UNIVERSITY OF WISCONSIN – MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 201 – DESIGN

Support Mechanism for Brachial Plexus Injury

Mid-semester Report

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05/05/2010

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Abstract

Injuries of the brachial plexus (set of nerves at the base of the neck) are severely debilitating and can cause paralysis of large portions of the arm and shoulder muscles. This paralysis leads to subluxation (sagging) of the humeral head from the acromion. Those with a brachial plexus injury must therefore wear a sling almost constantly. However, there are a very limited number of slings on the market that significantly reduce shoulder subluxation without being too restrictive. Thus, the objective of this project is to create a sling tailored for brachial plexus injuries. Based on a set of requirements compiled from the advice of a brachial plexus patient at the UW hospital, the team developed three alternative slings, chose a final design to pursue, and constructed a prototype. Testing to assess the effectiveness of the design was completed and showed that the sling adequately reduces subluxation but the overall comfort could be improved.

Background

Brachial Plexus Injuries

The brachial plexus is a set of nerves that leads from the spinal cord to various points in the arm as seen in Figure 1. These nerves are responsible for control and sensation throughout the shoulder, arm, and hand. Injury to the brachial plexus can cause arm paralysis, and the patient can lose feeling or feel pain in the hand and arm. This kind of accident is usually caused by the arm being pulled away from the body, stretching the nerves near the spinal cord [1]. In adults, brachial plexus injuries are usually due to traumatic events such as motorcycle accidents, snowmobile accidents, car accidents, gunshot wounds to the shoulder region, or tree limbs falling on the shoulder [2].

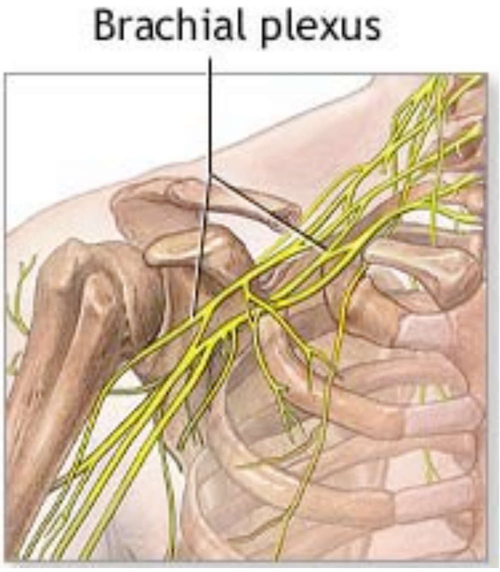

Figure 1: Drawing of the brachial plexus nerves that are attached to the spinal cord near the base of the neck. [3]

Stretch injuries of the brachial plexus can cause different types of damage to the nerves. The first type is avulsion, which occurs when the nerve roots become detached from the spinal cord. Unfortunately, in this type of injury, the nerves are unable to recover. However, surgery can be attempted to regain some muscle control. A second type of injury is scar tissue with conduction. This is when the nerve is surrounded by scar tissue, but can still conduct an electrical impulse through the nerve and therefore is still functional. These injuries will heal with time. The nerve can also be injured with impaired conduction ability. This is when scar tissue prevents the signal from traveling through the nerve, and surgery is needed to regain function [2].

There are three main repairs that can be utilized to fix injuries to the brachial plexus. The first and most successful procedure is neurolysis. This procedure involves removing the scar tissue from around the nerve. A second procedure, usually done when a section of the nerve is damaged, is nerve grafting. A surgeon removes the damaged part of the nerve and replaces it with a nerve graft from a different part of the body. The last procedure that can be performed is neurotization. This involves replacing a damaged nerve with an entirely new nerve, from the neck or the chest. These surgeries last four to seven hours and hospitalization is usually necessary for one or two days. After a few weeks, therapy begins and lasts for many months. Nerves heal only about an inch per month, so it can take years to fully recover [1]. Supportive slings must we worn throughout this recovery process.

Although brachial plexus repairs can give many patients full recovery of their arm, some are not successful. For these patients, there can be little to no return of sensation or movement. They can be left with partial or total limb paralysis. As a result, the limb muscles atrophy, ultimately leading to uncomfortable subluxation of the humeral head. Many brachial plexus patients must rely on shoulder and arm supporting splints to fix this subluxation.

The Patient

For the time being, the team is focusing on one patient, Eric. He was involved in a motorcycle accident on August 12, 2007 and was transported to the emergency room complaining of right forearm pain. There the doctors found that he had suffered avulsion of the C6 and C7 nerve roots as well as many other injuries including broken and fractured bones. The brachial plexus injury left Eric with no sensation or movement in his shoulder, arm, and hand. In January

Figure 2: Photograph of Eric's injured arm, showing muscle atrophy and subluxation. The blue arrow shows current position of the humeral head while the black arrow shows the desired position.

of 2008, Eric underwent a nerve transfer from the nerves in his ribs to the musculocutaneous nerve of the brachial plexus. Doctors were unable to successfully graft the other damaged nerve. Since then, he has regained functional use of this hand due to the surgery, but still suffers complete arm paralysis.

Eric has used many different slings and supportive braces to help him go on with everyday life. At one point, he wished to go back to school, but was unable to because of the difficulties he had keeping his hand in a usable position. The team's ultimate goal is to satisfy Eric's needs and to enhance his quality of life.

