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 a new and improved design. In order to satisfy the client's design requirements for an effective, convenient, and single lightweight device, the team explored different shapes to hold the hand open and different mechanisms to attach the shape to the hand. After analysis from design matrices and consultation with a physical therapist, the M&M shape and pill-shape were the chosen design components for the final prototype. However, since this device was highly personalized to fit the client's needs, two prototypes were fabricated to determine which design works best for her. The final product has been tested and surveyed by the general public with a positive result. The client also expressed similar positive feedback. A more generalized device could be fabricated in the future and possibly distributed to others who are also suffering from hemiparesis and may benefit from using 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. In fact, more than 4 million people in the United States are living with after-effects of stroke [1]. 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 [2,3].

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 [4-13].

Stretching is a main component of physical therapy, the most frequently implemented method of rehabilitation for stroke victims. Rehabilitation through physical therapy is highly individualized [14-19]. Despite variance from patients, however, there are some general trends. One such trend is relaxation of an entire side of the body through manipulation if one specific muscle group. For example, some patients find that by abducting their thumb at its base, they actually reduce the spasticity throughout their body. Currently, the mechanisms behind this phenomenon are far from understood. However, one theory proposes that by relaxing hand muscles and preventing sensory overload, the body can attribute more attention to other muscle groups. Unfortunately, this is pure conjecture [20]. The specific movement and positioning of the thumb as well as the extent of spastic reduction vary from patient to patient. One patient that 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

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

that when she pulls her left thumb away from her hand, she 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 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 previous device is its inconvenience. For this reason the new device needed to be a single compact device. The components needed to be effectively secured to each other so the device could easily be removed. Furthermore, the device needed to effectively open her hand, since this has been known to relax the entire left side of her body, improving her gait. Since the device was designed specifically for the client, the dimensions of the device were to be based off of the measurements of the client's hand (Figure 2). When the device is in use, it needs to be capable of being easily put aside by turning it to the back of her hand. It needed to incorporate a lightweight, breathable, and washable material, such as cotton. Finally, the device needed to be colorful and aesthetically pleasing.

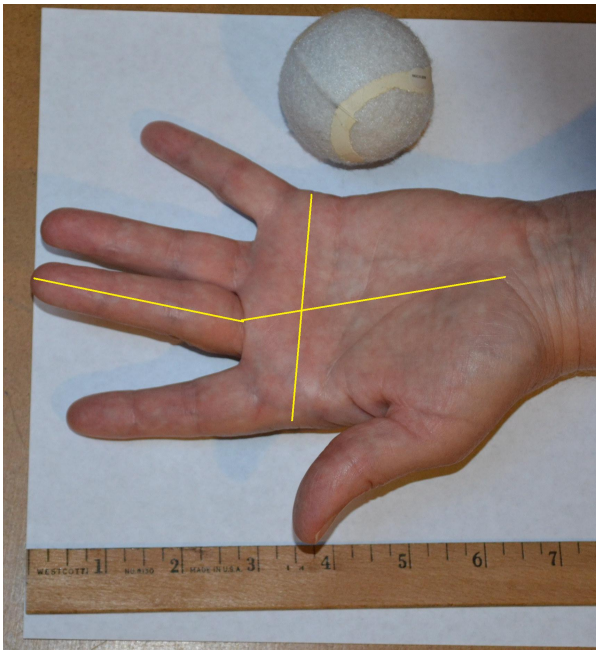

Figure 2: The client's hand. The yellow lines mark the three areas where measurements were taken using the program ImageJ. Measured lengths: 2.797 inches (middle finger), 3.064 inches (palm width), and 3.578 (palm length).

Overview of Designs

The proposed design consisted 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 was a method of connection. This was to 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.

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 based on the client's current design but have slightly varying dimensions. 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. This ensure 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 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 to 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 could 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 it complements the contours of the user's fingers and 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 flattened shape allowed it to slide easily around the side of the client's hand to the back. The sphere made it more difficult to do this same motion 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 effect 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 was 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 flattened 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 not allow it to be hidden easily. 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 consists of two parts: a fabric strap and an attachment mechanism to secure the shape to the strap. The fabric strap would be made out of colorful cotton as requested by the client. To allow for proper placement of the shape, the strap should rest slightly above the palm, near where the fingers meet the hand. Across the back of the hand is 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. While both designs would successfully accomplish numerous design criteria, the team has determined that the elastic design would allow for easier use with one hand than the Velcro design.

