Investigation into the Immediate Effect of Ankle Taping on Temporal Spatial Gait Parameters and Affected Ankle Kinematics in Ambulant Adult Hemiplegic Patients

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DECLARATION

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SYSTEMATIC REVIEW ABSTRACT

BACKGROUND

Ankle Foot Orthoses (AFOs) are considered as the most suitable lower limb orthosis to correct gait deficits related to ankle instability. AFOs are recommended to minimize gait deviations and to correct drop foot or equinus foot in hemiplegic patients.

OBJECTIVES

To identify the effectiveness of different ankle orthoses and/or supports on the temporal, spatial, kinetic and kinematic gait parameters. To critically appraise the methodological quality of the included studies and to provide a description of the studies with a view to identify opportunities to improve future research quality.

METHODS

Search strategy

A comprehensive search was conducted between March and October 2010, and updated in August 2011. Thirteen computerized bibliographic databases were individually searched, namely PubMed Central, Cohrane Library, CINAHL, OT Seeker, SPORTDiscus, PsyARTICLE, PEDro, Proquest, Biomed Central, Science Direct, Clinicaltrials.gov, Web of Science, and Ingenta Connect. All databases were searched since their inception. The following key terms were used: stroke, hemipleg*, assistive device*, ankle foot orthos*, AFO, (splint*), taping, and strapping. A secondary search (pearling) was conducted by screening the reference lists of all eligible full text studies. The authors of the unpublished studies were conducted to minimize publication bias.

Selection criteria

The following selection criteria applied: all relevant randomized and non-randomized controlled trails published in English; participants were post-stroke patients older than eighteen years; interventions included any type of ankle foot orthosis (AFO), ankle taping or strapping and ankle foot splint without any additional intervention and the comparison/control groups were limited to walking without support, either barefoot or walking with shoes only. Studies were excluded when the outcome measures did not focus on at least one of the following: temporal spatial gait parameters, kinetic gait parameters or kinematic gait parameters.

Data collection and analysis

Two reviewers independently selected trials for inclusion and assessed methodological quality. The data was extracted by the primary reviewer and validated by a second reviewer. In event of disagreement, a third reviewer was asked to re-evaluate until consensus could be reached. Homogenous data were statistically summarized in sub-group meta-analysis using Revman© Review Manager Software. The results of heterogeneous data were summarized in a narrative form.

MAIN RESULTS

The search yielded 11134 initial hits. Sixteen studies met the inclusion/exclusion criteria. The studies investigated the immediate effect of various types of AFOs on a broad range of temporal spatial gait parameters mainly gait speed, cadence, stride and step length. Only two studies reported on the kinetic and six on various kinematic gait parameters. The meta-analysis yielded significant improvement in gait speed (0.06 m/s; 95% CI 0.04, 0.08. $p < 00001$), walking cadence (5.41; 95% CI 3.79, 7.03. $p < 00001$), stride length (6.67; 95% CI 3.29, 10.06. $p < 00001$) and step length (2.66; 95% CI 1.59, 3.72. $p < 0.00001$).

CONCLUSION

AFOs are effective to improve mobility, gait speed, cadence, stride and step length for post-stroke patients and may have a positive impact on the daily function of post-stroke patients. . The long term benefit or adverse effects of AFOs are still inconclusive. The effectiveness of AFOs on the kinetic and the frontal- or transverse- plane joint kinematics is largely unresolved. There is insufficient evidence to either support or refute the effectiveness of taping/strapping and splinting of the ankle on hemiplegic gait.

EXPERIMENTAL STUDY ABSTRACT

BACKGROUND

Temporal, spatial and affected ankle kinematic gait parameters of adults with hemiplegia are significantly different from the normal able-bodied population. Enabling hemiplegic patients to walk is a major goal of rehabilitation programs. Taping of the plegic ankle could be utilized by therapists as external support of the ankle to improve foot position and placement during gait rehabilitation.

OBJECTIVE

The purpose of the study was to describe the immediate effect of neutral ankle taping on temporal spatial gait parameters and ankle joint kinematics of the affected ankle in ambulant adult hemiplegic patients.

METHODS

A clinical trial using a crossover randomized testing order was conducted on a convenient sample of ten ambulant hemiplegic patients at the Physiotherapy and Motion Analysis Clinic, Faculty of Health Sciences, Stellenbosch University, Tygerberg, Cape Town, South Africa.

The affected ankle joint was taped in a neutral talocrural dorsiflexion/ plantarflexion and neutral hindfoot inversion/ eversion position using rigid adhesive tape (5 cm). The gait parameters were analysed according to the Plug-In Gait Model using a motion analysis system (Vicon Nexus 1.1.7; Vicon Motion System Limited, Oxford, UK). The analyses were repeated six times for each testing condition and the average values were used for further analysis. The data were analyzed using Least Square Means tests and post hoc Fisher (Least Significant Difference) LSD multiple comparison tests to determine the significant differences at 95% confidence level.

RESULTS

The main results of the study indicate that taping of the affected ankle joint in a neutral position does not significantly improve ($p>0.5$) temporal spatial gait parameters and ankle joint kinematics in ambulant adult hemiplegic patients. The following positive trends were however found and need to be further explored in larger homogeneous study samples: ankle taping of ambulant adult hemiplegic patients has limited benefits on selected temporal parameters as ankle taping could potentially improve cadence. Ankle taping could decrease plantarflexion of the plegic leg at initial contact.

CONCLUSIONS

A systematic review revealed no conclusive evidence either to support or refute the beneficial effects of ankle taping on gait parameters of ambulant adult hemiplegic patients. Ankle taping of ambulant adult hemiplegic patients has potential clinical benefits on temporal, spatial and affected ankle kinematics, gait cadence and affected leg swing and stance duration.

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ABBREVIATIONS

AFOs:	Ankle-foot orthoses
COM:	Center of mass
COP:	Center of pressure
DCRC:	Delft Community Rehabilitation Center
GRFs:	ground reaction forces
KAFO:	Knee- ankle-foot orthosis
L/RANK:	Left and right ankle
L/RHEE:	Left and right heel
L/RTIB:	Left and right tibia
L/RTOE:	Left and right toe
L/RASI:	Left and right anterior superior iliac spine
L/RKNE:	Left and right knee
L/RPSI:	Left and right posterior superior iliac spine
L/RTHI:	Left and right thigh
PAFOs:	Plastic-ankle-foot orthoses
SACR:	Sacral
TBH:	Tygerberg Hospital
2-D:	2 dimensions
3-D:	3 dimensions

DEFINITIONS

Ankle stability: It is a term used to describe the ligamentous and muscular structure that support the ankle foot complex which include the proximal and distal tibiofibular joints ligaments and the ligaments that support the subtalar joint and limit extreme joint range of motion, particularly calcaneal inversion (Mueller, 2005).

Splinting: It is a treatment option usually required to maintain position, correct a contracture or to encourage function and can be made from several materials, e.g. plaster materials, thermoplastics or neoprene. Some patients require two splints: one may need to be worn at night to maintain joint position and another during the day to aid independence (Bromley, 2005).

Taping/strapping: Taping or strapping is the application of adhesive (elastic or rigid) on the skin, to physically align muscles or joints in a certain position (Amminaka & Gribble, 2005).

GAIT TERMINOLOGY

Cadence: It is the number of steps taken by a person per unit of time. Cadence may be measured as the number of steps per second or per minute (Olney, 2005).

Center of mass (COM): The human's centre of mass lies approximately anterior to the second sacral vertebra (S2) when all the segments of the body are aligned in the anatomical position. Location of the COM depends on the proportions (weight distribution) of the human body (Levangie, 2005).

Center of pressure (COP): It is the point on the ground through which a single resultant force appears to act, although in reality the total force is made up of innumerable small force vectors, spread out across a finite area on the surface of the platform (Whitte, 2007).

Degree of toe-out: It is the angle of foot placement (FP) and may be found by measuring the angle formed by each foot`s line of progression and a line intersecting the center of the heel and the second toe (Olney, 2005).

Double support Duration (time): It is the amount of time spent with both feet on the ground during one gait cycle (Olney, 2005).

Foot contact area: The area of the floor touched by the foot during the stance phase (Macellari, Giacomozzi & Saggini, 1999).

Gait kinematics: The study of the joints` range of motion during walking (Gibson, Jeffery & Bakheit, 2006). The geometric description of motion during walking in terms of the displacement, joint range/angles, position and orientation of body segments and the corresponding linear and angular velocities and acceleration of body segments and joints; but without reference to the forces involved.

Gait kinetics: The study of the forces acting on the body and the powers generated by it during walking (Gibson et al., 2006).

Gait speed: The rate of forward motion of the body, which can be measured in meters or centimeters per second, meters per minute, or miles per hour. Scientific literature favors meters per second (Olney, 2005).

Ground reaction forces: It is the forces applied downward to the ground by the foot and upward by the ground to the foot (Olney, 2005).

Initial contact (IC): (Also called heel contact or heel strike). It is the event that referring to the instant at which the heel of the leading extremity strikes the ground (Olney, 2005).

Initial Swing (ISw): It is the event when the toe leaves the ground and continues until maximum knee flexion occurs (Olney, 2005).

Loading response (LR): It is gait event which begins at initial contact and ends when the contralateral leg lifts off the ground at the end of the double-support phase. It occupies about 11% of the gait cycle (Olney, 2005).

Mid-Stance: 50% of the time interval from initial contact to pre-swing (Gibson et al., 2006).

Mid-Swing: 50% of the period from pre-swing to the next initial contact (Gibson et al., 2006).

Moments: Internal moments are moments generated by the muscles, joint capsules and ligaments to counteract the external forces acting on the body. However, these external forces such as GRF produce external moments about the joints (Olney, 2005).

Pre-Swing (PSw): It is the last 10% of the stance phase and begins with initial contact of the contralateral foot (at 50% of the gait cycle) and ends with toe-off at 60% of the gait cycle (Olney, 2005).

Stance duration: The time taken from initial contact on one leg to pre-swing on the same leg (Macellari et al., 1999).

Stance phase: The period when one foot is in contact with the ground, expressed as a percentage of the walking cycle (Macellari et al., 1999).

Step: It is the sequence of events between contact of one foot and the next contact of the opposite foot (Huxham, Gong, Baker, Morris & Lansek, 2006).

Step length: The distance between a point on one foot at its contact and the same point on the opposite foot at the next contact along the direction of progression (Huxham et al., 2006).

Step duration (time): It is the interval between the contact of one foot and the next contact of the opposite foot (Huxham et al., 2006).

Step width: The terms step width and stride width (SW) can be used interchangeably and both represent the distance between a point on one foot, usually at it is initial contact (IC)/ foot strike and the same point on the other foot at the subsequent contact (Huxham et al., 2006).

Stride: It is the sequence of events between contact of one foot and the next contact of the same foot (Huxham et al., 2006).

Stride duration (time): It is the interval between contact of one foot and the next contact of the same foot (Huxham et al., 2006).

Stride length: The distance between a point on one foot at the initial contact and the same point on that foot at its next initial contact (Huxham et al., 2006).

Swing phase: The period when one foot is moving from pre-swing to the next initial contact, expressed as a percentage of the walking cycle (Macellari et al., 1999).

Swing duration: Is the time taken from pre-swing of one leg to the initial contact on the same leg (Kyriazis & Rigas, 2002).

Terminal stance (TSt): begins when the body is directly over the supporting limb at about 30% of the gait cycle and ends at a point just before initial contact of the contralateral extremity at about 50% of the gait cycle (Olney, 2005).

Terminal swing (TSw): It is the period from the point at which the tibia is in the vertical position to a point just before initial contact. It occurs after mid-swing when the limb is decelerating in preparation for initial contact (Olney, 2005).

Pelvic obliquity: Is the angle of rotation of the medio-lateral axis of the pelvis out of the horizontal plane (Baker, 2001).

Pelvic rotation: It is the angle of rotation of the pelvis about the vertical axis. It is the angle which the projection of the medio-lateral axis of the pelvis makes onto the horizontal plane with the laboratory medio-lateral axis (Baker, 2001).

Pelvic tilt: It is the angle of rotation about the medio-lateral axis of the pelvis (Baker, 2001).

Walking cycle: It is the period from initial contact of one foot to the next initial contact of the same foot (Macellari et al., 1999).

Width of base of support: It is the distance between a point on one foot, usually at it is initial contact and the same point on the other foot at the subsequent contact (Huxham et al., 2006).

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CHAPTER 1

INTRODUCTION

Stroke is the third most common cause of death and long-term disability in developed countries worldwide (WHO 2007). In South Africa, stroke was found to be the fourth most common cause of death (Connor & Bryer, 2005), and the leading cause of adult disability (Connor, Thorogood, Casserly, Dobson & Warlow, 2004). The prevalence in terms of disability is also higher in South Africa compared to developed countries (Boston, 2005). The survival rate for acute stroke has risen considerably in developed countries mainly due to the improvement in medical care (Turnbull, Charteris, & Wall, 1995). Around 80% of stroke survivors are discharged home and live for at least five years after the onset of a stroke (Saban, Sherwood, DeVon & Hynes, 2010). It is estimated that about 50% to 65% of post stroke survivors present with residual physical disability. Stroke therefore is thought to be the leading cause of long-term disability in adults (Mudge, Barber & Stott, 2009).

The pathophysiological basis of stroke is damage to the central nervous system caused by brain hemorrhage or lack in the arterial blood supply of the brain (Connor & Bryer, 2005; Olney & Richards, 1996). The effect of a stroke is varied and depends on the type of lesion, size, injured part, time since stroke onset (Internet Stroke Center, 2010; Jorgensen, Nakayama, Raashou & Olsen, 1995), and whether the patient received any rehabilitation (Tyson & Rogerson, 2009). Stroke patients often present with significant physical, psychological, and functional impairments that have an impact on their activities and quality of life (Desrosiers, Rochette, Noreau, Bourbonnais, Bravo & Bourget, 2006). These patients may also present with cognitive impairments, urinary incontinence, speech difficulties (Saban et al., 2010) and gait deviations (Bohannon, Horton & Wikholm, 1991). These gait deviations are recorded in around 70% of people following stroke and it is noted that on admission, more than 86% of patients admitted for rehabilitation are unable to ambulate independently (Jorgensen et al., 1995).

Walking after stroke has been described as slow, laborious, uncoordinated and abrupt due to muscle weakness, spasticity, impaired sensorimotor control (Bohannon et al., 1991), as well as the loss of the ability to control selective joint movements (Turnbull & Wall, 1995). Additional characteristics are slower walking speeds, decrease in gait cadence, shorter stride length, asymmetries in the temporal phases of the gait cycle (Turnbull & Wall, 1995), shorter step length and asymmetric patterns of movement (Chen, Patten, Kothari & Zajac, 2005). The hemiplegic gait pattern is also characterized by foot drop during the swing phase, a lack of heel strike and a medio-lateral ankle instability during the stance phase of the plegic leg (Rao, Chaudhuri, Hasso, Souza, Wening, Carlson & Aruin, 2008). Impaired dorsiflexion of the talocrural joint at pre-swing, reduced ankle dorsiflexion in swing and at initial contact, and reduced ankle power generation at push-off also contribute to the hemiplegic gait (Olney, Griffin, Monga & McBride, 1991).

To reduce these gait complications and to restore the walking ability of stroke patients, intensive functional rehabilitation programs (Desrosiers et al., 2006), orthoses and walking aids are often recommended in the sub-acute phase (Tyson & Rogerson 2009). Several types of ankle-foot orthoses (AFOs) are often recommended to minimize gait deviations by correcting a drop foot or equinus foot (Teasell, McRae, Foley & Bhardwaj, 2001). AFOs can influence the temporal spatial gait parameters such as gait speed, cadence, stride length, step length, stance and swing duration; as well as the affected ankle joint kinematics (Park, Chun, Ahn, Yu & Kang, 2009; Bleyenheuft, Caty, Lejeune & Detrembleur, 2008; Fatone & Hansen, 2007; Gök, Küçükdeveci, Altinkaynak, Yavuzer & Ergin, 2003). Ankle taping is considered an alternative ankle support technique, it can be used effectively as a temporary brace when an AFO is not available or is not cost-efficient (Bohannon, 1983). Hillier & Masters (2005) reported that ankle taping of the plegic ankle assists in achieving earlier heel-strike, maximum foot pressures during stance phase and increase the foot contact area. The stroke patients also reported perceived ankle stability during the gait cycle (Hillier & Masters, 2005).

The effectiveness of ankle taping is described in two theories, namely the mechanical theory and proprioception theory (Sawkins, 2005). The mechanical theory suggests that taping added mechanical support to the ligaments and limits the extreme ranges of motion at the talar and subtalar joints (Sawkins, 2005). Therefore, ankle taping immediately reduced inversion (Ricard, Sherwood, Schulthies & Knight, 2000; Lohrer, Alt & Gollhofer, 1999), eversion (Gross, Batten, Lamm, Lorren, Stevens, Davis & Wilkerson, 1994), and plantarflexion ranges in patients with chronic ankle instability (Lohrer et al., 1999). The proprioception theory suggests that taping may enhance proprioception and stimulate muscular control (Sawkins, 2005). Ankle taping therefore may provide orientation to promote appropriate foot placement, and it has also been hypothesized that taping may increase cutaneous input of the afferent nerves (Sawkins, 2005).

To evaluate if therapeutic interventions such as surgery, physiotherapy, medications, orthotics, and particularly, ankle taping, improve the gait pattern of a stroke survivor, clinical gait analysis are often recommended (McGinley, Baker, Wolfe & Morris, 2009). Clinical gait analysis typically seeks to discriminate between normal and abnormal walking as well as assessing change in walking over time (McGinley et al., 2009). The methods for identifying gait impairments after stroke include clinical assessment scales, observational gait analysis and instrumented measurement techniques of various complexities (Stokic, Horn, Ramshur & Chow, 2009). However, recent studies described the use of three dimensional gait analysis (3-DGA) as a valid laboratory based instrument in evaluation of post-stroke gait dysfunction and parameters (Park et al., 2009; Bleyenheuft et al., 2008; Fatone & Hansen, 2007; Gök et al., 2003). An intensive systematic literature review concluded that there are no published reports on the effect of ankle taping on the temporal spatial gait parameters such as gait speed, cadence, stride and step length as well as the ankle kinematics of post-stroke patients (See Chapter 2).

In South Africa, the health budget is already stretched, due to the costs of managing chronic diseases, such as HIV/AIDS and tuberculosis (Chopra, Lawn, Sanders, Barron, Karim, Bradshaw, et al., 2009). Although AFOs are

proven to be effective in minimizing gait deviations in stroke patients (Teasell et al., 2001) it is also expensive and extended waiting periods occur before patients' are issued with custom-made orthoses. There is a need for an alternative ankle foot device such as ankle taping, which is cost effective, easy to apply and could serve some of the functions of AFOs in the interim while patients are waiting for their AFOs to be manufactured or cannot afford AFOs. Taping of the plegic ankle could be utilized by therapists' as external support of the ankle to improve foot position and placement during gait rehabilitation. The main aim of this study will be to investigate the immediate effects of ankle taping on temporal spatial gait parameters and ankle joint kinematics of the affected and unaffected ankle in ambulant adult hemiplegic patients as measured by 3-D Gait Analysis.

A systematic review and analysis of the current evidence for the effectiveness of different type(s) of foot and ankle orthoses and/or supports (including taping, strapping and splinting) on temporal spatial, kinetic and kinematic gait parameters in adults with hemiplegia was undertaken and are presented in the following chapter.

CHAPTER 2

SYSTEMATIC REVIEW

2.1 INTRODUCTION

Stroke remains the primary cause of disability and presents an ongoing international health care problem (Bajaj, Schernhammer, Haidinger & Waldhor, 2010). The survival rate for acute stroke has risen considerably due to the improvements in medical care (Turnbull et al., 1995). Around 80% of stroke patients live for at least five years after the onset of a stroke (Saban et al., 2010). It has been reported that 50% to 65% of post-stroke survivors present with residual physical disability (Mudge et al., 2009). This includes psychological and functional impairments such as abnormal gait pattern that have an impact on their quality of life (Desrosiers et al., 2006).

Walking is the most important functional task of humans (Zajac, Neptune & Kautz, 2002). However, after a stroke the walking pattern is altered due to loss of the ability to control selective joint movements resulting in slow, laborious, uncoordinated and abrupt movements (Turnbull et al., 1995). The post-stroke walking deviations vary according to the site, size, type of lesion and the length of time since stroke onset. These deviations occur in 70% of stroke patients (Jorgensen et al., 1995). The hemiplegic walking pattern is characterized by a foot drop during the swing phase of the plegic leg, a lack of heel strike, a sagittal plane knee instability and medio-lateral ankle instability in stance (Rao et al., 2008). Additional characteristics such as slower walking speed, reduced gait cadence and stride length and asymmetries in the temporal phases of the gait cycle have also been documented (Turnbull et al., 1995).

Intensive functional rehabilitation programs are offered in the sub-acute phase to reduce the activity limitations experienced after a stroke. Even with these interventions, some hemiplegic patients will not be able to resume their previous activities (Desrosiers et al., 2006). The major goal of these programs is often to restore the walking ability of the hemiplegic patient. To lessen the

walking deviation and improve the walking ability of these patients, orthoses and walking aids have been recommended. In particular, the Ankle-foot orthosis (AFO) is considered the most suitable lower limb orthosis to correct any gait deficit related to ankle instability (Gok et al., 2003). There are several types of AFOs, all of which assist the plegic leg during the walking cycle (Rao et al., 2008; Gok et al. 2003) such as plastic, metallic and articulated AFOs. Although, AFOs are recommended to minimize gait deviations and to correct drop foot or equinus foot in hemiplegic patients, the effects of different types of AFOs on the hemiplegic gait have not been documented (Gok et al., 2003).

Ankle joint taping is a common prophylactic measure used by athletes to prevent inversion injuries (Delahunt, O'Driscoll & Moran, 2009). It is commonly used to reduce sprain incidence in athletes (Wilkerson, 2002). Ankle taping may be beneficial for the rehabilitation of the gait pattern in hemiplegic patients. It is cost effective and allows more active ankle movement and improved sensation during the walking cycle. Taping can influence the stride duration as well as foot contact area and maximum pressure during the stance phase of the plegic leg (Hillier & Masters, 2005).

The methods for identifying hemiplegic gait impairments include clinical assessment scales, observational gait analysis and instrumented measurement techniques of various complexities (Stokic et al., 2009). The purpose of clinical gait analysis is to differentiate between normal and abnormal walking and to assess change in walking over time. Gait analysis can be used to evaluate the effectiveness of therapeutic interventions such as surgery, physiotherapy, medications and orthotics in particular AFOs (McGinley et al., 2009).

The literature on the impact of AFOs on gait in adults with hemiplegic has been reviewed by Leung & Moseley (2002). These authors reported an absence of randomized controlled trials and confirmed the value of AFOs in terms of improved temporal spatial gait parameters and oxygen consumption but not for other types of ankle foot support and the effect on kinetic or the kinematic gait parameters. Nevertheless, the authors emphasized the variability of the types of orthoses and the poor methodological quality of the reviewed studies. Therefore this review aimed to systematically determine and analyze the

current evidence for the effectiveness of different type(s) of foot and ankle orthoses and/or supports on temporal spatial, kinetic and kinematic gait parameters in adults with hemiplegia.

2.1.1 Review questions

The primary questions for this systematic review were the following:

- What is the effectiveness of ankle foot orthoses on gait parameters in adult hemiplegic patients compared to walking barefoot or with shoes alone?

- What is the effectiveness of foot and ankle supports (taping, strapping and splinting) on gait parameters in adult hemiplegic patients compared to walking barefoot or with shoes alone?

2.1.2 Aim of review

The aim of this systematic review was to systematically identify, collate and analyze the current evidence for the effectiveness of different types of foot and ankle orthoses and/or supports on temporal spatial, kinetic and kinematic gait parameters in adult hemiplegic patients.

2.2 SPECIFIC OBJECTIVES

The specific objectives of this systematic review were to:

- Identify the effectiveness of different types of foot and ankle orthoses and/or supports on the following gait parameters in adult hemiplegic patients:

    - Temporal spatial gait parameters (including but not confined to gait speed, cadence, step length, stride length, width of the base of support, stance time, and swing time).

    - Kinetic gait parameters (including but not confined to moments, center of pressure [COP] and joint forces).

  - Kinematic gait parameters (including but not confined to linear and angular acceleration of joint angles or segment positions of the lower limbs, and pelvic position or movements such as tilt, obliquity and rotation).

- Provide a description of data (e.g. study sample; age of participants; type of intervention; outcome measurements) of the included studies.

- Critically appraise the methodological quality of the included studies with a view to identify opportunities to improve future research quality.