Current Slings

Approximately 200,000 people a year suffer from brachial plexus injuries in the United States alone [2], yet there are very few support devices specifically focusing on the injury. There are many devices on the market that do not fix the subluxation of the shoulder but can be used to provide limited support. Examples of these are braces and wraps. Wraps are used to immobilize the shoulder, but do not have enough support to eliminate subluxation. They are also difficult to apply with only one arm. Braces provide more support and can be easier to put on, but once again are not designed to reduce subluxation.

Within the limited slings available that fix subluxation there is much room for improvement. One of these slings is the Givmohr as shown in Figure 3. Designed specifically to reduce shoulder subluxation, this sling wraps around the body and down through the hand. A plastic piece gripped by the hand is pulled up by the straps, reducing shoulder subluxation [4]. However, the plastic piece held by the hand is hard and uncomfortable, and prevents the wearer from using their hand. It also cannot be worn under clothes due to the placement of the straps. These traits are not desirable for Eric.

Figure 3: Givmohr sling [5]

A second sling of interest is the Wilmer sling, which is shown in Figure 4. This sling was designed at the Delft University of Technology for patients with a paralyzed arm. It reduces subluxation by supporting the elbow, rather than the hand. A wire support runs down the forearm and is attached to a plastic plate for the hand to rest on [6]. Although this sling is successful in reducing shoulder subluxation, the strapping leads to uncomfortable pinching under the shoulder, and once again, the hand is not completely free.

Although there are multiple slings on the market, none of them are ideal for patients with brachial plexus injuries. We hope to improve on the methods used by current slings to come up with an optimal design for Eric.

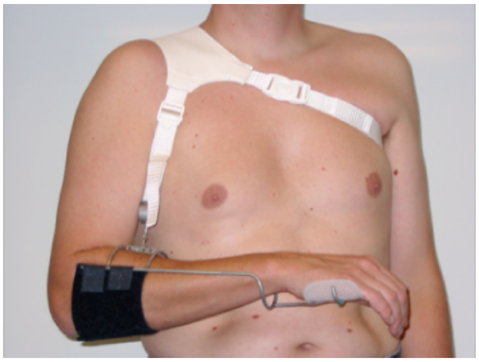

Figure 4: Wilmer sling [4]

Problem Statement

As detailed above, brachial plexus injuries can be very debilitating. However, there are few slings designed for these injuries on the market and the slings that do exist are not ideal. Injury to the brachial plexus results in loss of motor function and subluxation of the humeral head from the shoulder socket as seen in Figure 5. The goal of this project is to create a prototype of a sling that reduces subluxation by lifting the humeral head and provides enhanced comfort for the user. Although many brachial plexus patients desire an improved sling, the focus of this project is on Eric. In the future, the design has the potential to help other patients.

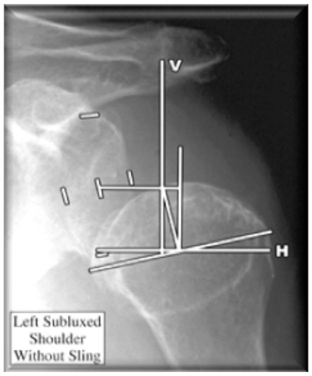

Figure 5: X-ray image of shoulder subluxation showing a large gap between the humeral head and shoulder socket. [5]

Design Specifications

Based on the inadequacies of current slings on the market and conversations with Eric, a set of requirements for a sling tailored to Eric's condition was compiled. The most important aspect that must be considered is shoulder, arm, and forearm position. Lifting the arm to reduce shoulder subluxation is essential to any sling we propose. Currently, the distance between Eric's acromion and humeral head is two finger widths (approximately 3.7 cm). The sling should ideally reduce that distance to zero finger widths. Another key requirement is that Eric's right hand be held in a useful position. Therefore, the sling should hold Eric's right elbow at his side and at 90˚ angle with his forearm pointing straight forward and parallel to the floor. If time permits, a hinge mechanism that enables variation in elbow position will be incorporated. The upper arm should be at a 20˚ angle away from the body for maximum comfort. Furthermore, the sling should accurately secure Eric's arm in these specified positions during repeated use and prevent the flaccid arm from excessively swinging away from the body.

As expected, comfort and safety are also of utmost importance in a successful sling design. Eric intends to wear the sling whenever he goes out in public, so this device must permit up to eight hours of comfortable wear. To accomplish this, the sling should be lightweight and adequately distribute the weight of the right arm. Components of the sling must not cut off circulation or cause chafing. Materials that are breathable and lightweight should be chosen to minimize overheating. Also, any materials in direct contact with the skin should be hypoallergenic, soft, and non-irritating. Additionally, the sling should facilitate easy one-handed application and removal.

Aesthetics of the sling, while not the most important factor, is another area that must be addressed. The main requirement in this category is that the sling be concealable under clothing including long sleeve shirts. Any visible components should be black in color. Also, the sling should enhance the cosmetic appeal of Eric's greatly atrophied right arm by adding bulk. Currently, Eric's right upper arm is 5.1 cm smaller in circumference than his left, so the proposed sling should add two inches to the circumference of the upper arm.

Other specifications relate to the performance of the sling and budgetary constraints. Because slings can be easily soiled, the proposed prototype should be washable. Furthermore, all components of the slings should be non-flammable and be able to withstand body, ambient, and electric drying temperatures (maximum of 150^{o} C without deformation. Sling components should be designed for repeated loading to maximize life in service. Lastly, due to a limited budget, all materials and fabrication should not exceed $200.

