HAND-HELD DEVICE TO REDUCE SPASTICITY

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ABSTRACT

Stroke is one of the leading causes of death and disability in the United States, commonly resulting in hemiparesis, the partial weakening of one side of the body. Relaxation of tense muscles can reduce spasticity and improve functioning of the body. The client, a sufferer of hemiparesis, has discovered that the relaxation of her hand can reduce spasticity in her gait. She has fabricated her own device but has requested for a new and improved design. In order to satisfy the client's design requirements for an effective, convenient, and single lightweight device, the team has explored three different shapes to hold the hand open and three different mechanisms to attach the shape to the hand. After analysis from design matrices, the M&M shape and the pocket attachment were the chosen design components for the preliminary prototype. However, since this project is highly personalized to fit the client's needs, multiple prototypes with different shapes and attachment mechanisms will be fabricated to determine which design works best for her. The final product will be tested, surveyed by the general public, and possibly distributed to others who are also suffering from hemiparesis and can benefit from this device.

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INTRODUCTION

Stroke is one of the leading causes of death and adult disability in the United States, taking about 135,000 lives a year, and crippling countless more. Hemiparesis, the partial weakening or reduced functioning of one side of the body, is a common result of stroke. One of the devastating symptoms of hemiparesis, spasticity, is the involuntary tightening of certain muscle groups along the affected side [1].

In recent years several methods to reduce spasticity have been discovered. One such method, electrical stimulation, physically reduces tension in muscles through electrical current. Injections of botulinum toxin (botox) can also limit plasticity's effects on the body. Despite its simplicity, stretching is also very effective in increasing one's range of motion and relaxing spastic muscles.

Stretching is a main component of physical therapy, the most frequently implemented method of rehabilitation for stroke victims. In spite of its widespread use, physical therapy is one of the least researched rehabilitation methods. However, there is an observed phenomenon that by abducting the thenar muscle groups—the muscles located at the base of the thumb, connecting it to the hand—from the palm, spasticity can be reduced throughout one's body [3, 4]. The specific movement and positioning of the thumb as well as the extent of spastic reduction vary from patient to patient. One patient who finds incredible benefit from this motion, is the client, Carol Rohl.

Background and Motivation

Carol, a musician and physically active woman, suffered from a stroke seven years ago, and has since been hemiparetic. She experiences reduced functioning along the left side of her body. Her spastic muscles clench and tighten involuntarily. This spasticity causes a somewhat awkward gait when she walks. However, she discovered that when she pulls her left thumb away from her hand, she actually reduces some of the tension along her left side, improving her gait. Unfortunately, she is not aware of any commercially available designs that accomplish this

Figure 1: The client's current device, composed of a mini tennis ball and a jogger's strap.

movement, so Carol began designing and crafting her own.

The current device she implements, as seen in Figure 1, consists of a mini tennis ball placed within a jogger's strap around her left hand. Although effective in opening her hand and relaxing her left side, Carol has found that this device is incredibly inconvenient. Since it is made of two separate components, it is difficult to maneuver. In search of a more compact, efficient design she came to UW-Madison's Biomedical Engineering department.

Design Criteria

The major disadvantage with the client's current device is its inconvenience. For this reason the new device must be a single compact device. The components must be effectively secured to each other so the device can easily be removed. The device must effectively open her hand, in order to achieve the main goal of the project in relaxing her left side and improving her gait. Since the device is being designed specifically for the client, the dimensions of the device are to be based off of the measurements of the client's hand (Figure 2). When the device is in use, it must be capable of being easily put aside, perhaps by turning it to the back of her hand. It should be made from a lightweight, breathable, and washable material, such as cotton. Finally, the device should be colorful and aesthetically pleasing.

