionnaire and return it. Your participation is entirely voluntary.

Through your participation we hope to understand the current practices in CVA/stroke rehabilitation. We hope that the results of the survey will be useful for future treatment of CVA/stroke patients and we hope to share our results by publishing them in scientific journals and presenting them at conferences so that clinicians and therapists can use them.

There are no risks to you for participating in this survey. We guarantee that your responses will not be identified with you personally. By sending the completed survey back, you will be giving us consent to use this information in our research. To facilitate the return of the completed questionnaire we are including a self-addressed stamped envelope for your convenience.

If you have any questions or concerns about completing the questionnaire please feel free to contact us at the address given below. This study has been approved by the Office of Research Compliance at the Kansas University Medical Center.

Sincerely,

Pradeep Natarajan

Research Team:

Wen Liu, PhD, Patricia Pohl, PT, PhD, S.Omar Ahmad, OT, PhD, Arvin Agah, PhD, Ashley Oelschlaeger (DPT student), Pradeep Natarajan (Ph.D. Candidate).

Contact Information:

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The University of Kansas Medical Center

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Kansas City, Kansas 66160

A.2 Questionnaire

This questionnaire pertains to upper extremity rehabilitation of CVA/stroke patients. You will also be asked about your educational background and your current approach to treating CVA/stroke patients. Please complete the questionnaire if you participate in the treatment of CVA/stroke patients.

Questionnaire

1) Background and Treatment Approach

What year did you complete your school training as an occupational/physical therapist and what is your degree (BS, MSPT, DPT, PhD, etc.)?

What profession are you in (please select one)?

Occupational Therapy

Physical Therapy

Other, please specify: _____

Which method(s) of CVA/stroke treatment were you taught in your school training?
(Please select ALL that apply)

- Bobath/NDT
- PNF/Brunnstrom
- Davies
- Carr and Shepherd
- Constrained Induced
- Other, please specify: _____

Which method(s) of CVA/stroke treatment do you practice in your profession?
(Please select ALL that apply)

- Bobath/NDT
- PNF/Brunnstrom
- Davies
- Carr and Shepherd
- Constrained Induced
- Other, please specify: _____

How long have you been treating CVA/stroke patients? _____

Do you work with adults or children or both?

- Adults Children Both

Within which type(s) of care have you worked with CVA/stroke patients? (Please select ALL that apply)

- Acute care
- Nursing home
- Rehabilitation unit
- Home health
- Outpatient clinic
- Other, please specify: _____

Have you had any additional training after graduation specific to the rehabilitation of individuals with stroke?

- Yes
- No

If you answered "Yes" to the above question, please specify the type of training:

Do you participate in continuing education?

- Yes
- No

If you answered “Yes” to the previous question, please select the type(s) of continuing education you participate, from the following list:

- Attend seminars/conferences
- Read professional literature
- Involved in research
- Write books/manuals
- Other, please specify: _____

Approximately how often do you read professional literature on CVA/stroke?

- Every week
- About once a month
- Rarely
- Never

Please indicate your level of agreement with the following statements.

You incorporate concepts of motor learning from current literature in your practice.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

II) Aim of Treatment

Re-educate normal movement.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

Facilitate postural adjustments.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

Facilitate adaptation to function.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

Prevent secondary complications in neuromuscular function.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

III) Pertaining to Tone

In patients where tone is present, normalizing tone is important when facilitating movement.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

The practice of functional tasks may normalize the patient’s tone and access more normal movement patterns.

- Strongly Agree Agree Unsure Disagree Strongly Disagree

Inhibition of spasticity does not necessarily result in movement; movement needs to be facilitated.

Strongly Agree Agree Unsure Disagree Strongly Disagree

IV) Facilitation of Movement

Proximal stability is a pre-requisite of distal selective movement.

Strongly Agree Agree Unsure Disagree Strongly Disagree

Treating proximal stability will not necessarily result in recovery of distal movement in the limbs; distal movement needs to be facilitated.

Strongly Agree Agree Unsure Disagree Strongly Disagree

The therapist's role is to facilitate normal movement components.

Strongly Agree Agree Unsure Disagree Strongly Disagree

CVA/Stroke patients need hands-on training.

Strongly Agree Agree Unsure Disagree Strongly Disagree

CVA/Stroke patients need task oriented functional practice.

Strongly Agree Agree Unsure Disagree Strongly Disagree

CVA/Stroke patients need hands-on **and** task oriented functional practice.

Strongly Agree Agree Unsure Disagree Strongly Disagree

Activating movements bilaterally makes use of ipsilateral movements to promote recovery of the affected side.

Strongly Agree Agree Unsure Disagree Strongly Disagree

V) Function

In patients where the potential for recovery of normal movement exists, therapists should delay performing certain activities if they are reinforcing abnormal movement patterns.

Strongly Agree Agree Unsure Disagree Strongly Disagree

Changing the patient's ability to move does not necessarily improve the patient's ability to perform functional tasks.

Strongly Agree Agree Unsure Disagree Strongly Disagree

Intensive training of single plane movement patterns can carry over into activities of daily living.

Strongly Agree Agree Unsure Disagree Strongly Disagree

If the proper software tools are available and easy to use, would you incorporate robot assisted motor rehabilitation in addition to standard therapy treatments?

Yes No Unsure

VI) Specific Questions in Motor Rehabilitation

Active assistive movement is useful in patients with muscle weakness.

Strongly Agree Agree Unsure Disagree Strongly Disagree

In your opinion, what should be done to the speed of movement for individuals with *high tone*? Velocity should _____

Increase Remain constant Decrease

In your opinion, what should be done to the speed of movement for individuals with *low tone*? Velocity should _____

Increase Remain constant Decrease

Patients presenting with limited active range of motion would begin with small amplitude movements.

Strongly Agree Agree Unsure Disagree Strongly Disagree

Patients presenting with limited passive range of motion would begin with small amplitude movements.

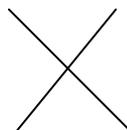
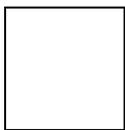
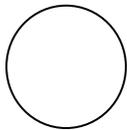
Strongly Agree Agree Unsure Disagree Strongly Disagree

Passive range of motion is important for treatment.

Strongly Agree Agree Unsure Disagree Strongly Disagree

Which single plane movement pattern would be most beneficial? (Please rank them with '1' being the most beneficial and '4' the least).