Design Alternatives

Sleeve Design

The first design alternative incorporates a sleeve concept consisting of a single nylon strap, a thermoplastic forearm support, and the sleeve itself as seen in Figure 6. The sleeve would be made of neoprene and mesh materials. Neoprene would be located in the weight-bearing areas such as the material covering the right shoulder and looping under the left arm. Mesh would be integrated into the material covering the upper arm, forearm, and back components to make the sling light and breathable. The design of the sleeve would facilitate easy one-handed application and removal because the user could slide it on like a shirt and fasten it with the Velcro front closure. Furthermore, the sleeve would serve as the base structure for the other components of the design such as the nylon straps, thermoplastic supports and padding. The nylon straps would be sewn into the sleeve for added support and better weight distribution. One strap would follow the contour of the arm so the sling would fit under most clothing and would have a hiker's clip attached to allow easy connection to the straps that run under the elbow. An adjuster similar to those on a backpack would enable tightening to decrease subluxation. The elbow strap would pass through the sleeve under a padded thermoplastic forearm support. This forearm support would be formed to fit the user, extend to the balance point of the forearm, keep the arm at a 90 ˚ angle, and be held in place by the sleeve. Lastly, the sleeve design would provide bulk to an atrophied arm via a removable padded insert on the upper arm.

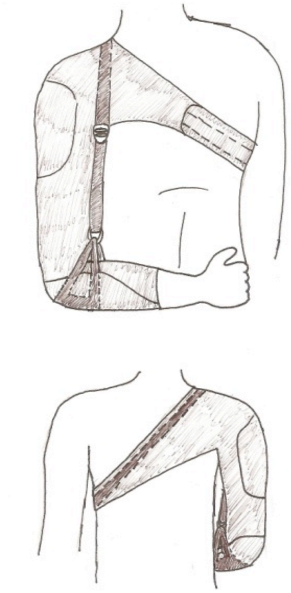

Figure 6: Sketch of front view (top) and rear view (bottom) of the proposed sleeve design.

The sleeve design has several advantages and limitations. As mentioned above, the advantages of this design are easy application and removal, reduction of subluxation, and the ability to conceal it under clothing. Furthermore, the prototype would be machine washable and provide the desired cosmetic appeal to the injured arm. However, there are a few limitations as well. The main concern is that a sleeve may overheat in warm weather or during extended use. Also, this design requires large amounts of material and extensive sewing, so fabrication may be difficult.

Backpack Design

The premise of the second alternative is a backpack concept consisting of two over the shoulder straps, an elbow strap, a half sleeve, and a thermoplastic forearm support as seen in Figure 7. The "backpack" straps would be made of neoprene rather than nylon to enhance comfort on the skin/strap interface. These straps would crisscross in the back through a plastic slider that could move up and down to adjust strap position. There would also be a clip across the chest to allow further adjustment of the straps and improve weight distribution. Additionally, this design facilitates one-handed application and removal. A half sleeve that covers the user's upper arm would be attached to the right shoulder strap. The sleeve would provide bulk to an atrophied arm and reinforce the elbow support strap. This adjustable strap would be sewn into the sleeve and would travel down the outside of the arm, under the elbow, and up the inside of the arm. It would reduce shoulder subluxation by lifting the elbow. A padded thermoplastic forearm support would be fitted to the user, attached to the elbow strap, and extend to the balance point of the forearm to keep the elbow at a 90˚ angle.

Like other designs, the backpack design has advantages as well as limitations. The main advantage of this design is that it improves weight distribution with an extra shoulder strap that would enhance comfort. Other benefits include reduction of subluxation, the ability to wear under clothing, one-handed application, and washability. Drawbacks to the backpack design include possible discomfort due to the number of straps on the bare skin and the awkward attachment of the elbow strap.

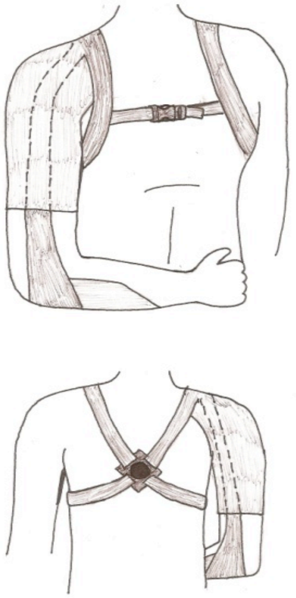

Figure 7: Sketch of front view (top) and rear view (bottom) of the proposed backpack design.

Boomerang Design

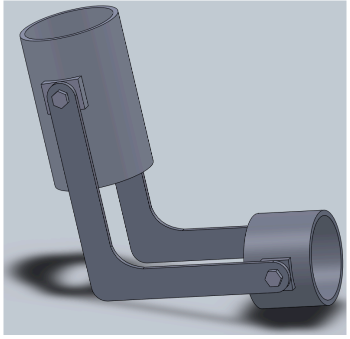

Figure 8: A SolidWorks schematic of the boomerang design element showing the basic premise for attachment of the rigid boomerang piece to each cuff. This rigid piece would support the lower arm at the desired carrying angle and reduce unwanted movement of the lower arm while allowing hand mobility.

