UNIVERSITY OF WISONSIN-MADISON

Water Resistant Boot for Walking Cast

Department of Biomedical Engineering

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[3/14/2012]

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Abstract
This report presents information regarding a design that can be used to cover lower extremity serial casts. This device is being designed specifically for an individual with spastic cerebral palsy. Spastic cerebral palsy causes an increase in muscle tonicity in the lower extremities, termed as hypertonia. One method of therapy is to use serial casts to stretch the affected muscles, which stimulates muscle growth. It is imperative that these serial casts remain dry to retain effectiveness; however, few products are currently available to properly cover these casts. Three separate designs are presented: a waterproof sleeve, a front zipping boot, and a bag boot design. All three designs are then analyzed using a weighted design matrix. After analysis, the bag boot design was chosen as the final design. Finally, details into the future construction, testing methodology, and further logistics are offered.

Background

Cerebral Palsy

Cerebral palsy affects one to three out of every one thousand children. However, that number increases drastically in infants born with low weights and in premature infants. Cerebral palsy is an abnormality of motor function and postural tone [1]. It is caused by abnormalities in parts of the brain that control muscle movements that occur before a child's birth, during a child's birth, or during the first 3 to 5 years of a child's life [2].

The abnormality in the motor system is the result of brain lesions that are non-progressive, meaning that the lesion does not produce ongoing degeneration of the brain [1]. The most common type of cerebral palsy is spastic cerebral palsy, occurring in 80% of all cases [3]. Spastic cerebral palsy refers to a condition in which the muscle tone is increased. The increased muscle tone is the result of damaged nerve receptors in the spine that are unable to properly receive gamma amino butyric acid. Gamma amino butyric acid acts at inhibitory synapses to relax skeletal muscles [4]. Additionally, the increased muscle tone causes rigid posture in one or more extremities, which leads to limitation of use of the affected extremity because of the inability to coordinate movement. However, the stiffness may be overcome by applying some force to the affected area. If the disease impairs the legs, the individual often has a scissoring posture in which the legs are extended and crossed. Along with muscle stiffness, increased deep tendon reflexes are another problem associated with this disease that causes the patient to walk on their toes, which is referred to as "toe walking" [1].

Figure 1: An example of a patient with a serial cast [6].

Serial Casting

Currently, non-operative treatment of toe walking can be conducted by a technique called serial casting. This method works by using a series of fiberglass casts to stretch soft tissue for an extended period of time [5]. Typically, the casting period ranges anywhere from 4 to 6 weeks. The cast must be removed each week in order to check the patient's skin and mobility. An example of a patient with a serial cast is shown in figure 1 [6].

Serial casting works on the premise that skeletal muscles are capable of modifying their structure in response to environmental changes. During serial casting, skeletal muscles are stretched for a prolonged time. During this period of stretching, a temporary re-alignment of the collagen fibers within the connective tissues occurs that stimulates growth of the muscle. The growth occurs by increasing the number of sarcomers (see section below) in a muscle fiber than results in longer fibers [7].

However, one of the major problems of serial casting is that although the patient may walk in the cast, it cannot get it wet. If a cast does get wet, it must be removed and then reapplied; otherwise infection or soft tissue deterioration may result. Ensuring that a cast is dry is very problematic in regions with inclement weather such as the Wisconsin winter. Another factor that makes this challenging is the increasing size of the casts as the dorsiflexion is increased over time, making footwear sizing a challenging target.

Targeted Muscles

When gamma butyric acid is not received by muscle relaxation receptors (as occurs in cerebral palsy) the muscles these receptors act on will have an increase in tonicity, a condition termed as hypertonia. Serial casting aims to stretch these specific muscles in hopes of lengthening them in order to treat the condition known as toe walking (Figure 2 and 3). The peroneus longus muscle is one of the muscles that are targeted by serial casting. It acts to evert and plantar flex the foot at the ankle. The peroneus longus muscle originates at the tibia and fibula and inserts on the medial cuneiform and first metatarsal. The calf muscles, composed of the gastrocnemis and the soleus, are another group of muscles targeted by serial casting. They act to plantar flex the foot and are connect to the calcaneus by the Achilles tendon. Serial casting also targets the posterior tibialis muscle, which act to evert and plantar flex the foot at the ankle. Additionally, they are involved in supporting the arch of the foot. The anterior tibialis muscles are another group of muscles that are targeted by serial casting. These muscles act to dorsiflex the foot at the ankle and invert the foot [10].

