Dynamic Sling to Support Upper Extremity Post Brachial Plexus Injury to Return to Active Lifestyle

Final Report

December 12th, 2012

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Abstract

The brachial plexus is a network of nerves in the shoulder that can cause varying levels of sensation and motor loss if damaged [1, 2]. Karen Blaschke is an occupational therapist with UW Hospitals and Clinics, and she works with patients that have experienced brachial plexus injury including our client, Margaret Overstake. Our design team was asked to create a dynamic sling that would allow someone with a brachial plexus injury to return to an active lifestyle. The sling should be adaptable for patients at different levels of rehabilitation. The final design we chose to pursue incorporates a chest strap with components that distribute the weight of the injured arm to the opposite shoulder. Usability and force distribution testing demonstrated that the design supports properties specified by the client and design requirements.

Problem Motivation

The brachial plexus is a network of nerves that provides the arm and shoulder with sensory perception and motor control [1, 2]. It originates from the cervical region of the spine, then wraps around the back of the neck and down through the back of the shoulder [3]. Divisions in the plexus neurons form the ulnar, radial, and median nerves which receive and transmit signals from the arm and hand [3]. This complex anatomical feature is often modeled as a tree because of its branching characteristics through the upper back and shoulder, as shown in Figure 1.

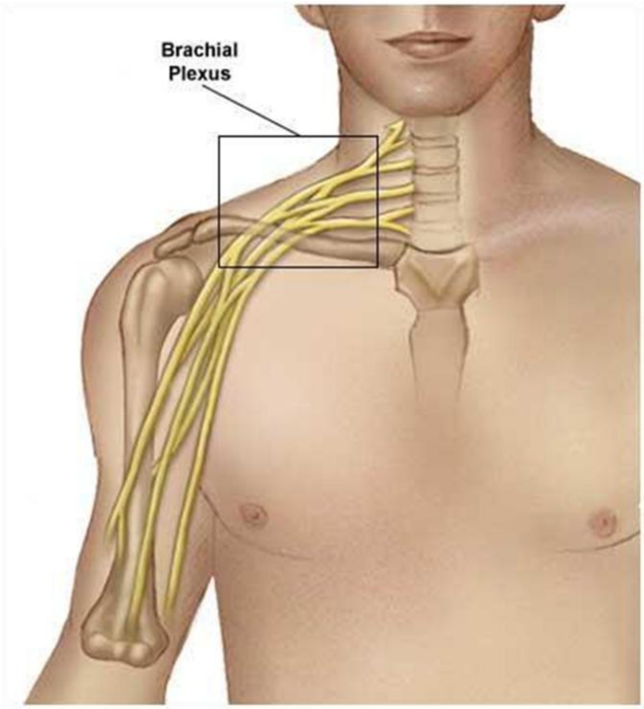

Figure 1: An anatomical depiction of the brachial plexus. This network of nerves originates at the spinal cord and branches through the shoulder and upper arm, innervating the entire limb [4].

Brachial plexus injury can result from various high-energy trauma accidents such as a long fall, sporting accident, or penetrating injury. The most common causes, however, are road traffic accidents during which the shoulder is intensely jarred, causing injury due to neural strain [3]. The four types of brachial plexus injury are categorized by the type of damage that has occurred [5,6]. Avulsion signifies the detachment of the nerve from the spinal cord and is the most severe case. Similarly, a rupture is a torn nerve, but not at the point where it attaches to the spinal cord. A neuroma refers to a torn nerve that has developed scar tissue, so it no longer functions normally. The final and most common type of brachial plexus injury is neuropraxia, which is stretching of the nerve [3, 5, 6]. Although neuropraxia still has a long recovery period, the probability for regaining function in the limb is greater than for the other three types.

Variation exists in the severity level of brachial plexus injuries, making each patient's recovery timeline unique [7]. The proximity of the injury to the spinal cord is also a factor that can affect rehabilitation and therapy regimes; if the injury is within the nerve root coming directly from the spinal cord, there is a lesser chance of recovery than if it is in the distal portion of the plexus [3].

In general, treatments from occupational and physical therapists are prescribed to gradually regain function in the limb. Initially, muscle movement is incredibly painful, but strength can slowly be regained over the course of two to five years [7, 8]. Some patients do make a full recovery, but the outcome is largely based on the individual [3].

Client Description

Karen Blaschke is a Registered Occupational Therapist in Rehabilitation Medicine with University of Wisconsin Hospitals and Clinics. Our other client, Margaret "Meg" Overstake, is a patient of Karen's that has suffered a brachial plexus injury. Meg is a working mother seeking to return to her normal exercise routine, which includes daily running. Running is a difficult task for Meg, as well as others with this injury, because she has not yet gained enough strength in her arm to lift and maintain running form. Both clients would like us to design a dynamic sling that holds the arm in running position, allowing a patient with a brachial plexus injury to return to an active lifestyle. The sling will allow for activity at varying levels of rehabilitation while being able to develop with the patient as they gain strength and function during the recovery process. Karen also envisions using the sling for other rehabilitation applications such as rotator cuff injuries.

Current Devices

Marketed Devices

Currently, a range of slings exists to support individuals experiencing brachial plexus injury. Again, recovery and rehabilitation regimes vary immensely, so device requirements will differ between patients. Immediately following the injury, the patient typically wears an immobilizing brace to prevent large movements of the shoulder and arm that may cause painful burning sensations [7,8]. The slings maintain a 90 degree angle at the elbow, and support the shoulder to prevent subluxation [3]. One example of an immobilizing sling is the *Rolyan Universal Sling & Swathe* produced by Patterson Medical (Figure 2) [9]. Another example that allows more movement is the *B-Cool Super Sling Plu*s, also distributed by Patterson Medical (Figure 3) [10].

Figure 2: The Rolyan Universal Sling & Swathe immobilizes the arm and shoulder immediately following a brachial plexus injury to decrease pain and prevent further injury [9].

Figure 3: The B-Cool Super Sling Plus maintains a constant elbow angle and allows for slightly more shoulder motion and use of the hand than the Rolyan model [10].

The *GivMohr Sling* was patented in 2005 and is the closest in function to the current design project (Figure 4) [11]. The *GivMohr Sling* is designed for patients reaching the end of rehabilitation, who wish to enhance their shoulder mobility. Its unique design allows dynamic motion in the shoulder while maintaining compression throughout the arm, reducing subluxation in the shoulder [11]. By supporting the shoulder, pain and discomfort is reduced and normal arm motion while walking is facilitated. One dissatisfying aspect of the *GivMohr Sling* is the plastic component that must be held in the user's hand during wear. The piece is what provides the force to lift the shoulder, but it hinders the ability to use the hand [7]. Although the sling maintains normal arm motion during walking, it lacks the support necessary for running and other high-energy activities.

Figure 4: The GivMohr Sling is the standard dynamic sling available on the market. The placement of the straps allows for motion in the shoulder. Holding the plastic hand-piece creates a compressive force through the arm that opposes shoulder subluxation, but prevents the wearer from using their hand [11].

Past Prototypes

Because her sling options were few and posed many limitations on her ability to return to running, Meg initiated the design process on her own during her rehabilitation (Figure 5) [8]. Her design used a Thera-band as the main body and strapping material of the sling. She held both ends in her hand and the rest wrapped over her shoulder, weaved through the straps of her sports bra, and came back down her arm under her elbow. She incorporated a sleeve made of sock to keep the Thera-band aligned properly underneath her elbow.