2.3 REVIEW METHODS

Prior to commencing this study, five electronic databases (PubMed, Cochrane library, Cinahl, Science Direct, and PEDro) were searched to verify if there were any published systematic reviews or meta-analyses reporting on the effectiveness of ankle foot orthoses and/or supports on gait parameters in adult hemiplegic patients. One systematic review was identified (Leung & Moseley, 2003) however, the reviewers decided to conduct a new systematic review since Leung & Moseley did not report on kinetic or kinematic gait parameters and more studies have been published in the last eight years.

A description of the systematic review process is provided in the section below. To achieve the review objectives, the inclusion and exclusion criteria were set, in particular the types of studies, participants, intervention, types of comparisons and the outcome of interest for the systematic review. Data extraction and synthesis are also explained. Lastly, to define the level of evidence and the methodological quality of the included studies, the methodological appraisal process that was followed, is described.

2.3.1 Inclusion criteria

2.3.1.1 Types of studies

All relevant randomized controlled trials (RCT's) and other experimental designs such as non-randomized control trials or quasi-randomised control trials, and before-after trials, were eligible to be included in this review. Only studies published as a full paper in the English language were included in this review.

2.3.1.2 Types of participants

Participants were limited to adults over eighteen years of age, diagnosed with hemiplegia as a result of cerebral vascular accident (also known as stroke) or brain injury. The participants were not limited due to gender, nationality, race, and culture.

2.3.1.3 Types of interventions

Studies were eligible to be included if the interventions included any type of foot and ankle orthoses and/ or supports such as:

- Ankle foot orthosis (AFO).
- Ankle taping or strapping.
- Ankle foot splint.

2.3.1.4 Types of comparison/control

Studies were eligible to be included in this review if the type of comparison was:

- Walking without support and either;
- Barefoot walking.
- Walking with shoes.

2.3.1.5 Types of outcome measures

The following outcomes of interest were included, but not confined to:

- Temporal spatial gait parameters as measured by using a gait pressure mat, stop watch and marks on the floor, photocells and timers, videography, walkway, or any similar measuring equipment.
- Kinetic gait parameters as measured by using active or passive marker systems with a force platform, 2-D or 3-D motion analysis systems or any similar measuring equipment.
- Kinematic gait parameters as measured by using passive or active marker systems, electromagnetic systems, electrogoniometers, 2-D or 3-D motion analysis systems, or any similar measuring equipment.

2.3.2 Exclusion criteria

2.3.2.1 Types of participants

Studies were excluded if the participants were under 18 years of age or diagnosed with any neurological conditions other than post-stroke hemiplegia such as Parkinson's disease, multiple sclerosis, muscular dystrophy or cerebral palsy.

2.3.2.2 Types of interventions

Studies were excluded if the interventions contained one of the following:

- Any lower limb orthosis or support other than a foot and ankle orthosis and/ or support such as:
    - Knee-ankle-foot orthosis (KAFO).
    - Hip or knee taping or strapping.
    - Hip or knee splinting.

- Any additional interventions combined with a foot and ankle orthosis and/ or supports (i.e. electrical stimulation or exercise program).

2.3.2.3 Types of outcome measures

Studies were excluded when the outcome measures did not focus on at least one of the following:

- Temporal spatial gait parameters.
- Kinetic gait parameters.
- Kinematic gait parameters.

2.3.3 Search strategy

An extensive search was conducted in April and October 2010 in all accessible library databases available at the Medical Library, Stellenbosch University, South Africa. Thirteen databases were searched, namely PubMed Central, Cohrane Library, CINAHL, OT Seeker, SPORTDiscus, PsyARTICLE, PEDro, Proquest, Biomed Central, Science Direct, Clinicaltrials.gov, Web of Science, and Ingenta Connect. All databases were searched since their inception to October 2010, thus no restriction was set on the publication date. Different search strategies were developed according to the indexing and search methods of each database. The following keywords were used: stroke, hemipleg*, assistive device*, ankle foot orthos*, AFO, splint*, taping, and strapping. MESH terms were used in PubMed and when applicable in other mentioned databases. Search strategies are illustrated in Appendix I. In addition, the principal reviewer conducted a secondary search (pearling) by screening the reference lists of all eligible full text studies. Therefore, the identified studies were retrieved and screened for eligibility. To minimize publication bias the primary reviewer identified studies by looking at the abstracts of international congress proceedings. The authors of the potential studies were contacted to obtain the detailed documents.

All possible titles were initially screened by the primary reviewer, followed by reading the abstracts of potential studies and finally the full text versions were obtained for the studies that met the inclusion and exclusion criteria. All the potential studies were independently verified by a secondary reviewer (GIJ).

2.3.4 Data extraction

Data were extracted from the selected studies by using the adapted “Joanna Briggs Institute” JBI data extraction form (Hemingway et al., 2006) (Appendix II). Extracted data were stored on a Microsoft Excel worksheet. The relevant information extracted from each included study included the title, author, and year of publication, study design, population, intervention, outcome measures, statistical test results and methodological quality score. The data were extracted by the primary reviewer (MA) and validated by the secondary reviewer (GIJ).

2.3.5 Level of evidence

Two reviewers (MA & GIJ) assessed the evidence of the retrieved studies using the JBI scale of level of evidence (Table 2.1). It determines the possible bias within different study designs, errors within the measurement procedures, and errors interpreting the results.

Table 2.1: JBI scale of level of evidence: Effectiveness

Level of evidence	Effectiveness
Level 1	Evidence obtained from a systematic review of all relevant RCT's
Level 2	Evidence obtained from at least 1 properly designed RCT
Level 3.1	Evidence obtained from well designed controlled trials without randomization
Level 3.2	Evidence obtained from well designed cohort case control analytical studies
Level 3.3	Evidence obtained from multiple time series with without an intervention. Dramatic results in uncontrolled experiments
Level 4	Opinion of respected authorities based on clinical experience, descriptive studies or reports of expert committees

2.3.6 Methodological appraisal

The tools recommended by the Joanna Briggs Institute were used to appraise the methodological quality of the included studies. Due to the diverse nature of the studies included in this review, two different JBI tools were used. The JBI critical appraisal checklist for randomised and pseudo-randomised studies consists of ten criteria (Appendix III). The JBI critical appraisal checklist for cohort/case control appraisal includes nine criteria (Appendix IV).

Before utilizing the JBI tools the three reviewers discussed and clarified each criterion included in the appraisal tools. A common understanding of the terms "unclear" and "not applicable" were explored, discussed and clarified a priori. Each study was independently reviewed by the first (MA) and second reviewer (GIJ). In the event of a disagreement, a third reviewer (MB) was asked to re-evaluate until consensus could be reached.

2.3.7 Data synthesis and analysis

Homogenous data were summarized statistically when two or more studies were comparable in terms of patient demographics, intervention or control (barefoot, shoe) and outcome measure(s). Revman© Review Manager Software (Revman© Information Management Systems, 2008) was used to perform the meta-analysis.

To provide meaningful clinical comparisons, studies were grouped according to intervention type (different AFOs). This enabled subgroup meta-analysis as well as provides an overall summary statistic for the effect of AFOs. The fixed effect, weighted differences and 95% confidence intervals (CI) were calculated for continuous data to analyze the effect sizes of the interventions. Statistical heterogeneity between trials were assessed using the I-squared statistic available in RevMan. The primary reviewer explored the factors that could lead to homogeneous analysis among the included studies and when statistically pooling was not appropriate, the results were summarized in narrative form.

2.4 RESULTS

2.4.1 Research results and description of studies

A total of 11134 initial hits were found during the search of the thirteen databases. Of these, 102 abstracts were reviewed. They included published studies and conference proceedings. Authors of conference proceedings were contacted by the principal reviewer for the full-text studies. None of the conference proceedings were included as nil authors responded. Fifty four full-text studies were subsequently considered as being eligible for use in this systematic review. Of these 54 full-text articles, 38 articles did not meet the inclusion/exclusion criteria in terms of study design; language, type of intervention and type of comparison. The main excluded studies are summarised in (Appendix V). Thus, 16 eligible full-text studies were included in this systematic review. The results of the search strategy for each database are presented in Appendix I. The search results are illustrated in Figure 2.1.

Databases	Initial Hits	Accepted titles	Accepted abstracts	Accepted articles	Duplicates between databases
Pupmed Central	3146	38	26	19	
Cochrane Library	623	24	15	6	
CINAHAL	1564	37	25	16	
OT Seeker	140	4	4	3	
SPORTDiscus	796	21	13	9	
PsyARTICLE	214	1	0	0	64
PEDro	610	7	4	2	
Proquest	480	12	9	7	
Biomed Central	688	4	0	0	
Science Direct	2100	27	21	7	
Clinicaltraials.gov	192	2	0	0	
Web of Science	198	32	23	16	
Ingenta Connect	383	3	1	0	
Total	11134	210	141	85	

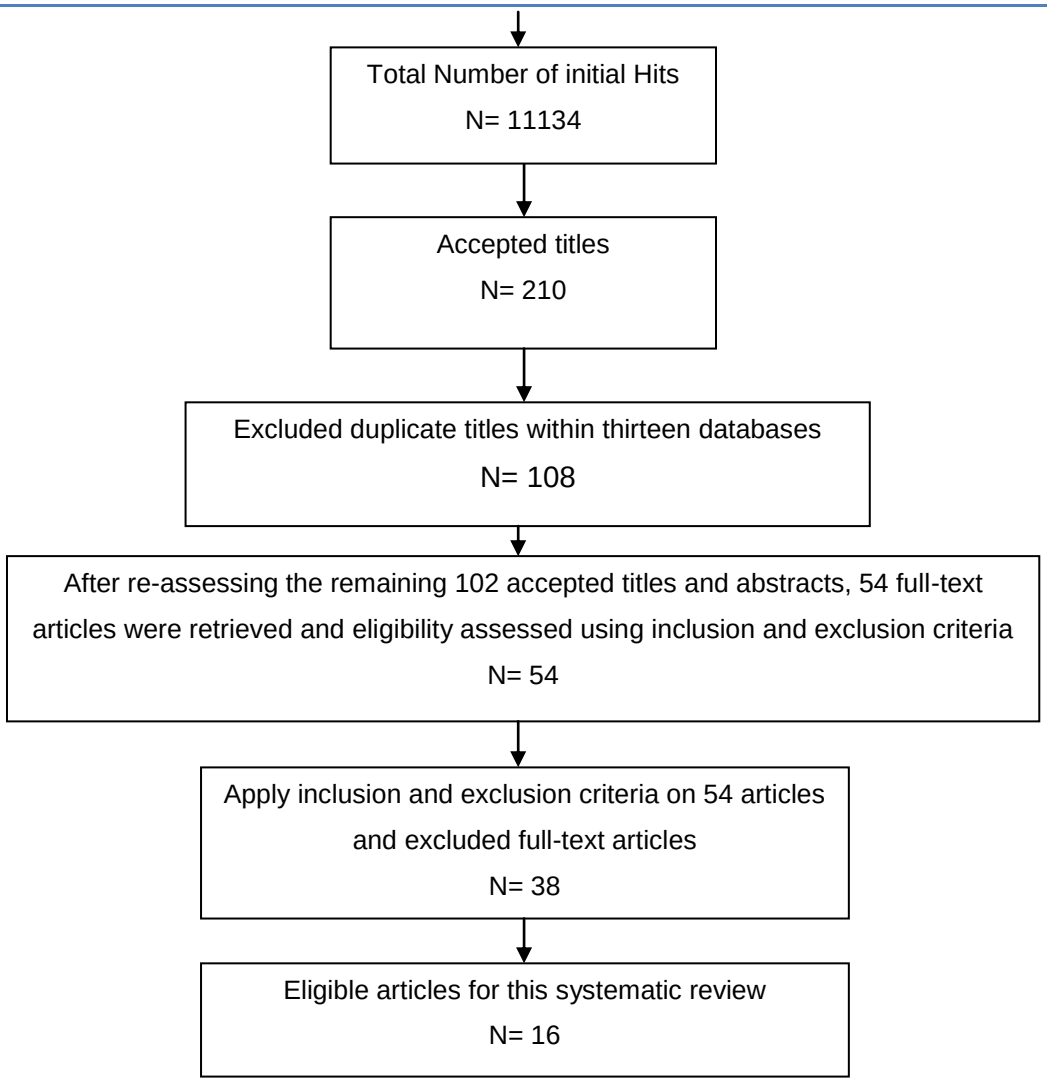


Figure 2.1: Search results

2.4.2 Risk of bias assessment

2.4.2.1 Evidence hierarchy

The sixteen eligible studies were classified according to the JBI scale of level of evidence (Table 2.2). de Wit, Buurke, Nijlant, Ijzerman & Hermens (2004) made use of a randomization procedure between two groups of participants and was classified as Level 2, while the majority of the identified studies were non-randomized experimental studies and thus classified as a Level 3.1. Only one Retrospective study was included and thus classified as a Level 3.1.The study design and the level of evidence are summarized in Table 2.2.

Table 2.2: Description of study design and the level of evidence

Study	Research design	Level of evidence
de Wit et al., 2004	Randomized control clinical trial	Level 2
Park et al., 2009	Cross-over repeated measures clinical trial	Level 3.1
Tyson & Rogerson, 2009	Cross-over clinical trial with randomized testing order	Level 3.1
Abe et al., 2009	Cross-over clinical trial with randomized testing order	Level 3.1
Pavlik, 2008	Cross-over clinical trial with randomized testing order	Level 3.1
Rao et al., 2008	Cross-over clinical trial with randomized testing order	Level 3.1
Bleyenheuft et al., 2008	Cross-over clinical trial with randomized testing order	Level 3.1
Fatone & Hansen, 2007	Cross-over clinical trial	Level 3.1
Pohl & Mehrholz, 2006	Cross-over clinical trial with randomized testing order	Level 3.1
Gök et al., 2003	Cross-over clinical trial with randomized testing order	Level 3.1
Tyson &Thornton, 2001	Cross-over clinical trial with randomized testing order	Level 3.1
Hesse et al., 1999	Cross-over clinical trial	Level 3.1
Hesse et al., 1996	Cross-over clinical trial	Level 3.1
Burdett, 1988	Cross-over repeated measures clinical trial	Level 3.1
Mojica et al., 1988	Cross-over clinical trial with randomized testing order	Level 3.1
Esquenaze et al., 2009	Retrospective study design	Level 3.2

2.4.2.2 Methodological Quality

The methodological quality of the included studies was assessed using the JBI critical appraisal checklist. Fifteen were assessed using the nine items of the

JBI critical appraisal checklist for cohort/ case controlled trails. The reviewers were not able to answer item number seven (7) and scored zero (0) since all the included studies reported the immediate effects of the AFOs and ankle foot supports. The fifteen studies were thus assessed using an eight item score and scores ranged between 5/8 and 8/8, with an average score of 7.06. Table 2.3 provides a brief summary of how each study scored on the JBI critical appraisal checklist.

Table 2.3: Scores according to JBI critical appraisal checklist for cohort/ case controlled trails.

Studies			JBI scoring criteria								
Number	Authors	Year of publication	Sample representative of population as a whole	Patients similar in the course of their condition	Bias was minimized in sample selection	Confounding factors were identified and strategies to deal with it stated	Outcomes were assessed objectively	Follow-up carried out over sufficient time	Outcomes were measured in reliable way	Appropriate statistical analysis used	Total score
			1	2	3	4	5	6	7	8	
1	Park et al.,	2009	1	1	1	0	1	1	1	1	7/8
2	Tyson & Rogerson,	2009	1	1	1	0	1	1	1	1	7/8
3	Abe et al.,	2009	1	1	1	0	1	1	1	1	7/8
4	Esquenaze et al.,	2009	1	1	1	0	1	1	1	1	7/8
5	Pavlik,	2008	1	1	1	0	1	1	1	1	7/8
6	Rao N et al.,	2008	1	1	1	0	1	1	1	1	7/8
7	Bleyenheuft et al.,	2008	1	1	1	0	1	1	1	1	7/8
8	Fatone & Hansen,	2007	1	0	0	1	1	1	1	1	6/8
9	Pohl & Mehrholz,	2006	1	1	1	1	1	1	1	1	8/8
10	Gök et al.,	2003	1	1	1	1	1	1	1	1	8/8
11	Tyson &Thornton,	2001	1	1	1	1	1	1	1	1	8/8
12	Hesse et al.,	1999	1	1	1	1	1	1	1	1	8/8
13	Hesse s et al.,	1996	1	1	1	1	1	1	1	1	8/8
14	Burdett et al.,	1988	1	1	1	0	0	1	0	1	5/8
15	Mojica et al.,	1988	1	1	0	0	1	1	1	1	6/8

Only one study (de Wit et al., 2004) was assessed using the eleven items of the JBI critical appraisal checklist for randomized and quasi-randomized trials and scored 6/11 (Table 2.4).

Table 2.4: Scores according to JBI critical appraisal checklist for randomized and quasi-randomized control trials for de Wit et al., 2004

No	JBI criteria	de Wit et al 2004
1	Random allocation	1
2	Blinding of the participants	0
3	Allocation concealed	0
4	Outcomes of withdrew people	0
5	Assessor blinding	0
6	Similarity baseline	1
7	Confounding factors	0
8	Validity of the outcomes measured	1
9	Reliability of outcomes measured	1
10	Statistical analysis	1
11	Follow-up	1
Total score		**6/11**

2.4.3 Characteristics of studies

Description of the study samples, interventions and outcome measures of the included studies are provided in the section below.

2.4.3.1 Study sample description

The participants included in the studies were post-stroke adult males and female patients. Only three studies included stroke patients with brain injury or tumor surgery. The age of participants ranged between 29-79 years. The average sample size was 20 participants. Time since stroke onset varied considerably and ranged from 36 days to 8.2 years (Table 2.5).

Table 2.5: Summary of study participants

Study	Country	Diagnosis	Sample size	Age (years) Mean ± SD	Time post stroke	Gender		Affected side	
						Male	Female	Right	Left
Park et al., 2009	Korea	Stroke	17	57.7 ± 7.5	36.8 ± 11.9 Days	10	7	11	6
Tyson & Rogerson, 2009	UK	Stroke	20	65.6 ± 10.4	6.5 ± 5.7 Weeks	Not specified		7	13
Abe et al., 2009	Japan	Stroke	16	29 - 79	2-113.8 Months	11	5	10	6
Esquenaze et al., 2009	Turkey	Stroke	42	60.9 ± 15.7	Not specified	23	19	17	25
Pavlik, 2008	USA	Stroke	4	60 ± 13.4	75 Months	3	1	2	2
Rao et al., 2008	USA	Stroke	Group 1 13	65.62 ± 13.48	0.68 ± 0.36 Months	8	5	6	7
			Group 2 27	61.03 ± 13.18	50.76 ± 37.49 Months	6	21	16	11
Bleyenheuft et al., 2008	Belgium	Stroke	10	49 ± 20	28 ± 18 Months	9	1	5	5
Fatone & Hansen, 2007	USA	Stroke	13	51.5 ± 6.8	8.2 ± 4.5 Years	7	6	3	10
Pohl & Mehrholz, 2006	Germany	Stroke 20 brain injury 8	28	51.7 ± 16.1	2.6 Months	20	8	10	18
de Wit et al., 2004	Nether-lands	Stroke	20	61.2	25.6 Months	12	8	9	11
Gök et al., 2003	Turkey	Stroke	12	54	67 Days	9	3	Not specified	
Tyson &Thornton, 2001	UK	Stroke	25	49.9 ± 1	8.3 ± 5.5 Months	16	9	16	9
Hesse et al., 1999	Germany	Stroke 20 Tumor surgery 1	21	58.2	9.4 Months	11	10	12	9
Hesse et al., 1996	Germany	Stroke16 Tumor surgery 3	19	52.2	5.1 Months	12	7	9	10
Burdett et al.,1988	USA	Stroke	19	61.9 ± 10.7	114.5 ± 108.5 Days	10	9	Not specified	
Mojica et al.,1988	Japan	Stroke	8	Range (46-66)	20.7 Weeks	5	3	5	3

2.4.3.2 Description of interventions

The different types of interventions used in the selected studies are summarized in Table 2.6. All included studies reported on the immediate effect of different types of AFOs on gait in hemiplegic patients. Fifteen of the included studies mentioned the exact type(s) or specifications of the AFO that was investigated. All the included studies mentioned that AFOs were fitted and fabricated to be appropriate for each participant according to their kinesiological and clinical needs. None of the included studies reported the effects of taping, strapping or splinting on the hemiplegic gait parameters.

In four studies (Esquenaze et al., 2009; Pavlik, 2008; Pohl & Mehrholz., 2006; Burdett et al., 1988), the types of AFOs were not similar within each intervention group. One of these studies (Esquenaze et al., 2009) did not mention the exact types of AFOs used but merely indicated that they were assigned according to the patients' clinical needs.

The types of comparisons (control) were standardized for each intervention group in all included studies, either AFOs versus barefoot or shoe alone walking not combination between the two, but were not similar across the included studies. A total of twelve intervention groups examined the effect of AFOs or supports in comparison to shoe walking. Ten intervention groups reported on the effect of AFOs compared to walking barefoot (Table 2.6).

Table 2.6: Description of interventions and control

Intervention	Study	Description of intervention	No	Control	
				Barefoot	Shoe
Plastic AFO	Park et al., 2009 (G 1)	Anterior AFO	17	√	
	Park et al., 2009 (G 2)	Posterior AFO	17	√	
	Tyson & Rogerson, 2009	Ossur Leaf Spring AFO	20	√	
	Abe et al., 2009	Three types of Plastic AFOs (Shoehorn-type PAFO, Double-Flexue joint AFO and flexure joint AFO	16	√	
	Rao et al., 2008 (G 1)	Custom- Molded Polypropylene AFOs	13		√
	Rao et al., 2008 (G 2)	Custom- Molded Polypropylene AFOs	27		√
	Bleyenheuft et al., 2008 (G 1)	Prefabricated AFO	10		√
	Fatone & Hansen, 2007	Custom, Thermoplastic-Articulated AFO	12		√
	de Wit et al., 2004	Three types of plastic Non-Articulated AFOs	20		√
	Gök et al., 2003 (G 1)	Seattle Polypropylene AFO	12	√	
	Tyson &Thornton, 2001	Plastic Hinged AFO with A metal ankle joint	25		√
	Mojica et al., 1988	Plastic AFO	8	√	
Metallic AFO	Bleyenheuft et al., 2008 (G 2)	Chignon Dynamic AFO	10		√
	Gök et al., 2003 (G 2)	Metallic AFO	12	√	
Valens Caliper	Hesse et al., 1999	Valens Caliper attached with Firm Shoe	21	√	
	Hesse et al 1996	Valens caliper	19	√	√
Ankle Brace	Burdett et al., 1988 (G1)	Air-Stirrup	19		√
Not specified*	Esquenaze et al., 2009	According to individual clinical needs	42	√	
	Pavlik, 2008	Polypropylene AFO (Articulated AFO and Solid AFO)	4		√
	Pohl & Mehrholz., 2006	Quasi-Double Stopped, Semi-Rigid AFO	28		√
	Burdett et al., 1988 (G2)	Metallic and Plastic AFO	11		√

***different types of AFO were used within each study group
G1 Group 1 / **G2** Group 2

2.4.3.3 Description of outcome measurements

The outcome measures used to calculate the temporal spatial, kinetic and kinematics gait parameters in all the included studies are summarized in Tables 2.7 to 2.9.

Outcome measures used to calculate the temporal spatial parameters

The temporal spatial gait parameters were assessed in all the included studies. Different instruments and testing procedures were used. The majority of the studies made use of a form of walkway often combined with a timer. However, numerous different walk tests and instruments were employed in the studies. These included force plates, paper walkways and ground walking tests of various lengths. To facilitate data analysis, outcome measure instruments were grouped into four categories (Table 2.7).

Table 2.7: Outcome measures used to calculate the temporal spatial gait parameters.

Study		Description of instruments
3-D motion analysis	Park et al., 2009	Motion analysis system
	Bleyenheuft et al., 2008	3-D Movement Analysis on A force-Measuring Treadmill
	Fatone & Hansen, 2007	Motion Research Analysis Laboratory
	Gök et al., 2003	Vicon 370 Motion Analysis System
Gait analysis system	Esquenaze et al., 2009	Electronic Gait Mat
	Rao et al., 2008	GAITRite System
	Hesse et al., 1999	Biaxial Goniometers (Penny & Giles, type 180) Infotronic system (Hermenes et al., 1986)
Walking test	Tyson & Rogerson, 2009	5 Meters Walking Test (Tyson & DeSouza, 2004)
	Abe et al., 2009	8 Meters Paper Walkway
	Pavlik, 2008	10 Meters Paper Walkway
	Pohl & Mehrholz, 2006	Platform Walkway (8 x 1.2 m) with two embedded Force Plates (60 x 40 cm).
	de Wit et al., 2004	10 Meters Walkway
	Tyson &Thornton, 2001	7 Meters Paper Walkway Foot Prints
	Hesse et al., 1996	10 Meters Walking Test, Stopwatch
	Mojica et al., 1988	10 Meters Walking Test
Other procedures	Burdett et al., 1988	Videotaping Procedure Footprint

Outcome measures used to calculate the kinetic gait parameters

Five studies assessed the effect of AFOs and Valens Calipers on kinetic gait parameters. Ground reaction forces (GRFs), mechanical work and center of pressure (COP) were assessed. Different instruments and procedures were used across these studies (Table 2.8).

