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Effectiveness of Postural Intervention via Manual Wheelchair Change

Feasibility of Teleconsultation Delivery

Jennifer Dee Hastings

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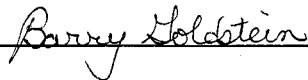


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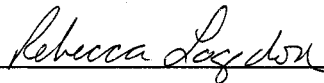
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Abstract

Effectiveness of Postural Intervention via Manual Wheelchair Change: Feasibility of Teleconsultation Delivery

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This study tested the following hypotheses: (1) Wheelchair configuration changes will change seated postural alignment, (2) Health outcome measures will improve after postural change and (3) Successful seating interventions are possible via a distance medicine model.

Prospective repeated measures design with subjects randomized at enrollment to either in-person intervention by the investigator or teleconsultation mediated intervention. Data were collected at baseline, post intervention and 3-months. Outcome Measures: Seated Height (SH), Wheelchair Users Shoulder Pain Index (WUSPI), Postural Scale for Wheelchair Users (PSWU), Satisfaction with Life Scale (SWLS)*, Pain Visual Analog Scale (VAS) and Pain Interference (*baseline and 3 months only). The primary comparison was between pre and post intervention scores on the outcome measures (within subject analysis) examining the effect of the intervention. The between group comparison explored the effectiveness of the teleconsultation intervention in relation to the gold standard of a hands-on clinic. A convenience sample of 13 subjects was enrolled across two investigative sites with analysis on 11 subjects who completed the study. Inclusion: SCI with ASIA Impairment Scale scores of A or B, motor level T1-T10 inclusive, age 18 or greater, one year or more post SCI, with non-specific musculoskeletal pain or discomfort in their wheelchair, who are full-time users of manual wheelchairs. Intervention:

custom specified wheelchair configuration change; generally decreasing inside seat to back angle via changes to seat plane or backrest alignment. Post intervention results: Increase in SH (postural alignment) was significant ($p=.03$), mean change of 1.01 inches; 95% confidence interval 0.13 to 1.9. Mean improvement (-9.6) on the WUSPI was significant ($p=.03$); 95% confidence interval -18.34 to -0.87. Decrease in worst pain intensity (-1.18) was significant ($p=.04$); 95% confidence interval -2.3 to -0.4. Remaining outcomes did not show significant change post intervention. The intervention effect was not maintained at 3-month follow up ($n=9$).

CLINICAL RELEVANCE:

Wheelchair configuration can alter seated posture, and improved postural alignment appears to improve health outcomes as measured by the WUSPI and Pain VAS. Feasibility of successful postural intervention via teleconsultation was supported by this preliminary study. Further work is needed on maintenance of the intervention effect.

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DEDICATION

To all my patients, over all the years, who have taught me so much.

SPECIFIC AIMS

The long-term goal of this research program is to improve healthcare provided to persons with spinal cord injury (SCI) by increasing the understanding of the interactions between postural alignment and musculoskeletal pain. The overall aim of this project is to improve the sitting positions of individuals living with SCI by extending the delivery of seating specialist advice to regions distant to specialty expertise. The underlying research question is as follows: Will health outcomes improve with improved seated posture? Evidence suggests that postural abnormality can generate musculoskeletal pain in full time wheelchair users. This investigator has shown in preliminary work that wheelchair configuration change can change the seated posture of persons with truncal paralysis due to SCI (J. Hastings, Fanucchi, & Burns, 2003). Clinical case reports have shown that musculoskeletal shoulder pain, cervical pain, low back pain, and peri-scapular pain can be resolved with changes in wheelchair configuration (J. Hastings, 2001; J. Hastings & Baker, 2000; Young, Goldstein, & Carroll, 1996; Young, Goldstein, & Eby, 1995).

The specific aims of this study are to: 1) determine if improved outcomes, including a reduction in musculoskeletal pain, will occur with improved posture and 2) to evaluate provision of a postural seating intervention via teleconsultation. A prospective repeated measures design was used, subjects were randomized after

baseline measures to receive either in-person intervention by the investigator or an intervention specified by the investigator, mediated by teleconsultation and delivered by on-site clinicians.

Specific aim #1: Determine if improved outcomes, including a reduction in musculoskeletal pain, will occur following improved posture in persons with SCI who use manual wheelchairs full-time.

Hypothesis #1 Wheelchair configuration changes will change seated postural alignment.

Hypothesis #2: Health outcome measures will improve after postural change.

The hypotheses were tested by the following objectives of pre and post intervention assessment:

1. Determine the change in seated height measurement as an indicator of postural alignment.
2. Determine the change in self-reported pain on two Visual Analog Scales and Pain schematic.
3. Determine the change in self-reported functional impact of pain on a Pain Interference Visual Analog Scale and the Wheelchair User's Shoulder Pain Index.
4. Determine the change in self-reported posture on the Postural Scale for Wheelchair Users.

5. Determine the change in self-reported scores on the Satisfaction with Life Scale.

Specific Aim #2: Evaluate the feasibility and effectiveness of providing seating intervention through teleconsultation.

Hypothesis #3: Successful seating interventions are possible via a distance medicine model.

Objective:

1. Determine the feasibility of using the inter-facility consultation feature of the computerized medical record of the Department of Veterans Affairs (VA) Health Care system as a secure data transmission of photographic and textual documentation for “Store and Forward” teleconsultation provision of an effective postural seating intervention.

In this study the within subject comparisons were made in all subjects regardless of group. The between group comparison evaluated these two methods of providing postural seating interventions. In the test model there was no direct interaction between the principal investigator (PI) who is a seating specialist clinician, and the subjects. A clinician enlisted as a site investigator collected intake demographics, body measurements, photographs and wheelchair measurements for the subjects in the teleconsultation group. All subject information was transmitted to the PI for interpretation and synthesis. The PI then specified the custom wheelchair configuration changes and the on-site clinician or designated wheelchair technician made the

specified changes. The test model was compared to the usual clinical practice of in-person intervention with a seating specialist both evaluating and providing the intervention in person. The desired outcome was that the groups would not be significantly different, however it was anticipated that there would be a difference but that it would not be appropriately examined with a between group statistical analysis.

BACKGROUND AND SIGNIFICANCE

There are between 225,000 and 288,000 people in the United States living with SCI (*Spinal Cord Injury Facts and Figures at a Glance*, 2005). The range of this number is because there is no official tracking of persons living with disability; rather the figures are computed based on census and incidence of new injury. The life expectancy of those who survive their first year post injury is approaching that of the general population. The majority of persons with new SCI are discharged to their pre-injury residence and many of these homes are in rural environments.

In the population of individuals with spinal cord injury, chronic pain is a comorbid condition in addition to the primary physical disability created by paralysis (Ballinger, Rintala, & Hart, 2000; Turner, Cardenas, Warms, & McClellan, 2001). Chronic pain is known to be a significant disabling condition. The SCI literature is replete with descriptive and prevalence studies about pain but there are fewer interventional studies or studies searching for causation. Secondary disability and pain have only recently become an area of scientific focus due to the now existing and growing number of individuals living with SCI and aging with the condition.

Pain after SCI can be categorized into two distinct types: neurogenic pain and musculoskeletal pain. Neurogenic pain is attributed to the central damage and has no mechanical cause at the site of experienced pain (Devulder, Crombez, & Mortier, 2002). Musculoskeletal pain is that caused by tissue injury to the

musculoskeletal system. Musculoskeletal pain can generally be reproduced with passive range of motion of the involved joint or resistance to the involved muscles. On occasion, musculoskeletal pain may have a diffuse referral pattern (pain expressed distant to the site of tissue damage), but the damaged tissue will also be involved with the experienced pain.

Musculoskeletal disorder is an understudied topic in people with SCI. The research in this area is without depth or precision. There are few outcome studies and much associative or correlative evidence with inconsistent definitions and idiosyncratic instruments. Theory based interventions are scarce or not identified. Additionally, the population is small and heterogeneous by level of injury, premorbid history and rehabilitation. All of this contributes to a level of uncertainty in this field. This insufficiency of data affects aspects of clinical care, particularly the diagnostic assessment, evaluation of contributory factors, identification of cause-and-effect relationships, and the development of a dependable treatment program.

In the past few years, scientific literature, textbooks, patient education materials, consumer guides, websites, and manuals state that repetitive motion or overuse results in a multitude of upper limb disorders in SCI. Although a presumptive etiology is implied, in fact little evidence exists that repetitive motion or overuse is responsible for the disorder under study. If however, the etiology is a repetitive motion disorder, attention to the biomechanical characteristics of the

upper extremity and the interrelationship to the spine must be a fundamental aspect of the treatment program.

Overview of Musculoskeletal Pain after Spinal Cord Injury

Shoulder pain is a topic of concern among those with SCI and their healthcare providers; it is a frequent topic of discussion or presentation at regional and national continuing education and scientific conferences. Shoulder pain is common in individuals who have SCI. Surveys and cross-sectional studies have demonstrated that shoulder problems are common in both paraplegia and tetraplegia (Ballinger et al., 2000; Dalyan, Cardenas, & Gerard, 1999; Escobedo, Hunter, Hollister, Patten, & Goldstein, 1997; Gellman, Sie, & RL, 1988; Pentland & Twomey, 1991; Sie, Waters, Adkins, & Gellman, 1992; Silfverskiold & Waters, 1991). However, there are differences in the reported prevalence of shoulder pain between studies, ranging from 33-73%. The wide range in prevalence rates may be explained by differences in study population characteristics, by differences in the diagnostic criteria used, and the lack of inter-examiner consistency between many items in the physical examination. A recent study investigating neck and upper back pain in the population found of a pain prevalence higher than that of the general population and no difference between groups with pain or no pain by injury level or type of wheelchair used (M. L. Boninger et al., 2003). In an earlier European study the authors found 84% of the subjects reporting back pain (Samuelsson, Larsson, Thyberg, & Tropp, 1996).

What is the cause of this pain? Why the high prevalence? The answers are elusive and to some extent have been obfuscated by an overriding belief of the inevitability of upper extremity pain due to the unnatural use of the arms in wheelchair propulsion and weight bearing. Musculoskeletal pain in wheelchair users has been attributed to weight bearing in the upper extremity and overuse due to the substitution of the arms for the usual function of the legs for general mobility. This paradigm has led to investigations of compression forces in the glenohumeral (true shoulder) joint space, hand rim forces in wheelchair propulsion and other force studies. The *assumption* of cause has led to limited work into any alternative mechanism for this musculoskeletal pain.

Dyson-Hudson and Kirshblum (2004) completed a systematic review of the literature on shoulder pain in the of spinal cord injured population covering an EMBASE search for the years 1974-2002 and Medline 1966-2002, and concluded that shoulder pain was more common in tetraplegia, complete injuries and women. They further identified the known risk factors for shoulder pain as older age, higher body mass index, poor seated posture, improper wheelchair set up, decreased flexibility and muscle imbalance. Unfortunately, they did not categorize the individuals with tetraplegia in terms of their functional ability. Are these individuals primarily power wheelchair users or are they individuals with lower level tetraplegia who are using manual wheelchairs and independently transferring? It is unclear from the literature. If the majority of these individuals are not using

their upper extremity for functional mobility it would undermine the assumption of overuse as the primary causal mechanism. The authors also cited rotator cuff injuries as the most common source of pain in chronic SCI, however they stated that the cause of the rotator cuff injury was multi-factorial.

Empirical clinical observations have led this investigator to conclude that a significant amount of the musculoskeletal pain reported by persons with SCI is related to postural malalignment. This belief is supported by Samuelsson's finding that 100% of the subjects in their study had spinal postural deformity and of those reporting pain 14/26 subjects believed sitting posture was contributing to their pain (Samuelsson et al., 1996). The Samuelsson study supported a finding by another Swedish researcher, Sundell [publication only in Swedish (Sundell, 1994)], who found that every able-bodied subject who was asked to sit in a kyphotic posture for two hours reported pain. The investigator hypothesizes that the habitual postural alignment of a wheelchair-using individual is a key component of the absence or presence of musculoskeletal pain. The general musculoskeletal concepts that underlie this belief are explained below.

Alignment and Pain

Normal standing alignment in the general population is a "plumb-line posture". This is such that a plumb line will drop through the ear, shoulder, hip and knee, in a manner to allow the creation (maintenance) of the normal spinal curves. The plumb line posture is known to take the least muscular work to maintain.

Essentially this posture capitalizes on gravity to assist in the maintenance of posture, with the line of gravity passing just posterior to the hip, and just anterior to the knee. Any deviation from this posture, for instance the flexion posture common to Parkinson's disease, is known to increase the work of standing. Postural abnormalities are also known to be associated with pain, for instance Greenfield found that forward head position predicts shoulder pain (Greenfield et al., 1995). Keegan illustrated that optimal health of the lumbar spine is promoted with sitting postures as closely approximately those in standing as possible (Keegan, 1953).

Alignment is also key for appropriate articular function. For example; malalignment of the foot into hyperpronation is known to increase knee pain secondary to aberrant forces across the knee created by the closed chain interactions. Muscles generally function to support or move a joint. In general if passive stability is insufficient, muscles will work harder to produce contractile support to the joint. Again, in the example of the hyperpronation in the foot, this will frequently lead to over activity in the anterior tibialis.

Muscles generally have a length in which they operate most efficiently. Muscles have the ability to be physiologically too short (active insufficient) or too long (passive insufficient). Muscles working outside of their appropriate length are disadvantaged and therefore may be less able to generate force or maintain force. Muscles also fall into general categories of physiology; phasic and tonic muscles having properties that work best for the particular function. Muscles are plastic and

can remodel, however, their initial disposition is set by function. Postural muscles are typically tonic muscles which work best in a mid to shortened length.

Pain can be perceived in a depleted muscle. This can be a muscle tapped of all glucose supply or working beyond its vascular capacity for refueling and waste removal. Pain can be perceived by a muscle working excessively; a muscle working beyond its capacity for force generation or at a frequency beyond its tolerance.

Mechanical pain in the musculoskeletal system can also be articular in origin. Malalignment created by muscle imbalance can figure into the creation of articular pain by not maintaining appropriate articular surface congruency. Patellofemoral pain is an example of articular pain secondary to muscle imbalance.

The shoulder and upper limb are designed to optimize mobility, which facilitates hand placement in several planes. The upper limb articulates with the axial skeleton via the pectoral girdle. Muscles and ligaments largely suspend the pectoral girdle in order to allow maximal movement and flexibility. The only bony articulation between the trunk and upper limb is at the sternoclavicular joint. The glenohumeral joint (true shoulder) has a lack of bony constraint throughout the normal range of motion. This design is essential for mobility; however, stability through bony factors is minimal. Stability is established by the soft tissues (e.g., ligaments, capsule, labrum, muscles) and alignment. End range stability is achieved when soft tissues, particularly the ligaments and capsule, are stretched to their

physiologic limit. Dynamic stability is achieved by concavity compression and glenohumeral balance (Matsen, Lippitt, Sidles, & Harryman, 1994) in mid-ranges. Concavity compression is a mechanism in which the humeral head is compressed into the glenoid fossa by muscles (particularly the rotator cuff musculature), thereby resisting translating forces. Glenohumeral balance is a stabilizing mechanism in which the glenoid fossa (therefore the scapula) is positioned in the most stable position (i.e., so that the net humeral joint reaction force passes through the glenoid fossa).

Because of the articulation to the axial skeleton, via the sternoclavicular joint the shoulder girdle is obligatory in its relationship to the spine. Spinal posture determines alignment and positioning of the scapula, which determines the resting lengths of the shoulder girdle musculature and therefore the biomechanical stability of the shoulder. Predisposition to shoulder tendinopathy is exacerbated by postural faults and it is suggested that postural correction is key to the nonsurgical management of tendinopathy (Davenport, Kulig, Matharu, & Blanco, 2005).

Characteristics of the Target Population

SCI results in paralysis of the voluntary muscle activity below the level of lesion. This paralysis can be complete or incomplete and accompanied by impairment or loss of sensory function. Alteration in articular mechanics of the shoulder occurs following higher levels of SCI as a result of denervation to some of the shoulder or truncal muscles. In C7 tetraplegia, for example, the shoulder

flexors, abductors, and external rotators are all neurologically intact and stronger whereas their antagonists are not fully innervated and therefore weaker. Control and position of the scapula is affected by neuromuscular factors and the position (and shape) of the thorax. Within the category of “paraplegia” there are different levels of motor ability. The individual with paraplegia has full motor innervation of the upper extremities but may be lacking in full trunk innervation. Those who are injured above the level of innervation of the trunk stabilizers have different mechanical stability than those with lower innervation.

The sub-set of the SCI population that is the focus of this project is those individuals who are motor complete between the levels of T1 and T10 inclusive. Individuals with this level of injury have significant truncal paralysis and therefore do not have normal trunk control against gravity. Compensatory strategies for absent trunk innervation include stabilization with the upper extremities and a “C sitting” spinal posture (Minkel, 2000). C sitting posture is with a posterior pelvic tilt and spinal flexion of the lumbar and thoracic spine. C sitting creates an overall shorter sitting posture and a tendency for a forward head position. In a study of sitting stability while performing a reaching task, Seelen and Vuurman (1991) noted that persons with SCI had significantly more electromyographic (EMG) activity in the latissimus dorsi and trapezius muscles than the able-bodied controls, which the authors suggested was a compensatory mechanism substituting for the absent erector spinalis. Similarly, Janssen-Potten and colleagues showed that

posterior pelvic tilt was associated with more EMG activity in the thoracic postural muscles (Janssen-Potten, Seelen, Drukker, Huson, & Drost, 2001). Normal trunk innervation allows unilateral or bilateral upper extremity tasks with trunk synergistic stabilization and indeed trunk extension allows for the final degrees of overhead reaching motion. The movement strategies of the individual with truncal paralysis differ significantly from the biomechanics used in the able-bodied population. The impact of the difference in trunk stabilization is illustrated in a study looking at motor lesion level and rotator cuff disorders, which found a significantly higher prevalence of rotator cuff disorder in the individuals with high level (defined as T2 to T7) paraplegia (Sinnott, Milburn, & McNaughton, 2000).

When an individual uses a manual wheelchair the propulsion of the wheelchair must be considered a potential stressor for the shoulder. Intuitively, push mechanics appear to be important. What are the positions in which the joints of the upper extremity are working? Evidence supports that the joint positions are a significant factor for forces across the joint. Boninger and colleagues (M. Boninger, Baldwin, Cooper, Koontz, & Chan, 2000) have suggested that optimal position of the rear axle is 2 inches forward of the shoulder for the least stresses to the upper extremity. It is important to evaluate whether the wheelchair configuration is dictating movement at the extremes of joint range of motion, in positions of instability, or requiring excessive motion. Extremes of joint range put muscles to work at a disadvantage, usually over-lengthened or over-shortened

causing physiologic insufficiency. For the shoulder, hyperextension or abduction and internal rotation are ranges of the joint that are not optimal for joint function because they are believed to be impinging positions for the rotator cuff muscles secondary to decreasing the sub acromial space.

However, because of the obligatory interaction between the spine and the shoulder girdle it is imperative to recognize spinal posture as the platform for upper extremity function. Therefore the joint angles of the upper extremity (for instance with wheelchair propulsion) cannot be ascertained without knowing the position of the trunk. In the same wheelchair with the hand at the top of the push rim (at 12:00) the shoulder and elbow positions and angles will differ if the buttocks are at the rear of the seat or slid forward, or if the trunk leans forward.

All individuals who use a wheelchair (any type) have certain environmental challenges. The most obvious is that they are shorter than the standing individual. This means to access much of the environment they will need to reach, often overhead. The lap created by sitting also dictates that reaching will mostly be into an abduction pattern, especially in the person with the inability to lean forward over their lap due to paralysis of the trunk extensors. Reaching to manipulate the environment (for instance cooking) will often be into abduction and internal rotation. This is especially detrimental if the position is held for an extended duration.

In an intact able-bodied individual full overhead reach is achieved only with spinal extension. Overhead reach becomes a more prevalent activity when your head height is in the range of four and a half feet. If the habitual seated posture is posterior pelvic tilt, spinal flexion, forward head and rounded shoulders, and the individual has no active spinal extension, reaching will be impaired and even potentially damaging to the joint structures secondary to increased impingement. However, this same individual can be provided with external support of an orthotic wheelchair and gain significantly improved reach (J. Hastings et al., 2003).

Orthotic seating and the pelvic stabilizing system through wheelchair configuration are concepts put forward by the PI (J. Hastings et al., 2003; J. Hastings & Goldstein, 2004; J. D. Hastings, 2000) and founded in the work of Keegan (Keegan, 1953) on the interaction of the pelvis and lumbar spine with the length of the muscles of the thigh and the principles of fabrication of orthoses. If wheelchair configuration can provide orthotic support to the spinal alignment then the wheelchair configuration can directly impact the articular function and biomechanics of the shoulder in such tasks as wheelchair propulsion, reaching and transfers.

Very little scientific literature looks at the impact of wheelchair configuration on posture, pain or mobility. Early work by Zacharkow (1984) addressed the issue of posture and the wheelchair and he recommended a number of modifications to a standard wheelchair to optimize spinal posture while allowing

balance and function. Harms (1990) did similar work comparing three standard wheelchair configurations used in England at the time and concluded that the sling upholstery created the most kyphosis and was the most uncomfortable for users. In a series of four case studies in persons with tetraplegia, Bolin and colleagues showed that wheelchair configuration changes did change posture and outcome measures of both pain and function (Bolin, Bodin, & Kreuter, 2000). In this investigation the authors used a seated height measure as an index of postural change. A similar seated height index was used in the current research. Janssen-Potten and colleagues did a series of lab based studies investigating the effects of chair configuration on balance in a bimanual reaching task and concluded that a posterior tilt was a stable position (Janssen-Potten, Seelen, Drukker, & Reulen, 2000), that a forward inclination (wedging up the back of the seat) would not create an anterior pelvic tilt (Janssen-Potten et al., 2001) and that the footrest did not appear to contribute to balance for reaching (Janssen-Potten, Seelen, Drukker, Spaans, & Drost, 2002). Tomlinson did a mathematical analysis and computer simulation to determine the impact of the wheelchair configuration on roll resistance maneuverability and stability (Tomlinson, 2000b). However, Tomlinson did not bring the backrest forward to perpendicular, which is believed to significantly impact seated stability and balance and is a key component of this investigator's pelvic stabilizing configuration. In personal communication the PI asked Tomlinson to plot the characteristics of a T6 individual into his simulated

equation and bring the backrest to vertical. Tomlinson found that, in his model, this change would result in an erect spinal posture with improved stability at least equivalent to the slump kyphotic sitting assumed with buttocks forward (Tomlinson, 2000a). More recently, a clinician in Europe has developed the “The Ergonomic Seating System” which is actually a frame design of a wheelchair that the designer calls a ‘wheeled orthosis’ (Van Breukelen, 2004). This system contains the key parameters of wheelchair configuration advocated by this PI. A study by Maurer and Sprigle (2004) looked at the seated pressure distribution of a seating configuration similar to that proposed by this investigator as the pelvic stabilizing system and found that there were no significant differences in peak pressures with the different seat slope inclination. Maurer’s study is important because it refutes one of the concerns of clinicians (that the configuration may increase ischial pressures) when presented with the orthotic wheelchair configuration advocated by this PI.

Theoretical Framework

Prevention science models suggest that the crux of prevention is to identify and reduce known risk factors while enhancing protective factors. Postural malalignment is a known risk factor for musculoskeletal pain, and optimal spinal alignment is a protective factor. In a study looking at the spinal deformities in adults who were acutely spinal cord injured prior to the age of 16, Bergstrom(1999) found a high prevalence of scoliosis and kyphosis. The author suggested that

habitual positioning in poor alignment was a contributing cause and that maintenance of seated posture that most closely mirrors the alignment of the spine in standing may prevent or reduce spinal deformity.

Identification of modifiable factors is essential to develop a treatment program. The support of optimal spinal posture is the key to prevention of malalignment and muscle imbalance and therefore this support is important to both prevent potential musculoskeletal pain and to treat existing pain secondary to malalignment and muscle imbalance. In the presence of trunk paralysis the immediate environment of the wheelchair and the extent to which it provides postural support is a modifiable factor and the target of the intervention in this study. The intervention in this study is *postural change*; wheelchair configuration modification is the mechanism of obtaining this intervention in a population with truncal paralysis secondary to SCI.

The theory of this investigator is that what is reported as 'shoulder pain' after spinal cord injury has two main and inter-related causes. The two components of pain are postural pain and pain at the shoulder generated from aberrant joint biomechanics. The posture of the individual is a direct predictor of pain and also indirectly contributes to pain through upper extremity biomechanics (Figure 1). Therefore, an intervention directed at correcting posture could be tested to see if there was less pain following improved postural alignment.

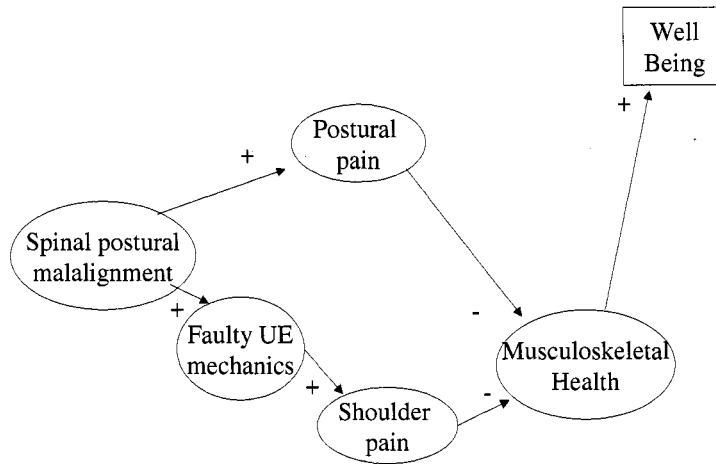


Figure 1: Schematic of Theorized Relationships

However, shoulder pain is not the only outcome of interest. Disability is defined as the limitations in ability to perform normal physical or social roles created by the existence of impairments. Secondary disability from a condition of musculoskeletal pain directly impacts one's well-being. Spinal postural malalignment can negatively impact health without the presence of pain. Postural malalignment can contribute to skin breakdown, impaired respiratory function and poor self-image. Physical health impairments, to the extent that they interfere with social engagement and life participation are known to be linked to lower quality of life (Putzke, Richards, Hicken, & DeVivo, 2002). Therefore, outcome measures in this project include measurements of perceived postural problems, sensory qualities of pain, pain interference, and of quality of life.

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Telemedicine

Telemedicine is a term used to cover any health care intervention using the assistance of technology. It is often collaboration between an urban medical center with specialty expertise and distant rural primary care providers or home health agencies. Originally the technology was the telephone and the medical information was shared over the telephone between clinical practitioners. As technology has changed the information exchanged has greatly expanded. Facsimile machines added the ability to send explicit requested data over phone lines. Video conferencing added a new dimension where it was possible to be viewing the assessment of the patient in real time, while discussion was also occurring between the clinicians. Real time teleconferencing has the disadvantage of requiring the two parties to be coordinated in scheduling of the information exchange and thus hampers consultation ability over greater distance with different time zones. Additionally, video conferencing requires television and video equipment close to a telephone line and sufficient lighting for clarity of picture.

“Store and Forward” telemedicine is a type of distance health care provision where the health information is collected from the patient, forwarded to the clinician for evaluation and then the clinical recommendation is returned, either directly to the patient or to an on-site care giver. This type of distant provision of healthcare has the advantage of not requiring synchronization of both parties and works extremely well when the medical information is being collected directly by

the patient at home and thus can be done during the evening hours. Physiologic monitoring of such vital signs as heart rhythms, blood pressure, oxygen saturation, pulmonary function and blood glucose levels can be directly transmitted over phone lines from the monitoring equipment.

A recent study of “TeleHome Care” from the University of Minnesota (Finkelstein, Speedie, & Potthoff, 2002) looked at the effectiveness of video conferencing, Internet access and physiological monitoring within a home health care setting. The length of care received as well as satisfaction with care and cost were evaluated. They found that there was no real difference between intensity and length of care received and that patients were all satisfied with care. The “TeleHome Care” groups showed increased satisfaction with flexibility, and the monitored group had increase feeling of ‘safety’. Cost per virtual visit was significantly less than actual visits; this analysis included the amortized equipment cost over the potential number of virtual visits that could be conducted with the available equipment at a rate of two per week over 2.5 years.