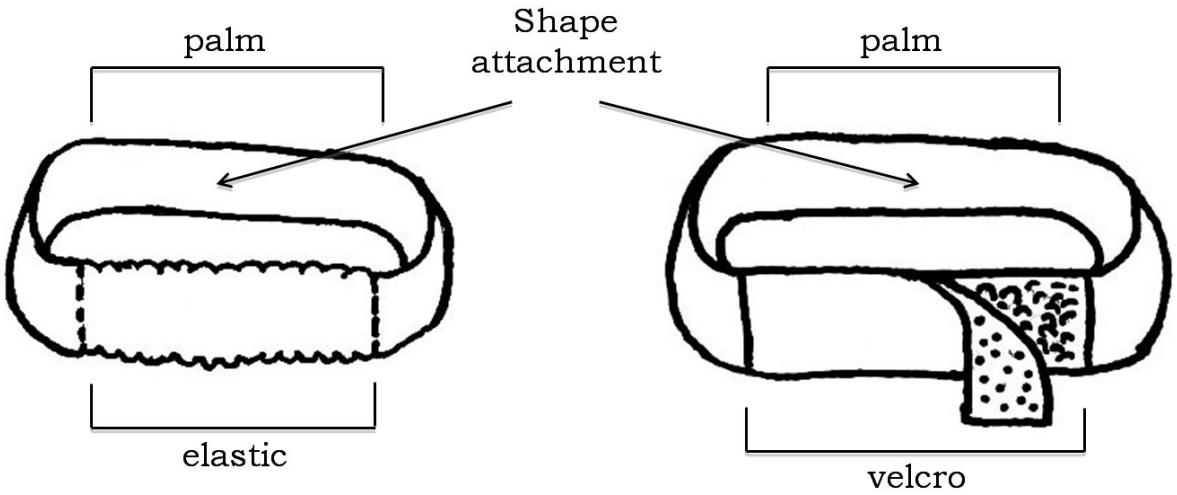

Figure 3: (a) Strap with elastic portion to lie across the back of the hand. (b) Strap with Velcro portion to lie across the back of the hand.

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. 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 4: a) The screw and cap design for a proposed method of attachment. b) The pocket design for a proposed method of attachment. c) The magnet design for a proposed method of attachment. The dashed box represents the location of the magnet within the strap.

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. Totaling the scores for each shape in each category yields the pocket design scoring the highest.

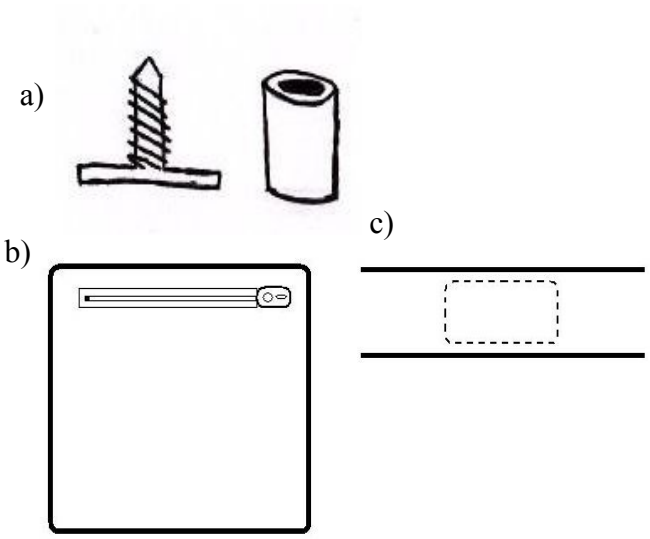

Figure 4: a) The screw and cap design for a proposed method of attachment. b) The pocket design for a proposed method of attachment. c) The magnet design for a proposed method of attachment. The dashed box represents the location of the magnet within the strap.

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

The final design choice consists of a sewn cotton strap, a thumb abduction loop, and a three dimensional shape.

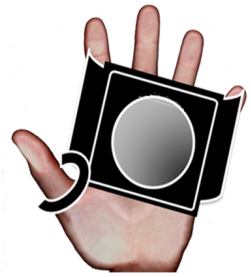

Figure 5: Prototype with M&M shape, and thumb loop.

The strap portion of this design was sewn from colorful cotton fabric in a tapered fashion, with the smaller diameter of the band resting on the back of the hand when in use. The final design also has an elastic band covered with cotton fabric for easy placement, movement, and removal of the strap. For comfort, a layer of cotton padding was added between the two layers of fabric of the strap.

The second component of the final design was an elastic thumb loop. This part was not initially in the preliminary prototype, but after meeting with physical therapist Judith Dewane, she expressed that abduction of the thumb is crucial in relaxation and reducing spasticity. Even though the shapes strive to abduct the thumb, this thumb loop gives additional support. It is attached to the elastic portion of the strap via Velcro so that its tightness around the thumb may be adjusted.