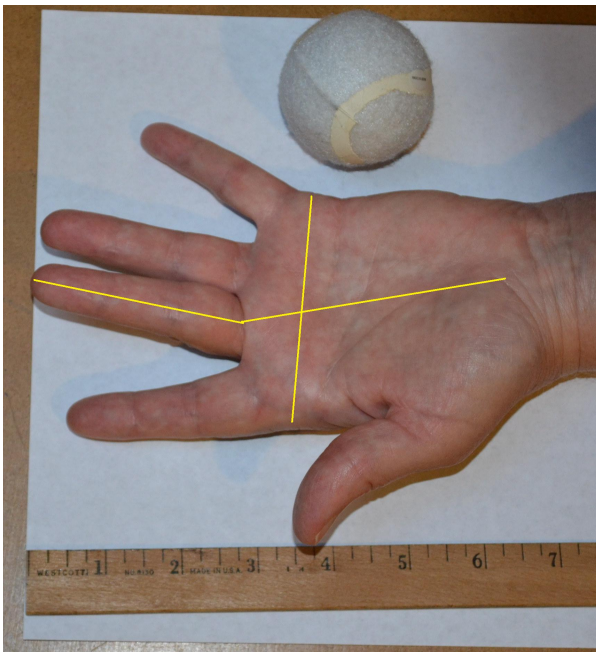

Figure 2: The client's hand. The yellow lines mark the three areas where measurements were taken using the program ImageJ. Measured lengths: 2.797 inches (middle finger), 3.064 inches (palm width), and 3.578 (palm length).

Overview of Designs

The proposed design consists of three main parts: a three-dimensional shape, a cotton strap, and a method of connection that bind the two. The main function of the strap and the shape is to maintain the hand in an open, relaxed position with maximum comfort and convenience. The other component is a method of connection. This will be used to attach the design together with a

strong enough bind to resist the hand from forming a fist, but allow the shape to be removable from the strap for washing. These main parts come together to ultimately improve the user's gait by easing open the muscles in their hand.

Shape Designs

The three proposed shapes for this project were a 2-inch diameter sphere, a 2-inch diameter M&M shape, and a 2-inch diameter rod. The diameter of each shape was chosen according to that of the client's current design but have varying dimensions in the other directions. While the sphere is the same as what the client has now, the design team chose the M&M shape because it has a 2-inch diameter along the major axis as seen from the top, and a 1.5-inch diameter along the minor axis, so that it can hold the fingers open, but also allows the shape to be more discreet when moved to the back of the hand when not in use. The third shape, a 2-inch long rod, was chosen for its ability to contour to a hand.

Evaluation of Shape Designs

Table 1: The design matrix for the shapes, which include a sphere, M&M and rod shaped designs.

Criteria (Weight)	Sphere	M&M	Rod
Performance (30)	28	25	20
Comfort (20)	16	18	17
Convenience (15)	13	14	10
Size (15)	10	14	13
Versatility (10)	8	9	5
Ease of fabrication (5)	5	5	3
Aesthetics (5)	3	4	3
Total (100)	83	89	71

The criteria used to compare the previously described shapes and their corresponding rankings for each category are summarized in Table 1. The performance criterion was given the highest weight due to the fact that the functionality of the shape largely determines the effectiveness of the device. Performance was defined as the ability of the shape to contribute in keeping the client's hand in an open and relaxed position. For this, the sphere scored the highest

due to the fact that when connected to a strap at the top of the palm, it can hold the fingers out substantially more than the other two shapes. Along those same lines, comfort is also a key element. The shape needs to fit into the contour of the hand so that the client can be comfortable using the device for short or long term use. The M&M shape was determined to be the most comfortable since when placed at the base of the fingers it complements the contours of the user's fingers and also the shape of the palm. The sphere's radius of curvature was too large to form to the palm, and the rod's irregular shape was not similar to the contour of a relaxed hand therefore these two received lower scores.

Convenience was next in weight, which was defined as the ability of the shape to be moved from the palm to the back of the hand to allow the user to perform two handed tasks without the restrictions of the shape. The M&M was considered to be the most convenient because the smaller radius of the oval-like shape allowed it to slide easily around the side of the client's hand to the back. Saying this, the larger radius of the sphere made it more difficult to do this same maneuver and therefore it received a lower score. Lastly, the rod received the lowest score because its irregular shape made it the most challenging to slide around the hand.

The overall dimensions of the shape with respect to the hand and its affect on functionality determined the score for the 'size' criterion. As the three shapes have similar diameters in one dimension, the other dimensions needed to be taken into consideration as well. The shape of the M&M scored the highest because the size of the two diameters allowed the simultaneous relaxation of the fingers and the mobility that is needed to slide it to the back of the hand or fit it under a sleeve when removing a jacket. For the first prototype, each shape is to be fabricated out of Smoothfoam, a more substantial version of regular packing foam. This means that the size is directly proportional to the weight of the shape, so this is also included in the category. The rod shape has the ability to keep all of the fingers spread, while minimizing the amount of weight in the design. The large volume of the sphere contributed to its heaviness and inefficiency, and therefore received a lower score.