However, in a similar study of “TeleHome Care” in Philadelphia the investigators found that the “TeleHome Care” group had significantly higher cost per patient per episode, \$1,700 versus \$390 (IPRE, 2000). The Philadelphia study had less travel time for the home care nurses and a different population under study as they used a diabetic population; in the Minnesota study the subjects had CHF or COPD. Additionally, the Philadelphia study had “TeleHome Care” as a supplement

to traditional care not a replacement. The group with “TeleHome Care” support had fewer hospitalizations during the time of study and factoring that into the overall cost of health care the authors concluded that the “TeleHome Care” was a cost effective method of delivery.

A recent study funded by the Department of Veterans Affairs (VA) looked at the reliable use and limits of telecommunication for the remote prescription of assistive technology (Cooper & Boninger, 2000). The study uses the term ‘TeleRehab’ and used interactive video and audio to increase availability of specialty services to remote patients. The project investigated the use of video conferencing for the evaluation of individuals for their seating and mobility needs. This study was funded through March of 2005. In the preliminary report, the authors suggested that telerehabilitation shows promise as a useful tool for wheelchair selection (Allegretti et al., 2003).

The VA Health Care System has been expanding its use of Internet based technology in support of healthcare. For example, in the VA Health Care Systems technology has been used to increase clinician access to clinical practice guidelines and inter-professional collegial discussions on a web-based platform. The VA Health Care System has also been using a computerized medical record system for nearly a decade. Patient information can be shared across a sub group of networked facilities called a Veterans Integrated Service Network (VISN) through secure sockets and it is possible to browse an entire medical record from a different VISN

facility. With the use of Virtual Private Network (VPN) clinicians can log on to the computerized medical record from remote sites. Inter-facility consultation is a new use of the computerized medical record whereby patient information is shared via a medical consultation and the clinician at the distant site receives a 'view alert' to the consultation and can then reply after assessing the patient data. This inter-facility consultation mechanism is intended to transmit text and image medical documentation.

The Puget Sound Health Care System of the VA has implemented a Dermatology Telemedicine program using the inter-facility consultation mechanism. To date this program is not using the image transfer ability due to insufficient coverage from Dermatology clinicians to interpret the images (Weenike, 2004).

The current study similarly used the inter-facility consultation mechanism for secure transfer of patient information including photographic images. This study is a "Store and Forward" use of teleconsultation and this was selected due to the advantage of asynchronous clinician scheduling. The use of static photographic images and supplemental patient data has significant cost savings over real time video conferencing, additionally accuracy in a still photograph is more readily attainable than adequate 3-dimensional video taping from a single camera placement.

Significance of Study

Postural deformity and musculoskeletal pain is common in individuals who have a SCI. The relevance of this high rate of pain lies with the increased longevity and the changing demographics of society. American society is aging and the burden to the healthcare system is predicted to increase to unprecedented levels in the coming decades. These facts make preventing secondary disability a priority for intervention and research.

The specific aim of this project was to determine if health outcomes were improved in a clinical trial after wheelchair configuration changes in a sample of persons living with SCI who presented with pain or seated discomfort. Three hypotheses were tested:

- H1). Wheelchair configuration changes will change seated postural alignment.
- H2). Health outcome measures will improve after postural change.
- H3). Successful seating interventions are possible via a distance medicine model.

If clinically meaningful change can be achieved through teleconsultation the implementation of such a program could have significant cost savings to the VA Healthcare Systems and improve access and decrease waiting times for veterans with seating needs.

PRELIMINARY STUDIES

The principal investigator has studied issues concerning the shoulders and postural alignment of persons with SCI for the past 15 years. This work has illuminated the importance of individualized wheelchair configuration modifications both for the improvement of posture and the avoidance of pain. Out of this work the PI and colleagues have developed a prevention and treatment program for postural alignment problems and pain-related issues for individuals with SCI who are full-time wheelchair users. Four major principles are the underpinning of that program: Optimal spinal postural alignment is the platform for musculoskeletal health, proper biomechanical use of the upper extremity will preserve pain free function, wheelchair configuration controls postural alignment in persons with truncal paralysis, and certain wheelchair configurations will provide orthotic support to the paralyzed trunk. Four peer-reviewed articles, three abstracts, the development of departmental programs at two hospitals and numerous case studies have resulted from these efforts.

Implications of Elbow Arthrodesis for Individuals with Paraplegia: A Case Study

Postural alignment and corresponding functional problems were first addressed in an article written by this investigator in 1993. In this case study of clinical decision making concerning an individual with paraplegia, the functional evaluation of self care skills possible with two different elbow fusion positions was investigated. The superiority of a 30-degree fusion over a 90-degree position was

supported but the ramifications of a fusion in the distal upper extremity joint for the shoulder function and spinal alignment were also discussed. The key wheelchair modification to avoid seated postural malalignment and maintain manual wheelchair propulsion ability was the use of asymmetrical handrim diameters. This case study had many facets but key among them was that modification of the wheelchair configuration to accommodate the elbow fusion could ameliorate negative postural sequelae (Young, 1993).

This publication was followed by a series of platform and poster presentations more specifically dealing with the 'weight bearing shoulder' of persons with SCI. Clinical observations had led the PI and colleagues to conclude that the literature on issues of the shoulder in SCI was lacking and biased. To characterize the prevalence of shoulder pain and functional impairment a descriptive study was undertaken at the Puget Sound VA Health Care System SCI Service (Seattle VA).

The Weight Bearing Shoulder Following Spinal Cord Injury

In 1995, the PI and colleagues presented a study that challenged the prevailing contention that shoulder pain was a major cause of functional limitations in persons with paraplegia. In a survey study the investigators had found that 52% of the population reported shoulder pain but only 5 of the 29 subjects reported both pain and functional loss without pre-existing shoulder injury (prior to SCI). The investigators also challenged the notion of weight bearing as the etiology of

shoulder pain, finding that the most common complaint of pain in their subjects was with overhead reaching activities (Young et al., 1995). Based on these findings and clinical observations it was hypothesized that there would be a lower prevalence of shoulder pain among individuals receiving their acute rehabilitation at the Seattle VA. This hypothesis was premised in the unique practice characteristics at the Seattle VA. Key among the care practices was the primary use of rigid frame manual wheelchairs with orthotic configuration supporting postural alignment. Further, a transfer technique emphasizing hands down, hip flexed body mechanics was taught, which was believed to protect the biomechanics of the shoulder. Thus began the development of a prevention and treatment program for shoulder pain in the SCI population.

Prevention and Treatment Program for the Weight Bearing Shoulder

The following year the PI presented the results of a prospective study looking at the outcomes of patients presenting with shoulder pain who were enrolled in the non-surgical treatment program. This paper built on prior work and offered a prevention and treatment program for shoulder pain in the 'weight bearing shoulder'. The prevention and treatment program was developed out of the belief that the unique features of the rehabilitation approach at the Seattle VA were the explanation of the lower prevalence of shoulder pain, thus the program systematized the practice. The shoulder protection program consisted of four key elements: 1) avoid damaging patterns of shoulder use, 2) optimize postural

alignment, 3) balance the musculature around the shoulder, and 4) patient education.

A case series of patients, who had been rehabilitated elsewhere and presented to the Seattle VA with shoulder pain, was studied to test the hypothesis that this prevention and treatment program would ameliorate pain in persons who did not have optimal postural orthotic support from their wheelchair configuration and were therefore using the upper extremity with improper biomechanics. Fourteen cases were treated with the shoulder protection program and were formally studied. The key intervention of the program was wheelchair configuration change to provide orthotic support to spinal postural alignment. Functional tasks were also surveyed for improper biomechanics and alternate strategies for movement taught. The program was successful in resolving the pain of seven individuals, reducing the pain in five and in two there was no change in their pain status. These last two individuals had been full-time wheelchair users for 42 and 47 years respectively. Time since injury has been significantly correlated with shoulder pain (Dyson-Hudson & Kirshblum, 2004) which is also confounded by advancing age. In the general population there is an increase in shoulder pathology with aging. Only four individuals had limitations to functional activities that persisted after the program interventions. Of these individuals, one had used a wheelchair for only five years; the other three were the longest users in the population (39, 42, 47 years)(Young et al., 1996).

The PI and colleagues had observed an increased number of referrals for rehabilitation after rotator cuff repair and there was an interest in evaluating pain and function after conservative management compared to rotator cuff repair.

Rotator Cuff Repairs in Individuals with Paraplegia

The recommendation for a conservative approach to shoulder pain and rotator cuff impairments was published in a paper discussing the poor success of surgical repair in this population of patients. The four basic principles already articulated underpin the conservative approach; proper biomechanical use of the upper extremity, spinal alignment as a platform for biomechanics and the wheelchair as an orthotic support for postural alignment. Postural alignment was seen as a key piece of the intervention because of the recognition of posture as the platform for upper extremity biomechanics. The position of the scapula and thus the mechanics of the glenohumeral joint are obligatorily effected by the alignment of the spine. In the absence of postural spinal muscular power it was noted that the posterior muscles of the scapula were substituting as postural stabilizers and this was believed to be a direct source of fatigue and pain and well as indirectly creating abnormal joint mechanics at the glenohumeral joint and potentiating pain (Goldstein, Young, & Escobedo, 1997).

Hip Subluxation and Scoliosis in Individual with Paraplegia

Scoliosis is multi-planar and can have many negative sequelae, including cervical and shoulder pain. A pattern of functional scoliosis secondary to hip

subluxation or dislocation was recognized by the PI in a number of patients presenting with musculoskeletal pain complaints. The PI presented a poster on this clinical pattern and offered a hip protective protocol based on the common clinical characteristics found in a retrospective chart review of cases of hip subluxation (Young, Giertz, & Goldstein, 1998). Because it is a functional scoliosis it can be resolved with an ipsilateral pelvic lift if the body has remained flexible. The amelioration of musculoskeletal pain with a postural correction is premised in the basic principle that the spinal alignment is the platform for upper extremity biomechanics.

Clinical Observation

The interaction between postural alignment and shoulder pain had become very clear to the PI. The observed pattern was that SCI patients with clinical referrals to the PI for shoulder pain would respond to an intervention of only a postural change and have resolution of the pain complaints. The PI's emerging theory was that some of the 'shoulder pain' reported is actually postural pain in the peri-scapular muscles from over work. Another component of the reported pain was believed to be mechanical joint pain or muscular pain in the supporting musculature, created by the joint being used in malalignment secondary to the poor postural support. This theory would support the hypothesis that if an individual has pain in pushing a wheelchair the joint is working in a malalignment. In contrast, if a joint is used in proper alignment there will be no pain.

Wheelchair Adjustment to Eliminate Shoulder Pain in An Adult with Cerebral Palsy

This hypothesis was supported by a case where shoulder pain was eliminated in an individual with cerebral palsy by adjusting the wheelchair to change the angles of excursion of the shoulder during propulsion. This individual had propelled with a hyper-extended shoulder and after adjustment to the chair to create a more neutral shoulder alignment his pain was completely resolved. This case was presented in a poster at the American Physical Therapy Association Combined Sections meeting 2000 and then published in Physical Therapy Case Reports (J. Hastings, 2001).

Postural Maintenance During Pregnancy in a Woman with T7 Paraplegia

Conceptually, a wheelchair configuration with orthotic support is carefully set up to match the available lower extremity range of motion of the user and support/substitute for their absent postural strength. The importance of matching the configuration of the wheelchair to the available range of motion of the individual was highlighted by work with a woman with T7 paraplegia through the months of her pregnancy. Her progressively changing body dimensions required the wheelchair configuration to change with her to maintain good spinal alignment which aided in her respiratory ability as well as preventing neck and shoulder pain. The size of the wheelchair did not need to change, the configuration, in particular the angles between the seat and backrest, did need to change (J. Hastings & Baker, 2000).

The four major principles for prevention and treatment of postural alignment and pain issues developed through the work of the PI have been incorporated into the standard of practice at the Seattle VA (where the PI had been the supervising therapist and responsible for the training of the therapists in wheelchair prescription and seating for ten years). A wheelchair provided to newly injured individuals will have a fairly set specification of parameters. Starting with a positive seat slope (usually 2-4 inches of difference front to rear with higher level injuries requiring more slope) a perpendicular backrest (measured to the floor) and a backrest set relatively short (at approximately the bottom of the ribs). The wheelchair will then be fine-tuned to the user's balance and comfort and to interface with immobilization devices. This platform of seating position is not universal across the nation or even across the city. Therefore, it was determined that there was a need to do a controlled study to show that this wheelchair configuration did indeed improve postural alignment and should be incorporated into routine care of newly injured spinal cord injury patients.

Wheelchair Configuration and Postural Alignment in Persons with Spinal Cord Injury

A formal study was done to compare the seating prescribed at the Seattle VA with the usual production configuration of two common wheelchairs in terms of the postural support provided. The study received IRB approval; the results were presented at the American Spinal Injury Association (ASIA) annual meeting and published in a full article (J. Hastings et al., 2003). The design was a single session

cross over with random assignment to the order of the three wheelchair configurations. The sample was one of convenience solicited from the population of patients served by the Seattle VA SCI unit. Inclusion criteria were persons with ASIA Impairment Scale Scores of A or B with motor levels between C6 through T10 inclusive, who used wheelchairs for full-time mobility and had no medical conditions, which disallowed sitting for the period of the research session. Exclusion included overt postural deformity, and significant loss of range of motion. Two sagittal plane photographs of each subject in each wheelchair were taken, one at rest and one with right arm reaching as high as possible without contralateral support. Linear and angular measurements were taken from the digital photographs. Data analysis consisted of comparisons of these measures across wheelchair situations. The 'test' wheelchair, which was configured in the usual manner of the Seattle VA (described above), was found to improve posture and humeral elevation (J. Hastings et al., 2003).

This study included elements that are used again in this dissertation work. Measurements from sagittal plane photographs comprise the proximal measure for the current research. Experience from the above study and a second pilot study have clarified the procedure for photographs and points for measurement. The 2003 study also showed that the wheelchair configuration changes sagittal plane postural alignment. This is fundamental to the current research. The current study hypothesizes that postural changes can be achieved through wheelchair

configuration change, and that these changes will improve health outcome measures.

The measurements taken in the crossover study were cumbersome and time consuming. The apparent thigh measurement used in the study appeared to be the most straightforward, but it did not show significance in the findings. The other straightforward measure was the humeral elevation; this was simple to measure and showed significant change. It was deduced that a similar linear seated height measure might be readily measured. A retrospective chart review was proposed and received IRB approval to test the feasibility of the linear measurement of seated height from clinical photographic documentation and to determine the effect size of custom seating interventions as indicated by the postural measure.

A Retrospective Chart Review Of Custom Seating Interventions To Improve Postural Alignment In Wheelchair-Using Individuals (Unpublished).

This study was completed on a convenience sample of 18 patients who had sought seating interventions from the investigator over a 5-year period; all were full-time wheelchair users secondary to neurological impairments. Three of the charts had insufficient documentation and were excluded from analysis. In this study the seated height measure met the validity criterion and showed significant change. The effect size (mean change score/standard deviation of the change scores) of customized seating intervention as measured by seated height was

calculated to be 1.25 which suggests that the change can be seen by the naked eye and that small samples will show significance.

Cyber Seating

The ability to provide postural intervention through wheelchair configuration changes from a distance was shown in this case work. The PI had an opportunity to aid an individual from Central America who was reporting significant shoulder and low back pain interfering with function. The recommended seating interventions were determined from subjective information transmitted by email and the concurrent analysis of digital photographs attached to the email messages. Lay helpers of the individual did the actual changes to the wheelchair locally. The result of this Internet mediated intervention was a complete resolution of the low back pain and the shoulder pain that was limiting function in this individual with T4 paraplegia. The case concerning this Internet mediated seating intervention was presented in a poster at the ASIA annual meeting (J. Hastings, 2003). The experience of successfully intervening with a postural seating intervention via wheelchair configuration change without ever physically meeting the individual is the lynchpin of the plan to study a teleconsultation postural seating intervention in comparison to the hands-on usual care for seating interventions. By happenstance, the individual in this case tracked down the PI (who had changed jobs) to report his current status. The following is an excerpt of his email:

“After four years- remember you helped me in 2001- I am doing well instead of the shoulder problem- working and living my life fine on my wheelchair”.

Instrument Development: A Postural Scale for Wheelchair Users

The PI developed an instrument to measure the subjective perception of posture in wheelchair users as an outcome measure for this dissertation research. Upon finalizing the initial instrument a study was proposed to test the psychometrics of the scale. IRB approval was received for a self-report mail in survey. The sample was recruited from advertisement and flyers with snowball sampling encouraged. Forty-one questionnaires were returned. Item analysis resulted in a refinement of the scale with reduction to a 16-item scale. Construct validity was established during development and concurrent validity was established with correlation to a single item (embedded). The internal reliability of the scale in the sample was very good for a new scale (Cronbach’s $\alpha=.86$). Test-Retest reliability on 7 subjects with a 2-week interval showed a mean total scale score change of 1.3 on a scale with a range from 0-48, the total scale scores were correlated at $r=.7$ (J. Hastings, 2005).

RESEARCH DESIGN AND METHODS

Overall Study Design

This study was a prospective quasi-experimental design with repeated measures across subjects to control for baseline differences in the outcome measures. Subjects were randomized to group for comparison of two alternative intervention modes. A delayed treatment control was designed into the study in hopes of showing the stability of the outcome measures in a “no treatment” interval. The design called for two baseline measures to allow the ability to assess the difference between treatment and no treatment by comparison of the change in outcome measures between time 1 and time 2 (which is the interval with no treatment) and the change between time 2 and time 3 (the interval with treatment). Maintenance of the outcome was assessed by comparison between time 3 and time 4 (at three months post intervention).

Settings

The VA provides health care for veterans in a national system, which is divided into VISNs or sub group of working networked facilities. VISN 20 includes the northwestern states. SCI care inside the VA is a specialized service with specifically designated centers. SCI specialty care in the VA is delivered in a Hub and Spoke system. The SCI Hub for VISN 20 is located at the Puget Sound Health Care System Seattle Campus. Smaller hospitals and outpatient clinics have primary

care centers for SCI veterans, which are associated with an SCI center (Hub) and are designated SCI “spoke” facilities. Primary care providers come for training at the SCI centers and have a rudimentary knowledge of SCI special needs and are specially trained on signs and symptoms that require referral to the specialty center. Guidelines for care delivery explicitly preclude seating evaluation and intervention at the spoke sites with the expectation of referral to the SCI center (Hub). The planned use of the spoke clinics for recruitment for this study is due to the lack of specialized seating expertise at the spoke clinics.

Subjects for this study were specifically recruited outside of VISN 20 as the SCI Specialty Center of the Puget Sound VA is an established center of excellence for seating interventions (the home clinic of the PI) and the patients served by this center should not have unmet needs.

Two facilities were selected as distant sites for this research study from a list of potential sites provided by the administrative staff of the Chief Consultant of the VA SCI/D Service. The selection criteria included: Potential need for improved seating among the patients served, the number of patient encounters in the past year and location within one time zone of Seattle. The sites selected were in the same VISN and will be designated Site 1 and Site 2 throughout this report. Site 1 had 146 patient encounters in the fiscal year prior to the study and Site 2 had 139. The Chief Consultant of the VA SCI/D Service endorsed this project prior to the initial overture to key contacts at each site. Cooperation agreements were confirmed with

both sites, with commitments for space and dedicated clinical staff time over 4 months from May through August 2005.

Site investigators were established prior to beginning the research project. Extensive information exchange occurred over email and phone conversations in the months leading up to the study. The PI provided on-site training to the site investigators in the month prior to enrolling subjects. A written manual on the research project was left with the site investigators including all procedural instructions, instruments and documentation templates.

Personnel

Personnel for this project included the PI, two site investigators, one wheelchair technician, and a designated VA PI at Site 1 (this was a requirement for the local IRB, his participation was minimal but he was the 'responsible physician' for the study). The roles of the primary personnel are described below.

The PI :

- Wrote the proposal and the human subjects applications for the overall study.
- Submitted to the UW and Puget Sound IRB authorities.
- Wrote the human subject applications and assisted the site investigators with gaining local approvals for the project.
- Provided training to local investigators.

- ❑ Created and provided all templates, guidelines and written training manuals for the local investigators.
- ❑ Provided all intervention and collected all data for the in-person treatment group after the initial enrollment session.
- ❑ Completed all photographic analysis and seated height measurement for both groups.
- ❑ Provided the wheelchair configuration change specifications (intervention) for both groups.
- ❑ Responded to all inter-facility consultation for the teleconsultation group.
- ❑ Provided all reminder calls and administrated subject payment.
- ❑ Completed all data analysis.
- ❑ Authored this report.

The site investigators were responsible for gaining local IRB approval for the project. At Site 1 this task fell to the designated PI, at Site 2 it was the site investigator. The site investigators were responsible for local enrollment of subjects, which includes appropriate informed consent, screening for inclusion and collection of baseline data on all subjects from their site. The site investigator was then responsible for the random assignment to group (following pre-established process) and scheduling into the appropriate clinical track. For the teleconsultation group the site investigator completed the intake evaluation following guidelines and templates provided and then initiated the inter-facility consultation to the PI.

After receiving the specifications for wheelchair configuration change (the consult report from the PI) the site investigator was responsible for completing the wheelchair modification and collecting data in the second teleconsultation appointment (in Site 1, the wheelchair configuration work was delegated to a technician under guidelines and supervision of site investigator). The site investigator was similarly responsible for teleconsultation appointment number three.

Training for Site Investigators

The PI visited each site and provided a presentation on the theoretical foundation of the study and the principles of orthotic seating intervention, and the specific data collection and intervention techniques used in this study. The site investigators received training in seating intake evaluation and passive range of motion measurements. The site investigators and the wheelchair technician (Site 1) received training in the usual adjustments of wheelchairs for postural support. Both site investigators demonstrated their ability to collect correct data on a mock subject. Guided data collection forms were used for all information collection. Both sites had a complete training and procedures manual left after the training session. The written manual for the study included photographs, intake forms and checklists. Study photographs were taken with a digital camera and downloaded into computer for transfer to the PI. Both site investigators were provided with a camera for the study, in person training in how to use the camera and left with the

owner's manual instructions. Additionally, at both sites a computer support staff member was designated for assistance with image capture and training was provided from this source as well.

Target Sample

A power analysis considering the mixed model design and use of repeated measures ANOVA on a single sample with an estimated correlation of .5 in the 4 repeated measures yielded a power of .80 with 8 subjects with an effect size of .89, $\alpha=.05$ (Stevens, 2002). This analysis used the seated height proximal measure as the index.

Target enrollment was 10 subjects from each of the facilities, for a total of 20 subjects. The target enrollment was set higher than the 8 subjects suggested by the power analysis to improve the power on the distal outcome measures. The study was designed to accommodate as many as 18 subjects from each facility with a total of 36 possible subjects.

All persons who contacted the site investigators during a 4-month study period were screened for inclusion in the study. Eligible subjects were enrolled as they presented throughout the study period. Enrollment ended on the last day of August as planned in the cooperation agreements with each study site.

The sample was drawn from the patient population of the VA Health Care systems who are spinal cord injured and receive their care at either of the two designated facilities. Human subjects committee approval was obtained from the

University of Washington IRB, the Site 1 VA Medical Center IRB and the University of Arizona who serves as IRB for the Site 2 (UW is the IRB for the Puget Sound Health Care Systems). Approval was also obtained from the VA Research and Development Committees of the Puget Sound VA, and both site VA medical centers.

Inclusion Criteria

1. SCI with American Spinal Injury Association (ASIA) Impairment Scale (ASIA, 1996) scores of A or B, motor level between T1 and T10 inclusive.
2. Aged 18 years or greater.
3. One year or more post the date of SCI.
4. Presenting with complaints of non-specific musculoskeletal pain in the shoulder, neck or peri-scapular region, general discomfort while seated in their wheelchair or observed sagittal plane postural malalignment.
5. Full-time users of manual wheelchairs classed as lightweight or ultralight (Medicare K4 or K5).

Rationale for inclusion criteria

1. The ASIA impairment scale is a classification of the extent of the spinal cord injury. Motor level between T1 and T10 inclusive indicates that all individuals will have impaired trunk motor control and those with T1 would also have mild impairments in hand function, with loss of intrinsic hand motor power. The classification of A and B indicate the amount of

completeness of the SCI. Individual's with A scores are motor and sensory complete below the level of injury and those with a B score have sensory sparing below the level of injury.

*A modification was requested to allow inclusion of individuals with motor level of injury between T1 and T12 and was approved; however no subjects were recruited after the modification.

2. The VA Health Care System serves adult veteran populations.

** A special modification request was submitted in Site 1 to allow inclusion of a non-veteran employee of the VA who otherwise met the eligibility criteria, this was approved and one non-veteran was enrolled.

3. The one year post SCI date inclusion criterion was used to insure that the subjects had attained a level of stability in their medication management and were using permanent equipment (rather than loaned), additionally one year post has been a standard used in the literature to operationally define 'chronic' spinal cord injury.

4. The intervention in this study was postural alignment change through wheelchair configuration change, the theorized musculoskeletal pain this intervention addressed are listed in this inclusion criteria. The intervention addressed sagittal plane postural alignment.

5. The wheelchair classification codes were used to insure the adjustability of the wheelchairs. The intervention under study was postural change brought about by wheelchair configuration changes.

Exclusion Criteria and Justification

1. Significant frontal plane postural deformity.

Frontal plane (frontal plane is the two dimensional cardinal plane passing from medial to lateral and viewed from the anterior or posterior direction parallel to the long axis of the body) deformity is a more complex issue and requires skilled evaluation that cannot be assessed from static photographic documentation.

2. Current pressure ulcer.

Sitting is generally contraindicated with pressure ulceration.

3. Any medical condition not allowing participation in transfers and sitting.

The intervention required multiple transfers and habitual sitting in wheelchair to ascertain outcomes.

4. Inability to self- inspect skin on sitting surfaces.

The intervention changed the seated posture of the individual and as a safety precaution each participant was asked to monitor skin for any adverse changes.

5. Ankylosing spondylitis (a spine fusing disorder) or heterotopic ossification (bone growth in the joint periphery which limits range of motion, usually into flexion) in the lower extremities, or significantly limited lower

extremity range of motion which does not allow the subject to fit into the pelvic stabilizing configuration.

The intervention under study was a change in wheelchair configuration.

Conceptually the change in wheelchair configuration will be to a position of orthotic support, thereby creating a force support system to improve alignment of the spine. Flexibility is an inherent need for successful intervention.

Persons with spinal cord injury are routinely on a regime of medications for control of secondary conditions caused by SCI (e.g. antispasmodics, anticholinergics, bowel medications). Subjects were asked to refrain from medication changes during the duration of the study and at the end of the study they were asked about any changes in medications during the study period (no changes were reported). There were no exclusions based on medication use.

Instruments/Outcome Measures

Demographic information was gathered on a self-report questionnaire which is a component of the Wheelchair Users Shoulder Pain Index developed by Curtis (Curtis et al., 1995). With permission some additional questions were composed and added for this study. Information included age, gender, SCI level, year of SCI, height and weight, make and model of wheelchair, musculoskeletal history related to the shoulder, neck and back and a survey of basic functional mobility.

Three types of measurements were made during this research project, a single proximal outcome measure, distal outcome measures, and process measures. The outcome measures were assessed at multiple time points with planned comparison of the scale scores measured before and after intervention. Distal outcome measures included measurement of perceived postural problems, measures of sensory qualities of pain, measures of pain interference, and a measure of quality of life.

Proximal Outcome Measure

Seated height is the proximal measure. Seated height was measured from photographs taken at baseline and post intervention. The intervention of this study was a change in postural alignment; the mechanism of creating this change is wheelchair configuration change. The proximal measure of seated height was expected to show a change to greater values of seated height (taller- more erect sitting) post intervention.

The architecture of the spine is well known and the obligatory interactions of the vertebrae with motions of spinal flexion, extension, rotation and lateral side bending have been established (Kapandji, 1987). The pelvis, as the base of the spine, has a certain vertical height in upright-seated posture. In the condition of posterior pelvic tilt the height of the pelvis is rotated from vertical toward horizontal concomitantly there is obligatory spinal flexion and therefore the overall seated height will decrease in a condition of posterior tilt.