Circular _____ Square _____ Diagonal _____ Other (please specify) _____



In your opinion, which of the following aspects is most important in determining the progress of the patient? (Please rank them with '1' being the most important and '5' the least important.)

_____ Speed _____ Accuracy _____ Strength
_____ Number of repetitions (endurance) _____ Other (Please specify)

If you have any comments on the questionnaire or the topics it deals with, please share them with us. We value your time and thank you for your participation.

Appendix B – Survey Statistics

This appendix contains the basic statistical results of the survey conducted to collect expert knowledge on stroke rehabilitation. It shows the questions asked along with the responses from the therapists. The respondents were divided into two groups, namely occupational therapists (OTs) and physical therapists (PTs). The basic statistics are shown for each group separately.

Basic Statistics from the Survey

Total number of questionnaires sent out = **320**

Number of respondents that returned the questionnaire because they were not qualified = 6

Number of questionnaires that were returned as undeliverable = 9

Effective number of questionnaires sent to qualified therapists = $320 - 15 = \mathbf{305}$

Number of respondents that completed the survey = 110 (3 respondents do not have enough experience with CVA but completed the questionnaire)

Number of qualified responses = **107**

Response rate = $111/305 = \mathbf{36.39\%}$

A) Background and Treatment Approach

A1) What year did you complete your school training and what is your degree?

Number of respondents that specified year of graduation from school = 93

Average year of graduation = 1994

Number of respondents that specified educational background = 106

Respondents with Master's degree = 47

Respondents with Bachelors degree = 56

A2) What profession are you in?

Total number of responses = 107

Number of respondents who are OTs = 51

Number of respondents who are PTs = 55

Number of respondents who are both OTs and PTs = 1

A3) *Which method(s) of CVA/stroke treatment were you taught in your school training?*

Total number of responses = 107

Number of respondents who have had school training in Bobath/NDT = 102

Number of respondents who have had school training in PNF/Brunnstrom = 106

Number of respondents who have had school training in Davies = 7

Number of respondents who have had school training in Carr and Sheperd = 11

Number of respondents who have had school training in Constraint Induced Movement Therapy = 12

Number of respondents who have had school training in Other methods = 14

A4) *Which method(s) of CVA/stroke treatment do you practice in your profession?*

Total number of responses = 107

Number of respondents who practice Bobath/NDT in their profession = 99

Number of respondents who practice PNF/Brunnstrom in their profession = 91

Number of respondents who practice Davies in their profession = 3

Number of respondents who practice Carr and Sheperd in their profession = 9

Number of respondents who practice Constraint Induced Movement Therapy in their profession = 25

Number of respondents who practice Other methods in their profession = 13

A5) *How long have you been treating CVA/stroke patients?*

Total number of responses = 107

Average years of experience in treating stroke patients = 12.6 years

A6) *Do you work with adults or children or both?*

Total number of responses = 106

Number of respondents who work only with adults = 80

Number of respondents who work only with children = 4

Number of respondents who work with both adults and children = 22

A7) *Within which type(s) of care have you worked with CVA/stroke patients?*

Total number of responses = 107

Number of respondents who work in Acute Care = 81

Number of respondents who work in Nursing Home = 55

Number of respondents who work in Rehabilitation Unit = 75

Number of respondents who work in Home Health = 45

Number of respondents who work in Outpatient Clinic = 81

Number of respondents who work with Other types = 5

A8) *Have you had any additional training after graduation specific to the rehabilitation of individuals with stroke?*

Total number of responses = 105

Number of respondents who have had additional training after graduation = 71

Number of respondents who have NOT had additional training after graduation = 34

A10) *Do you participate in continuing education?*

Total number of responses = 106

Number of respondents who participate in continuing education = 105

Number of respondents who do NOT participate in continuing education = 1

A11) *If you answered “Yes” to the above question, please select the type(s) of continuing education you participate.*

Total number of responses = 105

Number of respondents who Attend seminars/conferences = 105

Number of respondents who Read professional literature = 76

Number of respondents who are Involved in research = 4

Number of respondents who Write books/manuals = 1

Number of respondents who are involved in Other activities = 7

A12) *Approximately how often do you read professional literature on CVA/stroke?*

Total number of responses = 107

Number of respondents who read Every week = 4

Number of respondents who read About once a month = 43

Number of respondents who read Rarely = 62

Number of respondents who Never read = 2

A13) *You incorporate concepts of motor learning from current literature in your practice.*

Total number of responses = 108			OTs = 50		PTs = 57	
Strongly Agree	8	7.407%	4	8.000%	4	7.018%
Agree	68	62.963%	31	62.000%	37	64.912%
Unsure	23	21.296%	12	24.000%	11	19.298%
Disagree	8	7.407%	2	4.000%	5	8.772%
Strongly Disagree	1	0.926%	1	2.000%	0	0.000%

B) Aim of Treatment

B1) Re-educate normal movement.

Total number of responses = 109			OTs = 50		PTs = 56	
Strongly Agree	52	47.706%	26	50.000%	26	46.429%
Agree	55	50.459%	24	46.154%	30	53.571%
Unsure	2	1.835%	2	3.846%	0	0.000%
Disagree	0	0.000%	0	0.000%	0	0.000%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

B2) Facilitate postural adjustments.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	40	36.364%	17	32.692%	23	40.351%
Agree	68	61.818%	33	63.462%	34	59.649%
Unsure	2	1.818%	2	3.846%	0	0.000%
Disagree	0	0.000%	0	0.000%	0	0.000%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

B3) Facilitate adaptation to function.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	51	46.364%	26	50.000%	25	43.860%
Agree	51	46.364%	26	50.000%	24	42.105%
Unsure	5	4.545%	0	0.000%	5	8.772%
Disagree	3	2.727%	0	0.000%	3	5.263%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

B4) Prevent secondary complications in neuromuscular function.