Table 2.8: Outcome measures used to calculate kinetic gait parameters.

Study	Outcome measure	Moments	GRFs	Mechanical work	COP
Bleyenheuft et al., 2008	3-D Movement Analysis on a Force Measuring Treadmill Anatomical Markers (Davis et al., 1991) Methods of Willems et al., 1995, Detrembleur et al., 2003	√	-	√	-
Fatone & Hansen, 2007	Motion Analysis Research laboratory	-	-	-	√
Pohl & Mehrholz, 2006	Platform Walkway with two Force Plates (Stussi et al., 1980 & Hesse et al., 2004)	-	√	-	-
Gök et al., 2003	Two Force Plates with simultaneous measurement of the limb position	√	√	-	-
Hesse et al., 1999	Biaxial Goniometers (Penny & Giles, type 180) Infotronic System (Hermenes et al., 1986)	-	√	-	-

√ parameter tested / **-** parameter not tested
GRFs Ground reaction forces
COP Center of pressure

Outcome measures used to calculate the kinematic gait parameters

Six studies reported on the effect of AFOs and Valens Calipers on the kinematic gait parameters in adult hemiplegic patients. The selected studies measured the sagittal angles of different affected lower limb joints. None of the selected studies reported on the frontal or transverse joint angles (Table 2.9).

Table 2.9: Outcome measures used to calculate kinematic gait parameters

Study	Outcome measure	Sagittal Joint angles			Pelvic tilt	COG
		Hip	Knee	Ankle		
Park et al., 2009	3-D Gait Analysis (Motion Analysis System)	√	√	√	-	-
Bleyenheuft et al., 2008	3-D Movement Analysis on A force Measuring Treadmill Markers Model of Davis et al. (1991)	-	√	√	-	-
Fatone & Hansen, 2007	Motion Analysis Research laboratory Helen Hayes marker Set	-	-	√	-	-
Gök et al., 2003	3-D motion analysis (Vicon 370)	√	√	√	-	-
Hesse et al., 1999	Biaxial Goniometers (Penny & Giles, type 180) Infotronic System (Hermenes et al., 1986)	-	-	√	-	-
Burdett et al., 1988	Videotaping Procedure	√	√	√	-	-

√ parameter tested **/ -** parameter not tested
COG Center of Gravity

2.4.4 The effect of AFOs and ankle foot support on temporal spatial gait parameters

All the included studies (n=16) examined the effect of AFOs on temporal spatial gait parameters. This includes the temporal (n=16) and the distance gait parameters (n=14). Temporal gait variables included gait speed, cadence, stance time, swing time, single support time, double support time, stride time and step time. Distance gait variables included stride length, step length, step width and degree of toe-out.

2.4.4.1 The effect of AFOs and ankle foot support on temporal gait variables

Sixteen studies reported on the immediate effect of AFOs on the various temporal gait variables. The majority of the included studies reported on the immediate effect of different types of AFOs on the gait speed and cadence (Table 2.10).

Table 2.10: Summary of the studies in which temporal variables are reported

Study	Temporal variables							
	Speed or velocity	Cadence	Stance time	Swing time	Single support time	Double support time	Stride time	Step time
Park et al., 2009	√	√	-	-	√	√	-	-
Tyson & Rogerson, 2009	√	-	-	-	-	-	-	-
Abe et al., 2009	√	√	-	-	-	-	-	-
Esquenaze et al., 2009	√	√	√	√	-	√	-	-
Pavlik, 2008	√	-	-	-	-	-	-	-
Rao et al., 2008	√	√	√	-	-	-	-	-
Bleyenheuft et al., 2008	√	√	-	-	-	-	-	-
Fatone & Hansen, 2007	√	-	-	-	-	-	-	-
Pohl & Mehrholz, 2006	-	-	-	-	-	√	-	-
de Wit et al., 2004	√	-	-	-	-	-	-	-
Gök et al., 2003	√	√	-	-	-	√	-	√
Tyson &Thornton, 2001	√	√	-	-	-	-	-	-
Hesse et al., 1999	√	√	√	√	-	√	-	-
Hesse et al., 1996	√	√	-	-	-	√	-	-
Burdett et al., 1988	√	-	-	-	-	-	√	-
Mojica et al., 1988	√	√	-	-	-	-	-	-

√ parameter tested **/ -** parameter not tested

The immediate effect of AFOs on gait speed in adults with hemiplegia

Fifteen studies reported on the immediate effect of AFOs and ankle foot supports in gait speed. Gait speed was measured as meters per second, centimeters per second, or meters per minute. In order to summarize and synthesize the data, the reviewers recalculated the gait speed in meters/seconds (Figure 2.1).

Five studies (Abe et al., 2009; Park et al., 2009; Tyson & Rogerson, 2009; Gök et al., 2003; Mojica et al., 1988) report on the effect of Plastic AFOs (PAFOs) versus barefoot walking. The data of 73 participants were analyzed. There was no statistically significant effect in favour of PAFOs *(0.03 m/s; 95% CI -0.02, 0.08. p = 0.24).*

Four intervention groups (Bleyenheuft et al., 2008; "2 Groups" Rao et al., 2008; de Wit et al., 2004) reported on the effect of PAFOs versus shoe walking. This analysis included the data of 70 participants and the results favored walking with PAFOs *(0.05 m/s; 95% CI 0.03, 0.08. p = 0.005).* This analysis reported an extremely low heterogeneity ($I^2 = 0$).

Two intervention groups (Hesse et al., 1999; Hesse et al., 1996) investigated the effect of Valens Caliper versus barefoot walking. The analysis included the data of 40 participants. There were no significant effects in favour of the Valens Caliper *(0.08 m/s; 95% CI - 0.00, 0.16. p = 0.06).* Unacceptably high statistical heterogeneity *($I^2 = 82\%$)* was reported.

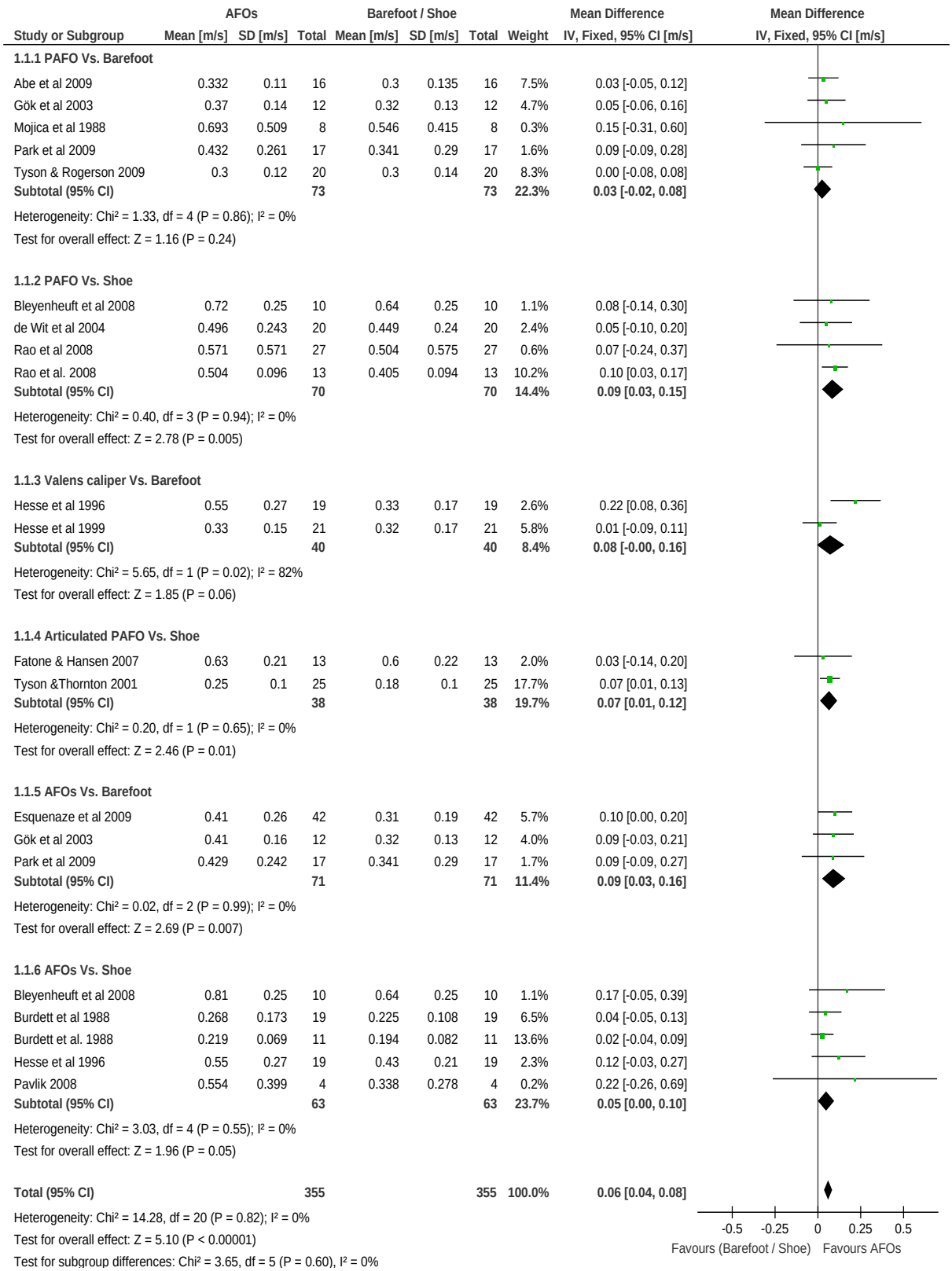
Two studies (Fatone & Hansen, 2007; Tyson &Thornton, 2001) reported on the effect of Articulated PAFOs versus shoe walking. The analysis included the data of 38 participants. A statistically significant effect on gait speed in favour of articulated PAFOs *(0.07 m/s; 95% CI 0.01, 0.12. p = 0.01)* was found.

Three intervention groups (71 participants) investigated the effect of different types of AFOs on walking speed (Esquenaze et al., 2009; Park et al., 2009; Gök et al., 2003). The exact type of AFOs in each of these groups was either not fully described or no other studies reported on the same type of AFO. However, the effect of AFOs in the three groups was compared to shoe

walking. A meta-analysis showed a significant effect in favour of walking with AFOs *(0.09 m/s; 95% CI 0.03, 0.16. p = 0.007)* (Analysis 1.1.5). Another meta-analysis conducted in five intervention groups (63 participants) reported on the effect of different types of AFOs and Air-Stirrup versus shoe walking (Bleyenheuft et al., 2008; Pavlik, 2008; Hesse et al., 1996; “2 Groups” of, Burdett et al., 1988). This meta-analysis found a significant effect of walking with AFOs on gait speed *(0.05 m/s; 95% CI 0.00, 0.10. p = 0.05)* (Figure 2.1/Analysis 1.1.6).

Across all the intervention groups of the included studies (355 participants), walking with AFOs or ankle foot supports, compared to walking without AFOs either barefoot or using shoes only, significantly improved the gait speed *(0.06 m/s; 95% CI 0.04, 0.08. p < 00001)* (Figure 2.1/Analysis 2.1).

Figure 2.1: Forest plot depicting the immediate effect of AFOs or ankle foot supports versus either barefoot or shoe walking on gait speed in adults with hemiplegia



PAFO: Plastic AFO

***I²*:** Statistic for quantifying inconsistency

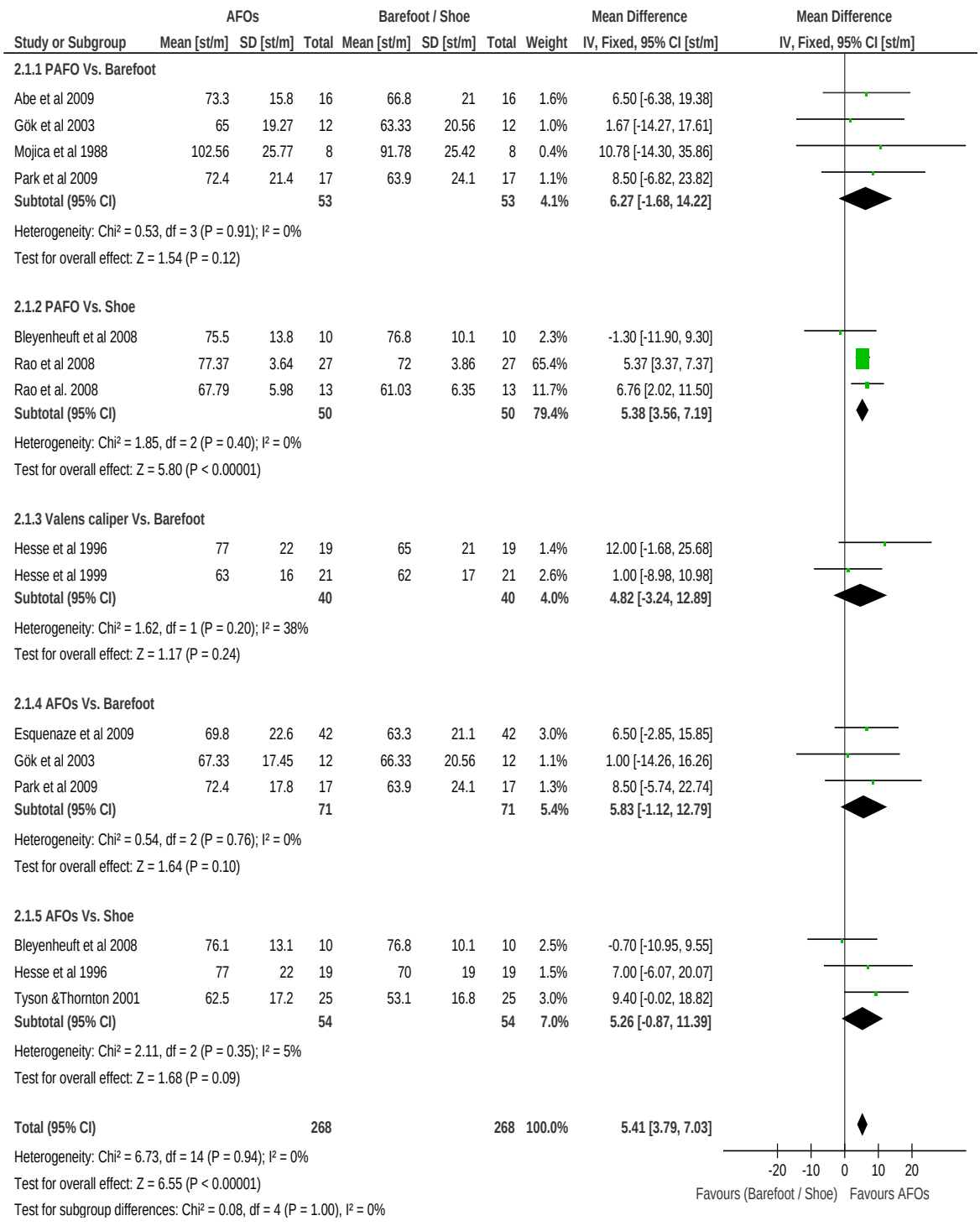
The immediate effect of AFOs and ankle foot supports on gait cadence in adults with hemiplegia

Ten studies reported on the effect of AFOs and ankle foot supports on gait cadence. Fifteen intervention groups were tested to investigate the immediate effect on gait cadence. Gait cadence was measured in steps per minute in the included studies. Five subgroup meta-analyses were performed with data grouped and analyzed according to the exact type of AFOs and the control group of either walking barefoot or walking with shoes only. Findings are summarized in Figure 2.2.

Only one subgroup (Bleyenheuft et al., 2008 & “2 Groups” of Rao et al., 2008) showed a significant effect in favor of walking with PAFO versus shoe walking *(5.38; 95% CI 3.56, 7.19; P < 0.00001)* (Figure 2.2/Analysis 2.1.2).

The intervention groups of all studies reported on the effects of AFOs and ankle foot supports on gait cadence (268 participants). The meta-analysis showed a statistically superior effect when patients walked with AFOs or ankle foot supports, compared to walking barefoot or using shoes only *(5.41; 95% CI 3.79, 7.03. p < 00001).* Figure 2.2 displays the results of this analysis.

Figure 2.2: Forest plot depicting the immediate effect of AFOs and ankle foot supports versus either barefoot or shoe walking on gait cadence in adults with hemiplegia



PAFO: Plastic AFO

***I²*:** Statistic for quantifying inconsistency

The immediate effect of AFOs and ankle foot supports on plegic leg stance duration in adults with hemiplegia

A total of four studies reported on the effect of AFOs and ankle foot supports on the stance duration of the plegic leg and the duration was calculated as a percentage per gait cycle.

One tested group (Esquenaze et al., 2009) showed a significant increase in plegic leg stance duration when wearing AFOs or supports compared to either barefoot walking or shoes only. These studies were not sufficiently similar in terms of intervention or type of comparison to allow meta-analysis. Findings are summarized in Table 2.11.

Table 2.11: The immediate effect of AFOs and ankle foot supports on plegic leg stance duration in adults with hemiplegia

Study	Plegic leg stance duration			
	Condition		No	P value
	Intervention	Control		
Park et al., 2009	PAFOs	Barefoot	17	NS
	Anterior PAFOs	Barefoot	17	NS
Esquenaze et al., 2009	AFOs	Barefoot	42	0.001
Rao et al., 2008	PAFOs	Shoe	13	NS
	PAFOs	Shoe	27	NS
Hesse et al., 1999	Valens caliper	Barefoot	21	NS
NS No significant difference (intervention vs. control) P > 0.05				

The immediate effect of AFOs on plegic leg swing duration in adults with hemiplegia

Two studies (Esquenaze et al., 2009; Hesse et al., 1999) reported on the effect of AFOs on the plegic swing duration in the adults with hemiplegia. Both of these studies showed significant reduction in percentage swing duration ($p = 0.0001$, $p < 0.05$) when the patients walked with an AFO or a Valens caliper compared to barefoot walking.

The immediate effect of AFOs and ankle foot supports on double support walking duration in adults with hemiplegia

A total of six studies (Table 2.12) reported on the effect of AFOs and ankle foot supports on the duration of double support. It was measured as a percentage or seconds per gait cycle in twelve groups. However, various terms were used to describe the outcome such as percent of double support, double support time and double stance duration. Clinical heterogeneity among the included studies precluded meta-analysis of the results. Findings are summarized in Table 2.12.

Three tested groups showed significant increases in the duration of double support, when the patients walked with an AFO or ankle support compared to either barefoot or shoe walking (Esquenaze et al., 2009; Pohl & Mehrholz, 2006; Hesse et al., 1999). Hesse et al. (1999) studied the effect of a Valens caliper on the affected leg double stance duration in two walking conditions through the gait cycle. Initially, when the affected leg was in front of the intact leg and then when the affected leg was behind the intact leg (terminal). Wearing the Valens caliper compared to barefoot walking resulted in significant increase in the percentage of terminal double stance duration ($p < 0.05$). In contrast, wearing the Valens calipers resulted in non significant change in the percentage of initial double stance duration (See Table 2.12).

Table 2.12: The immediate effect of AFOs and ankle foot supports on double support duration in adults with hemiplegia

Study	Double support duration			
	Condition		No	P value
	Intervention	Control		
Park et al., 2009[a]	PAFOs	Barefoot	17	NS
	Anterior PAFOs	Barefoot	17	NS
Esquenaze et al., 2009[a]	AFOs	Barefoot	42	0.0001*
Pohl & Mehrholz, 2006[a]	Articulated PAFOs	shoe	28	0.0072*
Gök et al., 2003•	PAFOs	Barefoot	12	NS
	Metallic AFOs	Barefoot	12	NS
Hesse et al., 1999[a]	Valens caliper†	Barefoot	21	NS
	Valens caliper‡	Barefoot		< 0.05*
Hesse al., 1996[a]	Valens caliper†	Shoe	19	NS
	Valens caliper‡	Shoe		NS
	Valens caliper†	Barefoot	19	NS
	Valens caliper‡	Barefoot		NS

***** Significant increase (intervention vs. control) p > 0.05
NA Not significant (intervention vs. control)
† Duration of double stance measured when the affected leg in front of the intact leg (initial)
‡ Duration of double stance measured when the affected leg behind the intact leg (terminal)
[a] percent per cycle used as a unit of measurement
• Seconds per cycle used as a unit of measurement

The immediate effect of AFOs and ankle foot supports on stride and plegic leg step duration in adults with hemiplegia

Only one study (Burdett et al., 1988) reported on the immediate effect of AFOs and ankle foot supports on stride duration. The stride duration was measured in seconds per stride. This study reported no significant differences in stride duration wearing an AFO, either metallic or plastic compared to walking with shoes only. The same finding was reported when wearing an Air-stirrup brace but compared to walking with shoes only.

Only one study (Gök et al., 2003) reported on the immediate effect of AFO on the plegic step duration. Twelve participants were used in two intervention groups in this study; both reported that wearing an AFO (either plastic or metallic) resulted in no significant change on the plegic step duration.

2.4.4.2 The effect of AFOs and ankle foot supports on distance gait variables

Table 2.13 summarizes the studies in which the effect of AFOs and ankle foot supports on specific distance gait parameters versus barefoot and shoe walking was reported. Fourteen studies reported on the immediate effect on the various distance gait variables. Findings of each tested variable are separately discussed and illustrated in Forrest plot analyses or Tables.

Table 2.13: Summary of the studies in which distance gait variables are reported

Study	Distance variables			
	Stride length	Step length	Step width	Degree of toe-out
Park et al., 2009	√	-	-	-
Tyson & Rogerson, 2009	-	√	-	-
Abe et al., 2009	√	√	√	-
Esquenaze et al., 2009	-	√	√	-
Pavlik, 2008	√	√	-	-
Rao et al., 2008	-	√	-	-
Bleyenheuft et al., 2008	√	-	-	-
Fatone & Hansen, 2007	-	√	√	-
Pohl & Mehrholz, 2006	-	-	-	-
de Wit et al., 2004	-	-	-	-
Gök et al., 2003	-	√	-	-
Tyson &Thornton, 2001	√	√	-	-
Hesse et al., 1999	√	-	-	-
Hesse et al., 1996	√	-	-	-
Burdett et al., 1988	√	√	√	√
Mojica et al., 1988	√	-	-	-
√ parameter tested / **-** parameter not tested				

The immediate effect of AFOs and ankle foot supports on the plegic leg stride length in adult hemiplegic patients

A total of nine studies reported on the immediate effect of different types of AFO and ankle foot supports on stride length (Abe et al., 2009; Park et al., 2009; Bleyenheuft et al., 2008; Pavlik, 2008; Tyson &Thornton, 2001; Hesse et al., 1999; Hesse et al., 1996; Burdett et al., 1988; Mojica et al., 1988). Within these studies, thirteen intervention groups were tested. The stride length was measured either in meters (m) or centimeters (cm) and expressed as a mean and standard deviation across the tested groups. In order to statistically summarize the data, the reviewers converted the mean and standard deviation from meters to centimeters and utilized the centimeters as a measurement unit in all the included studies.

