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Preliminary Design Report

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Device for acute hand rehabilitation after stroke

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Problem Summary

The project is to design a portable device that will facilitate hand rehabilitation in the acute phase after stroke, first three months. The device will be simply attachable to the impaired arm, be comfortable for the user and be able to accommodate various size arms for almost complete universal use. Rehabilitation of the hand will include trying to improve supination/pronation, flexion/extension, and distal movements of the impaired hand; supination/pronation movements will be the primary focus. To assist in the movement of the hand during rehabilitation, the design will incorporate a TENS unit.

Background Information

Stroke is a cardiovascular disease that affects the brain by blocking a blood vessel that delivers oxygen and nutrients that are necessary for brain function. When the blood vessel becomes blocked, blood no longer supplies the cells in the brain, resulting in cells death where the blockage occurred. Effects of stroke are based on several factors including in which section of the brain that the obstruction occurred. Hemiplegia is a common disability that occurs from strokes, the affected side of the body is the opposite of the hemisphere of the brain where the blockage occurred.

Stroke is the leading cause of adult disability in the United States. A stroke occurs an average of once every 45 seconds in this country. Of the stroke victims in the United States, 72% are above the age of 65ⁱ. The scientific community researches and develops ways to help stroke patients rehabilitate impaired limbs, and in severe cases whole bodies from the semi-paralysis following strokes.

Recovery of upper extremity function is independent of the overall level of stroke severity. Rehabilitation strategies to focus on upper limb function include neurodevelopment techniques, motor relearning, biofeedback, splinting, constraint-induced movement therapy, robot-induced therapy and electrical stimulation. Electrical stimulation along with these methods may be associated with additional recovery in the motor and sensory functions of the hand. Electrical stimulation often comes from a TENS unit. A TENS unit delivers electric pulses through skin patches to assist in movement or help deter atrophy. Some problems with TENS units are that discomfort has been reported by some patients when the amplitude has been placed too high. However, when the TENS unit was at the minimum level to cause full wrist stimulation, the patients reported no discomfortⁱⁱ.

There is a great variance of sizes of arms and hands within the population. Similarly, there is a difference between males and females. The normal grip radius of the arm varies from 14.9 in to 18.9 in, 37.8 cm to 48 cmⁱⁱⁱ. The low value of the range is the radius of the low value for women. This value is of the 2.5% of the population of women, it is two standard deviations below the median value of women aged 18-65. The higher value is that of the 97.5% of men, since the men's value was larger than the women were. This value is two standard deviations

ⁱ The American Heart Association (2006) www.americanheart.org

ⁱⁱ Yozbatiran, N. "Electrical stimulation of wrist and fingers for sensory and functional recovery in actor hemiplegia." (2006). Clin Rehabil. Volume: 20, Issue:1, Pages:4-11

ⁱⁱⁱ Diffrient, N. Humanscale. (1981). Vol. 7.

above the median value for men age 18-65. To be as universal as possible, the design should accommodate this range of arm radius values.

Other studies on hand rehabilitation have demonstrated mimicry of movement by the good hand has improved the outcomes during rehabilitation. Using both arms/hands within rehabilitation therapy will increase regaining a greater range of motion within impaired limb^{iv}.

There are several constraints for the design to make it optimal for our client's needs. Mostly patients in wheelchairs will use the device. Therefore, it must be small and lightweight enough to be fixed to a wheelchair and then removed after use. Ideally, it will be mounted on a wheelchair tray that clips on the armrests of the chair. The tray is 24" x 20" and ½ inch thick. The system needs to be comfortable and non-imposing to the patients. The device will be used during physical therapy sessions a maximum of three times per day, with each session lasting from 0.5-2 hours. The device must be composed of materials that can be sterilized using alcohol or other anti-bacterial solutions between uses. Patient engagement is also a key-facet of our design, as we want patients to be engaged so that they will want to come back to do physical therapy. Our device needs to have some form of patient engagement beyond the physical motion of the hand. In addition, our device needs to be universal, i.e. it needs to be able to work either the right or left hand as well as accommodate patients with arm sizes within two standard deviations of the average. The physical therapists who moderate the usage of our device will use a TENS unit attached to the patient's arm to help those patients who do not have the necessary strength for movements corresponding to therapy. Since the TENS unit has electrodes that attach to the arm, the device needs to allow space for the placement of these patches. The complete product design specifications are in Appendix 1.