Total number of responses = 109			OTs = 52		PTs = 56	
Strongly Agree	36	33.028%	20	38.462%	16	28.571%
Agree	67	61.468%	29	55.769%	38	67.857%
Unsure	5	4.587%	3	5.769%	1	1.786%
Disagree	1	0.917%	0	0.000%	1	1.786%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

C) Pertaining to Tone

C1) In patients where tone is present, normalizing tone is important when facilitating movement.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	35	31.818%	21	40.385%	14	24.561%
Agree	62	56.364%	29	55.769%	32	56.140%
Unsure	8	7.273%	3	5.769%	6	10.526%
Disagree	5	4.545%	0	0.000%	5	8.772%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

C2) The practice of functional tasks may normalize the patient's tone and access more normal movement patterns.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	27	24.545%	15	28.846%	11	19.298%
Agree	58	52.727%	31	59.615%	27	47.368%
Unsure	14	12.727%	2	3.846%	13	22.807%
Disagree	11	10.000%	5	9.615%	6	10.526%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

C3) Inhibition of spasticity does not necessarily result in movement; movement needs to be facilitated.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	14	12.727%	6	11.538%	8	14.035%
Agree	74	67.273%	37	71.154%	36	63.158%
Unsure	15	13.636%	8	15.385%	8	14.035%
Disagree	7	6.364%	2	3.846%	5	8.772%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

D) Facilitation of Movement

D1) Proximal stability is a pre-requisite of distal selective movement.

Total number of responses = 109			OTs = 51		PTs = 57	
Strongly Agree	43	39.450%	21	41.176%	22	38.596%
Agree	51	46.789%	24	47.059%	26	45.614%
Unsure	7	6.422%	2	3.922%	5	8.772%
Disagree	7	6.422%	4	7.843%	3	5.263%
Strongly Disagree	1	0.917%	0	0.000%	1	1.754%

D2) Treating proximal stability will not necessarily result in recovery of distal movement in the limbs; distal movement needs to be facilitated.

Total number of responses = 109			OTs = 51		PTs = 57	
Strongly Agree	23	21.101%	11	21.569%	12	21.053%
Agree	70	64.220%	36	70.588%	33	57.895%
Unsure	11	10.092%	2	3.922%	9	15.789%
Disagree	4	3.670%	1	1.961%	3	5.263%
Strongly Disagree	1	0.917%	1	1.961%	0	0.000%

D3) The therapist's role is to facilitate normal movement components.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	31	28.182%	16	30.769%	15	26.316%
Agree	69	62.727%	34	65.385%	34	59.649%
Unsure	5	4.545%	2	3.846%	3	5.263%
Disagree	5	4.545%	0	0.000%	5	8.772%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

D4) CVA/Stroke patients need hands-on training.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	61	55.455%	28	53.846%	32	56.140%
Agree	44	40.000%	21	40.385%	23	40.351%
Unsure	4	3.636%	3	5.769%	1	1.754%
Disagree	1	0.909%	0	0.000%	1	1.754%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

D5) *CVA/Stroke patients need task oriented functional practice.*

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	47	42.727%	22	42.308%	25	43.860%
Agree	57	51.818%	28	53.846%	28	49.123%
Unsure	5	4.545%	2	3.846%	3	5.263%
Disagree	1	0.909%	0	0.000%	1	1.754%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

D6) *CVA/Stroke patients need hands-on and task oriented functional practice.*

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	63	57.273%	29	55.769%	33	57.895%
Agree	43	39.091%	21	40.385%	22	38.596%
Unsure	3	2.727%	2	3.846%	1	1.754%
Disagree	1	0.909%	0	0.000%	1	1.754%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

D7) *Activating movements bilaterally makes use of ipsilateral movements to promote recovery of the affected side.*

Total number of responses = 109			OTs = 51		PTs = 57	
Strongly Agree	27	24.771%	15	29.412%	12	21.053%
Agree	64	58.716%	30	58.824%	33	57.895%
Unsure	17	15.596%	6	11.765%	11	19.298%
Disagree	1	0.917%	0	0.000%	1	1.754%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

E) Function

E1) *In patients where the potential for recovery of normal movement exists, therapists should delay performing certain activities if they are reinforcing abnormal movement patterns.*

Total number of responses = 109			OTs = 52		PTs = 56	
Strongly Agree	15	13.761%	7	13.462%	8	14.286%
Agree	54	49.541%	27	51.923%	26	46.429%
Unsure	19	17.431%	9	17.308%	10	17.857%
Disagree	20	18.349%	9	17.308%	11	19.643%
Strongly Disagree	1	0.917%	0	0.000%	1	1.786%

E2) *Changing the patient's ability to move does not necessarily improve the patient's ability to perform functional tasks.*

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	8	7.273%	2	3.846%	6	10.526%
Agree	71	64.545%	36	69.231%	34	59.649%
Unsure	11	10.000%	3	5.769%	8	14.035%
Disagree	16	14.545%	8	15.385%	8	14.035%
Strongly Disagree	4	3.636%	3	5.769%	1	1.754%

E3) *Intensive training of single plane movement patterns can carry over into activities of daily living.*

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	6	5.455%	5	9.615%	1	1.754%
Agree	34	30.909%	16	30.769%	18	31.579%
Unsure	30	27.273%	15	28.846%	14	24.561%
Disagree	38	34.545%	16	30.769%	22	38.596%
Strongly Disagree	2	1.818%	0	0.000%	2	3.509%

E4) *If the proper software tools are available and easy to use, would you incorporate robot assisted motor rehabilitation in addition to standard therapy treatments?*

Total number of responses = 110			OTs = 52		PTs = 57	
Yes	30	27.273%	11	21.154%	19	33.333%
No	26	23.636%	11	21.154%	14	24.561%
Unsure	54	49.091%	30	57.692%	24	42.105%

F) Specific Questions in Motor Rehabilitation

F1) Active assistive movement is useful in patients with muscle weakness.

Total number of responses = 110			OTs = 52		PTs = 57	
Strongly Agree	38	34.545%	21	40.385%	17	29.825%
Agree	68	61.818%	30	57.692%	37	64.912%
Unsure	2	1.818%	0	0.000%	2	3.509%
Disagree	2	1.818%	1	1.923%	1	1.754%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

F2) In your opinion, what should be done to the speed of movement for individuals with high tone? Velocity should _____

Total number of responses = 105			OTs = 52		PTs = 52	
Increase	3	2.857%	1	1.923%	1	1.923%
Remain Constant	22	20.952%	14	26.923%	8	15.385%
Decrease	78	74.286%	37	71.154%	41	78.846%
Unsure/Other comments	4	3.810%	4	7.692%	4	7.692%

F3) In your opinion, what should be done to the speed of movement for individuals with low tone? Velocity should _____

Total number of responses = 106			OTs = 52		PTs = 53	
Increase	55	51.887%	28	53.846%	27	50.943%
Remain Constant	44	41.509%	23	44.231%	20	37.736%
Decrease	4	3.774%	1	1.923%	3	5.660%
Unsure/Other comments	5	4.717%	5	9.615%	5	9.434%

F4) Patients presenting with limited active range of motion would begin with small amplitude movements.