The boomerang design involves a boomerang-shaped rigid piece which is attached to the upper and lower arm with two cuffs (Figure 8). The boomerang-shaped piece would be made of a rigid polymer or low-density, lightweight metal. The structural aspects of this piece are critical as the strongpoint of the design is that it maintains the desired holding angle for the patient. By placing the boomerang piece on both the inner and outer sides of the arm, the dynamic shifting of the hand about the humeral axis is greatly reduced. This component would attach to a cuff on the upper humerus and middle forearm. These cuffs would be a synthetic fabric (mesh, neoprene, or nylon), fastened by Velcro straps to adhere tightly to those positions. A rigid material would run around the central perimeter of each cuff and have a pin attachment, through which the holes in the boomerang could be mounted. Means of mounting include either fastened or detachable components.

The upper cuff would have a strap which runs around the left side of the neck from the front of the right arm to the back of the right arm, connected by a strap over the right shoulder as shown in Figure 9.

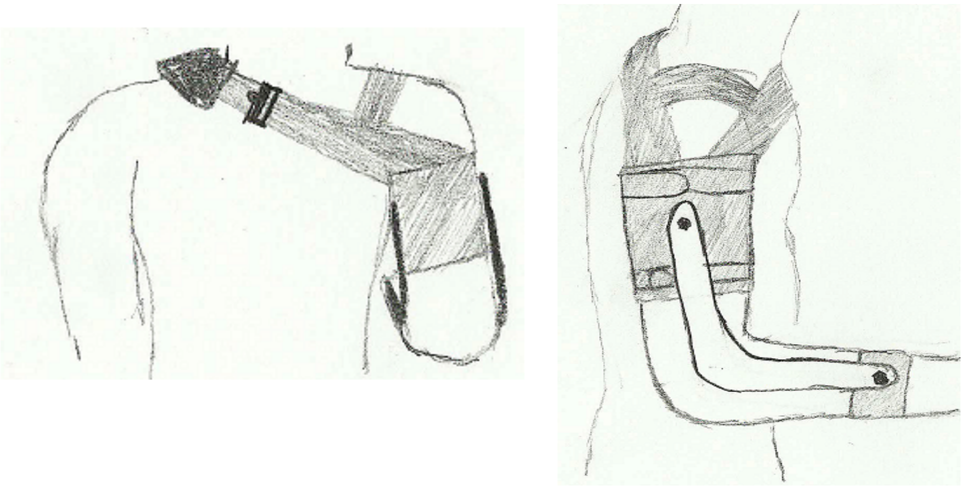

Figure 9: These two sketches show the back and side view of the boomerang design. The main strap would be cushioned around the neck with an adjustable clasp. Each cuff is fastened via Velcro fasteners.

The boomerang concept offers some strong points for the requirements of the solution. The arm is restricted to very little flexional or torsional movement as desired by client. This concept also allows room for a future additional adjustable component to be added to the boomerang piece to allow for multiple carrying positions of the affected arm. Also, as heavily stressed by the client, the design would be feasibly worn under clothing so as to conceal the majority of straps and sling components.

However, the sling has flaws in its design as well. Although the subluxation would be reduced, the lack of a strap around the elbow limits subluxation reduction. Since the sling must lift a minimum of 46.7 N (4.76 kg) at the elbow, a cuff simply wrapped around the upper arm would not offer adequate support. Also, getting the boomerang sling on would become a time-consuming task due to the many components.

Design Matrix

The three design alternatives explained above were placed into a design matrix to evaluate their respective potential to produce a prototype which solves the design problem. Criteria were developed by the team in collaboration with the client and patient to ensure that the solution most efficiently solved multiple problems with current slings available. These criteria were then assigned a value corresponding to their importance to a successful prototype. The matrix can be seen in Table 1 below.

Table 1: The design matrix for the brachial plexus sling design project. The boomerang design scores significantly below the other design options, which will be melded together to form a hybrid of the two concepts.

Criteria		Design Alternatives		
Considerations	Weight	Sleeve	Backpack	Boomerang
Subluxation reduction	30	25	27	20
Easily worn/put on	15	14	12	8
Ability to conceal under clothing	15	15	15	15
Weight distribution	10	7	9	6
Cost	10	8	6	6
Fabrication complexity	10	9	8	6
Carrying position	5	2	2	4
Cosmetic enhancement	5	5	5	4
TOTAL	**100**	**85**	**84**	**69**

The heaviest weight criterion for the project was subluxation reduction. If a final sling fits all other requirements but fails to reduce the subluxation of the humerus, the project is essentially useless. The sleeve and backpack designs offer substantial support of the arm along the axis of the humerus to hold up the weight of the arm and reduce subluxation by pulling the humeral head back into the acromion. Since the boomerang only pulls the arm up by the cuff around the upper and lower arm, slipping of the skin and weight of the arm will greatly reduce effectiveness.

The other heavily weighted requirements for the device are that it can be easily put on with limited functionality of the patient and being able to conceal the majority of the sling under clothing. All three alternatives were designed to ensure that they could be worn underneath the patient's clothing and thus received full points in the category. With regards to easily getting into the device, the boomerang again falls behind the other two designs, for reasons previously mentioned. The backpack concept scores a point lower than the sleeve idea since the backpack involves the twisting of the torso and pulling of arms through two straps instead of one.

Weight distribution presents another critical component of the design. This category incorporates both adequate biomechanical distribution of the weight, as well as comfort of the strapping layout. Intuition says that the strapping layout of the boomerang design fails to spread weight of the arm out effectively and creates comfort problems due to the strap around the neck. The sleeve design solves this issue better since it incorporates an easily detachable hiking clip to support the weight just in front of the elbow, but does not split the weight across both shoulders. Therefore, the backpack is the best option with regards to distribution since the weight is adequately spread across the body and through the ‘X-clip’ across the back of the sling.