For this study a single postural index was used: overall seated height (SH). SH is defined as the vertical measurement between a point marked on the seat rail 2 inches forward of the junction of the seat and backrest cane to a horizontal line at the highest point of the head (Figure 2). Seated height was measured from a point on the seat rail rather than the floor due to the fact that a component of the wheelchair configuration change may be to lower the rear frame of the wheelchair, therefore the measurement that will reflect the erectness of the spine is from the seat. Increase in this measurement indicates increased spinal extension. This postural index was selected because it can be measured from directly observable sites on the photographs without requiring markers on the body or removal of clothing beyond the external items such as coats and hats. An unpublished pilot study using seated height measured from clinical photographic documentation found the measure to be a valid indicator of postural change and a reliable measurement with intraclass correlation for unordered pairs of .99 and .98.

The intent of the proximal measurement is to show postural change, specifically in the spinal alignment. The 'gold standard' for measuring spinal alignment is with X-rays. However, cost is prohibitive and further there are issues with the feasibility of using radiographic film to capture the alignment while seated in the individual's wheelchair. Wheelchairs are metal, plastic and rubber and the metal components will show as artifact on the radiograph and most X-ray

equipment is not designed to be used for film taken in a position of sitting without moving to the designated X-ray table.

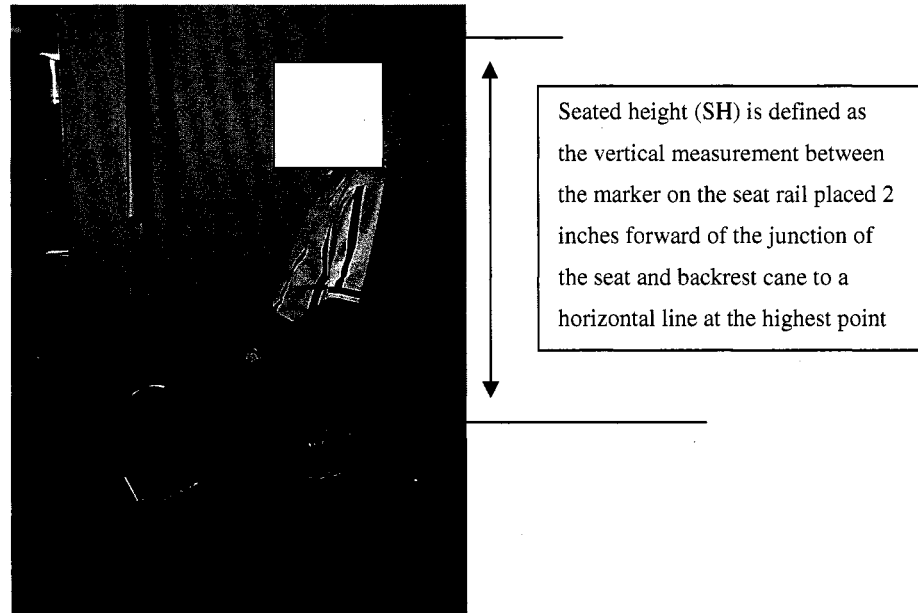


Figure 2: Operational Definition of Seated Height

The PI measured seated height from the digital photographs with linear metric measurement. Photographs were printed to the same referent scale for each subject. There was some discrepancy between subjects due to photograph quality and resolution.

Photographs were taken with a digital camera following specific guidelines. Photographs taken by site clinicians were downloaded from the camera and attached by image capture to the computerized medical record. The images then

were exported to a word document for printing. Photographs taken by PI during in-person clinical appointments were downloaded from camera to computer and into a word document and were not imported into the medical record.

Distal Outcome Measures

Pain

Three instruments were used to measure pain. The Wheelchair Users Shoulder Pain Index (WUSPI) was used to assess the functional impact of pain in the shoulder. This instrument was developed by Curtis in 1995 (Curtis et al., 1995) and has been frequently used in the past decade as a pain measure in the population of SCI. Curtis reports internal reliability $\alpha=.97$ and stability in test-retest analysis with interclass correlation at .99. The WUSPI is considered a one-dimensional scale to reflect the functional cost of shoulder pain. The instrument is 15-items self-reported on a visual analog scale (VAS) for each item anchored at no pain and worse pain ever experienced. The total scale score has a range from 0-150 and can be modified to a performance corrected scale if subjects do not do some of the items assessed in the questionnaire. Performance corrected scale scores were used for this analysis. Individual item analysis was also done to see if there was more change on items where posture would be more likely to impact the function.

A single item was used as a direct measure of pain interference. This measure read: "How much has any pain above the level of your spinal cord injury interfered in your ability to perform your usual activities in the past week?" This

item was rated on a VAS anchored at not at all and usually or severely. Pain interference is a measure of disability and a referent therefore of musculoskeletal health.

A VAS was used to assess the sensory quality of pain. The subjects were asked to rate two conditions: 1) Rate your current pain and 2) Rate the worse pain you have had in the last three days. The VAS is a 10 cm. horizontal line anchored at no pain and worst possible pain upon which the subjects placed a mark to indicate their level of pain. The score is determined by a linear measurement from the left anchor to the mark. Subjects were also asked to indicate the area that relates to their pain on two schematic diagrams to represent current and worse pain. The VAS was therefore a referent of postural pain, shoulder pain or both.

All instruments using visual analog scales were scored in the same manner. The measurement was from the left anchor in centimeters to two decimal places.

Posture

The Postural Scale for Wheelchair Users (PSWU) was developed by the PI to measure the subjective perception of problems with seated posture. This scale has been pilot tested (n=41) and shown to have internal reliability at $\alpha = .86$. On a very small sub-sample (n=7) a test-retest correlation was found at an acceptable level of $r = .7$, and the scale mean differences were not significantly different. On a small clinical sample (n=5) measured before and after an intervention the change in the total scale score means were significantly different ($p = .0001$). Construct

validity was established during development. The PSWU is designed as a multidimensional scale but the domains have yet to be established with factor analysis. The scale is 16 items, self-report with 4-point Likert levels of agreement anchored at completely disagree and completely agree.

Quality of Life

Quality of Life was measured by the Satisfaction with Life Scale (SWLS) (Diener, Emmons, Larsen, & Griffen, 1985). This scale has been used in the SCI population and was found to significantly correlate with pain interference (Putzke et al., 2002). The scale consists of five statements with levels of agreement rated on a 7-point Likert scale anchored at strongly disagree and strongly agree. It is considered a one-dimensional scale measuring general well-being.

Process Measures

Other clinical process measurements were taken during the course of this research project including lower extremity range of motion, leg length and wheelchair measures. The on-site investigator, using goniometry, evaluated lower extremity passive range of motion measures. Goniometry is a well-established method of measuring motion at various joints of the body and is a standard procedure of evaluation for occupational and physical therapists. The skill of goniometric measurement is taught at technical and junior college level to Physical Therapy Assistants. It is usually accorded a single session in a laboratory setting for instruction in the technique for a particular joint measurement. The three

goniometric measurements required for the study were demonstrated to the site investigators during the training visit and demonstrated back to the PI. Written instructions with pictorial examples were included in the site training manual. The goniometric measurements were not outcome measures but were used by the PI for determining the wheelchair configuration change recommendations. Goniometry has a known inter-rater reliability of 5 degree error.

Leg length measurements were taken as a simple linear measurement with a metal tape measure between the mat surface and the posterior aspect of the flexed knee. Not maintaining the knee at 90 degrees of flexion or misreading the tape measure can cause error in this measurement. The technique for measurement was demonstrated to the site investigators during the training visit and demonstrated back to the PI. Written instructions with pictorial examples were included in the site training manual. This measure was not an outcome measure but was used in the determination of wheelchair configuration change.

Wheelchair measurements were made with a metal tape measure. Instructions, demonstration and practice by the site investigator or wheelchair technician were done during the training visit and all measurements had written instructions and pictorial examples in the site training manual. Wheelchair measurements were not outcome measures but were used in the determination of wheelchair configuration change recommendations.

Figure 4 illustrates the flow of procedures. The subjects once enrolled, completed a series of baseline measures and were then randomized to group, either teleconsultation or clinic. Depending on the group they were then scheduled into the next open clinic time or continued with an appointment with the site investigator. The same clinical information was obtained during the appointments for both groups with the use of an intake interview template and guidelines for PROM evaluation, wheelchair measurement and photographs. The seating specialist clinician (PI) typically included additional assessments or questions during the clinic visit and no attempt was made to restrict the performance of the 'gold standard' in-person seating clinic. The seating clinics also included empirical trials, which were not a component of the teleconsultation intervention group. In addition to the potential added clinical assessment as a component of the clinic intervention there was also a difference in the number of appointments. The in-person seating clinic was one long session (3 hours) with a follow up by phone or if needed in clinic the next day. The teleconsultation group was scheduled for 3 separate appointments each approximately one hour long.

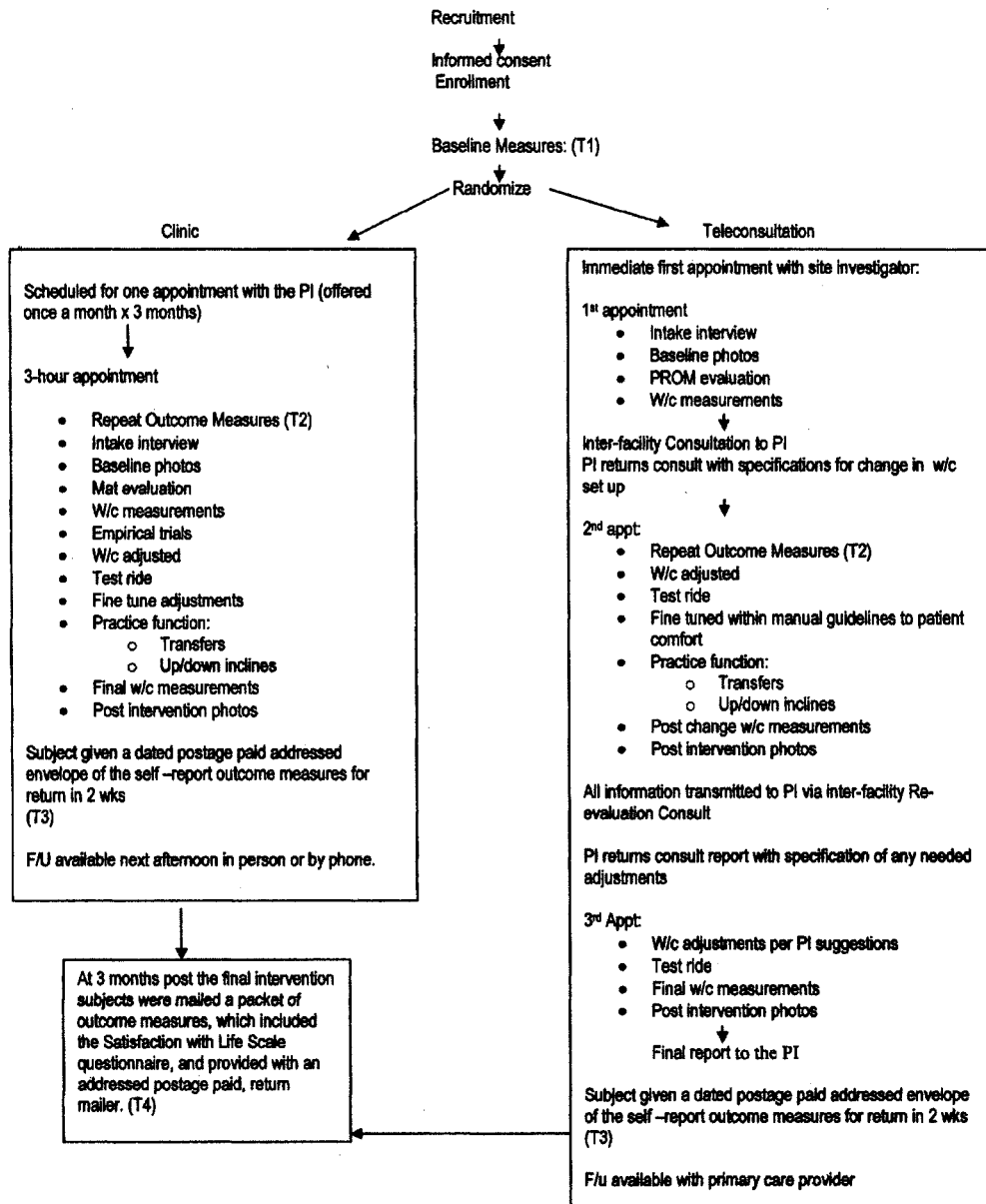


Figure 3: Flow of Procedures

Details of Clinic Appointments

The subjects randomized to the teleconsultation group were planned to have a series of structured appointments following protocol. The planned appointment protocol was as follows: Upon arrival the subject will transfer (with assistance provided as needed) to an evaluation mat and intake lower extremity passive range of motion (PROM) numbers will be recorded. While the subject is out of his wheelchair, specific measurements of the wheelchair will be taken following an intake form. A marker will be placed on the right seat rail 2 inches forward of the backrest. The subject will then transfer back into his wheelchair, and be asked to assume their usual comfortable sitting position. Two photographs will be taken following protocol from the front and the right side of the subject. The subject will be scheduled for an intervention appointment 2 weeks from the date of the baseline appointment.

At the completion of the intake appointment all the intake information is to be immediately transmitted by inter-facility consultation to the seating specialist clinician (PI) for synthesis and determination of the wheelchair configuration change specifications. The seating intervention plan will be custom designed and a specific plan for wheelchair configuration changes will be transmitted back to the site and will be confirmed with the site investigator one week prior to the interventional appointment to insure all necessary material and equipment is obtained and present at the interventional appointment.

When the subject arrives for the intervention appointment (teleconsultation appointment #2) they will be asked to repeat the outcome measures. They will then get out of the wheelchair so that the changes can be made to the chair. After changes, the subject will return to his wheelchair. The subject will take a supervised test ride of their wheelchair, which will include safety checks for functional wheelchair mobility to insure the patient is secure in the newly configured wheelchair. If necessary the wheelchair will be fine tuned within the manual guidelines to patient comfort. Once no further configuration changes are necessary (the subject is comfortable and safe in the changed chair) the specific measures of the wheelchair will be recorded (while the subject is out of the wheelchair). Once the subject returns to his wheelchair and assumes a comfortable seated position the two resting position photos, sagittal and frontal plane will be taken. The subject will be scheduled for a follow up appointment in one week, and given phone numbers to call for any untoward occurrences in the intervening week.

Intervention information will be sent to the PI via the inter-facility consultation immediately post appointment. After synthesis of this information the PI may recommend some fine-tuning of interventions at the one week follow up (teleconsultation appointment #3). At follow up appointment photos will be taken when subject arrives. If any further modifications are done at this appointment, more photos and measures will be taken post intervention. If no further wheelchair modifications are performed the appointment will be used to practice functional

activities or transfers or wheelchair skills, which may be changed with the wheelchair configuration.

In practice there were some variations from this protocol, some of the variations were due to the technical difficulties with the inter-facility consultations and will be discussed in a later section, others were simply scheduling difficulty with the site investigators joint obligation to provide clinical care and to work on this study, especially when meshing with the subjects' personal scheduling conflicts. Site 1 worked with a wheelchair technician, which increased the complication for scheduling and created some confusion about who was acquiring equipment. In one case, even though the PI had provided the prescribed equipment for the purpose of use in the study, the equipment was ordered through usual VA purchasing process and this significantly delayed the intervention. The subject who withdrew without completing the intervention (teleconsultation Site 1) had a similar delay caused by equipment acquisition.

At the end of the session in which the wheelchair changes were finalized all subjects in both groups were given a packet of outcome measures (T3). The packet was dated on the outside with the date to return the completed packet. The T3 packet was returned in a postage paid envelope. The PI sent a reminder note to each subject in the week they were to complete the T3 packet. The PI also made phone call reminders to all subjects within 3 days of the hoped for outcome measure completion.

Three months post the date of the completed intervention the PI mailed a packet of outcome measures (T4) to the participant. This packet included repeat instructions and a letter thanking them for participation and requesting any unstructured information they wished to share in addition to the information on the questionnaires. The T4 packets were returned in postage paid envelopes.

Data Analysis

The data were coded and double entered into Excel (Office 2000) spreadsheets for cleaning. The cleaned data were imported into SPSS (11.5) for statistical analysis. Demographic and baseline data were analyzed to determine if there was any difference between the study groups. Distributions of data were evaluated for normalcy and where normal distribution was present parametric statistics were used and when the data was not normally distributed non-parametric statistics were used.

This study was designed with two independent variables: treatment group (with 2 levels) and time (with four levels) (Figure 5). Outcome measures were assessed at each time with the exception of the Satisfaction with Life Scale, which was assessed only at T1 and T4.

	T1	T2	T3	T4
Clinic	No Rx	Intervention		No Rx
Teleconsultation	No Rx	Intervention		No Rx

Figure 4: Schematic of Study Variables

The interval between T1 and T2 was planned as 2-4 weeks in duration but tended to vary with the shortest interval at one week. The interval between T2 and T3 was planned to be two weeks, with T2 being collected at the beginning of the intervention appointment and T3 returned by mail two weeks after the intervention. Because T3 was collected by mail the exact date of completion is not known but all T3 data packets were received within 4 weeks. The interval between T3 and T4 was planned to be 3 months, again there is some variability due to the return by mail of the T4 packet.

Specific Aim #1, which reads: Determine if improved outcomes, including a reduction in musculoskeletal pain, will occur following improved posture in persons with SCI who use manual wheelchairs full-time, addresses the efficacy of the intervention. Analysis of the proximal outcome measure tests hypothesis #1 which is: Wheelchair configuration changes will change seated postural alignment. The SH measurements before and after intervention were analyzed for difference and direction. The mean change value was used with a Student's t-test for this analysis.

Planned pair-wise comparisons of the mean scale scores at baseline and post-intervention, and between the post-intervention and longitudinal scores were analyzed to test hypothesis #2 which reads: Health outcome measures will improve after postural change. Correlations between the change in scale scores and change in seated height were also analyzed.

The second Specific Aim of this study, which reads: Evaluate the feasibility and effectiveness of providing seating intervention through teleconsultation, was not evaluated with a statistical analysis. Because the hoped for finding was that there would a beneficial change in the teleconsultation group and yet that there would likely be more benefit in the clinic group there is not an appropriate statistical analysis to evaluate this question. The patient centered benefit of the teleconsultation was explored and time spent on teleconsultation communications, downtime from computer inaccessibility and any other threats to feasibility were documented.

STUDY RESULTS

Participants

Solicitation, Enrollment and Retention

Solicitation of participants was primarily accomplished by direct mailing to potentially eligible subjects who were enrolled in two spinal cord injury clinics within the VA Health Care System. The clinic coordinator at each site compiled a list of names and addresses from the computer registry of all individuals enrolled in their clinic with the designated ASIA impairment levels for inclusion. At least one clinician familiar with the caseload of the clinic sites reviewed the list and eliminated names of those known to either not fit the remaining inclusion criteria or have medical issues that excluded them from participating. The group on the final list was then mailed an informational letter inviting their participation in the study. Those who had not responded to the first mailing were sent a reminder postcard one month later. The informational letter was also printed in the statewide Paralyzed Veteran's of America (PVA) newsletter. Flyers were also posted in each facilities outpatient clinic waiting areas.

In total 40 letters were mailed, responses were received from 16 persons in the initial mailing and two responded to the postcard. The posting in the PVA newsletter resulted in only one additional response, for a total of 19 responses. The

response was disproportionate across the sites with 12 responders in Site 1 and 7 in Site 2 (Table 1).

Table 1: Recruitment

	Site 1	Site 2
Mailed/response	18/11	22/7
Advertisement response	1	0
Enrolled	7	6

There is no means to compare responders to non-responders given that the only information known to the PI is the ASIA impairment levels; there was no difference on this measure. Of the 19 individuals who were assessed for eligibility, six were enrolled at Site 2 and seven at Site 1.

Five individuals were excluded from enrollment because they did not meet the eligibility criteria, and one declined after clarifying the time commitment. Final enrollment included thirteen subjects who were randomized between two treatment groups. Seven were assigned to the clinic group and six to the teleconsultation group. Block randomization was done, stratified by site, in order to insure distribution to both groups. The informed consent process was completed by the site investigator and all subjects had signed the informed consent prior to randomization.

Demographics

Thirteen subjects enrolled in the study however two withdrew after enrollment and therefore are not included in the analysis. All subjects were male. All had motor complete thoracic paraplegia. Table 2 shows the key demographics of the sample.

Table 2: Key Demographics

Variable	Range (mean)
Age	40-84 (54)
Yrs of wheelchair use	5-33 (18.6)
No. of transfers	4-90 (21)

The participants (n=11) ranged in age from 40 to 84 years with a mean of 54 years. The mean age was skewed due to two subjects over 80 years old. By chance both of these subjects were randomized to the clinic group. Thus, there was an age difference between the groups; the clinic group (n=6) ranged from 47 years to 84 years (mean 61) and the teleconsultation group (n=5) ranged from 40 years to 55 years (mean 46).

The marital status of the sample varied, the most common category was divorced (n=4), followed by married (n=3). Two individuals self identified as single and two as widowers. There was no difference between groups in terms of marital status. The majority of the sample was not currently employed (n=7). One of the participants was not a veteran; this was the only participant who identified as

employed at a full time level. Three other participants indicated employment, one at thirty hours a week and the others at half time.

The body mass index (BMI) for all participants was calculated from the height and weight information extracted from the medical records. BMI ranged from 21 to 30.5 with a mean of 24.5. There was no difference between groups on this measure.

The years of wheelchair use of all participants ranged from 5 years to 33 years with a mean of 18.6 years. This was well distributed between groups with the clinic group ranging from 8-29 years (22.7) and the teleconsultation group from 5-33 years (13.8) though the mean years of wheelchair use was lower in the teleconsultation group.

All participants indicated an ability to drive, five individuals reported driving a van with a lift and four a car, the remaining two reported a trunk/sports utility vehicle or other. There was no difference between groups in terms of the vehicles used.

The number of transfers reported on a daily basis ranged from 4-90. The individual stating 90 daily transfers was queried for accuracy of this answer and replied, "it is at least that". The mean number of reported daily transfers was 21. All but one participant reported that they were independent in transfers, the remaining individual required assistance and use of a transfer board. In both the clinic group and the teleconsultation group there was one outlier on the number of

transfers reported. The individual reporting 90 daily transfers was in the teleconsultation group while the individual who reported dependent transfers and stated they only did four transfers a day was in the clinic group. The advanced transfer skill of off-the-floor transfers was reported by 6 of the 11 participants. Wheelchair skills were a mix, with 7 of 11 reporting the ability to jump up four-inch curbs and only 5 of 11 reporting the use of a wheelie to descend a steep incline. In general, the teleconsultation group had a higher level of wheelchair and transfer skills.

Two of the eleven participants reported shoulder pain prior to wheelchair use in the medical history component of the baseline questionnaire; five individuals reported current shoulder pain (one of whom reported the shoulder pain prior to wheelchair use). Neck pain and back pain prior to wheelchair use were each reported on one out of eleven questionnaires; with current neck pain reported on two and current back pain on six of the eleven questionnaires. By chance all of the participants reporting pain prior to SCI were assigned to the teleconsultation group. Four of the five participants reporting current shoulder pain on the medical questionnaire were assigned to the clinic group. Both participants with current neck pain were assigned to the clinic group and four out of six reporting current back pain were assigned to teleconsultation.

Lost To Follow Up

All participants (n=11) completed the post intervention outcome measures. Two subjects were lost to the longitudinal follow up. One subject (clinic) became ill and was hospitalized; resolution of the hospitalization is not known. The longitudinal data were for the purpose of examining the stability of any change post intervention. Because the intervention was to the wheelchair (wheelchair configuration change) data from an individual who spent a considerable amount of time confined to bed would not reflect on the intervention. The second subject (teleconsultation) lost to follow up did not respond to requests for the final packet. Figure 6 shows the flow of participants from recruitment through analysis.

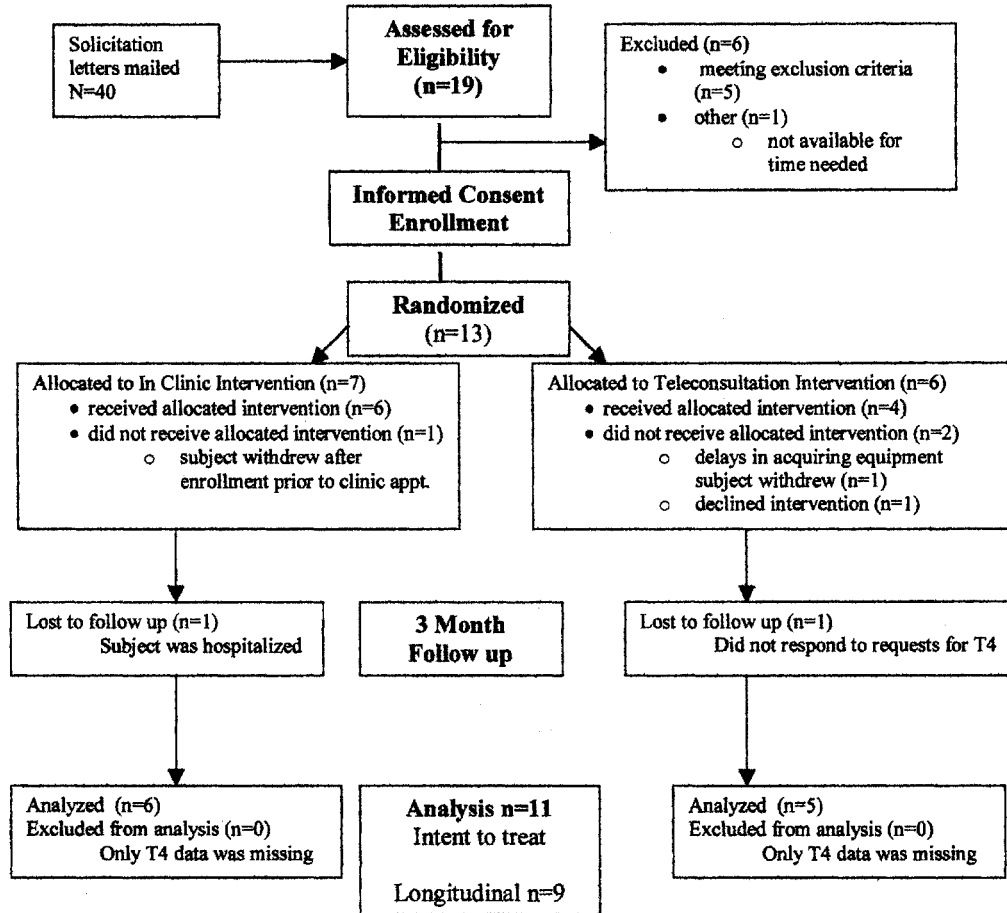


Figure 5: Tracking Participants through the Study

Intervention

Delivery of the Intervention

The planned delivery of intervention for the clinic group was one long single session appointment with an available follow up on the next day. One of the

six participants in the clinic group required the second day appointment; in all other cases the participants were seen one single session for duration of 1.75 to 3 hours. The one second-day appointment (1.5 hours) was at the clinician's judgment due to extensive configuration changes. All participants were contacted by phone on the day after configuration changes were completed to determine if a follow up was needed and all declined stating they had no concerns with the changes to their chairs in their home environments.

The planned delivery of intervention in the teleconsultation group was over the course of three one-hour appointments (intake, intervention, fine-tuning). The intake appointment followed enrollment and consent for those randomized to teleconsultation and consisted of physical measurements of the lower extremity and measurement of the current wheelchair configuration, and photo documentation of current sitting posture. The intervention appointment was planned to be scheduled prior to subject's departure from the first appointment and was to be scheduled for two weeks hence. The intake information was sent via inter-facility consultation to the seating clinician, who then returned a completed consult with the instructions for specified wheelchair configuration changes. Appointment number two (intervention) was anticipated at one hour duration for the changes to the wheelchair; in all cases the duration of this appointment was in excess of one hour. At the completion of this appointment the plan was for the site investigator to send a progress report and photo documentation of outcome to the PI. The third

appointment, intended to be scheduled one week hence, was for the purpose of fine-tuning the wheelchair changes based on the seating clinician's evaluation of the outcome photographs. In all cases of teleconsultation the instructions after the first intervention appointment were more than fine-tuning. They were instead *corrections* of misapplied changes. The deviations were recognized upon inspection of the post intervention photograph. Teleconsultation appointments at Site 2 required 4 appointments in 2 of the 3 participants. Teleconsultation appointments at Site 1 exceeded 5 appointments in all cases. One subject from this site withdrew due to excessive time demands (he had yet to receive any intervention by his third visit because of equipment confusion). The limitations and obstacles for teleconsultation delivery of this intervention will be discussed in depth in a later section.