Total number of responses = 109			OTs = 52		PTs = 56	
Strongly Agree	8	7.339%	4	7.692%	4	7.143%
Agree	66	60.550%	33	63.462%	33	58.929%
Unsure	19	17.431%	10	19.231%	9	16.071%
Disagree	16	14.679%	5	9.615%	10	17.857%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

F5) *Patients presenting with limited passive range of motion would begin with small amplitude movements.*

Total number of responses = 109			OTs = 52		PTs = 56	
Strongly Agree	9	8.257%	4	7.692%	5	8.929%
Agree	62	56.881%	28	53.846%	34	60.714%
Unsure	21	19.266%	13	25.000%	7	12.500%
Disagree	17	15.596%	7	13.462%	10	17.857%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%

F6) *Passive range of motion is important for treatment.*

Total number of responses = 108			OTs = 52		PTs = 55	
Strongly Agree	14	12.963%	9	17.308%	5	9.091%
Agree	73	67.593%	38	73.077%	34	61.818%
Unsure	13	12.037%	5	9.615%	8	14.545%
Disagree	7	6.481%	0	0.000%	7	12.727%
Strongly Disagree	0	0.000%	0	0.000%	0	0.000%
Unsure/Other comments	10	9.259%	10	19.231%	10	18.182%

F7) *Which single plane movement pattern would be most beneficial? (Please rank them with '1' being the most beneficial and '4' the least).*

Total number of responses = 105

	Rank			
	1	2	3	4
Circular	19	68	10	1
Square	1	12	78	5
Diagonal	80	16	5	0
Other	5	0	3	1

(Scoring: Rank1 = 4 points; Rank 2 = 3 pts; Rank 3 = 2 pts; Rank 4 = 1 pt)

Circular = $4*19 + 3*68 + 2*10 + 1*1 = 301$ points

Square = $4*1 + 3*12 + 2*78 + 1*5 = 201$ points

Diagonal = $4*80 + 3*16 + 2*5 + 1*0 = 378$ points

Other = $4*5 + 3*0 + 2*3 + 1*1 = 27$ points

F8) *In your opinion, which of the following aspects is most important in determining the progress of the patient? (Please rank them with '1' being the most important and '5' the least important.)*

Total number of responses = 106

	Rank				
	1	2	3	4	5
Speed	0	16	21	55	10
Accuracy	62	18	14	8	1
Strength	16	43	29	14	1
Number of Repetitions	12	24	38	24	4
Other	16	1	0	1	0

(Scoring: Rank1 = 5 points; Rank 2 = 4 pts; Rank 3 = 3 pts; Rank 4 = 2 pts; Rank 5 = 1 pt)

Speed = $5*0 + 4*16 + 3*21 + 2*55 + 1*10 = \mathbf{247 \text{ points}}$

Accuracy = $5*62 + 4*18 + 3*14 + 2*8 + 1*1 = \mathbf{441 \text{ points}}$

Strength = $5*16 + 4*43 + 3*29 + 2*14 + 1*1 = \mathbf{368 \text{ points}}$

Number of Repetitions = $5*12 + 4*24 + 3*38 + 2*24 + 1*4 = \mathbf{322 \text{ points}}$

Other = $5*16 + 4*1 + 3*0 + 2*1 + 1*0 = \mathbf{86 \text{ points}}$

Appendix C – Sample Interview with Expert

In this appendix, a sample of one of the interviews/discussions that was carried out with a clinical therapist is presented.

Meeting time: **10/25/2005 (Tuesday) at 4pm**

Trina L. Schulz, MS
Manager of Occupational Therapy
Email address: tschulz@kumc.edu
Phone Number: (913) 588-6788

G032 Wescoe Pavilion
Mail Stop 1046
3901 Rainbow Boulevard
Kansas City, KS 66160

Q: Given the capabilities of the robot what kind of movement patterns would you suggest for the patient to be trained by the robot?

A: Translate very basic patterns into robotic movement patterns. For example feeding pattern (or dressing or grooming patterns) is one of the most commonly used training pattern (feeding pattern can be a simple right to left or left to right movement). It is highly repetitive and more likely to remain unchanged. The patient will be required to repeat the same pattern over a long period of time in real life scenario. Repeating the same pattern with similar forces over a long period of time will enable them to learn the pattern.

Relate the patterns to everyday tasks - like washing the face, inserting the arm through the sleeves of the shirt, pulling up the pants, etc.

Q: How do you deal with spasticity?

A: Use sustained force but not overpowering (in other words move the affected arm very slowly).

Q: What are some patient conditions to be taken into consideration before starting the robotic training?

A:

- Head, neck and trunk control – forcing the patient to an upright position will cause inconvenience to the patient (tilting the head/trunk 20-30 degrees is acceptable).
- Vision and visual perception
- Hearing
- Minimal or moderate cognitive functions
- Cutaneous sensations
- Proprioceptive functions
- Fine motor functions
- Changes in tolerance of pain

The basic idea is that the patient should be actively engaged in the treatment. If the patient is not actively engaged they'll lose interest and get frustrated with the training.

Q: Are there any initial factors to be taken into account – like age, gender, etc?

A: Probably not for this type of robotic training.

Q: When can we put the stroke patient in this type of robotic training?

A: After a couple of days in rehabilitation we can start the robotic training.

Q: How long does a stroke patient usually spend in therapy everyday?

A: On average a stroke patient spends about 3 hours per day in therapy. This mainly includes occupational therapy, physical therapy and speech therapy.

Q: What are some questions we can ask the other experts in a survey?

A:

- What activity (movement pattern) would they do first?
- Would you like the robot to work independently or would like a hands-on approach?
- Would you normalize spasticity before the training?
- Would you use spasticity?
- Would you use an affected arm or not?
- Would you remediate or accommodate?

Q: Can you give us any contacts for further expert interviews?

A: Nancy J. Lawrence, Occupational Therapist. (913) 588-6789

Appendix D – Subject Consent Form

In this appendix the consent form that was approved by the Human Subject Committee is presented. This consent form was used to obtain the consent of the human subjects who participated in this study.

CONSENT FORM Expert System-Based Post-Stroke Robotic Rehabilitation For Hemiparetic Arm HSC# 10878

INTRODUCTION

As a person with stroke, you are being invited to participate in a research study about the use of the InMotion² robotic system in the rehabilitation of stroke survivor's affected arm. This research study will be conducted at the University of Kansas Medical Center with Wen Liu, Ph.D. as the principal investigator. Approximately 10 subjects will be enrolled at KUMC.