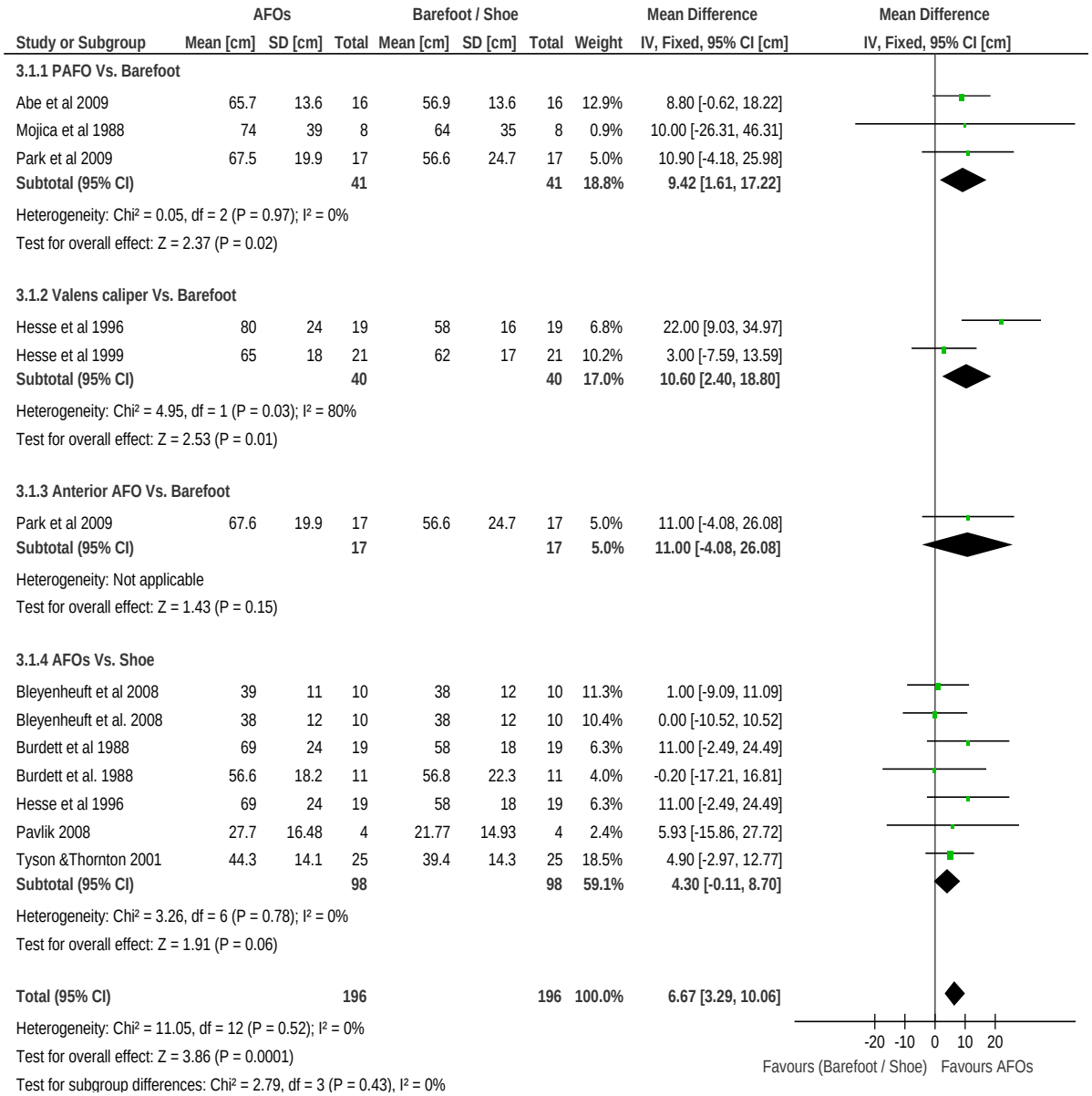
Four subgroup meta-analyses were performed and data were grouped and analyzed according to the exact type of AFOs and the control group either walking barefoot or walking with shoes only. Findings are summarized in Figure 2.3.

Three intervention groups (Abe et al., 2009; Park et al., 2009; Mojica et al., 1988) investigated the effect of PAFOs versus barefoot walking (41 participants), while none of the included groups investigated the effect of walking with PAFOs compared to walking with shoes only. Meta-analysis showed statistically significant effects on stride length in favour of PAFOs *(9.24; 95% CI 1.61, 17.22. p = 0.02)* (Figure 2.3/Analysis 3.1.1).

Two intervention groups (Hesse et al., 1999; Hesse et al., 1996) investigated the effect of Valens Calipers versus barefoot walking. 40 participants. Meta-analysis showed statistically significant effects in favour of walking with Valens Calipers *(10.60; 95% CI 2.40, 18.80. p = 0.01)* on stride length. The heterogeneity was high *(I^2 = 80%)* (Figure 2.3/Analysis 3.1.2). The other two subgroup meta-analyses (Park et al., 2009 & “2 Groups” of Bleyenheuft et al., 2008; Pavlik, 2008; Tyson & Thornton, 2001; Hesse et al., 1996; “2 Groups” of Burdett et al., 1986) showed no significant effect in favour of walking with AFOs (Figure 2.3/Analyses 3.1.3 & 3.1.4).

Across the intervention groups of all studies reporting on the effects of AFOs and ankle foot supports on stride length (196 participants), a meta-analysis showed superior increases in stride length when patients walked with AFOs or ankle foot supports, compared to walking without AFOs either barefoot or using shoes only *(6.67; 95% CI 3.29, 10.06. p < 00001).* Figure 2.3 displays the results of this analysis.

Figure 2.3: Forest plot depicting the immediate effect of AFOs and ankle foot supports versus either barefoot or shoe walking on stride length in adults with hemiplegia



PAFO: Plastic AFO

***I²*:** Statistic for quantifying inconsistency

The immediate effect of AFOs and ankle foot supports on plegic leg step length in adults with hemiplegia

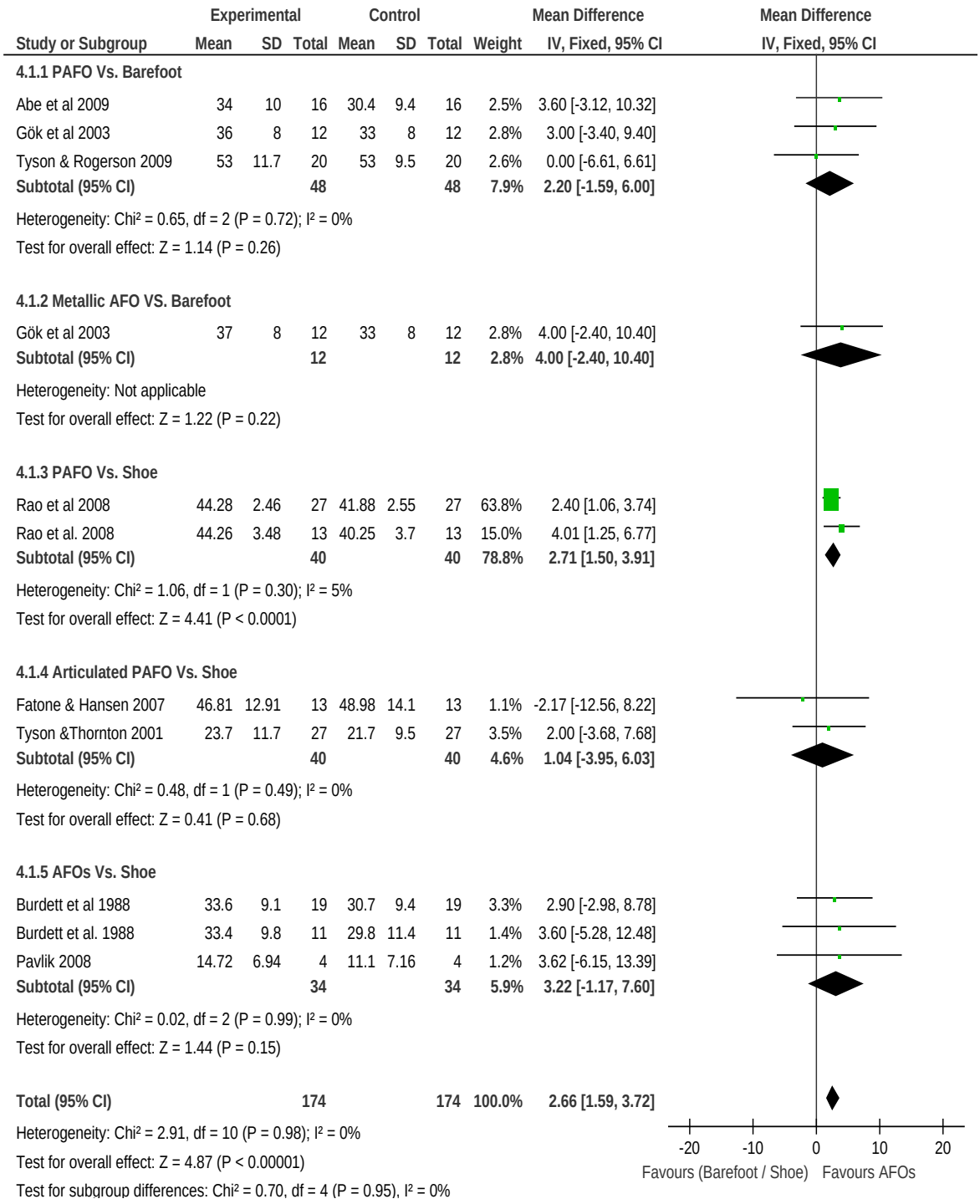
Eight studies reported on the immediate effect of different types of AFOs and ankle foot supports on plegic leg step length (Abe et al., 2009; Tyson & Rogerson, 2009; Pavlik, 2008; Rao et al., 2008; Fatone & Hansen, 2007; Gök et al., 2003; Tyson &Thornton, 2001; Burdett et al., 1988). Within these studies, eleven intervention groups were tested. The step length was measured in either centimeters or meters as a mean and standard deviation across the tested groups. In order to statistically summarize the data, the reviewers converted the mean and standard deviation from meters to centimeters and utilized centimeters as a measurement unit in all the included studies.

Five subgroup meta-analyses were performed since data were grouped and analyzed according to the exact type of AFOs and the control group either walking barefoot or walking with shoes only. Only one study Esquenaze et al. (2009) was excluded from this analysis since the step length was measured as a percentage in the gait cycle. All analyses showed acceptable level of statistical heterogeneity. Findings are summarized in Figure 2.4.

Rao et al. (2008) investigated the effect of walking with PAFOs versus walking with shoes only in two intervention groups (40 participants). Meta-analysis showed a statistically significant effect in favour of walking with PAFOs *(2.71; 95% CI 1.50, 3.91. $p < 0.0001$)* (Figure 2.4/Analysis4.1.3). The other subgroup meta-analyses (Figure 2.4/Analyses 4.1.1, 4.1.2, 4.1.4 & 4.1.5) were not statistically significant.

Across the intervention groups of the included studies (174 participants), walking with AFOs or ankle foot supports, compared to walking without AFOs either barefoot or using shoes only, statistically improved the plegic step length *(2.66; 95% CI 1.59, 3.72. $p < 0.00001$)* (Figure 2.4).

Figure 2.4: Forest plot depicting the immediate effect of AFOs and ankle foot supports versus either barefoot or shoe walking on plegic step length in adults with hemiplegia**.**



PAFO: Plastic AFO

***I²*:** Statistic for quantifying inconsistency

The immediate effect of AFOs and ankle foot supports on the step width in adults with hemiplegia

A total of four studies (Abe et al., 2009; Esquenaze et al., 2009; Fatone & Hansen, 2007; Burdett et al., 1988) reported on the immediate effect of different types of AFOs and ankle foot supports on the walking step width. Within these studies, five intervention groups were tested. Various terminologies were used to define the outcome such as step width, width of base of support and base width. The mean and standard deviation of step width was measured in centimeters or meters for each tested group across the included studies. Findings are summarized in Table 2.14.

The reported studies were not sufficiently homogeneous in term of intervention or type of comparison to allow meta-analysis. However, three tested groups in three different studies reported significant improvements in walking step width after wearing an AFO, compared to either walking barefoot or with shoes only. Burdett et al. (1988) reported that wearing the Air stirrup or an AFO (either plastic or metallic) did not significantly change the step width (See Table 2.14)

Table 2.14: The immediate effect of AFOs and ankle foot supports on the step width in adults with hemiplegia

Study	Step width			
	Condition		No	P value
	Intervention	Control		
Abe et al., 2009[a]	PAFOs	Barefoot	16	0.034*
Esquenaze et al., 2009•	AFOs	Barefoot	42	0.0001*
Fatone & Hansen, 2007[a]	Articulated AFOs	Shoe	12	0.016*
Burdett et al., 1988[a]	Air Stirrup	Shoe	19	0.207**
	Metallic/plastic AFO	Shoe	11	NS

NS Not significant (intervention vs. control) at $p > 0.05$

***Significant increase (intervention vs. control)

****No significant difference (intervention vs. control)

[a]The step width measured in cm

• The step width measured in Meter

The immediate effect of AFOs and ankle foot supports on the plegic leg toe-out angle in adults with hemiplegia

Only one study Burdett et al. (1988) investigated the immediate effect of AFOs and the Air stirrup brace on the plegic toe-out angle. However, the toe-out angle did not change when wearing either of Air stirrup, Metallic or Plastic AFO. Table 2.15 summarizes the findings.

Table 2.15: The immediate effect of AFOs and ankle foot supports on the degree of toe-out angle in adults with hemiplegia

Study	Plegic toe-out angle(º)			
	Condition		No	P value
	intervention	Control		
Burdett et al., 1988	Air Stirrup	Shoe	19	0.320**
	Metallic/plastic AFO	Shoe	11	NS

(º) Degree

NS Not significant (intervention vs. control) at $p > 0.05$

****No significant difference (intervention vs. control)

2.4.5 The effect of AFOs and ankle foot supports on the kinetic gait parameters of the adults with hemiplegia

The effect of different types of AFOs and ankle foot supports on the kinetic gait variables versus either barefoot or shoe walking are reported and illustrated in Tables under the following subheadings.

The immediate effect of AFOs on the plegic leg joints moments in adults with hemiplegia.

Only one of the included studies investigated the immediate effect of AFOs on plegic lower limb joints moments. Gök et al. (2003) observed a significant decrease in the knee flexion moment while the patients walked with a metallic AFO compared to barefoot walking ($p < 0.05$).

Furthermore, the metallic AFO led to a greater decrease in knee flexion moment compared to the plastic AFO. No significant differences were reported in mean hip flexion and extension moments, knee extension, valgus, and plantarflexion moments using either a plastic or metallic AFO versus barefoot walking. Table 2.16 summarizes the effect of AFOs on the plegic leg joint moments.

Table 2.16: The immediate effect of AFOs on the plegic lower limb joints moments in adults with hemiplegia.

Study	Condition		No	Outcomes	P value
	Control	Intervention		Joint Moments	
Gök et al., 2003	Barefoot	Plastic AFO	12	Hip flexion moments	NS
				Hip extension moment	NS
				Knee flexion moment	NS
				Knee extension moment	NS
				Valgus Moments	NS
				Ankle plantar flexion moment	NS
		Metallic AFO	12	Hip flexion moment	NS
				Hip extension moment	NS
				Knee flexion moment	< 0.05*
				Knee extension moment	NS
				Valgus Moments	NS
				Ankle plantar flexion moment	NS

NS Indicate no significant (intervention vs. control) $p > 0.05$

***Significant decrease (intervention vs. control)

The immediate effect of AFOs on the mechanical work of adults with hemiplegia

One study reported on the immediate effect of AFOs on internal and external mechanical work during walking. Bleyenheuft et al. (2008) showed a significant decrease in external mechanical work using either a PAFO or chignon AFO compared to shoe walking (p = 0.003). Thus the vertical work significantly reduced with both AFOs compared to shoes only (p = 0.006). The internal work was improved with each orthosis, but this improvement was not statistically significant when compared to shoe walking. Table 2.17 summarizes the effect of AFOs on the mechanical work variables.

The total mechanical work was significantly improved when the patients walked with an AFO (Plastic or chignon) compared to shoe walking (Table 2.17).

Table 2.17: The immediate effect of AFOs on mechanical work of hemiplegic patients

Study	Condition		Outcomes	P value
	Control	**Interventions**	**Mechanical work (J Kg^{-1} m^{-1})**	
Bleyenheuft et al., 2008	Walking with shoe	Plastic AFO	External work	0.003*
			Vertical	0.006*
			Internal work	0.072**
			Total work	0.001*
		Chignon AFO	External work	0.003*
			Vertical	0.006*
			Internal work	0.072**
			Total work	0.006*

*Significant difference (intervention vs. control)

**No significant difference (intervention vs. control)

The immediate effect of AFOs on the center of pressure (COP) of adults with hemiplegia

One study reported on the immediate effect of AFOs on sagittal location of the first COP during walking. Bleyenheuft et al. (2008) observed a significant alteration in the sagittal plane location of the first COP point. It moved posterior toward the center of the ankle joint (p= 0.001) when the patients walked with an AFO (plastic or chignon) compared to shoe walking. Moreover, wearing an AFO resulted in more uniform forward progression of the COP compared with shoe walking.

2.4.6 The effect of AFOs and ankle foot supports on the plegic leg kinematics in adults with hemiplegia

Six studies reported on the immediate effect of AFOs and ankle foot supports on sagittal plane kinematics of the plegic leg joints. There are no results on the long term effects or the joint kinematics in other planes (i.e. frontal or transverse).

The effect of AFOs and ankle foot supports on the joint kinematics of plegic leg joints at various points in the gait cycle are discussed and illustrated in Tables under the following subheadings.

The immediate effect of AFOs and ankle foot supports on the kinematics of affected hip joints in adults with hemiplegia

Three studies reported on the effect of AFOs on the kinematics of the affected hip (Park et al., 2009; Gök et al., 2003). Burdett et al. (1988) examined the effect of an Air-Stirrup ankle brace. Findings are summarized in Table 2.18.

Walking with an AFO resulted in no statistical difference on maximal hip flexion at both gait cycles (stance or swing) relative to either barefoot or shoe walking. The same finding was also reported when the patients walked with an Air-Stirrup brace compared to shoe walking. None of the identified studies found significant changes in hip flexion angles at the various points of the gait cycle (See Table 2.18).

Four intervention groups were tested to assess the effect of AFOs on hip extension angles. None of these showed significant changes in the identified angles when the participants walked with an AFO compared to either barefoot or shoe walking.

Table 2.18: The immediate effect of AFOs and ankle foot supports on the kinematics of the affected hip joint in adults with hemiplegia.

Study	Condition		No	Outcome	P value
	Control	Intervention		Degrees of hip angles	
Park et al., 2009	Barefoot	Anterior PAFOs	19	Max flexion at stance	NS
				Max extension at stance	NS
				Max flexion at swing	NS
		PAFOs	19	Max flexion at stance	NS
				Max extension at stance	NS
				Max flexion at swing	NS
Gök et al., 2003	Barefoot	PAFOs	12	Max hip flexion	NS
				Max hip extension	NS
		Metallic AFO	12	Max hip flexion	NS
				Max hip extension	NS
Burdett et al., 1988	Shoe	Plastic and Metallic AFO	11	Flexion at foot-strike	NS
				Flexion at mid-stance	NS
				Flexion at heel-off	NS
				Flexion at pre-swing	NS
				Flexion at mid-swing	NS
	Shoe	Air-Stirrup	19	Flexion at foot-strike	NS
				Flexion at mid-stance	NS
				Flexion at heel-off	NS
				Flexion at pre-swingo	NS
				Flexion at mid-swing	NS

Max Maximal

NS No significant deference (intervention vs. control) P > 0.05

The immediate effect of AFOs and ankle foot supports on the kinematics of affected knee joints in adults with hemiplegia

A total of four studies (Bleyenheuft et al., 2008; Park et al., 2009; Gök et al., 2003; Burdet et al., 1988) reported on knee kinematics in adult hemiplegic patients. Within these studies, eight intervention groups were tested. The sagittal knee angles at various points in the gait cycle were unchanged by the use of an AFO or Air-Stirrup brace relative to barefoot or shoe walking. None of the tested groups showed significant effects of the AFOs and ankle foot supports in changing the degrees of knee flexion and extension at any of the stance sub-phases. The same finding was reported on knee flexion and extension during the swing sub-phases. Therefore, the different types of AFOs and ankle foot supports did not influence the knee position during gait cycles of the hemiplegic patients. Table 2.19 summarized the effect of different types of AFOs and supports on the various knee sagittal angles.

Table 2.19: The immediate effect of AFOs and ankle foot supports on the kinematics of the affected knee joint in adults with hemiplegia

Study	Condition		No	Outcome	P value
	Control	Intervention		Degrees of knee angles	
Park et al., 2009	Barefoot	Anterior PAFOs	19	Max flexion at stance	NS
				Max extension at stance	NS
				Max flexion at swing	NS
				Max extension at swing	NS
		PAFOs	19	Max flexion at stance	NS
				Max extension at stance	NS
				Max flexion at swing	NS
				Max extension at swing	NS
Bleyenheuft et al., 2008	Shoe	PAFOs	10	Position of knee at heel-strike	NS
				Max knee flexion during stance	NS
				Max knee extension during stance	NS
				Max knee flexion at pre-swing	NS
		Chignon AFOs	10	Position of knee at heel-strike	NS
				Max knee flexion during stance	NS
				Max knee extension during stance	NS
				Max knee flexion at pre-swing	NS
Gök et al., 2003	Barefoot	PAFOs	12	Max knee flexion	NS
				Max knee extension	NS
		Metallic AFO	12	Max knee flexion	NS
				Max knee extension	NS
Burdet et al., 1988	Shoe	Plastic and metallic AFO	11	Flexion at foot-strike	NS
				Flexion at mid-stance	NS
				Flexion at heel-off	NS
				Flexion at pre-swing	NS
				Flexion mid-swing	NS
	Shoe	Air-Stirrup	19	Flexion at foot-strike	NS
				Flexion at mid-stance	NS
				Flexion at heel-off	NS
				Flexion at pre-swing	NS
				Flexion mid-swing	NS

Max Maximal
NS No significant difference (intervention vs. control) $p > 0.05$

The immediate effect of AFOs and ankle foot supports on the affected ankle joint kinematics in adults with hemiplegia

A total of six studies reported on the sagittal kinematics of the affected ankle joint (Bleyenheuft et al., 2008; Park et al., 2009; Fatone & Hansen, 2007; Gök et al., 2003; Hesse et al., 1999; Burdett et al., 1988). Within these studies, ten intervention groups were tested, and the ankle angles were measured at various points in the gait cycle. These angles were measured in degrees as a unit of measurement except in the study of Hesse et al. (1999) which was not specified. Table 2.20 summarised the effect of different types of AFOs and supports on the various ankle sagittal angles.

Park et al. (2009) showed that the maximal ankle dorsiflexion at swing phase significantly improved when wearing an AFO compared to barefoot walking ($p < 0.05$). Thus this improvement reduced the foot drop of hemiplegic patients.

Bleyenheuft et al. (2008) reported a statistically significant difference between walking with the “chignon” AFO and walking with shoes only ($p = 0.009$), i.e. favouring the AFO. The ankle dorsiflexion in the mid-swing significantly improved when walking with a “chignon” AFO compared to walking with shoes only ($p = 0.006$).

Fatone & Hansen (2007) showed a significant decrease in the ankle plantarflexion angle toward the neutral position at initial contact when the patients walked with the articulated PAFO compared to barefoot walking ($p = 0.001$). A significant alteration of ankle angle at mid-swing from plantarflexion to slight dorsiflexion was also shown ($p = 0.012$).

Gök et al. (2003) showed significantly increased ankle dorsiflexion at heel strike and mid-swing when walking with an AFO either plastic or metallic compared to walking barefoot ($p < 0.05$). However, the metallic AFO was more effective in improving dorsiflexion than the PAFO at heel strike as well as mid-swing.

Hesse et al. (1999) studied the ankle excursions while the patients were wearing a Valens caliper relative to barefoot walking. The study showed improvement in the ankle dorsiflexion during stance phase (+ 201.2%), while

the plantarflexion during the swing phase decreased (-71.2%). However, no statistical comparison was established.

Burdett et al. (1988) showed significantly decreased ankle plantarflexion at pre-swing as a result of walking with an Air-stirrup brace versus unbraced/shoe walking ($p = 0.04$). In contrast, walking with AFOs (plastic or metallic) versus shoe walking resulted in less plantarflexion at foot-strike ($p = 0.019$).

Table 2.20: The immediate effect of AFOs and ankle foot supports on the kinematics of the affected ankle joint in adults with hemiplegia.

Study	Condition		No	Outcome	P value
	Control	Intervention		Degrees of ankle angles	
Park et al., 2009	Barefoot	Anterior PAFOs	19	Max dorsiflexion at stance	NS
				Max dorsiflexion at swing	< 0.05*
		PAFOs	19	Max dorsiflexion at stance	NS
				Max dorsiflexion at swing	< 0.05*
Bleyenheuft et al., 2008	Shoe	PAFOs	10	Position of ankle at heel-strike	NS
				Max ankle dorsiflexion at mid-stance	NS
				Position of ankle at mid-swing	NS
		"Chignon" AFOs	10	Position of ankle at heel-strike	< 0.05*
				Max ankle dorsiflexion at mid-stance	NS
				Position of ankle at mid-swing	< 0.05*
Fatone & Hansen, 2007	Shoe	Articulated AFOs	12	Plantarflexion at initial contact	< 0.05*
				Plantarflexion at mid-swing	< 0.05*
Gök et al., 2003	Barefoot	PAFOs	12	Dorsiflexion at heel-strike	< 0.05*
				Dorsiflexion at mid-swing	< 0.05*
		Metallic AFO	12	Dorsiflexion at heel-strike	< 0.05*
				Dorsiflexion at mid-swing	< 0.05*
Hesse et al., 1999	Barefoot	Valens Caliper	21	Dorsiflexion during stance	Not specified
				Plantarflexion during swing	Not specified
Burdett et al., 1988	Shoe	Plastic and metallic AFO	11	Dorsiflexion at foot-strike	< 0.05*
				Dorsiflexion at mid-stance	NS
				Dorsiflexion at heel-off	NS
				Dorsiflexion at pre-swing	NS
				Dorsiflexion at mid-swing	--
	Shoe	Air-Stirrup	19	Dorsiflexion at foot-strike	NS
				Dorsiflexion at mid-stance	NS
				Dorsiflexion at heel-off	NS
				Dorsiflexion at pre-swing	< 0.05*
				Dorsiflexion at mid-swing	NS

Max Maximal
NS No significant difference (intervention vs. control) $p > 0.05$
***Significant difference (intervention vs. control)

2.5 DISCUSSION

The current review is the first to systematically determine and analyze the current evidence for the effectiveness of different types of foot and ankle orthoses and/or supports on kinetic and kinematic gait parameters and the first meta-analysis on the effectiveness of AFOs on the temporal spatial gait parameters in adults with hemiplegia.