Configuration Changes

The intervention in this study was *postural change*; wheelchair configuration modification to improve the orthotic postural support provided by the wheelchair was the mechanism of obtaining this intervention in a population with truncal paralysis secondary to SCI.

The participants all had unique combinations of wheelchair, cushion and backrests (Table 3). All of the wheelchairs used by subjects in this study were classified as Ultralight manual wheelchair (Medicare K0005) except one, the Invacare 9000, and this wheelchair was replaced with a K0005 wheelchair at the

completion of the study. Six of the eleven wheelchairs were manufactured out of titanium. Six of the wheelchairs were rigid frame wheelchairs with customization of the features.

Table 3: Presenting Equipment Combinations of The Subjects

Wheelchair	Cushion	Backrest
Invacare 9000	Latex Foam	Upholstery
Tilite X	Roho High Profile	Jay2
Quickie DT	Roho Low Profile	Upholstery
Invacare A4	Jay2	Jay2
Quickie Ti	Roho High Profile	Varilite Fast Box
Quickie Ti	Roho High Profile	Jetstream
Tilite SX	Varilite Solo	Adjustable Upholstery
Hall Hallmark	Stimulite	Jay Extreme
Quickie 2	Jay Extreme	Upholstery
Topend Terminator Ti	Roho High Profile	Upholstery
Tilite SX	Roho High Profile	Upholstery

All of the cushions used by the participants in this study are marketed as appropriate for high skin risk with the exception of the Jay Extreme, which is marketed as appropriate for moderate skin risk, and the foam cushion that is not appropriate for this population (this cushion was replaced prior to baseline at onset of study). Three of the eleven cushions are also marketed as pelvic positioning products. Five of the eleven participants had after market backrests on their wheelchairs. All are marketed as improving postural support and all but the Jet Stream offer angle adjustability.

The seat slopes prior to intervention ranged from a minimum of .06 to a maximum of .39 and a mean slope of .12. Seat slope is the ratio of the difference

between the front and rear seat to floor height divided by the seat depth. The participant with a slope of .39 was in a custom fixed-frame wheelchair and there was no ability to adjust the slope within the constraints of this study. When eliminating his data the range was .06 to .25 with a mean of .10. An important component of the seating intervention was a change in the seat slope. The mean increase in slope after intervention (n=11) was .06 (95% confidence interval .027 to .101) which was statistically significant at $p=.003$.

Changes to the backrest configuration were also a component of the intervention. In all cases where the backrest angle was changed (n=9), the change was to close the angle (bring the backrest canes more forward, out of recline). One subject included in the analysis (intent to treat) participated in data collection but refused any wheelchair configuration changes. Another subject had a fixed-frame wheelchair, which would not allow backrest angle changes.

These wheelchair configuration changes resulted in an overall decrease in the inside seat-to-back angle. The components of this change are the backrest position and the slope of the seat plane. The mean change in composite inside seat-to-back angle was a decrease of 3.4 degrees, which was statistically significant at $p=.001$ (95% confidence interval 1.85 to 4.87). Figure 6 illustrates the change in wheelchair configuration.

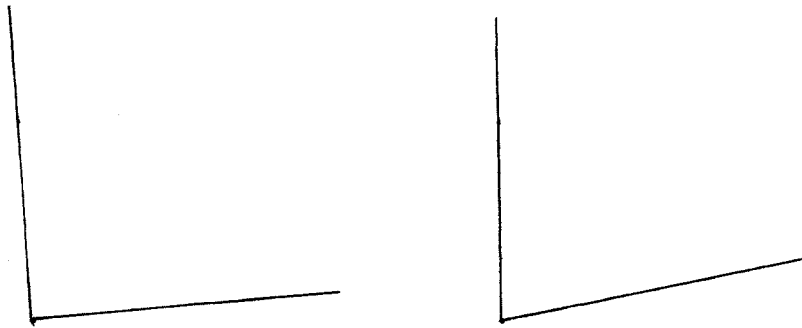


Figure 6: Relative Chair Configuration

Schematics are based on the mean slopes and mean backrest angles before and after intervention.

Additional backrest changes included change to equipment and height. No after market backrest was removed, in one case a Jay 2 backrest was installed to replace upholstery, and in two cases adjustable tension upholstery was installed to replace standard upholstery. The change in backrest height was usually to lower the height; this was done in 5 of the 10 individuals accepting intervention. Each of these subjects was using upholstered wheelchair backrests and the average amount of decreased height was 1.4 inches. In two cases, both with after market backrests, the height of the backrest was raised, this was done to appropriately align the contours of the after market backrests to the anatomical curves of the user. In the other three cases the backrest height was not changed.

Footrest height was infrequently changed. Footrest height was raised in 2 subjects and lowered in one. No changes were made to seat width or depth or footrest drop angle.

Results and Discussion Of Specific Aim #1

Specific aim #1: Determine if improved outcomes, including a reduction in musculoskeletal pain, will occur following improved posture in persons with SCI who use manual wheelchairs full-time.

Specific objectives of pre and post intervention assessment tested the following hypotheses.

Hypothesis #1 Wheelchair configuration changes will change seated postural alignment.

Hypothesis #2: Health outcome measures will improve after postural change.

Objectives:

1. Determine the change in seated height measurement as an indicator of postural alignment.
2. Determine the change in self-reported pain on two Visual Analog Scales and Pain schematic.
3. Determine the change in self-reported functional impact of pain on a Pain Interference Visual Analog Scale and the Wheelchair User's Shoulder Pain Index.

4. Determine the change in self-reported posture on the Postural Scale for Wheelchair Users.
5. Determine the change in self-reported scores on the Satisfaction With Life Scale.

Post Intervention Results

Table 4 summarizes the results of the proximal outcome measure.

Table 4: Paired T test results for the Proximal Outcome Measure

Proximal Outcome	Mean change	Std Dev	P value	95% Confidence interval	
Seated Height	+ 1.01 (inches)	1.32	0.03*	0.13	1.9

*significant at p=.05

Change in Postural Alignment

The proximal outcome measure of Seated Height was used to assess change in seated postural alignment. The post intervention increase of 1.01 inches in Seated Height was statistically significant (p=. 03; 95% confidence interval of .13 and 1.9). The first hypothesis of the study which reads: wheelchair configuration changes will change seated postural alignment, was therefore supported.

Health Outcomes

Psychometrics. All of the instruments used for distal outcome measures showed good internal consistency in this sample. The Cronbach's alpha values for each scale are listed in Table 5.

Table 5: Psychometrics of Instruments

Scale	Cronbach's Alpha
Wheelchair Users Shoulder Pain Index	0.95
Posture Scale for Wheelchair Users	0.80
Satisfaction with Life Scale	0.81

The second hypothesis of this study which reads, health outcome measures will improve after postural change, was tested by analysis of the distal outcome measures. The distal health outcomes were measured by self-report questionnaires. The original data analysis plan was to compare baseline (T1) and a second baseline measurement (T2) for stability of the scales and examine the difference between change scores at T2 and change scores after the intervention (T3). However, a number of subjects neglected to complete the T2 outcome measures due to site investigator error. Therefore, in light of the small sample size, comparisons were made between scores at T1 and scores at T3. These data points represent baseline and two weeks post intervention. Table 6 presents the results for the paired t test of the outcome measures comparing baseline and post intervention measures (n=11). The second hypothesis is partially supported by these results.

Table 6: Paired T test results for the Distal Outcome Measures

<i>Distal Outcomes</i>	Mean change	Std Dev	P value	95% Confidence interval	
Wheelchair Users Shoulder Pain Index (WUSPI)	- 9.61	12.2	0.03*	- 18.34	- 0.87
Pain Intensity worst current	- 1.18	1.69	0.04*	- 1.18	- 2.31
	+ 0.58	1.83	0.32		
Pain Interference	- 0.83	2.77	0.34		
Posture Scale for Wheelchair Users (PSWU)	- 1.91	6.46	0.35		

* Significant at p=0.05

For the distal outcome measures declining scale score is indicative of improvement

Wheelchair Users Shoulder Pain Index (WUSPI). One subject was excluded from analysis on this instrument because there were notations on his form that indicated he was answering pertaining to groin pain. The internal consistency of the scale in this sample was good with a Cronbach's alpha of 0.95. The range of scores at baseline was between 0 and 62.6 and the range after intervention was between 1.35 and 30.5 on a scale that ranges from 0-150 points. The direction of change was favorable (decreasing total scale score) with the mean change of -9.6 points. The mean change was statistically significant (p=.03) with a 95% confidence interval of -18.34 and -0.87.

Pain VAS. The VAS for Pain was used to score the current pain and the worse pain in the last three days. The range of scores for Worst Pain Intensity at baseline was between 1.0 and 9.7, and the range after intervention was between 0.2 and 9.2 on a scale that ranges from 0-10 points. Worst Pain intensity scores decreased after intervention with the mean change of - 1.18 points. The mean change was statistically significant (p=.04) with a 95% confidence interval of -2.31 and -0.04.

The range of scores for Current Pain Intensity at baseline was between 0 and 6.8 and the range after intervention was between 0 and 7.9 on a scale that ranges from 0-10 points. Mean Current Pain Intensity scores were unchanged after intervention ($p=.32$).

Pain Interference. A VAS was used to measure Pain Interference. Subjects were asked to indicate how much any pain above their level of spinal cord injury had interfered in their ability to perform usual activities in the past week. The range of scores for Pain Interference at baseline was between 0 and 9.5 and the range after intervention was between 0 and 5.3 on a scale that ranges from 0-10 points. Mean Pain Interference scores did not change after intervention ($p=.34$).

Posture Scale for Wheelchair Users (PSWU). The internal consistency of the scale in this sample was adequate with a Cronbach's alpha of 0.8. The range of scores on the PSWU at baseline was between 9 and 33 (21) and the range after intervention was between 6 and 33 (19) on a scale that ranges from 0-48 points. Mean PSWU scores did not change after intervention ($p=.35$). The PSWU is a multi-dimensional scale and the subscale changes will be examined in the discussion.

Correlation. None of the change scores on the distal outcome measures correlated significantly with the change in SH. Relationship trends were seen between the change in SH and change in the total scale score on the PSWU as well

as between the change in Pain Interference and the change in seat-to-back angle (an indication of the amount of intervention).

Longitudinal Results

The longitudinal results were collected by self-report questionnaires (T4) mailed to the participants at 3 months post completion of the intervention and returned by mail in a postage paid addressed envelope. Reminder calls were made as necessary. The average time between mailing out T4 packets and the receipt of the completed packet was 3.5 weeks; the quickest turn around was in one week and the slowest at 6 weeks. The longitudinal data therefore reflects, on average, nearly 4 months post intervention.

One individual was lost to longitudinal follow up due to hospitalization; a second did not return the T4 packet after reminders by mail and telephone. For longitudinal analysis n=9 unless otherwise noted. Table 7 summarizes the longitudinal results for planned comparisons.

Table 7: Paired T test results for comparison of T3 and T4 (3-month follow up)

Outcome measure	Mean change	Std Dev	P value	95% Confidence interval	
Wheelchair Users Shoulder Pain Index (WUSPI)	8.66	8.14	0.01*	2.4	14.9
Pain Intensity worst current	1.12	1.34	0.05*	0.0	2.24
	0.35	2.20	0.67		
Pain Interference	1.47	2.33	0.09		
Posture Scale for Wheelchair Users (PSWU)	0.11	5.37	0.95		
Satisfaction with Life Scale (SWLS)	-1.89	7.64	0.48		

* Significant at p=0.05

On all outcome measures the higher the total scale score the more of a problem, with the exception of the SWLS where a higher score reflects higher satisfaction with life.

Wheelchair Users Shoulder Pain Index (WUSPI). The range of scores after intervention was between 1.35 and 30.5 and the range at follow up was between 0.45 and 43.2 on a scale that ranges from 0-150 points. The direction of change was toward baseline (increasing total scale score reflecting increased pain) with the mean change of 8.7 points. The mean change was statistically significant ($p=.01$) with a 95% confidence interval of 2.4 and 14.9. The scores at follow up were not statistically significant from baseline scores.

Pain VAS. In addition to the two subjects lost to follow up a third indicated pain sites on the locator schematic but gave no value for intensity and hence the longitudinal analysis for the Pain VAS are with a sample of 8.

The range of scores for Worst Pain Intensity after intervention was between 0.2 and 9.2 and the range at follow up was between 1 and 10, on a scale that ranges from 0-10 points. Worst Pain intensity scores increased at follow up with the mean change of 1.1 points. The mean change was statistically significant ($p=.05$) with a 95% confidence interval of .001 to 2.24. The scores at follow up were not statistically significant from baseline scores.

The range of scores for Current Pain Intensity after intervention was between 0 and 7.9 and the range at follow up was between 0 and 5, on a scale that ranges from 0-10 points. The mean Current Pain Intensity scores were not significantly different at follow up ($p=.67$).

Pain Interference. The range of scores for Pain Interference after intervention was between 0 and 5.3 and the range at follow up was between 0 and 9, on a scale that ranges from 0-10 points. The mean Pain Interference scores were not significantly different at follow up ($p=.09$).

Posture Scale for Wheelchair Users (PSWU). The range of scores on the PSWU after intervention was between 6 and 33 and the range at follow up was between 1 and 32, on a scale that ranges from 0-48 points. The mean PSWU score were not significantly different at follow up ($p=.90$).

Satisfaction With Life Scale (SWLS). The Satisfaction with Life Scale was used as a measure of Quality of Life (QOL). This measure was assessed at baseline and at the long-term follow up T4. The internal consistency of the scale in this sample was adequate with a Cronbach's alpha of 0.81. The range of scores on this scale at baseline was between 15 and 34; the range of scores at follow up was between 10 and 32. This scale is a Likert agreement scale with possible scale totals ranging from 5 to 35. A higher score reflects a higher satisfaction with life. Mean SWLS score were not significantly different after intervention ($p=.48$).

Qualitative Data

Qualitative data were solicited in an unstructured "comments" page, included in each of the follow up questionnaire packets. The instructions were "feel free to provide any comments on the process, or your outcome, which you think may not be covered in the questionnaires or is something you particularly want the

investigators to know”. Additionally, the subjects had the cell phone number of the PI and had been encouraged to contact her with any questions or concerns throughout the duration of the study. All qualitative data were received immediately post intervention in the T3 packet or by phone in the month after intervention. There were no negative comments regarding the chair adjustments, however, the individual who declined intervention (204) offered some insight into what he considered a negative feature of the suggested change. The transcribed comments are below with an indication if the information was received by phone.

Post intervention unstructured comments.

102 (teleconsultation)

“I feel very stable now, not wobbly in the top like I used to. I definitely like the changes. My chest is back more, my torso more upright. I am not slouching as much, it has improved my posture considerably.” (phone)

“I really appreciate your doing this study and making it nationwide, giving us an opportunity. It is like sex, the best you know is the best you’ve had. We didn’t know how to change things.” (phone message)

“....my new position has changed the way I sit and push with my arms and I can push farther without my shoulders aching.”

104 (clinic)

“I am less fatigued, more comfortable, overall better. Wow!” (phone message)

“I have had many benefits since August 10th. I feel much more comfortable now when I push my chairs. It seems easier to push and with less effort than it did before you adjusted my chairs on the 10th.”

107 (clinic)

“I never knew that comfortable and being in a wheelchair were compatible. I just assumed they weren't. It is like being reborn.” (phone message) *this subject injured for 29yrs

“I believe the wheelchair adjustments made an improvement on my sitting style/posture. I believe this has and will further improve my quality of life.”

201 (clinic)

“I like everything, it is much more comfortable, transfers are no problem. I do have more difficulty with push ups but I can get used to it.”

204 (teleconsultation-declined intervention)

“I am too old to have my legs higher in front.”

205 (teleconsultation)

“The adjustments that--- made to my chair has been very helpful.”

206 (clinic)

“The adjustments that you made to my T-Lite chair has improved my posture, especially when sitting at my computer. I don’t lean on my elbows as much as I used to.”

Discussion

The enthusiastic reports in the subjective comments suggest a clinical meaningfulness that was not appreciated in all of the outcome measures. It may be that the benefits of seating are so individualistic that it is difficult for a standardized measure to be sensitive enough to capture the change. It is important that the proximal measure of SH was found to be statistically significant as this is the measure of the actual postural change. For there to be any value in analysis of the distal outcome measures it was first necessary to have an intervention effect.

The research question was: To what extent does postural improvement matter to the health and well being of the subjects? The post-intervention results were promising with significant changes to both worst pain intensity and the functional cost of pain as measured by the WUSPI. The explanation of the results on the other outcomes may be a measurement issue compounded by a lack of power. The study was powered to show statistical change on the proximal outcome measure of SH. The investigator had pilot study data to show a large effect size of the intervention as measured by SH. The investigator also had separate pilot study

data to support the use of the PSWU in a postural impact study. The PSWU was developed by the investigator and appeared to have good sensitivity to postural change when pilot tested with a clinical sample. While the other instruments have been used in the SCI population, there was no indication of their sensitivity to change attributable to the study intervention.

The instruments for the outcome measures were selected in hopes of capturing a spectrum of potential effects of the postural intervention while imposing a minimal subject burden. The WUSPI and the SWLS are two scales that have been frequently used in the SCI population; therefore the potential for comparison to other interventional impact was a consideration in selecting these instruments. Pain VAS is used clinically and is a common research measurement for pain intensity. The construct of pain interference has been tested using a single item from the SF-36 and in this study a single item pain interference measure was used to capture this construct. Although the instruments were selected intentionally for this study, in hindsight they may have been less than ideal for measuring the effect of this intervention.

Posture

The Posture Scale for Wheelchair Users was designed as a scale to measure the subjective perception of postural problems. In this convenience sample, not specifically recruited for postural problems, (recruitment was for musculoskeletal pain and or discomfort in wheelchair) it is possible that the questions on the scale

and the enrollment in a posture study heightened the participants' attention to postural concerns thereby biasing their future answers on the scale. Floor effect is also at issue. The PSWU was designed as an outcome measure and a clinical screening tool for the need for seating referral. The suggested cut points for seating referral are a total scale score greater than or equal to 50% of the total possible (24) or any subscale score greater than or equal to 75% of the subscale possible (9). The subjects in this study generally had low baseline scores on the scale. Using the recommended clinical referral points, only 5 of the originally enrolled 13 subjects qualified for referral. One of these subjects withdrew from the study; in the four subjects remaining who met threshold, the mean was 29.5 at baseline and 22.25 after intervention. The seven and a quarter-point difference did not reach statistical significance in the small sample but may be clinically meaningful. Two of these four subjects dropped below referral threshold after intervention. It is possible that the sensitivity of the PSWU is such that it will only pick up changes in a clinical population. In other words, if the subject does not meet threshold for a clinical referral for seating intervention at baseline, the scale is not sensitive enough to pick up a change. Figure 7 shows the difference between the entire sample and those who met clinical referral threshold.

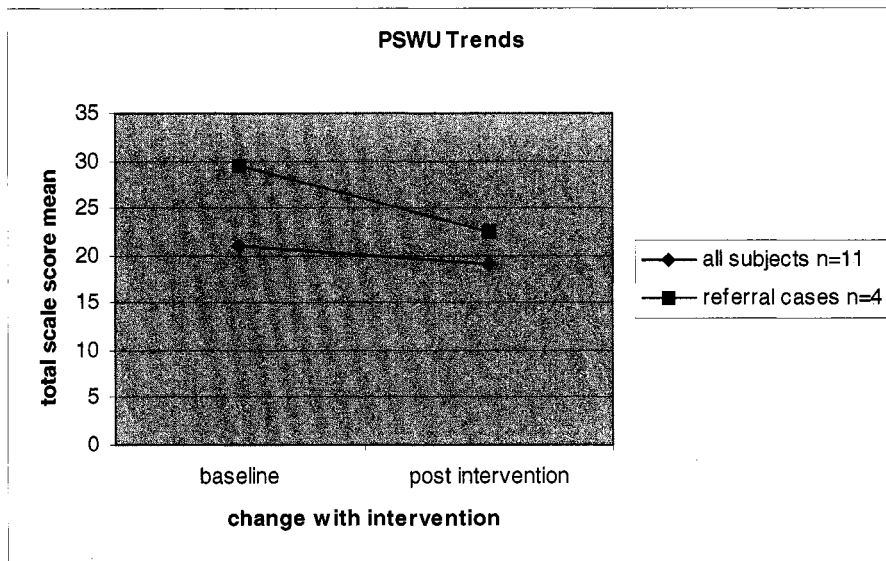


Figure 7: Change in PSWU Scale Scores after Intervention

The comparison is between all the subjects and those cases whose baseline scores on this scale indicated referral for seating intervention.

Furthermore, the intervention may have disproportionately impacted the different sub-scales. The PSWU was developed as a multi-dimensional scale with sub scales for pain, personal aesthetics, health and function. When looking at the subscale changes after intervention it is interesting to note that only personal aesthetics went up (more of a problem) after intervention (Figure 8). In the four clinical referral cases all subscale scores improved but personal aesthetics showed very little change (Figure 9). It is possible that enrollment and participation in a study that directed attention to seated posture increased the subjects' awareness and concern about their personal appearance. The changes in sub-scales scores post-intervention did not show statistical significance.

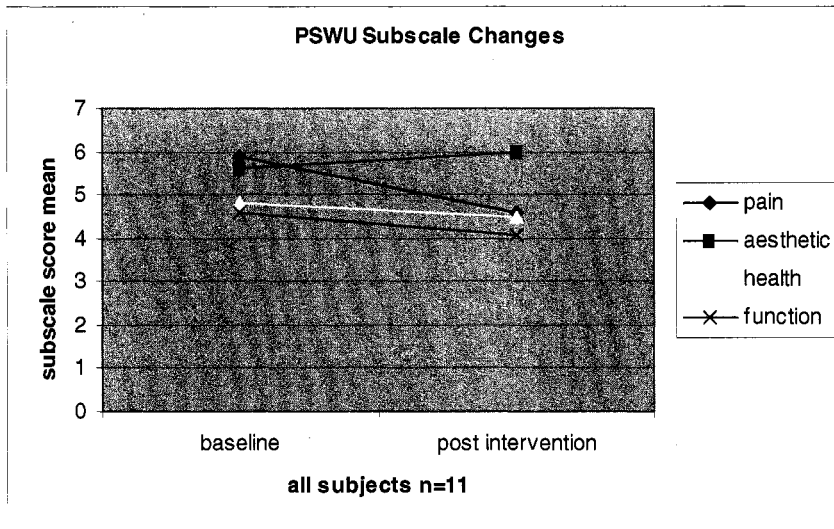


Figure 8: PSWU Subscale Changes after Intervention for the Entire Sample
The subscale of aesthetic shows a worse score after intervention with all other subscales improving.

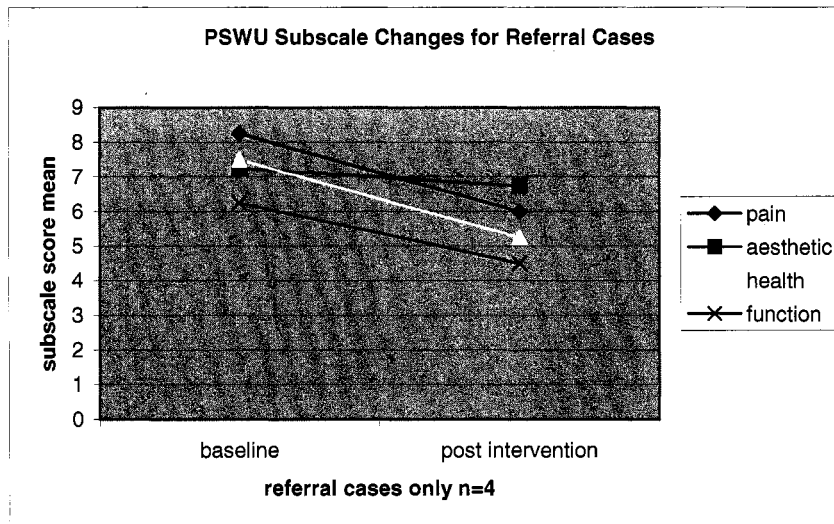


Figure 9: PSWU Subscale Changes for Referral Cases
These cases represent those with baseline scores on this scale indicating referral for seating intervention. In this group all subscales show improvement after intervention, the least change is in the subscale aesthetic.

The single items of the scale were inspected for the area of most impact of the intervention. Acknowledging the multiple comparisons on the data from this small sample, there did appear to be one single item that did show statistically significant change after intervention. Item number 11, which reads “My chair is not supportive enough”, showed significant improvement in the study sample (mean change of 0.45, 95% confidence: 0.10-0.81, $p=.01$). This change showed stability at T4.

Pain

The other four distal outcome indices that were measured post-intervention and again at the longitudinal point, pertained to pain and were therefore extremely susceptible to confounders during the follow up period. Participants were instructed to not change their wheelchair, cushion or backrest configuration for the duration of the follow-up without alerting the researcher. They were also asked to report any medication changes; none were reported. In the four months between intervention and follow-up there were many factors of life left uncontrolled. All of the pain outcome measures were susceptible to influences outside of the impact of the intervention. For instance, one subject wrote a letter in his T4 packet explaining that he was “sorry about the increased pain” and said he “knows he is sitting better” but his power assist wheels were broken and had been for the months prior to his completing the T4 packet. Power assist wheels are motorized propulsion of the wheelchair actuated by the hand-rims. Without the power assist the individual’s roll

resistance was significantly increased, and due to his habitual use of power assist wheels, his fitness and endurance for propulsion without the assist were severely compromised. This situation would directly and negatively influence his scores on the Pain VAS for current and worse pain, pain interference measure and the Wheelchair Users Shoulder Pain Index. Another participant suffered a specific traumatic back injury with a known mechanism. The back injury was not related to the change in wheelchair configuration but significantly and negatively influenced his scores for current and worst pain and pain interference.

With intent to treat analysis the data of both of these subjects are maintained in the longitudinal analysis. Additionally, two other subjects who were essentially controls are also included in the analysis. One subject had a wheelchair that was very customized and fixed frame and could allow only the most minor adjustment. The other individual explicitly declined intervention and received none. Figure 10 shows the total scale scores of this single subject over the course of the study. The most variability is in the performance corrected WUSPI; however baseline and longitudinal scores are essentially the same. All of the other measures were fairly stable with pain VAS scales and SWLS showing slight worsening.

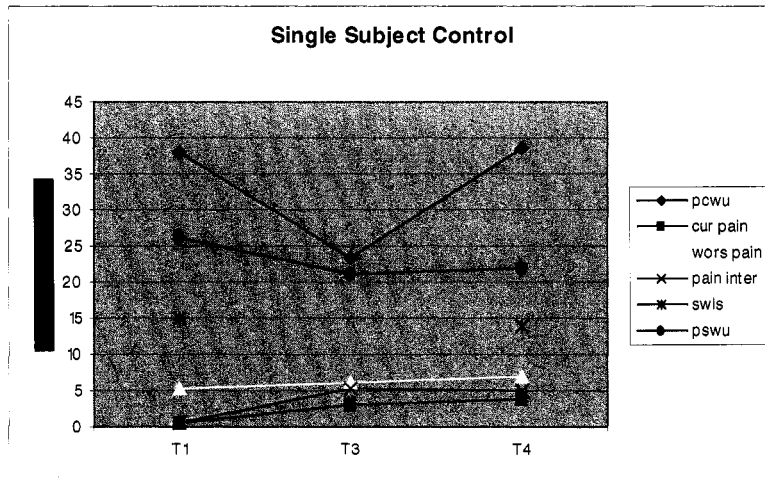


Figure 10: Single Subject Control
Stability of the scales in the single subject who did not receive intervention.

Pain VAS. The Pain VAS measures may have also had some problems with clarity. The pain interference measure specifically asked the respondent to report how much “any pain above the level of your spinal cord injury interfered”, but neither the current nor the worst pain intensity lines restricted the pain to above the level of SCI. Because many of the participants indicated pain sites on the pain locator schematic that were below the level of injury it is difficult to be certain that the pain interference was actually restricted to above injury sources. The intervention in this study was designed to address musculoskeletal pain from a postural source or upper limb musculoskeletal pain due to poor biomechanics in the upper limb. Neurogenic pain, which is the most likely type of pain identified below the level of SCI, would not be addressed with this intervention.