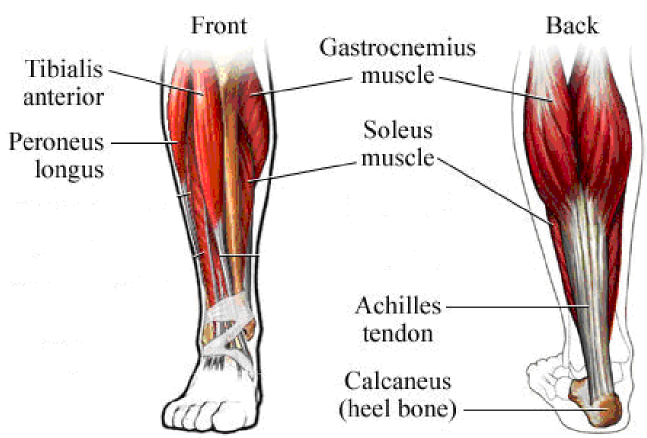

Figure 2: Anatomy of the lower leg [8].

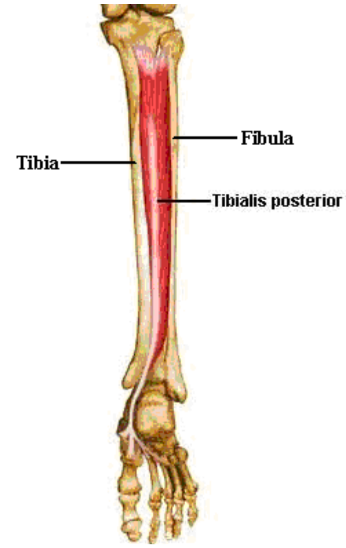

Figure 3: Anatomy showing the tibia, fibula, and the tibialis posterior [9].

Client Information:

Dr. Donita Croft, who practices in Pulmonary Disease and Critical Care Medicine and Internal Medicine, has requested a device that will keep her 7 year old daughters serial cast dry. Further, it is Dr. Crofts request that the device allow her daughter to perform some physical activities, such as playing on the playground.

Problem Motivation

The client's request for a water resistant boot to cover walking casts stems from the need to protect the integrity of the walking cast and ensure patient safety during wet and inclement weather conditions. When a walking cast comes into contact with moisture, whether from outside conditions or perspiration, tissue damage can occur. The size, rigidity and changing dimensions of the walking cast does not allow for patients to wear typical protective footwear. Without a full range of ankle motion it is impossible to slide a walking cast into winter boots, hence the need for a new style of footwear.

Current Practices

To prevent moisture penetration into the walking cast the client implements a combination of water proof socks and an open toed cast boot. The open toed cast boot, shown in Figure 4, is a common method to provide an even surface for the patient to walk and stand on. The open toed boot also provides minimal traction with a shallow tread.

Figure 4: An example of an open toed cast boot [5].

The water proof socks are capable of preventing outside moisture from coming in contact with the walking cast. The problem with this method is that the water proof socks are not breathable, and perspiration builds in the toe region of the cast. Also, water proof socks are only manufactured up to a certain diameter which limits the size of the cast over which they can be stretched. The rough fiberglass material the casts are composed of makes it extremely difficult to stretch the non-elastic socks over the cast.