Figure 5: Meg created her own sling for running while recovering from her brachial plexus injury. She wrapped a Thera-band around her hand and wove it through an elbow sleeve made from a sock. It then passed up through her sports bra straps and back down to her hand where she held it for the duration of her run [8].

Design Requirements

The design requirements within the Product Design Specifications in the Appendix are explained here in further detail. Requirements for design fall into one of three major categories: safety requirements, client requirements, and patient comfort.

Because the device will be used during rehabilitation, safety requirements are critical in ensuring the sling will cause no harm to an already injured individual. The dynamic sling must fit snugly to the patient's arm but not so tight as to hinder blood flow in the arm. Since the wearer may have reduced skin surface sensitivity due to neural damage, the device should be designed to minimize the chance of pressure sores or chaffing. Also, the sling must not cause any additional damage to the shoulder and arm which may result from lack of proper support or undesired pressure on the injured shoulder. It should also be noted that if the product were to be marketed, it would require approval from the FDA.

In addition to safety requirements, the device must also function as required by the client. The client has specified that the sling must support the patient's arm during activities involving moderate shoulder motion, so none of its components should restrict movement of the shoulder joint. The device should also support the elbow at a user-adjustable angle while still permitting some flexion and extension of the arm. The sling will be an adult size, unisex fit and adjustable to offer support for a wide range of body types. During recovery, the device should allow varying levels of support for the user to choose from as arm strength increases. The device should maintain functionality throughout the entire course of recovery. Since full recovery is not always attainable, it would be ideal if the device lasts upwards of 10 years. It is also necessary that the sling function properly in both indoor and outdoor settings and be constructed from washable, water resistant materials.

Since the sling may be worn for extended periods of physical activity, care should also be taken in maximizing the comfort of the sling without compromising functionality. It is important that the sling can be put on and adjusted using only one arm. The device should be adjustable in size and support to fit the needs of the patient. To promote ease of use, the sling must be lightweight (not exceeding 1 kg) so that it can easily be carried with one arm and worn with little to no detectable weight imbalance. The materials used in the design should be breathable and should not cause any irritation or discomfort to the patient's skin. Because it will often be worn in public, the device should be aesthetically pleasing and simple in appearance.

Design Alternatives

The Backpack Design

This design, as seen in Figure 6, consists of two shoulder straps to be worn similarly to those found on a backpack. A short strip of elastic material connects the two straps across the back (a). Arm support is achieved by means of an adjustable and partially elastic band which is connected to a wrist brace at one end and the back side of the nearest shoulder strap at the other. The elasticity of the material is attained by layering slack, sturdy strap with a segment of elastic to give stretch with a stopping point (b). Another adjustable band runs from the wrist to an elbow cuff and then up the back of the arm to attach at the same point on the shoulder strap as the previous band. The elbow cuff is held in place by Velcro fasteners around the arm.

The Backpack Design is simple to put on with one hand because it comes as one piece, leaving only the elbow and wrist components for adjustment once the sling is on the body. The strap connecting the back of the elbow with the shoulder mimics the behavior of the deltoid muscle to support the injured arm. When considering long term comfort, the strapping is low enough on the torso to prevent chaffing in the underarm region and does not rub on the back of the neck. The length and resistance of the elastic piece (b) can be exchanged to accommodate patients at different points in the rehabilitation process.

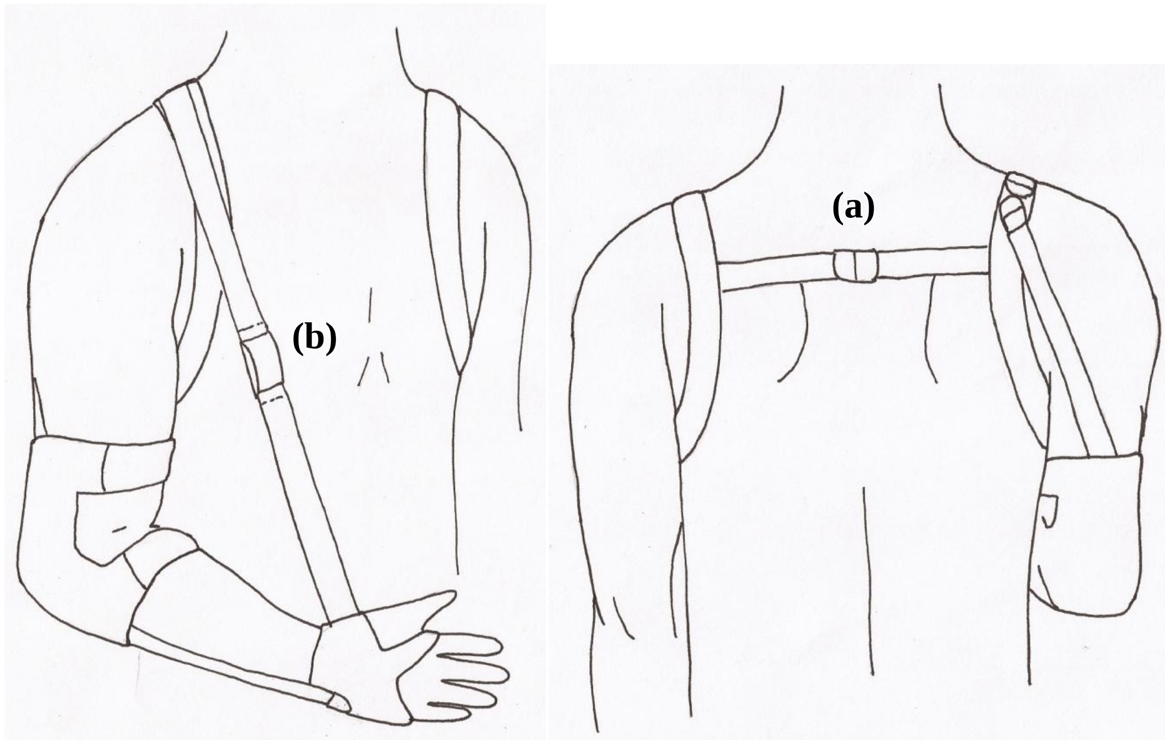

Figure 6: Front and back views of the backpack design. The design consists of two straps, an arm support between the injured shoulder and wrist, and a removable elbow component. Letters on the figure correspond to descriptions in the text. (a) Strap connection across the back. (b) Layer of strap over elastic segment to provide flexibility with a stopping point.

The Ring Design

The ring design in Figure 7 consists of two straps that slide onto the shoulders similar to the previous design, but are connected in an "X" shape across the back with a ring (a). Another strap runs across the upper chest, connecting the right and left shoulder straps. An arm support component is attached at the back upper shoulder strap, comes down under the elbow, attaches at the hand near the base of the thumb joint, and returns to anchor at the shoulder. This strap contains a short elastic segment allowing for a changing elbow angle (b). A wrist brace provides both a connection for the strap and wrist support. A cup-style support fits under the elbow and has narrow Velcro or elastic fasteners across the top of the arm to keep the cup in place.