WUSPI. This measure showed significant improvement immediately post intervention with a significant return toward baseline at the longitudinal

measurement. The Wheelchair User's Shoulder Pain Index is a one-dimensional scale, which reflects the functional cost of shoulder pain. The scale has a range from 0-150. The baseline range of scores in this sample was from 0 to 62, which means the entire sample's scores were in the lower 40% of the scale. This lack of heterogeneity may have affected the sensitivity of the scale. After intervention the range of scores was between 1.35 and 30.5. Therefore all scores were in the bottom 20% of the scale. The T4 movement toward baseline was statistically significant but the mean scores ranged between 0.45 and 43, therefore still in the bottom 28% of the scale. This change was statistically significant but may not be clinically meaningful. Because many of the baseline and post intervention scores were at the bottom of the scale they would have a tendency to increase due to regression toward the mean.

The scale has 15-items on which the subject rates his shoulder pain while performing the cued task. Table 8 provides the cues for each of the items that showed the highest scores in this study sample. Prior work by the PI had found that the most common shoulder complaint was with overhead reaching activity (Young et al., 1995) and this is supported by item 07 of the WUSPI being amongst the highest mean scores.

Table 8: Items from the WUSPI

Item cue	Baseline Mean
03: transferring from a wheelchair to a tub or shower	2.9
04: loading your wheelchair into a car	2.5
07: lifting objects down from an overhead shelf	2.2
05: pushing your chair for 10 minutes.	2.0

The intervention in this study was postural change and would be theoretically expected to directly impact the last two items. After intervention the mean score for item 07 decreased to 1.5 and the mean score for item 05 decreased to 1.05. Neither single item change was found to be statistically significant, but may reflect the clinical meaningfulness reported in the qualitative comments. Item 05 showed a trend toward significance at $p=.06$.

Pain Location. Subjects indicated the location of their pain on a schematic. Figure 11 shows the schematic upon which the pain locations were indicated, the location codes were added for analysis. Subjects could indicate multiple locations for pain. At baseline two subjects indicated no current pain and no subjects indicated specific shoulder pain. The majority of the pain sites indicated were located in the axial trunk with indication at the neck, upper thoracic, lower thoracic and lumbar regions (sites 1, 3, 5 and 6) reflecting 83% of the pain sites indicated. At T3, after intervention, 63% of the reported pain was located in the axial trunk with no sites indicated in the neck. One subject, who declined intervention, reported new pain in bilateral shoulders at T3. At the longitudinal assessment 38%

of the reported pain was located in the axial trunk, with two subjects reporting no current pain.

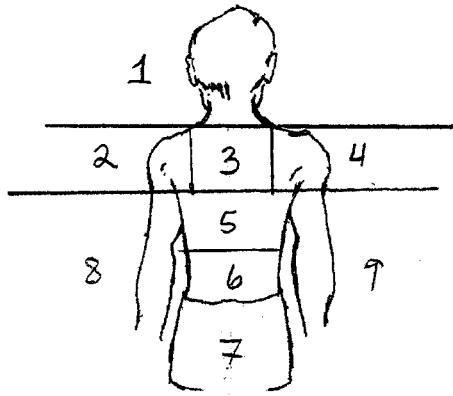


Figure 11: Pain Locator Schematic with Overlay of Coding

The high prevalence of the postural pain at baseline and the decline in postural pain after intervention supports the PI's theorized mechanism of musculoskeletal pain in this population. The discrepancy between pain location when specifically asked to indicate the site of pain and the scores on the "shoulder pain" index also supports the PI's hypothesis that postural pain can be misrepresented as shoulder pain. Many subjects who indicated no sites of pain in the areas coded 2 and 4 on the schematic scored the items of the WUSPI indicating shoulder pain with activity. Although pain may manifest in activities tested on the WUSPI and may even be perceived in the shoulders, if the cause is postural

malalignment any treatment directed specifically to the shoulder will not be successful.

Quality of Life

In this study there was no significant change found in the measure of QOL after intervention. Post and Noreau (2005) suggest that there are three main approaches to looking at QOL which include: Health-related quality of life, well-being and QOL as a superordinate construct. Diener's Satisfaction with Life Scale (SWLS) is designed to measure global cognitive judgments about one's life. It is a subjective well-being scale. It was selected, in part, because it does not bias negatively for individuals with physical disability. However, because it is not a health related quality of life tool it may be less sensitive to change after a clinical intervention directed at impairment.

Results and Discussion Of Specific Aim #2

Specific Aim #2: Evaluate the feasibility and effectiveness of providing seating intervention through teleconsultation.

Hypothesis #3: Successful seating interventions are possible via a distance medicine model.

Objective:

1. Determine the feasibility of using the inter-facility consultation feature of the computerized medical record of the VA HealthCare system as a secure data transmission of photographic and textual documentation for 'store and

forward' teleconsultation provision of an effective postural seating intervention.

Process

The inter-facility consultation, which was the basis of the teleconsultation delivery of the seating intervention, required the development of templates that were imported into the Medical Record, the Computerized Patient Record System (CPRS). The templates were developed by the PI with assistance of the Clinical Applications Coordinator (CAC) at the Puget Sound VA. The CAC is a licensed physical therapist and expert in the clinical capabilities of the CPRS. The CAC also facilitated the actual activation of the inter-facility consultation links and then electronically delivered the templates to the corresponding sites CAC. In addition to the consult and note templates for medical record text, it was also necessary to set up a virtual 'clinic' at the Puget Sound VA, which accepted the consultations from distant sites. The study PI was established as the sole clinician with access and rights to this clinic (SCI Seating Intervention) and was the only clinician who would receive view alerts when the clinic received a consult. A designated consult note title was created for use in the CPRS, again this note title was restricted to use only by the study PI. At each of the study sites similar virtual clinics were established to allow a non-count research activity, to differentiate from billable service, while using the CPRS for the inter-facility exchange of patient information.

Separate note titles were not created at the sites and the progress notes were filed under the title routinely used by each clinician.

To initiate the inter-facility consult, the site investigator would use the menu in CPRS for inter-facility consultation. The SCI Seating Intervention consult title would appear as an option and once selected a template would open. Figure 12 shows the template for the seating consultation.

Template: SEATING INTERVENTION INTERFACILITY (SEA)

Client's name: B <TAB>
Age: 28 Sex: MALE
Height: 74 in (188.0 cm) (12/29/2004 14:00)
Weight: 177.4 lb (80.5 kg) (02/14/2005 10:16)
Marital Status: WIDOW/WIDOWER
SCI Level: T6
Extent of SCI: INCOMPLETE

REASON FOR REFERRAL:
"

CLIENT MEASURES AND RANGES: <click to view diagram>

Hip flexion without posterior pelvic tilt:	Lc:	Rc:
Hip extension without anterior pelvic tilt:	Lc:	Rc:
Hamstring length, hip at 90 deg(inside angle):	Lc:	Rc:
Thigh length from to popliteal to inches to 1/8":	Lc:	Rc:
Dorsiflexion ROM:	Lc:	Rc:

SEEN ISSUES: Yes No (If yes, describe:)

CLIENT'S LEVEL OF FUNCTION:
Independent wheelchair propulsion: Yes No
Independent transfer: Yes No

CURRENT SYSTEM INFORMATION:
Make/Model of chair/wheel:
Diameter of rear wheel (in inches):
Make/Model of backrest if add-on:
Dimensions (width X height):
Make/Model of cushion:
Dimensions (width X height):
Any modifications:

MEASURES AND ANGLES: <click to view diagram>

A - Seat depth:	inches
B - Seat width:	inches
C - Backrest height:	inches
D - Forearm height:	inches
E - Frame seat to floor height:	inches
F - Seat seat to floor height:	inches
G - Seated angle seat to back:	degrees
H - Back to footrest angle:	degrees

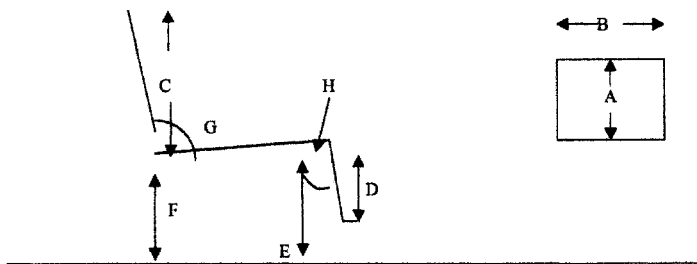
CLIENT KEY CONCERNS:
(Ask the client what is most important for him/her as an outcome of potential change. Then ask if there are any situations to change, for instance, for the chair to be any higher or will this cause trouble with transfers or under table clearance?)

* Indicates a Required Field Preview OK Cancel

Figure 12: Seating Intervention Inter-facility Consult Template

Before any data would be entered into the template, a pop-up box opened reminding the site investigator to take photographs of the subject with instruction on the features of the requested photographs. The information required in this template was acquired during the intake appointment for the study. Imbedded in the template were two web links for explanatory schematics (Figures 13 and 14) to aid in the understanding of the requested information. In actual practice, the site investigators had printed hard copies of the pop-up box and the schematics, so that they could have the instructions during the intake appointment. Then the intake assessment was transcribed to the computer template after the appointment was completed. After completing the inter-facility consult, the site investigator then had to create a progress note in the local chart and attach the photographs to this note through the image capture software.

Wheelchair Measurement chart for
SEATING INTERVENTION INTERFACILITY (SEA) consult request



A-Seat depth:

B-Seat width:

C-Backrest height:

D-Footrest length:

E-Front seat to floor height:

F-Rear seat to floor height:

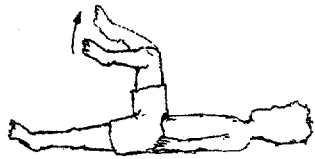
G-Inside angle seat to back:

H-Seat to footrest angle:

Figure 13: Explanatory Schematic for Wheelchair Measures

Client Measure Schematics for
SEATING INTERVENTION INTERFACILITY (SEA) consult request

Hamstring length: hip at 90 degrees, passively move lower leg into extension. Measure inside thigh to lower leg angle with first resistance.



Thigh Length. With hip at 90 degrees measure the vertical distance between mat and posterior tendons in the popliteal space.

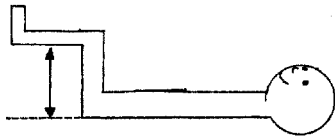


Figure 14: Explanatory Schematic for Subject Measures

The PI, upon receiving a view alert for a new consult, would open the consult in the Puget Sound CPRS. The completed template would appear in a free form text. To supplement the information in the consult text, the PI then accessed the site CPRS via remote access to view the photographs. After analysis of the subject's information the PI would make the recommendations for wheelchair configuration changes using the Seating Intervention Consult Report template

(Figure 15). The site investigators then used the progress report template to document the intervention appointment (Figure 16).

Template: SEATING INTERVENTION CONSULT REPORT

The following changes in seating are recommended:

SEAT SLOPE:

- Create a positive seat slope by raising the front of the seat:
- Create a positive seat slope by lowering the rear of the seat:
- (other)

Re-align caster housing to perpendicular

SEAT DEPTH:

- Shorten seat depth:
- Mount backrest with forward hardware
- Change front side frame
- Fold over upholstery
- Remove footrest

BACKREST:

- Lower the backrest to * inches
- Move backrest inside angle to * degrees
- Change to adjustable tension upholstery
- Mount after-market backrest * inches above seat

Remove after-market backrest to * inches

FOOTRESTS:

- Raise footrest to * inches
- Lower footrest to * inches
- Change footplate angle * degrees

Exchange hangers

Reverse mount footrest

SUMMARY OF EQUIPMENT NEEDED:

CONFIGURATION:

	ORIGINAL	PLANNED	
A - Seat depth:	*	in *	in
B - Seat width:	*	in *	in
C - Backrest height:	*	in *	in
D - Footrest height:	*	in *	in
E - Front seat to floor height:	*	in *	in
F - Rear seat to floor height:	*	in *	in
G - Inside angle seat to back:	*	deg *	deg
H - Seat to footrest angle:	*	deg *	deg

Discretionary adjustments:

Report final chair configuration numbers and document post-change status with photographs.

OK Prev Next OK Cancel

Figure 15: Seating Intervention Consult Report Template

SEATING CONFIGURATION:	PLANNED	ACTUAL
A - Seat depth:	* in	* in
B - Seat width:	* in	* in
C - Backrest height:	* in	* in
D - Footrest height:	* in	* in
E - Front seat to floor height:	* in	* in
F - Rear seat to floor height:	* in	* in
G - Inside angle seat to back:	* deg	* deg
H - Seat to footrest angle:	* deg	* deg

Discretionary adjustments:
(report any needed discretionary seating adjustments)

Client's subjective comment:

Safety and transfer check completed: Yes No
Post-change photographs attached: Yes No
Clinician concerns: None

* Indicates a Required Field Preview OK Cancel

Figure 16: Seating Intervention Progress Report Template

Results

In the entire sample there was a statistically significant treatment effect with an improvement in sagittal plane posture as measured by Seated Height. Sub-group analysis comparing the two types of delivery showed some differences in the treatment effect on Seated Height. The mean increase in the teleconsultation group (n=5) was .62 inches (p=.27), whereas the mean increase in the clinic (n=6) group was 1.35 inches (p=.08). The difference between the amounts of change effected by the intervention in the different delivery forms was not statistically significant but may be clinically meaningful. When evaluated for statistical significance in the sub-group alone, neither mean change reaches statistical significance, which is most likely a function of the small sample size. Subjective comments from the

participants who were involved in the teleconsultation group supports that there was benefit from the intervention delivered via the teleconsultation mode.

The third hypothesis of the study which reads: successful seating interventions are possible via a distance medicine model, is supported by the results of this preliminary study. However, the sample was small and it is important to note that of the six individuals randomly assigned to the teleconsultation group one declined intervention and one withdrew without receiving intervention. In the clinic group, one subject withdrew after randomization but before he began any of the intervention procedures. It is possible that the use of an intermediary between the specialist and the participant created a lack of 'buy in', or confidence, in the recommended changes.

Time and efficiency are also an issue in delivery of seating via teleconsultation. In this study, the time commitment of the teleconsultation participants was in all cases greater than the longest time commitment of the clinic participants. Teleconsultation requires the exchange of patient information between the site clinician and the seating specialist; for this study there were planned intervals of time between information exchange and subject appointments. The intent of the planned intervals was to insure that the appropriate equipment was in place, and the site investigator understood the planned equipment modifications thereby allowing an efficient use of the appointment time.

Lack of familiarity with the equipment was a problem for the site investigators. Training was provided prior to the enrollment of subjects and this training was intended to describe and demonstrate the most common equipment changes and any unusual components that may be dealt with. A training manual with pictures of the components and written explanations of the potential changes was also provided. However, the training was distal to the actual clinical application of the knowledge and due to a lack of familiarity and practice with the equipment; it was insufficient to allow the site investigators to feel confident in the delivery of the interventions. Therefore more communication was required than originally planned for in the study design. In most cases, in addition to the inter-facility consult report (text instructions for the recommended intervention) there was also one to two telephone calls or emails between the site investigator and the seating specialist (PI) for clarification of the intervention. Even with this added communication there were two cases where the PI was able to immediately detect a mistake in the application of the intervention from the post-intervention photographs which required correction (subjects would return for additional appointments to rectify the equipment set up). In one case of a multi-component adjustment, the site investigator and wheelchair technician were not able to make one of the changes due to missing equipment. They elected to make only two of the three changes, not understanding that the interaction of all three components was required to make the intervention effective.

Teleconsultation is beset with problems that are created by the same technology that makes it possible. The ever-advancing technologies of digital communication and software interfaces are a challenge when attempting to create a workable inter-facility communication.

For this feasibility study the PI elected to work in the VA health care systems because this is a networked care system with an extensive computerized medical record and the ability to remotely access medical records between facilities within a secure system. The VA has an established system for remote access to the computer network called VPN or Virtual Private Network. It is accessed through broadband or a dial up modem with password-protected access. For this project, remote access was needed for the PI to read and respond to inter-facility consultations sent from any investigative site to the Puget Sound base of teleconsultation. Meaning, if the PI was actually at Site 1, she could receive and respond to the teleconsultation sent from Site 2 to Seattle.

Although the VA is a national health care system with oversight and budget from a central office, there are a myriad of local facility interpretations of national policy and guidelines. Each facility has its own intra-facility networked computer system (Local Area Network or LAN). The local Information Resources Management (IRM) technical support staff maintains the LAN. The local staff is in charge of maintaining and trouble shooting both the software and the hardware at

the local facility. Each local facility has a group of persons who are responsible for the clinical applications of the computer technology. For example, all VA facilities have an image capture capability in their computerized medical record by which photographic, schematic or scanned images can be imported into the medical record and linked to a chart note. However, local Automated Data Processing Application Coordinator (ADPAC) controls which clinical staff have access to view the images and who has the authority to import images. Clinical applications coordinators (ACC) are responsible for developing appropriate clinical applications and training staff. There are large variations across facilities in terms of who is authorized to use this technology and how its use is implemented. Additionally, the skill and technologic literacy of the ADPAC and ACC personnel differs widely across facilities.

Furthermore, VA facilities are not all running the same versions of software packages for clinical applications. Significant to this study, the image capture and image display software were different across facilities as were the Computerized Patient Record System (CPRS) software. Occasionally, there are national mandates to upgrade to a particular version of software, with the intent to standardize systems. The upgrade is now done online with an automatic download upon signing into the network. Unfortunately, this is distributed through the local networks requiring physical connection to the LAN for the system to upgrade. In this project the PI went, overnight, from having a working system of remote access to all

investigative sites' computerized medical records, to not being able to access any of the investigative sites' computerized medical records. This included the Puget Sound VA where the investigation was based. In order to be able to access the Puget Sound medical records, the PI needed to first plug the laptop into the network system (via hardwired cable on site) and then the automatic downloaded upgrade occurred upon signing into the network with passwords. This upgrade would not happen when signed on via VPN even with a call in to the IRB help desk; the security of the remote access system blocked the upgrade from occurring and blocked the help desk from being able to 'manipulate' the computer from afar.

After the laptop software upgraded so that the software on the laptop was compatible with the server, the PI was able to access the Puget Sound CPRS. However, the PI could still not access the Site 1 or Site 2 medical records, receiving an error message that the "server and the client (laptop) are not running the same version", despite the fact that they were.

There were also issues of hardware and software incompatibility. The image display software has additional issues in that if the program cannot recognize a resolution it assumes it is insufficient and incompatible and will not allow images to be viewed. The brand new Dell Inspiron 600m Lap Top purchased for this project could not be used as the image software would not open and gave an error message "the resolution is too low". However the resolution of the laptop far exceeded the parameters and could not be set as low as the standard for the

software. An alternative VA owned laptop was acquired for use during the first half of the study. Eventually this laptop was no longer available and the original Dell was used after advisement that the firewall of the laptop was blocking the access. This firewall had been installed by the ADPAC as a required feature for use of remote access to CPRS. Once the security on the laptop was disabled the programs would run. The instruction to disable the firewall was from an image software specialist at the Puget Sound VA, but was not known by the ADPAC or other IRM personnel who were consulted in attempts to establish the technology platform for this study. Table 9 shows study down time due to computer issues.

Table 9: Chronology of Technology Difficulties For Duration of Study

Date	Issue
6/23	final access codes issued by Site 1 facility, this is one month after recruitment began
6/28	PI lost all access including base Puget Sound remote access
7/5	regained remote access to Puget Sound medical record (continued no contact to Sites)
7/12	remote access to Site medical records re-established but imaging software lost
7/13	image display re-instated
7/21	moved all connection software to new laptop due to hardware issues, imaging interface problems recurred
7/22	all remote access and imaging is re-established
7/26	Site 2 investigator unable to find the inter-facility consultation templates
7/28	applications coordinator resolves problem, software had been sent but not activated
8/2	VISN 20 network VPN is down, unknown cause, unable to access site facilities via secure network.
8/3	Remote access restored.
8/3	Site 2 investigator cannot import images from camera. He has software installed and was trained by his coordinator and the PI but cannot recall steps trained by his coordinator. Due to delay in Site 2 start the image capture software had updated from that used when PI did training. Site 2 has sent first teleconsult but there are no photo images accompanying consult.
8/15	Image capture issues resolved in Site 2
9/2	Site 2 investigator cannot locate the progress note template and decides to use open narrative note format rather than pursue locating/activating the template.
10/26	reviewing completed work- in the Site 2 medical record the second consult closure- the PLAN does not appear even with display results In the record for (202) a plan is in the Seattle record under consult tab, and note tab. In Site 2 record there is only the first consult report that says photos received. On third try requesting the results it showed up; not certain site clinician saw this information.

Technology is evolving and individual skills and task responsibility are acquired by some personnel at such a pace that even their supervisors are not completely aware of the abilities and coverage of their team. The conundrum of the PI's blocked access to remote records was further exacerbated by the fact that the individual who had originally set up the lap top remote access was on vacation and

apparently no one in the medical center was cross trained to cover in his absence. Thus, the study had to stall until this individual's return. This meant that teleconsultation subjects at Site 1 were put on hold with second appointments scheduled at 3-4 weeks post enrollment to allow for the PI to regain remote access to the medical record.

The inter-facility consultation was set up so that a consult is originated at the distant site, e.g. Site 1, and the text information about the subject is transmitted on a consult template (developed for this project) for the PI clinician to access through the Puget Sound CPRS. However, integral to the interpretation of the subject data was inspection of photographs of the subject seated in their wheelchair. This key piece is what distinguishes this type of consultation from simply a text-based case consult. The 'tele' component is the transmission of digital photographs along with the text information for interpretation.

Because of a 'programming issue' it is not possible to attach images (photographs) to a consult request or consult report. Images can only be attached to local progress notes. Therefore, to gather all of the information to analyze the needs of the subject the PI needed to access the Puget Sound CPRS and read the text information, then separately access the local site CPRS (remotely via VPN) and view the photographs. Then the PI returned to the Puget Sound CPRS to write the consult report.

This section began with the statement that there is a rapid evolution of technology. Even during the duration of this study, a number of changes have been made to the software systems of the VA medical records that have eliminated some of the obstacles encountered during the study. First the image viewing software has changed so that a clinician can remotely access any images collected at any VA medical center once signed onto the patient's medical record. Thus, the need to access the local CPRS to view a local progress note with an attached image is no longer an issue. Images are still not attached to a consult, so there is the need for the site clinician to create a separate note and attach the photograph. However, upon receipt of the consult the seating clinician can import all images of the patient.

What Worked

A concern in setting up the inter-facility consultation was the potential time delay from the time of consult initiation to the time of receipt by the PI due to the need for the patient to be registered at the new facility. This was not found to be a problem with consult alerts generated within 24 hours of consult initiation.

The intake template and the photographs provided adequate information for the PI to determine the needs of the individual and create the prescriptive intervention. More information would have increased the accuracy of the prescriptions. For instance, more photographs with more views of the individual seated in their wheelchair would be an asset; in particular, a photograph of the back of the individual. In addition more information on available adjustment in the

wheelchair or prior alterations that have been made to the wheelchair would also have been useful. For example: is the current backrest at its highest or lowest available setting? This could be added to the text intake form and ascertained by the site clinician with little additional training. The follow-up photographs were found to be essential for determining the accuracy of the intervention.

What Did Not Work

Site clinicians need more than the information on the consult report. They would benefit from a telephone conference after receiving the consult report and prior to scheduling the patient to clarify any unfamiliar prescriptive changes. Additionally, having the seating specialist on call and available during the intervention would alleviate errors and delays in delivering a proper intervention. Real-time ability to assess the follow-up photograph would be very helpful and allow improved care to the veteran. This could be done with the site clinician immediately importing the post intervention photographs into the CPRS and alerting the specialist by phone or pager. The veteran could take a short break or test ride of the wheelchair while the photographs were reviewed and then return for final adjustment or confirmation of the correctness of the set up.

The current system of the images not attached to the text consult is a problem that needs to be remedied for a working system of seating via teleconsultation. This problem created the need to have access to the local medical records and created much of the access and interface problems faced during this

study. Although the advances in the image viewing software have solved part of the problem there still is the problem of the additional work. The extra step needed to create a separate medical record document to add the photographs resulted in delay of the photographs being received by the seating specialist and in some cases resulted in missing information.

In this project, 6 individuals were randomized to the teleconsultation arm of the study. However, only 3 of those individuals received the designated intervention as planned. One subject (Site 2) had a very small intervention offered which he did not allow the site investigator to do (the prescribed plan was to do an in clinic trial as the change was small and dependent on subjective feedback). This same subject went home and independently administered the intervention contacting the PI directly for follow up. This subject was included in the study analysis because after speaking with the PI he returned to the site investigator for additional follow up and he completed the study questionnaires. This scenario suggests a lack of confidence in the site clinician. A second subject (also Site 2) simply refused the intervention outright. A third subject who was randomized to teleconsultation but did not receive the intervention (Site 1) reported becoming frustrated by the delays and was also not convinced enough of the potential benefit to continue once the equipment was obtained. In contrast, all subjects randomized to the clinic group received interventions during the designated 3 hour

appointment, only one required the allotted follow up appointment to complete the intervention.

The simple interpretation of this project shows clear superiority of the clinic delivery. However, the comparison is not the comparison that should be made when thinking of the care distribution in the VA system. All participants were seen at a Spoke Facility SCI clinic. This Spoke Facility was in the same or close proximity to the participants' residence. In the usual care scenario the specialty-seating clinic for these veterans is at the SCI Center which is an average of 270 miles from the site cities. Therefore, when thinking about the convenience or burden for the teleconsultation group the comparison should be made to receiving similar care at their center. Once an individual is at the center all care would typically be received within the inpatient stay or outpatient lodging appointments. The delay would be the time to gain an appointment. The burden would be the travel to the center and time lost from their job or home.

Johnson and Eicher (2004) offer an economic framework for teleconsultation which suggests that the following equation be used when considering the benefits of teleconsultation:

$$B=AE\alpha S\beta$$

B is the health benefit, A is the features of the disease or condition being treated, E is the equipment required for the treatment, alpha is the weight of the importance of the equipment for the treatment and S is the skill of the clinician with beta the

weight of the importance of the skill. For the teleconsultation tested in this study the differential for the skill of the clinicians (the on-site clinician and the seating specialist) was very high. The importance of the skill is also high. Therefore, the use of teleconsultation in this situation is predicted to have a high cost benefit. In a system, such as the VA, with mandated care, the evaluation of benefit should be done at both a system level and at a patient centered benefit.

Implications

This preliminary study supports the feasibility of teleconsultation for the delivery of seating interventions. The secure transmission of subject related data via the inter-facility consultation mechanism and image-viewing software was adequate to support intervention prescription. As delineated above, several improvements could be made to implement an efficient system. One consideration is how the use of a distant seating specialist would best serve the needs of the veterans.

All participants recruited to this study who received the intervention reported benefit from the intervention. Only half of the subjects could be categorized as needing minor interventions, while the other half had intervention specifications for multiple parameter changes. There may be an unmet need for specialty consultation and/or training at the SCI center serving these veterans. It may be possible that a teleconsultation between a seating expert and the clinicians at the SCI center would better serve the system as a whole.

Because there were issues with equipment familiarity and efficient application of the prescribed intervention, it may be that teleconsultation could aid the efficient delivery of seating intervention but in a different architecture. An alternative to the structure of teleconsultation in this study would be for the intake information in the inter-facility consultation to be used by a specialist to plan an intervention and prescribe needed equipment for changes, which would be locally acquired, and then the patient could be scheduled for a clinic date during which time the specialist is physically present to do the work. Sending a specialist to SCI Spoke Facility clinic sites for scheduled interventions (full day specialty clinics) on a half yearly or quarterly basis would afford greater access than currently available at SCI centers.

LIMITATIONS OF THE OVERALL STUDY

The most important limitation to this study, which threatens the ability to attribute the changes seen to the intervention, is the lack of a control group. The original design did have an extended baseline with a repeat of the outcome measures after a period of no intervention. Unfortunately, this plan was foiled by missing data. The study did have a single subject control, which was a serendipitous occurrence when one participant declined the intervention but participated in all of the outcome measurements across the time points. Plot profiles of his data show that the outcome measures were fairly stable with a slight trend towards getting worse with no intervention.

