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ABSTRACT

VIBROTACTILE SENSORY SUBSTITUTION FOR POST-STROKE REHABILITATION

**by
Carlos X Rosado**

The aftermath of a stroke leaves people with side effects such as speech and hearing problems, and loss of sensation in one side of their body. Sensory feedback in the hand is used to assess if the individual is using appropriate grip force to hold and use objects; lack of sensory feedback can lead to dropped or damaged objects, and possible hand injury. Existing force biofeedback devices are overly complex and difficult to use in the home. The goal of this project is to provide increased environmental awareness of hand grip force for individuals with reduced hand sensation. Although hand functionality is complex; a lightweight, low profile glove was created that measures a selected set of finger joint angles and force on finger tips. An algorithm was developed that combines this information to determine the current posture of the hand, and also provides the appropriate vibrotactile feedback to another location on the body that might allow individuals to recover some sense of touch. The method was between 96% and 100% successful in providing the appropriate vibrotactile feedback for normal and large grip forces. Predicting when objects were grasped too loosely was a greater challenge; leading to a separate study showing that appropriate grip force is related to object diameter. This project has identified a unique configuration of sensors and a initial algorithm that can be used improve sensory feedback for rehabilitation to help individuals recover some hand functionality.

**VIBROTACTILE SENSORY SUBSTITUTION
FOR POST-STROKE REHABILITATION**

by
Carlos X Rosado

**A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Biomedical Engineering**

Department of Biomedical Engineering

May 2007

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APPROVAL PAGE

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FOR POST-STROKE REHABILITATION**

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To the one with many names that has put people on my path in order to make me a winner.

Have not I commanded thee? Be strong and of a good courage; be not afraid, neither be thou dismayed: for the LORD thy God is with thee whithersoever thou goest. Joshua 1:9

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It is ten o'clock at night, and tomorrow is my defense day. While the clock on my desk is clicking ticking, ticking, I cannot help looking back. Rushing my application to grad school and looking for a possible advisor, I had the privilege of being interviewed by Dr. Lisa K. Simone.

I remember sitting in front of her desk with my hands sweating. Explaining to her the basics of my thesis idea, she decided to take me under her wing. Since that day she became the keystone, with powerful insights and interesting questions, she guided me and help me to finish this thesis. I also remember Dr. Richard Foulds who without questions provided me with important equipment needed in the project to keep it moving. Dr. Andrew Meyers, who always made time to check my circuits and help me to fix them, and Dr. Bruno Mantilla who encourage me to get into the biomedical field.

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CHAPTER 1

INTRODUCTION

1.1 Statement of the Problem

According to the American Heart Association more than seven-hundred thousand Americans suffer a stroke every year. [1]. Almost forty percent of the people who have experienced a stroke return home with some kind of impairment. The most common are speech and hearing problems, lack of physical strength and mobility, depression, and loss of sensation. Sensory deficits may also affect perception and self awareness; neglect is a common symptom after stroke in which the individual may ignore one of their limbs or half of their body [2]. Because stroke often causes deficits or paralysis on one side of the body, known as hemiplegia, individuals return home relying on the assistance of family caregivers or professional assistance, which can become prohibitively expensive [2]. Activities such as grabbing a spoon, a cup, a can, or changing clothes may become almost impossible to do.

One reason why individuals who have suffered a stroke have difficulty with daily tasks is because they have lost partial or total sensation on the affected side. When someone grabs an object with his/her hands, the physical contact with the skin surface, activates afferent nerves that induce a signal which travels to the brain; this conveys information which the person interprets to know if they have touched the object and how strongly they are grasping the object. This sensation, along with the perception of joint and muscle movement, is known as haptic perception, and this awareness of the body and

its parts is important for effectively performing activities with the hand. For example, if an individual lacks haptic perception he might have difficulty knowing if he is grabbing an object with enough force not to drop it. Without this sensory feedback, individuals must rely more on other feedback such as visual information.

Products have been developed that can reproduce haptic perception, known as haptic feedback systems. These can be used to provide the missing sensory information. One example is the CyberGrasp™ (Immersion Corporation, San Jose, CA), a glove which is combined with the Cyber Glove to measure joint angles and forces. This sophisticated system can be used in a virtual reality environment to provide a feeling of contact with a virtual surface. Micromotors are placed on the fingers and parts of the palm. They vibrate on the area of the hand that is in contact with the virtual surface. While this is very good for virtual reality environments, it is less useful for individuals who have lost sensation on their fingers following a stroke. It is also a very expensive system (currently over twenty-one thousand dollars) which would be difficult to deploy in the home and community.

Therefore, there is currently a need to develop an inexpensive sensory feedback system that increases the level of environmental awareness to assist individuals with daily activities and to help them realize the amount of force they are using with the affected hand.

1.2 Goals of the Thesis

The goal of this work is to develop a system which can sense forces on the hand as an individual touches and uses objects, and to create and apply the appropriate haptic feedback to another part of the body that still has sensation. The feedback presented at different locations on the body represents specific information about the grasp force, including if the force is too high, too low, or changing. The goal is that the individual will feel and interpret the haptic feedback and then correct the amount of grip force they are using before an object is dropped or injury occurs. Although much of the sensory and feedback technology to meet this goal already exists, it has not been embraced for daily rehabilitation purposes such as that proposed here. A large market exists that includes individuals with sensory deficiencies who can really benefit from this type of device.

In order to create the haptic feedback, vibrating micromotors are placed on the skin. This type of haptic feedback is referred to as vibrotactile feedback. To sense grip force and hand posture, sensors using piezoresistive materials are used which are very sensitive to deformation due to pressure or bending. There are two sets of sensors used in this work: one measures joint angles and the other measures force. Measurements of joint bending and fingertip and palm forces were processed through a LabView™ program to provide the most adequate haptic feedback. An algorithm has been created that controls the vibrating micromotors accordantly with the force applied. These motors are physically located on the other side of the body where the stroke has not affected the individual's sensory system.

By creating this feedback and transmitting it to an unaffected area of the body, the goal is to teach the individual to correctly interpret the vibration feedback and to

determine if he/she is appropriately grabbing the object or not. Currently three motors are implemented. The first motor vibrates momentarily to indicate increasing or decreasing of force. The second motor signifies that the object is being grabbed with too much force. The third motor signifies that the object is in danger of falling. The second and third motors continue to provide feedback until the potentially dangerous condition is corrected. This should help the individual have some sense of the force they are using to interact with their environments.

CHAPTER 2

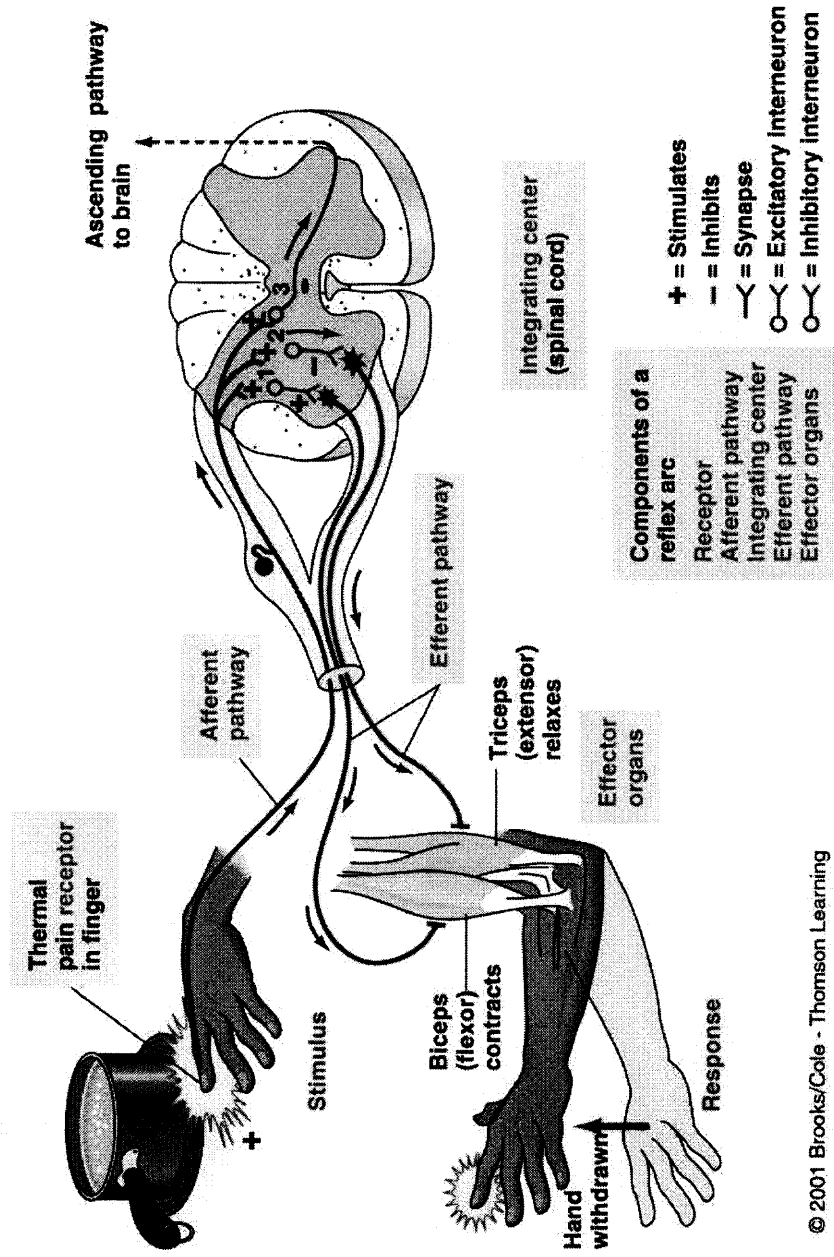
BACKGROUND

2.1 Physical effects of stroke

According to the American Heart Association, there are about 5,500,000 people who have survived a stroke and are currently living in the society. Every year, this number is approximately increased by seven-hundred-thousand [1]. There are mainly two types of strokes, ischemic and hemorrhagic. Both alter the normal flow of blood to the brain. This can prevent blood from reaching some parts of the brain or flood parts of the brain, killing the brain cells [3]. Cells cannot survive without oxygen more than four to five minutes and without glucose more than fifteen minutes; after this time, cells start dying [4].

The resulting effects of a stroke depend upon its location and severity; normal physical functions are usually impaired. A stroke may cause several other effects; for example, a shortage of blood in the temporal lobe may cause vision perception problems such as hemianopsia or language processing problems such as aphasia. If the stroke occurs in the somatosensory area, which is responsible for motor actions such as walking and using the arm, the individual will experience motor function problems such as hemiplegia where there is total or partial inability to move one side of the body, or paresis where the eye muscles are paralyzed [4]. Following a stroke, an individual often suffers more damage in the neighboring area of the brain, aggravating the strokes effects. The severity of impairments depends on how much of the brain is damaged [5].

To understand how a stroke can affect sensory and motor function, it is useful to understand the basic signaling pathways through the brain for these functions. Using the upper extremity and the reflex response when touching a hot object as an example, these pathways are shown in Figure 2.1. Sensory receptors of the hand include mechanoreceptors: Pacinian corpuscles, Meissner's corpuscles, Merkel's discs, and Ruffini⁴⁰ corpuscles. These cells are located between the skin and the sensory nerve and are very good indicators of pressure and temperature. For example the Meissner's corpuscles are very sensitive to slight touch, while the Pacinian corpuscles detect deep pressures and high frequency vibrations. The information received from these cells travels through the afferent neurons in the hand to the posterior horn. Here the signal is projected to the efferent paths to influence muscle control. The sensory signal is also transmitted to an ascending spinal track to the pons, midbrain and eventually the thalamus. Here the signal is distributed to the respective areas of the brain responsible haptic sensation shown in Figure 2.2. Following the stroke, the efferent neurons pathways may still be intact, however, the sensory message is never processed or is incompletely processed, and therefore, the individual's ability for voluntary action is compromised.



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Figure 2.1 Path of the reflexes. Travel of the stimulus from the hand to the spinal cord (Sherwood:[6]).

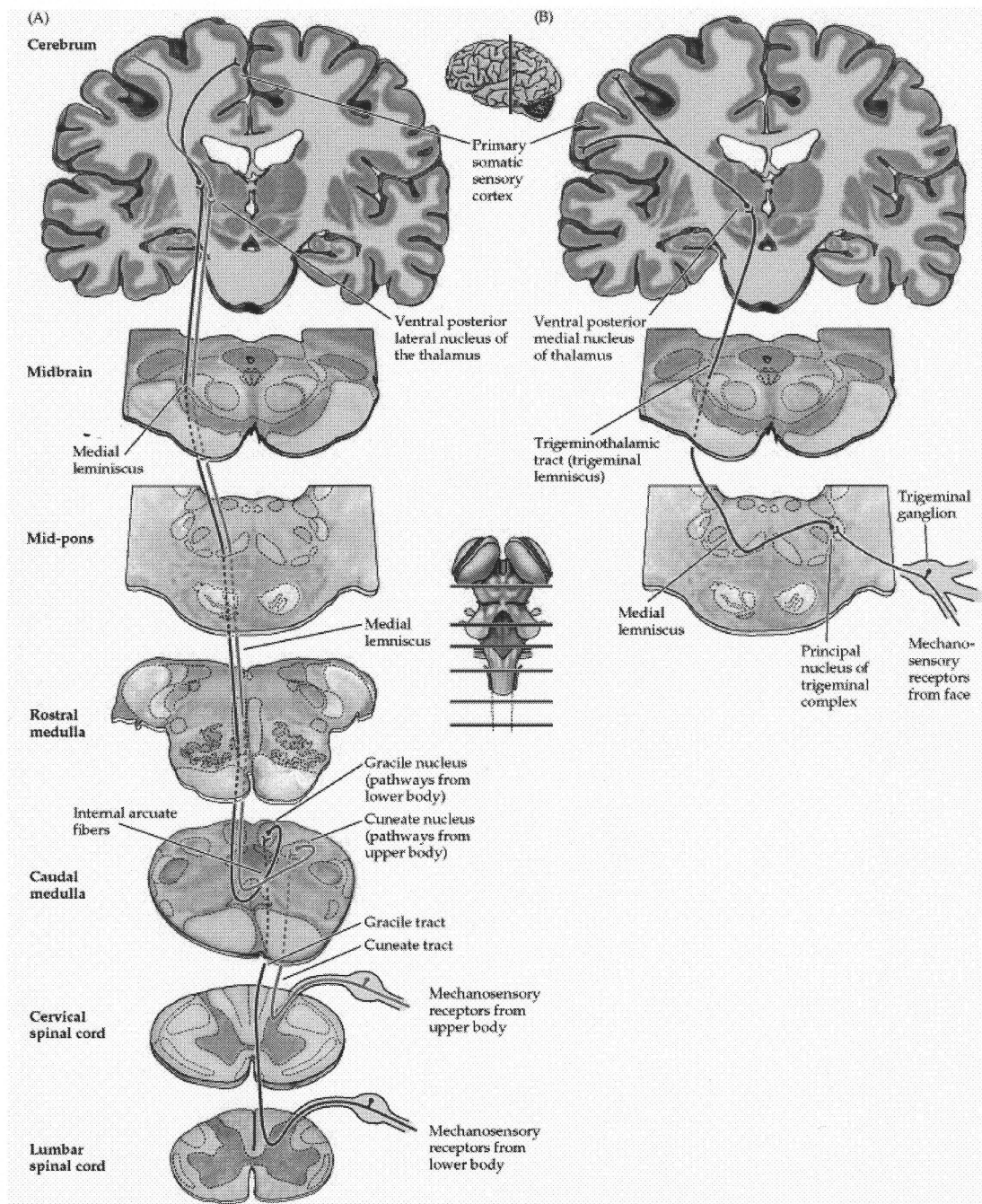


Figure 2.2 Traveling of the signal from the spinal cord to the brain (Sherwood:[6]).

A common effect is paralysis, which may range in severity from mild to severe. The individual can also experience hemiparesis, a weakening condition of the limbs, or hemiplegia, a total paralysis also on one side of the body. Hemiparesis also causes a loss of motor control movements, making regular activities such as walking or dressing very

difficult or impossible. An individual's movements are often unstable, with some lack of coordination. Actions that an individual takes for granted can become very difficult to execute after the stroke.

Another side effect occurs when an individual becomes unaware of one side of his body. This condition is called neglect, and as a result, the individual might forget to take care of it. For example, the individual might forget to dress the affected side, or be aware that it has become injured.

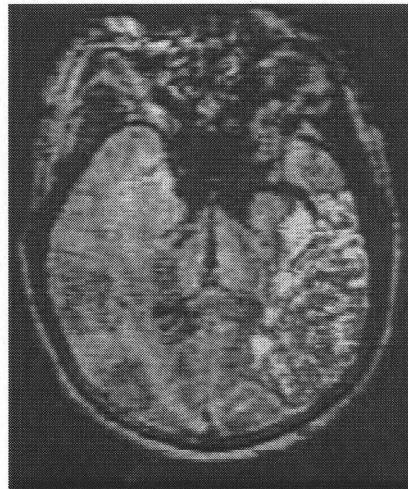


Figure 2.3 Brain Stroke: The purple area is the area damaged by the stroke. It corresponds to the parietal lobe area. Common symptoms are Hemiplegia, Broca's aphasia, sensitive loss; reduced attention span (Brass [7]).

Approximately eighty-five percent of stroke survivors have some sort of upper limb dysfunction [8] that often includes spasticity or loss of motor tone. Spasticity is a common side effect of stroke in which the muscles are inappropriately contracted, making it is very difficult to fully stretch or open the joints. As a result, arm and hand function is limited because joints do not have full range of motion and dexterity is limited. The individual has difficulty opening the hand to grab an object, or manipulate

it. Hypertonicity is another common side effect. The individual is unable to generate enough muscle control to grasp objects with an appropriate level of force to hold and manipulate them effectively. The average strength for a hand grip among healthy women is about 34 lb and men 54 lb [9]. These values are considerably lower for individuals following a stroke, where the range varies from 2.5 lb to 25 lb [10].

As a result of these physical and motor-related side effects of stroke, regular activities like changing clothes or grabbing a spoon to eat are now often done with assistance. In order to function effectively in society and to compensate for functional loss, individuals often begin to rely on someone else for help. This leads to loss of independence and as a result, psychological disorders such as depression are very common [2]. The aftermath of a stroke is a serious problem and a very challenging situation for individuals and their caregivers.

In addition to loss of motor function, many individuals have also lost sensation. According to a study done by Klaus [8], sixty-five percent, or 3,500,000 of the survivors have lost sensation on the affected side. The amount of sensory loss depends on the area and severity of the stroke. For example in Figure 2.1 one can see that the individual is touching a hot object and reacting to the hot stimulus. The signal travels from the hand to the brain, but if the somatosensory area is damaged, the reflect reaction could be completed removed or altered. The more damage in a particular area, the more function loss is presented. Even with a partial lack of sensation, individuals can easily hurt themselves by being unaware of a dangerous stimulus such as fire or sharp edges.

Even if an individual can generate enough force in the hand and fingers to manipulate daily objects, the loss of sensory information can make these tasks difficult.

