

Neurological Shoulder Subluxations: The search for better support

- Jamie B. Rennick, MSOTR/L, CBIS

EXECUTIVE SUMMARY

Despite their label, current shoulder positioning devices often ignore the multi-factorial concerns therapists and patients have identified when trying to effectively treat an acute subluxation that is the result of a brain injury. Neurological shoulder subluxations are not the same as orthopedic subluxations and thus they cannot be treated the same; they require much more comprehensive attention than existing devices give them. Current research identifies the glenohumeral shoulder subluxation as one possible root cause of shoulder pain and reports that the best intervention for subluxations is prevention. Acute rehabilitation teams are managing the neurologically subluxed shoulder as a 'after thought' and are quite often limited in their choice of neuromuscular reeducation techniques because of patient-reported pain. Practicing clinicians and research publications frequently describe a myriad of reasons why existing glenohumeral (GH) subluxation products are less than favorable in real-world therapy application:

- Existing slings maintain support at the shoulder in standing, but not sitting.
- Most slings support above the elbow rather than below where it has been documented to be more effective.
- Current systems have limited adjustability for tonal changes during recovery.
- Hemiparetic arm slings typically strap the opposite shoulder and cause axillary break down or skin irritations on the less affected arm.
- The complex strapping system on some slings frustrate caregivers and clients to the point of not wanting to wear the device.
- Existing arm slings ignore the distal arm leaving the wrist and fingers unsupported and in need of a second support system if the whole arm is flaccid.
- Patients report new pain in their neck, wrist, or axillary region with present-day slings and only tolerate them for short time periods.

Although several companies have tried to offer improved positioning for the shoulder subluxation, none are effectively addressing the reported problems unique to neurological injuries nor are they taking an aggressive approach that supports EBP recommendations to prevent the condition in the first place. The LuxArm Shoulder Subluxation Brace & Arm Support System (LuxArm System) looks at the shoulder from a realistic and neurological perspective and then applies an innovative design that is effective, friendly and potentially proactive if applied early enough post injury. Its semi-customizable and adaptable materials accommodate the patient's needs as they progress through the many phases of recovery. The LuxArm System is compatible with

other existing treatment techniques and provides consistent support through the day, a practical concept not yet seen in clinical practice.

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INTRODUCTION

“Necessity... the mother of invention” -Plato

No one wants to be in a position where they need rehabilitation; however, nearly one million people each year have a stroke or other neurological injury that requires such services. Most of this population require therapy before returning home [1] due to the complexity of cognitive and physical impairments that result from the incident. Therapy services are often required to learn how to regain control over paretic muscles so one can sit up, walk, talk, toilet, dress, eat, comprehend, reason and do a multitude of other daily activities. This type of rehabilitation takes months to years of intense focus and dedication not only for the patient, but also for those friends and family members who are acting as caregivers during the recovery process. The average length of stay (LOS) for a stroke diagnosis in an acute hospital in 2009 was 5.3 days, nearly 50% shorter than it was in 1989. Furthermore, the American Heart Association predicts the cost of caring for those with a stroke is expected to double in the next 20 years [2]. That downward trend [2] paired with the increasing number of people who survive a stroke, created a valuable service need for short-stay hospitals and long-term care facilities to start the rehabilitation process before returning home. Unfortunately, these institutions are also experiencing shorter LOS approvals by insurance companies. Now, more than ever, therapists and skilled clinicians are faced not only with the challenge of rehabilitating complex cognitively and physically impaired patients, but also to progress those patients at a much faster rate.

Over the years we have come to understand rehabilitation as a process where the goal is to restore one to good health or useful living through therapy and education. Rehabilitation teams, patients and families strive to achieve progress in as many different areas as possible during that recovery period; however, improvement requires time. Yet, the numbers don't lie. Each subsequent decade shows rehabilitation teams being given less and less time with their patients. Insurance policy limitations & patient progress requirements are strict and must be met weekly for patients to continue getting therapy, so therapy teams must stay current on the latest research/data; provide the most advanced technology to their clients; and achieve the strongest outcomes in the shortest time possible. Rehabilitation teams must be quick to identify existing problems/barriers to those desired meaningful outcomes and attempt to find solutions faster than ever before.