You do not have to participate in this research study. Before you make a decision to participate, you should read the rest of this form. Participating in research is different from getting standard health care. The main purpose of research is to benefit future patients and society in general. You might get personal benefit from participating in this study, but you should understand that the purpose of research is to create new knowledge.

BACKGROUND

Each year, more than 700,000 Americans suffer a stroke. Approximately half of stroke survivors are moderately or minimally impaired and loss of arm function is considered to be a major problem among chronic stroke survivors.

Rehabilitation of a stroke survivor's affected arm is very repetitive and the long-term availability of therapists is not always possible. To address these challenges, robotic systems have been used to help therapists with the repetitive tasks of rehabilitation, but until recently, the robotic systems could not analyze information and monitor the progress of the stroke survivor.

A computer program known as expert system has been created for the InMotion² robot. This program will analyze information, monitor the progress of the stroke survivor's rehabilitation and help therapists make decisions about rehabilitation and future exercises. Because of the program's ability to analyze information and make suggestions about therapy, it is called an

expert system.

The InMotion² robot is approved for use in stroke therapy; however, the computer program is still experimental.

PURPOSE

The purpose of this study is to determine if the InMotion² robot is accurate and effective in the rehabilitation of hemiparetic arm (the arm that is affected by a stroke).

PROCEDURES

If you are eligible and decide to participate in this study, your participation will last approximately four (4) weeks. Your participation will involve two (2) training sessions per week, and each training session will last approximately 1 ½ hours.

Three experiments will be done in this study; however, you will not participate in all three experiments. You will be randomly assigned (like flipping a coin) to the control group or to the test group. The control group will participate in experiments 1 and 2. The test group will participate in experiments 1 and 3. No matter which group you are in, you will be trained on the InMotion² robot.



InMotion² robot in the Neuromuscular Research Laboratory



InMotion² robot being used by a patient

(Interactive Motion Technologies, Inc., 2005).

Experiment 1. *All subjects will participate in this experiment. You will be seated in front of a monitor and speakers. Your arm will be strapped into a sling that is connected to the arm of the rehabilitation robot. During the experiment, you will be shown four (4) different patterns on the monitor and will be asked to move the robot handle to various targets on the pattern. Your movements will be represented by the image of a yellow colored circle on the monitor. You will be asked to repeat this activity 10 times with a resting period between each time. This session will last approximately 1 ½ hours.*

The information gathered in experiment 1 will be used by the robot to create training exercises for you.

Experiment 2. *Subjects in the control group will participate in this experiment. If you are in the control group, you will be seated in front of a monitor and speakers. Your arm will be strapped into a sling that is connected to the arm of the rehabilitation robot. During the experiment, you will be shown different training exercise patterns on the monitor, and you will be asked to move the robot handle to various targets on the pattern. Your movements will be represented by the image of a yellow colored circle on the monitor. You will be asked to repeat this activity about 30 times with a resting period between each time. You will repeat experiment 2 at two (2) training sessions per week for four (4) weeks. Each session will last approximately 1 ½ hours.*

Experiment 3. *Subjects in the test group will participate in this experiment. If*

you are in the test group, you will be seated in front of a monitor and speakers. Your arm will be strapped into a sling that is connected to the arm of the rehabilitation robot. During the experiment, you will be asked to move the robot handle to various targets on the pattern. Your movements will be represented by the image of a hand on the monitor. In this experiment, the robot will either assist you as you move the robot handle or it will provide resistance as you move the robot handle. You will be asked to repeat this activity about 30 times with a resting period between each time. You will repeat experiment 2 at two (2) training sessions per week for four (4) weeks. Each session will last approximately 1 ½ hours.

RISKS

As a result of the repetitive activities, your arm, hand or fingers may become tired and/or sore. Resting periods between the activities will be offered to help with this.

There may be other risks that have not yet been identified, and unexpected side effects that have not been previously observed may occur.

NEW FINDINGS STATEMENT

You will be informed if any significant new findings develop during the course of the study that may affect your willingness to participate in this study.

BENEFITS

You may or may not benefit from participating in this study. The rehabilitation therapy may help you regain or improve your control of your arm that was affected by the stroke. It is hoped that additional information gained in this research study may be useful in the treatment of other patients with stroke.

ALTERNATIVES

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you receive at University of Kansas Medical Center.

You may receive currently available treatment for rehabilitating your affected arm, such as visiting a physical or occupational therapist.

COSTS

There are no costs for participating in this study.

PAYMENT TO SUBJECTS

You will not be paid for participating in this study.

IN THE EVENT OF INJURY

In the event you experience a serious side effect during this study, you should immediately contact Dr. Wen Liu at (913) 588-4565. If it is after 5 p.m., a holiday or a weekend, you should call (913) 526-2250.

If you have a bodily injury as a result of participating in this study, care will be provided for you at the usual charge. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs of that care to the extent insurance does not cover them. Payment for lost wages, disability or discomfort is not routinely available. You do not give up any of your legal rights by signing this form.

INSTITUTIONAL DISCLAIMER STATEMENT

If you believe you have been injured as a result of participating in research at Kansas University Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Compensation to persons who are injured as a result of participating in research at KUMC may be available, under certain conditions, as determined by state law or the Kansas Tort Claims Act.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

Efforts will be made to keep your personal information confidential.

Researchers cannot guarantee absolute confidentiality. If the results of this study are published or presented in public, information that identifies you will be removed.

The privacy of your health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission (“authorization”) for KUMC to use and share your health information for the purposes of this research study. If you decide not to sign the form, you cannot be in the study.

To do this research, we need to collect health information that identifies you. We will collect information from activities described in the Procedures section of this form and from your medical record.

Your study-related health information will be used at KU Medical Center by Dr. Liu, members of the research team, the University of Kansas Hospital

Medical Record Department, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

All study information that is sent outside KU Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your health information will not expire unless you cancel it.

