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Sit-To-Stand Ability Following Ankle Joint Mobilizations In Patients With Hemiplegia

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ABSTRACT

Introduction: People with central nervous system pathology frequently demonstrate ankle contractures that interfere with function. The purpose of this study was to determine if ankle joint mobilizations increased passive ankle mobility and improved sit-to-stand function in five patients with hemiplegia following a stroke. Methods: Data collection occurred over 13-15 sessions using a single-subject ABA design. Baseline measurements were collected in the first 3-6 sessions, followed by intervention and measurement sessions and one follow-up measurement session that occurred two weeks later. During each session, eight sit-to-stand measurement trials were performed. Ankle range of motion, kinematic data, and time to complete the task were measured using an electromagnetic tracking system (Flock of Birds®) and motion analysis software (MotionMonitor™). The intervention consisted of joint mobilizations to increase ankle dorsiflexion, performed on the hemiplegic lower leg at the proximal/distal tibia-fibula and talocrural articulations. Data analysis: Ankle mobility data and time to complete the sit-to-stand task were graphed for visual and statistical comparison. The C Statistic was used to identify the presence of a trend in the baseline data compared to the intervention data. Ankle kinematics were analyzed qualitatively to provide a description of the movement strategy. Results: Joint mobilizations increased passive ankle ROM in all five subjects, with statistically significant changes as determined by C statistic analysis. These improvements were maintained in the two week follow-up session. No significant trends were found for peak-to-peak ankle excursion during sit-to-stand, and a gradual

decrease in time for sit-to-stand was noted during both baseline and intervention sessions. Analysis of ankle kinematics revealed varying patterns of change for the individual subjects. Conclusion: Although joint mobilizations were effective at improving ankle mobility in five subjects with hemiplegia, these improvements did not appear to directly affect sit-to-stand function. The subjects did seem to benefit from practicing this functional task as part of the repeated measure design, as demonstrated by a gradual decrease in time to perform sit-to-stand and improved consistency in ankle kinematics. One recommendation for future research is to incorporate additional interventions to specifically encourage the patient to use their increased ankle mobility during functional tasks.

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Chapter I

INTRODUCTION

Ankle joint contractures are a common occurrence in people with chronic hemiplegia secondary to a cerebral vascular accident (CVA). A contracture is caused by prolonged restriction in joint range of motion (ROM) that results in shortening of the muscle and soft tissue around a joint. The presence of an ankle joint contracture may prevent a person with hemiplegia from positioning their foot appropriately on the floor prior to attempting to stand from a sitting position. This sit-to-stand (STS) task is an important functional movement. Not only is it a prerequisite for gait, but it is also important in toileting, dressing, and transferring. These are all functional mobility skills that can have a great impact on a person's quality of life. Elderly people with limited ankle joint mobility have been found to have decreased balance (Mecagni, Smith, Roberts, & O'Sullivan, 2000) and may be at a greater risk for falls (Gehlsen & Whaley, 1990), especially during dynamic position changes like moving from sitting to standing. In fact, a correlation was found between how quickly the STS movement is performed and the likelihood of falling in people with hemiplegia following a stroke (Cheng et al. 1998).

Therapeutic interventions designed to improve ankle joint mobility in this population has traditionally consisted of tone-reduction techniques

(Davies, 1985). However, there is limited support available on the effectiveness of these techniques to decrease tone, improve ankle joint mobility, or improve function.

With prolonged immobility following a stroke, musculoskeletal restrictions may develop and cause additional ROM loss. These types of limitations may be treated appropriately by joint mobilization techniques (Cochrane, 1987; Harris & Lundgren, 1991; Tyson, 1998). A treatment approach based on impairments rather than on medical diagnosis allows the use of techniques to address musculoskeletal restrictions even in a patient with a primary neurologic pathology such as CVA. There is some support for the use of joint mobilizations as an intervention to increase ROM in the extremities of patients with peripheral nervous system pathology (Dijs et al., 2000), although it has not been extensively studied.

If joint mobilizations can help people with ankle joint contracture rise from a chair more safely and with less effort, they may require less assistance for the task and their fall risk may potentially decrease. Therefore, joint mobilizations may be a valuable technique that physical therapists could use to help with the management of patients with hemiplegia following CVA.

The purpose of this study is to determine if ankle joint mobilizations will increase ankle passive ROM and improve STS ability in a patient with hemiplegia following a CVA. The research hypotheses for this study are that

joint mobilizations will be effective in increasing ankle mobility (i.e. passive ROM) in patients with hemiplegia following a CVA, and that increased ankle mobility will result in improved performance of the STS task.

Chapter II

RELATED LITERATURE

Ankle Joint Kinematics

Dorsiflexion is the movement of the foot towards the anterior surface of the lower leg. This motion occurs primarily at the talocrural joint, which is the articulation between the distal end of the tibia (medial malleolus), the lateral malleolus of the fibula, and the talus bone of the foot. The talocrural joint is considered to be a hinge joint with one degree of freedom of motion.

When a 90 degree angle is formed at the talucrural joint by perpendicular positions of the fibula and lateral forefoot, this is considered a "neutral" ankle position at 0 degrees. A more acute angle formed by the foot moving dorsally closer to the tibia is referred to as dorsiflexion, and a larger angle formed by the foot moving farther away from the tibia is referred to as plantar flexion. By convention, any restriction in motion that prevents a person from achieving a neutral ankle position is referred to as negative dorsiflexion. For example, a patient whose range of motion is limited so that they are 10 degrees away from achieving neutral is referred to as having −10 degrees of dorsiflexion.

In addition to the talocrural joint, the proximal and distal articulations between the tibia and fibula also contribute to dorsiflexion, even though only a few degrees of motion occur at these joints (Smith, Weiss, & Lehmkuhl,

1996). The fibula rests on the talus bone of the foot, which is flared. During dorsiflexion, the medial and lateral malleoli must separate slightly to accommodate the wider aspect of the talus (Radakovich & Malone, 1982). To accomplish this, the fibula swings upward and outward slightly which causes motion to occur at both the proximal and distal tibiofibular articulations.

The axis for the dorsiflexion motion is referred to as a triplanar axis because it falls between the three planes of the body: sagittal, frontal, and horizontal (Smith et al., 1996). Although a majority of the dorsiflexion motion occurs in the sagittal plane, some components of this motion occur in both the horizontal and frontal planes (Lundberg, Goldie, Kalin, & Selvik, 1989).

When a body part is moved in a relaxed subject, passive resistance will be encountered from three potential sources. First, the inertia of the limb produces initial resistance. Second, viscoelastic properties of the muscle, connective tissue, and joint capsule will resist movement. Third, a stretch reflex may be evoked which causes a muscle contraction that opposes the movement (Gottlieb, Agarwal, & Penn, 1978). The stretch reflex is activated in healthy subjects when the limb is moved rapidly, and this reflex may be hyperactive in subjects with CNS damage.

When passive range of motion (ROM) at the joint is limited, this is referred to as a joint contracture (Halar, Stolov, Venkatesh, Brozovich, & Harley, 1978). Passive mobility of skeletal joints may be limited by tightness in one of the many principal structures that surround the joint. These

structures may be classified as either contractile or non-contractile (Kaltenborn, 1999). Contractile elements include the muscle with its tendons and attachments, and non-contractile elements include the ligaments and joint capsules. Passive stiffness is the resistance to elongation of these tissues without active resistance by the opposing muscle groups. The contribution of muscle stiffness may be very difficult to distinguish from connective tissue stiffness encountered when a body part is moved.

Joint capsular tightness may be demonstrated by a capsular pattern of restriction at the joint. In the ankle, restriction of both plantar flexion and dorsiflexion indicates a capsular pattern (Kaltenborn, 1999). Tendons and ligaments are viscoelastic structures composed primarily of collagen. The collagen molecules form cross-links to form microfibrils, which aggregate to form bundles (Carlstedt & Nordin, 1989). Factors such as pathology, immobilization, and aging can alter the biomechanical properties of these structures.

Joint Contractures after Cerebrovascular Accident

A CVA may cause a variety of motor and sensory impairments that contribute to the development of joint contractures, and there is a high incidence of contractures in patients following central nervous system (CNS) damage. In fact, 76% of patients admitted to an inpatient rehabilitation center

following craniocerebral trauma were found to have an ankle joint contracture (Yarkony & Sahgal, 1987).

In patients who have sustained a CVA, one of the most common contractures is the loss of dorsiflexion motion in the ankle on the hemiplegic side. Halar et al. (1978) found that the gastrocnemius muscle belly is actually shorter on the hemiplegic side compared to the unaffected side, with no difference in Achilles tendon length.

Increased resistance to passive movement of the ankle in patients with hemiplegia after CVA may be caused by many complex factors. Damage to the motor cortex of the central nervous system frequently results in spasticity, which presents as hyperreflexia and velocity-dependent muscle hypertonia. Non-neural factors are also known to increase resistance of joint movement and contribute to the development of contractures. These factors include changes in mechanical properties of muscle and connective tissue not only resulting from the CVA, but also as a result of loss of strength and the aging process in this population.

Neural factors. A lesion of the CNS may result in stretch reflex hyperactivity and hypertonia (i.e. spasticity), which contribute significantly to calf muscle stiffness (Gottlieb et al., 1978; Vattanasilp, Ada, & Crosbie, 2000). An increase in passive joint stiffness has been consistently found to occur at the ankle in patients with hemiparesis compared to the contralateral ankle and to healthy controls (Given, Dewald, & Rymer, 1995; Hufschmidt &

Mauritz, 1985; Sinkjaer & Magnussen, 1994; Thilmann, Fellows, & Ross, 1991).

Sinkjaer et al. (1994) defined "reflex stiffness" as the component of total ankle joint stiffness mediated by stretch reflex mechanisms. In subjects with hemiparesis, they found that although reflex stiffness is higher in the hemiparetic leg compared to the contralateral leg, the stiffness of both legs was larger when compared to healthy subjects.

Spasticity in the foot and ankle is commonly cited as the cause of significant gait deviations in people who have hemiplegia after stroke (Ryerson, 1988). Therefore, rehabilitation efforts frequently focus on the reduction of spasticity through therapeutic procedures to inhibit tone, pharmacological measures, or surgical procedures.

Physical therapists may use sustained tendon stretching at the ankle either manually or through weight bearing activities in order to inhibit tone (Davies, 1985; Ryerson, 1988). A passive stretch must be maintained for a prolonged time to demonstrate sustained changes in ROM (Farmer & James, 2001). A 30 minute sustained stretch applied daily over a four-week period was not effective in improving ankle ROM in subjects with spinal cord injuries (Harvey, Batty, Crosbie, Poulter, & Herbert, 2000). The application of serial casts to provide a constant, sustained stretch has been shown to be effective in increasing ROM at the ankle in individuals with traumatic brain injury (Barnard et al., 1984; Booth, Doyle, & Montgomery, 1983; Conine, Sullivan,

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Mackie, & Goodman, 1990; Moseley, 1997). Several of these authors also noted a reduction in spasticity in these subjects, although spasticity was routinely measured by a subjective estimate of the amount of passive resistance encountered rather than specific neurophysiological measures such as the H-Reflex or EMG activity.

Other medical interventions to address spasticity in this population include a variety of pharmacologic medications that act as a CNS depressant or surgical procedures such as selective dorsal rhizotomies (Katz, 1988). However, treatment of spasticity may not have a significant effect on a patient's functional performance, as there does not appear to be a relationship between spasticity, weakness, or loss of dexterity (O'Dwyer, Ada, & Nielson, 1996).

Non-Neural Factors. A growing number of researchers have examined the influence of changes in intrinsic muscular properties and connective tissue on passive ankle stiffness in people with neurologic pathology (Hufschmidt et al., 1985 for example). People who have sustained a CVA seem to have biomechanical or non-neural changes that contribute significantly to the amount of stiffness felt at the joint, over and above the influence of spasticity, or hyperactive stretch reflexes.

Passive muscle resistance encountered during slow passive movements is exclusively due to intrinsic muscular properties because the stretch reflex is velocity-dependent. Hufschmidt et al. (1985) found an

increase in elastic resistance due to structural changes in the joint capsule as well as increased plastic resistance due to muscular changes. These changes emerged one year after the initial manifestation of spasticity, and the changes occurred independent of reflex activity.

Thilmann et al. (1991) also used slow passive movements to examine ankle stiffness in people with hemiparesis, but they compared these subjects to healthy controls who demonstrated a high degree of calf stiffness ("stiff normals"). Interestingly, they found that although the hemiparetic ankles had higher stiffness levels than the non-paretic ankles, the "stiff normal" subjects had even higher levels of stiffness. However, these subjects demonstrated a normal gait pattern in spite of the passive biomechanical changes. The subjects with hemiparesis demonstrated gait deviations consistent with calf stiffness, perhaps because they encountered the increased stiffness as adults, when the locomotor pattern is already established (Thilmann et al., 1991). Alternatively, perhaps the other sensorimotor consequences of the stroke limited these subject's ability to compensate.

Given et al. (1995) found that passive ankle stiffness was greater in the hemiplegic ankle than in the contralateral ankle in patients with spasticity, as would be expected by the previous discussion of stretch reflex mechanisms. However, they also found that passive stiffness at the ankle was greater than passive stiffness at the elbow joints both in subjects with hemiplegia and control subjects. They attributed this finding to non-neural

contributions to joint stiffness: there is a greater amount of intramuscular connective tissue, greater percentage of slow-twitch muscle fibers, and greater cross-section of muscle area at the ankle compared to the elbow.

A phenomenon called "thixotrophy" in the muscles may contribute even more resistance to the movement of a joint following CVA (Vattanasilp et al., 2000). Muscle behaves as a thixotrophic substance because increased stiffness is demonstrated when it has not been moved recently, with decreased resistance to movement after being stretched or moved. A thixotrophic response has been demonstrated in people after CVA in the calf muscles, although there was not an abnormally high response compared to controls (Vattanasilp et al., 2000). Using EMG to monitor involuntary muscle activity during stretch, a comparison of prolonged static stretching and cyclic calf stretching in people with stroke found decreased ankle stiffness with either technique (Bressel & McNair, 2002). These results provide evidence that the thixotrophic response contributes to exaggerated ankle joint stiffness in patients after stroke.

Finally, O'Dwyer et al. (1996) examined spasticity and muscle contracture in patients who had recently (within one year) had a stroke. Although they examined the upper extremity, their findings are relevant for this discussion. They found increased passive resistance in the elbow joint in the absence of stretch reflex activity even at high velocity movements in these subjects. This increased stiffness was attributed to the presence of

contracture, rather than the influence of spasticity. These adaptive muscle and connective tissue changes occur relatively rapidly after stroke and seem to be responsible for the clinical impression of hypertonia. This may explain why tone-reduction techniques do not appear to effectively improve range of motion or functional performance.

Effect of Immobilization. Following a CVA, a patient may not actively move their limb as often because of impaired functional mobility, impaired motor control, and lower extremity weakness. This "immobilization" that results is further compounded by the frequent use of non-articulated ankle-foot orthotics to enhance ankle stability during gait. Immobilization resulting from decreased motor function and restricted limb motion can lead to further mechanical changes and joint contracture.

Studies of rats have revealed that immobilization causes an increased rate of collagen synthesis, with fibers laid down in a random orientation (Amiel, Woo, Harwood, & Akeson, 1982). A review of animal and human research found several other relevant changes that occur in synovial joints with prolonged immobilization (Akeson, Amiel, Abel, Garfin, & Woo, 1987). Ligament fibrils are disorganized with the development of adhesions between connective tissue surfaces. Increased joint stiffness results from these adhesions as well as the random insertion of new collagen fibers in the joint and joint capsule. This disordered deposition of fibrils impedes flexibility in the

normally extensible joint capsule and results in a joint contracture. This process occurs over a matter of weeks and may take months to recover.

Gillette and Fell (1996) used a rat model to examine the contribution of the joint capsule to passive stiffness in a healthy joint following a period of immobilization. They measured the amount of hindlimb passive tension into dorsiflexion before and after cutting the Achilles tendon. The joint capsule contributed 45% of the passive joint stiffness in the normal rats and 25% in rats who were immobilized for seven days. Therefore, joint capsular tightness may contribute significantly to passive stiffness encountered when a limb is moved.

Immobilization also leads to disuse atrophy of the muscle. In patients who have had a CVA, this certainly may complicate the weakness resulting from hemiparesis and lead to further immobilization of the ankle joint in a viscous cycle. Recently, Shaffer et al. (2000) found that subjects immobilized for eight weeks following an ankle fracture (who presented with no CNS abnormalities) had decreased plantar flexor peak torque as well as impaired function. It may be expected that these types of changes would occur in anyone with limited lower extremity mobility after a prolonged period of time.

Effects of Aging. The majority of people who have a CVA are elderly. Therefore, in addition to all of the factors discussed above, changes that occur as part of the aging process may also influence ankle joint mobility. Active and passive joint range of motion has been found to decrease with age

in general, and at the ankle joint specifically (James & Parker, 1989; Walker, Sue, Miles-Elkousy, Ford, & Trevelyan, 1984;).

Gajdosik, Vander Linden, and Williams (1999) examined this ROM loss at the ankle in detail to determine the influence of age on passive elastic stiffness of the calf muscle. They found that ankle ROM was decreased secondary to a shortened calf musculotendinous unit, although passive elastic stiffness of the calf muscle was not increased. They speculated that the decreased calf ROM may be due to the decrease in the number of sarcomeres, motor units, or decreased muscle mass that occurs with age.

Limitations in ankle mobility may be correlated to ankle weakness (Mueller, Minor, Schaaf, Strube, & Sahrmann, 1995) and frequency of falls in the elderly population (Gehlsen et al., 1990). Mecagni et al. (2000) found moderate correlations between ankle dorsiflexion ROM and performance on balance tests in their study of elderly women. They concluded that tightness specifically in noncontractile tissues of the ankle may have contributed to the decreased balance scores:

> "We believe that future studies should assess the impact of articulatory
> techniques, such as joint mobilizations, and specific stretching on
> improvements on ankle ROM and balance" (p. 1009).

Summary. The increased resistance to passive stretch that is commonly attributed to spasticity may thus be secondary to adaptive muscle changes or passive joint stiffness caused by non-neural factors. Several

researchers have found increased stiffness in muscle fibers and connective tissue in the hemiplegic extremities of subjects post-CVA, in the absence of stretch reflex activity or spasticity. These factors are further complicated by the effects of immobilization and the effects of aging that commonly occur in this population.

Because of multiple contributing factors, ankle plantar flexion contractures are frequently present in people with hemiplegia resulting from a CVA. The impact of these contractures is negative as they limit a patient's ability to perform functional mobility tasks. For example, an ankle plantar flexion contracture may prevent a subject from positioning the foot in an optimal weight bearing position when attempting to perform the STS task.

Joint Mobilizations

Joint mobilizations, or passive movements of the articular surfaces, are indicated for mechanical joint dysfunction in which there is restriction of accessory motion leading to pain or ROM limitation. Accessory movement occurs within a joint and surrounding soft tissues and is necessary for normal ROM (Kaltenborn, 1999). The amount of joint play may be determined manually to indicate whether there is restriction in the non-contractile elements of the joint (e.g. joint capsule, ligaments).

Joint mobilizations may be used to stretch a hypomobile joint capsule. Kaltenborn (1999) has identified three grades of joint mobilization force.

Grade I or II manual traction or gliding may be used to assess joint play as noted above, and may be applied first as a trial treatment to determine the patient's initial response to the technique. Grade III mobilizations stretch the tissues crossing the joint. The stretch should be maintained for at least one minute, and the treatments should be continued as long as improvement in joint play is noted following the mobilization stretch (Kaltenborn, 1999).

Several joint mobilization procedures are recommended for ankle hypomobility, specifically with restricted dorsiflexion motion. These are: traction and posterior glides at the talocrural joint, anterior-posterior glides at the distal tibiofibular joint, and anterior-posterior glides at the proximal tibiofibular joint (Kaltenborn, 1999).

Cochrane (1987) first explored the use of mobilizations in people with CNS dysfunction in an essay discussing the use of this intervention to treat shoulder capsular dysfunction in children with CNS deficits. In a similar type of essay, Harris et al. (1991) discussed indications and precautions for the use of mobilizations on children with CNS dysfunction. Both of these articles called for the need to research the efficacy of these techniques in a neurological population. However, the only research to date is a case study presented by Tyson (1998) of an adult with mild hemiparesis secondary to cerebral palsy. Joint mobilizations were used to address ROM restrictions in the shoulder, elbow, wrist, and hand. Although "dramatic improvements" (p.

294) in passive and active motion were reported, no objective ROM measurements were included in the case study.

Research to support the use of ankle joint mobilizations even for people without central nervous system pathology is limited. One recent study did explore the use of ankle joint mobilizations in a small group of patients with limited ankle mobility and diabetic neuropathy (Dijs et al., 2000). They found that ten sessions of mobilizations at the tibiotalar joint, subtalar joint, midfoot, metatarsalphalangeal, and interphalangeal joints were effective in increasing passive ROM at each of these joints, as measured by goniometry. An additional ten sessions did not significantly improve ROM any further. These researchers did not measure functional performance.

A randomized, controlled trial of anteroposterior ankle joint mobilizations in subjects with acute ankle sprains was found to effectively increase joint ROM and improve gait performance (Green, Refshauge, Crosbie, & Adams, 2001). The only other study that explored ankle joint mobilizations investigated the application of a single Grade V manipulation to the ankle joint of healthy adults (Nield, Davis, Latimer, Maher, & Adams, 1993). Improvements in ROM were not noted, but obviously this study is limited by the application of this treatment to a healthy sample without known impairments. A significant increase in ROM would not be expected in a normal subject without pathology.

Further research to support the use of this commonly used treatment is clearly warranted. The data from several pilot studies performed in 1998, 1999, and 2000 (unpublished data) suggest that joint mobilizations may be effective in improving passive ankle ROM in subjects following a CVA. The first pilot study (1998) examined one session of ankle joint mobilizations with a group of six subjects post-CVA. The variability of subject characteristics in this group and the limited change expected with only one session of joint mobilizations led to the use of a single-subject research design for the next two pilot studies.

In 1999 and 2000, repeated measurements were taken with single subjects during baseline sessions without intervention (A phase), sessions with ankle joint mobilizations (B phase) and post-intervention sessions (second A phase). The subjects did demonstrate improved passive ankle ROM during the intervention, but the study of functional performance was limited by the use of a video camera to measure kinematic ankle motion. Rotation of the lower extremity was observed to occur during the sit-to-stand motion, which precluded accurate two-dimensional analysis of ankle motion. Furthermore, the subjects required physical assistance to perform the sit-to-stand motion, and therefore had significant weakness or other motor control issues in addition to restricted ankle motion.

There appears to be a valid theoretical rationale for the use of ankle joint mobilizations to improve joint mobility in people with hemiplegia after

CVA. Ankle plantar flexion contractures in this population appear to have a non-neural component that may respond to interventions directed at increasing connective tissue extensibility.

Sit-to-Stand Task

The sit-to-stand movement is an important functional skill that has generated a great deal of research interest. A recently published review of research identified 39 experimental studies, 19 of which were published 1995-2001, that investigated the effects of movement determinants on the STS movement (Janssen, Bussmann, & Stam, 2002).

STS in healthy subjects. The normal STS movement has a typical sequential movement pattern that involves movement of the head, trunk, and lower extremities. Schenkman et al. (1990) identified key biomechanical events in the movement pattern and proposed four phases of rising. Phase I (Flexion Momentum), begins with initiation of head movement and ends before the buttocks lift from the chair seat. Phase II (Momentum Transfer) begins with seat lift off and ends when maximal ankle dorsiflexion is achieved. Phase III (Extension Phase) involves extension of the ankle, knee and hip. This is followed by Phase IV (Stabilization), although it may be difficult to identify an end point for this phase because of normal sway during quiet stance (Schenkman, Berger, O Riley, Mann, & Hodge, 1990). The mean time for the subjects in this study to perform the STS task was 1.95 seconds, and

the mean time to complete Phase I and II (time to peak ankle dorsiflexion) was 0.83 seconds, or 43% of total time.

Other researchers have found that healthy, young subjects have a total STS movement time ranging from 1.37 to 1.88 seconds (Alexander, Schultz, & Warwick, 1991; Cheng et al., 1998; Fleckenstein, Kirby, & MacLeod, 1988; Hanke, Pai, & Rogers, 1995). Kotake et al. (1993) reported that 45.1% of total sit-to-stand time occurs in the stages leading up to peak ankle dorsiflexion in healthy young subjects.

During the STS motion from a standard chair height, maximal ankle dorsiflexion has been found to range from 17.9 to 28 degrees (Burdett, Havasevich, Pisciotta, & Simon, 1985; Doorenbosch, Harlaar, Roebroeck, & Lankhorst, 1994; Rodosky, Andriacchi, & Andersson, 1989). Total segmental excursion at the ankle was found to be 19.69 degrees in a group of healthy women (Ikeda, Schenkman, O Riley, & Hodge, 1991).

STS in elderly subjects. The elderly often have difficulty with transitional movements, such as rising from a seated position, which puts them at risk of falling. This may be because elderly subjects may have decreased segmental range of motion and lower extremity strength. Knee extensor strength has been found to be a limiting factor in rising from low chairs for functionally impaired elderly subjects (Hughes, Myers, & Schenkman, 1996). However, the research seems to demonstrate that healthy elderly subjects perform the STS task very similarly to younger

subjects discussed previously. The key events and biomechanical phases described by Schenkman et al. (1990) were consistent with the phases described in a population of elderly subjects (Millington, Myklebust, & Shambes, 1992).

VanderLinden, Brunt, and McCullock (1994) found that healthy elderly adults have a 1.44 second STS movement time, with 0.8 seconds to reach peak ankle dorsiflexion (55.5% of total time). These values are very similar to those reported previously for healthy young subjects. Vander Linden concluded that healthy elderly were able to modify their STS movement strategy to compensate for lack of ankle motion or increased speed demands without variation in the relative timing of phases (VanderLinden et al., 1994).

Ankle motion demonstrated during the STS task in healthy elderly is also comparable to younger subjects with maximal ankle dorsiflexion of 28.7 degrees (Ikeda et al., 1991), and mean total ankle excursion ranging from 17.6 degrees (Ikeda et al., 1991) to 22 degrees (VanderLinden et al., 1994).

Functionally impaired elderly subjects who require the use of armrests to successfully complete the task may increase the time significantly. Elderly subjects with rheumatoid arthritis were found to take 3.5 seconds to perform the STS transfer (Munro, Steele, Bashford, Ryan, & Britten, 1998), and subjects with mild functional impairments (unable to descend four stairs reciprocally) had a STS movement time of 2.44 seconds (Hughes, Myers, & Schenkman, 1996; Hughes & Schenkman, 1996). These researchers

concluded that the subjects placed more value on safety than on successfully rising from a chair, and were not willing to increase their momentum if that meant sacrificing stability. Hughes, Weiner, Schenkman, Long, and Studenski (1994) discussed the strategy of "base of support rearrangement" in subjects who used several motions to position themselves before rising rather than using a more efficient momentum transfer strategy.

Alexander et al. (1991) found that elderly subjects who were unable to rise without the use of an armrest took an average of 3.16 seconds to perform the task (when using armrest). Interestingly, although these subjects also had a prolonged absolute time of 1.21 seconds to peak dorsiflexion, the percent of time in this phase was 39.4% of total, which is relatively less than reported for healthy groups. These subjects appeared to spend a greater proportion of STS time on the extension and stabilizations phases of the task.

The initial position of the foot appears to be critical in healthy subjects of all ages (Khemlani, Carr, & Crosbie, 1999; Shepherd & Koh, 1996; Stevens, Bojsen-Maller, & Soames, 1989; VanderLinden et al., 1994;). If the foot is too far forward, subjects demonstrate increased muscle activity, greater excursion of head movement, increased pressure on hip and knee joints, and increased duration of movement phases when completing the task. After an extensive review of experimental studies investigating the STS task, Janssen et al. concluded that foot positioning and the use of armrests are major determinants of STS performance (Janssen et al., 2002). Subjects with

hemiplegia may be unable to place the foot in an optimal weight bearing position because of unilateral loss of ankle ROM.

STS in subjects with hemiplegia. Several studies have analyzed the STS task specifically in people with hemiplegia. An investigation of EMG activation patterns concluded that there was an alteration in motor sequence and decreased motor unit output on the affected side of subjects with hemiplegia (Lee, Wong, Tang, Cheng, & Lin, 1997). Other researchers have found these subjects tend to have a asymmetrical body weight distribution away from their hemiparetic leg compared to controls (Cheng et al., 1998; Engardt & Olsson, 1992). The average loading of the paretic leg was found to be 24-29% of body weight by Cheng et al. (1998) and 34.7- 39% of body weight by Engardt, Ribbe, and Olsson (1993). It appears that patients in this population are able to improve their symmetry during this task if given a verbal cue to rise "evenly" (Engardt et al., 1992) or if given the opportunity to practice with the augmented feedback of an auditory signal (Engardt, 1994; Engardt et al., 1993; Fowler & Carr, 1996). These practice interventions were developed based on contemporary theories of motor control and motor learning. Alternatively, a four-week intervention program based on NDT guidelines did not improve kinematic or kinetic parameters of rising from a chair (Hesse, Schauer, Peterson, & Jahnke, 1998).

People who have hemiplegia appear to take a longer time than healthy elderly to stand up from a chair. Even relatively high-functioning subjects with

hemiplegia who were able to stand up without the use of armrests were found to take from 1.975 seconds (Hesse, Schauer, Malezic, Jahnke, & Mauritz, 1994) to 2.1 seconds (Hesse et al., 1998) to stand up from a chair. Ada and Westwood (1992) found that subjects with hemiplegia were able to improve their STS time from 2.28 seconds to 1.57 seconds after an intensive rehabilitation program.

Cheng et al. (1998) found that patients following a CVA who had experienced a fall required a statistically significantly longer time to stand up (4.32 seconds) compared to post-stroke non-fallers (2.73 seconds) and healthy age-matched controls (1.88 seconds). This longer time may be required to compensate for increased center of pressure sway in both the mediolateral and anteroposterior directions during the STS task found by several researchers (Cheng et al., 1998; Hesse et al., 1994; Lee et al., 1997; Yoshida, Iwakura, & Inoue, 1983). The increased difficulty with the STS task noted by these researchers may be caused by multiple factors, including musculoskeletal impairments.

The systems theory of motor control and the theory of learned non-use may be used to help explain the relationship between impairments such as restricted ankle motion and functional limitations such as sit-to-stand. The systems theory states that the outcome of functional movement results from the complex interaction of many systems (Horak, 1991). These systems may include the cardiac, psychological, or neurological systems within the

individual performing the task, in addition to external systems such as the environment and the nature of the task to be performed. Movement strategies emerge from the interaction of these multiple systems. Limitations within one system (e.g. musculoskeletal) may cause a subject to alter the movement strategy in order to accomplish the task goal (e.g. get up from a chair). This compensatory strategy may not be the most efficient or most effective, but it will be learned if practiced repetitively.

While the systems theory may explain why a person with limited ankle ROM might adopt a strategy that includes the use of a forward foot posture and decreased weight bearing on the hemiplegic leg during the STS task, the theory of learned non-use may explain why a person with the ability to use a limb does not actually use that limb for functional tasks (Taub & Wolf, 1997). Attempts to use the limb may be negatively reinforced because of the difficulty encountered when the movement is very slow, uncoordinated, or fatiguing. This may be the reason why a person with hemiplegia continues to choose a strategy that minimizes the use of the weaker leg during the sit-to-stand movement, even if they are capable of using the limb. As discussed previously, researchers have confirmed that people with hemiplegia demonstrate asymmetrical weight bearing, decreased speed of movement, and difficulty with forward translation of body weight during sit-to-stand (Cheng et al., 1998; Engardt, 1994; Engardt et al., 1992; Engardt et al., 1993; Fowler et al., 1996). Based upon these findings, it is imperative to find an

intervention that may counteract the effects of learned non-use and allow the subject to function with greater ease of movement. The purpose of this study was to determine if ankle joint mobilizations were effective in improving STS function in this population.

Single-Subject Study Design

This study utilized a single-subject research design with multiple subjects. This design arose from clinical psychology and is synonymous with N = 1 research trials (Zucker et al., 1997), idiographic model (Ottenbacher, 1990a), time series method, and within-subject comparisons (Gonnella, 1989). In this design, an independent variable is manipulated in one subject with repeated measurements over a period of time.

By using an individual subject as its own control, an experimental analysis of behavior may be achieved. This design has the additional advantage of clinical relevance, as the practicing clinician is interested in producing a clinically significant effect with an individual patient rather than a statistically significant effect with a large group (Kazdin, 1982). In fact, the process of applying the single-subject paradigm has several similarities to the process of administering therapeutic procedures in physical therapy practice, and can be integrated easily into the clinic to provide the evidence necessary to advance the science of clinical practice (Gonnella, 1989; Ottenbacher & Hinderer, 2001).

The single-subject research design is different than an uncontrolled case study or case report. These often include detailed patient descriptions, but there is no attempt to manipulate an independent variable to determine its effect on the target behavior or dependent variable (Backman & Harris, 1999). The single-subject study design may be preferable to group research designs where individual behavioral changes may be lost by averaging performance across several subjects (Kazdin, 1982), which may contribute to the generally poor use of research findings by clinical practitioners (Ottenbacher, 1990a). Traditional randomized controlled experimental designs are often difficult to employ in the clinical setting.

The single-subject design allows the identification of specific patient characteristics that may be relevant for improved performance, and generalizability may be established through replication of this design with multiple subjects (Ottenbacher, 1990a). Initial replication of the study with subjects possessing similar characteristics may be followed by systematic replication using different subject characteristics, different settings, or different therapists (Backman et al., 1999). The combination of several single-subject trials may provide both a population estimate of treatment effectiveness and a distinct estimate of effectiveness for each individual patient (Zucker et al., 1997).

Single-subject research designs require continuous assessment with repeated observations over time, which allows the study of the course of

treatment process as well as the outcome (Ottenbacher, 1990a). This allows the investigator to examine the pattern and stability of a behavior before the treatment is initiated and to determine the effects of the intervention once it is introduced. The baseline assessment serves both a descriptive function, to describe the existing behavior and extent of the individual's problem, and a predictive function, to project what the behavior would be in the future without an intervention (Kazdin, 1982).

The stability of baseline performance is an important characteristic that is required to reliably predict future performance. As a general rule, the greater the variability in baseline data, the more difficult it is to draw conclusions about the effectiveness of the intervention (Kazdin, 1982). Because the motor control strategies used by people with neurologic pathology may fluctuate greatly, the design of this study attempted to minimize the impact of such variability.

Traditionally, single-subject research employs an ABAB design that alternates the baseline condition (A phase) with the intervention condition (B phase). The effects of the intervention are most clear if performance improves in the first B phase, reverts back to baseline during the second A phase, and improves again when treatment is resumed in the second B phase (Kazdin, 1982). During the intervention phase, a comparison can be made between the predicted continued behavior extrapolated from the baseline phase and the actual behavior that occurred with the intervention. The second A phase,

or reversal phase, restores the baseline conditions and can reinforce what the behavior might have looked like without an intervention. If the behavior does not revert toward baseline levels during this phase, the improvements found during the intervention phase may have been due to extraneous factors, or the behavior may have been permanently changed as a result of the intervention. Although the clinician usually hopes that a behavior change will be permanent, this effect may limit the internal validity of a research study (Kazdin, 1982) because there would not be reversal of the behavior when treatment is withdrawn.

A multiple-baseline design may use an AB format across several different subjects instead of the second baseline phase to determine the intervention effects. This design requires the introduction of the intervention to several (e.g. four or five) different subjects at different points in time. For example, the baseline phase for subject 1 may consist of three sessions, and the baseline phase for subject 2 may be six sessions. This design minimizes problems with carry-over effects and other threats to internal validity inherent in the ABA design (Zhan & Ottenbacher, 2001).

Backman, Harris, Chisholm, and Monette (1997) reviewed 40 papers pertaining to rehabilitation that utilized a single subject design published from 1985 - 1996. Seven studies were identified that used a multiple baseline design across different subjects, and the number of subjects studied ranged from two to five. The authors identified two examples that effectively used of

this design to examine treatment effectiveness, and both of these studies used four subjects with baselines of varying length. The baseline period should consist of at least two observations to accurately describe the behavior without the intervention. However, if the baseline is too long, a practice effect may cause improved behavior before the intervention is applied (Kazdin, 1982).

Furthermore, if the intervention is intended to have an effect on two behaviors (e.g. ankle ROM and sit-to-stand function in this study), examining performance of both behaviors strengthens the inferences that the intervention was effective since both behaviors should change at the point the intervention was introduced (Kazdin, 1982).

Although a second baseline or reversal phase is not included in this design, a follow-up measurement may be made several weeks or months later to determine whether the change in behavior was indeed permanent.

Data Analysis. There is support that the data generated from this single subject design will be useful to determine stability of the measure and compare trends during the different phases. Based upon the research previously cited, the treatment may be determined to have had an effect on the dependent variable if there is a clear change in level and trend when the treatment is introduced and that change is replicated in additional phases or with additional subjects (Wolery & Harris, 1982). However, several research studies have found poor agreement between raters using visual analysis only

(Harbst, Ottenbacher, & Harris, 1991). Health care professionals or students who were asked to interpret AB graphs were more confident and more consistent when quantitative information was provided to supplement visual analysis (Hojem & Ottenbacher, 1988; Ottenbacher, 1990b).

Statistical methods may assist with interpreting data in a single subject design when there is unstable baseline data or when there are small treatment effects that may be ignored in visual analysis, and these methods have the advantage of limiting experimenter bias (Nourbakhsh & Ottenbacher, 1994). Traditional statistical estimates of averages and variabilities are biased by the serial dependency inherent in repeated measures gathered from the same patient (Ottenbacher et al., 2001).

Several statistical procedures have been identified to supplement visual analysis and control for the serial dependency found in the repeated measures of a single subject. These include trend estimation using the split middle technique or "celeration line", time series analysis, C statistic, and two-standard deviation band method (Backman et al., 1999; Blumberg, 1984; Nourbakhsh et al., 1994; Tryon, 1982; Wolery et al., 1982).

Nourbakhsh and Ottenbacher (1994) compared the use of the split-middle method, two-standard deviation band method, and the C statistic, with both hypothetical and previously published AB data. The percent agreement between the three tests was low (38%), with greater agreement for graphs with large treatment effects. The two-standard deviation band method

appeared to be the least accurate method when baseline data are variable and was most sensitive to extreme values. The researchers recommend multiple approaches to the analysis of single-subject data, one of which should be visual analysis. The statistical methods used in this study include calculation of the C statistic as described by Tryon (1982) to determine whether statistically significant trends exist within and between the phases.

Measurement Procedures: Flock of Birds.

The "Flock of Birds" is an electromagnetic tracking system (Ascension Technology, Burlington, VT) used for motion analysis. The position and orientation of receiving antenna sensors are measured with respect to a transmitting antenna. The transmitting antenna is fixed in space and is driven by a pulsed DC current. The signals from the receiving sensors may be measured up to 144 times per second. The six degrees of freedom measured include three positions (x, y, and z coordinates) and three Eulerian angles (yaw, pitch, and roll).

This system is useful for measuring 3D joint positions in a clinical setting, and the measurements are relatively fast and easy to perform compared to camera-based motion analysis systems (Meskers, Vermeulen, de Groot, van der Helm, & Rozing, 1998). A published case report used this system to monitor wrist active ROM to describe the progress of a patient's rehabilitation program (Slobounov, Simon, Sebastianelli, Carlson, & Buckley, 1996).

Accuracy of this system has been examined by several investigators. Potential sources of error include random noise, receiver - transmitter distance, metal interference in the room, and skin movement over underlying muscles and tendons (Riess & Abbas, 1997).

Milne, Chess, Johnson, and King (1996) examined positional and rotational accuracy and resolution using a grid board. They found the optimal separation range between receiver and transmitter to be 22.5 - 64.0 cm. Within this operation zone, position and rotational errors were less than 2%, and the device is sensitive enough to read positional changes of 0.25 mm and rotational changes of 0.1 degrees. These values are similar to those reported by the manufacturer. Riess et al. (1997) confirmed that error was larger at locations further away from the transmitter in a similar study, and they developed several models that may be used to compensate for measurement errors. This source of error was minimized in the present study by placing the transmitting unit on a wooden platform in a position so that all of the sensors were within a 36" radius of the unit.

Because the presence of metal in the environment may cause a disturbance of the electromagnetic field (e.g. steel-reinforced concrete floors), a position calibration procedure must be performed prior to measurements. Although Milne et al. (1996) found that the Flock of Birds is not sensitive to most metals used in surgical implants, Meskers, Fraterman, van der Helm, Vermeulen, and Rozing (1999) found significant distortion in measurements

caused by steel-reinforced concrete even one meter above the floor. The Motion Monitor software system (Innovative Sports, Chicago, IL) may be used to identify distortion in the electromagnetic field caused by metal in the environment. This potential source of error may be limited by minimizing the amount of metal in the environment (e.g. use of a plastic chair for the sit-to-stand task).

When the Flock of Birds is used to study joint motion, two sensors may be placed on the body segments adjacent to that joint. A third sensor may be used as a pointer to identify the position of surrounding bony landmarks. Reliability was found to be high using this method with an artificial elbow joint, as long as the measurement of bony landmarks was standardized (Stokdijk et al., 2000).

The reliability of this system has also been investigated for use in the lower extremity. Umberger, Nawoczenski, and Baumhauer (1999) examined sagittal plane motion of the first metatarsophalageal (MTP) joint in cadaver foot specimens and found excellent reliability (intraclass r > 0.99). Furthermore, Slobounov et al. (1999) measured active and passive knee ROM measurements in healthy human subjects using both the Flock of Birds system and traditional goniometry. No significant difference was found between most of the measures taken with these two systems.

There are no published studies of the reliability of using this system to measure ankle joint ROM. Therefore, the reliability of using this system to

measure passive and active ankle motion was determined prior to the initiation of data collection for this research study using a healthy subject. The subject was a 23 year-old female without neuromuscular abnormalities. Two electromagnetic sensors from the Flock of Birds system, consisting of plastic pieces attached to wire leads, were applied with velcro straps on the shank and foot body segments of the right lower extremity. While the subject stood in the standard anatomical position, a third sensor was used to digitize the following points as directed by the Motion Monitor software system set-up procedures: medial knee joint, lateral knee joint, medial ankle joint, lateral ankle joint, and second metatarsal. The transmitting unit was placed on a wooden platform in a position so that all of the sensors were within a 36" radius of the unit, and the subject's foot was placed with her heel on the edge of a small platform to allow full range of dorsiflexion and plantar flexion motion at the ankle.

In one session, the following eight measurements were performed twice using the "goniometer" function of the Motion Monitor software: active plantar flexion with knee flexed to 90 degrees, active plantar flexion with knee extended fully, active dorsiflexion with knee flexed to 90 degrees, active dorsiflexion with knee extended fully, passive plantar flexion with knee flexed to 90 degrees, passive plantar flexion with knee extended fully, passive dorsiflexion with knee flexed to 90 degrees, passive dorsiflexion with knee

extended fully. These measurements were also taken using a standard

goniometer, and all measurement values are presented in Table 1.

Ankle ROM measurement	Flock of Birds			Goniometer		
	1	2	Average	1	2	Average
Active PF with knee flexed	63.59°	64.27°	63.93°	60°	60°	60°
Active PF with knee extended	60.6°	63.56°	62.08°	53°	52°	52.5°
Active DF with knee flexed	23.55°	24.46°	24.01	34°	39°	36.5°
Active DF with knee extended	9.58°	8.2°	8.89°	18°	18°	18°
Passive PF with knee flexed	52.64°	62.86°	57.75°	51°	54°	52.5°
Passive PF with knee extended	49.42°	58.05°	53.74°	45°	43°	44°
Passive DF with knee flexed	21.26°	22.97°	22.07°	30°	28°	29°
Passive DF with knee extended	14.55°	9.51°	12.03°	17°	16°	16.5°

Table 1: Ankle range of motion measurements used to determine reliability

and validity. Measurements were taken with the Flock of Birds system and a

standard goniometer in a healthy subject.

Intrarater reliability of the Flock of Birds system measurements was

determined by comparing the two measurements taken for each of the eight

motions using this system, presented in the first two columns of Table 1. The

intraclass correlational coeffiecient was calculated using the equation for

model (3,1), which is appropriate for testing intrarater reliability with multiple

scores from the same rater (Portney & Watkins, 2000). Intrarater reliability was found to be high with an ICC (3,1) of 0.994.

Concurrent validity was also established by comparing the average of two measurements taken with the Flock of Birds system to the average of two ankle ROM measurements taken with a goniometer as presented in Table 1. The correlation between these values was found to be high with a Pearson coefficient (r) of 0.966.

These values for reliability and validity are considered sufficiently high for clinical research (Portney et al., 2000). The values presented here are for a healthy subject using the set up procedure recommended by the software system. However, the methodology for this study incorporated some modifications of this set up procedure to accommodate subjects with hemiplegia, which may have adversely affected the reliability and validity of the system. These modifications are discussed in detail in the methods section.

Test-retest reliability was calculated retrospectively for the subjects in this study, using the repeated baseline measures found prior to introducing the intervention. The consistency of these measurements was affected by variability of the subject's ROM values secondary to the presence of spasticity in this population. ICC (3,1) was calculated to be 0.77 for the baseline measurements as reported in Table 2. This is considered a moderate – good level of reliability (Portney & Watkins, 2000).

Ankle DF ROM measurement	1st baseline session	2nd baseline session
Subject A	-1.28°	-3.62°
Subject B	-3.15°	-6.44°
Subject C	-12.98°	-24.45°
Subject D	-7.2°	-7.45°
Subject E	-2.11°	-0.48°

Table 2: Passive ankle range of motion measurements taken with the Flock of Birds system used to determine test-retest reliability. Measurements were taken during separate baseline sessions in subjects with hemiplegia following CVA.

Summary

The purpose of this study was two-fold: first, to determine if joint mobilizations are effective in increasing ankle joint flexibility in patients with hemiplegia following CVA. The research hypothesis was that ankle mobility as determined by passive ROM measurements will be increased following joint mobilizations. The second purpose of this study was to determine if increased ankle mobility results in improved performance of the sit-to-stand task. The research hypothesis was that improvements in passive ROM will result in a greater ankle joint excursion during the STS task while performing the task more quickly and efficiently.

Chapter III

METHODS

This study used a single-subject multiple baseline AB design, repeated with five individual subjects, to examine the effect of ankle joint mobilizations on ankle motion and STS function of subjects with hemiparesis following CVA. This study was approved by the Institutional Review Boards of Seton Hall University and the University of Medicine and Dentistry of New Jersey (Appendix A).

Subjects

Five subjects, recruited through local rehabilitation centers via posted flyers and presentations to stroke support groups, completed this study. The first five subjects who met the inclusion criteria and were willing to participate in the study were accepted, resulting in a sample of convenience. Subject inclusion criteria were: (1) diagnosed with a CVA with resultant hemiparesis six months to one year prior to participation in the study; (2) less than eight degrees of passive ankle dorsiflexion range of motion on the hemiparetic side with the knee flexed as measured with a goniometer; (3) demonstrated ability to transfer from a sitting to a standing position without physical assistance; and (4) at least 18 years of age. Subjects were excluded from the study if they presented with any of the following: (1) ankle joint hypermobility; (2) ankle joint effusion from trauma or inflammation; (3) rheumatoid arthritis, advanced osteoarthritis,

following: (1) ankle joint hypermobility; (2) ankle joint effusion from trauma or inflammation; (3) rheumatoid arthritis, advanced osteoarthritis, unhealed ankle fracture, or neoplasm; (4) language or cognitive deficits that will impair the patients' ability to give informed consent; or (5) currently receiving physical therapy intervention.

Subject demographics are presented in Table 3. The subjects ranged in age from 49 to 70 years old (mean 62.8), and duration of time since CVA, ranging from 7 to 11 months (mean 8.6). The subjects completed 3 to 6 baseline sessions and 8 to 11 intervention sessions as presented in Table 4. Sessions were scheduled three times each week at the same time of day in order to standardize the effects of environmental factors.

	Sex	Age (yrs)	Time since CVA (mo.)	Hemi plegic side	Require armrest for STS	Modified Ashworth Scale / clonus	Assistive Devices for amb.
Sub A	M	66	8	L	Y	1+ / N	WBQC, AFO
Sub B	M	70	10	L	Y [a]	1+ / Y	SBQC
Sub C	F	62	7	R	Y	2 / Y	SBQC, MAFO
Sub D	M	49	8	L	Y	2 / Y	SPC, MAFO
Sub E	F	67	11	R	N [b]	2 / Y	SBQC, MAFO
Mean (SD)		62.8 (8.2)	8.8 (1.6)				

Table 3. Subject demographics, including description of functional level.

a: subject inconsistently required armrest throughout study but used for majority of trials. *b:* subject required armrest initially but did not use after the second session.

	# of Baseline Sessions (A)	# of Intervention Sessions (B)	Follow up Assessment
Sub A	6	8	Y
Sub B	4	11	Y
Sub C	3	10	N
Sub D	3	10	Y
Sub E	3	11	Y

Table 4. Number and type of sessions for each subject. Follow up assessment occurred two weeks after the intervention was discontinued.

Procedures

Once it was determined that an individual subject met the selection criteria, the investigator explained the purpose of the study and all items in the informed consent form (Appendix B). Information collected during the initial session included height, weight, side of hemiparesis, current functional status, ankle ROM on the non-hemiplegic side, and ankle ROM on the hemiplegic side with the knee extended. As required by state licensing laws, the subject's physician was contacted to provide a referral for physical therapy to allow participation in this study.

During each measurement session, the following procedures were carried out by the primary investigator. The subject was seated on a sturdy wooden or plastic chair, and shoes and socks were removed. The height of the chair was individually selected for each subject so that the hip and knee of the non-hemiplegic side were flexed to approximately 90 degrees.

Hypertonicity of the calf musculature was then assessed using the Modified Ashworth Scale (Appendix C) while the subject was seated. Following the criteria of the test, the subject's foot was moved rapidly into dorsiflexion and a grade was assigned to indicate the amount of resistance encountered.

To measure passive and active ankle range of motion (ROM), the subject's heel was placed on the far edge of a 4 inch high platform to stabilize the ankle, allow full movement in both the plantarflexion and dorsiflexion directions, and maintain the knee at a constant 90 degrees of flexion. The subject's position for these measurement procedures is illustrated in Figure 1. For the passive ROM measurements, the subject was instructed to relax while the ankle was passively moved in the plantar flexion and dorsiflexion directions. The ankle was moved to the end of the available range of motion where a firm end feel was noted on overpressure (Kisner & Colby, 1996), with the subtalar joint in a neutral position, and a measurement was taken with a standard goniometer with alignments as described by Clarkson (2000). While seated in the same position, active ROM measurements were taken with a

standard goniometer by asking the subject to press his or her toes down towards the floor for plantar flexion and to bring the toes up towards the head for dorsiflexion.
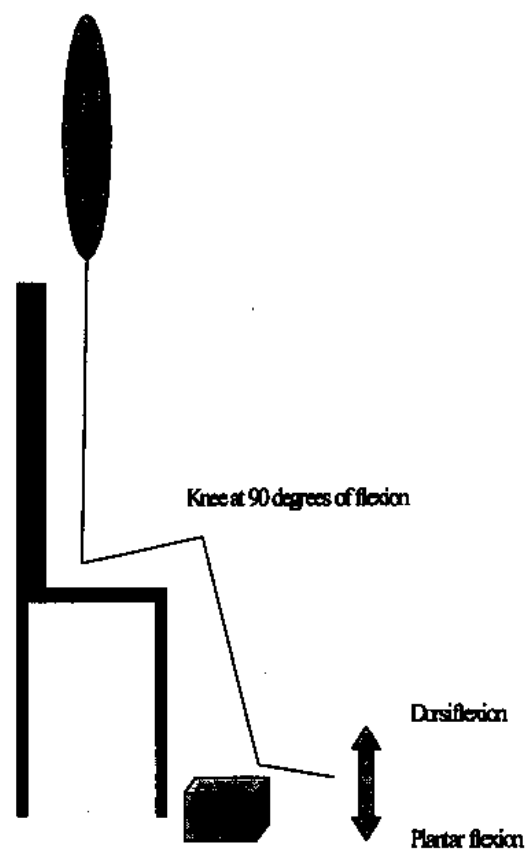

Fig. 1. Diagram of subject position for ankle range of motion measurements.

Once these goniometric measurements were documented, the subject was set up with the Flock of Birds (Ascension Technology, Burlington, VT) motion analysis system. This electromagnetic tracking system is useful for measuring three-dimensional joint positions in a clinical setting with a high degree of accuracy. The position and orientation of receiving antenna sensors are measured with respect to a transmitting antenna. The transmitting antenna is fixed in space and is driven by a pulsed direct current. Six degrees of freedom are measured for each receiving antenna, including three positions (x, y, and z coordinates) and three Eulerian angles (yaw, pitch, and roll). The Motion Monitor software system (Innovative Sports, Chicago, IL) was used to interface with the Flock of Birds sensors and convert the data coordinates to human joint angles using a standardized set up procedure. Prior to initiating data collection, the lack of metal interference in the environment was confirmed by inspecting the stability of data for individual sensors placed known distances apart using the calibration procedures in the software system.

The standardized set up procedure recommended in the software system had to be modified for the subjects in this study. Normally, the subjects would stand in the standard anatomical position, while a third sensor is used to digitize the bony landmarks on the limb. However, the subjects in this study had difficulty standing unsupported for a long period of time and were unable to align the hemiplegic limb symmetrically in order to achieve the

standard anatomical position. After consultation with technological support personnel at Innovative Sports, the set-up procedures were performed with the subject in a seated position as illustrated in Figure 2. In this position, assistance could be provided to align the knee over the foot and ankle to simulate the standardized anatomical position of the lower limb.

Sensor on head

Knee at 90 degrees of flexion
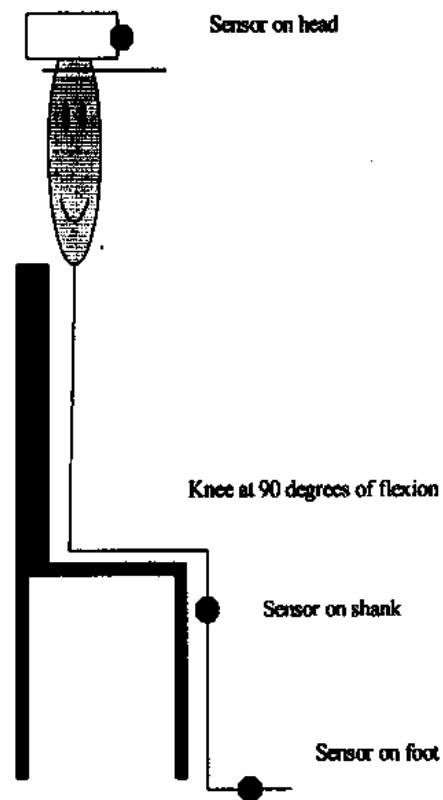
Sensor on shank

Sensor on foot

Fig. 2. Diagram of subject position for modified Flock of Birds set up procedure.

To determine the consistency of this modified set-up procedure during each session for each subject, the ankle ROM measurements found with a standard goniometer as described previously were compared with the ankle ROM measurements found using the Flock of Birds / Motion Monitor system as described below.

Two electromagnetic sensors, consisting of plastic pieces attached to wire leads, were applied with velcro straps on the shank and foot body segments of the hemiplegic lower extremity as illustrated in Figure 2. A third sensor was used to digitize the following points as directed by the software system: medial knee joint, lateral knee joint, medial ankle joint, lateral ankle joint, and second metatarsal. Each bony landmark was identified twice, and the centers of the knee and ankle joints were determined by the software using the average of the medial and lateral landmark positions. After set-up, the third sensor was placed in an elastic band attached to a hat placed on the subject's head to mark the onset of head and trunk motion. The transmitting unit was placed on a wooden platform in a position so that all of the sensors were within a 36" radius of the unit while the subject was seated.

The process for measuring active and passive ankle ROM described previously was repeated with the subject seated and the heel of the foot stabilized on the edge of a small platform, with the knee in 90 degrees of flexion, as illustrated in Figure 1. For the passive ROM measurements, the subject was instructed to relax while the ankle was passively moved in the

plantar flexion and dorsiflexion directions. The ankle was moved to the end of the available range of motion where a firm end feel was noted on overpressure, with the subtalar joint in a neutral position. Using the "goniometer" function of the Motion Monitor software, minimal and maximal ankle flexion range of motion points are displayed on the computer screen. The investigator did not look at the computer screen while moving the subject through passive range of motion in an attempt to minimize experimenter bias. Once the passive measurements were documented, the computer screen was reset. While seated in the same position, active ROM measurements were taken by asking the subject to press his or her toes down towards the floor for plantar flexion and to bring the toes up towards the head for dorsiflexion. The values for passive and active ROM were documented using data collection sheets as presented in Appendix D.

Although the reliability and validity of the Flock of Birds measurements were found to be sufficiently high using a healthy subject, the goniometric and Flock of Birds measurements were compared in each session to ensure that the values were accurate because the set up procedures were modified to allow the subjects to remain seated instead of standing. If the difference between the goniometric and computerized measurements was greater than 5 degrees in any session, the set up procedures were repeated.

In preparation for the STS motion, the subject was given the following instructions: "put your feet as far back underneath you as possible while

keeping your heels on the floor", and "stand from a seated position without using the armrest of the chair if possible at a fast but safe speed". The subject was permitted to practice the STS movement twice. The subject was guarded during this motion, and assistance was provided if necessary. Only one subject (A) required assistance or guarding, the other four subjects were independent with the STS motion. Following the two practice trials, eight trials of the STS motion were performed with ankle kinematic data collected by the Flock of Birds system, and recorded on video for later visual analysis.

The subject was permitted to use a self-selected foot position for trials 1 - 4 in order to determine if the subjects chose to use a more advantageous foot position as the data collection progressed. Subjects were assisted into a symmetrical foot position for trials 5 - 8 to standardize foot position, with both knees flexed 100 degrees and medial borders of the feet 10-15 cm apart. Use of the armrest and foot position during all trials were recorded in a notebook. A 60-second rest period was provided between STS trials if needed. Once these initial measurements were taken, the subject returned to the seated position, concluding the baseline measurement sessions (A).

Intervention. During the intervention sessions (B), ankle joint mobilizations (Kaltenborn, 1999) were performed prior to any measurement procedures. The subject was seated in the chair in the same position as described previously with both feet resting on the floor. The joint mobilizations were performed to the proximal tibia-fibula, the distal tibia-fibula, and the

talocrural articulations of the hemiplegic lower leg by the investigator. The proximal and distal tibiofibular joints were mobilized first in an anterior and posterior direction with the knee flexed slightly. The talocrural joint was mobilized next in a loose packed position, with an emphasis on gliding the talus posteriorly on the tibia.

All joint mobilizations were applied with Grade I or II manual traction and gliding during the first session, and Grade III movements for the remainder of the sessions, as described by Kaltenborn (1999). Each mobilization lasted for approximately 1 to 2 minutes. Following the intervention, the subject underwent post-treatment measurement procedures using the same methods as described above.

All five subjects tolerated the joint mobilization intervention without complication or pain during the course of the study. One of the subjects (B) noted acute onset of low back pain prior to the tenth session, secondary to a loss of balance at home. He chose to continue to participate fully in the study.

The subjects did not receive any additional intervention as part of this study. The subjects were not currently receiving physical therapy intervention outside of the study, and were instructed to maintain the same activity levels and exercises performed at home throughout the course of the study.

Follow-up: Two weeks after discontinuing the intervention, four of the subjects returned for measurement procedures as described previously

without the provision of any intervention. Subject C did not return for her follow-up appointment for personal reasons.

Data Analysis

The dependent variables for this study included active and passive ankle ROM, ankle angle over time, peak-to-peak ankle excursion, time to peak dorsiflexion, and total time for STS.

Seated active and passive ankle ROM were collected using a traditional goniometer and recorded using the "goniometer function" of the Motion Monitor software as described previously.

Ankle and time variables for the STS task were collected using the Flock of Birds system and Motion Monitor software. The onset of the STS movement was identified as the first movement of the sensor on the subject's head in the forward direction. To standardize the identification of STS onset for all trials and all subjects, a virtual event marker was used to identify the frame where the head sensor moved >1 mm as the start of the STS movement. The end of the STS movement (stable in standing) was identified using cessation of movement of the sensor below the knee in the anterior / posterior plane. A virtual event marker was used again to identify the frame where this sensor moved < 0.5 mm as the end of the STS movement for all trials and all subjects. The placement of virtual event markers is illustrated in Figure 3. These markers were confirmed by viewing the lower leg and head

animation in the Motion Monitor software, and watching the videotapes of

each trial.
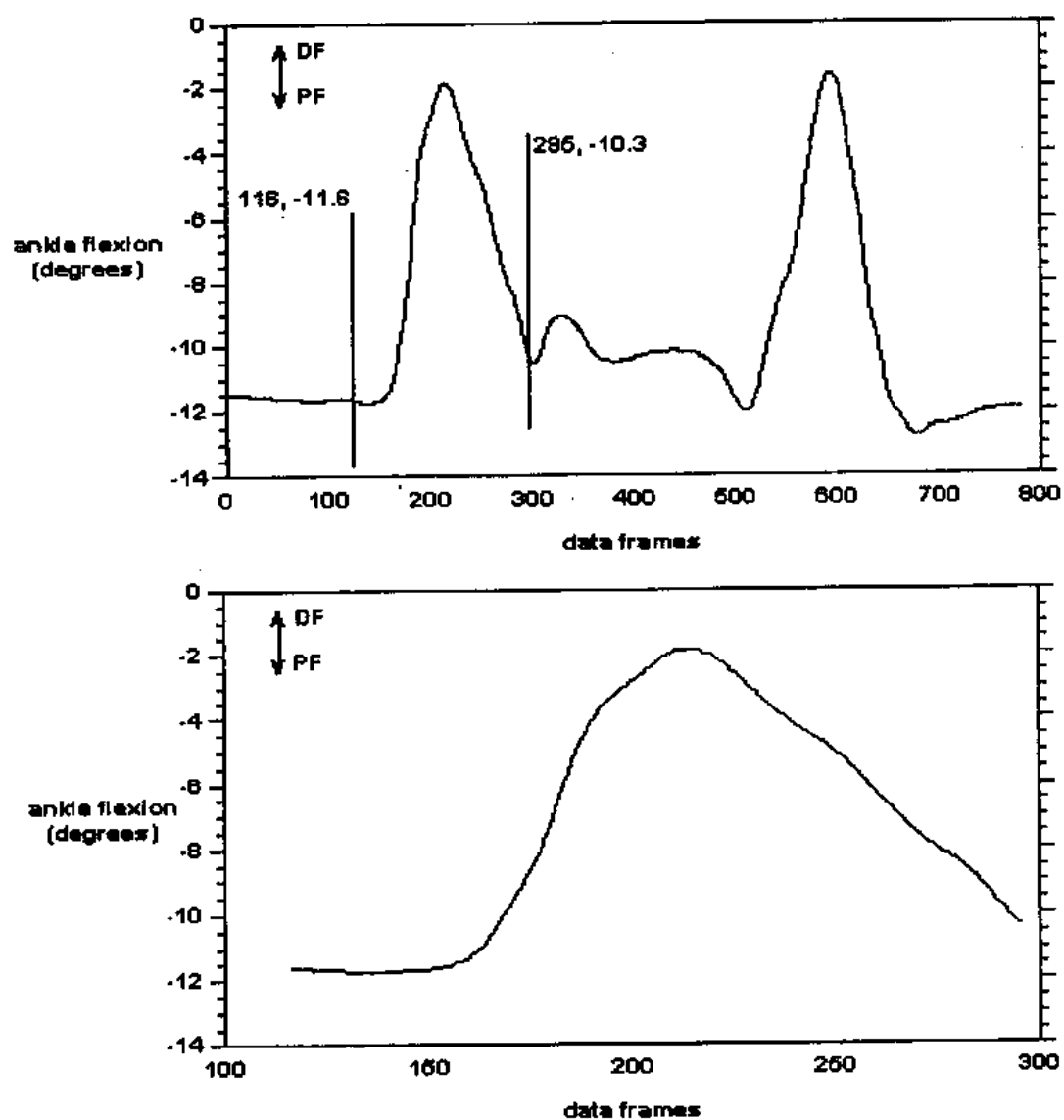
Fig. 3. Demonstration of data analysis procedure for one randomly selected

trial. Top figure represents total ankle flexion data collected, including rest

prior to STS, STS motion, stable standing, and stand-to-sit. The first vertical line represents virtual event marker #1, synchronized with the beginning of movement of the sensor on the subject's head (frame 116), and the second vertical line represents virtual event marker #2, synchronized with the cessation of movement of the sensor of the subject's shank (frame 295). The bottom figure represents the relevant STS ankle flexion data between these two markers that was saved for further analysis.

For subjects who required more than one attempt to successfully stand, all ankle flexion data was included in analysis from the start of head movement to the point where successful static standing was reached. Therefore, these trials had more than one peak of ankle flexion angle included in analysis (see Figure 4 for an illustration).
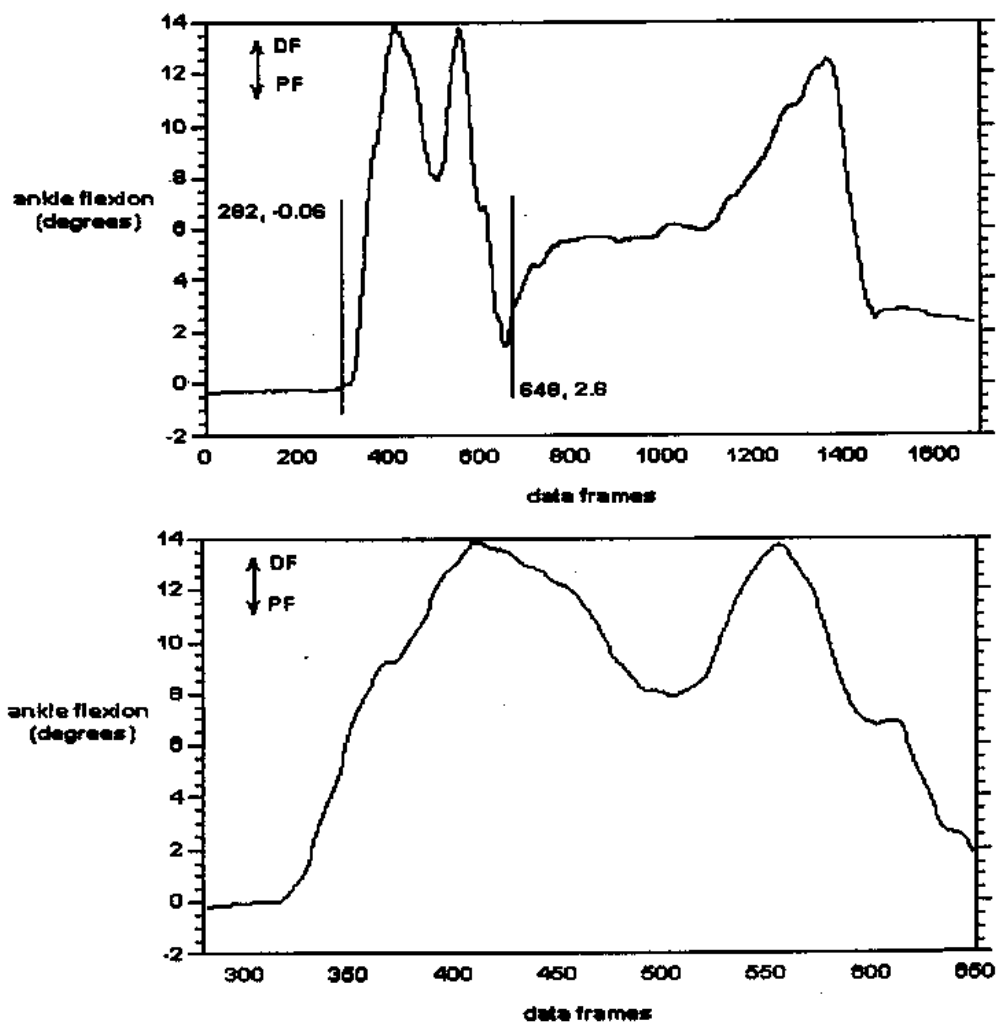
Fig. 4. Demonstration of data analysis procedure for one sample trial where

subject required more than one attempt to successfully stand. Top figure

represents total ankle flexion data collected, including rest prior to STS, two

STS attempts, stable standing, and stand-to-sit. The first vertical line

represents virtual event marker #1, synchronized with the beginning of

movement of the sensor on the subject's head (frame 282), and the second

vertical line represents virtual event marker #2, synchronized with the

cessation of movement of the sensor of the subject's shank (frame 648).

Bottom figure represents the relevant STS ankle flexion data between these

two markers that was saved for further analysis.

The ankle angle data between the onset frame and offset frame were

exported to Microsoft® Excel 2000 files for further analysis. Ankle angle over

time graphs were generated as depicted in the bottom graphs of Figures 3

and 4. Peak-to-peak ankle excursion during each trial was identified by the

difference between maximum and minimum ankle angle values for each trial,

and the means and standard deviation values for the eight trials collected

during each session were computed for each subject. The total STS time and

time to peak dorsiflexion for each trial were calculated using the number of

frames divided by 87 measurements per second, and the means and

standard deviations for the eight trials in each session were computed as

well.

The videotapes for every trial in every session were viewed separately

to confirm that the onset of movement identified with the computer system

was consistent with the videotaped session. For example, if a subject

adjusted their head prior to the start command, that may have been falsely

identified as the onset of the STS movement using the computer system. The

videotapes also provided information on whether the subjects required an

armrest or physical assistance, took more than one attempt to successfully stand, or moved their feet prior to or during the STS movement.

All the measurements collected for the five individual subjects were graphed for visual comparison of the initial baseline sessions to the intervention sessions to determine if there was a change in the measure for each individual subject. The C statistic is a simplified time series analysis that can be used on small data sets to evaluate the effectiveness of interventions (Tryon, 1982). Statistical significance is determined by dividing C by its standard error, which gives a z value that can be interpreted using the normal probability table for z scores. The C statistic was calculated first for Phase A data to determine whether a statistically significant trend was present in the baseline values. The presence of a trend prior to the introduction of the intervention would indicate a potential threat to internal validity, such as the influence of maturation effects or testing effects on the variable of interest. If a trend was not found, the data from Phase B were appended to the Phase A data and reanalysis was performed. A significant z score would indicate that the trends in phase A and B are different. A one-tailed test with an alpha of 0.05 ($z \geq 1.645$) was used according to the methods described by (Tryon, 1982) to establish statistical significance.

Chapter IV

RESULTS

Ankle Range of Motion

Initial passive dorsiflexion values ranged from −10 degrees (Subject D) to +2 degrees (Subject A). The values for passive ankle dorsiflexion declined during the baseline phase for Subject A, increased slightly for Subjects B, C, and E, and stayed the same for Subject D. Visual analysis of Figure 5 reveals changes in level and trend once the intervention was introduced for all subjects. Use of the C statistic ($\alpha = 0.05$; $z \geq 1.645$) for baseline values revealed non-significant trends during the baseline phase of the study for each subject and statistically significant trends when the intervention phase data were added to the analysis (data presented in Table 5). This indicates that the treatment was effective in increasing passive ankle dorsiflexion values in all five subjects. These changes were generally maintained in the follow up sessions two weeks after discontinuing the intervention.
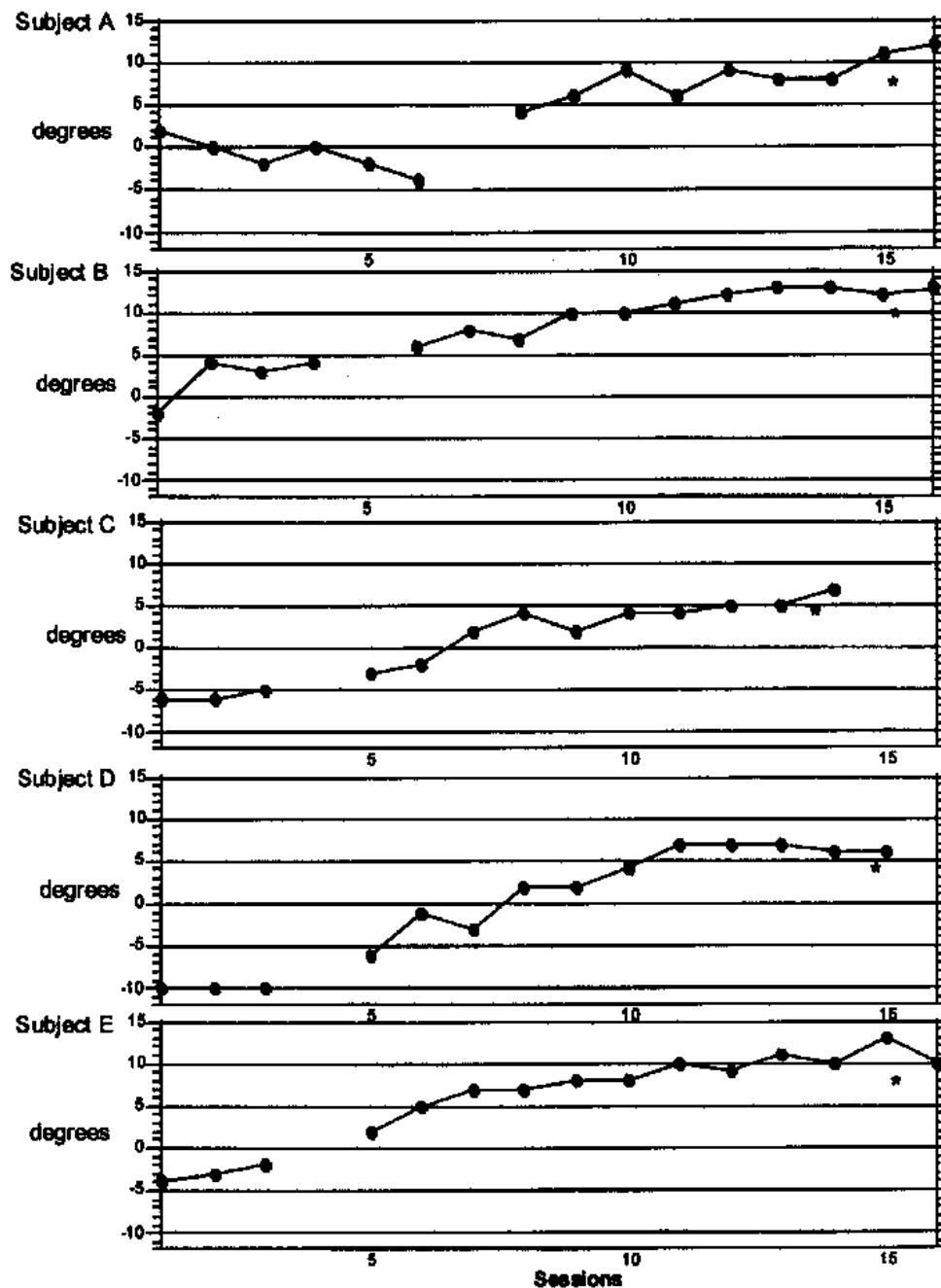
Fig. 5. Passive ankle dorsiflexion across baseline and intervention sessions

for all subjects. Values are individual measurements recorded with a standard

goniometer. Break in each line indicates separation between baseline and

intervention session data for each subject. Final data point is for two-week

follow up session for subjects A, B, D, and E. * trends in intervention phase

are significantly different than trends in baseline phase as determined by C

statistic analysis (α = 0.05, z ≥ 1.645).

	Baseline mean (standard deviation)	Baseline z score	Intervention mean (standard deviation)	Total z score
Sub A	-1.0° (2.1)	1.61	8.11° (2.2)	3.45 *
Sub B	2.25° (2.87)	0.64	10.5° (2.39)	3.79 *
Sub C	-5.7° (0.58)	0.71	2.8° (3.16)	3.61 *
Sub D	-10.0° (0)	0	2.8° (4.49)	3.74 *
Sub E	-3.0° (1.0)	1.41	8.3° (2.9)	3.84 *

Table 5. Passive ankle dorsiflexion data for all subjects. Mean values and

standard deviations were calculated from individual measurements collected

during multiple sessions. * trends in intervention phase are significantly

different than trends in baseline phase as determined by C statistic analysis

(α = 0.05, z ≥ 1.645).

Active ankle range of motion (measured as degrees from full active

plantar flexion to full active dorsiflexion) did not appear to change as

dramatically with the intervention on visual analysis of Figure 6. The baseline

values for Subject A were found to have a significant trend using the C

statistic, although the trend was in a downward direction so analysis was

continued. The baseline values for the other four subjects were found to be

non-significant, so the C statistic was used for all intervention phase data. A

statistically significant trend was found for active range of motion for Subjects

A and B, indicating that the intervention had an effect on those subjects, but

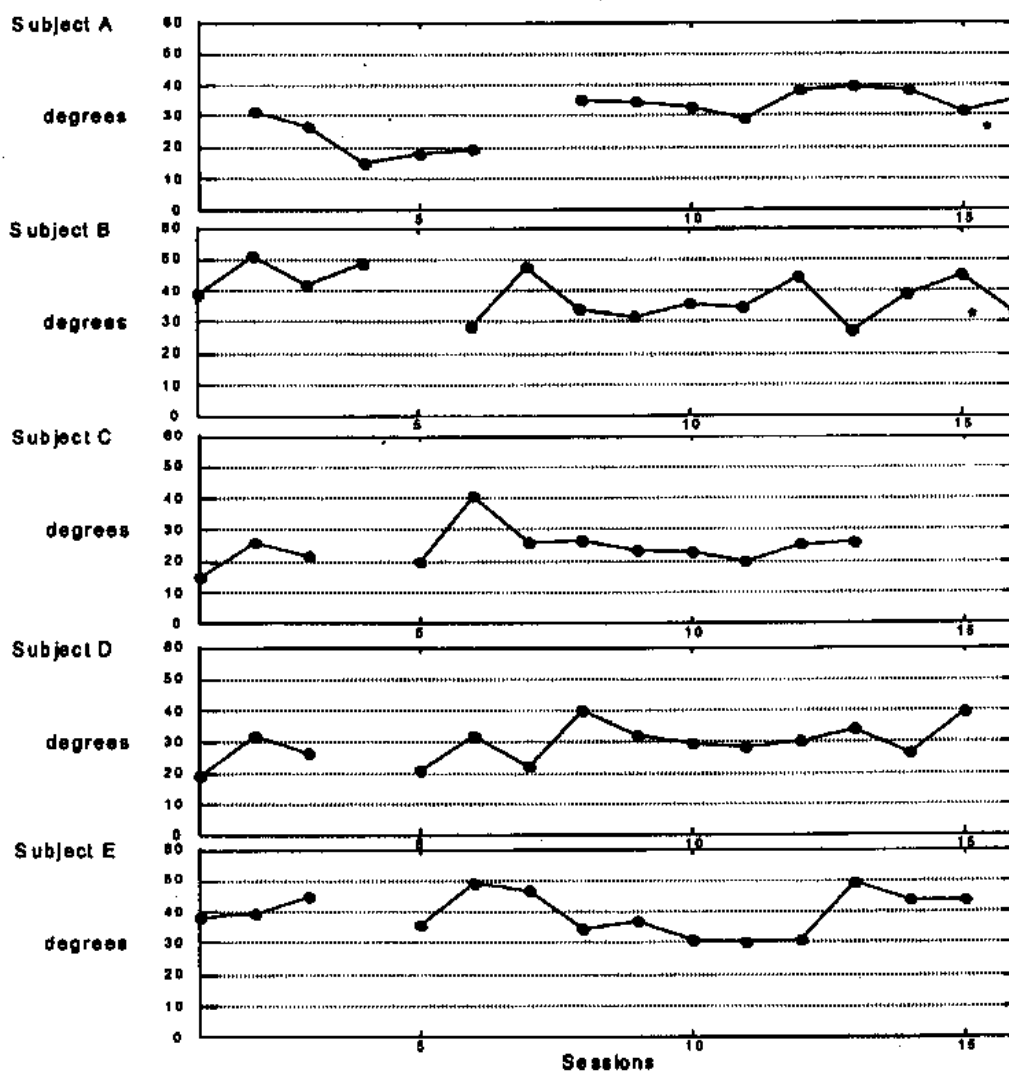not for Subjects C, D, and E. These values are presented in Table 6.

Fig. 6. Active ankle range of motion across baseline and intervention sessions

for all subjects. Values are individual measurements of maximal plantar

flexion to maximal dorsiflexion recorded with a standard goniometer. Break in

each line indicates separation between baseline and intervention session data for each subject. Final data point is for two-week follow up session for subjects A, B, D, and E. * trends in intervention phase are significantly different than trends in baseline phase as determined by C statistic analysis ($\alpha = 0.05$, $z \geq 1.645$).

	Baseline mean (standard deviation)	Baseline z score	Intervention mean (standard deviation)	Total z score
Sub A	22.13° (6.71)	1.83 **	34.99° (3.36)	2.62 *
Sub B	26.0° (6.06)	0.01	36.08° (4.08)	1.8 *
Sub C	13.33° (3.51)	1.4	17.2° (4.1)	1.0
Sub D	26.33° (14.84)	1.1	25.09° (7.27)	1.31
Sub E	38.67° (2.52)	0.97	45.17° (5.57)	0.32

Table 6. Active ankle range of motion data for all subjects. Mean values and standard deviations were calculated from individual measurements collected during multiple sessions. ** baseline trend was statistically significant but data analysis was continued because baseline data had a negative slope (see Figure 6). * trends in intervention phase are significantly different than trends in baseline phase as determined by C statistic analysis ($\alpha = 0.05$, $z \geq 1.645$).

Sit to Stand Function

Peak-to-peak ankle excursion during each trial was determined by calculating the difference between peak plantar flexion and peak dorsiflexion values for each STS trial, and the means and standard deviation values for

the eight trials collected during each session were computed for each subject as presented in Table 7. Peak-to-peak ankle excursion during sit-to-stand did not appear to be affected by the intervention, as noted on visual analysis of Figure 7 which presents a composite graph of ankle excursion during STS for all subjects. On statistical analysis, there were no significant trends during baseline and none found when the intervention was added for Subjects A, C, D, and E. Subject B did demonstrate a statistically significant decrease in peak-to-peak ankle excursion after the intervention was introduced, which would not be expected to occur with increased ankle ROM. Although all the subjects did have improved passive ankle ROM in the intervention phase, they did not demonstrate a concurrent improvement in the amount of ankle motion used during the STS task.

	Baseline mean (standard deviation)	Baseline z score	Intervention mean (standard deviation)	Total z score	Final baseline session mean	Final intervention session mean
Sub A	14.81° (3.01)	0.65	14.83° (2.69)	1.03	10.92°	11.06°
Sub B	21.03° (3.07)	0.58	14.61° (2.77)	2.6 *	21.21°	13.01°
Sub C	13.42° (2.18)	1.11	13.23° (1.91)	1.21	11.78°	16.47°
Sub D	11.54° (1.35)	0.4	10.76° (1.63)	1.48	12.48°	12.41°
Sub E	19.81° (3.1)	1.18	18.31° (3.65)	0.1	19.0°	13.63°

Table 7. Peak-to-peak ankle excursion during sit-to-stand for all subjects.

Mean values and standard deviations were calculated from the means of

eight measurements collected during each session. * trends in intervention

phase are significantly different than trends in baseline phase as determined

by C statistic analysis ($\alpha = 0.05$, $z \geq 1.645$).
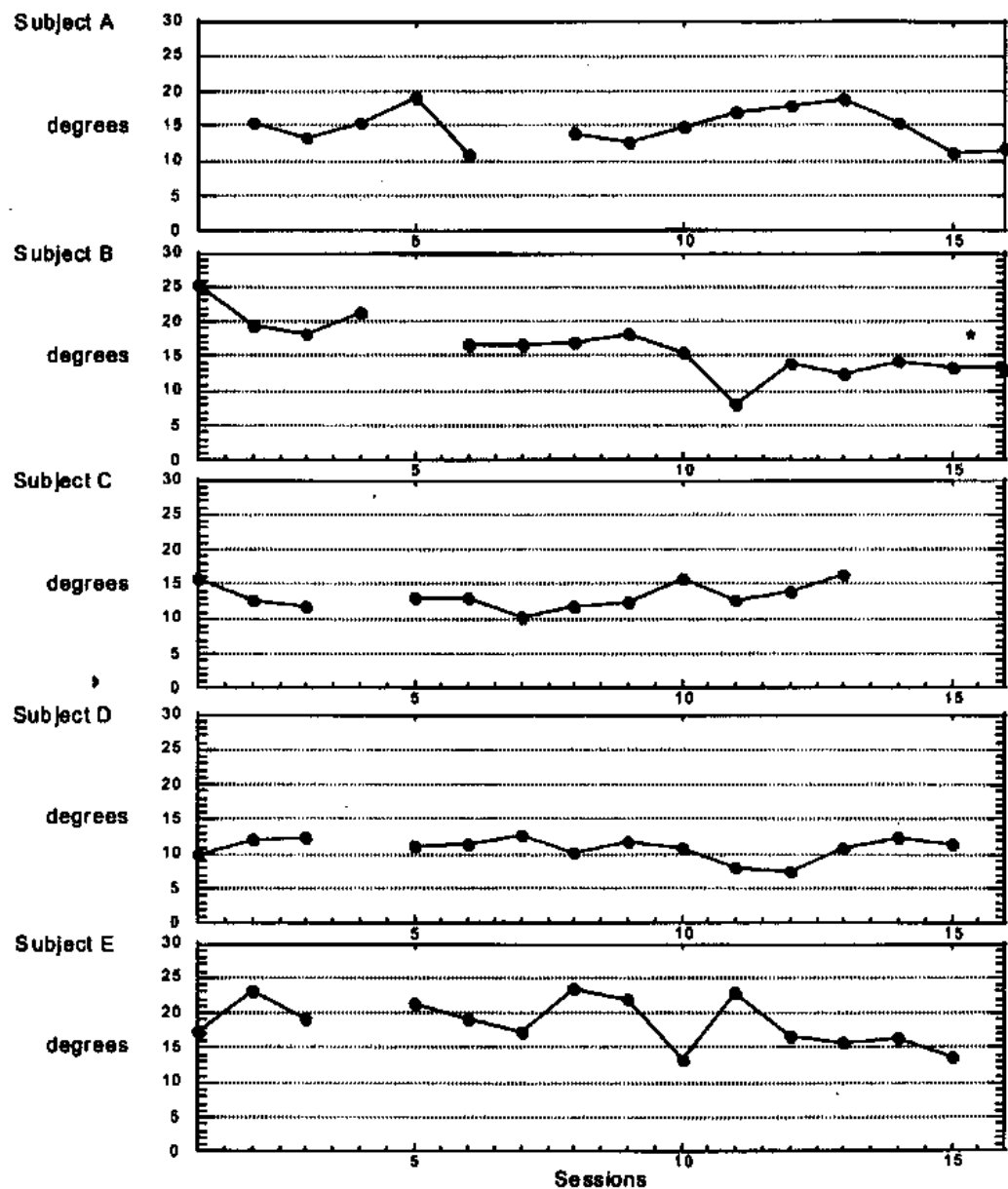
Fig. 7. Peak-to-peak ankle excursion during sit-to-stand across baseline and

intervention sessions for all subjects. Values presented are means of eight

trials recorded during each session. Break in each line indicates separation between baseline and intervention session data for each subject. Final data point is for two-week follow up session for subjects A, B, D, and E. * trends in intervention phase are significantly different than trends in baseline phase as determined by C statistic analysis ($\alpha = 0.05$, $z \geq 1.645$).

A gradual decrease in time to perform the STS task was noted during both the baseline and intervention phases for all the subjects as presented in Figure 8. Statistical analysis using the C statistic revealed statistically significant trends of decreasing time in the baseline sessions for Subject B but no significance for Subjects A, C, D, and E. Addition of the intervention phase data to this analysis revealed statistically significant trends for Subjects A in a decreasing direction and for Subject B in an increasing direction. No significant trends were found as a result of the intervention for Subjects C, D, and E (refer to Table 8). It is also noted that the STS time for Subject A increased back to baseline levels at the two-week follow up.

Fig. 8. Average sit-to-stand time across baseline and intervention sessions for all subjects. Values presented are means of eight trials recorded during each session. Break in each line indicates separation between baseline and intervention session data for each subject. Final data point is for two-week

follow up session for subjects A, B, D, and E. * trends in intervention phase

are significantly different than trends in baseline phase as determined by C

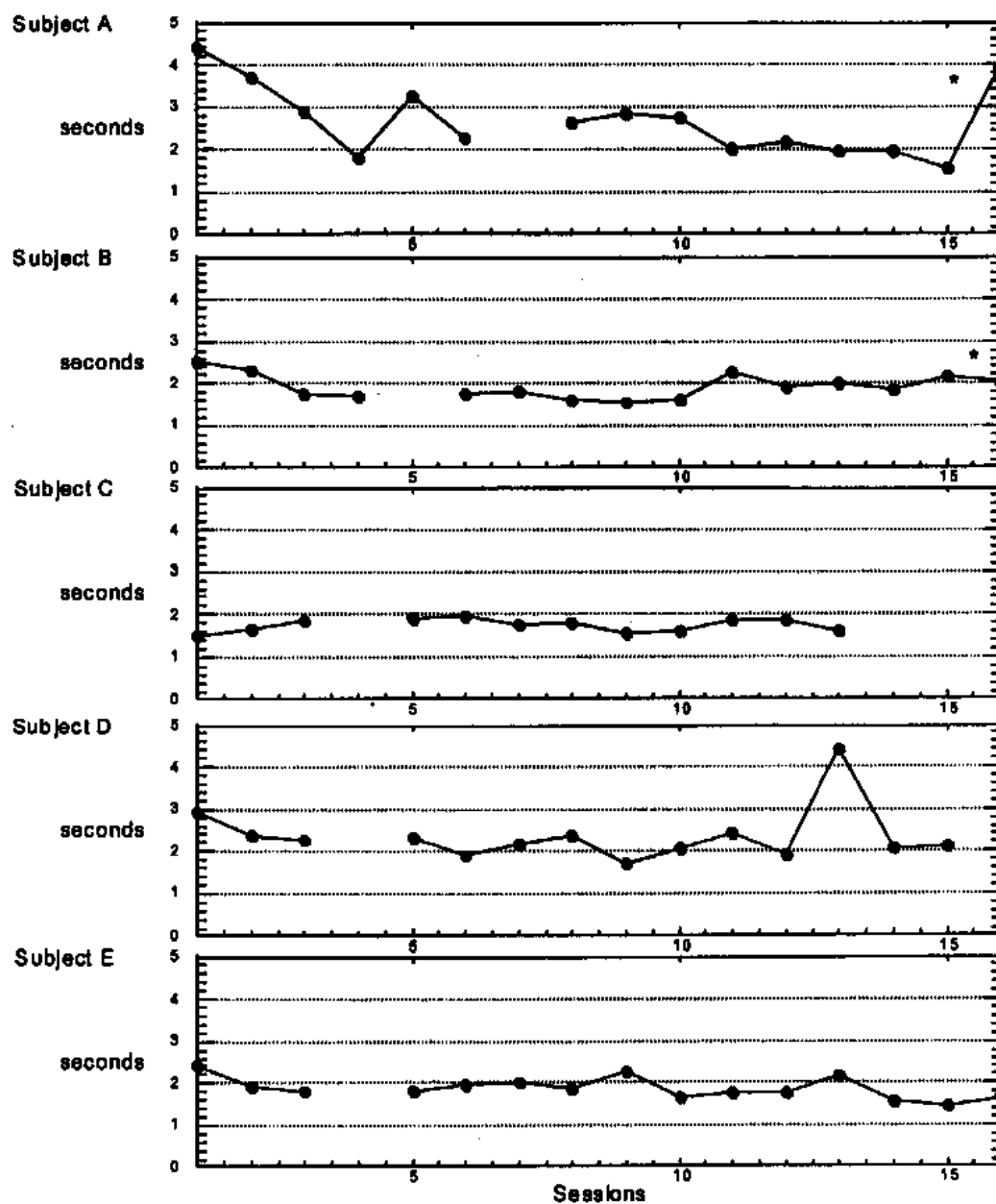statistic analysis (α = 0.05, z $\geq$ 1.645).

	Baseline mean (standard deviation)	Baseline z score	Intervention mean (standard deviation)	Total z score	Final baseline session mean	Final interven. session mean
Sub A	3.06 sec (0.75)	1.02	2.41 sec (0.71)	1.67 *	2.28 sec	1.53 sec
Sub B	2.09 sec (0.41)	1.67 **	1.86 sec (0.24)	2.16 *	1.73 sec	2.01 sec
Sub C	1.68 sec (0.17)	1.4	1.78 sec (0.14)	1.5	1.86 sec	1.63 sec
Sub D	2.52 sec (0.35)	0.4	2.32 sec (0.73)	0.79	2.27 sec	2.05 sec
Sub E	2.06 sec (0.33)	0.98	1.85 sec (0.25)	1.14	1.83 sec	1.45 sec

Table 8. Average time in seconds to perform sit-to-stand for all subjects.

Mean values and standard deviations were calculated from the means of

eight measurements collected during each session. ** baseline trend was

statistically significant but data analysis was continued. * trends in

intervention phase are significantly different than trends in baseline phase as

determined by C statistic analysis (α = 0.05, z $\geq$ 1.645).

As a component of the total time, time from the start of the motion to

peak ankle dorsiflexion, or Phase I and II as identified by Schenkman et al.

(1990), was analyzed as a separate variable and as a ratio of total time (refer

to Figure 9). A significant trend for the intervention was found for Subject A, which implies that the time to peak dorsiflexion was affected by the intervention for this subject. No other significant trends for this variable were found for the other subjects.
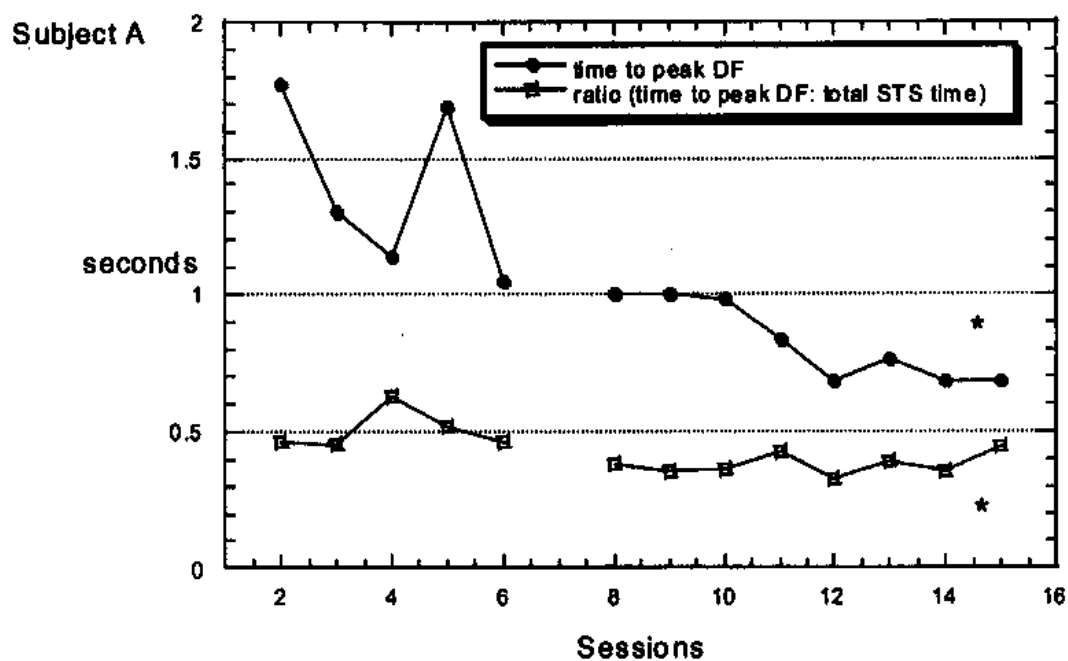

Fig. 9. Average time to peak dorsiflexion during sit-to-stand across baseline and intervention sessions for Subject A. Values presented are means of eight trials recorded during each session. Break in each line indicates separation between baseline and intervention session data for each subject. Final data point is for two-week follow up session. * trends in intervention phase are

significantly different than trends in baseline phase as determined by C statistic analysis ($\alpha = 0.05$, $z \geq 1.645$).

A qualitative description of ankle kinematics during the STS task was also analyzed to identify changes during the intervention phase. The ankle flexion pattern of a healthy subject is presented in Figure 10 using the same motion analysis equipment and procedure as for the subjects in this study. A correction was applied to these measurements secondary to a calibration error, and the values and shape of this curve is similar to that reported by Kralj et al. (1990) in a normative study. The kinematic graph in Figure 10 presents ankle angle over time. Key event markers are included in this figure to correlate the ankle motion to the phases of STS as described by Schenkman (1990). The starting point of this graph (Event 1) indicates the initial resting position of the ankle when the subject initiates STS by moving the head forward. As head movement continues forward, the subject plantarflexes slightly (Event 2) to generate forward momentum for the task. This initial phase corresponds to Phase I (Flexion Momentum) and was identified by analysis of a sensor on the subject's head not indicated in this figure. After the buttocks lift off the chair, peak ankle dorsiflexion (Event 3) indicates the end of Phase II (Momentum Transfer). Phase III (Extension) is characterized by extension of hip, knee and ankle (Event 4) into a fully upright standing posture. Phase IV (Stabilization) continues until the subject is stable

in standing, as determined by cessation of movement in the sensor on the lower leg (Event 5).
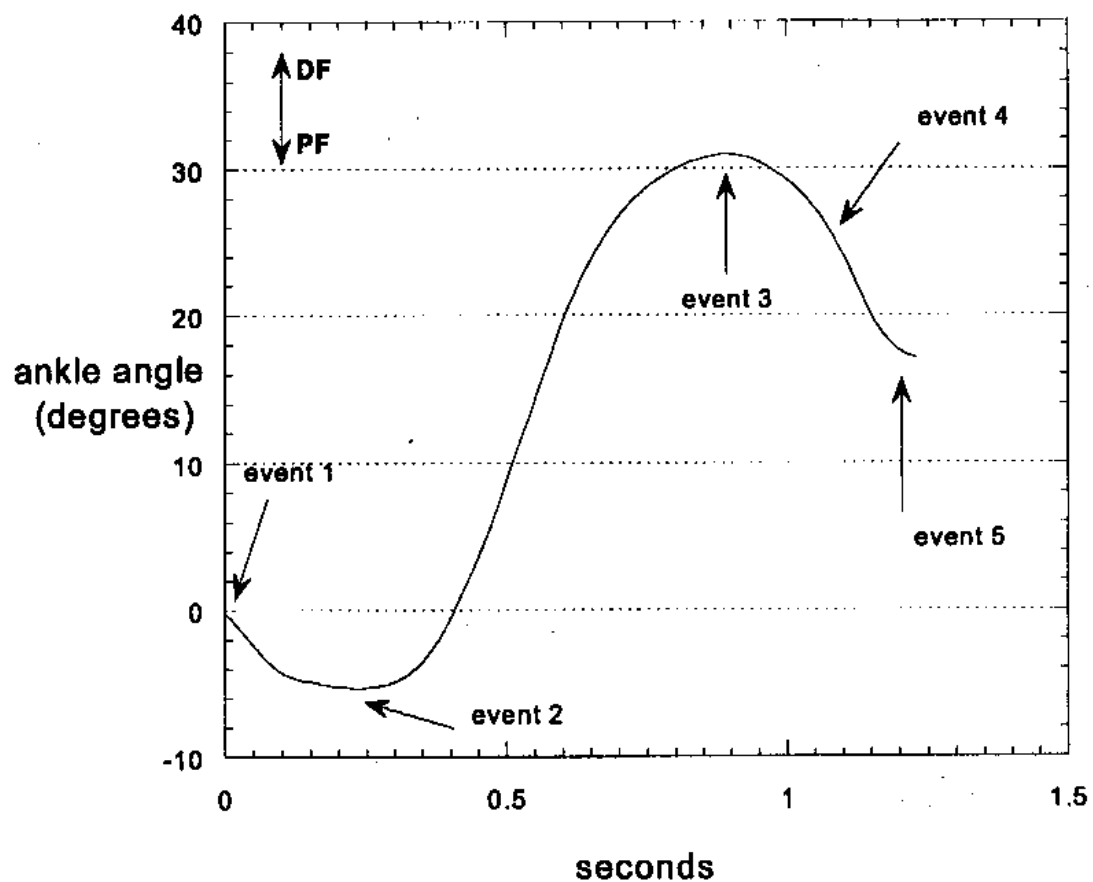
Fig. 10. Ankle flexion during sit-to-stand task in a healthy subject. Key events are indicated by arrows. Event 1: Resting position of the ankle when the STS task is initiated with onset of head movement. Event 2: Ankle plantarflexes as head movement continues forward. Event 3: Peak ankle dorsiflexion. Event 4:

Extension of ankle as upright standing posture is achieved. Event 5: Stabilization.

The ankle kinematics of the subjects in this study may be compared to the healthy subject shown in Figure 10. Differences between the ankle kinematics in the initial baseline session and the final baseline session for each subject may be due to early task practice during the baseline phase. Differences between the final baseline and the final intervention session may be due to the joint mobilizations and continued task practice. The follow up session may then be compared to all of these other sessions to identify whether any changes persisted two weeks after discontinuing the focused practice and intervention. Eight superimposed trials from each of these sessions are presented for each subject in Figures 11 – 15, along with the same single trial from a healthy subject presented in Figure 10 superimposed in bold on each graph. Note that the end point for each trial was defined as when the subject achieved stable standing as indicated by the cessation of movement of the shank sensor. Therefore, the duration of the ankle flexion curve is not consistent between trials for each subject or between subjects. Both axes of the four graphs for each subject were standardized to allow comparison.

Kinematic data from Subject A are presented in Figure 11. The initial baseline session (top graph) actually includes data from the second session

because there was an error in data collection during the first session. Although Subject A starts the motion with the ankle in a dorsiflexed position, there does not appear to be an initial plantarflexion rocking motion following the onset of head movement in any of the sessions. From the starting position, the ankle dorsiflexes followed by plantar flexion as the subject extends and stabilizes. In comparison of the initial baseline session to the ankle flexion pattern of the normal subject in Figure 10 and the middle two graphs, several differences are apparent on visual analysis. Peak dorsiflexion occurs at varying times and amplitudes between the eight trials, and the time until the subject has stabilized (cessation of data collection) is variable and much longer. In both baseline sessions, the there is one trial with two peaks. This trial represents an attempt to stand that was unsuccessful: the subject initiated head movement, rose partway off the chair then fell back and immediately tried again in a successful standing attempt. In the last baseline session graph (second from top), peak dorsiflexion occurs earlier and less time is required to achieve stabilization. This trend continues in the last intervention session (third graph), which also shows that the curves are smoother and there appears to be greater consistency between trials. However, the subject's ankle flexion pattern in the follow up session (bottom graph) reverts to the initial baseline pattern, with delayed peak dorsiflexion, erratic patterns and one trial that required multiple attempts.

Fig. 11. Ankle angle during sit-to-stand for Subject A. The top graph includes

eight superimposed trials from the first baseline session, the second graph

includes eight superimposed trials from the last baseline session, the third

graph includes eight superimposed trials from the last intervention session,

and the bottom graph includes eight superimposed trials from the follow up

session. The trial from a healthy subject presented in Figure 10 is included on these graphs in bold.

Kinematic data from Subject B are presented in Figure 12. The starting ankle position is variable between sessions, although slight plantar flexion from the starting position is noted during the initial flexion momentum phase for all the sessions (comparable to Event 2 in Figure 10). The subject starts with the ankle in a dorsiflexed posture during the initial baseline session (top graph). The shape of individual curves in this session appears to be consistent with the kinematics demonstrated by the healthy subject, although the timing is not consistent between the trials. In the last baseline session (second graph), the subject starts with the ankle in a plantar flexed posture. Decreased time, earlier peak dorsiflexion, and increased consistency is noted in this session compared to the initial baseline. In the intervention session (third graph), the ankle is even more plantar flexed to start. The peak occurs later, and the duration is longer than in the final baseline. However, the trials remain consistent between each other. The ankle is closer to a neutral position in the follow up session (bottom graph). Peak dorsiflexion occurs a little earlier, decreased time and increased consistency, especially in the first part of the curve, are noted compared to the last intervention session.
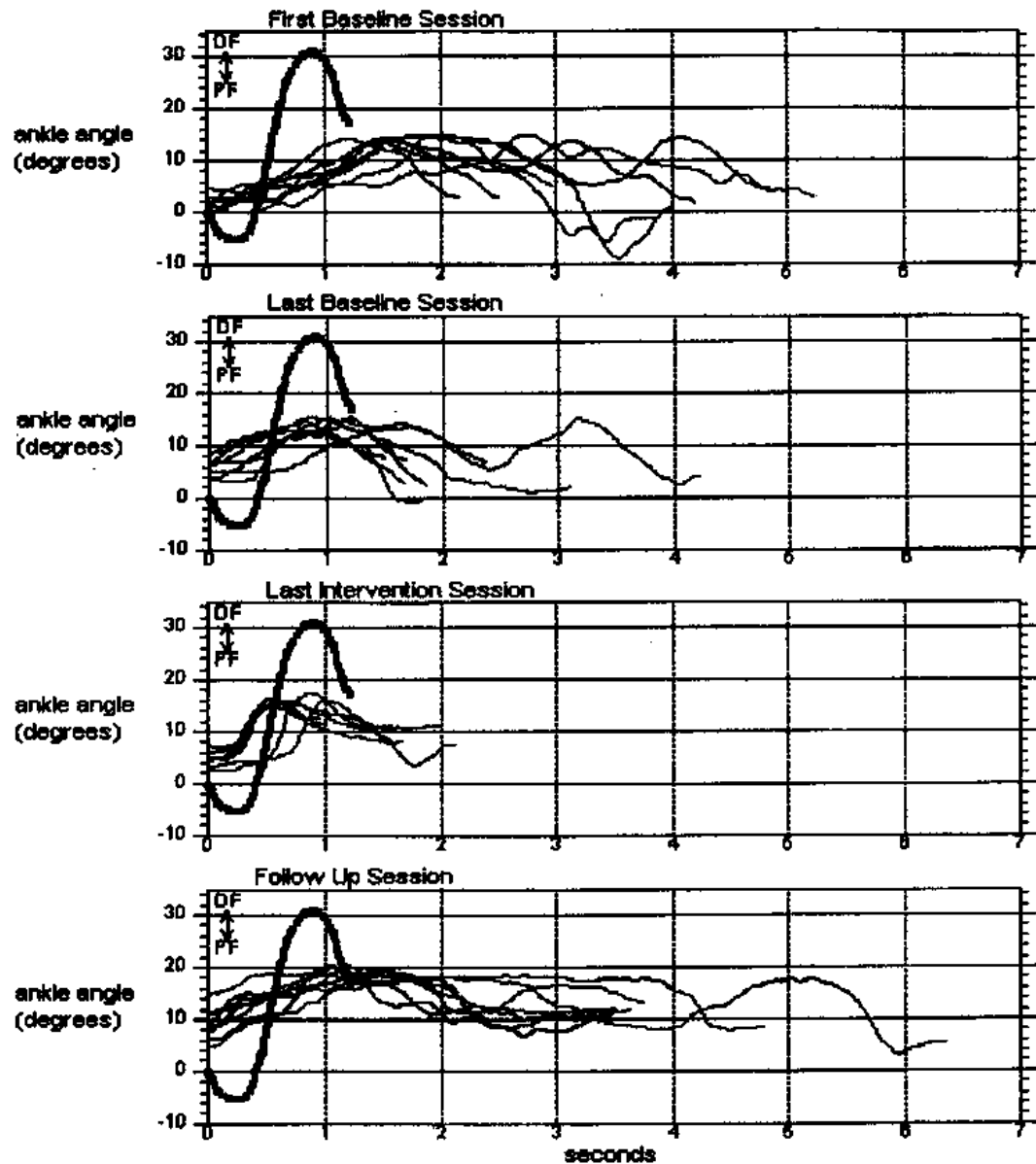
Fig. 12. Ankle angle during sit-to-stand for Subject B. The top graph includes

eight superimposed trials from the first baseline session, the second graph

includes eight superimposed trials from the last baseline session, the third

graph includes eight superimposed trials from the last intervention session,

and the bottom graph includes eight superimposed trials from the follow up

session. The trial from a healthy subject presented in Figure 10 is included on these graphs in bold.

Kinematic data from Subject C are presented in Figure 13. This subject did not return for follow up, so there is no graphical comparison for this session. The shape of the curves in all the sessions appear similar to that of the healthy subject and to each other, with only minor variations between sessions. In the initial baseline session (top graph), the ankle is in a plantarflexed position, and slight plantar flexion appears to occur during the first phase. In the last baseline session (middle graph), the ankle is positioned in slight plantar flexion and this positioning appears more variable between trials than in the other sessions, although the shape of the curves is more consistent. Peak dorsiflexion is delayed and the total time is longer than in the initial baseline session. In the intervention session (bottom graph), the ankle is consistently positioned in a neutral ankle posture to start. The peak is earlier although the curves are less consistent than in the baseline session.

First Baseline Session

Last Baseline Session

Last Intervention Session

seconds
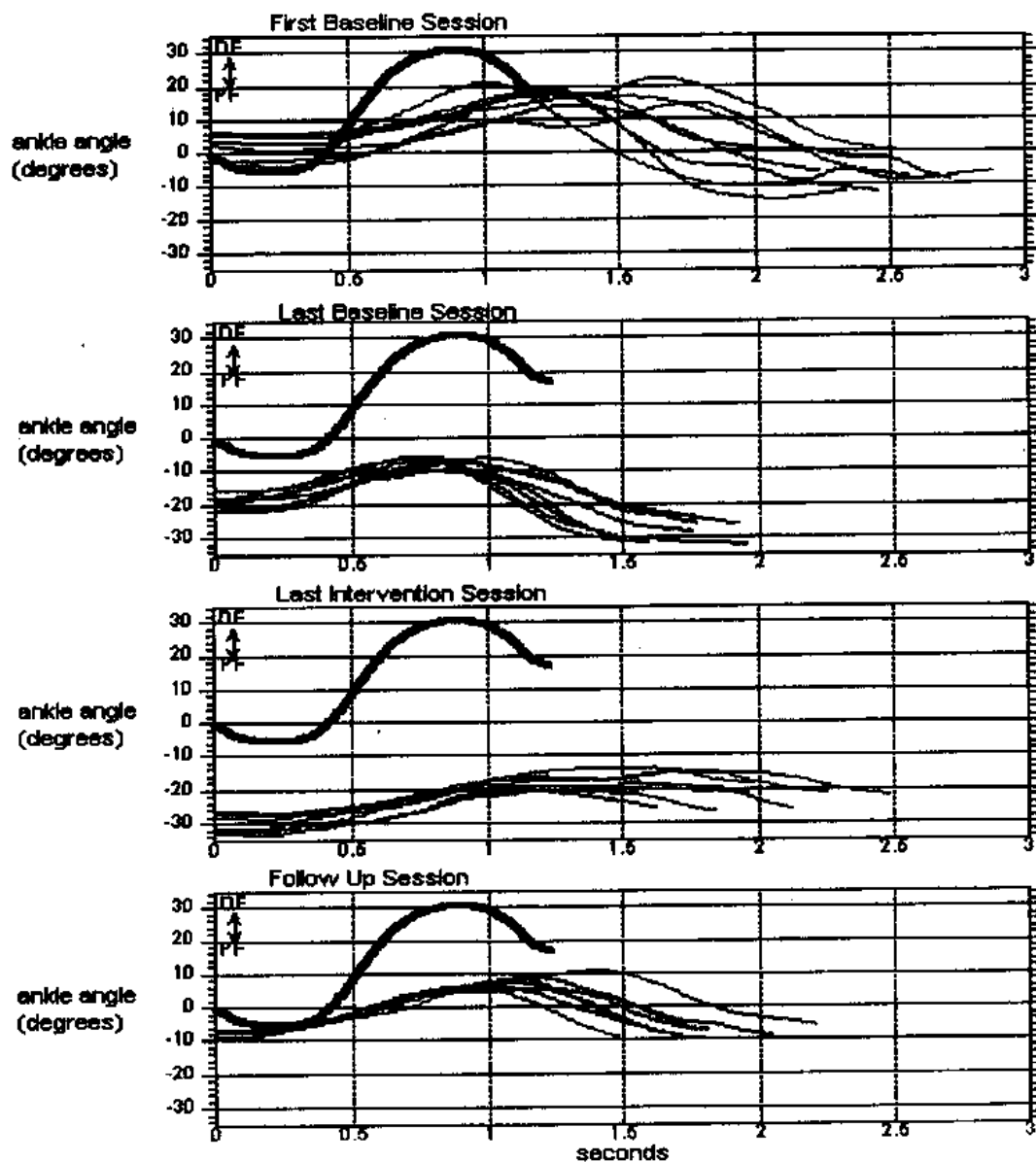
Fig. 13. Ankle angle during sit-to-stand for Subject C. The top graph includes

eight superimposed trials from the first baseline session, the middle graph

includes eight superimposed trials from the final baseline session, and the

bottom graph includes eight superimposed trials from the final intervention

session. The trial from a healthy subject presented in Figure 10 is included on these graphs in bold.

Kinematic data, ankle angle over time, from Subject D are presented in Figure 14. The ankle is consistently positioned close to a neutral posture during the first baseline session (top graph), the last intervention session (third graph), and the follow up session (bottom graph). In the last baseline session (second graph), the ankle is plantarflexed and variable between trials. The time to peak is approximately the same for all sessions, except that it seems to come slightly later in the last intervention session. In comparison to the initial baseline session, trends of gradually decreasing time and increasing consistency between trials are noted. This trend of improvement does continue into the two-week follow up session for this subject.

Fig. 14. Ankle angle during sit-to-stand for Subject D. The top graph includes

eight superimposed trials from the first baseline session, the second graph

includes eight superimposed trials from the last baseline session, the third

graph includes eight superimposed trials from the last intervention session,

and the bottom graph includes eight superimposed trials from the follow up

session. The trial from a healthy subject presented in Figure 10 is included on these graphs in bold.

Kinematic data from Subject E are presented in Figure 15. There was an error in data collection for the final follow up session, so that data is not presented. The shape of the curve and time to peak dorsiflexion in all the sessions appears very similar to the kinematics of the healthy subject. The ankle starting position changes from slight plantar flexion in the first baseline session (top graph), to slight dorsiflexion in the last baseline session (middle graph), and plantar flexion in the last intervention session (bottom graph). Following the initial session, there is a trend for gradually increasing consistency between trials and gradually decreasing time for subsequent sessions.

First Baseline Session

ankle angle
(degrees)

Last Baseline Session

ankle angle
(degrees)
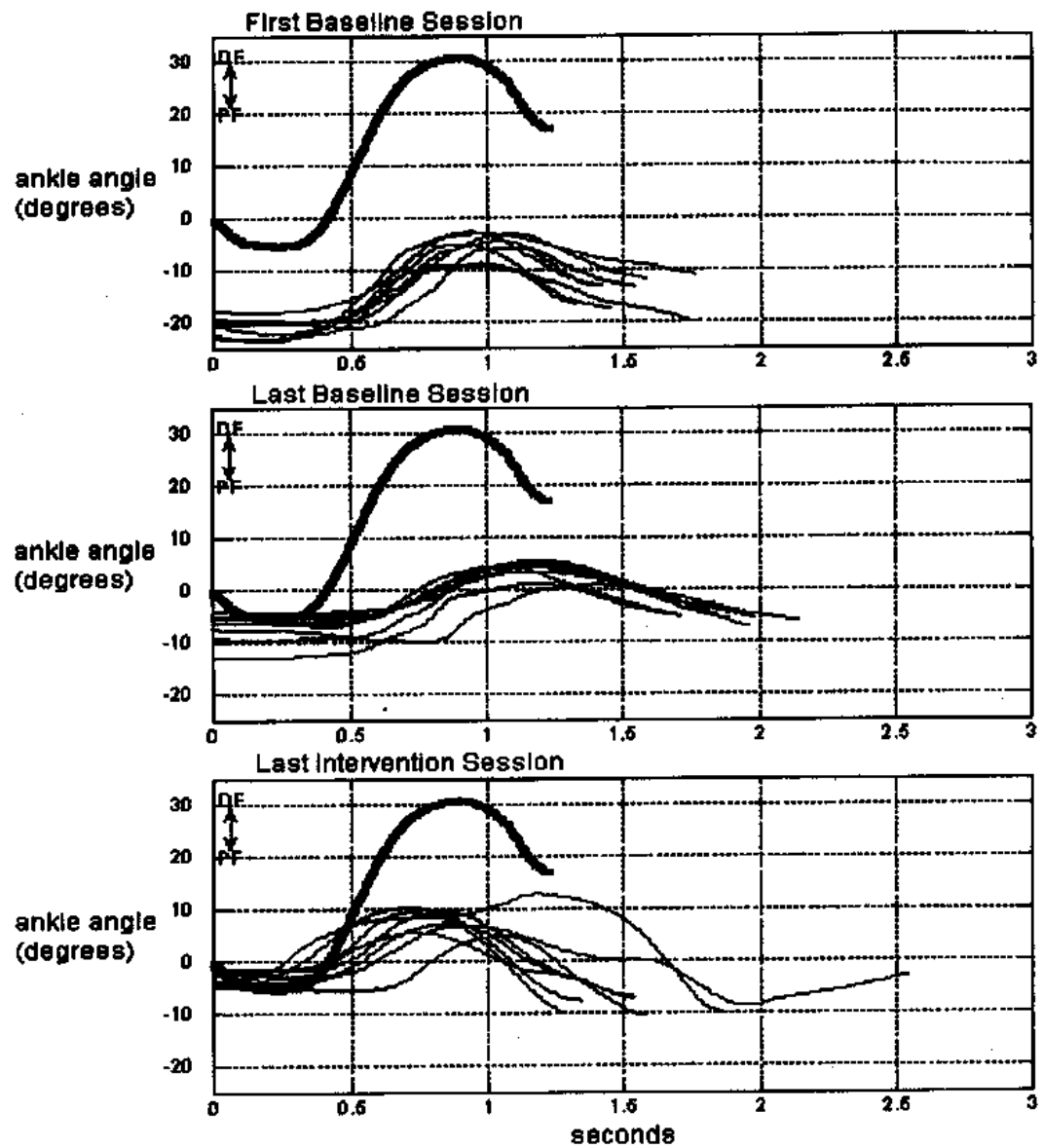
Last Intervention Session

ankle angle
(degrees)

seconds
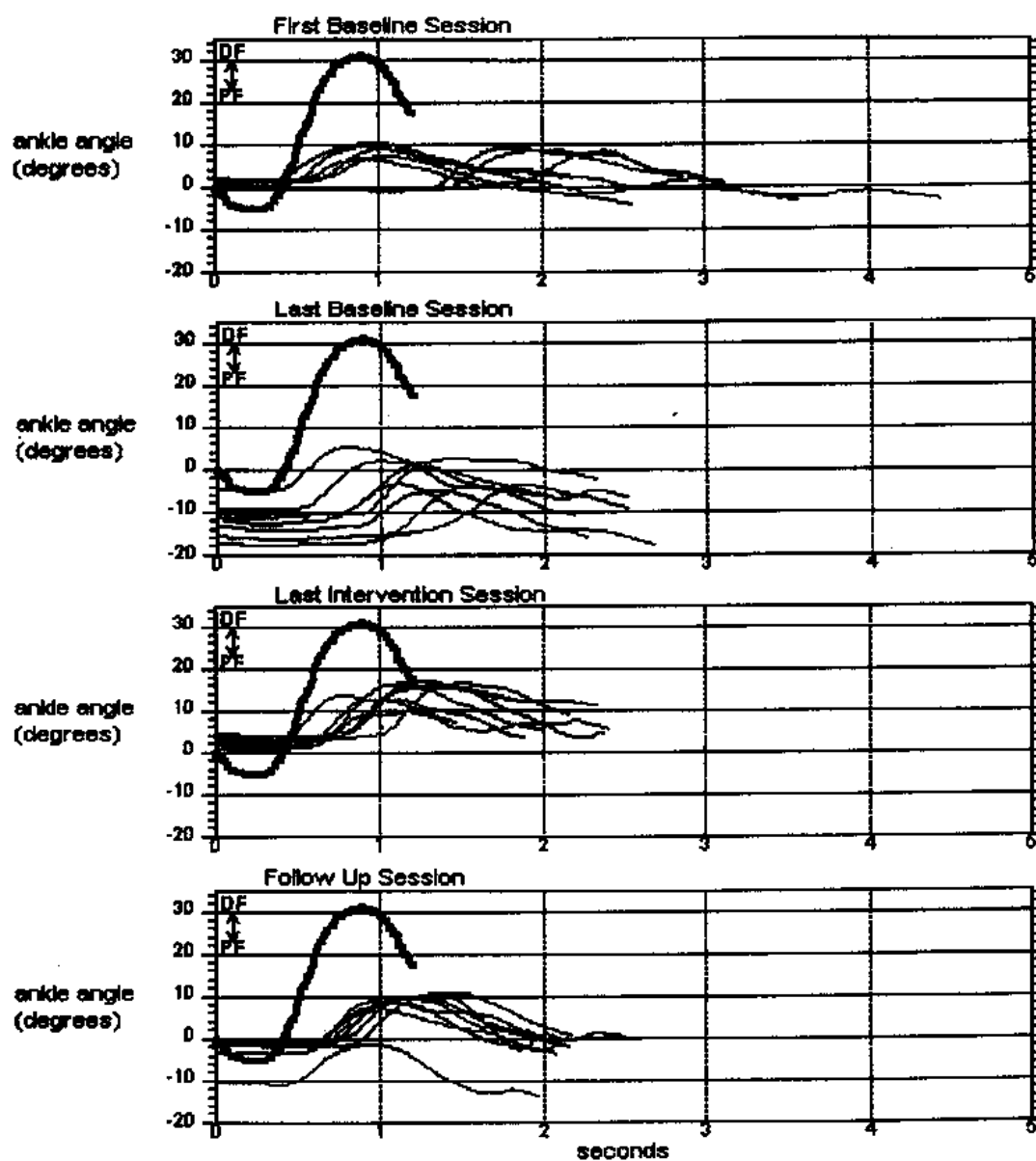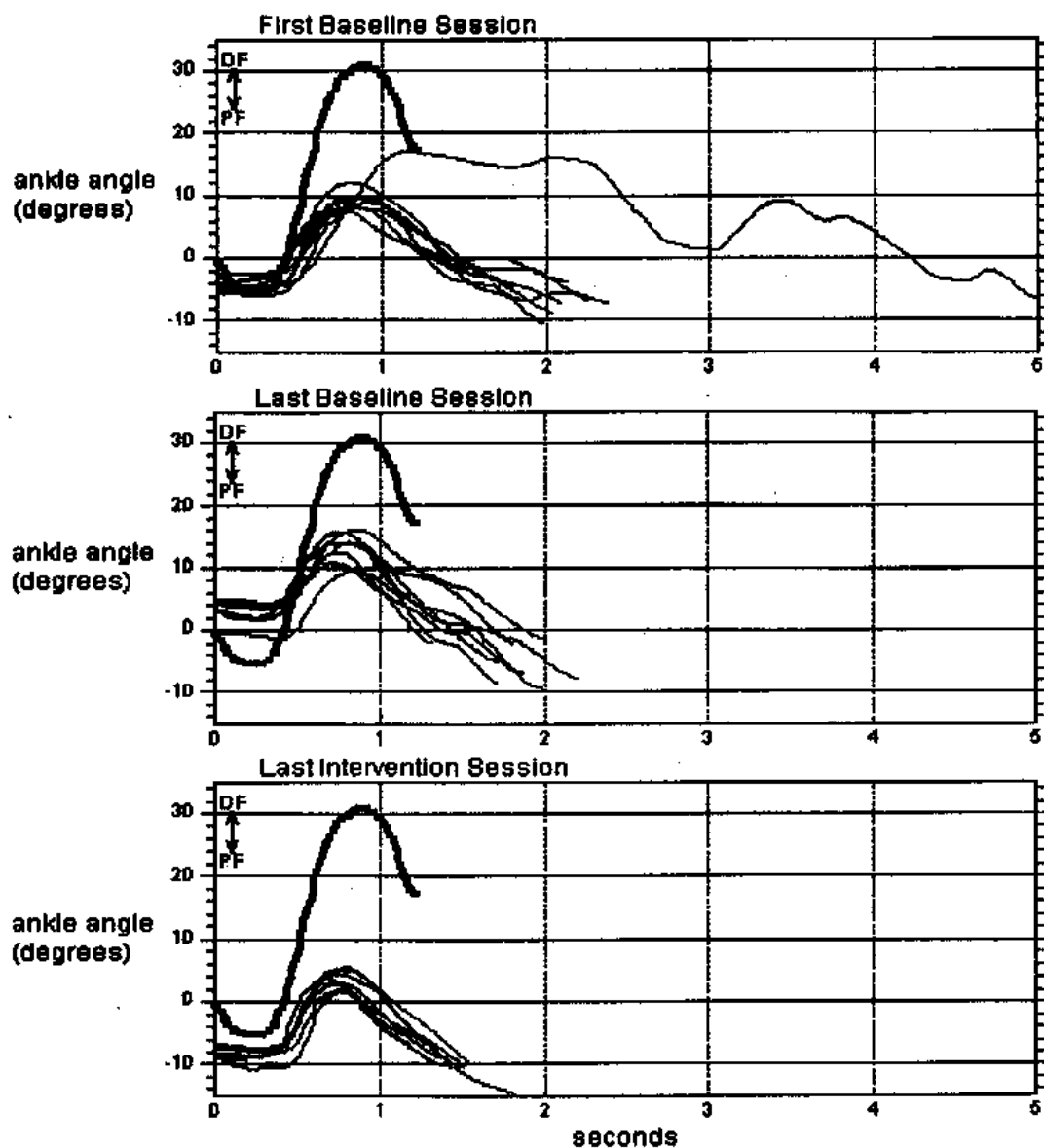
Fig. 15. Ankle angle during sit-to-stand for Subject E. Top graph includes

eight superimposed trials from the first baseline session, middle graph

includes eight superimposed trials from the last baseline session, and bottom

graph includes eight superimposed trials from the final intervention session

(B). The trial from a healthy subject presented in Figure 10 is included on these graphs in bold.

Other indications of changes in STS strategy were noted when observing the trials on videotape. Subject A was noted to require physical assistance during the STS transfer for 52.1% of the baseline trials. In these trials, the subject appeared unstable once standing and required a steadying hand in addition to the use of his cane for support. The frequency of trials where assistance was required dropped to 20.8% in the intervention trials.

As presented in Table 9, Subjects A, C, and D were unable to stand without the armrest during the baseline sessions. However, in the intervention trials, Subjects C and D decreased their reliance on an armrest to perform STS. Subject E also used the armrest for all the trials in the first baseline session but did not require the armrest for any of the subsequent sessions. Subject B increased his use of the armrest during the intervention sessions, most specifically after he noted the onset of low back pain.

	% of Baseline trials	% of Intervention trials	% change scores
Subject A	100	100	0
Subject B	53.1	97.9	+ 44.8
Subject C	100	93.8	- 6.2
Subject D	100	95	- 5
Subject E	16.7	0	- 16.7

Table 9. Use of armrest by all subjects in study. Values represent the percent of all trials where the subject elected to use one or both armrests as noted on videotaped review, and percent change scores.

Subjects A and B had a significant number of unsuccessful trials during the baseline session (12.5% and 9.4% respectively) as noted in Table 10. During videotape analysis of these trials, the subjects were observed to initiate the STS motion, rise partway up out of the chair and unexpectedly fall back into the chair. They were permitted to keep trying until successful, and occasionally required more than two tries to stand. The frequency of this occurrence dropped during the intervention trials for both subjects. The incidence of multiple attempts for STS was small for Subjects C, D, and E during both the baseline and intervention trials.

	% of Baseline trials	% of Intervention trials	% change scores
Subject A	12.5	6.9	- 5.6
Subject B	9.4	0	- 9.4
Subject C	0	3.7	+ 3.7
Subject D	0	3.8	+ 3.8
Subject E	4.2	2.2	- 2

Table 10. Multiple attempts to stand for all subjects in study. Values represent the percent of all trials where the subject attempted to stand and was unsuccessful, falling unexpectedly back into the chair as noted on videotaped review, and percent change scores.

The videotape review also revealed that Subjects A, B, and D frequently repositioned their feet after initiating the STS motion. Before the STS movement all subjects were asked to position their feet or were provided assistance to obtain a symmetrical foot position. However, these subjects

frequently were observed moving one or both feet forward or back during the forward trunk movement phase, during the standing process, or once fully standing. The frequency of this occurrence is noted in Table 11. All three of these subjects repositioned their feet much less frequently during the intervention sessions.

	% of Baseline trials	% of Intervention trials	% change scores
Subject A	89.6	79.2	- 10.4
Subject B	15.6	2.1	- 13.5
Subject C	0	0	0
Subject D	33.3	1.3	- 32
Subject E	0	0	0

Table 11. Repositioning of feet for all subjects in study. Values represent the percent of all trials where the subject moved one or both feet after the onset of STS as noted by forward head movement.

Finally, several subjects made unsolicited comments regarding the intervention. The subjects noted a sense of greater flexibility and improved ease with gait, stairs, and car transfers. One subject (A) returned to his physician to request an articulating AFO after completing the study, and one subject (B) was able to begin using a straight cane in the community instead of a quad cane used previously.

Chapter V

DISCUSSION

The purpose of this study was to determine whether ankle joint mobilizations increased ankle passive range of motion and improved sit-to-stand function in patients with hemiplegia following a CVA. The first research hypothesis was that joint mobilizations would be effective in increasing ankle mobility as measured by passive ROM in patients with hemiplegia. This hypothesis was supported by all five of the individual subjects participating in this single subject design study.

Normal dorsiflexion ROM has been reported to be 22.75 degrees in people aged 40-49, and 15.39 degrees in people aged 60-84 (Gajdosik et al., 1999). Prior to the introduction of the intervention, each of the five subjects in this study demonstrated a significant ankle plantar flexion contracture, ranging from an average of –10 degrees (Subject D) to 2.25 degrees (Subject B) of dorsiflexion for all baseline sessions prior to the intervention. The variability in passive ROM measurements within each subject during the baseline phase was not unexpected. Because hypertonicity in the calf muscles was noted in all subjects, the amount of passive ROM at the ankle may vary according to medication levels, psychological stress, and general health status. There is also potential for measurement error using the goniometer and the Flock of Birds system. For these reasons, there was an

attempt to schedule data collection sessions during the same time of day and repeated measures were taken until a stable baseline was achieved. Retrospective analysis of these baseline measures showed moderate – good test-retest reliability.

Subjects A and B had the greatest fluctuation in passive ROM measurements during baseline, with a 6 degree variation. Subject A experienced some minor medical problems during the baseline sessions, recovering from a flu and experiencing fluctuations in blood pressure and blood glucose level during the period of sessions 3 to 5. For this reason, this subject's baseline sessions were extended to a total of six, and because the ROM trend during these 6 sessions was in a downward direction, it seemed appropriate to begin the intervention at that time even though some fluctuation continued. Subject B had a large fluctuation between the first and second baseline session, then only 1 degree of difference between sessions 2, 3, and 4. Therefore it seemed that his ROM measurements had stabilized following session 4.

Slight increasing passive dorsiflexion trends were noted in the baseline sessions for Subjects B, C, and E even though these trends were found to be non-significant with statistical analysis. It is possible that these small trends were a result of introducing the repeated STS practice that occurred during baseline.

After participating in the study, all five of the subjects had statistically significant improvement in dorsiflexion ROM. Three of the five subjects (A, B, and E) had greater than 10 degrees of ankle dorsiflexion during the final intervention session. The other two subjects (C and D) began the study with more severe contractures but still improved to greater than 6 degrees of ankle dorsiflexion by the end of the study. Not only is this magnitude of improvement in passive ROM statistically significant, it is also clinically important because these values are much closer to the ROM required for functional tasks. Furthermore, these improvements were maintained two weeks after discontinuing the intervention.

This study revealed that ankle joint mobilizations can be effective in improving ankle joint mobility in patients with central nervous system pathology, such as a CVA. Dijs et al. (2000) found that 10 sessions of joint mobilizations improved ankle joint mobility by 6 degrees in patients with diabetic neuropathy and limited joint mobility. Green et al. (2001) found that single sessions of joint mobilizations improved ankle dorsiflexion ROM 2 – 4 degrees in subjects with acute ankle sprain.

Active ankle mobility was found to be increased significantly in two subjects (A and B) with the introduction of the intervention. Although this finding was statistically significant, the effect was not as robust as for passive motion. The intervention was specifically aimed at improving passive joint extensibility by stretching the connective tissue. However, it is conceivable

that subjects who gained passive mobility may have begun to use that motion actively.

Because the risk of CVA increases with age, the subjects who participated in this study were younger (mean 62.8 years) than many of the people who have a stroke. These subjects all sustained the CVA less than 11 months prior to participation in this study. Decreased connective tissue extensibility is associated with aging and prolonged immobility, so these subjects may have had a better response to the intervention than older subjects or people with chronic CVA might. However, these subjects were all more than 7 months post-CVA, and it was assumed that their impairments would not change without intervention at this point.

Both male and female subjects and subjects with CVA in either hemisphere were represented in this study. Although there was some variability in functional levels, degree of ankle contracture, and degree of hypertonicity, all of the subjects appeared to benefit from the intervention as demonstrated by an increase in passive ROM. From these results, it seems appropriate to address musculoskeletal impairments such as ankle joint contracture in patients with neurologic pathology. Further study with a larger population is needed to determine which subject characteristics are most likely to benefit from this specific intervention.

The second research hypothesis was that improved ankle mobility would result in improved performance of the sit-to-stand task. Theoretically, an increase in available ankle motion would result in improved efficiency of movement and decreased time to perform the task.

Although passive ROM at the ankle improved in all five subjects, peak-to-peak ankle excursion during the STS task did not change during the course of this study. It has been demonstrated that healthy elderly have ankle joint excursion during the STS task of 22 degrees by (VanderLinden et al., 1994) and 28.7 degrees (Ikeda et al., 1991). Subjects A, C, and D demonstrated consistently less ankle excursion than normal during STS during both the baseline and intervention phases. Subjects B and E had excursion values that were comparable to normal during the baseline session. Subject B demonstrated a statistically significant downward trend in the intervention sessions, indicating that less ankle excursion was used in the intervention phase than in the baseline phase. This subject experienced the onset of acute low back pain prior to session 10 and, although he chose to continue to participate in the study, his movement strategy for the subsequent sessions was altered secondary to his discomfort. Subject E did not appear to change excursion values in the intervention phase of the study.

Because the use of ankle motion during STS by these subjects did not improve, it appears that the joint mobilizations did not contribute to a specific change in STS function. However, during the course of the study these

subjects did experience repeated STS practice opportunities by virtue of the repeated measurement design. Although the intent of the baseline sessions was to allow for the subjects to experience repeated practice prior to the intervention, there may have been insufficient practice opportunities. It was assumed that sit-to-stand was a familiar motor task that these subjects performed on a regular basis as part of daily household and community ambulation. However, there may have been aspects of the task as performed in the research setting that made it a novel task for the subjects as described below.

When asked to stand up from a chair while barefoot, several subjects commented that they had not stood up without shoes or braces since sustaining their stroke. It has been shown that barefoot performance of balance and mobility tests is decreased compared to walking shoes in healthy elderly (Arnadottir & Mercer, 2000). The request to stand without an armrest appeared to surprise some of the subjects, as they all reported that they habitually used an armrest to perform the task and had not attempted to stand without one prior to this study. The use of an armrest has been described as an important determinant of the STS movement that may influence foot position and joint excursion (Janssen et al., 2002). The subjects may have benefited from prolonged continued practice with gradual attempts at decreasing upper extremity support on the armrest. Subjects C, D, and E were able to eventually consistently stand without the use of the armrest, but

subjects C and D were not successful in standing without upper extremity support until almost the end of the intervention sessions.

The intervention sessions provided repeated STS practice opportunities in addition to the gradual increase in passive ROM that resulted from the intervention. Any improvements in STS function such as decreased time to perform the task, change in kinematics, or change in strategy during the intervention sessions most likely occurred as a result of this practice.

Time to perform the STS task is an indication of movement efficiency, and an increase in time has been found to correlate with falls in people post-CVA (Cheng et al. 1998). Analysis of changes in ankle angle over time graphs and in general motor strategy as observed on videotape may also provide a measure of movement efficiency.

Subject A demonstrated a statistically significant decrease in time for STS. This subject had the longest initial STS time at 4.5 seconds in the first baseline session, which is comparable to the subjects post-CVA who were experiencing falls as described by Cheng (1998). This subject required physical assistance, more than one attempt, and movement of his feet for a majority of trials in the baseline sessions. This subject had the greatest number of baseline sessions (6) because his performance was highly variable. Through participating in this study, he did progress to requiring less physical assistance, less movement of his feet, and less frequently required more than one attempt to stand. This subject also demonstrated decreased

time to perform Phase I and II of the STS motion, as time to peak dorsiflexion. Perhaps the joint mobilizations did have an impact on this subject's ease of ankle motion, allowing for increased speed of this aspect of the movement even though actual peak-to-peak joint excursion did not improve.

Qualitative analysis of the ankle angle over time graphs showed trends of earlier peak dorsiflexion, more consistent movement strategies, and decreased time to reach stabilization between the baseline sessions and between the baseline and intervention session. Although the passive ankle flexibility was maintained at the two-week follow up session, none of the other improvements were retained. This indicates that although repeated practice may have been beneficial for this individual subject's STS performance, continued task practice was required to maintain these benefits.

Subject B had a STS time similar to people with hemiplegia who are able to stand without armrests (Hesse et al. 1994; Hesse et al. 1998) during the baseline sessions and demonstrated an increase in time the onset of acute low back pain in the middle of the study. On the ankle angle over time graphs, improvements in decreased time to achieve stabilization, earlier peak dorsiflexion, and improved consistency were noted between the two baseline sessions, indicating a benefit of practice. However, at the final intervention session, while the subject was still experiencing back pain, increased time and later peak dorsiflexion was noted, along with increased reliance on the armrest. It appears that Subject B did not demonstrate improvements in the

intervention phase because the movement strategy was altered secondary to low back pain. Unlike Subject A, improvement was noted at the two-week follow up session in comparison the last intervention session with decreased time and increased consistency.

The average time to perform STS for Subject C in the baseline sessions was comparable to times reported in the literature for healthy elderly (VanderLinden et al. 1994). No change in time was noted during the baseline or intervention sessions, which may have reflected the fact that this subject was already performing the task at a relatively fast speed. The shape of the ankle kinematic curve for Subjects C and E were very similar to the curve for the healthy subject even in the initial baseline sessions. This indicates that they may have already demonstrated an efficient movement strategy at the ankle prior to participating in the study. Both of these subjects had minor trends of improving efficiency in the baseline and intervention sessions (decreasing time, increasing consistency) and were able to decrease their reliance on the armrest. No follow up data was available for these two subjects.

Subject D demonstrated a time consistent with the subjects following stroke who had not fallen as described by Cheng (1998). A decreased time was noted specifically within the first few sessions, resulting perhaps from initial task practice rather than the intervention or extended practice. Subject D also demonstrated trends of improved consistency in the ankle angle over

time graphs, earlier peak dorsiflexion, and decreasing time between the two baseline sessions and the last intervention session. Decreased reliance on the armrest and less frequent foot repositioning was also noted for this subject. These trends continued to improve in the follow up session, indicating that the movement strategy was retained unlike Subject A.

Chapter VI

CONCLUSION

The primary finding of this study was that joint mobilizations were effective in improving passive ankle joint ROM in five subjects with hemiparesis following a CVA. Although there did not appear to be a direct relationship between improved ankle mobility and sit-to-stand function, several of the subjects appeared to benefit from practicing this functional task as part of the repeated measure design.

Functionally-impaired elderly who require use of the armrest may demonstrate an inefficient movement strategy (Hughes & Schenkman, 1996), including movement of the feet just prior to the motion as described by (Hughes et al., 1994) and as demonstrated by several subjects in this study. Because all of the subjects used an armrest for at least some of the trials, this may have affected the results of STS performance and the use of ankle motion during the task. Changes in efficiency for task performance may have resulted from the intensive task practice provided in this study.

Although passive ankle ROM did improve in these subjects, other impairments were also present and may have had a greater impact on sit-to-stand function. Use of newly gained ankle mobility may have been hindered by an inability to activate muscles, incoordination of muscles, or hypertonicity

among other impairments. The instructions given to the patient to put their feet back underneath them with their heel on the floor may not have been sufficient to teach the subject how to use the new ankle motion. These subjects may have demonstrated learned non-use of the hemiplegic lower extremity in the STS task, and they may have benefited from a more specific intervention to help them overcome this non-use.

There were several limitations in the design and methodology of this study that may have influenced the findings. The choice of a single subject design was supported by the variability of subject characteristics and their response to the intervention and repeated practice. However, generalizability is extremely limited with such a small number of subjects. Larger studies with randomly assigned control groups would improve the ability to generalize these findings to a larger population. There is also a significant practice effect when using a repeated measures design, which certainly influenced the STS performance of the subjects in this study.

Although sufficient reliability and validity of the measurement tools were established with a healthy subject prior to data collection, several adjustments had to be made with the study population that may have affected the accuracy of the data collected. Specifically, calibration of each subject's lower limb had to be made in a sitting position instead of the recommended neutral standing posture. It is recommended that the receiver and transmitter for the Flock of Birds system be less than 64 cm apart or approximately 25

inches. In this study, this distance was maintained at less than 36 inches, which may have affected the accuracy of the sensor readings. To compensate for any inaccuracies, the difference between peak plantar flexion and peak dorsiflexion was used as the primary dependent variable rather than comparing absolute peak dorsiflexion values between sessions.

Investigator bias may have been present, because the all measurements were taken by the primary investigator of this study. An attempt was made to limit this by blocking visual access to the computer screen during data collection. In addition, the data for each subject was not analyzed until that subject had completed participation in the study. All joint mobilization interventions were provided by the primary investigator as well.

To improve the validity of the findings of this study, recommendations for future research would include repeating the study with a greater number of subjects, and including at least one subject who received repeated STS practice only without any intervention. Evaluation of knee and hip motions on the hemiparetic limb, as well as kinematics of the opposing limb, would provide a comprehensive view of the linked system and capture any compensations for ankle mobility limitations in the hemiplegic limb. People with hemiplegia tend to distribute their weight asymmetrically, and it would have been helpful to be able to assess any changes that occur in this through forceplate analysis.

Although the subjects in this study did not appear to use the gains in ankle motion for the STS task, they reported anecdotally that they felt that their walking was smoother and several subjects noted improved ability to climb stairs and get into a car. Future studies should include analysis of these functional activities or a health status questionnaire to capture changes in overall quality of life that may occur from participating in the study.

Other recommendations for future research would include incorporating an additional intervention to specifically encourage the patient to use the new ankle mobility, such as biofeedback regarding muscle activation or ankle position, manual guidance, active ankle exercises, or walking practice.

REFERENCES

Ada, L., & Westwood, P. (1992). A kinematic analysis of recovery of the ability to stand up following stroke. Australian Physiotherapy, 38(2), 135-142.

Akeson, W.H., Amiel, D., Abel, M.F., Garfin, S.R., & Woo, S.L.-Y. (1987). Effects of immobilization on joints. Clinical Orthopedics and Related Research, 219, 28-87.

Alexander, N.B., Schultz, A.B., & Warwick, D.N. (1991). Rising from a chair: Effects of age and functional ability on performance biomechanics. Journal of Gerontology: Medical Sciences, 46(3), M91-M98

Amiel, D., Woo, S.L.-Y., Harwood, F.L., & Akeson, W.H. (1982). The effect of immobilization on collagen turnover in connective tissue: A biochemical-biomechanical correlation. Acta Orthopedics Scandinavia, 53, 325-332.

Arnadottir, S.A., & Mercer, V.S. (2000). Effects of footwear on measurements of balance and gait in women between the ages of 65 and 93 years. Physical Therapy, 80(1), 17-27.

Backman, C.L., & Harris, S.R. (1999). Case studies, single-subject research, and N of 1 randomized trials: Comparisons and contrasts. American Journal of Physical Medicine and Rehabilitation, 78(2), 170-176.

Backman, C.L., Harris, S.R., Chisholm, J.A., & Monette, A.D. (1997). Single-subject research in rehabilitation: A review of studies using AB, withdrawl, multiple baseline, and alternating treatments designs. Archives of Physical Medicine and Rehabilitation, 78, 1145-1153.

Barnard, P., Dill, H., Eldredge, P., Held, J.M., Judd, D.L.M., & Nalette, E. (1984). Reduction of hypertonicity by early casting in a comatose head-injured individual. Physical Therapy, 64(10), 1540-1542.

Blumberg, C.J. (1984). Comments on "A simplified time-series analysis for evaluating treatment interventions". Journal of Applied Behavior Analysis, 17, 539-542.

Booth, B.J., Doyle, M., & Montgomery, J. (1983). Serial casting for the management of spasticity in the head-injured adult. Physical Therapy, 63(12), 1960-1966.

Bressel, E., & McNair, P.J. (2002). The effect of prolonged static and cyclic stretching on ankle joint stiffness, torque relaxation, and gait in people with stroke. Physical Therapy, 82(9), 880-887.

Burdett, R.G., Havasevich, R., Pisciotta, J., & Simon, S.R. (1985). Biomechanical comparison of rising from two types of chairs. Physical Therapy, 65(8), 1177-1183.

Carlstedt, C.A., & Nordin, M. (1989). Biomechanics of Tendons and Ligaments. In M. Nordin & V. H. Frankel (Eds.), Basic Biomechanics of the Musculoskeletal System. (pp. 59-74). Philadelphia: Lea & Febiger.

Cheng, P., Liaw, M., Wong, M., Tang, F., Lee, M., & Lin, P. (1998). The sit to stand movement in stroke patients and its correlation with falling. Archives of Physical Medicine and Rehabilitation, 79, 1043-1046.

Clarkson, H.M. (2000). Musculoskeletal Assessment: Joint Range of Motion and Manual Muscle Strength, 2nd ed. (pp. 341-342). Philadelphia: Lippincott Williams & Wilkins.

Cochrane, C.G. (1987). Joint mobilization principles: Considerations for use in the child with central nervous system dysfunction. Physical Therapy, 67(7), 1105-1109.

Conine, T.A., Sullivan, T., Mackie, T., & Goodman, M. (1990). Effect of serial casting for the prevention of equinus in patients with acute head injury. Archives of Physical Medicine and Rehabilitation, 71, 310-312.

Davies, P.M. (1985). Steps to Follow. New York: Springer-Verlag.

Dijs, H.M., Roofthooft, J.M.A., Driessens, M.F., De Bock, P.G.E., Jacobs, C., & Van Acker, K.L. (2000). Effect of physical therapy on limited joint mobility in the diabetic foot: A pilot study. Journal of the American Podiatric Medical Association, 90(3), 126-132.

Doorenbosch, C.A.M., Harlaar, J., Roebroeck, M.E., & Lankhorst, G.J. (1994). Two strategies of transferring from sit-to-stand: The activation of monoarticular and biarticular muscles. Journal of Biomechanics, 27(11), 1299-1307.

Engardt, M. (1994). Long term effects of auditory feedback training on relearned symmetrical body weight distribution in stroke patients: A follow up study. Scandinavian Journal of Rehabilitation Medicine, 26, 65-69.

Engardt, M., & Olsson, E. (1992). Body weight while rising and sitting down in patients with stroke. Scandinavian Journal of Rehabilitation Medicine, 24, 67-74.

Engardt, M., Ribbe, T., & Olsson, E. (1993). Vertical ground reaction force feedback to enhance stroke patients' symmetrical body weight distribution while rising / sitting down. Scandinavian Journal of Rehabilitation Medicine, 25, 41-48.

Farmer, S.E., & James, M. (2001). Contractures in orthopaedic and neurological conditions: A review of causes and treatment. Disability and Rehabilitation, 23(13), 549-558.

Fleckenstein, S.J., Kirby, R.L., & MacLeod, D.A. (1988). Effect of limited knee flexion range on peak hip moments of force while transferring from sitting to standing. Journal of Biomechanics, 21(11), 915-918.

Fowler, V., & Carr, J. (1996). Auditory feedback: Effects on vertical force production during standing up following stroke. International Journal of Rehabilitation Research, 19, 265-269.

Gajdosik, R.L., VanderLinden, D.W., & Williams, A.K. (1999). Influence of age on length and passive elastic stiffness characteristics of the calf muscle-tendon unit of women. Physical Therapy, 79(9), 827-838.

Gehlsen, G.M., & Whaley, M.H. (1990). Falls in the elderly: Part II, balance, strength, and flexibility. Archives of Physical Medicine and Rehabilitation, 71, 739-741.

Gillette, P.D., & Fell, R.D. (1996). Passive tension in rat hindlimb during suspension unloading and recovery: Muscle/joint contributions. Journal of Applied Physiology, 81(2), 724-730.

Given, J.D., Dewald, J.P., & Rymer, W.Z. (1995). Joint dependent passive stiffness in paretic and contralateral limbs of spastic patients with hemiparetic stroke. Journal of Neurology, Neurosurgery, and Psychiatry, 59, 271-279.

Gonnella, C. (1989). Single-subject experimental paradigm as a clinical decision tool. Physical Therapy, 69(7), 601-609.

Gottlieb, G.L., Agarwal, G.C., & Penn, R. (1978). Sinusoidal oscillation of the ankle as a means of evaluating the spastic patient. Journal of Neurology, Neurosurgery, and Psychiatry, 41, 32-39.

Green, T., Refshauge, K., Crosbie, J., & Adams, R. (2001). A randomized controlled trial of a passive accessory joint mobilization on acute ankle inversion sprains. Physical Therapy, 81(4), 984-994.

Halar, E.M., Stolov, W.C., Venkatesh, B., Brozovich, F.V., & Harley, J.D. (1978). Gastrocnemius muscle belly and tendon length in stroke patients and able-bodied persons. Archives of Physical Medicine and Rehabilitation, 59, 476-484.

Hanke, T.A., Pai, Y.C., & Rogers, M.W. (1995). Reliability of measurements of body center-of-mass momentum during sit-to-stand in healthy adults. Physical Therapy, 75(2), 105-118.

Harbst, K.B., Ottenbacher, K.J., & Harris, S.R. (1991). Interrater reliability of therapists' judgments of graphed data. Physical Therapy, 71(2), 107-115.

Harris, S.R., & Lundgren, B.D. (1991). Joint mobilizations for children with central nervous system disorders: Indications and precautions. Physical Therapy, 71(12), 890-896.

Harvey, L.A., Batty, J., Crosbie, J., Poulter, S., & Herbert, R.D. (2000). A randomized trial assessing the effects of 4 weeks of daily stretching on ankle mobility in patients with spinal cord injuries. Archives of Physical Medicine and Rehabilitation, 81, 1340-1347.

Hesse, S., Schauer, M., Malezic, M., Jahnke, M., & Mauritz, K. (1994). Quantitative analysis of rising from a chair in healthy and hemiparetic subjects. Scandinavian Journal of Rehabilitation Medicine, 26, 161-166.

Hesse, S., Schauer, M., Peterson, M., & Jahnke, M. (1998). Sit-to-stand manoeuvre in hemiparetic patients before and after a 4-week rehabilitation programme. Scandinavian Journal of Rehabilitation Medicine, 30, 81-86.

Hojem, M.A., & Ottenbacher, K.J. (1988). Empirical investigation of visual-inspection versus trend-line analysis of single-subject data. Physical Therapy, 68(6), 983-988.

Horak, F.B. (1991). Assumptions Underlying Motor Control for Neurologic Rehabilitation. In Anonymous, Proceedings from the II Step Conference: Contemporary Management of Motor Control Problems. (pp. 11-27). Alexandria, VA: APTA.

Hufschmidt, A., & Mauritz, K.-H. (1985). Chronic transformation of muscle in spasticity: A peripheral contribution to increased tone. Journal of Neurology, Neurosurgery, and Psychiatry, 48, 676-685.

Hughes, M.A., Myers, B.S., & Schenkman, M. (1996). The role of strength in rising from a chair in the functionally impaired elderly. Journal of Biomechanics, 29(12), 1509-1513.

Hughes, M.A., & Schenkman, M. (1996). Chair rise strategy in the functionally impaired elderly. Journal of Rehabilitation Research and Development, 33(4), 409-412.

Hughes, M.A., Weiner, D.K., Schenkman, M., Long, R.M., & Studenski, S.A. (1994). Chair rise strategies in the elderly. Clinical Biomechanics, 9, 187-192.

Ikeda, E.R., Schenkman, M.L., O Riley, P.O., & Hodge, W.A. (1991). Influence of age on dynamics of rising from a chair. Physical Therapy, 71(6), 473-481.

James, B., & Parker, A.W. (1989). Active and passive mobility of lower limb joints in elderly men and women. American Journal of Physical Medicine and Rehabilitation, 68(4), 162-167.

Janssen, W.G.M., Bussmann, H.B.J., & Stam, H.J. (2002). Determinants of the sit-to-stand movement: A review. Physical Therapy, 82(9), 866-879.

Kaltenborn, F.M. (1999). Manual Mobilization of the Joints: The Kaltenborn Method of Joint Examination and Treatment. (5th ed.). Oslo, Norway: Olaf Norlis Bokhandel.

Katz, R.T. (1988). Management of spasticity. American Journal of Physical Medicine and Rehabilitation, 108-113.

Kazdin, A.E. (1982). Single-Case Research Designs: Methods for clinical and applied settings. New York: Oxford University Press.

Khemlani, M.M., Carr, J., & Crosbie, W.J. (1999). Muscle synergies and joint linkages in sit-to-stand under two initial foot positions. Clinical Biomechanics, 14, 236-246.

Kisner, C. & Colby, L.A. (1996) Therapeutic Exercise: Foundations and Techniques, 3rd Ed. (p. 6). Philadelphia: F.A. Davis.

Kotake, T., Dohi, N., Kajiwara, T., Sumi, N., Koyama, Y., & Miura, T. (1993). An analysis of sit-to-stand movements. Archives of Physical Medicine and Rehabilitation, 74, 1095-1099.

Kralj, A., Jaaeger, R.J., & Munih, M. (1990). Analysis of standing up and sitting down in humans: Definitions and normative data presentation. Journal of Biomechanics, 23(11), 1123-1138.

Lee, M.Y., Wong, M.K., Tang, F., Cheng, P., & Lin, P.S. (1997). Comparison of balance responses and motor patterns during sit-to-stand task with functional mobility in stroke patients. American Journal of Physical Medicine and Rehabilitation, 76, 401-410.

Lundberg, A., Goldie, I., Kalin, B., & Selvik, G. (1989). Kinematics of the ankle/foot complex: Plantarflexion and Dorsiflexion. Foot and Ankle, 9(4), 194-200.

Mecagni, C., Smith, J.P., Roberts, K.E., & O'Sullivan, S.B. (2000). Balance and ankle range of motion in community-dwelling women aged 64-87 years: A correlational study. Physical Therapy, 80(10), 1004-1011.

Meskers, C.G.M., Fraterman, H., van der Helm, F.C.T., Vermeulen, H.M., & Rozing, P.M. (1999). Calibration of the "Flock of Birds" electromagnetic tracking device and its application in shoulder motion studies. Journal of Biomechanics, 32(6), 629-633.

Meskers, C.G.M., Vermeulen, H.M., de Groot, J.H., van der Helm, F.C.T., & Rozing, P.M. (1998). 3D shoulder position measurements using a six-degree-of-freedom electromagnetic tracking device. Clinical Biomechanics, 13, 280-292.

Millington, P.J., Myklebust, B.M., & Shambes, G.M. (1992). Biomechanical analysis of sit-to-stand in elderly persons. Archives of Physical Medicine and Rehabilitation, 73, 609-617.

Milne, A.D., Chess, D.G., Johnson, J.A., & King, G.J.W. (1996). Accuracy of an electromagnetic tracking device: A study of the optimal operating range and metal interference. Journal of Biomechanics, 29(6), 791-793.

Moseley, A.M. (1997). The effect of casting combined with stretching on passive ankle dorsiflexion in adults with traumatic head injuries. Physical Therapy, 77(3), 240-247.

Mueller, M.J., Minor, S.D., Schaaf, J.A., Strube, M.J., & Sahrmann,S.A. (1995). Relationship of plantar-flexor peak torque and dorsiflexion range of motion to kinetic variables during walking. Physical Therapy, 75, 684-693.

Munro, B.J., Steele, J.R., Bashford, G.M., Ryan, M., & Britten, N. (1998). A kinematic and kinetic analysis of the sit-to-stand transfer using an ejector chair: Implications for elderly rheumatoid arthritic patients. Journal of Biomechanics, 31, 263-271.

Nield, S., Davis, K., Latimer, J., Maher, C., & Adams, R. (1993). The effect of manipulation on range of movement at the ankle joint. Scandinavian Journal of Rehabilitation Medicine, 25, 161-166.

Nourbakhsh, M.R., & Ottenbacher, K.J. (1994). The statistical analysis of single-subject data: A comparative examination. Physical Therapy, 74, 768-776.

O'Dwyer, N.J., Ada, I., & Nielson, P.D. (1996). Spasticity and muscle contraction following stroke. Brain, 119, 1737-1749.

Ottenbacher, K.J. (1990a). Clinically relevant designs for rehabilitation research: The idiographic model. American Journal of Physical Medicine and Rehabilitation, 69(6), 286-292.

Ottenbacher, K.J. (1990b). Visual inspection of single-subject data: An empirical analysis. Mental Retardation, 28(5), 283-290.

Ottenbacher, K.J., & Hinderer, S.R. (2001). Evidence-based practice: Methods to evaluate individual patient improvement. American Journal of Physical Medicine and Rehabilitation, 80, 786-796.

Portney, L.G., & Watkins, M.P. (2000). Statistical Measures of Reliability. In L. G. Portney & M. P. Watkins (Eds.), Foundations of Clinical Research: Applications to Practice, 2nd ed. (pp. 557-586). Upper Saddle River, NJ: Prentice Hall Health.

Radakovich, M., & Malone, T. (1982). The superior tibiofibular joint: The forgotten joint. Journal of Orthopedic and Sports Physical Therapy, 3(3), 129-132.

Riess, J., & Abbas, J.J. (1997). Evaluation of FNS control systems: Software development and sensor characterization. Biomedical Sciences Instrumentation, 33, 197-202.

Rodosky, M.W., Andriacchi, T.P., & Andersson, G.B.J. (1989). The influence of chair height on lower limb mechanics during rising. Journal of Orthopaedic Research, 7, 266-271.

Ryerson, S.D. (1988). The Foot in Hemiplegia. In G. Hunt (Ed.), Physical Therapy of the Foot and Ankle. (pp. 109-131). New York: Churchill-Livingston.

Schenkman, M., Berger, R.A., O Riley, P.O., Mann, R.W., & Hodge, W.A. (1990). Whole-body movements during rising to standing from sitting. Physical Therapy, 70(10), 638-650.

Shaffer, M.A., Okereke, E., Esterhai, J.L., Elliot, M.A., Walter, G.A., Yim, S.H., & Vandenborne, K. (2000). Effects of immobilization on plantarflexion torque, fatigue resistance, and functional ability following an ankle fracture. Physical Therapy, 80(8), 769-780.

Shepherd, R.B., & Koh, H.P. (1996). Some biomechanical consequences of varying foot placement in sit-to-stand in young women. Scandinavian Journal of Rehabilitation Medicine, 28, 79-88.

Sinkjaer, I., & Magnussen, I. (1994). Passive, intrinsic and reflex-mediated stiffness in the ankle extensors of hemiparetic patients. Brain, 117, 355-3.

Slobounov, S.M., Simon, R., Sebastianelli, W., Carlson, A., & Buckley, W.E. (1996). Application of scientific instrumentation in a clinical setting. Journal of Sport Rehabilitation, 5, 251-261.

Slobounov, S.M., Simon, R.E., Bush, J.A., Kraemer, W.J., Sebastianelli, W., & Slobounova, E. (1999). An alternate method of range of motion measurement. Journal of Strength and Conditioning Research, 13(4), 389-393.

Smith, L.K., Weiss, E.L., & Lehmkuhl, L.D. (1996). Brunnstrom's Clinical Kinesiology. (5th ed.). Philadelphia: F.A. Davis Co.

Stevens, C., Bojsen-Maller, F., & Soames, R.W. (1989). The influence of initial posture on the sit to stand movement. European Journal of Applied Physiology, 58, 687-692.

Stokdijk, M., Biegstraaten, M., Ormel, W., de Boer, Y.A., Veeger, H.E.J., & Rozing, P.M. (2000). Determining the optimal flexion-extension axis of the elbow in vivo: A study of interobserver and intraobserver reliability. Journal of Biomechanics, 33, 1139-1145.

Taub, E., & Wolf, S.L. (1997). Constraint induced movement techniques to facilitate upper extremity use in stroke patients. Topics in Stroke Rehabilitation, 3(4), 38-61.

Thilmann, A.F., Fellows, S.J., & Ross, H.F. (1991). Biomechanical changes at the ankle joint after stroke. Journal of Neurology, Neurosurgery, and Psychiatry, 54, 134-139.

Tryon, W.W. (1982). A simplified time-series analysis for evaluating treatment interventions. Journal of Applied Behavior Analysis, 15, 423-429.

Tyson, S. (1998). The use of musculoskeletal techniques in adult cerebral palsy. Physiotherapy Research International, 3(4), 292-295.

Umberger, B.R., Nawoczenski, D.A., & Baumhauer, J.F. (1999). Reliability and validity of first metatarsophalangeal joint orientation measured with an electromagnetic tracking device. Clinical Biomechanics, 14, 74-76.

VanderLinden, D.W., Brunt, D., & McCullock, M. (1994). Variant and invariant characteristics of the sit-to-stand task in healthy elderly adults. Archives of Physical Medicine and Rehabilitation, 75, 653-660.

Vattanasilp, W., Ada, L., & Crosbie, J. (2000). Contribution of thixotropy, spasticity, and contracture to ankle stiffness after stroke. Journal of Neurology, Neurosurgery, and Psychiatry, 69, 34-39.

Walker, J.M., Sue, D., Miles-Elkousy, N., Ford, G., & Trevelyan, H. (1984). Active mobility of the extremities in older subjects. Physical Therapy, 64(6), 919-923.

Wolery, M., & Harris, S.R. (1982). Interpreting results of single-subject research designs. Physical Therapy, 62(4), 445-452.

Yarkony, G.M., & Sahgal, V. (1987). Contractures: A major complication of craniocerebral trauma. Clinical Orthopedics and Related Research, 219, 93-96.

Yoshida, K., Iwakura, H., & Inoue, F. (1983). Motion analysis in the movements of standing up and sitting down from a chair. Scandinavian Journal of Rehabilitation Medicine, 15, 133-140.

Zhan, S., & Ottenbacher, K.J. (2001). Single subject research designs for disability research. Disability and Rehabilitation, 23(1), 1-8.

Zucker, D.R., Schmid, C.H., McIntosh, M.W., D'Agostino, R.B., Selker, H.P., & Lau, J. (1997). Combining single patient (N-of-1) trials to estimate population treatment effects and to evaluate individual patient responses to treatment. Journal of Clinical Epidemiology, 50(4), 401-410.

APPENDIX A

Institutional Review Board Approval Forms

UMDNJ
UNIVERSITY OF MEDICINE &
DENTISTRY OF NEW JERSEY

Office of the Institutional Review Board
Newark Campus

INSTITUTIONAL REVIEW BOARD
NOTICE OF APPROVAL

IRB PROTOCOL NUMBER: M-104-2001
(REFER TO THIS NUMBER WHEN MAKING INQUIRIES)

PRINCIPAL INVESTIGATOR/DEPT: Patricia M. Adams, MPT/School of Health Related Professions

CO-INVESTIGATOR (S):   Genevieve Pinto Zipp, PT, EdD; Dianna Glendinning, PT, PhD
and Mary Ann Clark, PT, EdD

TITLE: Sit-to-Stand Ability Following Ankle Joint Mobilizations in Patients with Hemiplegia

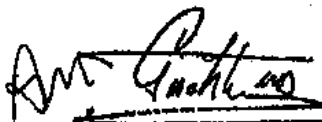**PERFORMANCE SITE (S):**   UMDNJ-School of Medicine-Stratford Campus

SPONSOR PROTOCOL NUMBER: N/A

TYPE OF REVIEW: FULL [ ]   EXPEDITED [X] #4a

TYPE OF APPROVAL: NEW [X]   RENEWAL [ ]   ADVERTISEMENT [X]

APPROVAL DATE: May 22, 2001   **EXPIRATION DATE:**   May 21, 2002

1. **ADVERSE EVENTS:** Any adverse event(s) or unexpected event(s) that occur in conjunction with this study must be reported to the IRB Office immediately (x3608).
2. **RENEWAL:** Approval is valid until the expiration date of the protocol. You are required to apply to before your expiration date for as long as the study is active. *Renewal forms will be sent to you; but it is your responsibility to ensure that you receive and submit the renewal in a timely manner.*
3. **CONSENT FORM:** All subjects must receive a copy of the consent form; the original signed copy of must be kept in a secure place by the principal investigator. **Number of consent forms approved for this study: 1**
4. **SUBJECTS:** Number of subjects approved at this site: **5**
5. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.
6. Approval is granted on the condition that any deviation from the protocol will be submitted, in writing, for separate approval.
7. **CONDITION OF APPROVAL:** Principal investigator must submit a copy of IRB approval from Seton Hall University.

Charles Tischler, M.D., Chair, IRB

May 25, 2001
Date

DHHS Multiple Project Assurance Number: <u>M1466-01NR</u>

C: chair

UMDNJ
UNIVERSITY OF MEDICINE &
DENTISTRY OF NEW JERSEY

Office of the Institutional Review Board
Newark Campus

INSTITUTIONAL REVIEW BOARD
NOTICE OF APPROVAL OF CONTINUATION

IRB PROTOCOL NUMBER: M-104-2001
(REFER TO THIS NUMBER WHEN MAKING INQUIRIES)

PRINCIPAL INVESTIGATOR/DEPT: Patricia M. Adams-Gillarden, M.P.T./School of Health Related
Professions

CO-INVESTIGATOR(S): Genevieve Pinto Zipp, P.T., Ed.D.; Diana Glendinning, P.T., Ph.D. and Mary Ann Clark, P.T., Ed.D.

TITLE: Sit-to-Stand Ability Following Ankle Joint Mobilizations in Patients with Hemiplegia.

PERFORMANCE SITE(S); UMDNJ-School of osteopathic Medicine/Stratford Campus

SPONSOR/ PROTOCOL NUMBER: N/A

TYPE OF REVIEW: FULL [ ] EXPEDITED [X] #4A

TYPE OF APPROVAL: NEW [ ] RENEWAL [X]

APPROVAL DATE: May 28, 2002 **EXPIRATION DATE: May 27, 2003**

1. **ADVERSE EVENTS:** Any adverse event(s) or unexpected event(s) that occur in conjunction with this study must be reported to the IRB Office immediately (x3608).
2. **RENEWAL:** Approval is valid until the expiration date of the protocol. You are required to apply for renewal prior to your expiration date for as long as the study is active. Renewal forms will be sent to you, but it is your responsibility to ensure that you receive them and submit the form(s) in a timely manner.
3. **CONSENT FORM:** The attached stamped consent has been approved by the IRB. All subjects must receive a copy of the approved consent form; a copy of the signed consent must be kept included in the subject's medical/patient record; the original signed copy must be kept in a secure place by the principal investigator. Number of consent forms approved: 1
4. **SUBJECTS:** Number of subjects approved at this site: 5
5. The investigator(s) did not participate in the review, discussion, or vote of this protocol.
6. APPROVAL IS GRANTED ON THE CONDITION THAT ANY DEVIATION FROM THE PROTOCOL WILL BE SUBMITTED, IN WRITING, FOR SEPARATE APPROVAL.

Charles Tischler, M.D., Chair, IRB

May 29, 2002
Date

DHHS: Federal-Wide Assurance Identifier: FWA00000036

cc: Department Chair

SETON HALL UNIVERSITY
1 8 5 6

May 21, 2001
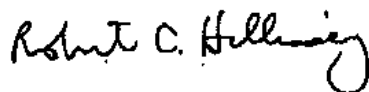
Ms. Patricia Adams
222 Shady Lane
Marlton, NJ 08053

Dear Ms. Adams:

The Institutional Review Board For Human Subject Research at Seton Hall University reviewed your Proposal entitled "Sit-to-Stand Ability Following Ankle Joint Mobilizations in Patients with Hemiplegia". Your project has been approved as amended by the revisions submitted to the Chair of the IRB. Enclosed please find the signed Request for Approval form for your records.

The Institutional Review Board approval of the project is valid for a one year period from the date of the original approval letter. Any changes to the research protocol must be reviewed and approved by the committee prior to implementation. Thank you for your cooperation and best wishes for the success of your research.

Sincerely,

Robert C. Hallissey

Robert C. Hallissey, Ph.D.
Acting Chair
Institutional Review Board

c: Genevieve Pinto-Zipp

/fs

REQUEST FOR APPROVAL OF RESEARCH, DEMONSTRATION OR

RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

PROJECT TITLE: Sit-to-Stand Ability Following Ankle Joint Mobilizations in Patients with Hemiplegia

CERTIFICATION STATEMENT:

In making this application, I(we) certify that I(we) have read and understand the University's policies and procedures governing research, development, and related activities involving human subjects, and that I(we) shall comply with the letter and spirit of those policies. I(we) further acknowledge my(our) obligation to (1) obtain written approval of significant deviations from the originally-approved protocol BEFORE making those deviations, and (2) report immediately all adverse effects of the study on the subjects to the Chairperson of the Institutional Review Board Involving Human Subjects and to the Director of the Office of Grants and Research Services, Seton Hall University, South Orange, NJ 07079.

Patricia M. Adams, MPT   4/11/01

RESEARCHER(S) OR PROJECT DIRECTOR(S)   DATE

Please print or type out name below signature

Genevieve Pinto Zipp, PT, EdD   4/9/200

RESEARCHER'S ADVISOR OR DEPARTMENTAL SUPERVISOR   DATE

Please print or type out name below signature

Diana Glendinning, PT, PhD   4/9/2001

RESEARCHER'S ADVISOR OR DEPARTMENTAL SUPERVISOR   DATE

Please print or type out name below signature

Mary Ann Clark, PT, EdD   4/9/2001

RESEARCHER'S ADVISOR OR DEPARTMENTAL SUPERVISOR   DATE

Please print or type out name below signature

The request for approval submitted by the above researcher(s) was considered by the IRB for Research Involving Human Subjects Research __3/01__ meeting.

The application was approved __✓__ not approved __ by the Committee. Special conditions were _____ were not __✓__ set by the IRB. (Any special conditions are described on the reverse side.)

Robert C. Hill   5/21/01

CHAIRPERSON, SETON HALL UNIVERSITY INSTITUTIONAL   DATE
REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

9

SETON HALL UNIVERSITY.

1 8 5 6

May 1, 2002

Patricia Adams Gillardon
436 Stokes Road
Shamong, NJ 08088

Dear Ms. Adams Gillardon:

The Seton Hall University Institutional Review Board has reviewed your Continuing Review application for your research proposal "Sit-to-Stand Ability Following Ankle Joint Mobilizations in Patients with Hemiplegia."

You are hereby granted another 12-month approval from the date of this notice. If any changes are desired in this protocol, they must be submitted to the IRB for approval before implementation.

Thank you for your cooperation.

Sincerely,

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

Cc: Genevieve Pinto-Zipp, Ed.D.

APPENDIX B

Informed Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY:

Sit to Stand Ability Following Ankle Joint Mobilizations
in Patients with Hemiplegia

RESEARCH STUDY:

I, _____, have been asked
to participate in a research study under the direction of <u>Patricia Gillardon,</u>
<u>MPT and Genevieve Pinto Zipp, PT, EdD</u>. Ms. Gillardon is an Assistant
Professor at UMDNJ and a doctoral candidate at Seton Hall University.
Dr. Zipp is an Associate Professor at Seton Hall University (Graduate
Programs in Health Sciences). Other professional persons who work with
them as study staff may assist or act for them.

PURPOSE:

The purpose of this research study is to find out if stretching the ankle
joint will help people who have had a stroke stand up from a chair. A
certain amount of motion is necessary in order to position the foot on the
floor appropriately before standing up. Therefore, the results of this study
may be important for all patients who have had a stroke and who have
difficulty standing up from a chair because they do not have full ankle
movement.

DURATION:

My participation in this study will consist of sessions scheduled three
times per week over a five to eight-week period. Each session will last
approximately 45 minutes. Two weeks after finishing the study, I will
return for two additional measurement sessions.

PROCEDURES:

I have been told that during the course of this study, the following will occur:

1. I will be randomly assigned (like a flip of a coin) to either receive therapy intervention or not receive therapy intervention.
2. I will be seated in a sturdy chair.
3. My shoes and socks will be removed and small sensors (plastic pieces with wires attached) will be placed on my shin and foot and secured with velcro straps.
4. My foot will be moved up and down several times to take measurements.
5. I will be asked to place my feet as far back underneath me as possible while keeping my heels down on the floor. Then, I will stand up from the chair at a fast but safe speed. This will be videotaped and recorded on a computer. I will be allowed to rest for 60 seconds, then asked to stand again. This will be repeated for a total of twelve times with a 60 second rest period between each.
6. During some of the sessions, I will have my ankle stretched while sitting in the chair. This will take approximately six minutes and is a painless procedure commonly performed by licensed physical therapists.

SUBJECTS:

I will be one of 5 subjects who participate in this trial. All subjects are people who had a stroke six months – 1 year ago, have weakness on one side of their body, have ankle tightness, are able to stand up from a chair without help, and are over 18 years of age.

EXCLUSIONS:

I should not participate in this study if any of the following apply to me:

1. Severe problems in my weak ankle, such as too much motion, swelling, arthritis, broken bone, or cancer.
2. Language or cognitive problems that make it difficult for me to understand this paper.
3. Currently receiving physical therapy treatment.

RISKS/DISCOMFORTS:
I have been told that the study described above may involve the following risks and/or discomforts:

The technique used to stretch my ankle is not typically painful. I may feel some pressure as my lower leg and foot are held in the stretch position. This technique is a normal part of physical therapy practice and the risk of injury with this procedure is very minimal. However, if I experience any pain or discomfort, I should let the therapist know and the technique will be stopped immediately.

I may feel tired after standing up from the chair. If I feel that 60 seconds is not enough of a rest, I should let the therapist know and I will be permitted to rest as long as I need to before continuing.

There may also be risks and discomforts that are not yet known.

BENEFITS:
I have been told that the benefits of participating in this study may be: increased motion at my ankle joint and /or the ability to stand up from a chair easier and faster. However, it is possible that I may receive no benefit from participating in this study.

ALTERNATIVES:
I can choose not to participate in this study.

NEW FINDINGS:
During the course of the study, I will be told about any new information that may affect my willingness to remain in the study.

CONFIDENTIALITY:
Every effort will be made to maintain the confidentiality of my study records. Officials of the University of Medicine and Dentistry of New Jersey and research study co-investigators (Dr. Pinto Zipp, Dr. Glendinning, Dr. Clark) will be allowed to inspect sections of my medical and research records related to this study. If the findings from the study are published, I will not be identified by name. My identity will remain confidential unless disclosure is required by law.

FINANCIAL COSTS TO THE SUBJECT:
I understand there will be no cost to me for my participation in this study.

MEDICAL THERAPY FOR INJURY:

Medical treatment will be arranged by UMDNJ for participants who sustain physical injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment. No additional financial compensation is available.

RIGHT TO REFUSE OR WITHDRAW:

I understand that my participation is voluntary and I may refuse to participate, or may discontinue my participation at any time, without penalty or loss of benefits to which I am otherwise entitled. I also understand that the investigator has the right to withdraw me from the study at any time.

INDIVIDUAL(S) TO CONTACT:

If I have any questions about my treatment in this study, I can contact Patricia Gillardon at (856) 566-7185 or at: MPT Program, PCC 228, 40 E. Laurel Road, Stratford, NJ 08084.

This project has been approved by the Institutional Review Board of UMDNJ. If I have any questions about my rights as a research subject, I can contact: Charles Tischler, M.D. Chair, Institutional Review Board, UMDNJ-Newark Campus IRB at (973) 972-3608.

This project has been reviewed and approved by the Seton Hall University Institutional Review Board for Human Subjects Research. The IRB believes that the research procedures adequately safeguard the subject's privacy, welfare, civil liberties, and rights. The Chairperson of the IRB may be reached through the Office of Grants and Research Services. The telephone number of the Office is (973) 275-2974.

I will receive a copy of this consent form if I agree to participate in this research study.

_____ subject's initials

SIGNATURE OF SUBJECT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study, realizing that I may withdraw without prejudice at any time.

Subject: Name: _____

              Signature: _____

Witness: Name: _____

              Signature: _____

Date: _____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge the subject,
_____, (or his/her parent/legal guardian)
has assimilated the entire content of the above consent form, and understands the study and its risks well. The subject's questions and those of his/her parent or legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator: Name: _____

                  Signature: _____

Witness: Name: _____

              Signature: _____

Date: _____

APPENDIX C

Modified Ashworth Scale

MODIFIED ASHWORTH SCALE

The Modified Ashworth Scale (MAS)
for Grading Spasticity

0   No increase in muscle tone

1   Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the ROM when the affected part(s) is moved in flexion or extension

1+   Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM

2   More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved

3   Considerable increase in muscle tone, passive movement difficult

4   Affected part(s) rigid in flexion or extension

Reference: O'Sullivan, S.B. & Schmitz, T.J. (2001). Physical Rehabilitation, 4th ed. Philadelphia: F.A. Davis Company.

APPENDIX D

Sample Data Collection Form

SUBJECT CODE:_____

height
weight:

hemiplegic side:

DATE	MAS	GONI: PROM knee flex		Flock of Birds: PROM knee flex		Flock of Birds: AROM knee flex	
		DF	PF	DF	PF	DF	PF