One of those great barriers well documented in stroke rehabilitation literature lies in and around the shoulder. Hemiplegic shoulder pain (HSP) and shoulder subluxations are some of the most common complications after stroke and neurological injuries that limit functional progress [3-8]. Shoulder pain begins as early as 2 weeks post stroke. It often results in significant long-term disability, impedes use of rehabilitation interventions and limits patients' ability to reach their maximum functional arm potential [8-10]. Shoulder subluxations (see Figure 1) or glenohumeral subluxations (GHS) affect up to 81% of patients with hemiplegia and often occur during the flaccid stage of stroke

Figure 1: Shoulder Subluxation



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recovery [3,4,6, 11-12]. Improper shoulder positioning due to lost muscle tone and lack of upper extremity support when out of bed contribute to subluxations [3-4,13] and serve as risk factors for shoulder pain and other secondary upper body complications [4-6].

For years clinicians and researchers have recognized and discussed the problem of current interventions for shoulder pain & subluxations resulting from neurological injuries, yet no solution has been strongly adopted by the rehabilitation community. Most existing data consequently suggests that prevention is the key to both GHS and HSP. Practicing therapists will tell you it is vital that the entire rehab team, including the patient and family members, proactively manage and/or prevent shoulder pain to increase patients' tolerance for later implementation of neuromuscular education training techniques. Moreover, research specifies early and consistent application of proper biomechanical joint positioning at the shoulder is critical in the rehab process because it supports maintaining normal muscle & soft tissue length around the joint [3,14-15]. Literature has documented inconsistent effectiveness with current GHS interventions and techniques [7-8,16-18] and thus therapists often "punt" in hopes that something will work. So, if best practice supports these early interventions for GHS, but historical use of existing support slings, strapping and functional electrical stimulation have had controversial results [4-5,7,16-17], why aren't we addressing this barrier more seriously? Why aren't we listening to the research and doing more to prevent neurological shoulder subluxations and shoulder pain rather than just putting a Band-Aid on them?

The answer is obvious: 1) the shoulder is one of the most complex and vulnerable joints on the body due to its large capacity for range of motion and 2) it's hard to address so many issues in just one device. Many factors need to be considered in order to effectively stabilize the glenohumeral joint and the paretic arm. Current interventions, while successful to some degree, never fully encompass all the concerns patients and therapists face. We have data to anticipate treatment barriers and we have knowledge & experience to compensate for limitations; yet, we don't have a good solution. If rehabilitation teams want to make functional arm progress, then they really need to think proactively when it comes to the neurological shoulder, pain and subluxations.

Few innovators have been bold enough to address these long-standing issues presented by current support systems for the neurological shoulder. Typical orthopedic sling designs don't have to account for the wrist/hand alignment nor do they have to consider the length of time the device will be worn. Unlike the orthopedic subluxation that can heal in 8-12 weeks, the neurological one can take multiple months to years to recover. Devices that support this type of injury need to accommodate numerous changes in muscle tone during the recovery phases, various positioning needs, changes in mobility levels and most importantly, they must address the problem without creating new injuries. Certainly if this were an easy task to achieve a device would have already been invented and the research would reflect its efficacy.

BACKGROUND/PROBLEM STATEMENT

“Insanity: doing the same thing over and over again expecting different results.”

-Albert Einstein

Stroke and neurological injuries are difficult and costly problems. Of the 795,000 people who suffer a stroke each year in the United States (US), approximately 144,000 die, 466,000 are new cases and 185,000 are recurrent episodes [19,21-23]. Four out of every five American families over the course of a lifetime will be impacted by stroke, and four million Americans currently live with its lingering effects, making stroke the leading cause of serious, long-term adult disability in the US [20,24]. An estimated 33% of stroke survivors need help caring for themselves and 70% cannot return to their previous occupations [8]. According to research by the American Heart Association (AHA) and Centers for Disease Control (CDC), the estimated 2009 direct and indirect cost to cover inpatient care, rehabilitation, and follow-up care for lasting deficits of stroke was \$68.9 billion [19,25]. In 2010, the effects of stroke alone cost the United States nearly \$73.7 billion [19,26], which was an \$11 billion dollar increase from 2007 [27].

Given the number of persons affected and considerable cost for their care, much work has been done to identify clinical practices yielding the most satisfactory outcomes for GHS [4,6-8]. Research has found that proactive, early intervention to support and stabilize the shoulder complex is critical for two reasons:

- 1) Proper biomechanical positioning reduces secondary damage to the shoulder joint and capsule, and
- 2) Proper support and positioning ameliorates pain [3,5-8,17].