The main differences between the Ring Design and the Backpack Design are the back element and chest strap. The chest strap connects the shoulder straps across the front of the body to prevent undesirable sliding and loosening. The ring differs from the back strap in that it distributes the tensile forces radially to the mid-back rather than horizontally across the upper back. The resistances and lengths of elastic are exchangeable, and the effort required to put on the device is comparable to the Backpack Design.

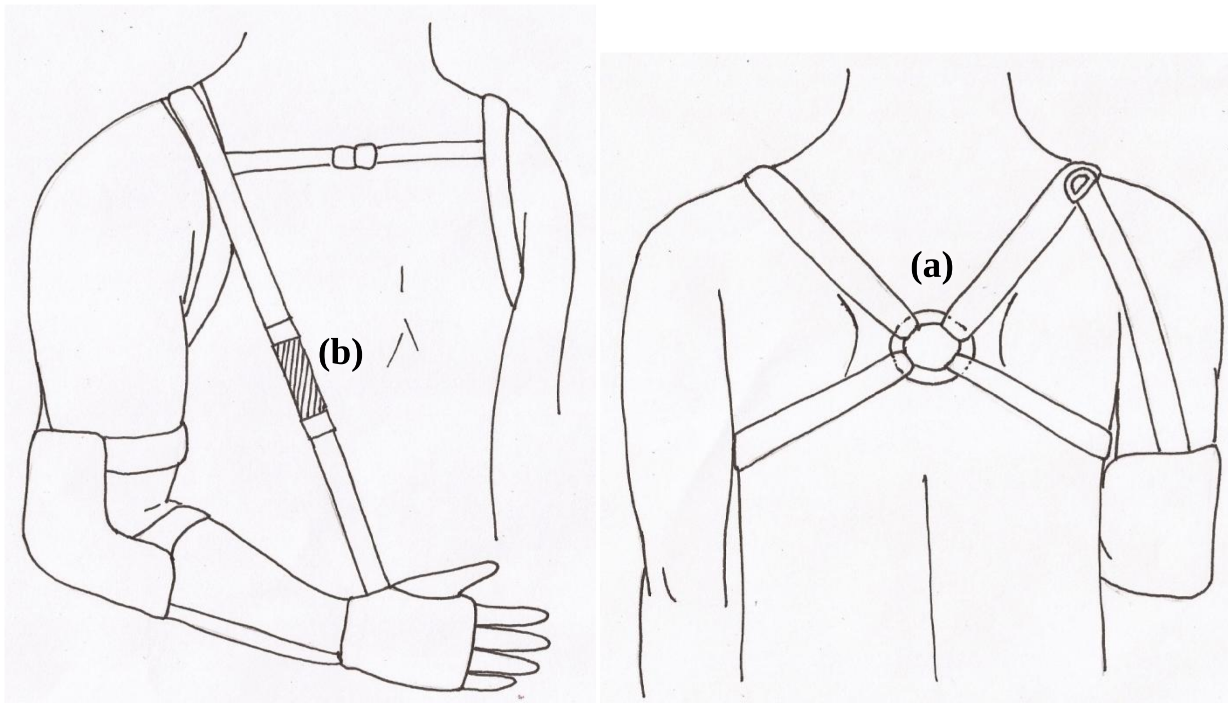

Figure 7: Front and back views of the ring design. The design consists of two straps connected by a ring, arm support, and a removable elbow component. Letters on figure correspond to descriptions in the text. (a) Ring connection on the back. (b) Elastic segment in strap that allows for movement of the arm.

The One-Strap Design

The one strap design can be seen in Figure 8. The main body of the sling is one continuous "Y" shaped piece (a). One end wraps adjustably around the chest, while the other branches off under the shoulder blade of the uninjured shoulder, wraps under the armpit and back over that shoulder. From this point it wraps to the back and over the injured shoulder where it attaches to a wrist brace on the injured arm. This attachment point allows adjustment of elbow angle. A sliding fabric strap in the back takes pressure off the back of the neck (b). An elbow strap attaches adjustably to the wrist brace and follows under the elbow, weaving through an elbow sleeve, and up the back of the arm. It weaves through a loop on the closest shoulder strap and clips into the far shoulder strap. The straps of the sling are made of a sturdy, yet stretchable material for support and comfort.

The One-Strap Design is a bit more challenging to put on due to the attachment points posterior to both shoulders. Minimal underarm strapping reduces the potential for chaffing and increases the range of motion. The fabric strap on the back symmetrically redistributes the tensile forces at thirty degree angles from the vertical to minimize sling displacement during use. Adjustable connection points around the chest and at the wrist make the sling usable for a greater range of body types than the Backpack and Ring Designs.

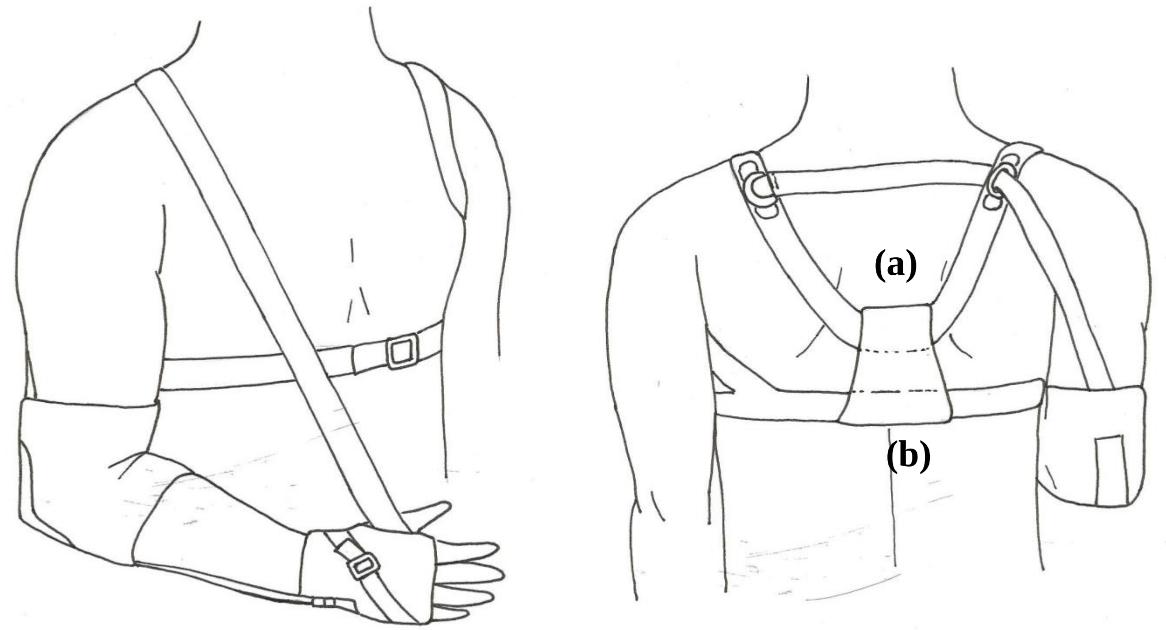

Figure 8: Front and back views of the one strap design. The design consists of one continuous strap of the same material, with a removable elbow component. Letters on the figure correspond to letters in the text. (a) "Y" shape configuration on the back. (b) Sliding fabric strap taking pressure off the neck.