Since it is important that this can be used during all four seasons outdoors, the shape needs to be designed to fit under a layer of clothing when not in use. The category to rate this was versatility. While the ellipse shape of an M&M would conveniently fit beneath the sleeve of a loose fitting coat or a mitten, the length of the rod would make it by far the hardest. Ease of fabrication and aesthetics were also included in the matrix, each with the lowest weight because

they did not directly impact the functionality of our design. All in all, the M&M shape received the highest score and will be the pursued design for the primary prototype.

Strap Designs

The strap portion of the device will consist of two parts: a fabric strap and an attachment mechanism to secure the shape to the strap. The fabric strap will be made out of colorful cotton as requested by the client. To allow for proper placement of the shape, the strap will rest slightly above the palm, near where the fingers meet the hand. Across the back of the hand will be either an elastic or Velcro portion (Figure 3). Both of the elastic and the Velcro materials would accomplish the specification of an adjustable and securable strap. They would also allow for easy movement away from the palm to perform two handed tasks or removal of the device all together. While both designs would successfully accomplish numerous design criteria, the team has determined that the elastic design will allow for easier use with one hand than would the Velcro design.

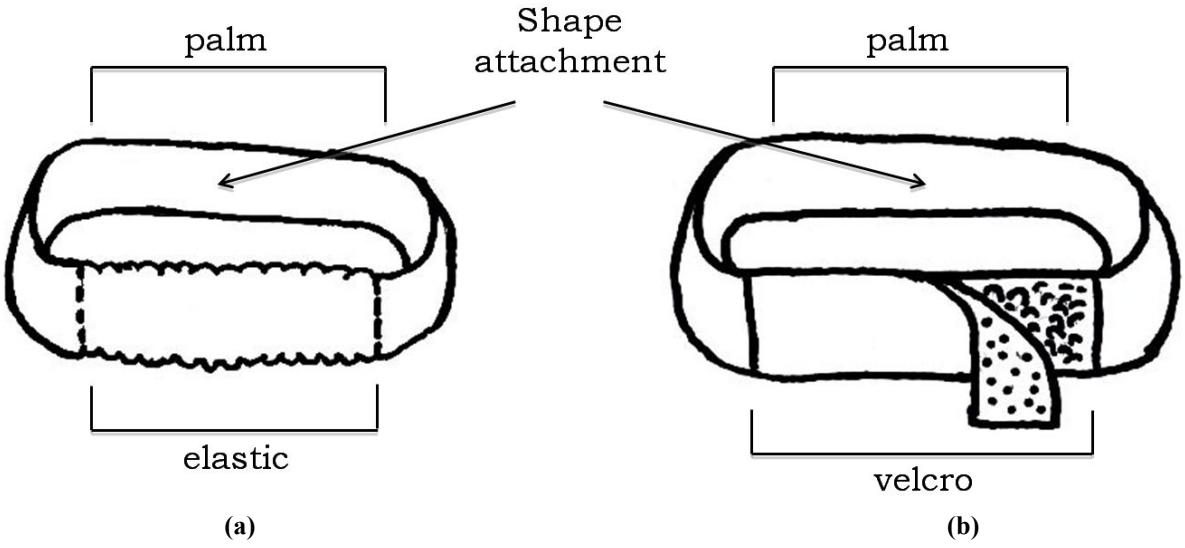

Figure 3: (a) Strap with elastic portion across to lie across the back of the hand. (b) Strap with Velcro portion to lie across the back of the hand.

Attachment Designs

Opposite from the elastic or Velcro portion of the strap will be the site of attachment of the shape. All three of these attachment mechanisms were designed to allow for removal of the shape while still providing a sufficiently secure attachment so the shape and strap function as one

unit. The purpose of removing the shape is to facilitate cleaning as well as allow for replacement of the shape.

Figure 4: The magnet design for a proposed method of attachment. The dashed box represents the location of the magnet within the strap.

The three proposed attachment mechanisms are a magnet, a screw and cap, or a pocket. In the magnet design, depicted in Figure 4, a magnet would be sewn into the strap, in between fabric layers and the other half of the magnet would be secured to the shape. For the screw design, a screw with a broad, flat head and a cap with matching threading would be used (Figure 5). The head of the screw would be sewn into the fabric of the strap with the threaded portion sticking out away from the hand. The cap would be inserted and glued into the shape. The third design, the pocket, would be sewn out of the same fabric as the strap and would feature a zipper on one side (Figure 6). The shape could then be easily inserted into the pocket through the zipper and the pocket would be sewn onto the strap.