QUESTIONS

You have read the information in this form. Dr. Liu or his associates have answered your question(s) to your satisfaction. You know if you have any more questions, concerns or complaints after signing this you may contact Dr. Liu or one of his associates at (913) 588-4565. If you have any questions about your rights as a research subject, you may call (913) 588-1240 or write the Human Subjects Committee, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

Your participation in this study is voluntary and that the choice not to participate or to quit at any time can be made without penalty or loss of benefits. Not participating or quitting will have no effect upon the medical care or treatment you receive now or in the future at the University of Kansas Medical center. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have a right to change your mind about allowing the research team to have access to your health information. If you want to cancel permission to use your health information, you should send a written request to Dr. Liu. The mailing address is Dr. Wen Liu, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

CONSENT

Dr. Liu (or his associates) have given you information about this research study.

They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

I freely and voluntarily consent to participate in this research study. I have read and understand the information in this form and have had an opportunity to ask questions and have them answered. **I will be given a signed copy of the consent form to keep for my records.**

Type/Print Subject's Name

Signature of Subject

Time

Date

Type/Print Name of Witness

Signature of Witness

Date

Type/Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Appendix E – Physician Approval

This appendix presents the documents that were used to obtain the physician approval for each human subject who participated in the study. All the documents were faxed to the physician and it includes a cover letter, a consent form for the physician, and a brief protocol summary of the study.

E.1 Physician Approval - Fax Cover Letter

Attention: Dr. Xxxx Yyyy, MD

June 27, 2007

Dr. Xxxx Yyyy, MD

[Physician's contact information]

Dear Dr. Yyyy,

Included in this FAX is information regarding a robot-aided motor training study that is being initiated at the University of Kansas Medical Center. Please refer to the fact sheet included with this FAX for a description of the study. Also included with this FAX is a form to indicate your approval for **Mr. Aaaa Bbbb** to participate in this study.

Your timely response to this request for your patient to participate in our study would be greatly appreciated! Please feel free to call me if you have any question regarding this study. I can be reached at (913) 588-4565. The form can be faxed back to **(913) 588-4568**.

Sincerely,

Wen Liu, Ph.D.

Assistant Professor

Department of Physical Therapy Education & Center on Aging

University of Kansas Medical Center

E.2 Physician Approval – Consent Form

June 27, 2007

Dr. Xxxx Yyyy, MD.

[Physician's contact information]

Dear Dr. Yyyy,

This letter is in regard to your patient **Mr. Aaaa Bbbb** who has expressed an interest in participating in a clinical trial of a robot-aided motor training program for stroke rehabilitation. The enclosed information sheet describes the study. A brief interview was conducted recently over the phone. We have tried to identify existing medical conditions that might make the motor training and test unsafe. To this point, **Mr. Aaaa Bbbb** meets all criteria for entry into the study.

We have not identified any contraindications preventing Mr. Aaaa Bbbb's recruitment in this study. If you are aware of any issues in her health history that may contraindicate her participation in the study, please indicate so in the comment section below.

Mr. Bbbb has already received information about the study and has given a verbal consent. Written consent will be obtained during a visit to the Neuromuscular Research Lab, prior to the first trial. **We now request your approval for Mr. Bbbb to participate in the clinical trial.** If you have any questions, please do not hesitate to call (913) 588 – 4565. **Please fax the completed form back to (913) 588 – 4568.**

_____ Approve

_____ Do not approve

Reason : _____

Patient's Name

Physician's Signature and Date

Comments :

Sincerely,

Wen Liu, PhD.,
Assistant Professor,
Dept. of Physical Therapy and Rehabilitation Sciences
The University of Kansas Medical Center.

E.3 Physician Approval – Protocol Summary

EXPERT SYSTEM BASED POST-STROKE ROBOTIC REHABILITATION FOR HEMIPARETIC ARM

Protocol Summary

Purpose

The purpose of this study is to develop an expert system based robot-aided motor training program for functional recovery of the paretic upper limbs in chronic stroke patients. The expert system (a computer program) will serve as a valuable tool for therapists in analyzing the data from the robot, helping them make the right decisions regarding the progress of the stroke patient, and suggesting future training exercises.

Procedure

Each participant will make a 3-hour visit to the Georgia Holland Cardiopulmonary & Neuromuscular Research Laboratory at the University of Kansas Medical Center for their initial assessments. The participant will be randomly assigned to an experimental or a control group. Those who are in the experimental group will undergo the robot-aided motor training in the presence of the expert system, while those in the control group will be trained in the same tasks, but without the expert system. All participants will be trained for a total of four weeks (two times per week). The end-training assessment will be conducted within 5 days after completion of training.

Training program:

1) Robot-aided motor training: The participant will sit in front of a computer monitor that provides a series of targets, holding a handle attached to the robot with his/her hand. The participant will be instructed to move the handle from one target to another as indicated on the monitor.

2) Expert System based robot-aided motor training: The procedure is the same as that of the robot-aided motor training except that the parameters (like assistive or resistive forces, range of motion, velocity of motion, etc) of the training exercise will be chosen by a computer program. All the parameters chosen by the computer will be scrutinized by a therapist and will either be approved or rejected. If the computer selected parameters are rejected, the therapist will manually select the appropriate parameters.

Outcome Measures

The motor function of the paretic arm will be evaluated using the robot. The participant will sit in front of a computer monitor holding a robot handle. The participant will be asked to move the handle from a central target to eight designated targets. Movement performance will be compared using pre- and post-training tests.

Appendix F – Subject Evaluations

This appendix consists of all the evaluations carried out for each human subject enrolled in the clinical study. It includes the screening evaluation, base-line and end-treatment evaluations completed by a therapist, as well as the quantitative evaluations completed using the robot.

F.1 Mini-Mental State Examination (MMSE)

Patient Name: _____ Rater Name: _____

Date: _____

Activity	Score
Orientation – one point for each answer	
Ask: “What is the: (year)(season)(date)(day)(month)?”	_____
Ask: “Where are we: (state)(county)(town)(hospital)(floor)?”	_____
Registration – score 1,2,3 points according to how many are repeated	
Name three objects: Give the patient one second to say each.	
Ask the patient to: repeat all three after you have said them.	
Repeat them until the patient learns all three.	_____
Attention and Calculation – one point for each correct subtraction	
Ask the patient to: begin from 100 and count backwards by 7.	
Stop after 5 answers. (93, 86, 79, 72, 65)	_____
Recall – one point for each correct answer	
Ask the patient to: name the three objects from above.	_____
Language	
Ask the patient to: identify and name a pencil and a watch. (2 points)	_____
Ask the patient to: repeat the phrase “No ifs, ands, or buts.” (1 point)	_____
Ask the patient to: “Take a paper in your right hand, fold it in half, and put it on the floor “ (1 point for each task completed properly)	_____
Ask the patient to: read and obey the following: “Close your eyes.” (1 point)	_____
Ask the patient to: write a sentence. (1 point)	_____