Design Matrix

In order to evaluate each of the three designs, a design matrix was constructed. Each design alternative was evaluated on the criteria of patient comfort, effectiveness, ease of use, adjustability, safety, and cost. The complete scoring breakdown for each design alternative can be seen below in Table 1. The one strap design scored the highest overall, and was therefore the pursued sling design.

Weight	Criteria	One Strap	Backpack	Ring
25	Patient Comfort	22	18	20
20	Effectiveness	18	12	15
20	Ease of Use	13	17	16
15	Adjustability	13	9	11
10	Safety	8	6	7
10	Cost	8	7	6
100	**Total**	**81**	**70**	**75**

Table 1: The design matrix breaks down how well each design alternative follows the criteria viewed as important based on design and client requirements. The maximum value for each criterion are on the left in the column labeled weight and each design was total to be given a score out of 100 which can be seen in the bottom row of the table. Top scorers in each category are highlighted in blue.

Patient Comfort

Patient comfort was seen as the most important factor in the design and was therefore given the highest weight of 25 in the design matrix. It is important for the patient to be comfortable while using the sling because the design will be used specifically for rehabilitation purposes. The one strap design will be the most comfortable for the patient due to the location of strapping and was therefore given 22 points in the matrix. This was followed by the ring design with a value of 20. The ring design allows for a more comfortable strap fit across the back of the patient, yet having the ring in the center of the back may be uncomfortable. The backpack design was given the lowest value of 18, with the belief that the horizontal strap across the back may cause discomfort.

Effectiveness

It is important that the sling is successful in maintaining support while remaining dynamic during activity. The ability of each design to distribute the weight of the injured arm to the opposite shoulder was also considered. For this reason effectiveness was weighted highly at 20 in the design matrix. All three designs would be successful in maintaining support for the patient during activity. However, the one strap design would allow the weight of the arm to be better distributed to both shoulders due to the strap running along the back of the arm and across to the uninjured shoulder. It was therefore assigned 18 points in the matrix. The other two designs scored fairly low in the matrix because the elbow strap is attached to the injured shoulder.

Ease of Use

Ease of use was also seen as a significant criterion, so it was given a weight of 20 in the design matrix. The patient will need to be able to put on and adjust the sling with one arm, and the number of components should be minimal so that the sling is easy to use. The backpack and ring designs would be the easiest for the patient to put on by themselves and so were assigned 17 and 16 points in the design matrix, respectively. The one strap design would be more difficult to put on with the use of one arm due to the intricate strapping, so it was assigned a value of 13 in the matrix.

Adjustability

Adjustability was an important design requirement and was given a weight of 15 in the design matrix. Adjustability is important so the design can fit varying body types and develop with the patient as they gain strength and mobility during rehabilitation. The one strap design would be easily adjustable in fit, but determining resistance adjustability is dependent on the materials available for use. Fit adjustability is demonstrated by the chest strap and lateral movement of the back piece horizontally to accommodate the patient's body type. The design is also capable of changing the arm strap length at the wrist to augment elbow angle. For these reasons the one strap design was given the highest value of 13 in the matrix. This was followed next by the ring design with a value of 11, which allows adjustment of fit in the back but not as significantly as the one strap design. Finally the backpack design was given the lowest value of nine. This design would almost require customization to the client's dimensions because it is nearly incapable of adjustment.

Safety

Safety was given a value of 10 in the design matrix because there are few ways that the patient can be harmed with the use of the sling. However, safety is important because patients may have reduced skin sensitivity, so the sling should not cause pressure sores and should not further injure the shoulder. The backpack design was seen as the least safe due to the segment of limited elasticity. This may cause a jerking movement that could be harmful to the patient so the design was given a value of six. The one strap design was given a value of eight in the design matrix because the materials used would be least likely to cause harm to the patient.

Cost

For the sling to be marketable upon completion, cost must be taken into account. Cost was seen as lower importance due to the simplicity of design materials needed, and was given a weight of 10 in the design matrix. However, it should also be affordable for varying incomes and be competitive with similar slings on the market. Components of the ring design, such as the hardware for the ring itself, were seen as more expensive in comparison to the other two designs and it was therefore given a value of six in the design matrix. Both the backpack and one strap designs would cost less to fabricate but the one strap design was given a higher value of eight in the matrix. The one strap design would be more cost effective because it would use a minimal amount of different materials throughout the device.

Preliminary Analysis

A free body diagram of the one strap design was used to analyze weight distribution across the device (Figure 9). For simplification, analysis was made without the removable elbow support, so the calculations are expected to represent the maximum weight to be carried by the injured shoulder. Due to this and the symmetric nature of the sling, the force on each shoulder was found to be equivalent in this configuration. The weight on each shoulder was calculated to equal 0.742 times the weight of the supported arm. For complete analysis and equations, see Appendix.

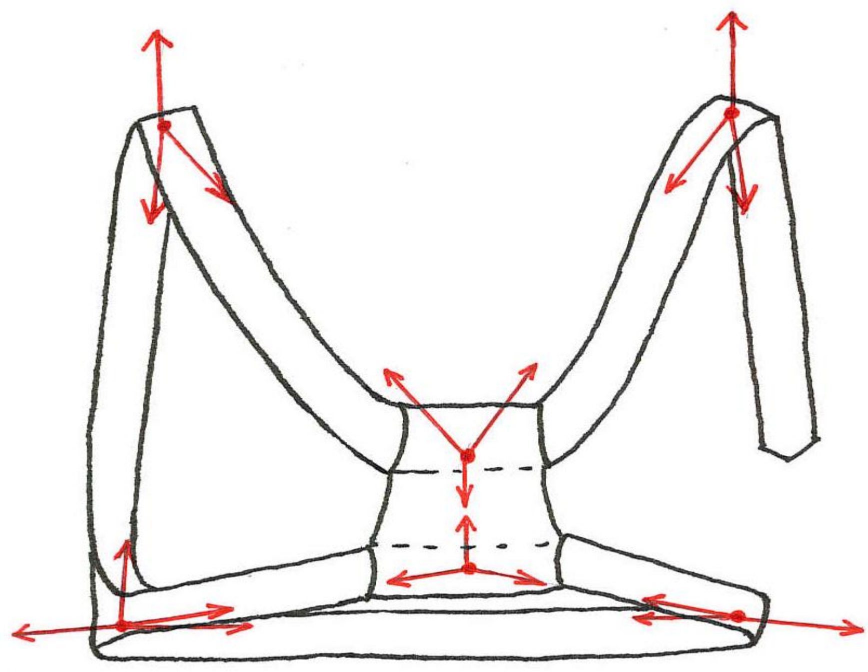

Figure 9: Free body diagram of the one strap design. FDy represents the force on the shoulder while FDG represents the weight of the arm. Full calculations and equations can be found in the Appendix.

Final Design

The final design is similar to the One-Strap Design but with several modifications. The sling is composed of several separate straps rather than one continuous strap. Encircling the chest is a two inch wide elastic strap that is fastened to itself in the front using an adjustable Velcro component looped through a ring. The main sling strap is attached to the chest strap under the uninjured arm. It then wraps over the left shoulder to the back where it loops through another ring. From there, the strap returns to the front over the injured shoulder and ends with a metal ring (Figure 10). A Thera-Band of length and resistance to suit the wearer runs from this strap to a dual ring connection on the wrist brace (Figure 11). In the back, a V-shaped segment of fabric strap paired with a metal ring is used to alleviate pressure on the neck. Fabric loops sewn on top of the primary strap behind each shoulder allow the attachment of a second Thera-Band to prevent the injured shoulder from subluxation (Figure 12). The second Thera-Band is anchored to an elbow support sleeve with a dual ring attachment (Figure 13). It was determined that a band connecting the wrist and elbow components was unnecessary because complete arm support is still maintained in its absence.

