UNIVERSITY OF WISONSIN-MADISON

Water Resistant Boot for Walking Cast

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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. It is imperative that these serial casts remain dry to retain effectiveness; however, very little is currently available to properly cover these casts. Three separate designs are presented including a water proof sleeve, a front zippering 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. After construction of the prototype, water resistance and gait testing were performed. Both show that the bag boot design fulfills the primary design requirements. Finally, the future and potential of this project are discussed.

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 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. 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 serial casts [5].

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, a kind of moldable plastic, to stretch soft tissue for an extended period of time [4]. Typically, the casting period ranges anywhere from 4 to 6 weeks. The casts must be removed each week in order to check the patient's skin and mobility. An example of a patient with serial casts is shown in figure 1 [5].

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, particularly the peroneus longus, the gastrocenemis, the soleus, and the anterior tibialis muscles (Figure 2), are stretched for a prolonged time [7]. During this period of stretching, a temporary re-alignment of the collagen fibers within the connective tissues occurs that stimulates growth of the muscle [8].

However, one of the major problems of serial casting is that although the patient may walk in the cast, it cannot get wet. While the fiberglass portion of the cast is waterproof, the soft cotton and synthetic lining inside it is not. If a cast does get wet, it must be removed and then reapplied; otherwise infection or soft tissue deterioration may result. Prolonged water contact to the skin causes the loss of the soluble natural moisturizing factors that are responsible for keeping the skin moist and pliable. Without these natural moisturizing factors, transepidermal water loss can result which is responsible for dry, scaly skin, and irritant dermatitis. Additionally, extended water exposure to the skin can result in penetration of foreign substances that can lead to infection [9].

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.

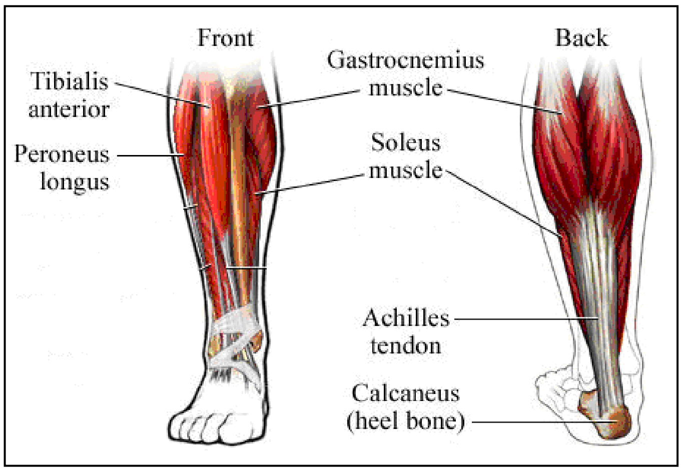

Figure 2: Anatomy of the lower leg showing the targeted muscles of serial casting [6].

Client Information:

Dr. Donita Croft, who practices in Pulmonary Disease and Critical Care Medicine and Internal Medicine, has requested a device that will keep the serial casts dry for her 7 year old daughter.

Problem Motivation

The clients request for a water resistant boot to cover walking casts stems from the need to protect the integrity of the walking cast and insure 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 3, 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 3: 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 they can be stretched over. 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 consideration 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 [10]. A non-waterproof fabric, such as nylon, cotton, or denim, coated with a waterproof spray will be compared to those fabrics.

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. 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 [11]. 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 [12].

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 4). 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 works, the material used must have a large elastic strain. This will enable the design to be deformed to allow 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.