Ask the patient to: copy a complex diagram of two interlocking pentagons. (1 point) _____

TOTAL (0-30): _____

F.2 Fugl-Meyer Form

Subject ID: _____ **Visit No.:** _____ **Date:** _____

Side Tested _____

Sensation:

1. Light touch (4) _____
 - a. upper arm (2) _____
 - b. palm of the hand (2) _____

2. Proprioception (8) _____
 - a. Shoulder _____
 - b. Elbow _____
 - c. Wrist _____
 - d. Thumb _____

Total sensory score (12) _____

Motor:

1. Reflexes (4) _____
 - a. Biceps _____
 - b. Triceps _____
2. Flexor synergy (12) _____
3. Extensor synergy (6) _____
4. Movement combining synergies (6) _____
5. Movement out of synergy (6) _____
6. Normal reflex activity (2) _____ (Only if score in test 5 is 6/6)
7. Wrist (10) _____
8. Hand (14) _____
 - a. Finger mass Flexion (2) _____
 - b. Finger Mass Extension (2) _____

c. Grasp (10) _____

Grasp I (2) _____ Grasp II (2) _____ Grasp III (2) _____ Grasp IV (2) _____
Grasp V (2) _____

9. Coordination/Speed (6) _____
Tremor (2) _____ Dysmetria (2) _____ Speed (2) _____

Total motor score (66) _____

Total Score for Upper Extremity (78) _____

F.3 Upper Extremity Motor Status Assessment (MS1 and MS2)

Patient Name: _____

Rater Name: _____

Date: _____

MOVEMENT SCALE — SHOULDER/ELBOW

0 = no volitional movement or no contraction

1- = contraction or patient initiating first few degrees of movement

1 = performs partly/incomplete or uncontrolled motion

1+ = lacking last few degrees of motion

2- = completes full range, decreased control or timing

2 = performs faultlessly (complete, controlled motion)

Place and hold (shoulder: 1B, 2B, 3B, 4B, 5B; elbow: 2B-0 or 1)

MOVEMENT SCALE — WRIST, HAND, AND FINGER

0 = no volitional movement or contraction

1 = performs partial movement

2 = performs complete movement faultlessly

Seated active range of motion (check wheelchair positioning)

Shoulder Movement

1. A. Shoulder flexion to 90°, elbow 0°, forearm neutral _____

Deltoid, Rotator Cuff

B. If placed, can position be held?

Deltoid, Rotator Cuff

2. A. Shoulder abduction to 90°, elbow 0°, forearm pronated _____

Deltoid, Rotator Cuff

B. If placed, can position be held? _____

Deltoid, Rotator Cuff

3. A. Shoulder flex 90° – 150° , elbow 0° _____
Deltoid, Rotator Cuff
- B. If placed, can position be held? _____
Deltoid, Rotator Cuff
4. A. Touch top of head _____
Deltoid, Rotator Cuff, Biceps Brachii, Triceps Brachii
- B. If placed, can position be held? _____
Deltoid, Rotator Cuff, Biceps Brachii, Triceps Brachii
5. A. Touch small of back _____
Subscapularis, Pectoralis Major, Latissimus Dorsi, Teres Major, Deltoid, Upper Trapezius
- B. If placed, can position be held? _____
Subscapularis, Pectoralis Major, Latissimus Dorsi, Teres Major
6. Scapular elevation _____
Upper Trapezius, Levator Scapulae
7. Protraction/retraction of the scapula arm supported on table or lap _____
Serratus Anterior, Rhomboids Major, Minor, Middle Trapezius
8. A. Shoulder flex 0° – 30° , elbow starts at 90° _____
Deltoid, Supraspinatus
- B. Shoulder to 30° extension with elbow flex, forearm supported on table _____
Latissimus Dorsi, Teres Major, Posterior Deltoid
9. A. Shoulder 0° , elbow 90° , shoulder internal rotation to abdomen _____
Subscapularis, Pectoralis Major, Latissimus Dorsi, Teres Major
- B. Shoulder 0° , elbow 90° , shoulder external rotation _____
Infraspinatus, Teres Minor
10. Touch opposite knee _____
Pectoralis Major, Triceps Brachii, Pronator Group

Elbow/Forearm

1. A. Forearm pronation from midposition shoulder 0° , elbow 90° _____
Pronator Group
- B. Forearm supination from midposition shoulder 0° , elbow 90° _____
Biceps Brachii, Supinator
2. A. Elbow 0° , fully flex _____
Biceps Brachii, Brachialis, Brachioradialis
- B. If placed, can position be held? _____
Biceps Brachii, Brachialis, Brachioradialis
3. Full elbow flexion, extend to 0° (gravity eliminated or against gravity) _____
Triceps Brachii
4. Touch opposite shoulder _____
Deltoid, Rotator Cuff, Pectoralis Major, Biceps

Motor Status Score – Shoulder/Elbow (MS1) _____

Wrist Movement

1. Wrist extension with shoulder 0°, elbow 90°, forearm pronated _____
Extensor Carpi Radialis Longus, Brevis, Extensor Carpi Ulnaris
2. Wrist flex with shoulder 0°, elbow 90°, forearm supinated _____
Flexor Carpi Radialis, Flexor Carpi Ulnaris
3. Wrist circumduction shoulder 0°, elbow 90°, forearm pronated _____
Extensor Carpi, Radialis, Ulnaris, Flexor Carpi Radialis, Ulnaris