Motivation for this project stems for the need for an intermediate rehabilitation system. Rehabilitation centers throughout the United States utilize systems of varying degrees of sophistication. The range is from squeezing a ball, to complete robotic arm systems that mirror movement. This project will fall in between these two systems. Another motivation is to design a comprehensive device, meaning that it should be universal and engaging. This device should make the patient forget about being in physical therapy. Further information that will be needed for the design is to get engagement preferences of the patients.

Design Components

Thus far, three main components for the designs were determined: arm support, patient interface, and patient engagement. The arm support will allow for isolated movement but hold the impaired arm in a comfortable position for the desired movements to be performed. This will allow for a greater range of motion than if the arm is to sit directly on the tray, which would limit the degrees of motion of the patients' hand movements (supination, pronation, distal and flexion/extension).

The second component our designs will focus on will be patient interface; the form in which the patient interacts with the device. Considerations for this component will be what the patient is holding and what motion(s) the interface will allow. This portion of the total design will also need to focus on the lack of finger dexterity the users will have. The patients will most

^{iv} Burgar, et al. "Development of robots for rehabilitation therapy: the Palo Alto VA/Stanford experience," (2000). Journal of Rehabilitation Research and Development Vol. 37 No. 6

likely need some form of assistance to grip the interface, unless it accommodates the rigidity of their hands.

The third component of the design is patient engagement. Patient engagement will be the interaction system between the patient and the system of rehabilitation. This component will be some sort of stimulus, hopefully, allowing the patient to forget they are in therapy.

Component one: arm support

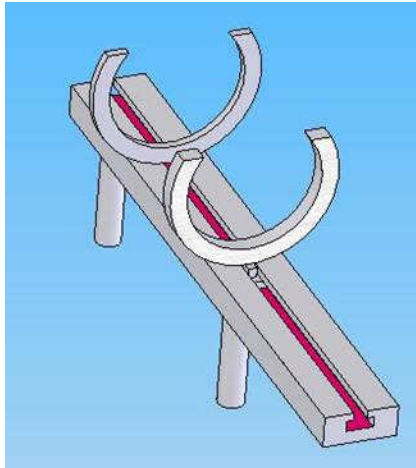


Figure 1

For the arm support, a single design incorporates the criteria for the arm constraint, seen in Figure 1. The armrest will employ an elevated arm restraint that will be universal and adjustable for the given patient. The arm will be secured by two U-braces that can slide forward and backward on a track running down the middle of the armrest. These moveable braces will allow for various sizes of arms to be secured comfortably in the system. An advantage of using two U-braces, instead of one long brace, is that there will be plenty of space between the braces for the physical therapists to attach the TENS unit to the patient's arm. The U-braces will have locks, to lock them in place once the proper spacing has been reached for the patient. The arm rest will also have adjustable height pegs supporting it from the tray top. With adjustable height pegs, the angle of the arm rests can be altered for optimal access to the device and comfort of the user. For extra support and to prevent compensatory arm movements, the U-braces will be moldable to add arm restraint, allowing rotation of the arm but preventing any bending at the elbow. This armrest may require a supplemental shoulder restraint because as patients struggle to move their impaired hand, they might try to compensate by moving their whole body to lean into the motion. A simple shoulder strap could remedy this concern while not interfering with the function of the armrest.