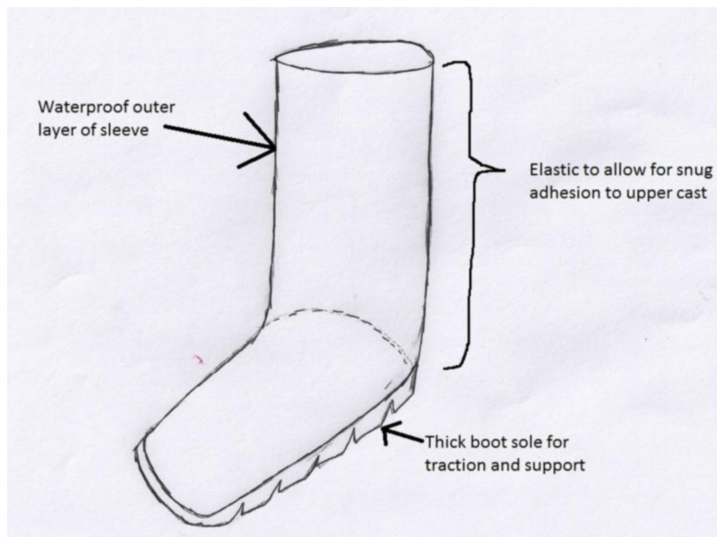

Figure 4: Waterproof sleeve design. This design makes use of an elastic upper region to secure the sleeve to the cast. A thick boot sole is attached to the bottom for traction and support. The sleeve will be made out of a waterproof material

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 5). 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. 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.

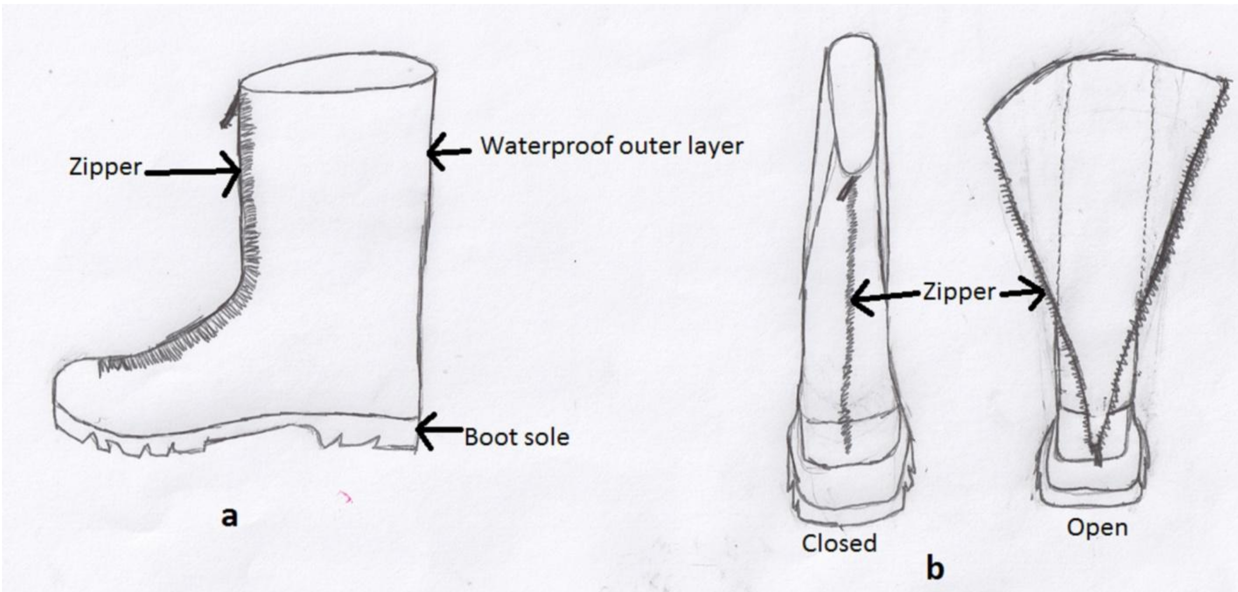

Figure 5: a) Side view of the zipper design. b) Front view of the zipper design closed and open. This design makes use of a front zipper to allow the user to easily put on and secure the boot. This is of concern because the cast does not allow one to flex their ankle.

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 6 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.