A good example is writing. Since the individual lacks sensation at the fingers, they may not grab the pencil with enough strength, allowing it to slip. It is very common that the individual tries to compensate for the lack of sensation by applying more force, which ends up locking their fingers and hand [11]. Therefore, individuals overcompensate by using a combination of wrist, elbow and shoulder movements to accomplish a writing task [11]. This results in a hand writing that is not smooth but rather distorted. However, it is possible that significant hand functionality and sensational recovery can be achieved with adequate therapy [8].

It is important to keep in mind that the sense of touch is more complex than just pressure or force applied on the skin. It helps make individuals aware of their surroundings, helps them maintain balance, detect temperature changes and even detect chemicals that may come in contact with the skin. One can infer that it is part of our defense mechanism from the environment. If there is a deficiency in this sense, it makes daily activities such as walking and grabbing objects more difficult because the sensory feedback information is missing. This lack can leave us disoriented and defenseless against any hazard in our environment. Often, individuals with this effect require extra assistance from their other senses or other people in order to function well.

2.2 Compensating for Sensory Loss - Sensory Substitution

To help an individual regain function following a stroke, many therapies are available for physical and occupational rehabilitation that focus on motor function and the performance of daily activities. Because some function may never be regained, clinicians and researchers have investigated a way to supplement or compensate for these losses. Individuals may compensate by using the other limb for some activities, or may use another sense to provide the missing information caused by sensory loss. An example of compensation or sensory substitution is a blind individual who uses of a cane to explore the environment. The cane is used to locate barriers, and transmits, in form of vibration, impulses to the hand holding the cane. The vibrations can be used to interpret the surface contour and roughness. This information helps the blind person walk by himself using the cane as guidance.

The main goal of sensory substitution is to replace a sense such as vision, hearing or touch with a method or tool that can stimulate the other senses to create an orientation in the environment that the missing sense used to provide. Another example of sensorial substitution is the use of Braille raised dots to represent letters that blind people can read using the sense of touch. Another is American Sign Language where hand gestures represent words. Substitution systems can also be machines or devices such as the Tactile Visual Substitution (TVS) which uses small actuators that vibrate in different physical or spatial locations to create a binary image. This allows blind people to recognize some objects. Some of the TVS systems must be placed on a relative large surface area on the body [12].

At the extreme, if the haptic sense is totally unavailable, it is possible for other parts of the brain to take over that function. Due to its plasticity, the brain can reshape to relearn some activities. A study done by Bach-y-Rita [13] shows by using vibrotactile devices, such as micromotors, that a blind person can re-orient himself in the spatial domain. This shows that it was possible to retrain parts of the sensory and neural processing system to process the missing sensory information, and to use other parts of the body to compensate and substitute the information what was provided by the non-working sense.

Sensory substitution is included in some virtual reality systems where objects in three dimensional environments can be view or manipulated by the individual. In many virtual reality systems, the sense of touch is replaced by auditory and visual clues. Users can interact in these artificial environments and perform a variety of activities. The most common virtual reality systems can be seen and used in arcades. Virtual games range from playing soccer, racing in a Formula 1 race car, military missions and others. The interactions in the game immerse the players. For example, the Formula 1 race car have vibrators on the steering wheels that make the user feel the road vibrations, and stereo sound by the driver's head to replicate the noise of other car's engines passing by.

Therapies involving the use of a virtual system have reported an improvement in movement speed and coordination in individuals [14]. However, a full recovery it is not always possible. Ergonomic systems similar to these are effective at training people to use special equipment, and for some rehabilitation therapies. One example of therapy training is driving simulators. Some systems are used to help people who had a spinal cord injury to learn how to drive special cars modified with hand controls. This is

particularly interesting since functions that were done by the feet such as feeling the brakes to come to a stop must be replaced by the use of the hand. Sensory substitution has not taken place but diversification of function has taken place since the hand now performs the functions which were previously fulfilled by the feet.

To use the hand appropriately, an individual must automatically integrate several kinds of information such as joint angles, pressure, force and temperature. Based on all of this information, the brain directs the muscles to apply the appropriate force to interact with the environment. Systems that attempt to provide haptic substitution must simulate or mimic this process.

Some instruments created by Immersion Co. (San Jose, CA) are specialized for hand use such as the CyberGlove, CyberGrasp and CyberTouch. The CyberGlove provides joint angle measurements. This information is important to determine the hand postures needed to grab a particular object. The CyberGrasp attempts to provide feedback force by opposing a natural movement by creating extra resistance when someone reaches and grabs an object. This information helps to determine the shapes and sizes of objects. The CyberTouch provides a set of micro motors placed on the end of the fingers which vibrate while dynamic forces are applied. In a virtual reality system the combination of these three systems gives the users the sensation of touching or grabbing something in the virtual environment. While these systems record and provide a wealth of information, they are expensive and somewhat bulky, making the performance of some activities difficult. Another device used to provide force feedback for precision activities is the PHANTOM (SensAble Technologies, Wolburn, MA). This device can be used in virtual environments and provides resistance to the motions in the virtual environment,

creating a sensation similar to the real world actions. This system is mainly focused on precision type of activities, and the force feedback is provided to the fingers.

The Tekscan GripTM (South Boston, MA) system is a lower-profile system using twenty individual sensors that measures forces while gripping and grasping objects. While the system allows users to grab normal objects, it cost ten-thousand dollars and covers most of the surface of the palm, which reduces the normal sense of touch.

Research done by Rizzo [15] uses the CyberGrasp and the PHANToM to develop a Virtual Therapeutics environment where haptic feedback is provided [15]. The PHANToM is used to simulate small tasks like inserting coins in a vending machine and the CyberGrasp is used for full hand activities. These two devices give some resistance and force that can be felt. Although this system has not been tested on individuals following stroke, it has great potential for those whose have still some sensation in the fingers in order to sense the micro motor feedback applied at the fingertips.

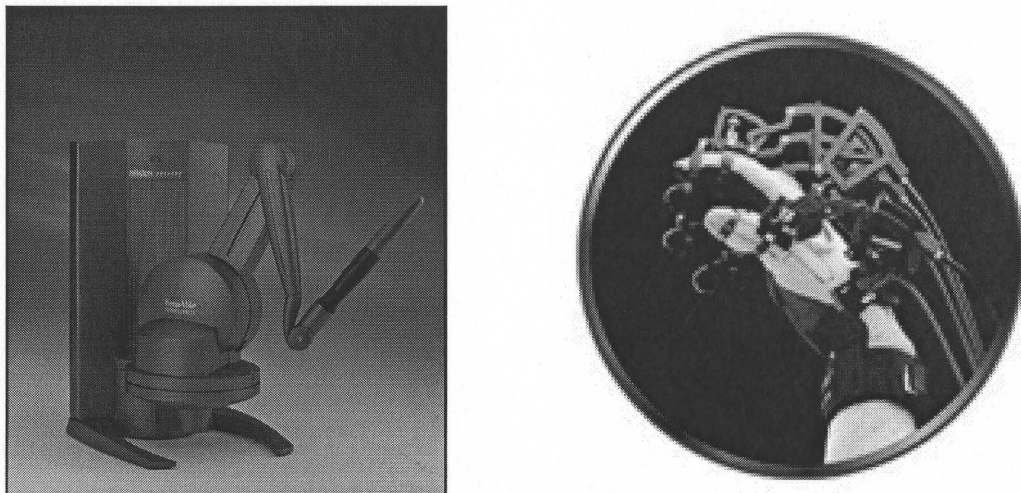


Figure 2.4 The PHANToM and the CyberGrasp (Rizzo: [15]).

Other therapies such as those proposed by Bouzit [16] use similar devices such as the CyberGlove and the Rutgers Master II; the Rutgers Master II is a device that creates

resistance which helps to simulate the physical sensation of an object in the virtual environment. These devices and systems allow the users to see their hand motions and feel objects. As result of these types of therapies, individuals with a stroke may improve hand functionality and strength. A disadvantage of the Rutgers Master II is that force actuators are located in the palm of the hand, making the device impossible to use while interacting with common objects. Force feedback for rehabilitation has also been used by other researchers in a controlled environment.

These force feedback rehabilitation processes are positive in that they create more realistic conditions in the virtual scenarios and help to take measurements that eventually would help to determine if the treatment is effective. They also help to develop more challenging scenarios and better therapies. They provide force feedback over a range of activities and force ranges, which is much more than just the minimal information needed to convey to an individual that their grip force is too tight or too loose. However, these devices have several disadvantages. First, methods that provide feedback directly to the hand will not be as effective for an individual with a stroke who has lost partial or total sensory input in the hand. In addition, these systems are not practical for providing force feedback while individuals participate in normal daily activities outside the clinic or research facility. These solutions are also expensive and not portable, making their applicability for home rehabilitation or use infeasible.

2.3 A Practical Solution

In order to develop a more efficient portable therapy, understanding how the hand functions and how it interacts with the external world is important in order to provide realistic force feedback about inappropriate grip force.

The hand-environment interaction is a combination of joint angles, forces and pressures as individuals interact with the environment. In order to determine if someone is using inappropriate force, it is first useful to determine what hand posture they might be using. Several different classification systems for hand postures have been proposed; the cylindrical, tip, hook, palmar, spherical [17] are the most common ones. To roughly classify hand function, postures and activities can be broken down into power and precision grasps. The power grasp is used to hold or pick up objects such as a book, brick, cans, and bottles. It “has high stability and force, because the whole hand and palm are used” [18]. The precision grip is used to perform fine activities that require precise coordination. The precision grasp has great dexterity, but lacks force, and is used to knit, and pick up tiny things such as earrings or pens. On the right side of Figure 2.5, one can appreciate that the force is mainly applied at the index and thumb while the middle, ring and pinky finger have the tendency to fully bend.

In other work done in the Functional Measurement Laboratory, the Shadow Monitor has been used to measure joint activities [19] while individuals with brain injury and healthy individuals perform different activities with their hands. Different types of hand postures can be detected using a reduced sensor set on the five Metacarpophalangeal (MCP) joints of one hand. In preliminary results, hand activities can be automatically classified into three different groups based on joint bending and

joint speed. These include closed whole hand precision activities (e.g., writing, feeding), open whole hand precision activities (manipulating small objects like checkers or pennies), and open whole hand power grasp activities (holding and manipulating larger objects like a can) [19].

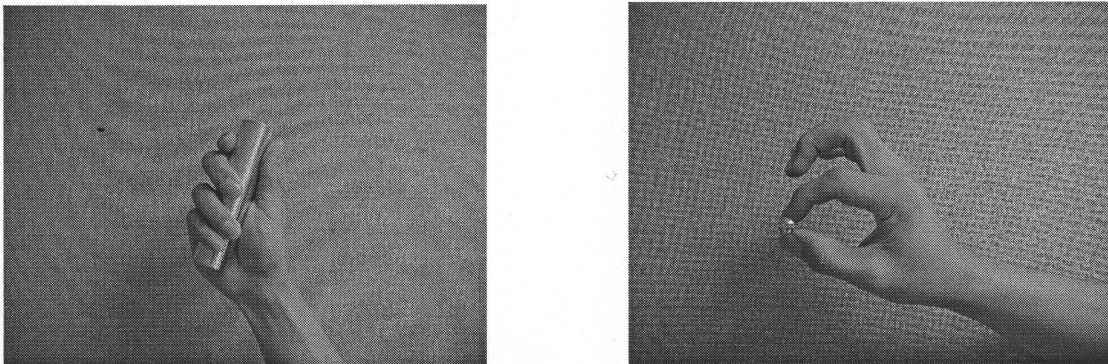


Figure 2.5 Power and Precision Grasp: the image to the left is a power grasp. It is characterized by the use of the palm and all of the fingers. The figure on the right is a precision grasp. It is characterized by the use of the fingers, in particular the thumb and the index finger (Mackenzie [17]).

Portability in this sensory substitution system is desirable, and has been successfully implemented by others. Vibration is used effectively for sensory substitution to provide feedback on balance control. Bach-y-Rita [13] reported an individual with poor balance control due to vestibular damage. The individual's balance was recorded using accelerometers, and feedback was provided using tactile receptors on the tongue to “produce a strong stabilization effect on head and body coordination in subjects with BVD [Bilateral Vestibular Damage].” The individual learned to replace the vestibular information with the new information provide by the tongue device. In this case, the sensory substitution could be provided in a small portable manner that an individual could wear outside the clinic.

To provide force feedback in the virtual environments, actuators or feedback elements can be placed physically close to area being simulated. For example, when using boxing video games, the vibrators are located on the gloves. Another example is a flight simulator where vibrators are in the joystick. If turbulence happens in the virtual flight, the pilot would experience the vibration on his joystick. This is good for training purposes and with healthy individuals, but much less appropriate for providing sensory feedback for individuals after a stroke. If the sensory perception is not functioning properly, as PhD Uri Feintuch, from Hadassah-Hebrew University Medical Center, Jerusalem, Israel, says in a letter response, “[i]n case the patient has total sensory loss in the hand...this system would be useless.” [20]. No matter how hard someone tries, if the brain area responsible for that area is damaged, the stimulus will not be acknowledged.

One approach to solve this problem is to provide sensory feedback on the opposite side of the body that has not been affected by the stroke. Vibration of micromotors provides the stimulus, and the number and/or position of the motors would indicate the amount of force and the type of grasp employed to do perform an activity. Micromotors would be almost unnoticeable to other people while still working on the same principle of sensory substitution/translation. If the amounts of force individuals are using is adequate or not, the motors will help them avoid accidents. By using fewer sensors but locating them in strategic locations, and by locating motors in areas with adequate sensation, this project provides a realistic alternative to current systems. Also this project makes the system portable and therefore the individual can use it outside of a controlled environment and in the home and community.

CHAPTER 3

METHODS: PROCEDURES AND SUBJECT TESTING

Many people who survive a stroke experience long lasting side effects. One such side effect is a reduced sense of touch in the affected hand. Normally, individuals use the sense of touch to control the amount of force that they use to hold and manipulate objects. Following a stroke, regular activities such as grabbing a can or a glass of water can be extremely difficult because the feedback normally received through the sense of touch in the hand and fingers is diminished. As a result, individuals may not grasp items tightly enough and may drop them, or may grasp them too tightly and damage the object or injure their hand.

The objective of this research is to create a biofeedback system that determines if the individual is applying the correct amount of force while manipulating an object, and provides haptic feedback if the force is not appropriate. This system could eventually be useful for those who have had a stroke where the sense of touch has been partially or totally damaged.

To develop the force feedback algorithm and test this device, work was completed in several steps which are outlined here. First, the hardware sensor and feedback system was designed, as described in Chapter 4. Next, an instrumented glove with bend and force sensors was used to collect representative data for a variety of power grasp and precision grip postures. Experimental subjects were asked to hold the objects with different degrees of force. With these data, an algorithm was developed to differentiate between power and precision grasp, and also to determine if the individual was holding the object too tightly or too loosely. As a second test, individuals again performed

different activities with the feedback algorithm in place, and the system was tested to see if the vibration feedback via the micromotors occurred at the right times. The device design and algorithm development specifics and the test results are presented in the following chapters.

3.1 Aims

Aim 1: Collect data in order to analyze hand posture and force applied during typical activities. These data will be used to develop the algorithm to determine what type of activity the individual is performing (power grasp or precision grip), and if the applied force is appropriate.

Aim 2: To develop a vibrotactile biofeedback system to relay haptic feedback to the user. The feedback will be in the form of small vibrating motors mounted on the body. The vibrators are similar to those used in a cell phone when it rings in “vibrate” mode. The exact placement of the sensors on the body is to be determined, but the aim is to keep them as close to the affected hand as possible, in a location where the sense of touch is not as affected. Possible sites include the back of the hand, the arm, or the torso.

Previously collected data shows that it is possible to develop patterns of joint angles (hand posture) that correspond to basic activities such as writing with a pen or picking up a can [21]. However, it is difficult to determine solely from hand posture if an individual is actually grasping an object, or is just holding the hand in a certain position. By adding information about the force measured on the palm and fingers, we can further refine what the individual is doing with the hand. This will allow us to predict hand activity and determine if the measured force is inappropriate. Hand posture and force will be used to create an algorithm that will provide haptic feedback in real time. This will allow the individual to make corrections to the applied hand force with the goal of preventing injury or inappropriate manipulation of objects.

3.2 Device

The device consists of several sensors to measure finger joint bend angle, and force at selected places on the fingers and palm. The concept is based on the Shadow Monitor, a wearable device to measure finger flexion using inexpensive and low profile bend sensors [21]. A picture of the system is shown in Figure 3.1.

Flexiforce A201 sensors (Tekscan, South Boston, MA) are thin flexible sensor containing a layer of pressure sensitive ink sandwiched between two conducting substrate layers. The sensor varies resistance with applied force. Joint flexion is measured using 3" Flexpoint bend sensors (Flexpoint, Draper UT).

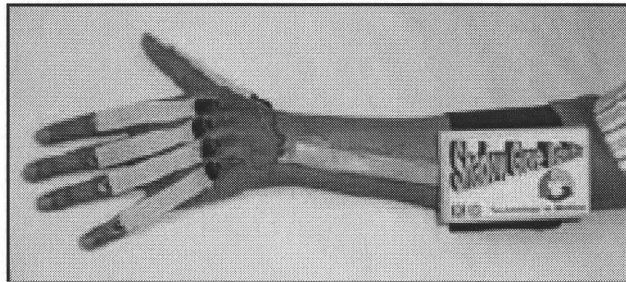


Figure 3.1 Wireless Shadow Monitor: used to measure finger joint activity over time (Simone [21]).

These analog data from force and bend sensors were collected using an National Instruments (NI USB-6251) analog-to-digital converter at a sampling rate of 1000 Hz and 16-bit resolution, and down sampled to 100 Hz. The signal conditioning circuitry for the sensors and feedback system are described in the Chapter 5. A force feedback algorithm was implemented in LabView™ version 7.1 and determines grip posture and evaluates the applied force for each posture. If the applied force is out of range (too tight or too loose), micromotors vibrate to provide this feedback to the wearer. A separate micromotor vibrator is used for each condition (too tight grip, too loose grip). In addition there is a third motor that monitors small changes of forces changes that warns the person about his action. The algorithm is described in Chapter 5 with software listings in Appendix A.

3.3 Subjects

A total of seven healthy individuals between the ages of 18 and 60 were invited to participate in the three parts of this study. Subjects were recruited by word of mouth, and completed the consent process and all protocols in accordance with a protocol approved the NJIT IRB.

The study was divided into three parts; Study Part 1: data collection to develop the threshold determination algorithm for Aim 1; Study Part 2: testing of the system for Aim 2; and Study Part 3: characterizing hand grip force versus object diameter based on observations from Aims 1 and 2. In Part 1, four individuals participated in the study, two men and two women. The average age of study participants was twenty-seven years, and ranged from twenty-two to forty years old. For Part 2, three individuals participated, one man and two women. The average age was twenty-eight with participants ranging from twenty-two to forty years old. For Part 3, seven individuals participated, four men and three women. The average age was twenty-seven with participants ranging from twenty-two to forty years old.