Component two: interaction with hand

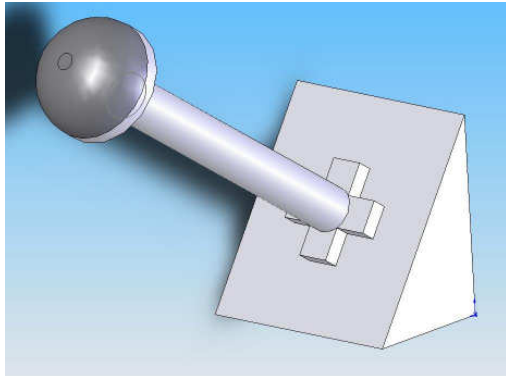
For the interface interacting with the impaired hand, three options were designed. One of the options is the "therapy cylinder," seen in Figure 2, consisting of three rings each with a diameter of 6" and depth of 3" joined together so the middle ring can rotate while the two outside rings stay fixed. The middle section contains a slot for the patient's hand, supported by plates from above and below. Therefore, when the patient performs supination and pronation of the wrist, the middle section of the cylinder will rotate. On the outside of the center ring, there are 1" 'fingers' that are extensions located to the left and right of the tube. The extensions push buttons that activate a function in the patient engagement system. Placement of these buttons will allow for maximum rotation during pronation/supination. There are two main advantages to this system for interaction with the hand. First, since the



Figure 2

patient's hand will be supported by two plates from above and below, little to no finger dexterity is required to be able to use the device. Second, the way the cylinder is constructed allows for a full range of motion in either the pronation or the supination direction. The only drawback to this design is that it is limited to the pronation/supination motions, having no capacity for flexion/extension or distal movements.

The second design for interaction with the impaired hand is a ball joint connected to a joystick, seen in Figure 3, like those used in video games. This interface has many advantages. The ball joint allows for the most degrees of freedom in the movement of the patients hand.



Pronation and supination are accomplished by twisting the top of the knob; distal movement is accomplished by moving the joystick left and right; flexion and extension are accomplished by pushing the joystick up and down. The ball joint interface has the freedom of movement for the whole range of exercises to be completed. The disadvantage of this design is that it is complex to build and the movements would have to be precise which could be difficult for the patient. Grasping the handle could also be potentially difficult

Figure 3

for the patients depending on the dexterity in their fingers.

The third possibility for hand interface is a t-bar handle. This handle will allow the supination and pronation movements of the impaired wrist. The t-bar handle will be on a telescoping stand that will allow vertical adjustment to accommodate different sized patients. An advantage of this handle is the degree of motion in the supination and pronation movements. However, this interface only allows for the one motion. Another disadvantage with the handle is that due to minimal finger dexterity the t-bar will be difficult to grasp. Assistance for grasping may be required; a possible solution to this would be placing an electromagnetic grip on the hand, which would allow for the necessary grasping of the handle.

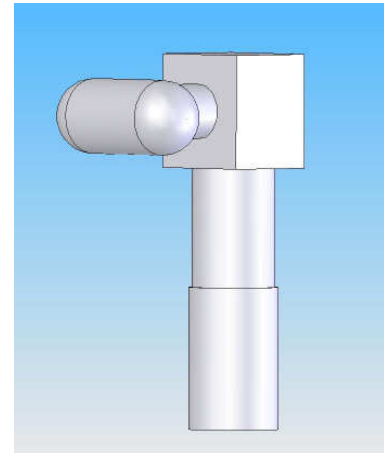


Figure 4

Component three: patient engagement

The last of the main components for this project is how to manipulate the device to make it engaging for the patient. There are two approaches for the patient engagement. The first is a mechanically driven art project that will use the ball joint interface, seen in Figure 5. At the base of a cylinder is a spinning wheel propelled by a small motor. Paint is dispensed onto the paper from the painting arm to create a design. The patient can control the device in three ways. First, the location of the paint dispenser can be controlled by the turning of the long arm along the spinning wheel's radius. Second, the color can be chosen by the rotation of the paint dispenser's head. Finally, an aliquot of paint can be delivered. These three means of interaction can be controlled by three different dimensions of the patient interface: pronation-supination, distal

movement, and flexion-extension. In order to encourage rehabilitation, physical therapists can challenge patients to mimic more complicated designs as they progress in therapy. Creating these designs can give a sense of achievement, and also act as a means to track the progress of the patient's dexterity.