Figure 10: Front view of the overall final design showing the Velcro chest strap, the ring connection at the shoulder, and the elbow and wrist components.

Figure 11: Wrist component of final design including the dual ring connection for the Thera-Band.

Figure 12: Back view of the overall final design showing the ring connection at the back as well as the fabric loops that guide the second Thera-Band from the elbow.

Figure 13: Elbow sleeve component of final design showing the sewed band for guiding the Thera-Band as well as the dual ring connection.

Fabrication

All fabrication was completed at the UW Orthotics Lab in Middleton, WI where a sewing machine and materials were readily available. The first step was to cut out and pin together all pieces of the sling. The chest strap was completed first, which required the sewing of a ring and Velcro onto the base material. Spacing for the Velcro was determined based on the waist circumference of size medium sling models on the market (80-90 cm). Throughout the fabrication process, team members tried on the sling to ensure fit, comfort, and dimensions for all body types and a range of sizes.

Next, the back V-strap and ring were sewed to the waist strap. The angle that optimized placement in the middle of the back without the straps bunching was approximately 60 degrees. Originally, the V-strap was sewed with folded loops so that it was adjustable horizontally, but the team decided this extra mobility in the sling shifted too much during use and made the device more challenging to put on. In the final design, the V-strap is permanently attached to the chest strap.

The elbow and wrist components were the final steps in the fabrication process. Dual metal rings were attached with strips of fabric on both braces. The location of the rings was optimized to reduce pulling in unintended directions. For example, the thumb hole on the wrist brace is unlined and stretched out very easily when the rings were pinned adjacent to the thumb joint. Moving the rings back towards the wrist joint minimized the deformation in the wrist brace that was caused by tension in the Thera-Band.

Testing

Usability Testing

To collect information about the sling's comfort and usability, a survey was created and distributed to thirty test volunteers. The original survey can be found in the Appendix. Data collected included qualitative questions and timed measurements of how long it took to put on the sling. About half of the volunteers were engineering students from the Discovery Center outside the Student Shop in the Engineering Centers Building. The remaining participants were friends of design team members.

After the test subject agreed to participate in the study, they were given the printed instructions (can also be found in the Appendix) and were allowed about two minutes to read through them. The test administrator repeated the following steps verbally for clarity: no motor control in your right arm can be used during testing, the table can be used for assistance, instructions can be looked at while putting on the sling, and questions may be asked but their quantity will be recorded. A labeled diagram of the device and several pictures showing the sling being worn were provided. Since the sling was presented in a disorganized manner as if it had just come out of a box, they were then allowed to arrange the sling to match the diagram. When they were ready, the timer was started and they could put on the sling to the best of their ability. Once the sling was on correctly, the subject was instructed to walk and jog around for at least thirty seconds to experience the sling's functionality. Then they took off the sling and completed the survey questions. One final, timed attempt of putting on the sling was recorded before dismissing the participant.

Raw data for the usability testing can be found in the Appendix. Tables two and three summarize the means and standard deviations for each evaluation category and time trials. To analyze the data, a Paired Sample T-test was performed to assess whether there was a difference between the two timed trials, with the null hypothesis being that there is no difference between trials. The test yielded a one-tailed p-value of 1.65x10-5, meaning that there is a significant difference between the two trials. These results suggest an improvement in the time it takes to put on the sling with repeated trials.

Ratings	Mean	Standard Deviation
Overall	4.37	0.615
Comfort	4.50	0.630
Usability	4.07	0.868

Table 2: Mean and standard deviation of the three categories evaluated, on a scale from 1 to 5, by the 30 subjects.

Time Trials (sec)	Mean (sec)
Trial 1	112.3
Trial 2	60.63

Table 3: Mean time taken to put on the sling by the 30 subjects for two separate trials.

Applied Force Testing

One element of the design requirements that was a key feature in determining product functionality was the amount of downward force applied on both the injured and uninjured shoulder during running. The sling was designed to redistribute the weight of the injured arm onto the uninjured shoulder to prevent discomfort and further injury.

To test this property, a dynamometer was borrowed from Dr. Bryan Heiderscheit that reads a maximum amount of force applied within a duration of time (Figure 14). One of the team members put on the sling and another helped hold the dynamometer in place between the shoulder and the sling strap (Figure 15). The wearer was instructed to run in place for five full arm swing cycles, and the maximum force value was recorded after three trials. The same procedure was repeated for both the injured and uninjured shoulders at elbow angles of 30, 45, 60, 90, and 120 degrees between the forearm and upper arm.

Data points were then analyzed and compared to specifications set forth in the PDS. The forces collected for each shoulder were divided by the user's total body mass to calculate a percentage. This calculated value should not exceed ten percent because the force on the shoulder should be less than ten percent of the total body weight, as described in the PDS. These values were then plotted on a graph comparing the forces to the angle of the elbow (Figure 16). The data demonstrates that a greater amount of the weight of the arm is distributed to the uninjured shoulder than the injured shoulder during running. Additionally, the amount of applied force increased with increasing elbow angle. Overall, the calculated values indicate that the force on both shoulders is less than three percent of the user's body weight. The raw data for the applied force test can be found in the Appendix.

A few sources of error may have altered the data during applied force testing. The dynamometer only recorded force values to two significant figures so it was sometimes challenging to determine if significant differentiation existed between angles. Also, the sling wearer was only jogging in place. Ideally, this test would have been conducted on a treadmill or in an actual running environment. At times, it was difficult to hold the dynamometer in place during movement. Maintaining a standard location and angle on the shoulder may alter the data used for analysis.

Figure 14: Dynamometer used for applied force testing. Force applied to the top is digitally displayed as the peak force.

Figure 15: Testing set up as described in the body of the paper. One team member held the dynamometer in place on the user's shoulder while the user jogged in place.