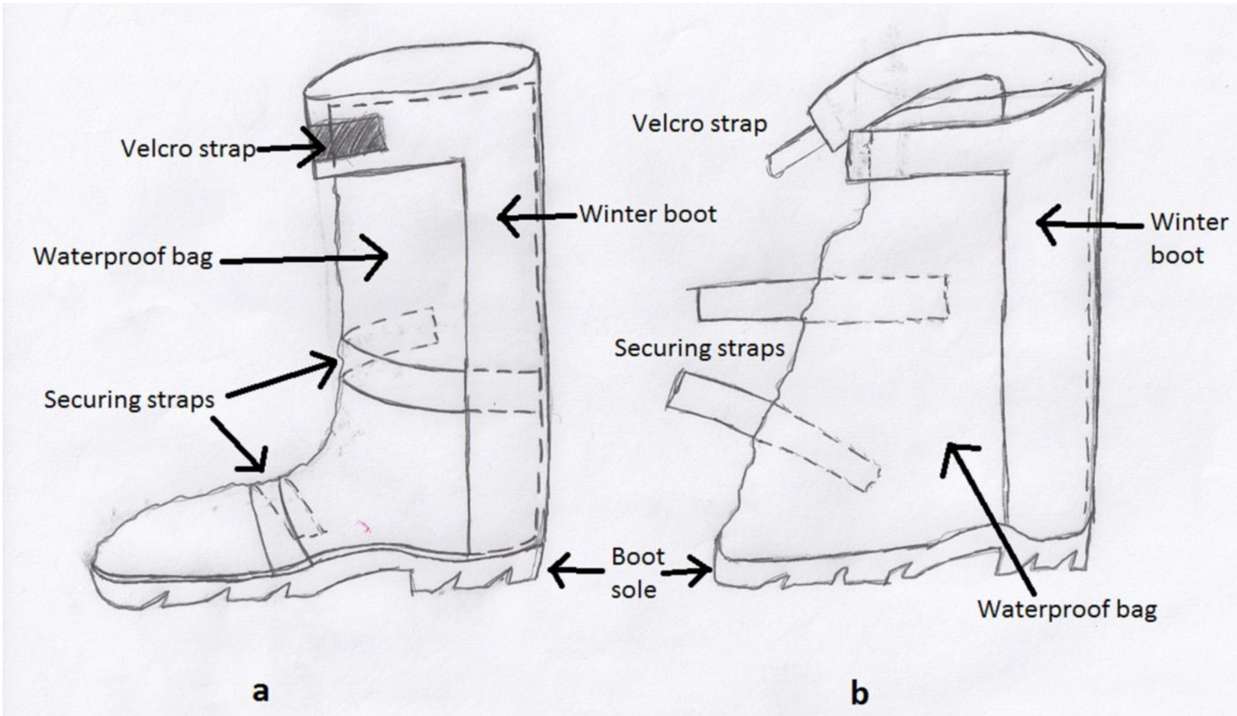

Figure 6: Modified winter boot design a) secured and b) open. This design attaches a waterproof bag to part of a winter boot, which remains for support. Two straps will be used to securely fasten the bag once the casted leg is positioned inside, with a Velcro strap attaching the winter boot portion.

Design Matrix

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 (figure 7), 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 remain 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.

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 7: The design matrix used to determine the final design.

Final Design: Bag Boot

The final design of the boot is made up of three main components. The base layer of the boot is made of an existing winter boot. Material is removed from the front of the boot, leaving only the sole and back portion. Figure 8 shows the size seven women’s boot which was used for the final prototype. The boot fabric allowed the Gore-Tex bag to be easily stitched into place. Small tabs of fabric were left in pace for straps and buckles to be sewn to. Also, the top of the boot is left intact to wrap up the bag portion.

The bag portion of the boot shown in figure 9 is comprised of 3-ply Gore-Tex, sewn into two separate bags. The outer Gore-Tex bag is sewn directly to the existing winter boot around the back edge and the sole. The inner Gore-Tex bag is stitched along the top edge to the inner bag. By having two separate bags there are no seams that penetrate both the inner and outer bag, making the inner bag completely waterproof. The flexibility of the Gore-Tex allows the bags to conform to the casts very easily, fitting a wide variety of different cast sizes and shapes into one size of boot.

Figure 8: Pre-manufactured boot

The black straps shown in Figure 10 are used to tighten the bag around the cast. Velcro was attached to the top portion of the winter boot which provides an easy way to secure the loose fabric. The buckles are low profile and are operated with a one push button. The straps are adjustable similarly to a back pack strap. The entire exterior of the finished boot was treated with NikWax waterproofer.

Figure 9: Dual layer Gore-Tex bags

Figure 10: Straps to secure cast

Testing

Determination of bag materials

To determine the material to use for the bag portion of the design, the main characteristic that was tested was water resistance. It was imperative that the material not only protect from leakage of water but also limit absorption. Testing was performed using 3 different materials: cotton, denim, and Gore-Tex. Data from these three materials were then compared to a completely water resistant control of plastic wrap.

To begin, a testing structure was created (Figure 11) that would be used to firmly hold the desired material in place about 30 cm high. For testing, a material is placed over the orifice (12 cm diameter) and secured in place by 5 nails.