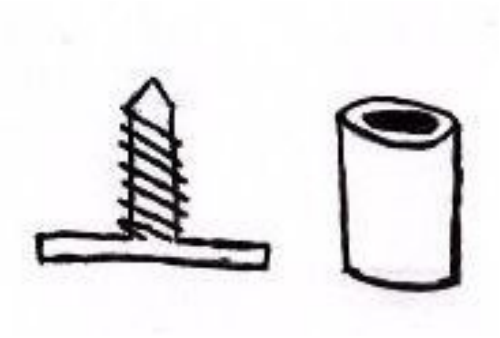

Figure 5: The screw and cap design for a proposed method of attachment.

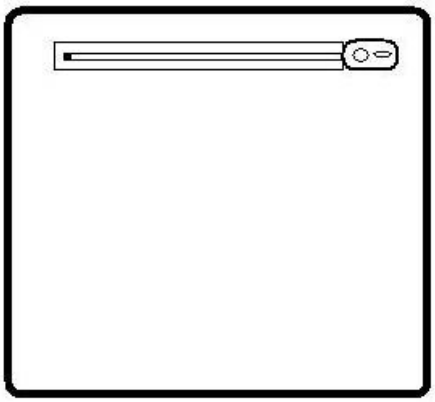

Figure 6: The pocket design for a proposed method of attachment.

Evaluation of Attachment Designs

In comparing the three designs, a number of criteria were considered. The most heavily weighted criterion was security, or how well each attachment mechanism holds the shape in the hand and to the strap. This was deemed most important since the main purpose of the device is to hold a shape securely in the hand as well as function as a single unit. Since the pocket containing the shape would be sewn directly to the strap, this design scored the highest in this

category. The next two criteria, ease of use and comfort were rated equally. Ease of use entails how easily the shape can be fixed to the strap with the use of only one hand and the magnet was given the highest rating for this category. It is equally important for the attachment mechanism to be comfortable as it will be in between the hand and the shape. Since the device will likely be used for many hours a day, the attachment mechanism should not be bulky and cause discomfort to the hand. The pocket won this category since the only material between the strap and the shape would be cotton fabric as opposed to metal in the other two designs. The other categories considered include: ease of fabrication, safety, weight, and cost. The weight and cost of all three designs would be fairly consistent and therefore did not receive a high weight. The magnet was deemed easiest to fabricate. Safety was rated lowest in the screw design since it contains a sharp point if the shape is not secured to the strap. The point break down for each design in each category is summarized in Table 2. In totaling score for each shape in each category yields the pocket design scoring the highest.

Table 2: The design matrix for the proposed attachment mechanisms: pocket, screw, and magnet.

Criteria (Weight)	Pocket	Screw	Magnet
Security (25)	23	18	15
Ease of use (20)	15	10	18
Comfort (20)	18	15	15
Ease of fabrication (15)	10	11	14
Safety (10)	9	5	8
Weight (5)	4	4	3
Cost (5)	3	4	3
Total (100)	82	67	76

Final Design

Based on the design matrices, the primary prototype will consist of the pocket attachment with the M&M shape to keep the hand open (Figure 7). In order to do this, the strap and pocket will be individually fabricated with cotton and then sewn together. The strap will slip over the hand via elastic or Velcro, depending on the preference of the client and ease of fabrication. The pocket will be large enough to house the M&M shape and a zipper will facilitate easy insertion and removal so that the shape can be replaced and the rest of the device can be washed.

Figure 7: Primary prototype with pocket attachment and M&M shape.

As mentioned previously, the primary prototype was dictated by the results and analyses from the design matrices. However, some of the designs mentioned earlier will also be constructed to physically analyze the design. Since the device is heavily personalized to fit the client's needs, user comfort and personal preference dictates the outcome of the final design, no matter the rankings from the design matrices. This device must accomplish the client's design criteria and only the client will know the success of the device on reducing spasticity. Therefore, multiple prototypes with different shapes, shape attachments, and strap designs will be fabricated and sent to the client for experimentation.

Ergonomics

The hand-held device is directly in contact with the human body and directly affects its movements and abilities. The International Ergonomics Association has defined ergonomics as the understanding of interactions among humans and other elements of the system in order to optimize human well-being and overall system performance [3]. This device strives to open the palm and relax the hand, thus reducing spasticity and improving walking gait. Comfort is of the utmost importance, and properties of the device (i.e. weight, size, versatility, etc.) ensure that unwanted burden on the hand is minimized. This results in a design with benefits that far outweigh potential risks. In addition, research and professional expertise will be consulted to further understand the interaction between the client and the device.