The within subject design uses the subjects as their own control so that variations in baseline status are accounted for. The proximal measure was a measure of immediate effect of the intervention and therefore can be more assuredly attributed to the intervention. In the clinic group there was no separation of time between the baseline photographs, the intervention, and the post intervention photographs with all occurring within the same research session. The teleconsultation group did have a variable amount of time after the baseline photographs until the post intervention photographs were taken. However, all photographs were taken after the same movement in and out of the wheelchair and therefore have accounted for the potential for the effect of 'settling' into the seat.

The size of the sample in this study is clearly a limitation. Eleven participants completed the intervention and outcome measures with only nine maintained through the follow-up. However, the homogeneity of the sample may strengthen the clinical applicability for the specific population of spinal cord injured men with motor complete paralysis between T1 and T10. The intervention is intended to address postural support needs of persons with truncal paralysis and all but one of the participants had SCI level between T4 and T7 indicating complete paralysis of the abdominal wall. The remaining subject had a T10 level of injury and therefore partial innervation.

Self-report questionnaires have inherent limitations. There may be confusion or misinterpretation of the questions, or there may be a bias toward positive response to please the investigator. In this study, the social desirability influence should have been limited due to the lack of prior relationship between the PI and the subjects. Inaccurate recall is also a potential issue. The questionnaires in this study asked for a variety of recall durations ranging from current pain intensity to asking for recall of pain history prior to SCI, which for one subject was 33 years. The use of multiple pain indexes also may have biased the individuals to report pain. There were instances where the demographic form (filled out first with intake) reported no pain but then pain was reported on subsequent questionnaires. A weakness in the study design was the plan to collect the outcome measures by mail.

CLINICAL IMPLICATIONS

The results of this study support the use of specific wheelchair configurations to provide orthotic stabilization to the paralyzed trunk for maintenance of sagittal plane posture. The fact that all presenting subjects had identifiable mis-configuration of their wheelchairs suggests a knowledge void among SCI clinicians and durable medical equipment providers.

Improved postural alignment was shown to improve health outcome measures in the immediate period post intervention. The failure for this benefit to be maintained over the long term may suggest a need for more frequent follow up or monitoring of seated posture; postural support from the equipment may change over time.

If wheelchair configuration is recognized as a means of supporting the postural alignment of persons with SCI and can be incorporated into early interventions, it may be possible to prevent the negative sequelae of the postural deviations and promote improved health outcomes.

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FUTURE WORK

The PI theorized that there are two significant and inter-related musculoskeletal pains experienced by individuals with SCI, postural pain and upper limb mechanical pain, both of which are exacerbated by postural malalignment. The results of this study support this theory. More work needs to be done on the functional implications of the optimal postural position, specifically how improved postural support will change the wheelchair propulsion ability.

In this study the population was limited to persons with complete truncal paralysis but full innervation of their upper limbs. Due to the noted improvements in the postural components of pain it would be interesting to look at the effects of the postural intervention on individuals with high level tetraplegia who have no, or very minimal, use of their upper limbs.

Future work in teleconsultation would want to include collection of data that could be evaluated for the patient centered benefit. For instance, how much is it worth to the patient to not have to travel for the service? Or what is the most important reason to prefer to get care locally? Consideration for moving the teleconsultation completely out of the clinical environment and into the home of the wheelchair user may also be of interest. Such an intervention would require addressing the means of secure transmission of the health information outside of a computerized medical system.

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APPENDIX A: LETTERS OF COOPERATION

Southern Arizona VA Health Care System

3601 South 6th Avenue
Tucson , AZ 85723
Phone: (520) 792-1450

Date: 31 Jan 05

To Whom it May Concern:

I have discussed the research project entitled Effectiveness of Wheelchair Configuration Modification as a Means of Changing Outcome Measures for Pain, Perceived Posture and Quality of Life in a Sample of Spinal Cord Injured Individuals who use Manual Wheelchairs Full-time; Feasibility Study for Seating Intervention Delivered via Teleconsultation and Comparison to Hands-on Intervention with Ms. Jennifer Hastings and have agreed to be the site investigator. I understand the responsibilities for this project and am willing and able to assume these responsibilities. I believe that this project is of great merit and will benefit veterans who have a spinal cord injury.

Please contact me if you have any questions.

Sincerely,



Demonbreun, PT Site Investigator

I approve of this commitment.

Mary West Service Line Chief

Carl T. Hayden VA Medical Center

650 E. Indian School Road

Phoenix , AZ 85012

Phone: (602) 277-5551

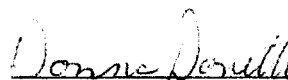
Date 7-2-05

To Whom it May Concern:

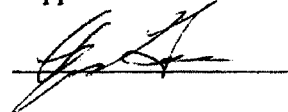
I have discussed the research project entitled Effectiveness of Wheelchair Configuration Modification as a Means of Changing Outcome Measures for Pain, Perceived Posture and Quality of Life in a Sample of Spinal Cord Injured Individuals who use Manual Wheelchairs Full-time; Feasibility Study for Seating Intervention Delivered via Teleconsultation and Comparison to Hands-on Intervention with Ms. Jennifer Hastings and have agreed to be the site investigator. I understand the responsibilities for this project and am willing and able to assume these responsibilities. I believe that this project is of great merit and will benefit veterans who have a spinal cord injury.

Please contact me if you have any questions.

Sincerely,

 Site Investigator

I approve of this commitment.

 Service Line Chief

APPENDIX B: INSTITUTIONAL REVIEW BOARD APPROVALS

UNIVERSITY OF WASHINGTON

Human Subjects Division
Office of Sponsored Programs Box 355752

HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION

BOX FOR COMMITTEE USE ONLY		
MASTER <input type="checkbox"/>	COMM <input type="checkbox"/>	INVESTIGATOR <input type="checkbox"/>
APPLICATION NO. 05-5663-V 01		

Send nine copies of this form (including one copy with original inked signatures) and nine copies of all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to the Human Subjects Division, Box 355752. Do not leave blanks. Attach one copy of each research proposal, grant or contract, and/or one copy of the protocol and investigator's brochure for clinical trials. Students should attach one copy of thesis or dissertation proposals. For information and assistance, visit our web site at <http://depts.washington.edu/hscr> or call (206) 543-0098. We will not accept handwritten and/or incomplete forms. (Use 10 point type or larger throughout application.) The contents of this application and attachments will be kept confidential within the limits of the law.

Check this box if your project falls into one or more of the minimal risk ("expedited") categories of research (see web site for listing of categories) and send us only two copies of all your materials.

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Correspondence will be directed to this person. You may designate a contact person other than yourself in section II, below.)

Name Jennifer D. Hastings Title PT, PhC Position Doctoral Student
 Department Psychosocial & Community Health Division School of Nursing
 Mail box or address 5719 18th AV NE, Seattle WA 98105
 Telephone 206 499 9704 Fax 206 522-1426 e-mail hastij@u.washington.edu

RECEIVED
Human Subjects Div
FEB 23 2005

II. CONTACT PERSON (Provide all the information requested. This person does NOT have signatory authority with regard to this application.)

Name Jennifer D. Hastings Title PT, PhC Position Doctoral Student
 Mail box or address 5719 18th AV NE, Seattle, WA 98105
 Telephone 206 499 9704 Fax 206 522-1426 e-mail hastij@u.washington.edu

UW

III. TITLE OF PROJECT: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

IV. SIGNATURES: The undersigned acknowledge that: 1. this application represents an accurate and complete description of the proposed research; 2. the research will be conducted in compliance with the recommendations of and only after approval has been received from the Human Subjects Review Committee (HSRC). The principal investigator is responsible for reporting any serious adverse events or problems to the HSRC, for requesting prior HSRC approval for modifications, and for requesting continuing review and approval.

A. Investigator: Jennifer D. Hastings PT, PhC [Signature] 2/16/05
TYPED NAME PLUS SIGNATURE DATE

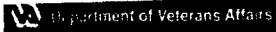
B. Faculty sponsor (for student): Karen Schopp PhD [Signature] 2/16/05
TYPED NAME PLUS SIGNATURE DATE

C. The Chair, Dean, or Director signing below acknowledges that this proposed activity has received intra-mural review and approval of scientific merit and investigator-qualification.

Mary Salazar EdD [Signature] 2-17-05
TYPED NAME PLUS SIGNATURE DATE

<u>[Signature]</u>	<u>4/8/05</u>	APPROVE <input checked="" type="checkbox"/> DISAPPROVE <input type="checkbox"/>
HUMAN SUBJECTS REVIEW COMMITTEE SIGNATURE	DATE	
Subject to the following conditions: <u>Submit IRB approvals + approved consent forms from both AZ sites when available</u>		
Period of approval is one year, from <u>4/8/05</u> through <u>4/7/06</u>		

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED



REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

TITLE: Effectiveness of Postural Intervention via Manual Wheelchair Change; Feasibility of Teleconsultation Delivery		
VAMC: VAPSHCS	Principal Investigator: Donald J. Sherrard	
Reviewing Institution: University of Washington Human Subjects Division	ID Number: 05-5663-V 01	Review Date: 3/16/2005

COMMITTEE FINDINGS:

- 1) The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills. YES
 NO
 N/A
- 2) The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. YES
 NO
 Confidentiality Agreement
- 3) Every effort has been made to decrease risk to subject(s)? YES
 NO
- 4) The potential research benefits justify the risk to subject(s)? YES
 NO
- 5) If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she will not have to participate; d) If there exists any question about the subject's competency, the basis for decision on competency has been fully described. YES
 NO
 N/A
- 6) If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. YES
 NO
 N/A
- 7) Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. YES
 NO
- 8) Comments: (Indicate if Expedited Review)

RECOMMENDATION: **APPROVED** **DISAPPROVE/REVISE**

SIGNATURE OF CHAIR: 	Date: 4/8/05
---	------------------------

Date: April 27, 2005

From: Chairman, Research and Development Committee (S-151)

Subj: Proposal reviewed by R&D on March 10, 2005

To: Barry Goldstein, MD (S-128-SCI)
Jennifer Hastings, PhC, MS (S-128-SCI) ✓

1. Your project, **“Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery”** was reviewed by the Research and Development Committee at their meeting on March 10, 2005. All applicable subcommittee approvals and/or clarifications have been obtained and approval to start is now granted. Your RDIS approval number is #0007.
2. You must inform the office of any significant changes to your protocol (such as design modification, change in PI, etc.). If this project has a human study component you must send us a copy of each IRB action, e.g., an approved modification, annual renewal or termination.
3. If the project is non-VA funded, you must send us a copy of the notification of award (NIH) or other statement of funding award.



John C.S. Breitner, MD, MPH

Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

Project/Program Title: Effectiveness of Postural Intervention Via Manual Wheelchair Change: Feasibility of Teleconsultation Delivery

Principal Investigator: Bradley Buckhout, MD

VAMC: 644 - Carl T. Hayden Veteran's Affairs Medical Center

Review Date: April 13, 2005

COMMITTEE FINDINGS

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills. YES NO

Reviewed Consent Version Date: 3/9/2005 Approved Consent Version Date: 3/21/2005

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. YES NO

3. Every effort has been made to decrease risk to subject(s)? YES NO

Reviewed Protocol Version Date/No. 2/11/2005 Approved Protocol Version Date or No. 2/11/2005
Approved Investigator's Brochure Dated N/A

4. The potential research benefits justify the risk to subject(s)? YES NO
Approved for number of subjects to be consented 18

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: (a) the research can't be done on competent subjects; (b) there is no risk to the subject, or if risk exists, the direct benefit to subject is substantially greater; (c) if an incompetent subject resists, he will not have to participate; (d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described. YES NO

6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution. YES NO N/A

7. Were the members of minority groups and women included in the study population whenever possible and scientifically desirable. YES NO

8. Comments (If Expedited Review, explain): Full Review *Expedited Review

*The research involves collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (see attached documents).

Approved for (no. of months) 12 Expiration Date 4/12/06

RECOMMENDATION: APPROVE DISAPPROVE / REVISE
Comments: Approve pending minor changes to informed consent Memo Attached

SIGNATURE OF CHAIRMAN [Signature] DATE 4/13/05

**Department of
Veterans Affairs**

Memorandum

Date: April 28, 2005

From: Chair, R&D Committee

Subj: New Protocol Review
Effectiveness of Postural Intervention via Manual Wheelchair Change: Feasibility of
Teleconsultation Delivery

To: Bradley Buckhout, MD (GECS)

Thru:

The R&D Committee conducted a review of this protocol at its meeting on April 27, 2005.

After consideration of the scientific quality of the study, the Committee voted to:

- approve the study.
- approve the request for closure.
- disapprove the study for the reasons given below.

If you have any questions or need assistance, please contact Matt Banaszak, Research AO, at 6697 or Grace Moreno, Program Support, at 7224.

 For Felsetta
James Felsetta, MC
Chair, R&D Committee

4-27-05
Date

Human Subjects Protection Program
<http://www.hrb.arizona.edu>

10 May 2005

THE UNIVERSITY OF
ARIZONA.
TUCSON ARIZONA

1350 N. Vine Avenue
P.O. Box 245137
Tucson, AZ 85724-5137
(520) 626-6721

Dale Demonbreun, B.S., M.P.T.
Physical Medicine/Rehabilitation
VA Medical Center

RE: HSC #05-59 EFFECTIVENESS OF POSTURAL INTERVENTION VIA MANUAL
WHEELCHAIR CHANGE; FEASIBILITY OF TELECONSULTATION DELIVERY

Dear Mr. Demonbreun:

We received your 5 May 2005 letter and accompanying revised Consent Form/PHI Authorization Form (5/4/05 Versions) and corrected Recruitment Letter/Advertisement and updated Verification of Training Form and Project Approval Form for the above referenced project. All of the conditions as set out in our 27 April 2005 letter to you (relevant to the *26 April 2005 full Board review* of this project) have been met. Therefore approval for this subjects-at-risk project is granted and the enclosed Consent Form and PHI Authorization Form reflect an *expiration date of 26 April 2006*.

The Institutional Review Board (IRB) of the University of Arizona has a current *Federalwide Assurance* of compliance, *FWA00004218*, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee (IRB) and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,



David G. Johnson, M.D.
Chairman, Biomedical Committee
UA Institutional Review Board

DGJ:rs

cc: Departmental/College Review Committee

Department of Veterans Affairs

Memorandum

Date: June 16, 2005

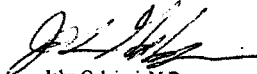
From: Chair, Research and Development Committee (151)

Subj: Review of Research Proposal

To: Dale Demonbreun, MPT, BS (3-11NH)


1. Your research proposal entitled "Effectiveness of Postural Intervention via Manual Wheelchair Change: Feasibility of Teleconsultation Delivery" was reviewed by the following Research Committees on the dates indicated. The action taken by each Committee is shown. Your project number is 0002.

Research and Development Committee, 06/15/05. Approved



John Galgiani, M.D.

APPENDIX C: APPROVED INFORMED CONSENT FORMS

	Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 1 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

1. Purpose of study: Jennifer Hastings is a board certified clinical specialist in neurologic physical therapy and a PhD candidate, who has been a physical therapist with the Seattle VA SCI Service for more than 15 years. This study is her dissertation research. We would like to better understand the relationship between seated posture and health for people who use a wheelchair full time due to spinal cord injury. We hope that the results of this study will help people with spinal cord injury to have less pain and discomfort from wheelchair use in the future. We are also interested in whether effective seating interventions can be provided using a telemedicine format where the seating specialist is distant to the seating clinic. We hope that the results of this study will improve access to better seating for people who use wheelchairs in the future. This study is being conducted at the Carl T. Hayden VA Medical Center in Phoenix, AZ, and the Southern Arizona VA Health Care System in Tucson, AZ. Ten participants will be recruited from each facility. To be eligible to participate, you must have motor complete spinal cord injury between the levels of T1 and T10, use a manual wheelchair full-time for mobility and be more than one year from your date of injury. We are particularly interested in persons who are uncomfortable with how they are sitting in their wheelchair or have longstanding neck, back or shoulder pain.

If you are in any other study, you must inform the Principal Investigator now.

2. Description of the study, procedures to be used, and how long it will last: The following information describes your participation in this study which will last up to a total of 4 hours over the course of up to four clinic visits plus an additional 30 minutes for completion of the follow up questionnaires, most of your participation in the study will be completed within one month of enrollment with the follow up questionnaire after 3 months.

When you contact the therapist investigator to say you are interested in being in this study you will first be asked a number of questions to screen for eligibility in the study. If you qualify to participate you will be given an appointment with this investigator. Upon agreeing to participate in the study you will be given a packet of questionnaires to fill out, this will take approximately 30 minutes.

You will now be assigned by a random procedure, like the flip of a coin, to either the "in-person" group or the "teleconsultation" group.

Subject's Name: _____, _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____ - _____ - _____


VA FORM
JAN 1990

10-1086

Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005
Not To Be Used After: APR 14 2006
IRB Study No.: _____ (will be assigned after committee approval)

	Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 2 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

The study coordinator, Jennifer Hastings, will specify the interventions for both groups.

If you are assigned to the "in-person" group you will be scheduled into the next available "in-person" clinic with the study coordinator. Research seating clinics are scheduled once a month.

If you are assigned to the "teleconsultation" group your appointment will continue. The investigator will now ask you to transfer to a therapy mat (help will be provided with the transfer if needed) and then take measurements of the range of motion of your legs. The investigator will also take a measure of your leg length. While you wait on the mat the investigator will measure your wheelchair. Next you will transfer back into your wheelchair into a usual position of comfort. Now the investigator will take photographs of you while seated in your wheelchair, these photographs will be from the front and the right side and will include your face and your entire body and wheelchair. You will be fully clothed in the photographs, though you will be asked to remove any outer jackets or hats. At this time the intake appointment is completed. The information obtained during the intake appointment will be entered into your computerized medical record and transmitted to the lead investigator by an inter-facility consultation.

Those in the "in-person" clinic will have all of the same procedures described for the teleconsultation appointments performed during their research seating clinic appointment.

If you are in the "teleconsultation" group you will have two more appointments of approximately one-hour duration and one week apart. "Teleconsultation" is a form of health care delivery where the patient is seen by a local clinician who consults via technology, in this case the computerized medical record, with a specialist who is distant. The specialist evaluates information collected by the local clinician to make their recommendations.

If you are in the "in-person" group you will have one 3-hour appointment at the next available research seating clinic.

At the second appointment, in both groups, your wheelchair will be adjusted to improve the postural support provided by the wheelchair.

Subject's Name: _____, _____ **Date:** _____
Last First

Soc. Sec. No. (9 digits): _____ - _____ - _____


VA FORM
JAN 1990

10-1086

Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: ~~APR 12 2005~~ MAY 2 2005
Not To Be Used After: _____
IRB Study No.: _____ (will be assigned after committee approval)

 Department of Veterans Affairs Cari T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 3 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

Potential changes in your wheelchair include:

- The backrest height being changed,
- The backrest angle being changed,
- The seat slope being changed

Depending on the type of wheelchair you use it may not be possible to optimally set up the wheelchair for postural support without additional equipment, in this case you will be potentially offered:

- New wheelchair backrest upholstery,
- A new backrest (this may require removal of the backrest by quick release hardware to fold the wheelchair)
- A base wedge to use under your cushion.

In this study we will not change your seat cushion.

After your wheelchair has been adjusted you will be asked to return to your chair and perform a number of function and safety checks to insure that you feel comfortable taking the wheelchair in the new configuration. At the end of the appointment another set of photographs will be taken. A follow up will be available the next day for the in-person clinic group and the next week for the teleconsultation group, to address any fine-tuning of the wheelchair changes that might be needed.

Two weeks after the final seating appointment you will be asked to repeat the packet of questionnaires and return them by mail in a postage paid envelope. These questionnaires are identical to those you will complete on the enrollment visit. They are self-report scales concerning your pain intensity and its location and whether or not it interferes with function and how you feel about your seated posture.

Three months after the final seating appointment you will be asked to complete and return another packet of questionnaires.

For the duration of your involvement in the study you are asked to refrain from seeking any new interventions for neck, arm or shoulder, or back pain or discomfort and keep a record of any medication

Subject's Name: _____, _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____


VA FORM
JAN 1990

10-1086

Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005
Not To Be Used After: APR 12 2006
IRB Study No.: _____ (will be assigned after committee approval)

 Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 4 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

changes. If for whatever reason you modify your wheelchair or cushion after the seating appointments please contact the investigator and let them know of the change.

You may decline to answer any question on any questionnaire or during any interview and you may withdraw from the study at anytime.

3. Reasonably foreseeable discomforts or inconveniences of the study: This study requires that you participate in either three one-hour appointments at the clinic over a four-week period or one three-hour long session. The frequency or duration of the appointments may be inconvenient.

4. Reasonably foreseeable risks of study: This study will involve tests and measures that are routine in the delivery of physical therapy to patients with spinal cord injury. The transfers required in this study may be more frequent or in greater number than you are used to performing. The investigators are all experienced therapists who can assist in transfers if needed. It is possible that you may be sore or fatigued by the activity of the seating clinics.

The intervention offered in this study is a change in posture by changing the postural support provided by the wheelchair. Changing posture may be initially inconvenient for you and may require some adjustment of your home environment, for instance your knees may be higher or you may sit taller. Therapist investigators will work with you to avoid any inconvenience and a follow up appointment is available if something simply does not work for you. At the end of the intervention session, you will be given an explicit list of the changes that have been made to you wheelchair and you will be given any and all parts that may have been removed. You can decide to undo the changes that were made at any time but you are requested to inform the investigator if you make any change to your wheelchair. If you have any concerns for your physical health at anytime during this study you should contact your SCI clinician whether you believe there is a connection to the study intervention or not.

Some people may be uncomfortable being photographed. The photographs are for analysis of your posture and wheelchair configuration, they will be viewed by the lead investigator as part of the determination of recommendations for wheelchair changes. The photographs will be stored as images in the computerized medical record of the VA Healthcare System. The Computerized Medical Record is a password-protected system with access restricted to medical care providers.

Subject's Name: _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____

VA FORM
JAN 1990

10-1086


Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005

Not To Be Used After: APR 12 2006

IRB Study No.: _____ (will be assigned after committee approval)

 Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 6 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

12. **Contact for questions:** If you have any questions about the conduct of this study, you should contact Bradley Buckhout, the Principal Investigator at (602) 277-5551 ext. 7008, or the Chairperson of the Research and Development Committee at the Carl T. Hayden VAMC (602) 277-5551, ext. 7224. If you have any questions about your rights as a subject in this study, you should contact the Chairperson of the Human Subjects Subcommittee (also known as the IRB) at the Carl T. Hayden VAMC (602) 277-5551, ext. 7224.

13. **Authorization for release of protected health information for research purposes:** This part of the consent is authorization for release of your protected health information for research purposes and gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study, and might be shared
- Why your personal health information is being used
- Which of our personnel may use or disclose your personal health information
- Who, outside of the Veterans Health Administration (VHA), might receive your personal health information
- How long will VHA be able to use or disclose your personal health information
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

13.a. **What personal health information about you will be collected in this study, and might be shared (disclosed)?**

By signing this document, you will authorize the Veterans Health Administration (VHA) to provide Bradley Buckhout MD and his research team to access, collect, use for research purposes, and release the following personal health information during your involvement with this research study:

- Name
- Address
- Telephone number
- Current and past medications or therapies

Subject's Name: _____, _____ Date: _____
Last First


Soc. Sec. No. (9 digits): _____ - _____ - _____

VA FORM
JAN 1990

10-1086

Subject's Initials
Version Date: 3-24-05

This Form IRB Approved: MAY 2 2006
Not To Be Used After: APR 12 2006
IRB Study No.: _____ (will be assigned after committee approval)

 Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 7 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

- Information from a physical examination concerning lower extremity range of motion and thigh length
- Information concerning skin health and history of decubitus ulcers (pressure sores)
- Information concerning heterotopic ossification (bone growth around the joints)
- Photographs of you while seated in your wheelchair

13.b. Why is your personal health information being used?

Your personal contact information is important for the VHA research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you.

13.c. Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other VHA staff associated with the study).
- The VHA Institutional Review Boards and the Human Research Participant Protection Program Committee (the committees charged with overseeing research on human subjects) and the VHA Research Compliance Officer.
- The VA Research & Development Office (the office which monitors research studies locally)
- Authorized members of the VHA workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

13.d. Who, outside of the Veterans Health Administration (VHA), might receive your personal health information?

Subject's Name: _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____


VA FORM
JAN 1990

10-1086

Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005
Not To Be Used After: APR 1 2008
IRB Study No.: _____ (will be assigned after committee approval)

 Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 8 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Other collaborating academic research center(s) The study team at the Southern Arizona VA Health Care System who are jointly conducting this research
- Others: Karen Schepp PhD, Chair Supervisory Committee for the Dissertation Research of Jennifer Hastings at the University of Washington

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the Veterans Health Administration (VHA) information may no longer be covered by the federal privacy protection regulations.

- In all disclosures outside of the VHA, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.
- In records and information disclosed outside of the VHA, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.
- Your Medical Records and study data may be held and processed on computers.

13.e. How long will the VHA be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, VHA may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the VHA Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures done

Subject's Name: _____, _____ **Date:** _____
Last First

Soc. Sec. No. (9 digits): _____ **MAY 2 2005**

VA FORM
JAN 1990

10-1086


Subject's initials

Version Date: 3-24-05

This Form IRB Approved: _____

Not To Be Used After: APR 13 2005

IRB Study No.: _____ (will be assigned after committee approval)

 Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 9 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

solely for this research study and not as part of your regular care will be included in your medical record.

13.f. Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

13.g. Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at the address at the top of each page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. No information will be collected after you revoke the authorization. If you withdraw your permission to use your personal health information that means you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient.

13.h. AUTHORIZATION

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protection, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

I have read this authorization form and have been given the opportunity to ask questions. If I have questions later, I understand I can contact Donna Donetti at 277-5551 ext 6949. I will be given a signed copy of this authorization for my records. I authorize the use of my identifiable information as described in this consent.

Subject's Name: _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____

VA FORM
JAN 1990

10-1086

Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005
Not To Be Used After: APR 17 2006
IRB Study No.: _____ (will be assigned after committee approval)

	Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 10 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

14. RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. Dr. Buckhout or his/her research associate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other alternatives available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. In case there are study-related questions or medical concerns, I have been told I can call Donna Donetti during the day at 602-277-5551 extension 6949 or contact Jennifer Hastings 206 499-9704 after hours. For emergency care, call 911 or VA Life Support at (602) 277-5551, ext. 7199. If any medical problems occur in connection with this study the VA will provide emergency care. I have been informed that I can also contact my Primary Care Provider in case I have any additional medical problems or questions.

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I have read and signed this consent before any of the research-related procedures were started. I will receive a signed copy of this consent form.

Subject's Signature _____ Date _____

Signature of Person Obtaining Consent _____ Date _____ Name (print) _____

Signature of Witness _____ Date _____ Name (print) _____

Subject's Name: _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____

VA FORM
JAN 1990

10-1086


Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005

Not To Be Used After: APR 12 2006

IRB Study No.: _____ (will be assigned after committee approval)

	Department of Veterans Affairs Carl T. Hayden VA Medical Center 650 E Indian School Road Phoenix AZ 85012	VA Research Consent Form (Page 11 of 11)
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Principal Investigator/Researcher: Bradley Buckhout MD

Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

INVESTIGATOR'S STATEMENT: I certify that the individual obtaining consent is a member of my research team and has been fully trained to explain the nature, purpose, the potential benefits, and the possible risks associated with participation in this research study.

Signature of Principal Investigator _____ Date _____ Name (print) _____

Subject's Name: _____, _____ Date: _____
Last First

Soc. Sec. No. (9 digits): _____ - _____ - _____

VA FORM
JAN 1990

10-1086

Subject's Initials

Version Date: 3-24-05

This Form IRB Approved: MAY 2 2005
Not To Be Used After: APR 14 2006
IRB Study No.: _____ (will be assigned after committee approval)

APPROVED BY UNIVERSITY OF AZ HRD.
THIS STAMP MUST APPEAR ON ALL
DOCUMENTS USED TO CONSENT SUBJECTS.
DATE: 5-12-05 EXPIRATION: 7-16-06

SUBJECT'S CONSENT FORM

Project Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

You are being asked to read the following material to ensure that you are informed of the nature of this research study and of how you will participate in it, if you consent to do so. Signing this form will indicate that you have been so informed and that you give your consent. Federal regulations require written informed consent prior to participation in this research study so that you can know the nature and risks of your participation and can decide to participate or not participate in a free and informed manner.