Clinical therapists report that pain is a primary obstacle they face when implementing rehabilitative techniques for the upper extremity. Understandably, patients in pain are mentally distracted, unable to remain positive about their situation, and hindered when trying to participate in recommended therapeutic regimens. Conquering pain becomes yet another task on the tortuous path to stroke recovery; thus, tools that help ameliorate pain and maintain the integrity of the shoulder capsule are of critical importance to the therapists who are working with these individuals affected by hemiplegia.

Several slings and support systems have been developed to help stabilize the shoulder complex. Current examples include the Omo Nuerexa (Otto Bock®, Minneapolis MN), the GivMohr® Sling (GivMohr Corp., Albuquerque NM), and the Arm Escort (Maddak®, Wayne NJ). While effective in some circumstances, these and other devices have not been widely accepted for one or more of the following reasons:

- 1) Complicated strapping arrangements make donning difficult (particularly for the elderly, those with cognitive deficits and those who lack caregiver support);
- 2) Suspension near the hand does not provide adequate support while seated (research indicates suspension under the elbow is more effective for shoulder

- alignment);
- 3) Design encapsulates large regions of the shoulder/arm/hand, interfering with natural thermal regulation and making the user feel too warm and/or inhibiting the use of other simultaneous interventions such as e-stim or taping;
 - 4) Straps apply a heavy load across the user's ipsilateral trapezius or contralateral axillary region (causing additional pain, skin breakdown and muscle pathologies); and/or the
 - 5) Design promotes proper alignment of only parts of the upper limb when the entire hemiparetic arm should have support [15].

Figure 2: Examples of Existing Subluxation Slings



As a result of these frustrations, therapists are frequently spending valuable treatment time fabricating less-than-ideal support systems from materials lying around in their facilities (e.g. pillows, towels, foam wedges, etc.), patients settle for slings that only partially support the arm in one position (sitting or standing), or patients wear slings that can potentially exacerbate their injury (e.g. standard arm slings cause internal humeral rotation which promotes an anterior subluxation in the neurological population). With upper-limb rehabilitation there exists a recognized need for new support options, particularly ones that are comfortable, intuitive to use, can be readily donned (preferably independently by the subject), reduce pain, promote proper alignment of the entire limb, are compatible with other treatment interventions, and that offer greater dynamic support when sitting, standing, and ambulating.

Table 1: Current Interventions for the Shoulder

Subluxation Positioning	Pain Management
Pillows (bed)	Activity distraction
Wheelchair arm tray/wedge (sitting)	Change of position
Slings (transfers & ambulation)	Ice vs. Heat
NMES/e-Stim (as tolerated)	Massage
Taping (if skin permits)	Medications (oral, topical, iontophoresis, etc.)

These barriers require immediate and innovative solutions if we are going to advance rehabilitation of the hemiparetic arm. An intuitive and versatile device that can not only react to the existing problems, but also potentially prevent them could truly change the way we think about the neurologically impaired arm. Unconventional problem solving can advance treatment strategies for the paretic arm and possibly achieve what evidence-based research has been telling us for years...prevent the problem.

SOLUTION

“Design is not just what it looks like and feels like, it is how it works.”

-Steve Jobs

What if we could not only react to the problem of neurological shoulder pain, but also prevent it with consistent good positioning? What if there was a design that had the capability to do exactly what research suggests...prevent the shoulder subluxation from occurring in the first place?

The LuxArm Shoulder Subluxation Brace & Arm Support System is a semi-customizable device that correctly aligns the GH joint after a neurological subluxation, dynamically supports the complex hemiplegic wrist/hand and comfortably removes all shoulder suspension straps. It took over 8 years to develop and used an unconventional approach that addressed each concern directly. Early clinical trials concluded the device can reduce pain throughout the day whether sitting, standing, or walking. The LuxArm System has gotten the endorsement from real patients/caregivers, practicing physical & occupational therapists, physiatrists, rehabilitation nurses and has grabbed the attention of college universities. The configuration of the LuxArm System is so thoughtful in its design that it has the potential not only to serve as an intervention for acute neurologically-based glenohumeral shoulder subluxations, but also as a possible subluxation prevention device if applied early enough post onset of the initial brain injury.

Figure 3: LuxArm Shoulder Subluxation Brace & Arm Support System



The unique design of the LuxArm System is patient & clinician-friendly, addresses nearly all of the existing positioning challenges of a neurological arm, and adjusts across the different recovery phases (See Table 2). It has captured the attention of patients who are struggling to find a universal support system for their shoulder and hand, clinical occupational and physical therapists in the field and university researchers who want to study its potential. The LuxArm System has achieved 9 key factors with regard to the construction:

1. **Effective positioning**

Finger palpation measurements and x-rays taken during early clinical trials clearly show a reduction in the GH subluxation at the shoulder (See Figure 4) while the proximal arm is held in slight abduction to minimize

tightness often seen in the pectoral muscles. The forearm is supported without creating pressure on the olecranon and the wrist can be sustained at any degree of flexion or extension that is comfortable to the client. The thumb is supported at the metacarpal joint but not tied down distally as this is often one of the most sensitive areas of a recovering hand.