Design Requirements

The client has a requested a boot that will conform to the shape of the cast. This requires the boot to change shape with the cast as the dimensions of the cast are increased. Also, the boot must be able to be put on by the patient, without external assistance. Aside from ergonomics the cast boot needs to prevent moisture from penetrating into the fiberglass cast as well as be composed of a breathable material to limit build up of perspiration. The cast boot should resemble a standard winter boot, and not add unnecessary mass to the already large rigid walking cast. The device must have a non-slip tread on the bottom because it will be used in inclement weather conditions. The materials used in construction should not contain latex or other common allergens.

Design Alternatives

Common Materials and Methods

The three proposed design alternatives share some common characteristics. First, they will be composed of a waterproof material. One thought for this is a waterproof fabric, for which Gore-tex and Toray materials will be considered. Gore-tex is a material made from expanded polytetrafluorethylene (ePTFE), and is described as a strong, microporous material with low water adsorption and good weathering properties. The microporous material is a membrane that contains over 9 billion microscopic pores which are approximately 20,000 times smaller than a drop of water, but 700 times bigger than a molecule of moisture vapor; therefore, it is both water resistant and breathable [11].

Instead of using waterproof materials, it is also possible to use water proof sprays. Using sprays would allow for reapplication by the user, which offers an added convenience factor. However, it is important to note that the usability of a spray hinges on a suitable material being chosen. Thus, while it is possible that a spray could end up being the best choice, it is more likely that it would be used to reinforce any areas of weakness on the design. The two sprays that are being considered are Atsko Permanent Water Guard and NikWax Fabric and Leather Proofer. The Atsko permanent water guard is a solvent free, water-based fluorocarbon polymer that makes fabrics water and stain resistant. Some materials it is compatible with include cotton, wool, down, canvas, suede, polyester, Nylon, Gore-Tex, polypropylene, and imitation leather [12]. Similarly, NikWax is described as being an easy to apply water repellent that can be applied to any fabric, leather, or breathable lining (including Gore-Tex). Further, it does not contain any fluorocarbons [13].

Second, each design will incorporate treads from a winter boot. Because the final design will primarily be used during the winter months, it is crucial that the treads supply a significant amount of friction to decrease the potential of falling.

Waterproof Sleeve

The first proposed design to meet the needs of the client is a waterproof sleeve (Figure 5). The sleeve will be worn similar to a sock, being pulled up over and laying tightly on the cast. This will allow for two key design needs to be met. First, by being waterproof, this design will keep the cast free of unwanted moisture from the external environment. Second, by being elastic, the device will hold tight to the cast, eliminating the need for straps or other measures to hold it securely to the cast during motion. To ensure this design

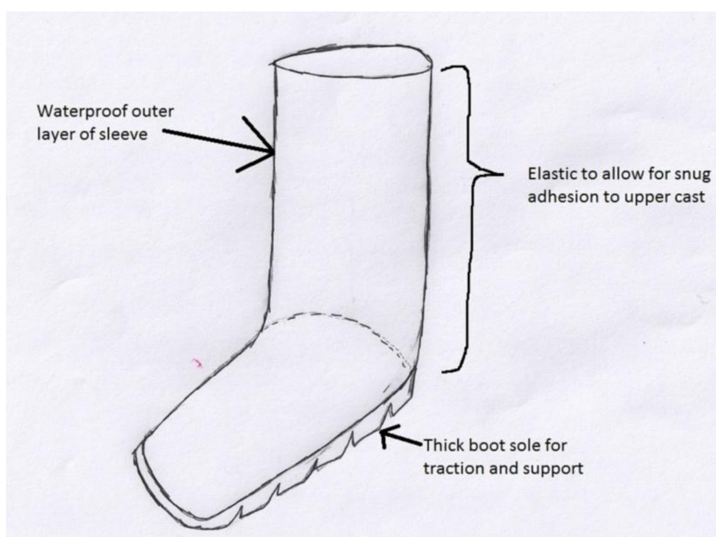

Figure 5: Waterproof sleeve design. This design makes use of an elastic upper region to secure the sleeve to the cast. A thick boot sole is attached to the bottom for traction and support. The sleeve will be made out of a waterproof material

works, the material used must have a large elastic strain. This will enable the design to be deformed, allowing for the insertion of the cast, without changing the elastic qualities of the material. However, the problem with relying on an elastic nature is the potential for deviations from a tight and supportive fit on all portions of the boot. That is to say that while one orientation may allow the design to fit perfectly another, possibly obscure design, may cause areas of loose fitting. The only additional materials needed for this design will be the elastic strips added to the upper portion of the sleeve.