The prototype was dictated by the results and analyses from the design matrices. However, since the device is heavily personalized to fit the client's needs, user comfort and personal preference ultimately dictated 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, two prototypes have been constructed, one with the pill shape and one with the M&M shape.

The flattened design of the shapes aids in two main ways: first, it provides a surface in case the client needs to use her hand to stabilize herself while wearing the device. Secondly, it allows it to be more discreet when the shape is moved to the back of the hand, allowing enough room that a sleeve could be pulled over it if needed. They were each constructed from different materials because, depending on client preference, a heavier device can aid in the reduction of the spasticity [20]. The pill shape was designed using SolidWorks rapid prototyping and constructed out of acrylonitrile butadiene styrene (ABS) plastic, giving it substantial weight. On

the other hand, the M&M shape was constructed from Smoothfoam, a rigid, lightweight material that a client may instead prefer.

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 [21]. 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.

TESTING PROCEDURE

In order to assess the effectiveness of the final designs, a sample of 20 college students was randomly selected to test and rate one of the designs. Prior to completing the survey, a form of consent was read and signed by each participant permitting publishing of any obtained data and guaranteeing anonymity. The survey asked for general information, such as gender, age, and any past notable hand injuries or problems (see Appendix for consent form and survey). Since the device was designed to fit the client's left hand size, each participant's left hand was measured as part of the testing process. The measurements taken were: length from the tip of the middle finger to where the palm meets the wrist, width at the widest point of the hand, and circumference around the widest point (Figure 6). The subjects then put the device on their left hand, with 10 participants testing the M&M design and the remaining 10 testing the pill design, assigned randomly. Next, the participants rated the device in a number of categories, each with a maximum rating of 5. The categories included: comfort of shape, comfort of fabric strap, comfort of elastic thumb loop, overall comfort, effectiveness (or how well the device holds the hand in an opened position), and convenience (or how well the device can be spun around to the back of the hand).

TESTING RESULTS AND DISCUSSION

Results

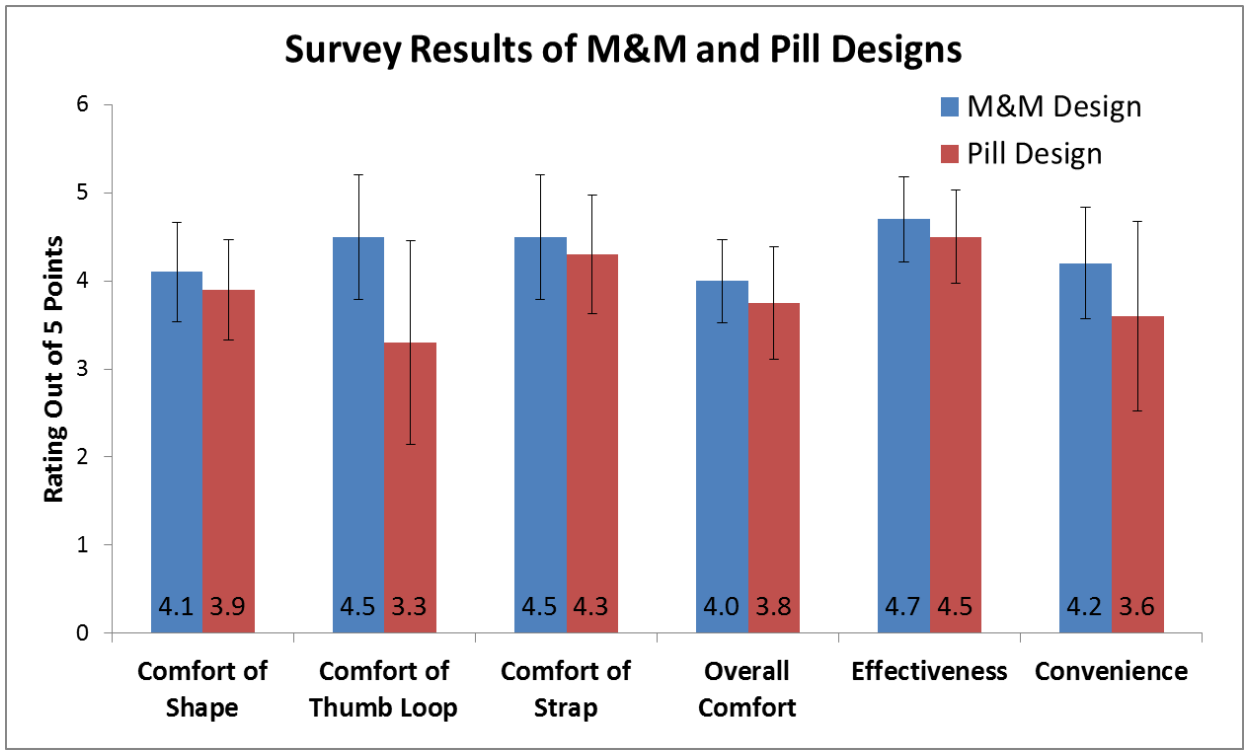

Figure 7: Averaged results and standard deviations of testing for each design with maximum ratings of 5.