3.4 Study Procedures

3.4.1 Study Part 1, Aim 1: Algorithm Development

Device donning: Flexpoint sensors were placed on the back of the metacarpophalangeal joints; specifically, on the ring, index and the thumb MCP joints. These sensors were used to measure joint bending and hand posture. In addition, five Flexiforce sensors were used to measure grip force on different locations on the hand. Three were placed on the tips of the fingers (thumb, index, and ring) and two were placed in the palm at the site of the index and ring MCPs. These sensors helped to determine how much force the subject was using to pick up an object and the type of grasp the individual was using to complete the task.

Threshold determination: While data were being collected by the computer, the subjects were asked to move their hand in different ways for bend calibration (while the hand was flat, and while the hand was clenched in a fist) and for force calibration (while not grabbing an object, while tightly grabbing an object, and while very lightly grabbing an object as it started to slip from the grasp). From these data, all other data collection trials were calibrated and described in Chapter 5.

Activities: While wearing the sensors, each individual was asked to perform several daily activities which were divided into two groups: power activities and precision activities. The precision grasp activities selected were using a mouse, writing with a pen, and using scissors, and the power grasp activities were holding a bottle, using a spray can, and holding a soup can. At the end of the session, the sensors and glove were removed.

3.4.2 Study Part 2, Aim 2: Device Testing

Device donning and calibration: Sensors were placed on the individual's hand as described in Study Part 1 above.

Activities: Individuals were asked to perform three subtests from the Jebsen Taylor Hand Function Test (a common physical therapy test to evaluate hand function) three different times [22]. Subtests included subtest 1 (writing with a pen), subtest 5 (stacking checkers), and subtest 7 (lifting large heavy objects – a 1 pound soup can). For each of these subtests, individuals were asked to perform the test with normal hand force, then with very heavy hand force (more tightly than they considered normal), and then with light enough grip force that it just dropped from their grasp. The force each individual used was not regulated. For each condition, the status of the micromotor vibrators was recorded to determine if the force feedback algorithm worked correctly. At the end of the session, the sensors and glove were removed.

3.4.3 Study Part 3: Force Testing

As a result of the calibration and force testing in Aims 1 and 2, it was found that each individual had different maximum force readings for different diameter objects. This third study was proposed after the completion of Aims 1 and 2 to explore the relationship between maximum grip forces and object diameter. This trial was performed without the sensors, using a standard hand grip dynamometer from Baseline®.

Activities: Nine maximum grip force trials were performed for each hand. Individuals were asked to hold the dynamometer and then squeeze it as tightly as possible for at least 1 second. The nine trials were divided into sets of three, with the hand dynamometer set to three different grip distances: 3 cm, 6 cm and 10 cm. The nine trials were performed in the following order in order to avoid the effects of fatigue: 10 cm, 6 cm, 3 cm, 10 cm, 6 cm, 3 cm, 10 cm, 6 cm, and 3 cm.

CHAPTER 4

METHODS: DESIGN OF THE SENSING AND FEEDBACK SYSTEMS

4.1 Measuring Force

To create a portable device to provide force feedback for stroke rehabilitation, the device must have a sensing system, an algorithm to predict hand posture and develop the appropriate feedback, and a feedback system to provide the tactile feedback. Several micro motors could be placed on different parts of the body to represent different kind of hand grasp and intensities. For example to express too much force a motor can go on the shoulder while the little of force motor could be place on the ribs.

A precision grasp is used for fine motor tasks like picking up a pencil. A typical amount of force use for this type of grasp is 3.8N [23]. In addition, most of the activities that require the use of a precision grasp use the thumb and the index finger primarily [23]. Considering that an average mechanical pen weights only 0.06 N, 3.8 N is more than enough force to lift it up and overcome friction to hold it while writing.

Another example would be holding a college textbook. Usually one uses the whole hand in a power grasp for this type of activity. The force to hold a small text book is approximately 6.8 N, while that for a bottle is approximately 2.16N. To determine the precise amount of force required to prevent an object from sliding out of the hand, one must know the object's friction coefficient. In daily activities, several objects are picked up thus it would be very hard to know every single friction coefficient and let the system know that the individual is grabbing a particular object, which is a challenge. For this project, a glove is used to increase the amount of friction.

4.2 Force and Bend Sensor Placement

To develop a system that helps a person to be aware of their hand activity, the system will need to have sensors that would determine the individual's course of action. The selected sensor placement depends on hand activities.

In daily activities, one uses partial power and precision grasp. In a previous study done by Hochstein [24] the hand grip used for most of the domestic activities was observed to be the partial power and partial power grip [24]. In order to place sensors on the fingers, it is important to recognize what fingers are used significantly in both types of grips, and measure activities at these fingers in order to understand each hand grip and differentiate them.

Table 4.1 Determining Sensor Placement

Table 1. Prevalence of osteoarthritis and mean flexion angles in digital joints in the precision and partial power grips

	Ranked prevalence of osteoarthritis ^a	Precision grip				Partial power grip				Normal range	
		Mean flexion (°)	SD	Mean SE	Mean SE	Relative flexion (%)	Mean flexion (°)	SD	Mean SE		Relative flexion (%)
<i>DIP joint (n = 6)</i>											
Index finger	49.2	29	13.1	5	34	50	10.7	4	58	86	
Middle finger	42.9	30	5	2	34	53	2.6	1	60	88	
Little finger	35.5	46	10.2	4	51	41	5.1	2	46	90	
Ring finger	32.4	34	2.4	1	39	50	5.9	2	57	88	
<i>PIP joint (n = 6)</i>											
Middle finger	20.9	62	5.8	2	55	78	5.2	2	70	112	
Index finger	17.4	57	5.5	2	51	71	7.8	3	63	112	
Ring finger	15.3	62	4	2	53	75	5.4	2	65	116	
Little finger	14.3	55	6.7	3	49	61	2.6	1	54	113	
<i>MCP joint^b (n = 4)</i>											
Index finger	13.2	47	8.3	4	50	48	9	5	51	94	
Middle finger	10.2	59	9.6	5	60	72	7	4	73	98	
Ring finger	4.1	60	10.5	5	59	78	7.8	4	77	101	
Little finger	2.9	63	7.9	4	57	86	8.9	5	77	111	
(n = 649)											
Correlation coefficient <i>r</i>		-0.88				-0.87				-0.58	(n = 20)
Probability <i>p</i>		<0.001				<0.001				<0.05	

^aMeans are means of subject means

SD, Standard deviation; SE, standard error; DIP, distal interphalangeal; PIP, proximal interphalangeal; MCP, metacarpophalangeal

^bThese figures represent the percentage of joints showing osteoarthritis in the study of Acheson et al. [4]

^cData derived from Alexander and Hochstein [1]

(Alexander: [25])

In Table 4.1 the standard deviation (SD) for the metacarpophalangeal joints of the index finger have high values (8.3 and 9) for precision and power grasp, suggesting that

the index is a good candidate to measure bend and force for both of the grips. Also the thumb is used for both of the hand grasps and opposes the fingers, playing a major role in the force measurements. In addition, the SD for the ring finger marks a noticeable difference in bending (10.3 and 7.8). This helps to differentiate between these types of grips. Only one set of sensors on the ring finger could make the differentiation task difficult. However another characteristic of the power grasp is the use of the palm; therefore, two sensors are being placed here to help to classify the types of grasp.

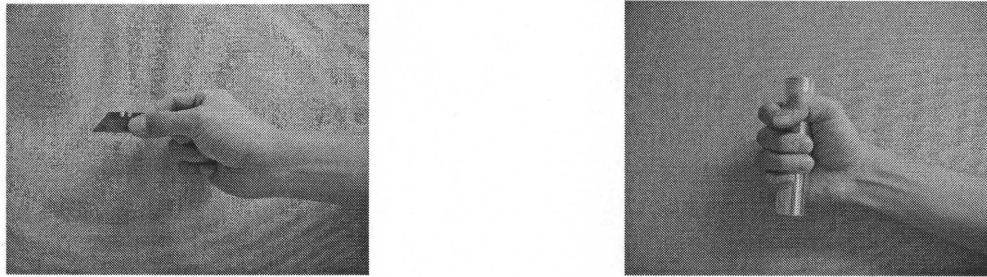


Figure 4.1 Precision grip and Power grip (Mackenzie [17]).

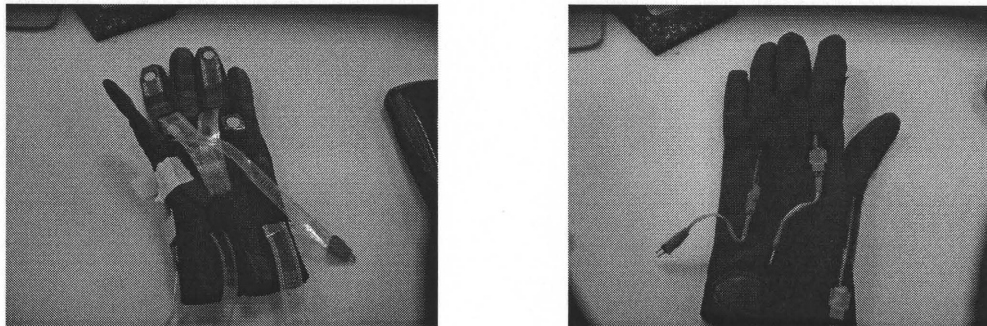


Figure 4.2 Prototype.

Figure 4.1 illustrates the difference between precision and power grip. In Figure 4.2, a prototype of the system developed here is shown. The Flexiforce sensors are shown on the right; these are located on the palm of the glove. The Flexpoint bend sensors are located on the back of the glove. These sensors locations help to determine the type of hand activity and the correct amount of force used.

4.3 Circuit Design

The signal conditioning circuits for the bend sensors and force sensors are shown in Figures 4.3 and 4.4. During daily activities, one is exposed to different types of temperatures. In order to compensate for normal thermal changes, a Wheatstone bridge is added to the system and a differential amplifier is connected after this to amplify the signal difference. The circuit below is used for the Flexiforce sensors (Tekscan, Boston, MA). For the Flexpoint (Draper, UT) circuit, an inverting amplifier is used. The information acquired from this circuit helps to reinforce the decision made by the algorithm regarding the type of grasp.

Force is measured using a combination of a Wheatstone bridge and a differential amplifier to collect the signal. The Wheatstone bridge consists of three resistors of ten mega-ohms each and a Flexiforce sensor (Tekscan, Boston, MA). In order to avoid making the device sensitive to environmental changes the resistors are placed in a Wheatstone bridge and they are connected to a differential amplifier. The author designed this circuit to determine the force applied to the object.

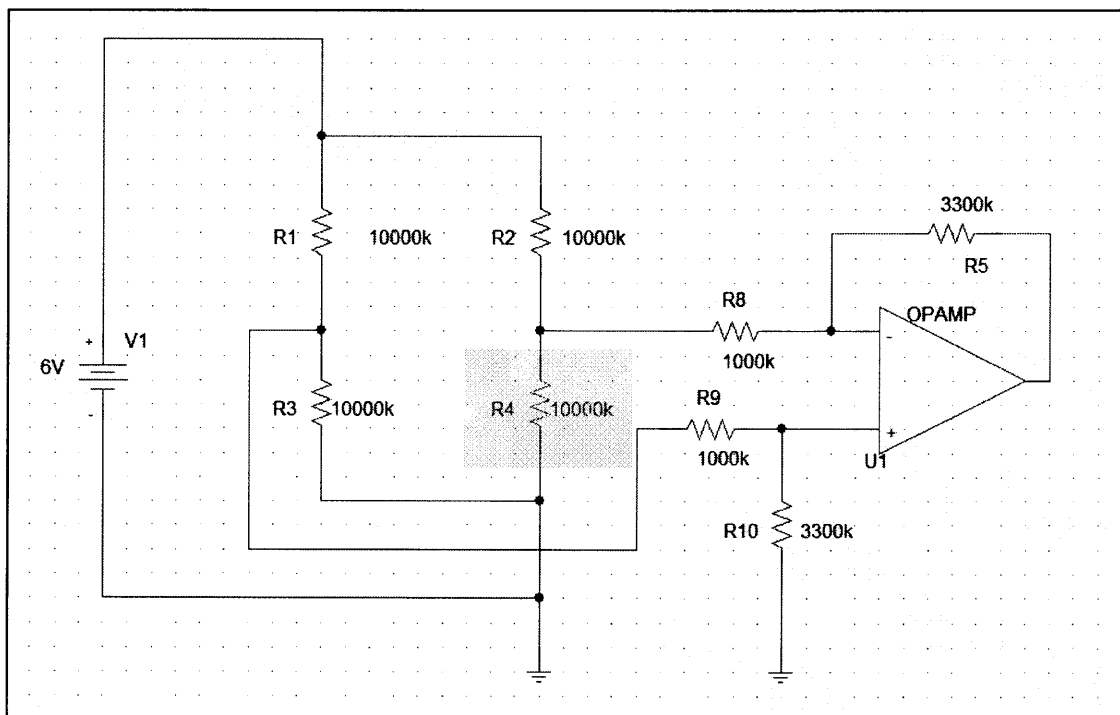


Figure 4.3 Flexiforce Circuit: this is the schematic for each Flexiforce sensor. The Wheatstone bridge is at the left and the differential amplifier at the right. R4 is the Flexiforce.

Joint angle bend is measured using Flexipoint (Draper, UT) sensors. These are placed in series with a one-hundred k Ω resistor Figure 4.3. When the Flexipoint (Draper, UT) bends, it changes resistance. This model for the Flexpoint sensor has been tested in a previous study using the Shadow Monitor designed by Dr. Simone [21]. The voltage difference is sent to a DAQmx card and then processed in a computer program. Based on the collected information, it determines if the amount of force is too much or appropriate for the joint angle and hand posture combination.

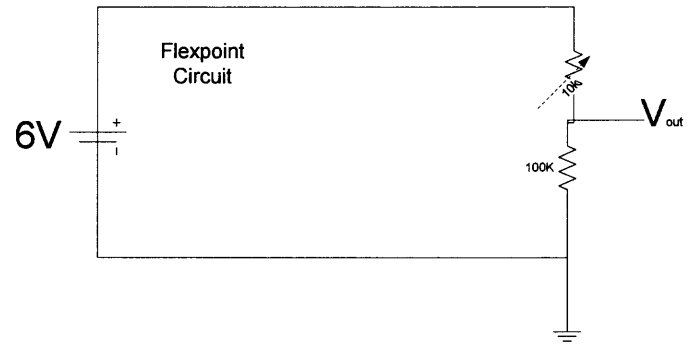


Figure 4.4 Flexpoint Circuit.

4.4 Basic Force Feedback Logic

Eight analog input signals from the sensors go to the DAQmx card which sends the information to the computer where a LabView™ program detects hand activity. If hand activity is detected, the algorithm differentiates between power grasp and precision grip. Depending upon the posture classification, will determines the appropriate force range for the grasp.

The biofeedback circuit consists of a digital output control signal from the DAQmx to a relay. The relay closes and allows current flow from a AA battery to the micromotors. This flow of current makes the motor vibrate; depending on the spatial domain, they signify insufficient or excessive force.

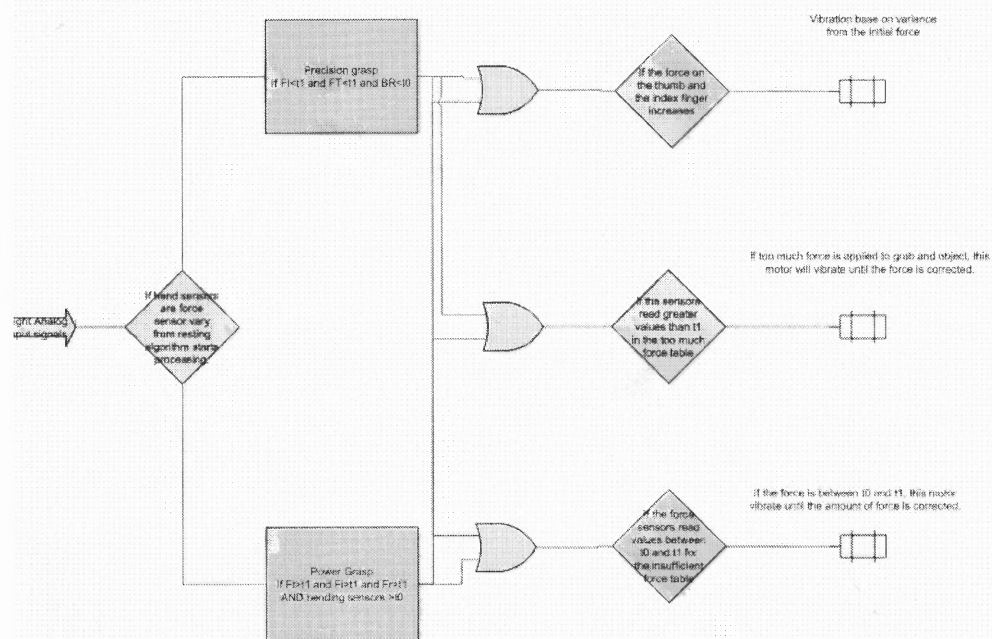


Figure 4.5 Block diagram of the incoming sensors, biofeedback algorithm and the external vibrating motors.

If the combination is the inadequate, for example if the algorithm detects that the force applied is not enough, a vibration feedback is provided using motors (JinLong Machinery, Brooklyn, NY) on the ribs (for example). On the other hand if the force applied is too much, a motor on the shoulder would vibrate. The exact location of the feedback motors would ultimately depend on an intact sensory area of the individual's body.

CHAPTER 5

METHODS: BASIC ALGORITHM DEVELOPMENT

5.1 Sensor Calibration

It is very important to determine a relationship between force, joint angle displacements and voltage. Each of the sensors was tested against a gold standard. Using a commercially-available device to measure pinch force (Baseline® Hand and Pinch Dynamometers), the relationship between force and voltage was determined. The range goes from one to seven pounds as shown in Figures 5.1 and 5.2. These ranges are enough to determine insufficient and excessive force used by the objects during our testing. The relationship is monotonically increasing, and linear enough that we can assume a linear relationship between maximum and minimum force values.

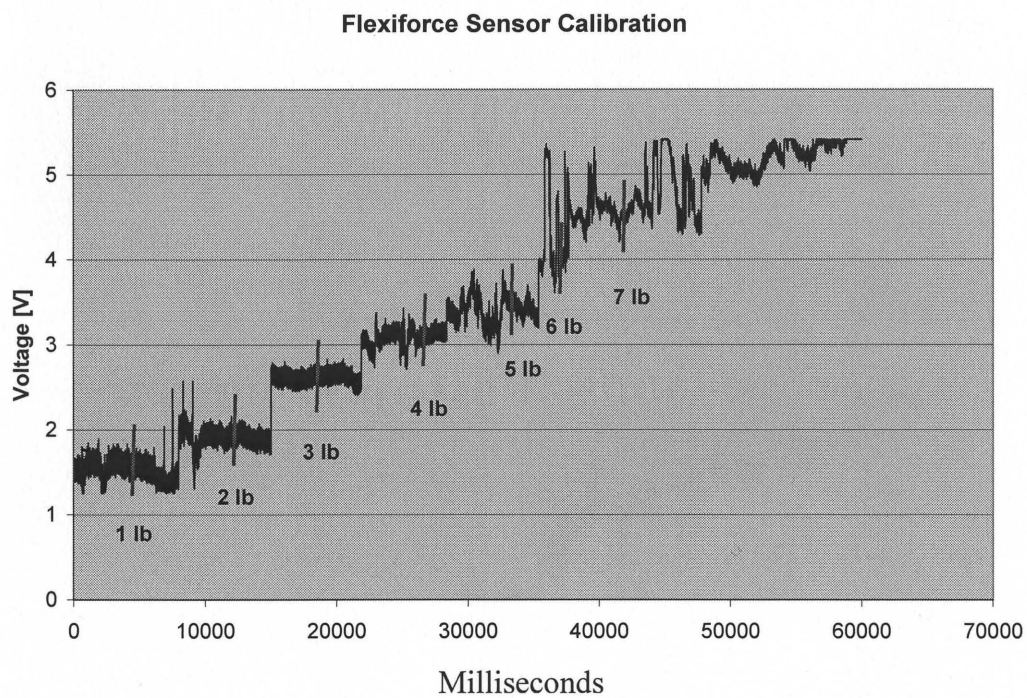


Figure 5.1 Sample calibration for the force sensors.