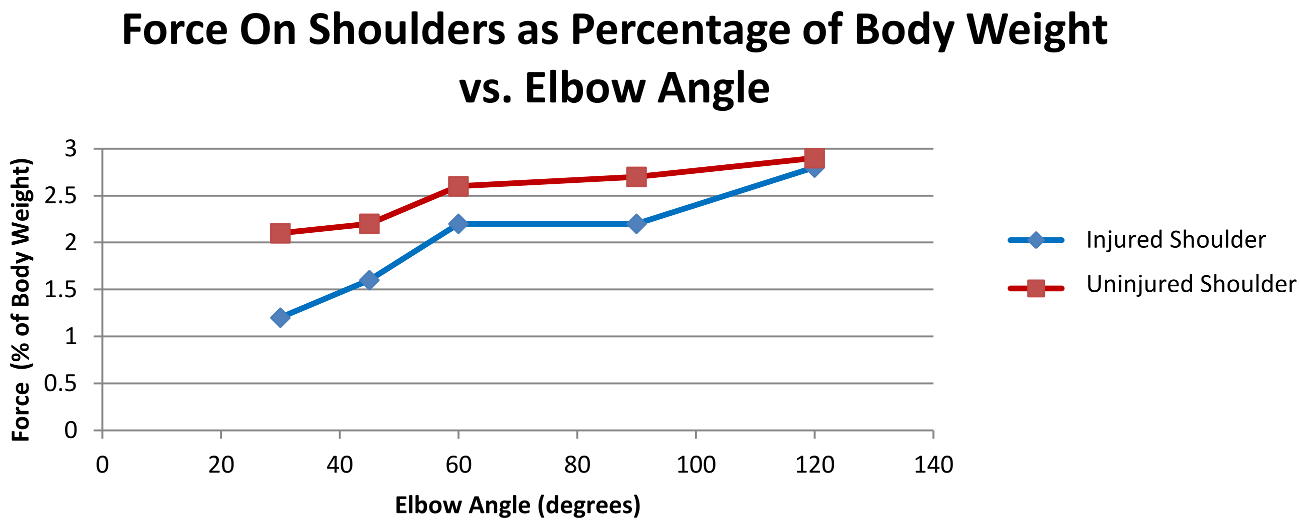

Figure 16: Graph displaying force on the shoulder as a percentage of the user's body weight versus elbow angle while running in place. Lines display forces on both the injured and uninjured shoulders. At all angles, the injured shoulder received less force than the uninjured shoulder.

Final Budget

Most of the materials for the design were obtained through donations from the UW Health Orthotics Clinic [12]. If marketed, the ideal cost of the device would be around $75.00 in order to be competitive with current slings on the market. Table 4 summarizes the out of pocket expenditure from the design team.

Item	Price
Elbow Support	$15.99
Wrist Support	$9.49
Total	**$25.48**

Table 4: The final team budget based on out of pocket expenditure for the device.

Future Work

Future work for the sling design will be focused on materials, functionality, and testing. Though the clients requested the sling be designed specific to Meg's injury, Karen foresees using it for other patients as well. Further advancement of the sling design could allow it to fit the various body types and rehabilitation levels of her patients. Changes to the design could also assist in the recovery process of different arm and shoulder injuries beyond brachial plexus damage.

With respect to materials, many adjustments could be made to enhance ease-of-use and comfort. Ideally a combination of thin, but sturdy neoprene and air-mesh fabrics would be used for the main body of the sling. This would allow the material to better conform to the body and be more breathable and washable. The combination of fabric should be visually different on the inside and outside of the sling's body, so that it can be untangled and put on more efficiently, especially when first removed from packaging. To improve ease-of-use, connection points where Thera-Band is fastened to the sling would use a clipping mechanism rather than a dual ring mechanism. This change would make it easier for the patient to assemble and adjust the sling with one arm.

Adjustments to improve functionality and adaptability have been noted as well. Currently, the sling fits to support an injury to the right arm only; by adjusting a few of the straps it can fit to support an injury to the left arm, but constraints at connection points do not currently allow complete functionality. In the future, improvements would be made to the design to accommodate injury to either arm. The current product was designed as a medium size based on the client's body type, but plans for the future include making the sling available in small, large, and extra-large sizes to accommodate a range of patient builds. Brachial plexus injury is only one of many injuries that the dynamic sling could serve. The elbow piece was designed specifically for Meg, but a variety of other attachments could be designed to aid in recovery of different injuries.

Due to obstacles in patient accessibility, the sling has yet to be tested on a patient with a brachial plexus injury. Having Meg and other patients with brachial plexus injuries test the sling, ideally while running, will allow a full evaluation of usability and help determine what particular adjustments should be made.

Timeline

Table 5 outlines the design team's goals for the semester and displays tasks that have been completed to date. Filled boxes represent the projected timeline and checks are tasks that were worked on or completed.

Tasks	**September**			**October**				**November**					**Dec**
	14	**21**	**28**	**5**	**12**	**19**	**26**	**2**	**9**	**16**	**23**	**30**	**7**
Product Development													
Research	**X**		**X**										
Brainstorming		**X**	**X**		**X**	**X**							
Design Matrix			**X**	**X**	**X**								
Design Prototype								**X**		**X**			
Order Materials							**X**						
Fabricate Prototype										**X**	**X**	**X**	**X**
Testing								**X**	**X**				**X**
Meetings													
Advisor	**X**	**X**	**X**	**X**	**X**	**X**			**X**	**X**	**X**	**X**	**X**
Client	**X**			**X**		**X**							
Team	**X**	**X**	**X**		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Deliverables													
Progress Reports	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
PDS	**X**	**X**			**X**								
Mid Semester PPT					**X**	**X**							
Mid Semester Report			**X**	**X**	**X**	**X**	**X**						
Final Report											**X**	**X**	**X**
Final Poster											**X**	**X**	**X**
Website Updates	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

Table 5: The design team's project schedule for the semester. Filled boxed represent the projected timeline and checks indicate the task was worked on or completed.

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Appendix

Dynamic Sling to Support Upper Extremity Post Brachial Plexus Injury to Return to Active Lifestyle – Running

Product Design Specifications
12/12/12

Group Members: Amy Martin, Lindy Couwenhoven, Stephen Monette, Clair Kurzynski
Advisor: Dr. John Puccinelli

Function:
The brachial plexus is the network of nerves that sends motor signals from the spinal cord to the shoulder, arm, and hand. Damage to these nerves results in various levels of control and sensation loss in the arm. The design of a dynamic sling will allow a patient with a brachial plexus injury to return to an active lifestyle. The sling will facilitate natural shoulder movement while maintaining elbow support during running. An adaptable resistance feature will be implemented, allowing the device to develop with the patient as they gain strength during rehabilitation.

Client Requirements:
- A device to support the arm during running or other physical activities
- Comfortable for long-term use (maximum three hours)
- Constructed from washable materials that are breathable and lightweight
- Adjustable in size and resistance to match level of rehabilitation
- Easy to put on within one minute with one hand

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance Requirements*: The sling should support the patient's arm while they engage in activities with moderate shoulder motion, so none of its components should restrict movement of the shoulder joint. Movement will be primarily in the sagittal plane during physical activity. The device should support an elbow angle set by the user and allow normal range of motion in the shoulder. Normal range of motion is defined as 150 degrees of abduction, 180 degrees of flexion, 45 to 60 degrees of extension, and 90 degrees of rotation [13]. The sling will also be adjustable for varying body types.

b. *Safety*: A snug fit to the patient's arm is necessary but should not be so tight that blood flow is restricted. Additionally, users may have reduced skin surface sensitivity, so the device should not cause pressure sores. Precautions need to be taken when designing the sling to prevent the user from causing more damage to the shoulder. The maximum force applied on the shoulder should not be more than ten percent of the user's body weight [14, 15].

c. *Reliability*: The sling should not slip or stretch beyond functional limits during usage.

d. *Life in Service*: Proper device function should be maintained throughout the entire course of recovery which is approximately four years. In the case that full recovery is unreachable, it would be ideal for it to last upwards of 10 years. During non-physical activity the sling may be worn for a maximum of eight hours.

e. *Operating Environment*: Although it will be used primarily during exercise both outdoors and indoors, the sling could have additional applications in the home or office.

f. *Ergonomics*: Functionality, comfort, and adjustability for patients of varying body compositions should be considered. It should also be easy to put on with the use of one arm and adjust for varying levels of patient arm strength during recovery.

g. *Size*: The sling will be an adult size (fitting a waist 80 to 90 centimeters in circumference), unisex fit and adjustable for further comfort and support. It should not be bulky so it can be easily worn with everyday clothing.

h. *Weight*: The device must be lightweight, a maximum of one kilogram, so that it can be easily lifted with one arm and worn with little to no detectable weight imbalance.

i. *Materials*: The sling will be fabricated from a washable, lightweight, and water resistant material. It will be in direct contact with the patient's skin during exercise, so precautions must be taken to prevent chaffing or discomfort.

j. *Aesthetics, Appearance, and Finish*: Because it will often be worn by patients in public, the device should be aesthetically pleasing. The design should therefore be relatively simple in appearance while still being functional.