This review demonstrated an increase in the number of published studies with improvement in the level of evidence and the methodological quality of the more recent published studies when compared to the previous systematic review (Leung & Moseley 2002). This improvement was found in the sampling procedures, number of included participants, number of measured variables and the instrumentation. However, the present review highlighted a lack of well designed randomized controlled trails (RCTs) since the majority of the studies were cross-over type designs with randomized testing order. The reviewed studies differed in the types of AFOs investigated, the design of comparison either walking barefoot or with shoes only, instrumentation and the procedures. Data were grouped and analyzed according to the exact type of AFOs and type of comparison (either walking barefoot or walking with shoes only). However, it is still possible that the above mentioned differences in methodologies could have impacted on the interpretation of the results.

Findings of the effectiveness of AFOs and ankle foot supports on the temporal spatial, kinetic and kinematic gait parameters are discussed in detail under the following headings.

2.5.1 The effects of AFOs on the temporal spatial gait parameters

The different types of AFOs and ankle supports were significantly effective in improving the hemiplegic gait speed, cadence, stride length and plegic step length. These improvements are believed to reflect progress in hemiplegic mobility and a measure of gait improvement after stroke (Rao et al., 2008; Collen, Wade & Bradshaw, 1990). The improvement in the cadence, plegic

step length and stride length lead to improvement in the gait speed. This symmetrical correlation between the temporal and spatial parameters is supported by the previous literature (Olney & Richards 1996). The gait speed is the product of step length and cadence and any improvement in either or both of these parameters, will improve the gait speed (Park et al., 2009; Bohannon, Andrews & Smith, 1988).

The current review demonstrated that few studies investigated the effect of AFOs on the plegic leg stance and swing duration. Esquenaze et al. 2009 was the only study that found an increase in plegic leg stance duration and a reduction of plegic swing duration. Therefore, the effectiveness of AFOs on these parameters requires further investigation. The AFOs improved the hemiplegic width of base of support (Abe et al., 2009, Esquenaze et al., 2009; Fatone & Hansen, 2007). Improvement in the gait symmetry parameters in hemiplegic patients wearing AFOs is a good indication of a balanced and more secure gait pattern (Pohl & Mehrholz, 2004).

The results of this review showed a lot of variation between the included AFOs and therefore the effectiveness cannot be inferred to a specific type of AFO conclusively. Only one study attempted to specify the footwear as the appropriate comparative baseline for assessing the effect of an AFO (Churchill, Hallign & Wade, 2003). Wang, Tang, Wu & Chen (2007) suggested that assessing the effect of AFOs compared to barefoot walking is essential in measuring the effect on indoor mobility and the shoes for outdoor mobility.

2.5.2 The effects of AFOs and ankle foot supports on the kinetic gait parameters

Kinetic variables involve less understood concepts such as intersegmental moments, work, mechanical energy and power. These variables are essential in explaining the gait deviations from the norm of the kinematic and temporal spatial parameters of the walking subject and it is useful in understanding the characteristics of hemiplegic gait. Unfortunately, few studies analyzed the effect of AFOs on the kinetic gait parameters (Bleyenheuft et al., 2008; Gök et al., 2003).

2.5.3 The effects of AFOs and ankle foot supports on the kinematic gait parameters

Burdett and colleagues (1988) compared the kinematic gait parameters of hemiplegic patients to those of able-bodied and found that hemiplegic patients showed decreased hip flexion at initial contact and during mid-swing and increased hip flexion at pre-swing. There was an increase in knee flexion at initial contact and a decrease at pre-swing and mid-swing. Ankle plantarflexion was increased at initial contact and mid-swing and decreased at pre-swing.

The current review demonstrated that few studies investigated the effect of AFOs on the kinematic gait parameters. There were a lot of variations in the examined AFOs and studied parameters. None investigated the effect on parameters in the frontal plane (ankle inversion/eversion). No changes to the sagittal plane kinematics at the hip and knee joints were observed when patients walked with AFOs (Park et al., 2009; Bleyenheuft et al., 2008; Gök et al., 2003; Burdett et al., 1988). These studies, mainly reported on the effect of AFOs on the ankle dorsiflexion/plantarflexion at mid-swing, initial contact, mid-stance and pre-swing. The different types of AFOs were significantly better than the Air-stirrup brace in improving the plegic ankle position at mid-swing and initial contact. This indicates that the AFO provides much better support and alignment of the plegic ankle during swing and initial contact. Facilitation of dorsiflexion is important even before initial contact for foot clearance and to limit compensatory clearance strategies. The improved ankle position at initial contact may result in a safer gait pattern and could lead to a reduction in falls. The support provided by the AFO may however prevent plantarflexion at pre-swing and limit forward progression. The different types of AFOs and Air-stirrup brace does not have a significant effect on the kinematics of the plegic knee, and hip, while the impact on the frontal plane and transverse plane joint angles and the pelvic kinematics remains unclear.

2.6 LIMITATIONS OF THE SYSTEMATIC REVIEW

This review has a number of limitations. The inclusion of studies only written in English and limits within the keywords could have eliminated some appropriate studies. The types of comparisons were limited to barefoot walking and walking with shoes only. Therefore, some studies were excluded if insufficient information was provided about the comparison baseline or when compared to able-bodied individuals (Appendix V). All the recruited participants for the included studies were able to walk independently, therefore it was difficult to classify (group) them according to either the severity of hemiplegia or the time since stroke onset.

2.7 CONCLUSIONS

Implications for practice

The overall quality of the evidence was high providing evidence to support the immediate effectiveness of AFOs in improving the hemiplegic gait speed, cadence, stride length, step length and the ankle position in sagittal plane. However, the effectiveness on daily functioning and the clinical implications on those not able to walk independently, the long-term benefits or adverse effects remain unresolved. The majority of the reviewed studies focused on investigating the effect of PAFOs but not which AFO design is most efficacious.

There is insufficient evidence to determine the impact of AFOs on improving the kinetic and the frontal and transverse plane ankle kinematic gait parameters. There is insufficient evidence to either support or refute the effectiveness of taping/strapping, splinting and other forms of foot ankle splinting on the hemiplegic gait.

AFOs is an effective lower limb orthosis to improve mobility, gait speed, cadence, stride and step length for post-stroke patients and may have an impact on the daily function of post-stroke patients.

Implications for research

There is a need for well designed, adequately powered randomized clinical trials to confirm the effectiveness in the short term and determine the long term and the adverse effects of AFOs. Studies to support or refute the effectiveness of taping/strapping, splinting and other forms of foot ankle splinting on the hemiplegic gait are also needed. Future studies should investigate more carefully which type of AFOs could benefit the hemiplegic patient and determine the appropriate comparative baseline, walking barefoot or with shoe only, for assessing the efficacy of the AFOs.

The effectiveness of the AFOs on the kinetic and the frontal-, transverse- plane joints kinematics remain largely unresolved. Therefore future studies should determine the effectiveness of AFOs and ankle supports on the gait parameters of these planes.

Numerous different walk tests are reliable in measuring some of the gait variables. However, the future research should take into account that the more developed instruments such as the Vicon (3D gait analysis) is found to be more reliable, accurate and it provides more gait variables.

Future studies should utilize the most sophisticated and developed instrumented measures to ensure meaningful effects.

CHAPTER 3

METHODOLOGY

The methodology of the study is presented in this chapter. Firstly, the research question, research aim, objectives, hypothesis, study design and sampling method are reported. This will be followed by a detailed description of the study procedures, data analysis and the ethical considerations.

3.1 RESEARCH QUESTION

Does taping the affected ankle joint in a neutral position improve temporal spatial gait parameters and ankle joint kinematics in ambulant adult hemiplegic patients?

3.2 AIM OF THE STUDY

The main aim of the study was to describe the immediate effect of neutral ankle taping on temporal spatial gait parameters and ankle joint kinematics of the affected and unaffected ankle in ambulant adult hemiplegic patients.

3.3 OBJECTIVES

The objectives of this study were to describe the immediate effect of ankle taping in ambulant adult hemiplegic patients on:

- Temporal gait parameters which include:
    - Gait speed.
    - Cadence.
    - Stance duration of the affected and the unaffected leg.
    - Swing duration of the affected and the unaffected leg.
- Spatial gait parameters which include:
    - Stride length of the affected and the unaffected leg.
    - Step length of the affected and the unaffected leg.

- Ankle joint kinematics of the affected leg in the sagittal plane during the following sub-phases of the gait cycle:
    - Dorsiflexion at initial contact.
    - Dorsiflexion at mid-stance.
    - Dorsiflexion at pre-swing.
    - Dorsiflexion at mid-swing.
- Ankle joint kinematics of the affected leg in the frontal plane during the following sub-phases of the gait cycle:
    - Ankle inversion or eversion at initial contact.
    - Ankle inversion or eversion at mid-stance.
    - Ankle inversion or eversion at pre-swing.

3.4 STUDY DESIGN

A clinical trial investigating the effect of ankle taping on gait parameters of ambulant adult hemiplegic patients using a crossover randomized testing order was conducted to answer the research question.

3.5 SETTING

The study took place at the “Physiotherapy and Motion Analysis Clinic” in the Faculty of Health Sciences, Stellenbosch University, Tygerberg, Cape Town, South Africa.

3.6 SAMPLE

The population consisted of ambulant adult hemiplegic patients following a cerebral vascular accident (stroke) currently managed at Tygerberg Hospital and Delft Community Rehabilitation Centre, Cape Town, South Africa.

3.6.1 Sampling method

A convenient successive sampling method was used to recruit patients with hemiplegia from Tygerberg Hospital and Delft Community Rehabilitation Centre, Cape Town, South Africa for the study sample.

Inclusion criteria

- Adults 18 years and older.
- Gender: males and females.
- Patients with a single stroke (first incident) affecting the right or left side within one year following the onset of the stroke, according to their medical files.
- Mentally able to comprehend and follow simple verbal commands or instructions such as walk, stand, etc. as assessed by the principal researcher.
- Passive range of motion (ROM) of the ankle, knee and hip was within a functional range for a normal gait pattern, as assessed by the patient's therapists (Appendix VI).
- Patients with or without any sensory or proprioception dysfunction.
- Patients able to walk barefoot for at least seven meters (the minimum walking distance to perform the procedure) over a firm surface without ankle foot orthosis and/or mobility devices, as assessed by the principal researcher.
- Patients currently receiving either physiotherapy or occupational therapy to improve their walking ability.

Exclusion criteria

- History of previous strokes.
- Presenting with bilateral hemiplegia.
- Orthopedic problems related to the lower extremity or neurological disorders other than stroke that might influence gait and/or balance e.g. Parkinsonism.

- Known allergies to the marker plaster or the therapeutic tape.
- Unable to apply ankle tape due to the presence of wound, ulceration or any skin damage.

3.6.2 Sample size

The stroke patients were assessed between March and August, 2011. Ten ambulant adult hemiplegic patients following stroke met the inclusion/exclusion criteria and were recruited to participate in this study.

3.7 RESEARCH ASSISTANTS AND TRAINING OF THE PRINCIPAL RESEARCHER

Two research assistants were involved in the study. Research Assistant (A) is the resident technician and a PhD physiotherapy candidate at the Motion Analysis Clinic. Research Assistant (B) is a sports physiotherapist at the Motion Analysis Clinic.

The principal researcher attended gait analysis courses* held at the Physiotherapy and Motion Analysis Clinic, Stellenbosch University during January and February 2011 before commencement of the study. Research Assistant (A), who has extensive experience in processing motion analysis data, was responsible for training of the principal researcher to process and interpret the raw data. The principal researcher was trained on the taping technique by Dr Susan Hillier, University of South Australia, Adelaide, Australia (Hillier & Masters, 2005). Research Assistant (B) was trained in taping technique by the principal researcher.

3.8 PROCEDURE FOR THE MAIN STUDY

The following sections describe the procedure followed in the current study for the recruitment, assessment, and gait analysis of the participants.

* Courses were presented by Prof Tom Novachech; Dr Michael Schwartz; Mr Adam Rozumalski and Mrs Sue Sohrweide from the Center for Gait and Motion Analysis, Gillette Children's Specialty Healthcare, St Paul, University of Minnesota, USA.

3.8.1 Recruitment of participants

Patients were recruited from Tygerberg Hospital (TBH) and Delft Community Rehabilitation Centre (DCRC). TBH, a tertiary care academic hospital located in Parow, Cape Town is the largest hospital in the Western Cape. The Physiotherapy and Occupational therapy departments at THB provide rehabilitation services to in- and out-patients for various conditions including stroke rehabilitation. Delft Community Rehabilitation Centre is an outpatient facility providing rehabilitation services to the local community of Delft for stroke and other conditions.

Physical and occupational therapists at the Departments of Physiotherapy and Occupational therapy in Tygerberg Hospital and Delft Community Rehabilitation Centre in Delft Day Hospital were provided with a list of the inclusion/exclusion criteria and were asked to provide names and file numbers of stroke patients. The files of the potential patients were screened by the principal researcher and information about age, gender, onset of stroke and medical history was collected for all patients. Patients' files were screened for previous medical, neurological and/or musculoskeletal problems that could preclude them from inclusion in the study (inclusion criteria).

Eligible patients were contacted and approached by the principal researcher to explain the nature of the study and to inquire about their willingness to participate in the study. The principal researcher interviewed all the potential patients either at their rehabilitation facilities or using a standardized telephonic interview sheet (Appendix VII). Appointments were made at the Motion Analysis Clinic for the first ten patients fulfilling the inclusion and exclusion criteria.

3.8.2 Randomization

Gait analysis was performed on the participants with and without ankle taping. Each participant had the same chance of walking either with or without the tape first according to the randomized testing order. The participants chose concealed envelopes containing a random testing order. Neither the principal

researcher nor the participants could be blinded to the intervention. The data were processed after completing the capturing of gait parameters for all participants. The participants were coded and the research assistant who processed the data was blinded to the testing order and the affected side.

3.8.3 Intervention

Research Assistant (B) was solely responsible for applying the tape on the affected ankle at the Motion Analysis Clinic. This ensured consistency in taping technique.

Each participant was comfortably positioned in a long sitting position on the treatment bed according to the method described by Delahunt et al., (2009). The hip and knee of the affected leg were slightly flexed to prevent increase in antagonistic tone of ankle dorsiflexion and knee flexor muscles. The affected ankle was placed and taped in a position of neutral talocrural dorsiflexion/plantarflexion and neutral hindfoot inversion/eversion (Figure 3.1; Hillier & Masters, 2005). A rigid adhesive 38 mm strapping tape was applied over a Fixomull stretch tape (5 cm) (Figure 3.2). It took 5-10 minutes to complete the taping procedure.

Tape was removed immediately following the analysis by carefully peeling it back over itself while pushing the skin in the opposite direction. Baby oil was used to facilitate the tape removal.

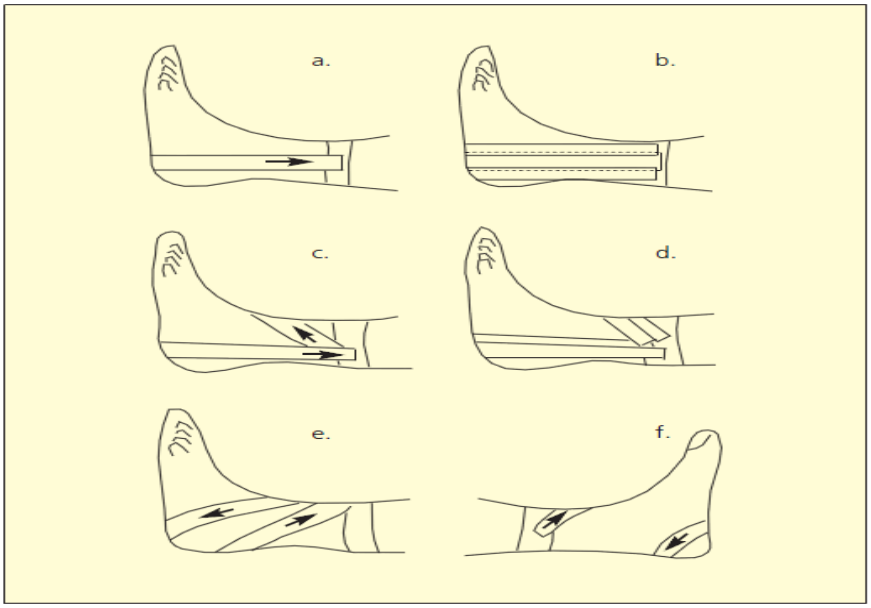


Figure 3.1: Neutral ankle taping technique (Hillier LS, Masters R. Does taping control the foot during walking for people who have had a stroke. International Journal of Therapy and Rehabilitation 2005; 12 No 2), with permission from the authors.

Figure 3.2: The rigid strapping tape and the Fixomull stretch tape**.**

3.8.4 Motion Analysis Laboratory

Vicon Nexus 1.1.7, a motion analysis system (Vicon Motion System Limited, Oxford, UK) was used for the analysis. This is a three dimensional (3D) system which is used in a wide variety of ergonomics and human factor applications for both digital and optical motion measurements and analysis. This system allows the researcher to work in real-time and to immediately visualize the investigations.

For this study eight T-10 cameras with Nexus 1.4 software system were used (Vicon Motion System Limited, Oxford, UK). The system combination can capture speeds of up to 2,000 frames per second. Vicon is one of the most sophisticated reliable (repeatability) systems in human motion analysis as well as hemiplegic gait analysis (Yavuzer, Oken, Elhan & Stam, 2008).

The Vicon Vegas CMOS sensors (markers) were used. These sensors provide a full frame (true) shutter along with the Vegas CMOS sensors. The markers were placed according to the sample Plug-in Gate Model (Vicon Motion System Limited, Oxford, UK).

3.8.5 Anthropometric measurements

Research Assistant (B) was responsible for the anthropometric measurements (Table 3.1). Body mass was calculated using an electronic scale. Ankle and knee widths were measured with an aluminium Anthropometer (Model 01291; Lafytte Instrument Company, India) with a range of 0 to 30 cm in 0.1 cm increments. Leg length and height were measured using a measuring tape.

Table 3.1: Detailed description of anthropometric measures and their measurements

Anthropometric	Description
Body Mass (kg)	Using electronic weight measuring scale.
Height (cm)	With a tape measure, standing barefoot against a wall.
Ankle Width (mm)	The medio-lateral distance across the malleoli. Measured with the patient in the supine position.
Knee Width (mm)	The medio-lateral width of the knee across the line of the knee axis. Measured with the patient in the supine position.
Leg Length (mm)	Full leg length, measured between the ASIS marker and the medial malleolus, via the knee joint. Measured with the patient in the supine position.

3.8.6 Gait analysis procedures

Marker placement

Sixteen markers were placed at standard sites according to the Plug-in gait model (Vicon Motion System Limited, Oxford, UK). Research Assistant (A) was responsible for marker placement and capturing of images. Figures 3.3 and 3.4 show anterior and posterior views of marker placements. Two markers (lateral malleolus and calcaneous) were removed to facilitate ankle taping and repositioned at the same sites over the tape (Figure 3.5). Marker calibration was done in both testing situations (with and without ankle taping).

Marker name and placement

L/RASI: Left and right anterior superior iliac spine.

L/RPSI: Left and right posterior superior iliac spine (immediately below the sacro-iliac joints, at the point where the spine joins the pelvis) These two markers are used as an alternative to the single sacral marker (SACR).

L/RTHI: Left and right thigh over the lower lateral one third surface of the left and right thigh.

L/RKNE: Left and right knee on the flexion/extension axis of the left and right knee.

L/RTIB: Left and right tibia over the lower one third surface of the left and right shank.

L/RANK: Left and right ankle on the lateral malleolus along an imaginary line that passes through the transmalleolar axis.

L/RHEE: Left and right heel on the calcaneous at the same height above the plantar surface of the foot as the toe marker.

L/RTOE: Left and right toe over the second metatarsal head, on the mid-foot side of the equinus break between the fore-foot.

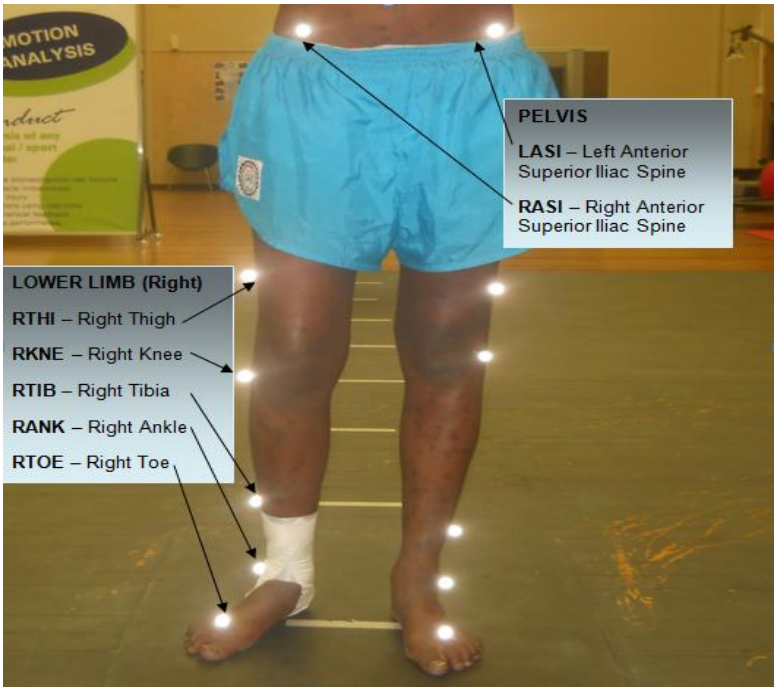


Figure 3.3: Anterior view of the marker placements

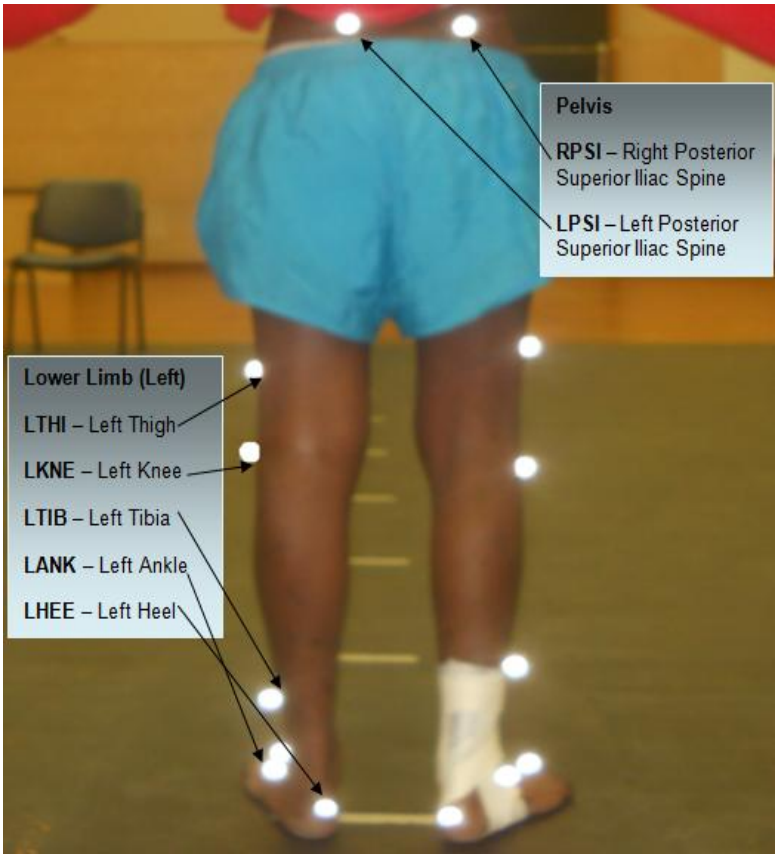


Figure 3.4: Posterior view of the marker placment

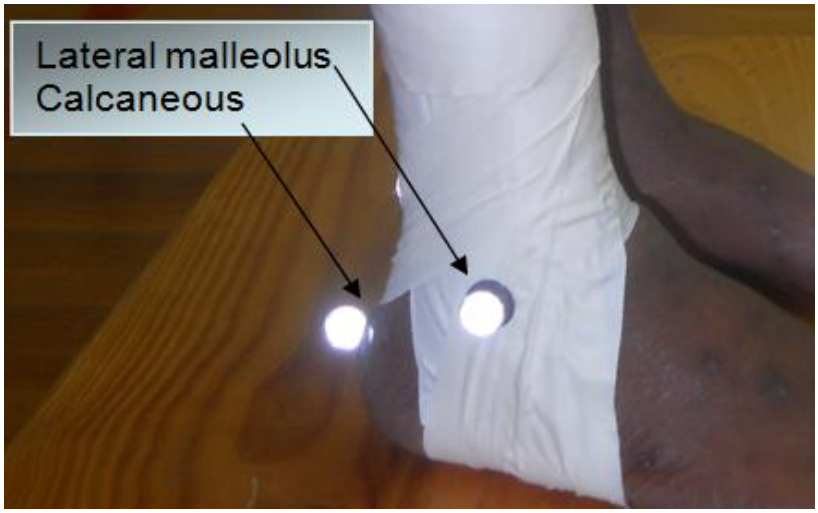


Figure 3.5: Lateral view of the lateral Malleolus and Calcaneous Markers

Gait capturing

Motion analysis was conducted while the participants walked at their most comfortable speed along a seven meter firm surface walkway in two walking conditions, barefoot (control) and with the affected ankle taped (experiment). To reduce measurement errors during gait analysis, analysis was repeated six times for each of the two conditions, e.g., the participants were asked to walk six times barefoot and also six times with a taped affected ankle (Park et al., 2009).