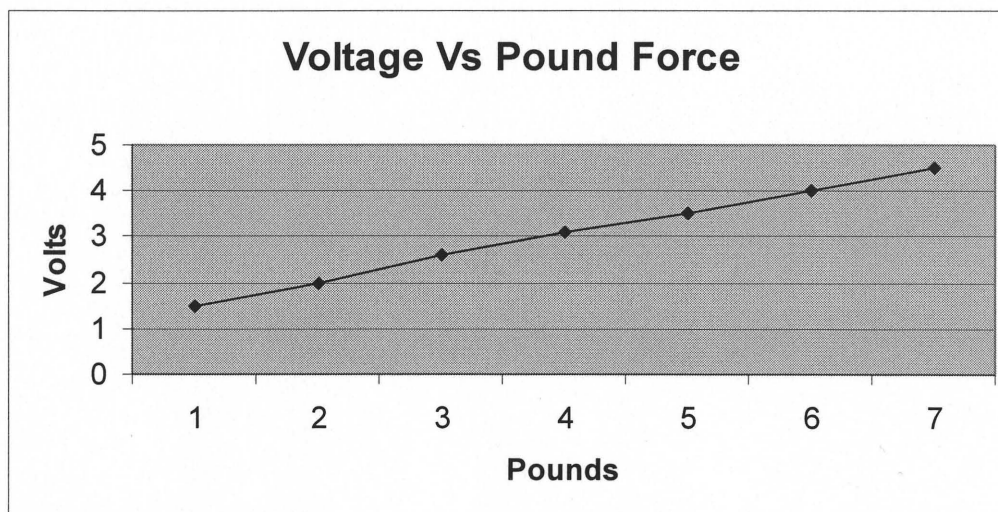


Figure 5.2 Experimental relationship between voltage and pounds.

The Flexpoint sensors were calibrated as well as shown in Figures 5.2 and 5.3. Using a manual goniometer, the bend angle at the MCP was measured at the same time as the sensor voltage. The relationship shown here is monotonically increasing, although not linear, which has been reported elsewhere [21].

To simplify calibration for each individual, the resulting calibration for all sensors assumes a linear relationship between maximum and minimum values, and the hand postures were computed as a percentage of full scale rather than reported as absolute force or bend angle. This assumption is possible because the force feedback algorithm is not based on absolute values.

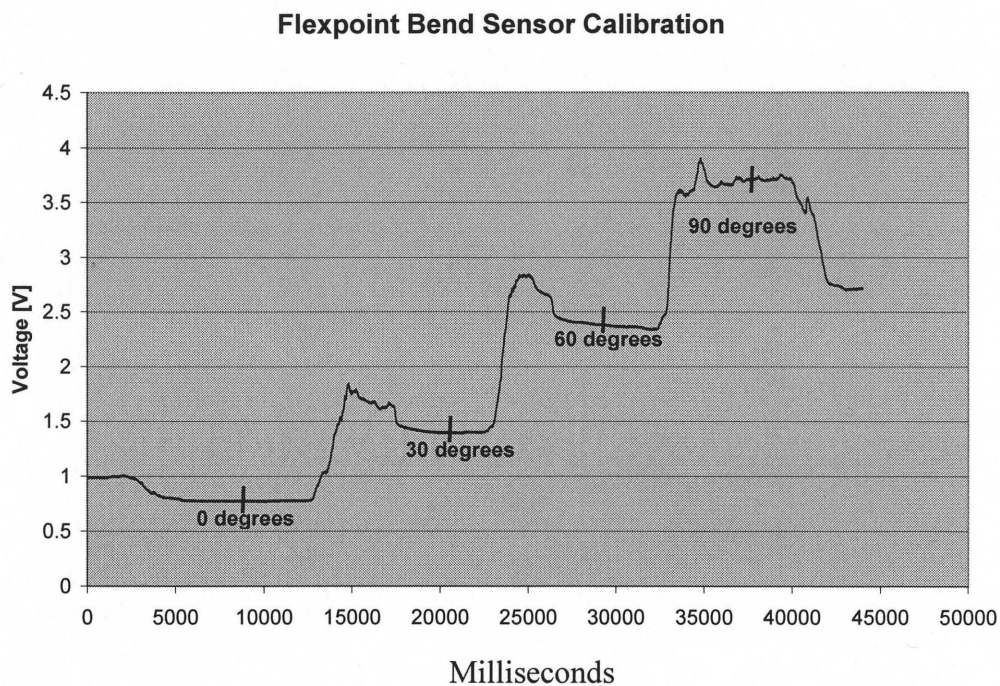


Figure 5.3 Sample calibration curve for bend sensors.

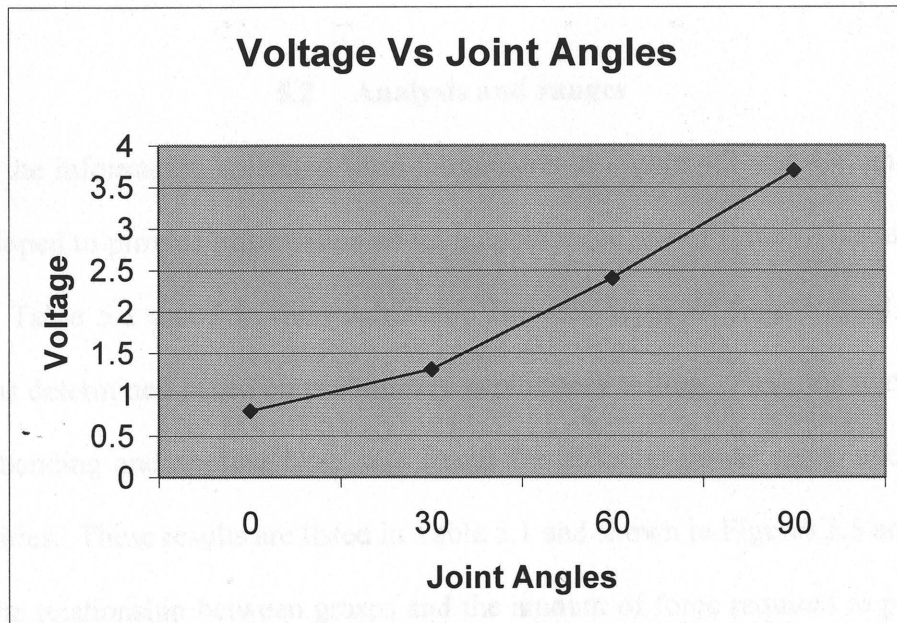


Figure 5.4 Experimental relationship between voltage and joint angles.

5.2 Analysis and ranges

Based on the information collected from the circuits in Figure 4.3 and 4.4, an algorithm was developed to provide information about inappropriate use of force. This algorithm is shown in Table 5.2 and 5.3; the relationship between types of fingers used and types ranges was determined based on preliminary exploratory testing. First, the average value for joint bending and applied force was found for different power grasp and precision grip activities. These results are listed in Table 5.1 and shown in Figures 5.5 and 5.6.

The relationship between grasps and the amount of force required to perform the task such as picking up a can, or writing with a pen is shown in Figure 5.5; user values are reported in terms of percentage of maximum value. In power grasp activities, a higher force is observed in all force sensors, with the most consistent readings in the thumb and ring fingers. For precision activities, high force was primarily observed on the thumb. Also, the corresponding relationship for joint angle bending is shown in Figure 5.6; thumb bending was less for precision activities while ring and index bending was generally higher. This information was used to develop the feedback algorithm. It used the data to first classify what type of grasp the individual is using and second make the individual aware that he is using inappropriate force while performing the desired hand activity.

Table 5.1 Average for Force and Bending Angles for the Respective Hand Postures

The average of the maximum force used								
	Ring F	Ring B	Index B	Index F	Thumb F	Thumb B	Palm1	Palm2
Soup Can MF	3.7189	1.4910	1.4474	2.2556	2.7151	1.3556	2.8181	1.4767
Beer Bottle	4.2843	1.5354	1.4333	3.0809	2.6950	1.3810	3.6558	1.7931
Flux OFF	3.6294	1.5089	1.4225	2.0464	2.6745	1.3255	2.8418	1.9190
	3.8775	1.5118	1.4344	2.4609	2.6948	1.3540	3.1053	1.7296
	3.48978	1.360578	1.290966	2.214852	2.425362	1.218618	2.794728	1.556658
The average of the minimum Force								
Mouse	0.2070	0.0009	0.0006	0.1728	0.1499	0.0003	0.1389	0.0336
Pencil	0.1128	0.0006	0.0002	0.0833	0.0700	0.0014	0.0867	0.0385
Scissors	1.2543	1.5308	1.6117	1.2640	1.7656	1.2971	1.3505	1.3020
	0.5247	0.5108	0.5375	0.5067	0.6618	0.4329	0.5254	0.4580

The red square represents the force sensors average data and the green highly square represent the data for the averaging bending sensors.

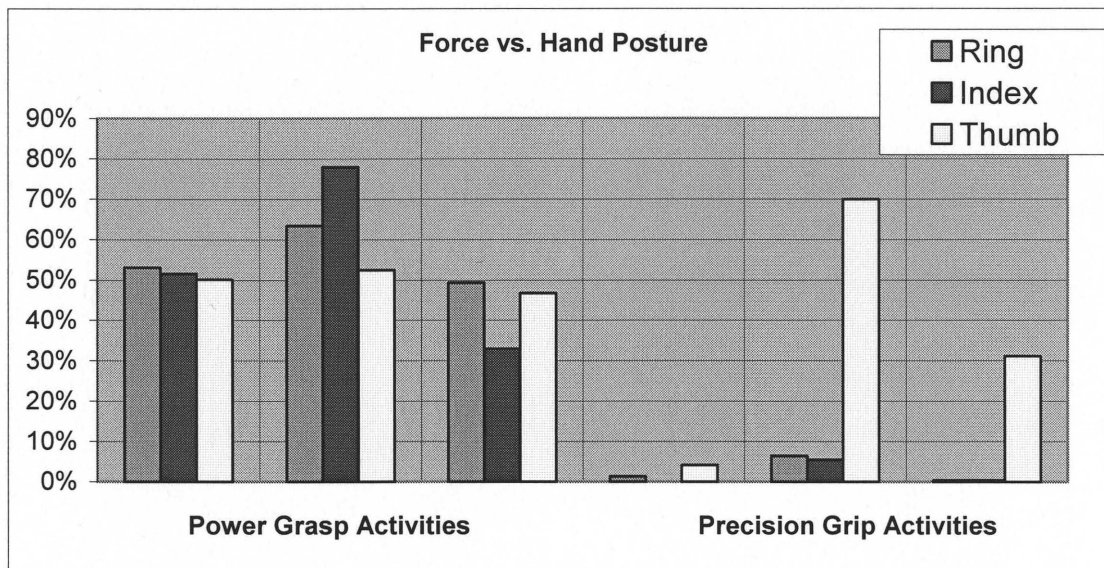


Figure 5.5 Relationships between Power: Grasp and Precision Grip: The minimum reference was obtained with no hand movement. The maximum reference point was obtained by asking the subjects to use the maximum strength to grab the desired object.

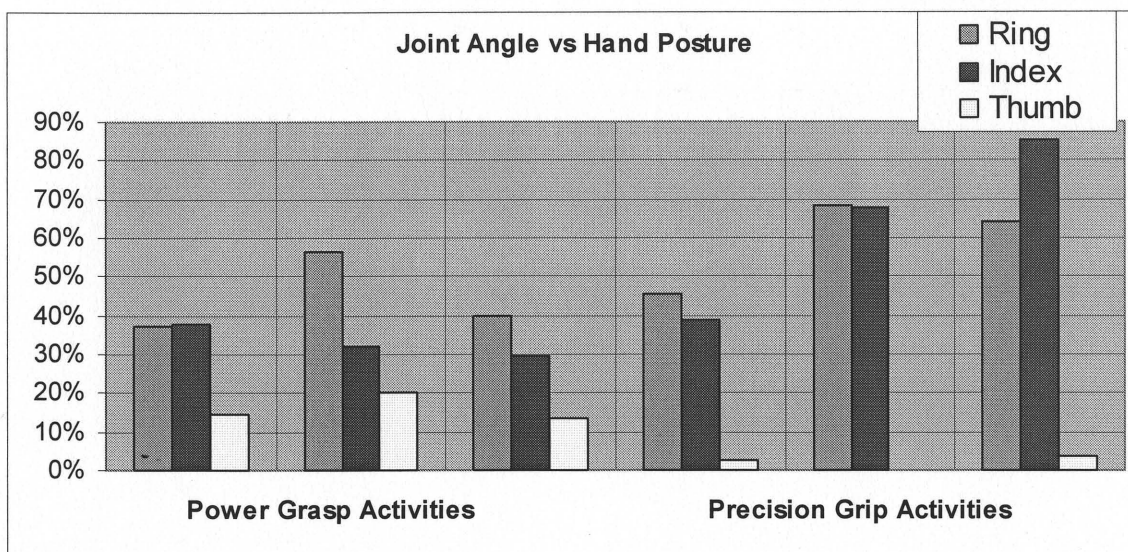


Figure 5.6 Joint angle Vs Hand Posture: The minimum angle was obtained from the flat hand position and the maximum by closing the fist completely.

Table 5.2 Classification of the Hand Grip Plus Excessive Force Use

Thresholds	T0	T1
Voltage	4.97	5.03

Ring Force	Sensor	Inputs		Motor		
	Index Force	Thumb Force		Interpretation	Motor Outputs	Warning Motors
	T0<FI	T0<FT	→	Precision	→	Y
T1<FR	T0<FI	T0<FT	→	Power Grasp	→	Y

Thresholds: t0-t4. F=Force sensor where I=index, T=thumb, R=Ring, P1=palm over index MCP, P2=palm over ring MCP.

The algorithm in Table 5.2 contains the logic to turn on the micromotor vibrator that corresponds to too much applied force. This table shows several thresholds that have been defined for an individual after force calibration (t0 through t1). Based on specific sensor readings and relevant joint bend trends listed above, the hand posture is interpreted as Precision or Power grasp. If the force is outside a threshold, the corresponding to the too much force algorithm the motor is turned on. Several different combinations can

result in this force warning; for example, either palm sensor over a certain threshold corresponds to a power grasp with excessive force. On the other hand, exceeding thresholds for thumb and index force sensors corresponds to excessive force in a precision grip. The intention is to prevent a person from breaking a fragile object on his hand. In addition a loop has been added to this system that compares the initial force used to grab an object, and if this force increases gradually in a 30% range, a warning motor turns on for a few seconds to alert the individual about the change in force.

Table 5.3 Classification of the Hand Grip Plus Insufficient Force Use

Thresholds	T0	T1
Voltage	1.25	1.5

Sensor Inputs			Motor Outputs		
Ring force	Index Force	Thumb Force	Interpretation	Warning Motors	
$T0 < FR < T1$	$T0 < FI < T1$		Precision	→	Y
$T0 < FR < T1$	$T0 < FI < T1$	$T0 < FT < T1$	Power	→	Y

Thresholds: t_0-t_1 . F=Force sensor where I=index, T=thumb, R=Ring, P1=palm over index MCP, P2=palm over ring MCP.

It is also important to consider the opposite case when an individual is holding an object too loosely, which can cause an accident. In Table 5.3 there are a set of values where this conditions combination might cause a warning motor to turn on. This second algorithm has the intention to make the person acknowledge that he might drop the object if he does not grab it tighter. Too-loose precision grip can be primarily determined by the index and thumb force sensors, while a too-loose power grasp uses more sensors.

It is the intention of this system to make the individual aware if the amount of force he is applying for a particular task is appropriate or not. If the appropriate amount of force is used, no motor feedback is provided. The individual is an essential part of the feedback loop because he takes the proper actions to correct any inappropriate force on his part.

CHAPTER 6

RESULTS

6.1 Aim 2 Testing – Study 2

The following three tables show the average sensor readings used for calibration for Study 2. Tables 6.1 and 6.2 include force sensor readings; Table 6.3 includes bend angle readings.

Table 6.1 Thresholds for Study 2, Aim 2 Showing Voltage Corresponding to Maximum and Minimum Force on Finger Tip Force Sensors for Participants

	Thumb Max Force	Thumb Min Force	Index Max Force	Index Min Force	Ring Max Force	Ring Min Force
Study3Sub1	5.4	1.25	5.4	1.25	5.2	1.25
Study3Sub2	5.4	1.25	4.82	1.25	5.4	1.25
Study3Sub3	5.2	1.25	5.4	1.25	5.1	1.25
Mean	5.3	1.25	5.3	1.25	5.24	1.25
Standard Deviation	0.13	0	0.3	0	0.17	0

Table 6.2 Thresholds for Study 2, Aim 2 Showing Maximum and Minimum Angle on Palm Force Sensors for Participants

	Palm 1 Max Force	Palm 1 Min Force	Palm 2 Max Force	Palm 2 Min Force
Study3Sub1	1.4	1.25	5.4	1.25
Study3Sub2	5.0	1.25	1.51	1.25
Study3Sub3	2.23	1.25	2.8	1.25
Mean	2.8	1.25	3.2	1.25
Standard Deviation	1.62	0	1.73	0

Table 6.3 Thresholds for Study 2, Aim 2 Showing Voltage Corresponding to Maximum and Minimum Angle for Participants

	Thumb Max Bend	Thumb Min Bend	Index Max Bend	Index Min Bend	Ring Max Bend	Ring Min Bend
sm01	1.07	1.01	3.6	1.05	4.06	1.52
sm02	1.05	1.02	3.61	1.09	4.04	1.48
sm03	1.02	0.89	3.8	1.11	4.03	1.47
Mean	1.04	0.97	3.67	1.08	4.04	1.49
Standard Deviation	0.02	0.07	0.11	0.03	0.01	0.02

The study participants completed the three activities, performing each of the activities three times at three different grasp forces. The results are summarized in Table 6.4. For individual results, success is defined in terms of whether the correct micromotor vibrators turned on or not. For using objects normally, success is defined as no motors vibrating. For squeezing too hard, success is defined if the “too much force” motor vibrates. For squeezing too loosely, success is defined if the “too little force” motor vibrates.