Cost is a category of the project which must be kept in mind since the client and patient didn’t have funding for us. Although the client has the capability of acquiring a few materials, the majority of the materials need to be purchased through a grant received by the team. Due to expected materials incorporated into each design, the three ideas received points accordingly to their cost effectiveness.

Difficulty of fabrication is yet another important aspect that had to be considered. The team is currently in contact with an orthotics supervisor who works out of Madison. Hopefully, this orthotics company will be able to offer suggestions and fabrication help throughout the remainder of the project. Nonetheless, certain components of the designs would create a massive headache when trying to fabricate. This explains why the boomerang design lost out on points since the pin connection of the static component to the cuffs would be extremely difficult to fabricate.

All three designs were conceived to hold the arm at a ninety degree angle directly in front of the body (not across the body). The matrix rates the ability of the sling to inhibit movement from this position. It also incorporates the ability to include a dynamic aspect of the design in the future so as to create multiple supporting angles. The rigidity of the boomerang offers excellent potential here, whereas the more simplified strapping of the sleeve and backpack designs could allow unwanted movement of the lower arm.

Due to lack of motor control of the upper arm, the patient has lost extensive muscle mass due to tissue deterioration in the upper arm and shoulder regions. The patient, who is an avid weightlifter, expressed an interest in enhancing the visual size of his arm and shoulder so as to restore a symmetrical look. Because all three designs could be modified in the future to better accommodate this wish, the designs each scored high in this category.

Upon evaluation of the three designs by the design matrix, the team acknowledged that the boomerang design was not a promising solution to the problem at hand. The two remaining designs scored only one point apart on the design matrix. After correlation and discussion amongst the team, a decision to create a hybrid sling was favored over pursuing the sleeve concept because of a one point edge. This hybrid sling, shown below, follows the premise of both designs. A sleeve completely encloses the upper arm and upper forearm. A supportive component is attached to the clavicle area with a detachable ratchet strap. The weight distribution of the backpack is however incorporated to create a more comfortable and evenly distributed solution.

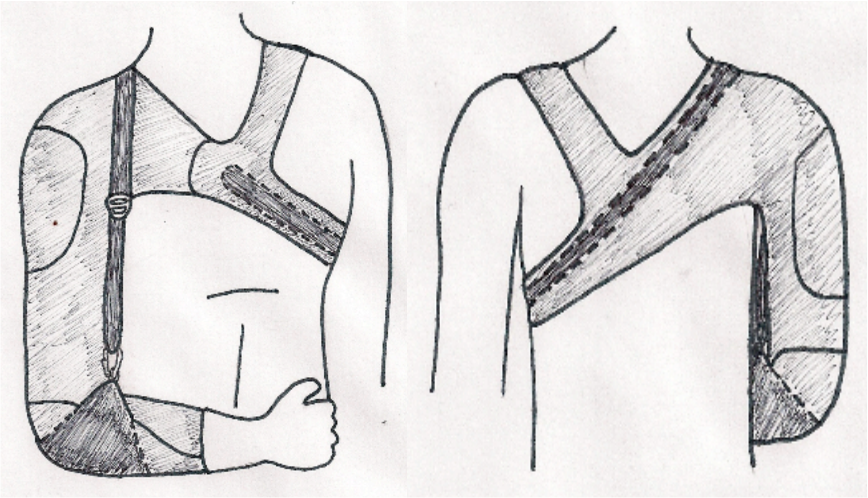

Figure 10: Sketch of the final design we will pursue, showing a hybrid of the backpack and sleeve designs.

Final Design

The final prototype has been altered from the mid-semester final design. First, the sleeve which was initially designed to cover the entire upper arm as well as some of the forearm was shortened to only cover some of the upper arm. The purpose of the designed sleeve was to bulk up the arm and it became evident to the team that a greater emphasis should be put on the functionality of the device before adding cosmetic appeal. Another reason for the shorter sleeve was in response to the criticism that the sling trapped heat in excess resulting in sweating. A need to tighten the non-slip neoprene sleeve was addressed by adding an adjustable tightening strap which fastens via Velcro patches. The strength of this adjustable strap was increased and made easier to tighten with one functional hand due to the frontal orientation. Another aspect that was adjusted was the incorporation of the thermoplastic frame to the backbone. Initially a synthetic fabric was wrapped around the elbow and used to enclose the thermoplastic and clip into a D-ring on the subluxation reducing strap as seen in Figure 10. Since the 0.5 cm polypropylene used for the thermoplastic has such strong structural properties, a strap was riveted directly onto the thermoplastic to connect to the subluxation reducing strap. The nylon webbing strap nearest the elbow on the thermoplastic frame was pulled up to reduce subluxation while the nylon webbing strap towards the hand aids in creating the desired perpendicular orientation of the elbow (see Figure 11). The subluxation strap is sewn along the contour of the neoprene across the back to the clavicle, where it is left freely hanging to allow for adjustment as well as better fit under clothing. An additional strap was necessary to restrict the subluxation strap from sliding away from the neck in order to increase stability of the sling. All components of the neoprene backbone are completely washable in cold or warm water and machine dryable. Conversely, the thermoplastic frame should be hand washed.

Figure 11: Clockwise from top left- Front view of the final prototype neoprene backbone; back view of final prototype neoprene backbone; Side view of thermoplastic frame of final prototype; Complete layout of final prototype components

Fabrication

Fabrication of the final sling was essentially comprised of two phases: fabrication of the neoprene backbone and machining of the thermoplastic frame. Once these were fabricated, the strapping mechanisms were included to combine each component together as a functional device.