Figure 11: The testing structure used. It stands 30 cm high and the hole is 12 cm in diameter.

Figure 12: The general testing setup consists of the material held firmly in place and a cup to catch the leaked water.

Figure 13: After 5 minutes water still resides on the material.

Once the testing structure was in place, a tared cup was placed underneath the orifice for collection. Then, a weighed amount of water was poured onto the material. Due to the weight of the water, the material sagged down into the orifice. This was deemed as the testing setup, and was allowed to sit unperturbed for 5 mins or until all of the water visibly leaked through or soaked into the fabric (Figure 12). If after 5 mins a puddle was still visible, as can be seen in figure 13, the material was carefully released from the testing structure and the remaining water was poured into a tared cup and weighed.

The amount of water that leaked through the material as well as the amount of remaining water were both weighed. Any unaccounted for water was assumed to be absorbed. From these weighed values the overall volumes of leaked and absorbed water were determined using the assumption that 1 g water is equivalent to 1 mL.

Results

Material	***Amount Leakage (mL)***	***Amount Absorbed (mL)***
Denim	117.64 ± 8.5	16.24 ± 0.6
Cotton	128.1 ± 5.5	9.18 ± 1.0
Gore-Tex	0	0.94 ± 0.2
Control	0	0.64 ± 0.2

Table 1: Data displays the average amount of water that was both leaked and absorbed for each material. Both denim and cotton performed the worst in all categories, whereas Gore-Tex and the plastic wrap control performed comparably**.**

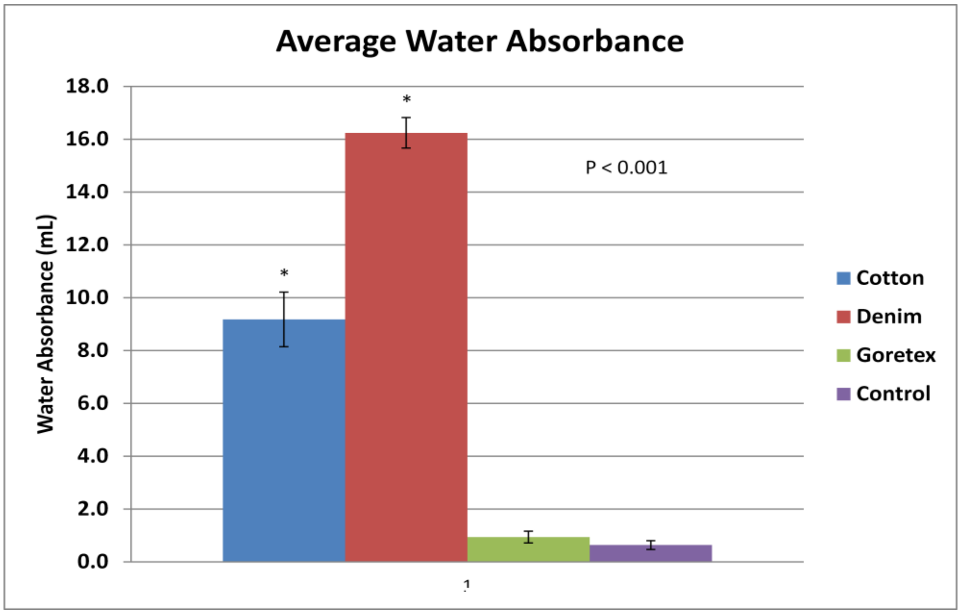

Figure 14: The average water absorbance off each material tested. Both the denim and cotton had a significant difference in water absorbance than the plastic wrap control. Gore-Tex shows no statistically significant difference.

To compare the absorbance of the materials to the plastic wrap control, a two-tailed independent student-T test was used. As can be seen in figure 14, both the denim and cotton performed significantly different than the negative control. Gore-Tex did not behave differently.

Table 1 shows the amount of leakage and absorbance from each of the materials. Both denim and cotton performed comparably, allowing more than 100 mL of water to leak through. Both Gore-Tex and the negative control allowed no leakage.

One point of interest that should be noted is the absorbance of both the plastic wrap control and the Gore-Tex. Though it is listed as absorbance, from observation as well touching the Gore-Tex it was quite apparent that no absorbance actually occurred. Therefore, it is quite possible that the unaccounted for water, which was defined as being absorbed, was actually simply lost through human error, adhering to the material, or was error in the scale. These possibilities are further supported by the fact that the plastic wrap control was reported as having absorbed a small volume of water, which does not occur.