To negate the effect of rehabilitation or any spontaneous recovery, participants were tested individually in a single day and no therapy was given either in the testing day or during the gait analysis. Participants were allowed to rest for approximately three minutes between the six trials of each measurement condition (Rao et al., 2008), and 5 minutes between the two walking conditions. The testing procedure for each participant was completed in a proximately 70 minutes.

A computerized calculation of temporal, spatial and affected ankle joint kinematics was done using Polygon software (Vicon Motion System Limited, Oxford, UK). These parameters were extracted from the Excel sheet of each trial and averaged. The timeframes of the investigated gait sub-phases were identified as follows:

- Initial contact was identified at the exact moment where the foot touches the ground.
- Mid-Stance was identified at 50% of the time interval from initial contact to toe off.
- Pre- swing identified at the exact moment where the foot lifts the ground.
- Mid-swing was identified at 50% of the period from toe off to the next initial contact.

3.9 STATISTICAL ANALYSIS

The patient's demographic, anthropometrics, temporal, spatial and kinematic data were entered on an Excel spreadsheet. A complete gait analysis involved a total of twelve gait trials for each participant. There were six gait trials without any intervention and six trials with the ankle taped. The average value of six repeated trials for temporal, spatial and kinematic parameters was calculated for the two walking conditions. Average values were used for statistical analysis.

The data were analyzed using the STATISTICA 10 (StatSoft Inc., Tulsa, OK, USA) statistical package. All analyses were performed under the supervision of Dr. Martin Kidd, Centre of Statistical Analysis at Stellenbosch University.

The Mean, Standard Deviation, minimum and maximum values were calculated for the demographics, anthropometrics and the temporal, spatial and kinematics gait parameters. The differences between the two gait trials (ankle with or without tape) were calculated. The data were analyzed using Least Square Means test and post hoc Fisher (Least Significant Difference) LSD multiple comparison tests to determine the level of significance between the two trials (statistical significance level $p<0.05$). Mean difference and the confidence intervals were reported.

3.10 PILOT STUDY

A pilot study was conducted on two participants, an adult student as well as hemiplegic patient who met the inclusion criteria of the study. The data of these two participants were not used in the study results.

The main aims of this pilot study were:

- To determine the ability of Plug-in Gait Model in providing the outcomes, mainly the ankle kinematics.
- To determine the responsibilities of the researchers and the availability of the necessary equipment.
- To determine the time needed to complete the analysis.

3.10.1 Findings of the pilot study

Ability of the plug-in gait Model in providing the study outcomes

The Plug-in Gait Model provided all the temporal, spatial, sagittal and frontal plane ankle kinematics, except the width of base of support which should be measured by using a force plate. These data could therefore not be collected in this trial. The marker calibration was done twice to avoid any measurement error due to the changes in the marker positions.

Responsibilities and venue of data collection

The research team became more familiar with the study nature and each knew his responsibilities. There was adequate space to perform the investigations and all the necessary equipment was available in the Motion Analysis Clinic.

Proposed time limit

The investigation for each participant took 70 minutes to complete and included anthropometric measurements, the taping intervention, marker placements, and capturing the gait pattern.

3.11 ETHICAL CONSIDERATIONS

The following ethical aspects were addressed:

Confidentiality:

- The personal information of each patient was kept confidential. Each participant was coded using the first surname letter and first name letter with a numeric number starting from one. Participants were also assured that the results will be published without disclosure of their identity.

Permissions:

- Approval from the Committee for Human Research at Stellenbosch University was obtained (**N10/11/372**; Appendix XI). The study was conducted according to internationally accepted ethical standards and guidelines of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.
- Approval was obtained from the Western Cape Department of Health, administration of PGWC and Tygerberg Hospital (Appendix XII) to conduct data collection on the premises.

Consent:

- Informed written consent to participate in the study was sought and collected from all participants (Appendix VIII). Information and consent were provided to each patient in his/her most understandable language (English, Afrikaans and Xhosa). Each participant was given a copy of the consent form for their own records.
- An indemnity form was completed by all participants who were provided with transportation to get to the Motion Analysis Clinic at Stellenbosch University (Appendix IX).

Voluntary participation:

- Participation in the study was voluntary. Each participant had the right to withdraw from the study at any time without penalty by notifying the researcher.
- The testing session was arranged so as not to clash with the patient's therapeutic schedule.

Advice and referral:

- The results were made available to the patients and all their questions were answered.

Financial benefits:

- The patients were assured that they would not have to pay to take part in this study, nor would they receive payment to participate.
- There was no cost involved for the participating patients and their transport cost was reimbursed.

Video recordings:

- All participants' recordings were safely stored at the Division of Physiotherapy, Stellenbosch University. None of these records will be used after the completion of the study, except for those who agreed to the use of their records for scientific presentations.

CHAPTER 4

RESULTS

The results of the study are presented in accordance with the study objectives in the previous chapter. The findings of the anthropometric measurements, temporal, spatial and the kinematic gait parameters are described individually in the following sections. A significant level of 5% ($p<0.05$) was used as guideline for determining statistical differences.

4.1 SAMPLE DESCRIPTION

Ten participants including six males and four females completed the study without any problems or interruptions. All the participants were post stroke patients with a mean age of 39.9 ± 12.47 years. The youngest participant was 21 years old and the oldest was 58 years old. Six participants presented with left side hemiplegia and four with right side hemiplegia. The mean time since the stroke onset was 79.2 ± 94.40 days (Table 4.1).

All participants were able to walk seven meters without the use of walking aids or devices. Appendix X describes the mean, standard deviation and range for anthropometric measurements of all participants.

Table 4.1: Description of study participants

No	Age	Gender	Hemiplegic Side	Number of days since onset of stroke	Walking Devices use for longer distances	Location
1	39	Male	Left	9	No devices	TBH
2	47	Male	Left	13	Elbow crutches	TBH
3	37	Male	Left	293	Elbow crutches & PAFO	DCRC
4	58	Male	Right	12	Elbow crutches	TBH
5	48	Male	Right	10	Elbow crutches	TBH
6	51	Male	Right	52	Elbow crutches	DCRC
7	25	Female	Right	23	Elbow crutches	TBH
8	26	Female	Left	170	Elbow crutches	TBH
9	47	Female	Left	145	Four point stick	TBH
10	21	Female	Left	56	PAFO	TBH

DCRC: Delft Community Rehabilitation Centre
TBH: Tygerberg Hospital
PAFO: Plastic ankle foot orthosis

Figure 4.1 illustrates the identification and the recruitment of the patients and the randomization of the testing order of the participants.

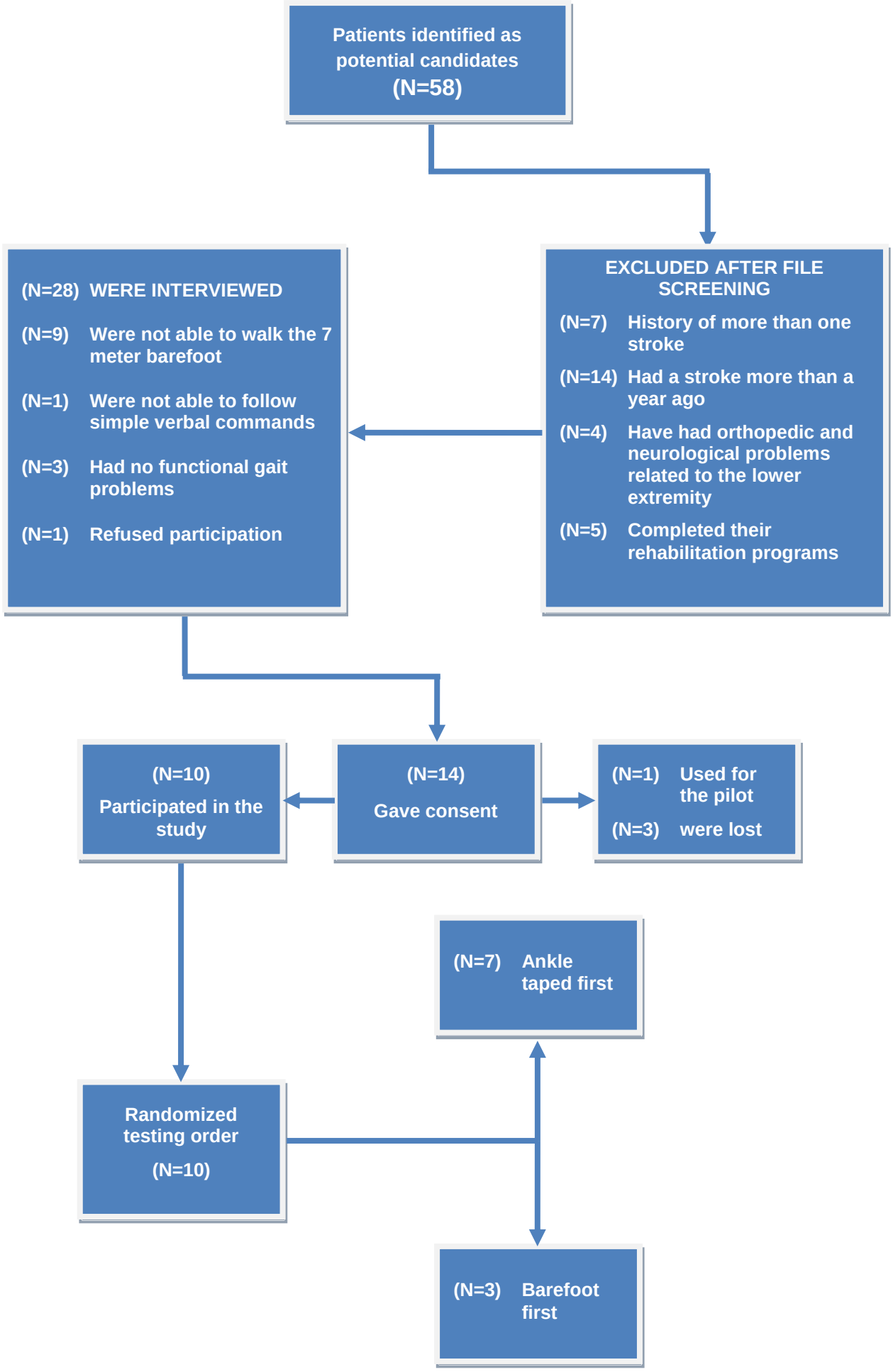


Figure 4.1: Flowchart of recruitment and the testing order of the participants

4.2 INTERACTIONS IN THE INTERVENTION ALLOCATION

Seven participants were randomized to walk with the ankle tape first and three walked barefoot first. Comparison between both testing situations showed no statistically significant difference between the two testing orders for all investigated parameters ($p>0.05$). Therefore, the results of the two testing situations were pooled and reported together.

4.3 TEMPORAL SPATIAL GAIT PARAMETERS

Temporal and spatial gait parameters were compared in two walking conditions: barefoot and with the ankle taped. The findings for each parameter are reported in the following sub-sections.

4.3.1 Temporal gait parameters

The effect of ankle taping on temporal gait parameters including gait speed, cadence, stance and swing duration of the affected and unaffected leg were compared. Table 4.2 shows the overall descriptive statistics of temporal gait parameters, significance level, mean difference and the 95% confidence interval.

Table 4.2: Descriptive statistics of temporal gait parameters and analysis (N=10)

Temporal parameters		Barefoot Mean ± SD	Ankle taped Mean ± SD	Mean Difference 95% Confidence interval	Significance (p<0.05)
Gait Speed (m/s)		0.54 ± 0.36	0.54 ± 0.33	0.01 (-0.04– 0.06)	0.616
Cadence (steps/min)		77.80 ± 25.44	81.80 ± 22.16	4.9 (-1.15 – 11.03)	0.098
Stance duration (%)	Affected	47.28 ± 5.46	45.97 ± 3.50	-1.6 (-4.49 – 1.20)	0.220
	Unaffected	53.32 ± 5.58	53.81 ± 3.33	0.9 (-1.63 – 3.45)	0.432
Swing duration (%)	Affected	19.57 ± 11.87	17.30 ± 8.41	-3.05 (-6.84 – 0.72)	0.099
	Unaffected	15.88 ± 7.08	15.77 ± 5.96	-0.1 (-1.31 – 1.55)	0.853

A mean difference in cadence of 4.9 steps/min (95% CI -1.15 - 11.03) was observed when the ankle was taped. However, this failed to reach significant improvement (p=0.09). The upper limit of the confidence intervals indicates that ankle taping could potentially improve the cadence by 11 steps/min. The wide CI could be related to the small sample and the large variation in gait parameters.

This improvement in cadence did not coincide with an improvement in gait speed of walking in this sample (0.01m/s; 95% CI 0.04 – 0.06. p = 0.61). The upper limit of the confidence interval indicates a maximum improvement of 6 cm/s in gait speed.

Taping of the ankle resulted in a reduction of the affected leg stance duration (-1.6 percent; 95% CI - 4.49 – 1.20. p = 0.22). This coincided with a reduction in the unaffected leg swing duration (-0.1 percent; 95% CI -1.31 – 1.55. p = 0.85). This linear relationship was not observed between the unaffected leg stance duration (0.09 percent; 95% CI -1.63 – 3.45. p = 0.43) and the affected leg swing duration (-3.04 percent; 95% CI -6.84 – 0.72). None of the observed

differences reached statistical significance in this sample. The clinical significance of the reported findings is not clear (Table 4.2).

4.3.2 Spatial gait parameters

The effects of ankle taping on spatial gait parameters including stride and step length of the affected and unaffected leg were compared. Table 4.3 shows the overall descriptive statistics of spatial gait parameters, significance level, mean difference and the 95% confidence intervals.

Ankle taping did not result in any significant differences in stride or step length of either leg. The lower limits of the 95% CI include values that indicated that the maximum potential effect of ankle taping is a decrease of 6cm in the stride length of both the affected and unaffected legs. The 95% CI also include values indicating a maximum potential decrease in step length of 3cm of both legs (Table 4.3).

Table 4.3: Descriptive statistics of spatial gait parameters and analysis (N=10)

Spatial parameters		Barefoot Mean ± SD	Ankle taped Mean ± SD	Mean difference 95% Confidence interval	Significance (p<0.05)
Stride length (m)	Affected	0.76 ± 0.29	0.73 ± 0.26	-0.01 (-0.06 – 0.03)	0.416
	Unaffected	0.77 ± 0.29	0.74 ± 0.27	-0.02 (-0.06 – 0.01)	0.266
Step length (m)	Affected	0.39 ± 0.15	0.38 ± 0.14	0.0 (-0.03 – 0.01)	0.588
	Unaffected	0.37 ± 0.14	0.35 ± 0.13	-0.01 (-0.03 – 0.01)	0.290

4.4 AFFECTED ANKLE KINEMATIC GAIT PARAMETERS

Kinematic gait parameters including sagittal and frontal plane kinematics were compared in two walking conditions: barefoot and with the ankle taped. Table 4.4 illustrates the overall descriptive statistics of affected ankle kinematic parameters, the significance level, mean difference and the 95% confidence intervals.

Table 4.4: Descriptive statistics of the affected ankle kinematic gait parameters and analysis

Ankle kinematics		Barefoot Mean ± SD	Ankle taped Mean ± SD	Mean difference 95% Confidence interval	Significance (p<0.05)
Dorsiflexion/ Plantarflexion	Initial contact	-6.04 ± 4.03	-4.62 ± 4.64	1.6 (-0.78 – 3.99)	0.160
	Mid-Stance	6.49 ± 5.75	6.30 ± 5.38	-0.2 (-2.38 – 1.79)	0.755
	Pre-Swing	-2.84 ± 6.47	-1.55 ± 4.44	1.03 (-1.74 – 3.82)	0.414
	Mid-Swing	-1.13 ± 7.27	-2.05 ± 6.17	-0.93(-4.29 – 2.42)	0.538
Inversion/ Eversion	Initial contact	-16.82 ± 21.40	-16.16 ± 12.42	0.5 (-10 - 11.5)	0.909
	Mid-Stance	-17.96 ± 21.47	-15.24 ± 14.51	2.9 (-6.9 – 11.7)	0.514
	Pre-Swing	-27.21 ± 19.91	-25.82 ± 17.94	1.1 (-4.4 – 6.7)	0.652
Values of <0 indicates plantarflexion in the sagittal plane and inversion in the frontal plane Values of >0 indicates dorsiflexion in the sagittal plane and eversion in the frontal plane					

Taping of the ankle resulted in a mean decrease in plantarflexion during the initial contact phase (1.6 degree; 95% CI -0.78 – 3.99). The upper limit of the confidence interval includes values which indicate a potential decrease in plantarflexion. The observed difference did not reach statistical significance in this sample (p = 0.16). The true estimate of the effect of taping on the position of the ankle during the remaining three phases of walking remains imprecise.

The confidence intervals of the mean difference in the position of the ankle in the sagittal and frontal plane include values which could be clinically beneficial (Table 4.4). None of the observed differences reached statistical significance in this sample

The estimated effect of ankle taping on ankle kinematics in the frontal plane also remains inconclusive (Table 4.4). While we were unable to demonstrate a real difference between the groups at initial contact ($p = 0.9$) mid-stance ($p=0.51$)- and pre-swing ($p=0.65$) respectively, we cannot be certain that the results are of no clinical importance due to the wide confidence intervals. The upper limits of the confidence intervals include values which could result in a clinically important decrease in inversion during the three phases of walking. Larger samples could provide a more precise estimate of the effect.

The main results of the study indicate that taping of the affected ankle joint in a neutral position does not significantly improve temporal spatial gait parameters and ankle joint kinematics in ambulant adult hemiplegic patients. The following positive trends were however found and need to be further explored in larger homogeneous study samples:

- Ankle taping of ambulant adult hemiplegic patients has limited benefits on selected temporal parameters. Ankle taping could potentially improve cadence.
- Ankle taping could decrease plantarflexion of the plegic leg at initial contact.

CHAPTER 5

DISCUSSION

5.1 INTRODUCTION

Temporal, spatial and kinematic gait parameters of hemiplegic patients are significantly different from that of the able-bodied population (Stokic et al., 2009; Wang et al., 2007; Olney & Richards, 1996). Ankle foot orthosis (AFOs) are the most common prescribed device to address hemiplegic gait deviations, leg alignment and affected ankle motion (Bleyenheuft et al., 2008; Rao et al., 2008; de Wit et al., 2004).

A systematic review and meta-analysis was conducted by the principal researcher in preparation for the main study and is described in Chapter 2. Sixteen studies that reported on the immediate effect of different types of ankle foot orthoses on hemiplegic gait parameters were included. The review revealed that AFOs are effective in improving the hemiplegic gait speed, cadence, stride length, step length and the affected ankle kinematic gait parameters in the sagittal plane. However, this review concluded that there is insufficient evidence to either support or refute the effectiveness of ankle taping on hemiplegic gait parameters. There is a need for an alternative ankle foot device such as ankle taping which is cost effective, readily available and could serve some of the functions of AFOs when costs are prohibitive or AFOs are unavailable. Therefore, the purpose of this study was to investigate the immediate effect of ankle taping on temporal spatial gait parameters and joint kinematics of the affected ankle.

A discussion of the results is presented in the following sections, including the effectiveness of ankle taping on temporal, spatial (5.2), and the affected ankle kinematic gait parameters (5.3), study design (5.4) and the study population (5.5).

5.2 TEMPORAL SPATIAL GAIT PARAMETERS

This is the first study to investigate the immediate effect of ankle tape on the temporal, spatial and affected ankle kinematics in ambulant hemiplegic adults. Even though none of the observed differences reached statistical significance in this sample, this study highlights potential clinical effects on specific temporal and spatial gait parameters. This includes an increase in gait cadence and swing duration accompanied by improvement in the position of the ankle in the frontal plane on initial contact. In the current study the stride and step length of the affected and unaffected legs were not influenced following the application of ankle tape. This study suggests that the clinical significance of taping on gait speed, step and stride length is questionable.

Hemiplegic patients demonstrate prolonged stance duration of the unaffected leg compared to the affected leg occupying a greater proportion of the full gait cycle and compared to the able-bodied population (Olney & Richards, 1996). In the current study, a decrease in swing duration of the affected leg was observed. It was expected that ankle taping would result in a more symmetrical gait pattern between the affected and the unaffected leg. The unaffected leg should thus have had a greater reduction in stance duration compared to the affected leg. However, this was not observed in the present study. The reduction in stance duration of the affected leg was accompanied by the reduction in swing duration of the unaffected leg while the reduction in the swing duration of the affected leg was not followed by the reduction in stance duration of the unaffected leg.

The available literature demonstrated that different types of AFOs improved the stance and swing duration as well as the stride and the step lengths in the hemiplegic patients (Esquenaze et al 2009; Hesse et al 1999). Rao et al., 2008 studied the effect of AFOs on gait speed in acute and chronic post stroke hemiplegic patients and demonstrated that gait speed was significantly increased in the two groups following the use of AFOs. A similar positive effect of AFOs on gait speed of hemiplegic patients was reported by others (Abe et al., 2009; Fatone & Hansen, 2007; de Wit et al., 2004; Gök et al., 2003). It is difficult to compare the results of present study to studies investigating the

effects of AFOs due to the differences in methodology and devices. According to the Hoffer Functional Ambulation Scale, a difference of 20 cm/s in walking speed is regarded as clinically relevant (Perry, Garrett, Gronley & Mulroy, 1995). Therefore, it can be assumed that the effect of ankle taping on gait speed in the current study was not clinically significant.

5.3 AFFECTED ANKLE KINEMATIC GAIT PARAMETERS

The application of tape resulted in minor displacement in ankle dorsiflexion/plantarflexion and inversion/eversion at initial contact, mid stance, pre-swing and dorsiflexion/plantarflexion at mid-swing. The fact that stroke patients might experience an increase in plantarflexion of 4.29 degrees during the mid-swing was disappointing. Nevertheless, although the effect was not statistically significant, ankle taping could improve ankle position and initial contact by decreasing plantarflexion. The fact that ankle taping resulted in a decrease of plantarflexion from mid swing to initial contact indicated that plegic strike pattern was returning towards normal. This could lead to a safer gait pattern and reduce the risk of falling. This trend towards a reduction in plantarflexion at initial contact were not accompanied by increased gait speed, stride and step length.

The kinematic parameters of hemiplegic patients are significantly different from the able-bodied population (Olney & Richards, 1996). Their lower limb kinematics are characterized by a drop foot of the affected leg during the swing phase and at initial contact (Rao et al., 2008). There is ankle instability with increased plantarflexion at initial contact, mid-swing and decreased plantarflexion at pre-swing in the sagittal plane (Olney & Richards, 1996).

Excessive ankle plantarflexion and inversion is a common impairment in the affected leg of hemiplegic patients (Fatone & Hansen 2007; Olney & Richards, 1996). Ankle taping in the current study decreased the excessive plantarflexion and inversion at initial contact,mid-stance and preswing. This could be the result of the direct effect of the tape on ankle joint stability or improved awareness of the ankle joint position during above-mentioned phases..

Hillier & Masters (2005) reported that taping can be used effectively in hemiplegic patients as an alternative technique/device when an AFO is not available or cost-effective. Taping provides support during barefoot walking, unlike the different AFOs required to be worn with a shoe (Hillier & Masters, 2005; Bohannon 1983).