For all of the subjects, the motors remained passive when individuals perform the three activities with a normal amount of force. In addition, the “too much force” micromotor vibrated appropriately 90% percent of the time for all subjects. When objects were grasped too loosely, the “too little force” micromotor failed to vibrate in most cases.

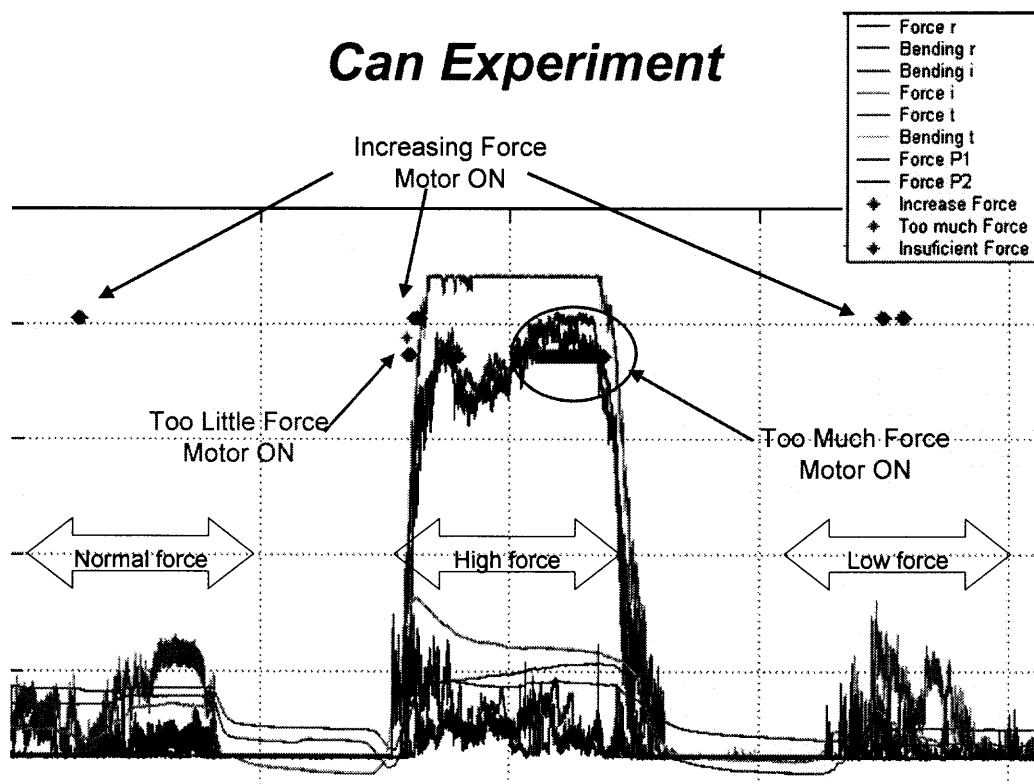


Figure 6.1 Motor output for can experiment. Recordings from fore and bend sensors are shown, with motor vibratory outputs indicated by solid dots.

Figure 6.1 displays the motor output response for one of the can tests. The experiment was repeated three times where the individual was asked to hold a small metal soup can with sufficient force (on the left), excessive force (in the middle) and minimal force (on the right). Excessive force caused the respective motor (represented by green dots) to trigger twice during this trial when the applied force exceeded a threshold. When the can was just about to be picked up and after contact was made, the motor for minimal force was triggered (red dot). This signifies there might have been a sensitivity and calibration issue. The rest of the results for the other test can be found in Appendix A.

Table 6.4 Force Feedback Algorithm Results for Study 3**A: Open Hand Power Test**

1: Hold can normally

2: Hold can tightly

3: Hold can loosely

Subject 1	Subject 2	Subject 3
3/3	3/3	3/3
3/3	3/3	2/3
0*/3	0*/3	0*/3

B: Open Hand Precision test

1: Stack checkers normally

2: Stack checkers tightly

3: Stack checkers loosely

Subject 1	Subject 2	Subject 3
3/3	3/3	3/3
3/3	3/3	3/3
0/3	0/3	0/3

C: Closed Hand Precision Test

1: Write squeezing normally

2: Write squeezing tightly

3: Write squeezing loosely

Subject 1	Subject 2	Subject 3
3/3	3/3	3/3
3/3	3/3	3/3
0/3	0/3	0/3

* Too loose motor fired momentarily when the subject released the can.

To summarize, the overall success rate of the system was different for the excessive force (96%) and too little force cases (0%). However it is important to note that for the power grasp, every time the subject released the can, the too-loose motor vibrated. This leads the author think that the problem is a sensitivity or threshold issue at least for the power grasp test, rather than a complete failure of the algorithm to predict too-loose grasping.

6.2 Exploring Hand Grip Force - Study 3

As a result of the failed low-force testing in Aim 2 above, the data were explored to see why this occurred. It was found that the maximum and minimum force values were different based on the diameter of the object grabbed. Therefore, the calibration procedure that required each individual to grasp a can at maximum and minimum force did not provide good calibration for smaller diameter objects. To explore this hypothesis, 7 subjects were recruited to test their maximum grip forces for different object diameters. The raw data for each subject is shown in Table 6.5, and the average data for all subjects together is shown in Figure 6.2.

For all subject trials except two, the maximum generated force decreased with increasing diameter. Subjects could generate the highest forces while the hand grip force dynamometer was set at a 3 cm separation, which corresponds roughly to a frying pan handle. Larger diameters corresponding to cans and boxes correspond to lower maximum forces. Because the maximum force is related to object diameter, the force feedback algorithm should include information about the object being manipulated in order to more accurately provide force feedback information.

Table 6.5 Maximum Grip Force Values for Different Object Diameters

Left hand								Mean	SD
Distance in cm	GS01	GS02	GS03	GS04	GS05	GS06	GS07		
10	54	53	54	63	33	44	57	51	10
6	64	54	69	73	38	57	73	61	13
3	67	63	74	86	36	61	77	66	16
Right Hand								Mean	SD
Distance in cm	GS01	GS02	GS03	GS04	GS05	GS06	GS07		
10	49	57	63	64	34	45	53	52	11
6	62	74	72	80	41	63	66	65	12
3	65	64	80	94	42	66	70	69	16

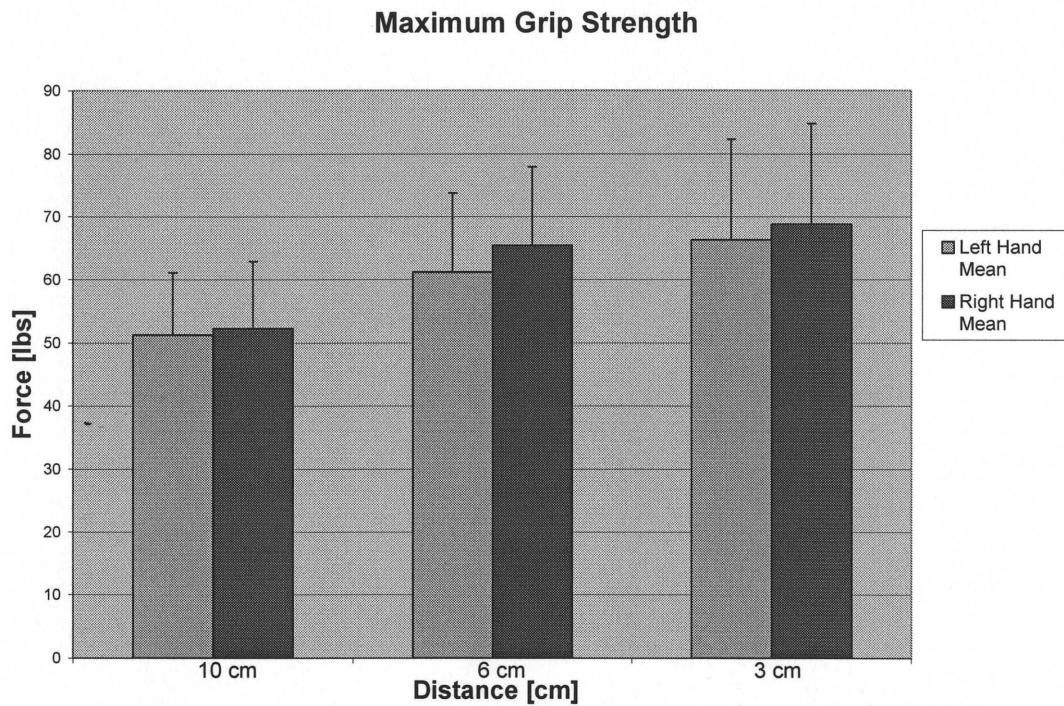


Figure 6.2 Maximum Grip Strength: Summarized results of maximum grip force for 7 subjects. Error bars represent standard deviation.

6.3 System Cost

This system has a lower cost than existing commercial systems, although the information presented here focuses on cost of materials rather than total costs. The total cost of the system components is shown in Table 6.6. Currently, the system is implemented with a separate A/D card and PC, although these can be replaced with a low cost embedded system in the next version of the device for approximately \$200.

Table 6.6 Approximate Hardware Cost

Product	Unit Price	Quantity	Total
Flexiforce sensors	12.50	5	62.50
Flexpoint sensors	8.00	3	24.00
10M Ω	0.56	8	4.48
3.3M Ω	0.15	6	0.90
1M Ω	0.25	6	1.50
10K Ω	0.15	3	0.45
			103.33

CHAPTER 7

SUMMARY AND CONCLUSION

In daily activities, hand functioning is vital to everyone. Using our hand provides us with information that helps us interact effectively with our surroundings. One vital type of information used for effective hand function is the sense of touch. The lack of this sense, especially on the hand, can lead to difficulty interacting with the environment and possibly undesired accidents. Unfortunately, loss of hand sensation often occurs following a stroke.

Some individuals with appropriate therapy after stroke can recover some motor control, but many are left with some haptic deficiency. This deficiency can negatively affect their live styles. The solution proposed here is to help these individuals regain some of their sense of touch by transferring the information received from the hand to another part of the body to help them acknowledge the missing information. Specifically, this work focused on detecting when individuals use inappropriate levels of force, and providing feedback to prevent a dropped object or injury.

To determine when inappropriate force is being used, basic hand postures such as power grasp and precision grip are detected using flexible bend sensors to measure joint angles. Force is measured at five points on the hand, and the location and magnitude of these values both complete classification of the hand posture, and determine inappropriate force ranges.

Flexiforce sensors have been placed on the ring, index, thumb tips, and at two locations on the palm. To develop the sensory feedback algorithm, data were collected and investigated to understand measured joint angles and forces that correspond to

different, known, hand activities. The power grasp is used to hold objects such as cans, hammers and other heavy objects. In this type of hand activity, all the sensors on the fingers and the palm are active. When someone uses his hand and applies too much force the most significant sign is shown by the index finger. The thumb is used as the main support while the palm and the other fingers give a complementary support. One by one of the sensors placed on these parts reach a saturation level. However, if the individual is grabbing an object so loosely that is about to fall from his hand, the support from the palm and the ring finger is low and the index finger begins losing its saturation value. This is the key to acknowledging when the individual is about to drop the object, but did not work correctly for all individuals. If any of these two conditions occurs, a micro motor will vibrate. The vibration of different motors placed in singular parts of the body will serve as warnings.

Other activities such as writing, cutting paper or clicking a mouse are classified as precision grip. For this activities more useful information is obtain from finger bending. The ring finger bends more than the others, while most of the force is exerted on the thumb. In these two situations, micro motor will vibrate to make the person aware of his hand's applied force.

Based on these common characteristics, the sensory feedback algorithm was developed. However, there is some variation in the common characteristics from individual to individual. The combination of fingers and palm varies from time to time. For example when grabbing a cup, the common thought would be that the main force is between the index and the thumb. However, occasionally one can observe that the force is redistributed between the other fingers, relieving some of the force from the index and

thumb in order to avoid slipping. Therefore, it is important to acknowledge that absolute values may not be a realistic alternative. A set of ranges and concentration of force and bending have made this algorithm work.

Another thing to consider is that the objects used in the algorithm development had similar dimensions and weights, but in real life, objects have different dimensions and different weights. For example the objects use in this study were a can, bottle for power grasp activities; however power grasp is used on objects with other diameters such as hammers and bigger bottles, where the flexion of the fingers and forces needed varies. The amount of force needed to lift and manipulate these objects varies with their weights and therefore their force thresholds in the algorithm are expected to be different. Keeping in mind that motors are only active if the individual grabs an object tightly or loosely, new values will have to be set accordantly to the activities.

7.1 Limitations of the System

This system has several advantages including low cost, lightweight materials, a small number of sensors, and real-time processing in the algorithm for instant force feedback.

In Table 6.6, the related cost for hardware is presented. This makes the system very affordable and inexpensive compared to the current systems that are available in the market. The system does not require a desktop computer or laptop in order to function. It can be implemented in a small microprocessor which are available in the market at relatively low cost. It requires a small number of sensors to perform its algorithm (rather than a full set of sensors for every joint and fingertip). Also as shown in Figure 4.2 the system is portable and light weight and therefore it can be used outside in the community. The system provides real time processing and instant force feedback which makes it practical to use.

On the other hand, this system has some disadvantages. For example, the force sensors have low durability and easily break. We have not determined the cause of this durability problem. This could potentially raise the cost of the system. In addition, the current system does not consider the different object diameters when evaluating maximum force, Table 6.5, and this must be included in the logic to make applicable for daily common activities.

7.2 Next Steps

In order to make the system practical, it must be implemented as an embedded system. This implementation will make the system completely wearable. Another implementation should be readjusting the logic to differentiate objects of different diameters and readjust the detection thresholds. The force sensors currently used must be reevaluated for this application. Currently the constant wear damages them, which changes their linearity.

Finally the solution presented here was based on performance of individuals who willingly participated on this research and for the specific objects selected. Additional work must be performed for this method to be useful for a wider range of users and objects. This research has shown that more patterns can be realized for usefulness and better detection of hand function. The promise of vibrotactile haptic feedback continues to grow as measurement systems become more lightweight and wearable, improving the potential to help individuals regain hand function and their live styles following a stroke.

APPENDIX A

SOFTWARE, RESULTS AND HARDWARE PICTURES AND DRAWINGS

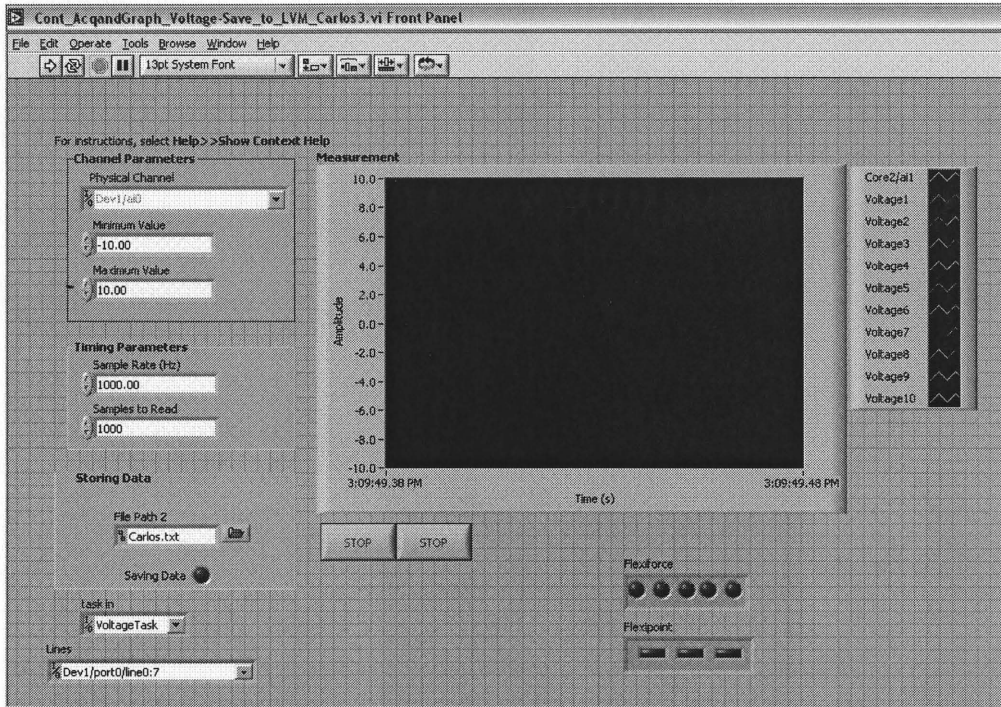


Figure A.1 Main front Panel

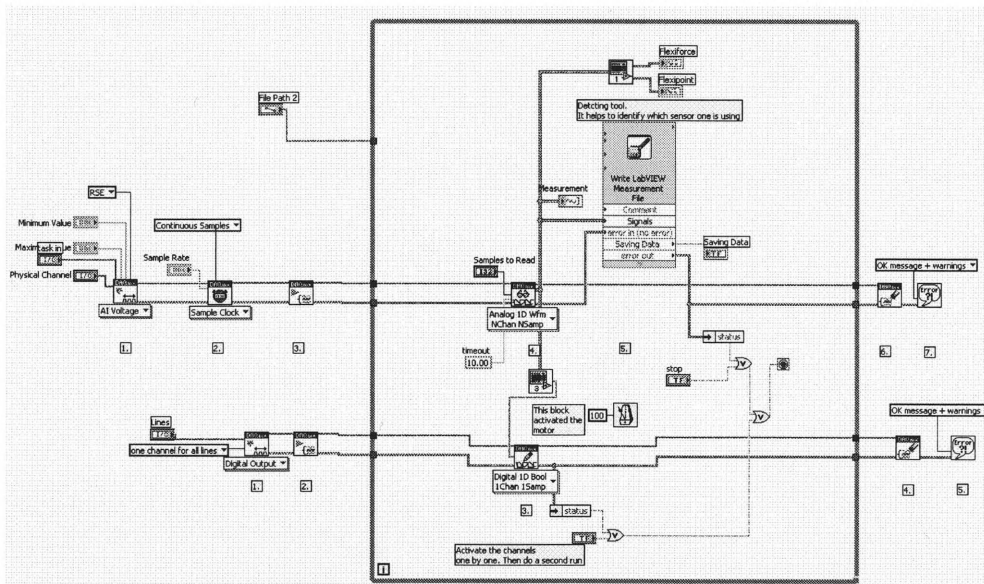


Figure A.2 Main Block Diagram for the Front Panel: Most of it provided by National Instruments.

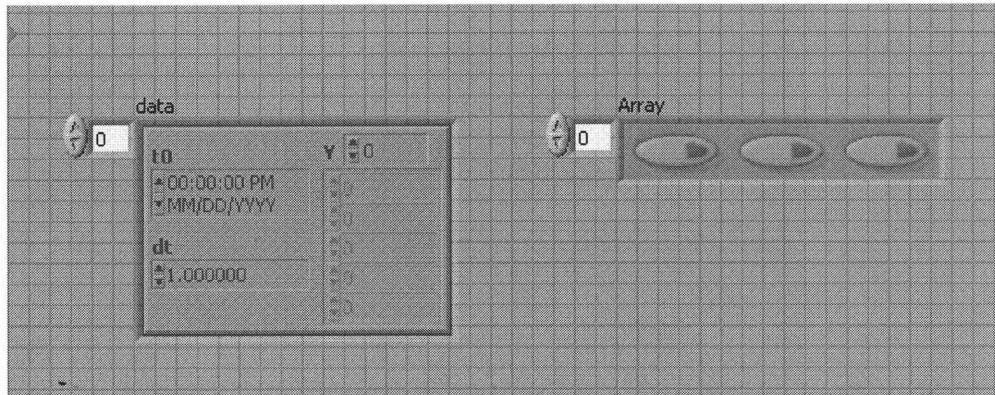


Figure A.3 Secondary Front Panel: The main logic development originates here.