2. Effective pain management

Anecdotal reports and pain scale measurements taken during clinical trials indicate most people experienced a reduction in arm pain with the LuxArm System. Reports of additional arm pain were not observed during the testing phases of the trials.

3. Comfortable

The off-loading padded belt system takes the majority of the arm mass from below the elbow and distributes it around the waist, where the body's center of gravity is more able to control/balance the weight. With the load on the waist rather than on the neck and shoulders, the client is more willing to wear the device throughout the day. The belt system also reduces asymmetrical alignment of the upper trunk, allowing for improved posture and balance, which can reduce the manifestation of secondary pain points. The soft elastic hand straps, padding throughout and pliable skeleton ensures not just comfort, but also customization to unique body shapes.

4. Compatible

The design team recognized that the support system may not be the answer to every subluxation case and therefore wanted it to be compatible with existing research interventions. The lack of shoulder suspension straps in this device means that therapist and/or caregivers can easily access the affected shoulder to apply e-stim, Kinesio tape, topical pain medications or thermal modalities without ever having to take it off. Simultaneous rather than sequential treatment interventions can be effortlessly achieved.

5. Transitional

Because the belt system sits on top of the hips and is not based on elastic strapping that requires tension, there is minimal migration of the device when transitioning from seated to stand to walking and vice-versa. This means that the shoulder and arm stay fully supported as the body moves; the device can be worn in a variety of positions, during mobility training, and during a variety of functional activities across the day with sustained support of the hemiparetic arm. The location of the belt on top of the hips also allows access to the waistband for toileting needs without removal of the device.

6. Durable

Extensive research and testing was done during the material development phases of the LuxArm System. It was important that the device be lightweight, strong, pliable, cost effective and sustainable enough to handle the wear and tear of multiple months of rehabilitation. Little

maintenance is required.

7. **Adjustable**

Every therapist knows that a neurological recovery goes through several phases during the healing process, some last only days while others last months. Multiple components on this system are adjustable by hand and/or by a simple hex key, which allows for quick modifications without a lot of hassle. The LuxArm System can handle changes in arm/wrist/finger tone, changes in body weight, hands with edema, changes in finger/wrist positioning needs, and changes in forearm rotation. No other current subluxation device can accommodate all those changes with such simplicity. The pliable skeleton of the forearm system, the one-handed ratchet buckle with the overlapping belt frame, and the sliding track for variable sized subluxations means the system can adapt to fit the patient's needs through every phase of their recovery. The patient doesn't have to conform to the limitations of the device or buy a new device every time something changes.

8. **Cleanable**

Life is full of spills, especially if you are learning to do things one-handed or with your non-dominant hand! The fabrics chosen for the LuxArm System are hand washable, antimicrobial, and durable.

9. **Intuitive**

Recovery is hard work. So the design team made it top priority to make a system that was simple and friendly to use on a daily basis. Complex strapping systems confuse not just patients and family members, but also experienced therapists and nursing staff. The LuxArm System removes all straps and has only 2 pieces that can either be left engaged for functional use or disengaged to meet the patient's neuromuscular exercise training needs. Initial fitting is strongly recommended by a therapist, but families and caregivers can be easily taught how to assist with donning/doffing and making simple adjustments. Once sized and fitted into the semi-customizable system, it is just a matter of putting it on. The molded shape will allow for the arm to fall into the correct position every time. Furthermore, every single client trialed in this device was able to remove it with one hand, no assist needed.