In summary, it could be stated that ankle taping did not result in statistically significant improvements in the temporal, spatial and affected ankle kinematic gait parameters. However, clinically significant improvements were observed which need to be confirmed with a larger sample.

5.4 STUDY DESIGN

A clinical trial was conducted using a crossover randomized testing order to answer the research question. The patients acted as their own control for each of the analysis situations (barefoot and ankle taped). There was no significance difference between the two analysis situations, barefoot first or ankle taped first, for all the studied outcomes. Therefore, the analysis situation did not affect the results of the study.

The gait analysis procedure required participants to walk seven meters: six times barefoot and six times with the ankle taped. Participants were allowed to rest for three minutes after each trial and five minutes before moving to the second testing condition in order to prevent the influence of fatigue. Rest intervals of 2 to 5 minutes have been reported by previous studies evaluating the effect of AFOs on gait parameters of ambulant hemiplegic patients (Park et al., 2009; Rao et al., 2008; Wang et al., 2007). Even with the given rest times between analyses the trials were conducted within 70 minutes. The rest periods could have been too short and fatigue might have influenced the patients' walking ability and pattern during the analyses. All analyses were performed in a single day for each participant. Even though Tyson and Rogerson (2009) reported that gait analysis performed in a single day would negate the effect of rehabilitation or any spontaneous recovery, the role of fatigue needs to be considered in future studies.

The reliability (repeatability) of gait parameters with minimal measurement error is important for quantitative gait analysis. The current study was conducted using one of the most sophisticated computerized motion analysis systems (Vicon Nexus 1.1.7; Vicon Motion System Limited, Oxford, UK) with the most developed capturing cameras and software. Yavuzer et al. (2008) reported that temporal, spatial and sagittal plane gait kinematic parameters measured by Vicon gait analysis system were repeatable and could be used to assess the treatment effects in stroke patients. Although using this system was labour intensive, it allowed the researcher to study clinically related gait parameters and ankle joint kinematics in much more detail compared to other simple devices such as stopwatches, video analysis, paper walkways and stickers (Rao et al., 2008).

5.5 STUDY POPULATION

The study sample was recruited using specific criteria, mainly according to the patients' ability to walk the minimum distance of seven meters to perform the gait analysis. Inclusion criteria required that participants were able to walk at least seven meters unaided. Participants were however expected to repeat the seven meters six times and had to walk a total of 84 meters without the use of a walking device. This could have caused fatigue and led to large variations between the participants as seen in the wide confidence intervals of the results.

The current study consisted of a small sample size that raised some concerns about the power of the study. To the researcher's knowledge, no previous studies investigated the effect of ankle taping on the temporal, spatial and kinematic gait parameters in hemiplegic patients. The average number of participants of various studies included in a systematic review (Leung & Moseley, 2002) evaluating the immediate effects of different types of AFOs on the temporal, spatial and kinematic gait parameters in hemiplegic patients was ten. Due to costs involved in Vicon analyses and limited funds, the principal researcher decided to describe the effect on a sample of only ten patients.

Average time since stroke onset for participants included in previous studies evaluating the effectiveness of different types of AFOs on gait parameters in

hemiplegic patients varied from 5 weeks to 28 months (Park et al., 2009; Wang et al., 2009; Bleyenheuft et al., 2008). The average time since stroke onset in the current study was approximately eleven weeks with majority of patients (N=7) between 1 to 8 weeks. This meant that patients were still in the acute recovery phase and might differ in the severity of walking disability (Jorgensen et al., 1995). Other factors that might have influenced the patients walking ability such as age, anthropometrics, spasticity or even flaccidity of plegic leg muscles could be possible factors that led to a wide variability of gait parameters and resulted in the wide confidence intervals.

The clinical implications, limitations and recommendations for future studies will be discussed in the next chapter.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

Ankle taping of ambulant adult hemiplegic patients has limited benefits on selected temporal parameters. Ankle taping could potentially improve cadence. Ankle taping did not result in any clinically important differences in the spatial parameters. Ankle taping could decrease plantarflexion of the plegic leg at initial contact. This is an important finding since improved ankle position at initial contact may result in a safer gait pattern and could lead to a reduction in falls as well as improves the patient's functionality. This could further be explored with larger study samples. The effect of ankle taping on the other kinematic gait parameters remains inconclusive.

6.2 LIMITATIONS OF THE STUDY

A relatively small sample size was a major limitation of the study reducing the power. This might have contributed to the insignificant differences observed in the analysis of temporal, spatial and affected ankle kinematic gait parameters. The small sample size influenced the results due to the potential variability between participants which was noted in wide confidence intervals of the reported outcomes.

A pseudo-taping technique was not used in the study which might have led the participants to expect improvement in their scores with the ankle taped. Only one style of tape and taping technique was used for all participants. It could be a limiting factor in a sense that the taping technique might need to be individualized to match the characteristics of different ankle biomechanics and deformities.

The current study described the immediate effect of ankle taping. It is possible that repeated use of ankle taping over time could affect the temporal, spatial and the affected ankle kinematics differently.

6.3 RECOMMENDATIONS

Studies with more similar baseline characteristics of the participants may provide more robust investigation of the effect of ankle taping.

Future research studies should combine force plates with motion analysis systems to study the effect of ankle tape on other clinically important gait parameters such as width of base of support, timing and distribution of plantar pressures, as well as the effect on knee and hip joint kinematic gait parameters.

Patients' opinions and satisfaction regarding the use of ankle taping for rehabilitation of hemiplegic patients should be evaluated.

Future research studies could investigate the effect of ankle taping in conjunction with rehabilitation programs, mainly with emphasis on facilitating improved ankle position at initial contact during gait retraining sessions. Another area for study could be to establish norms for hemiplegic gait taken into consideration the age of the patient and the time since the stroke.

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APPENDIX I: SYSTEMATIC REVIEW SEARCH STRATEGY – DATA BASES

Databases		Keywords/ MESH/ Major topics	Hits
Pubmed Central	1	("Stroke"[Mesh] OR "Hemipleg*"[Mesh]) AND "Gait"[Mesh]	2989
	2	#1 AND (assistive device*)	22
	3	#1 AND (ankle foot orthos*)	74
	4	#1 AND AFO	43
	5	#1 AND (splint*)	16
	6	#1 AND taping	2
	7	#1 AND strapping	0
Cohrane Library	1	(stroke OR hemipleg*) AND (gait OR walking)	573
	2	#1 AND (assistive device*)	4
	3	#1 AND (Ankle foot orthos*)	25
	4	#1 AND AFO	9
	5	#1 AND (splint*)	7
	6	#1 AND taping	5
	7	#1 AND strapping	0
CINAHL	1	(stroke OR “hemipleg*”) AND (gait OR walking)	1410
	2	#1 AND “assistive device*”	25
	3	#1 AND “Ankle foot orthos*”	68
	4	#1 AND AFO	33
	5	#1 AND “splint*”	12
	6	#1 AND taping	8
	7	#1 AND strapping	8
OT Seeker	1	(stroke OR “hemipleg*”) AND (gait OR walking)	128
	2	#1 AND “assistive device*”	1
	3	#1 AND “Ankle foot orthos*”	6
	4	#1 AND AFO	3
	5	#1 AND “splint*”	2
	6	#1 AND taping	0
	7	#1 AND strapping	0
SPORTDiscus	1	(stroke OR “hemipleg*”) AND (gait OR walking)	720
	2	#1 AND “assistive device*”	6
	3	#1 AND “Ankle foot orthos*”	35
	4	#1 AND AFO	23
	5	#1 AND “splint*”	7
	6	#1 AND taping	5
	7	#1 AND strapping	0
PsyAR TICLE	1	(stroke OR “hemipleg*”)	213
	2	#1 AND gait	0
	3	#1 AND walking	1

Databases		Keywords/ MESH/ Major topics	Hits
PEDro	1	Neurology AND gait	215
	2	#1 AND assistive device*	3
	3	#1 AND ankle foot orthos*	18
	4	#1 AND AFO	12
	5	#1 AND splint*	33
	6	#1 AND taping	30
	7	#1 AND strapping	0
	8	Neurology AND walking	214
	9	#8 AND assistive device*	1
	10	#8 AND ankle foot orthos*	19
	11	#8 AND AFO	9
	12	#8 AND splint*	30
	13	#8 AND taping	26
	14	#8 AND strapping	0
Proquest Medical Library	1	(stroke OR hemipleg*) AND (gait OR walking)	436
	2	#1 AND “assistive device*”	8
	3	#1 AND “Ankle foot orthos*”	17
	4	#1 AND AFO	11
	5	#1 AND “splint*”	5
	6	#1 AND taping	3
	7	#1 AND strapping	0
BioMed Central	1	(stroke OR “hemipleg*”) AND (gait OR walking)	572
	2	#1 AND (assistive device*)	54
	3	#1 AND (ankle foot orthos*)	35
	4	#1 AND AFO	8
	5	#1 AND (splint*)	12
	6	#1 AND taping	5
	7	#1 AND strapping	2
Science Direct	1	(stroke OR “hemipleg*”) AND (gait OR walking) AND (assistive device*)	893
	2	(stroke OR “hemipleg*”) AND (gait OR walking) AND (ankle foot orthos*)	641
	3	(stroke OR “hemipleg*”) AND (gait OR walking) AND AFO	322
	4	(stroke OR “hemipleg*”) AND (gait OR walking) AND (ankle splint*)	6
	5	(stroke OR “hemipleg*”) AND (gait OR walking) AND (ankle taping)	177
	6	(stroke OR “hemipleg*”) AND (gait OR walking) AND (ankle strapping)	61

Databases		Keywords/ MESH/ Major topics	Hits
Clinicaltrials.gov	1	(stroke OR hemiplegia OR hemiplegic) AND gait	85
	2	(stroke OR hemiplegia OR hemiplegic) AND walking	107
Web of science	1	(stroke OR "hemipleg*") AND (gait OR walking) AND (assistive device*)	31
	2	(stroke OR hemipleg*) AND (gait OR walking) AND (ankle foot orthos*)	103
	3	(stroke OR hemipleg*) AND (gait OR walking) AND AFO	40
	4	(stroke OR hemipleg*) AND (gait OR walking) AND (splint*)	15
	5	(stroke OR hemipleg*) AND (gait OR walking) AND taping	9
	6	(stroke OR hemipleg*) AND (gait OR walking) AND strapping	0
Ingenta Connect	1	(stroke OR hemipleg*) AND (gait OR walking	347
	2	#1 AND (assistive device*)	5
	3	#1 AND (ankle foot orthos*)	19
	4	#1 AND AFO	8
	5	#1 AND "splint*"	2
	6	#1 AND taping	2
	7	#1 AND strapping	0

APPENDIX II: ADAPTIVE JBI DATA EXTRACTIONS FORM (Hemingway et al., 2006).

Citation			
Reviewer			
Database:			
Authors:			
Title:			
Publication date:			
Journal:	Journal:		
	Volume:	Issue:	Page numbers:
Thesis / Dissertation:	Institution:		
Country where research was conducted:			
Type of study			

Participants			
Number of participants:	Total:	Completed study:	Withdrawn:
Gender:	Total ♂:	Total ♀:	
Randomized:	☐ Yes	☐ No	
Mean age:			

Intervention			
Intervention			
Group A	Control group B		
Interventions adequately described:	☐ Yes	☐ No	☐ Not clear

OUTCOME MEASURES

Definition_____

_____ **other outcome measures**

Outcome description	Scale/Measure

RESULTS

DICHOTOMOUS DATA

Outcome	Control group number/total number	Treatment group number/ total number

CONTINUOUS DATA

Outcome	Control group mean & SD (number)	Treatment group mean & SD (number)

AUTHORS' CONCLUSIONS

_____

_____

COMMENTS

_____

_____

APPENDIX III: JBI CRITICAL APPRAISAL CHECKLIST FOR RANDOMIZED AND PSEUDO-RANDOMIZED STUDIES

Assessment for : MacDonald, B - In J Effectiveness in Health Care (2001)

Type: Primary
User: Craig Lockwood
Design: Randomised Control Trial / Pseudo-randomised Trial

	Criteria	Yes	No	Unclear
1)	Was the assignment to treatment groups truly random?	○	○	○
2)	Were participants blinded to treatment allocation?	○	○	○
3)	Was allocation to treatment groups concealed from the allocator?	○	○	○
4)	Were the outcomes of people who withdrew described and included in the analysis ?	○	○	○
5)	Were those assessing outcomes blind to the treatment allocation?	○	○	○
6)	Were the control and treatment groups comparable at entry?	○	○	○
7)	Were groups treated identically other than for the named interventions?	○	○	○
8)	Were outcomes measured in the same way for all groups?	○	○	○
9)	Were outcomes measured in a reliable way?	○	○	○
10)	Was appropriate statistical analysis used?	○	○	○

APPENDIX IV: JBI CRITICAL APPRAISAL CHECKLIST FOR COHORT/CASE CONTROL APPRAISAL

	Criteria	Yes	No	Unclear
1)	Is sample representative of patients in the population as a whole?	○	○	○
2)	Are the patients at a similar point in the course of their condition/illness?	○	○	○
3)	Has bias been minimised in relation to selection of cases and of controls?	○	○	○
4)	Are confounding factors identified and strategies to deal with them stated?	○	○	○
5)	Are outcomes assessed using objective criteria?	○	○	○
6)	Was follow up carried out over a sufficient time period?	○	○	○
7)	Were the outcomes of people who withdrew described and included in the analysis?	○	○	○
8)	Were outcomes measured in a reliable way?	○	○	○
9)	Was appropriate statistical analysis used?	○	○	○

APPENDIX V: SYSTEMATIC REVIEW STUDIES EXCLUDED

Excluded Studies	Main reason of exclusion
Fatone et al., 2009	The study essentially investigates the effect of AFO alignment and the foot-plate length compared to the able-bodied adults; not to either walking barefoot or with shoe only.
Wang et al., 2007	The study compared the effect of AFO to walking without AFO. It is not clear what without AFO means since it could be walking barefoot or with shoe.
Iwata et al., 2003	The study compared the effect of an AFO when attached to an inhibitor bar to walking with AFO alone not to either walking barefoot or with shoe only.
Franceshini et al., 2003	The study compared the effect of AFO to walking without AFO. It is not clear what without AFOs means since it could be walking barefoot or with shoe.
Franceshini et al., 2002	The study compared the effect of AFO to walking without AFO. It is not clear what without AFOs means since it could be walking barefoot or with shoe.
Beckerman et al., 1996	The study compared a fixed AFO with a hinged AFO rather than walking barefoot or with shoe only.
Myazaki et al., 1997	The study was designed to evaluate the mechanical property of AFOs on the hemiplegic gait; not to investigate the effect on the gait parameters.
Wong et al., 1992	The study compared the gait parameters between two types of AFOs but no comparison to either walking barefoot or with shoe only.
Lehmann et al., 1987	The study compared the effect of the AFOs to the able-bodied walking; not to walking barefoot or with shoe only.
Corcoran et al., 1970	The study compared the effect of the AFOs to the walking with two types of braces and to the able-bodied walking; not to walking barefoot or with shoe only.

APPENDIX VI

The approximate hip, knee and ankle range of motion needed for normal gait

(Olney, 2005)

Joint	Movement	Functional degree
Hip	Flexion	20°
	Extension	20°
	Abduction	7°
	Adduction	5°
	Internal rotation	0°
	External rotation	7°
Knee	Extension to flexion	0°-60°
Ankle	Plantarflexion	25°
	Dorsiflexion	7°
	Inversion	15°
	Eversion	5°
	Internal rotation	5°
	External rotation	5°

APPENDIX VII: THE TELEPHONIC INTERVIEW SHEET AND SUBJECT DATA FORM

Name		
Address		
Tel NO		
Email		
Date		

……

N	Questions	Answer				E/NE
1	How old are you?				Year	
2	Did you have stroke or head injury?	Yes		No		
3	When did it happen? Less than one year or more than a year ago.					
4	How many times did it happen to you?					
5	Which side of your body is affected?	Rt	Lt	Both		
6	Do you have any other neurological problems apart from stroke or head injury?	**Yes**		No		
7	**If you don't mind what are these problems?**					
8	Are you struggling with walking?	Yes		No		
9	Do you have any other problems affecting your walking ability other than the stroke?	**Yes**		No		
10	**If you don't mind, what are these problems?**					
11	Are you receiving any kind of treatment? (PT, OT, rehab)	PT	OT	Med	Oth	
12	Are you using any assistive device to help you walk better?	**Yes**		No		
13	**What is the device that you are using now? is it Wheelchair, crutches, AFOs or others?**					
14	For around how long are you able to walk with this device?				Meters	
15	Are you able to walk without any assistive device?	Yes		No		
16	Did you try to walk without this device?	**Yes**		No		
17	**For how long, in meters?**				Meters	
19	Do you have other contact numbers so I can reach you to find out more details in the future?					

……
……
……
……

SUBJECT DATA FORM

Name: - ……
Date of Investigation: ……
Gender: Male…….. Female ……
DOB: - …… File Number: - ……
Address: - …… ……
…… ……..
Tel N: - ……
E-Mail: - ……

Diagnosis	Stroke……. ……	Head injury ……
Date of stroke onset		
Affected Side	Right ……	Left ……
Medical History		
Other problems-Neuro/Ortho		
Weight		KG
Height		MM
Leg Length	MM/ Left	MM/Right
Knee Width	MM/Left	MM/Right
Ankle Width	MM/Left	MM/Right
Device currently using		
Any device during the test	…… Why…… …… ……	
Rehabilitation	PT…… OT……Ortho…….. Speech…..... Others ……	
Barefoot walking		
Number of trials (BF)	N …… Notes: - …… …… …… ……	
Ankle taped walking		
Number of trials (AT)	N…… Notes …… …….. …… ……	
Patient feeling while walking with the ankle tape	…… …… ……	
Conflict of interest		

Notice……
……

APPENDIX VIII

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

ENGLISH, AFRIKAANS AND XHOSA

TITLE OF THE RESEARCH PROJECT:

Investigation into the immediate effect of ankle taping on temporal spatial gait parameters and affected ankle kinematics in ambulant adult hemiplegic patients

REFERENCE NUMBER: (**N10/11/372**)

PRINCIPAL INVESTIGATOR: Mohammad AL-Talahma (B.Sc Physiotherapy).

ADDRESS:

Division of Physiotherapy
Department of Interdisciplinary Health Science
Stellenbosch University
PO Box 19063
Tygerberg
7505

CONTACT NUMBER: 07 96210832

Your are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do initially agree to take part.

This study has been approved by the **Committee for Human Research at Stellenbosch University** and will be conducted according to internationally accepted ethical standards and guidelines of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The aim of the study is to investigate the immediate effect of ankle joint taping on walking ability in post-stroke patients. This research will be conducted at the Physiotherapy Motion Analysis Lab (Stellenbosch University, Tygerberg Campus). You will be asked to walk seven meters barefoot and with tape applied to your ankle. You will be asked to walk three times in each of these conditions. You will also be given ample rest during the investigation. Taping will be applied by the principal investigator to the ankle that was affected by the stroke. You will not receive any additional treatment during this investigation.

The following will be measured by the Vicon Motion Analysis System: walking speed, step length and ankle position. The analysis will be done by putting non-invasive markers on your body which will be visible to the Vicon Motion Analysis System. You will have to wear tighter fitting clothing to allow application of the markers. However, your body will remain fully clothed during all testing procedures.

The most appropriate times for testing will be agreed upon by the principal investigator, administration of the Vicon Motion Analysis Laboratory and according to your treatment schedule. The expected time to finish the procedure is approximately 60 minutes. With this study we hope to be able to recommend a supplementary intervention for post-stroke gait rehabilitation.

Why have you been invited to participate?

To conduct a scientific study, a set of inclusion criteria has been set. You fall within these criteria: you are an adult diagnosed with a single onset stroke

within the last year. You present with abnormal gait but are able to walk barefoot for seven meters without support.

What will your responsibilities be?

If possible, you may use your own transport to attend the appointment at the Physiotherapy Motion Analysis Lab at (Stellenbosch University, Tygerberg Campus). You will be reimbursed for your transport cost. In case you do not have transport, transport will be provided for you and you will be requested to sign an indemnity form. You will need to provide consent should you agree to participate in the study.

Will you benefit from taking part in this research?

There is no risk involved in taking part in this research project. Your participation will help the research team to recommend an intervention for walking rehabilitation after stroke. If the researchers recommend this technique as an effective treatment option, your therapist will be able to choose this technique as a part of your rehabilitation program.

Are there any risks involved in your taking part in this research?

There are no known risks involved in participating in this research project.

If you do not agree to take part, what alternatives do you have?

If you choose not to participate, your therapy will continue with your therapist. You will not suffer any negative consequences.

Who will have access to your medical records?

All the information collected for this project will be treated as confidential and will be protected. If this information is used in a thesis or publication, your identity will remain anonymous. Only the researchers will have access to the information. The records will be kept in safe storage in the Physiotherapy Division at Stellenbosch University. All video recordings will be destroyed after

the completion of study, except if you agree to have them used for scientific presentations.

What will happen in the unlikely event of some form of injuries occurring as a direct result of your taking part in this research study?

In the event that you are injured during testing, the research team will attend to your needs immediately and refer you to the most appropriate type of management.

Will you be paid to take part in this study and are there any costs involved?

You will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

1. You can contact Mohammad Al-Talahma at 07 96210832 if you have any further queries or encounter any problems.
2. You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by the research team.
3. You will receive a copy of this information and signed consent form for your own records.
4. The results of your gait analysis will be sent to you as soon as it is available. You will have the opportunity to discuss the results with the principal investigator as well as your physiotherapist.

Declaration by participant

By signing below, I (name)……..... agree to take part in a research study entitled 'Investigation into the immediate effect of ankle taping on temporal spatial gait parameters and affected ankle kinematics in ambulant adult hemiplegic patients'.

I declare that:

1. I have read or had read to me this information and consent form and that it is written in a language with which I am fluent and comfortable.
2. I have had a chance to ask questions and all my questions have been adequately answered.
3. I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
4. I may choose to withdraw from the study at any time and will not be penalised or prejudiced in any way.
5. I may be asked to leave the study before it has finished, if the researcher feels it is my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…….. On (*date*) ……...…….. 2011.

Signature of Participant or family member **Signature of witness**

Declaration by investigator

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understand all aspects of the research, as discussed above.
- I did/did not use a translator (i*f a translator is used, then the translator must sign the declaration below).*

Signed at (*place*) .....…..…….. On (*date*) ……...…….. 2011.

Signature of investigator **Signature of witness**

Declaration by translator

I *(name)* ……..…… declare that:

2. I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*) ……..……... using the language medium of Afrikaans/Xhosa.
3. We encouraged him/her to ask questions and took adequate time to answer them.
4. I conveyed a factually correct version of what was related to me.
5. I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her questions satisfactorily answered.

Signed at (*place*) .....…….. On (*date*) ……..…….. 2011.

Signature of translator **Signature of witness**

DEELNEMERINLIGTINGSBLAD EN -TOESTEMMINGSVORM

TITEL VAN DIE NAVORSINGSPROJEK:

'n Ondersoek na die onmiddellike effek wat 'n enkel verbinding sal hê op die looppatroon en verskillende enkelbewegings (kinematika) van volwasse hemiplegiese wat kan stap.

VERWYSINGSNOMMER: (**N10/11/372**)

HOOFNAVORSER: Mohammad AL-Talahma (B.Sc Physiotherapy).

ADRES:
Afdeling Fisioterapie
Departement Interdissiplinêre Gesondheidswetenskappe
Universiteit Stellenbosch
Posbus 19063
Tygerberg
7505

KONTAKNOMMER: 0796210832

U word genooi om deel te neem aan 'n navorsingsprojek. Lees asseblief hierdie inligtingsblad op u tyd deur aangesien die detail van die navorsingsprojek daarin verduidelik word. Indien daar enige deel van die navorsingsprojek is wat u nie ten volle verstaan nie, is u welkom om die navorsingspersoneel of dokter daaroor uit te vra. Dit is baie belangrik dat u ten volle moet verstaan wat die navorsingsprojek behels en hoe u daarby betrokke kan wees. U deelname is ook **volkome vrywillig** en dit staan u vry om deelname te weier. U sal op geen wyse hoegenaamd negatief beïnvloed word indien u sou weier om deel te neem nie. U mag ook te eniger tyd aan die navorsingsprojek onttrek, selfs al het u ingestem om deel te neem.

Hierdie navorsingsprojek is deur die Etiek Komitee oor Gesondheidsnavorsing van die Universiteit Stellenbosch **goedgekeur en sal uitgevoer word volgens die etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki en die Etiese Riglyne vir Navorsing van die Mediese Navorsingsraad (MNR).**

Wat behels hierdie navorsingsprojek?