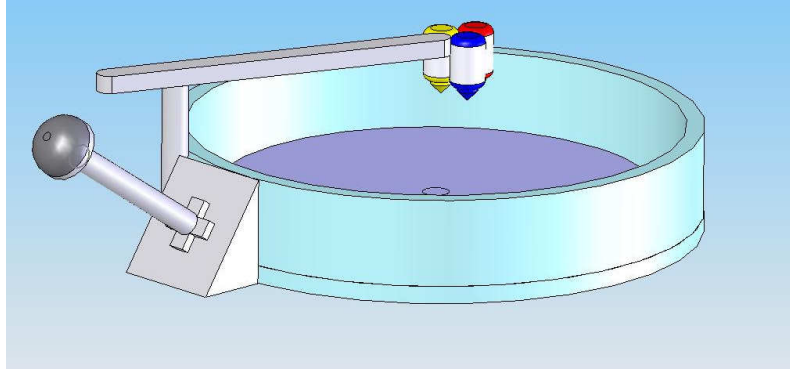


Figure 5

The second idea for patient engagement is to employ a virtual interaction. When patients move their hand, they will control the virtual environment. This virtual environment may be as simple as clicking to the next photo in a slideshow or as complicated as steering a car in a driving game. The system would be equipped with a 12" monitor where the virtual environment will be displayed. By allowing the patient to control the virtual environment with the motion of their arm, it gives both the patient and the physical therapist some feedback as to how much control the patient has of their movement. Also, the possibility of including a game increases the possibility of engaging the patient's attention during rehabilitation.

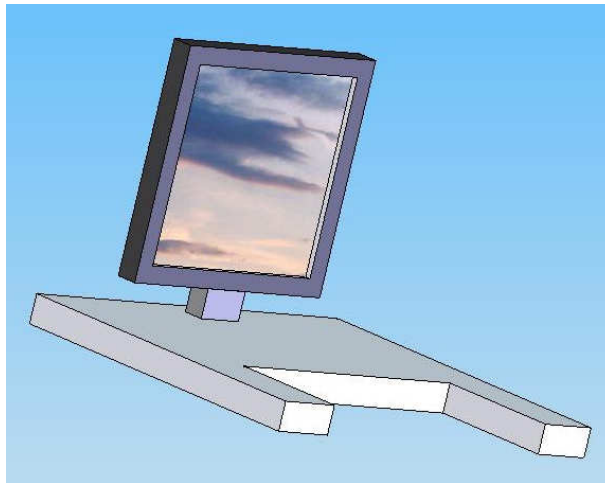


Figure 6

Proposed Design

The proposed solution to the problem is a combination of the preliminary design components. The therapy cylinder will be used for the patient interface because it allows free rotation for pronation and supination. Since the hand is supported inside of the cylinder, movement can be accomplished, even if the patient has low finger dexterity. The background research indicated using both hands could improve the outcomes of rehabilitation. Consequently, the proposed design is to incorporate a dual interface system. The restraining support will be placed on both arms to make the device symmetric and unbiased towards either the healthy or the paretic hand. An electric display will be used for patient engagement because it allows for the most freedom in the type of game or feedback for patients. These components will allow for straightforward interaction and swift adjustment to the use of the device.