It should be further noted that, while not shown, preliminary testing of both Atsko and NikWax water proofers showed that NikWax was the most effective.

Final Design Testing

To determine the overall effectiveness of the final design, two main attributes were tested: water resistance and effect on gait.

<u>Water Resistance</u>

The bag boot was tested and further compared to a pair of Baffin Cross Fire Polar Proven™ winter boots (Figure 15). Baffin Cross Fire Polar Proven™ boots were chosen due to their high resistance to all forms of precipitation.

Figure 15: Image of one of the control boots used for water resistance testing.

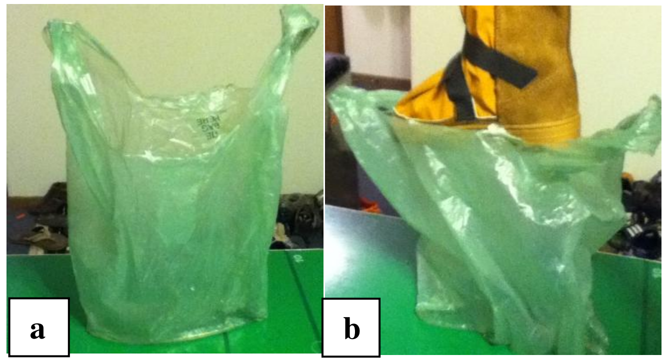

Figure 16: To test the water resistance properties of the boot, a green bag (a) was filled with approximately 400 mL of water and the boot was placed inside (b) and shaken.

Water resistance was tested by placing approximately 400 mL of water into a plastic bag (Figure 16). The plastic bag filled with water was then weighed by placing the bag into a tared cup. Each boot was then separately placed inside of the bag and the top was held shut. A hand was placed securely underneath the bag to ensure the water did not simply slump down under the boot. The bag was then vigorously shaken 15 times to ensure that the tested boot was sufficiently exposed to water. Next, the boot was slowly taken out of the bag and excess water was allowed to drip off for 20 sec. The bag was weighed again and the difference was deemed to be total water absorption.

Results

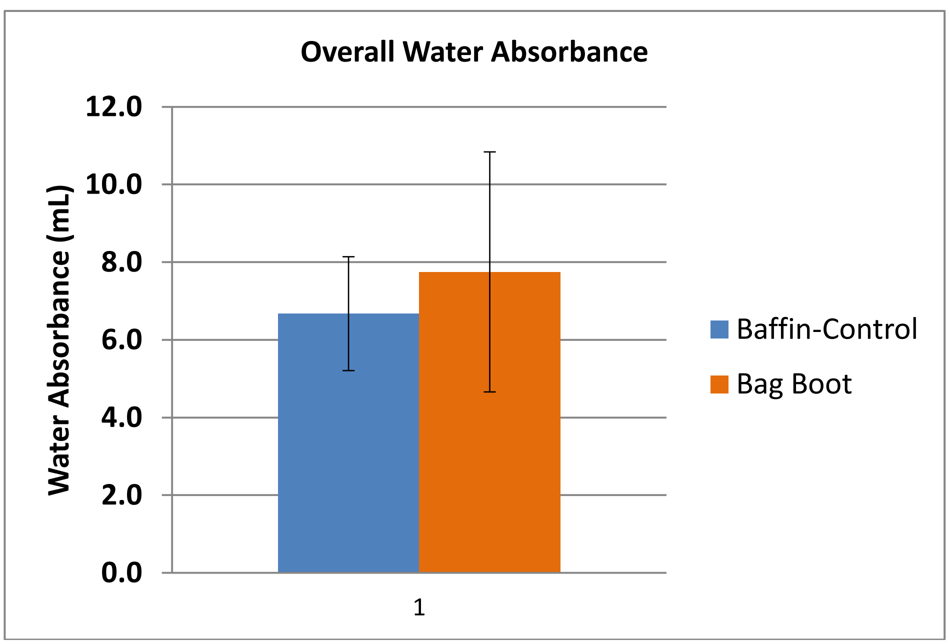

Figure 17: Data showing the overall water absorbance of both the Baffin-Control boots and the Bag boot. No significant difference was found.