PURPOSE

You are being invited to participate voluntarily in the above-titled research project. The purpose of this project is to better understand the relationship between seated posture and health for people who use a wheelchair full time due to spinal cord injury. The investigators hope that the results of this study will help people with spinal cord injury to have less pain and discomfort from wheelchair use in the future. They are also interested in whether effective seating interventions can be provided using a teleconsultation format where the seating specialist is distant to the seating clinic. The results of this study may improve access to seating advisement for people who use wheelchairs in the future.

SELECTION CRITERIA

The Principal Investigator or a member of his/her study staff will discuss the requirements for participation in this study with you. To be eligible to participate, you must have motor complete spinal cord injury between the levels of T1 and T10 and use manual wheelchairs full-time for mobility and be more than one year from your date of injury. These researchers are particularly interested in persons who are uncomfortable with how they are sitting in their wheelchair or have longstanding neck or shoulder pain. A total of 10 individuals will be enrolled in this study locally. Overall, a total of 20 individuals will be enrolled at multiple study centers.

ALTERNATIVE TREATMENT(S) There are specialized seating evaluation and interventions available at VA Spinal Cord Injury Centers. You should contact your personal physician for more information on options that would be appropriate for you.

PROCEDURE(S)

The following information describes your participation in this study which will last up to 4 hours over the course of up to four clinic visits plus an additional 30 minutes for completion of follow up questionnaires. Most of your participation in the study will be completed within one month (with the follow up questionnaire after 3 months).

When you contact the site investigator to say you are interested in being in this study you will

first be asked a number of questions to screen for eligibility in the study. If you qualify to participate you will be given an appointment with the investigator. Upon arrival for the appointment you will be given a packet of questionnaires to complete, which will take approximately 30 minutes.

You will then be assigned by a random procedure, like the flip of a coin, to either the "in-person" group or the "teleconsultation" group, both of which are described below.

The lead investigator of the multi-site study, Jennifer Hastings of the Seattle VA Medical Center, will specify the interventions for both groups. Jennifer Hastings is a board certified clinical specialist in neurologic physical therapy and a PhD candidate, who has been a physical therapist with the Seattle VA SCI Service for more than 15 years. This study is her dissertation research.

If you are assigned to the "in-person" clinic this session will be ended and you will be scheduled into the next available "in-person" clinic, (research seating clinics are scheduled once a month).

If you are assigned to the "teleconsultation" group your appointment will continue. The investigator will then request that you transfer to a therapy mat and help will be provided with the transfer if needed. Measurements then will be taken of the range of motion of your legs. The investigator will also measure your leg length. While you wait on the mat, the investigator will measure your wheelchair. Next you will transfer back into your wheelchair into a usual position of comfort. The investigator will take photographs of you while seated in your wheelchair. These photographs will be from the front and the right side and will include your face and your entire body and wheelchair. You will be fully clothed in the photographs, though you will be asked to remove any outer jacket or hat. At this time the intake appointment is completed. The information obtained during the intake appointment will be entered into your computerized medical record and transmitted to the lead investigator by an inter-facility consultation.

Those in the "in-person" clinic will have all of the same procedures described for the teleconsultation appointments performed during their research seating clinic appointment.

If you are in the "teleconsultation" group you will have two additional appointments of approximately one-hour each. These will be scheduled one week apart.

If you are in the "in-person" group you will have one 3-hour appointment at the next available research seating clinic.

At the second appointment, all subjects will have his/her wheelchair adjusted to improve the postural support provided by the wheelchair.

Potential changes in your wheelchair include:

- The backrest height being changed,
- The backrest angle being changed,
- The seat slope being changed

Depending on the type of wheelchair you use it may not be possible to optimally set up the wheelchair for postural support without additional equipment. In this case, you will be potentially offered:

- New wheelchair backrest upholstery,
- A new backrest (this may require removal of the backrest by quick release hardware to fold the wheelchair)
- A base wedge to use under your cushion.

In this study the investigators will not change your seat cushion.

After your wheelchair has been adjusted, you will be asked to return to your chair and perform a number of function and safety checks to insure that you feel comfortable taking the wheelchair in the new configuration. At the end of the appointment, another set of photographs will be taken. A follow up will be available the next day for the in-person clinic group, and the next week for the teleconsultation group to address any fine-tuning of the wheelchair changes that might be needed.

Two weeks after the final seating appointment you will be asked to repeat the packet of questionnaires and return them by mail to the primary investigator in a postage paid envelope.

Three months after the final seating appointment you will be asked to complete and return another packet of questionnaires.

For the duration of your involvement in the study, you will be requested to refrain from seeking any new interventions for cervical, upper extremity, or back pain or discomfort and to keep a record of any medication changes. If for whatever reason you modify your wheelchair or cushion after the seating appointments, the investigator must be contacted.

You may decline to answer any question on any questionnaire or during any interview, and you may withdraw from the study at anytime.

RISKS

This study will involve tests and measures that are routine in the delivery of physical therapy to patients with spinal cord injury. The transfers required in this study may be more frequent, or in greater number than you are used to performing. The investigators are all experienced therapists who can assist in transfers if needed. It is possible that you may be sore or fatigued by the activity of the seating clinics.

The intervention offered in this study is a change in posture by changing the postural support provided by the wheelchair. Changing posture may be initially inconvenient for you and may require some adjustment of your home environment, for instance your knees may be higher or you may sit taller. Therapist investigators will work with you to avoid any inconvenience and a follow up appointment is available if something simply does not work for you.

At the end of the intervention session, you will be given an explicit list of the changes that have been made to your wheelchair and you will be given any and all parts that may have been removed. You can decide to undo the changes that were made at any time, but you are requested to inform the investigator if you make any change to your wheelchair. If you have any concerns for your physical health at any time during this study you should contact your SCI clinician whether you believe there is a connection to the study intervention or not.

Some people may be uncomfortable being photographed. The photographs are for analysis of your posture and wheelchair configuration, they will be viewed by the lead investigator as part of the determination of recommendations for wheelchair changes. The photographs will be stored as images in the computerized medical record of the VA Healthcare System. The Computerized Medical Record is a password-protected system with access restricted to medical care providers. The consults and images will remain in your medical record and as such will be accessible to anyone with authorization and a password to enter into the computerized medical record.

BENEFITS

You may directly benefit from participation in this study because the study will give you access to a seating specialist without having to travel from your local health care facility. The results of this study may lead to improved access to specialty care through teleconsultation for persons who live distant to major medical centers.

CONFIDENTIALITY

Information about you is confidential. The information from the intake examination, the photographs and the procedures for wheelchair adjustment will be incorporated into your computerized medical record. The computerized medical record is an authorized access, password protected system. All data collected from the questionnaire will be coded for the study records. This information will not be incorporated into your medical record. The link between your name and the code will be kept in a secured location, separate from the study information, for two years after the final data collection. After which time the link will be destroyed. If the results of this study are published your name will not be used.

Whether or not you choose to be in this study will have no effect on your usual health care as provided by the VA Healthcare System.

PARTICIPATION COSTS AND SUBJECT COMPENSATION

There is no cost to you for participating except your time. If any equipment is needed for your wheelchair Prosthetics Service will purchase it at no expense to you. You will receive \$50 token of appreciation for your participation after returning the final questionnaire packet.

CONTACTS

You can obtain further information from the Local Principal Investigator Dale Demonbreun PT at 520 792-1450 x 1-6998.

Version Date: 5-04-05

Page 4 of 6

Subject's Initials

If you have questions concerning your rights as a research subject, you may call the University of Arizona Human Subjects Protection Program office at (520) 626-6721.

LIABILITY

Side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of yours or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm also may occur and require care. You do not give up any of your legal rights by signing this form. In the event that you require or are billed for medical care that you feel has been caused by the research, you should contact the local principal investigator Dale Demonbreun at 520 792-1450 x 1-6998.

AUTHORIZATION

Before giving my consent by signing this form, the methods, inconveniences, risks, and benefits have been explained to me and my questions have been answered. I may ask questions at any time and I am free to withdraw from the project at any time without causing bad feelings or affecting my medical care. My participation in this project may be ended by the investigator for reasons that would be explained. New information developed during the course of this study which may affect my willingness to continue in this research project will be given to me as it becomes available. This consent form will be filed in an area designated by the Human Subjects Committee with access restricted by the principal investigator, Dale Demonbreun PT, or authorized representative of the Rehabilitation Department of the Tucson VA. I do not give up any of my legal rights by signing this form. A copy of this signed consent form will be given to me.

_____ Subject's Signature	_____ Date
_____ Parent/Legal Guardian (if necessary)	_____ Date
_____ Witness (if necessary)	_____ Date

INVESTIGATOR'S AFFIDAVIT:

Either I have or my agent has carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who signed this consent form was informed of the nature, demands, benefits, and risks involved in his/her participation.

_____ Signature of Presenter	_____ Date
_____ Signature of Investigator	_____ Date

AUTHORIZATION FORM FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Project Title: Effectiveness of postural intervention via manual wheelchair change; feasibility of teleconsultation delivery

The United States government has issued a new privacy rule to protect the privacy rights of individuals enrolled in research. The Privacy Rule is designed to protect the confidentiality of an individual's health information. This document hereafter known as an "Authorization for Use and Disclosure of Protected Health Information for Research" describes my rights and explains how my health information will be used and disclosed for this study.

PURPOSE

I am being invited to participate voluntarily in the above-titled research project. The purpose of this project is to better understand the relationship between seated posture and health for people who use a wheelchair full time due to spinal cord injury. The results of this study may help people with spinal cord injury to have less pain and discomfort from wheelchair use in the future. This study is also intended to satisfy an interest in whether effective seating interventions can be provided using a teleconsultation format where the seating specialist is distant to the seating clinic. It is hoped that the results of this study will improve access to seating advisement for people who use wheelchairs in the future.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

This information will be used for completion of this study only. Upon arrival for the appointment I will be given a packet of questionnaires to fill out. This information will not be incorporated directly into my medical record, rather the data collected from the questionnaire will be coded for the study records. The link between my name and the code will be kept in a secured location, separate from the study information, for two years after the final data collection. Then the link will be destroyed.

The following information will be collected from my medical record or during the study sessions and incorporated into my medical record:

- *Name*
- *Address*
- *Telephone number*
- *Current and past medications or therapies*
- *Information from a physical examination concerning lower extremity range of motion and thigh length*
- *Information concerning skin health and history of decubitus ulcers*
- *Information concerning heterotrophic ossification*
- *Photographs taken while seated in your wheelchair*

This health information will be transmitted to the lead investigator by an inter-facility consultation through the computerized medical record. The Computerized Medical Record is a password-protected system with access restricted to medical care providers. The lead investigator will view the health information and the photographs in order to determine the recommendations for wheelchair changes.

As stated in the study description, the investigator will take photographs of me while seated in my wheelchair; these photographs will be from the front and the right side and will include my face and entire body and wheelchair. I will be fully clothed in the photographs, though I will be asked to remove any outer jacket or hat. The photographs are for analysis of my posture and wheelchair configuration. As with all personal information of this study, the photographs will be stored as images in the computerized medical record of the VA Healthcare System. The information about me is strictly confidential. If the results of this study are published my name will not be used.

Version: 5-4-05

APPROVED BY UNIVERSITY OF AZ HR.
THIS STAMP MUST APPEAR ON ALL
DOCUMENTS USED TO OBTAIN SUBJECTS.
DATE 5-10-05 EXPIRATION 4-26-06

page 1 of 2

Whether I choose to be in this study, or choose not to be in this study, will not affect my usual health care provided by the VA Healthcare System.

I have the right to access my PHI that may be created during this study as it relates to my treatment or payment. My access to this information will become available only after the study analyses are complete.

CONTACTS I can obtain further information from the principal investigator, Dale Demosbreun, PT at (520) 792-1450, ext 6998. If I have questions concerning my rights as a research subject, I may call the Human Subjects Protection Program office at (520) 626-6721.

AUTHORIZATION

I hereby authorize the use or disclosure of my individually identifiable health information. I may withdraw this authorization at any time by notifying the Principal Investigator in writing. The address for the Principal Investigator is 3601 S 6th Ave, Tucson, AZ 85723. If I do withdraw my authorization, any information previously disclosed cannot be withdrawn and may continue to be used. Once information about me is disclosed in accordance with this authorization, the individual or organization that receives this may redisclose it and my information may no longer be protected by Federal Privacy Regulations. I may refuse to sign this authorization form. If I choose not to sign this form, I cannot participate in the research study. Refusing to sign will not affect my present or future medical care and will not cause any loss of benefits to which I am otherwise entitled. This authorization will expire on the date the research study ends. I will be given a copy of this signed authorization form.

Subject's Signature

Date

Printed Name of Subject

Signature of Subject's Legal Representative (if necessary)

Date

Printed Name of Subject's Legal Representative

Relationship to the Subject

APPENDIX D: INSTRUMENTS

Wheelchair User's Shoulder Pain Index (WUSPI)

Subject ID _____

PARTICIPANT INFORMATION

Please answer the following questions to the best of your ability.

1. Age: _____
2. Sex (circle) 1. Male
 2. Female
3. Marital Status (circle) 1. Single
 2. Married
 3. Divorced
 4. Separated
 5. Widowed
4. A. How many years have you used a wheelchair? _____ years
 B. Type of wheelchair (circle): 1. Manual C.* Make _____
 2. Power Model _____
 3. Both
- 5.* What is your motor level of Spinal Cord Injury (write in if applicable)
 1. Cervical _____ 1. Complete
 2. Thoracic _____ 2. Incomplete
 3. Lumbar _____ 3. Don't know
 4. Sacral _____
- 6.* Average number of wheelchair transfers per day: _____
 (including transfers to/from bathroom, car, bed and other-count one direction as 1 transfer example:
 in and out of a car=2)
7. Are you: (circle) 1. Left-handed 2. Right-handed
8. A. Primary occupation: (circle the activity at which you spend the MOST time)
 1. Employed
 2. Student
 3. Volunteer
 4. Retired
 5. Other _____
 B. Total number of work/school hours per week _____ hours
 C. Total number of hours spent participating in sports/leisure activities per week: _____ hours
9. A. Do you drive?
 1. Yes
 2. No
 B. If yes, number of hours per week spent driving: _____ hours
 C. If yes, what type of vehicle: 1. Car
 2. Van with lift
 3. Van without lift
 4. Truck/utility vehicle
 5. other _____
- D.* Do you stow your own wheelchair into vehicle? 1. Yes 2. No
 If yes, please mark your usual placement of the wheelchair
 1. Behind the driver's seat
 2. In the front passenger seat
 3. In the rear passenger seat
 4. other _____

*these questions are additions or modifications to the WUSPI Demographic form with permission from Dr. Curtis
Wheelchair User's Shoulder Pain Index (WUSPI) ©1995 Curtis KA, Roach KE, Applegate EB, Amar I, Benbow C, Genecco TD, Gualano J

Wheelchair User's Shoulder Pain Index (WUSPI)

Subject ID _____

- 10.* Can you independently jump up a 4 inch curb? 1. Yes 2. No
- 11.* Do you use a wheelie to go down steeper inclines? 1. Yes 2. No
- 12.* Can you independently transfer off the floor to your wheelchair? 1. Yes 2. No

MEDICAL HISTORY (circle the appropriate responses below)

1. Did you have shoulder pain prior to wheelchair use? 1. Yes 2. No If yes, which shoulder? 1. Left 2. Right 3. Both
2. Have you had shoulder pain during the time you have used a wheelchair? 1. Yes 2. No
if yes, which shoulder? 1. Left 2. Right 3. Both
3. Have you had shoulder surgery? 1. Yes 2. No
if yes, which shoulder? 1. Left 2. Right 3. Both
4. Do you currently have shoulder pain? 1. Yes 2. No If yes, which shoulder? 1. Left 2. Right 3. Both
5. Have you sought medical attention for a shoulder problem? 1. Yes 2. No
if yes, who did you see? 1. Physician
2. Physical Therapist
3. Chiropractor
4. Other _____
6. Circle all of the following you have used to relieve shoulder pain:
1. Ice 2. Heat 3. Exercise 4. Meditation 5. Rest 6. None 7. Other _____
7. Has shoulder pain limited you from performing your usual activities during the past week? 1. Yes 2. No
8. Have you experienced hand or elbow pain or injuries during the time you have used a wheelchair? 1. Yes 2. No
- 9.* Did you have neck pain prior to wheelchair use? 1. Yes 2. No
- 10.* Do you currently have neck pain? 1. Yes 2. No
- 11.* Did you have back pain prior to wheelchair use? 1. Yes 2. No
- 12.* Do you currently have back pain? 1. Yes 2. No

WHEELCHAIR USERS SHOULDER PAIN INDEX

Place an "X" on the scale to estimate your level of pain with the following activities. Check box at right if the activity was not performed in the past week. Based on your experiences in the past week, how much shoulder pain do you experience when:

- 1. transferring from a bed to a wheelchair? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 2. transferring from a wheelchair to a car? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 3. transferring from a wheelchair to the tub or shower? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 4. loading your wheelchair into a car? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 5. pushing your chair for 10 minutes or more? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 6. pushing up ramps or inclines outdoors? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 7. lifting objects down from an overhead shelf? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 8. putting on pants? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 9. putting on a t-shirt or pullover? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 10. putting on a button down shirt? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 11. washing your back? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 12. usual daily activities at work or school? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 13. driving? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 14. performing household chores? No Pain [] _____ Worst Pain Ever Experienced [] _____
- 15. sleeping? No Pain [] _____ Worst Pain Ever Experienced [] _____

© Foundation for Wheelchair Pain Index (WSPPI) 1999. Order KA, Booklet BK, Appropriate ER, Annex T, Handbook C, Question TD, Question 7

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Kathleen Curtis, PT, Ph.D.
Director of Research and Special Projects
College of Health and Human Services
California State University, Fresno
2325 E. San Ramon Ave. M/S SR 136
Fresno, CA 93740-8031
559-278-5382 phone
559-278-8341 fax
email: kathleen@csufresno.edu

SCORING INSTRUCTIONS
WHEELCHAIR USER'S SHOULDER PAIN INDEX
(WUSPI)

Thank you for your interest in the WUSPI, the Wheelchair User's Shoulder Pain Index. Enclosed is a copy of the instrument as we are currently using it.

RAW WUSPI SCORE:

Measure the length of each 10 cm line at the point where the subject indicates an "X". The total score is calculated by taking the sum of all 15 item scores. Note the number of items completed. (There is an option for the respondent to check "not performed")

PERFORMANCE -CORRECTED WUSPI SCORE (PC-WUSPI)

Divide the RAW WUSPI SCORE (see above) by the number of items completed. Multiply this result by 15. This is the PC-WUSPI SCORE which accommodates for individuals who do not perform certain functions (such as individuals with tetraplegia) or for part-time wheelchair users (such as those who use the wheelchair only for sports participation).

I would appreciate a copy of the results of any study you do with the WUSPI so that I can keep an ongoing log of instrument use. Please send this information to:

Kathleen Curtis, PT, Ph.D.
Director of Research and Special Projects
College of Health and Human Services
California State University, Fresno
2325 E. San Ramon Ave. M/S SR 136
Fresno, CA 93740-8031
USA

If you have any questions, please don't hesitate to contact me. You can reach me by phone at (559) 278-5382 or by fax at (559) 278-8341. If you prefer you can also contact me by e-mail, my address is: kathleen@csufresno.edu.

Best wishes with your work.

Sincerely,

Kathleen A. Curtis, P.T., Ph.D.
Director of Research and Special Projects
College of Health and Human Services

Pain Descriptor and Locator
Time _____

Subject ID:
Date:

Use the line below to rate your **CURRENT** pain

Indicate on the line below how bad your pain is. The left end of the line means no pain; the right end means the worst possible pain.

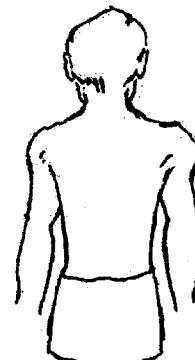
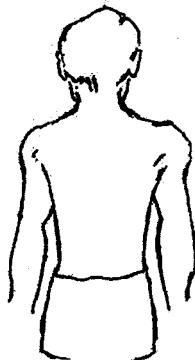
No Pain _____ Worst Possible Pain

Use the line below to rate the **WORSE** pain you have had in the last **THREE** days.

Indicate on the line below how bad your pain is. The left end of the line means no pain; the right end means the worst possible pain.

No Pain _____ Worst Possible Pain

Use the two schematics below to indicate the **LOCATION** of your pain.



How much has any pain above the level of your spinal cord injury interfered in your ability to perform your usual activities in the past week?

Indicate on the line below how much pain has interfered. The left end of the line means no interference; the right end means pain usually or severely interferes.

Not at all _____ usually or severely

Postural Scale for Wheelchair Users

This is a questionnaire to assess how you feel about your posture. Please read each statement below and then determine how strongly you agree or disagree with the statement. Please check the box that matches the strength of your agreement/disagreement.

	Completely Disagree			Somewhat Disagree			Somewhat Agree			Completely Agree			For administrative use only				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	P	A	H	F	
1. Whenever I see a mirror I tend to correct my posture in my wheelchair.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
2. I feel sitting upright in my wheelchair is 'work'.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
3. I worry that how I sit may lead to skin breakdown.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
4. My wheelchair was custom designed to meet my needs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
5. I limit how long I sit in my wheelchair due to discomfort.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
6. I think I could breathe easier if I sat differently.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
7. I have pain, or discomfort, that I think is related to how I sit in my wheelchair.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
8. I get tired during the day and I believe it is related to how I sit.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
9. I sit with my hips forward to improve my balance.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
10. I think my posture may lead to some problems down the line.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
11. My chair is not supportive enough.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
12. I think my muscular fatigue is due to how I sit in my wheelchair.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
13. I believe I have poor posture.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
14. I believe the way I sit makes my spasticity worse.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
15. I think I would look better if I could sit up taller.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
16. I feel good about how I look sitting in my wheelchair.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
	Totals																
	Overall Totals																

**Postural Scale for Wheelchair Users
(PSWU-16)**

The overall scale latent construct is a subjective perception of problematic posture. The theorized sub-scales are: Pain (P), Aesthetics (A), Health (H), and Function (F) Factor analysis has not confirmed the subscales.

Psychometrics:

Cronbach's Alpha = .86

Subscale to scale all significant; range .76-.86

Subscale to subscale all significant; range .40-.72

Item to subscale all significant; range .42-.88

Test-retest: $r=.73$

Scoring Instructions

The numerical value assigned to each box checked should be transcribed in the rectangle aligned on the right. Vertical columns are summed for the sub-scales. Add the sub-scales for a scale total. A higher score indicates a higher perception of problematic posture. Scale range is 0-48. Subscales range 0-12.

For Clinical use:

A total scale score of 24 (50%) or greater or any subscale of 9 (75%) or greater suggests referral for seating evaluation and intervention.

Abstract: Instrument Development: A Postural Scale for Wheelchair Users
Jennifer Hastings. Journal of Spinal Cord Medicine Volume 28 no. 2 2005 p 163.

Subject Number:
Date:

Satisfaction With Life Scale (SWLS) Form

Below are five statements with which you may agree or disagree. Using the scale below, indicate your agreement with each item by choosing the appropriate number associated with each item. Please be open and honest in responding.

	1 strongly disagree	2 disagree	3 slightly disagree	4 neither agree or disagree	5 slightly agree	6 agree	7 strongly agree
1. In most ways my life is close to my ideal.							
2. The conditions of my life are excellent.							
3. I am satisfied with my life.							
4. So far, I have gotten the important things I want in life.							
5. If I could live my life over, I would change almost nothing.							

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APPENDIX E: INSTRUMENT DEVELOPMENT-PSWU

Postural Scale for Wheelchair Users: An Instrument Development.

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Funding Sources:

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Abstract:

This article presents the development and pilot study psychometrics of a new instrument that is intended to serve the dual purpose of being a clinical outcome measure of change after seating intervention, and a screening tool used to determine need for seating intervention. Qualitative unstructured and semi-structured interviews of key informants began the item development followed by expert panel relevance rating. Item analysis for initial scale development is described. A descriptive pilot study of the scale was completed with a sample of 41 community living persons who use wheelchairs for mobility due to paralysis. Demographics of sample: Age 9-68; mean 41. Wheelchair use 2-51 years, mean 17. The final 16- item instrument had a Cronbach's alpha=.86, good item to subscale, subscale to subscale, and subscale to total correlation values. Test-Retest correlation $r = .7$.

Key Words: Instrument, Posture, Psychometrics, Reliability, Scale, Validity, Wheelchair

Introduction:

There are a growing number of persons living with functional limitations from a neurologic impairment who require seated wheeled mobility for daily function. Persons who use wheelchairs full-time are at high risk for secondary impairment and disability. Often, prolonged wheelchair use portends postural deformity and many authors have described kyphotic and scoliotic postures attributed to prolonged wheelchair use^{1,2}. There is a large amount of associative evidence that persons who use manual wheeled mobility have musculoskeletal upper limb pain³. However, there is emerging evidence that there is much musculoskeletal pain in persons who use power mobility thus challenging the direct link of upper limb use as the causal agent for the pain. Evidence supports the contention that optimal spinal postural alignment is a platform for normal shoulder biomechanics and therefore the absence of optimal spinal alignment is posited to be a causal factor in the development of musculoskeletal pain with wheelchair use. Normal upright postural alignment is optimized when the least muscular work is required to maintain alignment against gravity. In the absence of normal postural motor control the excessive work by posterior neck and scapular muscles is a source of postural pain. Persons who lack motor control of the trunk due to paralysis require external support for postural maintenance. Recent work has shown that it is possible to configure a wheelchair to create a postural stabilizing environment⁴.

For persons with paralysis who use wheelchairs, problems with posture can lead to an increase in medical problems as well as secondary disability. Poor posture may lead to lower self-esteem and therefore contribute to more social isolation. Wheelchair users often perceive, are aware, that they have postural problems but are not aware of how to fix them and are often frustrated by health professionals who cannot see their concern nor offer solutions. Because progressive postural deformity can lead to pain and skin breakdown it would be ideal to

capitalize on this perception of postural problems in order to provide early intervention and prevention of the negative sequelae.

Problem Statement

An outcome measure is needed that will assess the patient's perceived changes in health, function, and quality of life as a result of the postural intervention. Additionally, a screening tool is needed to help primary care providers determine the need for referral to seating specialists. An instrument is needed that reveals personal perception of postural issues, rather than an observational postural assessment, so that interventions can be targeted to more closely answer the concerns of the individual.

For research purposes an instrument is needed that will show change with intervention. This would require an instrument that has stability if there is no change and one that is sensitive enough to show change with the intended intervention. The requirements of a clinical tool are that it will have a low user burden including the ability to score and interpret readily, and have good face validity for clinicians.

A literature search was done to see if a 'perceived postural problems' tool existed. None was found. There are observational tools for assessing posture, but none was found that looked at the postural problems perceived by the individual. Initial search in instrument fields looking for postural assessment scales revealed no matches in CINAHL or PubMed. A search was done using the CINAHL database and key words of posture and physical therapy resulted 297 hits. The author reviewed the titles to cull to forty-four titles, and then reviewed the abstracts to cull to 18 and a review of the complete reference reduced the number of articles actually read to seven. The instruments described in the articles were either quantitative or if qualitative in nature they were observational so that the rater 'qualified' the posture. At this point it was determined that a new instrument would need to be developed. During the past 6 months other researchers have begun to

publish about the subjective assessment of posture¹, however they have made idiosyncratic measures for their own purposes without the rigorous steps of establishment of reliability and validity of the instrument.

Objective

The objective was to develop an instrument to measure a wheelchair using individual's perceived postural problems that will meet the needs as a research outcome measure and also the needs as a clinical screening tool.

The scale was developed to be self-administered suggesting that a main goal would be ease of use⁵. A goal was to have a scale that is brief and easy to complete. 12-16 items were anticipated in the final instrument. A Likert scale with four levels: totally disagree =0, somewhat disagree=1, somewhat agree=2, totally agree =3 was used, the four response categories requires the respondent to have an opinion on the item⁶. Likert scales are ordinal level of measurement and thus potentially less sensitive and with less power than a ratio based measure. However, Likert may be easier to complete for the user and will definitely be easier to score for the clinician, as scoring requires only simple summing rather than linear measurement and potential calculation with decimals.