Front Zipper

This design addresses concerns about being waterproof and ease of wear. A boot made from one of the waterproof materials will have a zipper in the front to securely protect the cast (Figure 6). By having the zipper, it will be easy to put on the boot, which is of importance as the primary users will be children and young teens. To wear, a user will unzip the boot, providing a large opening for the cast. At this point, he or she will place his or her foot into the boot. Once the base of the foot is firmly on the bottom of the boot, the front will be zipped up, securing the leg. This will remove the need for any tugging or pulling, as might be required to pull something on over the bulky and awkwardly shaped cast.

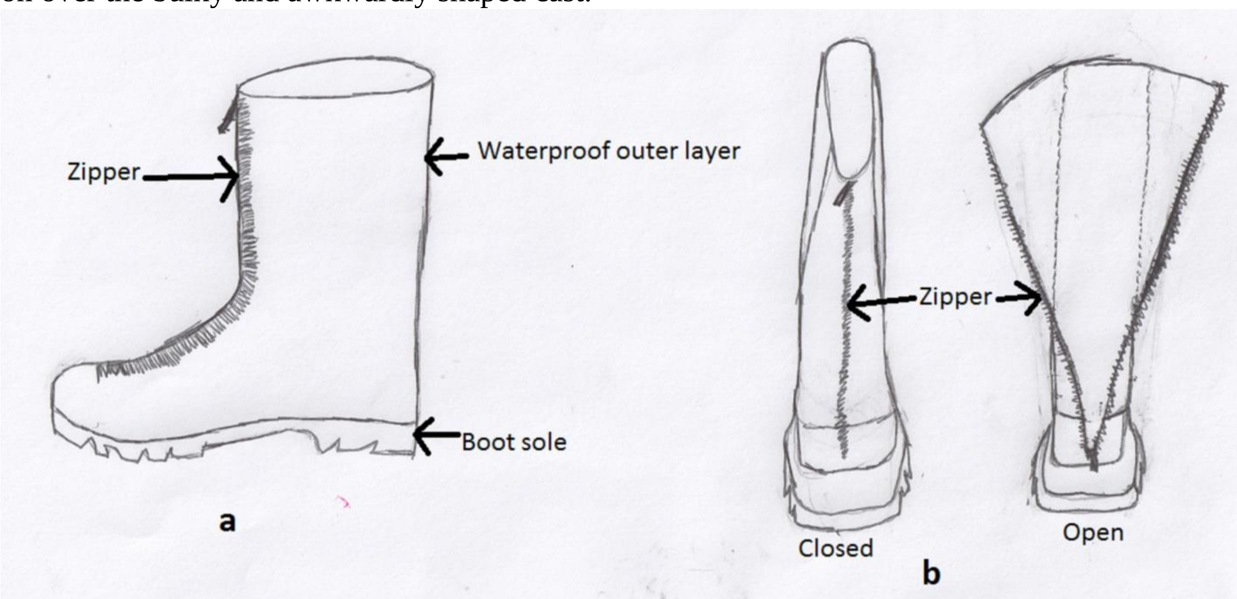

Figure 6: a) Side view of the zipper design. b) Front view of the zipper design closed and open. This design makes use of a front zipper to allow the user to easily put on and secure the boot. This is of concern because the cast does not allow one to flex their ankle.

Bag Boot Design

The bag boot design is basically a modification to a winter boot. By modifying a winter boot, multiple design concerns can be considered. The design shown in figure 7 seeks to meet the design needs while providing additional support and ease of wear. To start, most of the front of a normal winter boot will be removed, leaving just the base, part of the back, and part of the top. The base will remain to provide traction and foot support. The back will support the ankle and lower leg, and the top will remain to allow for snug securing of the boot to the leg.