Figure 17 shows that the bag boot design did not have a significant amount of water absorbance as compared to the control boots. Thus, it can be concluded that the bag boot design sufficiently meets the water resistant requirement. It should also be noted that neither the bag boot nor the control boot had any water leakage.

Gait Analysis

To ensure that the boot had no adverse affects on walking motion, particularly in the patient for whom it was designed, gait analysis was considered. Before testing was able to be performed, permission was obtained from the Human Subjects Institutional Review Board (IRB). According to the IRB, no oversight from their organization or the FDA would be needed because testing was limited to one patient, and the information collected was specific to that patient. Thus, we were able to proceed with the plan to assess impact on gait in the patient. In addition, parental permission was obtained as the patient is a minor.

Procedure

To assess gait, motion capture analysis was performed. A series of 29 markers were placed on the patient at each of her joints, which included her ankle, knee, hip, elbows, wrist, and shoulders. To establish a baseline for comparison, the patient first performed three walking passes while wearing the sandals currently accepted as footwear for individuals with serial casts. This was then repeated while wearing the prototype bag boot. During each walking pass, a series of six motion capture cameras tracked the marker in four dimensions: x, y, z, and time. From this, the absolute location of each marker could be tracked during an entire pass.

From the information gathered using the motion capture system, many different dynamic measurements could be calculated. Some key dynamic gait factors were ground reaction forces, cadence, stride length, step length, and how the hip, knee, and ankle angles changed during motion [13,14]. It was decided that all of these would be considered except ground reaction forces, which were not directly related to how the patient walked.

Results

It was decided that the key factor which would be considered was how the hip, knee, and ankle joint angles changed during motion, as this would be the easiest way to visualize a difference due to the boots. The results can be seen in Figure 18, with the blue line representing the boot, the red line representing the sandals, and the gray region representing the average for a healthy individual in the patient's age range ± two standard deviations.

In addition to joint angles, cadence, stride length, step length, and percent support time (the percent of time supporting on a given leg) were calculated with both the boots and sandals, and for each leg. The results can be seen in Table 2.

Analysis

Based on the joint angle measurements, it appears there is no adverse affect on gait when wearing the boots. For each angle, there was no statistical difference between the sandals and bag boots, as reported to us by the grad student who analyzed the data (exact p-values were not provided). In addition, both the knee and hip angles fell mostly within the two standard deviation window of a child without cerebral palsy. The only angle which showed significant change was the ankle, however this makes sense, as the patient's ankles were in hard plaster casts and could not flex.

When considering some of the other measurements, some differences do arise. The patient had a slower cadence (86.1±9.5 vs. 107.9±4.3 steps/min), and shorter stride (53.7±7.4 vs. 74.2± 4.9 cm) and step lengths (27.2±4.1 vs. 37.1±3.0 cm) in the boots when compared to the sandals. However, there were two key factors which likely led to this. First, it was the patient's first time wearing the boots, so she was not used to them. Second, the patient was openly opposed to participating in the testing, which likely affected the results. More testing would be needed to definiteively investigate these factors. It was promising though, that the percent total support and percent single support were similar between the types of footwear, indicating that although the subject may not have been walking as fast or reaching as far as may be possible, her walking motion was not affected.

When all of the dynamic factors are taken together, it appears that the bag boot design created has little to no adverse affect on gait.