2. Production Characteristics

a. *Quantity*: One sling will be designed with multiple, replaceable elements.

b. *Total Product Cost*: The target product cost is $75.

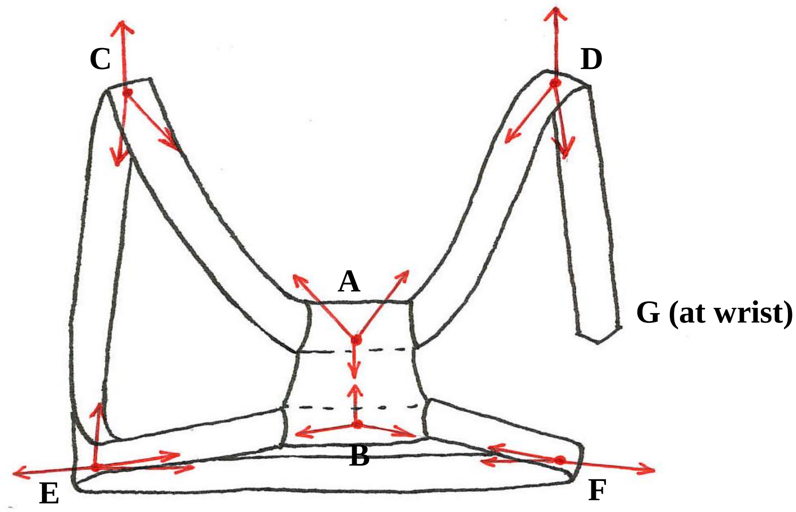
3. Miscellaneous

a. *Standards and Specifications*: If marketed, the product will require approval from the FDA.

b. *Customer*: The customer is any patient that has suffered a brachial plexus injury, with the design being particularly for those returning to an active lifestyle. The client also envisions the sling being helpful for other injuries such as bone fractures or rotator cuff injuries, and during post operational recovery.

c. *Competition*: Current slings on the market that are designed to support the arm and shoulder after a brachial plexus injury inhibit nearly all movement of the arm and shoulder joint. At the moment, there is no sling that allows natural arm movement during a run while still providing the necessary support.

Free Body Diagram Analysis



<u>Harness Piece</u>

At D:

$\Sigma F_x = 0$: $F_{DG} \cos(80°) - F_{DA} \cos(60°) = 0$

$\Sigma F_y = 0$: $F_{Dy} - F_{DG} \sin(80°) - F_{DA} \sin(60°) = 0$

→ $F_{DA} = F_{DG} [\cos(80°) / \cos(60°)]$

→ $F_{Dy} = F_{DA} \sin(60°) + F_{DG} \sin(80°)$

At A:

$\Sigma F_x = 0$: $F_{DA} \cos(60°) - F_{CA} \cos(60°) = 0$

$\Sigma F_y = 0$: $F_{DA} \sin(60°) + F_{CA} \sin(60°) - F_{AB} = 0$

→ $F_{CA} = F_{DA}$

→ $F_{AB} = 2 F_{DA} \sin(60°)$

→ Symmetry: $F_{Cy} = F_{Dy}$ and $F_{CE} = F_{DG}$

At E:

$\Sigma F_x = 0$: $F_{BE} \cos(15°) + F_{CE} \cos(80°) + F_{EF} - F_{Ex} = 0$

$\Sigma F_y = 0$: $F_{CE} \sin(80°) - F_{BE} \sin(15°) - F_{Ey} = 0$

At B:

$\Sigma F_x = 0$: $F_{BE} = F_{Ex}$

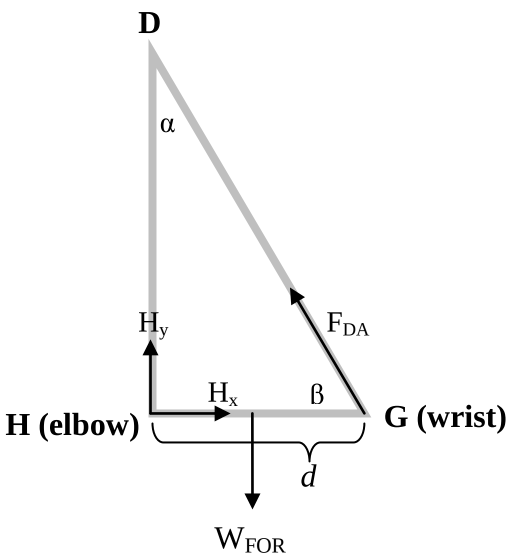
$\Sigma F_y = 0$: $F_{AB} - F_{BE} \sin(15°) - F_{BE} \sin(15°) = 0$

→ $F_{BE} = F_{Ex} / [2 \sin(15°)]$

At F:
$\Sigma F_x = 0$: $F_{Fx} - F_{EF} - F_{BF}\cos(15°) = 0$
$\Sigma F_y = 0$: $F_{BF}\sin(15°) - F_{Ey} = 0$

<u>Connection to Wrist</u>
W_{FOR} = weight of forearm
d = length of forearm
H = point at elbow

Angle assumptions:
90° elbow angle
30° angle between strap and upper arm (α)
60° angle between strap and forearm (β)



At H:
$\Sigma M_H = 0$: $-W_{FOR}(d/2) + d(F_{DA}\sin(60°)) = 0$
$\rightarrow F_{DG} = W_{FOR}/(2\sin(60°)) = 0.577(W_{FOR})$

Using equation from harness calculations:
$F_{Dy} = F_{DA}\sin(60°) + F_{DG}\sin(80°)$
$\rightarrow F_{Dy} = F_{DG}(1.286)$
$\rightarrow \mathbf{F_{Dy} = W_{FOR}(0.742)}$