A waterproof, adjustable liner will be attached to the interior of the remaining winter boot.

This liner will be loose, almost like a bag, so that the cast will be easily placed in it without need for force. Once the cast is correctly positioned inside of the liner, it will be tightened to snugly fit around the cast through the use of straps or Velcro. If straps are used, they will resemble the straps used in a backpack shoulder strap. They will make use of the same sort of material (taking advantage of its strength) sprayed to increased water resistivity, and identical clip to hold in place. The top of the winter boot will also be secured at this time in a similar manner. As the user grows, there will be a need for additional boots to accommodate the increased foot size, much in the same way growing children purchase new tennis shoes as their feet grow.

Water resistance is seen as being a strength for the bag boot. If constructed properly and with the correct materials the bag boot will be the most water resistant of any of the 3 designs; however, a point of concern comes from the necessity to construct the boot out of different components. Thus, it is vital that the points of attachment be carefully constructed and reinforced. While gait testing will be needed to verify the specific locations of interest, it can be assumed that the use of a cast will cause internal forces on the inside of the boot that are different than would be seen in an uncasted foot. Therefore, it is important that this design incorporates the added strength of the actual winter boot.

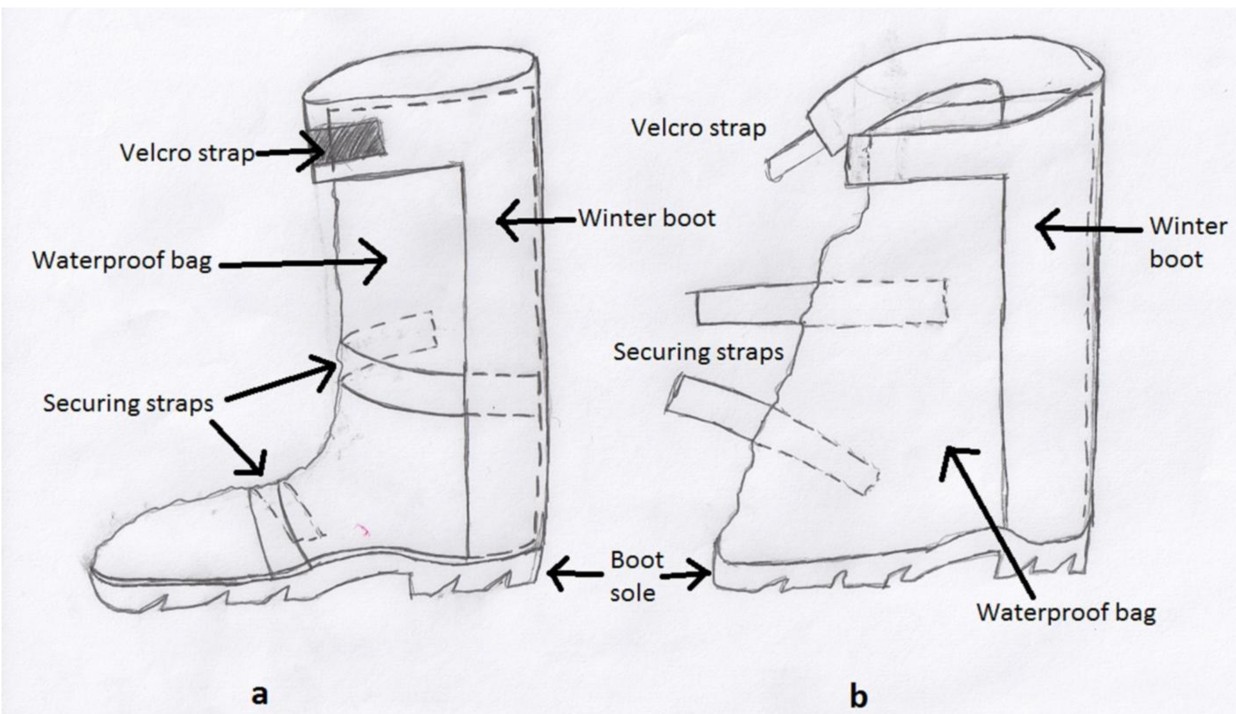

Figure 7: Modified winter boot design a) secured and b) open. This design attaches a waterproof bag to part of a winter boot, which remains for support. Two straps will be used to securely fasten the bag once the casted leg is positioned inside, with a Velcro strap attaching the winter boot portion.