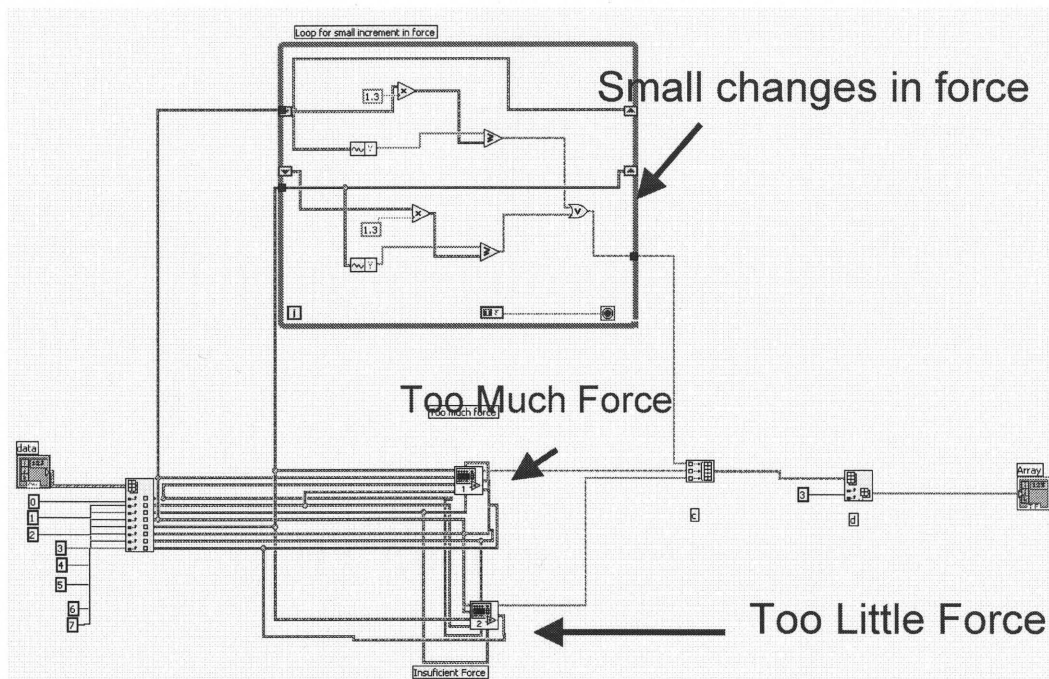


Figure A.4 Secondary Block Diagram: Division of the forces in Too Much, Insufficient and Gradually Increment.

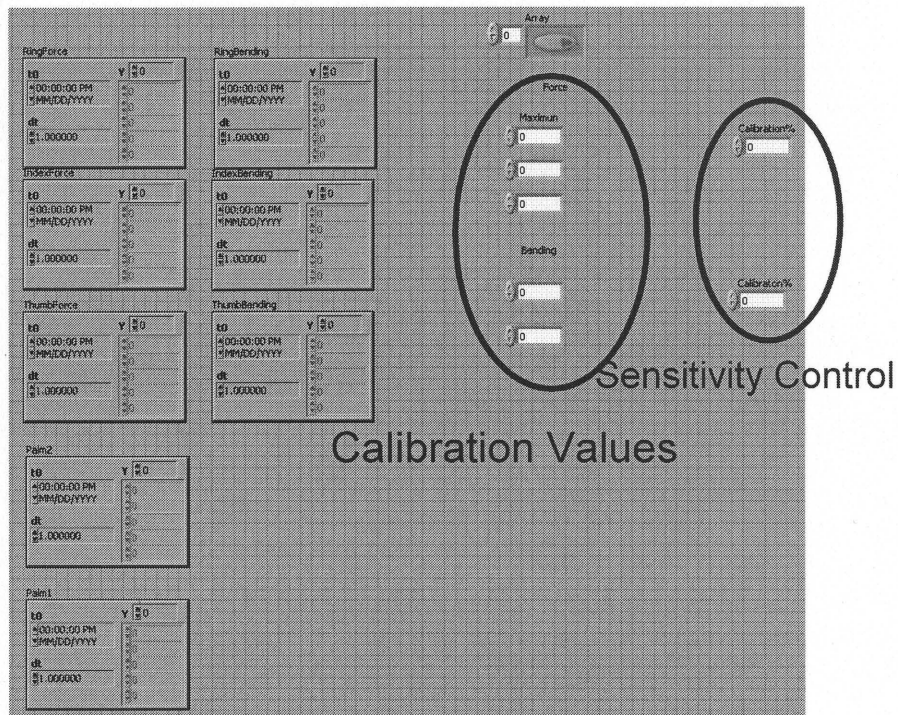


Figure A.5 Too Much Force Front Panel.

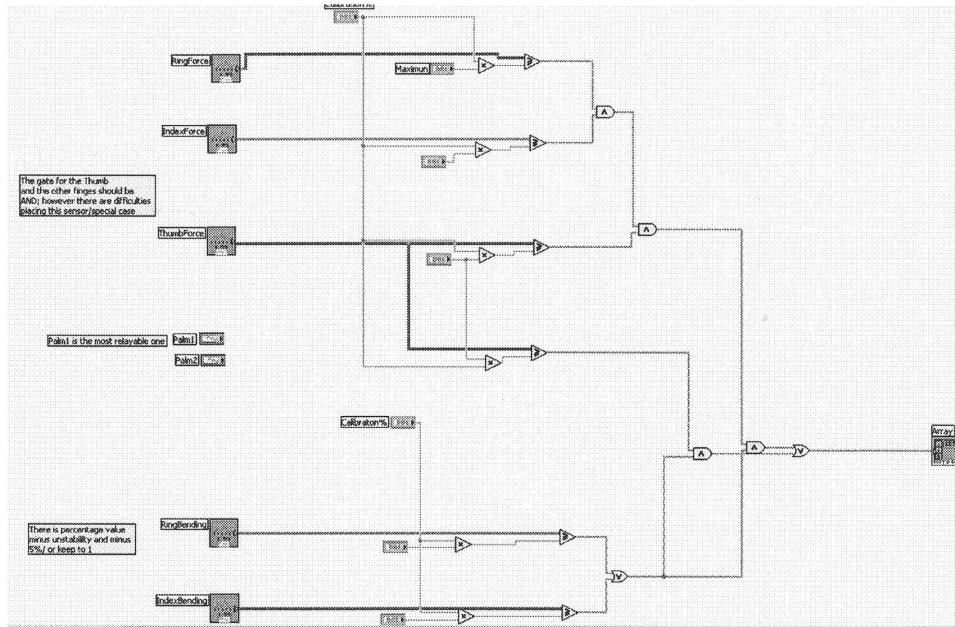


Figure A.6 Too Much Force Block Diagram.

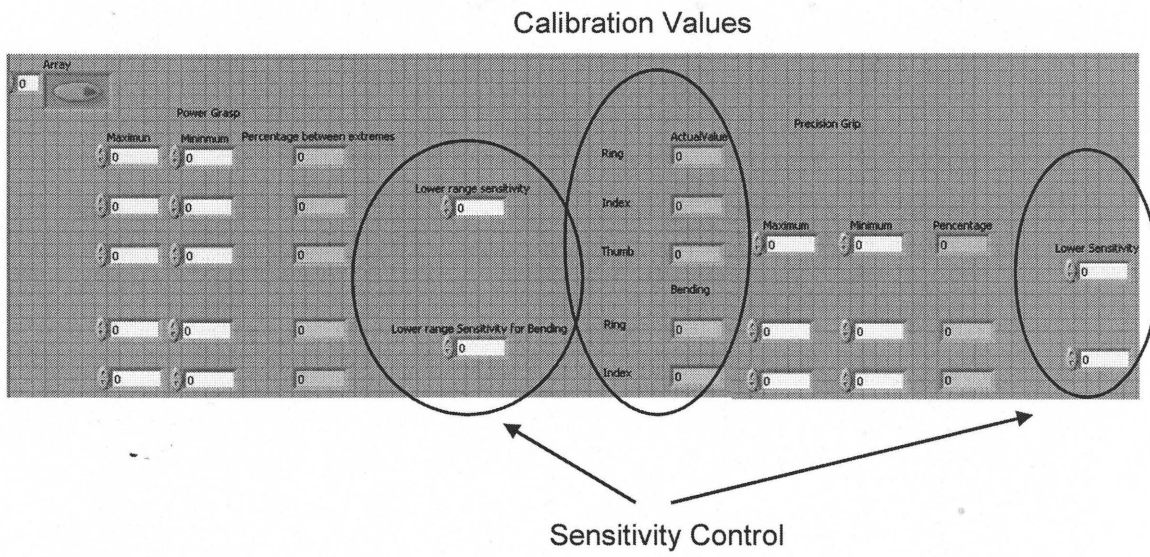


Figure A.7 Insufficient Force Front Panel.

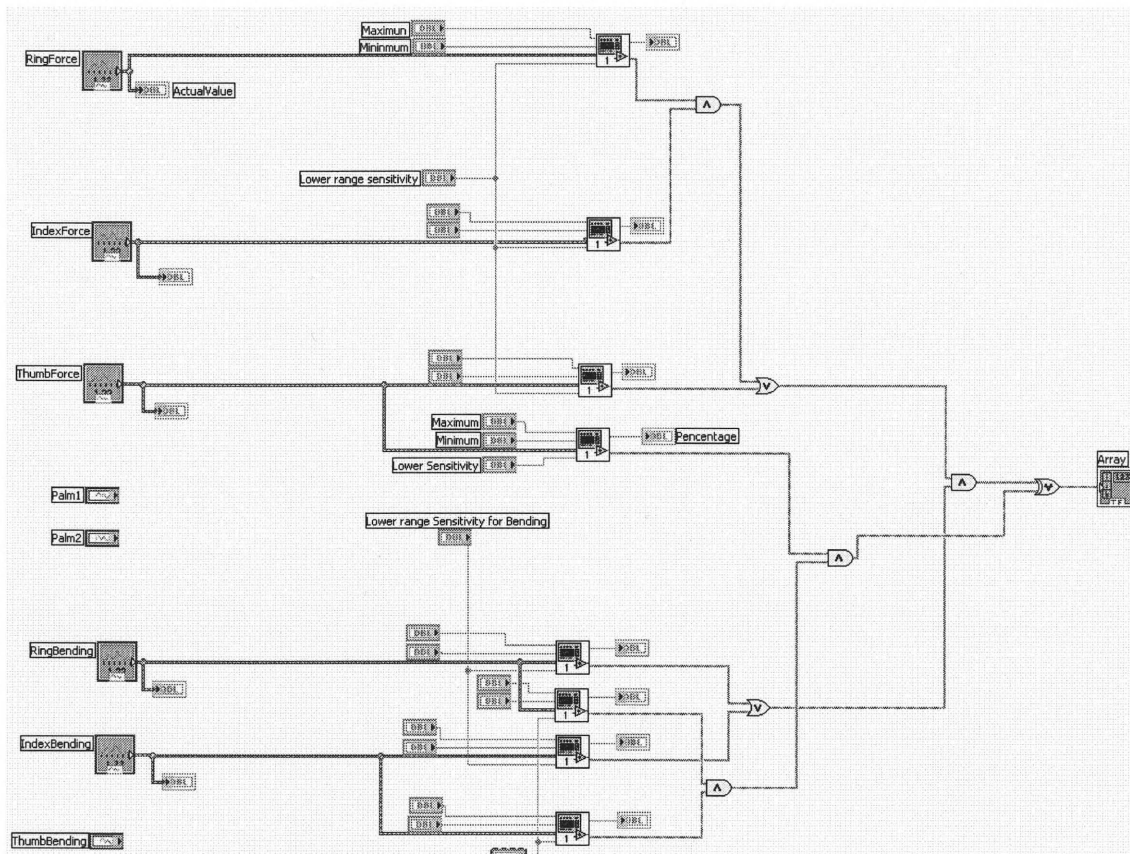


Figure A.8 Insufficient Force Block Diagram.

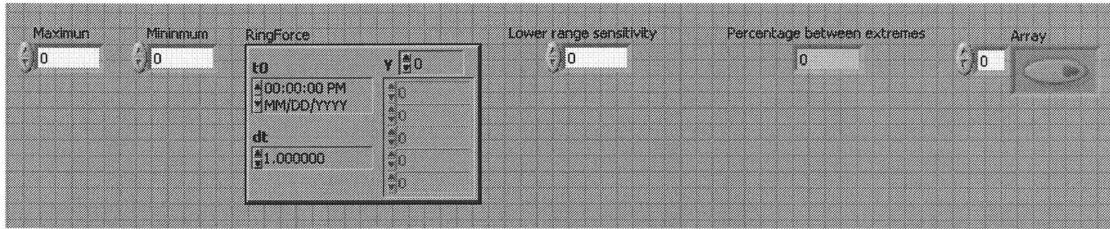


Figure A.9 Internal Logic for Insufficient Force Front Panel.

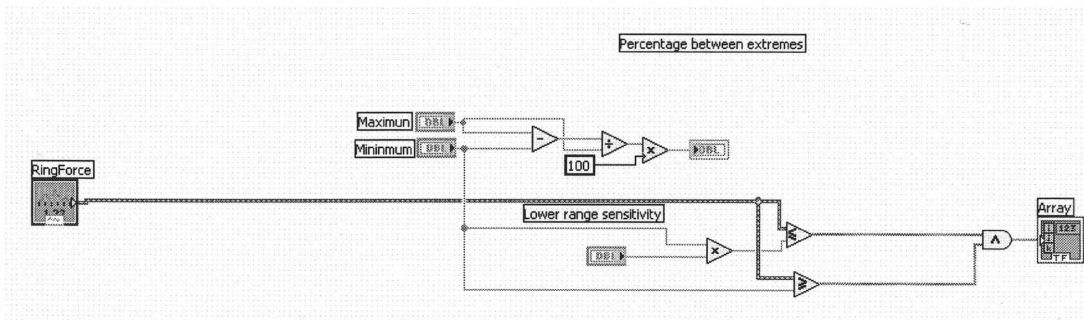


Figure A.10 Internal Logic for Insufficient Force Block Diagram.

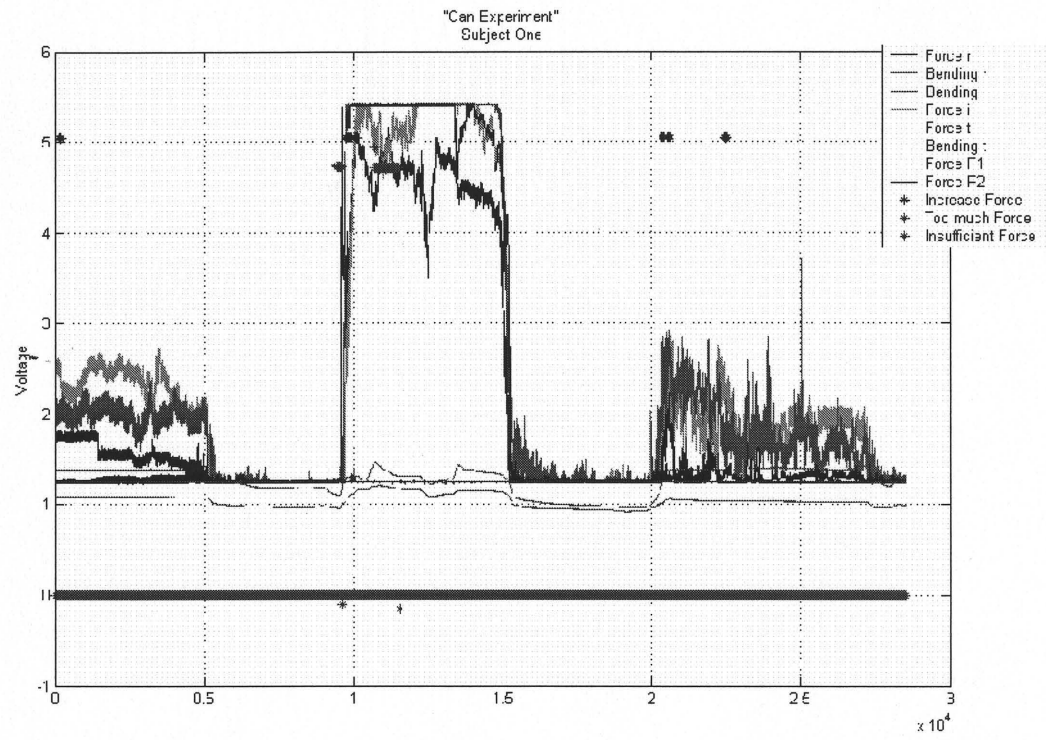


Figure A.11 Results for Holding a Can for Subject One.

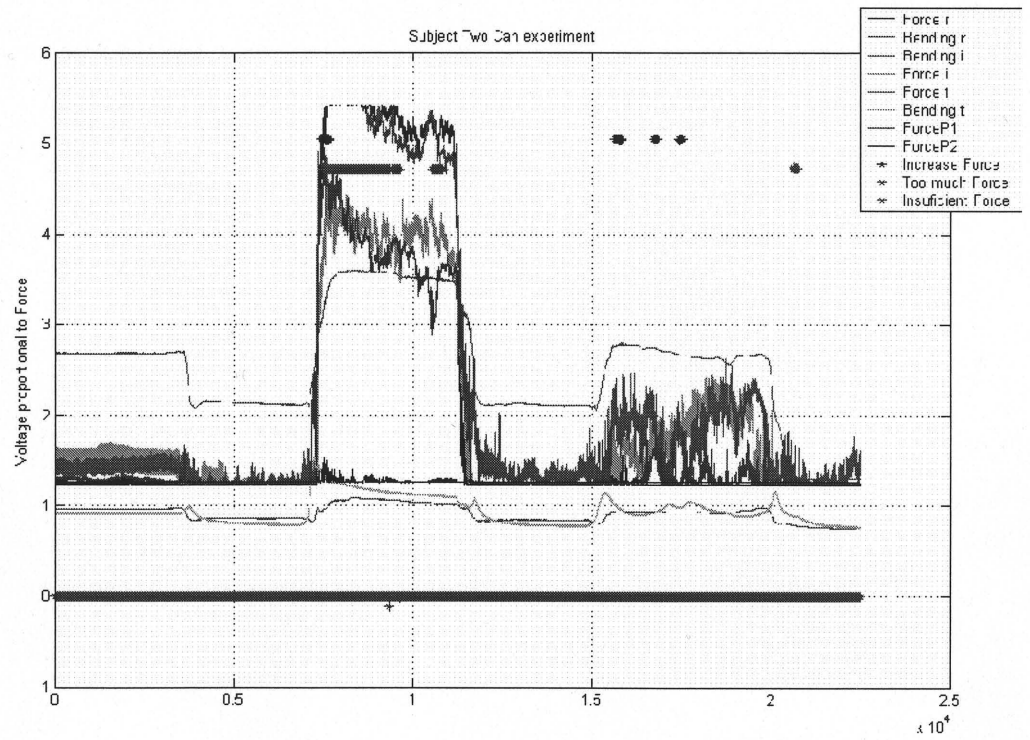


Figure A.12 Results for Holding a Can for Subject Two.