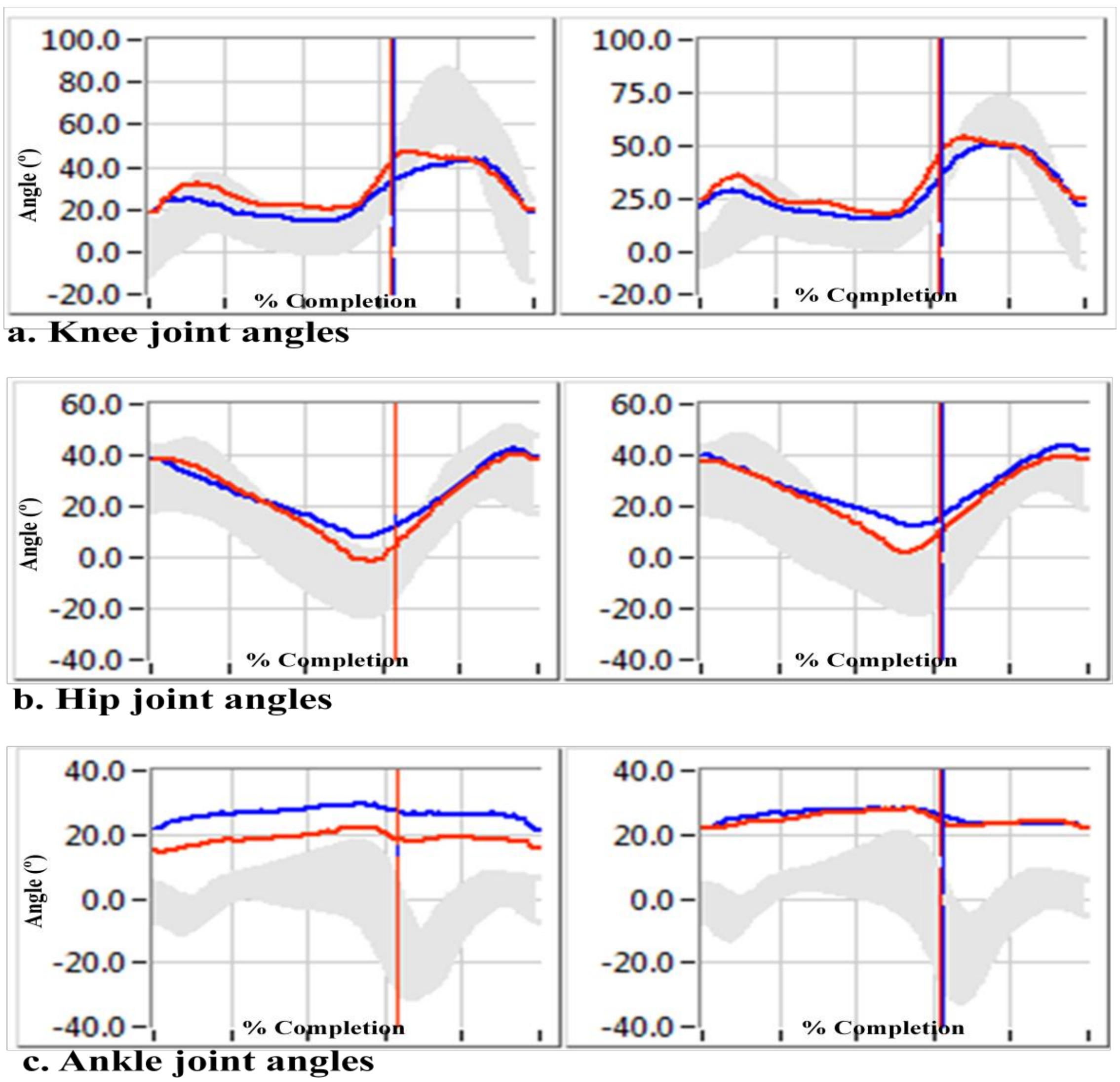

Figure 18: Average changes in knee, hip, and joint angles during one walking stride. Red = Shoe, Blue = Boot, Gray = Average seven-year-old girl without CP ± 2 standard deviations. There was no statistical difference between use of the shoe and bag boot.

Table 2: Spatial and temporal measurements for test subject with sandal and boot prototype. Results given as average ± standard deviation.				
	Right Leg		**Left Leg**	
	Sandal	**Boot**	**Sandal**	**Boot**
Cadence (steps/min)	109.6 ± 4.9	85.9 ± 9.0	106.2 ± 3.8	86.3 ± 10.0
Stride Length (cm)	74.1 ± 5.5	54.0 ± 6.8	74.3 ± 4.3	53.4 ± 7.9
Step Length (cm)	37.0 ± 3.0	26.2 ± 4.8	37.2 ± 3.0	28.2 ± 3.5
Total Support Time (%)	62.9 ± 1.5	63.5 ± 3.6	61.8 ± 1.2	62.8 ± 2.2
Single Support Time (%)	38.2 ± 1.2	37.2 ± 2.2	37.1 ± 1.5	36.5 ± 3.6

Ethical Considerations

To ensure that this design maintained high ethical standing, a number of different precautions were followed. One of the primary considerations was 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 was the comfort of our client, Dr. Croft, in terms of the design team working with her daughter. One specific area that relates to this was performing different tests with her daughter. The tests that were conducted included: taking different measurements, determining weights, as well as analyzing gait cycles. Further, to analyze and document the effectiveness of the final product it was advantageous to record Dr. Croft's daughter using the design. To ensure that a solid comfort level was present and maintained we thoroughly explained to both Dr. Croft and her daughter what the test entitled, what kind of equipment we would be using, as well as what we would expect from them.