Testing Raw Data

<u>Usability Testing</u>

Subject No.	Time 1 (sec)	Time 2 (sec)	Questions	Overall	Comfort	Usability	Date
1	128	55	1	3	4	4	12/4/2012
2	188	66	1	4	4	2	12/4/2012
3	218	76	5	3	5	4	12/4/2012
4	80	89	2	5	4	4	12/4/2012
5	68	52	0	5	4	5	12/4/2012
6	99	108	0	4	5	3	12/4/2012
7	60	82	0	5	4	5	12/4/2012
8	116	33	0	4	4	3	12/4/2012
9	100	45	2	5	5	4	12/4/2012
10	126	38	3	5	5	5	12/4/2012
11	64	28	1	5	5	5	12/4/2012
12	66	21	1	5	5	5	12/4/2012
13	38	47	1	4	5	5	12/4/2012
14	29	33	0	5	5	5	12/4/2012
15	81	64	0	5	5	5	12/4/2012
16	101	83	4	4	4	3	12/4/2012
17	124	112	0	4	5	4	12/4/2012
18	46	30	0	4	3	4	12/5/2012
19	59	29	0	4	5	4	12/5/2012
20	240	111	0	5	5	3	12/5/2012
21	65	48	0	4	5	3	12/5/2012
22	90	45	0	4	4	4	12/5/2012
23	240	47	0	5	4	4	12/5/2012
24	105	98	0	5	4	5	12/5/2012
25	254	88	0	4	4	3	12/5/2012
26	120	100	0	4	3	5	12/5/2012
27	129	54	1	4	5	5	12/6/2012
28	48	45	0	4	5	4	12/6/2012
29	108	52	0	4	5	3	12/6/2012
30	180	40	0	5	5	4	12/6/2012
Average	112.3333	60.63333	0.7333333	4.366667	4.5	4.066667	
Std. Dev.	62.53073	27.34263	-	0.614948	0.629724	0.868345	

t-Test: Paired Two Sample for Means

	Time 1	*Time 2*
Mean	112.3333333	60.6333333
Variance	3910.091954	747.61954
Observations	30	30
Pearson Correlation	0.387364836	
Hypothesized Mean Difference	0	
df	29	
t Stat	4.904854176	
P(T<=t) one-tail	**1.65224E-05**	
t Critical one-tail	1.699126996	
P(T<=t) two-tail	3.30448E-05	
t Critical two-tail	2.045229611	

Applied Force Testing

Elbow Angle (Degrees)	Injured Arm Force (lbs)	UnInjured Arm Force (lbs)	Injured % BW	Uninjured % BW
30	2	3.6	1.2	2.1
45	2.8	3.8	1.6	2.2
60	3.8	4.4	2.2	2.6
90	3.8	4.6	2.2	2.7
120	4.8	5	2.8	2.9
User’s body weight: 170 lbs				

Dynamic Sling Evaluation Form

Age:

Weight:

Height:

Sex:

Time taken to put on the sling (2 trails):

Trial 1: Trial 2:

Additional comments:

After using this device I feel (Please Circle):

1	2	3	4	5
Would not enhance mobility				Sling effectively solves the issue

Please rate the comfort of the device (Please Circle):

1	2	3	4	5
Fabric or fit was uncomfortable				Sling was very comfortable

Please rate the usability of this device (Please Circle):

1	2	3	4	5
Would not be able to put on the sling without assistance				Sling was easily put on with one arm

Note:

By signing this form I acknowledge that I am aware that my name and information stated on this page will not be used in any form of publication or presentation. I also release the following parties from liability resulting from my participation in this study: Lindy Couwenhoven, Clair Kurzynski, Amy Martin, Stephen Monette, and the University of Wisconsin-Madison.

Signature: Date:

BME Design Testing: Dynamic Sling

Debriefing

Thank you for participating in our prototype testing. Our device will be used by occupational therapists to assist clients recovering from brachial plexus injuries. The brachial plexus enervates the upper limbs, and injury can cause loss of motor control throughout the arm and hand. This device can help patients return to an active lifestyle, such as running, during their rehabilitation therapy. We ask that throughout testing, you simulate the actual conditions of use by not using your limb and allowing it to go slack. Again, thank you for your participation!

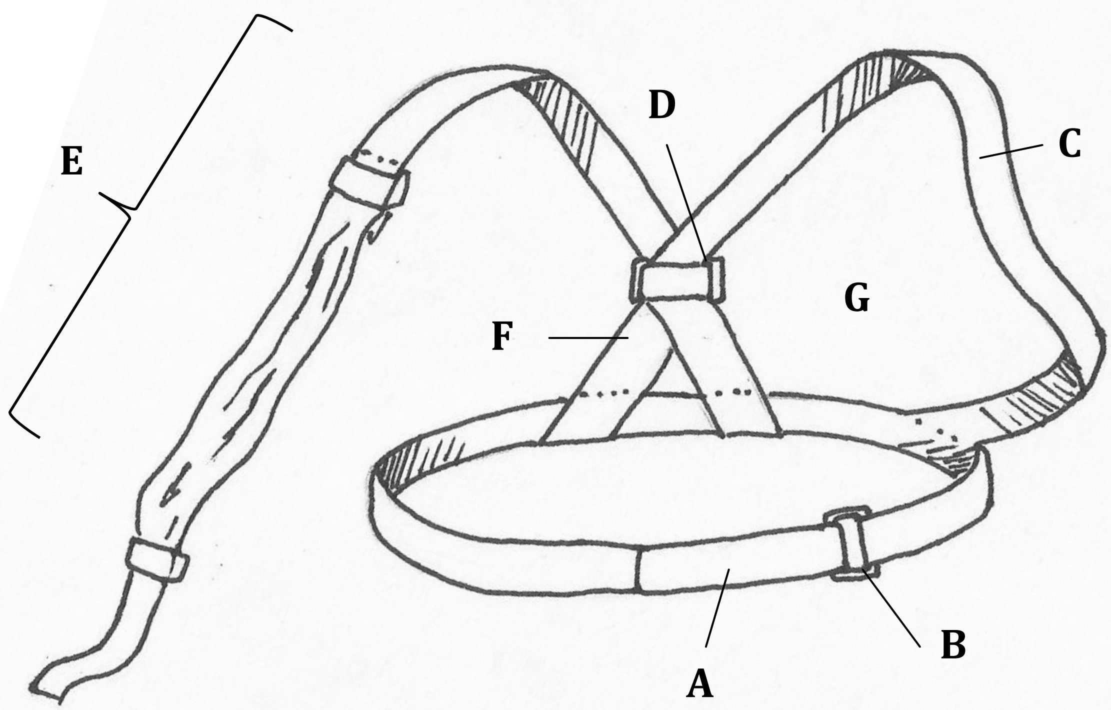
Instructions

Getting Started

- Arrange the sling so it corresponds to the labeled diagram.
- **Band E** will be provided by your rehabilitation therapist and they can assist you in securing it and selecting a resistance to best meet your needs.
- How to use the double rings (at wrist and elbow):
  - Guide band through *first* and *second* ring until desired length is reached.
  - Loop band back and through the *first* ring and pull until tight.

Instructions

1. Insert left arm into **Space G** and slide **Strap C** onto left shoulder.
2. Pull **Band E** and connected wrist brace over right shoulder for use in later step. Avoid twisting the strap.
3. Insert end of **Strap A** into **Ring B** and pull through to obtain a snug, comfortable fit around chest. Fold **Strap A** onto itself and secure with Velcro. Adjust the connecting loop of **Strap C** laterally across **Strap B** as needed.
4. Put on the wrist brace (connected to **Strap E**):
   a. **Band E** should be provided by your rehabilitation therapist and already secured in rings on wrist (see “Getting Started”) to the length that best fits your needs.
   b. Place thumb in wrist brace hole.
   c. Wrap brace around backside of hand then across the palm and thumb joint.
   d. Attach securely with Velcro on backside of hand adjacent to rings on wrist.


E
D
C
G
F
B
A