Design Matrix

Parameters	Total Weight	Waterproof Sleeve	Zipper	Bag Boot
Water Resistance	25	24	11	21
Shape Dynamics	20	13	13	18
Ergonomics	20	14	18	16
Client Preference	15	8	8	15
Feasibility	10	9	9	8
Safety	10	10	10	10
Total	100	78	69	88

Figure 8: The design matrix used to determine the final design.

To determine which design would be the final design for this project, all of the designs were compared using a design matrix. The design matrix breaks down the potential application of each design into 6 different categories: water resistance, shape dynamics, ergonomics, client preference, feasibility, and safety. These categories are considered to be the vital characteristics of a working and successful final design. Further, each category is administered a weight (column 2) based upon its importance toward a successful final design.

As can be seen in the matrix, water resistance was deemed to be the most important property of a successful design, and thus was administered a total weight of 25. A high score (16-25) for water resistance would require a design to be impermeable to water on a consistent basis, regardless of how it is placed over the cast. A top score (23-25) is given to a design that has no point of structural weakness that could potentially lead to leakage.

Shape dynamics and ergonomics, both given a total weight of 20, were determined to be the second most important qualities of a successful design. As previously mentioned, the serial cast used by the client is changed on either a weekly or biweekly basis. Thus, it is imperative that the design be able to accommodate this frequent change in shape. A high score (14-20) is given to a design that requires little effort to form to different cast shapes. A top score would be given if the previous claim holds true and the design is capable of fitting snuggly and comfortably in each of the differing shapes.

Ergonomics refers to the ease of attachment and removal of the design by the patient. A high score (16-20) is awarded to a design that is conceptually and physically easy to put on and take off, and remains securely in place.

Because the client, Dr. Croft, has specific experience with this problem it is imperative that her opinion hold weight on the final decision. Thus, a total weight of 15 was administered to her opinion of each design.

Feasibility and safety, both holding a weight of 10, are important criteria in any design process and thus must be included in the decision criteria. As can be seen by the matrix, all of the designs were deemed as being feasible and safe.

After each design was analyzed based on the criteria of the matrix, it was determined that the bag boot would be our final design choice. The bag boot showed high scores in both water resistance and shape dynamics. One minor area of concern lies in its ergonomic score. This stems from the bag portion of the boot. When the boot is put on, the bag portion will have to be folded over and sufficiently strapped down, which could be somewhat difficult (especially for a child). To address this issue, it is imperative that the material used for the bag is flexible and the strap system is easy to use.

Ethical Considerations

To ensure that this design maintains high ethical standing, a number of different precautions must be followed. One of the primary considerations is that a number of different products are currently available that deal with similar problems. Currently available products include a several brands of cast socks put out by companies such as *Cascade-USA*, *Sears*, *Colonial Medical Assisted Devices*, *Pro Therapy Supplies*, as well as others. It is important that these products be thoroughly researched to ensure that no patents are infringed upon.

Another important ethical aspect to consider is the comfort of our client, Dr. Croft, in terms of the design team working with her daughter. One specific area that relates to this is the potential of performing different tests with her daughter. Possible tests include: taking different measurements, determining weights, as well as analyzing gait cycles. Further, to analyze and document the effectiveness of the final product it would be advantageous to record Dr. Croft's daughter using the design. To ensure that a solid comfort level is present and maintained, it is important that if we do receive permission to interact with Dr. Croft's daughter, we thoroughly explain to both Dr. Croft and her daughter what we will be doing, what kind of equipment we will be using, as well as what we would expect from them.