To create a custom backbone, the team took sizing measurements and used them to create a felt pattern so that adjustments could be made before any neoprene was used. The neoprene was then cut based upon the felt pattern to minimize wasted material. The sleeve component of the sling backbone is made of the non-slip neoprene so as to increase friction of the sling-skin interface and thereby increase stability of the load bearing areas. The chest component is made of perforated neoprene since the material is strong and also offers increased breathability to the patient. All seams of the sling backbone were butted and sewn with a zigzag stitch so as to provide maximal comfort to the patient. Scuba gear patches (neoprene tape) were ironed over all seams to increase comfort and durability of seams. When sewing Velcro patches onto neoprene, a needle lubricant was used to prevent gumming of the needle from the Velcro's adhesive backing. Velcro on the sleeve was sewn directly onto the Dacron strap so that the strap could feed through a metal loop and tighten against itself. At the end of the strap a widened piece of Dacron was added to prevent the strap from sliding out of the metal loop to simplify putting on the sleeve with one hand.

The thermoplastic frame required a lengthy fabrication process. First, a thin cloth sock was placed around the patient's arm to allow easy removal of initial forming agent. Any wrinkles were smoothed out of the sock to create a tightly fitting form. Wetted fiberglass casting tape was wrapped around the sock on the patient's arm three layers thick and allowed to dry for about 10 minutes while patient's arm was held in desired position. The fiberglass casting tape was then cut off and stapled back together along the cut to create a complete form of the arm. Plaster was mixed with vermiculite to decrease density and structural integrity of the final mold. This plaster/vermiculite mix was poured into the fiberglass form and allowed to cure. Shortly after pouring as the mixture began to set, a steel rod was inserted three-quarters deep into the mold and centered circumferentially to allow the mold to be securely clamped in later stages. Removal of the fiberglass tape reveals the final plaster/vermiculite cast of the patient's arm.

In order to physically shape the thermoplastic frame, a sheet of 0.5 cm polypropylene was heated to its forming range (154^{o} C-163^{o} C). A 0.6 cm spacer was placed over the plaster/vermiculite mold to account for padding of the thermoplastic. The heated polypropylene was then stretched to form tightly around the plaster mold and 0.6 cm spacer. Once cured, the thermoplastic was removed from the mold, and lined with 0.6 cm aliplast foam padding. The thermoplastic frame was cut to the approximate desired size with a band saw and further shaved to exact size with a sanding disc which smoothes out the thermoplastic edges as well. Nylon webbing loops were cut down to the desired size and stitched with ends overlapped to maximize integrity of the rivet. A 0.3 cm drill bit was used to drill through the nylon webbing, thermoplastic frame, and aliplast foam. A copper rivet was placed with the head on the aliplast foam and the shaft sticking out past the nylon webbing. The copper fastener was pounded down until nylon webbing was completely fastened to the thermoplastic. Any excess portion of the copper shaft rivet was snipped off with a nail-puller and sharp, rough edges were pounded down with a mallet. This process was completed for all four rivets to securely fasten both nylon webbing straps.

The subluxation strap was stitched along the contour of the posterior neoprene backbone until the strap reached the clavicle, where it was left freely hanging to allow tightening of the strap and increased ability to conceal under the clothing. At the end of the subluxation strap, a D-ring was fastened via a simple loop stitched on the end of the Dacron strap. A plastic backpack adjuster was also used to allow simple adjustability of the sling to reduce subluxation. Another strap was stitched to the subluxation strap at a wider angle and wrapped under the left arm to the front of the torso to prevent the subluxation strap from sliding off the shoulder under high loads (see Figure 10). Finally, the right armpit of the neoprene backbone was trimmed to increase breathability of the final design.

Many of the materials were chosen to fit within given specifications of the project. It was measured and calculated through a free body diagram that the tensile force created by the load of the patient's right arm on the subluxation strap would be 73.4 N (7.48 kg). The Dacron straps used have a tensile strength of 55 MPa [7]. Since the subluxation strap on the prototype is 2.5 cm wide, the strap can support 3618 kg, far more than is necessary to support the patients arm. All Dacron straps were placed in a flame to melt the ends and prevent fraying. The non-slip neoprene on the sleeve as well as the secondary subluxation strap aid to stabilize the load supported on the Dacron subluxation strap. The Velcro patches must adhere with a total force of greater than 73.4 N to prevent the neoprene backbone from being pulled apart. The industrial strength Velcro strips used withstand to 302 kPa, generating enough strength to easily withstand the shear and stress forces applied [8].

Testing

The first type of testing done was measurement of the load distribution of Eric's arm using a force gauge. This was done by taking measurements at three points along Eric's lower arm- at the wrist with the elbow supported, at the balance point 22.9 cm from the elbow with the elbow supported, and at the elbow itself. The results found were that the sling will need to support 24.47 N (2.5 kg) at the balance point and 46.71 N (4.76 kg) at the elbow (see Figure 12). The suspension point of the arm should be closer to the elbow than the balance point of the forearm. The weight of the lower arm thereby

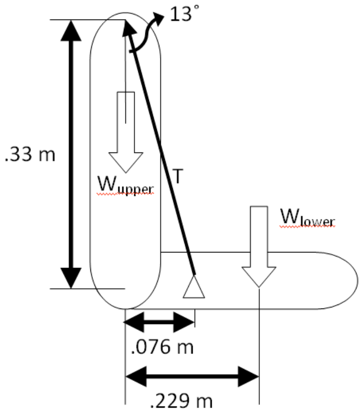

Figure 12: FBD of the arm based on patient measurements. W_{lower}=24.47 N; W_{upper}=46.71 N; T=73.40 N.

forces the upper arm upwards to reduce subluxation [9]. In the final prototype, the suspension point was 7.6 cm from the elbow which fits this requirement.