The items are written as declarative statements, which in general will mean that, a higher score (agreement) would indicate more of a postural problem. A 5th grade reading level was selected for the items. This is the level of patient education materials for the VA medical centers. An individual with full hand function is expected to be able to complete the scale in less than 10 minutes.

As a clinical screening tool cut points are required. Cut points will be established on the overall summary score and on subscales.

Method- Scale Development Process:

The process of item development began with qualitative work by collecting thoughts and impressions from representatives of the target population for the scale.

Informants

The target population representative will be identified as TP-1, TP-2 etc. The first unstructured interview was with a 44-year-old male with T4 paraplegia (TP-1) secondary to spinal cord injury (SCI) for 29 years. This individual had solicited the author for seating intervention. The interview was taped, with permission, while we discussed what his reasons for seeking intervention were. The second unstructured interview was with a 33-year-old male with T4 paraplegia (TP-2) secondary to SCI for 7 years who has been followed by a major rehabilitation center and professes to have good knowledge about postural and seating needs. The author solicited the help of this individual. This second interview was also taped with permission. A third individual was interviewed in a more structured manner, essentially asking her to discuss the points brought up by the first two individuals. This individual is a 21-year-old woman (TP-3) with lumbar paralysis from Spina Bifida who was seen by the author for requested seating intervention. This third interview was conducted partially in person and partially by e-mail. Information from the final two informants was solicited and obtained by telephone interview and by e-mail discussion. One is a 55-year-old male with paralysis from polio (TP-4) who has been a wheelchair user since he was a teenager and is a professional in the wheelchair industry as a vice president of sales. He also is an author of a column on wheelchair use in a monthly disability magazine. The last is a 27-year-old male with C7 tetraplegia (TP-5) secondary to SCI for 8 years who is a wheelchair athlete (quad rugby) a PhD student (philosophy) and a counselor at an SCI Resource Center for the state of Florida.

As noted above, the author came to the first target informant through his solicitation of consultation for seating issues. The group of informants was then constructed in a manner to reflect potential differences in need or issues over time since injury, injury level, etiology, gender, age and exposure to information or knowledge of seating and equipment issues. The final informant group ranged in

age from 21-55 years, duration of wheelchair use from 7-40 years and included congenital, disease acquired, and traumatic injury etiologies. There was only one female informant but this is reflective of the ratio of men to women in the overall population of full-time wheelchair users secondary to paralysis.

Item Generation

After the first in-depth interview was transcribed and reviewed, the author was struck by what appeared to be four dimensions to the construct of postural problems. Thereafter, informants would be specifically asked, at the end of an interview if the individual felt that these four dimensions: pain/discomfort; health/physiology; aesthetics/looks; and function were comprehensive or if anything was lacking? Additionally, they were asked if, when considering these dimensions, they had anything to add or had a specific question that should be included in the tool. All five target population representatives stated that they felt the construct was covered by these four dimensions.

The themes of the interviews and cogent points by individuals were combined with the author's personal clinical ideas and concepts from literature review and a list of items was generated. Original items were written in mixed format with questions, or statements and no effort for directionality. Once the original list was generated, the items were modified so that they were all in the form of declarative statements. An initial item list of 76 items was created which is considered an adequate number for a final scale anticipated to be 16 items⁷.

Next the author went through the 76 items and coded them for dimension. One of the individual's involved in the item development (TP-2) was also asked to code the items. The two raters differed in the coding of 7 items (90 % agreement) and both raters were unable to code 6 items into the four dimensions (100% agreement). In reviewing the items that were unable to be coded, the author determined that they were potentially important and would not be removed at this time. These items were monitored for performance in the next stages of review.

Relevance

The next stage of development was to identify content experts and have the items ranked for relevance. Clinical expertise was necessary criterion⁸ and the goal was for an interdisciplinary panel. Help was solicited from four rehabilitation professionals knowledgeable in seating issues: an Occupational Therapist, a Physical Therapist, a Nurse Practitioner and a Rehabilitation Physician. Additionally, one of the target population representatives (TP-1) was asked to rate the items. The content experts were given the following instructions:

The concept is perceived postural problems. The operational definition is that the individual who uses a wheelchair has perceived a problem related to his or her current seated posture.

Each item is a declarative statement that the individual will either agree with or disagree with.

Please rate the following items on a scale of 1 to 4 as to how relevant the statement is to the concept.

1 = the item is not relevant to postural problems

2 = the item needs major revision to be relevant to postural problems

3 = the item needs minor revisions to be relevant to postural problems

4 = the item is relevant to postural problems.

When you have completed rating the relevance please return to the list and fill in the dimension best categorizing the item-the key is at the bottom of the list.

1 = Pain/discomfort

2 = Aesthetics/looks

3 = Health/physiology

4 = Function

The completed relevance ratings were analyzed first for the correlations of the dimensions with the ratings of each expert. The author determined that the clinicians had not shown systematic bias in ratings afforded to the less medical dimensions of "aesthetics" and "function". These two dimensions were drawn

specifically from the target population informants and were stressed as important to the wheelchair user.

Narrowing down the item pool

All of the items, which had 80-100% agreement in domain, and an Average Relevance Rating (ARR) of greater than or equal to 3.0 were retained. This list was now 36 items. Next simulated answers to each item were given using the Likert scale with four levels: totally disagree =0, somewhat disagree=1, somewhat agree=2, totally agree =3 to see if an item would require reverse coding. Eight items were determined to need reverse coding. At this time it was apparent that some items needed minor revision to allow scoring. For instance, one item which will be reverse coded, required the addition of the word "sitting". The original item read: "I readjust my position if I need to use both hands". The revised item reads: "I readjust my sitting position if I need to use both hands".

Next items that were redundant were compared and either combined or the "better" item selected. "Better" was a judgment call by the author with some consideration of the expert relevance scores but this was not always deterministic. Items with multiple cues were revised or omitted. For example the following two items were combined. The original items read: "I know I sit with my hips forward; it helps me to push". And "I sit the way I do to improve my balance". The revised item reads: "I sit with my hips forward to improve my balance".

After cleaning the items, the domains of the items remaining were tallied. There were 5 items in the pain/discomfort domain, 9 in aesthetics, 7 in physiological/health and 7 in function. It was determined to decrease all domains to an equivalent number and five of each domain was selected. In general, items with a higher ARR were maintained, however, in the domain of aesthetics five items were dropped and a single item was picked up from the original item list. The single item which reads: "I feel good about how I look sitting in my wheelchair",

had a ARR score of 2.8 but 100% agreement as to domain and was deemed to cover the content of the other items.

The instrument now had 20 items, five per domain. A single item with a ARR score of 3.6 but zero agreement for domain and was selected as an independent item for which a score of 2 or 3 should lead to a referral regardless of the other scores. This item, which reads, "I would like to change things about the way I sit in my wheelchair", will be used as a concurrent validity measure on analysis of the pilot data. The average ARR for the items in the final pilot tool is 3.35, with a range from 2.8 to 4.0, 9 have 80 percent agreement for domain and the rest (excluding the independent item) have 100 percent agreement for domain.

Content Validity Index (CVI) was calculated for the items based on the relevance ratings from the expert panel. Using the method of CVI from Waltz and Bausell⁹, $CVI = \frac{\text{number of items rated 3 or 4}}{\text{total number of items}}$. There were 5 raters in this case and each rated 21 items on a 4-point scale (1-4), this results in 105 total ratings. 17 out of the 105 were not a 3 or 4. Thus, 88/105 ratings were 3 or 4 giving a $CVI = .86$. A minimum content validity index of 0.8 is suggested for a new scale⁹.

The order of the items on the piloted instrument was randomly selected. This decision was made over the idea of clustering the items by domain. It was believed that random ordering would prevent fatigue biasing the results for the last domain listed, additionally there is the potential of order effects with some difference in answers given if domains appeared to be ordered in a prioritization. Formatting the tool was an iterative process with many variations. The final version was selected considering practical concerns¹⁰ of simplicity of use and ease in scoring.

Pilot Study

A pilot study was done for psychometric testing of the instrument. University of Washington IRB approval was received for an anonymous survey design. A

descriptive pilot study of the scale was completed through self-report mail in survey with subjects recruited by advertisement and fliers; snowball sampling was used. Subjects for the pilot test were recruited from the population of community dwelling persons who use wheelchairs full-time for mobility due to paralysis. Participants included 41 persons with an age range from 9-68 with a mean of 41. Years of wheelchair use ranged from 2-51 years with a mean of 17 years. Thirty-seven participants had spinal cord injury with levels from C4- L1. The remaining 4 participants had polio, cerebral palsy (2) and spina bifida. Subjects who directly contacted the investigator were asked to retake the questionnaire 2 weeks after the initial completion in order to calculate test-retest reliability.

Results:

Table one shows the criterion levels for new scale item analysis^{6,7}. Cronbach's alpha was calculated to see the internal consistency of the items. Alpha values between 0.7 and 0.9 are hoped for to show reliability without redundancy in the items⁷; in this sample the piloted instrument had an alpha =.85.

The subscales in the instrument are function, pain, aesthetics and health. All of the subscale to total scale correlations of the piloted instrument in this sample were significantly correlated and high, however, it is possible that pain may have been higher than desired and a dominant component of the total scale. Analysis showed that the subscales of the piloted instrument were not correlating in a hoped for pattern. Although the reliability statistic alpha is a good value > .8 which is considered acceptable for a new scale, the subscale correlations and the subscale to item correlations indicate some problems in the piloted scale.

Inspection of the descriptive statistics revealed that some items were not powerful indicators as they showed very low variance with one item not even representing the entire range of the scale.

Various analyses were run and it was concluded that deleting four items and moving one item into a different subscale significantly improved the correlations.

Systematic item analysis has led to a reduction of items for a revised final scale with 16 items

Psychometrics of Final Instrument

Reliability

The subscales are function, pain, aesthetics and health. Subscales should correlate to the total scale in a range from .55 to .8. All of the subscale to total scale correlations of the final instrument in this sample are significantly correlated and high (Table two).

Sub scales should be correlated to each other at a level of ~ 0.4 . Table 3 below shows that the subscales are all significant and correlating above the .4

The items to subscale correlations are desired to be $> .5$. All of the items to subscale correlations of the 16-item instrument were significant ($p=0.01$). All items in the pain and function subscales are correlating over .5, the aesthetic subscale had one item correlation at .457, and the health subscale has one item correlation at .42.

Internal reliability (Cronbach's alpha) is acceptable for a new scale with a value of .8633 and a standardized item alpha of .8626.

Test-retest stability is illustrated by correlation of 0.7 or greater between the total scale scores for each test. In this pilot study we had seven subjects provide test-retest data. The total scale scores correlated at 0.7. The mean difference was 1.3 with a 95% confidence interval bounded at -4.7 and 7.2 ; the mean difference was not significant.

Validity

Construct validity was established during development with the use of target population informants and expert panel relevance rating.

Concurrent validity was evaluated with correlation of the total scale scores with a single embedded item in the piloted instrument. The piloted version of the

instrument had 21 items, one of which was an embedded single item for concurrent validity analysis. It was hoped that the total scale score would be highly correlated with this single item question. In this sample the final 16-item scale was significantly correlated ($r=.779$, $p=.01$). The concurrent validity item was a simple statement "I would like to change things about the way I sit in my chair". The high correlation shows that the scale is picking up a perception of problems with seating and it is also hoped that it may be picking up latent concerns that are not consciously perceived by the individual, those who do not directly know they have seating needs.

Factor Analysis was run for a preliminary look recognizing that subject numbers are too small (should have 10 subjects per item or 160 subjects for a valid run) however; it appears the scale is multidimensional but it may have 3 rather than 4 factors.

Discussion:

The development of this instrument has been methodical and rigorous. All attributes recognized by the Scientific Advisory Committee of the Medical Outcomes Trust 11 have been considered in the development with the exception of translation and cultural adaptation. Construct validity was established during development with the use of target population informants and clinician experts to establish face and content validity. Concurrent validity is established by the high correlation to a single item (embedded). Internal reliability is shown with a Cronbach's alpha of .86 for a sample of community dwelling wheelchair user ($n=41$). Test-retest subjects were too few to declare stability, however with 7 retests the total scale score is correlated at .7, which is the recommended value for a new instrument. Use of the scale as a pre and post intervention measure shows good potential. A significant difference was found when comparison was made between post intervention total scale score and the pre intervention total scale score. The sample size is very small with only 7 clinical cases however; the 2-

tailed probability is .0001 with a mean difference of 18 and a 95% confidence interval with boundaries of 13.4 and 22.6.

Conclusion:

The instrument needs further testing to establish predictive validity and greater numbers are needed to perform a confirmatory factor analysis. The instrument is available for use as presented here. Researchers and clinicians are requested to contact the author so that use of the instrument can be monitored. For clinical use the suggested cut points for seating referral are a total scale score of 24 (50% of possible high score) or greater or any subscale score of 9 (75% of high subscale score) or greater regardless of total scale score.

Acknowledgments:

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Table One: Criterion levels for New Instrument Internal Reliability

Analysis	Criterion level
Cronbach's Alpha	0.7-0.9
Subscale to total scale	0.55-0.8
Subscale to subscale	0.4
Item to subscale	0.5 or greater

Table Two: Subscale to Total Scale Correlations

	Subscales:	Function	Pain	Aesthetics
Health				
Total Scale Score Pearson Correlation		.759*	.861*	.788*
				.786*

* Correlation is significant at level of 0.01 (2 tailed)

Table Three: Subscale-to-Subscale Pearson Correlations

	Function	Pain	Aesthetics
Health			
Function	1	.459**	.588**
.406*			
Pain	.459**	1	.526**
.718**			
Aesthetics	.588**	.526**	1
.407*			
Health	.406*	.718**	.407*
1			

** correlation is significant at the 0.01 level (2-tailed)

* correlation is significant at the 0.05 level (2-tailed)

APPENDIX F: TRAINING MANUAL TABLE OF CONTENTS

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<i>How to initiate consult.....</i>	19
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CURRICULUM VITAE

Jennifer Hastings, PT, PhD, NCS

EDUCATION

- 2002-2006 University of Washington, School of Nursing
Doctor of Philosophy, Nursing Science
Dissertation: Effectiveness of Postural Intervention via Manual
Wheelchair Change; Feasibility of Teleconsultation Delivery
- 1982-1985 Boston University, Sargent College, Boston, MA
Masters of Science, Physical Therapy
Thesis: The long term use of lower extremity bracing following
spinal cord injury rehabilitation
- 1977-1981 University of California, Berkeley, CA
Bachelors of Arts, Physiology

RESEARCH ACTIVITY/FUNDING

- 2005-2006 Effectiveness of postural intervention via manual wheelchair
change; feasibility of teleconsultation delivery.
Funding: McLaws Grant, SON (3500), PVA grant (1500)
- 2004-2006 Pre-doctoral Fellow NIH Training Grant: T32HD7424
Rehabilitation Sciences Training Grant.
- 2003-2005 Instrument development and psychometric testing of postural
scale for wheelchair users. No funding support.
- 2002-2004 Pre-doctoral Fellow NIH Training Grant: TG 5T32NR007106-
Biobehavioral Nursing Research Training Program
- 2003-2004 Pilot study: A feasibility study of the measurement of thigh
length and seated height from clinical photographic records of
persons seated in wheelchairs. No funding support.

1999-2001 Wheelchair Configuration and Postural Alignment in Persons with Spinal Cord Injury: Primary Investigator. Randomized order, repeated measure design. Clinical Study. No Funding support.

CONSULTIVE AND ADVISORY POSITIONS

2004 Expert Reviewer (representing) American Spinal Injury Association
Preservation of Upper Limb Function Following Spinal Cord Injury: Clinical Practice Guidelines for Health Care Professionals.
Consortium for Spinal Cord Medicine Clinical Practice Guidelines
Paralyzed Veterans of America

1996-1998 Mono and Bi Ski Training Specialist
SKIFORALL, Seattle, WA

1990-1998 Major Medical Equipment Committee
DVA Puget Sound Health Care System, Seattle, WA

1993 Research and Development Advisor
MCI Technologies (wheelchairs)
Santa Clara, CA

PUBLICATIONS

Books/chapters

Hastings J, Goldstein B (2004). Paraplegia and the Shoulder. In Physical Medicine & Rehabilitation Clinics of North America Special issue: Shoulder Rehabilitation, Part II - Edited by Mark A. Harrast, Kirsten S. Paynter, Karen P. Barr. Vol 15/3 pp 699-718

Hastings J (2000). Seating Assessment and Planning. In Physical Medicine and Rehabilitation Clinics of North America-Spinal Cord Injury Issue Volume 11, No. 1. (pp.183-207). Philadelphia, PA: WB Saunders Co.

Goldstein B, Goetz L, **Young J**, Stiens SA, Burns S (1999). Treatment of Repetitive Motion Disorders. In Shankar K (Ed.), Exercise Prescription (pp. 363-401). Philadelphia, PA: Hanley and Belfas Inc.

Young, J H (1989, November/December) Range of Motion, Chapter 5 in Yes, You Can! A Guide to Self-Care for Persons with Spinal Cord Injury. Paralyzed Veterans of America

Refereed Journals

Hastings J, Fanucchi E R, Burns S P. (2003). Wheelchair Configuration and Postural Alignment in Persons with Spinal Cord Injury. Archives of Physical Medicine and Rehabilitation. Volume 84, April (pp528-534).

Hastings JD (2001) Wheelchair Adjustment to Eliminate Shoulder Pain in An Adult with Cerebral Palsy. Physical Therapy Case Reports May : 4 (3):170.

Goldstein B, **Young J**, Escobedo E (1997). Rotator Cuff Repairs in Individuals with Paraplegia. American Journal of Physical Medicine and Rehabilitation Vol. 76 July/August Number 4, (pp 316-322).

Young, J H (1993) Implications of Elbow Arthrodesis for Individuals with Paraplegia:
A Case Study. Physical Therapy, Vol. 73, Number 3/March (pp 194-201).

Other publications:

Hastings, J (2004, Sept/Oct) Posture Matters. Neurotransmitter American Association of Neuroscience Nurses NW Chapter

Young, J H (1993, September). The Inseam Rule. PT - Magazine of Physical Therapy

Young, J H (1990, March/April) Access Rowing. Sports 'N Spokes Magazine.

Young, J H (1988) Floor-to-Stand Transfer with Walker for Individuals with Bilateral Lower Extremity Braces. Clinical Management in Physical Therapy.

NATIONAL PRESENTATIONS

Hastings J*, Koontz A.

"Practical Tips for Protecting the Upper Extremity Limbs of Wheelchair Users".

VAKN live broadcast September 13, 2005: 1:00 - 3:00 PM (ET) Channel 1

Produced by the Department of Veterans Affairs Employee Education System &
The Spinal Cord Injury and Disorders Strategic Healthcare Group

**Responsible for development of 50% of content and Presentation*

Hastings J.

"Instrument Development: A Postural Scale for Wheelchair Users".

Poster Presentation: American Spinal Injury Association Annual Meeting
Dallas, TX May 2005

Abstract Published: Journal of Spinal Cord Medicine, 2005: 28 (2):163.

McDowell S, **Hastings J.**

"SCI Shoulders"

SCI SIG American Physical Therapy Association Combined Sections Meeting.
New Orleans, LA February 2005

Hastings J.

"The use of power: for whom, how and why?"

Neurology Section Roundtable-SCI SIG. American Physical Therapy Association
Combined Sections Meeting.

New Orleans, LA February 2005

Thomas W, **Hastings J**

"Increased Orthotic Support Improves Function In A Man Four Years Post
Traumatic Brain Injury".

Poster Presentation: American Physical Therapy Association Annual Meeting
Washington DC June 2003

Hastings J

"Cyber Seating"

Poster Presentation: American Spinal Injury Association Annual Meeting
Miami, FL April 2003

Abstract Published: Journal of Spinal Cord Medicine, Spring 2003: 26 (1):34.

Fanucchi E R, **Hastings J**, Burns S P.

“Wheelchair Configuration and Postural Alignment in Persons with Spinal Cord Injury
Platform Presentation: American Spinal Injury Association Annual Meeting
Long Beach, CA May 2001

Abstract Published: Journal of Spinal Cord Medicine Spring 2001 : 24 (1): 6.

Hastings J, Baker L

“Postural Maintenance During Pregnancy in a Woman with T 7 Paraplegia.”

Poster Presentation: American Spinal Injury Association Annual Meeting
Chicago, IL April 2000

Abstract Published: Journal of Spinal Cord Medicine Spring 2000: 23(1): 35.

Hastings JD, Ingram DJ

“Wheelchair adjustment eliminates shoulder pain in adult with cerebral palsy.”

Poster Presentation: American Physical Therapy Association CSM
New Orleans, LA February 2000

Abstract Published: Neurology Report 1999;23 (5):195.

Young J, Giertz K, Goldstein B

“Hip Subluxation and Scoliosis in Individuals with Paraplegia”

Poster Presentation: American Spinal Injury Association Annual Scientific Meeting
Cleveland, OH April 1998

Abstract Published in Journal of Spinal Cord Medicine April 1998

Young J, Goldstein B, Carroll L

"Prevention and Treatment Program for the Weight-Bearing Shoulder"

Paper Presentation: American Spinal Injury Association Annual Scientific Meeting
Seattle, WA. April 1996

Abstract Published: Journal of Spinal Cord Medicine 19(2):114.

Young J, Goldstein B, Eby P

"The Weight-Bearing Shoulder Following Spinal Cord Injury"

Poster Presentation; American Paraplegia Society Annual Conference
Las Vegas, NV September 1995

Abstract published: Journal of Spinal Cord Medicine 18(4):301-302.

LOCAL PRESENTATIONS

“Assessment for Lower Extremity Orthotic Intervention in Spinal Cord Injury”
Northwest Prosthetics and Orthotics Regional Conference
Seattle, WA April 2005

“Trouble Shooting Seating for the SCI Client”
Trauma Rehabilitation Symposium-Spinal Cord Injury Management
Seattle, WA January 2003

“Postural Interactions: A Case Presentation of Shoulder Pain Intervention Based on Seating”
Spinal Cord Injuries Issues and Advances
Contemporary Forums
Seattle, WA May 1999

“SCI Shoulder Pain: Concepts, Prevention and Treatment”
Spinal Cord Injuries Issues and Advances
Contemporary Forums
Seattle, WA May 1999

“Wheelchair Seating for Patients with Neurologic Impairments,
Postural Evaluation as a Foundation for Seating”
American Academy of Physical Medicine and Rehabilitation
Seattle, WA November 1998

Continuing Education Conducted

“What about Cushions?”
SCI Forum 1.5 CEU
University of Washington Medical Center
Seattle, WA November 2004

“Back Pain, Wheelchair Seating and Posture”
SCI Forum 1.5 CEU
University of Washington Medical Center
Seattle, WA May 2003

“Orthotic Principles in Seating”
Mary Bridge Children’s Hospital- 9 contact hours
Tacoma, WA September 20-21 2002

“Understanding, Preventing and Treating Shoulder Problems Among Patients who are Wheelchair Users”, in:
Issues in Physical Therapy Management of Patient’s with Systemic Pathology and Complex Medical Conditions
University of Puget Sound
Tacoma, WA June 2002

Postural Deformities, the Skeleton and Seating
PT WA Pierce and Thurston Counties-Educational Offering, 1 contact hour
Tacoma, WA April 2001

“SCI Functional Skills Training”
Harborview Medical Center
3 hour course to OT/PT staff on Acute Neuro, Inpatient Neuro and CORP.
Seattle, WA November 2000

Spinal Cord Injury and Disorders Seating Symposium
VA Puget Sound HCS
Invited Faculty, provided 6 contact hours including:

“Wheelchair Seating for Patients with SCI;
Postural Evaluation as a Foundation for Seating”
“Simple Concepts for Seating the SCI Individual; the Wheelchair as an Orthosis”
“Common Abnormal Postures with SCI: Anatomical Interactions”
“Wheelchair Selection for Patients with SCI”
“Case Presentations of Seating Changes for Patients with SCI”
“Food for Thought: SCI Practice in Light of Current Science”
Seattle, WA October 2000

“A Good Seat is No Small Feat- Learn to Optimize Your Patient’s Seating”
PT WA Pierce and Thurston Counties-Educational Offering, 1 contact hour
Tacoma, WA April 2000

“SCI Rehabilitation: Laying the Foundation for a Lifetime of Musculoskeletal Health”
PT WA Fall Conference –Educational Offering, 6 contact hours
Seattle, WA October 1999

“Repetitive Strain Injuries in Wheelchair Users: Cause, Prevention, and Treatment” (Faculty: M Boninger, R Cooper, J Hastings, L Spruil) one day course
Presymposium Workshop-Fifteenth International Seating Symposium
Orlando, FL March 1999

“SCI Rehabilitation, an Update”
(6.5 contact hour course)
Providence Health Systems Continuing Education
Everett, WA January 1999

LICENSE TO PRACTICE

1986-present State of Washington, 025208 PT000034438
1985-1988 State of Massachusetts, 5661

BOARD CERTIFICATION

2000 Clinical Specialist in Neurologic Physical Therapy
 American Board of Physical Therapy Specialties

PROFESSIONAL ORGANIZATIONS

American Physical Therapy Association

American Spinal Injury Association

SPECIAL NATIONAL RESPONSIBILITIES

2000-2004 Vice chair, Spinal Cord Injury Special Interest Group
 Neurology Section-American Physical Therapy Association

2002-present Executive Committee-Spinal Cord Injury QUERI
 Quality Enhancement Research Initiative
 Department of Veterans Affairs

TEACHING

Courses Developed and Taught

- 2002 Physical Therapy 640-*Ambulatory Function*
.25 credits. Spring Semester. 75% responsibility.
- 2002 Physical Therapy 656-*Systemic Disease and Physical Therapy*
.25 credits. Spring Semester. 75% responsibility.
- 2001-present Physical Therapy Post Professional 591 (Krannert)
Advance Physical Therapy Practice for Adults with
Neurological Disorders: Medical and Rehabilitation Management
3 credits. Spring (variable). 50% responsibility
- 1998-2001 Physical Therapy 670 – *Cardiopulmonary Physical Therapy,*
Oncology and Ambulatory Function .5 credits.
Spring Semester. 75% responsibility.
- 1998-2001 Physical Therapy 661-*Student Clinic*
0 credits. Fall Semester. 10% responsibility.
- 1998-2003 Physical Therapy 645- *Adult Neurological Rehabilitation.* 1.5
credits.
Fall Semester. 100% responsibility.
- 1998-2003 Physical Therapy 651– *Student Neuro Clinic.*
0 credits. Spring Semester. 90% responsibility.

Other University of Puget Sound Teaching (guest speaker)

- 2000-2004 *in* Physical Therapy 660 –*Interdisciplinary Case-OT/PT* .
one seminar, Fall semester.
- 1998-2004 *in* Physical Therapy 671 *Sexuality and Disability, the role of*
the PT. one lecture in Fall semester.
- 1995-2004 *in* Physical Therapy 660 *Case Presentation on SCI Physical*
two seminars, Fall semester.

1995 Physical Therapy 305- *Functional Anatomy*

1995 Physical Therapy 671- *Special Topics*

THERAPIST POSITIONS HELD

2003-present SCI Clinical Specialist, Spinal Cord Injury Service, DVA Puget Sound Health Care System, Seattle, WA

1998-2003 SCI Clinical Specialist Consultant, Spinal Cord Injury Service DVA Puget Sound Health Care System, Seattle, WA

1999-2002 Clinical Specialist, Physical Therapist III
Comprehensive Outpatient Rehabilitation Program
Harborview Medical Center, Seattle, WA

1990-1998 Spinal Cord Injury Clinical Specialist, Spinal Cord Injury Service
DVA Puget Sound Health Care System, Seattle, WA
(Leave of absence 8/95-5/96)

1987-1990 Senior Therapist, Spinal Cord Injury Service
DVA Puget Sound Health Care System, Seattle, WA

1987 Acting Chief of Physical Therapy
DVA Puget Sound Health Care System, Seattle, WA

1986-1987 Staff Physical Therapist
DVA Puget Sound Health Care System, Seattle, WA

1986 Staff Physical Therapist
Easter Seals of Massachusetts
Worcester, MA