Future Work and Considerations

As we move forward with this project, it is important for us to be cognitive of problems we may face and to have some potential solutions worked out. One potential problem with this device is sanitation. Since their hand will be inside the device and they will be performing long duration exercise, perspiration is likely. To reduce this problem, we plan to make the hand interface from non-porous materials and build it with the ability to be rinsed or wiped with an alcohol solution for cleaning. Another potential problem could be the interfacing between the peripheral device and the display; we may not have enough computer or technical knowledge to make the ideal game or feedback mechanism. The balance of the device could also be an issue. The screen is going to be mounted towards the end of the tray and it is heavy compared to the rest of the components. We might be able to resolve this issue by using the hand cylinders as a counter balance and minimizing the size of the screen. We need to develop a secure means to attach our device to the wheelchair, because there is going to be forces exerted on our device by the patient. Given the physical situation of the patient, the direction and intensity of the force on the machine might be hard for the patient to control. Therefore, the system will need to be securely attached to the wheelchair.

Appendix

Product Design Specifications

This device will assist in hand rehabilitation in stroke victims in the first three months after stroke. The device should use FES to assist in the supination and pronation movements of the wrist.

Stroke is the leading cause of long-term disability in the United States. Hand impairment is prevalent in stroke patients and is particularly debilitating since it limits independence and the ability to use the hand to do real tasks like eating and drinking. The goal is to design a device to facilitate hand rehabilitation in the acute phase, the first 3 months, after stroke.

Design requirements:

- easily to attach to the impaired arm
- comfortable to wear
- accommodates various sized hands and forearms
- attach to either the left or the right arm
- portable and mobile to be used while seated in a wheelchair

- use functional electrical stimulation via an existing TENS unit, FES
- use electromagnets to assist in grasp and release of an object
- pronation and supination motions of the wrist

1. Physical and Operational Characteristics

- Performance Requirements*- The device will be used during physical therapy sessions. The sessions will be 3 times a week, for a maximum use time of 2 hours per sessions, and the sessions will continue for 6 weeks. Also, no more than 3 patients will use one device within a therapy session. So, the device will be used on an average of 18 hours a week. Loading and unloading of the device onto the wheelchair will be done by a physical therapist. The device should be able to be used on either arm and be used with a wide range of arm sizes. The device will focus on the supination and pronation movements of the wrist.
- Safety*- The FES should not cause discomfort to the user. The device should be easy to use for sanitary reasons. Also, the device should not impede with the movement of the wheels of the wheelchair.
- Accuracy and Reliability*- The device should allow for 270° rotation. The device should be able to rotate repeatedly for the durations of the sessions without change in rotational resistance of the device.
- Life in Service*- The system should work for 3 years, after that time the system would be replaced with a new system. The battery life for an alkaline battery in use is 140 hours.
- Shelf Life*- The shelf life should be able to sit on a shelf for 10 years. The only component that would have a shorter shelf life would be the battery, which is easily replaced.
- Operating Environment*- The device will be used within a hospital, in a clinical setting. It will be used indoors.
- Ergonomics*- The range of sizes of our device will fall within 2 standard deviations of the average size arm. Be able to accommodate any size arm without causing discomfort, itching. Also should not debilitate arm function by being strapped into a fixed position. The device should also be allowed to be adjusted and released by their good arm.
- Size*- Work within the confines of a desktop for a wheelchair which is the size 24" x 20", and also attach our system to any part of the wheelchair. The maximum volume of our device will be 24"x 20"x 18".
- Weight*- Less than 15 lbs
- Materials*- Hypo-allergenic materials that are easily cleaned.
- Aesthetics*- Should not be intimidating, unimposing, and interactive.

2. Production Characteristics

- Quantity*- 1
- Budget*- \$750.

4. Miscellaneous

- Standards and Specifications*- Since our device will be in the prototype phase, there are no FDA regulations that govern our project.
- Customer*- The user of this device will be within the age range of 45-80, so the device should be geared toward that audience. Variations could be made to the system to accommodate other ages.
- Patient-related concerns*- sterilization

- d. *Competition-* A BME design group from Marquette University.

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