Finally, if the design is to be used by Dr. Croft's daughter it is imperative that all safety hazards be taken into consideration. One area of concern is the sprays that could potentially be used. While both the Atsko and NikWax sprays claim to be safe, research should still be conducted to ensure adverse effects of the products have not been reported. Dr. Croft has informed us that her daughter does not have any allergies, but it is still important to review with Dr. Croft the materials that make up the device. When the boot is put on Dr. Croft's daughter it is crucial that it fits properly to avoid any hindrance in movement. That is, the boot should supply solid support and be as homogenous as possible with the cast. Because the boot will be placed on a rigid cast, constriction from having the boot too tight will not be an issue.

Future Works

In the coming weeks, it is imperative to continue to establish the details associated with the final design. One primary area of interest is the materials that will be utilized for the bag boot design. Material for the bag itself is the most important component at this point. Key properties for this material include: low water adsorption/absorption, breathability, flexibility, and durability. To determine which materials will be used, a substantial amount of testing and research will have to be performed. After preliminary research, 5 different options have been found: Nitrile, Gore-Tex, Atsko Permanent Water Guard, NikWax Fabric and Leather proof spray, or a combination.

Materials will be assessed by testing their ability to absorb and repel water. To do this, a mechanism will be constructed to fasten down any material to be tested. Then, water will slowly be poured over the material and allowed to either leak through, be absorbed, or (if the material is water resistant) pool on top. The water that leaks through will be collected in a tared container and weighed. Further, any water that pools can be poured off and subsequently weighed. Thus, any weight not accounted will be designated as being absorbed. Based on these measurements, the overall applicability of the fabrics/sprays will be determined. It should be noted that negative controls will include denim and cotton, while the positive control will be taken to be exactly no water absorption or leakage (a property of rubber).

Durability can also be assessed by using a similar methodology. Simulated wear and tear can be created on the material in question by inflicting damage using sand paper. To do this, sand paper will be scraped across the material for different amounts of time ranging from 0:30 – 5:00 mins. Next, the material will be subject to the same test previously described.

Absorptive properties can also be assessed by submerging the material in a weighed container of water and allowing time for the material to absorb water. After removal of the material, and allowing for any blatant excess to drip off, the weight of the water remaining in container can then be weighed to determine how much water was displaced. This value will be the amount absorbed. Further, this quantity can be divided by the area of the material used to determine how much water is absorbed per unit area (m^2).

Once the raw data is collected the best mode of analysis will be by plotting the percentage of leakage and absorption of each material tested. From this preliminary data further testing can be determined.

Potential other properties that can be tested include further analysis into durability, ability to be cleaned, as well as qualitative assessments of breathability and comfort. Further, if time permits, a motion capture analysis of Dr. Croft's daughter's gait while wearing the cast would be beneficial in determining exactly how the design should be constructed. That is, perhaps gait analysis would give insight into different internal forces that would be generated by the cast that are different than would come from an uncasted foot.

After determining what materials will be used for the bag portion of the design, it will then be important to look into what will be used for the boot itself. At this time it is a general consensus in the group that simply using a regular rubber boot will suffice. Though, if time permits, the design team would like to construct an aesthetically pleasing boot.

Finally, the construction of the boot itself will be performed. The first boot, which is currently being built, will not incorporate the material for the bag but instead simply look into how the boot itself will be adapted to attach the bag.

Cost Analysis:
The following items were obtained or purchased for our project (Figure 9). Additionally, even though the client gave no specified budget, the team's goal is to remain under $350 in the design, fabrication, and testing of the prototypes. However, it is the team's goal to have the market price of the final design to be less than $100 per pair.