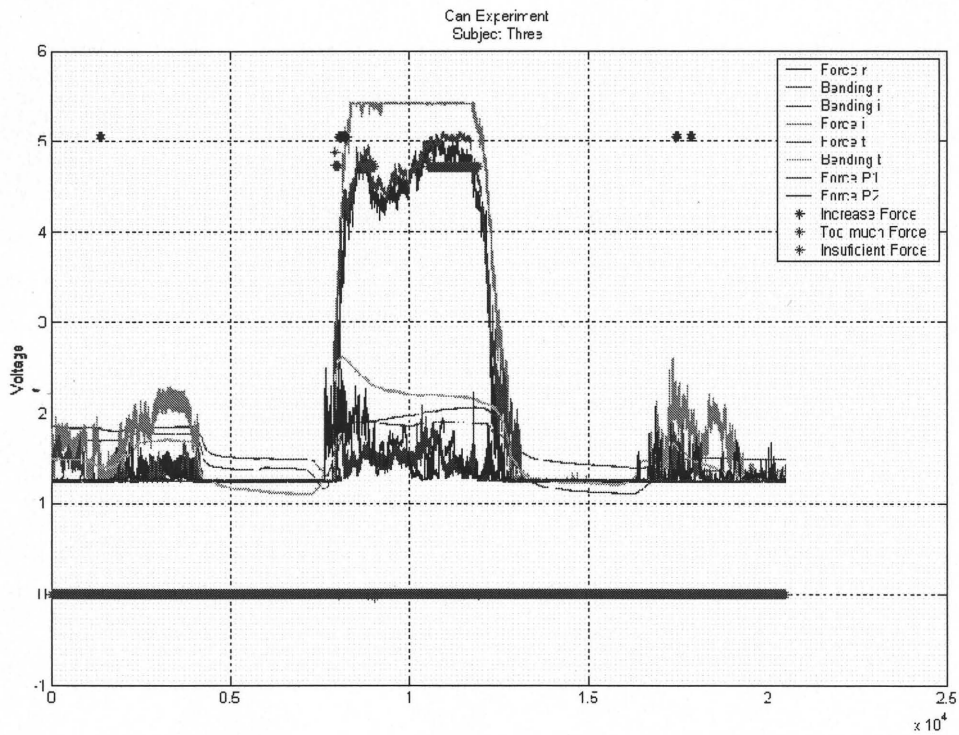


Figure A.13 Results for Holding a Can for Subject Three.

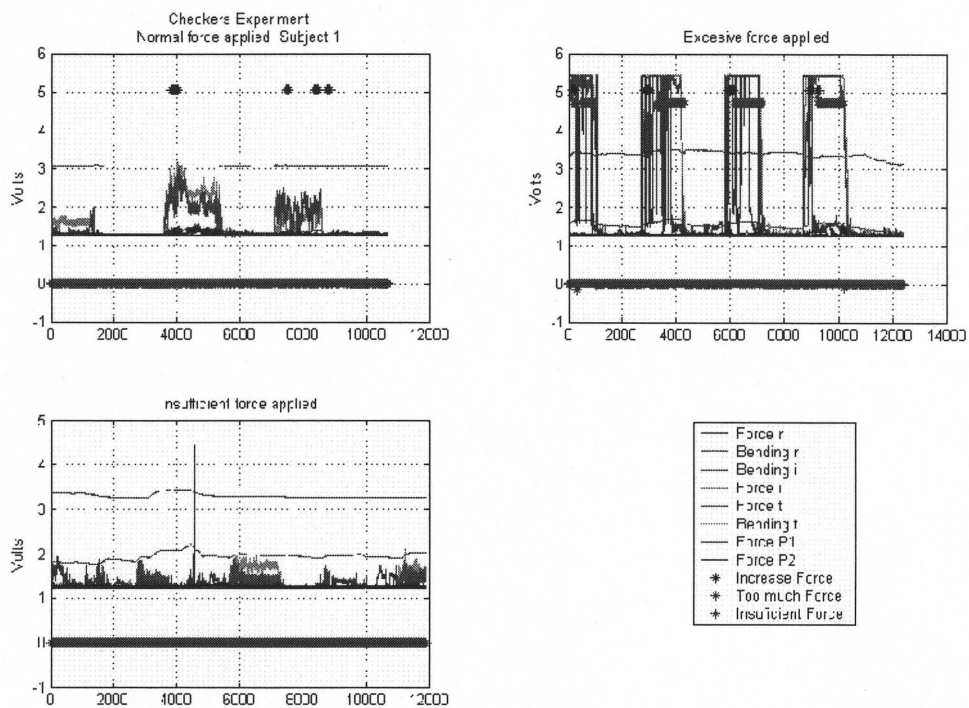


Figure A.14 Results for Stacking Checkers for Subject One.

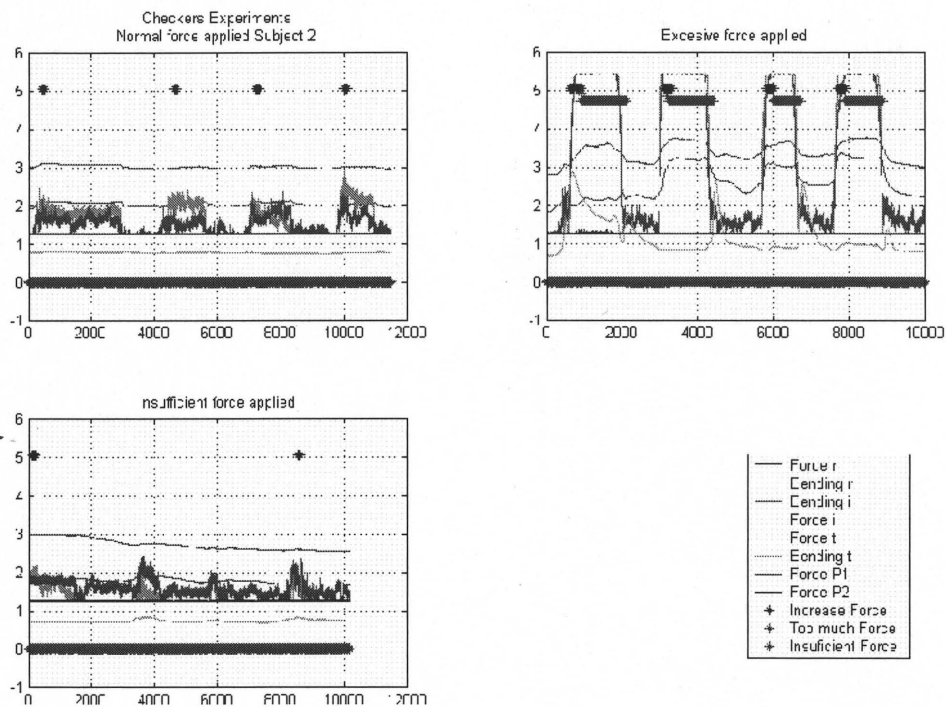


Figure A.15 Results for Stacking Checkers for Subject Two.

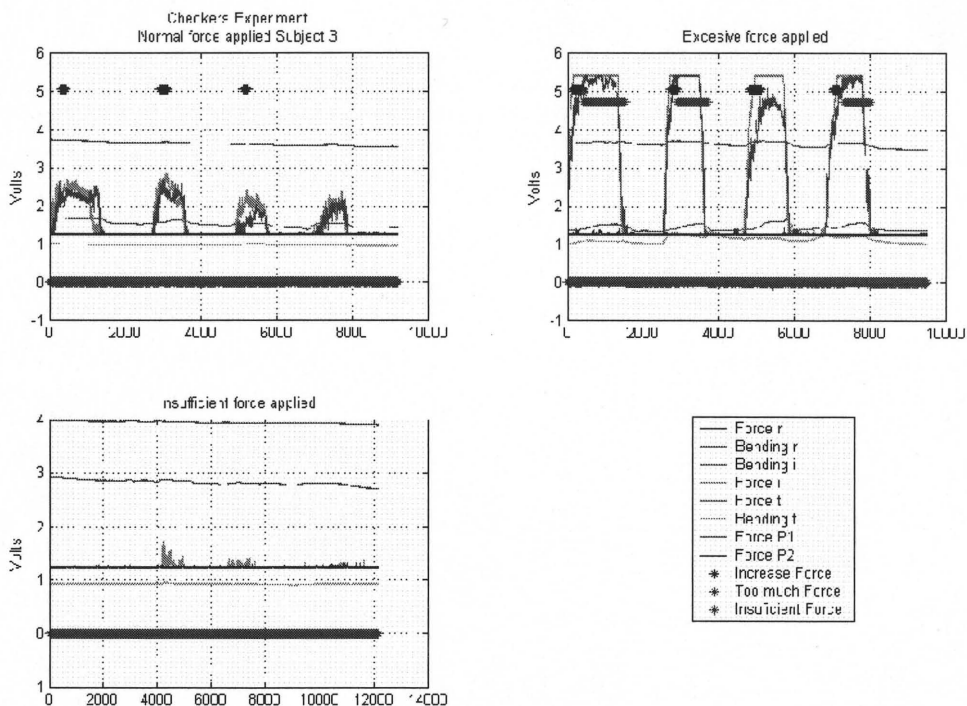


Figure A.16 Results for Stacking Checkers for Subject Three.

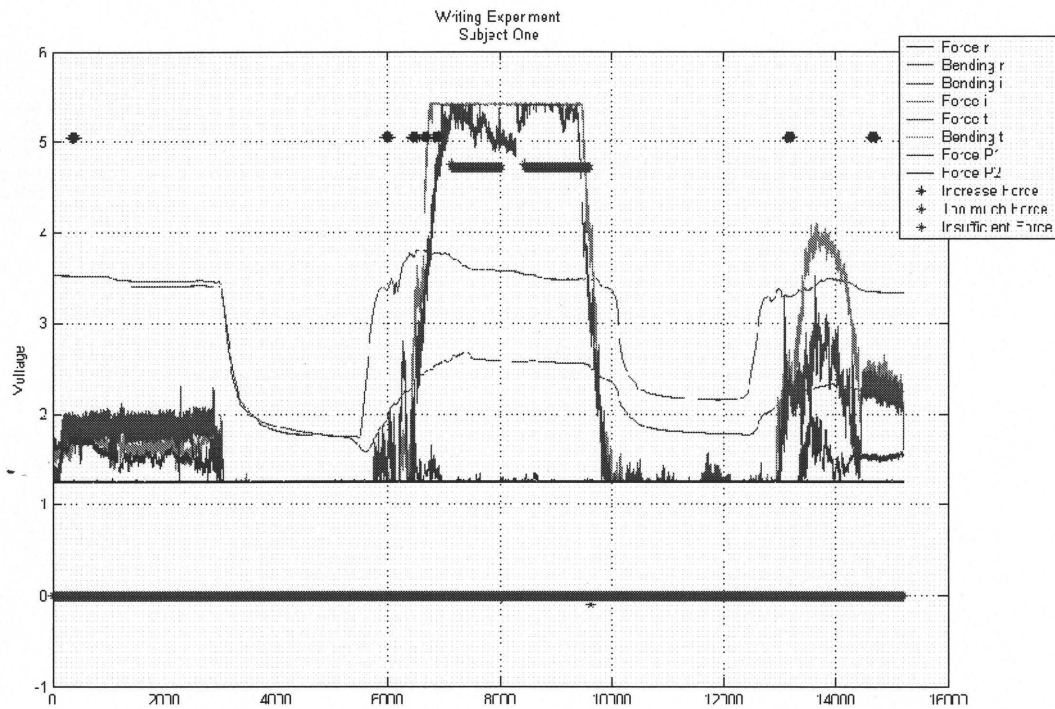


Figure A.17 Results for Writing for Subject One.

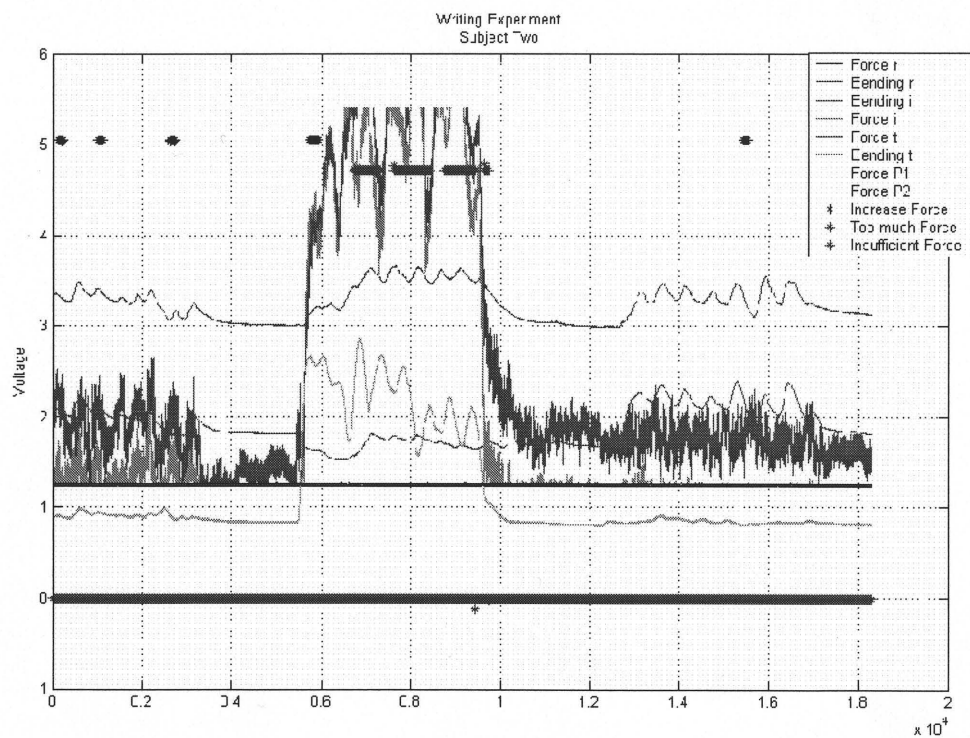


Figure A.18 Results for Writing for Subject Two.

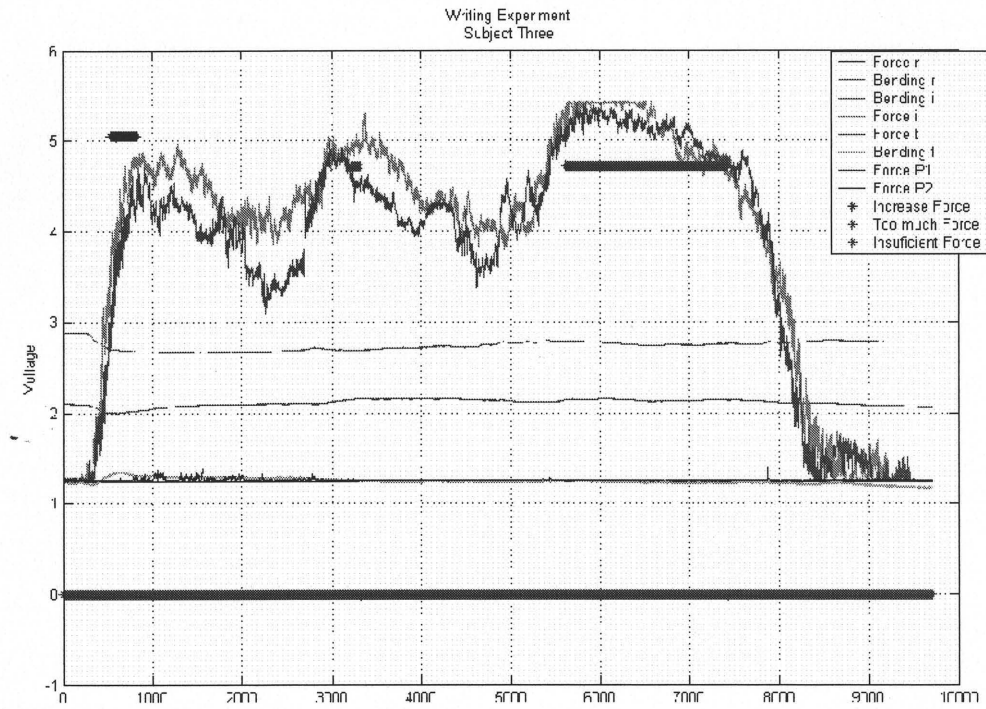


Figure A.19 Results for Writing for Subject Three.

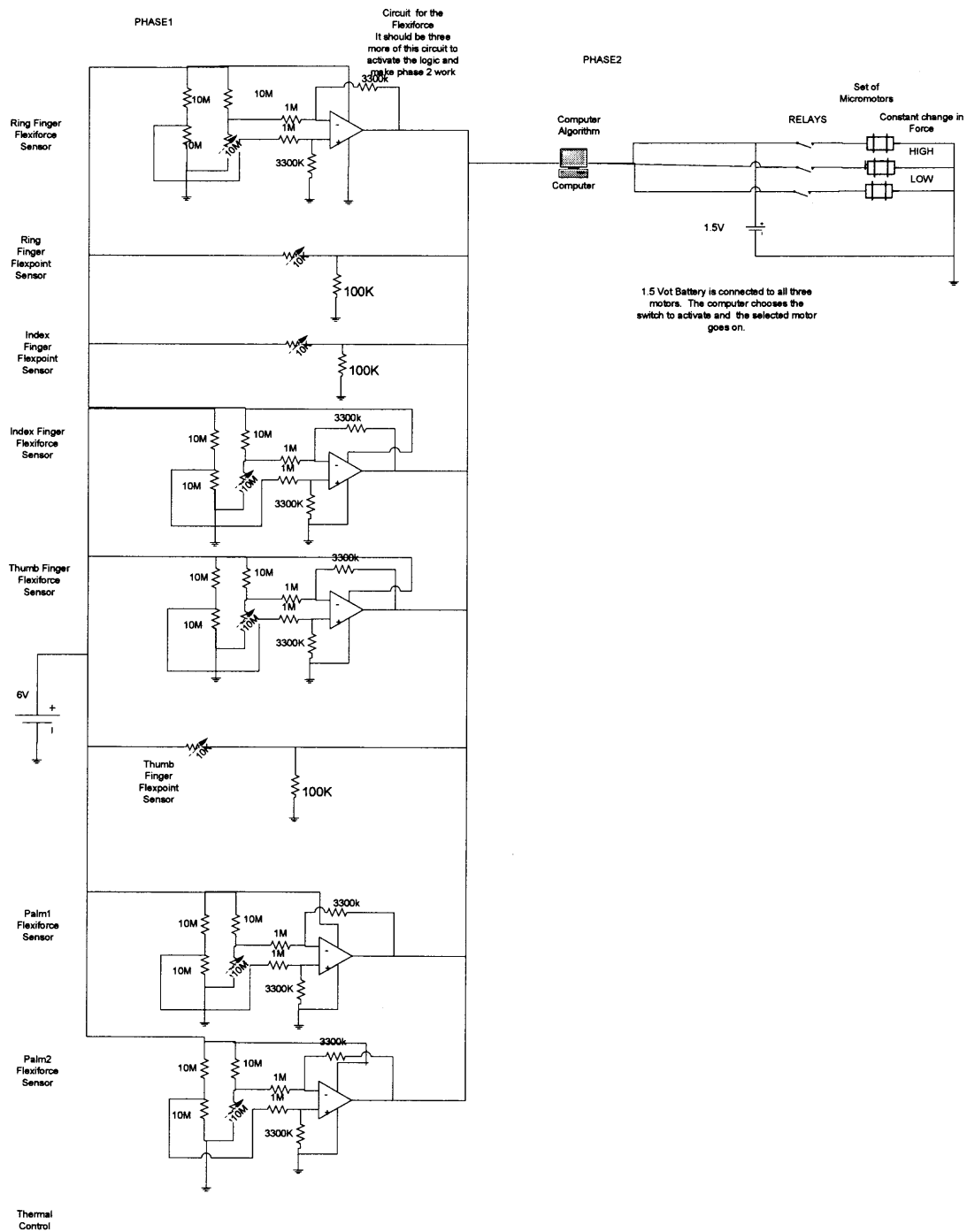


Figure A.20 Full Circuit.