The chart in Figure 7 shows the averages and corresponding standard deviations for each rated category. The blue denotes the M&M design and the red the pill design. The pill design had a lowest average rating of 3.3 and the lowest average for the M&M design was 4.0. Since the main purpose of the device is to hold the hand in an open, relaxed position, it is important to note that "effectiveness" had the highest average rating for both designs. In addition, the participants were asked if they would use the device should it be necessary and all answered yes.

Discussion

Although the device was designed to be a comfortable fit for the client's hand, there was no correlation between hand size and the participant's rating for each category despite a wide range of hand sizes in the test group. However, a few participants with hand sizes larger than our client's did express concern about whether extended wear of the device would restrict circulation. Despite an average lower rating for the pill design, the standard deviations for both designs in each category have considerable overlap and the difference between the two designs

may not be as significant as the lower averages suggest. Since this device is highly individualized, the most effective, comfortable, and convenient device will largely depend on which design best fits the client's needs, regardless of test subject's ratings. Since receiving the device the client is very pleased with the material, comfort, functionality, and aesthetics. However, the client did mention that the size of the object could be slightly smaller, although the current design functions well.

Semester Summary

After receiving its assignment the team began the semester with a client meeting with Dr. Bonnie Tompkins. The team then spent the following weeks brainstorming a design based off of the design criteria. Once several designs were established, the group began collecting possible materials from local stores and commercial websites. After the midsemester presentation, the group met with Dr. Judith Dewane for her expertise, during which the team discovered they would need to make modifications to the design, including the addition of a thumb loop. Taking into consideration the new criteria as well as the old, the group developed multiple prototypes, each consisting of a cotton strap with elastic and a shape sewn in. The group then presented the prototypes at the poster presentation and shipped the products to the client.

Ethical Considerations

The main ethical considerations for the development of this design are the use of human subjects. The device has been 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

Even though the final designs were finished, there are always future considerations that can potentially improve these devices. First, experimentation with different shape weights may change the effectiveness of the device. The pill shape is currently heavier than the M&M shape because it was rapid prototyped with a heavier material, but effects of weight on performance is currently unknown. Physical therapist Judith Dewane speculated that a heavier weight could weigh down the entire arm so that the arm and shoulder would relax as well, consequently relaxing the rest of the body.

Secondly, the device can be generalized so that it can be marketed to the public. In order to make the device more versatile, an adjustable strap with different sizes would be desired so that the device could fit comfortably for all hand sizes. Even though there was no correlation between hand size and comfort in testing, a few subjects with larger hand sizes raised concerns about reducing circulation. Therefore, more sizes would be necessary to ensure no safety concerns. Next, a pocket for the shape could also be made so that the shape could be removed or changed. It would allow the rest of the cotton fabric to be washed. A pocket was originally in the preliminary design, but fabrication of the design revealed that the pocket left too much space for the shape to move around, jeopardizing its effectiveness. This issue would need to be addressed in a future device, by adding a zipper or something similar. Lastly, different colors and patterns would help market the device and may appeal to more people.

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APPENDIX

Hand-held device: Product Design Specifications
December 12th, 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.

FORM OF CONSENT

We are conducting a survey to evaluate our design for BME Design 300/200. The information you provide may be published but will remain anonymous. Please let us know if you have any questions/concerns.

The following is a summary of our problem statement and the goals we intended to accomplish when designing and fabricating our device:

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.

I agree to take this survey and am aware that the information I provide will remain anonymous.

Name_____ Signature_____ Date_____

BME Handheld Device to Reduce Spasticity Questionnaire

1. Gender (circle one): Male / Female

2. Age: ____

3. Hand Measurements (in inches):

Length: _____

Width: _____

Circumference: _____

4. List any spasticity problems or notable hand injuries:

5. Rate (5 being the highest):
Comfort of Shape: 1 2 3 4 5

Comfort of Thumb Loop: 1 2 3 4 5

Comfort of Strap: 1 2 3 4 5

Overall Comfort: 1 2 3 4 5

Effectiveness (How well the device keeps hand in an open and relaxed position): 1 2 3 4 5

Convenience (How well the device can be moved to the back of the hand):

1 2 3 4 5

6. If needed, would you use this device? Yes / No

7. Other comments/suggestions?