During fabrication, regular fittings were done to test how well the prototype fit the patient and determine the best location for straps. After one of these fittings, it was apparent that an additional strap was needed to prevent the subluxation strap from sliding off the patient's shoulder. An additional strap was also required on the thermoplastic frame in order to create a perpendicular orientation of the elbow. These changes were subsequently made to the prototype as described in the final design section.

After the prototype was fabricated, subluxation testing was carried out by palpitating the posterior side of the suprahumeral space as detailed by Hall, J et al [10] as seen in Figure 13. This determined the distance between the acromion and humeral head. The goal was to reduce subluxation from 3.7 cm to less than 1 cm. This goal was met—subluxation while wearing the device was approximately 0.7 cm and the patient said the arm was more comfortable. The final weight of the prototype was measured using a force gauge and was found to be 5.10 N which is well under the requirement of 9.81 N. Additionally, the patient was timed in putting the sling on as well as removing the sling. The patient was able to put the sling on in 110 s which is well under the requirement of 180 s. Removal of the sling took 17 seconds which is again well under the 180 s requirement.

Figure 13: Performing subluxation testing while patient wears sling.

Daily use testing was performed in which the patient took the prototype for a weekend, wore it, and gave feedback. Limited feedback was gained due to noncompliance of patient. The questionnaire intended to receive data is attached in Appendix II. The main complaint was that the sling was fairly hot—the perforated neoprene was less efficient at cooling than previously thought. The forearm was positioned against the torso with more internal rotation than desired. However, the patient was happy with the level of subluxation reduction and the ability to conceal the device underneath clothing.

Cost Analysis

As previously mentioned, the budget of this project was strictly limited to $200 provided through a grant for Madison area rehabilitative projects that the team applied for earlier this semester. This budget created limitations on the material and fabrication possibilities available and afforded the opportunity for creative engineering. Although many slings used for brachial plexus injuries on the market such as the Gunslinger and WILMER shoulder orthosis cost between $250 and $300, the final cost of the prototype was $89.20 due in large part to the donations of the UW Health Orthotics clinic. The majority of funds were spent on the perforated neoprene as seen below in Table 2. Even though a great deal of the time and labor for sewing of the neoprene components of the sling were donated by Judy Stankevitz, the team needed to purchase the materials necessary to aid in fabrication such as sewer's lubrication, neoprene tape, and neoprene glue. The only piece of hardware the team purchased was the D-ring used to attach to subluxation strap to the thermoplastic component. The remaining elements including the Dacron strapping, thermoplastic casting, strap adjuster, and slip-resistant neoprene were donated by the UW Health Orthotics clinic as well as the time and labor to guide the team in constructing the thermoplastic component of the prototype.

Table 2 Description of materials purchased and tabulation of total cost.

Description	Vendor	Cost
Perforated neoprene sheet (51" x 41.5")	Foamorder.com	$60.87
Sewing tape and glue specifically for neoprene	Aqua Center of Green Bay	$16.57
3 packages of Velcro strips	Jo-Ann Fabrics	$6.77
Sewer's lubricant	Jo-Ann Fabrics	$3.42
D-ring	Ace Hardware	$1.57
Slip-resistant neoprene	UW Health Orthotics	Donated
Dacron strapping	UW Health Orthotics	Donated
Thermoplastic casting supplies	UW Health Orthotics	Donated
Plastic strap adjuster	UW Health Orthotics	Donated
Total		$89.20

Ethical Considerations

While this project does not deal directly with large-scale animal or human subject testing, ethical concerns such as patient safety, honest data, and clear citations still remain. Before all fittings with Eric, the prototype was checked to ensure safety. For example, sharp edges were smoothed and all pins from sewing were removed. Furthermore, all data collected was honest and based on direct conversation and testing with the patient, client, and orthotics supervisor. Most of the data collected was qualitative and concerned with the comfort and ease of use for the wearer as this project focused only on one patient. Quantitative data for reduction of subluxation and time testing were taken only once. In the future, both subluxation and time to don and doff should be tested several times on different days to ensure repeatability of the test as well as durability of the sling. At this time, the prototype is only intended for use by Eric. However, human subject testing would be necessary in the future to expand the use of this design to other patients; all proper protocols and procedures would need to be completed at that time. Lastly, all citations the team utilized were clearly labeled throughout the design notebooks and all technical communication. The majority of the outside sources used were only to gain background knowledge of brachial plexus injuries and slings currently on the market. While the biomechanical principles of the arm used to affirm the proper function of the prototype were based on a journal article found, all design ideas formulated by the team entirely original.

Future Work

Future prototypes would ideally be improved in five main areas: comfort, forearm position, bulking up the right shoulder (aesthetics), addition of a hinge mechanism, and adaptation for use with other brachial plexus or stroke patients. To improve comfort, a more breathable material could be found or the amount of neoprene used could be reduced and ventilation added. However, the potential problem with different fabrics is lack of structural integrity. Another potential alternative would be to use straps in weight bearing areas without a neoprene base, since Eric indicated that heat was a bigger concern to him than the slight discomfort of strap on skin. In addition, a professionally fabricated prototype could be commissioned that would have enhanced fit and durability.