Product	**Company**	**Amount**	**Price**
Gore-Tex® 3-Layer Waterproof Breathable Ripstop Nylon - Peacoat	Rockywoods.com	One square yard	Subtotal: $22.99 Shipping:$3.80 **<u>TOTAL</u>: $26.79**
"Nikwax Fabric and Leather, 4.2-Ounce"	Amazon.com	4.2 oz can	Subtotal: $8.75 Shipping: $5.58 **<u>TOTAL</u>: $14.33**
Rubber Boots	Wal-Mart	1 Pair	**<u>TOTAL</u>: $21.00**
Atsko Permanent Water Guard	Atsko	20 oz	Free
Total:			**$62.12**

Figure 9: A table of the items purchased thus far.

Timeline Evaluation:

To remain on task in completing the final design, a schedule was composed and followed as strictly as possible, as shown in Figure 10. More client meetings were conducted than planned. This was the result of an ambitious team coming up with many designs early in the semester; thus, it was necessary to meet with the client to gain immediate feedback. One team meeting was missed on the week of the 9th of March. This was during the week that the team ordered its materials and it was more efficient for the team to discuss where to go further when the supplies arrived.

Task	**Jan**	**Feb**				**March**					**April**					**May**	
	27	**3**	**10**	**17**	**24**	**2**	**9**	**16**	**23**	**30**	**6**	**13**	**20**	**27**		**4**	**13**
Project R&D																	
Determine Final Design					X												
Prototyping						X	X										
Testing																	
Deliverables																	
Progress Reports		X	X	X	X	X	X										
Midsemester						X	X										
Final Poster																	
Tong Presentation																	
Meetings																	
Client			X	X	X												
Team			X	X	X		X										
Advisor	X	X	X	X	X	X	X										
Website																	
Update	X	X	X	X	X	X	X										

Figure 10: A table of the projected timeline.

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Appendix

PDS

Cast Boot

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Function: The client, Dr. Donita Croft, has asked us to construct a boot for her daughter's cast. Her daughter has cerebral palsy, which causes an inhibition in dorsiflexion. Once a year, for approximately 4 months, her daughter is fitted with a cast which is used to slowly dorsiflex her feet. The cast itself is not waterproof and thus must be covered when she is outside. Currently no commercial products are available to cover the cast; however, the patient has used winter boots as well as a water proof sock and a medical boot.

Client Requirements

- Must keep the cast clean and dry when used outdoors
- Must be water resistant and durable
- Should be easy to put on and take off
- Needs to have some flexibility in terms of size
- Light weight and easily used by a child

Physical and Operational Characteristics

- *Performance requirements:*
  - Should keep the cast dry and clean, thus being water resistant and durable
- *Safety:*
  - The device must be made out of non allergenic materials such as latex.
  - Should have treads for traction
- *Accuracy and Reliability*
  - Must fit the patient well (not too tight or loose0
  - Should keep dry and clean 100% of the time
- *Life in Service:*
  - The device must be usable for at least 2-3 years
- *Shelf Life:*
  - Used for about an hour a day
  - Easily storable.
- *Operating Environment:*
  - Will fit over cast
  - Should fit within the given boot (unless a different mechanism is used)
  - Key is to be able to work in winter climate which includes: puddles, slush, and snow
- *Ergonomics:*

        - Comfortable for patient.
        - Must be easy for patient to put on without help.
        - Must maintain its position with normal patient movement.
    - *Size:*
        - Patient has slightly larger than a childrens 13 size shoe
        - Should go at least a foot up the cast, not necessarily the entire cast
    - Weight:
        - Should be light because a child will be using it
    - *Materials:*
        - Patient has no allergies
        - If future production is possible, may want to have latex-free
    - *Aesthetics, appearance, and finish:*
        - Shouldn't look overly medical
        - Blue, Black, Purple
- **Production Characteristics**
    - *Quantity:*
        - At least one
    - *Target Product Cost:*
        - Less than $100
- **Miscellaneous**
    - *Standards and Specifications:*
        - There is nothing on the market for this problem, so no specifications
    - *Customer:*
        - Customer would like the ability to possibly construct at home when our design becomes too small, but this is not imperative
    - *Patient-related concerns*:
        - Breathability
        - Easy to put on
    - *Competition:*
        - There is currently no products on the market for this problem