APENDIX B

IRB FORM

This is the form used to have the approval consent from the individuals who participated in this study.

PLEASE PRINT OR TYPEDate: February 20, 2006

**HUMAN SUBJECT RESEARCH REVIEW FORM
NEW JERSEY INSTITUTE OF TECHNOLOGY
INSTITUTIONAL REVIEW BOARD**

Name of Principal Investigator(s): Lisa K. Simone Ph.D.

NJIT Address: Department of Biomedical Engineering
Fenster Hall, Room 675
University Heights
323 Martin Luther King Jr. Boulevard
Newark, NJ 07102

Department: Biomedical EngineeringE-mail Address: lisa.k.simone@njit.edu

NJIT Affiliation (Check):

Faculty Student Other (Describe: _____)

*Note students and doctoral candidate applying for IRB approval must submit written documentation from their faculty advisors (via e-mail) stating that research is being conducted under their supervision.

Project Title: Join angle and force on the fingers for hand rehabilitation

This project will be conducted:

On Campus Off Campus Both

Is this research funded by outside source(s)? Yes No

If yes, indicate name(s) and type of funding source(s):

Name of Funding Source(s):
Type: Government (County, State or Federal) Foundation Corporation
 Other (Describe: _____)

Anticipated Starting Date of Project: February 28, 2006Anticipated Closing Date of Project: April 20, 2006Number of Subjects: 3

NOTE: All principal investigators, faculty, and students who will be interfacing with human subjects in this study must complete an online training course in the protection of human subjects. This course can be accessed by going to the US Department of Health and Human Services' Office for Human Research Protection website (<http://www.hhs.gov/ohrp/>) and clicking on "Education." At the bottom of this page, you will see the tutorial for the training module for assurances. All certificates indicating course completion must be submitted with this application.

To Principal Investigator: In addition to the questions below, please furnish copies of any questionnaires interview formats, testing instruments or other documents necessary to carry out the research.

The completed forms should be sent to: Dawn Hall Apgar, PhD
dawn.apgar@njit.edu
 Chair, IRB
 DD Planning Institute – CABSR
 Campbell 330
 New Jersey Institute of Technology
 University Heights
 Newark, NJ 07102-1982

-
- I. Project Title:

 2. List the names and status (faculty, student, etc.) of the persons conducting the research:
 - a. Principal Investigator(s):
Lisa K. Simone Ph. D
 - b. Other Members of Research Team:
Carlos X Rosado B.A, Collaborator
Brad J Galego, B.A, Collaborator
Manish T Raval, B.A, Collaborator
 - c. NJIT Faculty Advisor(s) if Student Project:
Lisa K. Simone, Ph.D., NJIT Faculty

 3. Describe the objectives, methods and procedures of the research project. This summary will used to describe your project to the IRB. Use up to 2 pages, if necessary. You may also attach a copy of an abstract or full research proposal describing this work.

Introduction and Specific Aims

The objective of this research is to collect data from joint angles and force use in daily day activities. The information collected will be used to develop and algorithm that thru micro motors will provide haptic feedback in real-time. This system could be use full for patients who have had a stroke where the sense of touch has been partially or totally damage.

Most of the people who survive a stroke suffer from a reduce sense of touch. For these people regular activities such as grabbing a can or a glass of water tend to be extremely difficult because they lack or have a diminish sense of touch. Previous collected data shows that there are similar patterns in hand postures that can be use to create an algorithm that could provide haptic feedback in real time.

One of the major advantages of this system is a low cost. Therefore several models can be built to the study. The information collected can be analyzed objectively and appropriate pattern can be determined.

Aim1: Collect data in order to analyze hand posture and force applied to realize typical activities.

Methods

Data Acquisition:

The device is composed of several flexible and pressures sensors that are mounted a glove that can be were by the subject. When an individual grabs any object, he bends his fingers and presses on an object. The flexpoint sensors change its resistance due to the bending and the flexiforce sensor also changes their resistance when pressure is applied to them. The data is collected and analyzed by using a DAQmx card and process in LabView and Matlab programs.

Subjects: The study protocol will be submitted to and approved by the NJIT IRB before it is implemented. After completing a written consent process, subjects agreeing to participate will be enrolled in the evaluation. Three healthy individuals will participate in Aim 1 bench testing, lasting approximately one hour

Protocols: Aim 1 (3 subjects): The joint angle and force ranges would be measure. This data will be average to determine the array of motion and minimal force require for lifting an object up. Three flexpoints would be place on the back of the hand from the knuckles to about the third metacarpophalangeal. These sensors would measure the fingers range of motion while the patient grabs an object. The fingers selected are the ring, index and the thumb. In addition, five more sensors, flexiforces, would be place on the anterior part of the hand. Three of them would be place on the tip of the finger and two in the palms. These sensors would help to determine how much force the subject is using to pick up and object and the type of grasp the individual is using to complete the task.

6. What is the age of the subjects and how will they be recruited?

There are not major requirements. The subjects would be healthy people among the ages of twenty to twenty-six years old.

7. Attendant risks: Indicate any physical, psychological, social or privacy risk or pain, which may be incurred by human subjects, or any drugs medical procedures that will be used. (This includes any request for the subjects to reveal any embarrassing, sensitive, or confidential information about themselves or others.) Also, indicate if any deception will be used, and if so, describe it in detail. Include your plans for debriefing.

There is minimal risk involve in this study. One possible risk is a little bit of discomfort from wearing the glove with the sensors on it, perhaps a small rash from skin contact with the sensors. Another potential risk is small electrical shocks of few millivolts if the wire connections are peel off. However if careful isolation is used, this risk can be avoid. No psychological or mental risks are anticipated. Hand tiredness is also not be expected either because subjects are asked to hold objects on their hands for about ten to fifteen seconds using day to day hand postures.

8. Evaluate the risks presented in 7.
- a. Is it more that would normally be encountered in daily life?

No. The subjects are asked to hold small and medium cans or bottles, and perform task such as writing, cutting paper and clicking a mouse which are very common daily activities. Therefore, they must be familiar with these activities and they are not subject to any other ones.

- b. Do your procedures follow established and accepted methods in your field?

Yes. All protocols have been established and used in the field. Individuals are asked to perform daily activities while wearing the device, such as the Jebsen Taylor Hand Function Test, which is a common test used to assess hand function during 7 activities (writing, turning pages, picking up small objects, simulated feeding, stacking checkers, picking up large light cans, and picking up large heavy (1 pound) cans). We previously completed an IRB-approved protocol at KMRREC performing many of the same activities proposed here with healthy individuals and individuals with brain injury without any adverse events. The motion analysis protocol has been documented in Rash (1999) and involves placing small markers on the skin at different locations on the hand using double sided tape. As individuals move their hands, cameras detect the location of the markers and store these data to a computer. These systems have been used extensively in biomechanics research, animation, sports training, etc.

Jebsen R H, Taylor N, Trieschmann RB, Trotter M, Howard L. (1969). An Objective and Standardized Test of Hand Function. Archives of Physical Medicine and Rehabilitation, 50 (6), 311-319.

Rash GS, Belliappa PP, Wachowiak MP, Somia NN, and Gupta A. (1999). A Demonstration of the Validity of a 3-D Video Motion Analysis Method for Measuring Finger Flexion and Extension. Journal Of Biomechanics, 32(12), 1337-1341.

9. How will the risk be kept at a minimum? (e.g. describe how the procedures reflect respect for privacy, feeling, and dignity of subject and avoid unwarranted invasion of privacy or disregard anonymity in any way.) Also, if subjects will be asked to reveal any embarrassing, sensitive, or confidential information, how will confidentiality of the data be insured? Also include your plans for debriefing. If subjects will be placed under any physical risk, describe the appropriate medical support procedures.

Protection Against Risk: In order to safeguard against these risks, the researchers will carefully screen participants prior to selection to minimize the potential side effects. If a participant complains of skin irritation or any other discomfort due to sensor placement or marker placement, the trial will be stopped. If at any time the participant becomes uncomfortable with the study, he or she can end participation with no penalty. He or she will be instructed before the study begins that they can stop participation at any time. In the event that medical intervention is required, a call to 911 will be placed. Public Safety will also be notified immediately after calling 911, and any adverse reactions will be reported to the IRB. Students working on this project will be informed of these procedures.

Finally, all studies have the potential "risk" of confidentiality. HIPAA regulations have already been instituted to maintain confidentiality. In order to fully understand all

privacy risks, all students and staff involved in the study will have passed HIPAA and the protection of human subjects training courses. In order to safeguard confidentiality, as we have done with past studies, all participants will be identified by a subject number (including all electronic materials). Participant names will be matched with their number only on a master list. This master sheet will be filed in a locked cabinet Dr. Simone's office and will be accessible only to personnel directly involved with this study. All other means of participant identification (e.g., test protocols) will be by subject number only.

10. Describe the benefits to be derived from this research, both by the subject and by the scientific community (this is especially important if research involves children).

There are no immediate benefits to the subjects involved in this study; however, benefit to individuals in the future makes the project worthwhile. The device and measurement methods developed during this project will be used as tools and outcome measures in future research. This project is not a self-contained project, but is the first part of a larger line of research to better characterize and understand movement disorders that affect an individual's ability to perform basic daily activities. With a more reliable measurement method comes better understanding, and improved treatment and interventions that potentially improve the lives of persons who survive a stroke.

Objective outcome measures are critical to evaluate clinical conditions and treatments, and to compare results from subject to subject and with trials performed in multiple locations. Subjective scales have intra- and inter-operator variability that can be avoided by using an objective measure. This would allow clinicians to evaluate functional gains from interventions and to determine the appropriate feedback require to help the patients recover.

In addition, these measurement methods can be used in a variety of research projects such as examining diurnal patterns of finger position to understand the source of disability, and establishing efficacy of pharmacological interventions. Using objective, repeatable methods provides a solid foundation for future studies on understanding neurological and neuromuscular disorders.

- II. Describe the means through which human subjects will be informed of their right to participate, not to participate, or withdraw at any time. Indicate whether subjects will be adequately informed about the procedures of the experiment so that they can make an informed decision on whether or not to participate.

Upon initial contact, subjects will be invited to participate. Participants will receive verbal and written descriptions of the entire study process, and their consent will be recorded on consent forms in approved format which have been by the IRB. All questions raised by the subject will be answered prior to obtaining the signature.

The subject will be informed during this process that they have the right to withdraw at any time during the study without penalty.

12. Complete the attached copy of the Consent Form and the Institutional Review Board will make a determination if your subjects will be at risk. This Consent Form must include the

following five pieces of information: (1) The purpose of the research, (2) the procedures involved in the work, (3) the potential risk of participating, (4) the benefits of the research, (5) that the subjects are free to withdraw from the research at any time with no adverse consequences.

See form below.

- I3. Furnish copies of questionnaires, interview formats, testing instruments or other documents to carry out the research. If questionnaires are not complete please submit an outline of the questions to be used. You will have to submit the completed questionnaire to the Committee before the research can begin.

A questionnaire will be used to assess user comfort of the device. It will include questions regarding fit, comfort, ease of use, and explore how the user's felt the device affected their ability to perform daily activities. This questionnaire is attached, and was included with the NIH grant application that was approved.

Participants will perform activities of the Jebsen Taylor Hand Function Test, a commercially-available test Dr. Simone has previously acquired.

- I4. If the subjects will be minor children, complete Consent Form as prescribed in paragraph I2 for signature by parent or guardian. If the project is approved (regardless of the Board's determination concerning risk), it will be necessary that a Consent Form be secured for every minor child.

We will recruit individuals 20 years and older.

- I5. Attach copy of permission of facility to conduct the proposed research (if other than NJIT).

Kessler Medical Rehabilitation Research and Education Corporation (KMRREC) is Dr. Simone's previous place of employment, and she has verbal agreements and assurances that this work will continue as a collaboration at both KMRREC and NJIT. Dr. Simone recently received an NIH grant to perform this work; KMRREC investigators were listed on the grant. The proposal included in this IRB package is also being submitted to the KMRREC IRB (both will be the same) under the advice and direction of Dr. Richard Greene. Written IRB approval from KMRREC will be provided to the NJIT IRB when that approval is received.

Complete a Consent Form Using the Model Below:

NEW JERSEY INSTITUTE OF TECHNOLOGY
323 MARTIN LUTHER KING BLVD.
NEWARK, NJ 07102

(a) CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Portable low-cost monitor for functional hand measures

RESEARCH STUDY:

I, _____, have been asked to participate in a research study under the direction of Dr(s). Lisa Simone
 Other professional persons who work with them as study staff may assist to act for them.

PURPOSE:

The purpose of this study is to evaluate a portable monitor that measures how my fingers bend while I perform daily activities.

DURATION:

My participation in this study will last for 1 to 2 experimental sessions which are 1 to 26 hours long.

PROCEDURES:

I have been told that, during the course of this study, the following will occur:

If I am selected to participate in Evaluation I ("Device Testing"), an evaluator will move my finger joints to assess my hand function. The glove will be placed on my hand. I will be asked to move my fingers in different ways. This will take a maximum of 2 minutes to complete for each action. I will be asked to complete a questionnaire at the end. The entire session will last no more than one hour. (Healthy individuals only)

PARTICIPANTS:

I will be one of about 3 participants to participate in this trial.

EXCLUSIONS:

I will inform the researcher if any of the following apply to me:

- I am under the age of 16.
- I have communication difficulties which may significantly impede my ability to complete the tasks of the study (i.e. aphasia)

(For ABI subjects, only)

- I have a history of a significant neurological condition (e.g., treatment for Seizure Disorder), other than acquired brain injury (ABI).
- I sustained a stroke or traumatic brain injury (TBI) less than 4 months ago.
- I have finger joints that are fixed in a bent position and immovable.
- Any treatment involving botulinum toxin, phenol, or alcohol injection for hand function in last three months.
- I currently use of an intrathecal baclofen infusion pump.
- Here has been any change to any oral spasticity medications in the last 30 days (if applicable).

(For Healthy Control subjects, only)

- I have significant reduced range-of-motion in my wrists, hands, or fingers.
- I have a history of significant neurological condition (e.g., stroke, treatment for Seizure Disorder, TBI)

RISKS/DISCOMFORTS:

I have been told that the study described above may involve the following risks and/or discomforts:

There is a small risk that participating in this study may cause physical tiredness in my arm or hand. However, I am free to take a break from the study whenever I want to.

There is a small risk that participating in this study may cause irritation on my hand where the monitor is placed. If this occurs, I am free to end my participation in the study.

There also may be risks and discomforts that are not yet known.

I fully recognize that there are risks that I may be exposed to by volunteering in this study which are inherent in participating in any study; I understand that I am not covered by NJIT's insurance policy for any injury or loss I might sustain in the course of participating in the study.

CONFIDENTIALITY:

I understand confidential is not the same as anonymous. Confidential means that my name will not be disclosed if there exists a documented linkage between my identity and my responses as recorded in the research records. Every effort will be made to maintain the confidentiality of my study records. If the findings from the study are published, I will not be identified by name. My identity will remain confidential unless disclosure is required by law.

VIDEOTAPING/AUDIOTAPING: (NEED TO INCLUDE ONLY IF APPLICABLE)

I understand that I will be video and audio taped during the course of this study. Video and audio tapes will be stored for (3 years) after the end of this project (April 1, 2011). After that time, the tapes will be erased by recording over my recorded sessions.

Video/audio will primarily be used for analysis of how I use my hand while performing activities. However, the investigators may use the video for educational or presentation purposes. In these cases, I will not be identified, and if my face appears in the video, it will be blacked out or otherwise obscured.

The tapes will be stored in a locked office at NJIT and will not be made available to anyone except (insert names) who are involved in this research.

PAYMENT FOR PARTICIPATION:

I have been told that I will receive compensation for my participation in this study. If I participate in Evaluation 1 "Device Testing or Evaluation 2 "Hand Function Testing", I will receive \$50. If I participate in Evaluation 3 "24 Hour Testing", I will receive \$200 if all equipment is returned (even if broken) at the completion of the study.

RIGHT TO REFUSE OR WITHDRAW:

I understand that my participation is voluntary and I may refuse to participate, or may discontinue my participation at any time with no adverse consequence. I also understand that the investigator has the right to withdraw me from the study at any time.

INDIVIDUAL TO CONTACT:

If I have any questions about my treatment or research procedures, I understand that I should contact the principal investigator at:

Lisa Simone, Ph.D.
Assistant Research Professor
Department of Biomedical Engineering
New Jersey Institute of Technology
University Heights, Newark, NJ 07102
Phone: (973) 596-2982 Fax: (973) 596-5222
Email: lisa.simone@njit.edu

If I have any addition questions about my rights as a research subject, I may contact:

Dawn Hall Apgar, PhD, IRB Chair
 New Jersey Institute of Technology
 323 Martin Luther King Boulevard
 Newark, NJ 07102
 (973) 642-7616
 dawn.apgar@njit.edu

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Subject Name: _____ Signature: _____

Date: _____

SIGNATURE OF READER/TRANSLATOR IF THE PARTICIPANT DOES NOT READ ENGLISH WELL

The person who has signed above, _____, does not read English well, I read English well and am fluent in (name of the language) _____, a language the subject understands well. I have translated for the subject the entire content of this form. To the best of my knowledge, the participant understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered to the complete satisfaction of the participant (his/her parent/legal guardian).

Reader/Translator Name: _____

Signature: _____

Date: _____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge, the participant, _____,
has understood the entire content of the above consent form, and comprehends the study.
The participants and those of his/her parent/legal guardian have been accurately answered
to his/her/their complete satisfaction.

Investigator's Name: _____

Signature: _____

Date: _____

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