Ethical Considerations

The main ethical considerations for the development of this design are the use of human subjects. The device will be tested on the client, as well as the general public, and protocol for experimentation with human subjects must be followed. In preparation for subject testing, all members of the team have successfully completed the CITI Collaborative Institutional Training for Human Subjects Research. This course educates on history and ethical principles, defining research with human subjects, informed consent, researching with protected populations and vulnerable subjects, and financial conflicts of interest. The ethical considerations presented in this course will be applied to future human subjects testing as the device is used and evaluated by the public.

Future Work

As mentioned previously in the final design, multiple prototypes will be fabricated for physical experimentation and for others to give feedback. Fabric for the strap and pocket, sphere and M&M shapes, zippers, elastic, Velcro, and padding have already been purchased for use in the prototypes. The rod, magnet attachment, and screw attachment still need to be purchased. After fabricating, these prototypes will be sent to the client in Maine to receive her feedback and suggestions for the final design.

In addition to the client's feedback, the team will be contacting physical therapists and neurologists around the area to receive their expertise and comments on the designs, as well as general information about spasticity and walking gait. The team will test all of the prototypes, and surveys will be conducted to the general public to evaluate the designs. Subjects participating in the survey will primarily consist of undergraduate students. Although the team will try to survey a randomized, large, participant pool, limitations such as time and money ultimately dictate the outcome. These surveys will include rankings on comfort, security, ease of use, convenience, versatility, and aesthetics. Taking all of the feedback and improvements into account, a refined final product will be fabricated and sent to the client, Carol.

Moreover, based on public interest and success of the final product, more could be fabricated and sent to other stroke victims. There may be other people experiencing similar problems as the client, in which case the device could help reduce spasticity in more than just one case.

REFERENCES

[1]"Spasticity." *We Move: Worldwide Education and Awareness for Movement Disorders*. N.p., n.d. Web. 8 Oct 2011. http://www.wemove.org/spa/.

[2]"Spasticity and Paralysis." *National Stroke Association*. N.p., n.d. Web. 8 Oct 2011. <http://www.stroke.org/site/PageServer?pagename=SPAST>.

[3] "Definition of Ergonomics." International Ergonomics Association. N.p., 31 08 2011. Web. 19 Oct 2011. <http://www.iea.cc/01_what/What is Ergonomics.html>.

APPENDIX

Hand-held device: Product Design Specifications
October 26, 2011
Client: Dr. Bonnie Tompkins & Carol Rohl
Team: Clara Chow, Sara Schmitz, Emily Florence, Devon Moloney
Advisor: Tracy Puccinelli

Problem Statement

After experiencing a stroke, our client has had problems with walking due to a weakened left side. She has found that placing a ball in her hand allows her hand to relax, which consequently improves her walking gait. Our goal is to design a convenient, easy to operate hand-held device to relax her hand when walking, while at the same time easy to relocate or remove for tasks with both hands.

Client Requirements

- Hand-held device to help improve walking gait
- Rigid shape attached to securing mechanism
- Easily moveable
- Lightweight and washable
- Breathable material
- Aesthetically pleasing

Design Requirements

1. Physical and Operational Characteristics
    a. *Performance requirements:* Device must improve walking gait by relaxing the hand. Should be easy to use and moveable to be used on a daily basis.
    b. *Safety*: Must be securely fastened without restricting circulation.
    c. *Accuracy and reliability:* Device must be secure when in use and successfully keep the hand relaxed.
    d. *Life in Service/Shelf Life:* Should ideally last for 10 years with frequent daily use. Should withstand weathering and occasional washing.
    e. *Operating Environment:* Should withstand temperatures from -20°F to 100°F. Device is typically used outdoors.
    f. *Ergonomics:* Should be comfortable for the user and rest lightly on the hand. Device should not deform during use and withstand up to 100 lbs.
    g. *Size:* Shape diameter should be approximately 2 inches. Needs to be portable and comfortably sit on the hand.
    h. *Weight:* Less than 150 g.
    i. *Materials:* Lightweight, breathable material such as cotton for the strap and shape covering. Shape should also be rigid.
    j. *Aesthetics, appearance, and finish:* Client prefers a colorful product (red, green, or blue). Device should be refined and polished.

2. Production Characteristics
    a. *Quantity:* At least one device ready to use.
    b. *Target Product Cost:* System less than $100.

3. Miscellaneous
    a. *Standards and Specifications:* Meets health and safety regulations.
    b. *Customer:* To be used by Carol and possibly other clients with similar problems.
    c. *Patient-related concerns:* Patient has no allergies, confidentiality issues, or other concerns at this time.
    d. *Competition:* There are no similar devices in the market used for this purpose.