Finally, because the design used Dr. Croft's daughter, it was imperative that all safety hazards be taken into consideration. Dr. Croft informed us that her daughter does not have any allergies, but it was still important to review with Dr. Croft the materials that made up the device. When the boot was put on Dr. Croft's daughter it was crucial that it fit properly to avoid any hindrance in movement. That is, the boot needed to supply solid support and be as homogenous as possible with the cast. Because the boot was placed on a rigid cast, constriction from having the boot too tight was not an issue.

Future Work

The final design prototype was successfully tested and meets the primary client requirements. Gait analysis and water testing show the cast boots are waterproof and do not significantly impair the gait of the patient. There are, however, several improvements that can be made to make a more ergonomic and marketable design.

The first area that needs to be addressed is the method for securing the boots to the cast. The buckles, straps and Velcro provide ample stability but they are difficult for the patient to secure alone. Adding a drawstring system to the top of the bag would greatly reduce the difficulty in securing the boots. A drawstring system could be sewn into the interior of the dual layer Gore-Tex that would provide an easy way for the patient to tighten the boots by pulling one string. Ideally the drawstrings would be sewn into the outer Gore-Tex layer to ensure no water can penetrate. Aside from making the boots easier to tighten this will provide a cleaner look and a more aesthetically pleasing final boot.

To enable the patient to put on the boot from a sitting or standing position a small loop or tab should be installed on the top front portion of the bag. This gives the patient an area to hold on with as the cast is slid into the bag portion of the boot. As the material wears it is likely that the bag section of the boot will not stand open on its own, so this tab will be essential for user ergonomics.

To cut down on cost the outer layer of Gore-Tex can be replaced with a cheaper similarly waterproof material such as canvas. The inner layer of Gore-Tex will be capable of keeping the cast completely dry and a more durable outer canvas layer will lessen manufacturing cost as well as increasing the stability of the bag.

The existing boots that were used to create the final prototype can be manufactured differently for the sole purpose of the bag boot. Cutting down on material cost and manufacturing cost for the outer boot and sole will cut down on total production cost. Also, in the boot used for the final prototype the sole is made of a suede rubber composite, which in testing has shown to absorb water. A harder rubber should be used for the bottom of the boot that will not absorb water and will also diminish the overall height and profile of the boot.

For manufacturing purposes sizing constraints for a variety of cast sizes will need to be determined. Ideally the cast boots could be sized similarly to shoes, allowing the consumer to receive a proper fitting boot. All of the changes mentioned would be easily applicable to the existing design. Making these boots easy to manufacture will maximize profit margins if the boots were to become commercially available.

Cost Analysis:

The following items were obtained or purchased for the final design (Figure 19). The design team's goal was to ensure that the final design could be made for under $100, which it was. However, when looking at the pricing it is clear that many prices could be decreased if mass production were to occur.

Product	**Company**	**Amount**	**Price**
Gore-Tex® 3-Layer Waterproof Breathable Ripstop Nylon - Caramel	Rockywoods.com	One square yard	Subtotal: $22.99 Shipping:$3.80 **TOTAL: $26.79**
"Nikwax Fabric and Leather, 4.2-Ounce"	Amazon.com	4.2 oz can	Subtotal: $8.75 Shipping: $5.58 **TOTAL: $14.33**
Manufactured Boots	Amazon	1 Pair	**TOTAL: $29.99**
Black Nylon Straps	N/A	Unit	$2.69
Buckles/Thread/Velcro		4	$12.96
Total:			**$86.76**

Figure 19: A table of the items purchased

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Appendix

PDS

Cast Boot
(5-9-2012)
Taylor Jaraczewski, Baljit (Jay) Kler, Joe Benert, Lucas Schimmelpfenning

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 loose)
  - 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 children's 13 size shoe
        - Should go at least a foot up the cast, not necessarily the entire cast
        - The boot it self is from a size 7 women's boot.
    - 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, Brown
        - Resemble a girls Ugg boot.
- **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