Figure 4: *Left:* Shoulder subluxation without support; *Right:* Shoulder subluxation with the LuxArm System

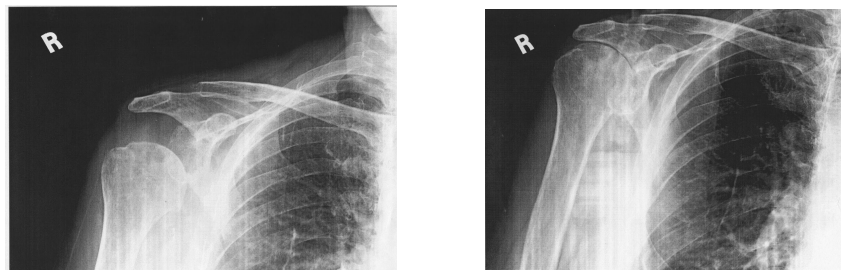


Table 2: LuxArm Design Components

	<p style="text-align: center;"><u><i>Belt System</i></u></p> <ul style="list-style-type: none"> ● Malleable lightweight aluminum for stability ● Bilateral hip pads to off-load the shoulder and evenly balance the weight of the hemiparetic arm near the body's center of gravity ● Adjustable hidden sizing mechanism to fit over/under thick or thin clothing ● Angled sliding track to accommodate any size subluxation and provide alignment of the distal arm ● Ratchet buckle for easy one-handed donning/doffing ● Quick-release rubberized ball forearm locking system ● Dense padding for comfort ● Soft antimicrobial material to prevent bacterial growth (washable)
	<p style="text-align: center;"><u><i>Forearm System</i></u></p> <ul style="list-style-type: none"> ● Removable forearm to accommodate daily routines and therapy without the removal of the whole belt system ● Pliable lightweight mesh aluminum to mold around the tonal needs of the wrist and fingers ● Soft padding to prevent pressure points ● Elastic Velcro strapping for comfort and quick adjustability ● Sliding forearm track for customized distal arm positioning ● Removable antimicrobial material for hand washing ● Circular pin connector for shoulder rotational flexibility

KEY ENDORSEMENTS

- ❖ “They knocked it out of the park. It is a great device.” (Doug, participant in LuxArm clinical trial)
- ❖ “A truly innovative design and product to serve our neurological patients with arm weakness. The expertise, tenacity and evolution of this product is state of the art and our patients will love this product.” (Karen, occupational therapist with 26+ years experience in out-patient & in-patient rehabilitation)
- ❖ “As a RN helping a patient with the brace, I felt it was much easier to don/doff than other support devices...Another thing about the LuxArm is that it provides shoulder stabilization for flaccid upper extremities in a functional position, but was not super bulky or stiff.” (Joanne, Vice-President of nursing with 10+ years hospital experience)

CONCLUSION

The time to advance shoulder subluxation interventions is now. If rehabilitation specialists continue to treat the neurological glenohumeral subluxation the way we have always done, the research will continue to show we are less than effective in our treatment strategies. It is time to face the complex barriers the shoulder presents and not just put a Band-Aid on them. We need to act early and consistently to minimize and/or prevent subluxations and pain from occurring in the shoulders of our neurological population. Recovering from a brain injury is a long and arduous process. It is a process where acute rehabilitation teams are expected to work wonders in a matter of a few weeks. Unfortunately, when it comes to the shoulder many therapists are forced to use trial-and-error science with existing slings. They are using valuable treatment time to fabricate a variety of systems for patient comfort and therapeutic positioning needs across the day. Clients and families are desperate in their search for an effective arm management system and spend valuable time and money looking for devices that work for them, only to experience disappointment and frustration with each trial.

The shoulder is complex to manage and the hemiparetic arm experiences many changes during the recovery period. Clients with neurological impairments need a user-friendly and reliable support system that can work in conjunction with other evidence-based interventions. They need adaptable support across the day and throughout the many months of rehabilitation. Clients want to avoid secondary neck or axillary pain by eliminating heavily loaded suspension straps on their less affected side. And since the neurological shoulder subluxation does not occur in isolation, they want an all-encompassing system that can support their distal arm. Existing science from the backpacking industry has taught us additional weight is most stable when carried on the hips and research has shown good early biomechanical positioning to be preparatory for more advanced treatment interventions. The LuxArm System provides that stable support while also positioning the entire hemiparetic arm, a concept that has never been explored before now.

The LuxArm Shoulder Subluxation Brace & Arm Support System is not a 'quick fix' for a complex problem, but it does break new ground in how we apply the information we have learned from research. This system is our next best practice option for acute subluxation positioning and it has the potential to do more, prevent subluxations altogether. No other existing subluxation device can offer as much sustained support throughout the entire hemiplegic arm *and* across the many phases of recovery. The paretic arm deserves VIP treatment as early as possible if it is going to be functional again in our two-handed world.

With proper education, appropriate tools and early intervention, HSP & GHS don't have to be major barriers in therapy anymore. Anticipating and preventing shoulder problems while we support the ever-changing needs of the recovering hemiplegic arm is truly the direction therapists need and want to be taking in a progressive rehabilitation process.

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