Die doel van hierdie studie is om te bepaal wat die onmiddellike effek van enkelgewrig verbinding sal wees op die stapvermoë van pasiënte wat ’n beroerte gehad het. Hierdie navorsing sal by die Fisioterapie en Bewegingsanalise-kliniek (Universiteit Stellenbosch, Tygerberg-kampus) uitgevoer word. U sal gevra word om sewe meter kaalvoet te loop met ’n verband om u enkel. U sal altesaam drie keer kaalvoet en drie keer met die enkel verbinding moet loop. U sal oorgenoeg ruskans kry tydens die ondersoek. Die hoofnavorser sal die verband aansit om die enkel wat deur die beroerte geraak is. U sal geen ekstra behandeling tydens hierdie ondersoek ontvang nie.

Die Vicon-bewegingsanalisestelsel sal die volgende meet: die spoed waarteen u stap, die lengte van u treë, en die posisie van u enkel. Die ontleding sal gedoen word deur ingreepvrye plakkers op u liggaam wat deur die Vicon-bewegingsanalisestelsel gelees kan word. U sal redelik noupassende klere moet aantrek sodat die plakkers aangesit kan word. U sal egter tydens al die toetsprosedures ten volle geklee bly.

Die hoofnavorser en die personeel van die Vicon-bewegingsanalisekliniek sal volgens u behandelingsprogram saam bepaal wat die mees gepaste tye vir hierdie toetse sal wees. Die prosedure sal ongeveer 60 minute duur. Ons hoop om deur hierdie studie bykomende behandeling te kan bied vir pasiënte wat ’n beroerte gehad het en wie se stapvermoë herstel moet word.

Waarom is u genooi om deel te neem?

Om ’n wetenskaplike studie uit te voer is ’n stel insluitingskriteria opgestel. U val binne hierdie kriteria: U is ’n volwassene persoon wat vir die eerste keer gediagnoseer is met ’n beroerte binne die afgelope jaar. U stapvermoë is abnormaal, maar u kan sonder ondersteuning sewe meter kaalvoet loop.

Wat sal u verantwoordelikhede wees?

Indien moontlik, kan u van u eie vervoer gebruik maak om u afspraak by die Fisioterapie en Bewegingsanalisekliniek (Universiteit Stellenbosch, Tygerberg-kampus) na te kom. U sal vir u vervoerkoste vergoed word. Indien u nie vervoer het nie, sal vervoer vir u voorsien word. U sal ’n vrywaringsvorm moet teken, asook ’n toestemmingsvorm indien u instem om aan hierdie studie deel te neem.

Sal u voordeel trek deur deel te neem aan hierdie navorsingsprojek?

Daar is geen risiko's verbonde aan deelname aan hierdie navorsingsprojek nie. U deelname sal die navorsingspan help om ingrypende behandeling voor te stel vir die herstel van 'n pasiënt se stapvermoë ná 'n beroerte. Indien die navorsers dié tegniek as 'n doeltreffende behandelingsmoontlikheid aanbeveel, sal u terapeut dit as deel van u herstelprogram kan gebruik.

Is daar enige risiko's verbonde aan u deelname aan hierdie navorsingsprojek?

Daar is geen bekende risiko's verbonde aan die deelname aan hierdie navorsingsprojek nie.

Watter alternatiewe is daar indien u nie instem om deel te neem nie?

Indien u sou kies om nie aan hierdie studie deel te neem nie, sal u voortgaan met u terapie by u terapeut. Daar sal geen negatiewe gevolge vir u wees nie.

Wie sal toegang hê tot u mediese rekords?

Al die inligting wat vir hierdie projek ingesamel word, sal as vertroulik beskou en beskerm word. Indien hierdie inligting in 'n tesis of publikasie gebruik word, sal u identiteit nie bekendgemaak word nie. Slegs die navorsers sal toegang tot die inligting hê. Die inligting sal by die Afdeling Fisioterapie van die Universiteit Stellenbosch in veilige bewaring gehou word. Alle video-opnames sal vernietig word wanneer die studie voltooi is, behalwe as u sou instem dat dit in wetenskaplike voorleggings gebruik kan word.

Wat sal gebeur in die onwaarskynlike geval van 'n besering wat mag voorkom as gevolg van u deelname aan hierdie navorsingsprojek?

Indien u tydens die toetse beseer sou word, sal die navorsingspan onmiddellik aan u behoeftes aandag gee en u na die mees gepaste persoon vir behandeling verwys.

Sal u betaal word vir deelname aan die navorsingsprojek en is daar enige koste verbonde aan deelname?

U sal nie betaal word vir u deelname aan hierdie navorsingsprojek nie. Dit sal u ook niks kos om aan die navorsingsprojek deel te neem nie.

Is daar enigiets anders wat u moet weet of doen?

1. U kan Mohammed Al-Talahma by 079 621 0832 skakel indien u enige verdere vrae het of enige probleme ondervind.

2. U kan die Etiese Komitee vir Gesondheidsnavorsing by 021 938 9207 skakel indien u enigsins bekommerd is of klagtes het wat nie bevredigend deur die navorsingspan gehanteer is nie.

3. U sal ’n afskrif van hierdie inligtings- en toestemmingsvorm vir u veilige bewaring ontvang.

4. Die uitslae van die ontleding van u stapvermoë sal aan u gestuur word sodra dit beskikbaar is. U sal die geleentheid kry om dit met die hoofnavorser sowel as u fisioterapeut te bespreek.

Verklaring deur deelnemer

Met die ondertekening van hierdie dokument onderneem ek, …….....……...……...……., om deel te neem aan ’n navorsingsprojek getiteld (*Titel van navorsingsprojek)*.

Ek verklaar dat:

Ek hierdie inligtings- en toestemmingsvorm gelees het of aan my laat voorlees het en dat dit in ’n taal geskryf is waarin ek vaardig en gemaklik mee is.

Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.

Ek verstaan dat deelname aan hierdie navorsingsprojek **vrywillig** is en dat daar geen druk op my geplaas is om deel te neem nie.

Ek te eniger tyd aan die navorsingsprojek mag onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.

Ek gevra mag word om van die navorsingsprojek te onttrek voordat dit afgehandel is indien die studiedokter of navorser van oordeel is dat dit in my beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te *(plek*) .....…….. op *(datum*) ……...……..
2005.

Handtekening van deelnemer **Handtekening van getuie**

Verklaring deur navorser

Ek *(naam)* ……..…… verklaar dat:

Ek die inligting in hierdie dokument verduidelik het aan …….……..

Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.

Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.

Ek ’n tolk gebruik het/nie ’n tolk gebruik het nie. (*Indien ’n tolk gebruik is, moet die tolk die onderstaande verklaring teken.)*

Geteken te *(plek*) .....…….. op *(datum*) ……...……..
2005.

Handtekening van navorder **Handtekening van getuie**

Verklaring deur tolk

Ek *(naam)* ……..…… verklaar dat:

Ek die navorser *(naam*) ……..……. bygestaan het om die inligting in hierdie dokument in Afrikaans/Xhosa aan *(naam van deelnemer)* ……..... te verduidelik.

Ons hom/haar aangemoedig het om vrae te vra en voldoende tyd gebruik het om dit te beantwoord.

Ek ’n feitelik korrekte weergawe oorgedra het van wat aan my vertel is.

Ek tevrede is dat die deelnemer die inhoud van hierdie dokument ten volle verstaan en dat al sy/haar vrae bevredigend beantwoord is.

Geteken te *(plek*) .....…….. op *(datum*) ……...……..
2005.

Handtekening van tolk **Handtekening van getuie**

INCWADANA ENEENKCUKACHA YALOWO UTHATHA INXAXHEBA KUNYE NEFOMU YESIVUMELWANO

ISIHLOKO SEPROJEKTHI YOPHANDO:

Uphando ngeziphumo ezifunyanwa kwangoko xa kusolulwa iqatha ngokobunjani bemeko yexeshana bendlela elime ngalo nokushukuma kweqatha kubantu abadala abazizigulane ezikwazi ukuhamba

INOMBOLO YESALATHISI: (**N10/11/372**)

UMPHANDI OYINTLOKO: Mohammad AL-Talahma (B.Sc Physiotherapy).

IDILESI:

Division of Physiotherapy
Department of Interdisciplinary Health Science
Stellenbosch University
PO Box 19063
Tygerberg
7505

INOMBOLO YOQHAGAMSHELWANO: 07 96210832

Uyamenywa ukuba uthathe inxaxheba kwiprojekthi yophando. Nceda thatha ixesha lokufunda ulwazi oluvezwe apha, oluza kuthi luchaze iinkcukacha zale projekthi. Nceda buza nayiphi na imibuzo emalunga nayiphina indawo ongayiqondi ngokupheleleyo kubasebenzi besi sifundo okanye kugqirha. Kubaluleke kakhulu ukuba waneliseke ngokupheleleyo yinto yokuba ucacelwe kakuhle ukuba esi sifundo singantoni na kwaye ungabandakanyeka njani. Kwakhona, ukuthatha kwakho inxaxheba **kungentando yakho ngokupheleleyo** kwaye ukhululekile ukuba ungarhoxa ekuthatheni inxaxheba. Ukuba uthi hayi, oku akusayi kuchaphazela ukungavumi kwakho nangayiphina indlela. Ukwakhululekile ukuba uyeke kwesi sifundo naninina, nkqu nokokuba ubuvumile ukuthatha inxaxheba ekuqaleni.

Olu phando luvunywe ngabajongene nokuziphatha ngokusesikweni **kweKomiti ePhanda ngomntu kwiYunivesithi yaseStellenbosch** kwaye luza kwenziwa ngokwemigaqo esesikweni yophando eyamkelekileyo kwiSaziso sehlabathi sika-Helsinki, iMigaqo eLungileyo yoMzantsi Afrika yokuSebenza eKliniki kunye

neBhunga lezoPhando ngamaYeza (MRC) iMigaqo yokuziphatha kwezoPhando.

Simalunga nantoni esi sifundo sophando?

Injongo yesifundo kukuphanda ngeziphumo ezenzeka kwangoko ngokolulwa kwelungu leqatha ekuzameni ukuba izigulane ebezihlaselwe sisitrowukhi zikwazi ukuhamba. Olu phando luza kwenziwa yiLebhu eHlola indlela ohamba ngayo okwenziwa yingcali enyanga ngokuthambisa amalungu omzimba (kwiYunivesithi yaseStellenbosch, kwiKhampasi yaseTygerberg). Uza kucelwa ukuba uhambe iimitha ezisixhenxe libotshiwe iqatha lakho uhamba unganxibanga zihlangu. Uza kucelwa ukuba uhambahambe kathathu kwimeko nganye. Uza kunikwa ithuba lokuba uphumle xa kusenziwa olu phando. Ukolulwa ngokubotshwa kuza kwenziwa ngumphandi oyintloko kwiqatha elaye lachatshazelwa sisitrowukhi. Alukho olunye unyango oza kulufumana xa kusenziwa olu phando.

Oku kulandelayo kuza kuthathwa imilinganiselo yiNkqubo eHlola ukuhamba nokushukushukuma yeVicon: isantya sokuhamba, ubude ekubekeni unyawo nendlela elime ngayo iqatha. Uhlahlelo luza kwenziwa ngokubekwa kwezinto eziphawulayo ezingazi kukuhlasela eziza kubekwa emzimbeni wakho eziza kubonakala kwiNkqubo eHlola ukuhamba nokushukushukuma yeVicon. Kuza kufuneka unxibe impahla ekubambayo ukwenzela kukwazi ukusetyenziswa ezi zinto ziphawulayo. Kanti, umzimba wakho uza kuhlala unxityiswe wonke kuzo zonke iinkqubo eziza kwenziwa zolu hlolo.

Awona maxesha afanelekileyo okwenza olu hlolo kuza kuvunyelwana ngawo nomphandi oyintloko, abakulawulo kwiiLebhu zokuhlola ukuhamba zakwaVicon nangokwamaxesha akho okufumana unyango. Ixesha elilindelekileyo lokugqiba lo mgaqo liqikelelwa kwimizuzu engama-60. ngesi sifundo sithemba ukuba singakwazi ukucebisa ngeendlela ekunokungenelelwa ngazo ukuncedisa ukubuyiselwa kwisimo sangaphambili sokuhamba emva kokuba uhlaselwe sisitrowukhi.

Kutheni umenyiwe ukuba uthathe inxaxheba?

Ukuba wenza isifundo senzululwazi, kukho uluhlu lweendlela ezisetyenziswayo zokuquka ezibekiweyo. Nawe uphantsi kwezi ndlela zisetyenziswayo: Ungumntu omdala ofunyaniswe uhlaselwa sisitrowukhi kanye kunyaka ophelileyo. Uhamba ngendlela ethile engaqhelekanga kodwa uyakwazi ukuhamba ngeenyawo unganxibanga zihlangu iimitha ezisixhenxe ungakhange uncediswe.

Luyakuba yintoni uxanduva lwakho?

Ukuba kunokwenzeka, ungasebenzisa isithuthi sakho ukuya kula madinga okuya eLebhu ukuze kuHlolwe indlela ohamba ngayo yingcali enyanga ngokuthambisa amalungu omzimba (kwiYunivesithi yaseStellenbosch, kwiKhampasi yaseTygerberg). Uza kubuyiselwa iindleko zesithuthi sakho. Xa ungenaso isithuthi, uza kubonelelwa ngesithuthi kwaye uza kucelwa ukuba utyikitye ifomu yokhuselo. Kuza kufuneka usinike iswivumelwano ukuba uyavuma ukuthatha inxaxheba kwesi sifundo.

Ingaba uza kuzuza ekuthatheni inxaxheba kolu phando?

Akukho bungozi buza kubakho ngokuthatha kwakho inxaxheba kule projekthi yophando. Ukuthatha kwakho inxaxheba kuza kunceda iqela elenza uphando ukuba linike iingcebiso zongenelelo zokuba uncedwe ukuba ukwazi ukuphinda uhambe emva kokuba uhlaselwe sisitrowukhi. Ukuba abaphandi bacebisa ukuba le ndlela lolona nyango lusebenzayo, lowo ukunyangayo uza kukwazi ukukhetha le ndlela njengenxenye yenkqubo yokubuyiselwa kwisimo sangaphambili.

Ingaba zikho iingozi ezibandakanyekayo ekuthatheni kwakho inxaxheba kolu phando?

Akukho bungozi buza kubakho ngokuthatha kwakho inxaxheba kule projekthi yophando.

Ukuba awuvumi ukuthatha inxaxheba, loluphi olunye unyango oza kulufumana?

Ukuba ukhetha ukungathathi nxaxheba, unyango lwakho luza kuqhubeka nalowo ukunyangayo. Awuzi kuba nangxaki eza kukuchaphazela kakubi.

Ngubani oza kufumana ingxelo yakho yamayeza?

Zonke iinkcukacha ezifunyenweyo zale projekthi ziza kugcinwa ziyimfihlelo kwaye ziza kukhuselwa. Ukuba ezi nkcukacha zisetyenziswa kwithisisi okanye nakoluphi na

ushicilelo, igama lakho liza kuhlala lingaziwa, alizi kusetyenziswa. Ngabaphandi kuphela abaza kufikelela kwezi nkcukacha. Iingxelo ziza kugcinwa kwindawo ekhuselekileyo kwiCandelo lePhysiotherapy kwiYunivesithi yaseStellenbosch . Ionke ushicilelo lwevidiyo luza kutrshatyalaloswa ukugqitywa kwesi sifundo, ngaphandle kokuba uyavuma ukuba zisetyenziswe kwimiboniso yezesayensi.

Kuza kwenzeka ntoni kwimeko yesehlo esingalindekanga sokwenzakala ngenxa yokuthatha kwakho inxaxheba kwesi sifundo sophando?

Xa unokuthi wenzakale xa kusenziwa uhlolo, iqela elenza uphando liza kujongana neemfuno zakho kwangoko zize zikugqithisele kwabona balawuli bafanelekileyo.

Ingaba uza kuhlawulwa ngokuthatha inxaxheba kwesi sifundo kwaye ingaba kukho iindleko ezibandakanyekayo?

Awuzi kuhlawulwa ngokuthatha kwakho inxaxheba kwesi sifundo. Akuzi kubakho zindleko oza kuzihlawula, ukuba uthatha inxaxheba.

Ingaba ikho enye into ekumele uyazi okanye uyenze?

1 Uza kuqhagamshelana noMohammad Al-Talahma kwa-07 96210832 ukuba uneminye imibuzo okanye ufumana ezinye iingxaki.

2 Ungaqhagamshelana neKomiti ePhanda ngoMntu kwa-021-938 9207 ukuba kukhona okukuxhalabisayo okanye unezikhalazo ezingakhange ziphendulwe kakuhle liqela elenza uphando.

3 Uza kufumana ikopi enezi nkcukacha nefomu yesivumelwano etyikityiweyo ukuze uzigcinele.

4 Iziphumo zokuhlahlelwa kohlobo ohamba ngalo ziza kuthunyelwa kuwe kanye nje ukufumaneka kwazo. Uza kuba nethuba lokuxoxa ngeziphumo nomphandi ophambili kunye nengcali enyanga umzimba ngokuwuthambisa.

Isvumelwano salowo uthatha inxaxheba

Ngokuytyikitya ngezantsi, Mna (Igama) ……..……. ndiyavuma ukuthatha inxaxheba kwisifundo sophando esibizwa ngokuba ”Uphando ngeziphumo ezifunyanwa kwangoko xa kusolulwa iqatha ngokobunjani bemeko yexeshana bendlela elime ngalo nokushukuma kweqatha kubantu abadala abazizigulane ezikwazi ukuhamba”.

Ndazisa ukuba:

1. Ndilufundile okanye ndalufunda olu lwazi kunye nefomu yesivumelwano kwaye ibhalwe ngolwimi endilwaziyo nendikhululekileyo ukuluthetha

2. Bendinalo ithuba lokuba ndibuze imibuzo kwaye yonke imibuzo yam iphendulwe ngokwanelisayo.

3. Ndiyakuqonda ukuba ukuthatha inxaxheba kolu phando kube **kukuzithandela kwam** kwaye andikhange ndinyanzelwe ukuba ndithathe inxaxheba.

4. Ndingakhetha ukusishiya isifundo naninina kwaye andisayi kohlwaywa okanye ndigwetywe nangayiphi indlela.

5. Usenokucelwa ukuba usishiye isifundo phambi kokuba siphele, ukuba ugqirha wesifundo okanye umphandi ukubona kuza kukunceda oko, okanye ukuba andisilandeli isicwangciso sesifundo, ekuvunyelenwe ngaso.

Kutyikitywe e .....…..…….. -*(indawo)* ngo-……...……..*(umhla)* ngo-2011.

…… ……

Ukutyikitya kwalowo uthatha inxaxheba **Ukutyikitya kwengqina**

Isivumelwano somphandi

Mna *(igama)* …… ndiyafunga ukuba:

- Ndilucacisile ulwazi olu kweli xwebhu ku-……..……...
- Ndimkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndiyaneliseka kukuba uyakuqonda ngokwanelisayo konke okumalunga nophando okuxoxwe ngasentla.
- Ndisebenzise/andisebenzisanga toliki. (*Ukuba itoliki isetyenzisiwe kumele ityikitye isaziso ngezantsi.*

Kutyikitywe e.....….....……..-(*indawo*) ngo……...…….. -(umhla) ngo-2011.

....

Ukutyikitya komphandi **Ukutyikitya kwengqina**

Isivumelwano setoliki

Mna *(igama)* …… ndazisa ukuba:

- Ndicele umphandi (*igama*) …….. acacise ngeenkcukacha ezikolu xwebhu ku-……..(*igama lalowo uthatha inxaxheba*) ndisebenzisa ulwimi lwesiBhulu/lwesiXhosa.
- Ndimkhuthazile ukuba abuze imibuzo kwaye athathe ixesha elifanelekileyo ukuba ayiphendule.
- Ndimxelele eyona nto iyiyo malunga nokunxulumene nam.
- Ndiyaneliseka kukuba lowo uthatha inxaxheba ukuqonda ngokupheleleyo okuqulathwe kolu xwebhu lwesivumelwano okwazisiweyo kwaye nemibuzo yakhe yonke iphendulwe ngokwanelisayo.

Kutyikitywe e-.....…..……..(*indawo*) ngo-……...…….. (*umhla*) ngo-2011.

…….. ……..

Ukutyikitya kwetoliki **Ukutyikitya kwengqina**

APPENDIX IX

CONSENT AND INDEMNITY FOR TRANSPORT OF PARTICIPANTS

I, the undersigned ……, hereby consent to my transportation to the Medical School, Stellenbosch University by motor vehicle in the accompaniment of either the researcher or research assistant for the purpose of participating in the study entitled: Investigation into the immediate effect of ankle taping on temporal spatial and ankle kinematic parameters in adult ambulant hemiplegic patients

I accept all financial responsibilities for all damages and/or loss in connection with the transportation (in case of accident, theft of property from the motor vehicle or hijacking), whether the vehicle is parked at the testing venue or while on route on a Public road.

Signature: ……. **Witness:**

Place: …….. **1. ……**

Date: …….. **2. …….**

APPENDIX X

PARTICIPANTS' ANTHROPOMETRIC MEASUREMENTS (N=10)

Anthropometrics	Mean ± SD	Range
Weight (kg)	77.97 ± 22.41	43.4 - 107.5
Height (cm)	167 ± 7.99	157 – 182
Left leg Length (mm)	895.5 ± 52.65	830 – 985
Right Leg length (mm)	896 ± 54.81	825 – 990
Left Knee Width (mm)	106.3 ± 11.76	89 – 126
Right Knee Width (mm)	107.4 ± 11.41	91 – 126
Left Ankle Width (mm)	69.1 ± 5.47	60 – 77
Right Ankle Width (mm)	70.1 ± 5.74	61 – 80
*Standard deviation		

APPENDIX XI

Ethics Committee Approval

UNIVERSITEIT•STELLENBOSCH•UNIVERSITY
jou kennisvennoot • your knowledge partner

24 November 2010 **MAILED**

Mr M Al-Talahma
Department of Physiotherapy
4th Floor
Teaching Block

Dear Mr Al-Talahma

Investigation into the immediate effect of neural ankle taping on temporal special and ankle parameters in adult ambulant hemiplegic patients

ETHICS REFERENCE NO: N10/11/372

RE : APPROVED WITH STIPULATIONS

It is a pleasure to inform you that a review panel of the Health Research Ethics Committee has approved the above-mentioned project with STIPULATIONS on 24 November 2010, including the ethical aspects involved, for a period of one year from this date.

1. The second paragraph of the indemnity form should be deleted as participants would be covered by the road accident fund.
2. It is recommended to refer to post-stroke patients as patients or persons with hemiplegia following stroke or traumatic brain injury.

This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in ALL future correspondence. You may start with the project. Notwithstanding this approval, the Committee can request that work on this project be halted temporarily in anticipation of more information that they might deem necessary.

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly and subjected to an external audit.

Translations of the consent document in the languages applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Please note that for research at primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact

Verbind tot Optimale Gesondheid · Committed to Optimal Health
Afdeling Navorsingsontwikkeling en -steun · Division of Research Development and Support
Posbus/PO Box 19063 · Tygerberg 7505 · Suid-Afrika/South Africa
Tel: +27 21 938 9075 · Faks/Fax: +27 21 931 3352

persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Hélène Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

Approval Date: 24 November 2010

Expiry Date: 24 November 2011

Yours faithfully

MS CARLI SAGER
RESEARCH DEVELOPMENT AND SUPPORT
Tel: +27 21 938 9140 / E-mail: carlis@sun.ac.za
Fax: +27 21 931 3352

APPENDIX XI

Permission Tygerberg Hospital

DEPARTMENT of HEALTH
Provincial Government of the Western Cape

Tygerberg Academic Hospital and
Mitchells Plain & Tygerberg Oral Health Centres

lblinde@pgwc.gov.za
tel: +27 21 938-5752 / fax: +27 21 938-6698
Private Bag X3, Tygerberg, 7505
www.capegateway.gov.za

REFERENCE : Research Projects
ENQUIRIES : Dr M A Mukosi

Date: 30 MAR 2011

ETHICS NO: N10/11/372

Mr M Al-Talahma
Dept of Physiotherapy
4th Floor
Clinical Building
University of Stellenbosch

Dear Mr M Al-Talahma

Ref: Investigation into the immediate effect of neural ankle taping on temporal special and ankle parameters in adult ambulant hemiplegic patients.

PERMISSION TO CONDUCT YOUR RESEARCH AT TYGERBERG HOSPITAL

In accordance with the Provincial Research Policy and Tygerberg Hospital Notice No 40/2009, permission is hereby granted for you to conduct the above-mentioned research here at Tygerberg Hospital.

DR D ERASMUS
CHIEF DIRECTOR: TYGERBERG HOSPITAL
23/03/2011