Hand

1. Fingers—mass flexion (fingers to palm) _____
Flexor Digitorum Superficialis, Profundus, Flexor Digiti Minimi
2. Fingers—mass extension _____
Extensor Digitorum, Extensor Indicis, Extensor Digiti Minimi
3. Hook grasp _____
Flexor Digitorum Superficialis, Profundus
4. Intrinsic plus position _____
Interossei Volar, Dorsal
5. Thumb adduction _____
Abductor Pollicis Longus, Abductor Pollicis Brevis
6. Thumb adduction _____
Adductor Pollicis
7. Opposition to base of digit _____
Opponens Pollicis
8. A. Opposition to digit 2 (tip pinch) _____
B. Opposition to digit 3 (tip pinch) _____
C. Opposition to digit 4 (tip pinch) _____
Opponens Pollicis, Flexor Digitorum Superficialis, Profundus, Flexor Pollicis Longus, Interossei
D. Opposition to digit 5 (tip pinch) _____
Opponens Pollicis, Opponens Digiti Minimi, Flexor Pollicis Longus, Flexor Digitorum Superficialis, Profundus, Interossei
9. A. Opposition to digit 2 (pad pinch) _____
B. Opposition to digit 3 (pad pinch) _____
C. Opposition to digit 4 (pad pinch) _____
D. Opposition to digit 5 (pad pinch) _____
Opponens Pollicis, Flexor Pollicis Brevis, Abductor Pollicis Brevis, Flexor Digitorum Superficialis, Profundus, Interossei, Opponens Digiti Minimi
10. Controlled grasp with soda can grasp, place 2–4 inches away, release _____
11. Pincer grasp with pen (sign name, date, or 3 vertical lines) _____
12. Lateral pinch with key _____

Motor Status Score – Wrist/Hand (MS2) _____

Total movement scale _____

F.4 Motor Activity Log (MAL)

Patient Name: _____

Rater Name: _____

Date: _____

Activities in the Dutch 26-Item Motor Activity Log

The MAL consists of a semi-structured interview for the patient to assess the use of the paretic arm and hand during activities of daily living. Two scores are given for each activity, 1 for the amount of use (AOU) and 1 for the quality of movement (QOM) of the paretic arm. The questions concern activities performed during the past week or, occasionally, the past year. After an initial screening question to verify that the activity at issue has been performed during the time-frame at issue, the patient is asked how much the affected arm participated in this activity. Possible scores range from 0 (never use the affected arm for this activity) to 5 (always use the affected arm for this activity). To measure QOM, the patient is asked how well the affected arm helped during this activity. Possible scores range from 0 (inability to use the affected arm for this activity) to 5 (ability to use the affected arm for this activity just as well as before the stroke).

For each activity the first question is:

Did you perform this activity during the past week?

If the answer is "No," the score is "Not applicable."

If the answer is "Yes," the next questions are:

How much did your affected arm participate in this activity? (AOU scale)

Possible scores range from 0 (never/not at all) to 5 (always/during all the time); and

How well did your affected arm help during this activity? (QOM scale)

Possible scores range from 0 (inability to use the affected arm for this activity) to 5 (ability to use the affected arm just as well as before the stroke).

Sum scores are calculated for the amount of use and quality of movement scales separately. To calculate the sum score, the sum of the activity scores is divided by the number of activities performed

Motor Activity Log Score Sheet

Activities in Original Version (Taub 1993)	AOU	QOM
Steady oneself while standing*		
Put arm through sleeve of clothing		
Carry an object in hand from place to place		
Eat with knife and fork [†]		
Comb hair		
Pick up cup by handle		
Handcraft/card playing/hobbies [‡]		
Hold a book, journal or magazine/turn pages for reading [‡]		
Use towel to dry face or other part of the body		
Pick up glass		
Pick up tooth-brush and brush teeth		
Shaving/make-up		
Use key to open door		
Letter writing/typing		
Additional Activities in Dutch Version (Van der Lee 1999)		
Pour coffee/tea		
Peel fruit or potatoes		
Dial a number on the phone		
Open/close a window		
Open an envelope		
Take money out of a wallet/purse		
Undo buttons on clothing		
Do up buttons on clothing		
Undo a zip		
Do up a zip		
Cut nails		
Other optional activity		

F.5 Modified Ashworth Scale

Patient Name: _____

Rater Name: _____

Date: _____

- 0 (0): No increase in muscle tone
- 1 (1): Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
- 1+ (2): Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range of movement (ROM)
- 2 (3): More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved Considerable increase in muscle tone passive, movement difficult
- 3 (4): Considerable increase in tone, passive movement difficult
- 4 (5): Affected part(s) rigid in flexion or extension.

SCORE: _____

F.6 Quantitative Measures using the Robot

Initial Testing - Data Sheet

Subject ID: _____

Date: _____

[NOTE: Make sure to record each and every trial data. Refer to the study protocol.]

1. Center of Y-axis: _____ meters

2. Active Range of Motion (AROM): _____ meters

[NOTE: All range values are short by 0.007m due to the 0.0035m radius of the target ball and the source ball. According the Tcl programs as soon as the two balls touch each other the target is reached. This means that the actual range reached is 0.007m less, i.e., if the AROM is specified as 0.14m then the actual range reached by the subject before the target moves is only 0.133m]

3. Velocity: _____ cm/sec

4. Passive Range Of Motion (PROM): _____
_____ meters

5. Min. required assistive force: _____
_____ N/m

6. Max. tolerable resistive force of affected arm: _____
_____ N/m

7. Max. tolerable resistive force of unaffected arm: _____
_____ N/m

Appendix G – Subject Training

This appendix includes the training data sheet that were used for manual record keeping.

Strength Training - Data Sheet

Subject ID: _____ **Date:** _____

[NOTE: Make sure to record all the data in a data file.]

Resistance value: _____ N/m.

Trial #	Targets unable to reach	Resistance value (if different from above)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

PROM Training - Data Sheet

Subject ID: _____ **Date:** _____

[NOTE: Make sure to record all the data in a data file.]

Assistance value: _____ N/m.

Trial #	Targets unable to reach	Assistance value (if different from above)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Appendix H – Exit Survey

This appendix includes the exit survey that was used to get feedback from the stroke patients who participated in the study.

Exit Survey for Stroke subjects

Subject ID: _____

Date: _____

Scoring Scale:

DISAGREE				AGREE			
Strongly	Moderately	Somewhat	Little	Little	Somewhat	Moderately	Strongly
0	1	2	3	4	5	6	7

No.	Statement	DISAGREE				AGREE			
		0	1	2	3	4	5	6	7
1	Comfortable with the robot therapy								
2	Enjoyed doing therapy with the robot								
3	Believe the therapy was beneficial								
4	Would like to do more robotic therapy								
5	Would have been a better experience if you were working alone with the robot								
6	Would not mind working with the robot alone (on your own) if it was guaranteed by the therapist to be safe								
7	Would make me feel better/safer if a therapist is supervising the robotic therapy								
8	Would rather work with the robot than a therapist								

9. Were you familiar with (or heard about) robotic therapy before you enrolled for the first study using the robot? Yes / No

10. What can we do to make the therapy sessions more enjoyable or entertaining or interesting?

11. Do you have any suggestions for us?