Since Eric gave relatively low ratings for forearm position, a second generation prototype would refine forearm position so the hand is positioned radially out from the body for increased functionality. However, this would be difficult to do while still allowing for concealment entirely under the clothes.

Additional features could be integrated into the design later to improve cosmetic appeal and functionality. For example, bulk could be added to the right shoulder by creating a mold of the left shoulder as well as a stylized cap that would mimic the appearance of the left shoulder. Also, a hinge mechanism at the elbow could also be incorporated to allow for greater range of arm positioning. Lastly, in the future, the sling could be adapted for use with other brachial plexus or stroke patients.

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Appendix I

Product Design Specifications – February 26, 2010

Project #2: Shoulder and Arm Support/Sling

Team Members

Sarah Czaplewski – Team Leader
Megan Halley – BSAC
Nathan Retzlaff – Communicator
Kayla Stankevitz – BWIG

Problem Statement

A sling or other method of support is needed for patients with injuries to the brachial plexus nerves that control the shoulder and arm muscles. Damage to these nerves can result in partial or total loss of motor function of the arm and subluxation of the humeral head from the shoulder socket. Current slings are non-ideal because they hinder patient movement, are uncomfortable to wear, and do not hold the arm in its natural position. The goal of this project is to design an effective and patient-friendly support mechanism that corrects the aforementioned faults of current slings.

Client Requirements

- **Shoulder Placement:** The support device must lift and hold shoulder in a comfortable and natural position. It would be ideal for device to lock shoulder in a position.
- **Useful Forearm/Hand Position:** The forearm should be straight out rather than across the body to enable better use of the hand. No constraints or straps should interfere with hand or wrist movement.
- **Comfort:** Material needs to be breathable to avoid overheating. Also, the device should be easy to put on with only one arm.
- **Aesthetics:** The support should be able to be worn primarily beneath clothes. Any visible components should be black. Also, final design should make the right arm appear larger and more cosmetically pleasing.

Design Requirements

1. **Physical and Operational Characteristics**
   a. *Performance Requirements:* The sling must reduce shoulder subluxation to a zero finger width gap between the humeral head and the acromion. Also, the prototype must be

able to support at least 100 N (10.2 kg). As a necessity of the user, the sling should be easy to put on and remove with one hand in 180 s. If time permits, a hinge mechanism at the elbow should be implemented to allow variation in forearm position.

   b. *Safety:* Any part of the design, especially straps, in contact with skin should not cause severe irritation or cut off circulation. All materials used must be non-allergenic.

   c. *Accuracy and Reliability:* The device should support the arm in the same position and at the same angles every use. The position of the elbow should be at a 90°angle and the forearm should have 0° external rotation and elevation.

   d. *Life in Service:* The device needs to withstand approximately 8 hours of use per day. The user will wear the support when at work or while going out in public, but usually not at home. Also, materials of the sling should be able to withstand multiple washes.

   e. *Operating Environment:* All components of the design should be able to withstand temperatures up to 150° C, as well as moisture from perspiration. Accidental bumping of the sling should not cause damage.

   f. *Ergonomics:* The supporting device should evenly distribute the weight of the flaccid arm so user's posture and gait are minimally affected.

   g. *Size:* The user should be able to wear the sling under clothing comfortably. The smaller the sling is, the more cosmetically pleasing it will appear.

   h. *Weight:* The sling should be as light as possible for the comfort of the user and not exceed 9.81 N.

   i. *Materials:* All materials should be non-allergenic and non-flammable. Also, material covering the skin should be breathable. Materials that can become easily soiled should be washable.

   j. *Aesthetics:* The majority of the device should be able to be worn beneath the users' clothing. Any visible components should be black.

2. **Production Characteristics**
   a. *Quantity:* One functional prototype of the sling is needed and should be tailored to fit Eric, the target patient. If time permits a second prototype should be completed to give Eric a sling to wear while the other is being washed.

   b. *Product Cost:* Total cost of materials and fabrication should not exceed $200.
3. **Miscellaneous**
   a. *Standards and Specifications:* The developed support device will adhere to the specifications laid out by the primary user.

   b. *Customer:* The primary user of sling will be Eric, one of our client's patients. In the future, the design may be adapted to other brachial plexus or stroke patients.

c. *Competition:* There are many slings on the market. Two slings designed specifically for brachial plexus injuries are the Giv-Mohr sling and WILMER sling.

Appendix II

Sling Prototype Questionnaire

Circle the number that you think is appropriate for each of the following questions with five being the best and one being the worst. Rate this sling compared to previous slings you have used. Feel free to make comments in addition to circling a number any question.

1) Reduction of subluxation

   1 2 3 4 5

2) Useful position of right forearm and hand

   1 2 3 4 5

3) Ease of putting on the sling

   1 2 3 4 5

4) Ease of removal of the sling

   1 2 3 4 5

5) Overall comfort of sling while wearing

   1 2 3 4 5

6) Weight of the sling (1 – too heavy 5 – lightweight)

   1 2 3 4 5

7) Comfort of perforated neoprene/skin interface

   1 2 3 4 5

8) Comfort of blue neoprene/skin interface

   1 2 3 4 5

9) Ability to conceal under clothing

1 2 3 4 5

Greatest benefits/best aspects of the sling are:

Biggest drawbacks/shortcomings of the sling are:

Improvements that your feel should be made:

Other comments: