WALKING AFTER STROKE:

Interventions to restore normal gait pattern

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İnterventies om het normale looppatroon te verbeteren

Thesis

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Ipsen Farmaceutica

To Ata, Reha, My Parents and

My Patients…

Contents

Chapter 1

Introduction

1.1 Definition and epidemiology of stroke

Stroke is the leading cause of adult disability and inpatient rehabilitation admissions in the USA[1,2]. Approximately 400/100 000 persons over the age of 45 years have a first stroke each year in the United States, Europe, and Australia[3]. According to International Stroke Trial reports, at 6 months after stroke, about 20% are dead, 50% are independent and 30% are dependent in self-care[4]. In Turkey, the annual incidence rate of stroke is 167 per 100 000 population[5]. Fatality rate is 19.7% during the first month and 37 to 57% are discharged from neurology clinics with severe impairments[6].

Dependence in mobility is one of the primary reasons of admission for inpatient rehabilitation after stroke. Much effort goes into helping these patients regain the ability to walk at least in the home prior to discharge. In spite of these efforts, approximately 35% of survivors with initial paralysis of the leg do not regain useful walking function, and 25% of all survivors are unable to walk without full physical assistance[7].

1.2 Characteristics of hemiparetic gait

Stroke patients exhibit varying deficits in perception, muscle strength, motor control, passive mobility, sensation, tone and balance[8-16]. These impairments have significant effects upon walking ability. The exact combination of the imparments depends on the extensiveness and location of the brain damage. Other factors that might influence the level of limitation in walking activity are learning ability, coping skills, motivation, medical co-morbidities, physical endurance levels, family support, housing and the amount and type of rehabilitation training[13,14]. Even patients with functional ambulation display very different gait patterns compared with able-bodied persons thus increasing the risk of falling. Marked variation in gait patterns across stroke patients has also been noted[16].

Hemiparetic gait is characterized by slow and asymmetric steps with poor selective motor control, delayed and disrupted equilibrium reactions and reduced weight bearing on the paretic limb[12,14-18]. Smooth and symmetric forward progression of the body is impaired with a large variation in gait patterns related to the degree of recovery[19]. Well-controlled intra-limb and inter-limb coordination is replaced by mass limb movement patterns (synergies) on the paretic side requiring compensatory adjustments of the pelvis and non-paretic side. Compensatory movements necessary for ambulation produce abnormal displacement of the center of gravity, resulting in increased energy expenditure[20].

Previous stroke studies have reported altered kinematic and kinetic gait profile in both magnitude (peak and valley angle, moment and power), and pattern (shape and direction of curves) indicating an impaired ability to generate and grade the forces that control limb movement[10,16,20-23]. Hemiparetic gait is often characterized by stiff-legged gait (reduced range of knee motion) and drop foot (lack of ankle dorsiflexion during swing) leading to raised hip during swing. Kim and Eng investigated gait characteristics of 20 chronic community-dwelling stroke patients and concluded that stroke patients use different strategies to achieve the goal of walking[23]. Their findings did not show a relationship between gait pattern and walking velocity and did not support the goal of “normalization” of movement patterns in management of stroke patients. A cause-effect relationship between impairments of stroke and gait pattern can not yet be determined in order to guide training programs.

1.2.1 Postural control

Postural control has been defined as the act of maintaining, achieving or restoring a state of balance during any posture or activity[24]. As well as problems with moving and controlling limbs, many hemiparetic patients also experience difficulty in maintaining balance, because a defect in the “body image” causes them to ignore the affected side. They suffer from severe postural instability and postural asymmetry during quiet standing in the frontal and sagittal planes[25]. They present an asymmetrical pattern of lateral movements and greater excursions of the pelvis (excessive excursion of the center of gravity) than healthy subjects walking at similar speeds[26]. The accelerations are asymmetrical, with the highest values occurring when weight bearing is on the paretic side. This suggests difficulties in controlling the lateral motion of the trunk segment, which might be very important for maintaining balance in locomotor activities. Impaired balance is often related to uneven weight bearing, increased energy expenditure and may be associated with laterally directed falls and a high risk of fractures in these subjects[27,28].

1.2.2 Gait symmetry

Asymmetric steps are a characteristic of hemiparetic gait, with the paretic limb having a shorter stance time and step length than that of the non-paretic limb. It has been reported that the degree of asymmetry is related to the degree of motor recovery[17,29] and spasticity of the affected ankle plantarflexors[30]. Abnormalities in standing balance and asymmetry during single-limb stance are assumed to be related to a decreased ability to bear weight on the hemiplegic side[30]. The weight shift to the paretic side is essential in walking as it allows the non-paretic limb to be moved and, consequently, a step to be taken. The ability to maintain single-limb support is an important determinant of gait stability[22]. Thus, single-support stability training helps to achieve more symmetric gait in stroke patients with hemiparesis[21]. Gait asymmetry leads to increased energy expenditure and risk of falls. Consequently, improvement in symmetry provides an important clinical marker of recovery and functionality[21,22,30,31].

1.2.3 Selective motor control

Stroke patients with poor selective motor control walk with synergistic mass patterns of the affected lower leg rather than isolated joint movements. Simultaneous activation of the quadriceps with the gluteus maximus causes a mass extension pattern during the stance phase. The mass flexion pattern then causes synergistic contraction of the hip flexors, knee flexors, and ankle dorsiflexors during the swing phase[32]. This primitive motor control produces the primitive patterned limb movement and inhibits normal progression during walking. It has been suggested that treatment strategies for stroke patients with poor motor control should focus on isolated and selected joint movement training to break up the mass synergistic pattern and improve walking pattern[32]. Isolated ankle dorsiflexion while hip and knee are in extension is the first sign of selective motor control after stroke.

1.3 Treatment of hemiparetic gait

Treatment for a stroke begins immediately in the hospital with acute care, helping the patient to survive and avoid another similar attack. The next step, spontaneous recovery, happens naturally to most patients due to resolution of edema or reperfusion of the ischemic penumbra. Much of the recovery after the initial two weeks is likely due to brain plasticity[33]. Functional reorganization of sensory and motor systems is well documented after stroke[34-36]. Regaining lost sensory and motor abilities usually happens during the first few weeks of recovery, but steady progress can take place over a longer period of time. Recovery mechanisms may include unmasking of pre-existing connections, activity-dependent synaptic changes, sprouting of new axon terminals and formation of new synapses[35]. Functional neuroimaging studies showed that reorganization is enhanced by rehabilitation programs after stroke[36]. There is strong evidence that stroke patients benefit from early organized multidisciplinary care[37] and exercise programs in which functional tasks are directly and intensively trained[38]. Organized multidisciplinary care is characterized by early mobilization and multidisciplinary rehabilitation (including physiotherapy) co-ordinated by regular team meetings[39]. It has been shown that functional specificity and the progressive complexity of tasks being trained are the key variables of motor training and cortical reorganization[40,41].

The goal of a stroke rehabilitation program is to regain the ability to function and return to a productive and satisfying life. Rehabilitation can achieve these goals by either restoring body functions, by compensation for any body dysfunction, or by combination of both[42]. Walking ability is one of the most important functions because independent ambulation is essential for community reintegration and social participation. Thus, gait training accounts for a large proportion of time spent in stroke rehabilitation. Any limitation in an activity may be due to impairments in different body functions, so that specific training to restore impaired body functions will have the highest chance to improve activity levels. If body functions cannot be regained, various orthosis and aids are prescribed for substitution and compensation of lost body functions. Bipedal walking requires harmonization of three basic body functions: 1) maintenance of balance and upright posture of the upper body; 2) cyclical movement of lower extremities; and 3) generation of propulsive forces[43]. So, restoration of normal movements of the trunk, pelvis, and lower extremity while walking, improving symmetry and weight bearing on the paretic side, and to establish an energy-efficient walk are the most important goals of gait training in stroke patients[17,18].

Tailor-made physiotherapy is an important part of rehabilitation after stroke. A number of physiotherapy approaches have been developed based on different ideas about how people recover after a stroke. Central to these are approaches based on 'neurophysiologic' principles, 'motor learning' principles and 'orthopedic' principles. However there is no evidence that any one approach was clearly better than another at improving leg strength, balance, walking speed or the ability to perform everyday tasks[24].

1.3.1 Postural control

Pre-ambulation programs are used to improve strength, coordination, and range of motion, facilitate proprioceptive feedback, develop postural stability, develop controlled mobility in movement transitions and develop dynamic balance control and skills. Parallel bar activities consist of moving from sitting to standing, standing balance and weight-shifting activities, hip-hiking, standing push-ups, stepping forward and backward, forward progression, and use of assistive device with appropriate gait pattern[24]. Another way to address postural control deficits is to provide the individual with feedback from a force platform while balance activities are performed[44].

1.3.2 Gait symmetry

Facilitation of various weight bearing muscles by therapists[45], visual and auditory feedback of patients' weight distribution[46], backward walking[31] and musical motor feedback[47] are used to restore gait symmetry, whereas shoe wedges and lifts are used to compensate gait asymmetry after stroke[48]. Lennon et al.[49] reported the beneficial effects of physiotherapy based on the Bobath concept of the weight bearing ability of the hemiplegic side. They attributed the results to improvement in the compensating ability of the non-paretic side after a mean of 17 weeks of outpatient therapy. The Bobath concept aims at the normalization of tone, facilitation of more normal movement patterns as well as the act of walking to improve walking ability in stroke patients[50].

1.3.3 Selective motor control

Many techniques are used in the attempt to help the stroke patient regain selective motor control of the affected limbs. Controlled outcome studies have failed to establish the superiority of one technique over another[24]. Being the general aim of a neurodevelopmental technique, therapists aim for restoration of a more physiological gait pattern[51]. If the patient is unable to initiate movement after stroke, effective strategies may include direct facilitation of movement using extereoceptive, proprioceptive and reflex stimulation techniques, superimposed upon the patients' own attempts to control their body movements. Treatment should involve the patient using the hemiplegic side in volitional motor tasks. The more the patient can be made to use the affected side, the greater the chance of increased sensory awareness and function. The presentation of repeated sensory stimuli will maximize use of residual sensory function and CNS reorganization. Stretch, stroking superficial and deep pressure and weight bearing with approximation can all be used during therapy to increase sensory output. Constraint-induced movement therapy[52], bilateral training[53], motor imagery[54], use of a mirror[55,56], mental practice[57], electromyographic (EMG) biofeedback[58,59], robot-assisted therapy[60], functional vibratory stimulation[61], acupuncture[62] and electrical stimulation[63] techniques are used for muscle re-education and facilitation to re-establish voluntary control of body positions and movements after stroke.

Ankle dorsiflexor muscle strength of the affected side was reported to be the primary determinant for gait velocity and temporal asymmetry[64]. Buurke et al. investigated the muscle co-ordination of stroke patients longitudinally and reported that the only changes were in tibialis anterior and gastrocemius muscles[65]. In a meta-analysis of eight studies, Moreland et al. concluded that EMG biofeedback is superior to conventional therapy alone for improving ankle dorsiflexion muscle strength[59].

1.4 Quantitative analysis of hemiparetic gait

Walking ability can be evaluated qualitatively or quantitatively by using various clinical and laboratory tests. Many studies on the recovery of hemiparetic gait have used ordinal functional assessment scales such as the Rivermead Mobility Index, the Barthel Index, the Functional Independence Measure, the Functional Ambulation Categories, and the Timed Up-and-Go Test in which gait is categorized into 3-7 categories according to the distance, time and need for help. Although these scales are easy to apply and affordable, more challenging and nominal tests are needed to detect further improvements due to their ceiling effects for ambulatory stroke patients[66]. They were designed to measure only basic activities and, as such, do not capture patients' performances in more advanced participation activities.

The most widely used qualitative method to measure walking ability after stroke is walking velocity[38,67]. It has been reported as a reliable and responsive predictor of functional status[68-70.] Although walking velocity is a useful overall gait measure, it is not adequate to evaluate full gait pattern. Walking velocity is influenced by many factors, ranging from primary impairments of stroke (lack of selective motor control and poor balance) to secondary, compensating contribution of the non-paretic side and trunk[71]. Changes in walking velocity may even be a behavioral adaptation to the individual's perceived limits of stability[72]. Moreover, the protocols used to measure walking velocity vary considerably between studies (walking short versus long distances, at fast versus self-selected speeds)[73].

The resultant hemiparetic gait pattern following stroke is a mixture of deviations as well as the compensatory motion dictated by residual functions, so that each patient must be examined, and his own unique gait pattern must be identified and documented. Quantitative gait analysis is the best way to understand the complex multifactorial gait dysfunction of hemiparetic patients[14,74]. It helps to identify deviations from normal gait, to determine functional problems, to formulate a treatment plan that will bring quantifiable results, and to follow the outcome of the treatment[75,76]. Gait can be quantified by time-distance measures, kinematics, kinetics and electromyography. Data may offer suggestions for clinical intervention[77]. Buurke et al. reported that muscle activation pattern do not change over time after stroke[65]. However, kinematic and kinetic characteristics of gait differ according to the level of motor recovery and time since injury. It has been shown that practice of close-to-normal movements, muscle activation driving practice of movement and repetition of desired movements are effective in the reacquisition of coordinated and skilled movement after stroke[78]. Tailor-made interventions that specifically target and measure restoration of normal gait pattern after stroke may be more efficacious.

Four groups of gait pattern numbered I to IV, in order of increasing severity, has been defined for children with spastic hemiplegia[79]. Such grouping helps building treatment algorithms for children with cerebral palsy however, it is not clear whether same classification is valid for adult hemiplegic patients. Moreover, in a recent study it was concluded that exact agreement was unacceptable for some gait patterns using those groupings, so that kinematic data from 3D instrumented gait analysis and video should be used together when using the grouping scales.

1.4.1 *Postural control*

Postural control is most commonly evaluated by force platform systems in terms of postural sway (increased displacement of center-of-mass (COM) within the base of support), symmetry (amount of weight on each side) and limits-of-stability measures[80]. It has been shown that postural sway in the frontal plane is specific for the postural control[81] and responsive to balance training after stroke[82].

Force platform systems (posturography) are designed to provide visual or auditory feedback to patients regarding the locus of their COM or center-of-pressure (COP), as well as training protocols to enhance postural control. Posturographic data are also used as an outcome parameter to assess the effectiveness of the treatment. However, in controlled trials, if the control group has not received balance training by posturography, the experimental group has the advantage of experience with the system and may get higher scores in the post-treatment assessment. In order to avoid this 'learning effect', it is not advisable to use the same system for both treatment and assessment.

Quantitative gait analysis systems are the best alternative to posturography to assess postural control via the COM path (pelvic excursions in sagittal, coronal and transverse planes) and symmetry in weight bearing. Control of pelvic motion is critical to the maintenance of total body balance since the weight of the head, arms and trunk acts downward through the pelvis. Kinematic and kinetic studies of upper-body motion in the frontal plane have shown that the trunk is precisely controlled and highly dependent upon the motion of the pelvis[83].

1.4.2 *Gait asymmetry*

To quantify the extent of the temporal and spatial asymmetry of gait pattern, symmetry deviations (unaffected side–affected side, expressed as a fraction of the stride duration)[47], symmetric index (dividing the absolute difference of unaffected and affected by their average)[84] or asymmetry ratios (1-(affected/unaffected))[30,64] can be calculated. Step length, single support time and percentage of stance phases of the paretic and non-paretic sides are the most frequently compared parameters. Goldie et al[85] reported that increase in single support time on the paretic side is a good indicator of increase in weight bearing on the paretic side, whereas increase in single support time on the non-paretic side is a good indicator of better paretic leg advancement. They pointed that if the goal of treatment is to increase gait velocity and to improve gait pattern, treatment strategies should be directed toward reducing non-paretic single support time. By focusing only on increasing affected single support time, a more symmetrical gait pattern may be achieved, but velocity is likely to decrease. Lin et al[64] investigated the gait symmetry of 68 chronic ambulatory stroke patients and reported dorsiflexor strength of the paretic side to be the primary determinant of temporal gait symmetry.

Haart et al[82] reported that assessment of weight-shifting capacity provides unique information about balance recovery after stroke and can be used as an outcome parameter to develop new rehabilitation strategies. Eng et al[86] have shown that weight bearing ability can be reliably measured by force plates in terms of vertical ground reaction forces and used as an outcome measure in stroke patients. The amount of pelvic excursion in the frontal plane is also reported to reflect the variability in weight bearing on each leg during the single support phase[87].

1.4.3 Selective motor control

Selective ankle dorsiflexion represents good motor control after stroke. Ankle dorsiflexion has been used to assess the supraspinal sensorimotor network for the neural motor control of walking[88]. Besides qualitative and quantitative clinical assessments, ankle joint rotation angles in the sagittal plane during the gait cycle can also be measured using quantitative gait analysis systems, as well.

1.5 Outline of the thesis

The objective of this thesis is to investigate the effects of various interventions on postural control, gait symmetry and selective motor control of hemiparetic patients with stroke. To provide a rationale for the proper selection of therapeutic interventions, we assessed the effectiveness of balance training, electrical stimulation, arm sling and AFO to improve hemiparetic gait pattern after stroke. Treatment outcome was evaluated by relevant clinical assessments together with time-distance, kinematic and kinetic gait characteristics measured by a quantitative three-dimensional gait analysis system.

Chapter 2 evaluates the within-session and between-session repeatability of time-distance and sagittal plane kinematic gait parameters in 20 hemiparetic patients with sub-acute stroke. A test-retest design was used in which the patients were tested during two sessions within a two-hour period.

Chapter 3 evaluates the effects of a task-oriented force platform biofeedback balance training on the walking velocity, postural control, weight shifting, symmetry, selective motor control and functional ambulation of hemiparetic patients with sub-acute stroke. Forty-one patients (mean (SD) age of 60.9 (11.7) years) with hemiparesis after stroke (median time since stroke 6 months) were randomly assigned to an experimental or a control group. The control group (n=19) participated in a conventional stroke inpatient rehabilitation program, whereas the experimental group (n=22) received 15 sessions of balance training (using force platform biofeedback) in addition to the conventional program.

Chapter 4 addresses the immediate arm sling effects on walking velocity, trunk movements, center of gravity excursions and paretic side weight bearing of 31 hemiparetic patients with sub-acute stroke. In a single session, crossover (with and without an arm sling), controlled design, quantitative gait data of the patients were compared with those of age-matched and gender-matched able-bodied control subjects.

Chapter 5 investigates whether NMES combined with a conventional stroke rehabilitation program is more effective than the conventional program alone in facilitating recovery of selective motor control in the lower extremity, and in improving gait kinematics of hemiparetic patients with sub-acute stroke. A total of 25 consecutive inpatients with stroke (mean age of 55 years) all within 6 months post-stroke and without volitional ankle dorsiflexion were studied. Both the NMES group (n=12) and the control group (n=13) participated in a conventional stroke rehabilitation program, 5 days a week for 4 weeks. The NMES group also received 10 minutes of NMES to the tibialis anterior muscle of the paretic limb, 5 days a week, for 4 weeks.

Chapter 6 investigates whether sensory-threshold electric nerve stimulation (SES) combined with a conventional stroke rehabilitation program is more effective than the sham-SES and the conventional program in facilitating recovery of selective motor control in the lower extremity, and in improving gait kinematics of hemiparetic patients with sub-acute stroke. A total of 30 consecutive inpatients with stroke (mean age of 63.2 years), all within 6 months post-stroke and without volitional ankle dorsiflexion were studied. Both the SES group (n=15) and the placebo group (n=15) participated in a conventional stroke rehabilitation program, 5 days a week for 4 weeks. The SES group also received 30 minutes of SES to the paretic limb, whereas the control group received sham-stimulation.

Chapter 7 evaluates and compares the biomechanical effects of metallic and plastic ankle foot orthosis on kinematic and kinetic gait characteristics of 12 hemiparetic patients who had no selective ankle dorsiflexion on the hemiplegic side while walking. Mean age of the group was 54 (range 39–65) years; mean time since stroke was 67 (range 30–270) days. Patients were using either a single-point or three-point cane. Both a Seattle-type polypropylene AFO and a metallic AFO were specially moulded and fitted for each patient. Quantitative gait data without and with orthosis were compared.

Chapter 8 discusses the strength and limitations of the interventions and the quantitative gait analysis method and presents possible directions for future research.

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Chapter 2

Repeatability of lower limb three-dimensional kinematics in patients with stroke

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2.1. Abstract

The within- and between-session repeatability of time-distance and sagittal plane kinematic gait parameters were evaluated in 20 hemiparetic patients with sub-acute stroke. A test-retest design was used in which the patients were tested during two sessions within a two-hour period. Each session comprised three consecutive trials. The intraclass correlation coefficients (ICCs) for time-distance parameters ranged from 0.82 to 0.99. The within-session coefficient of variation (CV%) for time-distance parameters ranged from 3.9 to 14.1, whereas between-session CV% ranged from 6.1 to 17.2, showing similar but higher variability. The within- and between-session CV% for sagittal plane kinematics of the paretic lower limb ranged from 3.6 to 32.4.

The results indicate that time-distance parameters and sagittal plane gait kinematics of the paretic lower limb, measured by the Vicon 370 quantitative gait analysis system, are repeatable and can be used to assess treatment effects after stroke.

2.2. Introduction

Three-dimensional (3D) quantitative gait analysis systems are widely used for clinical decision making and to evaluate the outcome of therapeutic interventions after stroke[1-3]. The reliability (repeatability) of gait parameters with minimal measurement error is an important issue in the clinical use of results of quantitative gait analysis. It is important to investigate whether a variation between measurements is a treatment effect or solely due to variation in the measurements. If measurement errors conceal important gait deviations, meaningful information will be lost. On the other hand, if the limitations of the measurement are not known, small deviations may be considered meaningful thereby leading to 'over-interpretation'. It is necessary to know whether the outcome results exceed the measurement error. Variation between different occasions should be due to actual improvement/deterioration and not to random error[4,5].

Schwartz et al. designed an experimental protocol to investigate inter-therapist, inter-session and inter-trial errors of 3D quantitative gait data (using the Vicon 512 and Vicon Clinical Manager software) in healthy subjects. They classified the variations in measured gait patterns as intrinsic (which occur naturally through within-session or subject-to-subject variability) or extrinsic variations (which arise from experimental errors and are candidates for quality improvement measures). They suggested that intrinsic errors cannot be reduced but need to be measured as a baseline for comparison, whereas extrinsic variation arises from various methodological sources[5]. Besides the natural variability in the gait of persons (intrinsic variability such as gait velocity), we should be aware of the numerous potential sources of error during preparation of the subjects (e.g. anthropometric measurements, marker placement), data collection (calibration of the cameras, skin motion), data processing (definitions of the points of toe-off and initial contacts) and interpretation of the data (extrinsic variability) [5-11].

Every gait analysis laboratory should determine measurement errors for both healthy subjects and for patients, in order to improve the quality of the data collection and interpretation. We earlier reported high test-retest repeatability of time-distance, kinematic and kinetic measurements of healthy subjects in our gait laboratory[12]. However, it is not yet known how reliable and repeatable 3D gait kinematics are for patients with stroke. The within- and between- session repeatability of time-distance parameters after stroke have been investigated in a hospital setting[13-15] and in the home environment[16,17], showing higher repeatability in within-session than in between-sessions of walking velocity in stroke patients. Walking velocity is a preferred outcome parameter after stroke because it remains sensitive to change even after three months post-stroke. However, the disadvantage of walking velocity as an outcome parameter is that it does not inform about the movement patterns, even though normalization of movement patterns is one of the therapeutic aims. Ideally, kinematic and kinetic gait analysis should be used to guide the therapy and to optimize the success of therapeutic strategies as soon as the patient gains independent walking[18]. Therefore, the aim of this study was to assess the repeatability of the time-distance parameters and sagittal plane gait kinematics of patients with stroke.

2.3. Methods

2.3.1. Participants

The trial included 20 consecutive patients with hemiparesis after stroke who met the study criteria. The mean age and time since stroke ± standard deviation (SD) were 54.2±13.3 years (from 38 to 68 years) and 6.5±6.9 months (from 1 to 13 months), respectively. Stroke was defined as an acute event of cerebrovascular origin causing focal or global neurologic dysfunction lasting more than 24 hours,[19] and diagnosed by a neurologist and confirmed by computed tomography or magnetic resonance imaging. Patients were required to meet the following criteria for inclusion in the study: (1) first episode of unilateral stroke with hemiparesis, (2) ability to understand and follow simple verbal instructions, (3) ambulatory before stroke, (4) ability to stand with or without assistance and to take at least one or more steps with or without assistance. The protocol was approved by the Ankara University Ethics Committee. Written informed consent was given by all participants.

2.3.2. Design

A test-retest design was used where the patients were tested during two sessions on the same day approximately 2 hours apart (between 10 am and 4 pm). All markers were removed and reapplied for the second session. This method was chosen to avoid any clinical change or improvement of the patient from one day to another, and to be able to explore the changes attributable only to the two repeated sessions[4]. Each session comprised three consecutive trials. The first trial was regarded as a 'warm-up' and was not included in the calculations[16]. Anthropometric measurements and marker placement were performed by the same technician, and data were processed by the same physician (both had 8 years experience with the VCM marker placement and operation of the Vicon system).

2.3.3. *Gait analysis*

Anthropometric data including height, weight, leg length and joint width of the knee and ankle were collected. Fifteen passively reflective markers were placed on standard and specific anatomical landmarks: sacrum, bilateral anterior superior iliac spine, middle thigh, lateral knee (directly lateral to the axis of rotation), middle shank (the middle point between the knee marker and the lateral malleolous), lateral malleolous, and heel and forefoot between the second and third metatarsal head [20]. After patients had been instrumented with retroreflective markers, static trials were recorded. The patients were instructed to walk at a self-selected speed barefoot, looking forward in the plane of progression, during which time data capture was completed. Five infrared cameras with a sampling frequency of 60Hz recorded the 3D spatial location of each marker as the subject walked. The 3D gait data were collected with the Vicon 370 system[a] and processed by the Vicon Clinical Manager (version 3.2) software.

2.3.4. *Data Analysis*

Repeatability refers to the reliability (repeatability) of values of a measurement in repeated trials in the same subjects. Better repeatability means better precision of single measurements and better tracking of changes in measurements in both the clinical and research setting. The main measures of repeatability are within-subject random variation and retest correlation[21-25]. Within-subject random variation can be expressed as a coefficient of variation (CV) or standard error of measurement (SEM) [26]; both represent typical error in a measurement. The CV is particularly useful for representing the repeatability of performance tests. The variation represented by typical error may be due to the subject's biological status or to the equipment's technological noise. Because it is dimensionless and is not affected by the absolute values, CV is preferred in repeatability studies of gait analysis systems[21, 27]. In the present study, the CV, defined as the ratio of the standard deviation (SD) to the mean value, was calculated for each subject as a measure of within-session and between-session repeatability [4,21,28.] A measurement following an intervention should exceed this measurement error to indicate a real improvement or deterioration [26,29].

Retest correlation of time-distance parameters and selected peak and valley points of the paretic lower limb were assessed by the intraclass correlation coefficient (ICC) and the confidence interval (CI) of the ICC, using one-way analysis of variance[30]. The typical error (within-subject random variation) is a pure measure of variation within each subject, whereas the retest correlation provides information on the repeatability of the rank order of subjects on retest. A high correlation means the subjects will mostly keep their same places between tests, whereas a low correlation means they will all be mixed up. The ICC (which is a measure of correlation that considers variance) describes the agreement between the repeated measures. This approach is an appropriate statistical method to study agreement between sets of interval data for any sample size. The evaluation criteria and standards for ICC values are accepted as follows: values ≥ 0.75 represent excellent repeatability, 0.4-0.74 represents adequate repeatability, and values ≤ 0.40 represent poor repeatability[31]. We analyzed the data using SPSS[b] 11.5 for Windows. Significance was set at .05. Data are presented as means and SD, unless otherwise indicated.

2.4. Results

The characteristics of the subjects are presented in Table 1. The within- and between-session repeatability indexes (CV% and ICC) are presented in Tables 2 and 3. The within- and between-session repeatability index values of all assessed parameters were very close to each other Table 3.

Table 1: Characteristics of the study group

Variable		n=20
Age (years)		54.2±13.3
Sex (women/men)		7/13
Type of injury (ischemia/hemorrhage)		12/8
Paretic side (right/left)		11/9
Sensory (impaired/normal)		9/11
Time since stroke (months)		6.5±6.9
FIM motor items		55.1±14.7
Height (cm)		167.4±6.8
Weight (kg)		71.3±11.3
Brunnstrom stages	I-III	9
	IV-VI	11

Values are mean ± SD for age, time since stroke, functional independence measure (FIM) motor items, height and weight

2.4.1. Time-distance parameters

Among the assessed time-distance parameters, step length showed the highest variability whereas the most reliable parameter was walking velocity with an ICC of 0.99 and 0.98 (Table 3) and a CV% of 3.9 and 6.1 (Table 2) for within- and between-session assessments, respectively.

Table 2: Within- and between-session coefficient of variation (CV%) of paretic side time-distance parameters and sagittal plane kinematics of patients with stroke

Variable*	Within-session CV%	Between-session CV%
Walking velocity	3.9	6.1
Cadence	10.0	12.0
Step length	14.1	17.2
Single support time	13.5	16.1
Double support time	12.0	13.4
% of stance phase	9.6	11.4
Pelvic tilt peak	8.6	10.3
Pelvic tilt valley	15.3	18.4
Pelvic excursion	8.6	23.4
Hip initial contact	23.5	25.1
Hip extension	9.7	10.6
Hip flexion in swing	3.6	5.7
Hip excursion	5.2	10.0
Knee initial contact	29.6	32.4
Knee extension	17.1	19.3
Knee flexion in swing	16.8	18.9
Knee excursion	4.1	8.8
Ankle initial contact	25.7	26.3
Ankle dorsiflexion in stance	21.4	21.5
Ankle plantarflexion	24.8	27.1
Ankle dorsiflexion in swing	30.9	31.0
Ankle excursion	7.1	15.8

* On the paretic side

2.4.2. Lower limb kinematics

Knee angle at initial contact and peak ankle dorsiflexion at swing showed the highest variability with a between-session CV% of 32.4 and 31.0, respectively (Table 2). The lowest variability was found for peak hip flexion angle at swing (CV% 3.6 for within- and 5.7 for between-session analysis, Table 2). Retest correlation of all assessed gait parameters were high with an ICC of over 75. Total excursion values were more reliable than individual peak and valley points for pelvis, hip, knee and ankle joints.

Table 3: Within-session and between-session ICC and 95% CI of time distance and kinematic variables

Variable	**Within-session ICC_{T1-T2}**	**95% CI**	**Between-session ICC_{S1-S2}**	**95% CI**
Walking velocity	.99	.97-.99	.98	.97-.99
Cadence	.85	.68-.94	.84	.67-.93
Step length	.85	.68-.93	.82	.65-.92
Single support time	.84	.67-.93	.83	.66-.93
Double support time	.86	.68-.94	.83	.65-.94
% of stance phase	.84	.67-.93	.83	.66-.93
Pelvic tilt peak	.96	.92-.98	.98	.95-.99
Pelvic tilt valley	.93	.84-.97	.92	.82-.96
Pelvic excursion	.95	.90-.98	.89	.77-.95
Hip initial contact	.91	.80-.96	.93	.89-.96
Hip extension	.95	.89-.97	.96	.92-.99
Hip flexion in swing	.92	.82-.96	.98	.92-.99
Hip excursion	.97	.93-.98	.89	.75-.95
Knee initial contact	.97	.94-.98	.94	.86-.97
Knee extension	.96	.91-.98	.95	.91-.99
Knee flexion in swing	.94	.86-.97	.97	.88-.98
Knee excursion	.99	.98-.99	.91	.79-.95
Ankle initial contact	.95	.88-.97	.97	.93-.98
Ankle dorsiflexion in stance	.96	.92-.98	.98	.96-.99
Ankle plantarflexion in swing	.95	.90-.98	.97	.94-.99
Ankle excursion	.97	.92-.99	.94	.86-.97

ICC=intraclass correlation coefficient

2.5 Discussion

Measurements are not useful if clinicians are not completely confident in the results of those measurements[32]. The present study revealed good to excellent within- and between-session repeatability of time-distance parameters and 3D gait kinematics in patients with stroke. The repeatability of time-distance parameters in the present study was comparable to that reported previously for stroke[13-16;] i.e. high ICCs of 0.92-0.97 for within- and between-session repeatability of gait velocity in stroke patients were reported, indicating high consistency within the patients on repeated testing. Hill et al. examined the test-retest repeatability of the Clinical Stride Analyzer in 22 subjects with stroke. Although they reported high within-session repeatability coefficients (ICC>0.85) for time-distance parameters of stroke patients, they stated that the use of two consecutive measurements for interpreting an individual patient's change would not be a sensitive method for monitoring progress or deterioration during rehabilitation, because of wide 95% CIs. The CIs take into account the random and systematic error. Some of the strategies that they suggested to decrease error sources were to increase data collection per measurement, to use serial measurements on each patient, or to use less rigorous CIs[13]. In the present study, in spite of narrow and acceptable 95% CIs for walking velocity, the step length and single support time revealed wider 95% CIs than walking velocity, comparable to other studies[14-16].

In an earlier study, we reported between-session ICCs of walking velocity and step length in healthy subjects of 0.88 and 0.93, respectively[12]. In patients with stroke, the within- and between-session repeatability of time-distance parameters was very close to that of healthy subjects in our laboratory study. Westhoff et al. investigated the test-retest repeatability of 3D gait data of healthy subjects using the Vicon Motion Analysis system. They reported excellent test-retest repeatability in time-distance parameters and sagittal plane kinematics, and suggested that the tool was very valuable in both the analysis and the outcome evaluation of conservative and operative procedures in movement disorders[33]. Kadaba et al. investigated the repeatability of gait variables of healthy subjects including kinematic, kinetic, and electromyographic data waveforms and spatiotemporal parameters[7]. Forty healthy subjects were evaluated 3 times a day on 3 separate test days while walking at their preferred or normal walking speeds. The repeatability was excellent for kinematic data in the sagittal plane, both within a test day as well as between test days. In the frontal and transverse planes, joint angle motion yielded good repeatability within a test day but was poor between test days. They attributed the poor between-day repeatability of joint angle motion in the frontal and transverse planes partly to variation in the alignment of markers. However, they concluded that, in general, the results demonstrate that with the subjects walking at their normal speed the gait variables are quite repeatable, thereby suggesting that it may be reasonable to base significant clinical decisions on the results of a single gait evaluation[7].

Thorpe et al. reported poor to excellent repeatability (ICC 0.05-0.93; CV 2.2%-92.9%) of time-distance parameters in 57 healthy children using the GAITRite electronic walkway[27]. Steinwender et al. compared the within- and between-session repeatability of time-distance, kinematic and kinetic parameters of 20 normal and 20 diplegic children due to CP. They reported lower repeatability of gait analysis data in spastic children compared to normal children and attributed this result to marker placement errors and restricted joint range of motion due to spasticity in the group with CP. In their study, the within- and between-session CV% of walking velocity for children with CP was 6.6 to 9.7 which is higher than in the present study (3.9 to 6.1, Table 3) [21]. The higher variability of walking velocity in diplegic children than in adults with stroke might be due to bilateral involvement and/or young age.

Measurement error is a statistical term that covers variation from whatever source. It is important to realize that the variation in measurement may arise from the motion capture in the sense of technological error, or from the patient due to biological variation in gait. Several parameters may potentially affect the repeatability of quantitative gait measures. Pomeroy et al. investigated inter- and intra-rater reliability of raters using the GaitMat II to measure time-distance gait parameters of stroke patients; they reported that the GaitMat II may have acceptable inter-rater reliability if raters have experience of gait analysis, but disagreement may increase when stroke patients exhibit more abnormal gait patterns[34]. Schwartz et al. suggested that within-session repeatability measures the intrinsic repeatability of gait patterns, thereby serving as an important reference level to which the extrinsic sources of error can be compared[5]. For able-bodied subjects between-session variability has been attributed to anthropometric measurements, error in marker replacement, skin marker movement, estimation of joint centers, spatial resolution of the motion capture systems and inherent physiological variability during locomotion[5,7,35]. In the present study, within- and between-session variability were very close to each other suggesting that subject variability (intrinsic such as walking velocity, motor recovery or spasticity) was responsible for most of the errors. Low between-session variability (close to that of the within-session) may also be attributed to our well-trained technician who applied all the markers. Moreover, data processing was performed by the same experienced physician, all cameras were linearized, calibration was performed daily, and the camera positions and parameters were optimized regularly to allow for the least possible measurement error. It would be interesting for future studies to investigate whether the repeatability of gait parameters differs among groups of stroke patients with, for example, fast versus slow walkers, good versus bad motor recovery, etc.

In this study, we found total excursion values more reliable than individual peak and valley values at pelvis, hip, knee and ankle. Carlson et al[36] suggested using the total excursion of pelvis, hip, knee, and ankle in the data analysis rather than actual maximum and minimum values to minimize errors inherent in minor changes in marker placement between sessions. In therapeutic intervention trials, while comparing before- and after-gait data, it would be better to use total excursion values to minimize errors.

Results from the repeatability analysis can be used to define limits for the smallest change that may indicate relevant improvements, both for a group of patients and for individual patients. A measurement tool can be considered highly reliable, as indicated by the various statistical methods and indices, but may not be sufficiently sensitive to detect a real (clinical) improvement following, for example, an intervention. In the present study we reported an analysis of the CV% for each outcome variable to illustrate the size of change that is expected after an intervention, as compared to changes solely related to sampling error. For example, in our sample, a change between two measures of walking velocity of more than 6.1% could be considered a clinically meaningful change.

We conclude that, in our sample of stroke patients, the repeatability of time-distance parameters and sagittal plane kinematic gait measurements is good to excellent with small CIs. The smallest detectable change of assessed variables should be taken into consideration before clinical decision making and during intervention trials.

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Suppliers

a. Vicon; Oxford Metrics Ltd, 14 Minns Estate, West Way, Oxford, OX2 0JB, UK.

b. Version 11.5; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606, USA.

Chapter 3

The effects of balance training on gait late after stroke: a randomized controlled trial

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3.1 Abstract

Objective: To investigate the effects of balance training, using force platform biofeedback, on quantitative gait characteristics of hemiparetic patients late after stroke. **Design:** Randomized, controlled, assessor-blinded trial. **Setting:** Rehabilitation ward and gait laboratory of a university hospital. **Subjects:** Forty-one patients (mean (SD) age of 60.9 (11.7) years) with hemiparesis late after stroke (median time since stroke 6 months) were randomly assigned to an experimental or a control group. **Interventions:** The control group (n=19) participated in a conventional stroke inpatient rehabilitation program, whereas the experimental group (n=22) received 15 sessions of balance training (using force platform biofeedback) in addition to the conventional program. **Main Outcome Measures:** Selected paretic side time-distance, kinematic and kinetic gait parameters in sagittal, frontal and transverse planes were measured by using a three-dimensional computerized gait analysis system, one week before and after the experimental treatment program. **Results:** The control group did not show any statistically significant difference regarding gait characteristics. Pelvic excursion in frontal plane improved significantly (p=0.021) in the experimental group. The difference between before-after change scores of the groups was significant for pelvic excursion in frontal plane (p=0.039) and vertical ground reaction force (p= 0.030) in favour of experimental group. **Conclusion:** Balance training, using force platform biofeedback, in addition to a conventional inpatient stroke rehabilitation program is beneficial in improving postural control and weight bearing on the paretic side while walking late after stroke.

3.2 Introduction

Balance is a prerequisite for all functional activities and depends on the integrity of the central nervous system. Following stroke, some patients will never be able to stand, whereas those who achieve to stand have delayed and disrupted equilibrium reactions, exaggerated postural sway (in both sagittal and frontal planes)[1,2], and reduced weight bearing on the paretic limb[3,4] and increased risk of falling[5,6]. Various therapeutical approaches can be applied after stroke based on, for example, neurophysiologic, motor learning or orthopaedic principles. However, they do not specifically target on balance, and there is no evidence that any of these approaches is more effective than another in promoting the recovery of postural control[7].

Balance is an essential part of sitting, sit-to-stand and walking activities. Impaired balance and increased risk of falling toward the paretic side is found to be significantly correlated with locomotor function, functional abilities and length of stay in inpatient rehabilitation facilities[7-10]. Therefore, falls and injury prevention strategies are suggested as an integral part of each person's rehabilitation plan after stroke[6]. The relearning of postural control through external visual and auditory biofeedback is believed to be an effective therapy for improving balance control[1, 11,

[12]. It is thought that by giving patients additional visual information, they will become more aware of the body's displacements and orientation in space. In a Cochrane review, Barclay-Goddard et al[13] searched the results of seven randomized clinical trials and indicated that providing feedback from a force platform resulted in improved stance symmetry after stroke but did not improve balance during active functional activities, nor did it improve overall independence. In a recent review, van Peppen et al[14] reported that the additional value of visual feedback in bilateral standing compared with conventional therapy shows no statistically significant effects on symmetry of weight distribution between paretic and non-paretic limb while standing, postural sway in bilateral standing, balance and gait performance tests. On the other hand, Matjacic et al[15] presented the effectiveness of balance training by using kinesiological gait analysis on one patient with chronic hemiparesis. Other than this case report, all reviewed studies measured postural sway and weight-shifting ability while the patients were standing on the force plates (posturography), and used only gait velocity to assess gait performance. Posturographic data has been used both for therapeutic purposes enabling visual and auditory feedback to patients and as an outcome parameter to assess the effectiveness of the treatment. However, in controlled trials, if the control group will not receive balance training by posturography, experimental group takes the advantage of the experience with the system. The same system both for treatment and assessment should not be used in order to avoid this "learning effect". Quantitative gait analysis is effective for monitoring gait performance in stroke patients, as well as guiding therapy and documenting improvement[16-20]. The present study was designed to evaluate the effects of a task-oriented force platform biofeedback balance training on the gait pattern of hemiparetic patients with stroke using quantitative kinematic and kinetic gait analysis.

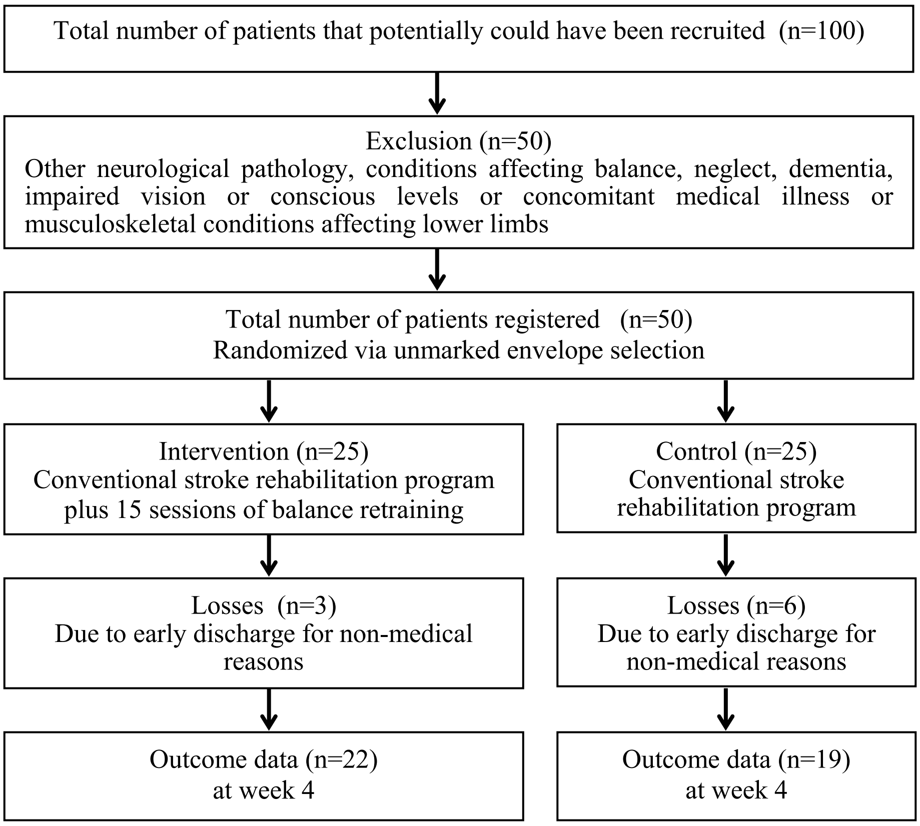
3.3 Methods

3.3.1 Participants

The trial included a sample of 41 (25 men, 16 women) inpatients with hemiparesis after stroke, with a mean (SD) age of 60.9 (11.7) years and a median time since stroke of 6 months. Stroke was defined as an acute event of cerebrovascular origin causing focal or global neurological dysfunction lasting >24 hours, and diagnosed by a neurologist and confirmed by computed tomography or magnetic resonance imaging. Patients recruited in this study were referred from all over Turkey for inpatient rehabilitation. Generally, in Turkey, an estimated 50% of the stroke population is referred to a rehabilitation centre if they cannot return home directly after dismissal from the hospital. Patients were required to meet the following criteria for inclusion in the study: 1) first episode of unilateral stroke with hemiparesis, in the territory of the internal carotid artery, 2) ability to understand

and follow simple verbal instructions, 3) ambulatory before stroke, 4) ability to stand with or without assistance and to take at least one or more steps with or without assistance, 5) no medical contraindication to walking. They were excluded if they had a history of any other neurological pathology, conditions affecting balance, neglect, dementia, impaired vision or conscious levels or concomitant medical illness or musculoskeletal conditions affecting lower limbs (Figure 1). The stage of motor recovery of the lower limbs was determined by Brunnstrom's Motor Recovery Stage (BMRS)[21]. The Functional Independence Measure (FIM) was used to assess activity limitation[22]. The reliability and validity of the Turkish version of the FIM has been previously well documented in our clinic[23]. The protocol was approved by the Ankara Physical Therapy and Rehabilitation Education and Research Hospital Ethics Committee in Ankara, Turkey, and all subjects provided written informed consent prior to data collection.

Figure 1: Flow diagram for randomized subject assignment in this study



3.3.2 Design

An assessor-blinded, randomized controlled design was used. The physician who performed the gait analysis was blinded to the use of the balance training program; however, neither the patients nor the physiotherapists who deliver the intervention were blinded, because it was impossible to do so. Patients were randomly assigned to one of the two groups after initial evaluation. We used the block randomization method in order to ensure an equal number of patients in each group. Blocks were numbered, and then a random-number generator program was used to select numbers that established the sequence in which blocks were allocated to one or the other group. A resident who was blinded to the research protocol and was not otherwise involved in the trial operated the random-number program. After randomization, 25 patients were assigned to the control group (conventional rehabilitation program) and the remaining 25 were assigned to the experimental group (conventional rehabilitation program plus balance training). Three patients from the experimental group and six patients from the control group dropped out of the study because they discharged themselves early from our rehabilitation clinic, due to non-medical problems. Hence, outcome data were obtained from the remaining 41 patients (Figure 1). The control group did not receive placebo intervention because it would not be logical to ask the patients to stand in front of a dark screen, doing nothing. None of the patients missed more than two scheduled therapies during the study.

3.3.3 Intervention

Subjects in both the experimental (n=22) and the control group (n=19) participated in our conventional stroke rehabilitation program, 5 days a week, 2-5 hours/day, for 8 weeks. The conventional program is patient-specific and consists of neurodevelopmental facilitation techniques, physiotherapy, occupational therapy, and speech therapy (if needed). Physiotherapy focused on positioning, range of motion and progressive resistive exercises, together with training in endurance, walking and activities of daily living. Postural control exercises include maintenance of standing and shift of the weight loads to the paretic side. Therapists combine elements of Brunnstrom’s movement therapy, Bobath neurodevelopmental treatment and proprioceptive neuromuscular facilitation techniques according to the patients’ needs and performance. This personalized rehabilitative care is designed to help the patient regain the ability to function as independently as possible at home, work, and in the community. It involves learning to perform the daily activities of living in order to achieve the best possible quality of life.

In addition to 8 weeks of conventional program, the experimental group received 15 minutes of balance training once daily, 5 days a week for 3 weeks[1,24,25], using the Nor-Am Target Balance Training System[a] in “standing stability” mode. The Nor-Am device is a portable balance trainer system including a dual forceplate composed of 4 load cells that detect pressure. Connected to a monitor, it provides visual representation of a person’s center of gravity. Menu-driven exercise tasks depict still or moving targets on the computer monitor. Subjects stood with one barefoot on each forceplate with their eyes open (according to the manufacturer’s instructions). Support devices or personal assistance were provided when needed. The subjects were instructed to maintain or shift their weight, in the sagittal and frontal plane as appropriate, to make the representation of their center of gravity reach the targets presented visually. In this study, because the Nor-Am device was used for intervention purposes only and not for assessment, data obtained from the balance trainer were not analyzed statistically.

3.3.4 Quantitative gait analysis

Three-dimensional positions of 15 reflective markers attached to the subjects were tracked using an optical motion measurement system VICON 370[b] as each subject walked at a self-selected speed. The Vicon Clinical Manager (VCM) (version 3.2) software was used to calculate joint angles as ordered rotations between anatomically aligned reference frames associated with adjacent body segments. Anthropometric data including height, weight, leg length and joint width of the knee and ankle were collected. Ground reaction forces (GRF) were measured using two Bertec[c] forceplates. The first trial was regarded as a ‘warm-up’ and familiarization trial to the laboratory and was not included in the calculations. The best data of three trials were used in the analysis. The trial, in which all the markers were clearly and automatically identified by the system, was designated as the best data. Reliability of our quantitative gait analysis data in healthy subjects[26] and stroke patients[27] has been shown.

Time-distance parameters

Walking velocity, cadence, step length and single support time of all participants were documented for the paretic and non-paretic sides. Asymmetry is a well-known feature of the hemiparetic gait and the restoration of gait symmetry is important in order to regain a physiological gait pattern[28]. To quantify the extent of the temporal and spatial asymmetry of gait pattern, the single-support time asymmetry ratio and the step length asymmetry ratio were calculated, respectively, as follows[29]:

The greater these ratios, the greater the asymmetry.

$$\text{Single - support time asymmetry ratio} = \left[\frac{\text{single - support time (affected)}}{\text{single - support time (unaffected)}} \right]$$

$$\text{Step length asymmetry ratio} = \left[\frac{\text{step length (affected)}}{\text{step length (unaffected)}} \right]$$

Kinematic and kinetic parameters

Pelvic excursions (the difference between peak and valleys of the curve in degrees) in sagittal, frontal and transverse planes were evaluated. Excursions of the paretic hip, knee and ankle were documented only in the sagittal plane. Peak extensor and abductor moments of the hip, peak extensor moment of the knee, and peak plantar flexor moment of the ankle at the paretic side during stance were documented. Peak vertical GRFs normalized by bodyweight for each participant were used to evaluate the weight bearing on the paretic side.

3.3.5 Data analysis

Data analysis was performed using SPSS for Windows version 11.5[d]. Mann-Whitney U test and chi-square test (χ^2) were used to compare demographic and baseline characteristics of the two groups. Comparisons between pre- and post-treatment gait data within each group were analyzed using Wilcoxon test. In order to investigate whether experimental group changed by more than the control group, we calculated change scores (subtracting the after score from the before score) for each group and compared them by using Mann-Whitney U test. We preferred non-parametric statistics because of the abnormal distribution of the data. Significance was set at 0.05.

3.4 Results

Demographic and clinical characteristics of the patients are presented in Table 1. The two groups were similar in terms of age, gender, time since stroke, type of injury, paretic side, lower extremity BMRS and FIM scores. Table 2 presents pre- and post-treatment data on the comparison of the groups in terms of baseline clinical and quantitative gait characteristics.

Table 1: Characteristics of the two study groups

Variable	Experimental (n=22)	Control (n=19)	p-value
Age (mean(SD) in years)	59.8(11.6)	62.1(12)	0.574
Sex (women/men)	10/12	6/13	0.281
Time since stroke (mean (SD) in months)	11.1(24.6)	5.5(3.5)	0.305
Time since stroke (median in months)	6	5	0.334
Type of injury (Ischemia/Hemorrhage)	15/7	16/3	0.472
Paretic side (Right/Left)	9/13	6/13	0.755
BMRS lower extremity	4.0(0.9)	4.2(1.0)	0.578
FIM ambulation	8.8(3.0)	9.4(3.2)	0.412
FIM total	81.4(16.0)	85.4(20.3)	0.638

NOTE: SD: standard deviation, the values are mean (SD) for age, time since stroke, Brunsstrom's Motor Recovery Stage (BMRS), Functional Independence Measure (FIM), number of persons for gender, type of injury and paretic side.

3.4.1 Time-distance and kinematic parameters

Baseline assessments revealed that in spite of randomization, patients in the control group had better pelvic mobility in the frontal plane than experimental group (p=0.007). Experimental group had significant improvement in pelvic excursions in the frontal plane (p=0.021) after treatment and the difference in change scores was significant (p=0.039) in favour of experimental group (Table 3). Neither group had significant changes in hip, knee and ankle excursions after treatment (Table 2).

3.4.2 Kinetic parameters

Neither group had a significant difference between pre- and post-treatment knee and ankle moments at the paretic side (Table 2). Peak hip extensor moment of the paretic side in stance improved significantly only in the experimental group (p=0.023), but the difference in change score was not significant. There was a statistically significant difference in change scores of vertical GRF first peak (N % bodyweight) (p=0.030) in favour of experimental group (Table 3).

Table 2: Outcome measures in the experimental group and the control group

Outcome measures	Pre-treatment		p-value§	Post-treatment	
	Experimental	Control		Experimental	Control
Walking velocity (m/sec)	0.36(0.2)	0.44(0.2)	0.146	0.44(0.2)	0.45(0.2)
Cadence (steps/min)	69.9(17.7)	77.3(16.1)	0.154	77.8(16.1)	75.8(18.7)
Step length (m)	0.30(0.10)	0.31(0.10)	0.990	0.34(0.12)	0.33(0.09)
Single-support time (sec)	0.40(0.09)	0.44(0.11)	0.307	0.41(0.08)	0.45(0.10)
Step length asymmetry ratio	0.64(0.45)	0.08(0.05)	0.097	0.44(0.27)	0.30(1.5)
Single-support time asymmetry ratio	0.28(0.16)	0.11(0.27)	0.058	0.24(0.20)	0.14(0.19)
Pelvic tilt (degrees)	7.7(4.4)	6.2(5.3)	0.155	6.8(3.7)	6.3(5.4)
Pelvic obliquity (degrees)	7.0(2.7)	4.7(2.2)	0.007	5.9(2.5)	5.0(3.0)
Pelvic rotation (degrees)	11.1(5.0)	9.7(3.6)	0.637	10.3(5.6)	8.7(4.5)
Hip† (degrees)	24.8(9.6)	25.4(9.1)	0.396	25.2(8.9)	26.4(9.1)
Knee † (degrees)	31.3(12.5)	34.3(13.0)	0.229	32.3(13.6)	35.1(11.8)
Ankle † (degrees)	21.5(14.5)	18.0(11.4)	0.512	18.9(11.0)	20.0(12.9)
Peak hip extensor moment	-0.13(0.3)	0.05(0.5)	0.465	0.06(0.2)	0.12(0.4)
Peak hip abductor moment	0.71(0.2)	0.85(0.3)	0.157	0.70(0.3)	0.80(0.3)
Peak knee extensor moment	0.26(0.3)	0.40(0.3)	0.081	0.30(0.2)	0.38(0.3)
Peak ankle plantar flexor moment	0.73(0.3)	0.97(0.4)	0.088	0.75(0.4)	0.92(0.4)
Vertical GRF 1st peak (N % bodyweight)	88.5(9.5)	92.5(8.3)	0.329	90.1(8.4)	90.3(6.1)

NOTE: Values are mean (SD), moments are in stance (Nm/kg), § P-value is for comparison of the groups in terms of pre-treatment values, † sagittal plane total excursion in degrees

3.5 Discussion

Hemiparetic gait is characterized by slow and asymmetric steps with delayed and disrupted equilibrium reactions and reduced weight bearing on the paretic limb[16,18,20]. Restoration of normal movements of the trunk, pelvis, and lower extremity, and improved weight bearing on the paretic side while walking are some of the most important goals of stroke rehabilitation[30]. This study reveals that a task-oriented balance training with force platform biofeedback in addition to a conventional stroke rehabilitation program provides more benefit than a conventional stroke rehabilitation program alone, in terms of pelvic excursions in the frontal plane and weight bearing on the paretic side, while walking.

Table 3: Comparison of the change scores after treatment in the experimental group and the control group

Outcome Measures	Experimental	Control	p-value
Walking velocity (m/sec)	0.08 (0.17)	0.01 (0.14)	0.283
Cadence (steps/min)	7.90 (15.3)	1.47 (10.1)	0.069
Step length (m)	0.03(0.09)	0.02(0.09)	0.804
Single-support time (sec)	0.01(0.07)	0.01(0.09)	0.536
Step length asymmetry ratio	0.19(1.9)	0.38(1.5)	0.347
Single-support time asymmetry ratio	0.04(0.12)	0.03(0.27)	0.503
Pelvic tilt (degrees)	0.91 (3.10)	0.17 (3.77)	0.527
Pelvic obliquity (degrees)	1.12 (2.06)	0.47 (2.15	0.039
Pelvic rotation (degrees)	0.71 (4.85)	0.68 (4.67)	0.861
Hip† (degrees)	0.50 (8.47)	0.35 (6.19)	0.968
Knee † (degrees)	1.02 (6.17)	0.15 (10.9)	0.286
Ankle † (degrees)	3.24 (11.0)	1.88 (14.5)	0.443
Peak hip extensor moment in stance (Nm/kg)	0.19 (0.29)	0.06 (0.54)	0.538
Peak hip abductor moment in stance (Nm/kg)	0.02 (0.26)	0.05 (0.34)	0.538
Peak knee extensor moment in stance (Nm/kg)	0.03 (0.21)	0.01 (0.29)	0.775
Peak ankle plantar flexor moment in stance (Nm/kg)	0.08 (0.24)	0.11 (0.41)	0.067
Vertical GRF 1st peak (N % bodyweight)	0.50 (3.93)	-3.57 (6.52)	0.030

NOTE: GRF: ground reaction force, BMRS: Brunsstrom's Motor Recovery Stage, N: newton
† sagittal plane total excursion in degrees

Walking velocity is a preferred outcome parameter for hemiparetic gait research as it is easy and reliable to measure[19]. Slow walking velocity has been attributed to a lack of selective motor control and poor balance[31]. However, rehabilitation programs do not mainly focus on increasing velocity because it may cause a more abnormal gait pattern and result in safety problems. In this study, after treatment, walking velocity improved in the experimental group but the difference was not significant. The majority of patients in both groups showed an asymmetrical gait pattern with less step time on the paretic side than on the non-paretic side. Spatio-temporal asymmetry is a characteristic of post-stroke gait and leads to increased energy expenditure and risk of falls[32,33]. Consequently, improvements in gait symmetry provide an important clinical marker of recovery[28,29]. Hesse et al[34] found no significant improvement in gait symmetry after an intensive four weeks inpatient rehabilitation program based on a neurodevelopmental technique. In agreement to their findings, neither group showed a significant improvement after treatment in terms of gait symmetry in our study.

It has been shown that patients with hemiparesis have asymmetric trunk movements with increased pelvic excursion in frontal plane[18,33,35]. Kinematic and kinetic studies of upper-body motion in the frontal plane have shown that the trunk is precisely controlled and highly dependent upon the motion of the pelvis[36-38]. Control of pelvic motion is critical to the maintenance of total body balance since the weight of the head, arms and trunk acts downward through the pelvis. Dynamic balance of the head, arms and trunk about the supporting hip is dependent upon the control of pelvic motion by the hip musculature (hip muscle moment) and the coupling between the pelvis and upper trunk. Haart et al[33] suggested that stroke patients suffer from severe postural instability and postural asymmetry during quiet standing in the frontal and sagittal planes; however, functional improvements during rehabilitation are most prominent in the frontal plane. Dault et al[39] suggested that sagittal plane imbalance in healthy elderly and stroke patients may be largely due to the effects of aging, whereas frontal plane imbalance is much more specific for the postural problems associated with stroke, they proposed that visual feedback may help stroke patients to better correct their frontal plane asymmetry and imbalance.The total pelvic excursions in sagittal and frontal planes while walking were investigated in this study and found that excessive pelvic excursion in the frontal plane decreased significantly in the experimental group with a significantly higher change score, indicating a better postural control. Bujanda et al[40] found a strong correlation between motor recovery of the lower extremity and frontal plane kinematics of the trunk after stroke. It has been shown that hip abductor and adductor muscles are highly responsible for balance control in the frontal plane by controlling equal weight-shifting between the paretic and non-paretic sides after stroke[41.] These findings support the idea that treatment techniques improving the motor function of the paretic lower limb, particularly those aiming to exercise the hip abductor/adductor muscles, would improve symmetry and balance and might consequently reduce the risk of falling after stroke.

Impaired balance in post-stroke patients is often related to uneven weight bearing[32,40]. Haart et al[3] reported that assessment of weight-shifting capacity provides unique information about balance recovery after stroke and can be used as an outcome parameter to develop new rehabilitation strategies. Eng et al[42] have shown that weight bearing ability can be reliably measured by forceplates in terms of vertical GRF and used as an outcome measure in stroke patients. In our trial, patients in the experimental group showed a better increase than control group in weight bearing ability on the paretic side after treatment.

There are limitations in this study. Precaution must be taken in generalizing the results, as our findings and conclusions are based on the population of subacute stroke inpatients, survived from first stroke, without severe cognitive deficits and with some ability to walk in the gait analysis laboratory. In spite of randomization, unfortunately, the control group revealed slightly better gait pattern than the experimental group. The difference between the groups in baseline pelvic excursion in the frontal plane was statistically significant. Better initial values of gait characteristics might have caused a ceiling effect in the control group. Another limitation is the lack of long-term follow up results. When patients are discharged it is not possible to evaluate them by computerized gait analysis, mainly due to socio-economic problems. Another limitation might be the lack of an untreated control group to rule out spontaneous recovery. However, because all subjects had been referred to our center for inpatient stroke rehabilitation, on ethical grounds we could not withhold therapy. Moreover, this is an RCT in which we can expect that both the experimental and control groups have a similar chance of spontaneous recovery. Control group did not receive a placebo therapy which may cause a bias as experimental group received more attention from the therapist even it was only 15 minutes extra.

It has been shown that hip abductor and adductor muscles are highly responsible for balance control in the frontal plane by controlling equal weight-shifting between the paretic and non-paretic sides after stroke[41]. Future studies may investigate the effects of balance training on muscle activation pattern of hip abductor muscles by dynamic electromyographic recordings while walking.

Clinical Message

Balance training, using force platform biofeedback, in addition to a conventional inpatient stroke rehabilitation program is beneficial in improving postural control and weight bearing on the paretic side while walking late after stroke.

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Chapter 4

Effect of an arm sling on gait pattern in patients with hemiplegia

Gunes Yavuzer, Süreyya Ergin.

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4.1. Abstract

Objective: To investigate the effect of an arm sling on gait patterns of patients with hemiplegia. **Design:** Crossover design of 3-dimensional gait analysis and concomitant video recordings performed during a single session. **Setting:** Rehabilitation ward gait laboratory of a university hospital. **Participants:** Thirty-one patients (20 men, 11 women) with hemiplegia with an average age of 53.1±9.7years and 31 age-, sex-, height-, and weight-matched able-bodied persons. **Interventions:** All patients with hemiplegia and able-bodied controls walked at self-selected speed over a 10-m walkway, either with or without an arm sling. **Main Outcome Measures:** Time-distance, kinematic, and kinetic parameters of gait. **Results:** The able-bodied group did not show any difference in gait parameters while using the sling. However, in patients with hemiplegia wearing a sling, walking speed and stance period of the paretic side increased, double support time of the paretic side decreased, excursion of the center of gravity (COG) decreased, and weight bearing of the paretic side increased. **Conclusions:** An arm sling improved gait, especially during gait training sessions of patients with hemiplegia who have impaired body image and excessive motion of the COG.

4.2. Introduction

Shoulder subluxation is a very common problem in patients with hemiplegia with stroke.[1] Because shoulder subluxation may be associated with pain, reflex sympathetic dystrophia, decrease in shoulder range of motion (ROM), and additional functional disability, preventive measures and appropriate treatment of shoulder subluxation are suggested as early and vigorously as possible.[2] Although the traditional treatment for shoulder subluxation in patients with hemiplegia is to use some type of arm sling, the efficacy and timing of its use is still controversial.[3,4] Arm slings have been shown to be effective in decreasing subluxation and pain for some patients after hemiplegia.[5] However, the positioning of the arm produced by a sling not only interferes with functional activities but also enhances the flexor synergy of the upper extremity.[4] Chantraine et al[3] advised against splinting the hemiplegic shoulder and recommended a search for new modalities like functional electric stimulation to provide treatment for the subluxed and painful shoulder joint. In our clinic, arm slings are applied to patients with hemiplegia during the flaccid period of the paretic upper extremity and removed when there is enough spasticity to position the shoulder or voluntary motor activity appears. Even during the flaccid period, patients are not encouraged to use the sling during their occupational therapy sessions. We observed that despite warnings by the rehabilitation team, some of our stroke patients insisted on wearing their sling, especially during walking in the ward. The reason for their preference was their “feeling more stable and secure.” The impact of slings on gait stability, safety, and efficiency in hemiplegia has not been evaluated. This study was designed to investigate the effect of an arm sling on gait patterns of patients with hemiplegia.

4.3. Methods

4.3.1 Participants

Subjects were 31 consecutive inpatients with hemiparesis caused by stroke (20 men, 11 women), with an average age of 53.1±9.7 years, and 31 able-bodied persons matched for age, sex, height, and weight. Able-bodied persons were picked from among the pool of our laboratory reference data. Inclusion criteria for hemiparetic patients were (1) first episode of cerebrovascular accident verified by computed tomography or magnetic resonance imaging, (2) ability to understand and follow commands, (3) ambulatory before stroke, (4) no medical contraindication to walking, and (5) ability to walk independently. All subjects provided written informed consent before data collection. Mean time since stroke ± standard deviation (SD) was 61.2±12.5 days (range, 24–75 days). Fifty-two percent had a right-side brain lesion. Twenty five patients had hemihypoesthesia (established by routine sensory examination), 12 had neglect, and 4 patients had a mild attention deficit (established by the Behavioral Inattention Test[6]). By using Brunnstrom stages of recovery for the upper extremity, 7 patients were classified as stage I, 18 patients as stage II, and 6 patients as stage III.[7] The matched controls did not have musculoskeletal or neurologic deficits. They exhibited normal ROM and muscle strength, and had no apparent gait abnormalities. All hemiparetic patients and able-bodied persons wore a single-strap sling during the gait trials. Single-strap slings are preferred because they are simple, inexpensive, easy to don, and sufficient to support the arm and glenohumeral joint.[8]

4.3.2 Study Design

All the patients and the controls walked on a walkway barefoot twice on the same day, randomly with and without arm sling, at a self-selected speed. Individuals assigned odd numbers walked without the arm sling first and vice versa for those given even numbers so that the randomization scheme balanced the number of individuals who received the sling first versus second. A crossover design was used because a blinded protocol is impractical if not impossible with this type of intervention.

4.3.3 Assessments

Fifteen passively reflective markers were placed on the following standard and specific anatomic landmarks: sacrum, bilateral anterior superior iliac spine, middle thigh, lateral knee (directly lateral to axis of rotation), middle shank (the middle point between the knee marker and the lateral malleolus), lateral malleolus, heel, and forefoot between the second and third metatarsal head.[9] After retroreflective markers were applied to the subjects, they were instructed to walk at a self selected speed over a 10-m walkway; data capture was completed at this time. The best data of 3 trials was used in analysis. The trial in which all the markers were clearly and automatically identified by the system was determined as best data.

Three-dimensional gait data were collected with the Vicon 370 system.[a] Concomitant videotape recordings of the subjects' gait were also performed. Five cameras recorded (at 60Hz) the 3-dimensional spatial location of each marker as the subject walked. All time distance (walking velocity, step time, step length, double-support time, percentage of stance phase), kinematic (joint rotation angles of pelvis, hip, knee, and ankle in sagittal, coronal, and transverse planes), and kinetic (ground reaction forces, moments and powers of hip, knee, and ankle) data were processed by using Vicon Clinical Manager software.[a] Kinetic data could only be collected for 8 patients with hemiplegia because the step length of the other patients was not enough to clear the forceplate for the second step. Calibration of the motion analysis system was performed daily. Anthropometric data including height, weight, leg length, and joint width of the knee and ankle were collected.

4.3.4 Data Analysis

Data analysis was performed by using SPSS for Windows, version 8.0.b Comparisons of hemiplegic and able-bodied groups in terms of age, gender, height, and weight were performed by using the Student *t* test. Time-distance parameters (walking velocity, step time, step length, double-support time, percentage of stance phase) and kinematic variables (excursion of pelvis, hip, knee, and ankle in sagittal, coronal, and transverse planes) of each group (hemiplegic patients, able-bodied persons) with and without arm sling were compared by using a *t* test for paired samples. Because kinetic data could only be collected for a sample of 8 patients, peak vertical force was compared using the Wilcoxon matched-pairs signed-rank test.

4.4. Results

Comparisons of hemiplegic and able-bodied groups in terms of age, gender, height and weight are presented in table 1. Time-distance parameters for both groups with and without the arm sling are shown in table 2. Excursion of the center of gravity

(COG) in the sagittal, coronal, and transverse planes; excursion of the hip, knee, and ankle in the sagittal plane; peak vertical force on the paretic side of persons with hemiplegia; and the same side for the matched able-bodied persons are shown in table 3. The control group did not show any difference in gait parameters between trials with and without an arm sling (p>.05). However, when walking with a sling, the patients with hemiplegia showed an increase in the velocity and the percentage of stance phase of the paretic side and a decrease in the double support time, which were statistically significant (p<.05). With the application of the arm sling, excursion of the COG was decreased in all planes (p<.05). The scaled vertical force values of the subgroup of 8 stroke patients increased on the paretic side with use of an arm sling (p<.001). Video recording of the patients with hemiplegia ambulating without the arm sling revealed a fall of the trunk toward the limb being lifted during swing. Fall of the trunk improved with the use of the arm sling.

Table 1: Comparisons of hemiplegic and able-bodied groups for age, gender, height and weight

	Hemiplegic	Able-bodied	P
Age (y)	53.1±9.7	54.0±8.4	.198
Gender (M/F)	20/11	20/11	1.00
Height (cm)	163.2±9.6	162.0±8.9	.112
Weight (kg)	74.5±11.2	75.2±9.4	.156

NOTE: Values are mean±SD for age, height, and weight and n for gender.
Abbreviations: M, male; F, female.

Table 2: Time-distance parameters of patients with hemiplegia and able-bodied persons with and without arm sling

	Hemiplegic patients			**Able-bodied persons**		
	Without arm sling	**With arm sling**	**p**	**Without arm sling**	**With arm sling**	**p**
Walking velocity (m/s)	.34±.13	.46±.14	.036	1.32±.30	1.32±.40	.988
% of stance phase (paretic side)	53.7±3.6	59.9±4.1	.011	31.2±2.3	61.0±2.4	.975
Step time (s)	1.5±.80	1.4±.60	.745	.56±.02	.55±.02	.890
Step length (m)	.31±.02	.32±.05	.798	.69±.03	.68±.03	.850
Double support time (s)	1.18±.09	.67±.02	.043	.22±.05	.22±.06	.964

Table 3: Excursion of COG, excursion of hip, knee, and ankle, peak vertical force with and without arm sling

	Hemiplegic patients		p	Able-bodied persons		p
	Without arm sling	**With arm sling**		**Without arm sling**	**With arm sling**	
Pelvic excursion in						
Sagittal plane	11.5±4.5	9.7±4.1	.017	1.5±0.3	1.5±0.3	.995
Coronal plane	9.9±3.5	9.0±2.9	.001	6.9±2.1	7.0±0.7	.895
Transverse plane	12.7±7.4	10.3±6.4	.011	10.8±1.2	10.5±0.8	.975
Hip excursion (deg)*	22.5±9.3	22.8±9.0	.975	44.3±4.6	44.0±4.4	.988
Knee excursion (deg)*	25.4±13.5	25.5±12.0	.950	64.1±11.2	64.0±10.5	.989
Ankle excursion (deg)*	13.5±9.5	13.7±5.5	.929	17.4±2.1	17.5±1.9	.968
Peak vertical force (N)(n=8) †	700±47	810±51	.001	920±50	919±48.9	.978

NOTE: Values are mean±SD.
* In sagittal plane
† On paretic side in patients with hemiplegia; same side for able-bodied persons.

4.5. Discussion

Despite some uncertainity about their efficacy and timing, arm slings are still the most preferred treatment modality for shoulder subluxation in stroke patients.[3] This study is the first (to our knowledge) to show the beneficial impact of an arm sling on the gait patterns of patients with hemiplegia. Hemiparetic gait is characterized by slow speed, a short stance phase, poorly coordinated movements, and decreased weight bearing on the weak leg.[9,10] Restoration of normal movements of the trunk, pelvis, and lower extremity while walking; increasing the walking speed; and improved weight bearing on the paretic side are the most important goals of gait training in stroke patients.[10,11] In this study, with the application of an arm sling, walking speed and the percentage of stance period increased, double support time of the paretic side and the excursion of COG decreased, and weight bearing of the paretic side increased. However, the able-bodied persons did not show any differences in gait parameters between trials with and without arm sling.

Trunk movements were investigated using video recordings of patients and controls while they walked with and without arm sling. Video recordings of the patients with hemiplegia walking without an arm sling revealed a fall of the trunk toward the limb being lifted during swing. Fall of the trunk improved with the use of arm slings. Lifting the opposite limb for a step removes the support for that side. Instability is avoided by a shift in the body vector toward the stance limb and strong contraction of the hip abductors to support the unstable pelvis. Patients with hemiplegia with an impaired body image are unaware of the location of their bodyweight line. Having no sense of instability, they fail to make any postural adaptations.[12] Arm slings may serve as a feedback mechanism and remind the patient of his/her arm, helping postural adaptations. Some of the patients studied had attention deficit and neglect toward the paretic side. An arm sling may help these patients pay more attention and position the paretic arm correctly.[4] Minimizing the displacement of the body's COG from the line of progression is a significant way to reduce the muscular effort of walking and, consequently, to save energy.[12] Through a mixture of 6 motion patterns, called determinants of gait, the magnitude of vertical and horizontal displacements is reduced. In addition, abrupt changes in direction are avoided, which is another energy-saving maneuver. Pelvic motion in 3 planes smooths the path of the body's vertical travel and saves energy.[12] It has been shown in previous studies that patients with hemiplegia display an excessive excursion of the COG, which indicates the inefficiency of their gait.[13] The total excursion of the COG in sagittal, coronal, and transvers planes was investigated in this study and found to be higher for patients with hemiplegia than for able-bodied persons while walking without a sling. A statistically significant decrease in the excursion of the COG was found in patients with hemiplegia when they used the arm sling, indicating a more efficient gait.

Carlson et al[14] suggested using the total excursion of pelvis, hip, knee, and ankle in the data analysis rather than actual maximum and minimum values to minimize errors inherent in minor changes in marker placement between sessions. Although all the data were collected on the same day in this study, in some of the individuals, markers had to be reset because they fell off; in those cases, the analysis for that particular condition (either with or without arm sling) was repeated. To minimize errors, total excursion values were used in comparisons. There was no difference in hip, knee, and ankle excursions between the 2 trials with and without the sling for either groups. Scaled vertical force values of all 8 stroke patients for whom these data could be collected revealed an increased weight bearing on the paretic side with the use of an arm sling. Because none of the 8 patients with hemiplegia had neglect or an attention deficit, some other mechanisms must be responsible for the improvement in their gait pattern.

Many physiotherapists are reluctant to use walking aids because of their detrimental effect on trunk and pelvis movements and on walking ability. Tyson[11] has investigated the trunk kinematics and the effect of walking aids in patients with hemiplegia and observed a large lateral trunk displacement orientated to the non-paretic side. The use of a walking aid and the type of walking aid (eg, cane, tripod) did not affect subjects' trunk movements or walking velocity. Just as physical therapists do not want their patients with hemiplegia to use walking aids, occupational therapists do not want them using arm slings during therapy sessions, especially during daily life because a sling interferes with functional activities and enhances the flexor synergy of the upper extremity.[4] However, wearing an arm sling on the paretic side seems to affect positively the stability and efficiency of walking. Many treatments are prescribed for improving hemiparetic gait, such as proprioceptive neuromuscular facilitation, functional electric stimulation, electromyographic biofeedback, nerve blocks, and isokinetic exercises.[15-22]

4.6. Conclusion

Among other interventions, an arm sling can be applied to improve gait, especially during gait training sessions of patients with hemiplegia who have impaired body image and excessive motion of the COG.

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Chapter 5

Neuromuscular electric stimulation effect on lower extremity motor recovery and gait kinematics of patients with stroke

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5.1. Abstract

Objective: To evaluate the effects of neuromuscular electrical stimulation (NMES) of the tibialis anterior (TA) muscle on motor recovery and gait kinematics of patients with stroke. **Design:** Randomized controlled assessor blinded study. **Setting:** Rehabilitation ward and gait laboratory of a university hospital. **Patients:** A total of 25 consecutive inpatients with stroke (mean age of 55 years), all within 6 months post-stroke and without volitional ankle dorsiflexion were studied. **Intervention:** Both the NMES group (n=12) and the control group (n=13) participated in a conventional stroke rehabilitation program (CSRP), 5 days a week for 4 weeks. The NMES group also received 10 minutes of NMES to the TA muscle of the paretic limb. **Main outcome measures:** Brunnstrom's stages of motor recovery and kinematic characteristics of gait. **Results:** Brunnstrom stages improved significantly in both groups ($p<0.05$). In total, 58% of the NMES group and 61% of the control group gained voluntary ankle dorsiflexion. Between-group difference of percent change was not significant ($p>0.05$). Gait kinematics was improved in both groups but the difference between the groups was not significant. **Conclusion:** NMES of the TA muscle combined with a conventional stroke rehabilitation program was not superior to conventional stroke rehabilitation program alone, in terms of lower-extremity motor recovery and gait kinematics.

5.2. Introduction

Despite undergoing rehabilitation, many people are left with a walking deficit after stroke [1]. Motor weakness, poor motor control, and spasticity result in an altered gait pattern, poor balance, risk of falls, and increased energy expenditure during walking [2-4]. Ineffective ankle dorsiflexion during swing (drop foot) and failure to achieve heel strike at initial contact are common problems that disturb gait pattern after stroke [5,6]. Voluntary ankle dorsiflexion in the lower extremity is a stand point indicating the achievement of selective motor control [7]. Once voluntary movement is achieved (Brunnstrom stages II or higher), synergistic patterns are then modified to selective (out-of-synergy) patterns. Many treatments are prescribed to increase gait efficiency of chronic stroke patients who cannot perform voluntary ankle dorsiflexion, such as 1- or 2-channel peroneal nerve stimulators [8-10], functional electrical stimulation (FES) [11-15], and solid ankle foot orthosis [16].

FES refers to the regular use of electrical stimulation in order to achieve overall functional improvement for the patient[13]. Studies of subjects late after stroke (>6 months) have shown that FES has a positive orthotic effect on walking ability[8,13-15]. Thompson and Stein[17] reported that increased activation of the tibialis anterior muscle during FES-aided walking increased afferent inputs to the central nervous system and thereby influenced plasticity in normal subjects. Khaslavskaia[18] et al. have shown that repetitive electrical stimulation of the common peroneal nerve leads to long-standing sensorimotor cortical reorganization in healthy subjects. It is possible that more benefit could be gained by provision of neuromuscular electric stimulation (NMES) early after stroke[19].

In this study, we hypothesized that repetitive dorsiflexion of the ankle by NMES may enhance selective motor control and improve gait kinematics during the first 6 months after stroke. Our purpose was to determine whether combining NMES with a conventional stroke rehabilitation program is more effective than a conventional program alone in facilitating recovery of selective motor control in the lower extremity, and in improving gait kinematics after stroke.

5.3. Methods

5.3.1 Participants

The study included 25 consecutive inpatients with hemiparesis resulting from stroke. Their mean age and time since stroke ± standard deviation (SD) was 55.3±8.2 years and 2.4±1.1 months, respectively. Stroke was defined as an acute event of cerebrovascular origin causing focal or global neurological dysfunction lasting >24 hours[20], as diagnosed by a neurologist and confirmed by computed tomography or magnetic resonance imaging. Patients were required to meet the following criteria for inclusion in the study: 1) first episode of unilateral stroke with hemiparesis during the previous 6 months, 2) a score between 1 and 3 inclusive on Brunnstrom's stages for the lower extremity, 3) ability to understand and follow simple verbal instructions, 4) ambulatory before stroke, 5) no medical contraindication to walking, or to electrical stimulation, 6) ability to stand with or without assistance and to take at least 1 or more steps with or without assistance. The protocol was approved by the Ankara University Ethics Committee.

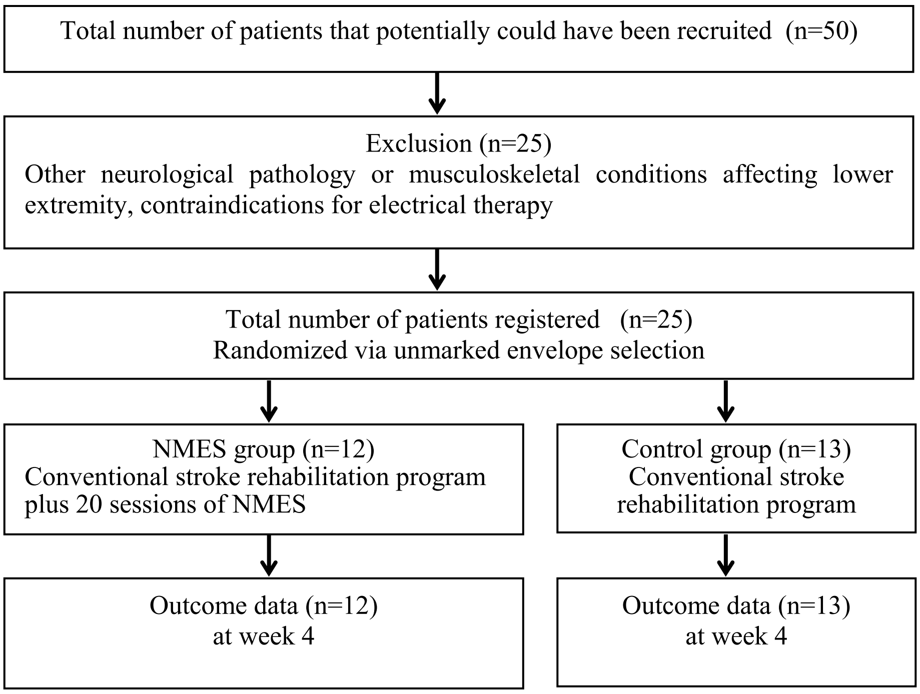
5.3.2 Sample size

The required sample size was determined by using the pooled estimate of within-group SDs obtained from pilot data. The minimal effect size for NMES in motor recovery has been reported as .54 for stroke patients [21]. Power calculations indicated that a sample of 25 subjects would provide an 80% (β=.20) chance of detecting a 20% (α=.05) difference in improvement between the groups.

5.3.3 Design

We used an assessor-blinded, randomized, controlled design in this study. The physician who performed the gait analysis was blinded to the use of NMES; however, neither the patients nor the physiotherapist who delivered the NMES were blinded, because it was impossible to do so given the obvious muscle contraction produced. Patients were randomized after initial evaluation by selecting a sealed, unmarked envelope containing a letter that informed them of their group allocation[22]. The blinded physician prepared the envelopes and the physiotherapist who delivered the NMES held them. After randomization, 13 patients were assigned to the control group (conventional rehabilitation program) and the remaining 12 were assigned to the NMES group (conventional rehabilitation program plus NMES). The control group did not receive sham stimulation (Figure 1).

Figure 1: Flow diagram for randomized subject assignment in this study



5.3.4 Intervention

All 25 subjects participated in a conventional stroke rehabilitation program, 5 days a week, 2 to 5 hours a day, for 4 weeks. The conventional program is patient-specific and consists of neurodevelopmental facilitation techniques, physiotherapy, occupational therapy, and speech therapy (if needed). The NMES group also received 10 minutes of NMES to the tibialis anterior muscle of the paretic limb once daily, 5 days a week for 4 weeks, [23]. Two sponge-type electrodes with rubber carriers were placed on the target muscle close to the insertion points (bipolar placement). Transcutaneous NMES was given with the Sonopuls 992,[a] and a surged alternating current was used at a frequency of 80Hz to stimulate muscle contraction. The stimulator on time of 10 seconds consisted of 2 seconds of ramp up, and 1 second of ramp down. The off time was 50 seconds. The amplitude was adjusted to produce muscle contraction without affecting the patient's comfort [23, 24]. We did not ask patients to volitionally contract their muscles during the NMES application because any volitional effort may stimulate flexor synergy and spastic co-contraction.

5.3.5 Outcome Measures

Lower Extremity Motor Recovery

We assessed lower-extremity motor recovery using Brunnstrom stages for the lower extremity [7]. The 6 stages of the Brunnstrom scale for the lower extremity are: (1) flaccidity, (2) synergy development (minimal voluntary movements), (3) voluntary synergistic movement (combined hip flexion, knee flexion, and ankle dorsiflexion, both sitting and standing), (4) some movements deviating from synergy (knee flexion > 90 degrees and ankle dorsiflexion with the heel on the floor in the sitting position), (5) independence from basic synergies (isolated knee flexion with the hip extended and isolated ankle dorsiflexion with the knee extended in the standing position), and (6) isolated joint movements (hip abduction in the standing position and knee rotation with inversion and eversion of the ankle in the sitting position. We used the Brunnstrom scale because it reflects underlying motor control based on clinical assessment of movement quality. Brunnstrom stages I through III indicate more synergistic and mass movements, whereas stages IV through VI indicate isolated and selective movements[25]. Patients were classified into two subgroups in terms of motor stage, that is, those with no selective motor control (Brunnstrom stage ≤ III) versus those with some (Brunnstrom stage ≥ IV) control.

Gait kinematics

Our outcome parameters were walking velocity, step length, percentage of stance phase at the paretic side, sagittal plane kinematics of pelvis, hip, knee and ankle, maximum ankle dorsiflexion angle at swing, and maximum ankle plantarflexion angle at initial contact. Three-dimensional gait data were collected with the Vicon 370 system[b] and processed by the Vicon Clinical Manager (version 3.2) software.[b] Anthropometric data collected included height, weight, leg length and joint width of the knee and ankle. Fifteen passively reflective markers were placed on standard and specific anatomical landmarks: sacrum, bilateral anterior superior iliac spine, middle thigh, lateral knee (directly lateral to axis of rotation), middle shank (the middle point between the knee marker and the lateral malleolous), lateral malleolous, heel and forefoot between the second and third metatarsal head [2]. After subjects were instrumented with retro-reflective markers, they were instructed to walk at a self-selected speed over a 10-meter walkway, during which data were captured. Five cameras recorded (at 60Hz) the 3-dimensional spatial location of each marker as the subject walked. We used the best data of three trials in our analysis. The trial, in which all the markers were clearly and automatically identified by the system was accepted as providing the best data.

5.3.6 Statistical analysis

We analyzed the data using SPSS [c] for Windows. The group means between the NMES and the control group were compared using non-parametric paired and unpaired t tests. We preferred non-parametric statistics because of the abnormal distribution of the data. The percentage change between pre- and post-treatment data for both groups was calculated as 100 x [pre-treatment minus post-treatment]/pre-treatment. We used the chi-square test to compare the groups in terms of the number of patients with Brunnstrom stages I through III or IV through VI. Significance was set at .05.

Table 1: Characteristics of the two study groups

Variable	NMES (n=12)	Control (n=13)	p-value
Age (years)	56.3±7.5	54.2 ±8.1	0.25
Gender (Women/Men)	5/7	4/8	0.69
Type of injury (Ischemia/Hemorrhage)	10/2	10/3	0.54
Paretic side (Right/Left)	5/7	7/6	0.69
Time since stroke (months)	2.4 ± 1.7	2.3 ± 1.3	0.17
Height (cm)	163.2 ± 9.6	162.0 ± 8.9	0.11
Weight (kg)	74.5 ± 11.2	75.2 ± 9.4	0.16
BMRS (II/III)	3/9	3/10	0.59
Modified Ashworth Scale score	3.2±2.1	3.3±2.2	0.31
FIM admission score	69.2±27.4	67.2±19.4	0.21
Walking velocity (m/sec) mean±SD	0.18±0.03	0.45±0.26	0.02
median	0.20	0.39	

Values are mean ± SD or as indicated

5.4. Results

Initial and final evaluations were made 1 to 3 days before and after the 4 weeks of the treatment period. None of the patients missed more than one scheduled session during the study, and all of them completed the study. Demographic and clinical characteristics of the groups are presented in table 1. Age, sex, height, weight, injury characteristics, time since stroke, baseline Modified Ashworth Scale score of ankle plantarflexor muscles, Brunnstrom stages in the lower extremity, FIM instrument scores, and walking velocity were all similar in both groups.

Table 2: Outcome measures in the NMES group and the control group

Outcome measures	Pre-treatment		Post-treatment	
	NMES	**Control**	**NMES**	**Control**
BMRS lower extremity	2.7±1.1	2.9±1.2	4.8±1.3	4.1±1.1
Walking velocity (m/sec)	0.18±0.03	0.45±0.26*	0.23±0.11	0.51±0.22
Step length (m)	0.24±0.11	0.29±0.12	0.28±0.12	0.35±0.11
% of stance phase (paretic side)	58.7 ± 3.5	59.1 ± 2.5	59.9 ± 4.7	58.6 ± 3.8
Pelvis (°)†	11.2±6.7	6.02±3.3	10.0±5.2	4.7±2.9
Hip (°)†	15.6±9.6	27.3±10.0*	16.3±7.8	28.0±9.8
Knee (°)†	21.2±11.2	35.7±14.9*	22.9±15.7	36.6±9.9
Ankle (°)†	14.4±13.7	16.3±4.6	16.5±5.9	20.9±16.3
Maximum ankle DF at swing (°)	-6.2±2.3	-5.9±2.4	-4.5±3.1	-5.1±1.2
Maximum ankle PF at initial contact (°)	-12.8±0.9	-13.0±1.4	-11.2±4.5	-12.4±5.1

Values are mean ± SD.
Abbreviations: DF, dorsiflexion; PF, plantarflexion.
BMRS: Brunsstrom's Motor Recovery Stage
* p<.05

†sagittal plane total excursion in degrees

5.4.1 Lower Extremity Motor Recovery

Brunnstrom stages improved significantly in both groups ($p<0.05$) after the treatment. The difference between groups in terms of the percentage change, however, was not significant (table 2). In total, 7 patients (58%) in the NMES group and 8 (61%) in the control group gained voluntary ankle dorsiflexion. The between-group difference of percent change was not significant ($p>0.05$) (table 3).

Table 3: Percentage change after treatment in the NMES group and the control group

Outcome Measures	NMES Group (n=12)	Control Group (n=13)	p-value
ΔBMRS lower extremity	48*	41*	.25
BMRS from (I-III) to (IV-VI)	58	61	.51
ΔWalking velocity (m/sec)	16	15	.89
ΔStep length (m)	17	19	.34
Δ% of stance phase (paretic side)	2	1	.56
ΔPelvis (°)†	11	14	.86
ΔHip (°)†	4	3	.75
ΔKnee (°)†	8	3	.42
ΔAnkle (°)†	15	18	.45
ΔMaximum ankle DF at swing (°)	17	14	.62
ΔMaximum ankle PF at initial contact (°)	13	11	.71

Abbreviation: Δ, percentage change between pre- and post-treatment.
* $p<.05$

† Sagittal plane total excursion.

5.4.2 Gait kinematics

The 2 groups' mean values±SD of assessed parameters at pre- and posttreatment are presented in table 2. There was no significant difference between the groups in terms of all initial clinical characteristics except for walking velocity. Pre-treatment mean walking velocity values of the NMES group were significantly lower than those in the control group (p=.02). Time-distance and sagittal plane gait kinematics were improved in both groups, but the difference between pre- and post-treatment data for each group, and the percentage of change between the groups, was not significant (table 3).

5.5. Discussion

This study revealed that in our group of stroke patients, NMES of the tibialis anterior muscle combined with a conventional rehabilitation program does not provide additional benefit in terms of lower extremity motor recovery and gait kinematics.

Lower Extremity Motor Recovery

The primary outcome parameter of this study was achievement of voluntary ankle dorsiflexion at the paretic side, representing selective motor control. Ankle dorsiflexion is an important kinematic aspect of the swing and initial stance phase of the gait cycle. Ankle movement training facilitates brain reorganization, and the angle paradigm may serve as an ongoing physiological assay of the optimal type, duration, and intensity of rehabilitative gait training[26]. Dobkin et al[27] demonstrated that the supraspinal sensorimotor network for the neural control of walking can be assessed indirectly by ankle dorsiflexion.

Because none of our patients had voluntary ankle dorsiflexion at baseline evaluation, we did not ask them to actively participate in electrical stimulation in order not to stimulate flexor synergy of the lower extremity. Because repeated, task-specific exercise protocols induce brain reorganization[28-31], we hypothesized that repetitive dorsiflexion of the ankle by NMES may induce use-dependent brain reorganizations responsible for selective motor control of the ankle. It has been reported, however, that active, repetitive or triggered movement trainings that require skill acquisition[32,33] facilitate the motor recovery of stroke survivors[17,34-37]. Because our patients were cognitively inactive during the NMES therapy, electrically evoked ankle movements in dorsiflexion did not create any cognitive effort or investment. Khaslavskaia et al[18] used a similar repetitive electrical stimulation of the common peroneal nerve and observed a significant increase in motor cortical excitability which was more pronounced when agonistic voluntary exercise was coupled with electrical stimulation.

In a similar study, Yan et al[38] reported that 15 sessions of simple FES, given 30 minutes per session along with standard rehabilitation 5 days per week, improved motor recovery and functional mobility in acute stroke subjects, more than did placebo stimulation and standard rehabilitation, or standard rehabilitation only. In that study, Yan applied simple FES using surface electrodes on quadriceps, hamstring, tibialis anterior, and medial gastrocnemius muscles mimicking normal gait, while the affected lower extremity was supported in a sling. They measured isometric voluntary contraction of ankle dorsiflexor and plantarflexor muscles by joint torque and surface electromyography, and found that percentage increases in maximum isometric voluntary contraction torque and integrated electromyographic signals of the FES group were significantly larger than those of the control group. Although purpose of our study was similar to that of Yan (ie, to enhance neuroplasticity and remind patients how to perform the movement properly during electrical stimulation), the two studies differ both in patient characteristics and in treatment intervention and outcome parameters. Yan found a significantly larger percentage of voluntary ankle dorsiflexion in the FES group at the end of the first week. In that study, electrical stimulation (with 0.3ms pulses at 30Hz) was applied, starting at 8.7±5.8 days after stroke, to quadriceps, hamstring, tibialis anterior, and medial gastrocnemius muscles, for 15 sessions of 60 minutes each. In our study, we applied electrical stimulation (with 0.1ms pulses at 80Hz) only to the tibialis anterior muscle, for 20 sessions of 10 minutes each about 2.4 months after stroke as suggested elsewhere[23, 24]. There are no uniform guidelines that specify a certain number of NMES sessions or the duration of daily stimulation times. Although duration, intensity and selected mode of the electrical stimulation were not found to be associated with stroke outcome[13], the timing of the intervention is important. Natural recovery of walking function occurs within the first 11 weeks after stroke, and early and intensive treatment significantly improves motor and functional outcome[39]. Although most of the overall improvement in motor functions occurs within the first month after stroke, modulation of motor networks may still be possible in some patients up to 6 months later. The reliability of outcome studies of specific treatments during the early post-stroke rehabilitation is, however, limited by the variables of spontaneous recovery[34]. Thus, we included patients during the 2 to 6 months after stroke in order to prevent the variability of spontaneous recovery.

Gait kinematics

Both of our groups achieved an improvement in gait characteristics of the paretic side; however the between-group difference was not significant. Walking velocity is the most suitable temporal stride variable for measuring gait performance[40,41]. Burridge et al[5] reported that a 10% improvement in walking velocity was considered to be functionally relevant. In our study, although walking velocity increased both in the NMES (16%) and the control group (15%), the difference between pre- and post-treatment data was not significant, which may have been because of our small sample size. Unfortunately, there was a significant difference between the groups in baseline walking velocity. It is well known that lower extremity motor recovery[25] and functional status[42] are the main determinants of walking velocity. One may expect this difference to cause bias in the investigation; however, walking velocity is positively correlated with motor stages of the proximal lower extremity, but not with the motor stages of the ankle and foot[25].

We did not use placebo (sham) stimulation together with the conventional stroke rehabilitation program in the control group. This was mainly because of the short period of the stimulation (10 minutes), which was unlikely to cause a bias between the groups in terms of treatment intensity. Moreover, it has been reported that even the placement of electrodes on the skin is likely to stimulate mechanosensitive nerve fibers[43]. Thus, it has been suggested that in designing trials after stroke, a control group with no intervention except conventional rehabilitation could provide better information[44].

In conclusion, NMES of the tibialis anterior muscle combined with a conventional rehabilitation program was not superior to the conventional rehabilitation program alone, in terms of selective motor control and gait kinematics of our group of patients with stroke.

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Suppliers

[a] Enraf-Nonius B.V., Röntgenweg 1, P.O. Box 810, 2600 AV Delft, The Netherlands

[b] VICON, Oxford Metrics Limited, 14 Minns Estate, West Way, Oxford, OX2 OJB, UK.

[c] Statistical Package for the Social Sciences (SPSS) for Windows, Version 9.0; SPSS Inc., 444 N. Michigan Avenue, Chicago, IL. USA

Chapter 6

Effect of sensory-threshold electric nerve stimulation on motor recovery and gait kinematics after stroke: a randomized controlled study

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Submitted for publication

6.1 Abstract

Objective: To evaluate the effects of sensory-threshold electrical nerve stimulation (SES) of the paretic leg on motor recovery and gait kinematics of patients with stroke. **Design:** Randomized controlled double-blinded study. **Setting:** Rehabilitation ward and gait laboratory of a university hospital. **Patients:** A total of 30 consecutive inpatients with stroke (mean age of 63.2 years), all within 6 months post-stroke and without volitional ankle dorsiflexion were studied. **Intervention:** Both the SES group (n=15) and the placebo group (n=15) participated in a conventional stroke rehabilitation program, 5 days a week for 4 weeks. The SES group also received 30 minutes of SES to the paretic leg without muscle contraction, 5 days a week for 4 weeks. **Main outcome measures:** Brunnstrom stages of motor recovery and time-distance and kinematic characteristics of gait. **Results:** Brunnstrom stages improved significantly in both groups ($p<0.05$). In total, 58% of the SES group and 56% of the placebo group gained voluntary ankle dorsiflexion. Between-group difference of percentage change was not significant ($p>0.05$). Gait kinematics was improved in both groups but the between-group difference was not significant. **Conclusion:** In our patients with stroke, SES of the paretic leg was not superior to placebo, in terms of lower extremity motor recovery and gait kinematics.

6.2 Introduction

Sensory input can modulate reorganization of the motor cortex [1-3], which may be beneficial in therapeutic interventions to improve motor function in stroke rehabilitation[4]. Increased inflow of signals from sensory modalities could enhance plasticity of the brain and may partly explain beneficial effects of this treatment[5]. Afferent stimulation can be achieved in various ways [6-12]. Golaszewski et al. studied the effect of cutaneous stimulation of the hand in 6 healthy subjects in the immediate post-stimulation period during simple motor tasks with magnetic resonance imaging; they reported that the afferent stimulation, delivered below the sensory threshold, was associated with increased signals in the primary and secondary motor and somatosensory areas, including the supplementary motor area[13].

Peripheral electrical nerve stimulation enhances corticomotoneural excitability by activating group Ia large muscle afferents, group Ib afferents from Golgi organs, group II afferents from slow and rapidly adapting skin afferents, as well as cutaneous afferent fibers[1, 3, 14]. Long-term reorganization of the motor cortex has been reported for repetitive electrical stimulation of peripheral nerves of swallowing[1] and hand[3] muscles. Median nerve stimulation has been used for neuro-resuscitation of coma patients[15]. Khaslavskaia et al. showed in healthy subjects that reorganization can be elicited for lower limb muscles via repetitive stimulation of common peroneal nerve[14]. They concluded that changes in neural excitability related to lower limb muscle can be increased by using afferent input. In a case study, Sullivan and Hedman described a home program combining sensory amplitude electrical stimulation and neuromuscular electrical stimulation to the paretic arm, which increased upper extremity function even 5 years after a stroke[16]. Peurala et al. investigated the effects of cutaneous electrical stimulation of the paretic limb using glove or sock electrodes in patients with chronic stroke[12]. They reported that sub-threshold sensory stimulation may improve limb function late after stroke. Conforto et al. reported an improvement of pinch muscle strength during a 2 hour period of median nerve stimulation; they suggested that somatosensory stimulation may be a promising adjuvant to rehabilitation of the motor deficits in stroke patients[11]. These studies suggest that ascending sensory information can have an influence on cortical motor circuits and their descending pathways.

In a recent meta-analysis of Robbins et al. reported that there was insufficient research to make conclusions regarding the effectiveness of sensory-threshold electric stimulation on improvement in walking after stroke and suggested further controlled studies[17]. In this study, we hypothesized that sensory-threshold electrical nerve stimulation (SES) of the paretic leg may enhance selective motor control and improve gait kinematics during the first 6 months after stroke. The aim was to investigate whether SES combined with a conventional stroke rehabilitation program is more effective than the conventional program and sham-SES in facilitating recovery of selective motor control in the lower extremity, and in improving gait kinematics after stroke.

6.3 Methods

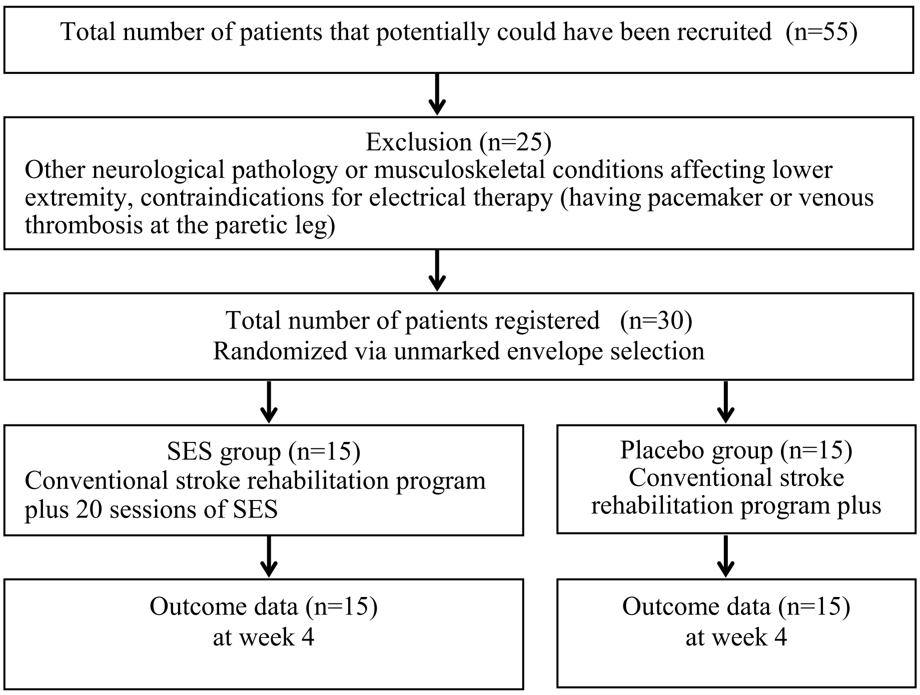
6.3.1 Participants

The trial included 30 consecutive inpatients with hemiparesis after stroke who met the study criteria. Patients were required to meet the following criteria for inclusion in the study: 1) first episode of unilateral stroke with hemiparesis during the previous 6 months, 2) a score between 1 and 3 inclusive on Brunnstrom stages of the lower extremity, 3) ability to understand and follow simple verbal instructions, 4) ambulatory before stroke, 5) no medical contraindication to walking, or to electrical stimulation (having pacemaker or venous thrombosis at the paretic leg), 6) ability to stand with or without assistance and to take at least one or more steps with or without assistance. The mean±SD age was 63.2±9.7 years and mean time since stroke was 3.4±2.1 months. Stroke was defined as an acute event of cerebrovascular origin causing focal or global neurological dysfunction lasting >24 hours, and diagnosed by a neurologist and confirmed by computed tomography or magnetic resonance imaging. The protocol was approved by the Ankara University Ethics Committee.

6.3.2 Design

A double-blind, randomized controlled design was used. The patients and the physician (GY) who performed the outcome measures were blinded to the use of SES, but not the therapist who delivered the electric stimulation. Patients were randomly assigned to one of the two groups after initial evaluation. We used the block randomization method in order to ensure an equal number of patients in each group. Blocks were numbered, and then a random-number generator program was used to select numbers that established the sequence in which blocks were allocated to one or the other group. A medical resident who was blinded to the research protocol and was not otherwise involved in the trial operated the random-number program. After randomization, 15 patients were assigned to the placebo group (conventional rehabilitation program plus sham-SES) and the remaining 15 were assigned to the SES group (conventional rehabilitation program plus SES) (Figure 1).

Figure 1: Flow diagram for randomized subject assignment in this study



6.3.3 Intervention

All subjects participated in a conventional stroke rehabilitation program delivered by multiple therapists, 5 days a week, 2-5 hours/day, for 4 weeks. The conventional program is patient-specific and consists of neurodevelopmental facilitation techniques, physiotherapy, occupational therapy, and speech therapy (if needed). The SES group also received 30 minutes of SES once daily, 5 days a week, for 4 weeks, to the common peroneal nerve of the paretic leg. Two 6x8mm "sponge" type electrodes with rubber carriers were placed on the anatomical localization of the common peroneal nerve (just below the capitulum fibulae of the lower leg) and on the belly of the tibialis anterior muscle, while the patients were in supine position[18]. The Sonopuls 992, ENRAF NONIUS[a] was used to deliver the asymmetric biphasic rectangular stimulation at a frequency of 35Hz with a pulse width of 240□s. The stimulation amplitude was adjusted at each session to the point where the patient perceived a mild tingling sensation (roughly 10mA), but below an observable or palpable muscle contraction. A duty cycle of 10 seconds on and 10 seconds off was used to minimize sensory habituation[16]. The same set-up was used for the placebo group without any stimulation. The machine was turned on so that there was a light to indicate that it was in operation. Patients in the placebo group were not told that they would feel the stimulation. Same therapist delivered the SES or sham-stimulation.

6.3.4 Outcome Measures

Outcome measures were performed by the same investigator (GY) 1-3 days before and after the 4 weeks of the treatment period in the rehabilitation ward.

Lower Extremity Motor Recovery

Lower extremity motor recovery was assessed using the Brunnstrom stages for the lower extremity[19]. The six grades of the Brunnstrom stages for the lower extremity are: (1) flaccity, (2) synergy development (minimal voluntary movements), (3) voluntary synergistic movement (combined hip flexion, knee flexion, and ankle dorsiflexion, both sitting and standing), (4) some movements deviating from synergy (knee flexion exceeding 90 degrees and ankle dorsiflexion with the heel on the floor in the sitting position), (5) independence from basic synergies (isolated knee flexion with the hip extended and isolated ankle dorsiflexion with the knee extended in the standing position), and (6) isolated joint movements (hip abduction in the standing position and knee rotation with inversion and eversion of the ankle in the sitting position. The Brunnstrom stages were chosen because it reflects underlying motor control based on clinical assessment of movement quality. In the lower extremity, voluntary ankle dorsiflexion is a stand point indicating the achievement of selective motor control [19]. Once voluntary movement is achieved, synergistic patterns are then modified to selective (out-of-synergy) patterns. Brunnstrom stages I-III indicates more synergistic and mass movements, whereas stages IV-VI indicate isolated and selective movements. Patients were classified into two subgroups in terms of motor stage, i.e. those with none (Brunnstrom stages ≤ III) versus those with some (Brunnstrom stages ≥ IV) selective motor control[20].

Gait kinematics

Walking velocity, step length, percentage of stance phase at the paretic side, sagittal plane kinematics of pelvis, hip, knee and ankle, maximum ankle dorsiflexion angle at swing, and maximum ankle plantarflexion angle at initial contact were selected as outcome parameters. Three-dimensional gait data were collected with the Vicon 370 system[b] and processed by the Vicon Clinical Manager (version 3.2) software. Anthropometric data including height, weight, leg length and joint width of the knee and ankle were collected. Fifteen passively reflective markers were placed on standard and specific anatomical landmarks: sacrum, bilateral anterior superior iliac spine, middle thigh, lateral knee (directly lateral to axis of rotation), middle shank (the middle point between the knee marker and the lateral malleolous), lateral malleolous, heel, and forefoot between the second and third metatarsal head[21]. The subjects were instructed to walk at a self-selected speed over a 10-meter walkway during which data capture was completed. Five cameras recorded (at 60Hz) the three-dimensional spatial location of each marker as the subject walked. The best data of three trials were used in analysis. The trial in which all the markers were clearly and automatically identified by the system, was determined as providing the best data.

6.3.5 Statistical analysis

Data were analyzed using SPSS for Windows version 9.0[c]. The percentage change between pre- and post-treatment data for both groups was calculated as 100 x [pre-treatment minus post-treatment]/pre-treatment. The group means and percentage changes were compared between the SES and the placebo group using non-parametric paired and unpaired t tests. The Chi-square test was used to compare the groups in terms of the number of patients with Brunnstrom stages for lower extremity I-III or IV-VI. We preferred non-parametric statistics because of the abnormal distribution of the data. Significance was set at 0.05.

Table 1: Characteristics of the two study groups

Variable	SES (n=15)	Placebo (n=15)	p-value
Age (years)	61.9±10.01	64.4 ±9.8	.51
Sex (women/men)	8/7	6/9	.20
Type of injury (ischemia/hemorrhage)	12/3	10/5	.86
Paretic side (right/left)	8/7	9/6	.67
Time since stroke (months)	3.5 ± 2.1	3.4 ± 2.3	.18
Height (cm)	161.5 ± 11.7	163.0 ± 9.9	.13
Weight (kg)	81.5 ± 9.7	79.2 ± 11.4	.24
Brunnstrom stages (II/III)	3/12	2/13	.17
FIM admission score	72.3±18.3	73.4±16.6	.75
Walking velocity (m/sec)	0.31±0.18	0.36±0.22	.85

NOTE: Values are mean ± SD or n

Table 2: Outcome measures in the SES group and the placebo group

Outcome measures	Pre-treatment		Post-treatment	
	SES	Placebo	SES	Placebo
Brunnstrom stages of lower extremity	3.2±1.6	3.3±1.2	4.1±1.4*	3.5±0.9*
Walking velocity (m/s)	0.31±0.18	0.36±0.22	0.34±0.11	0.37±0.20
Step length (m)	0.29±0.11	0.28±0.16	0.32±0.12	0.30±0.12
% of stance phase (paretic side)	59.1 ± 3.5	58.0 ± 5.5	58.7 ± 4.7	58.9±5.7
Pelvis (°)†	13.2±5.7	12.2±3.3	10.3±6.2	11.0±3.1
Hip (°)†	16.6±8.6	17.3±10.0	16.9±7.8	17.7±7.9
Knee (°)†	25.4±10.2	27.7±14.9	27.9±11.7	28.1±9.8
Ankle (°)†	17.1±12.7	16.1±3.8	18.5±4.9	16.6±9.9
Maximum ankle DF at swing (°)	-5.9±2.3	-5.8±2.6	-4.6±4.1	-4.3±1.5
Maximum ankle PF at initial contact (°)	-1.8±0.9	-3.0±1.5	1.2±7.5	-2.1±1.2

NOTE: Values are mean ± SD
Abbreviations: DF, dorsiflexion; PF, plantarflexion
*p<.05.

†Sagittal plane total excursion.

6.4 Results

Initial and final evaluations were made 1-3 days before and after the 4 weeks of the treatment period. None of the patients missed more than one scheduled session during the study, and all of them finished the study. Demographic and clinical characteristics of the two groups are given in Table 1. Age, gender, height, weight, injury characteristics, time since stroke, baseline Modified Ashworth Score of ankle plantarflexor muscles, Brunnstrom stages in the lower extremity, Functional Independence Measure scores and walking velocity were not statistically different between the groups.

Table 3: Percentage change after treatment in the SES group and the placebo group

Outcome Measures	SES Group (n=15) (%)	Placebo Group (n=15) (%)	p-value
Δ Brunnstrom stages of lower extremity	46	44	.31
Brunnstrom stages from (I-III) to (IV-VI)	60	53	.09
ΔWalking velocity (m/sec)	13	13	.97
ΔStep length (m)	18	19	.34
Δ% of stance phase (paretic side)	2	1	.60
ΔPelvis (°)*	12	14	.89
ΔHip (°)*	4	3	.75
ΔKnee (°)*	7	3	.44
ΔAnkle (°)*	16	19	.47
ΔMaximum ankle DF at swing (°)*	22	25	.44
ΔMaximum ankle PF at initial contact (°)*	14	12	.70

Abbreviation: Δ, percentage change between pre- and post-treatment.

* sagittal plane total excursion.

6.4.1 Lower Extremity Motor Recovery

There was a statistically significant improvement in pre- to post-treatment mean Brunnstrom scores in both groups ($p<0.05$). However, the difference between the two groups in terms of the percentage change was not significant (Table 2). In total 60% (n=9) of the patients in the SES group and 53% (n=8) of the patients in the placebo group improved from Brunnstrom stages (I-III) to Brunnstrom stages (IV-VI). The between-group difference of the percentage change was not significant ($p>0.05$) (Table 3).

6.4.2 Gait kinematics

The mean±SD values of assessed parameters of the groups at pre- and post-treatment are given in Table 2. There was no significant difference between the groups in any of the initial clinical characteristics. Time-distance and sagittal plane gait kinematics were improved in both groups. However, neither the difference between pre- and post-treatment data for each group nor the percentage of change between the groups was not significant (Table 3).

6.5 Discussion

This study reveals that SES of the paretic leg in addition to a conventional rehabilitation program does not provide additional benefit in terms of lower extremity motor recovery and gait kinematics in our group of patients with stroke. The primary goal of this study was achievement of voluntary motor control in the lower extremity and consequently improve gait pattern after stroke. Dobkin et al. demonstrated that assessment of ankle dorsiflexion gives information about neural control of walking[22]. We followed the isolated ankle dorsiflexion of the patients by both clinical examination (Brunnstrom stages) and using quantitative gait analysis. Clinically, more than 50% of our patients in both groups gained selective ankle dorsiflexion with similar percentage changes. However, changes in gait kinematics were not significant in any of the groups. Walking velocity is the most suitable temporal stride variable for measuring gait performance[16]. Burridge et al. reported that a 10% improvement in walking velocity was considered to be functionally relevant[23]. In the present study, although walking velocity increased both in the SES (13%) and in the placebo group (13%), the difference between pre- and post-treatment data was not significant.

In spite of encouraging results of afferent stimulation of hand after stroke in terms of voluntry motor control[11,12,16,24], there is no evidence yet for lower extremity[17]. In an RCT by Chen et al, stroke patients received sensory-threshold electric stimulation via electrodes placed over the Achilles' tendon and gastrocnemius for 20 minutes, 6 times a week for 1 month[25]. They reported significant improvement in gait speed. Peurala et al treated subjects with sensory-threshold electric stimulation on the foot and ankle for 30 minutes, twice a day for 3 weeks and reported significant improvement in motor recovery but not in gait speed[12]. Both studies used a 10-m walk test and subjects were in the chronic stage of recovery.

In a recent meta-analysis, Robbins et al reported that motor threshold electric stimulation improves gait speed and can be an effective tool in the rehabilitation of patients after stroke[17]. In motor stimulation, the current intensity is high enough to exceed motor threshold and evoke muscle contractions which are associated with cutaneous, muscle and joint proprioceptive afferent feedback.

However, in sensory stimulation, the low current intensity evokes a sensory reaction without muscle contraction, associated only with cutaneous afferents. In our study both the SES and the placebo group achieved an improvement in gait characteristics of the paretic side; however, the between-group difference was not significant.

In a Cochrane review, the results of 24 randomized controlled trials of electrostimulation delivered to the peripheral neuromuscular system which was designed to improve voluntary movement control, functional motor ability and activities of daily living was reported[26]. In this review, Pomeroy et al reported that the majority of findings in favor of electric stimulation were found when it was compared to a group of stroke patients who were not receiving any treatment. There were no differences between either electrostimulation and placebo or between electrostimulation and another type of physical therapy. For the placebo group, we used sham-stimulation together with the conventional rehabilitation program. Because it has been reported that even the placement of electrodes on the skin is likely to stimulate mechanosensitive nerve fibers[27], we might have caused an iatrogenic afferent sensory input in our placebo group.

We delivered the electric stimulation without any active involvement of the patients. However, it has been shown that active repetitive movements are key factor in recovery after stroke, but beyond simple repetition, an element of problem solving is also required[28]. A recent review reported that triggered stimulation was more likely to yield improvements in motor control than non-triggered stimulation after stroke[29]. They did not detect a relationship between stimulation parameters, duration of stimulation and subject characteristics and clinical outcome. Same group suggested that the behavioural experiences that induce long-term plasticity in humans are likely to be those activities that are important and meaningful, and require cognitive investment and effort. Thus, repetitive movement therapy where the subject is cognitively involved in generating the movement is more likely to be important and meaningful.

There are no uniform guidelines concerning the overall duration of electrical stimulation or for the daily stimulation time. Although it is reported that duration, intensity and selected mode of the electrical stimulation are not associated with stroke outcome, the timing of the intervention is important[30]. In the present study, we included patients during the first 2-6 months after stroke. Natural recovery of walking function occurs within the first 11 weeks after stroke, and early and intensive treatment significantly improve motor and functional outcome. Although most of the overall improvement in motor functions occur within the first several months after stroke[31], modulation of motor networks may still be possible in chronic stroke patients.

In conclusion, sensory-threshold stimulation of the paretic leg in addition to a conventional rehabilitation program is not superior to the conventional rehabilitation program and placebo, in terms of selective motor control and gait kinematics of our group of patients with stroke.

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Suppliers

[a] Enraf-Nonius B.V. Röntgenweg 1 P.O. Box 810, 2600 AV Delft, The Netherlands.

[b] VICON, Oxford Metrics Limited, 14 Minns Estate, West Way, Oxford, OX2 OJB, UK.

[c] Statistical Package for the Social Sciences (SPSS) for Windows, Version 9.0; SPSS Inc., 444 N. Michigan Avenue, Chicago, IL. USA

Chapter 7

Effects of ankle foot orthosis on hemiparetic gait

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7.1. Abstract

Objective: Ankle foot orthosis (AFOs) are widely used to provide optimal ambulation in people with hemiplegia. In this study we evaluated the mechanical effects of metallic and plastic AFOs on severely hemiparetic stroke patients. **Methods:** Twelve hemiparetic patients were analysed on a Vicon 370 Motion Anaysis System. Spatiotemporal, kinematic and kinetic parameters were measured. **Results:** The two types of orthosis generally had similar positive effects on hemiparetic gait parameters, increasing cadence, walking speed, single and double step length, ankle dorsiflexion nagle at heel strike and swing. The metallic AFO was betterat increasing the ankle dorsiflexion angle than the plastic AFO. **Conclusion:** Hemiparetic gait was improved by both orthosis. However, metallic AFOs provided better stabilization of the ankle, allowing improved heel strike and push-off.

7.2 Introduction

Ankle foot orthosis are commonly used to control ankle motion and provide optimal ambulation in patients with hemiplegia. The Seattle design plastic AFOs and metallic AFOs are the most widely prescribed AFOs in hemiplegic patients, presumably due to their good mediolateral stability toe clearance and dorsiflexion resistance. 1,2 Comparison of the effects of different AFOs on hemiparetic gait pattern have not been documented before.[2–4] The aim of this study was to evaluate and compare the mechanical effects of plastic and metallic AFOs on the same patient with hemiplegia.

Twelve hemiparetic stroke patients (3 women, 9 men), who had no ankle control on the hemiplegic side while walking, participated in the study after giving their consent. Mean age of the group was 54 (39–65) years; mean time since stroke was 67 days (30–270). Patients were using either a single point or three point cane. None had fixed deformity at the ankle. Three patients had a moderate degree of spasticity in plantar flexors (Modified Ashworth Grade 2–3). None of them had neglect phenomenon, communication problems or proprioceptive sensory impairment.

Both a Seattle type polypropylene AFO and a metallic AFO were specially moulded and fitted for each patient. During manufacture of the metallic AFO a rigid sole plate extending to the head of the metatarsals was attached to a Blücher shoe and a stirrup assembly was riveted to the sole plate. This was attached to two metal uprights which were fixed with a rigid posterior calf band and leather closure. The dorsiflexion angle of the AFOs was adjusted to 90 degrees. All the patients had an opportunity for walking practice with each orthosis before gait analysis to ensure proper fitting and to allow necessary adjustments to be made. The Vicon 370 Motion Analysis System was used for gait analysis. Ground reaction forces (GRF) were collected using two force plates (Bertec, Columbus, OH, USA) with simultaneous measurement of the limb position. All the gait data of a patient was collected on one day to avoid any changes due to recovery. Each subject was instructed to walk without any orthosis then an AFO on the same session, at a self-selected speed. The order of testing was randomized. Spatiotemporal (cadence, walking speed, step time, step length and double support time), kinematic (ankle dorsiflexion at heel strike and mid-swing), and kinetic parameters (knee flexion moment, GRFs) were measured at each condition. Practice trials were performed by each subject until they could consistently and naturally contact both of the force plates. Statistical Package for the Social Sciences (SPSS for Windows v.901) was used for statistical evaluation. Pairwise comparisons of gait parameters were done within the same group using the Wilcoxon signed ranks test.

Table 1 Gait parameters measured in three walking conditions (mean±SD)

Parameters	Without orthosis (a)	Plastic AFO (b)	Metallic AFO (c)	P a x b	P a x c	P b x c
Cadence (steps/min)	62.33±20.56	65.00±19.27	67.33±17.45	NS	NS	NS
Walking speed (m/s)	0.32±0.13	0.37±0.14	0.41±0.16	NS	<0.05	<0.05
Single step time (s)	1.20±0.52	1.12±0.41	1.03±0.33	NS	NS	NS
Double support time (s)	1.04±0.69	0.90±0.53	0.79±0.31	NS	NS	NS
Single step length (m)	0.33±0.08	0.36±0.08	0.37±0.08	<0.05	<0.05	NS
Ankle[a] dorsiflexion (degrees)	-16.18±10.84	-6.48±6.21	-0.37±4.37	<0.05	<0.05	<0.05
Ankle[b] dorsiflexion (degrees)	-12.38±13.04	-1.29±5.72	3.44±5.76	<0.05	<0.05	<0.05
Knee flexion moment (N/m)	0.36±0.25	0.32±0.24	0.20±0.16	NS	<0.05	<0.05

[a] Stance phase, [b] Swing phase, NS, nonsignificant.

7.3. Results

There were no significant differences in cadence, double support time, single step time and step length with the two types of AFOs. A significant increase in walking speed was observed with the metallic AFO. Ankle dorsiflexion at heel strike and mid-swing showed an increase with both types of AFO. The metallic AFO provided more dorsiflexion in these phases than the plastic AFO (Table 1). Maximum hip and knee flexion–extension angles showed no significant differences. The metallic AFO caused a greater decrease in knee flexion moment compared with bare walking and the plastic AFO. There were no significant differences in mean hip flexion–extension moments, knee extension, valgus moments, ankle plantar flexion moment, total ankle power or first vertical force peak. The shape of the vertical force curves showed a plateau pattern instead of normal double peak pattern in almost all of the cases during bare walking. We observed the change of plateau pattern to normal double peak pattern in six patients during walking with AFOs.

7.4. Discussion

Hemiplegia due to stroke impairs an individual's ability to walk and frequently causes severe disability. Inadequate ankle dorsiflexion during swing, mediolateral ankle instability and insufficient push-off during late stance frequently disturb normal walking patterns, causing slower walking speed, shorter step length and foot drag. An AFO is thought to be the most suitable lower limb orthosis to overcome any gait deficit related to ankle instability.[5] Walking speed, cadence, step length usually decrease in hemiparetic gait pattern.[6] The mean walking speed of subjects was very slow (0.3 m/s) compared with men aged over 60 who have a walking speed of 1.18 m/s.[7] Normal walking speed in healthy women 64 years of age and older is 0.96 m/s.[8] Although both AFOs increased the walking speed of patients, the mean value was still low compared with that of healthy people.

Hemiplegic patients usually have less dorsiflexion during heel contact and mid-swing due to loss of motor control, spasticity of the gastrocnemius- soleus group and ankle contracture. Although mean plantarflexion of the hemiparetic patients during swing was excessive, both orthosis decreased plantarflexion adequately for toe clearance. Better toe clearance provided by the metallic orthosis was most likely due to its greater resistance to plantarflexion compared with polypropylene orthosis. Knee stability is considerably affected by loss of ankle control and use of AFOs. The lack of forward movement of the centre of pressure on the ankle produces a markedly increased knee flexion moment in midstance when body weight is supported by the paralysed limb.[9] Both AFOs limited the excessive plantarflexion, forming a potential for dynamic knee instability. It is suggested that the greater the plantarflexion resistance of AFO, the greater the external bending moment at the knee.[2] In accordance with this, we noted a greater decrease in internal knee flexor moment with metallic orthosis. Lehman *et al*. observed a decrease in flexor moment with use of metallic AFO, however, they used AFOs set at 5° plantarflexion.[6]

Usually, heel strike and push-off phases are inefficient in hemiparetic gait due to decreased weight bearing and consequent shorter stance duration, mediolateral instability, striking on the ground with toes or sole of the foot and weak or absent plantarflexors.[10] Both AFOs changed the plateau pattern of curve to the usual double peak pattern in six subjects. This observation was presumably due to better stabilization of ankle joint mediolaterally and significant plantarflexion resistance offered by AFOs, allowing better heel strike and more effective push-off.

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Chapter 8

Discussion

In this thesis, we investigated the effects of various therapeutic interventions on gait characteristics of hemiparetic patients with stroke. The findings reveal that task-specific interventions together with external feedback (balance training with force platform feedback) and orthosis, either enabling feedback or substituting a lost function or both (arm sling and ankle foot orthosis; AFO) are effective in improvement of postural control and gait symmetry in hemiparetic patients with stroke. However, impairment-focused therapies without any volitional participation of the patients (neuromuscular or somatosensory electrical stimulation) are not superior to a conventional stroke rehabilitation program. Our data and converging evidence from previous studies support the superiority of a task-oriented training approach in which patients are both physically and mentally involved.[1, 2]

8.1 Postural control

In stroke rehabilitation, recovery of postural control is a prerequisite for regaining independence in activities of daily living.[3] In Chapter 3, we reported that balance training using force platform feedback together with a conventional stroke rehabilitation program decreased excessive lateral trunk excursions and enabled better weight shifting to the paretic side. In a previous study, Vearrier et al. investigated the efficacy of standard physical therapy (based on the task-oriented approach) delivered in an intensive massed practice paradigm (6h/day for 2 consecutive days) on ten chronic stroke subjects.[4] Therapy was mainly focused on the hemiparetic leg using tactile, verbal and auditory feedback regarding the gait symmetry. In agreement with our results they reported improvement in postural control and weight bearing symmetry, as well as a decrease in the number of falls.

In Chapter 4, we presented the immediate positive effects of an arm sling on postural control of hemiparetic patients with stroke. Early after stroke some hemiparetic patients experience an altered perception of the body's orientation in space and become unaware of the location of their body weight line. Shepherd and Carr suggested that it may be helpful to draw the patient's attention to this in order to understand the mismatch between their feeling and reality in space.[5] An arm sling might have served as a feedback mechanism and remind the patient of his/her arm and trunk, thus helping postural adaptations.

There are conflicting results about the effects of an AFO on postural control. Mojika et al. investigated the effect of an AFO on body sway in eight post-stroke hemiparetic patients and reported that an AFO decreased body sway in standing position.[6] They noted that when patients were not wearing an AFO, the centre of foot pressure moved toward the nonparetic limb and the body sway was larger. With an AFO, the centre of foot pressure shifted to the mid-position and body sway decreased. Chen et al reported that postural sway and postural symmetry were not significantly affected with an AFO[7]. Wang et al performed a similar study on 42 short-term (<6 months) and 61 long-term stroke patients. They reported improvement in body sway and weight bearing distribution with an AFO for only short-term stroke patients[8]. They attributed this result to the increased proprioception via afferent feedback from cutaneous receptors. Pohl and Mehrholz reported that wearing an AFO significantly improved postural sway in short term stroke patients[9]. In our study, in agreement with the findings of Chen et al[7], the AFO did not change the center of gravity (COG) excursions while walking. Control of the ankle joint is important to achieve a stable static balance by the so-called 'ankle strategy', in which the body is considered as a rigid mass pivoting about the ankle joints[10]. Sensibility, neuromuscular control and strength of muscles around the ankle are needed to perform this strategy[11]. None of our patients had proprioceptive deficit in the AFO study, so we believe that an AFO did not bring any additional benefit to COG excursions. Moreover, by limiting ankle joint movement, the AFO might have physically prevented a normal ankle strategy while walking. The main reasons for the contradictory findings regarding AFO are the differences in the study population and the type of AFO investigated. Mobility and spasticity level of the patient, stiffness of the material used, the position of the ankle joint in the orthosis (plantarflexion versus dorsiflexion), the hinges and the stops all change the results.

Neuromuscular or sensory-threshold electric stimulation of the paretic leg had no significant effect on postural control while walking in our hemiparetic patients with stroke.

8.2 Gait symmetry

Improvement in spatio-temporal and weight bearing symmetry of gait provide an important clinical marker of recovery in rehabilitation as they are associated with better motor functioning and functional independence[12,13]. The severity of asymmetric weight distribution during standing is negatively associated with motor function and independence,[14] so that the ability of weight bearing on the paretic side has been one of the most common outcome parameters used in stroke research.[15,16] In our study, balance training with force platform biofeedback and arm sling improved spatio-temporal asymmetry indexes.

Barclay-Goddard et al. [17] concluded in their review that forceplate feedback improved stance symmetry after stroke. On the contrary, van Peppen et al.[18] reported that the additional value of visual feedback in bilateral standing compared with conventional therapy shows no statistically significant effects on symmetry of weight distribution between paretic and non-paretic limb while standing. They attributed the contradictory findings to differences between the inclusion criteria and the number of included studies. Our findings revealed that balance training with force platform biofeedback significantly increased weight bearing on the paretic side while walking. Arm sling use also has immediate beneficial effects on weight distribution while walking.

Studies on patients with stroke have demonstrated that AFO improve spatio-temporal gait symmetry [9] and weight bearing on the affected limb[7-9]. It is reasonable to conclude that weight bearing through the affected leg improved with wearing an AFO because the AFO provided ankle stability by keeping the ankle joint in good alignment and by giving external support. DeWitt et al. investigated the efficacy of AFOs on 20 chronic stroke patients.[19] They reported beneficial effects in walking ability and they noted that their patients felt more self confident and experienced less difficulty while walking. It has been shown that an AFO increases walking velocity [6,7,20] and decreases mean total duration of the stance phase[7] in patients with stroke. However, in our study, neither plastic nor metallic AFOs had significant effects on weight bearing ability.

Neuromuscular or sensory-threshold electric stimulation of the paretic leg had no significant effect on spatio-temporal gait symmetry while walking in our hemiparetic patients with stroke.

8.3 Selective motor control

Recovery from stroke is based on the brain's capacity for reorganization and adaptation. Conventional therapies fail to restore normal gait to many patients after stroke. An emerging body of literature demonstrates that sensory stimulation and feedback applications may have a beneficial effect on selective motor control following stroke. Meta-analyses have reported that electric stimulation improved muscle strength[21] and gait speed[22,23] in hemiparetic patients after stroke. Robbins et al. suggested that motion analysis of subjects pre- and post-treatment could help determine if gait and motor patterns are modified by electric stimulation.[23] In Chapters 5 and 6, we investigated the effects of two different forms of electric stimulation on improvement of lower extremity selective motor control and quantitative gait characteristics of hemiparetic patients after stroke. Neither motor- nor sensory-threshold electric stimulation showed a significant benefit against conventional stroke rehabilitation program alone or together with a sham-electric stimulation on gait characteristics.

8.4. Limitations of the thesis

8.4.1 Study population

General characteristics of the study population are presented in Table 1. The findings and conclusions of this thesis are limited to the population of sub-acute stroke inpatients, who survived the first stroke without severe cognitive deficits and with some ability to walk in the gait analysis laboratory. So-called ‘some ability to walk’ might have caused a ceiling effect, as this ability is the final goal for some severe cases. Assessed treatments might have been more beneficial for hemiparetic patients who survived with severe motor and cognitive deficits, or if they had been delivered in the acute stage.

Table 1: General characteristics of the study population

	n	Age (years)	Time since stroke	Brunnstrom stages	FIM motor	FIM total
Repeatability	20	54.2(13.3)	6.5(6.9) (months)	I-III: 9 IV-VI: 11	55.1(14.7)	
Balance	41	60.9 (11.7)	8.4(18.2) (months)	I-III: 16 IV-VI: 25	56.8(15.5)	
Arm sling	31	53.1(9.7)	61.2(12.5) (days)	I-III: 31		46.0(14.2)
NMES	25	55.3(8.2)	2.4(1.1) (months)	I-III: 25		68.6(26.0)
SES	30	63.2(9.7)	3.4(2.1) (months)	I-III: 25		72.3(18.3)
AFO	12	54.0(9.5)	67.8(13.0) (days)	I-III: 12	Not calculated	

Values are in mean(SD), except for number of patients.
Abbreviations: n, number of patients; FIM, Functional Independence Measure; NMES, neuromuscular electric stimulation; SES, sensory-threshold electric stimulation; AFO, ankle foot orthosis.

Our study population may seem young (mean age 58 years) compared to other stroke studies with a mean age of 65[68]or 66 years[41,42]. However, it should be noted that studies which used quantitative gait analysis as an outcome parameter usually present relatively young mean ages (51[9], 53[24], 54[13], 57[25,26], 59[27] years). In previous descriptive stroke studies from Turkey, we reported the mean age of our stroke inpatients as 60 years old.[28,29] This shift to younger age in the present thesis might be due to our inclusion criteria. Mean time since stroke was 4 months when the patients were admitted to our rehabilitation ward and included into our study. One might expect to get better recovery at a younger age and during the early stages after stroke.

The therapeutic interventions used in this thesis are expected to give feedback to the patients to enhance motor learning and improve their gait pattern. Sensory processes including vision, audition, proprioception, touch and pressure can mediate feedback information that is available as a result of movement being performed. Therapists’ verbal cueing and coaxing[30], visual and auditory feedback from electromyography (EMG Biofeedback) [31], forceplate (balance and weight shift training), computer screen (virtual reality and web-based telerehabilitation) [32,33], mirror[34,35], and kinematic feedback from electrogoniometer[36] are all well-known examples used for stroke rehabilitation. In this thesis, we found that visual and auditory feedback via a forceplate, and sensory feedback via an arm sling improved postural control and weight shifting while walking. However, AFOs and electric stimulation modalities via afferent feedback from cutaneous receptors did not show the same improvement in assessed gait characteristics. It should be remembered that sensory deficits, visual and hearing problems as well as cognitive impairments may compromise motor learning via feedback after stroke. Proprioceptive impairment obstructs walking because it prevents the patient from knowing the position of the hip, knee, ankle or foot and the type of contact with the floor. As a result, the patient does not know when it is safe to transfer body weight onto the limb and walking becomes slow and cautious[37]. Unfortunately, we did not document the sensory functions of the patients during data collection and could not comment on the possible contribution of sensory deficits to the ineffectiveness of the interventions.

8.4.2 Treatment

Interventions were applied for 3-4 weeks (15-20 sessions) which might be short to observe significant benefits. Kwakkel reported that a minimal dose of at least 16 hour augmentation was necessary in determining the required exact dose of practice for functional effects to take place.[38]

In a Cochrane review, the results of 24 randomized controlled trials of electrostimulation delivered to the peripheral neuromuscular system which was designed to improve voluntary movement control, functional motor ability and activities of daily living was reported.[39] In that review, Pomeroy et al. concluded that the majority of findings in favor of electric stimulation were found when it was compared to a group of stroke patients who were not receiving any treatment. There were no differences between either electrostimulation and placebo or between electrostimulation and another type of physical therapy. Our control groups received a conventional stroke rehabilitation program alone or together with sham-stimulation which could also stimulate motor recovery.

There is strong evidence that early[38,40-42], intensive[43-45] and task-related training improved motor recovery and cortical reorganization after stroke[1,2, 48-56]. The task-oriented training approach mainly focuses on practice of identifiable functional tasks, rather than on movement patterns or underlying impairments. Cognitive involvement, functional specificity and the progressive complexity of tasks being trained are the key variables of motor training and cortical reorganization.[1,2, 45-60] In a review of animal and human neuroplasticity studies, Carey et al. compared the effects of the repetitive execution of simple motor tasks versus complex motor tasks[59]. They concluded that the acquisition of motor skill is enhanced by training conditions involving complex tasks and in-depth cognitive processing, compared to less difficult tasks. During task-specific training, there should be individualization of the training goals (i.e., tasks must be at the appropriate level for a patient's ability) and progression of the training goals over time (i.e., as the patient improves, tasks should become progressively more challenging).[57] It is well established that the environmental context of the training influences performance of the task.[60] Therefore, to retrain functional adaptation, it is important to provide environmental challenges that are similar to those that the patient will experience on return to his/her community.

We delivered the electric stimulation without any active involvement of the patients. It has been shown that active repetitive movements are key factor in recovery after stroke; however, beyond simple repetition, an element of problem solving is also required[61]. A recent review reported that triggered stimulation was more likely to yield improvements in motor control than non-triggered stimulation after stroke[62]. They did not detect a relationship between stimulation parameters, duration of stimulation and subject characteristics and clinical outcome. The same group suggested that the behavioral experiences that induce long-term plasticity in humans are likely to be those activities that are important and meaningful, and require cognitive investment and effort. Thus, repetitive movement therapy where the subject is cognitively involved in generating the movement is more likely to be important and meaningful. Significant improvements were reported in gait patterns when functional electric stimulation was applied in a multi-level approach in acute[63] and chronic stroke patients[48-50].

Recent evidence has shown that impairment-focused programs (biofeedback, electric stimulation, muscle strengthening) failed to generate functional improvements whereas therapies that administered functional training (treadmill training, constraint-induced movement therapy, external auditory feedback) improved activity levels[43]. It is believed that repeated, task-specific protocols induce brain reorganization to bring about functional improvements[45]. Landers reported that skilled rehabilitation instead of non-skilled rehabilitation (strength training or simple repetition) is more robust in driving cortical changes[46]. Shepherd and Carr stressed the importance of specifity effect in rehabilitation[64]. Practice of one function may not carry over to another unless they are dynamically similar. Many recent studies reported that a task-specific approach should be used rather than an impairment-focused approach to improve gait after stroke.

In this thesis, any of the interventions used caused a significant change in sagittal plane gait kinematics of our stoke patients. As a general rule, skill in performance increases as a direct function of the amount of practice. If the goal is to improve walking, gait itself as the task should be practiced. However, it is not possible to make every hemiparetic patient walk short after stroke. Clinicians have looked for subtasks of the gait to practice and master for walking activities[65].

Balance, muscle strength and symmetry are some but not all of these subtasks investigated. Practice of subtask outside of the gait cycle, however, may not transfer into the gait cycle. Emphasis on the balance subtask using static standing activities does not appear to transfer into a better gait pattern. The issue of task specificity should be considered when discussing the presence or absence of gait training effects. We cannot assume that pre-gait exercises or isolated muscle strengthening exercises will be activating the same part of the muscle that is needed in gait. The speed of the movement should also be considered when discussing task specificity of gait. Even the environment and task directly affects the learning and the movement, so that training should not be limited to indoor gymnasiums[60]. For successful motor learning, the desired motor task must be practiced in a pattern as close to normal as possible[50-52] and intensive practice must be provided.[54,55] Conventional gait training methods do not provide practice of a gait pattern that is close to normal, nor are many repetitions of the desired movement practiced.

Reduced dorsiflexion during swing phase of the paretic side is a common deviation after stroke. It may be due to weakness of dorsiflexors, spasticity of plantarflexors, passive stiffness of plantarflexors or ankle joint pathology[66]. In our electric stimulation studies, none of the subacute stroke patients had voluntary ankle dorsiflexion. They had a moderate spasticity at the plantarflexor muscles. However, we did not document the ankle joint pathology or passive stiffness. In a study by Lin et al, gait analysis of 68 chronic stroke patients with the ability to walk independently revealed that gait velocity and temporal asymmetry are mainly affected by the dorsiflexors strength, whereas dynamic spasticity of plantarflexors influenced the degree of spatial gait asymmetry[66]. They concluded that treatment aiming to improve different aspects of gait performance should emphasize different ankle impairments.

The goal of stroke rehabilitation should not only be the restoration of more normal gait patterns with selective motor control. Griffin et al. reported that symmetry does not play a role in promoting gait performance in stroke patients[67]. It is still questionable whether it is realistic to expect gait symmetry after stroke, while the brain itself is no longer symmetric. If the function cannot be restored it would be better to facilitate compensations to achieve better walking ability. Kollen et al have suggested that shifting the weight to the non-paretic side is a compensatory strategy in the standing position for regaining gait[68]. We might have spent too much time and effort to restore lost functions instead we might need to start applying compensatory strategies earlier to achieve a better walking ability.

8.4.3 Outcome measures

Most studies evaluate stroke outcome by using clinical tests. These tests explore one or more items on: velocity, symmetry, muscle strength, synergy, muscle tone and activities of daily living. Because quantitative gait analysis systems are expensive and labor demanding, few studies focused on the kinematic and kinetic characteristics of hemiparetic gait. However, we believe that if we know the recovery processes and the mechanisms that may influence recovery, interventions focusing on that area will be more beneficial.

We presented within- and between-session repeatability of time-distance and sagittal plane kinematic gait parameters in hemiparetic patients. In the repeatability study, within-session variability was 6.1% for walking velocity. Any higher difference between pre-treatment and post-treatment measurement would be reported as a treatment effect. However, in electric stimulation studies although both experimental and control groups revealed an improvement of 13 to 16% after the treatment, the difference did not reach statistical significance. Unfortunately, the characteristics of the study populations showed some diversity between the electric stimulation study and the repeatability study. For example, the mean time after stroke was much longer in the repeatability study than in the intervention studies (Table 1). For electric stimulation studies we included only acute stroke patients with poor motor control, but we did not apply the same inclusion criteria for repeatability study. Mean time since stroke was 6.5 months in the repeatability study and 11 of 20 patients had good motor control. This might hve causes some bias. Future studies should calculate the smallest detectable difference for quantitative gait data for different subgroups of stroke patients based on age, time since stroke and motor control level.

The repeatability of quantitative gait analysis does not mean that the measurements are also valid. The joint centers might not be correctly calculated. The validity studies of our Vicon gait analysis system were all performed on able-bodied subjects. Stroke patients might reveal lower validity due to trunk and lower extremity deformities and malalignments. Moreover, quantitative gait analysis laboratories measure the gait characteristics in an artificial environment. Even though we may obtain a successful walking pattern in the laboratory, this still does not necessarily prove that the patient will not have difficulties with outdoor walking, walking on uneven surfaces or slopes, steps, kerbs, or at traffic lights.

It has been suggested that gait velocity can be accepted as an outcome measure for patients who can walk faster than 0.34 m/s[69]. Force plate measurements are good for stroke patients if they have at least 0.25m of step length. Shorter step length makes kinetic measurement impossible. We could not show the repeatability of kinetic parameters. Moreover, the reported values for time-distance and kinematic parameters are valid for stroke patients with relatively better motor selective control during their first year after stroke (due to patient inclusion criteria). Quantitative gait analysis data might be useful to follow patient outcome when other indexes (such as the Barthel Index) present a ceiling effect.

Quantitative gait analysis reveals 124 parameters relative to time-distance, kinematic and kinetic variables to assess in sagittal, frontal and transverse planes[70]. It is not easy to decide on the best parameter among them to present the effectiveness of the therapeutic interventions. In a recent study, the inability to accept and transfer weight, and an inability to selectively move the pelvis and the paretic limb have been defined as the most common treatment problems of hemiparetic gait.[71] In this thesis, we could not show a significant difference in kinematic and kinetic gait parameters of stroke patients.

In electric stimulation studies, our primary outcome was achievement of voluntary ankle dorsiflexion at the paretic side which represents lower extremity selective motor control. We used two different methods to quantify ankle dorsiflexion: 1) Brunnstrom's stages; 2) maximum ankle dorsiflexion angle at swing measured by a computerized gait analysis system. Brunnstrom's stages are a clinical assessment method performed while the patient is lying in bed or sitting in a chair or standing, according to the motor recovery level. All these positions are static and were performed in the patients' room at the rehabilitation hospital in their usual gowns. However, quantitative gait analysis was performed in a less-comfortable laboratory setting: 5 infrared and 2 videocameras recorded the patient's gait while they were wearing only their underwear and had 15 markers attached to various anatomical landmarks on their body. In order to avoid possible errors due to inaccurate placement of the markers, these anatomical landmarks are indicated after careful palpation of the bone and skin at the pelvis and lower extremities by the laboratory team. The obvious artificial, unfamiliar and uncomfortable environment of the gait laboratory might have altered the walking function.

In electric stimulation studies, all four study groups showed significant improvement in Brunnstrom stages. More than half of the patients regained selective motor control at the end of the 4-week rehabilitation program. However, none of the groups showed a statistically significant improvement in maximum ankle dorsiflexion angle at swing or other assessed gait characteristics. Previous studies reported poor correlations between clinical examination measurements and dynamic motion[72]. Desloovere et al. documented fair to moderate correlations between gait analysis data and clinical measurements of 200 children with cerebral palsy. They discussed several factors that play a role in dynamic motion other than contractures, spasticity, strength and selectivity of different muscle groups[72]. In the clinical assessment all muscles are evaluated in a monoarticular way. However, bi-articular muscles behave differently during gait. We clinically evaluate isolated muscle groups at each joint level, but pathological gait is defined by interactions of multiple limitations, co-contractions and muscle synergies. The clinical examination focuses on primary and secondary problems, while pathological gait is characterized by compensation mechanisms to overcome these problems. In gait analysis motions are defined by mathematical joint models based on marker placement, which is a simplification of the real anatomical situation evaluated in the clinical examination. Finally, in the clinical examination, simple motions are evaluated at standardized velocity. In contrast, gait is complex, characterized by total patterns, intra-limb and inter-limb coordination, balance problems and interactions across planes and levels. Lennon et al. reported significant improvement on impairment, activity and participation scales after a mean 17.4 weeks of physiotherapy based on the Bobath concept in sub-acute stroke patients[71]. However, they did not observe any significant change in kinematic and kinetic gait parameters at the paretic side and concluded that motion analysis is too demanding as an outcome measure for stroke patients with limited locomotor recovery. In clinical decision-making both clinical measurements and quantitative gait analysis should be considered together. Buurke et al. investigated functional walking recovery of 13 stroke patients by using the Rivermead Mobility Index, the Functional Ambulation Category and the Barthel Index[73]. They found significant improvement in clinical tests but not in muscle co-ordination pattern after stroke. They suggested that the functional improvement of gait is related to mechanisms other than to the restoration of co-ordination patterns of both legs.

8.4.4 Lack of long-term follow up data

It is well known that stroke patients require long-term follow-up and assessment in order to demonstrate rehabilitation-induced effects. However, due to socioeconomic reasons in Turkey, we could only assess immediate post training changes and could not follow-up the patients after discharge from the rehabilitation ward. Future studies are needed to explore the long-term effects of these interventions on hemiparetic gait.

Ultimately, most hemiparetic patients with stroke generate an adaptive, individualized resultant walking pattern by adding behavioral compensation strategies based on their restored lost functions. It is not clear which subgroup reaches this level, which intervention, for how long and how much, alone or in combination, enhance this process. It may not be fair to the patients to compare this adaptive resultant walking pattern with the normal motor behavior of healthy subjects[74]. Gait training is often delayed during the early stages after stroke because normal gait pattern is thought to require preparation such as improved strength, weigh bearing, balance and coordination in order to prevent asymmetrical abnormal gait pattern. However, in spite of a comprehensive stroke rehabilitation program many stroke patients who achieved walking ability show an asymmetrical pattern with various compensatory deviations. Integrated by supra-spinal mechanisms, therapeutic interventions should assist stroke patients to establish this new individualized resultant gait pattern. Future studies should describe the ‘best functional adaptive gait pattern’ for hemiparetic patients with stroke, so that the therapeutic interventions are accepted successfully when this intended pattern has been achieved.

Gait deviations in patients with stroke are complex and include both biomechanical and neurological factors that may affect the ability to grade muscle force and control movement required for efficient locomotion. Research designed to identify motor control variables of gait dysfunction and to test the efficacy of treatment to improve gait is complicated by the variability among subjects with respect to diagnosis, area of lesion, etiology of dysfunction, functional ability and time of recovery. Although some general characteristics of hemiparetic gait have been identified, individual differences are great, emphasizing the need for individual assessment to identify problems and design exercise programs to address those problems. Examination of longitudinal changes in kinematic and kinetic parameters of locomotion will increase our understanding of the recovery processes. Spontaneous changes in recovery must also be identified to investigate the effects of therapeutic interventions to change gait characteristics in patients with stroke.

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Summary

Stroke is the leading cause of adult disability and inpatient rehabilitation admissions. In spite of many efforts, approximately 35% of stroke survivors with initial paralysis of the leg do not regain useful walking function. Many (potential) impairments and limitations have caused a marked variation in gait patterns among stroke patients. Hemiparetic gait is characterized by slow and asymmetric steps with poor selective motor control, delayed and disrupted equilibrium reactions and reduced weight bearing on the paretic limb. Although some general characteristics of hemiparetic gait have been identified, individual differences are great, emphasizing the need for individual assessment to identify the problems and design therapeutic interventions to address them. To provide a rationale for the proper selection of therapeutic interventions, we assessed the effectiveness of balance training, electrical stimulation, arm sling and AFO to improve hemiparetic gait pattern after stroke. Treatment outcome was evaluated by relevant clinical assessments together with time-distance, kinematic and kinetic gait characteristics measured by a quantitative three-dimensional gait analysis system. We concluded that task-specific interventions together with external feedback (balance training with force platform feedback) and orthosis, either enabling feedback or substituting a lost function or both (arm sling and AFO) are effective in improvement of postural control and gait symmetry in hemiparetic patients with stroke. However, impairment-focused therapies without any volitional participation of the patients (neuromuscular or somatosensory electrical stimulation) are not superior to a conventional stroke rehabilitation program.

Chapter 2 reports the within-session and between-session repeatability of time-distance and sagittal plane kinematic gait parameters in 20 hemiparetic patients with sub-acute stroke. The repeatability of gait parameters with minimal measurement error is an important issue in the clinical use of results of quantitative gait analysis. It is important to investigate whether a variation between measurements is a treatment effect or solely due to variation in the measurements. Besides the natural variability in the gait of persons (intrinsic variability such as gait velocity), we should be aware of the numerous potential sources of error during preparation of the subjects (e.g. anthropometric measurements, marker placement), data collection (calibration of the cameras, skin motion), data processing (definitions of the points of toe-off and initial contacts) and interpretation of the data (extrinsic variability). We used a test-retest design where the patients were tested during two sessions on the same day approximately two hours apart. Each session included two trials. Repeatability of all assessed gait parameters was good to excellent with an ICC of over 75 together with narrow confidence intervals. The most repeatable parameter was walking velocity with an ICC of 0.99 (within-session) and 0.98 (between-session). Variability of walking velocity was also low CV% 3.9 (within-session), 6.1% (between-session); however, peak ankle dorsiflexion at swing showed high variability with a between-session CV of 31.0%.

Chapter 3 discusses a randomized controlled study conducted to assess the effects of a task-oriented force platform biofeedback balance training on quantitative gait parameters of hemiparetic patients with sub-acute stroke. Forty-one patients with hemiparesis after stroke (mean age of 60.9 years, median time since stroke 6 months) were randomly assigned to an experimental or a control group. The control group (n=19) participated in a conventional stroke inpatient rehabilitation program, whereas the experimental group (n=22) received 15 sessions of balance training (using force platform biofeedback) in addition to the conventional program. Outcome was based on the walking velocity, symmetry (step length and single support time asymmetry ratios), postural control (pelvic excursions in terms of the difference between peak and valleys of the curve in sagittal, frontal and transverse planes), weight bearing (peak vertical GRFs normalized by bodyweight on the paretic side), sagittal kinematics (excursion of the paretic hip, knee and ankle joints) and kinetics (peak extensor and abductor moments of the hip, peak extensor moment of the knee, and peak plantar flexor moment of the ankle during stance) of the paretic leg. The control group did not show any significant difference regarding gait characteristics. Pelvic excursion in frontal plane improved significantly (p=0.021) in the experimental group. The difference between before-after change scores of the groups was significant for pelvic excursion in frontal plane (p=0.039) and vertical ground reaction force (p= 0.030) in favor of the experimental group. It was concluded that balance training, using force platform biofeedback, in addition to a conventional inpatient stroke rehabilitation program is beneficial in improving postural control and weight bearing on the paretic side while walking late after stroke.

Chapter 4 presents the immediate arm sling effects on walking velocity, trunk movements, center of gravity excursions and paretic side weight bearing of 31 hemiparetic patients with sub-acute stroke. In a single-session, crossover (with and without an arm sling), controlled design, quantitative gait data of the patients were compared with those of age-matched and gender-matched able-bodied control subjects. The able-bodied group did not show any difference in gait parameters while using the sling. However, in patients with hemiplegia wearing a sling, increased walking velocity and weight bearing of the paretic side, decreased excursion of the center of gravity (COG) (improvement in postural control), and improved gait symmetry. It was concluded that an arm sling improved gait, especially during gait training sessions of patients with hemiplegia who have impaired body image and excessive motion of the COG. It is known that hemiplegic patients with an impaired body image fail to make postural adaptations. Arm slings may serve as a feedback mechanism and remind the patient of his/her arm, thus helping postural adaptations.

Chapter 5 discusses whether NMES combined with a conventional stroke rehabilitation program is more effective than the conventional program alone in facilitating recovery of selective motor control in the lower extremity, and in improving gait kinematics of hemiparetic patients with sub-acute stroke. A total of 25 consecutive inpatients with stroke (mean age of 55 years, all within 6 months post-stroke and without volitional ankle dorsiflexion) were studied. Both the NMES group (n=12) and the control group (n=13) participated in a conventional stroke rehabilitation program, 5 days a week for 4 weeks. The NMES group also received 10 minutes of NMES to the tibialis anterior muscle of the paretic limb, 5 days a week for 4 weeks. Main outcome measures were Brunnstrom's stages of motor recovery and kinematic characteristics of gait. Brunnstrom stages improved significantly in both groups ($p<0.05$). In total, 58% of the NMES group and 61% of the control group gained voluntary ankle dorsiflexion. However, between-group difference of percent change was not significant ($p>0.05$). Gait kinematics was improved in both groups but the difference between the groups was not significant. It was concluded that NMES of the tibialis anterior muscle combined with a conventional stroke rehabilitation program was not superior to a conventional stroke rehabilitation program alone, in terms of lower-extremity motor recovery and gait kinematics. In this study, we delivered the electric stimulation without any active involvement of the patients. However, it has been shown that active repetitive movements are a key factor in recovery after stroke; however apart from simple repetition, an element of problem solving is also required.

Chapter 6 reports the effects of sensory-threshold electrical nerve stimulation (SES) of the paretic leg on motor recovery and gait kinematics of patients with stroke. A total of 30 consecutive inpatients with stroke (mean age of 63.2 years), all within 6 months post-stroke and without volitional ankle dorsiflexion were studied in this randomized controlled double-blinded study. Both the SES group (n=15) and the placebo group (n=15) participated in a conventional stroke rehabilitation program, 5 days a week for 4 weeks. The SES group also received 30 minutes of SES to the paretic limb without muscle contraction, whereas, the control group received sham-stimulation with the same set-up. Outcome was based on Brunnstrom's staging of motor recovery and time-distance and kinematic characteristics of gait. Brunnstrom stages improved significantly in both groups ($p<0.05$). In total, 58% of the SES group and 56% of the placebo group gained voluntary ankle dorsiflexion. The between-group difference of percentage change was not significant ($p>0.05$). Gait kinematics was improved in both groups but the between-group difference was not significant. It was concluded that SES of the paretic leg was not superior to placebo, in terms of lower extremity motor recovery and gait kinematics.

Chapter 7 discusses the biomechanical effects of metallic and plastic ankle foot orthosis on kinematic and kinetic gait characteristics of 12 hemiparetic patients who had no selective ankle dorsiflexion on the hemiplegic side while walking. Mean age of the group was 54 (range 39–65) years; mean time since stroke was 67 (range

30–270) days. Patients were using either a single-point or three-point cane. Both a Seattle-type polypropylene AFO and a metallic AFO were specially moulded and fitted for each patient. Quantitative gait data without and with orthosis were compared. Walking velocity and ankle dorsiflexion at swing improved significantly, however, postural control or weight bearing on the paretic side did not change with wearing an AFO.

Chapter 8 discusses the strengths and limitations of the interventions and the quantitative gait analysis method, and suggests some directions for future research. This thesis has some strenghts: 1) a randomized controlled design was used to assess the effectiveness of longitudinal treatments (balance training and both motor- and sensory-threshold electric stimulation), and 2) three dimensional quantitative gait characteristics were used as outcome parameters. Gait deviations in patients with stroke are complex and include both biomechanical and neurological factors that may affect their walking ability. Research designed to identify motor control variables of gait dysfunction and to test the efficacy of treatment to improve gait is complicated by the variability among subjects with respect to diagnosis, area of lesion, etiology of dysfunction, functional ability and time of recovery. Although some general characteristics of hemiparetic gait have been identified, individual differences are great, emphasizing the need for individual assessment to identify problems and design therapeutic interventions to address those problems. Examination of the changes in quantitative gait parameters of locomotion will increase our understanding of the recovery processes. Future studies investigating the spontaneous recovery of walking may be helpful to identify the recovery process and effects of therapeutic interventions in gait characteristics of stroke patients.

The findings and conclusions of this thesis are limited to the population of subacute stroke inpatients, who survived the first stroke without severe cognitive deficits and with some ability to walk in the gait analysis laboratory. So-called ‘some ability to walk’ might have caused a ceiling effect, as this ability is the final goal for some severe cases. Future studies may assess the effects of these therapeutic interventions for acute stroke patients who have survived with severe motor and cognitive deficits. A stroke population with intact sensory system might have benefited more from the investigated interventions as they all serve via increased afferent stimulation and feedback.

Another limitation of this thesis was the short duration of the interventions. Interventions were applied for 3-4 weeks with 15-20 sessions (a total of 3-10 hours) which might be too short to observe significant benefits. It has been reported that a minimal dose of at least 16 hours augmentation was necessary in determining the exact dose of practice required for functional effects to take place. Our control groups received a conventional stroke rehabilitation program alone or together with sham-stimulation which could also stimulate motor recovery. It has been shown that the majority of findings in favor of electric stimulation were found when it was compared with a group of stroke patients who were not receiving any treatment. We included only inpatients in order to achieve a homogeneous group, and it was not ethical to leave a group without any treatment. Future studies may investigate and compare the effects of the interventions on outpatients receiving other forms of treatment.

Quantitative gait analysis reveals 124 parameters relative to time-distance, kinematic and kinetic variables to assess in sagittal, frontal and transverse planes. It is not easy to decide on the best parameter among them to present the effectiveness of the therapeutic interventions. Future studies may focus on different more repeatable gait parameters with a longer duration of follow-up.

Finally, it should be remembered that the ultimate hemiparetic gait is an adaptive, individualized resultant walking pattern by the contribution of both neurological recovery and behavioral compensation strategies based on their restored lost functions. Future studies may describe the ‘best functional adaptive gait pattern’ for hemiparetic patients with stroke, so that the therapeutic interventions are accepted as successful when this intended pattern has been achieved.

Samenvatting

Een CVA is de belangrijkste oorzaak van beperkingen op volwassen leeftijd en van opname in een revalidatiecentrum. Ondanks vele inspanningen herstelt bij 35% van de overlevenden na een CVA met een verlamming van het been de loopfunctie onvoldoende. Veel (potentiële) functiestoornissen en beperkingen veroorzaken een grote variatie in looppatronen bij patiënten met een CVA. Het hemiparetische looppatroon wordt gekenmerkt door langzame en asymmetrische stappen met slechte selectieve controle over de spieren, vertraagde en onderbroken evenwichtreacties en verminderd gewicht nemen op het aangedane been. Hoewel sommige algemene kenmerken van het hemiparetische looppatroon bekend zijn, blijven individuele verschillen groot en dit benadrukt de noodzaak van individueel onderzoek om exacte problemen te identificeren en om therapeutische behandeling te ontwikkelen. Om een rationale te ontwikkelen voor een juiste selectie van therapeutische behandelingen hebben we de effectiviteit van balanstraining, elektrische stimulatie, een armsling en een enkel-voetorthese beoordeeld, voor zover deze ingrepen het hemiparetische looppatroon na een CVA verbeteren. Het resultaat van de behandeling werd geëvalueerd met relevante klinische testen, samen met tijd-afstand, kinematische en kinetische looppatrooneigenschappen, gemeten met een kwantitatief, driedimensioneel looppatroonanalysesysteem. We hebben geconcludeerd dat taakspecifieke interventies samen met externe feedback (balanstraining met krachtenplatform-feedback) en orthesen die of feedback geven, of een verloren gegane functie substitueren, of beide (armsling en enkel-voetorthese) effectief zijn in de verbetering van balanshandhaving en looppatroonsymmetrie in hemiparetische patiënten met een CVA. Functiestoornis georiënteerde therapieën zonder enige vrijwillige deelneming van de patiënten (neuromusculaire of somatosensore elektrische stimulatie) zijn echter niet beter dan conventionele CVA-revalidatieprogramma's.

In **hoofdstuk 2** wordt verslag gedaan van de binnen- en tussensessie herhaalbaarheid van tijd-afstand en kinematische looppatroon-parameters in het sagittale vlak bij 20 hemiparetische patiënten met een subacuut CVA. De herhaalbaarheid van looppatroon-parameters met minimale meetfout is een belangrijk onderwerp bij het klinische gebruik van de resultaten van kwantitatieve looppatroon-analyse. Het is van belang te onderzoeken of een verschil tussen de metingen een behandeleffect is of slechts het resultaat van variatie in de metingen. Naast de natuurlijke variatie van het looppatroon van personen (intrinsieke variabiliteit zoals loopsnelheid), moeten we ons bewust zijn van de vele potentiële bronnen van fouten gedurende het voorbereiden van de proefpersonen (bijv. antropometrische maten, het plaatsen van de markers), dataverzameling (calibratie van de camera's, bewegen van de huid), gegevensverwerking (definities van het punt van toe-off en initial hiel-contact) en de interpretatie van de data (extrinsieke variabiliteit). We hebben gebruik gemaakt van een test-retest design, waarbij patiënten werden getest gedurende twee sessies op dezelfde dag, met ongeveer 2 uur tussentijd. Tijdens elke sessie werden twee trials uitgevoerd. De herhaalbaarheid van alle gemeten looppatroon-parameters was goed tot uitstekend, met een ICC van meer dan 0.75 met kleine betrouwbaarheidsintervallen. De meest herhaalbare parameter was de loopsnelheid met een ICC van 0.99 (binnen de sessie) en 0.98 (tussen de sessies). De variabiliteit van de loopsnelheid was ook laag met een CV% van 3.9 (binnen de sessie), 6.1% (tussen de sessie). Echter, de maximale enkel dorsieflexie in de zwaaifase vertoont een hoge variabiliteit met een tussensessie CV van 31.0%.

In **hoofdstuk 3** wordt een randomized controlled study besproken die uitgevoerd is om de effecten vast te stellen van een taakgeorienteerd platform biofeedback balanstraining op kwantitatieve gangbeeld-parameters van hemiplegische patiënten met een subacute CVA. Eenenveertig patiënten met een hemiparese na CVA (gemiddelde leeftijd 60.9 jaar, mediane tijd sinds CVA 6 maanden) werden via loting toegewezen aan een experimentele en een controlegroep. De controlegroep (n=19) nam deel in een conventioneel intramuraal CVA-revalidatieprogramma, terwijl de experimentele groep (n=22) 15 sessies balanstraining kreeg (met gebruikmaking van een krachtenplatform biofeedback) toegevoegd aan het conventionele programma. De uitkomstmaten hadden betrekking op loopsnelheid, symmetrie (staplengte en single support time asymmetrie ratio's), balanshandhaving (bekkenbewegingen in de zin van verschil tussen het maximale en minimale deel van de curve in sagittaal, frontaal en transversaal vlak), gewichtname (piekverticale grondreactie-krachten genormaliseerd voor lichaamsgewicht aan de paretische zijde), sagittale kinematica (uitslagen van de paretische heup-, knie- en enkelgewrichten), kinetica (piek-extensor en abductormomenten van de heup, piek-extensormoment van de knie en piek-plantairflexiemoment van de enkel gedurende stand) van het aangedane been. De controlegroep vertoonde geen statistisch significante verbetering met betrekking tot de looppatroonkenmerken. In de experimentele groep verbeterden de heupuitslagen in het frontale vlak significant (p=0.021). Het verschil tussen voor en na metingen van de groepen was significant voor heupuitslagen in het frontale vlak (p=0,039) en verticale grondreactiekracht (p=0.030), in het voordeel van de experimentele groep. De conclusie was dat balanstraining met gebruikmaking van een grondreactiekracht biofeedbacksysteem, toegevoegd aan een conventioneel intramuraal CVA-revalidatieprogramma, een gunstig effect heeft voor het verbeteren van balanshandhaving en het gewicht nemen met het aangedane been gedurende het lopen in de chronische fase na CVA.

In **hoofdstuk 4** worden de onmiddellijke effecten van een armsling gepresenteerd op loopsnelheid, rompbewegingen, uitslagen van het aangrijpingspunt van de zwaartekracht en het gewicht nemen met de aangedane zijde van 31 hemiplegische patiënten in de subacute fase na CVA. Het kwantitatieve looppatroon en gegevens van de patiënten werden in één sessie met en zonder armsling vergeleken met gezonde controle proefpersonen die gematched waren op leeftijd en geslacht. De gezonde proefpersonen vertoonden geen verschil in looppatroon-parameters bij het al dan niet dragen van de sling. Echter, wanneer patiënten met een CVA de sling droegen ging de loopsnelheid omhoog, evenals het nemen van gewicht op de aangedane zijde en ging de excursie van het aangrijpingspunt van de zwaartekracht omlaag (wijzend op verbetering van handhaving van de balans) en verbeterde de symmetrie van het lopen. Geconcludeerd werd dat de armsling een positief effect heeft op het looppatroon, vooral gedurende de looptraining van patiënten met een hemiplegie die een verstoorde lichaamsperceptie en een excessieve beweging van het aangrijpingspunt van de zwaartekracht hebben. Het is bekend dat patiënten met een hemiplegie en een verstoorde lichaamsperceptie moeite hebben met het maken van houdingscorrecties. Armslings kunnen dienen als een feedbackmechanisme en herinneren de patiënt aan zijn/haar arm, waardoor aanpassingen van houding worden bevorderd.

In **hoofdstuk 5** wordt de vraag gesteld of NMES, gecombineerd met een conventioneel CVA-revalidatieprogramma, effectiever is dan een conventioneel revalidatieprogramma alleen bij het bevorderen van het herstel van selectieve bewegingscontrole van de onderste extremiteit en in het verbeteren van looppatroon-kinematica van hemiplegische patiënten met een subacuut CVA. Vijfentwintig opeenvolgende opgenomen CVA-patiënten (gemiddelde leeftijd 55 jaar), allen binnen 6 maanden na het CVA en zonder willekeurige enkeldorsieflexie) werden bestudeerd. Zowel de NMES-groep (n=12) en de controlegroep (n=13) namen deel aan een conventioneel CVA-revalidatieprogramma, 5 dagen per week gedurende 4 weken. De NMES-groep kreeg ook 10 minuten NMES op de m.tibialis anterior van het aangedane been, 5 dagen per week gedurende 4 weken. De belangrijkste uitkomstmaten waren Brunnstrom's fasen van herstel van het bewegen en kinematische kenmerken van het looppatroon. De Brunnstromscore verbeterde significant in beide groepen ($p<0.05$). In totaal bereikte 58% van de NMES-groep en 61% van de controlegroep willekeurige enkel-dorsieflexie. Echter, het verschil tussen de groepen van de percentageverandering was niet significant ($p>0.05$). De looppatroon-kinematica verbeterde in beide groepen, maar het verschil tussen de groepen was niet significant. Geconcludeerd werd dat NMES van de m.tibialis anterior, gecombineerd met een conventioneel CVA-revalidatieprogramma, niet beter is dan een conventioneel CVA-revalidatieprogramma alleen in termen van herstel van het bewegingsvermogen van de onderste extremiteit en de looppatroon-kinematica. In deze studie werd de elektrische simulatie uitgevoerd zonder actieve betrokkenheid van de patiënten. Er is echter aangetoond dat actieve herhaalde bewegingen een sleutelrol spelen in het herstel na een CVA, maar bovenop een simpele herhaling is ook een element van probleem oplossen vereist.

Hoofdstuk 6 doet verslag van de effecten van "sensory-threshold electrical nerve stimulation" (SES) van het aangedane been op het herstel van het bewegingsvermogen en looppatroon-kinematica van patiënten met een CVA. Dertig achtereenvolgende opgenomen patiënten met een CVA (gemiddelde leeftijd 63.2 jaar), binnen 6 maanden na het CVA en zonder willekeurige enkeldorsieflexie, werden bestudeerd in deze randomized controlled dubbelblinde studie. Zowel de SES-groep (n=15) als de placebogroep (n=15) nam deel aan een conventioneel revalidatieprogramma, 5 dagen per week gedurende 4 weken. De SES-groep kreeg ook 30 minuten SES van het aangedane been zonder spiercontractie, terwijl de controlegroep een namaakstimulatie in een zelfde opstelling kreeg. De uitkomsten waren gebaseerd op de Brunnstromscore voor herstel van het bewegingsvermogen en tijd-afstand en kinematische kenmerken van het looppatroon. De

Brunnstromscore verbeterde significant in beide groepen ($p<0.05$). In totaal bereikte 58% van de SES-groep en 56% van de placebogroep een willekeurige enkel-dorsieflexie. Er was geen significant verschil in de verbetering tussen de groepen. De looppatroon-kinematica verbeterde in beide groepen, maar ook hier was het tussengroepverschil niet significant. Geconcludeerd werd dat SES van het aangedane been niet beter is dan een placebo in termen van herstel van het bewegingsvermogen van het been en de kinematica van het looppatroon.

In **hoofdstuk 7** worden de biomechanische effecten besproken van metalen en plastic enkel-voetorthesen op de kinematica en kinetica van het looppatroon bij 12 CVA-patiënten die geen selectieve enkeldorsieflexie van het aangedane been hebben gedurende het lopen. De gemiddelde leeftijd van de groep is 54 (39-65) jaar; de gemiddelde tijd verstreken sinds het CVA was 67 dagen (30-270). De patiënten gebruikten óf een gewone óf een driepuntsstok. Zowel een Seattle-achtige polipropyleen enkel-voetorthese als een metalen enkel-voetorthese werden voor elke patiënt individueel op basis van een gipsmodel vervaardigd en aangemeten. De kwantitatieve looppatroongegevens met en zonder orthese werden vergeleken. De loopsnelheid en de dorsieflexie van de enkel in de zwaaifase verbeterden significant, maar de handhaving van het evenwicht of het nemen van gewicht op het aangedane been verbeterde niet met het dragen van een enkel-voetorthese.

Hoofdstuk 8 gaat in op de positieve en negatieve aspecten van de interventies en kwantitatieve looppatroonanalyse, samen met suggesties voor onderzoek in de toekomst. Dit proefschrift heeft twee sterke punten: 1) een randomized controlled design werd gebruikt om de effectiviteit van longitudinale behandeling zoals balanstraining en motor- en sensory-threshold electric stimulation te bepalen; 2) driedimensionale kwantitatieve looppatroonkenmerken werden gebruikt als uitkomstparameters. Afwijkingen van het looppatroon bij patiënten met een CVA zijn complex en bestaan zowel uit biomechanische als neurologische factoren die het looppatroon kunnen beïnvloeden. Onderzoek gericht op het vaststellen van variabelen van bewegingssturing, bij afwijkingen van het looppatroon en gericht op het testen van effectiviteit van behandeling bij het verbeteren van het looppatroon, wordt gecompliceerd door de grote variatie tussen personen met betrekking tot diagnose, plaats van het CVA, oorzaak van de afwijking, functionele beperkingen en hersteltijd. Hoewel enkele algemene kenmerken van het looppatroon na een CVA geïdentificeerd zijn blijven de individuele verschillen groot en dit wijst op het belang van een individuele beoordeling om problemen op te sporen en therapeutische interventies voor te schrijven om deze problemen te verminderen. Bestudering van de veranderingen in de parameters van het looppatroon zullen ons begrip van het herstelproces verbeteren. Toekomstige studies over het spontane herstel van het lopen kunnen nuttig zijn om het herstelproces en effecten van therapeutische interventies gericht op het looppatroon van CVA-patiënten vast te stellen.

De resultaten en conclusies van dit proefschrift beperken zich tot de populatie subacute CVA-patiënten die opgenomen zijn en het eerste CVA hebben overleefd, zonder ernstige cognitieve defecten en met enige loopfunctie in het bewegingslaboratorium. Het zogenaamde “enig vermogen te lopen” kan een plafondeffect veroorzaakt hebben omdat dit vermogen voor sommige ernstige CVA-patiënten het einddoel is van de behandeling. Toekomstige studies kunnen wellicht de effecten van deze therapeutische interventies vaststellen voor acute CVA-patiënten die overleven met ernstige defecten van hun bewegingsvermogen en hun cognitieve vermogen. Een populatie CVA-patiënten met intacte sensoriek zou misschien meer baat hebben gehad bij de onderzochte interventies, omdat deze interventies werken via een verhoogde afferente stimulatie en feedback.

Een andere beperking van dit proefschrift was de korte duur van de interventies. De interventies werden gedurende 3-4 weken vastgesteld, met 15-20 sessies (totale duur 3-10 uur), waardoor de tijd wellicht te kort was om significante positieve effecten vast te stellen. In de literatuur is beschreven dat een minimale dosis van tenminste 16 uur behandeling nodig is om het niveau te bereiken waarbij een functioneel resultaat plaatsvindt. Onze controlegroepen ontvingen een conventioneel revalidatieprogramma, alleen of in combinatie met een namaakstimulatie, waardoor ook het herstel van het bewegingsvermogen kan worden gestimuleerd. Het is beschreven dat het merendeel van de resultaten ten faveure van elektrische stimulatie gevonden werd wanneer dit werd vergeleken met een groep CVA-patiënten die geen enkele therapie ontvingen. Wij includeren slechts patiënten om een homogene groep te krijgen en het was niet ethisch de controlegroep zonder behandeling te laten. Toekomstige studies kunnen gericht zijn op het vergelijken van effecten van interventies op niet-opgenomen patiënten die op een andere wijze behandeld worden.

Kwantitatieve looppatroonanalyse resulteert in 124 parameters met betrekking tot tijd-afstand, kinematica en kinetica vastgesteld in sagittale, frontale en transverse vlakken. Het is niet eenvoudig een besluit te nemen over de beste parameter bij het presenteren van de effectiviteit van de therapeutische interventies. Toekomstige studies zouden zich kunnen richten op verschillende goed herhaalbare looppatroon-parameters met een langere follow-up.

Tenslotte is het belangrijk te beseffen dat het looppatroon na een CVA uiteindelijk een adaptief, individueel resultaat is met bijdrage van zowel neurologisch herstel en gedragsmatige compensatiestrategieën, gebaseerd op deels herstelde verloren gegane functies. Toekomstige studies kunnen wellicht de “beste functionele adaptieve looppatronen” voor hemiplegische patiënten na CVA beschrijven, zodat de therapeutische interventies als succesvol kunnen worden beoordeeld wanneer dit bedoelde patroon bereikt is.

Curriculum Vitae and List of Publications

M. Gunes Yavuzer was born on February 12th, 1968 in Kahramanmaras, Turkey. On completion of her high school education in Ankara, she was accepted by the Ankara University Medical School in 1986. After successfully graduating from that university with a medical degree in 1992, she did her residency on Physical Medicine and Rehabilitation (PMR) at Ankara University from 1992 to 1996. She has been working as a specialist (1996-2003) and full-time associate professor (2003 to date) in the same department with a commitment for both medical student and resident training, as well as patient care. In 1998 and 2003 she worked in Wayne State University, Rehabilitation Institute of Michigan, Research Department in Detroit, USA for 18 months. She received a certificate from the European Board of PMR in 2004. Her teaching and research interest areas are mainly neurorehabilitation and clinical gait analysis and she has been conducting extensive interdisciplinary research. She has been invited both nationally and internationally to give lectures on various subjects related to PMR but mostly on gait analysis. She is currently a member of the Editorial Board of the journals: Europa Medicophysica, Turkish Journal of Physical Medicine and Rehabilitation, and ACTA Rheumatologica Turcica. The author is married and has one son named Ata.

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